KET-005 Kinsa Smart Ear Thermometer™ Instructions For Use

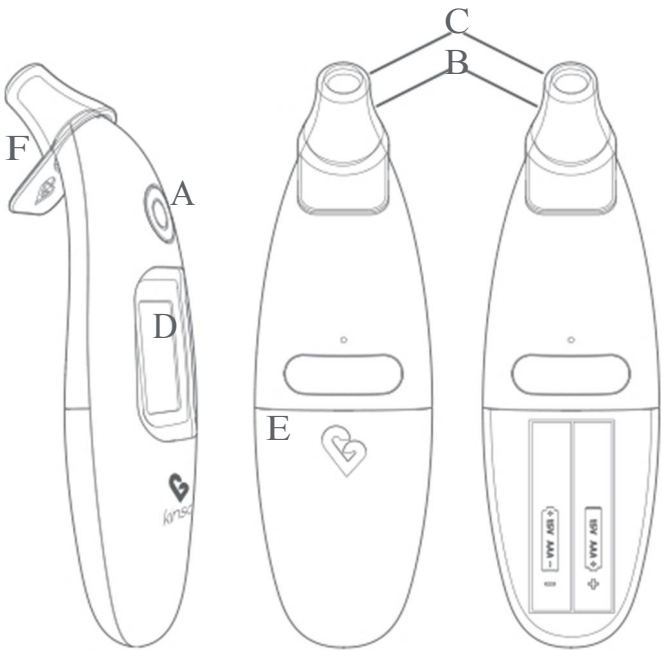
Thank you for purchasing the KET-005 Kinsa Smart Ear Thermometer™, a professionally accurate instrument for fast and easy temperature taking in the ear. Please read these instructions carefully to ensure accurate temperatures and safe operation.

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**.

kinsa™

Feel Better.

Product Description



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Available on the App Store

GET IT ON Google play

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.

Warnings And Precautions

- This thermometer functions with most 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 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.
- Kinsa recommends using a password on your smartphone to protect your information.
- The patient is an intended operator.
- Do not perform maintenance and checks during operation.
- The ear thermometer with installed probe cover is considered an applied part and has been tested and evaluated accordingly.

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.

The ear thermometer may be used by children only under adult supervision. Measurement is usually possible over the age of 6 months. In infants under 6 months, the ear canal is still very narrow so the temperature of the eardrum often cannot be recorded and the result displayed is often too low.

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.

To Set Up Your Thermometer For First Time Use

1. Open the battery door E.

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.

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.

Tips for Measuring Human Temperature

Bear in mind that the thermometer needs to have been in the room in which the measurement is taken for at least 30 minutes before use.

- Some people produce different readings in their left and right ear. In order to record temperature changes, always measure a person's temperature in the same ear.
- The ear thermometer may be used by children only under adult supervision. Measurement is usually possible over the age of 6 months. In infants under 6 months, the ear canal is still very narrow so the temperature of the eardrum often cannot be recorded and the result displayed is often too low.
- The measurement must not be taken in an ear affected by inflammatory diseases (e.g. discharging pus or secretion), after possible ear injuries (e.g. eardrum damage) or in the healing period after operative procedures. In all of these cases, please consult your doctor.
- Use of the thermometer on different persons can be inappropriate in the event of certain acute infectious diseases because of the possible spread of germs despite cleaning and disinfection. If you have any doubts, please consult your doctor.
- This thermometer may only be used without a disposable protective cover.
- If you have been lying on one ear for some time, the temperature is slightly raised. Wait a little while or measure in the other ear.
- As ear wax can affect the measurement, you should clean the ear before measuring if necessary.

Taking a Temperature

1. Tap the Power/Start button A 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.

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 = 40% battery	
	1 bar = 20% battery	
	0 bars = 5% battery	
HI 	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.
APP	Connect to Kinsa app.	Please refer to the set up process.
ERR	The operating temperature is not in the range 15°C–40°C	Operate the thermometer only between the specified temperature ranges.

Kinsa App Set Up Process

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.

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.

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.

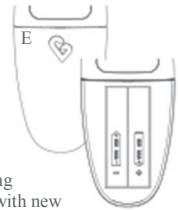
Keep the protective cap snapped onto the top of the thermometer when not in use to protect the tip from damage.

Replacing the Battery

The Kinsa Smart Ear thermometer is powered by 2 AAA batteries. The low battery icon displays when power is low.

To replace the batteries:

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



Close the battery cover.

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.

Note: For long durations of non-operation, please remove all batteries from the device. Batteries should be disposed of in accordance with local environmental and institutional policies.

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:	93.9 °F – 108 °F (34.4 °C – 42.2 °C)
Operating ambient temperature range:	59°F – 104 °F (15 °C – 40 °C)
Operating relative humidity:	0-95%RH (non-condensing)
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)
Typical Service Life : 3 years	
Temperature of Storage and Transporation Range:	–4 °F to 122 °F (–20 °C to 50 °C)
Humidity of Storage and Transporation Range:	0 – 95 % RH (non-condensing)
Batterytype:	Two AAA batteries
Batterylife:	Approx 2 years
Bluetooth:	Bluetooth 5
Operating、Transport & Storage Atmospheric Pressure:	700hPa~1060hPa
Guarantee of Quality:	Complies with ASTM E 1965-98, IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11

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.

