

FORA[®] IR20

EAR THERMOMETER



Operations & Procedures Manual
Long-Term Care and Home Health Care

Thank you for purchasing the **FORA IR20b** Ear Thermometer. This manual provides important information to help you to use the device properly. Before using this product, please read the following contents thoroughly and carefully.

If you have other questions regarding this product, please contact the place of purchase or call Customer Service at 1-888-307-8188.

The **FORA IR20b** is intended for multi-patient use in a long-term or home health care setting. Please note that the following procedures are provided only as a model to help your facility establish its own policy and procedures. Your own policy may differ depending upon the existing procedures. Please consult with the Director of Nursing for further guidance.

CAUTION: Please carefully read the User's Manual and all product instructions before using this Long-Term Care and Home Health Care Manual and administering temperature readings.

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CAUTIONS AND WARNINGS

- As with any thermometer, proper technique is crucial to getting accurate temperature readings. Please read this manual thoroughly and carefully before use.
- Always operate the thermometer in temperatures between 60.8°F to 104°F (16°C to 40°C) and relative humidity less than 95%.
- Always store the thermometer in a cool and dry place: temperatures between -4°F to 140°F (-20°C to 60°C); relative humidity less than 95%. Avoid direct sunlight.
- Avoid dropping the thermometer.
- Use only **FORA IR20b** probe covers for the infrared ear thermometer.
- For proper hygiene, do not share or reuse probe covers. Damaged probe covers may result in error display.
- Do not disassemble the thermometer.
- Basic safety precautions should always be observed, especially when the thermometer is used on or near children and disabled persons.
- This thermometer is not intended to be a substitution for a consultation with your physician.
- Keep probe covers out of reach of children.
- Temperature measurements may differ from left to right ear. Always measure by using the same ear.

RESTRICTIONS OF USE

This thermometer is clinically proven to produce accurate temperature measurements. However, please be advised if you have the following situations:

- The accuracy cannot be ensured for a person who has a deformity in their ear, which prevents the thermometer probe from properly being inserted into the ear canal.
- The accuracy cannot be ensured when blood or drainage is found in the ear canal.
- If ear drops or medications have been placed in one ear, take measurements from the other ear.
- For a person who wears an ear plug or hearing aid, remove the device and wait for 15 minutes before taking temperature.

NOTE:

Never try to clean inside your ears. You may accidentally damage the eardrum or its surrounding tissues. Remove excess earwax only when you can reach it with a clean cloth. Consult a physician if you suspect the presence of excess earwax.

INTENDED USE

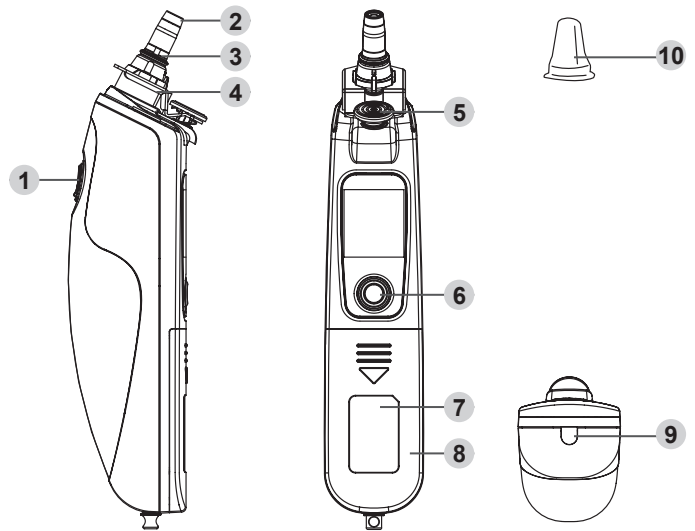
FORA IR20b ear thermometer is intended for the intermittent measurement and monitoring of human body temperature from the ear canal. The device is intended for professional use.

METER OVERVIEW

How does it work

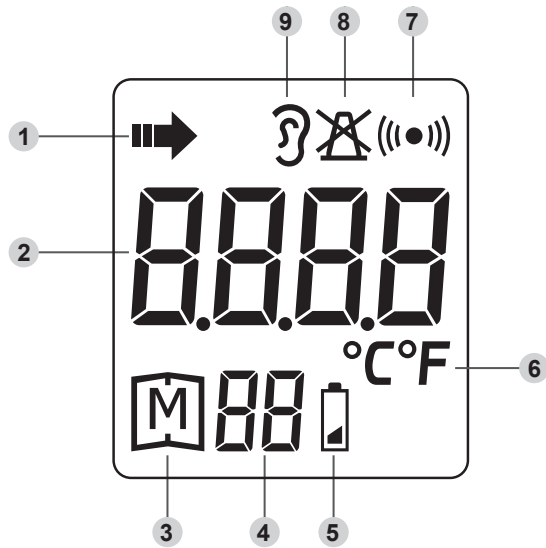
The thermometer measures the infrared heat generated by the eardrum and its surrounding tissue. The thermometer then converts the infrared heat generated into a temperature value shown on the LCD screen.

