SPEKTRA

Ready for TESTelligence!

White paper

Declaration of conformity

Edition 12-2020

1) Introduction

Is my measuring equipment still functioning properly? How can I be certain of the quality of the data and maintain it at a high level at all times? Regular calibration of your equipment by an accredited calibration laboratory will give you the answers you need to these questions.

Often confused with official verification, conformity statements or specification testing, calibration is essentially a measuring process to determine and document the deviation of a measuring instrument or a measurand relative to another instrument or another reference measurand that in this case is designated the standard.

In the calibration process, the measuring properties of the measuring equipment are determined by means of a series of measurements that are then compared with precise laboratory standards. During the subsequent conformity assessment, the results of the calibration are compared with permissible deviations determined previously. If the calibration results lie within these permissible deviations, it can generally be assumed that the equipment being tested is still functioning properly. Normally the specifications concerning the measurement accuracy of the equipment and the permissible deviations are determined by the manufacturer.

In practice, however, the decision as to whether the measuring object lies within the permissible deviation involves a complex procedure. As an accredited calibration laboratory we consider the following points:

- Quality and informative value of the conformity assessment issued
- Reliability for the customer when submitting the conformity statement
- Measurement uncertainties and tolerance limits
- Risk and probability of an incorrect declaration of conformity
- Trustworthiness of the decision for the customer

> The DIN EN ISO 17025:2018-03 standard clearly requires a decision-making rule. This calls for active cooperation between the accredited calibration laboratory and the customer as the owner of the measuring device.

In this white paper, we demonstrate our concept of taking into account the measurement uncertainty within the decision-making rules for conformity assessments. First we will clarify the central parameters of measurement uncertainty. After this we will address the conformity assessment and the standards and directives to which it refers. Finally we will present the decision-making rules that will be offered by SPEKTRA Schwingungstechnik und Akustik GmbH Dresden for future conformity statements.

2) Results and doubt: Parameters of measurement uncertainty

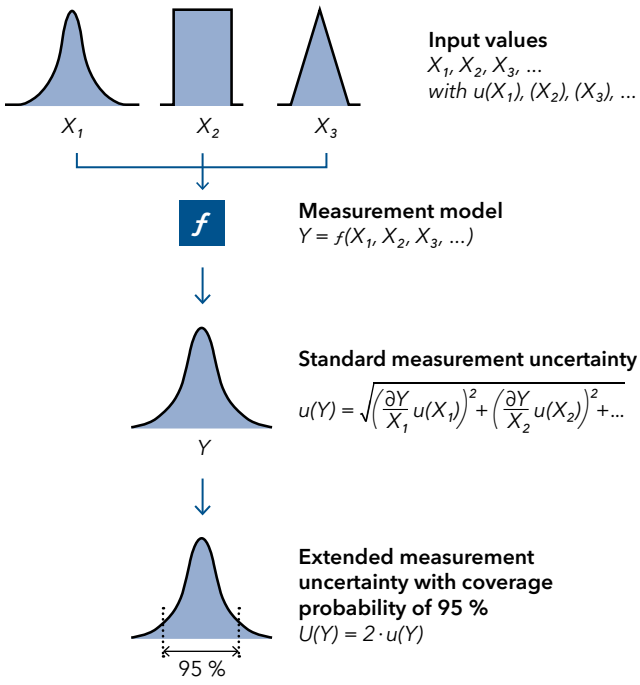
Do the values lie within the specification limits (tolerance) or outside them? Few questions within the field of calibration are so elementary. Yet few can be answered in so many different ways.

Every calibration procedure provides both a measurement value and an associated measurement uncertainty, which is documented in the calibration certificate. The conformity assessment of a calibration should take into account both the permissible tolerance and this measurement uncertainty. The term 'uncertainty' may not inspire trust at first, yet in the field of calibration its meaning is primarily a positive one. On the other hand, measurement uncertainty can be considered in different ways by interpreting the results through different normative guidelines.

