

An Accuracy Study of Contact and Non-Contact Clinical Thermometers at Songklanagarind Hospital, Thailand

Mahdee Samae, Ph.D.¹, Thanapong Kaewkhanitarak, M.Sc.², Theera Leeudomwong, Ph.D.³, Tassanai Sanponpute, M.Sc.¹

¹Medical Metrology Laboratory, National Institute of Metrology (Thailand), Pathumthani 12120, Thailand.

²Medical Equipment and Maintenance Center, Songklanagarind Hospital, Faculty of Medicine, Prince of Songkla University, Hat Yai, Songkhla 90110, Thailand.

³Department of Industrial Physics and Medical Instrumentation, King Mongkut's University of Technology North Bangkok, Bangkok 10800, Thailand.

Received 10 October 2023 • Revised 11 April 2024 • Accepted 21 May 2024 • Published online 26 December 2024.

Abstract:

Objective: This study aimed to assess and validate the accuracy of contact clinical thermometers (CCTs), clinical digital thermometers (CDTs), temperature probes, and non-contact clinical infrared thermometers (NCCITs), which are commonly used at Songklanagarind Hospital.

Material and Methods: The Medical Equipment and Maintenance Centre (MEMC) at Songklanagarind Hospital collected a total of 187 clinical thermometers, from various departments. This collection comprised of 45 temperature probes, 112 CDTs, and 30 infrared thermometers. All these thermometers underwent calibration at three distinct temperature points, via comparison with the secondary reference temperature standard (Pt100, SIKA). To assess the accuracy of the collected thermometers, an evaluation of the associated error and uncertainty was conducted. The maximum permissible errors (MPEs) were precisely defined as: ± 0.2 °C and ± 0.3 °C for CCT and ± 0.5 °C for NCCIT.

Results: The results revealed that all temperature probes, which represent 100% of the sample, demonstrated an average acceptable accuracy; determined by the average of the percentage of acceptable accuracy across three temperature calibration points, within the Maximum Permissible Error (MPE) range of ± 0.2 °C. However, only 14% of the CDTs showed an average acceptable accuracy within the MPE of ± 0.2 °C. Meanwhile, 51% of the CDTs met the MPE of ± 0.3 °C. Additionally, 90% of the NCCIT demonstrated superior acceptable accuracy compared to the MPE of ± 0.5 °C.

Contact: Tassanai Sanponpute, M.Sc.
Medical Metrology Laboratory, National Institute of Metrology (Thailand),
Pathumthani 12120, Thailand.
E-mail: tassanai@nimt.or.th

J Health Sci Med Res
doi: 10.31584/jhsmr.20241136
www.jhsmr.org

© 2024 JHSMR. Hosted by Prince of Songkla University. All rights reserved.
This is an open access article under the CC BY-NC-ND license
(<http://www.jhsmr.org/index.php/jhsmr/about/editorialPolicies#openAccessPolicy>).

Conclusion: This research emphasizes the significance of assessing the reliability and accuracy of clinical thermometers through calibration techniques; especially during the ongoing COVID-19 pandemic, which demands large-scale illness screening.

Keywords: clinical thermometer accuracy, contact and non-contact clinical thermometers, Songklanagarind Hospital, temperature calibration

Introduction

Body temperature serves as a fundamental indicator of an individual's health status; gaining heightened significance amidst the Coronavirus disease 2019 (COVID-19) outbreak. A healthy adult typically exhibits a temperature ranging from 36.5 °C to 37.5 °C¹, and clinical thermometers play a prominent role in measuring the body temperature.

Clinical thermometers can be broadly categorized into two types: Contact Clinical Thermometers (CCTs) and Non-Contact Clinical Infrared Thermometers (NCCITs). CCTs; such as Clinical Digital Thermometers (CDTs), are renowned for their speed and accuracy. For instance, TriMedika TRITEMP™, a UK-based manufacturer, reported an annual usage of 3 million CDTs in a 900-bed hospital². On the other hand, NCCITs have the advantage of sustainability and contactless temperature measurement, which is particularly beneficial for assessing forehead temperature³. However, it's important to note that some NCCIT models designed for fever screening demonstrated inaccuracies during the pandemic.

Typically, the use of inaccurate clinical thermometers during a health crisis can lead to improper treatment decisions, unnoticed spread of infections in healthcare settings, and risks to patient safety and clinical decision-making. The degradation of equipment over time can also affect the precision of measurements. Therefore, regular maintenance and calibration of hospital equipment are crucial for patient safety. Both the CCTs and the NCCITs

play vital roles in healthcare settings; however, their measurement accuracy requires careful examination through dedicated calibration techniques. Adherence to calibration standards in medical equipment evaluation is essential for reducing uncertainties and errors⁴. Thus, routine calibration ensures consistent standards and reliable equipment performance. The verification of thermometer accuracy involves using appropriate measurement methods; such as blackbody radiators (BBR) or measurement micro baths equipped with standard reference thermometers, as outlined by the American Society for Testing and Materials (ASTM)⁵.

The primary objective of this study was to investigate and confirm the accuracy of available Contact Clinical Thermometers (CCTs), including the Clinical Digital Thermometer (CDT) and temperature probe, as well as Non-Contact Clinical Infrared Thermometers (NCCITs), in accordance with their respective standards. The collection of these clinical thermometers was conducted across multiple departments under the management of the Medical Equipment and Maintenance Center (MEMC) at Songklanagarind Hospital.

Material and Methods

Experimental design

This research comprised two experiments: CCT and NCCIT. In the CCT experiment, we followed the evaluation criteria outlined in the ASTM E1112-00⁶ for electronic thermometers in medical settings and ISO 80601-2-56:2017 for clinical thermometers⁷. These standards

require compliance through the standard comparison method for clinical electrical thermometers; including those with maximum device display temperature values and those for continuous measurements. Calibration involved a measurement range of 34.0°C to 43.0 °C, with an MPE within ± 0.2 °C and ± 0.3 °C under standard conditions (room temperature 18 °C to 28 °C, relative humidity 30% to 70%), without condensation. Three standard reference points were used: 35.5 °C, 37.0 °C and 41.0 °C.

