Endress+Hauser
People for Process Automation

Heartbeat Technology for single-use instrumentation in Life Sciences

Device-internal performance assessment with excellent test coverage and regulatory compliance

Alex Mueller, Principal Expert Industry Manager Life Sciences, Endress+Hauser Flow, Switzerland

August 2025

Abstract

Endress+Hauser has established Heartbeat Technology with onboard verification as a true alternative for calibration of multi-use instrumentation in a regulated industry. Proline flowmeters from Endress+Hauser have a proven long-term stability, and Heartbeat Technology provides reliable and documented proof that the flowmeters perform according to specification based on the defined total test coverage. Highly stable and factory-traceable internal references with a redundant design are used as device-internal diagnostic and verification methods. The same technology is now also applied to the single-use portfolio and this article provides some insight into the technical details of Heartbeat Technology based on the Proline Promass U 500 single-use Coriolis mass flowmeter. More insights into the calibration of this single-use device can be found in the white paper “Compliant calibration and verification of single-use instrumentation in Life Sciences”.

1.1 Verification in cGMP environments

Daily on-site wet calibration of an installed single-use flowmeter (base unit and disposable component) in cGMP (current Good Manufacturing Practice) environments is typically not possible or practical due to the sterile boundary of the flow path. Heartbeat Technology is therefore the method of choice to fulfill the regulatory compliance requirement for a traceable instrument check prior to use.

Heartbeat Technology can detect potential issues with the flow tubes (e.g., due to mechanical damage) and drifts or defects in the electronic components of the transmitter. This is particularly true for applications where systematic faults can be ruled out. “Systematic” in this context refers to a defect or error in the device resulting from how it is used. An example of this would be corrosion on the tube because the selected material was not suitable for the fluid in question. Increased uncertainty due to instable process conditions, incorrect design or faulty installation also fall into this category. The causes result from how the device interacts with the application and from human errors. Systematic faults can thus be prevented through proper device design and commissioning and minimizing the risk of human mistakes.

The selection of the correct wetted parts material for the flowmeter is crucial to ensure biocompatibility in life-science applications. As corrosion, abrasion and leaching are not acceptable, a correct tube material must be selected in stage one of the process validation in order to prevent any product contamination. Therefore, in a cGMP environment, systematic faults can be largely excluded from any probability calculations. In this regard, it is important that the meter is selected and operated according to the manufacturer’s specification.

If systematic faults 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 throughout the product life cycle.

1.2 Safety by design

Total test coverage surpassing >95 % was made possible by introducing Heartbeat Technology into the development of the latest generation of Proline measuring devices. Aiming to achieve the highest possible safety and quality, devices with Heartbeat Technology only contain the most reliable components for the essential electronic and electromechanical parts within the flowmeter. With the aid of FMEDA (Failure Modes Effects and Diagnostic Analysis) according to IEC 61508, the entire measuring signal path starting at the process-wetted parts (e.g., the flow tubes) followed by the electromechanical components, the amplifier board, the main electronics and the outputs is analyzed for possible errors and their impact on the system. A qualitative measure is 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. For an internal component to be used as a diagnostic reference, it must fulfill special requirements such as factory traceability and exceptional long-term stability. Every reference component is specifically selected to provide highest measuring reliability and accuracy of the device with these requirements in mind.

For the most critical circuits and components, however, 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 on the measuring accuracy. As a result, two independent and redundant quartz clocks are implemented, greatly reducing the possibility of an undetected drift. Continuous monitoring of the synchrony is a requirement for reliability: a change of the reference is reliably detected because the rate of change and time of change are considered.

1.3 Overview of the signal flow of a Coriolis flowmeter categorized into five sections

Proline Promass U 500 implements this concept consequently, so that the resulting test covers the entire measuring path. The coverage is defined by the “total test coverage” (TTC).

The total test coverage 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 undetected random failures

λ_{TOT}: Rate of all theoretically possible random failures

Random electronics failures labelled “dangerous undetected (DU)” would, if they occur, distort the measured value output without notifying the user. The integrated self-monitoring of Proline Promass Coriolis flowmeters generally detects more than 95 % of all potential random failures (total test coverage > 95 %). This test coverage is relevant for the documentation of tests in quality-related applications and confirms that the flowmeter operates within its specified accuracy.

1.4 Total test coverage during verification

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

If Heartbeat Verification is initiated, the status of all diagnostic parameters is read and stored with a unique identifier in the failsafe memory of the flowmeter. Even though performing a verification does not significantly improve the test depth coverage compared to continuous diagnostics, due to the inherent safety design of the flowmeter, a “passed” result gives the user a high confidence in device functionality. In addition, a traceable and tamper-proof verification report can be generated, downloaded, printed or stored externally for audit documentation.