As a range, measurement uncertainty is a quantitative measure for the scatter of measuring results and enables a statement to be made about the quality and the level of confidence to be expected in the results. To assess measurement uncertainty, two elements of data are required: the range within which the true value of the measurand is expected and what is known as a confidence level that states how reliably the actual value lies within this range. The value of measurement uncertainty therefore helps to increase confidence in the measuring results.

The value of measurement uncertainty also makes it possible to compare different measurements with one another. To ensure the comparability of the measuring results, calibration laboratories are required to provide a transparent and standardized determination of the measurement uncertainty. Accreditation according to DIN EN ISO 17025:2018-03 guarantees that the measuring results shown on the calibration certificates are standardized and therefore comparable. The generally recognized procedure for determining a quantitative value of measurement uncertainty is described in the ISO/BIPM guideline *Guide to the Expression of Uncertainty in Measurement (GUM)*.

The measurement uncertainty is determined on the basis of the sequence shown there. The individual influencing variables X_i are described in accordance with their distribution as probability functions $u(X_i)$, offset with the associated sensitivities from the measurement model $Y = f(X_i)$ and combined by means of quadratic addition into a standard measurement uncertainty $u(Y)$. The standard measurement uncertainty $u(Y)$ is the degree of scatter of the measurement. To show a value range in which the true measured value lies with a determined level of probability (normally 95 %), the standard measurement uncertainty is multiplied by a coverage factor. In most cases a normal distribution is applicable. In this case the multiplier corresponds to the numerical value of 2.



3) Focus on confidence: The conformity assessment

Is my measuring equipment functioning properly? Every professional calibration is accompanied by an evaluation or conformity statement that includes a consideration of the permissible tolerance range and the measurement uncertainty. This results in borderline cases in which the measuring value lies within the specified tolerance range, but when the measurement uncertainty is taken into account with a given level of probability, it could also lie outside it.

What are the options to make a conformity statement? The decision about the procedure for preparing the conformity statement should be determined in writing by the owner of the calibration object. The regulations in this matter can be shown in normative documents such as legislation, standards and technical specifications, such as:

- DIN EN ISO 14253-1:2018 – Decision rules for verifying conformity or nonconformity with specifications
- ILAC-G8:2009 – Guidelines on the reporting of compliance with specification

In addition, individual customer requirements regarding tolerances or estimates of the permissible deviation or consideration of measurement uncertainty are permissible.

Within the framework of the conformity assessment, the consideration of the measurement uncertainty enable a correct decision to be made. This approach reduces the risk of an incorrect conformity statement to a minimum.

4) Decision-making rules: Consideration of measurement uncertainty in conformity assessment

How is concordance (or non-concordance) of the measuring results with the permissible tolerances determined?
If the measurement uncertainty is not taken into account in the decision, the conformity is deemed to be given as long as the measured value lies within the tolerance limits. Here the confidence level of the correct decision lies around ≥ 50 %. If the measurement uncertainty is taken into account, the requirements and specifications of standards and legislation help with the process of determination. These provide the guidelines for consideration of the measurement uncertainty and the associated conformity assessments for borderline cases.

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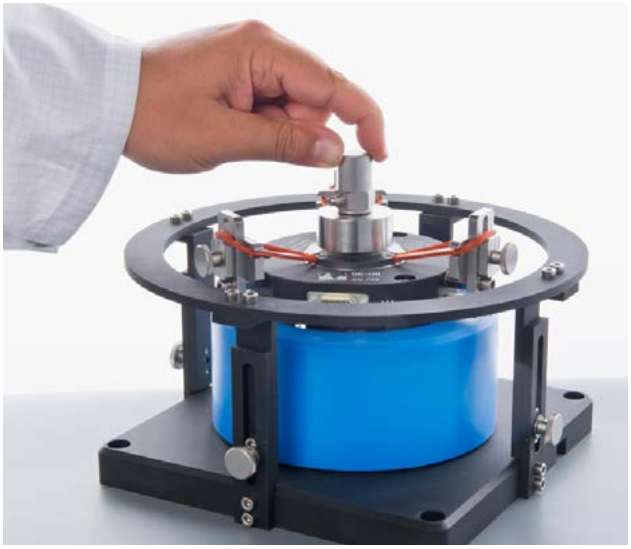