In the NCCIT experiment, we adhered to ASTM E1965-98 and IEC 80601-2-59:2017 for infrared thermometer accuracy. These standards specified an MPE of ± 0.5 within a skin temperature range of 34.4 °C to 39.0 °C^{8,9}. Accuracy was determined by comparing output temperatures with a calibrated infrared thermometer and a reference source, using a dry-block calibrator and a standard thermometer. Calibration in this experiment covered the range of 34.4°C to 39.0°C, with an MPE not exceeding ± 0.5 °C under standard conditions (room temperature 15°C to 35°C, relative humidity 15% to 85%), without condensation. Three standard reference points were used: 35.5°C, 37.0°C and 39.0°C.

Equipment

The temperature readings of the reference temperature source were taken using a standard digital thermometer (SDT) with a resistance temperature detector (RTD) (MH3710/GTF401, Pt100, SIKA, Germany), which had an uncertainty of 0.06 °C (coverage factor, $k=2$). The SDT with the RTD was calibrated by Inctech Metrological Center (IMC) Co., Ltd., with Certificate No. MT22-4141.

The reference temperature source (RTS) utilized a micro oil bath function (Temperature calibrator, Micro bath cavity TPM255S, SIKA, Germany), which included an internal silicone oil circulation system and a temperature-controlled stirred-liquid bath. The oil volume used was at least one liter, enabling the creation of a reference temperature within the operating temperature range. The

uncertainty of the reference temperature source was 0.08 °C (coverage factor, $k=2$). The RTS exhibited a temperature stability of ± 0.009 °C and a uniformity of ± 0.008 °C (Measurement certificate from Inctech Metrological Center (IMC) Co., Ltd., Cert No. MT22-4140).

Another reference temperature source, a dry block cavity-TPM255S from SIKA, Germany, was employed to generate the reference temperature. This temperature calibrator was used in conjunction with the TPM255S device.

According to the temperature calibration standard, the ambient temperature and humidity in the measurement area were monitored and maintained in the range of 18 to 28°C and 30 to 70% relative humidity (without condensation), respectively. These measurements were recorded using a digital data logger thermo-hygrometer (MHB-382SD, Mother Tool Co., Ltd., Japan). The accuracy of this thermo-hygrometer was specified as ± 0.8 °C and $\pm 4\%$ (reading) for humidity, within the range of 1% to 4% RH. It is worth noting that the ambient temperature and humidity in the calibration room varied due to air-conditioning and the time of day during the calibration process. To reduce the influence of outside temperature, a 15-minute acclimation period was observed for the unit under calibration (UUC) before initiating the calibration process.

Experimental setup

This research involved two experiments: the CCT and NCCIT. In these experiments, the UUC was calibrated by comparing it to the RTS using a specific calibration technique. The RTS had two functions: the micro bath function and the dry block calibrator function, which were used for calibrating the CCT and NCCIT, respectively. To initiate the measurement process, the RTS was set up in ascending order; starting from the lowest to the highest temperature points within the measurement range. The SDT with the RTD was placed in the working space of the micro bath cavity, and the temperature was gradually increased. The calibration measurement value was then obtained

from the stable standard digital thermometer, ensuring that the temperature change did not exceed 0.02°C. Each measurement was repeated five times to ensure accuracy (Figure 1).

The CDTs and NCCITs were calibrated in the calibration room (ISO/IEC 17025:2017, Accreditation No. calibration 0433) at the MEMC, Songklanagarind Hospital, while the body temperature probes were exclusively calibrated in the operating room (OR) of Songklanagarind Hospital. During the CCT calibration process, the UUC included four CDTs, which were immersed simultaneously into the socket holder of the micro bath cavity. Additionally, two temperature probes were immersed at the same time into the micro bath cavity. The immersion depth was maintained at a minimum of 1.5 cm to ensure direct temperature contact between the calibrator and the UUCs. The measurement setups for the CDTs and the body temperature probe are illustrated in Figure 1(A) and Figure 1(B), respectively. In the NCCIT calibration, the forehead infrared thermometer was initially set to either surface or object mode. It was then aimed at the direct center point at the end of the dry block cavity, with a distance of 5 cm

from the bottom of the cavity. The measurement setup for the forehead infrared thermometer is depicted in Figure 1(C).

Data analysis

In this study, we assessed the accuracy of temperature measurement using both CCT and NCCIT. Our evaluation specifically focused on measuring the error and associated uncertainty. For each measurement of temperature points, we conducted five repeated measurements using the UUC. The measurement results were obtained by averaging the readings from the UUC monitors (R_{UUC}) from the UUC monitors, and the mean readings from the SDT monitors (R_{SDT}). Subsequently, we calculated the error values (Error, ΔT) for each measurement using the below equation (1).

$$\text{Error, } \Delta T = R_{UUC} - R_{SDT} \quad (1)$$

In every measurement inconsistencies are common. This is due to various factors; such as human error, resolution limitations, and the uniformity and stability of both the Unit Under Calibration (UUC) and the Standard Digital Thermometer (SDT). These factors can introduce

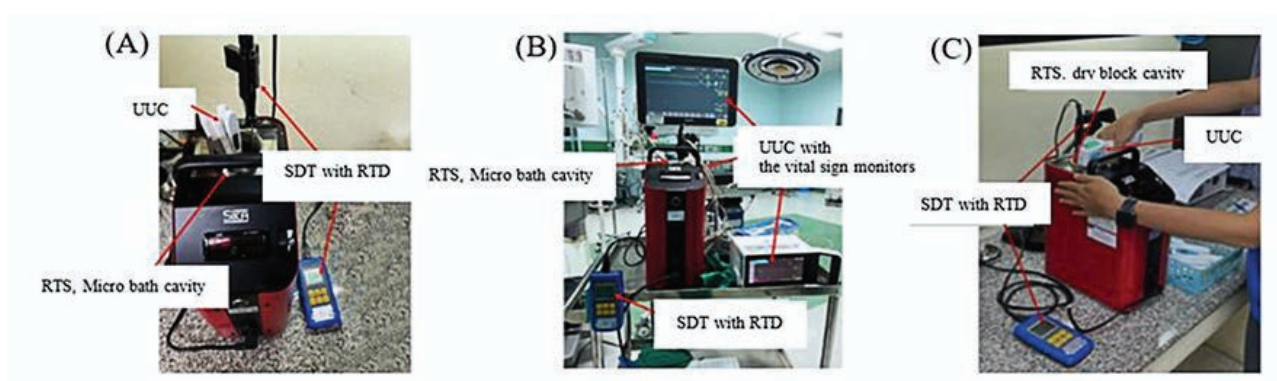


Figure 1 The illustration shows the calibration setup, which includes (A) the clinical digital thermometers (CDTs), (B) the body temperature probe with the vital signs monitor, and (C) the forehead infrared thermometer

uncertainties, which have been calculated using the guide to the expression of uncertainty in measurement (GUM)¹⁰.

