Introducing the greatest advancement in clinical thermometry in more than 30 years...

CAREGIVER®

The world's first non-contact device with TouchFree™ technology developed by the team that invented tympanic thermometry!

Our new **CAREGIVER®** thermometer offers instant, accurate temperatures and easy-to-use features that professionals have asked for:

- ✓ ***PROVEN ACCURACY...*** documented clinical precision in a wide range of medical settings.
- ✓ ***INCREASED EFFICIENCY...*** eliminates probe-cover costs and storage/transport logistics, reduces time for vital-signs, available without cart/trolley; no charger-base required, 10,000 temps from one set of AA batteries.
- ✓ ***INSTANT RESULTS...*** measurement in 1-2 seconds, reliable and repeatable.
- ✓ ***NON-CONTACT...*** delivers improved hygiene with reduced risk of cross-contamination and no probe-covers required!; minimizes risk of operator error, provides immediate access to measurement site, no patient disturbance.
- ✓ ***EASE OF USE...*** simple positioning, one-button operation, improved patient cooperation, bright backlit display and 30-temperature memory recall.
- ✓ ***MULTI-TASK CAPABILITY...*** also measures room temp, skin/surface temp with the flick of a switch; Celsius/Fahrenheit switchable with a touch.

This exciting new thermometer is rugged enough for hospital/office/clinic handling and still delivers professional precision you can depend upon!

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CGSS-2016-A

CAREGIVER®

THE CAREGIVER® PROFESSIONAL is a clinical-grade infrared thermometer for measurement of forehead temperature in adults, children, and infants without contact. It is designed for use in a wide variation of medical settings and can also deliver ambient/skin surface temperatures with the flick of a switch.

THE CAREGIVER® PROFESSIONAL	
TouchFree™ Operation →	No Direct Patient Contact
No Probe Covers →	Est. Savings of $250/year
No Scanning Required →	Less Chance for Operator Error
1~2 Second Response →	Time Efficient
Backlit Display →	Easy to Read

Physiological Justification for Measuring Temperature at the Forehead

Scientists researching the physiology behind circulation to the forehead using contact thermistors were able to showthat the blood supply to the forehead originates in and responds to changes in the internal carotid artery.*

Clinical Results - 200 Patient multi-site Study

- Overall Clinical Bias = 0.04ºF / Pediatric Bias = 0.25ºF
- Repeatability (Same Patient): Adult = 0.2ºF / Pediatric = 0.35ºF

*Heinz, E.R., Goldberg, H.I., & Traveras, J.M. (1964). *Experiences with Thermography in Neurologic Patients. Annals of the New York Academy of Sciences*, 121, 177-189.

Specifications

Displayed Temperature Range	BODY Mode: 94ºF to 108.5ºF (34.4ºC to 42.5ºC) SURFACE Mode: 32ºF to 140ºF (0ºC to 60ºC) Accuracy not specified below 71.6ºF (22ºC)
Storage Temperature Range	-4ºF to 140ºF (-20ºC to +60ºC)
Ambient Operating Range	50ºF to 104ºF (10ºC to 40ºC) 85% Relative Humidity or less.
Displayed Accuracy	From 96.8/102.2ºF ±0.4ºF (36 to 39ºC ±0.2ºC From 71.6/96.7ºF ±0.5ºF (22 to 35.9ºC ±0.3ºC) From 102.3/108.5ºF ±0.5ºF (39.1 to 42.5ºC ±0.3ºC)
Power	2 x 1.5v, AA Alkaline Batteries
Battery Life	>10,000 Temperatures Typical
Response Time	Approx. 1 Second
Size	(L x W x H) 150 x 48.48 x 55.16mm
This device has been tested and conforms to the following standards:	ASTM E1965-1998 CE This product meets the requirements of the applicable EC directives.
Type:	Non-contact Infrared Clinical Thermometer
Modes:	Clinical BODY Temperature SURFACE Temperature ROOM Temperature
Memory	30 Readings - Date and Time-stamped
Display	Backlit LCD
Scales	Celsius and Fahrenheit
Calibration	Factory Calibrated to ASTM standard, BioMed Technician may verify calibration on site

Ordering Information

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Included in the Box:

Caregiver® Thermometer, Sensor Cap, Instruction Manual, Quick Start Card, Warranty, 2-AA Alkaline Batteries.

CGSS-2016-A

The clinically proven, professional-grade Caregiver® touch-free thermometer...

Specifically engineered for quality and rugged performance!

