

No-touch Forehead Temperature Measurement in Two Clinical Settings

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Background. Healthcare personnel prefer devices that maximize efficiency while minimizing cross-contamination as well as cost. The Caregiver® (Thermomedics, Inc., Miami, FL), a new infrared non-contact forehead thermometer has been developed for clinical professional use. Our objective was to evaluate the clinical accuracy and repeatability of the Caregiver as compared to measurements obtained with an oral electronic thermometer in a family clinic and an out-patient pediatric clinic.

Methods. In a prospective fashion with patients acting as their own controls, patient care staff took repeated temperatures in two outpatient settings with the Caregiver and with an electronic predictive thermometer, the SureTemp™ (Welch-Allyn, Skaneateles, NY) used either orally or in the axilla. Reference measurements were oral in the family clinic and axillary in the pediatric clinic.

Results. In the sample of all ages, clinical accuracy (bias) was 0.04±0.67°F and repeatability 0.2ºF. In the pediatric sample, Caregiver temperatures were higher than axillary by 0.25±0.75ºF in all but infants where there was almost no difference (0.04±0.47ºF).

Conclusions. Clinical bias in both adult and pediatric patients was very good at 0.25°F or better. Clinical variability (Standard Deviation) was comparable to those of other studies using predictive oral or axillary temperatures as a reference. Clinical repeatability of the Caregiver was very good at 0.2°F for adults and 0.35°F for pediatric patients. Since the Caregiver uses an orally-referenced algorithm, average axillary readings in all but infants were lower than Caregiver readings by 0.25°F. Otherwise, average Caregiver readings were almost the same as oral temperatures.

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Introduction

Caregiver is a non-invasive clinical professional thermometer that reads human body temperature without touch in children and adults by detecting the body's infrared energy. It does so with a fast and simple one-button operation that minimizes cross-contamination.

Our objective was to evaluate the device by comparing temperature measurements obtained with the Caregiver to measurements obtained with a predictive oral electronic thermometer in a clinic setting.

The Caregiver measurements were taken in the "BODY" mode which incorporates an algorithm that adjusts the reading to an equivalent sublingual oral temperature.

Methods

We asked the patient care staff of a busy family practice clinic and an outpatient pediatric unit to obtain successive temperature measurements using the Caregiver thermometer and their own SureTemp thermometers normally in use in each setting. Patients had temperatures measured with both devices as a part of regular patient care. To obtain Caregiver temperatures, operators simply aimed the device at the middle of the patient's forehead from 1 to 3 inches away, pressed the button, waited momentarily for a tone to indicate the temperature had been obtained and then recorded the reading. They then obtained one oral or axillary reading using their standard method. Some Caregiver readings were done in triplicate in order to determine repeatability. Of the remainder, the majority were done twice, while about 16 sets of readings consisted of a single Caregiver and a single SureTemp reading. Age, gender and time of day were also recorded. After completion of all data collection in the respective locations, patient care staff provided feedback on a user preference survey. All temperatures were taken and are shown in degrees Fahrenheit for maximum resolution.

Results

Family Practice Clinic

In the course of two weeks, 7 trained clinic patient care staff members obtained 120 sets of successive temperature readings in 32 male and 88 female patients averaging 39 years of age. Eight staff members also completed a user preference survey. All sets contained at least one reading with each type of device.

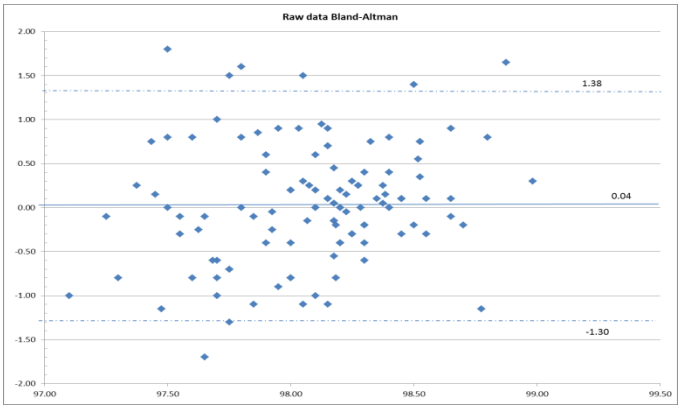
Means and standard deviations were calculated for all readings as shown in Table 1 below.

