RESEARCH ARTICLE

CONFORMITY ASSESSMENT OF TEMPERATURE MEASURING DEVICES USED IN FORENSIC SCIENCE LABORATORIES UNDER ISO/IEC 17025: 2017

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Abstract

Calibration is an expectation for quality management systems as well as a need for laboratories. If there is a need to measure the size in the laboratory, there is also a need to determine whether the measuring instrument used there is measuring with the desired accuracy. In our study, the suitability of the digital thermometer, which is one of the devices used in the forensic science laboratory during the examination of the evidence, was examined within the scope of ISO / IEC 17025: 2017 standard. The temperature of the environment is very important during the analysis of the evidence. Therefore, it is important to determine the measurement uncertainty and confidence interval in the thermometer that measures this temperature. For this reason, in our study, the calibration procedures were carried out by selecting the digital thermometer device and using the calibration method compared to the reference. Uncertainty budgets were prepared by calculating the measurement uncertainty parameters one by one. Conformity assessment was made according to the measurement results.

Introduction

Calibration is a process related to the reliability of the meter / assembly and a process that tells us how much the meter / assembly deviates from the actual value. Calibration does not mean adjusting the device and reducing the error of the device to zero, but it is not correct to think that the device does not deviate after the calibration process. In this process, measurement uncertainty must be specified besides the measurement error. Calibration is to indicate the relationship of the device with the true value in a certain confidence interval with a certain measurement uncertainty. In other words, it is to determine the metrological performance of the device. According to the measurement results, determining whether the device is suitable for use varies according to the tolerance determined by the user (Goldsmith, 2010).

Measurement uncertainty is related to the suspicion of the measurement process performed (Bell, 2001). A device can be very expensive, can be a very reliable brand, and the measurement result can also be error free, but even in such a case there is a doubt during measurement. Measurement uncertainty; The traceability of the reference device used depends on many parameters, such as the long-term performance of the reference device, the measurement...
oscillation during the calibration of the measuring instrument to be calibrated. Each calibration process has its own
uncertainty parameters that can occur, and as a result of their sum, there is always a measurement uncertainty, even
if the measurement result is error-free EA Laboratory Committee (2013).

The ISO / IEC 17025 General Requirements for Competency of Test and Calibration Laboratories Standard is an
internationally valid certificate / report of a calibration certificate / report prepared by an accredited laboratory,
while ensuring that a laboratory produces accurate results and reliability.According to ISO / IEC 17025 standard, the
laboratory, which must provide its technical competence, must provide many subjects such as establishment, quality
system, device equipment, traceability of devices, personnel training and experience, and suitability of methods
(Turkish Standards Institute, 2017; IslekveYukseloglu, 2018).

The ISO / IEC 17025 standard was first published in 1999 and its first revision was made in 2005. Due to the
developments in technology and market conditions since 2005, there has been a need to change and update the
standard (International Organization for Standardization, 2017). In line with this requirement, a comprehensive
revision of the standard was made in 2017. General configuration in 17025 standard in 2005; the scope, cited
documents, terms, definitions, management conditions, technical conditions, while the new standard configuration
revised in 2017 is the scope, cited documents, terms and definitions, general requirements, structural requirements,
resource requirements, process requirements, management system requirements (Turkish Standards Institute, 2017;
Turkish Accreditation Agency, 2005). The “Decision Rule” described in the ISO / IEC 17025: 2017 standard is one
of the most important changes made according to the ISO / IEC 17025: 2005 standard (Turkish Accreditation
Agency, 2018). According to this change, the laboratory should apply the decision rule and make conformity
assessment. It should state this decision rule in the reports given by agreeing with the customer which decision rule it applies (Turkish Accreditation Agency Revision, 2018).

Temperature devices used in forensic science laboratories are subject to calibration and the calibrations need to be
renewed at certain intervals determined by the laboratory (Islek and Yukseloglu, 2018). According to the calibration
results, the devices continue to be used in the laboratory or the suitability of the devices for use is discussed and
evaluated.