1.5 Test coverage

The definition of test coverage is explained by looking at the details of a Proline Promass U 500 single-use Coriolis mass flowmeter, which consists of three independent components:

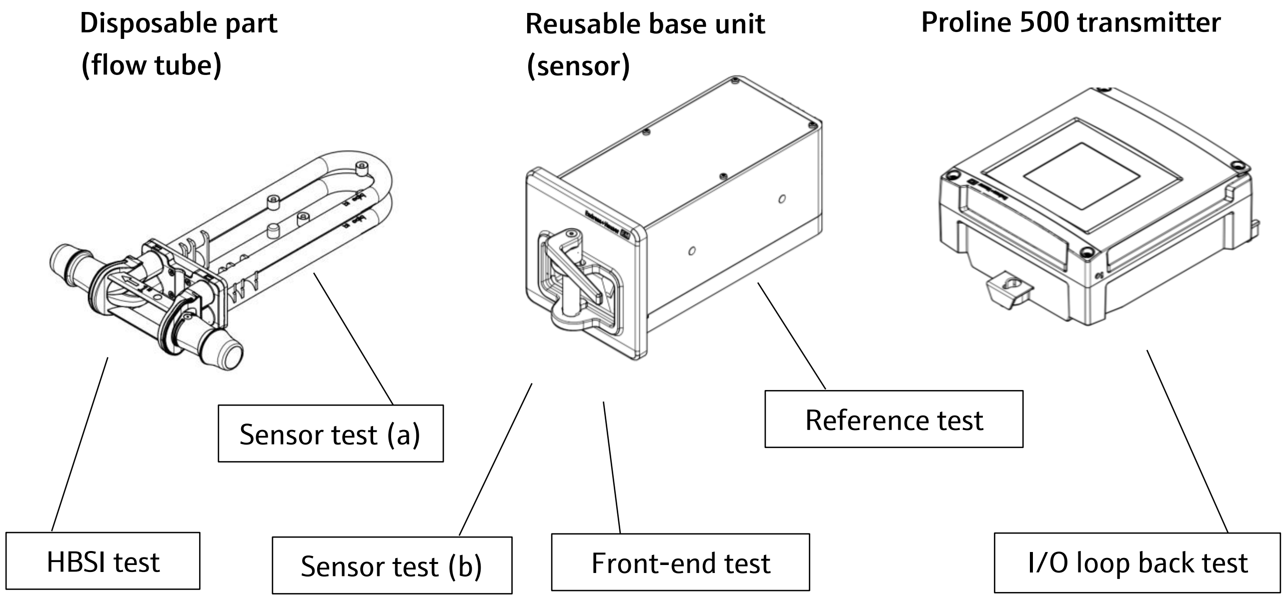

Figure 1: Test group overview.

Figure 1 illustrates the five test groups for a Proline Promass U 500 single-use Coriolis mass flowmeter. The entire signal chain from the disposable part to the Proline 500 output modules is included in the flowmeter verification.

1.5.1 Test group 1 – sensor a+b

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

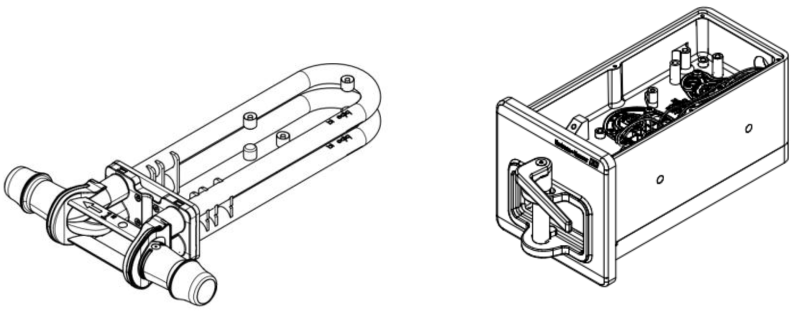

Figure 2: Internal components of a Proline Promass U 500 Coriolis sensor tested during Heartbeat Verification.

Test of resistance and insulation: detection of signal interruptions, insulation issues, short circuits, contact corrosion, cabling issues, mechanical damage, humidity inside the sensor, poor grounding and flow tube damage due to mechanical influences (part of HBSI).