4.1) DIN EN ISO 14253-1:2018 – Decision rules for verifying conformity or nonconformity with specifications

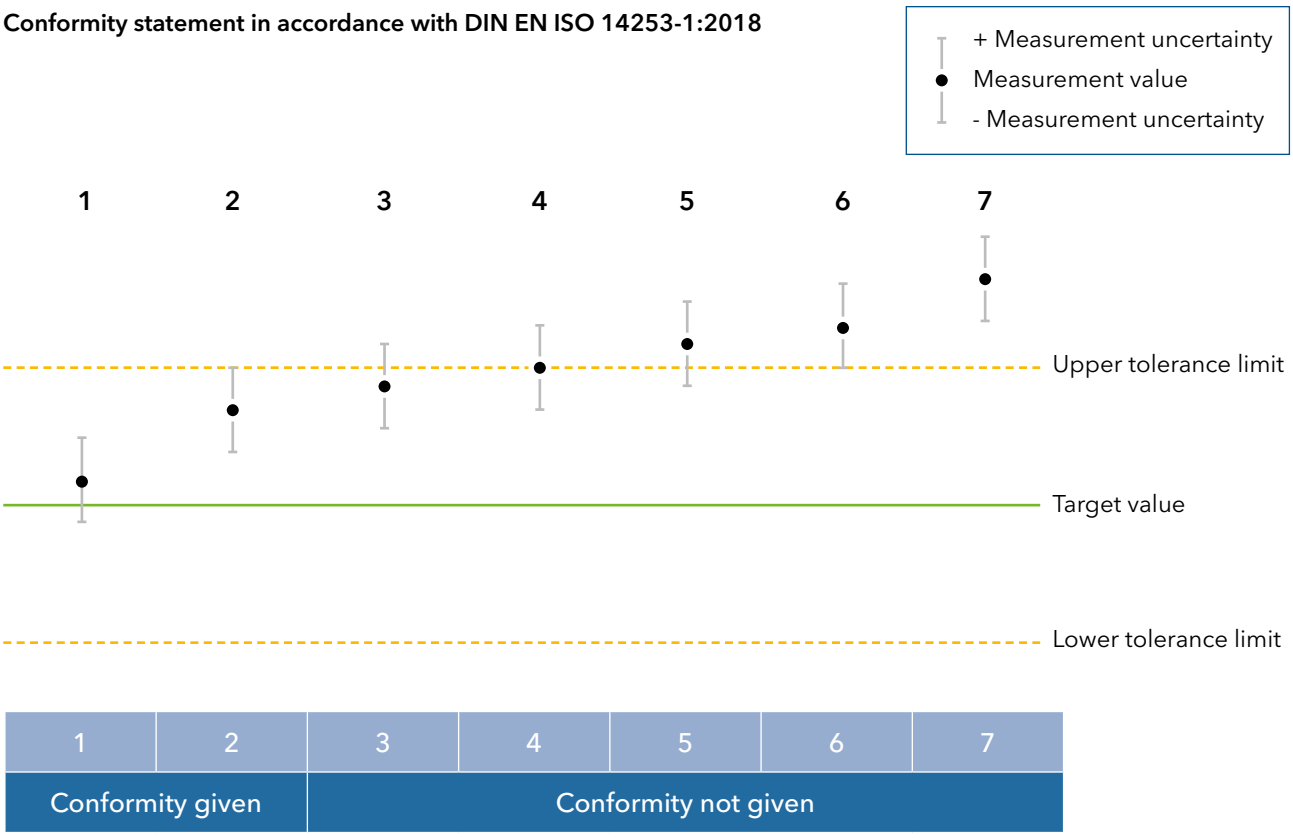
„5.2.1 Conformity with a specification is proven if the measured value lies within the acceptance range. The acceptance range is the specification range, less the safety distances considering the limit of the probability of conformity […] of 95 % […].“

