Pharma Process Safety Summit - Instrument Asset Health & Performance Monitoring

Purdue University May 7th 2019
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

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

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

- iTherm TrustSense TM37x
  - Self calibration

- QuickNeck/QuickSens

- OEM Packages based on Liquiline CM 44P - Optical Transmitter
  - Memosens CL582D - four-pole conductivity
  - Memosens C0523D - optical DO
  - Memosens CPS171D - pH
  - Cleanfit CPAP75 - Retractable holder

- iTherm TM 411
  - QuickNeck/QuickSens

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

- pH, DO: consistency in technology transfer

- Memosens in Production

- Memosens in Process Development

- Memobase+ in Lab

- Kaiser Optical
  - (door opener, pilot customers)

- Memograph M RSG45
  - Ethernet IP/Profinet
  - HART® Input

- Memosens in Process Development

- Memosens in Lab

- Memosens in Process Development

- Memosens in Production

- Memosens in Process Development

- Memosens in Process Development

- Memosens in Production
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
Pharma Process Safety – API Manufacturing

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

- PHA – Process Hazard Analysis
- What if –
- HAZOP (Hazard and Operability study)
- FMEA (Failure Mode and Effects Analysis)
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
- O2, CO2 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
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

Heartbeat Monitoring

Heartbeat Verification

Heartbeat Diagnostics

Continuous self-diagnostic of flowmeter
Heartbeat is certified by an independent body

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.
Access Locally or Remote

1. Display
2. On-site
   - Web server
   - FieldCare®
3. Remote
   - Control system
   - Asset management e.g. FieldCare®

“No man in the field”
No need to open the device
Verification – report example

Verification report

Customer: Karl
Device information:
- Device type: Flowmeter
- Model name: Nominal diameter
- Device name: Process ID

Installation:
- Install number: Endress+Hauser unit 1
- Calibration factor: 1.0000

Verification results:
- Overall result: Passed

Detailed results:
- Sensor: Passed
- Sensor voltage: Passed
- Display resolution: Passed
- Temperature sensor: Passed
- Flow probe: Passed
- Sensor integrity: Passed
- Sensor element module: Passed

Note:
-务必遵守维修报告的使用规定。
-对于未授权的维修报告，Endress+Hauser将不会提供服务支持。

Date: 2021.12.27
Customer’s signature: [Signature]
Operator’s signature: [Signature]

Endress+Hauser
People for Process Automation

Slide 20 04/29/2019 Ravi Shankar

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## Verification – report example

<table>
<thead>
<tr>
<th>Component</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensor</td>
<td>Passed</td>
</tr>
<tr>
<td>Inlet pickup coil</td>
<td>Passed</td>
</tr>
<tr>
<td>Outlet pickup coil</td>
<td>Passed</td>
</tr>
<tr>
<td>Measuring tube temperature sensor</td>
<td>Passed</td>
</tr>
<tr>
<td>Carrier tube temperature sensor</td>
<td>Passed</td>
</tr>
<tr>
<td>Pickup coil symmetry</td>
<td>Passed</td>
</tr>
<tr>
<td>Frequency lateral mode</td>
<td>Passed</td>
</tr>
<tr>
<td>Frequency torsion mode</td>
<td>Passed</td>
</tr>
<tr>
<td><strong>Sensor integrity</strong></td>
<td>Passed</td>
</tr>
<tr>
<td>Sensor electronic module</td>
<td>Passed</td>
</tr>
<tr>
<td>Zero point tracking</td>
<td>Passed</td>
</tr>
<tr>
<td>Reference clock</td>
<td>Passed</td>
</tr>
<tr>
<td>Reference temperature</td>
<td>Passed</td>
</tr>
<tr>
<td><strong>I/O module</strong></td>
<td>Passed</td>
</tr>
</tbody>
</table>
Asset Performance Monitoring

Instrument Values

- **Flow**
  - Value: 0

- **Temp**
  - Value: 82.22

- **Density**
  - Value: 255.35

- **Tube Damping**
  - Value: 297.81
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.
Calibration vs Verification

- What is the relation between calibration and verification results?
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
Use case

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

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

Traditional Flowmeter

Proline device with Heartbeat
Calibration Interval

- **Risk of Instrument out of spec**
  - **Operation Time (months)**

<table>
<thead>
<tr>
<th>Instrument A</th>
<th>Instrument B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proline device with Heartbeat</td>
<td>Traditional Flowmeter</td>
</tr>
<tr>
<td>- Long “unknown periods”</td>
<td>- High confidence due to short cycles</td>
</tr>
<tr>
<td>- High cost for calibration</td>
<td>- Minimized effort</td>
</tr>
<tr>
<td>- Process downtime</td>
<td>- No process downtime</td>
</tr>
</tbody>
</table>
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.

Abrasions particularly impact the curved sections inside the tube.

The density measurement can be tracked in addition, if the fluid is unchanged.
Heartbeat Diagnostics - Standard with Proline

Flowmeter health → information

- Process safety
- Product quality
- Operation & Maintenance

Supports

- OK
- Failure
- Check
Heartbeat Technology™ - Verification + Monitoring

Heartbeat Monitoring

Window into the process → data

- Operation & Maintenance
- Product quality
- Product safety

Heartbeat Verification

Flow meter functionality → verification

- Process safety
- Metrology
- Product quality

Pass / Fail
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
Heartbeat Monitoring example

Zoom reveals transient spikes at random intervals

Frequency fluctuation

-50 -40 -30 -20 -10 0 10 20 30 40 50 0 100 200 300 400 500 600 700
Heartbeat Monitoring example

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

Probable cause: entrained gas in process due to defective gasket in solenoid -V01

Spike occurs regularly immediately after manipulation of solenoid -V01!
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 Temperature

**Centrifugation System**
- Feed Temperature
- Centrate Temperature

**Centrate Pool Tank**
- Batch Temperature
- Air Filter Condensate Temperature
- Tank Condensate Temperature
- Product Filter Condensate 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

acceptable risk
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
- Every 12 month
  - Check
  - Remounting
  - Manual validation
  - Manual Docu
  - Certificate
Differentiator between verification and calibration is the traceability chain
Traceable - INLINE- Calibration with Heartbeat technology
Offline fixed point vs. Inline fixed point

Water triple point @0.01°C

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

Maximum Allowable Cooling Rate is 16.5°C (29.7°F) / min

Automated Calibration
- ceramic fix point
- measured RTD value
  = Deviation
  118.0°C - 118.1°C = -0.1°C
Only the reference for the RTD calibration has changed
Risk reduction by 100% Compliance and 0% effort
Cyclic quality checks will always leave a risk in between
100% Risk reduction

Calibration each DAY
What is the main benefit of calibration in the process?
No more RISK of undetected failures
Real time health information with Heartbeat diagnosis

- Failure
- Function check
- Maintenance required
- Out of Specification
Free programmable ranges for real-time monitoring
Automated documentation process of iTHERM TrustSens

every 12 months
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?

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