

Brief Caregiver® Testing Protocol and Data Collection Procedure

Purpose

The purpose of this protocol is to suggest an informal evaluation procedure that can be used to explore the clinical performance of the Caregiver®, a new infrared non-contact forehead thermometer, in a professional setting in which individuals of all ages are seen by clinical providers.

The protocol can be used to determine the Caregiver®'s clinical repeatability (closeness of successive readings) and determining how the BODY mode of the Caregiver® compares to currently used oral or axillary (fast) predictive devices (clinical bias).

Equipment

Caregiver® (1 or 2 units)

SureTemp Thermometer (or equivalent) (1)

Oral probe for SureTemp(1)

SureTemp Probe covers

Room Temperature Thermometer (Optional)

Data log sheets

Clip board and Pen

Preparation of work area

1. Set up thermometers and allow to equilibrate for 20 minutes
2. Patients should (as far as possible) be at room temperature for 20 minutes prior to measurements
3. Prepare/set up:
 - a. Probe covers in SureTemp receptacle?
 - b. Data log sheets/ clip board/ pen at the ready?

Sample and Devices.

Each registering patient who is to have vitals taken will be included in this evaluation with as many febrile as possible. We anticipate a minimum of 30 patients per intake area will be included in the project.

This is a product evaluation of a single new thermometer, the Caregiver®, not a clinical or research study, so no consent is necessary. The forehead thermometer is completely non-invasive and the patient will feel no discomfort. This, along with its speed, and not requiring the use of a probe cover are the advantages of the Caregiver®.

You will also use the SureTemp electronic predictive thermometer orally or in the axilla as you would normally. For example, if your patient is an infant or child under 3-5 years of age, you would probably take an axillary temperature.

Data collection

The following data are to be collected: The data record number (pre-filled), patient age in years (or months for a young child), gender, two forehead readings, usual oral or axillary reading and the route used, the approximate time of day and the date, which can be filled as the first and last each day and we will autofill later. We estimate the additional time required above your usual temperature intake process will not exceed 30 seconds per patient.

Sample Data Log Sheet (Full Page Log Sheet at end of this document)

Data #	Date	Age	Male or Female	Care-giver 1	Care-giver 2	Optional Care-giver 3	SureTemp Oral or Axillary	Oral or Axillary (O / A)	Appr. Time	Room Temp
1										
2										
3										
4										
5										
6										
7										

In addition, there will be an area for comments, - yours and the patients'. When we have completed evaluation at your site, we would like to have you provide us feedback with a very short questionnaire which is not included here.

Temperatures

Caregiver® Non-contact forehead readings.

The Caregiver always starts up in the BODY mode, which is used for clinical temperature measurement. Please, refer to the Quick Start instructions provided.

1. Make sure patient's forehead is free of perspiration and sweep aside any hair with your non-dominant hand.



2. Position the thermometer at about a 90 degree angle and 1 – 2 inches from the center of the forehead, (not above the temporal artery) and press and release the power button. When you hear the double beep, the reading is complete.
3. Record reading in the Caregiver 1 box.
4. Repeat 2 using about the same distance as before and record the reading in the Caregiver 2 box.
5. Optional: If time allows, record a 3rd Caregiver reading in the Caregiver 3 box. This will allow the computation of clinical repeatability.

SureTemp readings

6. Obtain your usual oral or axillary reading with the SureTemp thermometer.
7. Record the reading and the route you used.
8. Record room temperature (if available).

Notes/comments

Share with us any unusual observation the patient makes or questions asked, and let us know if you have any particular comment on a given patient experience.

Data Analysis

The clinical repeatability and clinical bias can be determined using the formulas described in either of the following references:

[1] ASTM E1965-98, Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature

[2] ISO 80601-2-56 International Standard:

Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement. (Section 201.102 Clinical Accuracy Validation)

CAREGIVER DATA LOG SHEET

Name of Clinic/Hospital _____

Caregiver Serial Number(s) _____ SureTemp Serial Number _____

Data #	Date	Age	Male or Female	Care-giver 1	Care-giver 2	Optional Care-giver 3	SureTemp Oral or Axillary	Oral or Axillary (O / A)	Appr. Time	Room Temp
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