

Quality by Design in Process Instrumentation

“How reliable is a self-calibrating device” and “Can I skip regular calibrations and maintain regulatory compliance”?

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Summary

In order to fulfill regulatory compliance the user is forced to perform periodically traceable calibrations on instruments to ensure product quality. But calibrations are costly, time consuming, cause process down time and additionally pose an increased risk for contamination due to broken process seals. Many instruments on the market today provide self-diagnostics features which give the user some level of information about the health of the device. However, most of them fail to provide conclusive and traceable evidence that the instrument is still operating according to specification. From an operator point of view an “ideal” instrument should be self-calibrating thus eliminating the need for external calibration altogether.

This paper will explain how process automation has evolved and how instruments now offer integrated solutions such as Heartbeat Technology™ which facilitate the implementation of “Quality by Design” (QbD) and provide full regulatory compliance. Offering the possibility to reduce or even eliminate wet calibrations without putting product quality at risk.

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PART 1

Life Science Industry and Regulatory Compliance

Quality by design



Technology transfer from R&D to a full-scale production is often problematic and inefficient due to a complex handover of knowledge, information and skills. If a process engineer is missing important information from earlier studies, it can cause significant delays downstream which means the product is getting late to market. In an attempt to improve this state of affairs, regulators and industries represented in the International Conference on Harmonization (ICH) have adopted the principle of Quality by Design (QbD). This means that the product's Critical

Quality Attributes (CQAs) as well as the CQAs of drug substance, excipients, intermediates or Critical Process Parameters (CPPs) impacting on drug product CQAs must be controlled and maintained during the manufacturing process within an appropriate limit, range or distribution to ensure the desired product quality. The resulting product quality is guaranteed as long as all critical production parameters stay within an acceptable range which is defined as the design space. If a process parameter is considered critical (CPP) it is of utmost importance that the relevant instrument provides accurate and reliable measuring results during the entire life cycle.

Quality by Design starts in an early phase of the product development and plays an important role for the correct selection of process instrumentation. It requires the use of technologies that support better knowledge management and that can collect more information from the process for a continuous improvement of the product and processes. If properly executed, QbD will help to eliminate over-designed facilities and improve process efficiency.

Today's practice and introduction to risk management

Still today it is common practice to treat every piece of equipment within a Life Sciences plant equally when it comes to maintenance. High cost for often unnecessary maintenance – for example recalibrations – is the result. A survey conducted in the pharmaceuticals sector, showed that 42% of respondents said they applied an annual calibration interval on process instruments, and another 42% said they calibrated even twice per year.

A better and more cost efficient way is to use a risk-based approach that classifies each piece of equipment in terms of its impact on product quality as defined by the FDA already in 2004 and define appropriate maintenance and calibration intervals accordingly. Quality risk management (QRM) is now a regulatory expectation, and it makes good business sense. The goal of the risk assessment is to increase process understanding and deliver safe and effective product to the patients.

The good thing for the life sciences industry – as far as risk management is concerned – is that most of the hard work has been done already by other industries such as aerospace or oil and gas. The challenge is how to take this knowledge and apply it to the Quality Risk Management (QRM) systems

as defined by ICH Q9. Risks are associated throughout the biopharmaceutical manufacturing process – from raw material supply through manufacturing and filling operations to final distribution. A number of assessment tools are available to evaluate, manage and mitigate the risk in a process. QRM tools used to identify the risks and develop strategy to minimize or control them include Failure Mode Effect Analysis (FMEA), Fault Tree Analysis (FTA), Preliminary Risk Analysis (PRA), Hazard Operability Analysis (HAZOP) and Hazard Analysis and Critical Control Points (HACCP).

To incorporate the safety parameters of the instruments into the QRM tool is crucial and sometimes problematic. Standard “off the shelf” process automation does not always provide the required parameters and information. Process instruments specifically designed to provide highest safety (e.g. developed according to IEC61508) is most suitable for critical applications. Results and detailed information about the safety design such as FMEDA data are readily available from the instrument manufacturer and can be used as direct QRM input for risk mitigation calculations.

Legal requirements for maintenance

Whether ISO9001:2008-7.6, GMP or WHO – all define in a similar way that equipment and instrumentation has to be calibrated or verified at specific intervals against measurement standards which are traceable to international or national standards. However, it is always the plant operator’s responsibility to define and execute a proper maintenance program.

Calibration cycles

The decision on how often to schedule re-calibration can be difficult; but product safety has always highest priority and product quality must never be jeopardized. The task at hand is to find the right balance between saving operational cost by extending intervals while ensuring the reliability of the process. The main issue with extended calibration cycles is the unknown period in-between calibrations.

The first step of a re-calibration is an as-found check where it is determined if the instrument was still operating within specifications before it was taken out of service for calibration. A failed “as-found” check can be critical and has to be further investigated for possible impact on product quality for the last calibration period. A substantial number of FDA warning letters are issued because remedial action has been considered insufficient: The actual root causes were not investigated sufficiently or not all. Possible reason may be that in-depth investigations in retrospect are very complex and time consuming and in some cases even impossible.

Calibrations are expensive but provide very clear results for the user. Even though many instruments have proven exceptional long-term stability which exceeds often the entire lifetime of the equipment they still have to be checked regularly to avoid legal implications.

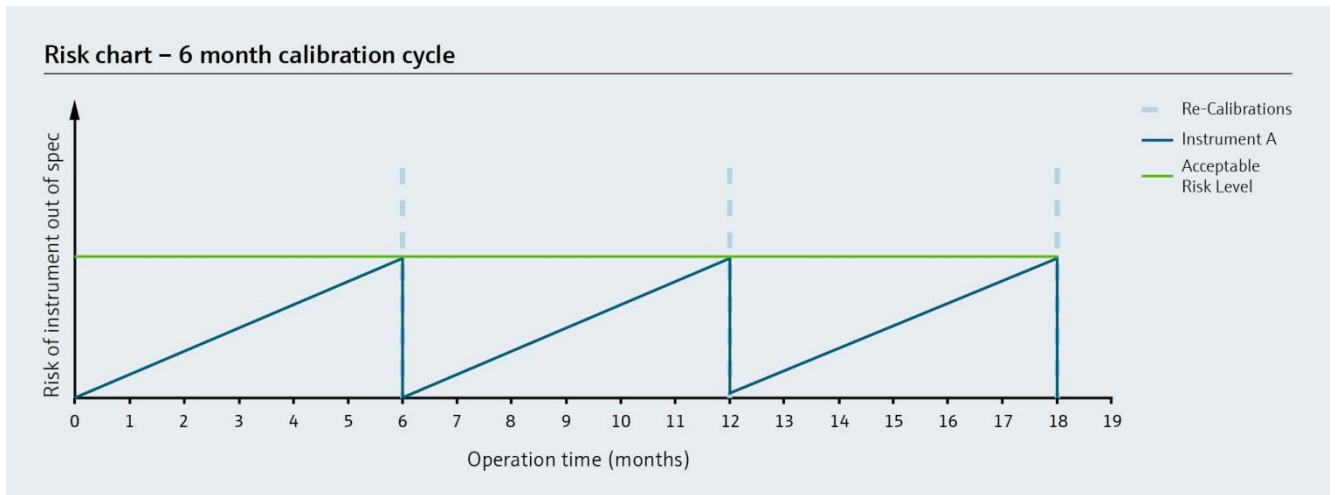


Figure 1: 6-month calibration cycle.

The recalibration cycle period in this example is 6 month, based on manufacturer's recommendation considering the average acceptable risk level. The criticality of the process parameter defines the maximum acceptable risk level. The averaged risk between calibrations shall always remain below the acceptable level. However, the possibility for an undetected "out-of-spec" situation gradually increases over time resulting in an increased risk for product quality issues.

Calibration versus verification

Legal requirements for regular checks are commonly fulfilled with wet calibrations. A **calibration** of an instrument, for example a flowmeter, is the determination and documentation of the difference between the display value and the correct value of a primary fluid (measurand) without technical intervention. Traceability is accomplished by a formal comparison to a standard which is directly or indirectly related to national standards. Detected deviations between the displayed value and the effective measured reference-value can be corrected after the calibration by adjusting the calibration factor. A calibration protocol is issued to document the findings and put on record for possible audits. The downside of wet calibrations is that the instruments typically have to be removed from the process in order to be connected to a calibration rig or a master meter. After the calibration the instrument is then sent back to the facility to be installed again. Damages during transport or handling can sometimes stay undetected and can lead to a situation that a freshly calibrated instrument is not performing according to specifications. Alternatively a mobile calibration cart can be used to perform a calibration on site. This method typically eliminates the need for dismounting the meter under test but still requires that the primary process loop is opened which increases the risk for contamination.

An alternative way to fulfill the legal requirements is an **on-board verification** of the device. Whereas the device runs an on-board diagnostics program where all relevant components of the instrument are checked in order to confirm and document that the instrument is still in factory conditions and that no parts have been altered, changed or have drifted.

