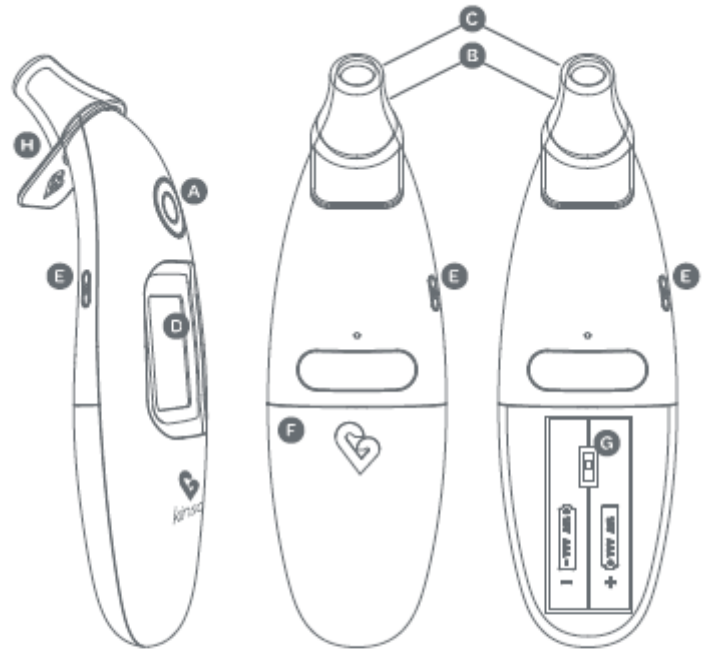


Kinsa Smart Ear Thermometer™ Instructions For Use

Thank you for purchasing the Kinsa Smart Ear Thermometer™, a professionally accurate instrument for fast and easy temperature taking in the ear. Please read these instructions carefully to ensure accurate temperatures and safe operation.

Your Kinsa Smart Ear Thermometer is designed for use with or without a mobile device. For the full experience including features such as symptom tracking and fever guidance, download the Kinsa app on the iTunes or Google Play store and connect your thermometer to your mobile device. To see the full list of supported devices, see kinsahealth.com/devices.



- A** Power On/Start button
- B** Probe
- C** Probe tip
- D** Display
- E** Bluetooth pairing button
- F** Battery door
- G** °C/°F switch
- H** Protective cap
- I** Kinsa mobile app

Indications For Use

The Kinsa Smart Ear Thermometer is intended to measure the human body temperature in the ear. This device is reusable for clinical or home use on both adults and children.

Warnings And Precautions

- This thermometer functions with Apple and Android mobile devices. Please see kinsahealth.com/devices for the full list of supported devices.
- Clean the probe before and after use.
- Never use the thermometer for purposes other than body temperature measurement. Please follow the safety precautions when using on children.
- The operating ambient temperature range for this thermometer is 59 - 104 °F (15 - 40 °C).
- Do not expose the thermometer to temperature extremes: (below -13 °F / -25 °C or over 131 °F / 55 °C) or excessive humidity (>95% RH).
- Use of this thermometer is not intended as a substitute for consultation with your physician.
- High, prolonged fever requires medical attention. Be sure to contact your physician.
- The thermometer is water resistant, not waterproof. Never dip the thermometer into water or other liquids. Do not boil the probe. For cleaning and disinfecting, please see [Cleaning and Storage](#).
- Keep out of reach of unattended children. Do not allow children to walk or run while taking a temperature.

Features of your Kinsa Smart Ear Thermometer

- Fast 1 second reading.
- Meets ASTM & ISO standards for professional accuracy.
- Gentle and easy to use in the ear.
- No probe covers needed.
- Conveniently displays in °F or °C.
- Water resistant, for safe cleaning.
- Use with or without your mobile device. Connects via Bluetooth Low Energy.
- Additional Smart functionality available through Kinsa app.

Body Temperature

Temperature readings vary from person to person, by age, time of day, and by site of measurement. For example, core body temperature often decreases with age. The best method to determine your own normal temperature is to use the thermometer when you are feeling well. Record your temperature twice a day (early morning and late afternoon) using the Kinsa app. Take the average of the two temperatures. This is considered your normal body temperature. Any variation from it may indicate some sort of illness and you should consult your physician.

Why Measure in the Ear?