The Caregiver Advantages	The Competition
Available Caregiver Clinical Accuracy Documentation (white papers 2011, 2013).	✓	✗
Full metal housing enclosing receiver and other electronic components.	✓	✗
Narrow field-of-view (FOV) sensor reduces risk of errors due to variability in "aiming" the thermometer.	✓	✗
No plastic components in optical path: lens, mirrors, etc.	✓	✗
FDA Clearance for clinical use (Class II) via searchable 510K specific to Caregiver.	✓	✗
On-screen display of 30 seconds vs. 5 seconds for other thermometers. Short view times could require re-takes.	✓	✗
AA batteries provide greater number of temps and increased backlighting vs. AAA batteries used by consumer-grade thermometers.	✓	✗
Established Professional Clinical Calibration protocol for routine hospital maintenance programs.	✓	✗
Covered by 2-year manufacturer's warranty vs. 1-year for most others.	✓	✗
Distributed and supported by nationwide network of experienced Professional Medical Specialty Dealers.	✓	✗

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CAREGIVER® FREQUENTLY ASKED QUESTIONS

http://www.thermomedics.com

Q. What is the "gold standard" for temperature-taking; how do you resolve discrepancies?

True core temperature is generally considered to be 1) Pulmonary Artery or 2) Esophageal or 3) Bladder temperature but these are obviously invasive. A calibrated mercury-in-glass thermometer used orally or rectally may be employed if properly left in place for about 3 minutes as a "referee device" for resolving temperature comparisons.

Alternatively, a properly placed electronic predictive thermometer used orally or rectally and set to the "monitor" mode may be employed. It's important to ensure that all comparisons are made in the proper "equivalence" mode on the thermometer being tested e.g. oral, rectal, axillary, etc. Temperatures taken at different sites will most often not be identical, but in sufficient agreement for routine clinical purposes.

Q. How does the single-point forehead temperature improve accuracy, repeatability, and consistency of readings?

By using only the center of the forehead, this technique avoids variation often encountered when the Right or Left areas of the oral cavity, ears, or temporal-swipe R-L action are employed. Unless the same spot is repeatedly used, temperature-trending becomes less dependable.

Q. How do we interpret a touchfree forehead temp reading?

As noted in the IFU and training video, the Caregiver® temp is equivalent to an Oral reading in nearly all situations. With children up to about 2-3 years of age, the forehead reading is essentially equivalent to a properly taken Axillary temp.

Q. Can the Caregiver be used on infants?

Yes, the device has been cleared by the FDA for use on infants.

See the clinical "white paper" on the thermomedics.com website for details. The forehead temperature in these cases has been deemed equivalent to a routine *Axillary Temperature*. In toddlers and older children, the readings are approximately equivalent to *Oral Temperature*, just as they are for adults of any age.

Q. Does the Caregiver emit any radiation or light during its operation?

No. The device reads only naturally emitted infrared signals from the skin and underlying blood supply; no light or other focusing effort is necessary. Therefore, there is no risk of the illumination awakening a sleeping patient.

Q. How do you manage to take even a 1-second touchfree temperature accurately on a squirming child?

As with other thermometers, especially IR tympanic units, it's advisable to gently stabilize the child's head with one hand while taking the nearly instant forehead reading with the other. This presents essentially no problem.

Q. Does skin color affect readings?

No. Infrared emissivity from dark-skinned to light-skinned patients remains essentially constant (i.e. 98%) and does not affect readings.

Q. Where is the Caregiver especially useful?

Caregiver provides strong routine temperature-taking in most medical settings; it can be particularly useful for :

- Hospitals, Physician's Offices, Clinics, Outpatient Centers, Visiting Nurses, School Nurses, LongTerm Care, etc.
- Intubated patients where oral temps are contraindicated and rectal readings are too difficult. Faster than tympanic with no probe cover concerns
- Elderly and disoriented non-compliant patients
- Sleeping infants and children (as long as forehead is exposed to the ambient air temperature)
- Post-surgical recovery rooms where patients are often emerging from anesthesia and unable to comply or aid in placement of oral, tympanic, or other temps

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Q. Why is the "adjustment" period necessary in some cases?

As with many IR thermometers, it is important to have the Caregiver® and the patient at a "comfortable" ambient temperature for up to 20 minutes after a patient has been in an unusually cold or hot environment. It is not routinely a challenge if the unit has been kept in a uniformly maintained thermal environment (e.g. exam room, patient room, etc.). Operators should exercise common sense in heavily air-conditioned rooms or when patients may be directly located under cooling vents or heat lamps. Consult the IFU manual for further details.

Q. What are the major benefits of not needing probe covers?

All of the following elements contribute to the benefits of Caregivers's no-probe cover protocol:

- Cost-reduction due to elimination of entire pc expenditure
- Increased storage space within or outside department; releases precious space in exam room drawers, Pyxis cabinets, warehouse, etc.
- Improved workflow potential due to elimination of search for pc's during examinations
- Reduction of waste materials produced by facility
- Elimination of problems associated with"non-use" or "re-use" of probe covers for Oral, Rectal, or Tympanic devices

Q. What other cost-savings are possible with the Caregiver?

Compared to devices that use covers, the savings are obvious. Less evident are the savings to be realized because replacement probes (Oral and Rectal, approx. $85.00 each) are not purchased several times annually as is routine with SureTemp® and other similar thermometers.