Verification of an instrument equipped with built-in verification capabilities can be performed without removing the instrument from the process. It may not even be required to interrupt the process as the verification tests can all be performed in the background.

During the on-board test all relevant internal parameters which are closely correlated to the main measurement are checked. The test only takes a few seconds and includes mechanical, electro-mechanical and electronic components. Pass/fail results are available immediately after the test providing the user with clear information if the instrument is still operating according to specification. The qualitative results of a verification have no lesser value than a wet calibration and can be used in an equal manner to prove that the device under test is still fit for the defined operation. The main advantage of an embedded verification is that the instrument does not have to be removed from the process and therefore the risks of damage due to the handling and cross contamination of the process loop are eliminated.

Traceable standards and diagnostics coverage

Calibrations and verifications have to be traceable to national or international standards in order to fulfill regulatory requirements. Wet calibrations achieve traceability by using calibration rigs accredited according to ISO 17025, or respective master meters. A more complex situation presents itself for devices with built-in self-verification functionality. Integrated solutions have to rely on a network of redundant components and built-in traceable references.

The entire signal chain of the instrument has to be analyzed for possible errors and their subsequent impact on the system and its measuring accuracy. Typically an FMEDA is used during the device design phase to identify critical components in the signal chain starting at the process-wetted parts followed by the electro-mechanical components, the amplifier board, the main electronic and the outputs. As a result, a proper safety measure has to be assigned to every critical path or component. Measures include consequent digital signal processing and continuous loop checks with the help of internal reference components. In order for an internal component to be used as a diagnostic reference it has to fulfill special requirements such as factory traceability and exceptional long-term stability. For the most critical circuits independent and redundant components are implemented reducing greatly the possibility of an undetected drift. Today it is possible to design instruments with a self-diagnostics coverage of 94% or higher (in accordance with IEC 61508), and prospective rates of dangerous undetected failures below.

Records keeping

In order to fulfill the regulatory requirements it is mandatory to keep records of calibrations and verifications. The results of a successful calibration including possible adjustments depend on the calibration rig and are provided in form of calibration certificates.

An instrument with on-board verification has to have the capability of creating a tamper-proof verification certificate without the need of external hardware such as computers. Therefore, such instruments have integrated PDF printers and non-volatile memory on board which create and store certificates and detailed verification data. The files and data are accessible for the user through any asset management system or can be downloaded anytime to a tablet or computer via the integrated web browser.

Verification on the go or periodical wet calibrations

The benefit of a built-in verification is that it can be initiated locally with minimal effort or remotely from the control system, even under process conditions. Because it is so easy and non-invasive the meter can be verified on a daily basis reducing drastically the unknown period which is typical for wet calibrations. In batch applications a system check can be initiated from the control system prior to starting the batch ensuring that all devices work properly. Such a system check greatly reduces the risk for unplanned shutdowns due to instrument failures.

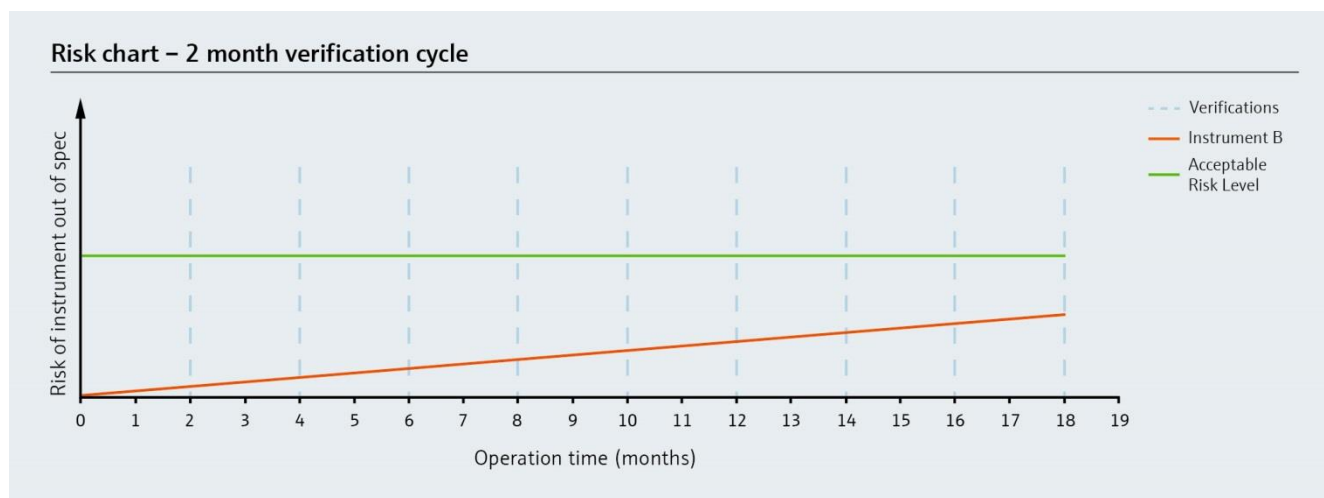


Figure 2: 2-month verification cycle.

The instrument (B) in this example has a significantly higher test coverage compared to instrument (A) in Figure 1. For audit documentation purpose the instrument is verified every 2 months by the means of built-in diagnostics. The supplied verification report is stored on-board and in the customers asset management system for easy access.

Conclusion

Wet calibrations are today still the most often used method to check an instrument and demonstrate regulatory compliance. State-of-the-art instruments with embedded verification capabilities offer now the chance to change this practice. Performing regular verification on the instrument can extend calibration cycles by a factor of 5 or higher without jeopardizing the quality or the regulatory compliance. Shorter unknown periods between checks lead to an increased confidence level and reduced risk for critical applications.

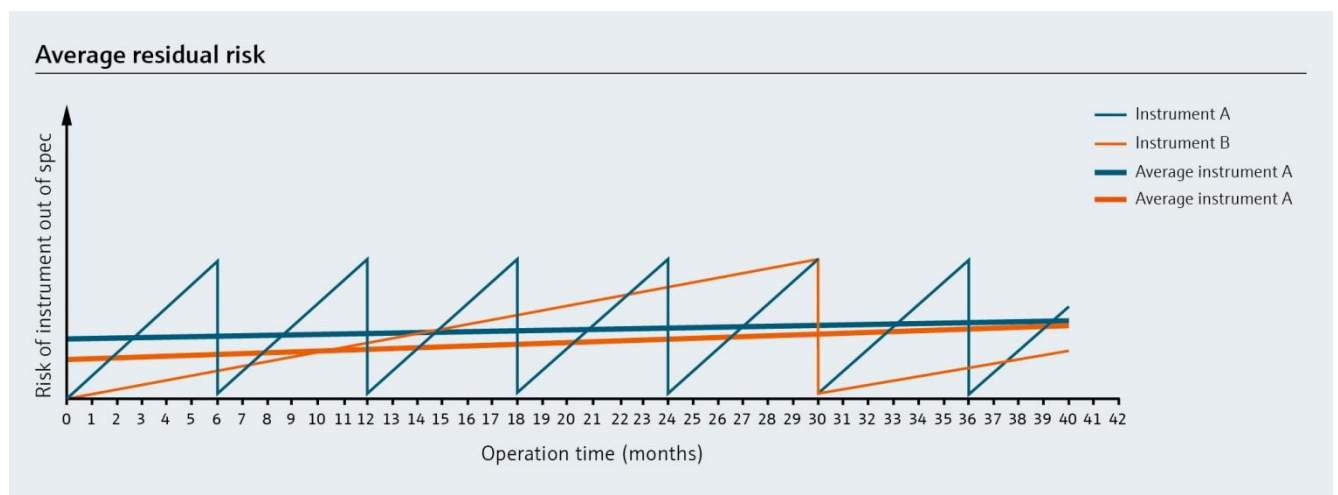


Figure 3: Calibration versus verification.

Two instruments are in operation (A and B). In order to guarantee the required risk level for this specific application, Instrument A has to be re-calibrated every 6 month based on manufacturer's recommendation and the safety parameters of the device. Instrument B is equipped with an inherent safety design and an embedded diagnostics and verification system. It is verified bi-monthly by the means of an automated diagnostics system. Due to the higher test coverage of the diagnostics system, Instrument B requires wet calibration only every 2.5 years. Instrument B is generating 80% savings on maintenance cost while at the same time achieving a significantly higher confidence level than instrument A.

Final Word

Built-in verification allows users to extend calibration cycles drastically and reduce OPEX (operating expenses) cost for re-calibration and maintenance while keeping the process fully compliant. Cross-contamination risk and process shutdown associated with recalibration are minimized accordingly.

Reinach, May 2015, Alex Müller/MTC

PART 2

Heartbeat Technology™

Summary

Endress+Hauser introduced Heartbeat Technology™ with on-board verification as a true alternative for calibration in a regulated industry. Proline flowmeters have a proven long-term stability and Heartbeat Technology™ provides reliable and documented proof that the flowmeters perform according to specification. Highly stable and factory-traceable internal references with a redundant design are used as device-internal diagnostic and verification methods. The following document will provide some insight into the technical details of Heartbeat Technology™ based on a Promass Coriolis mass flowmeter.