1.5.2 Test group 2 – front end

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

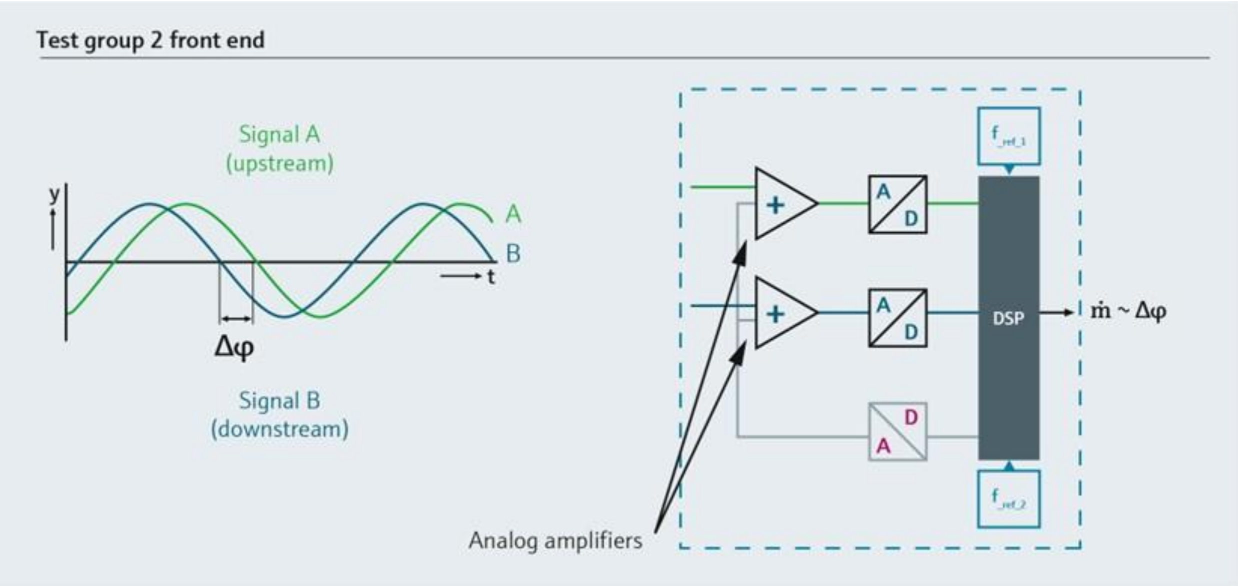

Figure 3: Test group 2 front end.

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

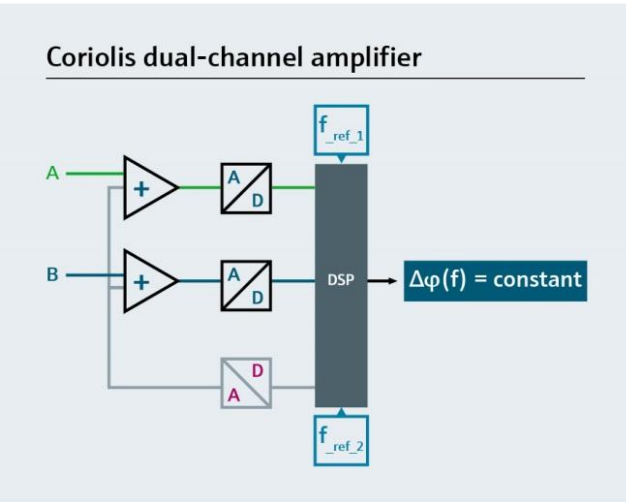

Figure 4: Coriolis dual-channel amplifier.

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

A verification signal is superimposed onto the two differential signals from the sensor (see magenta signal path in Figure 5. The verification signal allows the functionality of the front end to be tested independently 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 the stability of the front end to be verified.

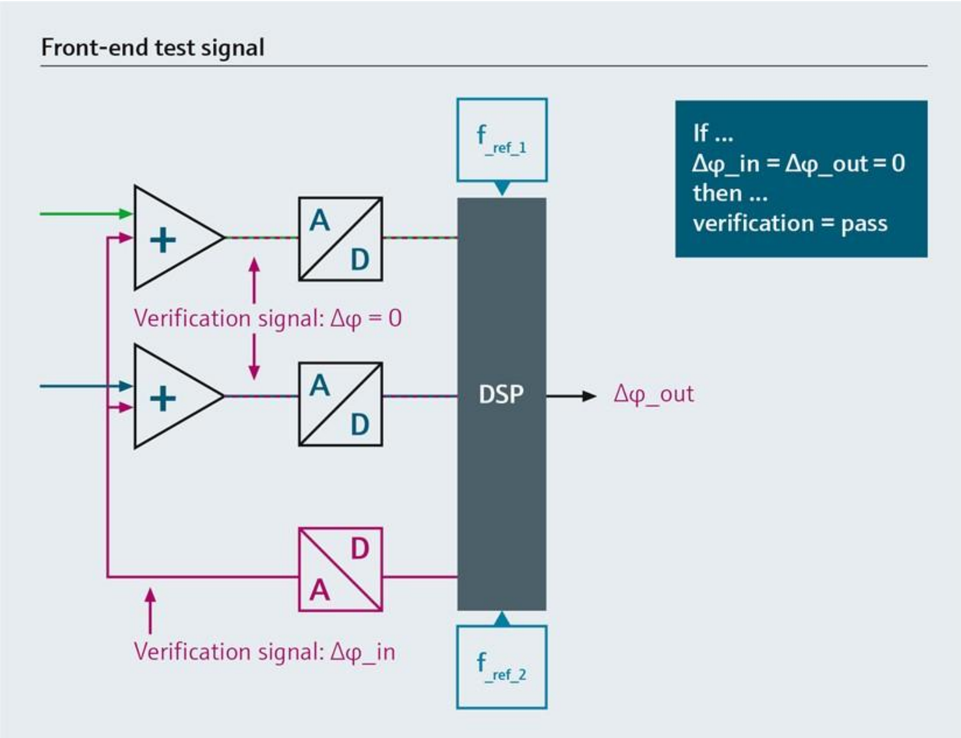

Figure 5: Front end test signal.