Q. What is the Warranty coverage for Caregiver?

The Caregiver is covered by a 2-year limited manufacturer's warranty. Optional Limited Lifetime Warranty is also available.

Q. Can the Caregiver be used, as well, on patients in higher acuity situations?

In any routine patient-care situation where an IR tympanic, Oral/Rectal Electronic, or Temporal Artery-swipe thermometer can be employed, the Caregiver should perform well. In very-high acuity settings (such as NICU, ICU, CCU) the patients are almost always constantly monitored and the readings continuously reported and recorded by hardwire or wireless to the nurse's station and other EHR collection locations. For "spot" temp checking, the Caregiver can certainly provide information in these or any routine medical setting.

Q. What are possible "pitfalls" to be recognized with any thermometry technique, depending on the measurement site?

Most temperatures taken in medical settings are subject to wide variations depending upon the following elements:

- Expertise of the operator: proper placement, dwell time, technique, use of clean/new probe covers each time
- Temperature of the thermometer itself should be stable; ambient adjustment circuitry
- Ambient and Patient conditions: A/C vents, heaters, air movement against skin, evaporative cooling in mucous membranes, mouth-breathing, recent ingestion of food or drink, presence of breathing tubes, nasal tubes, presence of fecal material in rectum, ear-wax buildup, etc.

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No-touch Forehead Temperature Measurement in Two Clinical Settings

Naja E. McKenzie PhD, RN & Gary O'Hara MSE

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.

Naja E. McKenzie is a clinical research consultant retained by Thermomedics, Inc. to conduct and supervise thermometry clinical research. Gary O'Hara is Chief Technology Officer for Thermomedics, Inc.

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.

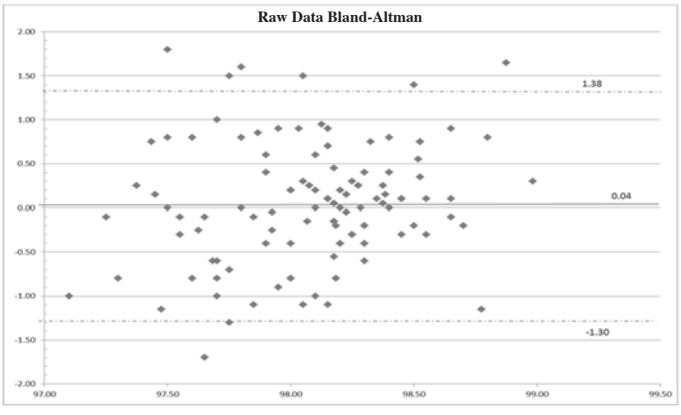
Means and standard deviations were calculated for all readings as shown in Table 1 below.

	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 High	CG Low	# Sets	ST High	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

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 °F 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.

Clinical validation of the CAREGIVER non-contact thermometer model PRO-TF200/ PRO-TF300 in febrile and afebrile patients of all ages

Naja E. McKenzie PhD, RN, Alice Huang & Gary O'Hara MSE

Background. The CAREGIVER Model PRO-TF200 and PRO-TF300 (Thermomedics, Miami, FL) are non-contact clinical professional thermometers are used to read human body temperature in children and adults through the determination of infrared energy from the middle of the forehead. Both models function identically, thus, they will be referred to hereafter as "Caregiver". The purpose of this paper is to describe the methods and findings of the CAREGIVER'S validation for clinical use.

Methods. Fully consented/assented, febrile and afebrile participants in this prospective study included adults (n=135) and children (n=160). Readings were compared to a reference thermometer (SureTemp Plus 690, Welch-Allyn, Skaneateles Falls, NY) to derive agreement (clinical accuracy) and repeatability.

Results. Agreement in the adult group was -0.2°F (-0.1°C) with a standard deviation of 0.50°F (0.28°C). In the pediatric group, agreement was 0.14°F(0.07°C) with a standard deviation of 0.42°F (0.22°C). Repeatability was 0.17°F in adults and 0.19°F in children.

Conclusions.

The CAREGIVER thermometer is designed to measure clinical body temperature from the center of the forehead without contact with the skin. Device agreement and repeatability both fall within current standards for clinical infrared thermometers.

Naja E. McKenzie is a clinical research consultant retained by Thermomedics, Inc. to conduct and supervise thermometry clinical research. Alice Huang is Associate Manager of Clinical Program, Taidoc Technology Corporation, Gary O'Hara is Chief Technology Officer for Thermomedics, Inc.

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 in children and adults 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 prospective 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 projected sample is described in Table 1.

