STRESS ENGINEERING SERVICES INC.

an employee-owned company

Clinical Accuracy Validation for the Withings BeamO Smart Thermometer

Test Protocol

Prepared for:
Withings
Issy-les-Moulineaux, France

September 23, 2024

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Contact: [redacted]

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Stress Engineering Services, Inc.

[redacted]

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1. Objective

This protocol applies to the Beamo Smart Temporal Thermometer SCT02 (Figure 1) manufactured by Withings (France). This device will be referred to as the "BeamO" in this protocol. The clinical accuracy validation protocol is intended to measure the clinical accuracy (clinical bias, limits of agreement, and repeatability) of the device as defined by ISO 80601-2-56 [1], Section 201.102, relative to a reference clinical thermometer. The reference device for this clinical accuracy validation will be the Withings Thermo thermometer SCT01 (Figure 2).

Figure 1: BeamO smart thermometer

Figure 2: Thermo smart reference thermometer

Figure 3: Exergen TAT-5000 reference thermometer.

2. Background / Introduction

The clinical accuracy of the BeamO Thermometer will be measured. Clinical accuracy as defined by ISO 80601-2-56 involves a series of measurements on a subject population using both the subject device and a reference thermometer which has established clinical and laboratory accuracy. The temperature measurements will be compared to measure the clinical bias, limits of agreement, and clinical repeatability of the BeamO device.

3. Test Devices

The validation testing will be performed using a single BeamO device and with a single Thermo device serving as reference thermometer for each test subject. The serial number of the devices will be recorded and noted in the test report.

4. Test Environment

The subject population is required to include both febrile and normal temperature subjects in specific age groups. Therefore, the clinical accuracy validation study is expected to be conducted at two or more locations. These include the facilities of Stress Engineering Services, located at [redacted] and one or more healthcare clinics. The clinical validation for the febrile populations will be conducted in coordination with clinical healthcare professionals. Locations are subject to change pending approval of the Institutional Review Board (IRB).

Personnel in the room will include the test participant, thermometer operator, and data recorder.

5. Test Participants

5.1 Subject Population

Subject population requirements are specified by ISO 80601-2-56 and are summarized in Table 1. A total of not less than 105 subjects must be included in the clinical accuracy validation, divided into 3 age groups (minimum 35 subjects per group). The first age group (less than 1 year of age) is further divided into subgroups of age less than 3 months, and subjects between 3 months and 1 year of age, with a minimum of 15 subjects required in each subgroup. Within each age group, at least 30% and not more than 50% of subjects must be febrile. As an example with exactly 35 subjects in group B, at least 11 and no more than 17 subjects must be febrile. For the purposes of this validation, "febrile" is defined as a temperature of 100.4°F or higher, as measured by the Thermo reference clinical thermometer.

Additionally, 2 or more hypothermic subjects from groups A2 and B (3 months or older to 5 years old) will be recruited. For the purposes of this study, "hypothermic" is defined as a temperature of 95°F (35°C) or lower, as measured by the Exergen TAT-5000 reference clinical thermometer.

Table 1. Human population requirements.

Group	Age	Afebrile (min)	Febrile (min)	Hypothermic (min)
A1	<3 months	12	6	0
A2	≥3 mo and <1 year	12	6	2
B	≥1 year and <5 years	24	11	
C	≥5 years	24	11	0

Exclusion criteria are defined by ISO 80601-2-56 and the Withings BeamO instructions for use, and include the following:

a. Preterm infants (current age plus length of gestation is less than 40 weeks)

b. Any subject who has taken antipyretics (e.g. ibuprofen, acetaminophen, aspirin) during the previous 2 hours.

c. Subjects with inflammation or scarring at the measurement site (the forehead).

d. Subjects with medical conditions known to affect temperature readings. These include patients taking certain medications (barbiturates, antipsychotics, thyroid medications) or those who have received recent immunizations.

5.2 IRB Review

Since this study involves human subjects, Institutional Review Board (IRB) approval must be obtained and be referenced in the test report.

5.3 Recruiting Method

SES will recruit all test participants in accordance with a set of screening criteria. A preliminary screener is provided as Appendix A. Participants will be asked to sign an IRB approved informed consent form.

5.4 Compensation

SES will compensate participants to cover their time as listed in Appendix A.

5.5 Identity Protection

SES will record the test participants' names as evidence that the clinical accuracy test involved identifiable individuals with the proper qualifications. However, none of the test data will be directly linked to the individual participants. Test data will be identified by test participant number alone, and the test participants' names will not appear in the test report.