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

1.5.3 Test group 3 – HBSI (Heartbeat Sensor Integrity)

HBSI is part of the sensor and flow tube verification procedure and based on reference values which have been recorded during the calibration of the disposable part at the factory. The reference values are stored on the disposable component in the form of a data matrix code and are referred to during verification. During normal operation, the measuring tubes of a Coriolis meter are excited at their natural frequency. This frequency provides the lowest tube damping (ratio of required drive power vs. tube amplitude) and therefore the best signal-to-noise ratio. The natural frequency of a Coriolis flowmeter depends upon the mechanical design and the fluid density. As the mechanical properties do not change under normal operations, the frequency is used to determine the fluid density.

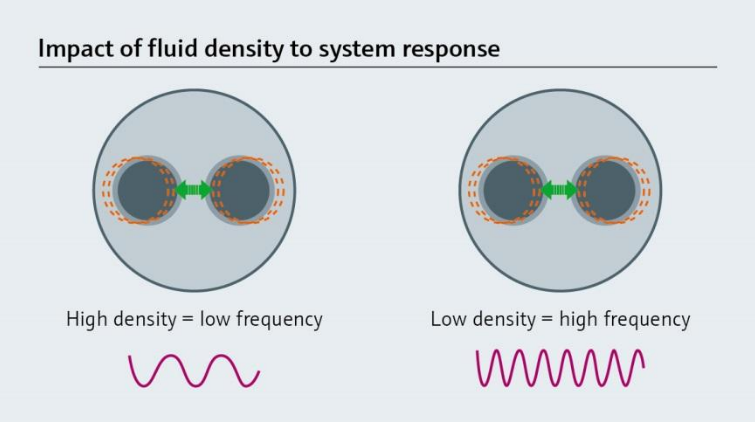

Figure 6: Impact of fluid density on system response.

The resonance frequency lowers with increasing density and rises if the density decreases. The density measurement works independently of the mass flow measurement and velocity.

1.5.3.1 HBSI is independent of process conditions

To eliminate the fluid influence during verification, a test signal is superimposed on the drive coil at a fixed offset frequency (see Fig. 7). Due to this fixed offset frequency, the test signal is not influenced by process conditions and therefore the test can be performed while the flowmeter is in the field and even under operation. The flowmeter continuously delivers accurate measuring results during verification. The offset frequency, however, has a higher tube damping value and causes increased power consumption during the test. Thus, it is recommended that the verification be performed while the process is under stable conditions, e.g., with homogeneous flow.

The system response to the test signal is evaluated by frequency band filters and a single benchmark value is calculated (HBSI value). Mechanical damage to the tubes would affect the system response and subsequently the HBSI benchmark. Predefined limits of this benchmark value allow for a clear pass/fail evaluation of HBSI.

1.5.3.2 HBSI value and threshold

The HBSI value is available for diagnostic and monitoring purposes and tracked as a percentage value. During factory calibration the value is set to zero. The threshold for deviations that will trigger an out-of-spec (fail) error message varies depending on the type of sensor. A single-use Coriolis flowmeter with its two-component design must allow for additional manufacturing and installation tolerances and has therefore a higher threshold when compared with a traditional multi-use Coriolis flowmeter.

Design	Sensor type	HBSI threshold
Multi-use	*Promass E, F, I, K, S, P, Q, O, A, H, X	± 4 %
Single-use	*Promass U	± 20 %

Table 1: Flowmeter design, sensor type and HBSI threshold.

