Endress+Hauser
People for Process Automation

Heartbeat Technology with Radar Accuracy Index

Best-practices for Life Sciences

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Summary

This document defines the manufacturer-recommended calibration and verification best-practices for Micropilot FMR60B, FMR62B, FMR63B, FMR66B and FMR67B free space radar equipped with Heartbeat Technology with Radar Accuracy Index (RAI) in the Life Sciences Industry according to Title 21 of the FDA's Code of Federal Regulations (FDA 21 CFR section 820) and DIN EN ISO 9001:2015 section 7.1.5/7.1.5.2 a

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Factory calibration

Micropilot FMR60B, FMR62B, FMR63B, FMR66B and FMR67B free space radar level measuring devices, as a part of final inspection, undergo traceable measurement distance comparison tests in production. They are factory calibrated under reference conditions on calibration rigs certified by NMi Certin B.V. and traceable to international measurement standards (certificate number NMi-1901638-01).
Device reports and/or calibration certificates are available online by entering the instrument serial number or ordering the paperwork to ship directly with the device.

Device reports and/or calibration certificates

Quality system regulation

In accordance with FDA 21 CFR sec. 820.72 and DIN EN ISO 9001:2015 sec. 7.1.5/7.1.5.2a the user shall ensure that the instrument is suitable for its intended purpose and is calibrated, inspected, checked, and maintained regularly. These activities and routines are required to be documented by the user.

Initial commissioning – establishing the calibration tables

If the user is intending to use the device for volume/mass indication of the liquid in the tank, the recommended first-time calibration is a full “wet calibration” carried out to establish, under specified conditions, the relationship between the liquid level in the tank and the volume/mass of that liquid. Typical procedures include the comparison between the reading of the radar level measurement device with volume/mass indication based on the calibration table. The table is established for a fixed storage tank or reactor of a defined geometry and the precisely dosed volume/mass of a reference liquid determined e.g. with the reference calibrated flowmeter under specified conditions.
All of the above-listed measurements (e.g. quantity of medium dosed, tank geometry, ambient and process conditions) contribute to the overall measurement uncertainty.

During initial commissioning, the manufacturer recommends the following:

- archive a digital copy of all device-specific parameters gained via the “saving of device data” functionality
- perform a Heartbeat Verification and archive the initial report
- and if considered necessary by the user: lock the device using the DIP switch present on the electronic insert and if required protect it from unauthorized access and parametrization using a housing sticker seal. This is to ensure that a modification of the level transmitter´s configuration (e.g. calibration table, empty/full calibration, etc.) can easily be identified in the field as part of the Heartbeat Verification-based preventive maintenance strategy described in this document.

Preventive maintenance – routine verifications

Regulatory compliance for periodic checks during the life cycle including installation qualification (IQ) can be achieved by the implementation of Heartbeat Verification or level/distance calibration on a certified calibration rig or volumetric/mass comparison measurement in a tank (wet calibration).

A. Heartbeat Verification

Heartbeat Verification is an integrated functionality of the new generation Micropilot free space radar equipped with Heartbeat Technology. All free space radars of the latest generation are equipped with Heartbeat Technology and Endress+Hauser recommends enabling this option. Heartbeat Technology offers diagnostic functionality through continuous self-monitoring (Heartbeat Diagnostics), the transmission of additional measured variables to an external condition monitoring system (Heartbeat Monitoring), and the verification (Heartbeat Verification) of free space radars without process interruption.

The achieved test scope using (continuous) Heartbeat Diagnostics and (periodic) Heartbeat Verifications is identical except for the RAI[1] test sequence. Heartbeat Technology complies with the requirements for traceable verification according to DIN EN ISO 9001:2015 section 7.1.5/7.1.5.2a “Monitoring and measuring resources” as certified by the independent third-party organization TÜV.

Heartbeat Verification verifies the function of the free space radar by checking secondary variables in the instrument correlated closely with the level output. A baseline of those values is established during the original factory final test and/or factory calibration. It is permanently stored in the non-volatile and secure memory of the free space radar and kept on file in the factory (Common Equipment Record).

During a Heartbeat Verification, actual test data are compared with the baseline data acquired during factory calibration and final test to detect any electronic component drift or electronic deterioration of the instrument.

