Pharma Process Safety Summit -Instrument Asset Health & Performance Monitoring

Purdue University May 7th 2019

Endress+Hauser
People for Process Automation

Endress+Hauser

We help our customers to improve their processes

Endress+Hauser USA Product Centers

Endress+Hauser GmbH+Co, Division Level & Pressure USA, Greenwood, Indiana
Level
Pressure
Inventory control components

Endress+Hauser Flowtec AG, Division USA, Greenwood, Indiana
Flow

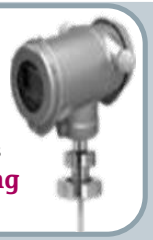
Wedgewood Analytical Anaheim, California
Liquid Analytical Instrumentation

Endress+Hauser Wetzer (Division USA) Greenwood, Indiana
Temperature
Registration
System components

Life Sciences Portfolio 2019

Promass, Promag 100/ 300/ 500
P sensor acc. ASME BPE
Heartbeat Technology

Cerabar / DeltapilotM
PMP55
PMP51
FMB50
FMD71/72
TempC
compact, precise, e-polish in standard
temperature shock optimized for dp level



Levelflex FMP53
New Housing

PMP23 PTB33B Liquipoint FTW23 FTW33
Fit for Bodycare

iTherm TrustSense TM37x
Self calibration

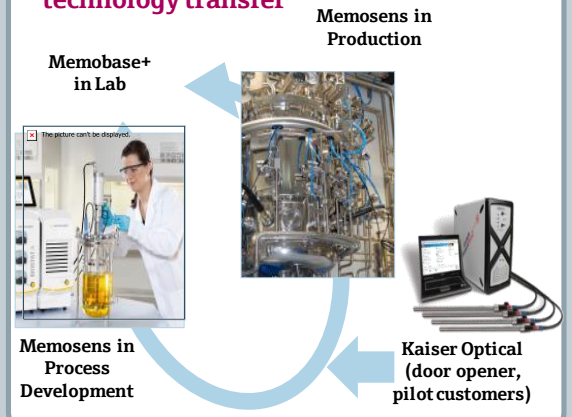
iTherm TM 411
QuickNeck/QuickSens

Memograph M RSG45
Ethernet IP/ Profinet
HART® Input

World class offering for LSI applications supporting cost control, availability and risk mitigation

Calibration service
ISO 17025 accreditation
Calibration Optimization
value add
Calibration Management Systems
CompuCal

pH, DO: consistency in technology transfer



OEM Packages based on
Liquiline CM 44P – **Optical Transmitter**

Memosens CLS82D - **four-pole conductivity**
Memosens COS23D - **optical DO**
Memosens CPS171D - **pH**
Cleanfit CPA875 – **Retractable holder**

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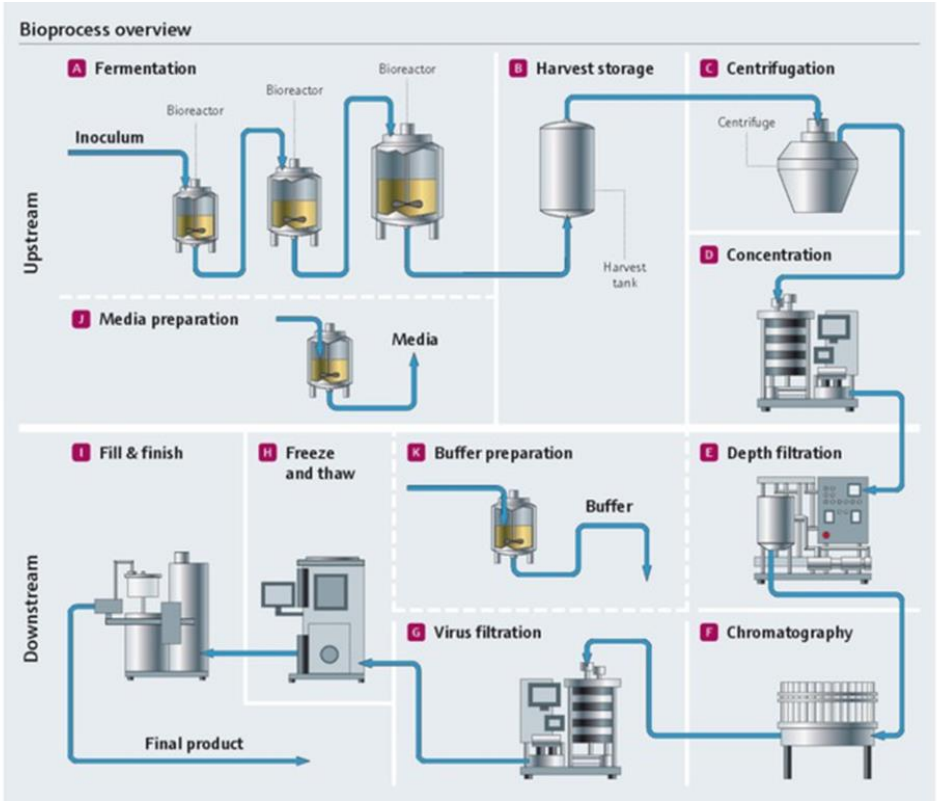
Pharma Process Safety

Process Safety = Process Integrity + Employee Safety

(People –Property – Environment)

Pharma Process Safety – Biotech Manufacturing Key Control Issues

- Over Pressurization
- Gases (O2, CO2, CH4, Others)
- Positive displacement pumps
- Chemical Acids +Bases
- Ergonomics (Bags of buffer salt solutions)
- Nitrogen Blanketing
- CIP/SIP
- Alcohol Solvents



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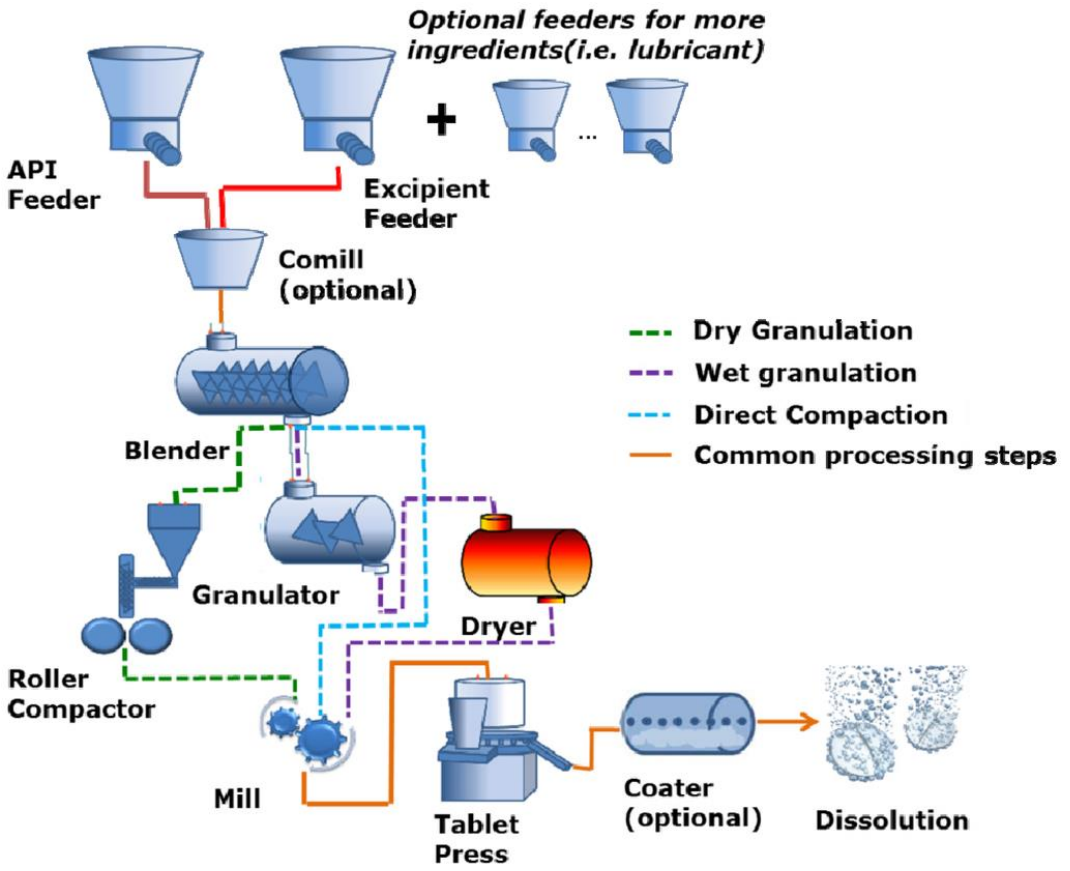
Pharma Process Safety – API Manufacturing

- Flammable Solvents (Nitrogen Blanketing)
- Thermal runaways runs (Flow Control of reactive components)
- Chemicals exposure
- Over Pressurization (Process Safety Devices , Process Safety Valve, Rupture Discs)
- Potent Compounds



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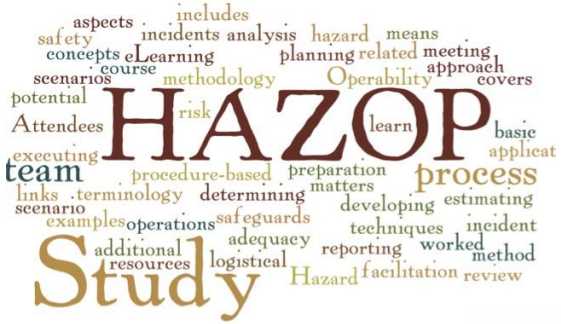
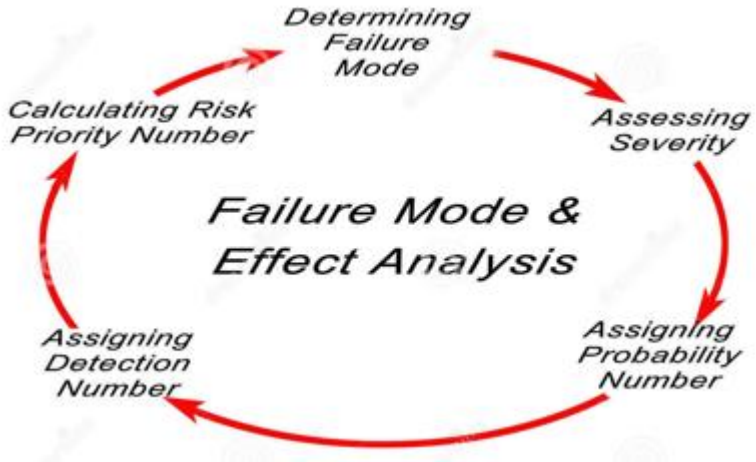
Risk Evaluation Common methods …

- PHA – Process Hazard Analysis
- What if –
- HAZOP (Hazard and Operability study)
- FMEA (Failure Mode and Effects Analysis)





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Instrumentation Assets

- Flow Control - to Prevent Out of Control Reaction Conditions
- Pressure Monitoring –to control or stop processes before over pressurization
- Pressure safety valves - To relive pressure when a failure occurs
- Temperature – Control and Monitoring – to prevent run away reactions or batch failures
- 02 , C02 and LEL Detections - To detect leaks and prevent employee exposure

The “Ideal” Instrument

- **Guaranteed quality in the production**
  - Devices with self diagnostics functionality ensuring correct measurement results
  - Delivering more process information
- **Demonstrating compliance with regulatory requirements**
  - Traceable re-calibrations
- **Reliable information about the status of the measuring device**
  - Supporting fast and quick remedy of error conditions
  - Detecting process up-sets and device errors
- **Less production down time due to re-calibrations**
  - Extending calibration cycles with on-board device verification functionality

Smart Instrumentation

- How reliable is a “self-verifying” device
- How reliable is a “self-calibrating” device

- Can I skip regular calibration and maintain regulatory & safety compliance?

