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 optimized for use with the free Kinsa app, but can be used alone as well. For the full experience including features such as symptom tracking and fever guidance, download the app on the App Store or Google Play store and connect your thermometer to your mobile device. For the full list of supported devices, see **kinsahealth.com/phones**.

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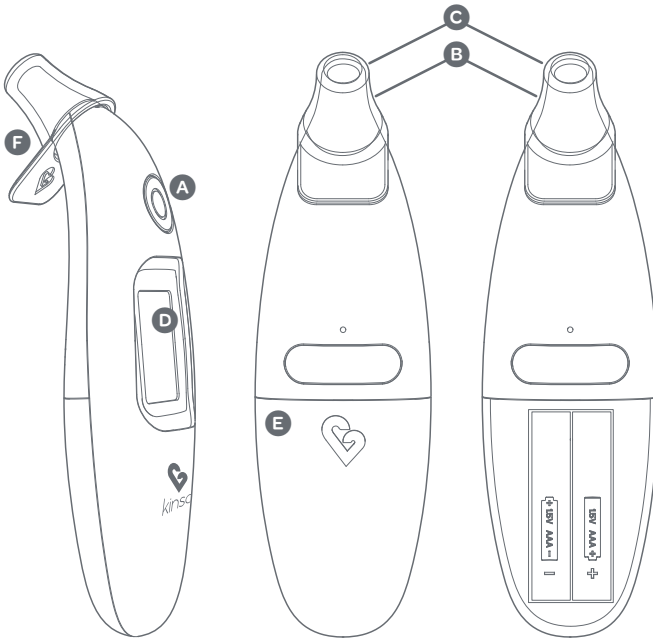
Product Description



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- **A** Power/Start button
- **B** Probe
- **C** Probe tip
- **D** Display
- **E** Battery door
- **F** Protective cap
- **G** Kinsa mobile app

Intended 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 older than 1 year old.

Warnings And Precautions

- This thermometer uses Bluetooth Low Energy 4.1 to communicate with Apple and Android mobile devices. Please see kinsahealth.com/phones 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 60.8 - 104 °F (16 - 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.
- Do not store the unit in direct sunlight or at high temperatures.
- Kinsa recommends using a password on your smartphone to protect your information
- WARNING Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to SmartEar. Otherwise, degradation of the performance of this equipment could result.
- WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Power line magnetic fields (in excess of 3A/m) should be kept at a distance to reduce the likelihood of interference. Warning keep DEVICE away from sources of high levels of power line magnetic fields (in excess of 30 A/m) to reduce the likelihood of interference
- Do not mix alkaline, standard or rechargeable batteries.
- Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this device.

Features of your Kinsa Smart Ear Thermometer

- Fast 1.5 second reading. Meets ASTM 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 eardrum 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 H F, Atlas of Human Anatomy, Novartis Medical Education, East Hanover, NJ, 1997, pp 63, 95.

To Set Up Your Thermometer For First Time Use

1. Open the battery door ⓔ.

2. Insert two AAA batteries (included), making sure the poles are in the right direction, into the thermometer. Snap battery door into place.

3. Enable Bluetooth on your mobile device.

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

5. Launch the Kinsa app. (The app will be on your Home screen or in your Apps folder depending on type of mobile device.)

6. Turn the thermometer on and follow the prompts to install.

7. 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 guidance.

Having trouble?

Your thermometer will display APP until it is connected with the Kinsa app. If your thermometer won't connect to the app, you can activate it on its own by turning it on and pressing the big white button 2 times in rapid succession. Note: viewing temperature history or receiving guidance will not be possible until the thermometer has been connected to the app. For additional support, contact Customer Happiness at *kinsahealth.com/contactus*

To Set Up Your Thermometer with Additional Mobile Devices

1. If you have the original phone, open Kinsa, go to “More,” select the thermometer to remove and choose “Forget Thermometer.”

2. On the additional mobile device, repeat Steps 3 through 7 above.

3. Your thermometer is now successfully connected to an additional mobile device.

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. First, gently tug the ear straight up and back. Next, fit the probe snuggly into the ear canal. Be sure to position the probe so that it is pointing toward the center of the head. Once in position, push and release the Power/Start button.

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

4. The temperature reading will be shown on the illuminated display. A smiling face icon indicates that the temperature is normal while a neutral or frowning face indicates a mild or high fever, respectively.

5. The thermometer will automatically turn off after 30 seconds of inactivity. The display will briefly flash OFF and it will go blank. You can also hold down the button to power off.

