Performance Testing of Fast Read Digital Thermometers[1]

Oleg Vesnovsky
Center for Devices and Radiological Health,
U.S. Food and Drug Administration,
10903 New Hampshire Avenue,
WO66-5429,
Silver Spring, MD 20993

L. D. Timmie Topoleski
Center for Devices and Radiological Health,
U.S. Food and Drug Administration;
Department of Mechanical Engineering,
2181 Glenn L. Martin Hall, Building 088,
University of Maryland-Baltimore County,
Baltimore, MD 21250

Lawrence W. Grossman
Center for Devices and Radiological Health,
U.S. Food and Drug Administration,
10903 New Hampshire Avenue,
WO66-5429,
Silver Spring, MD 20993

Jon P. Casamento
Center for Devices and Radiological Health,
U.S. Food and Drug Administration,
10903 New Hampshire Avenue,
WO66-5429,
Silver Spring, MD 20993

Liang Zhu
Department of Mechanical Engineering,
2181 Glenn L. Martin Hall, Building 088,
University of Maryland-Baltimore County,
Baltimore, MD 21250

1 Background

Body temperature monitoring of humans has been an important tool for diagnosing infections, detecting fever, monitoring thermoregulation functions during surgical procedures, and assessing postsurgery recovery. Temperature is measured at various body sites including the pulmonary artery, rectum, bladder, distal esophagus and nasopharynx, sublingual surface of the tongue, under the armpit, tympanic membrane, and forehead. Inexpensive, off-the-shelf digital thermometers are generally used to measure temperature orally or under the arm. Currently, many such thermometers are available with a "fast read" capability, where they produce temperature readings in 5–10 s.

In a previous study [1], we used a custom-designed, small thermistor bead-based thermometer (NIST traceable) and a computer data acquisition system to measure and record temperatures at a rate of 7 Hz ("reference thermometer"). Therefore, the reference thermometer records the temperature rise (transient data) from the initial contact with the skin until equilibrium. The small bead ensures rapid heat transfer and accurate temperature measurements. Relevant temperature measurements required at least 20 s, even with a sophisticated design and expensive support electronics.

In this study we conducted clinical temperature measurement research on children to evaluate the accuracy of three off-the-shelf digital thermometers (brands A, B, and C) compared to our reference thermometer [1]. The off-the-shelf thermometers state that 5–11 s are required to produce a temperature measurement, depending on the brand. All of the off-the-shelf thermometers claimed an accuracy of $\pm 0.2\,^{\circ}$F; while one manufacturer (brand A) specified that the accuracy was achieved in a water bath. Also some manufacturers stated that the axillary measurements will be lower than the oral measurements: 1 °F for brand A and 1–2 °F for brand C. Our experience with our reference thermometer indicates that longer than 5–11 s would be needed to measure body temperature with the claimed accuracy. The purpose of this study was to investigate the accuracy of the fast read thermometers compared to our reference thermometer.

2 Methods

The experimental procedures have been approved by the institutional review boards at both the University of Maryland-Baltimore County (UMBC) and the U.S. Food and Drug Administration. A total of 301 patients (infants to 18 years old) participated in this study when they visited a local pediatrician's office for a checkup or sick visit.

Temperatures were measured orally and in the armpit (axillary). In each case, an off-the-shelf thermometer and the reference thermometer were placed together in a disposable sheath and put under the participant's arm for approximately 2 min (120 s) to record axillary temperatures. After changing the disposable sheath, the thermometers were placed (again together) in the participant's mouth under the tongue for another 2 min to record oral temperatures. All temperature data and patient's age and gender were recorded and stored electronically. The measurement data were analyzed by dividing into four participant age groups (0–2, 3–6, 7–12, and 13–18 years). Within each age group, we further categorized the participant as "sick" or "healthy," based on the reason for their visit. We calculated the difference between the reference thermometer temperature and the temperatures measured simultaneously with the off-the-shelf thermometers. The results are presented as mean ± standard deviation (SD). The values between the mean + 1.96SD and mean − 1.96SD (distribution limits) represent the range within which 95% of the differences lie.

3 Results

Figure 1 presents temperature difference data at the axillary site for the healthy group. The number along the x-axis is the ages of the patients, varying from 1 to 18 years old. Positive differences imply that the off-the-shelf thermometer measurement was larger than that from the reference thermometer. For the brand A thermometer (Fig. 1), the differences scatter about the x-axis with an almost equal number of positive and negative differences. This suggests that in approximately half of the cases, the brand A thermometer overestimated, and in half the cases it underestimated, the temperature, at both the oral and axillary locations. The brand A thermometer was the most inaccurate in the 0–2 age group, with an SD of $\pm 1.9\,^{\circ}$F, and SD of at least $\pm 1.2\,^{\circ}$F for the other three age groups.

