

INTRODUCTION

Thank you for choosing **FORA IR20** ear thermometer. This innovative medical device relies on advanced infrared (IR) technology to measure temperature instantly.

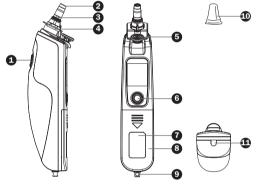
INTENDED USE

FORA IR20 ear thermometer is intended for the intermittent measurement and monitoring of human body temperature from ear canal. The device is intended for use by people of all ages for home and professional use.

HOW DOES IT WORK

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

APPEARANCE AND KEY FUNCTIONS OF THE THERMOMETER



- Scan Button
- 2 Probe Lens
- Probe
- Probe Cover Detector
- Probe Cover Ejection Button
- 6 On/Memory Button
- Manufacturing Label
- **8** Battery Cover
- Hook (for FORA IR20d)
- 1 Probe Cover
- Bluetooth Indicator (for FORA IR20b)

IMPORTANT SAFETY INSTRUCTIONS

READ THIS BEFORE USE. KEEP THESE INSTRUCTIONS IN A SAFE PLACE.

The following basic safety precautions should always be taken.

- 1. Close supervision is necessary when the thermometer is used by, on, or near children, handicapped persons or invalids.
- 2. Use the thermometer only for the intended use described in this manual.
- 3. Do not use the thermometer if it is not working properly, or if it has suffered any damage.
- ${\bf 4.} \ \ {\bf Do} \ \ {\bf not} \ \ {\bf use} \ \ {\bf accessories} \ \ {\bf which} \ \ {\bf are} \ \ {\bf not} \ \ {\bf supplied} \ \ {\bf or} \ \ {\bf recommended} \ \ {\bf by} \ \ {\bf the} \ \ {\bf manufacturer}.$
- Proper maintenance is essential to the longevity of your device. If you are concerned about your accuracy of measurement, please contact the local customer service or place of purchase for help.

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 $^{\circ}$ F to 140 $^{\circ}$ F (-20 $^{\circ}$ C to 60 $^{\circ}$ C); relative humidity less than 95%. Avoid direct sunlight.
- Avoid dropping the thermometer.
- $\bullet\,$ Use only FORA IR20 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.
- $\bullet\,$ 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.

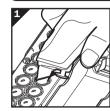
NOTE: Never try to clean inside your ears. You may accidentally damage the eardrum or its surrounding tissues. Remove excess earwax only when you can reach it with a clean cloth. Consult a physician if you suspect the presence of excess earwax.

LCD SCREEN



- 1 Temperature Scanning In Progress
- 2 Temperature Reading
- Memory Mode
- 4 Record Numbers
- **5** Low Battery Indicator
- **6** Temperature Unit
- **7** Communication Symbol (for FORA IR20b)
- **8** No Probe Cover Detected
- Ear Temperature Indicator

USING THE DEVICE





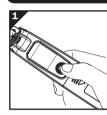
Replacing the Probe Cover

- 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.

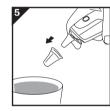
MEASURING TEMPERATURE











- **1.** Press and release the On/Memory button to turn on the thermometer. When ready, the thermometer displays the last measurement.
- ${\bf 2.}$ 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. " \mathfrak{F} " is shown together with a temperature value (" $((\bullet))$ " for IR20b only).
- ${\bf 5.}$ 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.

RESULT INDICATORS

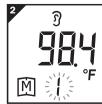
Temperature ≤ 89.5°F (31.9°C)	"Lo" with red backlight
89.6°F (32°C) ≤ Temperature < 100.3°F (37.9°C)	Result with green backlight
100.4°F (38°C) ≤ Temperature < 109.4°F (43°C)	Result with red backlight
Temperature ≥ 109.5°F (43.1°C)	"Hi" with red backlight

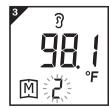
HINTS ON TAKING TEMPERATURES

- 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 temperature.
- 3. To take accurate readings, the ear must be free from excessive earwax build-up.

RECALLING THE MEMORY







Your thermometer stores last 10 readings in the memory.

- 1. Be sure the thermometer is OFF before recalling the memory.
- ${\bf 2.\ Press\ the\ On/Memory\ button\ to\ turn\ on\ the\ thermometer.}$

- 3. Press the On/Memory button for 3 seconds to enter memory mode. Each time you press the On/Memory button, a result will be displayed in the order of dates (latest result shown first), together with "M" and 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 On/Memory button again to return to the first one.
- 4. Exit the memory. Press On/Memory button again, and then the LCD will show "OFF" to exit memory.