Ear temperatures accurately reflect core body temperature, since the ear drum shares a blood supply with the temperature control center in the brain: the hypothalamus.¹ The Kinsa Smart Ear Thermometer monitors the infrared heat radiated from the eardrum and surrounding tissue and detects once an accurate temperature measurement has been taken.

¹ Netter HF, Atlas of Human Anatomy, Novartis Medical Education, East Hanover, NJ, 1997, pp 63, 95

To Set Up Your Thermometer For First Time Use



1. Download the Kinsa app from the iTunes App Store or Google Play. The app can also be downloaded by going directly to kinsahealth.com/download. Please see kinsahealth.com/devices for the full list of supported devices.



2. Enable Bluetooth on your mobile device.



3. Tap the "Kinsa" app icon on your home screen to open the application.



4. Open the battery door. Use the °C/°F switch to select the temperature scale for your display.



5. Insert two AAA batteries (included) into the thermometer. Snap battery door into place.



6. Tap the Power/Start button to turn on the thermometer.



7. The Kinsa app should automatically detect your Kinsa Smart Ear Thermometer. Your mobile device will ask for permission to pair with the thermometer. Select "Yes".



8. Your thermometer is now successfully connected to your mobile device. For future temperature readings, open the Kinsa app to automatically sync readings to your mobile device and assign to individual family members, add notes or symptoms/medications, and see fever guidance.

To Set Up Your Thermometer with Additional Mobile Devices



1. Download the Kinsa app from the iTunes App Store or Google Play.



2. Enable Bluetooth on your mobile device.



3. Tap the "Kinsa" app icon on your home screen to open the application.



4. On the thermometer, press and hold the Bluetooth pairing button for 3 seconds.




5. Your mobile device will ask for permission to pair with the thermometer. Select "Yes".



6. Your thermometer is now successfully connected to your additional mobile device(s).

Taking a Temperature

1. Tap the Power/Start button  to turn on the thermometer. You will hear a beep when the thermometer is ready to take a temperature. *During an internal self-check, the display shows all segments. The thermometer will be ready for temperature taking when the screen shows three dashes.*



2. Fit the probe snugly into the ear canal then push and release the Power/Start button.
 - a. For infants under the age of 1, gently tug the ear straight back to straighten the ear canal and ensure an accurate temperature reading.
 - b. For children over the age of 1 and adults, gently tug the ear straight up and back.

3. A beep will indicate when the temperature measurement is successfully completed. Temperature readings typically take 1 second.

102.5°








4. The temperature reading will be shown on the illuminated display. A smiley face will indicate a low, medium, or high temperature.
5. The thermometer will automatically turn off after 30 seconds of inactivity. The display will briefly flash OFF and it will go blank.

NOTE: Always take measurements in the same ear since temperature readings may differ from the right and left ear.

Kinsa recommends taking your temperature three times in the same ear and using the highest of those readings. This is especially important if you meet the following criteria:


- ① Newborn infants in the first 100 days.
- ② Children under three with a compromised immune system
- ③ Individuals unfamiliar with this thermometer

Understanding Your Thermometer Display

DISPLAY	SITUATION	SOLUTION
Bluetooth icon, blinking 	No mobile device paired	Download the Kinsa app & enable Bluetooth on your mobile device. Turn on the thermometer while the app is open and follow pairing instructions.
Phone with comment icon, blinking 	Thermometer has stored temperatures or messages to send to app	Open Kinsa app.
Battery icon, one section 	Battery is low but thermometer will still operate correctly	Insert new batteries.
Battery icon, empty, blinking 	Battery is critically low and may not operate correctly	Insert new batteries.
ERR 	Ambient temperature is not within allowed operating range (59-104 °F or 15-40 °C)	Allow the thermometer to remain for 30 minutes where temperature is within ambient range.
HI / LO 	Temperature taken is not within typical human temperature range (93.2-108 °F or 34-42.2 °C) HI = too high LO = too low	Make sure the probe tip and lens are clean. Make sure the thermometer is properly inserted. Then, take a new temperature. If you continue to encounter an error, contact Kinsa Customer Support.

Changing The Temperature Scale

If you wish to change the temperature scale of your thermometer:

1. Open the battery door 
2. Remove batteries
3. Use the °C/°F switch  to select the temperature scale for your display
4. Replace batteries and battery door



NOTE: temperature scale in app can be changed within app settings.

Cleaning And Storage

The probe tip is the most delicate part of the thermometer. It must be clean and intact to ensure accurate readings. To clean the probe tip, gently wipe the surface with a cotton swab or soft cloth moistened with rubbing alcohol.