For brand B (Fig. 1), the distribution limits were largest in the 3–6 age group (1.91 °F and −2.09 °F), followed by the 7–12 age group (0.97 °F and −1.8 °F), and then the 13–18 age group (0.78 °F and −1.68 °F). It is evident that brand B underestimated the temperature at the axillary site most of the time. In contrast, the mean values of the difference of brand C (Fig. 1) vary from 0.95 °F (13–18 age group) to 1.38 °F (3–6 age group), implying most of the time brand C overestimated the reference axillary temperature. The smallest SD in brand C occurs in the 3–6 age group and the largest SD is in the 7–12 age group. Calculations of the distribution limits show that the limits are (2.02, −0.02 °F),

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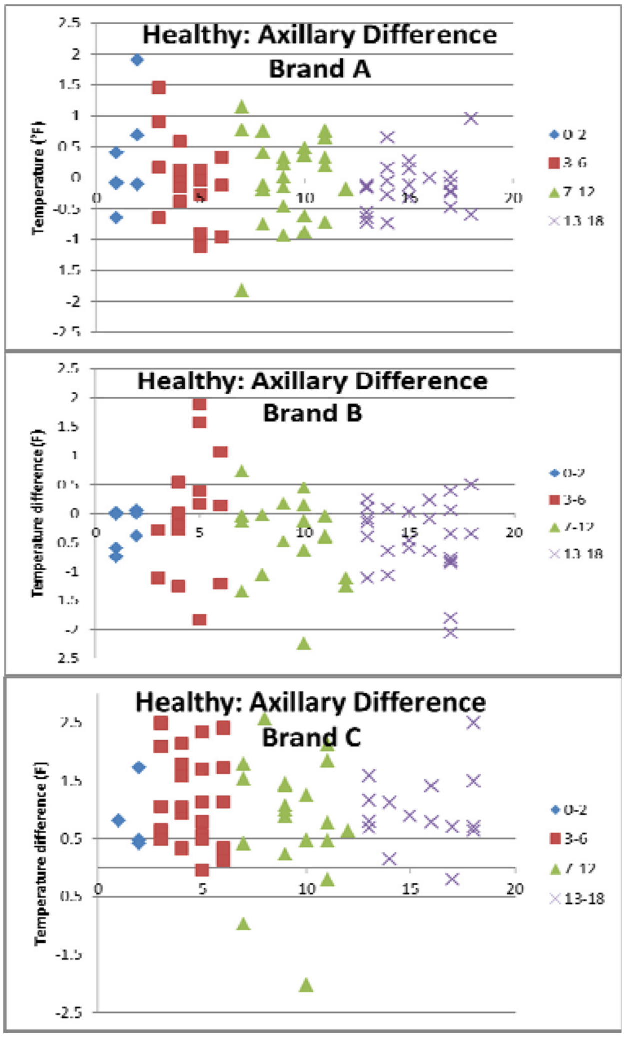

Fig. 1 Temperature differences between the three off-the-shelf thermometers and the reference thermometer after 2 min at the axillary sites for the healthy participants