	Caregiver 1	Caregiver 2	Caregiver 3	SureTemp Oral
Mean	98.1	98.1	98	98.1
Std Dev.	0.5	0.4	0.6	0.5

Table 1. Means (±SD) of Caregiver (x3) and SureTemp readings from Family Practice Clinic in ºF.

Initial mean difference (bias) with uncertainty (SD) was calculated using the SureTemp minus the mean of two Caregiver readings. A negative mean difference showed the Caregiver measured slightly higher than the SureTemp on average in 52 of 120 cases. The maximum difference between the Caregiver when the Caregiver was higher was 1.7°F. The maximum difference when the SureTemp was higher was 1.8°F.

An overall Bland Altman plot was constructed. Seven points fell outside the limits of agreement indicating these data points should be analyzed in detail. The limits of agreement (+1.38, -1.30) were somewhat larger than desired but comparable to other studies using a predictive electronic thermometer as the reference. The mean difference (bias) was a very acceptable 0.04°F.



Data were then sorted by device and operator. Mean difference with uncertainty were then calculated by device and operator. When analyzed by operator, patterns emerged that helped explain the somewhat wide dispersion of the data. As shown in Table 2, two operators obtained oral SureTemp readings that were much lower, on average, than those obtained by the rest of the operators. This suggests the possibility that these two operators may not have placed the oral probe consistently in the sublingual pocket to get an accurate oral reading.

Operator	Mean diff	Std Dev.	CG Hi	CG Lo	# sets	ST Hi	ST Low
1*	+0.4	0.5	99.4	98.1	10	98.6	97.4
2	-0.2	0.5	98.8	97.2	40	99.2	97.4
3	-0.2	0.6	99.0	97.3	10	99.1	97.2
4**	+0.2	0.8	98.8	97	30	99.7	96.6
5	-0.2	1.0	98.6	96.6	10	99.2	97.1
6	-0.2	0.5	98.6	97.3	10	98.9	97.5
7	-0.1	0.5	98.8	97.2	10	98.6	96.9

Table 2. Mean differences (±SD) between Caregiver (x3) and SureTemp, high and low Caregiver and SureTemp readings from Family Practice Clinic in ºF by operator.

*SureTemp readings are consistently lower than Caregiver indicating Operator 1 may not be placing the oral probe in the sublingual pocket.

** Operator 4 used both devices, CG5 first day 0.16°F(±0.9) and CG7 last day -0.31°F(±0.7).

As shown, while there were apparent differences in results from operators 1 and 4, operators 2, 3, 5, 6, and 7 were fairly consistent.

Operator 4 was the only operator to use both devices each on two different days. The mean difference of this operator's readings on the first day of the evaluation was 0.16°F(±0.9) meaning that SureTemp readings were higher than Caregiver readings. On the last day of the evaluation, the mean difference of this operator's readings was -0.31°F±(0.7), meaning that Caregiver readings were now on average higher than SureTemp readings. This can be an indication that the second Caregiver used by Operator 4 tended to read higher or that Operator 4 became more proficient over time at obtaining Caregiver but not the familiar SureTemp readings.

Bland-Altman plots are available for all operators on request.

For a more normative impression, data were then pooled for operators 2, 3, 5, 6, and 7 whose results were comparable and consistent. For these data, the mean difference was 0.2°F(±0.5) removing much of the variability from the readings. A Bland-Altman plot is available on request.

Next, the data set was analyzed by device. Two devices were used to obtain the forehead

temperature data in the clinic, CG5 and CG7. As shown in Table 3, the CG7 produced a lower mean difference and standard deviation, but differences were generally small.

Device	Mean diff	SD	# sets	ST High	ST Low
CG5	0.1	0.7	50	99.7	97.3
CG7	0.0	0.6	70	99.2	96.6

Table 3. Mean differences (±SD) between Caregiver (x3) and SureTemp, high and low SureTemp readings from Family Practice Clinic in ºF by Caregiver device.

On the whole, across operators, the CG5 tended to read a little lower than the corresponding SureTemp reading.

However, SureTemp readings were in many cases both considerably higher than and considerably lower than Caregiver readings.

Of note, however is the fact that in almost every case, the Caregiver readings were very consistent across repetitions and did not produce erratic readings. Given that the SureTemp was not used as a contact-equilibrium thermometer and is susceptible to operator error (perhaps not in sublingual pocket "under the tongue") and environmental error (mouth-breathing, gum chewing, cold drink in waiting room, etc.) more credence could be given to a Caregiver reading that is the same or nearly the same across two or three readings.