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 Children under three with a compromised immune system
② Individuals unfamiliar with this thermometer

Understanding Your Thermometer Display

DISPLAY		SITUATION	SOLUTION
Battery icon, empty, blinking		Battery is critically low and may not operate correctly	Insert new batteries.
Battery levels:		2 bars = 20–40% battery 1 bar = 5–20% battery 0 bars = less than 5% battery	
UPD	UPd	Firmware update in progress.	
APP	APP	Connect to Kinsa app.	
ERR	Err	Problem detected, check the app for details.	
Happy Face	☺	≥ 96.9°F (36.1°C) and < 100°F (37.8°C)	
Neutral Face	😐	≥ 100°F (37.8°C) and < 102.6°F (39.2°C)	
Sad Face	☹	≥ 102.6°F (39.2°C)	

Changing The Temperature Scale

If you wish to change the temperature scale of your thermometer, turn your thermometer on and then press the big white button two more times in rapid succession.

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

Replacing the Battery

The Kinsa Smart Ear thermometer is powered by 2 AAA batteries. The low battery icon displays when power is low. To protect the environment dispose of empty batteries at appropriate collection sites according to national or local regulations. Keep out of reach of young children, elderly, and pets. To replace the batteries:

1. Open the back battery cover by pressing on the Kinsa logo and applying downward pressure to slide it off.
2. Remove the old batteries and replace with new ones. Make sure the the batteries are in the correct polarity direction.
3. Close the battery cover.

Cleaning And Storage

To ensure your Smart Ear thermometer is recording accurate temperatures, it is very important to keep the probe sensor tip clean. To clean the probe tip, gently wipe it with a cotton swab or soft cloth moistened with alcohol. Gently circle the alcohol wipe around the inner sensor area at the tip of the Smart Ear. Be sure to clean the inner flat surface of the sensor - not just the rim. Never submerge your Kinsa or put it in boiling water or a dishwasher.

Keep the protective cap snapped onto the top of the thermometer when not in use to protect the tip from damage.

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:	60.8 °F – 104 °F	(16 °C – 40 °C)
Display resolution:	0.1 °F or °C	
ACCURACY FOR PATIENT TEMPERATURE RANGE	MAXIMUM LABORATORY ERROR	
95.0 °F – 107.6 °F (36 °C – 39 °C):	±0.4 °F	(±0.2 °C)
Outside this range:	±0.6 °F	(±0.3 °C)
LONG TERM STORAGE RANGES		
Temperature:	–4 °F to 122 °F (–20 °C to 70 °C) at water vapor pressure up to 50 hPa	
Humidity:	0 – 95 % RH (non-condensing)	
OTHER		
Battery type:	Two AAA batteries	
Battery life:	Approx 2 years	
Bluetooth:	Bluetooth Low Energy v4.1	
Operation Time/Number of procedures:	5000 uses or approx. 3 years	
Service Life:	5 years	

This thermometer conforms to the following standards:

ASTM Standard E 1965-98:2009 Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature
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 Note: This device complies with part 15 of the FCC Rules. Operationis 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. 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, which could theoretically cause harmful interference to radio communications. 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: increase the separation between the equipment and receiver, consult the dealer or an experienced radio/TV technician for help, or contact Kinsa customer support.
The equipment is suitable for use in domestic establishments and is tested to CISPR emissions Class B Group 1 as well a home healthcare immunity criteria found in IEC 60601-1-2 Table 4, 6, and Table 9. During the IEC 60601-1-2 immunity tests performed the thermometer will accurately measure temperature or display an error. Smart Ear utilizes Bluetooth Low Energy (BLE), which uses the 2.4 GHz ISM band. BLE operates between 2.402 and 2.480 GHz. Smart Ear transmits less than 0 dBm effective radiated power. To protect the environment, dispose of empty batteries at appropriate collection sites according to national or local regulations. Keep out of reach of young children, elderly and pets.

Manufactured By:

Kinsa, Inc
535 Mission Street, 18th Fl
San Francisco, CA 94105
www.kinsahealth.com
Customer Support: support@kinsahealth.com

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 warrantied 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
Temperature limitation
Humidity limitation
LOT Manufacturer batch code
REF Catalogue number
NON STERILE Non-sterile
Type BF applied part
Do not use if product is broken, damaged, or open
IP22

0120 REF L-10280 Rev A1 A-10240

FCC ID: 2AFEOE2

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For patents: kinsahealth.com/patents