Material and Methods:-
ISO / IEC 17025 Standard and Calibration of Temperature Measurement Devices in Forensic Science
Laboratories
Evidence that can be considered a crime must be moved to the forensic science laboratory, where it will be
examined in the best way without any damage. A mistake or a chain of mistakes that may occur in the examination
of the evidence carried to the laboratory may cause the judiciary to make a wrong decision, which in turn may not
find the place of justice. To prevent a potential error, crime evidence must be examined in accredited laboratories
(Bayram, 2012). Forensic science laboratories are experimental laboratories and are therefore managed according
to the ISO / IEC 17025 standard. The fact that forensic science laboratories have accreditation shows that they produce
technically reliable results. Expertise services provided by a forensic laboratory accredited according to the ISO /
IEC 17025 standard, the reliability of the measurements taken in the laboratory, the reliability of the examinations
and analyzes are documented nationally and internationally (Bayram, 2012). A forensic science laboratory working
according to the ISO / IEC 17025 standard has to calibrate the devices it has used at certain intervals. This process,
which is required by the standard, should be carried out by calibration laboratories accredited according to the ISO /
IEC 17025 standard (Turkish Accreditation Agency, 2018: Metrology Guidance). Thus, the laboratory has
information about the performance of the devices used, and initiates the relevant operations after calibration if
necessary.

Numerical Thermometer Calibration and Measurement Uncertainty Calculations
The forensic science laboratory needs various temperature devices such as digital thermometers, ovens, water baths,
refrigerators, and freezers to examine evidence related to a forensic event. To determine the reliability of the
measurements made with these devices, test measurements should be made on these devices by the calibration
laboratory that has accreditation periodically. Thus, it is possible to know in which confidence intervals the devices
produce results. If results are out of the desired tolerance ranges that are appropriate for the analysis, the effects of
the test can be prevented by taking precautions regarding the relevant devices. The method of comparison with fixed
point temperatures and comparison with reference devices is used in temperature calibrations (Nicholas and White,
2002; National Metrology Institute, 2013). The correction value $\Delta t$ of the digital thermometer calibrated according
to the comparison method with the reference device is defined as follows (European Association of National Metrology Institutes, 2019).

\[ \Delta t = t_r - t_c + \delta_{\text{resol}} + \delta_{\text{drift}} + \delta_{\text{resol,c}} + \delta_{\text{ice}} + \delta_{\text{r}} + \delta_{\text{dist}} + \delta_{\text{stability}} \]

\( t_r \) = temperature value that the reference reads, \( t_c \) = temperature value of the calibrated device, \( \delta_{\text{resol}} \) = certification contribution of the reference, \( \delta_{\text{drift}} \) = long term performance contribution of the reference, \( \delta_{\text{resol,c}} \) = resolution contribution of the reference, \( \delta_{\text{ice}} \) = thermal resource dispersion contribution, \( \delta_{\text{stability}} \) = thermal resource stability contribution, \( \delta_{\text{r}} \) = contribution of ice point measurements

Reference temperature value (\( t_r \)):
The reference temperature is the value that is read at the temperature source whose homogeneity-stability study has been performed with the traceable reference thermometer. This is done as follows: The reference and calibrated device depend on the indicator that reads the degree celsius. While the devices are inside the alcohol bath, the alcohol bath is set to -20 °C and it is waited for it to decrease to the desired temperature. After the temperature source goes down to -20 °C, another 30 minutes is waited for the system to stabilize. After the steady state occurs, 30 measurements must be taken for 30 minutes, with one measurement per minute from the reference thermometer. In line with these measurements, a calculation is made as specified in the formula below:

\[ \bar{q} = \frac{1}{30} \sum_{j=1}^{30} q_j = -20,16 °C \]

\( \bar{q} \) = arithmetic mean, \( q_j \) = individually observed values

Standard measurement uncertainty is obtained by calculating the experimental standard deviation according to the measurements taken from the reference as specified in the formula below:

\[ s = \sqrt{\frac{\sum_{j=1}^{n}(q_j - \bar{q})^2}{n-1}} = \sqrt{\frac{\sum_{j=1}^{30}(q_j - (-20,16 °C))^2}{30-1}} = 0,017 °C \]

\( s \) = experimental standard deviation, \( \bar{q} \) = arithmetic mean, \( q_j \) = individually observed values

The probability distribution is the normal distribution. Accordingly, the standard uncertainty contribution from the measurement repeatability of the reference thermometer is determined to be 0.017 °C.