Verification in GMP environments

Heartbeat Verification can be applied to extend the intervals for re-calibration. This is particularly true for applications where systematic errors can be ruled out. “Systematic” here means that a defect or error in the device was facilitated or caused by the manner of the device’s use. An example of this would be corrosion on the sensor because the sensor material is not suitable for the fluid in question. Increased uncertainty on account of the influence of process conditions, incorrect design or faulty installation also falls into this category. The causes are always due to the interaction between the device and the application. Furthermore, the causes are usually already present at the time of device installation or can be detected at the time of commissioning. Systematic errors can thus be prevented through proper design and commissioning of the device.

The selection of the right wetted parts material for the flowmeter is crucial to ensure bio-compatibility in a life science application. Corrosion, abrasion and leaching are not acceptable in order to prevent any process contamination. In GMP applications (Good Manufacturing Practice) the correct tube material is often defined in an early stage of the process validation; typically during the design qualification (DQ). Therefore, in a GMP environment, systematic errors such as corrosion and abrasion can be excluded from the probability calculations. Important in this regard is that the meter is selected and operated according to manufacturer’s specification.

If systematic errors appear – despite this effort, for example due to a process upset or human error –, they are likely to be detected by Heartbeat Technology™ and remedied at the beginning of the product lifecycle.

Safety by design

Diagnostics coverage of 94% is possible because Heartbeat Technology™ was a key component for the development of the latest generation of Proline measuring devices. Destined to achieve highest possible safety and quality, Heartbeat Technology™ heavily influenced the design and choice of components for the electronic and electromechanical parts within the meter. With the aid of FMEDA (according to IEC61508) the entire measuring signal path starting at the process-wetted parts (e.g. flow tubes)

followed by the electro-mechanical components, the amplifier board, the main electronic and the outputs were analyzed for possible errors and their impact on the system. As a result a safety measure was assigned to every critical path or component. Measures include continuous and flow-independent monitoring of both amplifier channels, consequent digital signal processing and continuous output loop checks with the help of internal reference components. In order for an internal component to be used as a diagnostic reference it has to fulfill special requirements such as factory traceability and exceptional long term stability. Every reference component is specifically selected with those requirements in mind to ensure highest measuring accuracy during the entire life cycle of the measuring device.

But for the most critical circuits and components even stricter measures are required. The accuracy of any Coriolis mass flowmeter depends on a correct time measurement to determine the phase shift which is generated by the Coriolis force. A drift of the internal clock has immediate consequences to the measuring accuracy. Therefore, as a consequence, two independent and redundant quartz clocks are implemented reducing greatly the possibility of an undetected drift. Monitoring continuously the synchrony is a requirement for reliability: A change of the reference is detected reliably because rate of change and time of change are considered.

Test coverage

The definition of test coverage is explained by looking at the details of a Coriolis mass flowmeter.

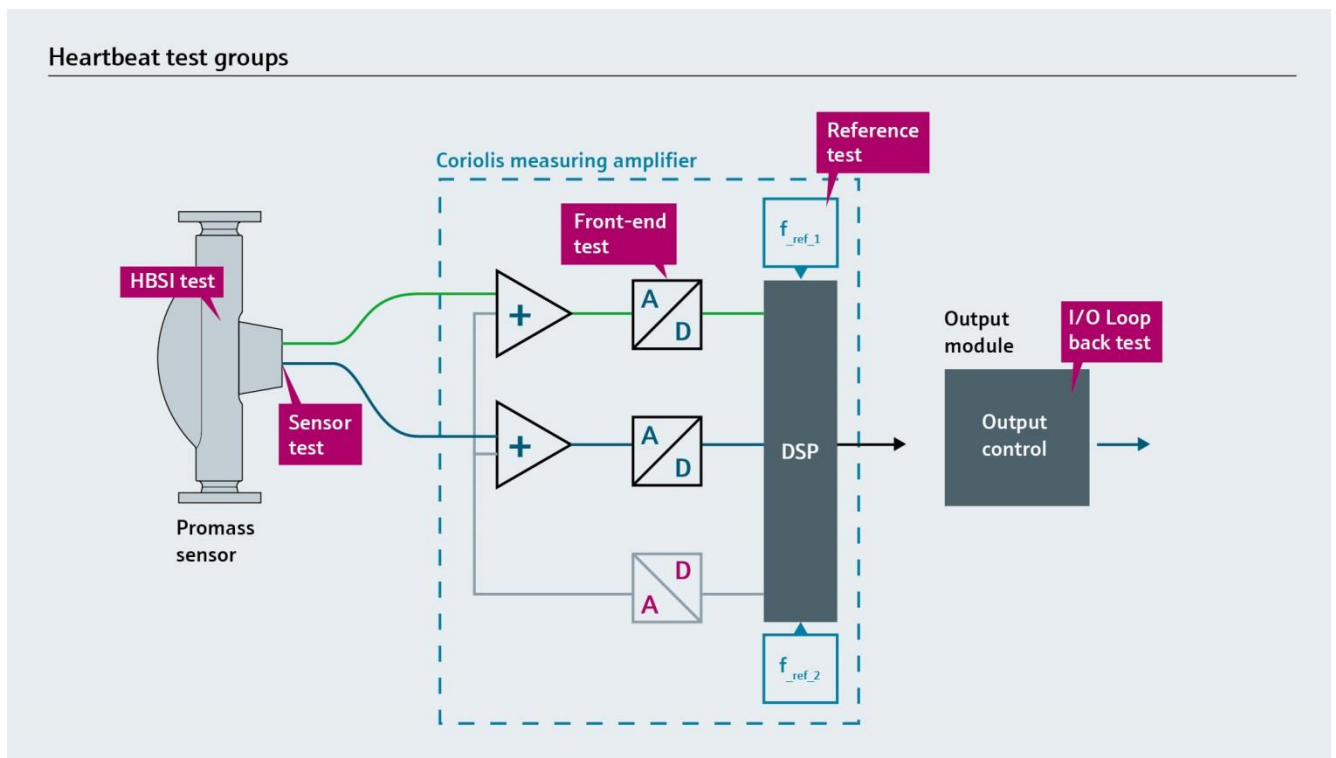


Figure 4: Heartbeat test groups.

The example illustrates the 5 test groups for a Proline Promass Coriolis mass flowmeter. The entire signal chain from sensor to output modules is included in the flowmeter verification.

Overview of the signal flow of a Coriolis flowmeter categorized into 5 sections

The new Endress+Hauser Proline devices consequently implement this concept so that the resulting test coverage is significantly higher than comparable instruments on the market. The crucial factor for this is the “total test coverage” (TTC), which indicates how efficient the tests are.

The TTC is expressed by the following formula for random failures (calculation based on FMEDA as per IEC 61508):

$$TTC = (\lambda_{TOT} - \lambda_{du}) / \lambda_{TOT}$$

λ_{du} : Rate of dangerous failures (dangerous undetected)

λ_{TOT} : Rate of all theoretically possible failures

Electronics failures labeled “dangerous” are those, which, when they occur, would distort or interrupt the measured value output. The integrated self-monitoring of Proline Coriolis flowmeters generally detects more than 94% of all potential failures (TTC > 94%). This test coverage is relevant for the documentation of tests in quality-related applications and ensures that the flowmeter works within its specified accuracy.

Diagnostics coverage during verification

If a device is equipped with Heartbeat Technology™, the following four test sections are monitored continuously and are part of the standard device diagnostics (sensor, front end, reference, I/O loop). The HBSI sensor test (Heartbeat Sensor Integrity) is only executed during verification on demand.

If a Heartbeat Verification is initiated, the current status of all diagnostics parameter is read and stored with a unique identifier in the failsafe memory of the flowmeter. A verification report in pdf format is generated based on the diagnostics data of this snapshot which can be downloaded, printed or stored externally for audit documentation.

Due to the inherent safety design of the flowmeter performing a verification is not (significantly) improving the test depth coverage. The purpose of instrument verification is to provide a tamperproof verification document which confirms the status of the device similar to a calibration certificate.

Test group 1 sensor

A sensor test includes electrical testing of excitation, electrodynamic pick-ups, temperature sensors and measuring tube(s).