Appearance and Key Function



- 1 Scan Button
- 2 Probe Lens
- 3 Probe
- 4 Probe Cover Detector
- 5 Probe Cover Ejection Button
- 6 On/Memory Button
- 7 Manufacturing Label
- 8 Battery Cover
- 9 Bluetooth Indicator
- 10 Probe Cover

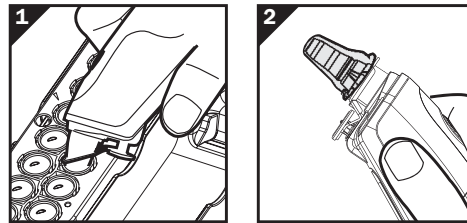
LCD Screen



- 1 Temperature Scanning In Progress
- 2 Temperature Reading
- 3 Memory Mode
- 4 Record Numbers
- 5 Low Battery Indicator
- 6 Temperature Unit
- 7 Communication Symbol
- 8 No Probe Cover Detected
- 9 Ear Temperature Indicator

EAR TEMPERATURE TESTING

Using the Device



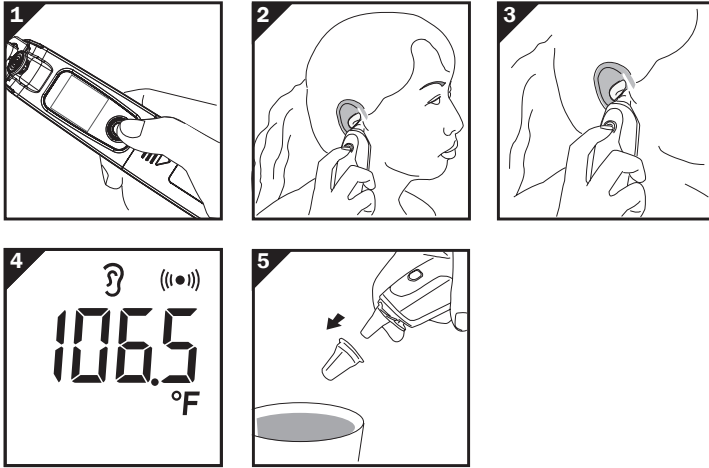
Replacing the Probe Cover

1. Check if the probe cover is clean and new. Press the infrared probe into the cartridge.
2. Secure the cover to the probe and remove it from cartridge.

NOTE:

- If a probe cover is not attached on the probe, LCD will show “~~X~~” until a new probe cover is firmly attached to the probe.
- The used probe cover should be removed after each measurement to ensure accuracy.
- To ensure proper hygiene, attach a new probe cover each time and do not touch its tip.

Measuring Temperature



1. Press and release the On/Memory button to turn on the thermometer. When ready, the thermometer displays the last measurement.
2. Gently fit the probe with a clean probe cover into the ear canal.
3. Press and release the Scan button. You will hear a beep to indicate the measurement is complete and the thermometer can be removed.
4. Read the result. “ \mathcal{B} ” is shown together with a temperature value.
5. Press the ejection button to discard the used probe cover into a trash can.

NOTE:

Turn off the thermometer by pressing On/Memory button twice. It will automatically turn off if left idle for 3 minutes.

Hints on Taking Temperatures

1. As with other thermometers, you may observe slight variations in consecutive measurements. **It is recommended that you take 3 temperature readings and use the highest one for the following situations:**

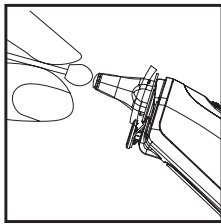
- Infants younger than 3 months old.
- Children younger than 3 years old and who have a compromised immune system and the presence / absence of fever is critical.
- When you are learning to use the thermometer.

2. Do not take a reading while the patient is moving and/or talking. Wait for 30 minutes after any of the following situations before taking a measurement:

- When the ear has been covered.
- After exercising, swimming, or taking a bath.
- When the patient has been exposed to extreme temperatures.

