

TEMPERATURE

1. Background and Rationale

Body temperature will be measured in Visit 9 with a digital read ear thermometer (Omron MC-514). This measurement will be used to explore the theory that a lower body temperature, leads to a slower metabolism, slower aging and lower mortality rate.

2. Equipment and Supplies

- Ear thermometer (Omron MC-514)

2.1 Maintenance

2.1.1 Cleaning the Unit

- Wipe off the casing of the unit with a soft, dry cloth, or with rubbing alcohol.
- When dirty, clean the lens only with a soft, dry cloth or cotton swab.
- Do not clean any part of the unit with detergent, thinner or benzene.
- Do not immerse in water.

2.1.2 Storing the Thermometer

- Keep your thermometer in the storage case after attaching a lens cover to protect the lens.
- Store thermometer in a place that is out of direct sunlight, is not in any extremes of temperature or humidity and is not likely to be affected by vibration, dust or shock.

2.1.3 Battery Replacement

- Use a lithium battery CR2032.
- Remove the screw and battery cover.
- Remove old battery; do not use a screw driver or metal tweezers to remove the battery.
- Place the new battery with the positive (+) side up.
- Replace the battery cover and tighten the screw.
- Dispose of any used batteries in accordance with local regulations.

3. Safety Issues and Exclusions

None.

4. Subject and Exam Room Preparation

The measurement should be taken in the exam room. The participant may be seated or standing.

5. Detailed Measurement Procedures

5.1. Preparing the Unit

5.1.1 Conversion between Fahrenheit and Centigrade

The temperature should be recorded in degrees Fahrenheit (°F). The unit should already be set to °F. If the device has been switched to degrees Celsius (°C), follow these procedures to switch it back to °F.

- a) Be sure the unit is in the off position (blank display).
- b) Press and hold the Button for 3 seconds until “°C” flashes and you hear one beep.
- c) Press button again; now “°F” flashes.
- d) After 5 seconds, the unit will shut off.

5.1.2 Before Each Use

The thermometer will not work unless a lens cover is applied correctly. For hygienic use, attach a new lens cover each time.

- Remove the old lens cover.
- Attach the new lens cover
- Insert new lens cover until it clicks.

5.2 Taking the Measurement

- a) Push button to turn on. (The display will illuminate for 2 seconds.)
- b) When the “°F” symbol flashes, insert the lens into the participant’s ear. Gently pull back the ear lobe before inserting for best results. Tugging the earlobe provides a direct line to the eardrum to maximize the accuracy of results.
- c) Listen for the ready beep (1 beep); an “O” symbol will appear indicating its reading. The angle is correct and its ready for measurement.
- d) Press button again while unit is placed in the ear, 4 beeps indicates that the measurement is complete.
- e) Remove probe from ear.
- f) Discard used lens cover, and replace with new one, so that the unit is ready for use again.
- g) Note: If you are going to repeat measurements, wait until “°F” flashes.
- h) The thermometer will automatically turn off about 1 minute after a temperature has been taken. There is no button to turn the power off manually.

5.3 Troubleshooting

Display	Meaning	Action
Nothing is displayed even after the unit is turned on.	Dead battery.	Replace battery.
	Polarities of battery (+ and -) are wrong.	Reposition the battery with correct polarities.
“°F” or “°C” flashes, but “O” symbol is not displayed.	The lens cover may be dirty.	Replace the lens cover with a new one.
	Lens may be dirty.	Clean the lens with a cotton swab.
	Ear drum may be blocked with earwax.	Remove earwax.
A “0 0” symbol is displayed.	The unit is working under high room temperature, where a special operation is needed.	Place the unit in the ear, wait 2 seconds. Press the button and wait for 4 beeps. Remove from ear, look at results.
After all the symbols on display illuminate, an image of a battery, covered by an “X” is displayed.	Low battery.	Replace battery.
The display light is not turned on.	Low battery.	Replace battery.
PC	Lens cover is not on Probe.	Attach the lens cover, then measure.
AA	Temperature if the unit is unstable.	Make sure unit remains at room temperature where measurement will take place. Allow 30 minutes to stabilize before using. (Normal range: 50°F to 104°F)
AL	The temperature of the unit is 50°F or below which is outside of the operating range.	
AH	The temperature of the unit is 104°F or above which is outside of the operating range.	
Er.1	May require service.	Turn on the unit again. If “Er.1” is displayed again, the unit may require service. Call Customer Service Dept: (800) 634-4350
H (°F)	The measured temperature was above the range of the thermometer.	Probe may not have been properly positioned in ear. The probe must be snug against the opening of the ear. Be sure lens cover is clean and ear canal is not blocked with earwax.
L (°F)	The measured temperature was below the range of the thermometer.	

6. Procedures for Performing the Measurement at Home

The procedures are the same as the in-clinic exam.

7. Alert Values/Follow-up/Reporting to Participants

None.

8. Quality Assurance**8.1 Training Requirements**

No special qualifications or experience are required to perform this assessment. Training should include:

- Read and study manual
- Attend SOF training session on techniques (or observe administration by experienced examiner)
- Practice on other staff or volunteers (Goal: minimize differences between repeat measurements)
- Discuss problems and questions with local expert or QC officer

8.2 Certification Requirements

- Complete training requirements
- Conduct exam on 2 volunteers:
 - According to protocol, as demonstrated by completed QC checklist

8.3 Quality Assurance Checklist

- Examiner replaces lens cover.
- Examiner removes thermometer after 4 beeps sound.
- Records temperature in °F on form.
- Tells participant temperature.