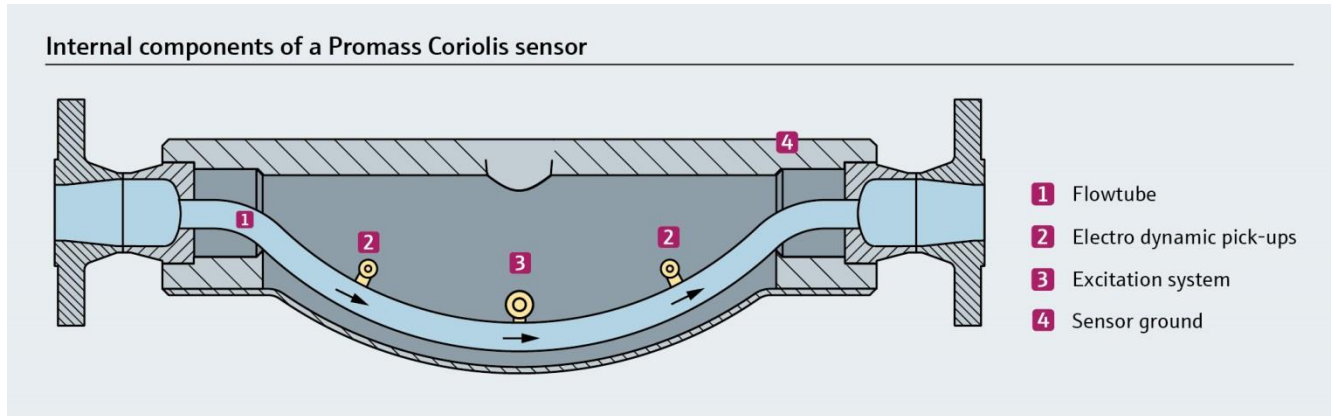


Figure 5: Internal components of a Promass Coriolis sensor tested during Heartbeat Verification. Test of resistance and insulation: Detection of signal interrupt, insulation issues, short circuits, contact corrosion, cabling issues, mechanical damage, humidity inside of the sensor, poor grounding and flow tube damage due to corrosion or abrasion (Part of HBSI).

Test group 2 HBSI (Heartbeat Sensor Integrity)

HBSI (Heartbeat Sensor Integrity) is part of the sensor verification procedure and based on reference values which have been recorded during the calibration of the flowmeter in the factory. The reference values are always stored in the flowmeter and referred to during verification. During normal operation the measuring tubes of a Coriolis are excited at their natural frequency. The natural frequency provides the lowest tube damping (ratio of required drive power vs. tube amplitude) and therefore best signal to noise ratio. The natural frequency of a Coriolis is depending on the mechanical design of the flowmeter and the fluid density. As the mechanical properties do not change under normal operations the frequency is used to determine the fluid density.

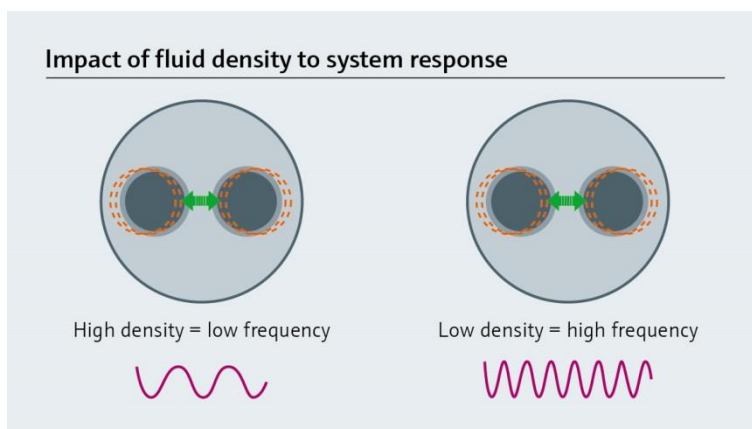


Figure 6: Impact of fluid density to system response. The resonance frequency lowers with increasing density and rises if the density decreases. The density measurement works independent from the mass flow measurement and velocity.

HBSI is independent of process conditions

To eliminate the fluid influence during the verification, a test signal is superimposed to the drive coil at a fixed offset frequency. The system response to the test signal is evaluated by frequency band filters and a single benchmark value is calculated (HBSI value). Damages to the tubes resulting from corrosion or abrasion affect the system response and subsequently the HBSI benchmark. Pre-defined limits of this benchmark value allow for a clear pass/fail evaluation of HBSI.

Due to the fixed offset frequency the test signal is not influenced by process conditions and therefore can be performed while the meter is in the field and even under operation. The flowmeter continuously delivers accurate measuring results during the verification. The offset frequency, however, has a higher tube damping value and causes increased power consumption during the test. Thus, it is recommended to perform the verification while the process is under stable conditions, e.g. with homogeneous flow.

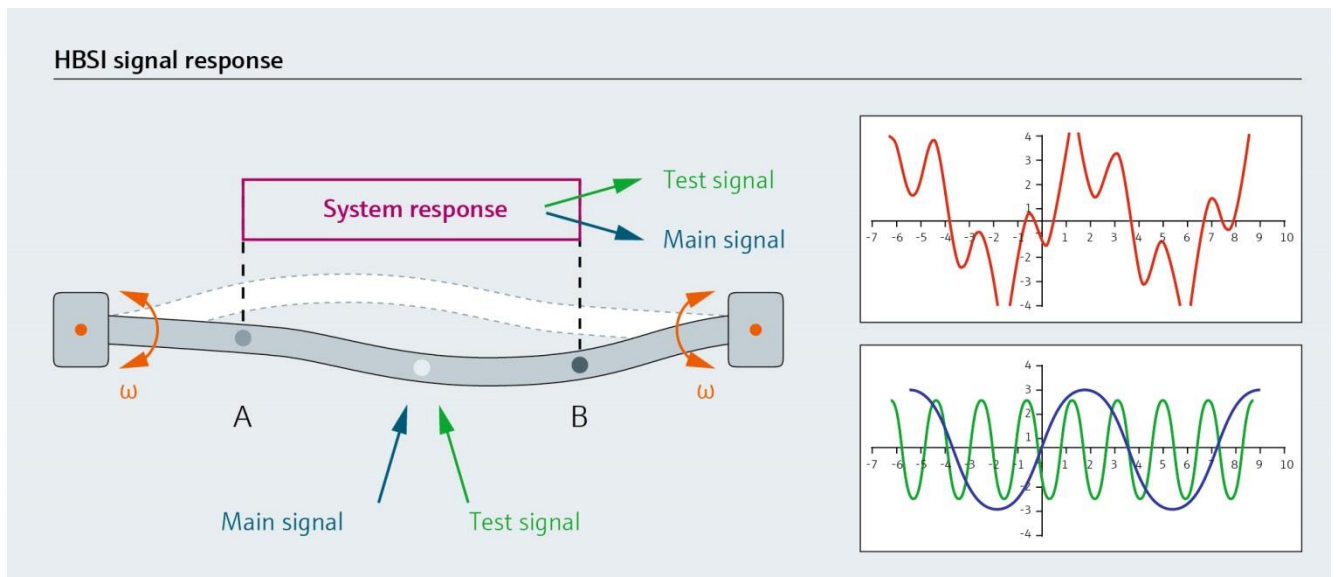


Figure 7: HBSI signal response.

A heartbeat test signal (green) is superimposed to the main drive power (blue) of the driving coils. The system response (red) consisting of flow measuring values and information about Heartbeat Sensor Integrity (HBSI) of the measuring tubes are evaluated by frequency band filters. A single HBSI value is compared to factory benchmarks stemming from the original factory calibration of the meter.

HBSI trending

The verification data are stored failsafe inside the flowmeter (up to 8 datasets) and can be downloaded into an asset management system for further evaluation. Trending the HBSI values provides information about slow changes of the sensor integrity and can be used for early detection of corrosion or abrasion.

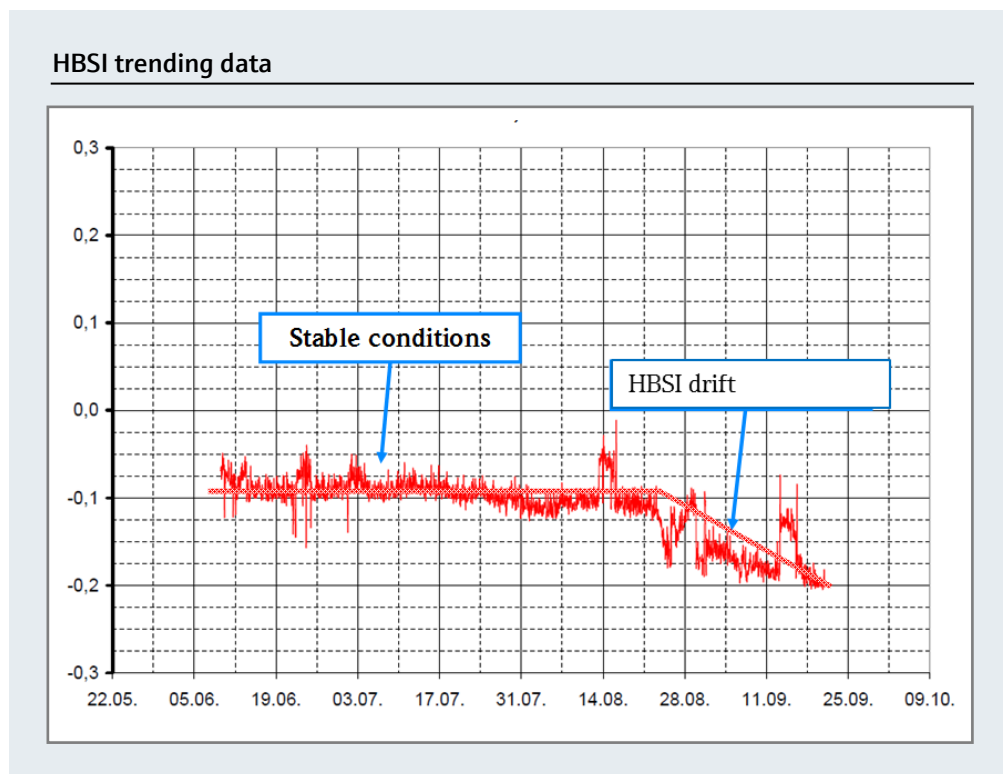


Figure 8: HBSI trending data.

