

Clinical validation of the CAREGIVER® non-contact thermometer model PRO-TF300 in febrile and afebrile patients age 0 to < 18

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Background: The CAREGIVER® Thermometer Model PRO-TF300 (Thermomedics Inc., Delray Beach, FL) is a non-contact clinical professional thermometer used to read human body temperature in children and adults through the determination of infrared energy from the middle of the forehead. The purpose of this paper is to describe the methods and findings of the CAREGIVER'S validation for clinical use in pediatric patients from newborns through adolescents.

Methods: Fully consented/assented, febrile and afebrile participants in this prospective study included children aged 0 to <18 years of age (n=160). Readings using the CAREGIVER were compared to readings with a reference thermometer (SureTemp® Plus 690, Welch-Allyn, Skaneateles Falls, NY) to derive agreement (clinical accuracy) and repeatability.

Results: Overall agreement was 0.14°F (0.07°C) with a standard deviation of ±0.42°F (0.22°C). Overall repeatability was 0.19°F (0.11°C).

Conclusions: The CAREGIVER thermometer is designed to measure clinical body temperature in all age groups. This study included children ages 0 to <18, measured from the center of the forehead without contact with the skin. Device agreement and repeatability both fall within current standards for clinical infrared thermometers.

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Introduction: Clinical thermometers are validated against international standards to assure users of their suitability for the determination of clinical temperature in patients for whom the devices are intended. CAREGIVER is a non-invasive clinical professional thermometer that reads human body temperature without touch by detecting the body's infrared energy. It does so without the need for probe covers and with a fast and simple one-button operation that minimizes cross-contamination.

Our objective was to re-validate the CAREGIVER in a larger sample against current laboratory and clinical standards for thermometry.

Laboratory accuracy: Prior to use in the clinical accuracy and repeatability tests, the laboratory accuracy of the CAREGIVER thermometer was validated in various operating environments from 60°F to 104°F and relative humidities ranging from less than 50% to 85% as called for in the ASTM E1965-98(2009) standard (1). Blackbody temperatures of 95°F, 98.6°F and 105.8°F were tested. The maximum laboratory bias for each of the blackbody temperatures and environmental conditions was found to be 0.2F°. This is better than the ±0.4F° requirement as specified in the ASTM standard and compliant with the ±0.2C° in the ISO 80601-2-56 standard.

Methods: In this study, with patients acting as their own controls, temperature measurements were obtained with SureTemp 690 oral electronic thermometers as reference (in predictive mode) and CAREGIVER(in Body mode) as test devices. Data were collected in Family Medicine (clinic, hospital and home care) and Pediatrics (outpatient, sick baby room, and hospital ward) departments at China Medical University Hospital (Taichung, Taiwan) between September, 2012 and August, 2013. The study was approved by the hospital's institutional review board (IRB) and all participants and/or parents signed informed consent/ assent to participate. The sample is described in Table 1.

Group	Age	Febrile	Afebrile	Total
Adol/Child	>5 yo <18 y-o	15	25	40
Child	1 – 5 y-o	15	25	40
Infant	1 - 12 mo	15	25	40
Neonate	0 - 1 mo	15	25	40
Total		60	100	160

Table 1. Characteristics of Sample.

In each area, three trained professional operators obtained triplicate CAREGIVER® readings by aiming the device at the middle of patient foreheads from 1 to 3 inches away, pressing the button, and waiting momentarily for a tone to indicate the temperature had been obtained. They then obtained one oral or rectal reading (depending on the age of the participant) using the SureTemp® 690 electronic thermometer as reference. Neonates, infants and children 1-5 y-o had rectal temperatures taken, while children and adolescents > 5 y-o < 18 y-o had oral temperatures taken with the SureTemp 690. The "BODY" mode incorporates an algorithm that adjusts the reading to an adult equivalent sublingual oral temperature.

Results: Means and standard deviations were calculated for all group readings as shown in Table 2.

Age Group (n)	Caregiver® Febrile Mean±SD	SureTemp® 690 Febrile Mean±SD	Caregiver® Afebrile Mean±SD	SureTemp® 690 Afebrile Mean±SD
Child /Adolescent (>5 <18 y-o) (n=35)	101.1°F±0.79 n = 15	101.3°F±0.76 n = 15	98.4°F±0.73 n = 20	98.5°F±0.70 n = 20
Child (1-5 y-o) (n=44)	101.0°F±0.60 n = 23	101.2°F±0.41 n = 23	98.9°F±0.69 n = 21	98.8°F±0.65 n = 21
Infant (28 days-1 y) (n=41)	101.3°F±0.51 n = 18	101.4°F±0.53 n = 18	98.3°F±0.65 n = 23	98.5°F±0.66 n = 23
Neonate (0-28 days) (n=40)	100.9°F±0.33 n = 12	101.1°F±0.32 n = 12	98.6°F±0.59 n = 28	98.8°F±0.52 n = 28
Pediatric Overall (0-18 y-o) (n=160)	101.1°F±0.6 n = 68	101.2°F±0.5 n = 68	98.5°F±0.7 n = 92	98.6°F±0.6 n = 92

Table 2. Means (±SD) of CAREGIVER® PRO-TF300 and SureTemp® readings from all departments in ºF.