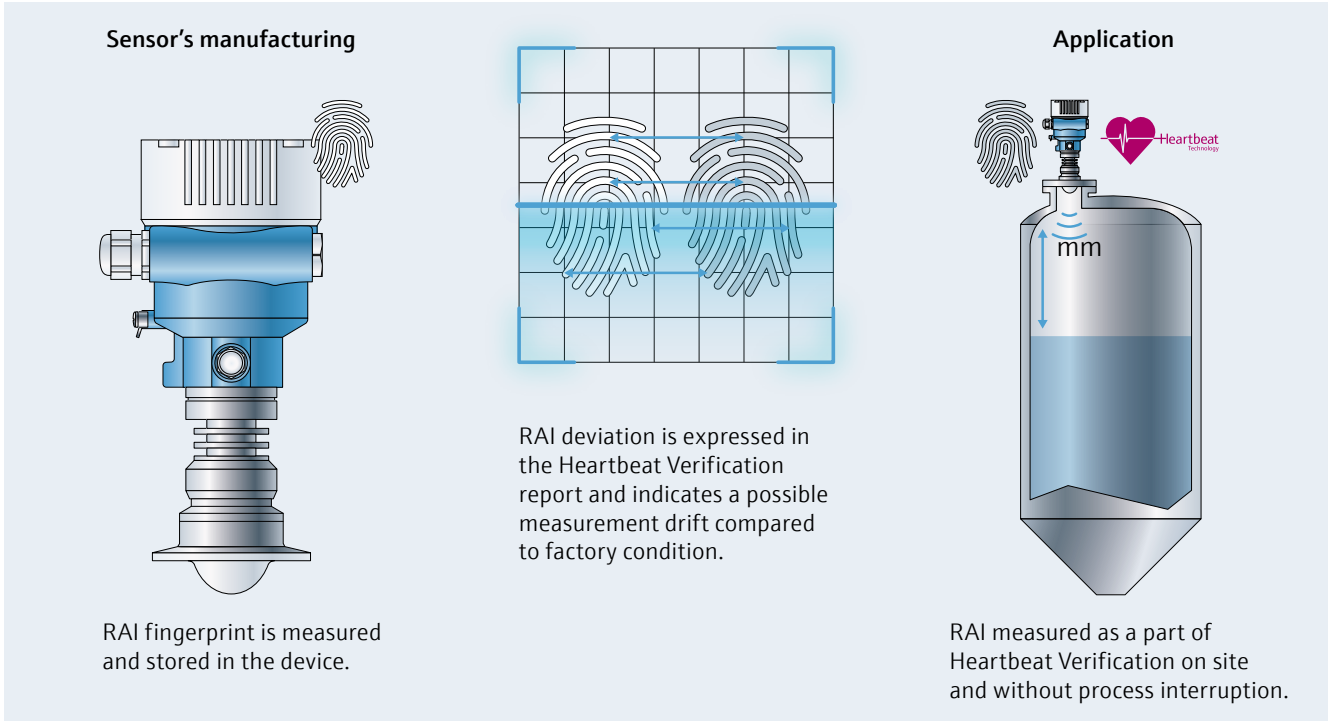

Figure 1: How Heartbeat Verification with Radar Accuracy Index works

[1] The RAI (Radar Accuracy Index) test sequence is part of Heartbeat Verification. It is based on traceable reference frequency values which have been measured and recorded during the Micropilot production and validated during factory calibration.
During the life of the radar sensor, changes of the RAI value from the value obtained during the sensor´s production (RAI deviation) can be a sign of deterioration of the electrical oscillator system caused for example by device aging. The actual RAI deviation value is determined each time a Heartbeat Verification test sequence is run by the operator and expressed in ppm (parts per million) of difference from the initial state of the device.

A failure of one of the hardware components that could lead to a measurement error outside of the specification is reliably detected by Heartbeat Technology with a defined total test coverage (TTC) as certified in above listed test report. The total test coverage (TTC)[2] is calculated based on an FMEDA[3] analysis. Heartbeat Verification results are traceable back to the factory calibration and final test by means of reference values saved in the device.
A Heartbeat Verification test result as "passed" confirms that the radar is still measuring level accurately: ±1 mm (0.04 in)[4] within a measuring range of 3300 mm (130 in)[5] under reference conditions, with a specified total test coverage >95%.