After a long stable period (time before 20.08) the HBSI value starts to drift indicating a change of the tube integrity (for example due to corrosion). Preventive maintenance actions can be planned reducing the risk for catastrophic failures and unplanned process downtime.

Test group 3 front end

Analogue components are – due to their inherent design – more prone to drift than digital components. Therefore, Promass is relying fully on digital components and digital signal processing whenever possible. The only exception is the front end input stage (amplifier) where the analogue signals from the sensor are processed.

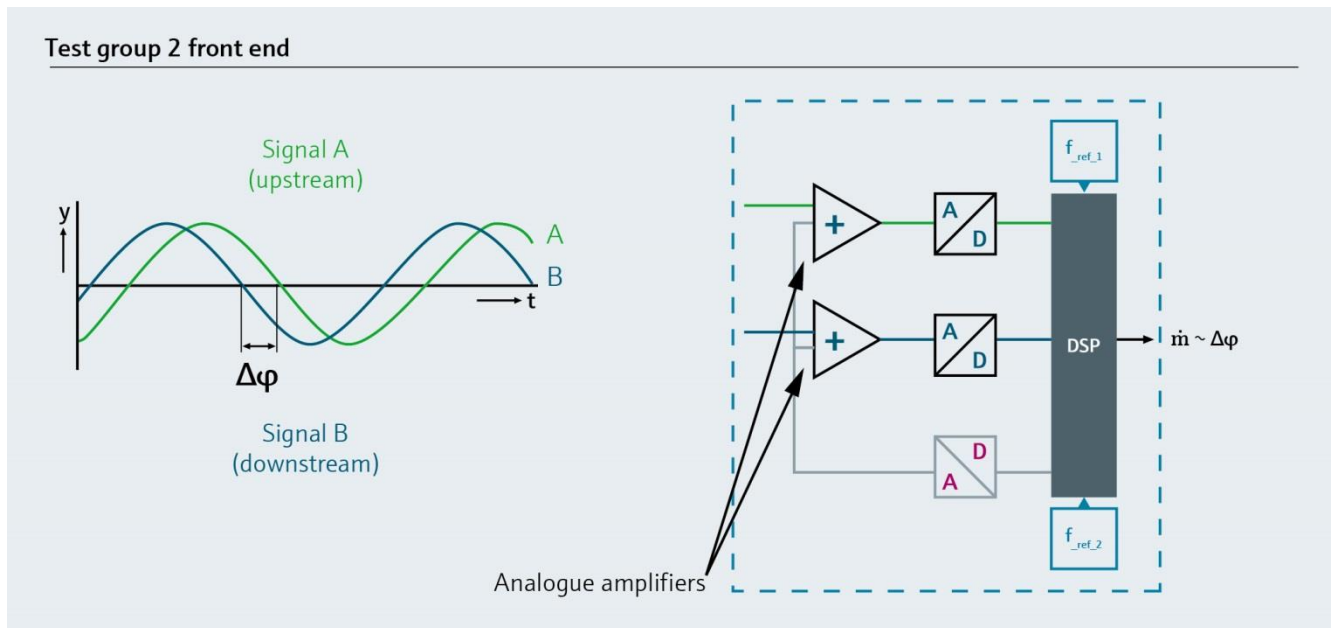


Figure 9: Test group 2 front end.

Each channel (A, B) requires two analogue amplifiers. These are the only critical analogue components in the signal path for a Promass Coriolis flowmeter.

The Coriolis measuring amplifier (ISEM) contains two completely symmetrical, but independent channels (channels A and B). The travel time of the signal in the amplifier is independent of the actual frequency ($\Delta\phi(f) = \text{constant}$).

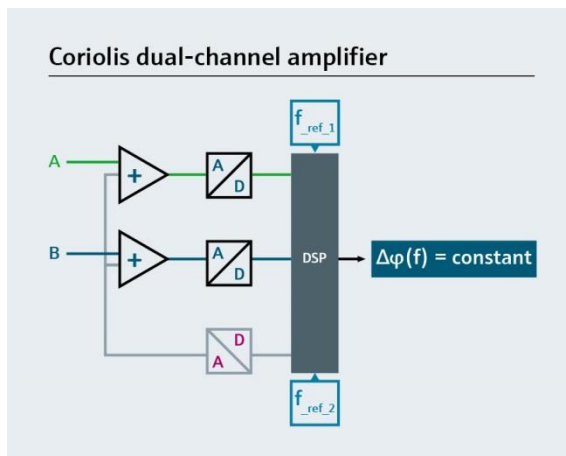


Figure 10: Coriolis dual-channel amplifier.

Each channel (A, B) requires two analogue amplifiers. These are the only critical analogue components in the signal path for a Promass Coriolis flowmeter.

A verification signal is superimposed onto the two differential signals from the sensor (see pink signal path in Figure 11). The verification signal allows to test the functionality of the front-end independent of the flow signal from the sensor, for example even at zero flow or if no sensor is connected. Since the identical test signal is applied to both channels, the resulting phase shift must always be zero ($\Delta\varphi = 0$). This allows verifying the stability of the frontend.

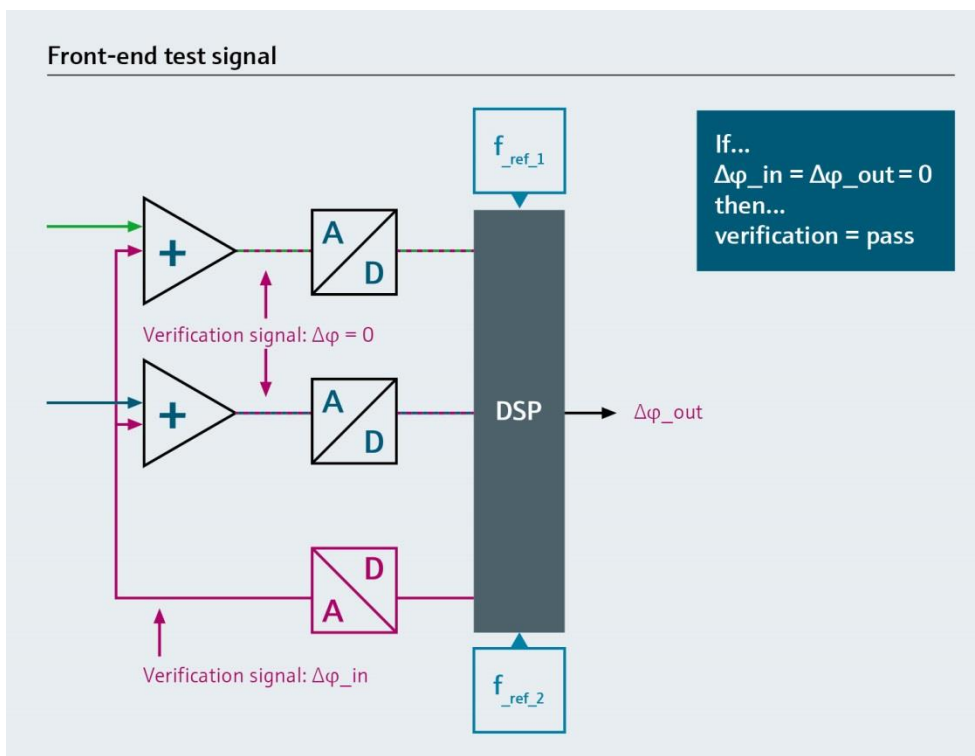


Figure 11: Front-end test signal.

A continuously applied test signal is testing the front-end amplifier of the Coriolis flowmeter.

Test group 4 reference test (redundant clocks)

The digital signal processor (DSP) relies on an internal frequency reference (clock-frequency). Any drift of this reference frequency would cause a proportional calibration shift. Example: A 0.1% drift of reference frequency causes 0.1% drift of flow output. In order to verify the stability of the frequency signals, two independent (redundant) reference clocks are used in the Promass amplifier (f_{ref_1} and f_{ref_2}).