**List not exhaustive and subject to change*

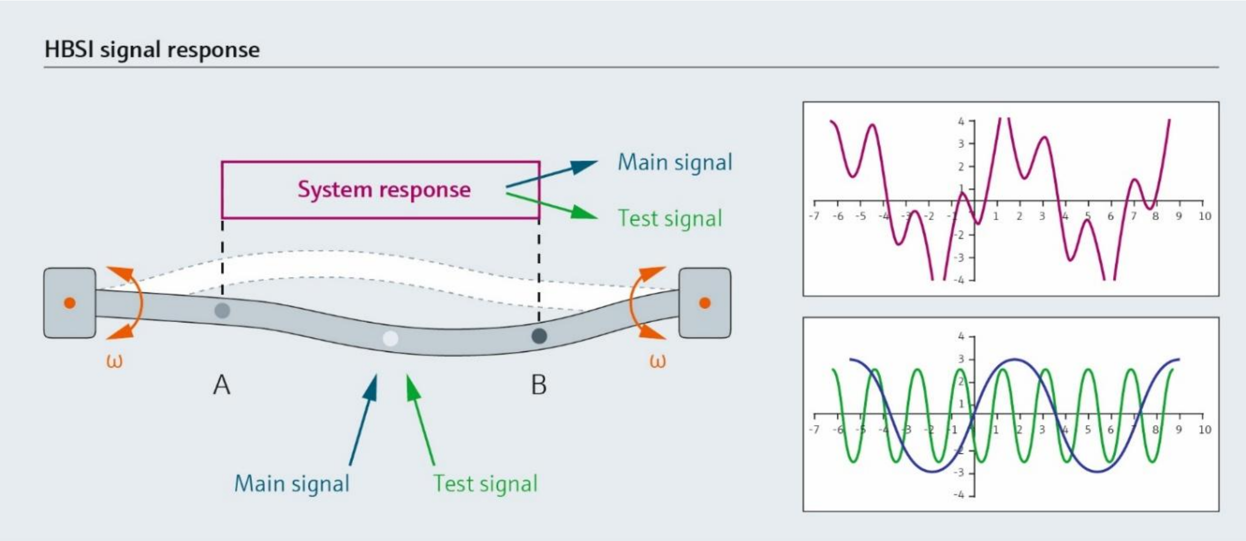

Figure 7: HBSI signal response.

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

1.5.3.3 HBSI trending

The verification data are stored failsafe inside the flowmeter (up to eight datasets) and can be downloaded into an asset management system for further evaluation. Trending the HBSI values provides information about changes of the sensor integrity and can be used for early detection of corrosion or abrasion. Figure 8 shows a real-life example of measuring tubes affected by corrosion.

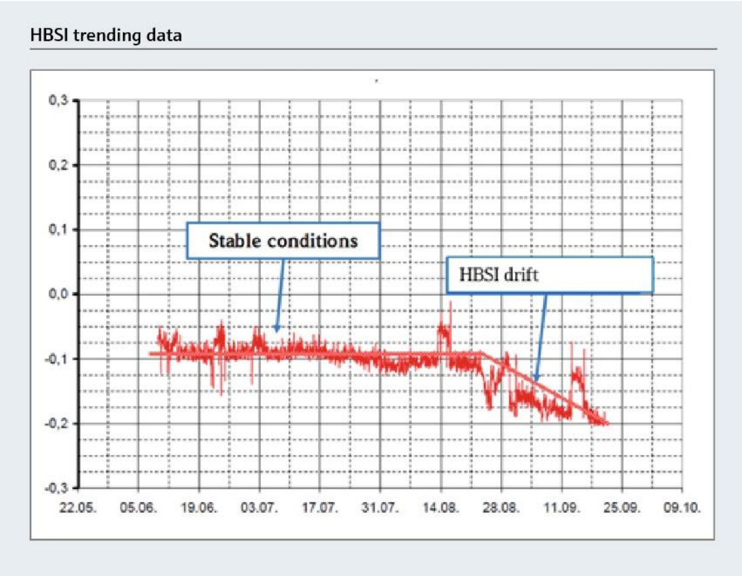

Figure 8: HBSI trending data.

After an initial stable period, the HBSI value starts to drift, indicating a change in tube integrity (e.g., due to corrosion). Preventive maintenance actions can be planned, thus reducing the risk for catastrophic failures and unplanned process downtime.

1.5.4 Test group 4 – reference test (redundant clocks)

The digital signal processor (DSP) relies on an internal frequency reference (clock frequency). Any drift in this reference frequency would cause a proportional calibration shift.

Example: A 0.1 % drift in reference frequency causes 0.1 % drift in flow output. To verify the stability of the frequency signals, two independent (redundant) reference clocks are used in the Promass amplifier ($f_{\_ref\_1}$ and $f_{\_ref\_2}$).