The uncertainty terms are determined through statistical calculation of repeated measurements (Type A), while others are derived from calibration certificates, system parameters, or environmental factors and their probability distributions (Type B). Briefly, Type A uncertainty is computed from a series of observations, whereas Type B uncertainty is evaluated using available information. Standard uncertainties, both Type A and Type B, can be combined using a method known as combined uncertainty, denoted as $U_c(T)$, either through summation in quadrature or root sum of the squares. According to the $U_c(T)$, the combined uncertainty of temperature is composed of various components. The u_{std} in Type A accounts for uncertainty arising from the standard deviation of mean values of the standard, while u_{uuc} in Type A represents uncertainty resulting from the standard deviation of the UUC. For each temperature, the standard deviation of the mean values ($s(x)/\sqrt{n}$) was calculated using deviations of the temperature readings. Additionally, $u_{\delta t_{std}}$ Type B, considers uncertainty caused by the standard source; $u_{\delta t_{uni}}$ takes into account uncertainty arising from the uniformity of the standard source, and $u_{\delta t_{stb}}$ incorporates uncertainty related to the stability of the standard source; with these uncertainties obtained from the calibration certificate report. Moreover, $u_{\delta t_{rstd}}$ represents uncertainty resulting from the resolution of the standard source; $u_{\delta t_{ruuc}}$ considers uncertainty stemming from the resolution of the UUC, and $u_{\delta t_{ds}}$ accounts for uncertainty arising from the drift of the standard source. One important aspect of uncertainty evaluation is the utilization of sensitivity coefficients (C_i). However, since all input quantities or uncertainty contributors are reported in the same unit of measure, employing the C_i of 1 allows for uncertainty calculation without affecting the results. To convert uncertainty to standard deviations, understanding probability distributions and their associated divisors is

essential. If a normal distribution is assumed, uncertainty is divided by its associated coverage factor, $k=2$; if a rectangular distribution is assumed, each uncertainty component is divided by the square root of 3. Additionally, an important parameter to consider is degrees of freedom (V_i). In statistics, V_i represents the number of values in the final calculation that are free to vary. To calculate V_i , one subtracts the number of constraints from the number of observations (n). In other words, when the coverage factor is based on a 95% confidence interval wherein $k=2$, V_i is infinite. In the evaluation of uncertainty, the combined uncertainty of temperature, denoted as $U_c(T)$, measured by the thermometers, is determined as specified in the equation below: (2).

$$U_c(T) = \sqrt{C_i^2 \frac{u_{std}^2}{\sqrt{5}} + C_i^2 \frac{u_{uuc}^2}{\sqrt{5}} + C_i^2 \frac{u_{\delta t_{std}}^2}{2} + C_i^2 \frac{u_{\delta t_{uni}}^2}{\sqrt{3}} + C_i^2 \frac{u_{\delta t_{stb}}^2}{\sqrt{3}} + C_i^2 \frac{u_{\delta t_{rstd}}^2}{2\sqrt{3}} + C_i^2 \frac{u_{\delta t_{ruuc}}^2}{2\sqrt{3}} + C_i^2 \frac{u_{\delta t_{ds}}^2}{\sqrt{3}}} \quad (2)$$

Once the combined uncertainty is obtained, effective degrees of freedom are calculated according to the GUM¹⁰; as follows in equation (3), specifying a coverage probability of 95%.

$$\text{Effective degrees of freedom} = \frac{U_c(T)^4}{\sum_{i=1}^n \frac{u_i^4}{v_i}} \quad (3)$$

The $U_c(T)$ is a commonly used metric for expressing measurement uncertainty. However, it is often necessary to provide an expanded uncertainty ($U(T)$), which defines a range around the measurement result encompassing a significant fraction of the distribution of values reasonably associated with the measured quantity. The calculation of $U(T)$ represents the final step in estimating measurement uncertainty. To derive $U(T)$, the $U_c(T)$ is multiplied by the coverage factor k . In this study, k represents an interval, with a confidence level of approximately 95%, calculated using the T -value of the Student's t -distribution based on the probability and the effective degrees of freedom. The estimated value of k is 2. Consequently, the $U(T)$

for temperature can be ascertained by multiplying $U_c(T)$ by k ; as demonstrated in Equation (4). The overview of uncertainty budget evaluation is provided in Table 1.

$$U(T) = U_c(T) \cdot k \quad (4)$$

In the validation of clinical thermometers, acceptable accuracy is ensured by establishing the acceptable range for the CCT, which combines the error (ΔT) and expanded uncertainty ($U(T)$) within the MPE. The acceptable accuracy of CCT should not exceed $\pm 0.2^\circ\text{C}$ and $\pm 0.3^\circ\text{C}$ (MPE_{CCT}). For the NCCIT, the acceptable accuracy should not exceed the MPE of $\pm 0.5^\circ\text{C}$ (MPE_{NCCIT}); as specified in equation (5).

$$\text{Acceptable accuracy} = \text{Error}, \Delta T + U(T) \leq MPE_{CCT, NCCIT} \quad (5)$$

To ensure proper management of clinical thermometers and guide appropriate decision-making, if the accuracy ($\text{Error}, \Delta T + U(T)$) falls within the MPE limit, the

device is deemed suitable for continued use. However, if the accuracy ($\text{Error}, \Delta T + U(T)$) exceeds the MPE limit, corrective actions as well as preventive action are required before the device can be used for any further processes. The corrective action and preventive action provide a structured approach for identifying the root cause of problems and resolving them. Following the successful implementation of corrective actions, the device undergoes recalibration to validate its accuracy. If the results are satisfactory, the device is permitted for use again. However, if the defect persists and cannot be rectified, the instrument is considered permanently damaged and must be decommissioned.