„6.1 The rules in this document are applicable where no previous agreement has been made between the supplier and the customer.“

The DIN EN ISO 14253-1:2018 standard describes a decision-making rule that normally only confirms conformity with a specification if the measured value lies within the permissible deviation with a confidence level of at least 95 %. In the other case the measuring result lies outside the acceptance range and non-conformity with the specification is indicated. Application of this decision-making rule ensures that the confidence level of the correct decision lies above 95 %.

Additionally, this standard gives the calibration laboratory the possibility of evaluating the measuring results of the calibration in a way that the customer considers appropriate and useful for his company and processes. In other words, for the owner of the measuring device, there is the possibility of agreeing on a different confidence level.

Conformity statement in accordance with DIN EN ISO 14253-1:2018



5) Conformity statement and decision-making rules at SPEKTRA Dresden

According to the requirements of DIN EN ISO/IEC 17025:2018, information is given about the decision-making rules to be applied by SPEKTRA Schwingungstechnik und Akustik GmbH Dresden for issuing a declaration of conformity.

Where the decision-making rules are stated in standards or specifications of the calibration method used, these are used as the basis for the conformity assessment. For a conformity statement to be given, sufficiently small measurement uncertainty in regard to the tolerance limits of the device under test is essential. For this reason we only issue conformity statements for which the measurement uncertainty of the measuring result is less than one third of the tolerance limits applied.

The DIN EN ISO 14253-1:2018 standard gives the calibration laboratory the possibility of evaluating the measuring results in accordance with the tolerance limits for calibration specified by the customer. In that case the conformity must be checked against this customer specification. In addition, the customer can choose between the two decision-making rules shown below or submit its own specifications for the conformity assessment to SPEKTRA.

> If the measuring device is not issued with the conformity statement, this does not mean that it is faulty.
>
> Often the tolerance ranges specified by manufacturers do not take measurement uncertainty into account.

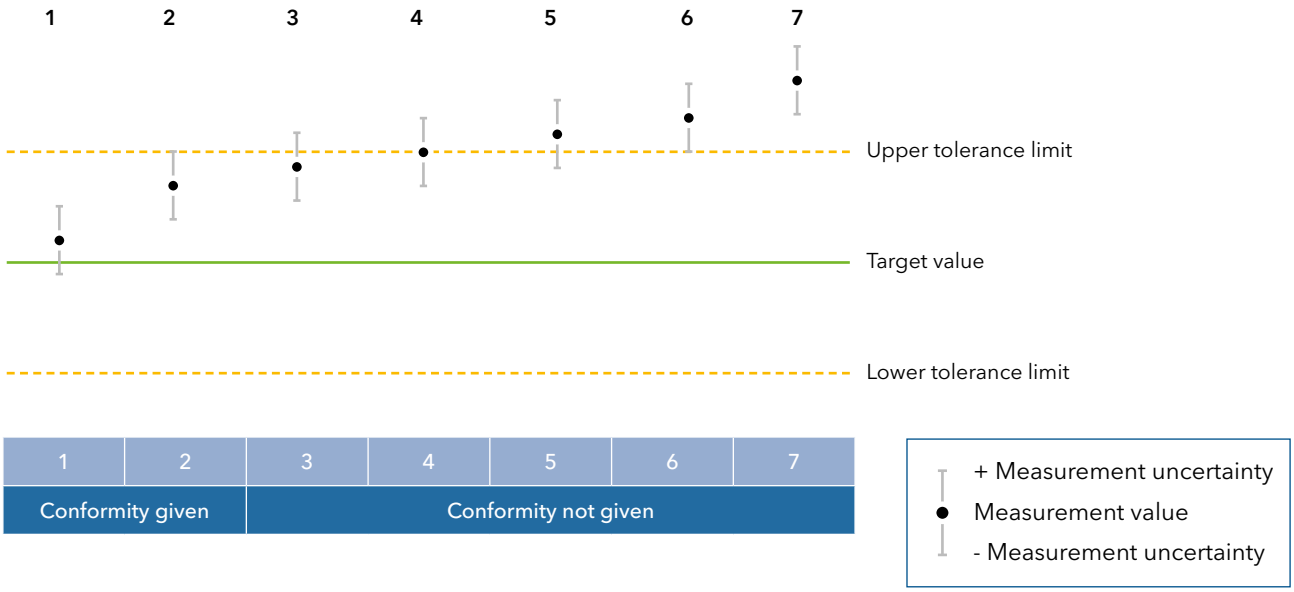
Benefits for measuring equipment owners and customers