Agreement (Mean bias ±SD) was then calculated by subtracting the mean of two successive CAREGIVER readings from the corresponding SureTemp 690 readings, calculating the mean ±SD of the biases as shown in Table 3.

Age Group (n)	Mean bias ±SD Febrile	Mean bias ±SD Afebrile	All
Child /Adolescent (>5 <18 y-o) (n=40)	0.19°F±0.50	0.12°F±0.28	0.14°F±0.42
Child (1-5 y-o) (n=40)	0.14°F±0.54	-0.04°F±0.67	0.06°F±0.61
Infant (28 days-1 y) (n=40)	0.11°F±0.40	0.16°F±0.28	0.14°F±0.34
Neonate (0-28 days) (n=40)	0.23°F±0.21	0.23°F±0.28	0.23°F±0.26
Pediatric Overall (0-18 y-o) (n=160)	0.16°F±0.45	0.13°F±0.41	0.14°F±0.42

Table 3. Mean bias (±SD) of adult and pediatric sample febrile and afebrile readings in °F.

Limits of agreement (±1.96 x 1SD) for the pediatric sample were calculated (+0.96, -0.68) and found to be comparable to or better than other published thermometer validation studies (2, 3). Bland-Altman plots were then constructed to illustrate agreement between reference and test thermometer. Figure 1 represents the entire Pediatric sample, while Figure 2 shows the Neonate sample. Plots of the remaining age group are available upon request.

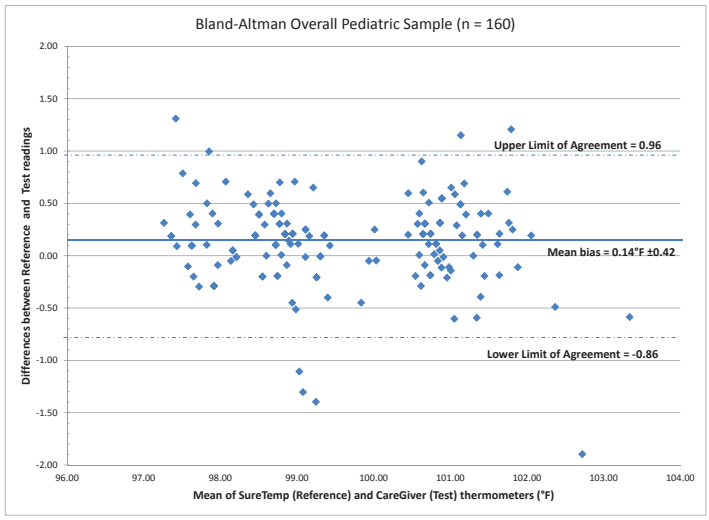


Figure 1. Bland-Alman plot of agreement between Reference (SureTemp® 690) and test (Caregiver) thermometers in afebrile and febrile patients 0-18 years of age (Oral/rectal sample).

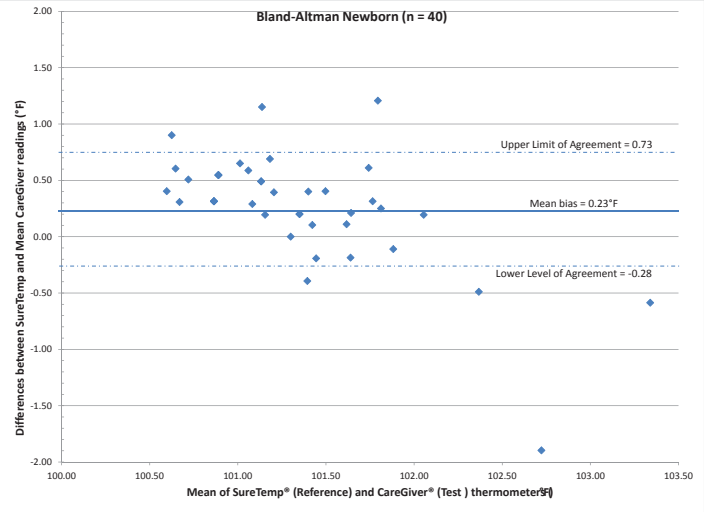


Figure 2. Bland-Altman plot of agreement between Reference (SureTemp 690) and test CAREGIVER® thermometers in afebrile and febrile neonates, 0 -28 days years of age (Rectal sample).