Result and discussion

The CDT testing of the CCT

In assessing the accuracy of the CCT, specifically the CDT from the AA brand used in Songklanagarind Hospital, we collected 112 devices. Our objective was to evaluate the error and associated uncertainty to determine the

Table 1 Uncertainty budget for temperature of clinical thermometers

| Term | Type | Probability distribution | V_i | C_i | Uncertainty contribution (U_i) |
|-----------------------------------|------|--------------------------|----------|-------|---|
| u_{std} | A | Normal | $n-1$ | 1 | $\frac{u_{std}}{\sqrt{5}}$ |
| u_{uuc} | A | Normal | $n-1$ | 1 | $\frac{u_{uuc}}{\sqrt{5}}$ |
| $u_{\delta t_{std}}$ | B | Normal | ∞ | 1 | $\frac{u_{\delta t_{std}}}{2}$ |
| $u_{\delta t_{uni}}$ | B | Rectangular | ∞ | 1 | $\frac{u_{\delta t_{uni}}}{\sqrt{3}}$ |
| $u_{\delta t_{stb}}$ | B | Rectangular | ∞ | 1 | $\frac{u_{\delta t_{stb}}}{\sqrt{3}}$ |
| $u_{\delta t_{rstd}}$ | B | Rectangular | ∞ | 1 | $\frac{u_{\delta t_{rstd}}}{2\sqrt{3}}$ |
| $u_{\delta t_{ruuc}}$ | B | Rectangular | ∞ | 1 | $\frac{u_{\delta t_{ruuc}}}{2\sqrt{3}}$ |
| $u_{\delta t_{ds}}$ | B | Rectangular | ∞ | 1 | $\frac{u_{\delta t_{ds}}}{\sqrt{3}}$ |
| Combined uncertainty | | | | | (2) |
| Effective degrees of freedom | | | | | (3) |
| Coverage factor k | | | | | 2 |
| Expanded uncertainty $U_{(95\%)}$ | | | | | (4) |

V_i =degrees of freedom, C_i =sensitivity coefficients

accuracy of all the collected thermometers. The accuracy testing of the CDT involved comparing it to clinical electrical thermometers at temperature points of 35.5 °C, 37.0 °C and 41.0 °C.

Generally, high accuracy is indicated when the measured value of UUC is very close to the actual value obtained from the monitors of the SDT. To analyze the frequency of errors, we utilized a valuable quality tool: the Pareto diagram. The aim of the Pareto chart was to identify the most frequently occurring accuracy by combining the error and expanded uncertainty ($\text{Error}, \Delta T + U(T)$). The accuracy of $\text{Error}, \Delta T + U(T)$ was represented by longer bars on the left and shorter bars on the right, based on

the count of the CDTs. Figures 2 (A–C) show the Pareto charts at 35.5 °C, 37.0 °C and 41.0 °C, respectively. The distribution of $\text{Error}, \Delta T + U(T)$ for the CDT was presented as ranging from 0.32 °C to 0.67 °C at 35.5 °C; from 0.20 °C to 0.40 °C at 37.0 °C, and from 0.16 °C to 0.41 °C at 41.0 °C. Notably, at 37.0 °C, the cumulative count of the CDT was particularly high at 90% in the ranges from 0.10 °C to 0.40 °C.

In terms of acceptable findings within the $\text{MPE} \pm 0.2$ °C of the CDT, they were approximately 2%, 22% and 18% at the temperature points of 35.5 °C, 37.0 °C and 41.0 °C, respectively. Similarly, within the $\text{MPE} \pm 0.3$ °C, the acceptable results were roughly 15%, 76% and 60% at the

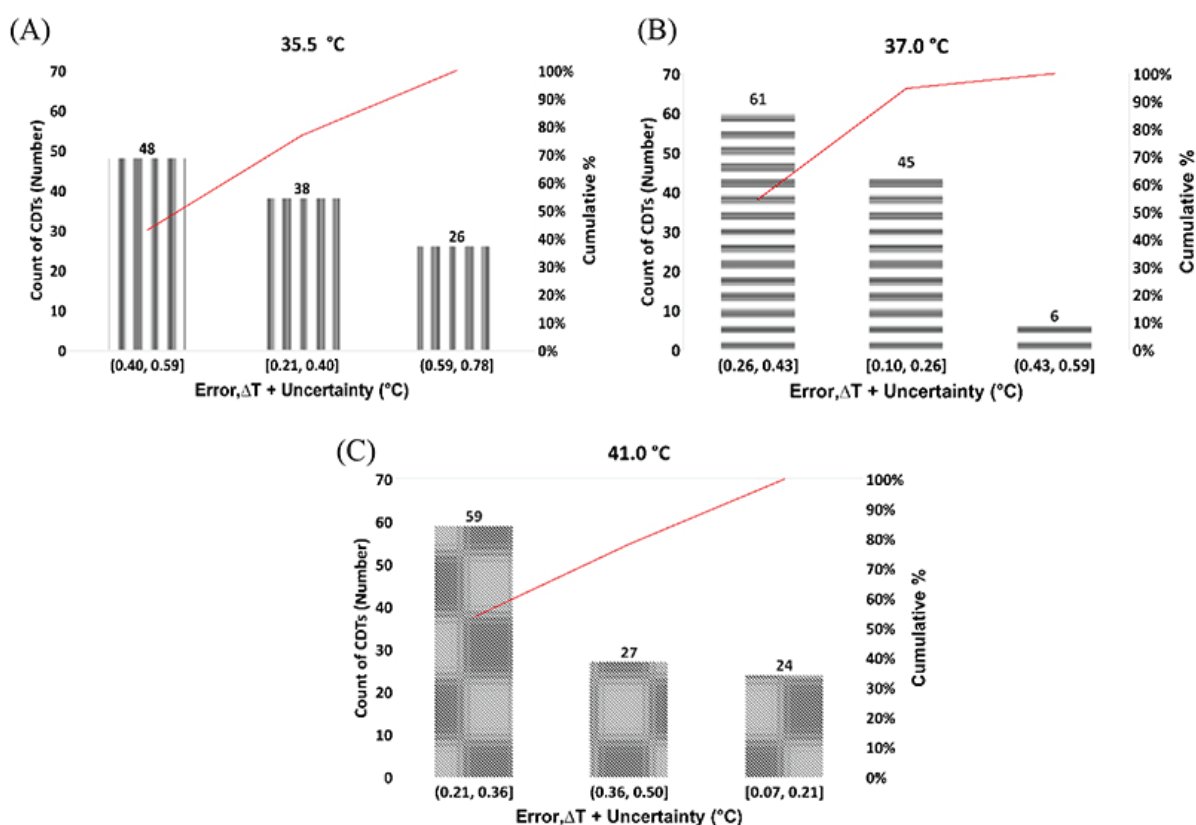


Figure 2 Illustration of the pareto charts showing the distribution of accuracy errors combined with uncertainty for the CDT, with AA brand at the temperature points: (A) 35.5 °C, (B) 37.0 °C and (C) 41.0 °C