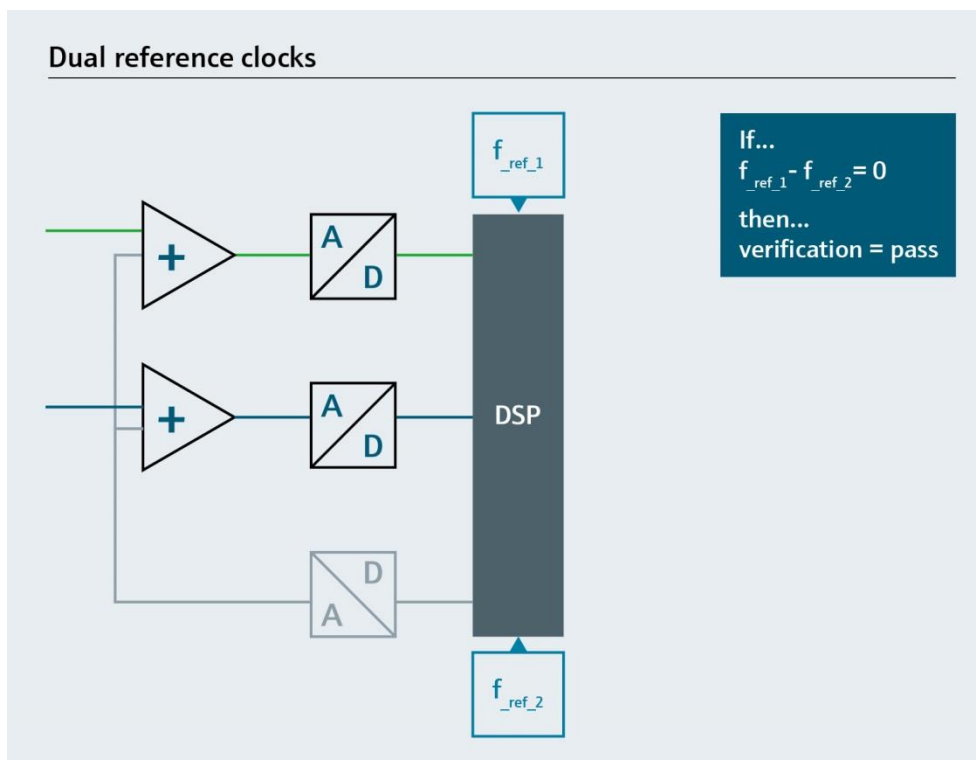


Figure 12: Dual reference clocks.

The stability of the frequency references confirms that there is no drift to the measurement and that the verification test of the front end is actually valid.

Redundant design for higher confidence

Using two independent clocks significantly decreases the risk of undetected drift. Only if both clocks would drift at the same rate in the same direction the error would remain undetected. The chance of such an undetected failure lies at 0.000000067. Or in other words: For 100,000 installed flowmeters the failure could appear in 1 device every 148 years.

During manufacturing of the flowmeter the clocks are calibrated against national traceable measurement standards. Combined with the proven long-term stability they provide a reliable reference signal for Heartbeat Verification.

Test group 4 I/O loop back

Integration of a flowmeter into a control system can vary depending on the installation. In case of fieldbus integration measurement, values are transmitted digitally which eliminates the risk of erroneous data. In case of traditional analogue integration – such as frequency/pulse or 4–20 mA loop – one has to assure that the signal which is delivered from the meter actually arrives in the same quality at the control system.

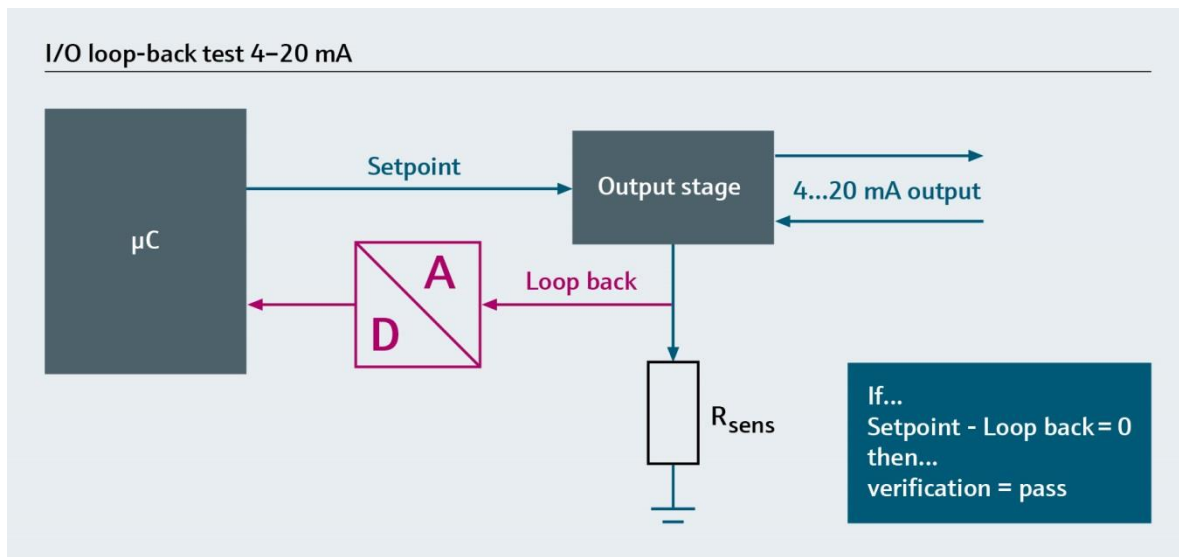


Figure 13: I/O loop-back test 4–20 mA. The actual output value is verified by a loop-back verification measurement. The set-point is compared to the actual output current at the output stage. The stability of the output and output load limits can be detected.

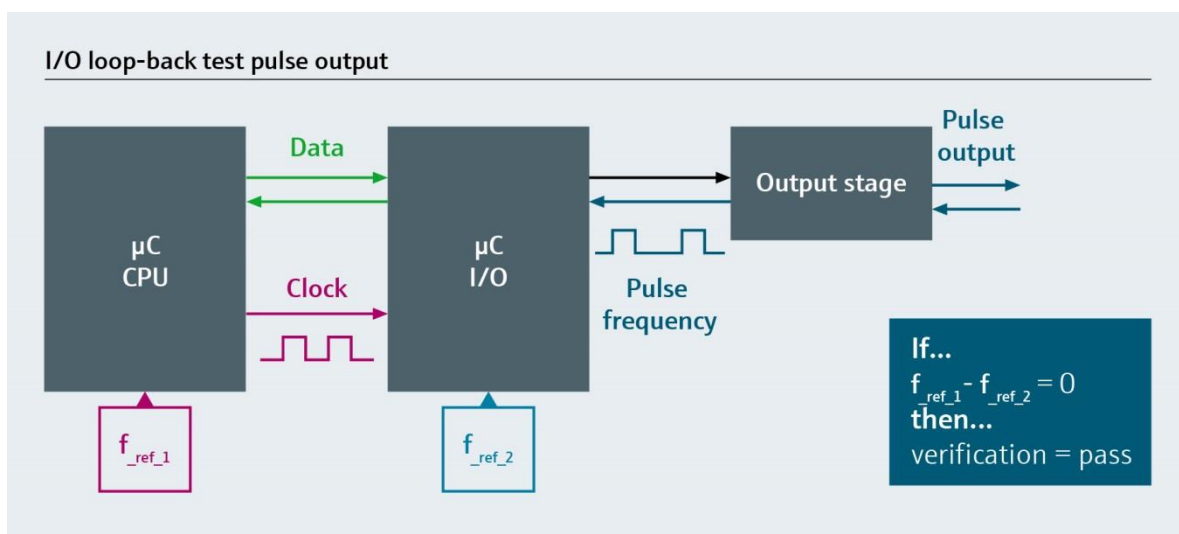


Figure 14: I/O loop-back test pulse output. CPU clock and frequency at the output (pulse frequency) are generated from different references (f_{ref_1} and f_{ref_2}). Frequencies are compared by “µC I/O”.

Long-term stability

Coriolis mass flowmeters have been used in various industries for many years. Endress+Hauser has installed more than 500,000 Coriolis flowmeters worldwide. Flowmeters are often gravimetrically tested in accordance with ISO/IEC 17025 in regular intervals to confirm their accuracy. The data of 3000 flowmeters re-calibrated at our facilities over the last 10 years have been evaluated to determine long-term stability under process conditions. This includes not only flowmeters installed under GMP conditions but also installations in harsh environments such as chemical and petrochemical plants. The results are not surprising as it is known facts that due to their inherent design Coriolis flowmeters provide exceptional long-term stability.

Results of this study have shown that 95% of all devices still operate within $\pm 0.2\%$ accuracy after 10 years of operation.

Customers can take advantage of this knowledge by optimizing the calibration and verification cycles of their devices. If a device is in fact tried-and-tested in operation – we see this is typically the case after one to two years of operation – we can rule out the potential for systematic errors to a large extent, particularly those caused by the influence of process conditions on the sensor.

