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RESEARCH ARTICLE

CONFORMITY ASSESSMENT IN INFRARED EAR THERMOMETER CALIBRATION

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Abstract

Body temperature is a basic physiological measurement used primarily for observation and diagnosis during surgery, pandemic diseases, intensive care, recovery or treatment. Various thermometers are clinically used for these measurements and can be divided into two categories, contact or non-contact. To have maximum confidence in the clinical performance of the temperature measuring instrument, it is important to calibrate the instrument traceable to the 1990 International Temperature Scale (ITS-90). The absence of traceable calibrations accredited to ISO/IEC 17025 can lead to insecurity in temperature measurement and in some cases can have a detrimental effect on patient care.Infrared or radiation thermometers are preferred in many different sectors from health to food, from automotive to agriculture, from iron and steel industry to chemistry due to their fast measuring capabilities, reasonable prices, wide measuring ranges and ease of use. In this study, ear thermometer calibration and measurement uncertainty calculations are investigated by using the traceability method via contact thermometer. Considering the maximum permissible error value of the device, conformity assessment is made according to the measurement result.

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Introduction:-

Although measuring temperature with optical systems is not as ideal as measuring body temperature with traditional methods (glass thermometer, chemical thermometer), it quickly replaces old classical methods (1). In the field of body temperature measurement, clinical studies in recent years have focused on practical infrared thermometers that can measure accurately, reliable and fast by providing thermal comfort with less contact (2)(3).

It is necessary to make measurements with high accuracy and precision with clinical type infrared thermometers operating in the body temperature range (36 °C…42 °C). Otherwise, it may lead to bad results such as erroneous measurements, wrong diagnosis and treatment. Calibration of clinical thermometers is an important need for accurate measurement and reliability of measurements. The most important part of the calibration system of infrared thermometers is the blackbody. The basic optical properties of blackbodies are their emissivity and reflectivity. There are two types of blackbody sources; flat plate and cavity type source(4)(5). The infrared ear thermometer measurement method relies on having some knowledge of the emissivity of human skin, because human skin is not blackbodies: the radiation they emit is always less than ideal. The most fundamental issue in measurements is the blackbody sources used in the calibration of all radiation thermometers. These systems do not pose such a problem in the calibration of an industrial type infrared or radiation thermometer because the operating range of the

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thermometer is not as specific as the human body temperature and does not require low uncertainty, but if you are measuring the temperature of the human body, the 0.5 °C error or uncertainty is very important. For this reason, these calibration systems need to be specially designed to measure with higher precision (ASTM 1998, EN 2003, JIS 2001). Measurement systems designed for calibration depend on multiple parameters such as surface shape, paint, material from which it is produced and measurements can be affected in the smallest difference under the specified conditions.(6)(7)(8)(9)(10)(11)(12)(13)(14)(15).

Although the "ASTM E 1965-98 Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature" standard has the specification for ear thermometers, it does not contain detailed information about the calibration process and how to calculate the measurement uncertainty of it (16). Since the ear thermometer is also a kind of radiation thermometer, the calibration process should be carried out according to the "ASTM E 2847 Standard Test Method for Calibration and Accuracy Verification of Wideband Infrared Thermometers" and "Measurement Standards Laboratory of New Zealand, MSL Technical Guide 22". These documents describe how metrological traceability can be determined by contact thermometer or radiometrically (transfer radiation thermometer as reference) (17)(18). In this study, ear thermometer calibration and measurement uncertainty calculations are investigated by using the traceability method via contact thermometer. Considering the maximum permissible error value of the device, conformity assessment is made according to the measurement result.

Material And Method:-

Ear Thermometer Working Principle

The ear thermometer is a kind of radiation thermometer. The detectors of radiation thermometers turn the radiometric signal in itself and display it as temperature on the screen. The relationship between signal and temperature is defined by the Sakuma-Hattori equation, a version of Planck's Law (17)(19):

$$\mathrm{S(T)} = \frac{\mathrm{C}}{\exp\left(\frac{\mathrm{c_2}}{\mathrm{AT+B}}\right) - 1}$$

$$\mathrm{T} = \frac{\mathrm{c_2}}{\mathrm{A.}\ln\left(\frac{\mathrm{C}}{\mathrm{S(T)}} + 1\right)} - \frac{\mathrm{B}}{\mathrm{A}}$$