Reference thermometer calibration certificate (\( \delta_{\text{cal}} \)):
To ensure traceability of the reference thermometer, it must be calibrated in an accredited calibration laboratory. Correction and measurement uncertainty from this calibration process are included in the uncertainty budget. The calibration certificate of the reference device is examined and the correction value at -20 °C is taken into account. This value is 0.1 °C in + direction. The extended measurement uncertainty (coverage factor \( k = 2 \)) in the calibration certificate of the reference for -20 °C is 0.04 °C. The probability distribution is the normal distribution. Accordingly, the standard uncertainty contribution from the calibration certificate of the reference thermometer is as follows:

\[ u(\delta_{\text{cal}}) = \frac{0.04 °C}{2} = 0,02 °C \]

Long-term performance of the reference thermometer (\( \delta_{\text{drift}} \)):
The calibration history of the reference thermometer is examined by looking at its performance over the years, and it is determined how long the device can slide by assuming how it will behave during the year. This is called the long-term performance of the reference thermometer. This uncertainty contribution is 0.03 °C by looking at the past calibration certificates of the thermometer examined for -20 °C. The probability distribution is a rectangular distribution. Accordingly, the standard uncertainty contribution from the long term performance of the reference thermometer is calculated as follows:

\[ u(\delta_{\text{drift}}) = \frac{0.03 °C}{\sqrt{3}} = 0,0173 °C \]

Resolution of the reference thermometer (\( \delta_{\text{resol,r}} \)):
The resolution is defined as the smallest perceived change in the display value. The reference thermometer reacts with changes of 0.01 °C. The probability distribution is a rectangular distribution. Accordingly, the standard uncertainty contribution from the resolution of the reference thermometer is calculated as follows:
\[ u(\delta_{\text{cal.,c}}) = \frac{0.01 \degree C}{2\sqrt{3}} = 0.0029 \degree C \]

**Temperature value of the calibrated thermometer \((t_c)\):**
The temperature value of the calibrated thermometer is the value that is read at the source of homogeneity-stability. 30 measurements are taken for 30 minutes from the calibrated thermometer. Measurements should be taken every minute, simultaneously with the reference thermometer. The average of the measurements taken from the calibrated numerical thermometer is calculated as follows:

\[ \bar{q} = \frac{1}{30} \sum_{j=1}^{30} q_j = -19.61 \degree C \]

\((q^- = \text{arithmetic mean}, q_j = \text{individually observed values})\)

Standard measurement uncertainty is obtained by calculating the standard deviation according to the measurements taken from the calibrated device.

\[ s = \sqrt{\frac{\sum_{j=1}^{30}(q_j - \bar{q})^2}{n-1}} = \sqrt{\frac{\sum_{j=1}^{30}(q_j - (-19.61 \degree C))^2}{30-1}} = 0.403 \degree C \]

\((s = \text{experimental standard deviation}, q^- = \text{arithmetic mean}, q_j = \text{individually observed values})\)

The probability distribution is a rectangular distribution. Accordingly, the standard uncertainty contribution from the measurement repeatability of the calibrated thermometer is 0.403 \degree C.