If the probe tip is damaged, please contact Customer Support.

Use a soft, dry cloth to clean the thermometer display and exterior. Do not use abrasive cleaners. Never submerge this thermometer in water or any other liquid. Store thermometer in a dry location free from dust and contamination and away from direct sunlight.

Replacing The Batteries

The thermometer is supplied with two AAA batteries. To ensure accurate temperatures, replace batteries when they are low. A low battery will be indicated on the display with a flashing icon.



Open the battery door. Remove old batteries and replace with new batteries, making sure the poles are in the right direction. Snap battery door into place.



To protect the environment, dispose of the product and empty batteries at your retail store or at appropriate collection sites according to national or local regulations.

Calibration

This thermometer is initially calibrated at the time of manufacture. If this thermometer is used according to the use instructions, periodic re-adjustment is not required. If at any time you question the accuracy of temperature measurements, please contact Customer Support.

Product Specifications

Displayed temperature range:	93.2 °F – 108 °F (34 °C – 42.2 °C)
Operating ambient temperature range:	59 °F – 104 °F (15 °C – 40 °C)
Display resolution:	0.1 °F or °C
ACCURACY FOR PATIENT TEMPERATURE RANGE	
95.0 °F – 107.6 °F (35 °C – 42 °C):	± 0.4 °F (± 0.2 °C)
Outside this range:	± 0.7 °F (± 0.4 °C)
LONG TERM STORAGE RANGES	
Temperature:	-13 °F to 131 °F (-25 °C to 55 °C)
Humidity:	15 – 95 % RH (non-condensing)
OTHER	
Battery type:	Two AAA batteries
Battery life:	Approx 2 years
Bluetooth:	Bluetooth Low Energy v4.0

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 accordance 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 of the following measures:

1. Reorient or relocate the receiving antenna.
2. Increase the separation between the equipment and receiver.
3. Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
4. Consult the dealer or an experienced radio/TV technician for help.
5. FCC Caution: To assure continued compliance, (example – use only shielded interface cables when connecting to computer or peripheral devices). Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.
6. 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 interference that may cause undesired operation.
7. This device complies with FCC radiation exposure limits set forth for an uncontrolled environment. End users must follow the specific operating instructions for satisfying RF exposure compliance. This transmitter must not be collocated or operating in conjunction with any other antenna or transmitter.

This thermometer conforms to the following standards:

ASTM Standard E 1965-98/2009 Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature

EN 12470-5: 2003 «Clinical thermometers» – Part 5: Performance of infrared ear thermometers (with maximum device)

IEC/EN 60601-1: 3/96 «Medical electrical equipment» – Part 1: General requirements for safety

IEC/EN 60601-1-2:2014 «Medical electrical equipment» – Part 1-2: General requirements for safety - electromagnetic disturbances and electromagnetic emissions

IEC 60601-1-11:2010 «Medical electrical equipment» – Part 1-11: General requirements for basic safety and essential performance - Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

FCC Rules - This device complies with part 15 of 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 interference that may cause undesired operation.

Manufactured By:

Kinsa, Inc
222 Broadway, 19th Fl
New York, NY 10038
www.kinsahealth.com
Customer Support: support@kinsahealth.com

 **EMERGO EUROPE**
Molenstraat, 15
The Hague, 2513 BH
The Netherlands










Limited Warranty:

Kinsa, Inc warrants this product against any defects that are due to faulty material or workmanship for a period of one year from the original date of consumer purchase or receipt as a gift. This warranty applies when used for normal household use in accordance with the Instructions for Use and excludes the battery and damage to the product resulting from accident or misuse. This product is not warranted when used in a professional environment.

In no event shall Kinsa, Inc be liable for any special, incidental, indirect, or consequential damages in connection with the purchase or use of this product or costs over the original cost of the product.

If the product should not perform to specifications within the warranty period, please contact Customer Support.

Explanation of Symbols

-  Consult instructions for use
-  Manufacturer batch code
-  Product contains no latex
-  Temperature limitation
-  Catalogue number
-  Type BF applied part
-  Humidity limitation
-  Non-sterile
-  Do not use if product is broken, damaged, or open

IP22 basic safety and essential performance requirements

CE₀₁₂₀
L-10252 Rev A
 A-10240

 
© Copyright 2015 Kinsa, Inc.
For patents: kinsahealth.com/patents