Asset Health & Performance Monitoring

- Self –Verifying Device Mass Flow Meter Promass P
- Self – Calibrating Device Temperature Sensor TrustSens

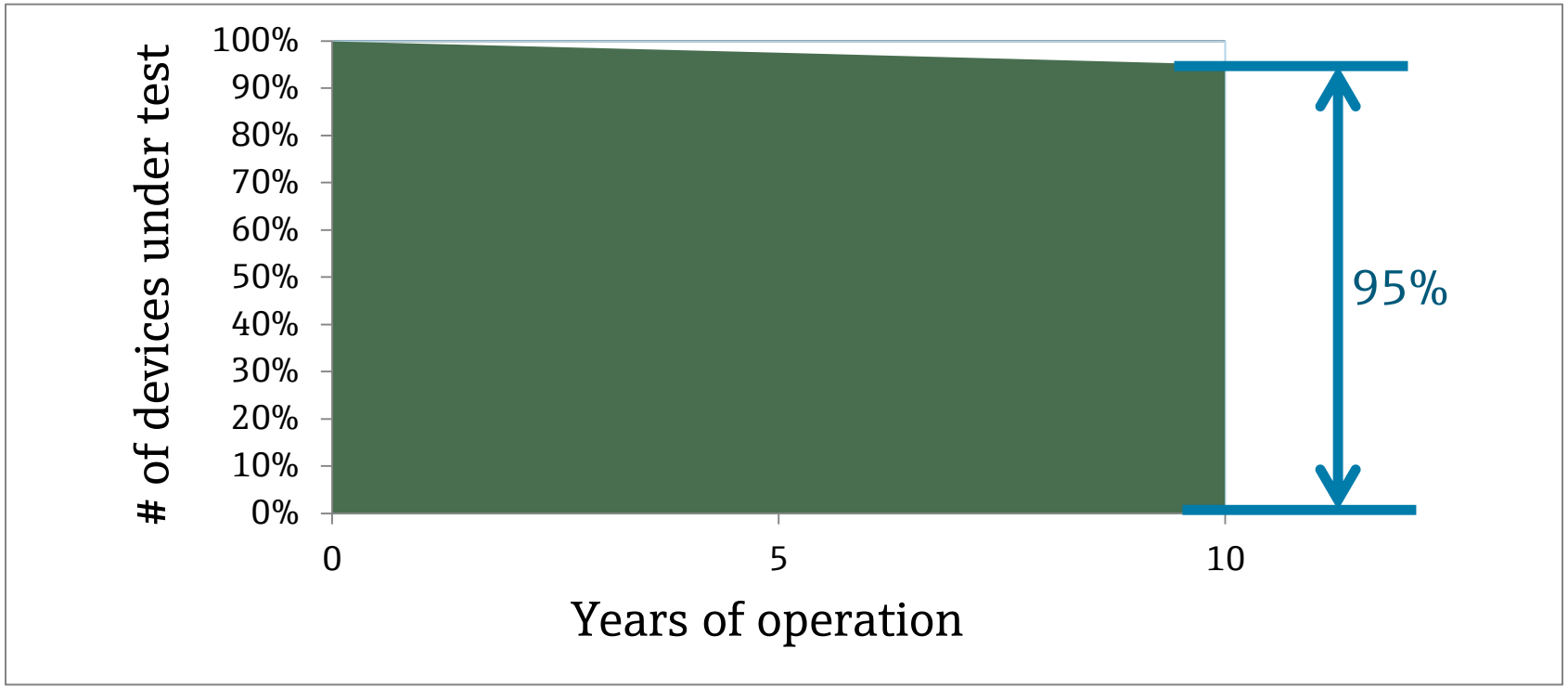
Long term stability

Coriolis mass flowmeters have been used in various industries for years.
Endress+Hauser has more than 500’000 Coriolis flowmeters installed worldwide.

Many flowmeters are gravimetrically tested in accordance with ISO 17025 in regular intervals to confirm their accuracy. The data of **3’000** meters re-calibrated at our facilities have been evaluated

Long Term Stability (10 years evaluation)

< 0.2% (uncertainty) **after 10 years ***



**based on 95% confidence level*

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Promass P

The Life Science specialist

- *Highest accuracy (0,1%)*
- *ASME BPE Certificate of Compliance to relevant scope*
- *Inspection certificates: EN 10204 3.1, MTR;*
  - for material, surface roughness, and delta ferrite.
- *Material selected according to ASME BPE*
  - 1.4435 / 316L, low delta ferrite
- *Wetted surfaces: Ra max=0.76 µm or Ra max=0.38 µm*
- *Electropolished flow tube and process connection and electropolished exterior: for sterile, easier cleanability and higher corrosion resistant surface*
- *Hygienic fully welded, sensor design for full drain ability*
- *Accredited flow calibration*
  - according to ISO/IEC 17025 (SCS/A2LA),
  - traceable density calibration

Heartbeat Technology

On-board Diagnostics, Monitoring and Verification

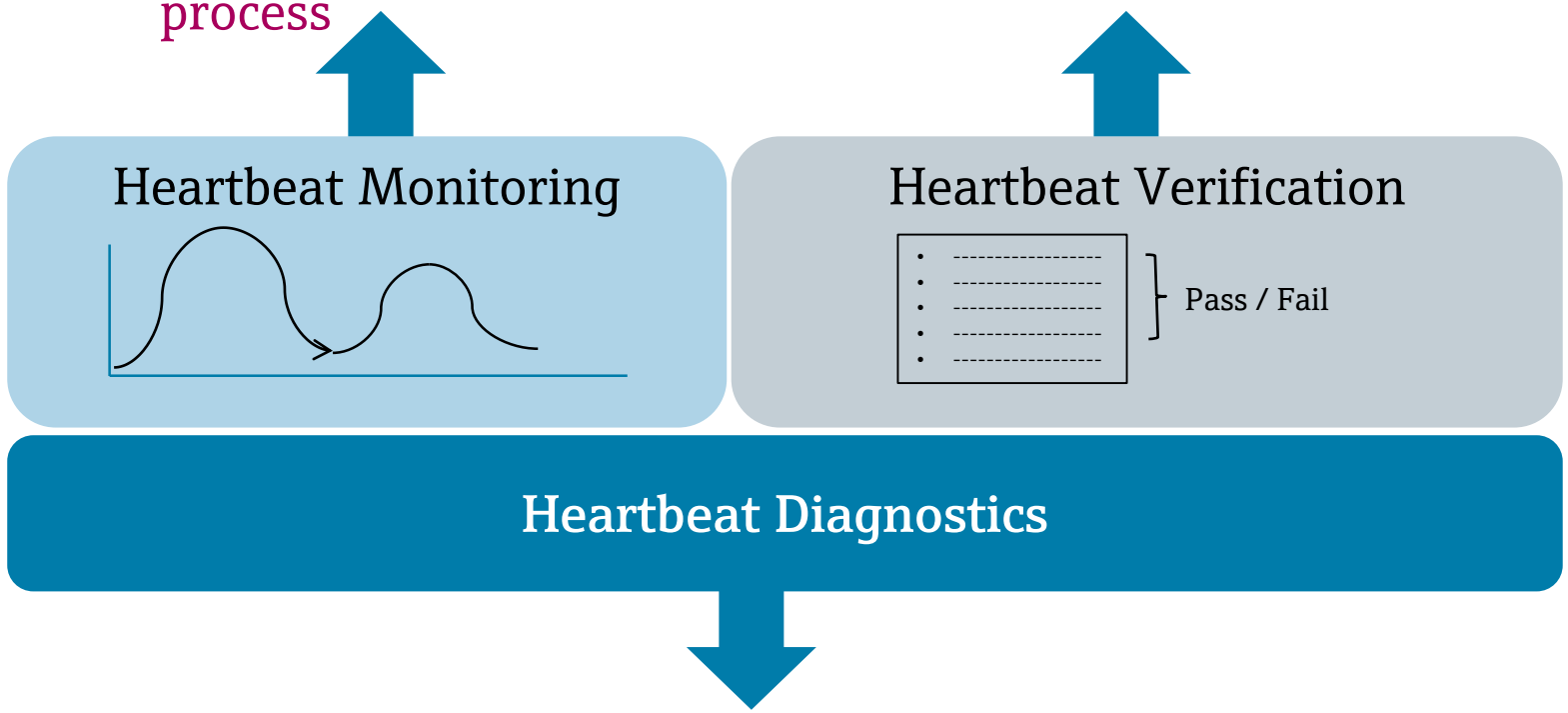
Heartbeat Technology provides continuous self-diagnostic, monitoring and verification on demand to ensure the correct flowmeter functionality, guaranteeing high plant availability and product quality – independent of process and ambient conditions.

Proline
simply clever

Heartbeat Technology ™ - in Operation

Continuous output of data influenced by process

On demand confirmation of flowmeter functionality



Continuous self-diagnostic of flowmeter

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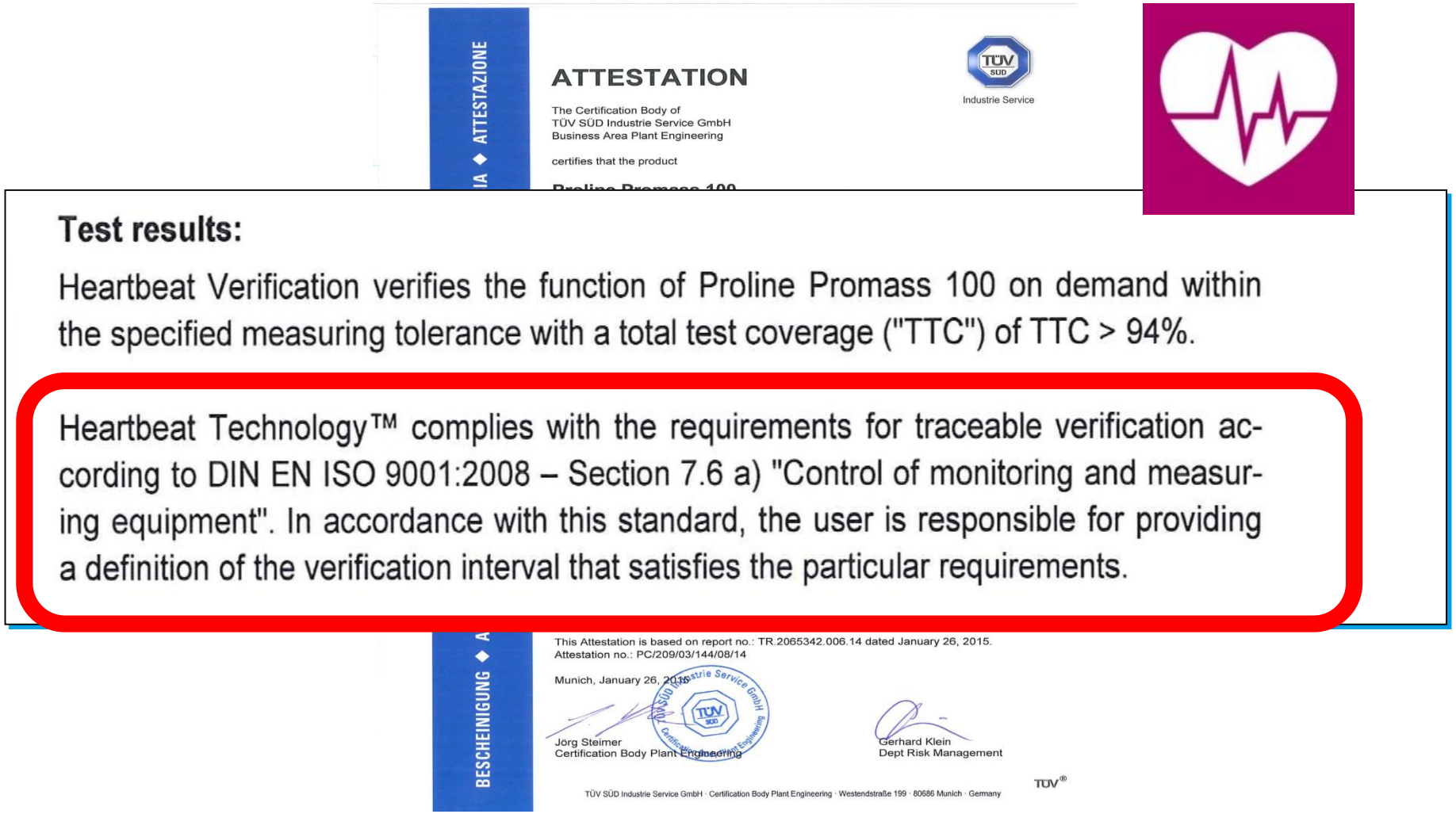
Heartbeat is certified by an independent body



ATTESTAZIONE ◆

ATTESTATION

The Certification Body of
TÜV SÜD Industrie Service GmbH
Business Area Plant Engineering

certifies that the product

TÜV SÜD Industrie Service

Test results:

Heartbeat Verification verifies the function of Proline Promass 100 on demand within the specified measuring tolerance with a total test coverage ("TTC") of TTC > 94%.

Heartbeat Technology™ complies with the requirements for traceable verification according to DIN EN ISO 9001:2008 – Section 7.6 a) "Control of monitoring and measuring equipment". In accordance with this standard, the user is responsible for providing a definition of the verification interval that satisfies the particular requirements.