S(T) = radiometric signal
T = temperature value (Kelvin)
A, B = values that vary according to the spectral range of the radiation thermometer and are calculated by the following formulas:

$$\mathrm{A} = \lambda_0\left(1 - \frac{\Delta\lambda^2}{2{\lambda_0}^2}\right)$$

$$\mathrm{B} = \frac{\mathrm{c_2}\Delta\lambda^2}{24{\lambda_0}^2}$$

λ_0 is the middle of its spectral range. For example, for a thermometer operating in the wavelength range of 8-14 µm, this value is 11 µm.

$\Delta\lambda$ is the width of the spectral range. For example, for a thermometer operating in the wavelength range of 8-14 µm, this value is 6 µm.

C = 1
c_2 = universal constant of 14387,752 µm·K

Metrological Traceability

The traceability of the calibration temperature can be determined in two ways: contact traceability or radiometric traceability (18). In this study, contact traceability was preferred by taking the platinum resistance thermometer as a reference to obtain low uncertainty.

Devices Used in Calibration and Their Requirements

Standard Blackbody (Cavity)

The blackbody is used as a source for infrared ear thermometer calibration. The cavity recommended by NIST is specified in the ASTM E 1965-98 standard (16).

Water Bath

The standard blackbody is placed in the water bath and the temperature stability of this bath is in the range of ± 0.02 °C.

Contact Thermometer

The actual temperature of the water should be verified by a traceable contact thermometer. In this study, a platinum resistance thermometer (Pt100) connected to the indicator reading degree Celsius (°C) was used.

According to the ASTM E 1965-98 standard, the reference device must have an uncertainty of 0.03 °C. Since the measurement uncertainty of the thermometer used in this study is 0.005 °C between 35.5 and 42 °C and the uncertainty of the indicator is 0.011 °C, the measurement uncertainty of the reference device used in the 95% confidence interval is calculated as follows:

$$U = 2 \text{ x} \sqrt{(\frac{0{,}005}{2})^2 + (\frac{0{,}011}{2})^2} = 0{,}012\ °\text{C}$$

In order to make sure that the temperature value measured from the reference resistance thermometer is correct, it is necessary to examine the calibration certificate of the resistance thermometer.

Reference Temperature (T)	*Resistance of PRT (R_T)*	*Measurement Uncertainty*
°C	Ω	°C
419,527	253,8647	0,006
231,928	187,5820	0,005
156,599	159,8259	0,005
29,7646	111,5954	0,004
-38,8344	84,7125	0,004
-80,0817	68,2113	0,020
0,0100	100,0096	0,004

The coefficients are entered into the reference display by calculating the coefficient according to the resistance values corresponding to the reference temperature. Thus, it is ensured that the temperature reading on the display is equal to the actual temperature. To obtain these coefficients, the Callendar-Van Dusen equation coefficients are used (20).

$t > 0\ °C \rightarrow R_t = R_0 \cdot (1 + At + Bt^2)$
$t < 0\ °C \rightarrow R_t = R_0 \cdot (1 + At + Bt^2 + C(t - 100°C)t^3)$

	Callendar-Van Dusen	unit
R_0	100.002441845	Ω
A	3,9108314864E-03	$° C^{-1}$
B	-5,8025110277E-07	$° C^{-2}$
C	-1.0828871275E-11	$° C^{-4}$

Measurement Equation

In radiation thermometers, the measurement equation is defined as (17)(18)(19):

$$S(T_{meas}) = S(T_s) + \frac{(1-\varepsilon_{instr})}{\varepsilon_{instr}}[S(T_w) - S(T_d)] + \frac{(\varepsilon_s - \varepsilon_{instr})}{\varepsilon_{instr}}[S(T_s) - S(T_w)]$$

- $S(T)$ = radiometric signal
- ε_s = source emissivity
- ε_{instr} = emissivity of radiation thermometer
- T_{meas} = temperature measured from radiation thermometer (K)
- T_s = source temperature (K)
- T_w = ambient temperature (K)
- T_d = detector temperature (K)

To bring the measurement equation of radiation thermometers into applicable form in laboratory environment ($T_w = T_{amb}$);

$$S(T_{exp}) = \frac{\varepsilon_{bb}S(T_{ref}) + (1-\varepsilon_{bb})S(T_{amb}) - (1-\varepsilon_{instr})S(T_d)}{\varepsilon_{instr}}$$

that formula is used (17).