Unfortunately, there were few febrile patients in the clinic during the time we collected data. According to staff, not many patients present with fever except during flu season.

Repeatability

Repeatability was calculated using the pooled standard deviations formula set out in the ASTM E1965-1998 standard. Statistically, repeatability was highly consistent at 0.2°F. No data points were excluded to arrive at this statistic.

Staff evaluation of the Caregiver devices was unanimously positive and staff did not experience any difficulties, nor did they suggest any changes in the Caregiver design.

Family Clinic Conclusions

This was a successful evaluation where we obtained a high quality of data, in most cases, with a typical group of clinical staff members. Looking only at data from those who were the most consistent (2, 3, 5, 6, and 7) we achieved low variability. However, it is vital to include more pediatric data before drawing definitive conclusions. It is also advisable to obtain a more controlled dataset using an oral contact equilibrium reference thermometer or an invasive core temperature reference.

Pediatric Clinic

We asked patient care staff of a pediatric out-patient clinic to obtain temperatures on patients as part of regular patient care using the design, methods and procedure described above.

In the course of three weeks, a total of 96 children aged 0 and up, had temperatures measured using the Caregiver, a no-touch forehead thermometer, for 3 successive readings and a SureTemp electronic predictive thermometer used in the axilla. The patients were stratified into 3 age groups as follows:

1. Age 0 to one year (n = 4)
2. 1 to five years (n = 48)
3. 5 years and up. (n = 41)

In group 3, the upper age limit was not specified. Three patients did not have age recorded.

In total, 47 males and 45 females were included. Four patients were not identified by gender.

For all cases, the mean difference between the SureTemp and the mean of the three Caregiver readings was -0.2°F(±0.8) with the Caregiver reading higher. There was a single case in which the SureTemp reading was approximately 3°F higher than three very consistent Caregiver readings with no way to account for the difference. We therefore omitted this case from the rest of our analysis.

For the remaining cases, the mean difference (bias) between the SureTemp and the mean of the three Caregiver measurements was -0.3 °F(±0.7) with the Caregiver reading higher.

The Caregiver was expected to read higher overall, since the SureTemp was used in the axilla and the Caregiver adjusts to a sublingual equivalent.

An axillary adjustment was derived by averaging the bias of the readings that fell inside the limits of agreement on the Bland Altman plot thus reducing the mean difference to 0 °F(±0.7). The axillary adjustment is hypothetical, specific to these data only and was calculated as 0.22°F.

The data were then analyzed by age group.

Group 1 was too small (n=4) to make any inference about the data, but the group's readings produced a mean difference of 0 °F(±0.5), meaning the axillary adjustment did not apply in this very small group. It should be kept in mind that this group is very likely to be warmed artificially or bundled, which

would elevate the axillary temperature in relation to the uncovered face.

Group 2 (n = 48) produced a mean difference of -0.2°F(±0.7) before adjustment for axillary and 0°F(±0.7) after adjustment for axillary.

Group 3 (n = 41) produced a mean difference of -0.3°F(±0.8) before adjustment for axillary and 0°F(±0.8) after adjustment for axillary. All figures are rounded to the nearest tenth of a degree.

Repeatability.

The Caregiver performed with excellent consistency in all 3 pediatric age groups. The overall repeatability was 0.35ºF. However, there are many low readings with the SureTemp leaving us with a good deal of uncertainty about the stability of our reference readings. A 3-5 minute monitor mode contact equilibrium thermometer should provide an improved reference.

Febrile patients.

The SureTemp thermometer registered a fever (>99°F axillary) in only 10 patients. The mean difference between the SureTemp axillary and Caregiver forehead reading was 0.1ºF(±1.1). The febrile sample is too small to permit any inference.

Pediatric Clinic Conclusions

The Caregiver performed well in the acute pediatric sample but with somewhat greater variability than in the family practice clinic sample.

Overall conclusions

Our evaluation of the performance of the Caregiver is very positive and encouraging in the patients tested. More evaluation needs to be done in febrile patients of all ages.

Bias and repeatability statistics were very good and variability was consistent with other studies using a predictive thermometer as reference.

A more stable reference such as a contact equilibrium thermometer used orally or rectally or a recognized invasive core temperature reference site such as esophageal, pulmonary artery or bladder would likely reduce variability.