Group	Age	Febrile	Afebrile	Total
Adult	>5 <67 yo	35	100	135
Adol/Child	>5 yo	15	25	40
Child	1 – 5 yo	15	25	40
Infant	1 - 12 mo	15	25	40
Neonate	0 - 1 mo	15	25	40
Total		95	200	295

Table 1. Characteristics of Projected Sample.

In each area, three trained professional operators obtained duplicate (or triplicate for repeatability) CAREGIVER readings by aiming the device at the middle of the patient's forehead 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. Thus, neonates, infants and children 1-5 y-o had rectal temperatures taken, while children and adolescents > 5-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 below.

Age Group (n)	Caregiver Febrile Mean ±SD	SureTemp 690 Febrile Mean ±SD	Caregiver Afebrile Mean ±SD	SureTemp 690 Afebrile Mean ±SD
Adult (>5<67 y-o) n=135	101.5°F ±1.07 n=35	101.6°F ±0.92 n=35	98.4°F ±0.46 n=100	98.1°F ±0.36 n=100
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 year) (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	101.2°F ±0.5	98.5°F ±0.7 n = 92	98.6°F 0.6±

Table 2. Means (±SD) of 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
Adult (>5<67 y-o) n=135	0.16°F ±0.46	-0.32°F 0.48	-0.20°F ±0.50
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 year) (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.

Bland Altman plots of adult data were constructed using the mean bias and standard deviation shown in Table 3.

The adult limits of agreement (1.96 x 1SD) were calculated (+0.82, -1.21) and found to be comparable to or better than other published thermometer validation studies (2, 3). In the adult sample, six points fell well outside the limits of agreement indicating these data points should be analyzed in detail. See Discussion section.

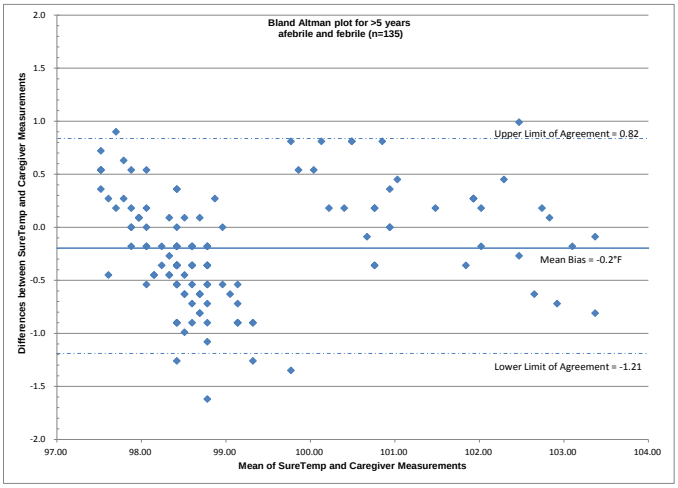


Figure 1. Bland-Alman plot of agreement between Reference (SureTemp 690) and test (Caregiver) thermometers in afebrile and febrile patients >5 <67 years of age (Oral adult sample).

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 (4, 5). Bland-Altman plots were then constructed to illustrate agreement between reference and test thermometer. Figure 2 represents the entire Pediatric sample, while Figure 3 shows the Neonate sample. Plots of the remaining age group are available upon request.

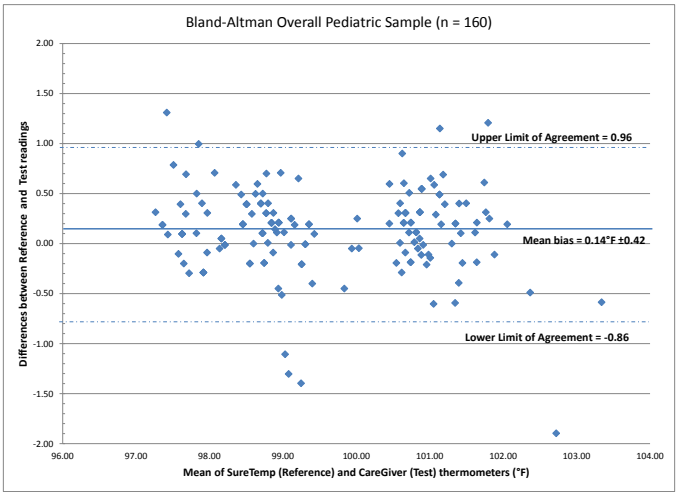


Figure 2. Bland-Altman plot of agreement between Reference (SureTemp 690) and test (Caregiver) thermometers in afebrile and febrile patients 0 - 18 years of age (Oral / rectal sample).