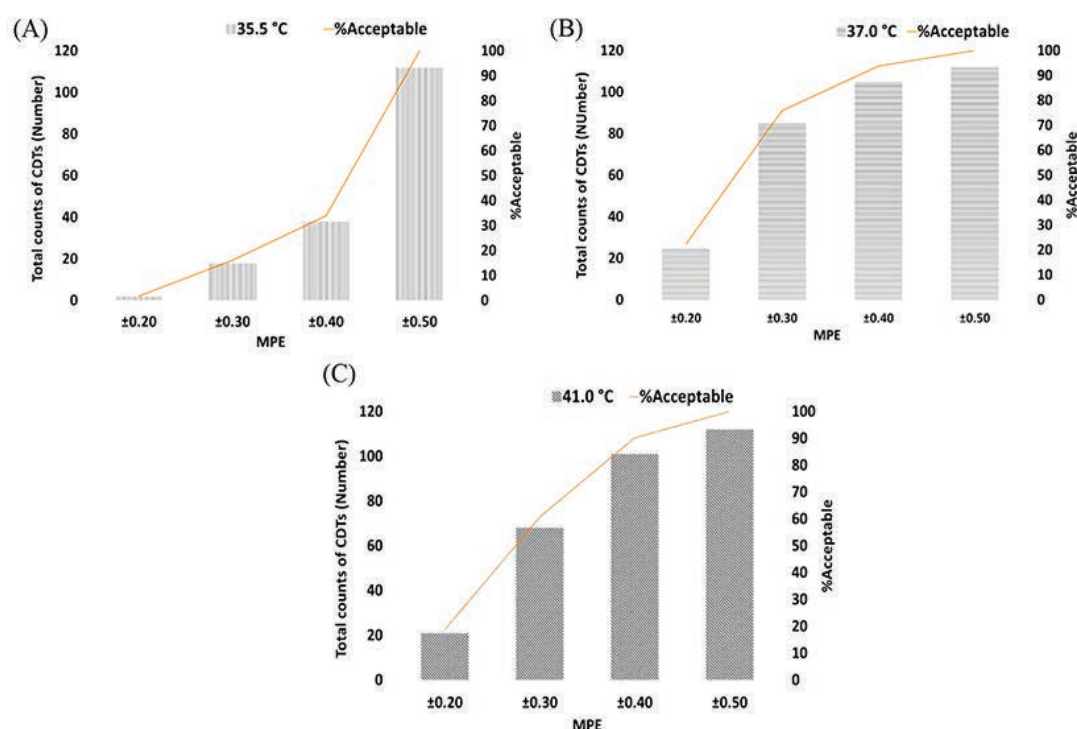


Figure 3 Charts depicting the percentage acceptance of CDTs at specific temperature points: (A) 35.5 °C, (B) 37.0 °C and (C) 41.0 °C, with MPE values of ± 0.2 °C, ± 0.3 °C, ± 0.4 °C and ± 0.5 °C

temperature points of 35.5 °C, 37.0 °C and 41.0 °C. Notably, as the MPE increased, the percentage of acceptable results for the CDT also increased, reaching up to 90% at every temperature point; particularly for an MPE of ± 0.5 °C, as shown in Figures 3 (A–C), at 35.5 °C, 37.0 °C and 41.0 °C, respectively. These findings indicate that it is crucial to thoroughly assess the accuracy and reliability of the CDT before using it as a practical measurement device; especially at the temperature point of 35.5 °C.

In previous studies on the accuracy of the CDTs, various thermometers have been verified. However, there is a limited understanding of their accuracy and reproducibility in diagnosing patients with suspected fever¹¹. This lack of knowledge extends to the accuracy and reproducibility of

these thermometers in similar diagnostic scenarios. In our study, it was discovered that the CDTs yielded approximately 90% acceptable results within the MPE of ± 0.4 °C at a critical temperature point of 37.0 °C in medical diagnosis.

The body temperature probe testing of CCT

Temperature probe measurements are generally reliable; however, inaccurate readings can occur due to faulty parts. Therefore, it is recommended that temperature probes be validated against a reference temperature before being used in clinical settings¹². This study specifically focused on AB-brand temperature probes used exclusively in operating rooms. A total of 45 probes, including 30 adult probes and 15 pediatric probes, were examined. The

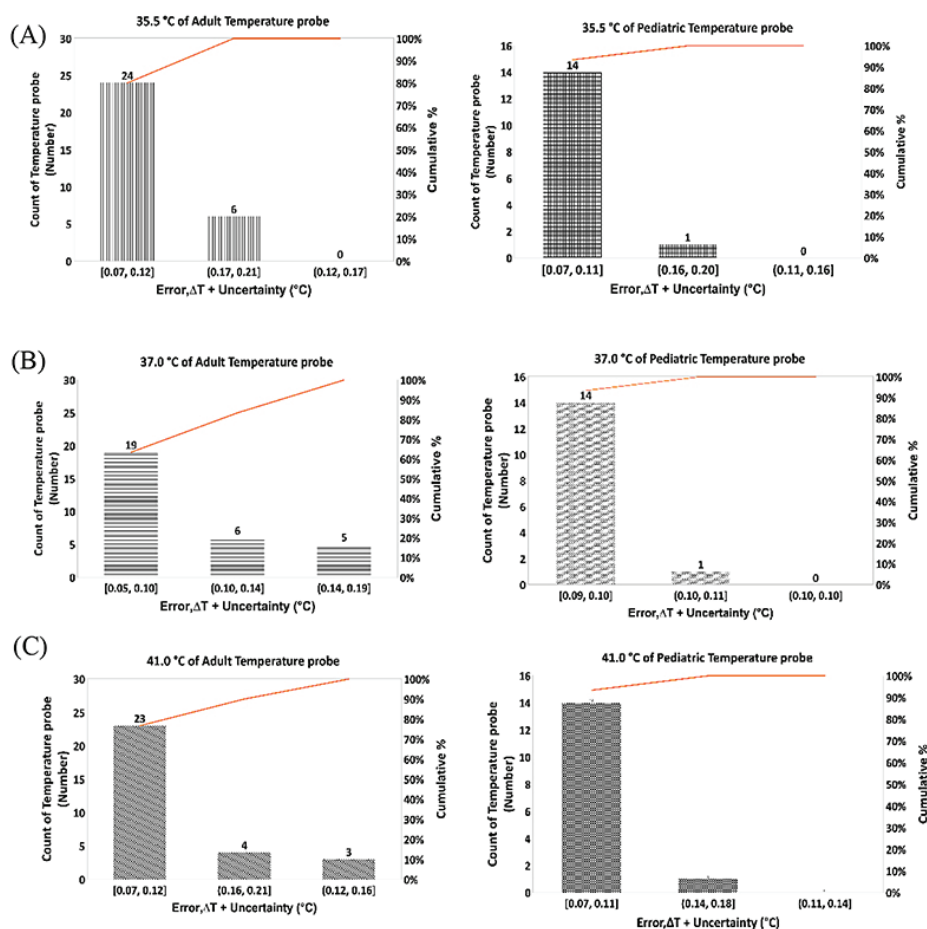


Figure 4 Illustration of the pareto charts representing the distribution of accuracy and error-combined uncertainty for temperature probes with vital signs monitors, for both adults and pediatric patients; at temperature points: (A) 35.5 °C, (B) 37.0 °C and (C) 41.0 °C