BESCHEINIGUNG ◆

This Attestation is based on report no.: TR.2065342.006.14 dated January 26, 2015.
Attestation no.: PC/209/03/144/08/14

Munich, January 26, 2015

Jörg Steimer
Certification Body Plant Engineering

Gerhard Klein
Dept Risk Management

TÜV SÜD Industrie Service GmbH · Certification Body Plant Engineering · Westendstraße 199 · 80686 Munich · Germany

Access Locally or Remote

3. Remote

- Control system
- Asset management e.g. FieldCare®

1. Display

2. On-site

- Web server
- FieldCare®

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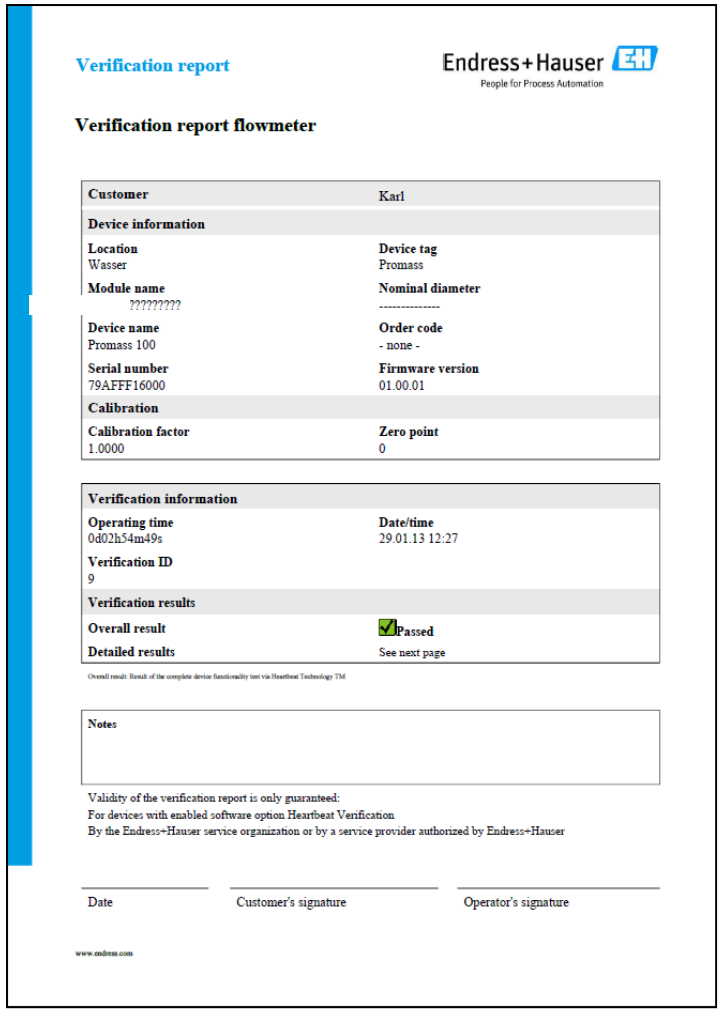
Verification – report example



Verification report

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People for Process Automation

Verification report flowmeter

Customer	Karl
Device information	
Location Wasser	**Device tag** Promass
Module name ?????????	**Nominal diameter** ----------
Device name Promass 100	**Order code** - none -
Serial number 79AFFF16000	**Firmware version** 01.00.01
Calibration	
Calibration factor 1.0000	**Zero point** 0

Verification information	
Operating time 0d02h54m49s	**Date/time** 29.01.13 12:27
Verification ID 9	
Verification results	
Overall result	☑ **Passed**
Detailed results	See next page

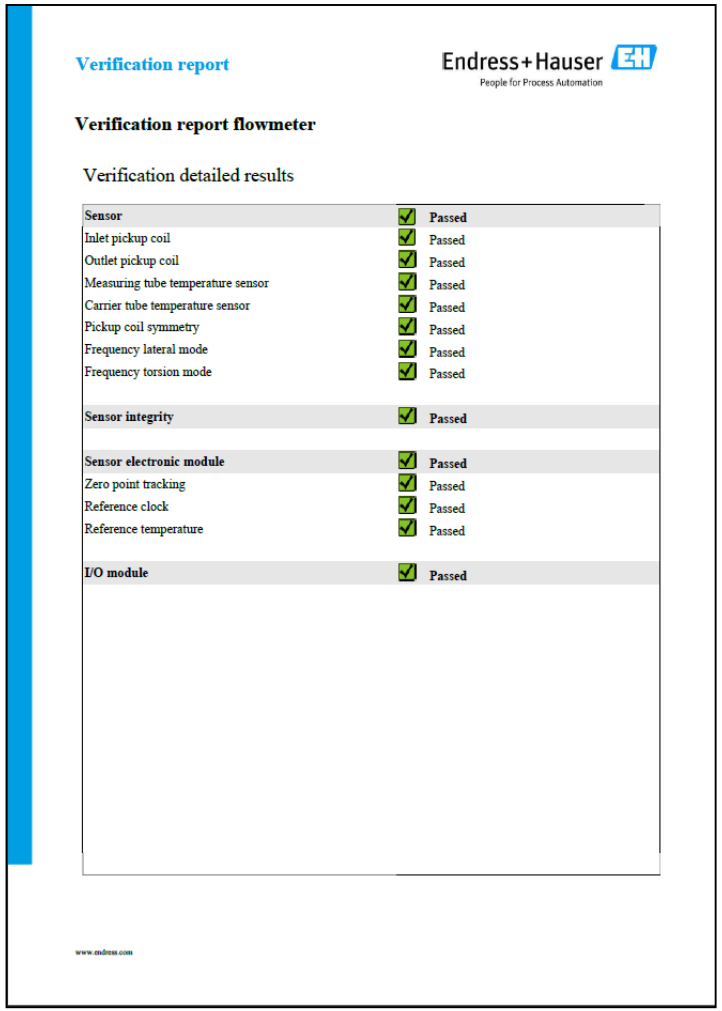
Overall result: Result of the complete device functionality test via Heartbeat Technology TM

Notes

Validity of the verification report is only guaranteed:
For devices with enabled software option Heartbeat Verification
By the Endress+Hauser service organization or by a service provider authorized by Endress+Hauser

Date | Customer's signature | Operator's signature

www.endress.com



Verification report

Endress+Hauser
People for Process Automation

Verification report flowmeter

Verification detailed results

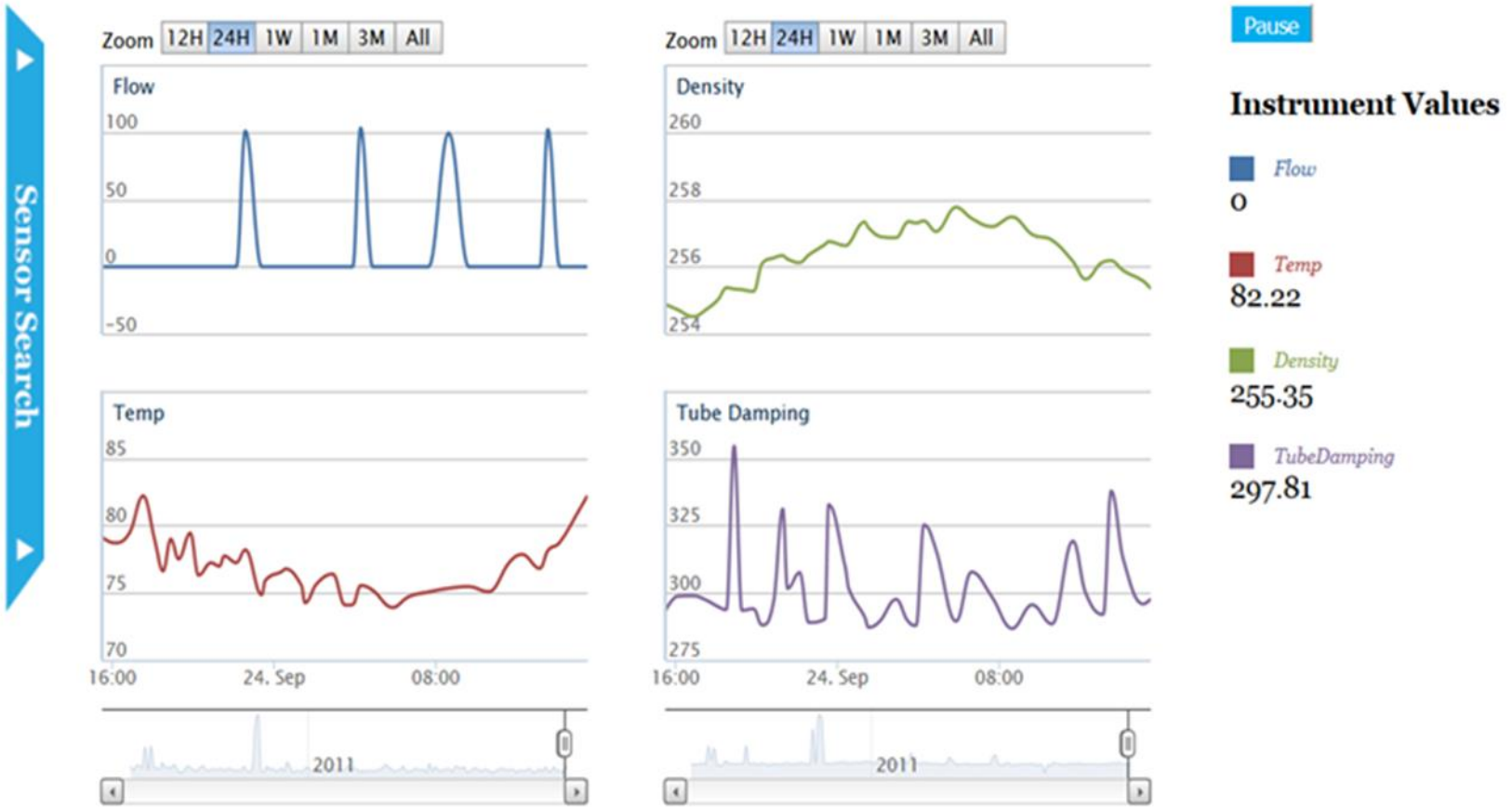
Sensor	☑ **Passed**
Inlet pickup coil	☑ Passed
Outlet pickup coil	☑ Passed
Measuring tube temperature sensor	☑ Passed
Carrier tube temperature sensor	☑ Passed
Pickup coil symmetry	☑ Passed
Frequency lateral mode	☑ Passed
Frequency torsion mode	☑ Passed
Sensor integrity	☑ **Passed**
Sensor electronic module	☑ **Passed**
Zero point tracking	☑ Passed
Reference clock	☑ Passed
Reference temperature	☑ Passed
I/O module	☑ **Passed**

www.endress.com

Verification – report example

Sensor	✓	**Passed**
Inlet pickup coil	✓	Passed
Outlet pickup coil	✓	Passed
Measuring tube temperature sensor	✓	Passed
Carrier tube temperature sensor	✓	Passed
Pickup coil symmetry	✓	Passed
Frequency lateral mode	✓	Passed
Frequency torsion mode	✓	Passed
Sensor integrity	✓	**Passed**
Sensor electronic module	✓	**Passed**
Zero point tracking	✓	Passed
Reference clock	✓	Passed
Reference temperature	✓	Passed
I/O module	✓	**Passed**

Asset Performance Monitoring



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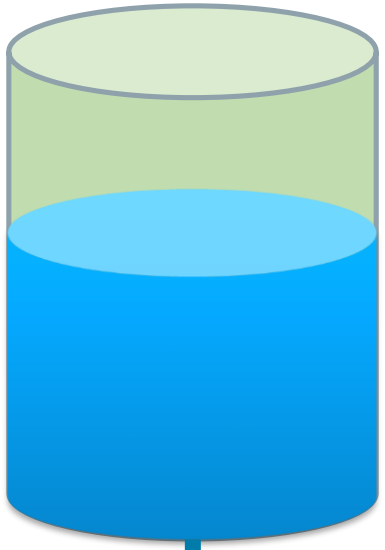
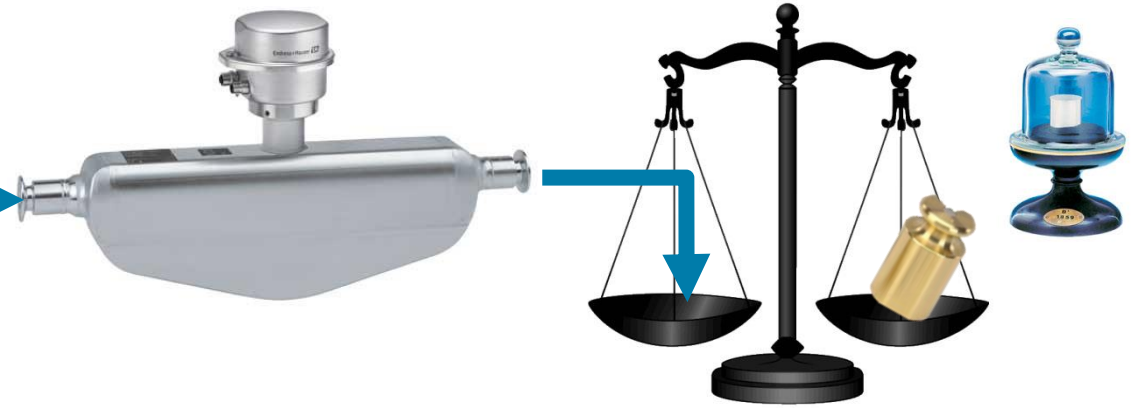
Calibration



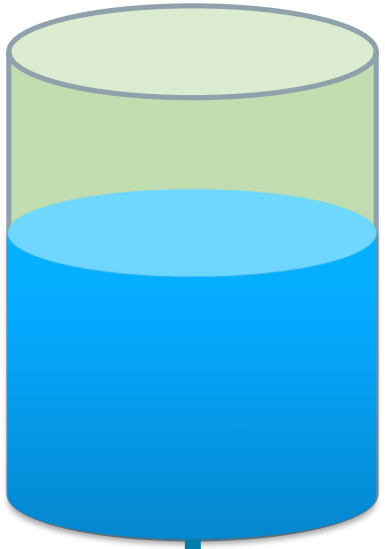
Calibration is the determination and documentation of the difference between the display value and the correct value without technical intervention.