VIEWING RESULTS ON A MOBILE DEVICE (FOR FORA IR20b)

You can transmit your data from the meter to your devices (e.g. smart phone, tablet, PC...) via Bluetooth. Please contact your local customer service or place of purchase for assistance. Please note that you must complete the pairing between the meter and Bluetooth receiver before transmitting data.

Pairing with your mobile device

- 1. On your mobile device, turn on the Bluetooth function and follow the pairing instructions inside of the APP (e.g., scan for the meter to add it into APP).
- 2. After each measurement, the Bluetooth will be turned on automatically to transmit data to APP.

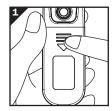
Bluetooth indicator on the meter

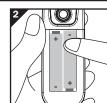
Bluetooth Indicator	Status
Flashing Blue	The Bluetooth function is enabled and waiting for connection.
Solid Blue	The Bluetooth connection is established.

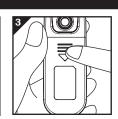
WARNING:

- While the meter is in transmission mode, it will be unable to perform a test.
- Make sure your device with iOS (6 or above) or Android System (4.3 or above) has turned on Bluetooth before transmitting the data and the meter is within the receiving range.

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
- 2. Place the new batteries in the battery compartment and press it in until the batteries are secured.
- 3. Reattach the battery cover.

NOTE:

- \bullet Although the thermometer works when " $\begin{picture}(1,0) \put(0,0){\line(0,0){100}} \put(0,0$ batteries to obtain an accurate result.
- Remove the batteries if stored for a long period of time.
- The batteries should be kept out of children. If they are swallowed, promptly see a doctor for help.
- Properly dispose of the batteries.

ABOUT NORMAL BODY TEMPERATURE & FEVER

Body temperature can vary from person to person. It also varies on different part 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 parts, even at the same time, should not be directly

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

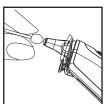
acetaminophen), or persons with certain chronic illnesses. Please consult your physician when you

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,

CARE & 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.

TROUBLESHOOTING

All error messages below would be shown together with 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
Err. I Err.2	Appear 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).
X	No probe cover detected.	Ensure the probe cover is fitted on firmly, or replace it with a new one.
Err.4 Err POS	Thermometer errors.	Review the instructions and re-start the measurement procedure. If the problem persists, please contact your dealer.
Err.5	Appears when the batteries can't provide enough power for a test.	Replace the old batteries with new ones immediately.

SPECIFICATIONS

Dimensions: 165 mm x 32.4 mm x 38.7 mm

Battery: 2 x 1.5 V AAA alkaline batteries External Output: Bluetooth (For FORA IR20b)

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 ±0.4°F (±0.2°C) for the range of 96.8°F to 102.2°F (36.0°C to 39.0°C)

 $\pm 0.5\,^{\circ}$ F ($\pm 0.3\,^{\circ}$ C) from 89.6 $^{\circ}$ F to 96.6 $^{\circ}$ F (32.0 $^{\circ}$ C to 35.9 $^{\circ}$ C) and from 102.4 $^{\circ}$ F to 109.4 $^{\circ}$ F (39.1 $^{\circ}$ C to

Temperature Unit: °F

Operating Temperature Range: $60.8\,^{\circ}\text{F}$ to $104\,^{\circ}\text{F}$ ($16\,^{\circ}\text{C}$ to $40\,^{\circ}\text{C}$)

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.

REFERENCE STANDARDS

Device Standard: Device Corresponds to the requirements of the standard for infrared thermometers. ASTM E1965-98, EN 12470-5, EN 60601-1-2:2007/AC:2010, EN 60601-1-4:1996, EN 60601-1-6:2010.

Electromagnetic Compatibility: Device fulfills the stipulations of the standard EN 60601-1-2.

The stipulations of EU-Directive 93/42/EEC for Medical Devices Class IIa have been fulfilled.

FEDERAL COMMUNICATIONS COMMISSION (FCC) STATEMENT

15.21

You are cautioned that changes or modifications not expressly approved by the part responsible for compliance could void the user's authority to operate the equipment.

15.105(b)

ssion (FCC) Statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in ac-cordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- · Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- 1. This device may not cause harmful interference and
- 2. This device must accept any interference received, including interfer-nence that may cause undesired operation of

FCC RF Radiation Exposure Statement:

- 1. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter
- 2. This equipment complies with FCC RF radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with a minimum distance of 20 centimeters between the radiator radiation

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Read instructions before use.

ForaCare, Inc.

893 Patriot Dr., Suite D, Moorpark, CA 93021 USA

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Toll Free: 1-888-307-8188 (7:00 am - 6:00 pm PST, Mon.-Fri.)

For assistance outside of these hours, please contact your healthcare professional.

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