The test report may include photographs for documentation of test methods, which may include test participants. However, such photos will not include the test participants' names or other identifiable information.

5.6 Risk to Test Participants

Participation poses minimal risks. Participants will not receive any medical treatments or diagnoses as part of this study. Minimal risks include:

- Participants might become fatigued during the test session.
- Participants might experience frustration, annoyance, impatience, or other negative emotions that mentally healthy individuals should handle without issue.

As part of protecting participants during each test session:

- The investigator will seek the test participant's informed consent. Consent forms for adult participants and child participants are attached as Appendix C and Appendix D, respectively.
- The investigator will instruct the test participant that s/he may withdraw from the test session at any time without cause or explanation without forfeiting the compensation.

- The investigator will advise the test participant that the session's focus is on the thermometer device repeatability and not the individual test participants.
- There will be a first aid kit and a telephone available to call 911 in the test room. CPR certified staff are on site.
- The test administrator will stop any participant actions that might result in injury to the participant.

6. Test Methodology

6.1 Operator Training

One or more clinical operators will be chosen to perform the temperature measurements for the clinical accuracy validation. Operator(s) will be selected by the partner clinical site and will be healthcare professionals (for example, registered nurse (RN), licensed practical nurse (LPN), Certified Clinical Medical Assistant (CCMA) or similar) with experience measuring patient temperatures. Each operator will be provided with both the BeamO and Thermo reference thermometer with the corresponding instructions for use and given the opportunity to become familiar with the operation of each device before beginning the clinical validation. Briefly, the instructions for use are as follows:

Thermo (Figure 4):

1. Remove protective cap
2. Press and release the button
3. Scan across the forehead from the center to the hair line up to 1 cm gap between probe and skin.
4. The device will vibrate when the measurement is complete; read temperature from display

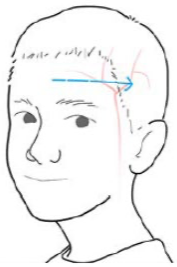

Figure 4: Illustration from the Thermo user manual.

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BeamO (Figure 5):

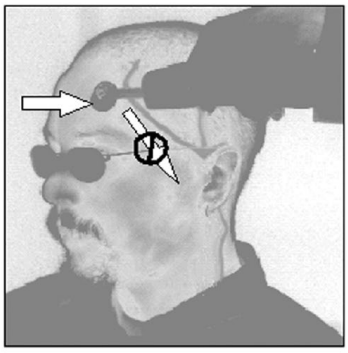
1. Press the joystick button for 3 seconds and release
2. Slowly scan once from the middle of the forehead to the top of the ear, up to 2 cm away from the skin.
3. BeamO will vibrate when the measurement is complete; read temperature from display.

Note, the BeamO is designed to be used in conjunction with a smartphone or tablet device, and Bluetooth connectivity to the device is required for initial thermometer setup. For the purposes of the clinical accuracy validation, the BeamO device will be provided to the clinical operator with this initial setup already completed.

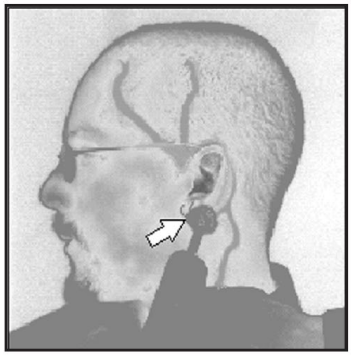
Figure 5: Illustration from the BeamO user manual.

Exergen TAT-5000 (Figure 6):

1. Place probe flush on the center of the forehead
2. Press and hold the button (keep depressed)
3. Slide the probe horizontally across the forehead to the hair line
4. Lift probe from forehead and touch on the neck just behind the ear lobe
5. Release button, read temperature from display



Measure only the exposed side. Brush hair aside if covering the TA area.



Brush hair away if covering ear.

Figure 6: . Illustration from the Exergen TAT-5000 user manual.

6.2 Study Session Methodology

Upon the test subject(s) arrival at the test location, the test staff will do the following:

1. Confirm the eligibility of the test subject according to the inclusion and exclusion criteria.

2. Present the test subject or test subject's parent/guardian, as applicable, the informed consent). The test administrator will inform the test subject that s/he may withdraw from the test session at any time without cause or explanation, and without forfeiting the compensation

3. Test subjects will be assigned an identification number, e.g. Subject 1.

6.2.1 Febrile Subjects

For each febrile subject in the study population, the clinical operator will perform the following steps.