Traceability is accomplished by a formal comparison to a standard which is directly or indirectly related to national standards



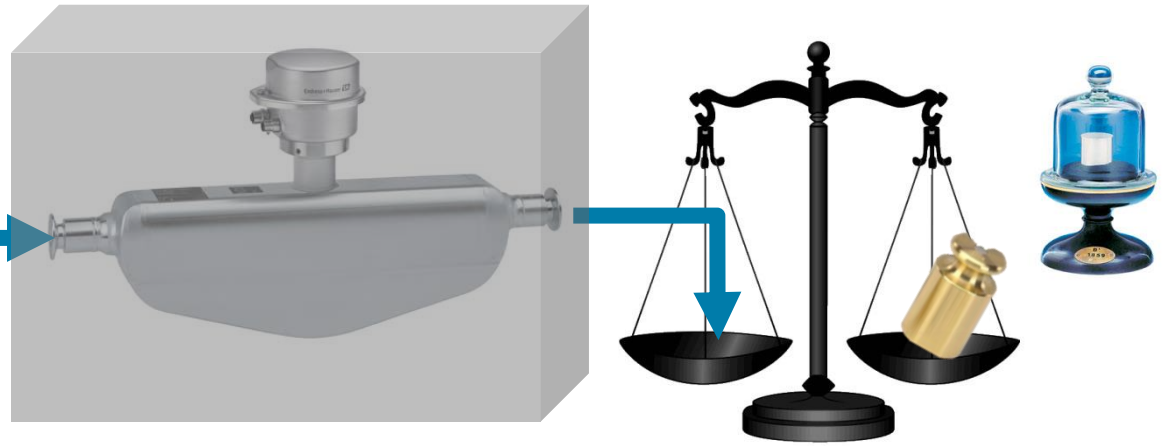
Gravimetric calibration rig

Calibration



During the calibration, the entire measuring device is seen as a “black box” where only the result of the measurement is considered.

Defects to the sensor are only detected if they have a direct impact to the measuring performance.

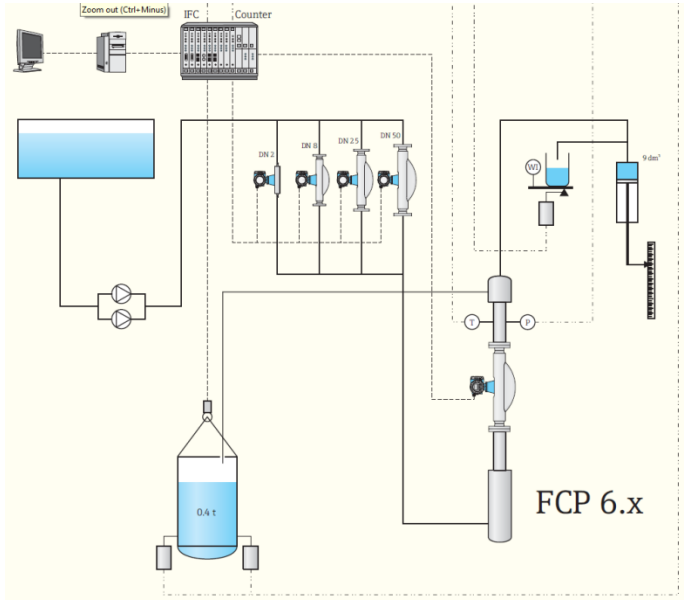


Gravimetric calibration rig

Calibration vs Verification

- What is the relation between calibration and verification results?

Calibration rig



Calibration report

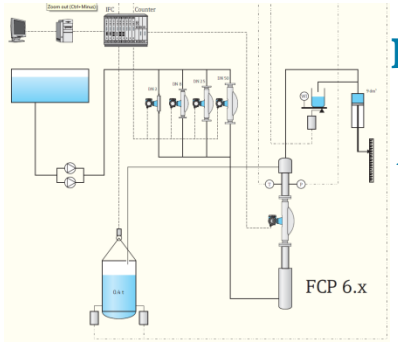
?

Verification report

Endress+Hauser

Calibration vs Verification

- Verification of flowmeter functionality based on flowmeter internal factory references and corresponding specifications
- During production process these factory references are calibrated based on traceable standards to establish a factory baseline



Production, calibration

Sensor
Inlet pickup coil
Outlet pickup coil
Measuring tube temperature sensor
Carrier tube temperature sensor
Pickup coil symmetry
Frequency lateral mode
Frequency torsion mode
Sensor integrity
Sensor electronic module
Zero point tracking
Reference clock
Reference temperature
I/O module

Factory references

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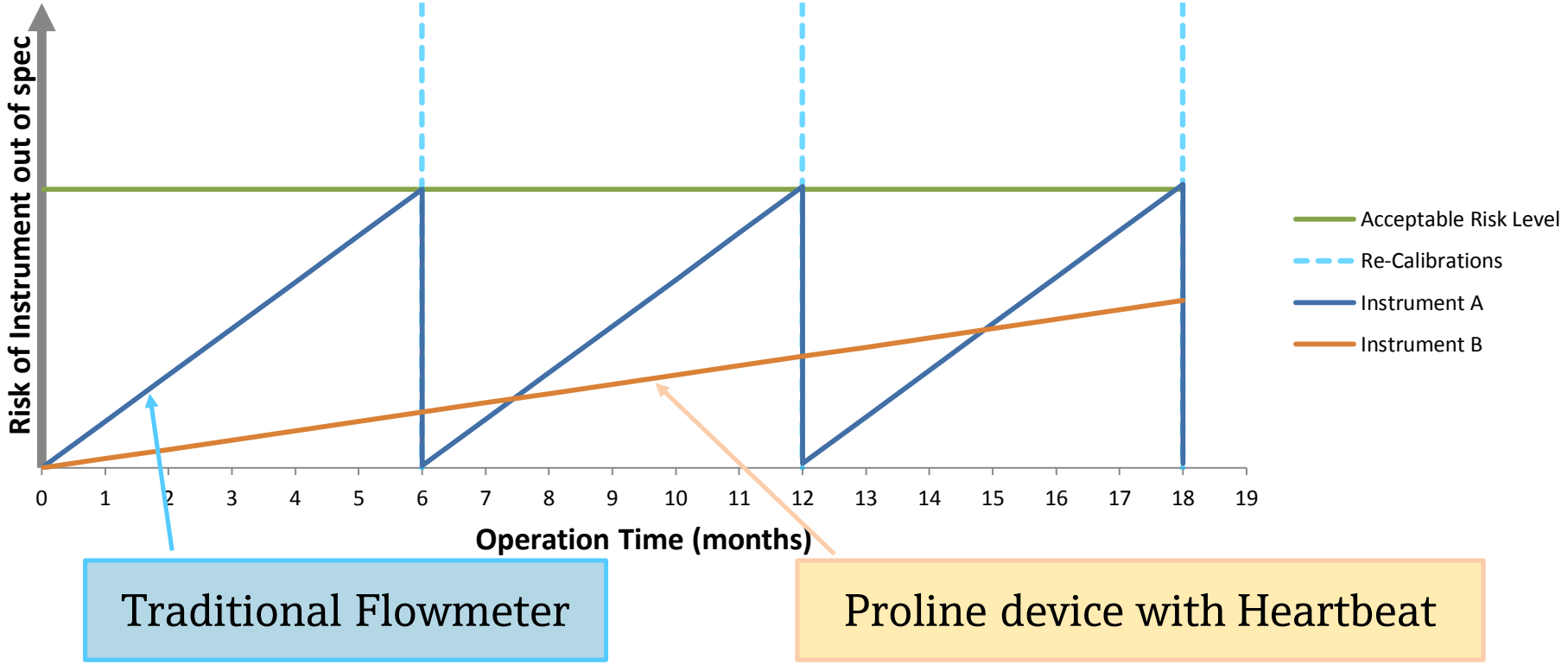
Use case

- What is in it for me?
- How can I implement Heartbeat?

Calibration Interval



- Long “unknown periods”
- High cost for calibration
- Process downtime

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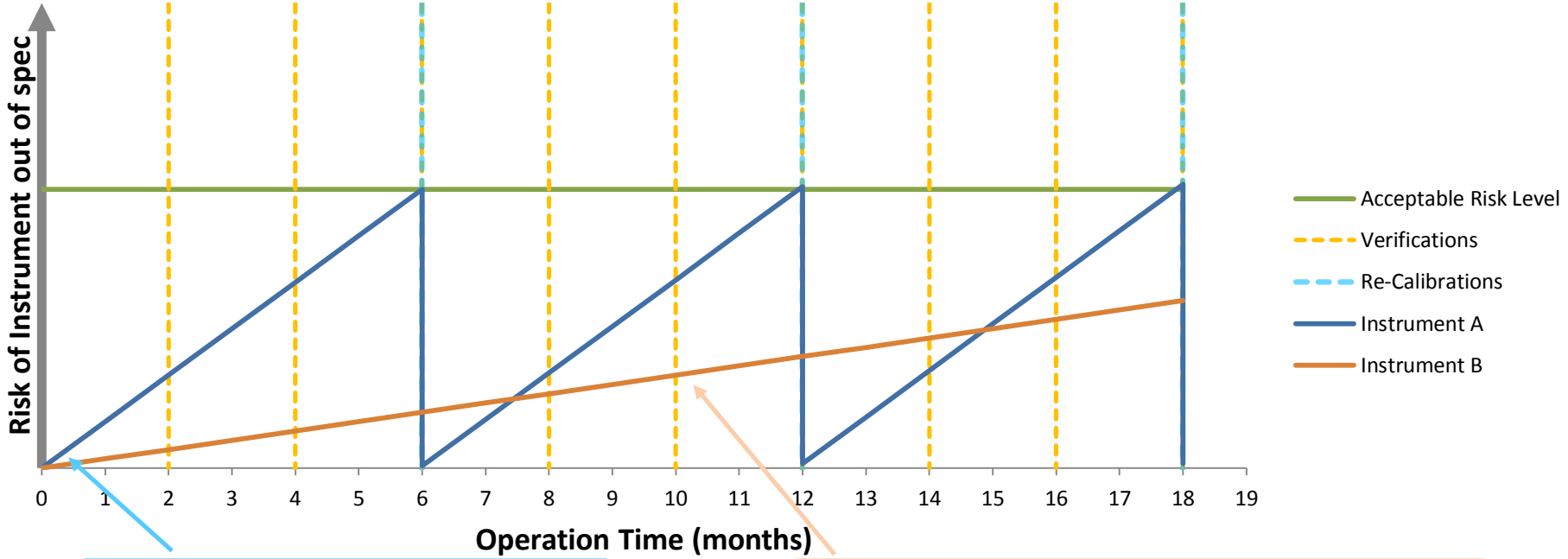
Calibration Interval



Traditional Flowmeter

- Long “unknown periods”
- High cost for calibration
- Process downtime

Proline device with Heartbeat

- High confidence due to short cycles
- Minimized effort
- No process downtime

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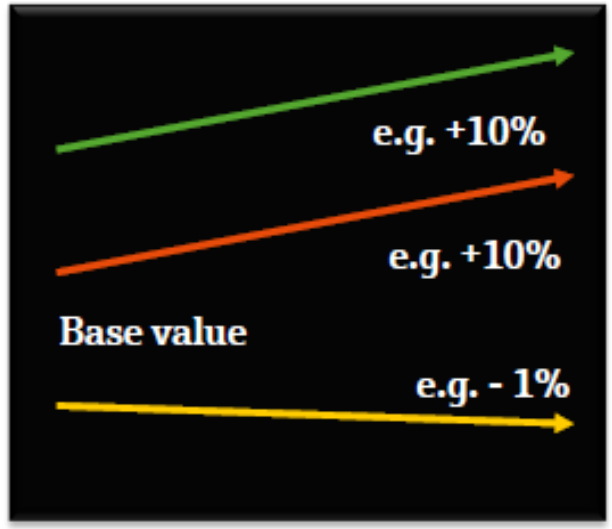
Coriolis - Coating build-up in the tubes

If the fluid's density and viscosity are stable, coating build-up can be detected by decreasing frequency, and concurrent increase in tube damping or signal asymmetry.



The density measurement can be tracked in addition, if the fluid is unchanged.