- You determine which rules are to be used for you
- High confidence level in the correct decision for the conformity statement
- A conformity statement can always be reached
- Traceability through recording of conformity statements according to strict requirements
- Future-proof: SPEKTRA always operates according to the latest requirements

If no specification is received from the customer about the decision-making rules to be used, SPEKTRA will use the following rules:

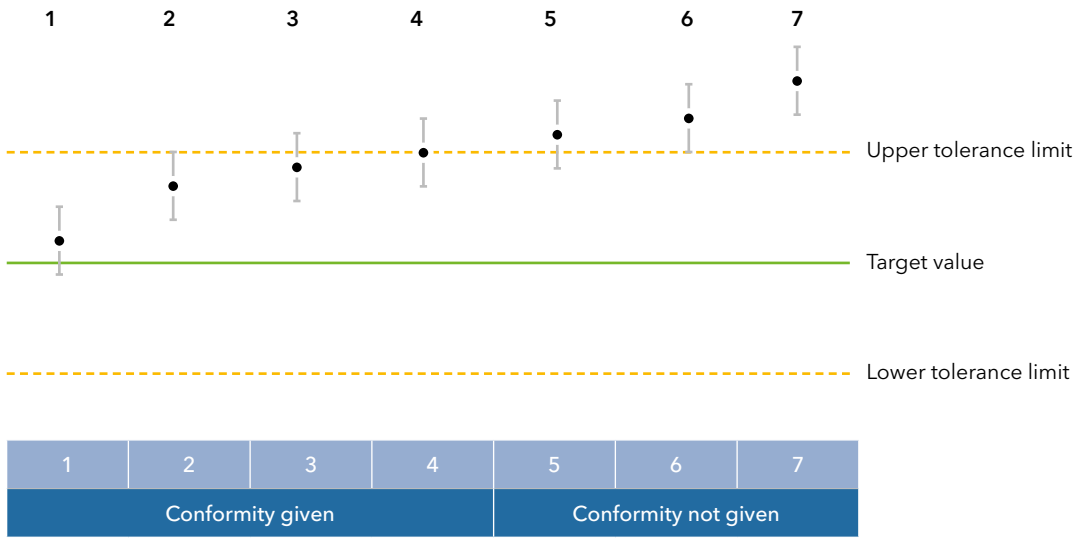
5.1) Conformity statement in accordance with DIN EN ISO 14253-1:2018-07

Application of this decision-making rule ensures that the confidence level of the correct decision lies above 95 %.



5.2) Conformity statement without consideration of measurement uncertainty

In this assessment of conformity, no measurement uncertainty is taken into account. Accordingly, conformity is given if the measured values lie within the specified tolerances. When this rule is applied, the confidence level in a correct decision regarding conformity lies around > 50 %.



Contact for further questions

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