Since ear thermometers measure from the ear canal, the emissivity value should be evaluated as 1 ($\varepsilon_{instr} = 1$)(16). In this case, the measurement equation is arranged as follows:

$$S(T_{exp}) = \varepsilon_{bb}S(T_{ref}) + (1-\varepsilon_{bb})S(T_{amb})$$

The ε_{bb} value is the effective emissivity of the heat source(17)(21)(22)(23). For the purpose of this study, emissivity of blackbody is considered equal to unity in accordance with ASTM E 1965-98 (16). That means T_{ref}(the actual temperature of the heat source) equals to T_{exp} (the temperature value expected to be read from the infrared ear thermometer). The deviation in this temperature value is recorded as the measurement error of the device.

Calibration Procedure

- In order for the device to adapt to the ambient conditions, the device is kept in the laboratory environment at least 30 minutes.
- The calibration points should be:
    - 35.5 °C, 37 °C, 39.5 °C, 42 °C (setpoint ± 0.5 °C)(24)
- The cavity is placed inside the water bath.
- The water bath is started and the system is expected to stabilize by adjusting the relevant temperature value.
- During the calibration, the front lens of the instrument should not be directly exposed to radiation from sources outside the cavity (18).
- When the water bath becomes stable, measurements are taken first from the reference thermometer and then from the device to be calibrated.
- At least 5 measurements are taken at each calibration point by keeping the device to be calibrated in line with the cavity opening.
- Before each measurement, it is necessary to wait for a while so that the detector of the device is the same as the ambient temperature.
- The calibration process is completed by taking measurements at all calibration points.

Measurement Uncertainty Calculations For 42 °C

Uncertainty From Reference Devices

Platinum Resistance Thermometer and Indicator Calibration Uncertainty

The traceability of the calibration temperature can be determined in two ways: contact traceability or radiometric traceability (18). Contact traceability is preferred to achieve low uncertainty (25).

In this case, the calibration temperature is the temperature measured from the platinum resistance thermometer connected to the indicator that reads degree Celsius (°C). When the calibration certificate of the devices was examined, it was seen that the measurement uncertainty of the platinum resistance thermometer at 42 °C was 0.005 °C. The probability distribution is normal. In this case, the standard uncertainty is calculated as:

$$\mathrm{u}_1 = \frac{0{,}005}{2} = 0{,}0025\ {}^{\circ}\mathrm{C}$$

The certificate uncertainty of the indicator that takes temperature reading is 0.011 °C. The probability distribution is normal. In this case, the standard uncertainty is:

$$\mathrm{u}_2 = \frac{0{,}011}{2} = 0{,}0055\ {}^{\circ}\mathrm{C}$$

Platinum Resistance Thermometer and Indicator Drift Uncertainty

The stability of the devices is determined according to their long-term performance (26). Calibration certificates of the reference device are examined and the change in deviations over the years is checked. The difference between the deviations is used as the drift uncertainty effect. Probability distributions are rectangular.

Standard uncertainty for Pt100 drift :

$$\mathrm{u}_3 = \frac{0{,}005}{\sqrt{3}} = 0{,}0029\ {}^{\circ}\mathrm{C}$$

Standard uncertainty for indicator drift :

$$\mathrm{u}_4 = \frac{0{,}01}{\sqrt{3}} = 0{,}0058\ {}^{\circ}\mathrm{C}$$

Uncertainty From Water Bath

Water Bath Homogeneity

The alcohol bath used as the source is set to 42 °C. Normally it is expected that the alcohol bath will be fixed at 42 °C in all parts of its internal volume. However, in practice it is not at 42 °C everywhere. There may be temperature changes in the lower and upper corners of the bathroom or on the right and left sides (27)(28). According to the experimental studies, the contribution of uncertainty arising from the homogeneity of the water bath is 0.03°C. The probability distribution is the rectangular distribution. Accordingly, the standard uncertainty is:

