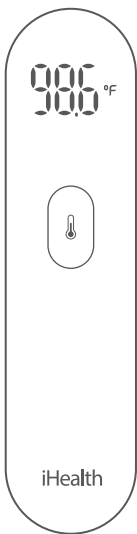


iHealth® PT3SBT

Wireless No-Touch Forehead Thermometer



OWNER'S MANUAL

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Introduction

Thank you for choosing our product.

This product is a high-tech infra-red (IR) thermometer designed to take human body temperature by measuring the energy of IR emitted from the forehead and it can transmit the temperature to a smart device with Bluetooth. The product will help you to assess you and your family members' health conditions easily and quickly.

Product Name: Wireless No-Touch Forehead Thermometer

Product Model: PT3SBT

Indications for Use

The Wireless No-Touch Forehead Thermometer is intended for the intermittent measurement of body temperature from the forehead on people of all ages. It can transmit the temperature to a smart device with Bluetooth and can be used by consumers in the household environment and by healthcare providers.

Safety Precautions

Warning

- Use of this thermometer is not intended as a substitute for consultation with your physician. Please consult your doctor if you have any doubt about the temperature reading.
- Keep the thermometer out of reach of children. For accidental swallowing of the battery or other components, please contact emergency services immediately.
- Batteries must not be thrown into an open fire or short circuited.

Caution

(1) Measurements

1. Thermometer readings should be regarded as a reference. Do not attempt self-diagnostics or self-treatment using the temperature readings. Please seek professional medical advice when necessary.
2. There is no absolute standard for human body temperature. Knowing your own normal body temperature range is important to accurately determine if you have a fever.
3. Make sure that the forehead of the subject is free from sweat, cosmetics, dirt, or grease before measuring.
4. Patients should not drink, eat, or be physically active before/while taking a reading. Wait 30 minutes before taking a measurement. Temperature readings taken when a body is in a state of stable equilibrium is more accurate and useful as a reference.
5. Do not take temperature measurement over scar tissue, open sores or abrasions.
6. Do not measure body temperature from scar tissues on the forehead as such tissues will affect temperature conduction of the body.
7. If there is a temperature difference between the thermometer storage area and the new ambient environment around the subject, please let the thermometer sit within the new environment for 30 minutes before taking the measurement.

8. Do not measure body temperature immediately after consuming a drug that raises body temperature. Temperature readings taken at this time will not be accurate.
9. It is normal for readings taken from continuous measurements to fluctuate within a small range. During continuous measurements, the subject's body temperature may be transmitted to the thermometer, affecting measurement accuracy. We recommend taking only up to 3 continuous readings within a short period.
10. Do not directly face the sun or an air outlet of an air conditioning or radiator device during the measurement as this will cause changes to the forehead temperature. Measurements should be taken in a stable environment where possible.
11. Do not measure body temperature in an environment with strong EM interference (examples include places close to a working microwave, induction cooker, or cellphone in-use) as EM interference may cause errors in the reading or even device failure.
12. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the product. Otherwise, degradation of the performance of this equipment could result.
13. This product should be considered a personal device. Clean and sanitize the product properly to prevent cross contamination.
14. To clean a dirty thermometer probe, gently swipe the probe using a cotton swab dipped in 70% isopropyl. Let the cleaned thermometer sit for at least 15 minutes before taking more measurements.
15. This infrared thermometer meets requirements established in ISO 80601-2-56:2017/AC:2018. It displays subject's temperature over a range of 89.6°F~109.4°F(32°C~42.9°C). Full responsibility for the conformance of this product to the standard is assumed by (manufacturer: ANDON HEALTH CO., LTD. Add: No. 3 Jinping Street, Ya An Road, Nankai District, Tianjin 300190, China).

(2) About the product

1. This product is a precision device. Return the product to its original packaging for proper storage after use. To ensure accurate measurements, avoid the device or probe contacting any liquid or droplets. Avoid tiny particles (such as dust or powder) falling into the probe.
2. Avoid dropping or subjecting the product to external forces. Do not disassemble or re-assemble the product on your own.
3. Do not directly touch the probe with your fingers or blow on it. Measurements taken using a damaged or dirty IR probe may be inaccurate.
4. Keep the product at a place inaccessible to children to prevent children from swallowing the batteries or small parts.
5. Do not throw the thermometer or batteries into fire to prevent explosions.
6. Remove the batteries from the thermometer if the device will not be used for more than one month.

7. If you are allergic to plastic/rubber, please don't use this device.
8. The materials (ABS, TPU, metal) of expect contact with patient had passed the ISO 10993-5 and ISO 10993-10 standards test, no toxicity, allergy and irritation reaction. They are in compliance with the MDD requirements. Based on the current science and technology, other potential allergic reactions are unknown.
9. The patient can be an intended operator. All functions of the unit can be used safely by patient.
10. This product should be considered a personal device. Clean and sanitize the product properly to prevent cross contamination.
If performance of the instrument may be adversely affected should one or more of the following occurred:
 - (1) Operation outside of the manufacturer-specified subject temperature range.
 - (2) Operation outside of the manufacturer-specified operating temperature and humidity ranges.
 - (3) Storage outside of the manufacturer-specified ambient temperature and humidity ranges.
 - (4) Mechanical shock.
 - (5) Manufacturer-defined soiled or damaged infrared optical components.
11. The patient is an intended operator.
12. This product contains batteries and recyclable electronic waste. To protect the environment, do not dispose of it in the household waste, but take it to appropriate local collection points.
13. This equipment complies with FCC RF radiation exposure limits set forth for an uncontrolled environment.
14. 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.
15. The manufacturer is not responsible for any radio or TV interference caused by unauthorized modifications to this equipment. Such modifications could void the user's authority to operate the equipment.
16. 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.