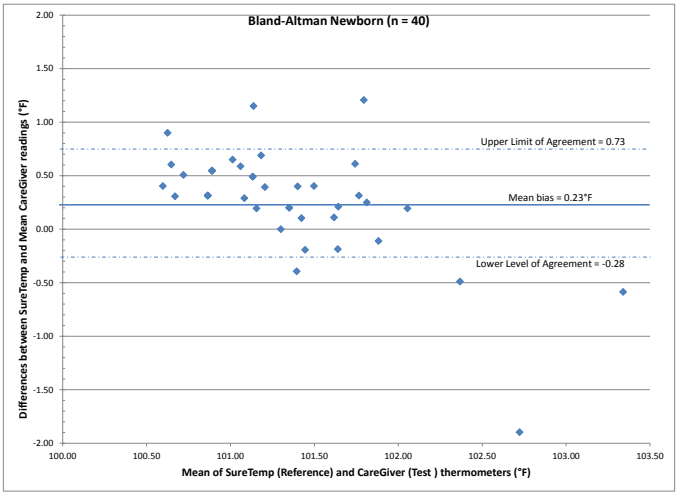


Figure 3. Bland-Altman plot of agreement between Reference (SureTemp 690) and test Caregiver thermometers in afebrile and febrile neonates, 0 -28 days years of age (Rectal sample).

Repeatability

Repeatability was calculated using the pooled standard deviations formula set out in the ASTM E1965-1998 standard (1)

where the value of s_r is the measure of clinical repeatability.

The repeatability by age group and febrile status in summarized in Table 3.

Device	n	Age group	Febrile Status	Repeatability
Pro-TF300	135	>5 - <67	All	0.17
Pro-TF300	35	>5 - <67	Febrile	0.21
Pro-TF300	100	>5 - <67	Afebrile	0.15
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	>1 mo. - <1 year	Febrile	0.11
Pro-TF300	23	>1 mo. - <1 year	Afebrile	0.16
Pro-TF300	12	0 - <1 mo.	Febrile	0.23
Pro-TF300	28	0 - <1 mo.	Afebrile	0.23

No data points were excluded to arrive at these statistics.

Discussion

This is the first validation study of the CAREGIVER non-contact forehead thermometer on febrile patients of all ages. 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 addresses in this study.

Accuracy generally incorporates agreement as described in early statistical work (Bland & Altman) and incorporated into international professional standards. Another concern for the clinical study is consistence 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 (Craig et al) 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 except in one group (afebrile adults >5 <67 y-o). The large bias appeared to be due to 5 large outliers which we examine below.

Analysis of Outliers

Upon closer analysis, 5 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. 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 0.2°C or 0.36°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, $R^2 = 0.90$ indicating a strong linear relationship.

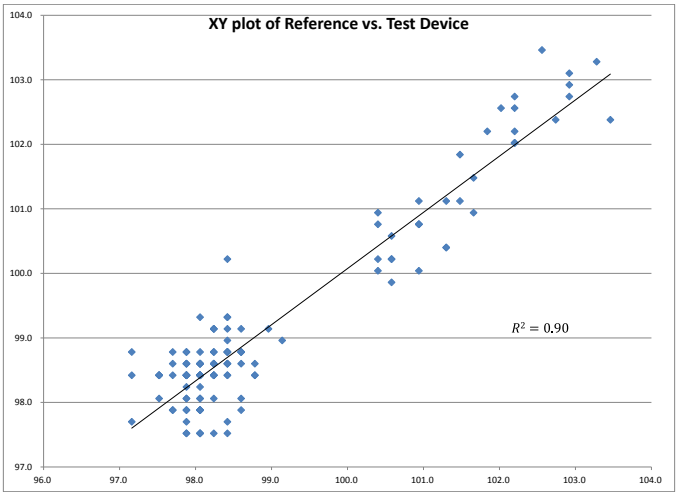


Figure 2. XY plot of SureTemp 690 vs. Caregiver in adult (>5 - <67 years-old) sample (n = 135).

Conclusion

The CAREGIVER is an infra-red non-contact clinical thermometer designed for professional clinical use. Our validation indicates a high level of agreement between the CAREGIVER and the reference device (SureTemp 690), thus assuring accurate and reliable readings in adults and children.

1. ASTM. E1965 - 98(2009) Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature. West Conshohocken. PA: ASTM International; 2009.

2. Chiappini E, Sollai S, Longhi R, Morandini L, Laghi A, Osio CE, et al. Performance of non-contact infrared thermometer for detecting febrile children in hospital and ambulatory settings. Journal of Clinical Nursing. 2011;20(9-10):1311-8. PubMed PMID: 21492277.

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S013-0515-01

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

Naja E. McKenzie PhD, RN, Alice Huang & Gary O'Hara MSE

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.

Naja E. McKenzie is a clinical research consultant retained by Thermomedics, Inc. to conduct and supervise thermometry clinical research. Alice Huang is Associate Manager of Clinical Program, Taidoc Technology Corporation, Gary O'Hara is Chief Technology Officer for Thermomedics, Inc.

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.