**Resolution of the calibrated thermometer \((\delta_{\text{resol.,c}})\):**
The indicator of the calibrated thermometer reacts as increasing or decreasing values of 0.1 \degree C. The probability distribution is a rectangular distribution. Accordingly, the standard uncertainty contribution from the resolution of the calibrated thermometer is as follows:

\[ u(\delta_{\text{resol.,c}}) = 0.00289 \degree C \]

**Thermal source distribution \((\delta_{\text{dist}})\):**
Alcohol bath used as a source is set at -20 \degree C. Normally, the expected alcohol is fixing at -20 \degree C in all parts of the internal volume. However, in practice it is not everywhere -20 \degree C. Temperature changes may occur in the lower, upper corners or right and left sides of the bathroom. The uncertainty contribution from this parameter, expressed as the thermal resource distribution, is 0.15 \degree C. The probability distribution is a rectangular distribution. Accordingly, the standard uncertainty contribution resulting from the thermal resource distribution is:

\[ u(\delta_{\text{dist}}) = 0.025 \degree C \]

**Thermal source stability \((\delta_{\text{stability}})\):**
It is defined as the stability of the thermal source for an extended period of time in an area determined in the interior volume of the alcohol bath. This study is not repeated for every device in every calibration. The uncertainty obtained as a result of the stability study of the temperature source (done once every 2 years) is used as fixed data in each calibration. The uncertainty contribution resulting from this parameter is 0.025 \degree C. The probability distribution is a rectangular distribution. Accordingly, standard uncertainty contribution from thermal resource stability:

\[ u(\delta_{\text{stability}}) = 0.025 \degree C \]

**Ice point measurements \((\delta_{\text{ice}})\):**
Ice point measurements are taken before and after calibration. Thus, uncertainty contribution is obtained by trying to obtain information about the characteristic of the thermometer.

*Ice point measurement taken when starting calibration;*  
\( t_{\text{ice, ref}} = 0.00 \degree C \) and \( t_{\text{ice, measured}} = 0.2 \degree C \)

*Ice point measurement taken after calibration;*  
\( t_{\text{ice, ref}} = 0.00 \degree C \) and \( t_{\text{ice, measured}} = 0.3 \degree C \)

According to the measurements made before and after calibration, the difference between the two measurements is taken and this contribution is 0.1 \degree C. The probability distribution is a rectangular distribution.
Accordingly, the standard uncertainty contribution from the ice point is as follows:

\[ u(\delta_{buc}) = \frac{0.1 \, ^\circ C}{\sqrt{3}} = 0.058 \, ^\circ C \]

**Combined standard uncertainty (u_c):**

The combined measurement uncertainty is calculated based on the standard uncertainties \( u(x_i) \) obtained, and the uncertainty contributions \( u(y) \) obtained by the product of the sensitivity coefficient (Evaluation of measurement data, 2008).

\[ u_c = \sqrt{(0.017)^2 + (0.02)^2 + (0.0173)^2 + (0.0029)^2 + (0.403)^2 + (0.0289)^2 + (0.0866)^2 + (0.025)^2 + (0.058)^2} \]

\[ u_c = 0.42 \, ^\circ C \]

**Extended measurement uncertainty (U):**

The uncertainty budget: statement containing measurement uncertainty, its components, their calculation and combinations. It includes measured size, estimated value, probability distribution, standard uncertainty type, standard uncertainty calculation, sensitivity coefficient and extended uncertainty value (The international vocabulary of metrology, 2012). Tab. 1 presents the uncertainty budget of the digital thermometer.

**Digital Thermometer Conformity Assessment**

Although the reference temperature average value we found as a result of the calculation we made under the 3rd heading is -20.16 °C, correction should be made according to the calibration certificate result of the reference thermometer. Therefore, corrected reference temperature is obtained by adding correction value to the value read during measurement. According to the calibration certificate, this correction value should be 0.1 °C in + direction. Accordingly, when the reference temperature value is -20.06 °C, the calibrated thermometer shows -19.61 °C ± 0.84 °C in the 95% confidence interval. The extended measurement uncertainty is expressed as the result of the multiplication of the standard measurement uncertainty by the factor \( k = 2 \), which provides a probability of approximately 95% coverage for the normal distribution (International Laboratory Accreditation Cooperation, 2013).

\[ U = k \cdot u_c = 2 \times 0.42 \, ^\circ C = 0.84 \, ^\circ C \]

If we apply the decision rule according to the tolerance given by the device user and want to evaluate the conformity for the device, we need to test the H0 hypothesis according to the EUROLAB Technical Report No.01 / 2017, Decision Rules Applied to Conformity Assesment document (European Federation of National Associations of Measurement Testing and Analytical Laboratories., 2017; European Federation of National Associations of Measurement Testing and Analytical Laboratories, 2017). It is decided whether the devices tested according to this hypothesis are suitable for use.