3. To take accurate readings, the ear must be free from excessive earwax buildup.

CARE AND CLEANING



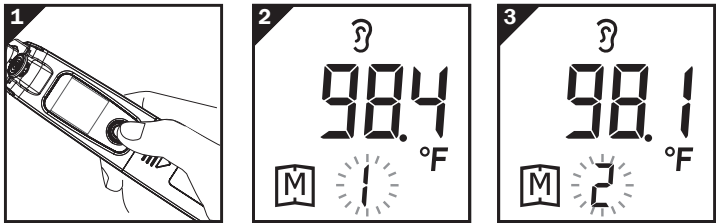
- The probe is not waterproof. Please wipe it with a clean and dry cotton swab.
- The body of the thermometer is not water-resistant. Never put the thermometer under a running tap or submerge it into water. Use a soft and dry cloth to clean it. Do not use abrasive cleaners.
- Store the thermometer in a cool and dry location free from dust and away from direct sunlight.

REVIEWING THE RESULTS

Results Indicators

Temperature $\leq 89.5^{\circ}\text{F}$ (31.9°C)	“Lo” with red backlight
89.6°F (32°C) \leq Temperature $< 100.3^{\circ}\text{F}$ (37.9°C)	Result with green backlight
100.4°F (38°C) \leq Temperature $< 109.4^{\circ}\text{F}$ (43°C)	Result with red backlight
Temperature $\geq 109.5^{\circ}\text{F}$ (43.1°C)	“Hi” with red backlight

Recalling the Memory



Your thermometer stores the last 10 readings in its memory.

1. Press the On/Memory button to turn on the thermometer.

2. Press the On/Memory button for 3 seconds to enter memory mode.

Press the On/Memory button to scroll through the last 10 records. A result will be displayed in the order of dates (latest results shown first), together with “M” and a number (from 1 to 10). When the memory is full, the oldest result is deleted as the new one is added. When the last record is displayed in the LCD, press the On/Memory button again to return to the first one.

3. Exit the memory.

Press the Scan button to exit the Memory Mode, then press the On/Memory button to turn the meter OFF.

ABOUT NORMAL BODY TEMPERATURE AND FEVER

Body temperature can vary from person to person. It also varies on different parts of the body and time of day. The following table shows the statistics of normal ranges from different body parts. Please keep in mind that temperatures measured from different body parts, even at the same time, should not be directly compared.

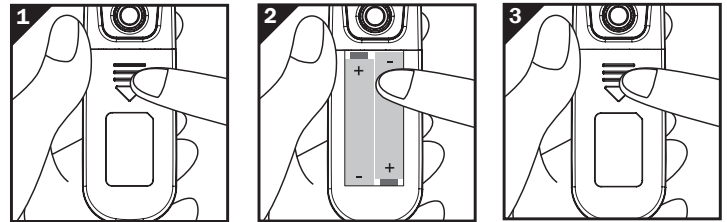
Fever indicates that the body temperature is higher than normal. This symptom may be caused by infection, overdressing or immunization. Some people may not experience fever even when they are ill. These include, but are not limited to, infants younger than 3 months old, persons with compromised immune systems, persons taking antibiotics, steroids or antipyretics (aspirin, ibuprofen, acetaminophen), or persons with certain chronic illnesses. **Please consult your physician when you feel ill even if you do not have a fever.**


Body Site	Normal Temperature Range*
Oral	95.9°F to 99.5°F (35.5°C to 37.5°C)
Axillary (underarm)	94.5°F to 99.1°F (34.7°C to 37.3°C)
Rectal	97.9°F to 100.4°F (36.6°C to 38.0°C)
Ear	96.4°F to 100.4°F (35.8°C to 38.0°C)

*Chamberlain, J. M. Terndrup, T. E., New Light on Thermometer Readings, Contemporary Pediatrics, March 1994.

MAINTENANCE


Replacing the Battery



The thermometer comes with two 1.5V AAA alkaline batteries. Replace them when “” appears. Please follow the steps for battery replacement.

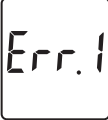
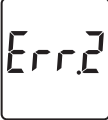
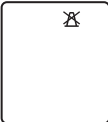
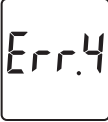



1. Remove the battery cover and remove the used batteries.
2. Place the new batteries in the battery compartment and press it in until the batteries are secured.
3. Reattach the battery cover.

NOTE:

- Although the thermometer works when “” appears, we still recommend that you change the batteries to obtain an accurate result.
- Remove the batteries if stored for a long period of time.
- The batteries should be kept out of the reach of children. If they are swallowed, promptly see a doctor for help.
- Properly dispose of the batteries.

TROUBLESHOOTING

All error messages below would be shown together with a red backlight. Please follow “what to do” to resolve problems. If the problem still exists, please call your local dealer for help.