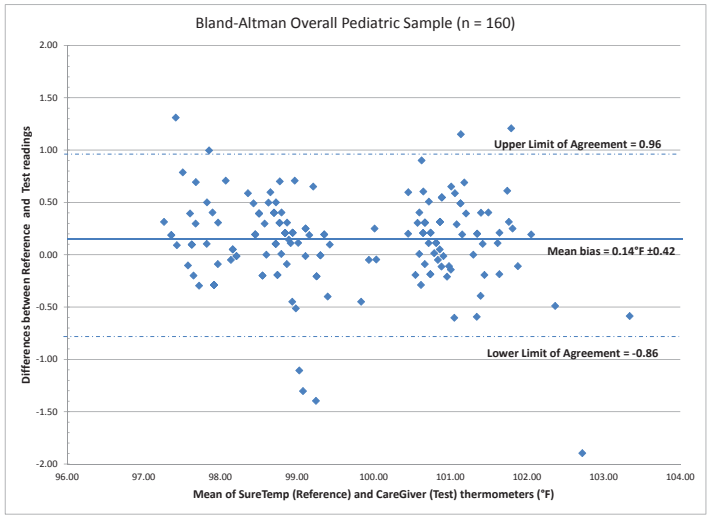


Figure 1. Bland-Alman plot of agreement between Reference (SureTemp® 690) and test (Caregiver) thermometers in afebrile and febrile patients 0-18 years of age (Oral/rectal sample).

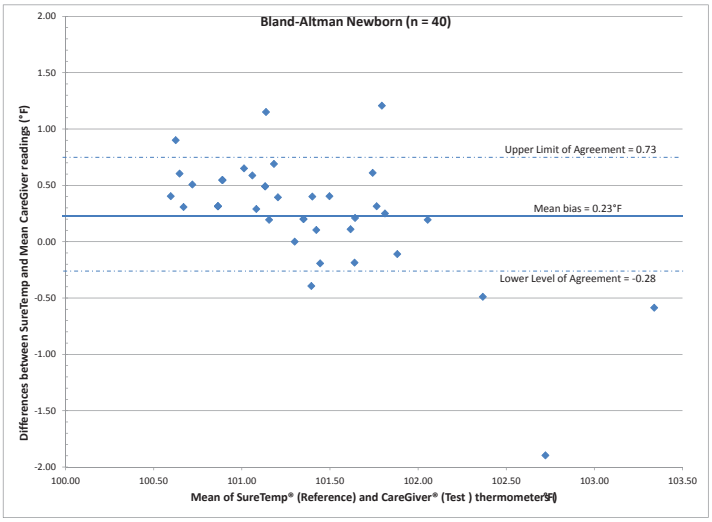


Figure 2. Bland-Altman plot of agreement between Reference (SureTemp 690) and test CAREGIVER® thermometers in afebrile and febrile neonates, 0 -28 days years of age (Rectal sample).

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.

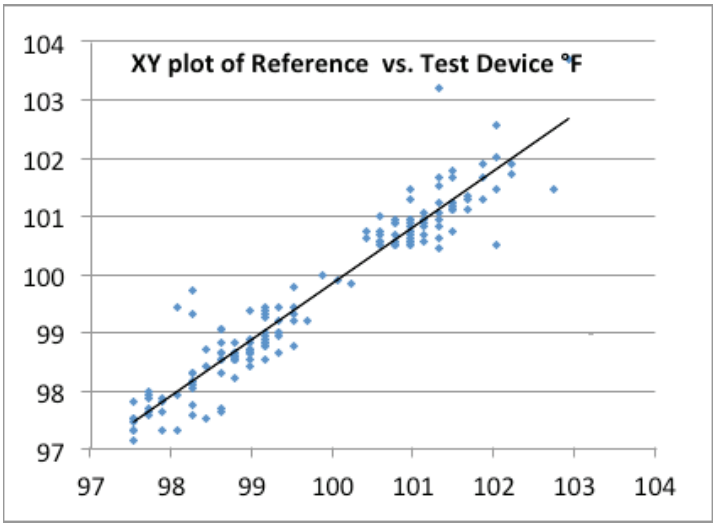
Discussion: This validation study of the Caregiver® non-contact thermometer involves afebrile and febrile patients ages 0 to <18. We sought to answer the research question of whether there is substantial clinical agreement and repeatability between the CAREGIVER test device and an established clinical 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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3. Nimah MM, Bshesh K, Callahan JD, Jacobs BR. Infrared tympanic thermometry in comparison with other temperature measurement techniques in febrile children. Pediatric Critical Care Medicine. 2006;7(1):48-55. PubMed PMID: 16395075.

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S024-1116-01

Use of the Forehead as an Accepted Site for Clinical Temperature

Applies to: Caregiver Model Non-contact Clinical Thermometers

The purpose of this review is to examine the research evidence to determine the suitability of the forehead as a reliable site for the measurement of body temperature. The scope of the analysis is limited to measurements taken from the middle of the forehead and not from over the temporal arteries.