accuracy testing of the body temperature probes involved continuous comparisons with clinical electrical thermometers at temperature points of 35.5 °C, 37.0 °C, and 41.0 °C.

For the adult temperature probes, the distribution of the $\text{Error}, \Delta T + U(T)$, ranged from 0.07 °C to 0.12 °C, 0.09 °C to 0.10 °C and 0.07 °C to 0.11 °C, at 35.5 °C, 37.0 °C and 41.0 °C, respectively. These temperature readings accounted for approximately 80% of the cumulative total. Similarly, for the pediatric temperature probes, the $\text{Error}, \Delta T + U(T)$ values ranged from 0.07 °C to 0.11 °C, 0.05

°C to 0.10 °C and 0.07 °C to 0.12 °C, at 35.5 °C, 37.0 °C and 41.0 °C, respectively. The accuracy results for both adult and pediatric temperature probes are presented in Figures 4 (A–C); at 35.5 °C, 37.0 °C and 41.0 °C, respectively. Importantly, all temperature probes exhibited good accuracy, closely aligning with the exact values.

In terms of body temperature probes, both the adult and pediatric probes demonstrated 100% acceptability within an MPE of at least ± 0.20 °C across all temperature points; as shown in Figure 5 (A–C). Furthermore, this

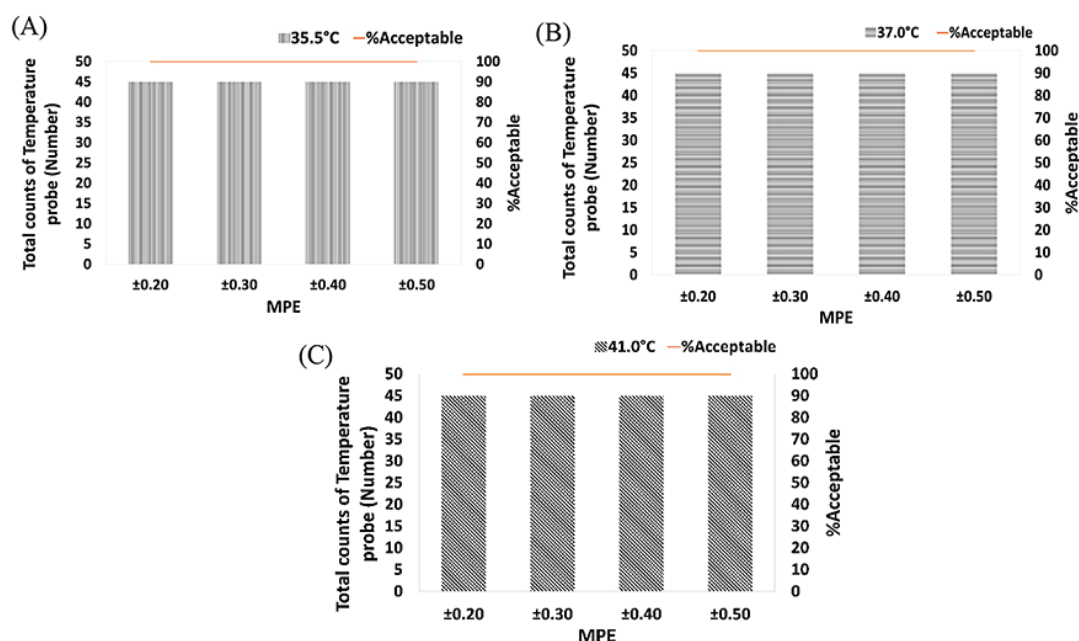


Figure 5 Diagram of the percentage of overall acceptable temperature probes at specific temperature points: (A) 35.5 °C, (B) 37.0 °C and (C) 41.0 °C, based on the MPE values of ± 0.2 °C, ± 0.3 °C, ± 0.4 °C and ± 0.5 °C

study found that the accuracy of the body temperature probes remained consistent, with deviations of less than 0.1 °C during a long-term stability test; particularly at the critical temperature point of 37.0 °C, which is of significant importance in medical diagnosis.

The infrared forehead thermometer testing of NCCIT

The purpose of this study was to assess the accuracy of infrared forehead thermometers. Thirty devices from different brands (F1, F2, F3, F4, F5, F6, F7, F8, F9, F10, F11, F12, and F13) were randomly selected from Songklanagarind Hospital. The accuracy of these thermometers was tested according to the requirements outlined in IEC 80601-2-59:2017⁸ and ASTM E1965-98:2016¹³, at three temperature points: 35.5 °C, 37.0 °C and

39.0°C. The accuracy of the NCCIT brand was depicted in a Pareto chart, focusing on the most frequently distributed Error, $\Delta T + U(T)$. The chart showed that the temperature readings for NCCIT thermometers had an Error, $\Delta T + U(T)$ range of -0.24 °C to 0.60 °C, -0.53 °C to 0.27 °C and -0.74 °C to 0.31 °C; at 35.5 °C, 37.0 °C and 39.0 °C, respectively. These readings accounted for approximately 90% of the cumulative total; as shown in Figures 6 (A-C).

To comply with the standard requirements, the NCCIT thermometers were expected to maintain a MPE within ± 0.5 °C. During the evaluation of NCCIT brands, all nine brands (F1, F3, F4, F7, F8, F10, F11, F12 and F13) demonstrated 100% acceptability within the MPE at all temperature points. The only brand that failed to find the MPE criteria was brand F9, likely due to device deterioration caused by prolonged usage. However, it is important to

note that the NCCITs used in this study constitute a limited sample size, and their results may not be fully representative of the entire population.