MESSAGE	WHAT IT MEANS	WHAT TO DO
 	Appears when environmental temperature is below or above system operation range.	Put the thermometer under operating temperature range of 60.8°F to 104°F (16°C to 40°C).
	No probe cover detected.	Ensure the probe cover is fitted on firmly, or replace it with a new one.
  	Thermometer errors.	Review the instructions and restart the measurement procedure. If the problem persists, please contact your dealer.
	Appears when the batteries can't provide enough power for a test.	Replace the old batteries with new ones immediately.

SPECIFICATIONS

Model No.: FORA IR20b

Dimension: 165 mm x 32.4 mm x 38.7 mm

Weight: 85.5 g

Battery: 2 x 1.5V AAA alkaline batteries

External Output: Bluetooth

Displayed Temperature Range:

89.6°F to 109.4°F (32°C to 43°C)

Display Resolution: 0.1°F / 0.1°C

Accuracy:

Meet the accuracy requirement specified in ASTM E1965-98. $\pm 0.4^{\circ}\text{F}$ ($\pm 0.2^{\circ}\text{C}$) for the range of 96.8°F to 102.2°F (36.0°C to 39.0°C); $\pm 0.5^{\circ}\text{F}$ ($\pm 0.3^{\circ}\text{C}$) from 89.6°F to 96.6°F (32.0°C to 35.9°C) and from 102.4°F to 109.4°F (39.1°C to 43.0°C)

Temperature Unit: °F

Operating Temperature Range:

60.8°F to 104°F (16°C to 40°C)

Operating Humidity: 95% RH or less

Storage Temperature Range:

-4°F to 140°F (-20°C to 60°C)

Storage Humidity: 95% RH or less

Memory Capacity: 10 measurements

The specifications may be changed without prior notice.

TRAINING TOOLS

Attachment 1: FORA IR20b Ear Thermometer Training Checklist

Use the following checklist to assess the trainee's understanding and knowledge of the following areas:

	TASK	(✓)
AREA	CLINICAL USE OF DEVICE	
Knowledge	Knows key features of FORA IR20b thermometer.	
	Principles of quality testing and QC materials.	
	Only uses FORA IR20b probe covers with the FORA IR20b thermometer.	
	Understands the important features, benefits and limitations of the FORA IR20b system.	
	Knows the proper method of disposing of used probe covers according to facility procedures.	
	Understands the displayed error messages and corresponding actions to take.	
	Understands the appropriate steps to take for troubleshooting.	
	Knows the actions to be taken when the results are abnormally high or low.	
	Understands the information required to be documented by law and by institution.	
Equipment	Identify the essential equipment used with the FORA IR20b thermometer.	
	Locates the serial number and SET buttons on the meter.	
	Knows the proper storage conditions of the thermometer and probe covers.	
	Knows how to maintain the meter.	
Practical	Demonstrates proper technique when performing a measurement.	
	Demonstrates the correct probe cover insertion technique.	
	Performs quality control tests at specific times and determines if the results are acceptable. Takes appropriate action if there is a problem.	
	Demonstrates the proper cleaning and disinfecting techniques for the FORA IR20b thermometer.	
	Performs meter set up, memory retrieval and data transmission operations.	
	Demonstrates the proper actions to take for inaccurate results.	


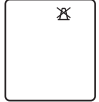
Training Completed by:

Name of Trainee	Date	Name of Instructor	Signature of Instructor

The trainee must complete the training of the FORA IR20b Thermometer before performing temperature readings on patients.

Attachment 2: FORA IR20b Thermometer Training Quiz

Complete the following questions to assess your understanding about using the FORA IR20b Thermometer to perform temperature measurements on residents:

NO.	QUESTIONS	ANSWER
1	When do you clean and disinfect the meter? a) After each use b) Daily c) Weekly d) Monthly	
2	When do you change a new probe cover? a) After each use b) Daily c) Weekly d) Monthly	
3	If you saw the following message on the meter's display, what action should you take?  a) Replace the battery b) Retest with a new probe cover c) Repeat the test when the room temperature is within 50°F to 104°F	
4	If you saw the following message on the meter's display, what action should you take?  a) Replace the battery b) Replace a new probe cover c) Repeat the test when the room temperature is within 50°F to 104°F	
5	The FORA IR20b Thermometer should be stored: a) At 39.2°F to 104°F (4°C to 40°C), below 85% humidity b) At -4°F to 140°F (-20°C to 60°C), below 95% humidity c) In the freezer	

Training Completed by:

Name of Trainee	Date	SCORE

Answers:

1.(a) 2.(a) 3.(a) 4.(b) 5.(b)

FORA[®] IR20

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