According to the H0 hypothesis:

- Hypothesis, H0: \( P (T_L \leq Y \leq T_U) \geq (1 - \alpha) \) acceptance if true.
- Hypothesis, if H0 is wrong red \( \rightarrow P (T_L \leq Y \leq T_U) <(1 - \alpha) \)

The device is suitable if the possibility of compatibility exceeds 95% of the PC, otherwise it is inappropriate. The probability of conformity is calculated as follows:

\[ P_C = P (T_L \leq \eta \leq T_U) = \Phi ((T_U - Y) / u) - \Phi ((T_L - y) / u) \]

* (H0 = Zero Hypothesis, \( T_L = \) Lower Tolerance Limit, \( T_U = \) Upper Tolerance Limit, \( 1 - \alpha = \) Confidence Level, \( Y = \) Measured Size, \( y = \) Measurement Result, \( PC = \) Probability of Compliance)

Microsoft Excel 2016 program is used in finding the PC formula and the following formulas are applied in the program: (European Federation of National Associations of Measurement Testing and Analytical Laboratories, 2017).
To find equation: \( \Phi \left( \frac{(TU - y)}{u} \right) \);  
\( = \text{NORM.DIST (upper tolerance limit (TU); measurement mean (y); combined standard uncertainty (u, k = 1); TRUE)} \)

To find equation \( \Phi \left( \frac{(TL - y)}{u} \right) \);

1) The measured value is -19.61 °C and the tolerance provided by the user is ± 1 °C. Considering that the reference temperature value is -20.06 °C, the decision rule should be tested according to the hypothesis below.

2) Hypothesis, \( H_0: P \left( -21.06 °C \leq -19.61 °C \leq -19.06 °C \right) \geq 0.95 \) acceptance if true.

\[ P_C = P \left( T_L \leq \eta \leq T_U \right) = \Phi \left( \frac{T_U - y}{u} \right) - \Phi \left( \frac{T_L - y}{u} \right) \]

\[ P_C = 0.90482 - 0.00028 = 0.90454 < 0.95 \]

Consequently, because the Hypothesis \( H_0 \) is wrong, the device is not suitable for use with this specified tolerance value.

3) Suppose that when the device is used within the tolerance range of ± 1.5 °C, it does not have a significant effect in the reports given by the forensic science laboratory. Accordingly, if we test the \( H_0 \) hypothesis with a tolerance value of ± 1.5 °C;

Hypothesis, \( H_0: P \left( -18.56 °C \leq -19.61 °C \leq -21.56 °C \right) \geq 0.95 \) acceptance if true.

\[ P_C = P \left( T_L \leq \eta \leq T_U \right) = \Phi \left( \frac{T_U - y}{u} \right) - \Phi \left( \frac{T_L - y}{u} \right) \]

\[ P_C = 0.993790 - 0.000002 = 0.993789 > 0.95 \]

Consequently, since Hypothesis \( H_0 \) is correct, the device is suitable for use with this specified tolerance value.

Tab. 1:- Digital thermometer calibration uncertainty budget.