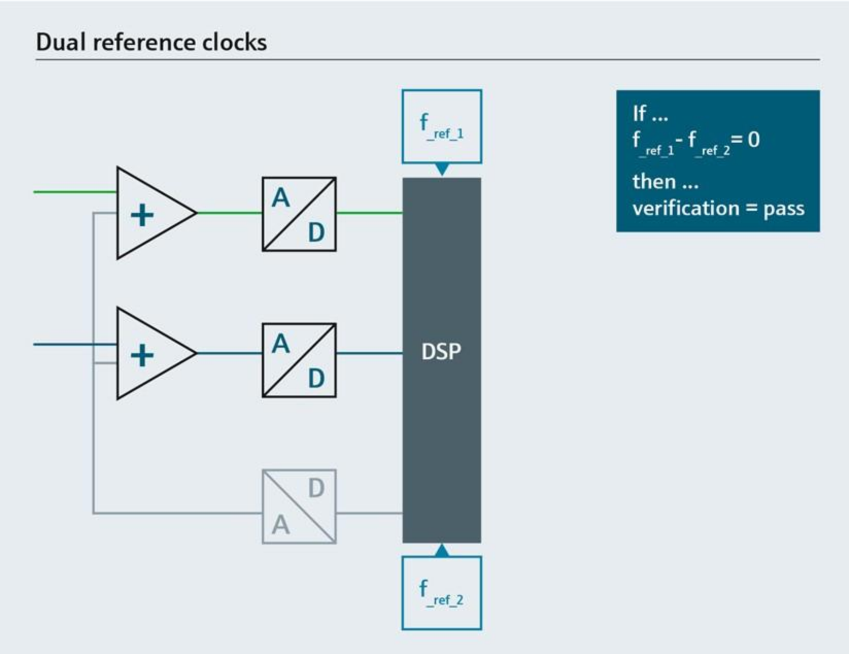

Figure 9: Dual reference clocks.

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 valid.

1.5.4.1 Redundant design for higher confidence

Using two independent clocks significantly decreases the risk of undetected drift. Only if both clocks were to drift at the same rate in the same direction, would the error 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 one device every 148 years.

During the 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.

1.5.5 Test group 5 – 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 analog integration – such as frequency/pulse or 4–20 mA loop – it must be ensured that the signal that is delivered from the flowmeter arrives in the same quality at the control system.

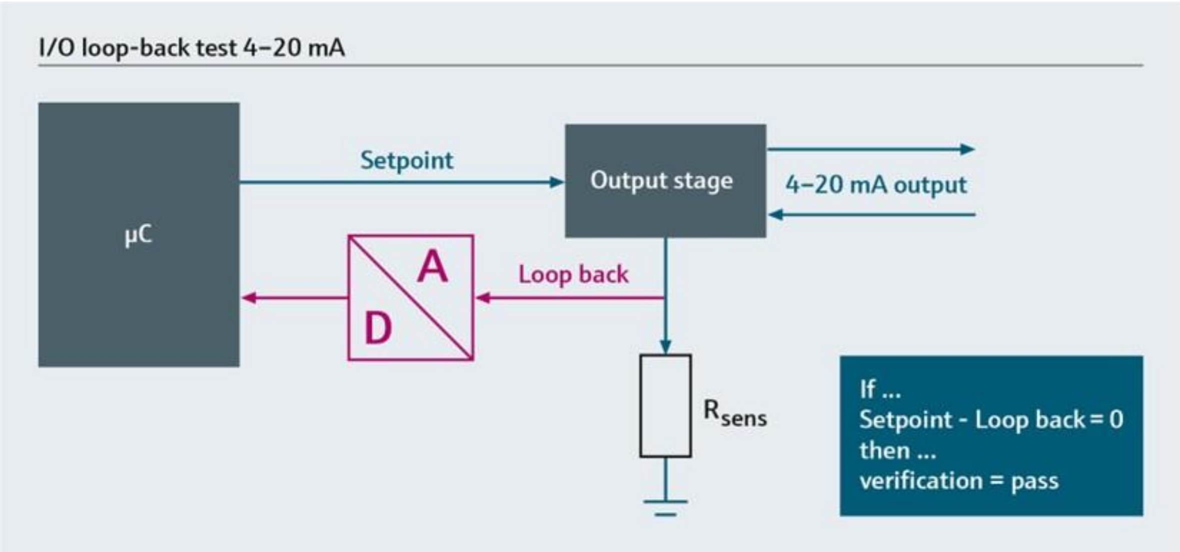

Figure 10: I/O loop-back test 4–20 mA.

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.

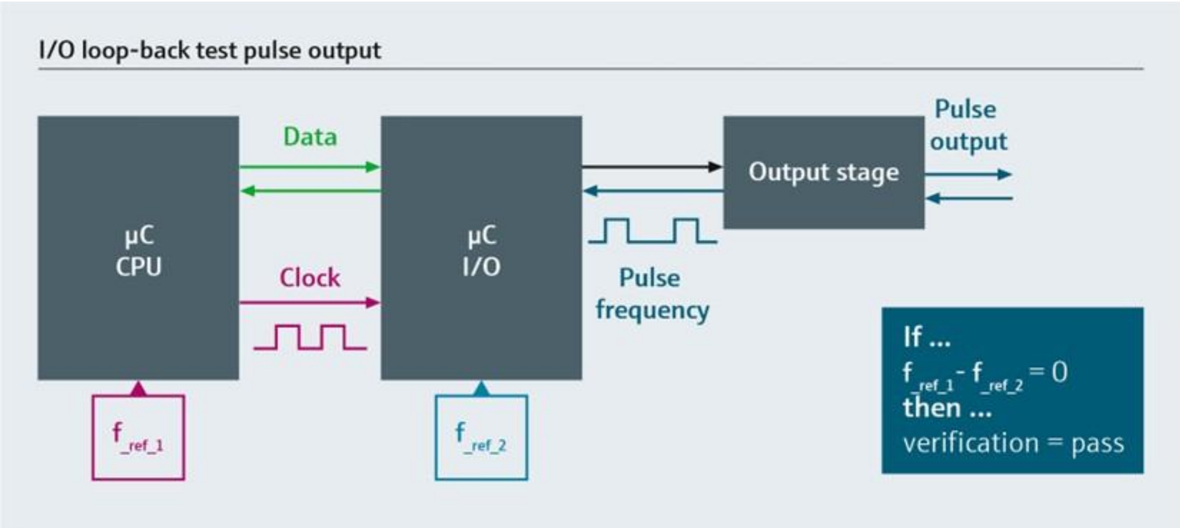

Figure 11: I/O loop-back test pulse output.