As early as 1964, scientists researching the circulation of the forehead have been able to show that the blood supply to the forehead originates in and responds to changes in the internal carotid artery (Heinz, Goldberg, & Taveras, 1964). Conrad and colleagues used thermistors to measure various non-temporal forehead temperatures with a high level of precision to identify compromised carotid circulation and concomitant altered forehead perfusion through comparison with normal values (Conrad, Toole, & Janeway, 1969). Subsequent studies centered mostly on perioperative temperature measurement with the forehead being of particular interest as a site that is readily accessible to the anesthesia team without having to rearrange surgical drapes.

The advent of liquid crystal phase-change forehead strips turned the attention of researchers from the characteristics and reliability of the forehead to the liquid crystal technology. The forehead continued to be found to track other sites quite well but about 4°F lower (Burgess, Cooper, Marino, & Peuler, 1978). The interest in forehead as a measurement site was also based on the need for continuous measurement during surgery and the liquid crystal strips were able to deliver that with reasonable precision (Lees, et al., 1978). Successive studies comparing forehead temperature with multiple sites continued to be confined to the perioperative area and the potential to measure clinical temperature extremes characteristic of the perioperative course (Tsuji, 1987; Tsuji, et al., 1984; Tsuji, Suma, et al., 1981; Tsuji, Tamura, Nemoto, & Togawa, 1981).

Two distinct aspects dominated this research:

- The forehead was an acceptable site for measuring body temperature and
- There was complete awareness that body temperature exists on a dynamic gradient and that measuring simultaneous temperatures at multiple sites will not yield identical measurements.

This awareness persisted until research moved out of the perioperative setting and into ordinary acute care at which point researchers began to consider the forehead strip inaccurate (Lewit, Marshall, & Salzer, 1982) when compared to glass mercury thermometers used orally and rectally when the readings did not match closely.

In order to summarize the trend in the use of the forehead as a temperature measurement site, we have assembled the most important studies characterizing the site and its clinical reliability and usefulness. It is our position that the forehead remains a highly reliable and appropriate site for measuring temperature and that infrared technology is ideal for taking advantage of its accessibility and reliability.

Author	Title	Subjects	Devices	Results	Conclusions	Recommendations
Conrad et al. (1969)	Thermistor recording of forehead skin temperature as an index of carotid artery disease.	Six normal and 35 adults with suspected cerebro-vascular disease	Thermistor probes taped to forehead around eyebrow and in orbit.	Consistent differences between forehead sites in normal. Higher above nasal area of brow. Marked decrease in that site when carotid flow compromised. Higher on non-affected side showing re-routing of blood flow.	Forehead temperature can be diagnostic of diminished carotid flow.	Normal values very stable and reliable.
Burgess et al., 1978	Continuous monitoring of skin temperature using a liquid-crystal thermometer during anesthesia.	20 adults undergoing coronary artery bypass surgery.	Liquid-crystal forehead strip, rectal, esophageal, axillary thermistors, readings every half hour and every few minutes during bypass.	Forehead temperature was ~4ºF lower than other measures but trended very closely even during rapid warming.	Strip closely parallels changes in body temperature.	LC strip performed well as trend indicator and may be a safe alternative means for routine temperature monitoring during anesthesia where exact core temperature is not critical.
Lees et al., 1978	An evaluation of liquid-crystal thermometry as a screening device for intraoperative hyperthermia	Six male adults undergoing whole-body hyperthermia (up to 41.8ºC) for cancer therapy.	Rectal, esophageal, and forehead skin thermistors with liquid crystal plastic forehead strip monitored every 5 to 10 minutes during 2 hour heating phase.	Forehead thermistor was highly correlated (r=0.88) with esophageal and thermistor with liquid crystal even more (r=0.94) and esophageal with Liquid crystal of r=0.97. Rectal was less well correlated as	Forehead temperatures reflect rising esophageal core temps in a highly linear manner with rapid response time. (Both thermistor and liquid crystal strips).	Liquid crystal devices are not as accurate as forehead thermistors but are useful as practical monitoring and screening devices during hyperthermic conditions. Favorite quote: “The rectum does