These findings regarding the accuracy of infrared forehead thermometers align with a previous report by Stacey J⁶, which identified error values ranging from -0.9°C to over 0.2°C , depending on the brand. The summary of the NCCITs in this study showed consistent acceptability rates of up to 80% within an MPE range of ± 0.3 to $\pm 0.5^{\circ}\text{C}$, at temperature points of 35.5°C , 37.0°C and 39.0°C , as shown in Figures 7 (A–C). However, there were lower percentages of acceptable NCCIT brands, such as F2, F5,

and F9, at all temperature points due to their lower detector sensitivities. NCCIT detectors are typically more sensitive at higher temperatures when particles move faster¹⁴ or the physical distance condition is not met, the flashing LED, or vibration should trigger an indication (warning for physical distancing and alteration for pyrexia warning, respectively). Therefore, if some NCCIT brands showed low acceptability rates according to the MPE, it could indicate deterioration of the NCCIT detector over its service life; especially during the COVID-19 outbreaks. These findings emphasize the importance of thoroughly evaluating the accuracy and reliability of NCCITs before using them as practical measurement devices.

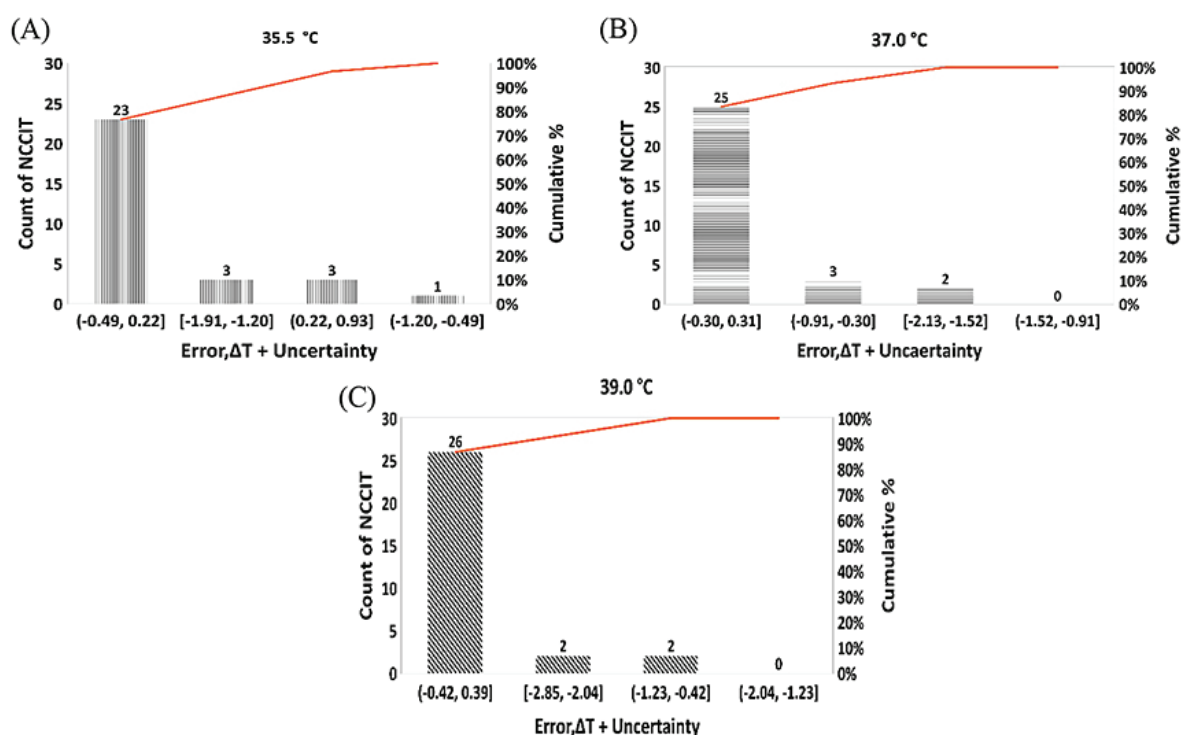


Figure 6 Pareto charts illustrating the distribution of error-combined uncertainty accuracy for the NCCIT at the temperature points of (A) 35.5°C , (B) 37.0°C and (C) 39.0°C

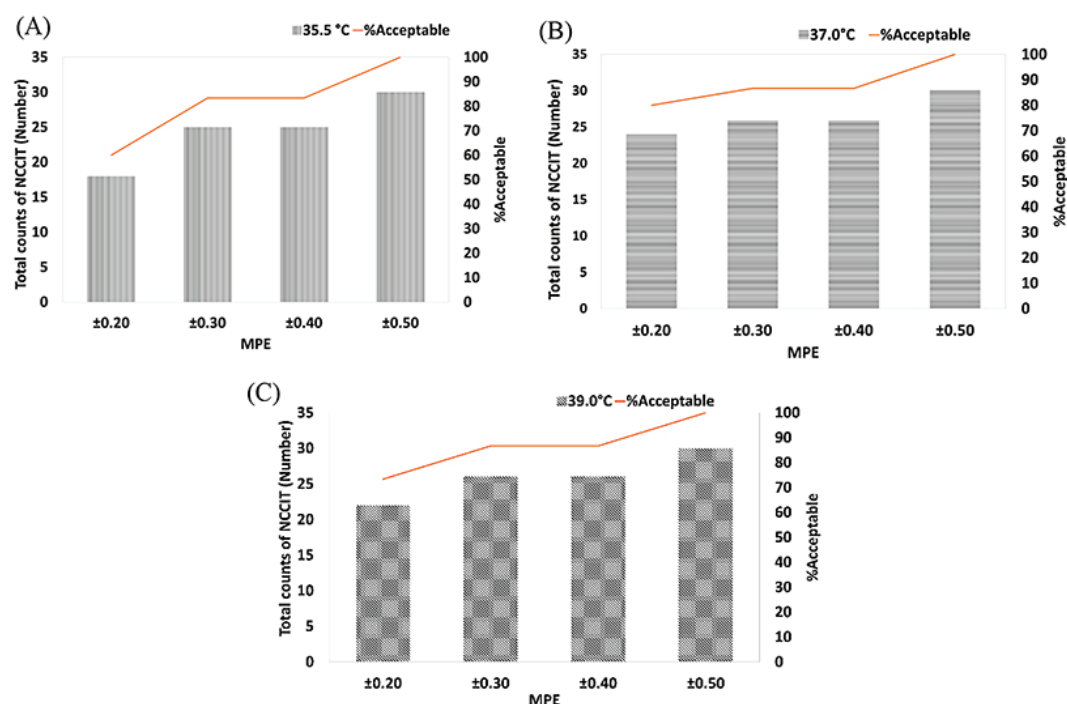


Figure 7 Diagram of the overall percentage of acceptable NCCIT readings at temperature points: (A) 35.5 °C, (B) 37.0 °C and (C) 39.0 °C, based on the MPE values of ± 0.2 °C, ± 0.3 °C, ± 0.4 °C and ± 0.5 °C