In case a volume/mass calibration table was implemented inside of the radar device to calculate the correspondence between the measured level and the volume/mass in the tank, it is the responsibility of the user to protect the device against unauthorized access at the end of the initial commissioning and to verify after a Heartbeat Verification is performed, whether the configuration of the device was not modified since the initial commissioning (e.g.: by checking the integrity of the housing sticker seal at the end of the initial commissioning/locking of the electronics with DIP switch).

B. Level/distance calibration on a certified calibration rig
Calibrations shall be traceable to a national or international standard. Typical procedures include a level imitation on a horizontal calibration rig with a metallic reflector and a laser distance standard.

C. Volumetric comparison measurement (wet calibration)
Calibrations shall be traceable to a national or international standard. Typical procedures include a comparison between the reading of the radar level measurement device, linearized for volume/mass indication for a stationary tank of defined geometry, and the precisely dosed volume/mass of a reference liquid.

Implementation recommendation

Heartbeat Verification (reference to A),

Endress+Hauser recommends a Heartbeat Verification to be performed once every 12 months of operation for continuous or prolonged batch applications.
For shorter batch operations, Heartbeat Verification can also be implemented as a part of the check-before-batch or check-after-batch routine and run prior/after each batch.
A traceable and tamper-proof verification report is generated, and the result is stored in the free space radar with each run of Heartbeat Verification.

[2] Based on IEC 61508 whereas TTC = $(\lambda_{TOT} - \lambda_{du}) / \lambda_{TOT}$

[3] Failure modes, effects, and diagnostic analysis (FMEDA) is a systematic analysis technique to obtain subsystem / product level failure rates, failure modes and diagnostic capability.

[4] The value is given for a Heartbeat Verification test status as "passed" and a Radar Accuracy Index deviation measured in the field is within the allowed defined bandwidth (±200 ppm) under reference conditions, with a specified total test coverage >95%.

[5] For measuring ranges greater than 3300 mm (130 in), the level accuracy linearly corresponds to ±3 mm per 10000 mm (±0.12 in per 394 in) measuring range under reference conditions, with a specified total test coverage >95%.

Level/distance calibration on a certified calibration rig (reference to B) and Volumetric comparison measurement – wet calibration (reference to C):

According to cGMP regulations, the calibration frequency shall be based on the criticality of the measuring point and adjusted accordingly by the user.
It is also possible to combine Heartbeat Verification with calibrations on a certified calibration rig or volumetric/mass comparison measurement (wet calibration) for increased reliability in critical applications. In this case, extended calibration cycles are accompanied by regular Heartbeat Verification.

Remedial action

If Heartbeat Verification is failed and Radar Accuracy Index deviation is outside of the allowed bandwidth (±200 ppm), the verification shall be repeated under a defined and stable process and ambient conditions.
If the result of the second verification is passed and the RAI deviation is within its specified bandwidth, the result of the first verification can be ignored.
If the verification repeatedly delivers a failed result and the RAI deviation remains outside of the specified bandwidth, the instrument should undergo calibration on a certified calibration rig.
Remedy actions based on the verification results and the diagnostic information of the instrument should be taken into consideration.
Please consult Endress+Hauser Service support to define the best course of action.

In case unauthorized access is detected in between periodic calibrations and/or Heartbeat Verifications tests, the manufacturer recommends:

- to track changes in the CRC checksum value[6], as compared to the initial commissioning state (available in the initial Heartbeat Verification report),
- to track changes in the device parameter list available via the “saving of device data” functionality.

Documentation and electronic device records

In accordance with FDA 21 CFR part 11 the tamper-proof Heartbeat Technology verification report generated electronically in .pdf format can be used to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records of the device.

WP01193F/00/EN/01.23

[6] CRC (Cyclic Redundancy Check) device configuration code together with the date and time of verification expressed in Heartbeat Technology verification report allows tracking the changes and adjustments in Micropilot essential device calibration/configuration in between verifications. Changes in those parameters reflect changes in the CRC device configuration code.