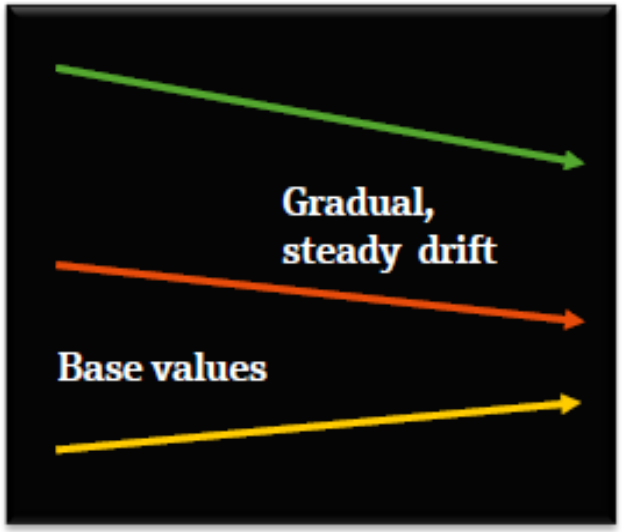
Coriolis - Corrosion /Abrasion

Corrosion may occur in manifold forms, so condition monitoring requires a variety of parameters, particularly here.

Tube damping

Signal asymmetry

Resonance frequency



The density measurement can be tracked in addition, if the fluid is unchanged.

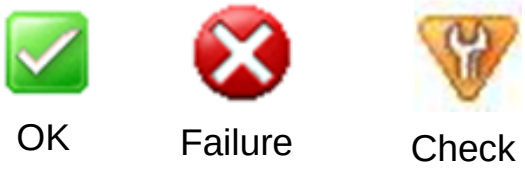
Abrasion particularly impacts the curved sections inside the tube.

Heartbeat Diagnostics - Standard with Proline

Heartbeat Diagnostics

Flowmeter health
→ information

supports



- Process safety
- Product quality
- Operation & Maintenance

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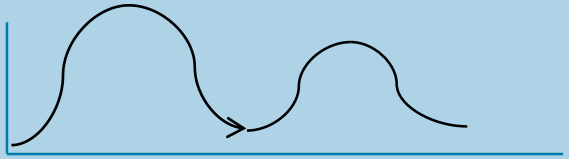
Heartbeat Technology™ - Verification + Monitoring

Heartbeat Monitoring

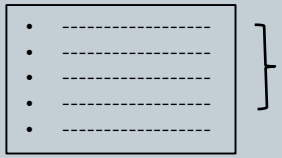


Window into the process
→ data

supports

- Operation & Maintenance
- Product quality
- Product safety

Heartbeat Verification



Flow meter functionality
→ verification

supports

- Process safety
- Metrology
- Product quality

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Heartbeat Monitoring

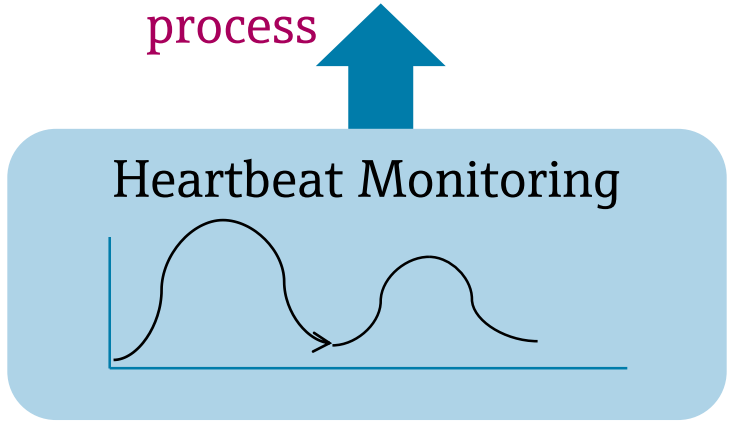
- Practical example

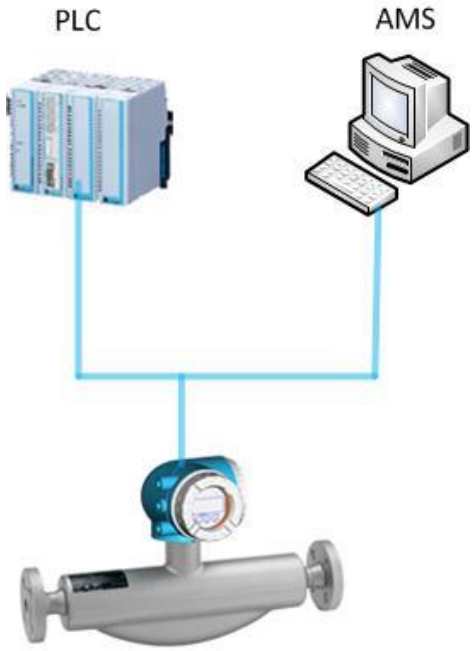
Heartbeat Monitoring – observation

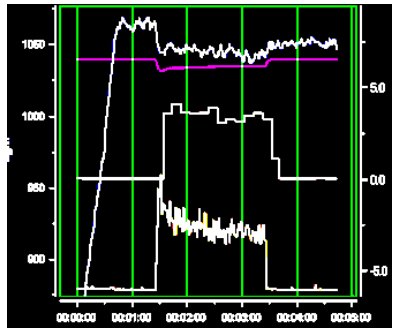
Continuous output of process related monitoring data to an external condition monitoring system (e.g. FieldCare)

Continuous output of data influenced by process

Heartbeat Monitoring

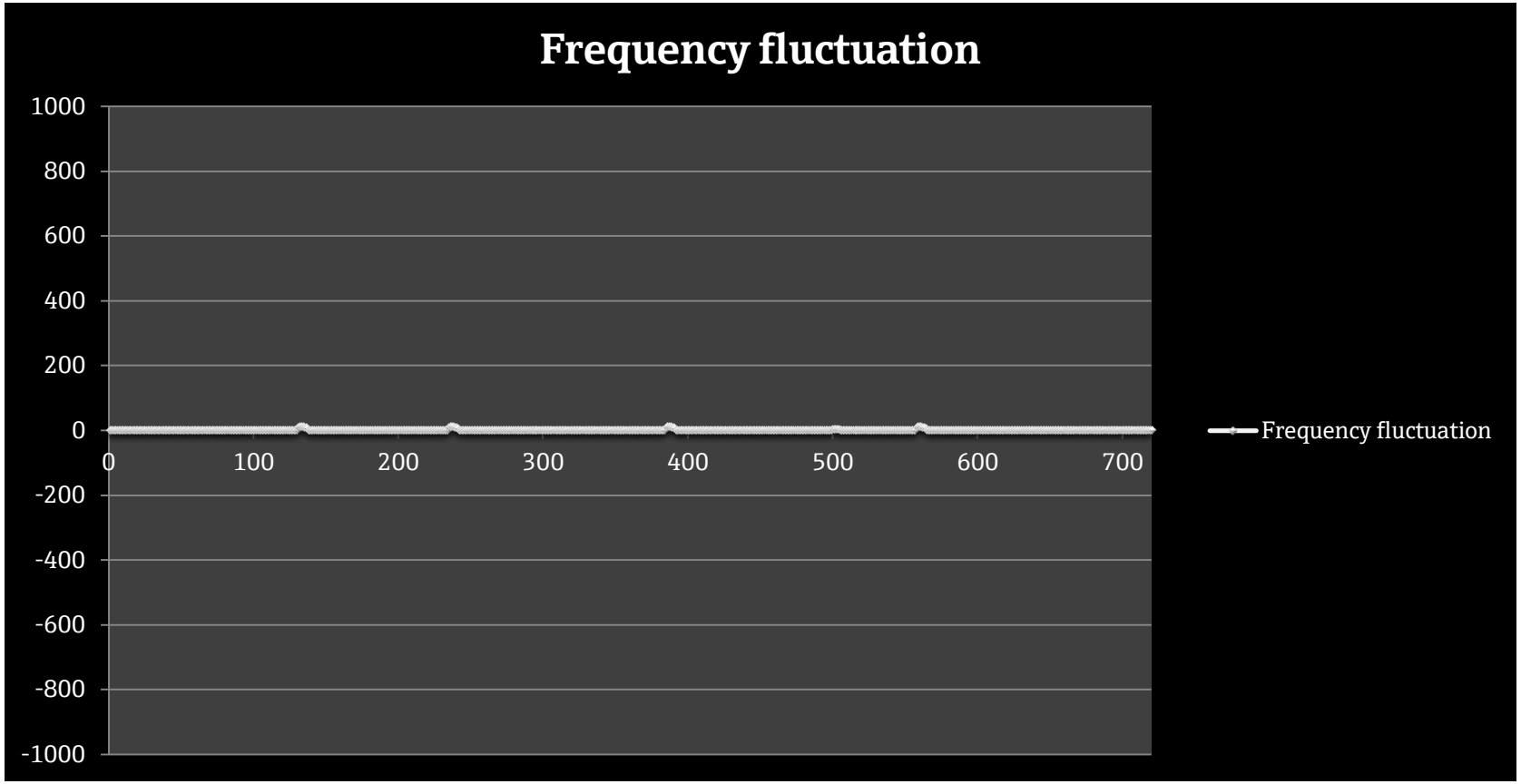






Heartbeat Monitoring example

Data logging frequency fluctuation measuring tube Promass



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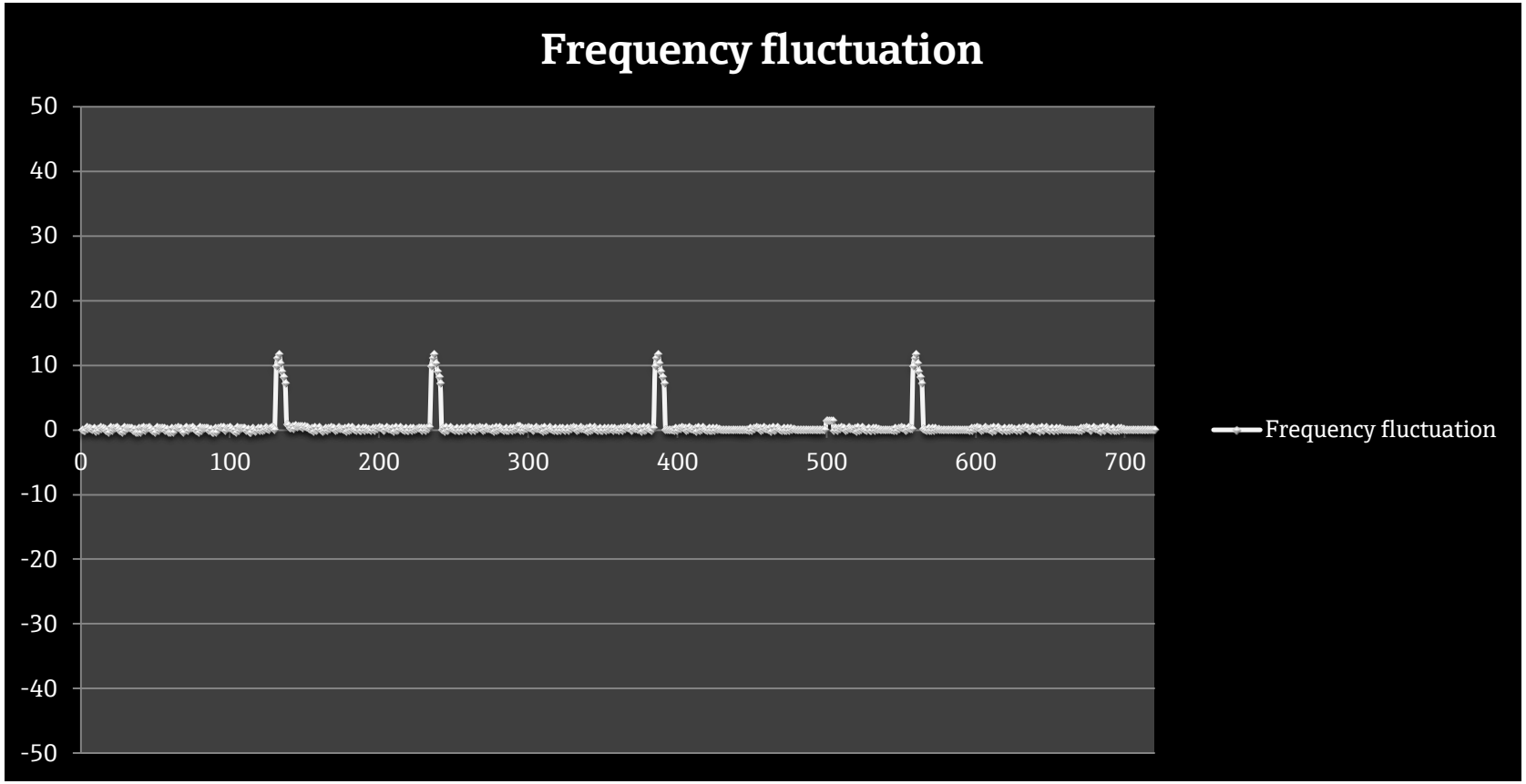
Heartbeat Monitoring example