1. Confirm the subject meets the inclusion criteria for the study and record the relevant participant data. Exclusion criteria were defined in Section 5.1. The required data for this study includes the age of the subject and the test subject identifier.
2. Confirm the patient stayed in the room for 10 minutes prior to taking any measurement.
3. Measure and record the temperature of the subject using reference Thermo thermometer.
    a. Two measurements with the reference Thermo thermometer with a gap of up to 1 cm from the forehead with approximately 5-10 seconds between measurements.
    b. Confirm the two reference measurements differ by no more than 0.4°F (the stated clinical accuracy of the Thermo device labeling). If the difference is greater than 0.4°F, discard both measurements and repeat step 3.

4. Measure and record the temperature of the subject using BeamO thermometer.

    a. 3 consecutive measurements* with the BeamO device with a gap of up to 2 cm from the forehead with approximately 5-10 seconds between measurements.

    *(1 measurement if the subject is febrile and less than 5 years old)

6.2.2 Hypothermic Subjects

For each hypothermic subject in the study population, the clinical operator will perform the following steps.

1. Confirm the subject meets the inclusion criteria for the study and record the relevant participant data. Exclusion criteria were defined in Section 5.1. The required data for this study includes the age of the subject and the test subject identifier.

2. Confirm the patient stayed in the room for 10 minutes prior to taking any measurement.
3. Measure and record the temperature of the subject using reference Exergen TAT500 thermometer.
    a. Two measurements with the reference Exergen thermometer with approximately 5-10 seconds between measurements.
    b. Confirm the two reference measurements differ by no more than 0.4°F (the stated clinical accuracy of the Exergen device labeling). If the difference is greater than 0.4°F, discard both measurements and repeat step 3.

4. Measure and record the temperature of the subject using BeamO thermometer.

    a. 3 consecutive measurements with the BeamO device with a gap of up to 2 cm from the forehead with approximately 5-10 seconds between measurements.

7. Data Collection

The subject and measurement data will be recorded on a form, attached to this protocol as Appendix E, or an equivalent format, to be sent to SES for data processing and analysis. The only patient data to be sent to SES will be the subject age and temperature measurements obtained with the Thermo and BeamO devices, along with yes/no answers to the exclusion criteria questions.

8. Evaluation

During the course of the clinical accuracy validation, SES will monitor the subject age and Thermo reference temperature data to track progress toward the sample size requirements defined by ISO 80601-2-56 for total subjects and febrile subjects per age group. SES will communicate with the clinical partner as needed to ensure the sample size requirements are met. Upon receipt of the complete data set which meets the subject population requirements, SES will perform the clinical accuracy calculations as defined by ISO 80601-2-56. The calculations will include:

Clinical Bias: the mean difference in temperature measured by the BeamO device and Thermo reference device on the same subject. This calculation is performed using the first measurement per subject with the BeamO device, if multiple measurements were taken.

Limits of Agreement: 2 times the standard deviation of the clinical bias measurement.

Clinical Repeatability: the pooled standard deviation of repeated measurements taken on the same subject using the BeamO device.

Per ISO 80601-2-56, there are no established acceptance criteria; these quantities will be reported for the BeamO device without judgment as to whether the results are acceptable or unacceptable.

9. References

[1]I SO 80601-2-56:2017(E). Medical electrical equipment – Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement. International Organization for Standardization, Geneva, Switzerland, 2017.

Appendix A: Recruiting Screener

Inclusion Criteria

1. **Consent:** Demonstrates understanding of the study and willingness to participate as evidenced by voluntary written informed consent and has received a signed and dated copy of the informed consent form.

2. **Age:** Participant age is among the categories

3. **Compliance:** Understands and is willing, able and likely to comply with all study procedures and restrictions.

Exclusion Criteria

1. **Personnel:** An employee of the sponsor or the study site or members of their immediate family.
2. **Medical Condition:**
    a. Preterm infants (current age plus length of gestation is less than 40 weeks)
    b. Has taken antipyretic in previous 2 hours
    c. Inflammation at the measurement site
    d. Medical conditions that affect temperature readings (barbiturates, thyroid, antipsychotics, recent immunizations)

Participant Withdrawal Criteria

Participants have the right to withdraw from the study at any time for any reason. The investigator also has the right to withdraw participants from the study in the event of protocol deviations, administrative reasons or other reasons.

Participant Replacement

Participants who do not complete the study will be replaced. The next available participant identification number will be assigned to the replacement participant.