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.

This 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 -2 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. FCC WARNING: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

FEDERAL COMMUNICATIONS COMMISSION INTERFERENCE 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 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.

RF exposure warning
The equipment complies with FCC RF exposure limits set forth for an uncontrolled environment.
The equipment must not be co-located or operating in conjunction with any other antenna or transmitter.

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

 Manufacturer batch code

 Product contains no latex

 Temperature limitation

 Catalogue number Non-

 Type BF applied part

 Humidity limitation

 sterile

 Do not use if product is broken, damaged, or open

 Dust and water rating

 FCC ID:2AFEOSE3

L-10252 Rev A

For patents: kinsahealth.com/patents

Manufacturer's declaration-electromagnetic emissions		
The Kinsa Smart Ear Thermometer is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the Kinsa Smart Ear Thermometer should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment-guidance (for home healthcare environment)**
RF emissions CISPR 11	Group 1	The Kinsa Smart Ear Thermometer uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Kinsa Smart Ear Thermometer is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Not applicable	

Manufacturer's declaration-electromagnetic immunity

The Kinsa Smart Ear Thermometer is intended for use in the electromagnetic environment (for home healthcare) specified below.

The customer or the user of the Kinsa Smart Ear Thermometer should assure that it is used in such an environment.

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment-guidance (for home healthcare environment)**
Electrostatic discharge(ESD) IEC 61000-4-2	Contact:±8 kV Air±2 kV,±4 kV,±8 kV,±15 kV	Contact:±8 kV Air±2 kV,±4 kV,±8 kV,±15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/output lines	Not applicable Not applicable	Mains power quality should be that of a typical home healthcare environment.
Surge IEC 61000-4-5	± 0.5kV, ±1kV line(s) to line(s) ± 0.5kV, ±1kV,± 2kV line(s) to earth	Not applicable Not applicable	Mains power quality should be that of a typical home healthcare environment.
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage dips: 0 % U_T; 0,5 cycle 0 % U_T; 1 cycle 70 % U_T; 25/30 cycles Voltage interruptions: 0 % U_T; 250/300 cycle	Voltage dips: Not applicable Not applicable Not applicable Voltage interruptions: Not applicable	Mains power quality should be that of a typical home healthcare environment. If the user of the Kinsa Smart Ear Thermometer requires continued operation during power mains interruptions, it is recommended that the Kinsa Smart Ear Thermometer be powered from an uninterruptible power supply or a battery.
Power frequency(50, 60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz and 60 Hz	The Kinsa Smart Ear Thermometer power frequency magnetic fields should be at levels characteristic of a typical location in a typical home healthcare environment.

NOTE UT is the a.c. mains voltage prior to application of the test level.

Manufacturer's declaration-electromagnetic immunity			
The Kinsa Smart Ear Thermometer is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the Kinsa Smart Ear Thermometer should assure that it is used in such and environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment-guidance (for home healthcare environment)**
Conducted RF IEC 61000-4-6	3 Vrms: 0,15 MHz – 80 MHz 6 Vrms: in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	Not applicable Not applicable	**Portable and mobile RF communications equipment should be used no closer to any part of the** Kinsa Smart Ear Thermometer including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	**Recommended separation distance:** $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ 80MHz to 800 MHz $d = 2,3\sqrt{P}$ 800MHz to 2,7 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Recommended separation distance between
portable and mobile RF communications equipment and the Kinsa Smart Ear Thermometer

The Kinsa Smart Ear Thermometer is intended for use in an electromagnetic environment (for home healthcare) in which radiated RF disturbances are controlled. The customer or the user of the Kinsa Smart Ear Thermometer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Kinsa Smart Ear Thermometer as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1,2\sqrt{P}$	**800 MHz to 2,7 GHz** $d = 2,3\sqrt{P}$
0,01	N/A	0,12	0,23
0,1	N/A	0,38	0,73
1	N/A	1,2	2,3
10	N/A	3,8	7,3
100	N/A	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Manufacturer's declaration-electromagnetic immunity

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

The Kinsa Smart Ear Thermometer is intended for use in the electromagnetic environment (for home healthcare) specified below.

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Test frequency (MHz)	**Band** a) (MHz)	**Service** a)	**Modulation** b)	**Maximum power** (W)	**Distance** (m)	**IMMUNITY TEST LEVEL** (V/m)	**Compliance LEVEL** (V/m) (for home healthcare)
385	380 –390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27	27
450	430 – 470	GMRS 460, FRS 460	FM c) ±5 kHz deviation 1 kHz sine	2	0,3	28	28
710	704 – 787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0,2	0,3	9	9
745							
780							
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0,3	28	28
870							
930							
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 217 Hz	2	0,3	28	28
1 845							
1 970							
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0,3	28	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9	9
5 500							
5 785							

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.