$$\mathrm{u}_5 = \frac{0{,}03}{\sqrt{3}} = 0{,}017\ {}^{\circ}\mathrm{C}$$

Water Bath Stability

Being at the same temperature for a long time in an area determined in the internal volume of the alcohol bath is defined as the stability of the bath (27)(28). This parameter is not repeated for every instrument in every calibration. According to the experimental studies, the uncertainty obtained as a result of the stability study of the water bath is used as constant data in each calibration. The uncertainty contribution resulting from this parameter is 0.02 °C. The probability distribution is the rectangular distribution. Accordingly, the standard uncertainty is:

$$\mathrm{u}_6 = \frac{0{,}02}{\sqrt{3}} = 0{,}012\ {}^{\circ}\mathrm{C}$$

Uncertainty From Standard Blackbody

Source Emissivity

The following formulas are used to calculate this effect (18).

$$\frac{\partial \mathrm{S}(\mathrm{T}_{\mathrm{meas}})}{\partial \varepsilon_{\mathrm{s}}} = \frac{1}{\varepsilon_{\mathrm{instr}}}\left[\mathrm{S}(\mathrm{T}_{\mathrm{s}}) - \mathrm{S}(\mathrm{T}_{\mathrm{w}})\right]$$

$$\mathrm{U}_{\varepsilon}(\mathrm{T}_{\mathrm{meas}}) = \frac{\partial \mathrm{T}_{\mathrm{meas}}}{\partial \varepsilon_{\mathrm{s}}}\mathrm{U}(\varepsilon_{\mathrm{s}}) = \frac{\frac{\partial \mathrm{S}(\mathrm{T}_{\mathrm{meas}})}{\partial \varepsilon_{\mathrm{s}}}}{\frac{\partial \mathrm{S}(\mathrm{T}_{\mathrm{meas}})}{\partial \mathrm{T}}}\mathrm{U}(\varepsilon_{\mathrm{s}})$$

where the source temperature T_s = 42 °C, the ambient temperature where the source is located T_w= 23 °C, the emissivity value of the device is ε_{instr} = 1 and U(ε $_s$) = 0.002;

$$\frac{\partial S(T_{meas})}{\partial \varepsilon_s} = \frac{1}{1}[0{,}0101771 - 0{,}0076947)] = 0{,}002482418$$

$$U_\varepsilon(T_{meas}) = \frac{\partial T_{meas}}{\partial \varepsilon_s} U(\varepsilon_s) = \frac{0{,}002482418}{0{,}000070718}\ 0{,}002 = 0{,}07\ °C$$

The probability distribution is normal.

$$u_7 = \frac{0{,}07\ °C}{2} = 0{,}035\ °C$$

Reflected Ambient Radiation

Reflected ambient radiation is also referred to as background radiation (22)(23). The probability distribution is normal.

The following formulas are used to calculate this effect (18).

$$\frac{\partial S(T_{meas})}{\partial S(T_w)} = \frac{1-\varepsilon_s}{\varepsilon_{instr}}$$

$$U_{REFL}(T_{meas}) = \frac{\partial T_{meas}}{\partial T}(T_w) = \frac{\partial S(T_{meas})}{\partial S(T_w)} \frac{\frac{\partial S(T_w)}{\partial T}}{\frac{\partial S(T_{meas})}{\partial T}} U(T_w)$$

where the source temperature T_s= 42, the ambient temperature where the source is located T_w= 23 °C, the emissivity value of the source ε $_s$ = 0.998, the emissivity value of the device ε_{instr}= 1 and U(T $_w$) = 2 °C;

$$\frac{\partial S(T_{meas})}{\partial S(T_w)} = \frac{1-0{,}998}{1} = 0{,}002$$

$$U_{REFL}(T_{meas}) = \frac{\partial T_{meas}}{\partial T}(T_w) = 0{,}002\ \frac{0{,}000059961}{0{,}000070718}\ 2 = 0{,}0033\ °C$$

$$u_8 = \frac{0{,}0033\ °C}{2} = 0{,}0017\ °C$$

Source Heat Exchange

It is the uncertainty arising from the difference between the temperature measured from a platinum resistance thermometer and the actual temperature of the surface (18)(29)(30). The probability distribution is normal.