Screener
Phone Screening and Study Invitation

NAME OF SPONSOR COMPANY: SES (Stress Engineering Services Inc.)
TITLE OF STUDY: BeamO Clinical Accuracy Validation
PROTOCOL NUMBER: [redacted]
NAME OF PERSON IN CHARGE OF THE RESEARCH STUDY: [redacted]

Hello. My name is _____ from _____ an independent marketing research firm. We are calling on behalf of SES, an Engineering consultancy firm. SES has asked us to invite adults with children under 5 years old for a study involving an infrared forehead-scanning thermometer. I want to assure you that your responses will be kept confidential. If you qualify and participate in the study, you will be compensated for your time.

1. Would you be willing to participate in a study about a clinical thermometer? It would involve arriving at our facility with your child and allowing the investigators to measure your child's body temperature several times by swiping a thermometer across his/her forehead. Both children and adults are needed for the study, so the investigators may measure your temperature with the same devices. The time commitment will be approximately 30 minutes and you would need to come to our facility to participate.

Yes	1	CONTINUE
No	2	THANK & TERMINATE

2. What is your child's age (in years and months) as of (today's date)? (more than 1 child may participate)

≥ 5 years old	1	NOTE AND CONTINUE TO Q.3
< 3 months	2	NOTE AND CONTINUE TO FOLLOWUP Q.23A
≥ 3 months and < 1 year	3	NOTE AND CONTINUE TO Q.4
< 5 years	4	

2A. (Only if reported age is < 3 months): Was your child born prematurely, at less than 37 weeks gestation?

No	1	NOTE AND CONTINUE TO Q.3
Yes	2	NOTE AND CONTINUE TO Q.2B

2B. (Only if pre-term birth is reported): Will your child's combined age plus weeks of gestation be more than 40 weeks today? For example, if your child was born at 34 weeks, will he/she be more than 6 weeks old today?

Yes	1	CONTINUE
No	2	THANK & TERMINATE

3. There are some medical conditions or medications that can affect temperature measurements taken with this type of thermometer. Please listen to the following list and simply answer yes or no if any of the following medications or conditions apply to your child: taking barbiturates or general anesthetics, thyroid medications, or antipsychotic medications? Are there scars or chronic inflammation on the child's temple (side of forehead)?

No	1	CONTINUE
Yes	2	THANK & TERMINATE
Prefers not to answer	3	THANK & TERMINATE

INVITATION

4. At this point, you qualify for this study. The study will take about 30 minutes and will be held at [redacted], which is about a 30-minutes drive from [redacted]. If you participate in the study, you will be paid [redacted].
5. Those who participate in these types of studies have told us they enjoy them. May I schedule you for this study?

SCHEDULE STUDY-------YES -1
THANK AND DISCONTINUE -------NO -2

6. When you arrive at the facility, you will be asked to sign a standard confidentiality agreement which simply states that you will not discuss the details of this study with anyone for a set period of time. Do you agree to sign this document?

YES -1
THANK AND DISCONTINUE -------NO -2

7. When you arrive at the facility, you will be asked whether any participants have taken fever-reducing medication in the previous 2 hours, or if they have had recent immunizations in the past few days. If the answer is yes, you may not be eligible to participate in the study, however you would still be compensated for your time. Please do not avoid or delay necessary medications simply to qualify for this study. Do you agree to this?

YES -1
THANK AND DISCONTINUE -------NO -2

8. We will be emailing information about the study to you. This email will include information about where the study will be held with directions to the facility. May I please have your email address? And may I have your home telephone number? Your cell number?

E-MAIL ADDRESS:_____

HOME TEL. #: _____ CELL #: _____

CONFIRM NAME AND TELEPHONE NUMBERS. RECORD ON FRONT OF SCREENER.

Thank you for agreeing to participate in this research study. Your participation is very important to us. If, for any reason, you will be unable to participate, please call [redacted]

Appendix B: Data Collection Form

Participant ID code		
Today's Date		
Participant Birthdate		
Subject Age		
	(years)	(months)

Start Time

	Exclusion Criteria	Yes	No
1)	Is the subject a preterm infant?	○	○
	if yes, please enter weeks of gestation _____		
2)	Has the subject taken fever-reducing medication in the past 2 hours? (acetaminophen, ibuprofen, aspirin)	○	○
3)	Is there inflammation or scarring at the measurement site?	○	○
4)	Has the subject received any immunizations in the past 3 days?	○	○
5)	Is the subject taking any of the following medications that may affect temperature measurements? Barbiturates or general anesthetics, thyroid medications, or antipsychotics	○	○

Temperature Measurements			
Device		Reading (°F)	
Withings Thermo	1)	_____	
	2)	_____	
		Reading (°F)	
Withings BeamO	1)	_____	_____
	2)	_____	_____
	3)	_____	_____