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".

1.6 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).

Due to the immediate relationship between the secondary variables and the primary measurand, Heartbeat Technology complies with the requirements for traceable verification according to ISO9001:2015, Clause 7.1.5.2 “Measurement traceability” as attested by the independent 3rd-party organization TÜV SÜD. Note: traceability of the flow measurement (i.e., the actual measurand) can only be achieved by flow calibration.

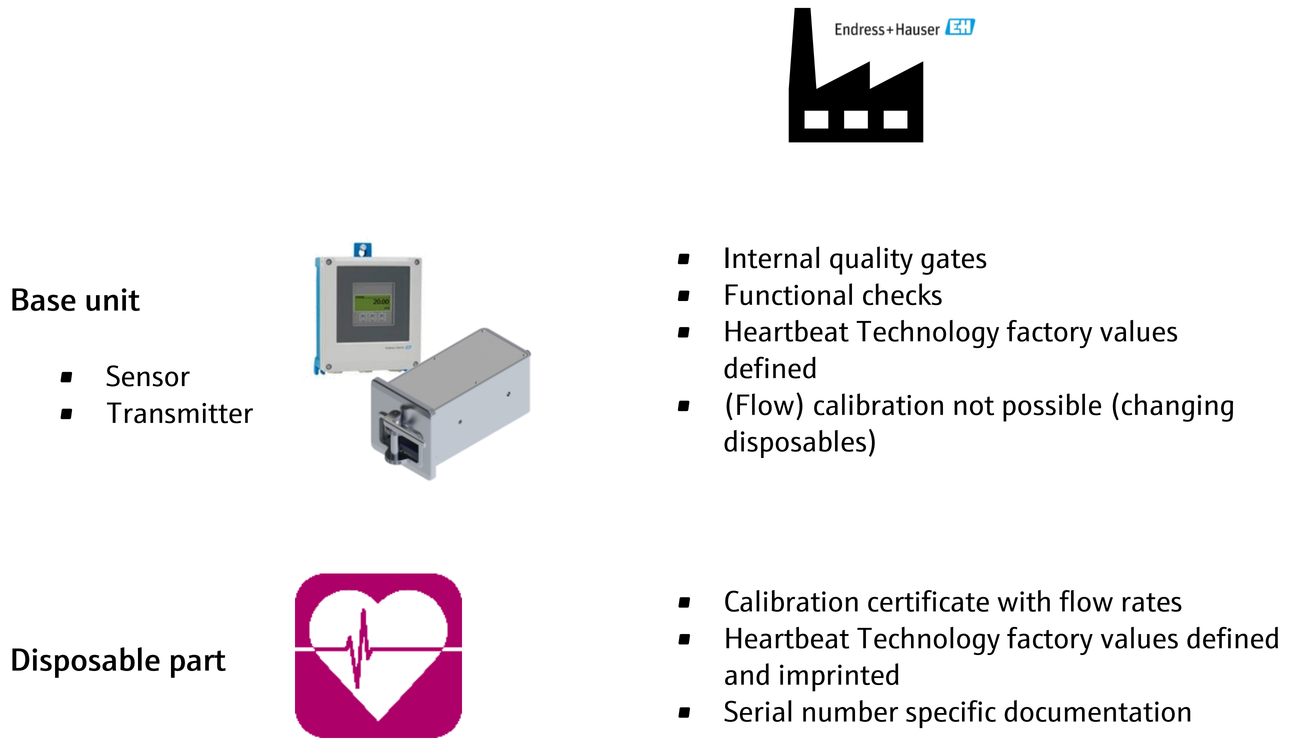

Figure 12: Factory references.

Verification of flowmeter functionality based on flowmeter internal factory references and corresponding specifications. During the production process, these factory references are calibrated based on traceable references to establish a factory baseline. You can find more information about Heartbeat Technology here: www.endress.com/heartbeat-technology

1.7 Data storage and reporting and accessibility

The results of Heartbeat Verification are stored in the transmitter. This includes a verification status (pass/fail) and the recorded (detailed) raw data. Data acquisition and interpretation are done internally and do not require human interaction. This has the advantage of making the functionality available for all operating and system integration interfaces.

The data stored in the flowmeter can be retrieved at a later point in time for further analysis 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. Lastly, this data allows for better maintenance planning, thus enabling cost savings, increasing plant availability and the efficiency of service and maintenance.