$$u_9 = \frac{0{,}01\ °C}{2} = 0{,}005\ °C$$

Ambient conditions

This uncertainty is related to the convection of heat. Depending on the heat flow around the heat sources , there may be variation in the homogeneity of the sources (18). To determine this effect, the effect can be calculated by increasing or decreasing the heat flux around the heat sources. The probability distribution is normal.

$$u_{10} = \frac{0{,}01\ °C}{2} = 0{,}005\ °C$$

Source Uniformity

It is the uncertainty due to the inhomogeneity of the temperature on the source surface (18)(30)(31). Radiation thermometers read the average value of the temperature within the viewing angle. Therefore, this situation is taken into account when calculating homogeneity, since there will be a temperature difference in the measurements according to a small area or a large area scan from the center of the temperature source. The probability distribution is rectangular.

For the homogeneity value of the cavity at 42 °C, 0.05 °C can be taken.

$$\mathrm{u}_{11} = \frac{0{,}05\ °\mathrm{C}}{\sqrt{3}} = 0{,}029\ °\mathrm{C}$$

Uncertainty From Infrared Ear Thermometer

Size-of-Source Effect

Radiation thermometers determine the temperature of an object by measuring the amount of infrared radiation emitted from a given area. The size of this area is determined by the optical system of the thermometer. Thermometers measure over aconstant angular field of view, often referred to as D:S. Ideally, the measured object should stay within this visual range, but in practice the visual range has no sharp lines, it is just an approximation. Therefore, the size of source effect (SSE:size-of-source) should be investigated to determine the actual field of view of the device (32)(33)(34)(35). Measurements are taken at distances of ± 10% of the measuring distance. The difference between the maximum and minimum measurement is included in the uncertainty calculation (30). The probability distribution is rectangular.

$$\mathrm{u}_{12} = \frac{0{,}05\ °\mathrm{C}}{\sqrt{3}} = 0{,}029\ °\mathrm{C}$$

Ambient temperature

It is the uncertainty effect depending on the detector temperature (17)(18)(26). It is related to how much the detector temperature takes into account the change in reflected ambient temperature. The thermometer is kept in the laboratory environment for enough time to adapt to the ambient conditions.

When we change the laboratory ambient temperature by 2 °C without changing the measuring setup (to ensure ± 1 °C), the change in the measured values is taken as the uncertainty contribution. The probability distribution is rectangular.

$$\mathrm{u}_{13} = \frac{0{,}05\ °\mathrm{C}}{\sqrt{3}} = 0{,}029\ °\mathrm{C}$$

Atmospheric Absorption

Atmospheric water vapor and carbon dioxide are the gas types that most affect absorption and emission in infrared applications. The effect of atmospheric absorption on uncertainty is very small, but still needs to be taken into account. Values from the BIPM document are used for this effect (18)(26). The probability distribution is normal.

For 42 °C for measurements less than 1 m;

$$\mathrm{U}_{\mathrm{atm}}(\mathrm{T}_{\mathrm{meas}}) = \frac{1}{\frac{\partial \mathrm{S}(\mathrm{T}_{\mathrm{meas}})}{\partial \mathrm{T}}} \frac{\mathrm{U}_{\mathrm{atm}}(\mathrm{S})}{\mathrm{S}}\ \mathrm{S}(\mathrm{T}_{\mathrm{meas}})$$

$$\mathrm{U}_{\mathrm{atm}}(\mathrm{T}_{\mathrm{meas}}) = \frac{0{,}0006}{0{,}000070718}\,.\,0{,}0101771 = 0{,}086\ °\mathrm{C}$$

$$\mathrm{u}_{14} = \frac{0{,}086\ °\mathrm{C}}{2} = 0{,}043\ °\mathrm{C}$$

Noise

It is the uncertainty effect that may affect the radiometric signal (26). Noise is the unwanted signal in the thermometer and the source of the noise can be electrical or physical. The values in the BIPM document are used for this effect. The probability distribution is normal.