| Size | Definition | Estimated value | Standard uncertainty | Standard uncertaintytype | Probability distribution | Sensitivity coefficient | Uncertainty contribution |
|------|------------|-----------------|----------------------|--------------------------|-------------------------|------------------------|--------------------------|
| \( x_i \) | referencetemperature value | -20.8°C | 0.0170°C | A | normal | 1 | 0.0170°C |
| \( \delta t_{cal} \) | calibration certificate of reference thermometer | 0.10°C | 0.0200°C | B | normal | 1 | 0.0200°C |
| \( \delta t_{dri} \) | long-term performance of reference thermometer | 0.00°C | 0.0173°C | B | Rectangle | 1 | 0.0173°C |
| \( \delta t_{res} \) | resolution of reference thermometer | 0.00°C | 0.0029°C | B | rectangle | 1 | 0.0029°C |
| \( t_c \) | Temperature value of the calibrated thermometer | -19.61°C | 0.4030°C | A | Normal | 1 | 0.4030°C |
| \( \delta t_{res} \) | resolution of calibrated thermometer | 0.00°C | 0.0289°C | B | rectangle | 1 | 0.0289°C |
| \( \delta t_{dis} \) | Thermal resource distribution | 0.00°C | 0.0866°C | B | rectangle | 1 | 0.0866°C |
Discussion:

The quality of a measurement is determined by validating / verification the relevant method, estimating the measurement uncertainty, ensuring traceability and ensuring continuity by quality control studies. When reporting the result of a measurement, there should be a numerical indicator that indicates the quality of the result so that those who use it can determine the reliability of that result. Without such an indicator, the measurement results cannot be compared with the values given among themselves, certificates or standards. It is therefore important to have a process that characterizes the quality of a measurement, is immediately applicable, easily understandable and generally accepted (International Laboratory Accreditation Cooperation, 2019; Altin, 2010). This is to calculate and express the uncertainty of the value obtained as a result of the measurement.

Determining whether the temperature devices used in forensic science laboratories are suitable for use is important in terms of forensic reports issued by the laboratory. Although forensic science laboratories have to determine in which acceptance range they should use the device they use, they may be “suitable” or “out of use” for the use of the device according to this specified acceptance range. A forensic laboratory should have chosen the calibration laboratory from which it will purchase service before performing the calibration process, and prefer an accredited calibration laboratory if possible (Trisna et al., 2020). It should carefully examine the best measurement uncertainties of the calibration laboratories in which it will receive service. For example, if the device with a tolerance of ± 0.5 °C is purchased from a calibration laboratory with the best extended measurement uncertainty of 0.5 °C, the device will not be compatible with the measurement uncertainty if the measurement result is incorrect even at 0.1 °C.

The 'tolerance' provided by the user should be reconsidered instead of excluding devices that are found inappropriate according to the calibration results. Forensic science laboratories can increase the tolerance of the devices by considering the test reports to be given. Regarding devices that are found inappropriate for use after calibration, calibration can be performed again by adjusting or repairing the devices if possible. Results are re-evaluated after calibration. If the result is not suitable for use as a result of operations such as tolerance, adjustment, repair, the device is no longer available and a new device needs to be purchased. After calibration, the results should be re-evaluated after calibration.

Documents “EA-4/02 Evaluation of the Uncertainty of Measurement in Calibration” and “EURAMET Calibration Guide - 8, Calibration of Thermocouples” are used as guides in digital thermometer calibrations. These documents are concerned with the calibration process, not to mention in what conditions the device may be suitable for use or out of use after calibration. Calibration results and evaluation are left to the user in these documents. In ISO / IEC 17025: 2017 standard; According to the results of the calibration, the calibration laboratory must agree with the customer and apply the decision rule and make the conformity assessment of the device to decide whether the devices are suitable for use.

Conclusion:

Documentation for "EUROLAB Technical Report - Decision Rules Applied To Conformity Assessment", "ILAC-G8 Guidelines on the Reporting of Compliance with Specification", "EUROLAB Cook Book Doc No.8, Determination of Conformance With Specifications Using Measurement Uncertainties – Possible Strategies". These are the guiding documents used in the evaluation. However, there is a general conformity assessment approach in these documents and there is no content especially regarding conformity assessment after temperature calibration.
For this reason, our study is a supplement to the temperature calibration and conformity assessment documents. It deals with the question of whether temperature devices can be used after calibration and is based on the “General Requirements Standard for Competence of ISO / IEC 17025 Test and Calibration Laboratories”. It is aimed to be a guide for studies to be carried out similar to this.

Conflict of interest
The author declare no conflict of interests.

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