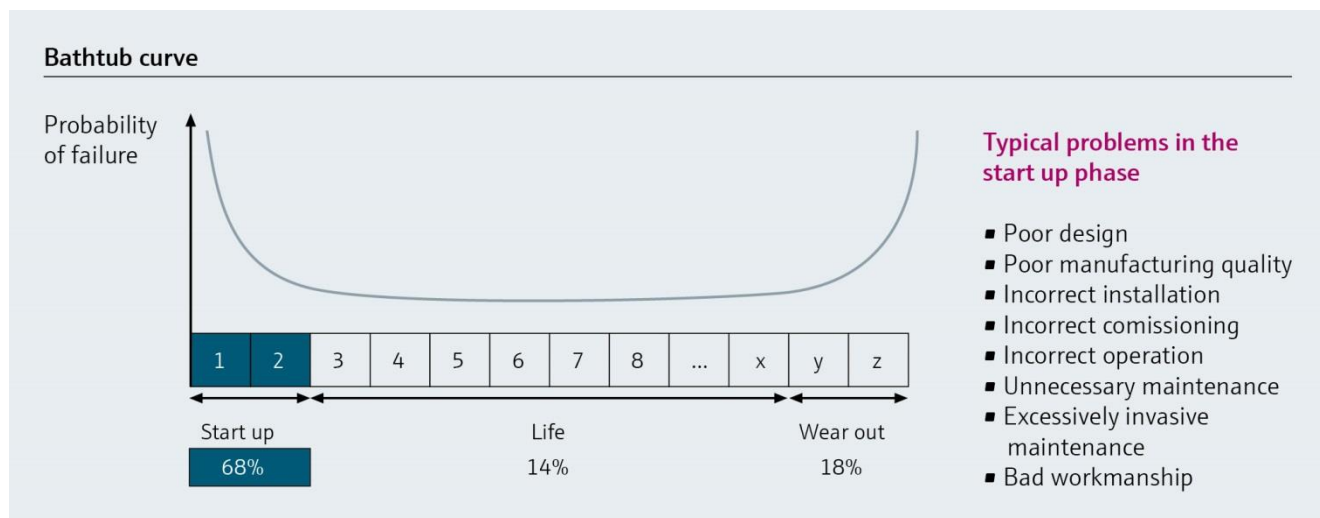


Figure 15: Bathtub curve.

The above curve suggests that almost 70% of all failures in the life cycle of a product occur in the first phase of its life cycle. While the probability of failure is high in the initial phase, it decreases quickly in the second phase and then stays at a constant and low level for a long time. The probability of failure does not increase again until the product nears the end of its technical service life. At that time, failure occurs on account of natural component aging instead of due to systematic errors.

Experience shows that state-of-the-art flowmeters which have no moving parts in the sensor – and operate wear-free as a result – have the same life-cycle curve. Their technical service life can continue far beyond 10 years.

Traceability

Heartbeat Technology™ relies entirely on internal references and still provides metrological traceability due to the inherent design of the new Proline flowmeters. To be effective, such integrated self-monitoring must be based on integrated traceable reference systems with proven long-term stability.

Heartbeat Verification is a traceable test method checking secondary variables correlated closely with flow output – but not the actual measurand. A factory baseline is established during the original factory calibration by calibrating the internal references based on traceable references: The evaluated baseline is permanently stored in the non-volatile and secure memory of the flowmeter (HistoROM) and kept on file in the factory (common equipment record).

It is paramount to ensure a reliable and stable internal reference signal independent of changing process or ambient conditions. In order to achieve a maximum level of assurance the primary reference signal is monitored by a second internal reference system (see Chapter about “redundant clock”, page 16).

Even though traceability applies only to the secondary references, but not to the actual measurand (e.g. flow, density, etc.) due to the immediate relationship between the secondary variable and primary measurand, Heartbeat Verification is accepted by the authorities (TÜV) as a metrologically traceable verification system according to ISO 9001:2008 (section 7.6a).

Note: Traceability of the flow measurement (i.e. actual measurand, e.g. flow, density) can only be achieved by a flow calibration.

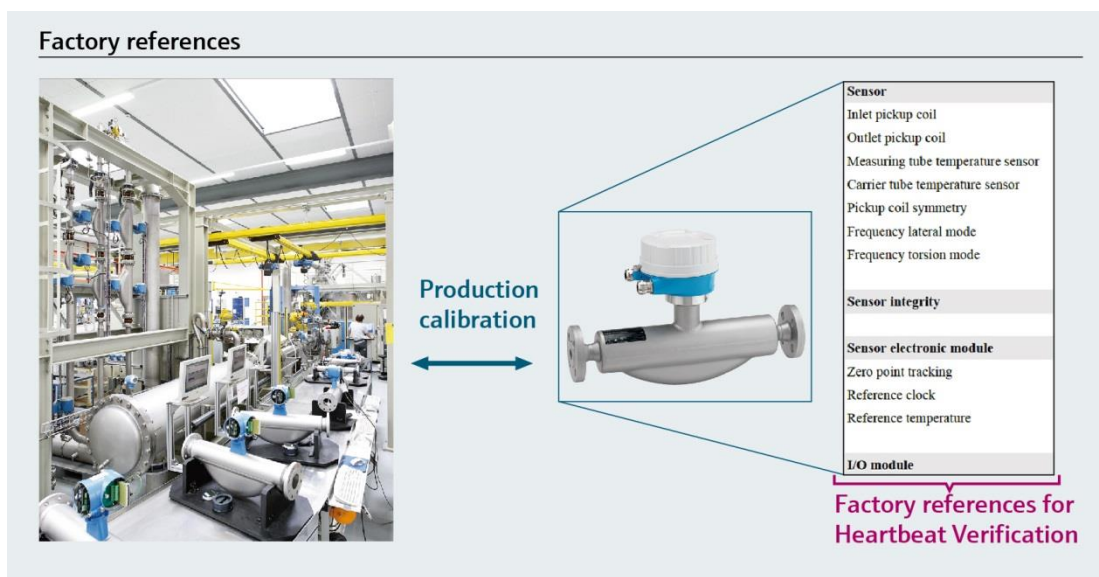


Figure 16: Factory references.

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

Data storage and reporting

The results of Heartbeat Verification are stored in the flowmeter. This includes a verification status (pass/fail) and the recorded (detailed) raw data. However, since verification is also a part of the device technology, data acquisition and interpretation are also done in the device. This has the advantage of making the functionality available for all operating interfaces and system integration interfaces.

The data stored in the flowmeter can be retrieved at a later point in time for further analyses and documentation. Verification reports can also be created offline for quality documentation. Furthermore, by comparing the data of multiple consecutive verifications, trends can be detected and systematically tracked during the life cycle of the measuring point. This allows for timely conclusions regarding the measuring point's state of health or process-specific influences on the measurement result and assists in preventing unexpected errors. And lastly, this data allows for better maintenance planning, thus allowing for cost savings on account of higher plant availability and increasing the efficiency of service and maintenance.

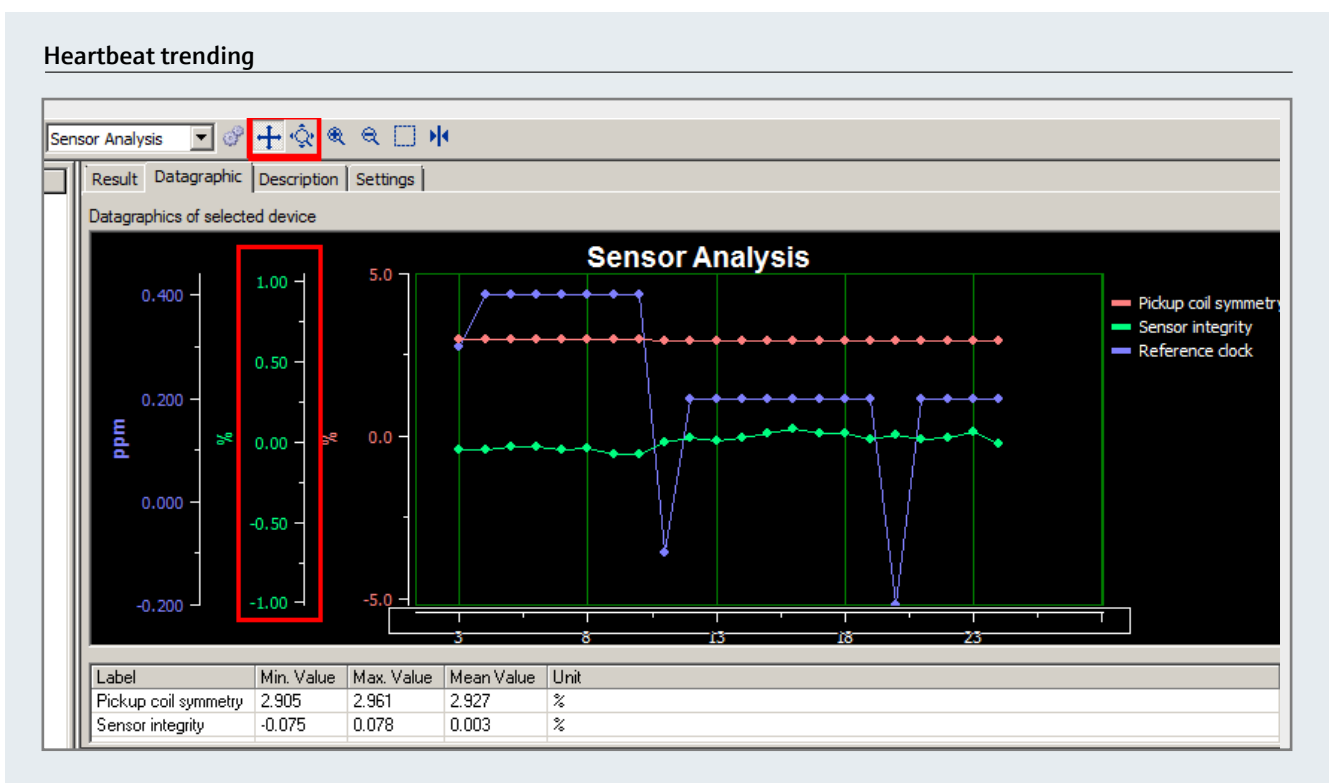


Figure 17: Heartbeat trending.