For 42 °C, this effect is 0.025 °C.

$$\mathrm{u}_{15} = \frac{0{,}025\ \text{°C}}{2} = 0{,}0125\ \text{°C}$$

Resolution

Resolution is the smallest change in display. The probability distribution is rectangular.
If the device under calibration reads with 0.1 °C changes, the resolution is ± 0.05 °C according to the rectangular distribution (18)(30).

$$\mathrm{u}_{16} = \frac{0{,}1\ \text{°C}}{2\sqrt{3}} = 0{,}0289\ \text{°C}$$

Measurement Repeatability

The arithmetic mean of n measurements taken from the calibrated device is calculated.

$$\bar{q} = \sum_{j=1}^{n} q_j$$

The standard deviation is calculated according to n measurements (36). The probability distribution is normal.

$$s = \sqrt{\frac{\sum_{j=1}^{n}(q_j - \bar{q}\ )^2}{n-1}}$$

Measurements taken at 42 °C;

	Reference	Measured
	42.01	42.1
	42.01	42.1
	42.02	42.2
	42.01	42.1
	42.02	42.2
average	42.01	42.14

The standard deviation of the measured values was obtained as 0.055 °C.

$$\mathrm{u}_{17} = \frac{\text{std deviation x t coefficient}}{\sqrt{5}}$$

When 5 measurements are taken, the value of the t coefficient for n-1=4 at the 68% confidence interval from the Student's t table specified in the GUM document is 1.14.

$$\mathrm{u}_{17} = \frac{0{,}055\ \text{°C x } 1{,}14}{\sqrt{5}} = 0{,}028\ \text{°C}$$

Combined Measurement Uncertainty and Expanded Measurement Uncertainty

Combined uncertainty of measurement is the standard uncertainty of the result of a measurement obtained from many other values and is expressed as the positive square root of the sum of the variance expressions calculated by considering how the change in these values affects the measurement result (36)(37). Accordingly, the combined uncertainty for independent input quantities is expressed as:

$$u_c(y) = \sqrt{\sum_{i=1}^{N}\left[\frac{df}{dx_i}\right]^2 \frac{u^2(x_i)}{{k_i}^2}}$$

$u_c(y)$ = combined uncertainty of the measured variable Y
$u(x_i)$ = uncertainty of component x_i
df/dx_i = Sensitivity coefficient (derivative of function f with respect to component x_i)
The coefficient from the probability distribution function of the uncertainty $k_i = u(x_i)$

The coverage factor (k) is used to expand the combined measurement uncertainty. The coverage factor is taken as 2. The resulting measurement uncertainty is in the 95% confidence interval.

$$U = k \times u_c$$
$$U = \sqrt{(u_1)^2 + (u_2)^2 + (u_3)^2 \ldots (u_{17})^2} = 0{,}18\ ^\circ\mathrm{C}$$

Measurement Uncertainty Budget

			35,5 °C	42,0 °C			35,5 °C	42,0 °C		35,5 °C	42,0 °C
	Uncertainty Sources		Uncertainty (°C)		Probability Distribution	Divider	Standard Uncertainty (°C)		Sensitivity Coefficient	Uncertainty Contribution (°C)	
	Symbol	*Quantity*									
Uncertainty Parameters of Reference Devices	u_1	Pt100 Calibration Uncertainty	0,005	0,005	normal	2,00	0,0025	0,0025	1	0,003	0,003
	u_3	Indicator Calibration Uncertainty	0,011	0,011	normal	2,00	0,0055	0,0055	1	0,006	0,006
	u_2	Pt100 Drift	0,005	0,005	rectangular	1,73	0,0029	0,0029	1	0,003	0,003
	u_4	Indicator Drift	0,010	0,010	rectangular	1,73	0,0058	0,0058	1	0,006	0,006
Uncertainty Parameters of Water Bath	u_5	Water Bath Homogenity	0,030	0,030	rectangular	1,73	0,017	0,017	1	0,017	0,017
	u_6	Water Bath Stability	0,020	0,020	rectangular	1,73	0,012	0,012	1	0,012	0,012
Uncertainty Parameters of Temperature Source (cavity)	u_7	Source Emissivity	0,047	0,070	normal	2,00	0,024	0,035	1	0,024	0,035
	u_8	Reflected Ambient Radiation	0,003	0,003	normal	2,00	0,002	0,002	1	0,002	0,002
	u_9	Source Heat Exchange	0,010	0,010	normal	2,00	0,005	0,005	1	0,005	0,005
	u_{10}	Ambient Conditions	0,010	0,010	normal	2,00	0,005	0,005	1	0,005	0,005
	u_{11}	Source Uniformity	0,050	0,050	rectangular	1,73	0,029	0,029	1	0,029	0,029
Uncertainty Parameters of Ear Thermometer	u_{12}	Size of Source Effect	0,050	0,050	rectangular	1,73	0,029	0,029	1	0,029	0,029
	u_{13}	Ambient Temperature	0,050	0,050	rectangular	1,73	0,029	0,029	1	0,029	0,029
	u_{14}	Atmospheric Absorption	0,083	0,086	normal	2,00	0,042	0,043	1	0,042	0,043
	u_{15}	Noise	0,025	0,025	normal	2,00	0,013	0,013	1	0,013	0,013
	u_{16}	Resolution	0,100	0,100	rectangular	3,46	0,029	0,029	1	0,029	0,029
	u_{17}	Measurement Repeatability	0,051	0,063	normal	2,24	0,023	0,028	1	0,023	0,028
	Expanded Measurement Uncertainty (k=2, %95)									0,17	0,18