Zoom reveals transient spikes at random intervals



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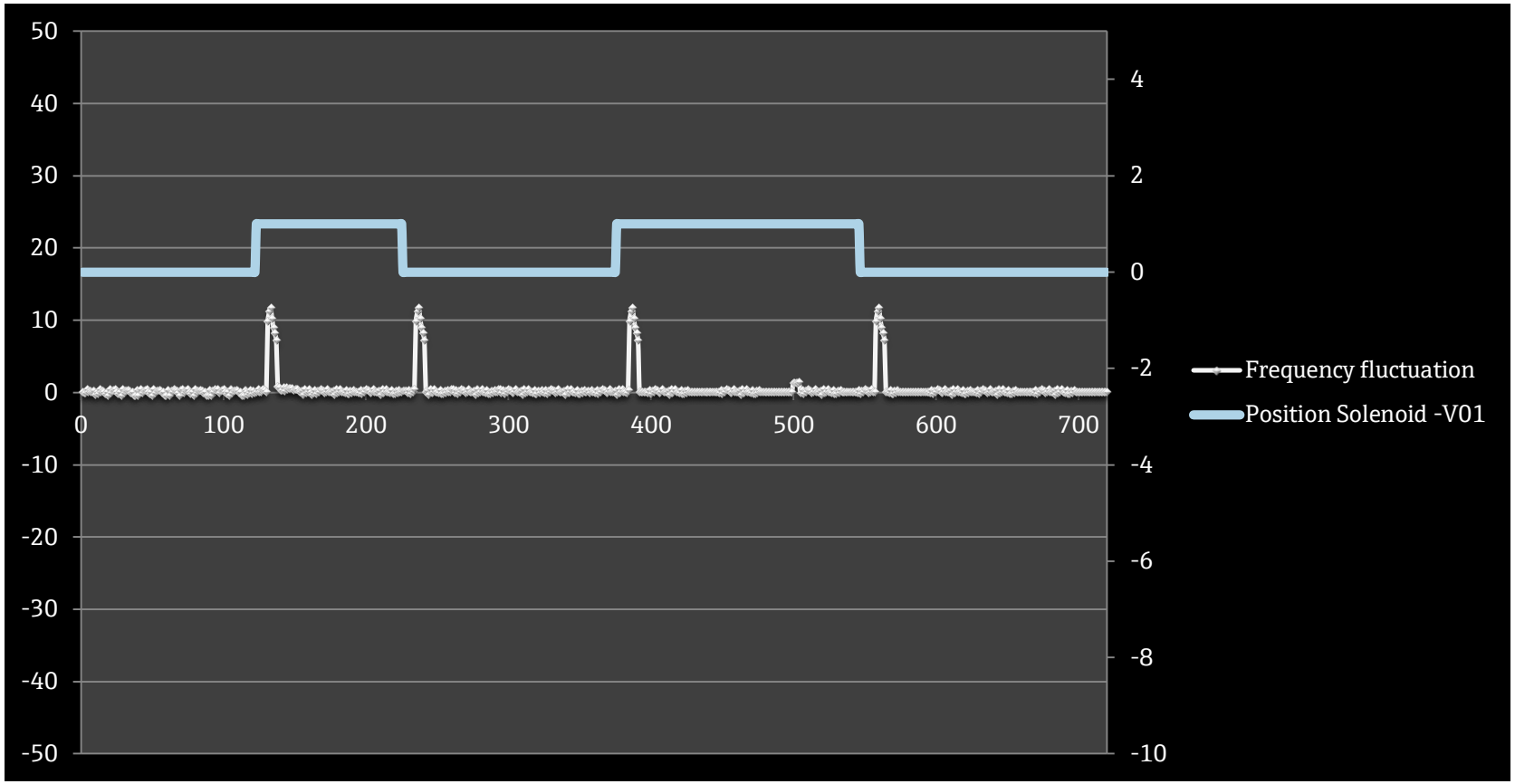
Heartbeat Monitoring example

Adding additional graph of process valve (dosing solenoid V-01)



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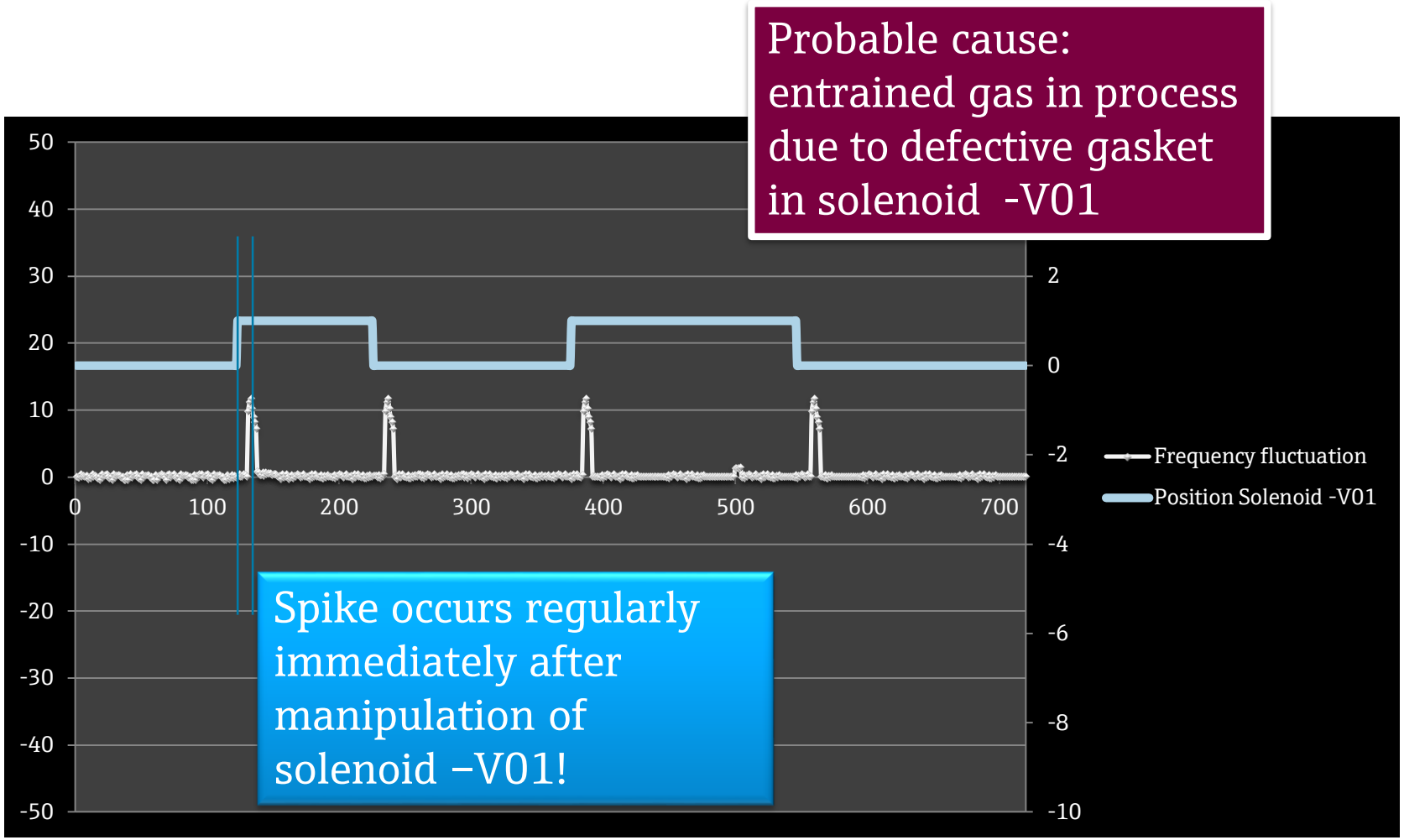
Heartbeat Monitoring example



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Asset Health & Performance Monitoring –

- Self –Verifying Device Mass Flow Meter Promass P
- Self – Calibrating Device Temperature Sensor TrustSens

Temperature Measurements !!! Over 500 to 1000 points

Fermentation System

- Batch Temperature
- Inoculation Transfer Line Trap Temperature

Media Preparation System

- Batch Temperature
- Air Inlet Filter Trap Temperature
- Transfer Line Trap Temperature
- Low Point Drain Trap Temperature
- CIPS Trap Temperature

Homogenization System

- Homogenizer Outlet Temperature
- Heat Exchanger Outlet Temperature
- Initial Hold Tank Temperature
- Initial Hold Tank Inlet Filter Trap Temperature
- Initial Hold Tank Low Point Drain Trap Temperature
- Homogenate Tank Temperature
- Homogenate Tank Inlet Filter Trap Temperature
- Homogenate Tank Low Point Drain Trap Temperatur

Centrifugation System

- Feed Temperature
- Centrate Temperature

Centrate Pool Tank

- Batch Temperature
- Air Filter Condensate Temperature
- Tank Condensate Temperature
- Product Filter Condensate Temperature

UFDF System

- Recycle Tank Temperature
- Jacket Supply Temperature
- Feed Temperature
- Transfer Filter Outlet Temperature
- Jacket Return Temperature

Product Pool Tank

- Batch Temperature
- Air Filter Condensate Temperature
- Tank Condensate Temperature
- Product Filter Condensate Temperature

CIP System

- CIP Supply Temperature
- CIP Return Temperature

Autoclave

- Chamber Temperature
- Jacket Temperature
- Load Temperature
- Vacuum Break Filter Temperature
- Filter Temperature