Conclusion

This study provides vital quantitative insights into the effectiveness of fever-screening devices; particularly the CCT and NCCIT. It also outlines optimal methods for calibrating and assessing the accuracy of various clinical body thermometers; including CDTs, temperature probes, and infrared forehead thermometers. The CCT's CDTs from a single brand showed limited acceptability within the ± 0.2 °C and ± 0.3 °C MPE ranges at all temperature points, with 90% falling within the acceptable ± 0.5 °C MPE range. Similarly, body temperature probes from the same brand demonstrated 100% acceptability within the ± 0.2 °C MPE range at all temperature calibration points, for both adult and pediatric probes. Among the 13 NCCIT brands, nine achieved 100% acceptability within the ± 0.5 °C MPE range at all temperature calibration points. The infrared forehead thermometers consistently maintained accuracy, with up to

80% falling within the ± 0.5 °C MPE range; particularly at the critical temperature point of 37.0 °C.

These results emphasize the importance of conducting comprehensive accuracy assessments for both CDTs and NCCITs before their practical use; especially during pandemics or disease outbreaks that require large-scale illness screening. Furthermore, this study focused on evaluating the routinely used body temperature thermometers at Songklanagarind Hospital in Thailand, confirming their compliance with the MPE standard. Moreover, it explored the potential suitability of these devices for future investments in temperature calibration setups throughout Thailand's hospital network.

Acknowledgement

The authors would like to express their gratitude to all the officers at the MEMC at Songklanagarind Hospital,

Thailand, for their invaluable assistance in providing the calibration room and facilitating the collection of body temperature thermometers. Special thanks are also due to Inctech Metrological Center (IMC) Co., Ltd., Thailand, for providing the SDT, with an RTD, and the reference temperature calibrator.

Author contributions

The authors, Mahdee Samae, drafted the proposal, conducted experiments, contributed to conceptualization and methodology, performed statistical analyses, and interpreted the results. Theera Leeudomwong, Thanapong Kaewkhanitarak, and Tassanai Sanponpute reviewed the proposal, interpreted certain results, provided critical feedback on the manuscript, participated in its revision, and revised the manuscript. All authors have read and approved the final manuscript.

Funding sources

The authors would like to express their sincere gratitude to the Office of National Higher Education Science Research and Innovation Policy Council (NXPO) and the National Science, Research and Innovation Fund (NSRF) via the Program Management Unit for Human Resources and Institutional Development, Research and Innovation (PMU-B) for generously funding this research in Thailand. This research has been made possible by the financial support provided under contract grant number B01F640054 and MOU No. MOU-CO-2564-16159-TH between the National Science and Technology Development Agency (NSTDA) and the National Institute of Metrology Thailand (NIMT).

Conflict of interest

The authors declare no conflicts of interest.

References

1. Sund-Levander M, Forsberg C, Wahren LK. Normal oral, rectal, tympanic and axillary body temperature in adult men and women: a systematic literature review. *Scand J Caring Sci* 2002;16:122–8.
2. Mekdade A. The Top Three Challenges Facing Hospitals Today: Infection Control, Sustainability & Costs. [homepage on the Internet]. Belfast: TriMedika; 2022 [cited 2022 Dec 28]. Available from: <https://trimedika.com/trimedika-ltd-looks-at-the-top-three-challenges-facing-hospitals-today-infection-control-sustainability-costs/>
3. Woodrow P, Higgs D, Lewis T, Whitney S, Buras-Rees S, O'Donnell A, et al. Comparing no-touch and tympanic thermometer temperature recordings. *Br J Nurs* 2006 1;15:1012–6.
4. Rudtsch S, von Rohden C. Calibration and self-validation of thermistors for high-precision temperature measurements. *Measurement* 2015;76:1–6.
5. Dornish M, Kaplan D, Skaugrud Ø. Standards and guidelines for biopolymers in tissue-engineered medical products: ASTM alginate and chitosan standard guides. *Ann N Y Acad Sci* 2001;944:388–97.
6. ASTM International. ASTM E1112-00: Standard specification for electronic thermometers for intermittent determination of patient temperature. ASTM Committee F04 on Medical and Surgical Materials and Devices. West Conshohocken, PA: ASTM International; 2011;p.19428.
7. ISO. ISO 80601-2-56: Medical electrical equipment—Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement. Geneva: International Organization for Standardization; 2017.
8. IEC 80601-2-59:2017. Medical electrical equipment—Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening. Geneva: International Organization for Standardization; 2017.
9. Ghassemi P, Pfefer TJ, Casamento JP, Simpson R, Wang Q. Best practices for standardized performance testing of infrared thermographs intended for fever screening. *PloS One* 2018;13:e0203302.

10. Bich W, Cox MG, Harris PM. Evolution of the 'guide to the expression of uncertainty in measurement.' *Metrologia* 2006;43:S161.
11. Pecoraro V, Petri D, Costantino G, Squizzato A, Moja L, Virgili G, et al. The diagnostic accuracy of digital, infrared and mercury-in-glass thermometers in measuring body temperature: a systematic review and network meta-analysis. *Intern Emerg Med* 2021;16:1071–83.
12. Smith J, Alcock G, Monk B, Jones R. Concordance of temperature measurements on preterm and term infants using oesophageal (core), axilla & skin methods in a neonatal intensive care unit. *J Neonatal Nurs* 2022;28:445–51.
13. ASTM. ASTM E1965–98: Standard specification for infrared thermometers for intermittent determination of patient temperature. ASTM Committee E20 on Temperature Measurement. West Conshohocken, PA, USA: ASTM International; 2016. p. 19428.
14. Kumar A, Kumar A, researcher, science section bihar bal bhawan kilkari, under dept. of education govt. of bihar, India. contactless temperature and distance measuring device: a low-cost, novel infrared-based “Badge”-shaped structural model for measuring physical distance and body temperature. *AIMS Electron Electr Eng* 2022;6:43–60.