Holmberg, 2010)			and IR Forehead HV-T36 (Ketonic), rectal and axillary Terumo C402.	repeatability though one had several outliers.. Bias rel to rectal:Thermofocus -0.8 and IR Forehead -1.0ºC	Forehead IR have good repeatability but a single linear offset cannot be applied.	
Chiappini et al., 2011(Chiappini, et al., 2011)	Performance of non-contact infrared thermometer for detecting febrile children in hospital and ambulatory settings.	251 children aged 3 to 8.6 years.	Axillary glass reference (>38ºC=febrile), IR forehead skin (Thermofocus)	Thermofocus repeatability 0.108ºC±0.095 ; axillary repeatability 0.114ºCC±0.103. Mean axillary temp 37.18ºC Mean IR Forehead 37.30ºC. Bias 0.07ºC±0.76 -0.62 LOA. Bland Altman done incorrectly. Used only axillary on x-axis not mean .	Forehead skin IR has advantage over ear IR because technique is not an issue. Forehead skin IR performed well relative to axillary , is less cumbersome than both axillary and ear.	Forehead IR can be used in children > 1 month and is comfortable for children.
Teran et al., 2011	Clinical accuracy of a non-contact infrared skin thermometer in paediatric practice	434 children aged 1 – 48 months.	Rectal glass reference, temporal artery, forehead non-contact	Forehead non-contact 0.029 ± 0.01°C; temporal artery −0.20 ± 0.27°C	Forehead non-contact infrared thermometer is reliable and accurate.	More studies needed.

A variety of conditions are described in the articles reviewed. The majority of findings confirm the forehead as a viable measurement site with some conditions and reservations. The 'deep forehead' thermometer is based on the zero-heat-flow principle achieved by using heavy insulation of the probe where it contacts the skin, thus eliminating the effect of ambient. While this is not possible in the case of IR, the use of the site is no less valid as a temperature monitoring site on the body.

A number of articles were critical of the liquid crystal display technology, but the use of the forehead was not disputed. Infrared forehead skin thermometers were found to be highly repeatable which is essential when attempting to construct an algorithm for estimation of core temperature. Comparisons with other sites varied in their favorability, but were generally found to be preferable over IR tympanic because technique is not an issue.

Many of these studies were conducted in challenging circumstances such as rewarming from cardiopulmonary bypass or cardiac arrest, during indoor or outdoor exercise, in outdoor mass screening settings and in artificially heated environments. Overall, the forehead was an acceptable site, while the measurement technology was variably successful. Of particular note are the several studies that show the excellent performance of forehead skin IR in premature neonates, a challenging population in whom thermoregulation is of particular interest, but as little manipulation of the infant as possible is desired.

The clear message is that the mid-forehead is a clinically acceptable site and that its repeatability makes the construction of a curvilinear algorithm a real and highly promising possibility.

CAREGIVER®

Caregiver® Thermometer Mounting and Security Options

Wall Mount Model WMT-TF

The Caregiver® Wall Mount provides a versatile solution for storage of thermometers in the PRO-TF Series. It may be secured to a wall, mounted on commonly used "rail" systems or attached to an IV pole basket with optional accessories. The system consists of custom molded wall mount, attachment pin for use with optional tethering devices, mounting screws and drywall anchors.

Basket Mount Adapter Model BSM-TF

The Basket Mount Adapter is used with the Wall Mount WMT-TF. It permits attachment of the Wall Mount to baskets typically used on IV poles.

Secure Tether Model SMT-TF

The Secure Tether provides high security mounting of Caregiver® with a 12-foot extended length coiled plastic-coated steel cable with security fittings. One end of the tether is securely attached to the Caregiver thermometer. The other end can be attached to the Wall Mount WMT-TF or to user's equipment. The included SecureMount™ key assures that attachment and removal is only by personnel holding the key.

12-ft. Coiled Cord Model CC12-TF

Strong, flexible and plastic coated for easy disinfection/cleaning. The slip ring at the end of the coiled cord can be attached to the security pin on the bottom of the wall mount. The opposite end is attached to the fitting on the Caregiver thermometer.

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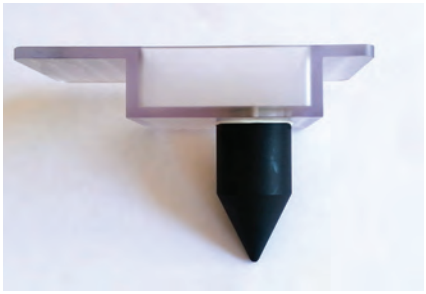
Non-contact Thermometer Calibration Checker System Model CC-TF

Calibration of the PRO-TF Series of Caregiver thermometers may be checked with the Model CC-TF System.

The system consists of three components:



Custom Blackbody Target
for Caregiver Thermometers.

6-liter circulating waterbath with 0.01°C stability, Digital interface, Stainless steel tank
Dimensions: 17.5" x 8" x 16"

Reference thermometer with 0.05°C accuracy and NIST calibration traceable certificate
Display Resolution: 0.01°F

Operation

The system is set up by filling the waterbath with water, placing the blackbody target (BB) into the waterbath opening and heating to the desired setpoint (2 setpoints are used between 93° and 103°F). The Reference thermometer is also inserted into the waterbath.
Once stable, the Caregiver thermometer is placed into the BB target in SURFACE mode and a reading is taken. The reading is then compared to the Reference thermometer.

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