Heartbeat Technology trending

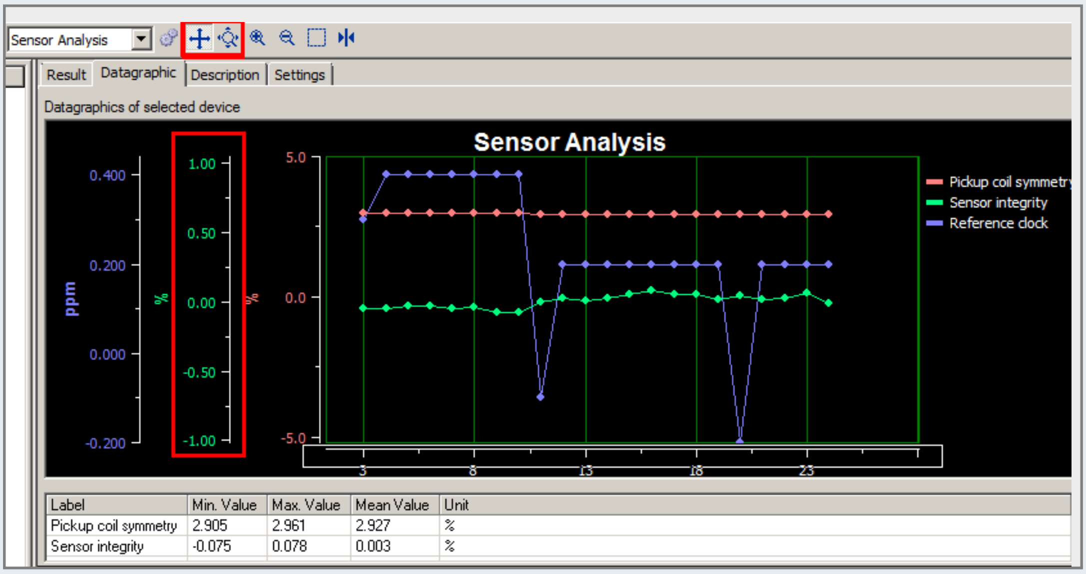

Figure 13: Heartbeat Technology trending.

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 traceable tamper-proof verification report. This report can also be generated manually after the automated commissioning process of Proline Promass U 500.

Verification report Promass 500

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Plant operator: Endress+Hauser

Device information	
Location	Reinach
Serial number	WA014402000
Device tag	
Module name	Promass U
Nominal diameter	DN25 / 1"
Sensor serial number	W3142602000
Device name	Promass 500
Order code	8U5BU1-1420/0
Firmware version	01.00.03

Calibration	
Calibration factor	0.64455
Zero point	-101.3

Verification information	
Operating time (counter)	3d03h42m09s
Date/time (manually entered)	---- ID:29
Verification ID	29
Verification mode	Standard verification

Verification result *	
☑ Passed	Details see next page

*Result of the complete device functionality test via Heartbeat Technology

Confirmation

Heartbeat Verification verifies the function of the measuring device within the specified measuring tolerance with confirmed total test coverage over the useful lifetime of the device and complies with the requirements for measurement traceability according to ISO 9001. You can find the attestation issued by an independent body on www.endress.com or directly here: Please click here

Notes

Date | Operator's signature | Inspector's signature

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Figure 14: Heartbeat Technology 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.

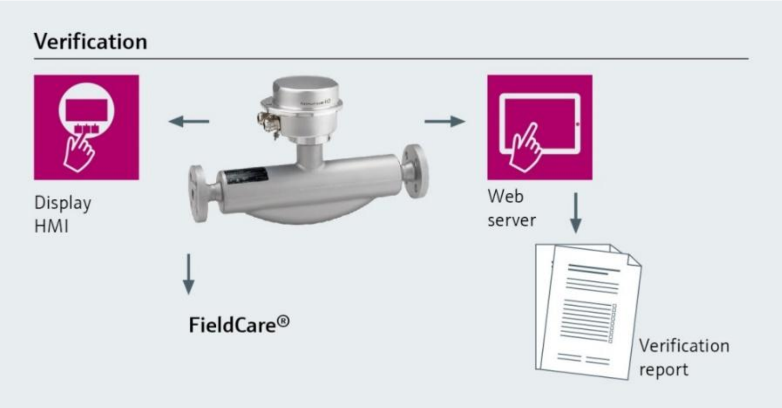

Figure 15: Access to and generation of Heartbeat Technology verification reports.

1.8 Conclusion

Heartbeat Technology provides an integrated approach to verifying the functionality of single-use Coriolis flowmeters in life sciences applications. By leveraging internal references and diagnostics, it enables continuous monitoring and traceable verification without breaking the sterile boundaries. Heartbeat Verification offers a practical solution for single-use instrumentation in GMP environments where traditional calibration methods are not feasible.

WP01261D/06/EN/01.25