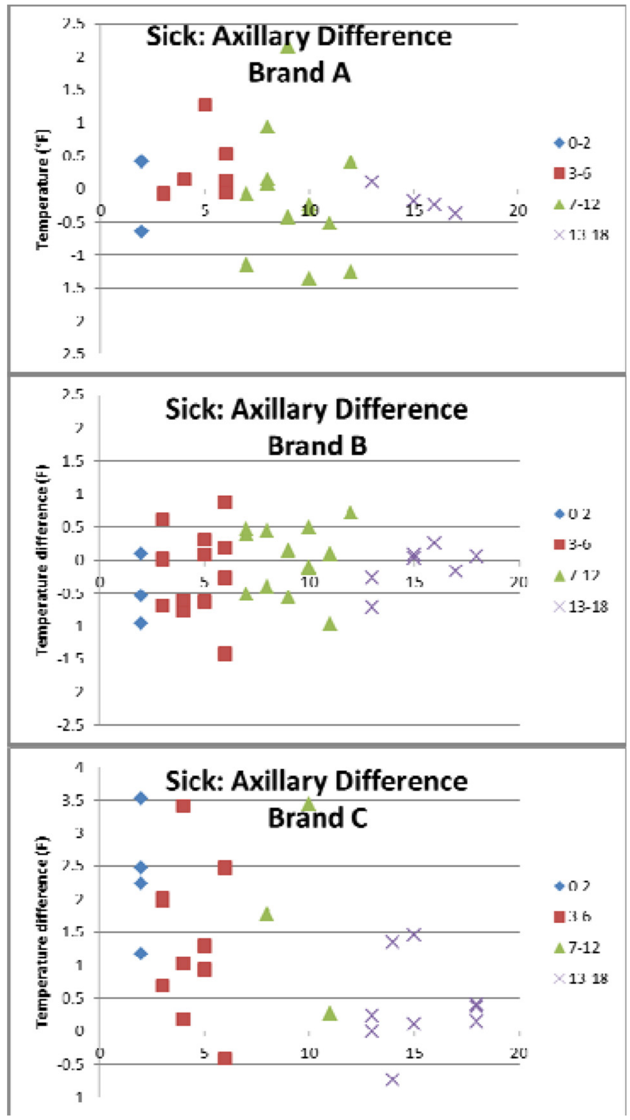

Fig. 2 Temperature differences between the three off-the-shelf thermometers and the reference thermometer at 2 min at the axillary sites for the sick participants

(3.25, −0.49 °F), (3.69, −1.42 °F), and (2.165, −0.25 °F), for the 0–2, 3–6, 7–12, and 13–18 age groups, respectively. The brand C thermometers generally overestimated the reference axillary temperature, by up to 3.7 °F in one instance.

Figure 2 presents temperature difference data at the axillary site for the sick group. Again, brand A thermometers deviated from the reference temperature on both the positive and negative sides, with an SD equal to 1.1 °F. brand B thermometers underestimated, more than overestimated, the reference axillary temperature. brand C thermometers overestimated the temperatures 92% of the time, by up to 3.5 °F in one instance.

For the three age groups with both oral and axillary temperature measurements, Table 1 gives the temperature differences measured by the off-the-shelf thermometers. The average differences from the reference thermometer (not shown) between the two sites are also all negative, suggesting that the measured axillary temperature is lower than the oral temperature of the same patient.

4 Interpretation

This study is the first to investigate the temperatures measured by off-the-shelf thermometers compared to a reference thermometer in a clinical setting with a large number of participants. Compared to the reference measurements after 120 s (2 min), the off-the-shelf thermometers routinely deviated from the reference temperature at the site, and those deviations were not consistent. The brand C thermometers had the greatest deviations of up to 3.7 °F, while the brand A thermometers had the lowest deviations; however, they still deviated by up to 1.9 °F. It is obvious that the tested off-the-shelf thermometers had lower accuracy than the indicated ±0.2 °F.

Because of our experience with the reference thermometer, which requires more than 20 s to reach a relevant temperature, it is possible that the off-the-shelf thermometers are not giving an actual temperature reading. Instead, they are calculating a temperature based on transient temperature values over the first 5–11 s of measurement, using an embedded algorithm. Although we did not show recorded transient data here, there was a wide variation in the transient temperature data. We believe that these differences can be caused by the environment and the physiology of the

Table 1 Difference between the axillary and oral temperatures in three age groups using the three off-the-shelf thermometers

Brand	3–6 years old	7–12 years old	13–18 years old
A	-1.27 ± 1.03 °F	-0.82 ± 0.84 °F	-0.53 ± 0.85 °F
B	-0.38 ± 0.78 °F	-0.92 ± 0.98 °F	-0.56 ± 0.55 °F
C	-0.53 ± 0.89 °F	-0.75 ± 1.10 °F	-0.14 ± 0.73 °F

patient. The temperature calculation in the off-the-shelf thermometers cannot take into account patient-based differences, which lead to different transient temperature responses during the first several seconds. Therefore, the inconsistent deviations are not surprising. Based on the data in Table 1, for the same off-the-shelf thermometer, the differences between axillary and oral results vary between age groups and they also differ from the manufacturers' suggestions. Therefore, simply adding a correction factor to the axillary temperature will not provide accurate body temperature estimate. Our results suggest the off-the-shelf thermometers do not achieve the claimed accuracy of $\pm 0.2\,^{\circ}$F.

Reference

[1] Vesnovsky, O. Topoleski, L. D. T., Grossman, L. W., Casamento, J. P., and Zhu, L., Evaluation of Temperature Transients at Various Body Temperature Measuring Sites Using a Fast Response Thermistor Bead Sensor, ASME 2013 Summer Bioengineering Conference (SBC2013), Sunriver, OR, June 26–29, ASME Paper No. SBC2013-14065.