Repeatability: Repeatability was calculated using the pooled standard deviations formula set out in the ASTM E1965-1998 standard (1) where the value of sr is the measure of clinical repeatability.

$$s_r = \sqrt{\sum_{i=1}^{N} \frac{D_{j1}^2 + D_{j2}^2 + D_{j3}^2}{6N}}$$

The repeatability by age group and febrile status in summarized in Table 4.

Device	n	Age group	Febrile Status	Repeatability
PRO-TF300	160	0 - <18	All	0.19
PRO-TF300	68	0 - <18	Febrile	0.20
PRO-TF300	92	0 - <18	Afebrile	0.19
PRO-TF300	15	>5 - <18	Febrile	0.19
PRO-TF300	20	>5 - <18	Afebrile	0.12
PRO-TF300	21	>1 - <5	Febrile	0.14
PRO-TF300	23	>1 - <5	Afebrile	0.04
PRO-TF300	18	>1mo - <1 yr	Febrile	0.11
PRO-TF300	23	>1mo - <1 yr	Afebrile	0.16
PRO-TF300	12	0 - <1 mo	Febrile	0.23
PRO-TF300	28	0 - <1 mo	Afebrile	0.23

Table 4. Repeatability by age group and febrile status.

No data points were excluded to arrive at these statistics.

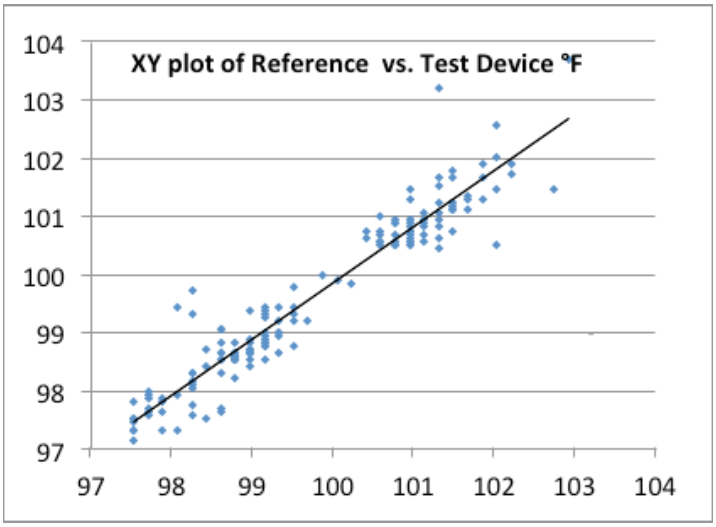
Discussion: This validation study of the Caregiver® non-contact thermometer involves afebrile and febrile patients ages 0 to <18. We sought to answer the research question of whether there is substantial clinical agreement and repeatability between the CAREGIVER test device and an established clinical thermometer used as reference device. In addition, we addressed laboratory accuracy.
Thermometry research publications first appeared in the 1980s when electronic thermometers were introduced to the professional healthcare market. Since then, clinicians have been hoping for an ideal thermometer. The essential features of such a device include accuracy, speed, safety, comfort and ease of use. Accuracy was the main feature addressed in this study.

Accuracy generally incorporates agreement as described in early statistical work (4) and incorporated into international professional standards. Another concern for the clinical study is consistency or reliability.

Our results suggest that the test non-contact device agrees closely with the reference device used in our study. Prior studies using agreement as an accuracy criterion have suggested that limits of agreement (5) must be relatively narrow for a small clinical bias to be significant. Our limits of agreement did not exceed 1.21 (absolute value). As shown in the tables above, clinical bias did not exceed 0.2°F.

Analysis of Outliers: Five negative bias points between reference and test device indicated that the reference device read lower than the test device. In all cases, the multiple test device readings were identical or nearly so. Since the reference device was used orally, and it is possible to place an oral probe outside the sublingual pocket and achieve a low reading, it is possible that the test device was correct. It is not possible to obtain an inaccurately high infrared reading unless the probe is first passed over a warmer surface or the patient is receiving external warming. When the outlier high readings were excluded from bias analysis, the mean bias of the data set was 0.15°±0.47. It is also important to note that the data were collected in °C and then converted to °F. Due to the 0.1°C resolution of the reference and devices under test, an additive difference of 1 LSD (least significant digit) represents 0.1°C or 0.18°F. Thus even the highest group bias (-0.32°F) is relatively small given the device resolution. In addition, oral predictive readings have been shown to increase variability.

In order to demonstrate the relationship between reference and test readings, an XY plot of the two sets of readings is presented below. As noted, R2 = 0.91 indicating a strong linear relationship.



Conclusion: The CAREGIVER® is an infrared non-contact clinical thermometer designed for professional clinical use. Our validation study indicates a high level of agreement between the CAREGIVER and the reference device (SureTemp® 690), thus assuring accurate and reliable readings in children age 0 to <18 years of age.

References

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