Heartbeat Verification allows trending of multiple data sets in FieldCare. Early signs of sensor deterioration can be detected and used for preventive maintenance.

Verification via Heartbeat Technology™ can be initiated with the push of a button locally or remotely from the control system even under process conditions. It only takes a few seconds and the results are available immediately with a clear pass/fail indication and a written tamper-proof verification report.

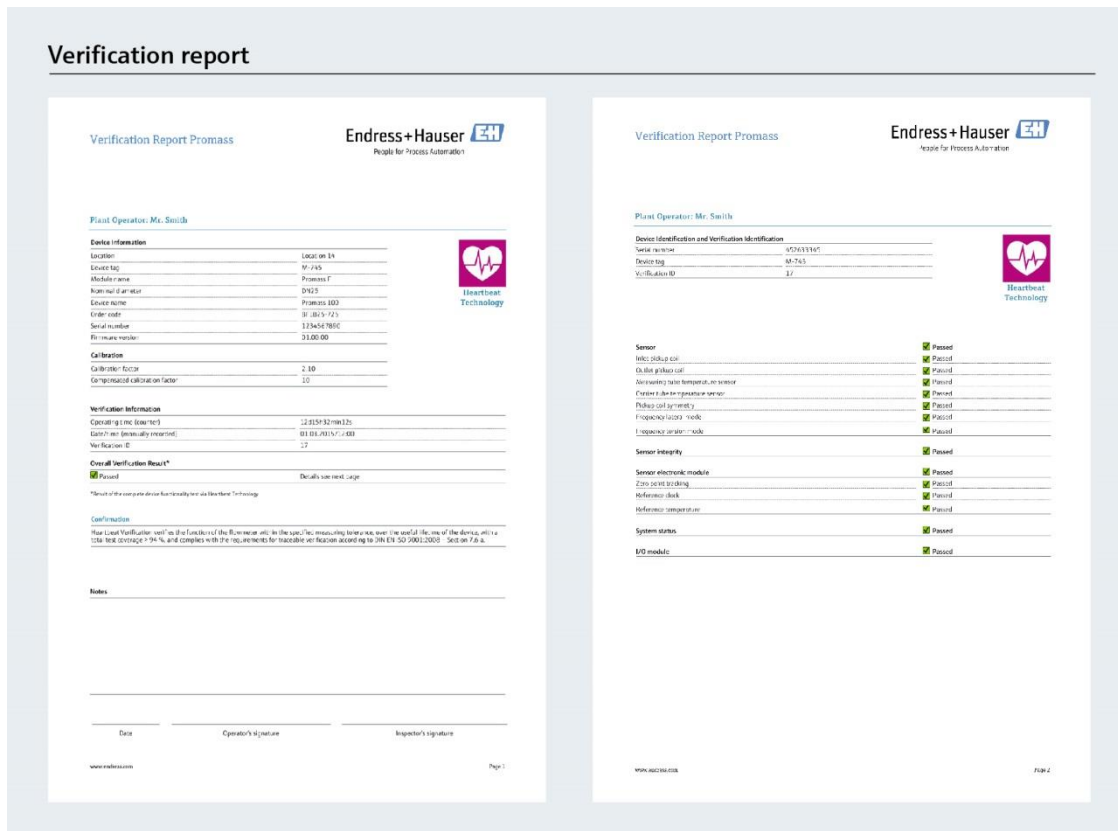
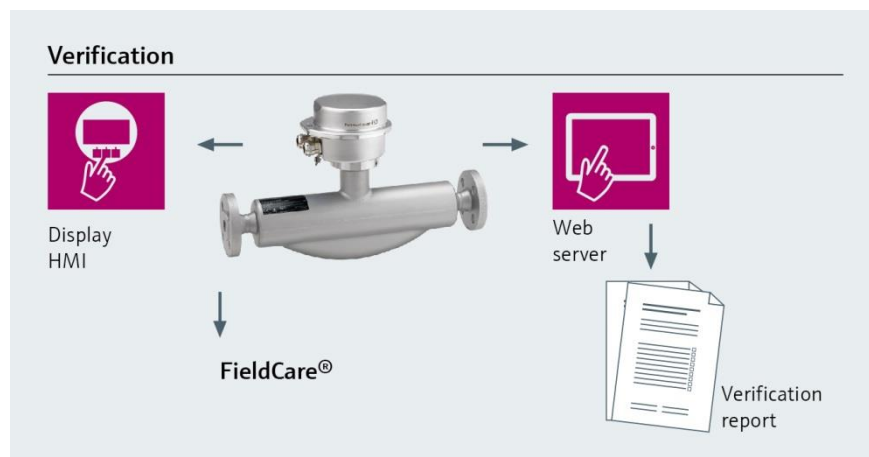


Figure 18: Verification report.

The verification report is generated directly in the flowmeter and provided as a tamper-proof pdf file. The file can be accessed directly via web server or downloaded remotely through a DCS or asset management control system.



No special hardware or software is required for verification and document generation. The entire functionality is imbedded onboard and even the verification results are stored in the fail-safe redundant memory. The verification reports for regulatory compliance can be downloaded and printed or stored in electronic (pdf) format.

Regulatory compliance

Heartbeat Technology™ fully complies with the requirements for traceable verification according to DIN EN ISO 9001:2008, Section 7.6 a “Control of monitoring and measuring equipment” (see TÜV attestation below). In accordance with this standard, the user is responsible for providing a definition of the verification interval that satisfies the particular requirements. These intervals have to be defined carefully and are part of the mandatory risk analysis. Performing regular Heartbeat Verification on the flowmeter can extend calibration cycles by a factor of 10 or higher without jeopardizing the quality or the regulatory compliance. In some cases it may even be possible to replace wet calibrations completely with Heartbeat Verification.

TÜV-Certificate



The certificate is titled "ATTESTATION" and is issued by TÜV SÜD Industrie Service GmbH, Business Area Plant Engineering. It certifies the product "Proline Promass 100 with Heartbeat Technology™" manufactured by Endress + Hauser AG, Kägerstraße 7, 4153 Reinach BL, Switzerland. The certificate states that the product complies with requirements for diagnostics and verification of flowmeters, specifically mentioning standards DIN EN IEC 61508-2:2011-02, Appendix C; DIN EN IEC 61508-3:2011-02, Section 6; and DIN EN ISO 9001:2008, (Section 7.6 a), Control of monitoring and measuring equipment. It also includes test results showing a total test coverage (TTC) of 94% for Heartbeat Verification. The certificate is based on report no. TR.2065342.006.14 dated January 26, 2015, and is attested no. PC/209/03/144/08/14. It is signed by Jörg Steimer, Certification Body Plant Engineering, and Gerhard Klein, Dept Risk Management, on January 26, 2015. The certificate features the TÜV SÜD logo and a vertical bar on the left with text in multiple languages: BESCHENIGUNG, ATTESTATION, 证明书, СВИДЕТЕЛЬСТВО, CONSTANCIA, and ATTESTAZIONE.

ATTESTATION

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

certifies that the product

**Proline Promass 100
with Heartbeat Technology™**

manufactured by

**Endress + Hauser AG
Kägerstraße 7
4153 Reinach BL
Switzerland**

complies with the following requirements:

Heartbeat Technology™ is a test method integrated in the measuring device for the diagnostics and verification of flowmeters when used in a particular application throughout the useful lifetime of the measuring device. Testing is based on internal factory-traceable references which are redundantly reproduced in the device. Heartbeat Technology™ includes Heartbeat Diagnostics and Heartbeat Verification.

Test specifications:
DIN EN IEC 61508-2:2011-02, Appendix C
DIN EN IEC 61508-3:2011-02, Section 6
DIN EN ISO 9001:2008, (Section 7.6 a), Control of monitoring and measuring equipment

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.

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

TÜV®