Conformity Assessment For 42 °C

While the average reference temperature value is 42.01 °C, the ear thermometer reads average 42.14 °C ± 0.18 °C at 95% confidence interval. The reported expanded uncertainty of measurement is expressed as the result of multiplying the standard uncertainty of measurement by the coverage factor k=2, which gives approximately 95% coverage probability for the normal distribution.

In "ASTM E 1965-98 Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature " document, while the maximum permissible error between 36 °C and 39 °C is 0.2 °C, the maximum permissible error between 39 °C and 42 °C is given as 0.3 °C (16). Accordingly, if we want to apply the decision rule and make a conformity assessment for the device, we need to test the (38)(39) H_0 hypothesis according to the document EUROLAB Technical Report No.01/2017, Decision Rules Applied to Conformity Assessment. According to this hypothesis, it is decided whether the tested devices are suitable for use or not. According to the H_0 hypothesis;

1. The hypothesis is accepted if H_0: $P(T_L \leq Y \leq T_U) \geq (1 - \alpha)$ is true.
2. The hypothesis is rejected if $H_0$is false $\rightarrow P(T_L \leq Y \leq T_U) < (1 - \alpha)$

If the probability of conformity, P_C, is 95% or more, the device is eligible, otherwise it is unsuitable. The probability of eligibility is calculated as:

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

* (H_0 = Zero Hypothesis, T_L = Lower Tolerance Limit, T_U = Upper Tolerance Limit, $1 - \alpha$ = Confidence Level, Y = Measured Magnitude, y = Measurement Result, P_C = Probability of Conformity)

The P_C formula and the following formulas were applied in the program within the scope of this study:

- $\Phi((T_U - y) / u)$;
=NORM.DIST(upper tolerance limit (T_U); mean of measurement (y); combined standard uncertainty (u, k=1);TRUE)
- $\Phi((T_L - y) / u)$;
=NORM.DIST(lower tolerance limit (T_L);measurement mean (y); $_{\text{combined}}$ standard uncertainty (u, k=1);TRUE)

The measured average value is 42.14 °C and the maximum permissible error is ± 0.3 °C. Considering that the reference temperature value is 42.01 °C, the decision rule should be tested according to the following hypothesis.

Hypothesis H_0: Accepted if $P(41.71\ °C \leq 42.14\ °C \leq 42.31\ °C) \geq 0.95$ true.

$P_C = P(T_L \leq \eta \leq T_U) = \Phi((T_U - y) / u) - \Phi((T_L - y) / u)$
$P_C = \Phi((42.31\ °C - 42.14\ °C) / 0.09\ °C) - \Phi((41.71\ °C - 42.14\ °C) / 0.09\ °C)$
$P_C = 0.970547 - 0.000001 = 0.9705 \geq 0.95$

The device is suitable for use at 42 °C as Hypothesis H_0 is correct.

Discussion And Conclusion:-

"ASTM E 2847 Standard Test Method for Calibration and Accuracy Verification of Wideband Infrared Thermometers" and "Measurement Standards Laboratory of New Zealand, MSL Technical Guide 22" are used as a guide on radiation temperature. When a conformity assessment is required for ear thermometers, "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" can be used as a guide (38)(40)(41).

This study is an addition to the ear thermometer calibration, measurement uncertainty calculations and conformity assessment documents. It deals with the question of whether ear thermometers can be used after calibration.

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