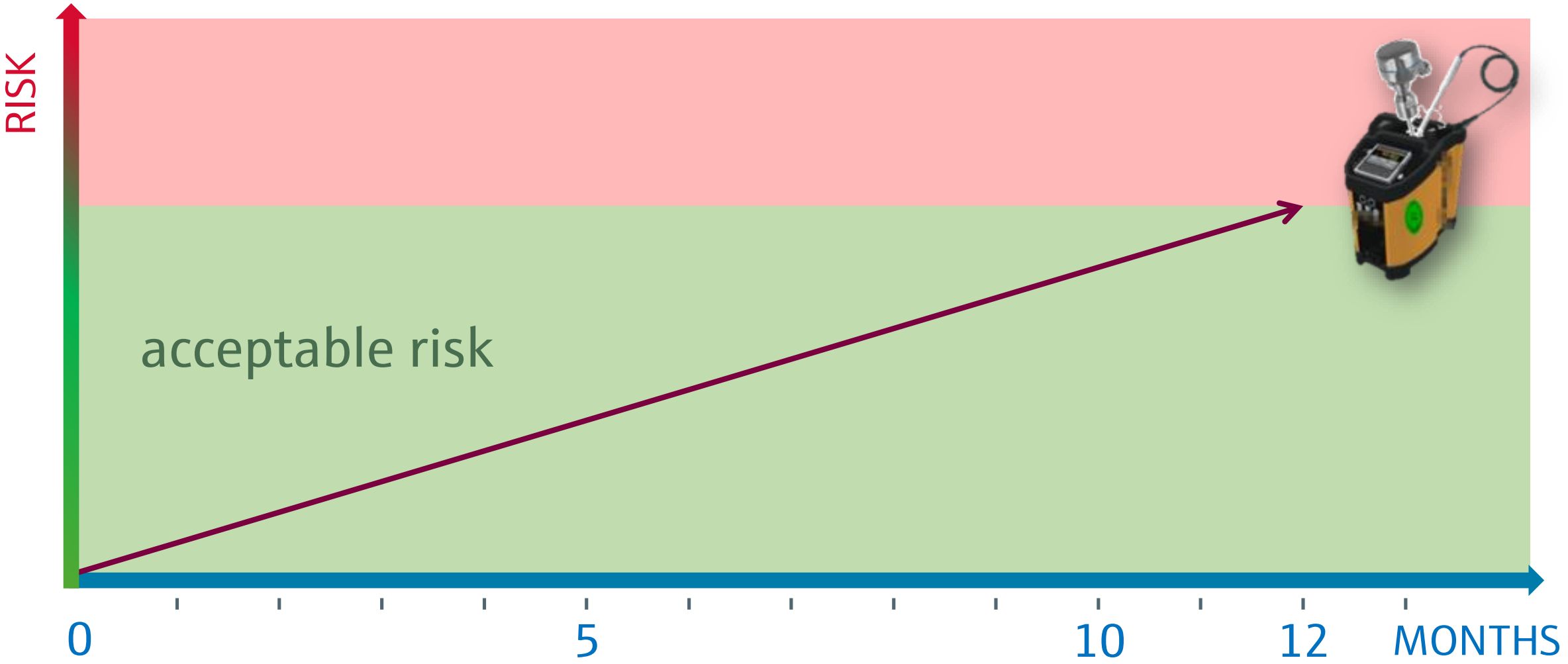
Introducing

The world's first

self-calibrating

temperature sensor

Risk based approach



Preconditions for a traceable - OFFLINE - Calibration

Reference

Regularly calibrated by a **third party.**

Block- or oil-calibrator

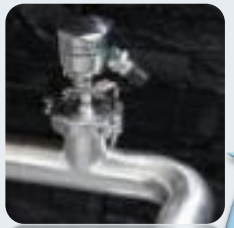
accuracy
homogeneity
repeatability

Reference thermometer

accuracy

Calibration

Regularly **Re-Calibration**
by **trained and skilled staff**



remove

check

every
12month

Manual
validation

Manual
Docu

Certificate

remounting

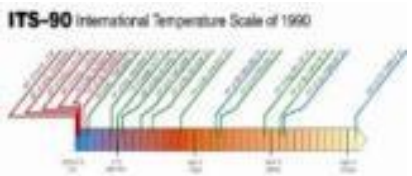
Endress+Hauser

Differentiator between verification and calibration is the traceability chain

DAkkS Deutsche Akkreditierungsstelle

Endress+Hauser

Customer



Endress+Hauser

Traceable - INLINE- Calibration with Heartbeat technology

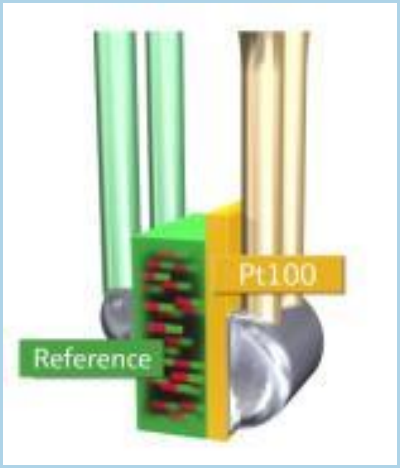
Block- or oil-calibrator

accuracy
homogeneity
repeatability

Reference thermometer

accuracy

Process



Endress+Hauser

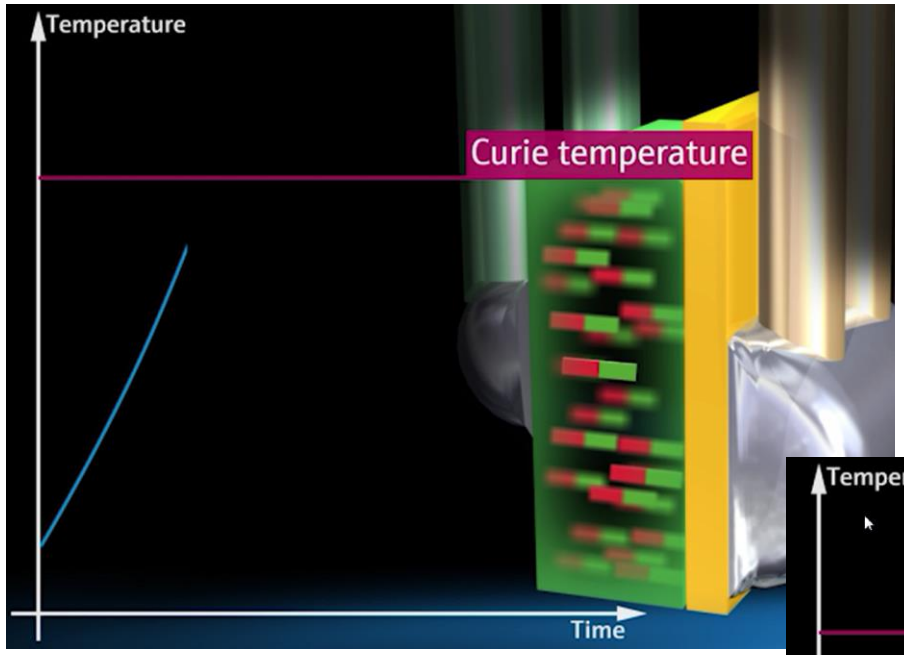
Offline fixed point vs. Inline fixed point

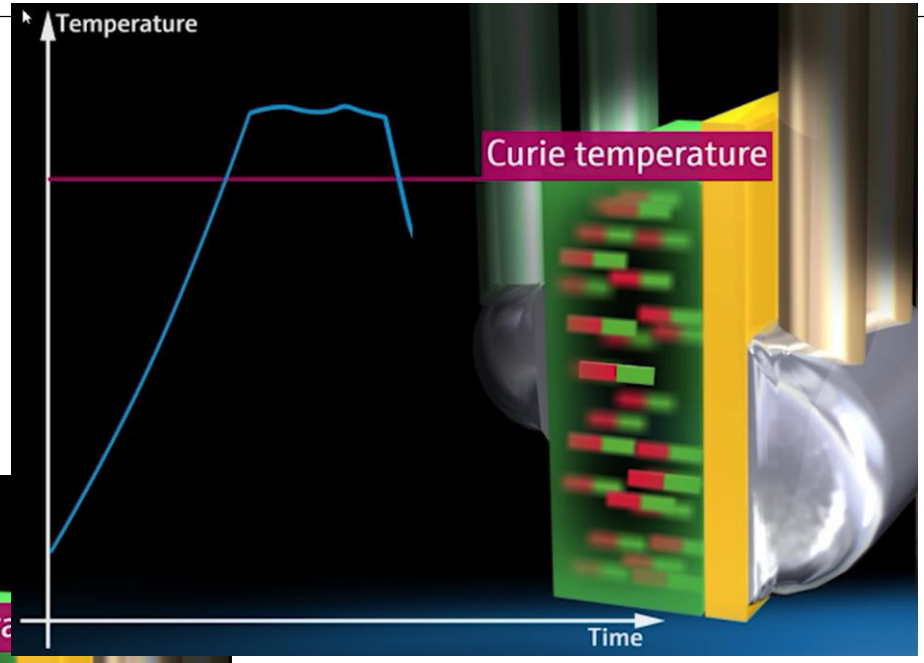
Water triple point @0.01°C

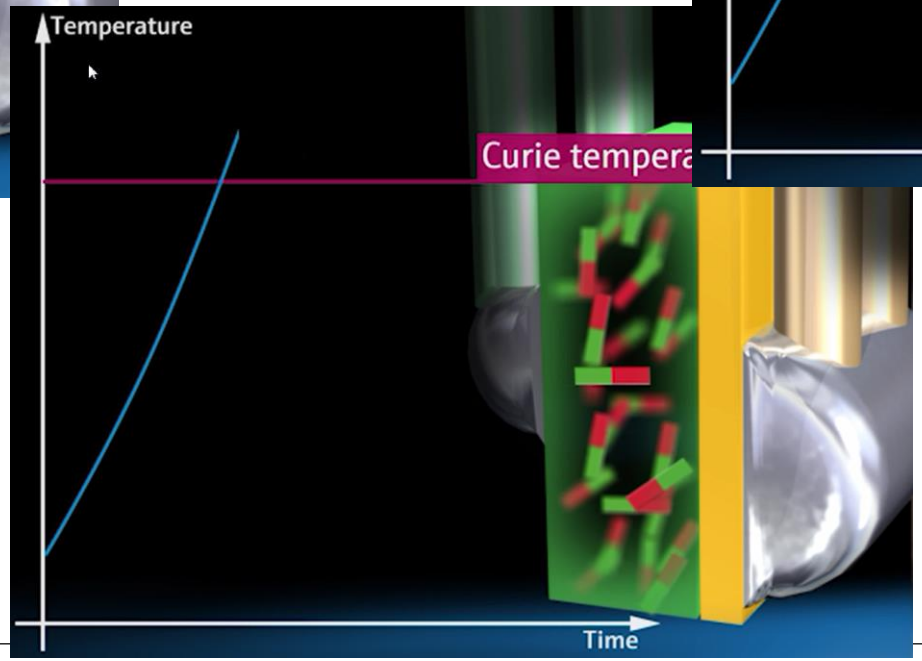
TrustSens Ceramic Curie point @118°C (244°F)

Endress+Hauser

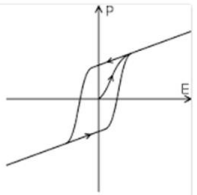
What is a Curie Point?







In physics and materials science, the **Curie temperature** (T_C), or **Curie point**, is the **temperature** at which certain materials lose their permanent magnetic properties, to be replaced by induced magnetism. The **Curie temperature** is named after Pierre **Curie**, who showed that magnetism was lost at a critical **temperature**.

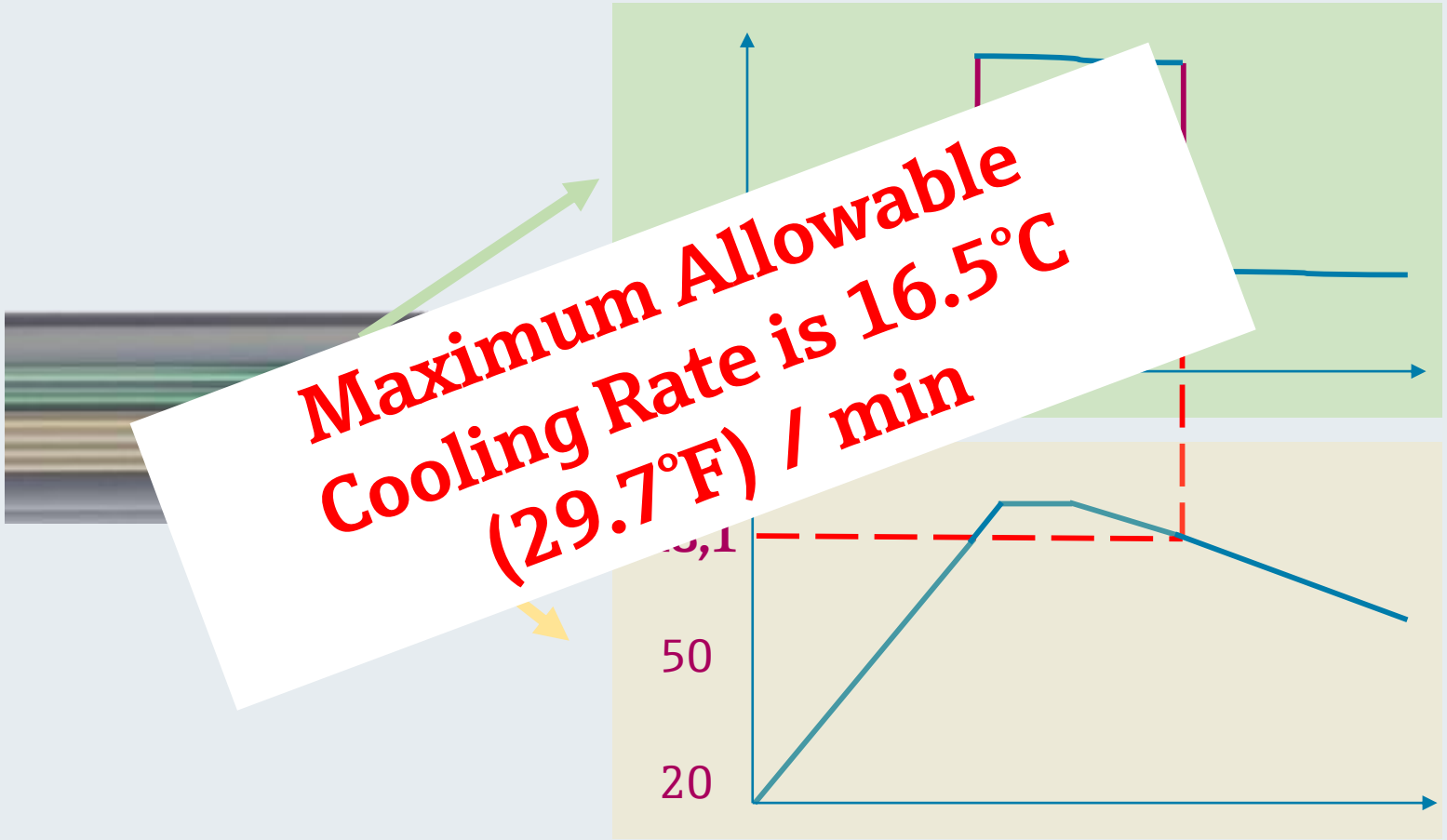


Curie temperature - Wikipedia
https://en.wikipedia.org/wiki/Curie_temperature

Endress+Hauser

Traceable - INLINE- Calibration with Heartbeat technology

Automated Inline Calibration



Automated Calibration

ceramic fix point

–

measured RTD value

=

Deviation

118,0°C-118,1°C=

-0,1°C

Endress+Hauser

Only the reference for the RTD calibration has changed

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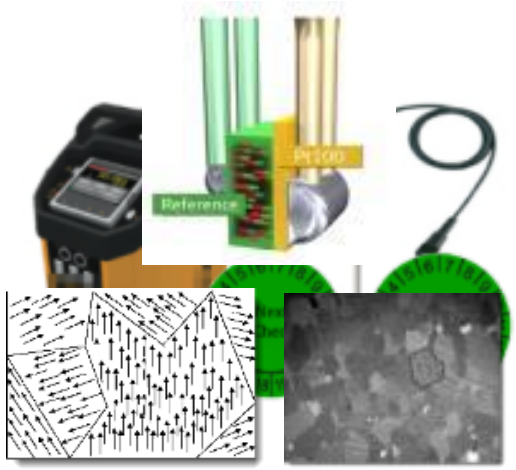
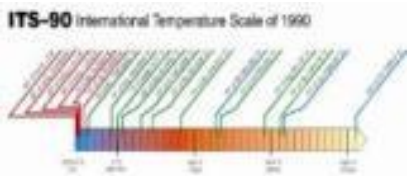
Endress+Hauser

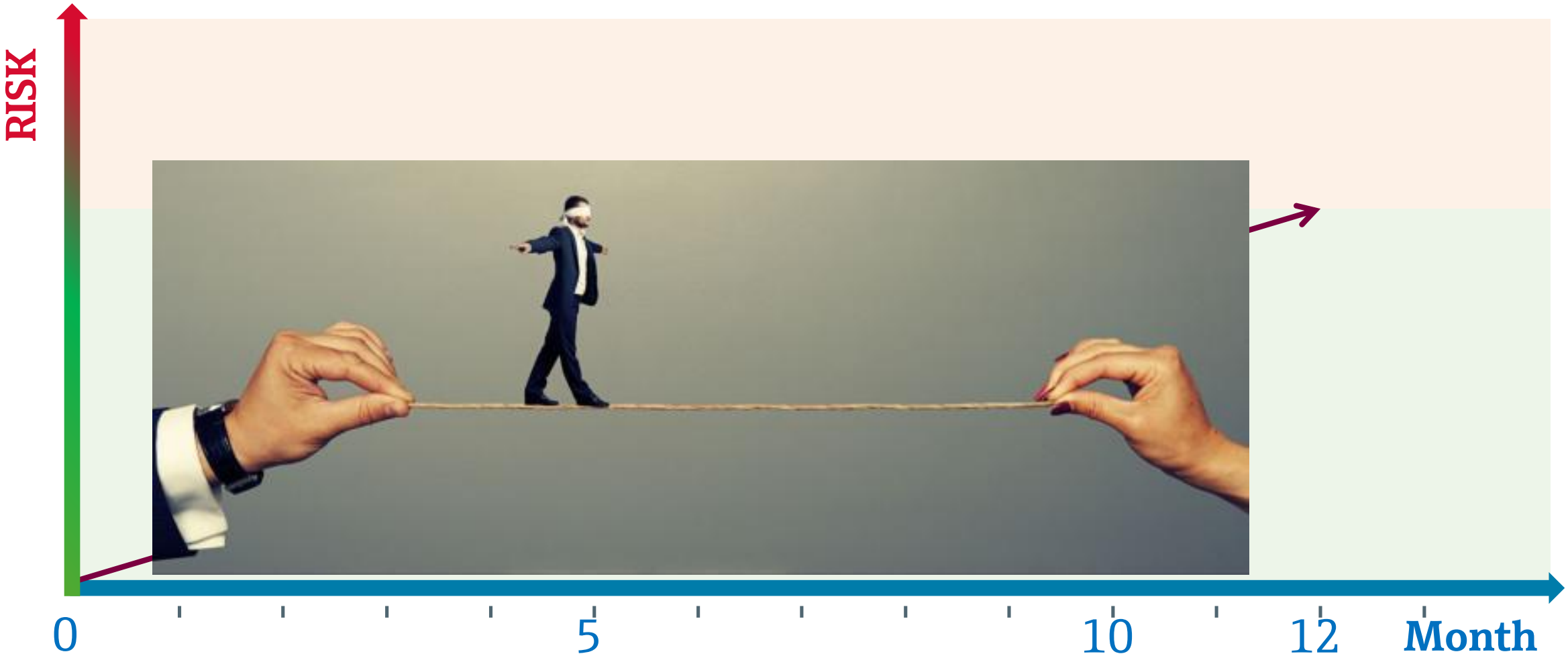
Customer





Risk reduction by 100% Compliance and 0% effort

Cyclic quality checks will always leave a risk in between



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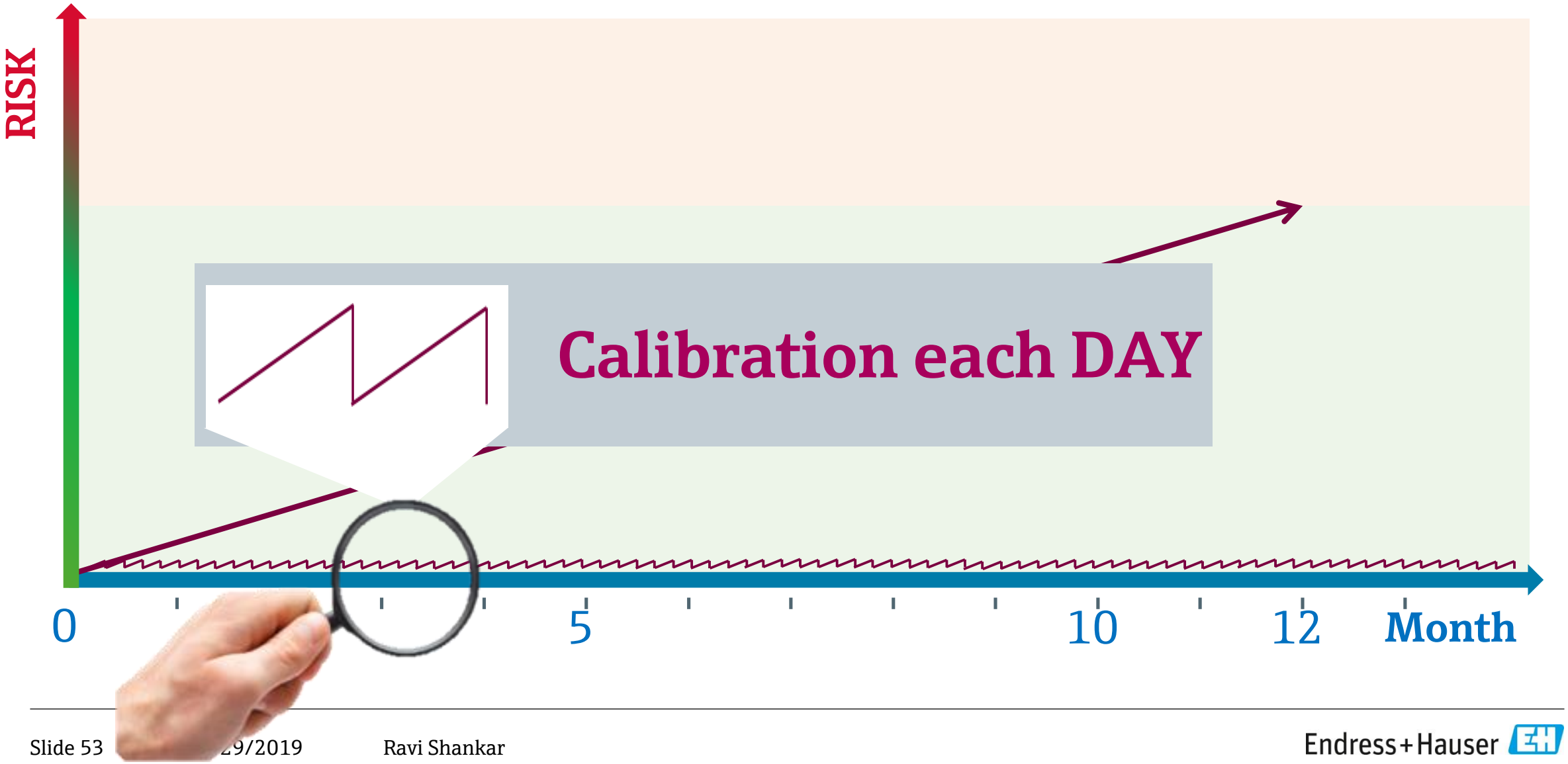
100% Risk reduction



What is the main benefit of calibration in the process?

No more RISK of undetected failures

Real time health information with Heartbeat diganosis

Failure

Function check

Maintenance required

Out of Specification

Endress+Hauser

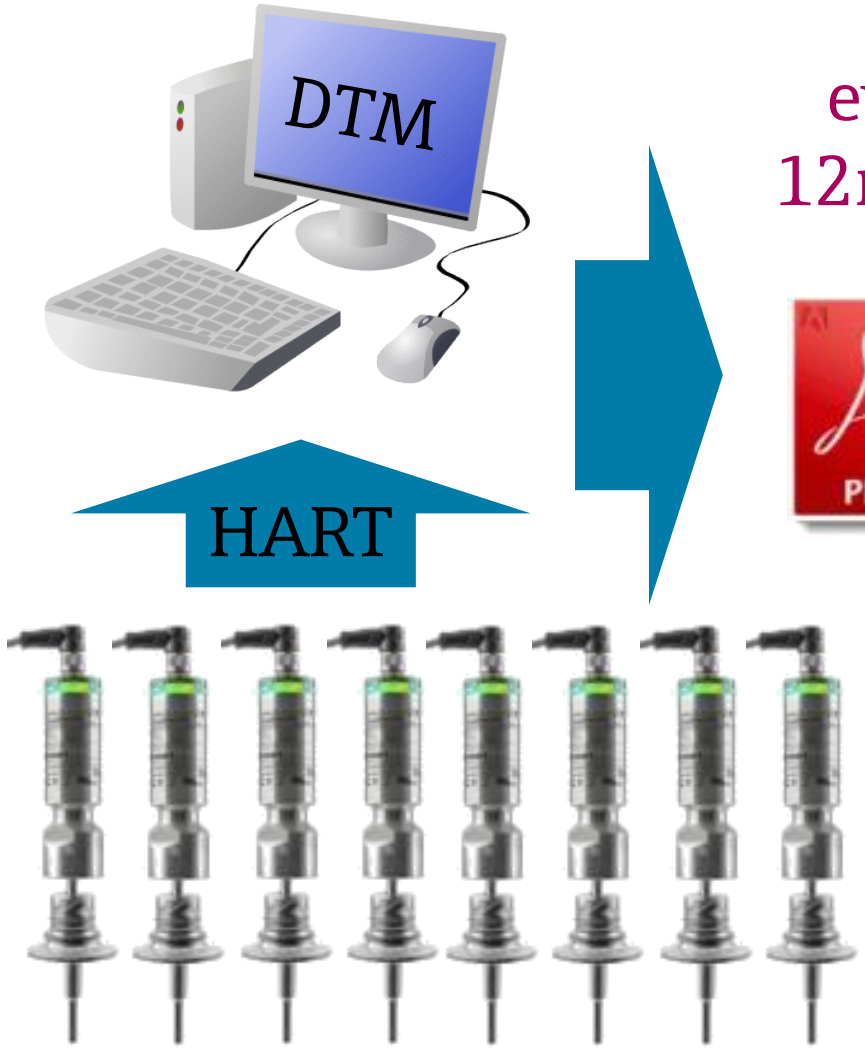
Free programmable ranges for real-time monitoring

Failure

Function check

In tolerance

Automated documentation process of iTHERM TrustSens



Endress+Hauser
People for Process Automation

Calibration certificate

Certificate-No.	H100001143C2
Date of issue (DD.MM.YYYY)	20.02.2017
Operating hours counter	1000h
E+H order number / position	1234567890 / 0090
Customer order number / position	1234567890 / 0010

Device	Order code	Serial number	Ext. order code
Thermometer	TM371-14L2/0	H1000141425	TM371-A1AAJAMAAT7

Tagging (TAG), on device	TIR-0
Tagging (TAG), fieldbus	TIR-0
Tagging (TAG), metal	TIR-0
Tagging (TAG), RFID	TIR-0
Tagging (TAG), Commissioning label	TIR-0

Standards used

Description of the Standard	Certificate No
Build in Ceramic Reference	

Description

The temperature values are according to the ITS-90.
The calibration at 118,0°C is performed automatically on the Curie point from the built in reference ceramic.
The Measurement uncertainty for the curie point is <0,3K.

Measurement results

Operating hours Counter	Referenz temperatur e	Measured Temperature value (calculated acc. To EN 60751)	Deviation	Measurement uncertainties (k=2)	Max. allowed deviation		Assessment	Calibration point ID
(h)	(°C)	(°C)	(°C)	(°C)	-(°C)	+ (°C)		
[1] 950	118,0	118,30	0,30	0,30	- 1,0	+ 1,0	ok	1465

[1] 0 Interruption(s) of the operating hours counter between count 1000h and 950h due device restart(s)

LoopCheck activ

The last signal pattern for LoopCheck was initiated at operating hours counter reading 905

The measurements uncertainty were estimated at twice the standard deviation.

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

Onsite versus TrustSens Calibration

Calibration with reference

+/- <0.2 °C uncertainty

TrustSens inline calibration

+/- 0.35 °C uncertainty

Calibration with dry block only

+/- 0.6 °C uncertainty

...thank you for your attention! Do you have any questions?

Visit us at www.endress.com