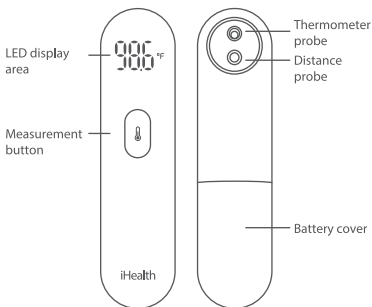
-Consult the dealer or an experienced radio/TV technician for help.

-This device and its antenna(s) must not be co-located or operating in conjunction with any other antenna or transmitter.

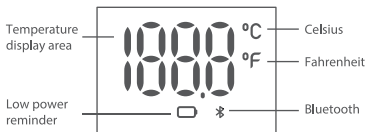
17. This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Overall Description

The thermometer is mainly comprised of a plastic casing, IR temperature sensor, MCU, vibration motor, LED display screen and batteries.



LED Screen Instructions



Device dimensions: 5.39 in x 1.34 in x 1.54 in

Screen dimensions: 1.01 in x 0.75 in

Product weight: 90 g

Product Performance

1. Measurement position: Centre of the forehead surface
2. Measurement distance: ≤ 1.18 in(3 cm)
3. Power source: **2 × 1.5V = SIZE AAA** batteries
4. Measurement range: 89.6°F-109.2°F(32°C-42.9°C)
5. Measurement precision: $\pm 0.4^{\circ}\text{F}/0.2^{\circ}\text{C}$ within 93.2°F-107.6°F (34°C-42°C), and $\pm 0.5^{\circ}\text{F}/0.3^{\circ}\text{C}$ for other temperature ranges.
6. Resolution: 0.1°F(0.1°C)
7. Clinical reproducibility: Within $\pm 0.5^{\circ}\text{F}(\pm 0.3^{\circ}\text{C})$

8. Operating conditions:

Temperature: 32°F-104°F(0°C-40°C)

Humidity: 15-95%RH, non-condensing

Atmospheric Pressure: 70~106kPa

9. Operation mode:

Adjusted mode: forehead

10. Expected service life: 5 years

11. Reference Body Site: Oral

12. Wireless communication: Bluetooth low energy

13. Software version: V1.0

ASTM laboratory accuracy requirements in the display range of 37 to 39°C (98 to 102°F) for IR thermometers is ± 0.2 °C (± 0.4 °F), whereas for mercury-in-glass and electronic thermometers, the requirement per ASTM Standards E667-86 and E1112-86 is ± 0.1 °C (± 0.2 °F).

Expected Use and Scope of Applications

This product mainly uses infrared sensors to measure the temperature of the human forehead and transmit the temperature to a smart device with Bluetooth. It can be used for babies, children, and adults. Infants and children cannot operate the thermometer; it is recommended that adults take the measurement.

Reminder: Temperature readings may differ according to skin tone and measurement distance.

Contraindications

It is not recommended for people whose measuring part has local lesions, such as inflammation, trauma, postoperative, etc.

Instruction For Use

The patient is an intended operator. The patient can measure, transmit data and change battery.


(1) Installing the product

Insert two batteries into the battery compartment on the back of the device. The product will initiate a self-check and then enter the standby mode (if the device indicates low battery power, then replace the batteries to ensure ample power supply).

(2) Measurement process

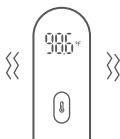
- 1 Aim the thermometer probe at the center of the forehead and keep the probe 1.18in (3cm) away from the forehead (the optimal distance is about the width of an adult's index finger). Do not touch the forehead with the probe. The infrared thermometer measurement window should be held perpendicular to the forehead and the subject should remain steady.




- 2 Gently press the measurement button [] to start the measurement.



- 3 The device will vibrate once a reading is obtained. Once the measurement is successful, the reading will be displayed on the screen. The whole time is about 1s. If the measurement is failed, the device will not vibrate the screen but display [- - - °F] instead.



If the [] icon on the thermometer screen is always on, the measured temperature data can be uploaded to the smart device.

Possible reasons for measurement errors include:

- A. Measurement distance is greater than 1.18in (3cm);
- B. Environment temperature does not meet measurement requirements or there is an excessively large temperature difference;
- C. Target temperature exceeds measurement range.



(3) Power off


If no more measuring is required, simply let the device sit idle for 8 seconds to power off automatically.


(4) Unit switching

1. When the device is powered OFF, press and hold the measurement button for 8 seconds to enter unit switching mode. Under this mode, both °C and °F should flash at the same time.
2. Under this mode, press the measurement button to switch to Fahrenheit or Celsius. The corresponding symbol of the selected unit after switching will flash.
3. After selecting the unit, press and hold the measurement button for 8 seconds to leave the unit switching mode.

Reminder: If you do not press and hold the measurement button for 8 seconds to confirm the unit selected before the screen switches off, the system will consider the switch as a failure and retain the original unit for temperature measurements.

(5) Installing and replacing batteries

Each time the thermometer is started, the battery will be automatically detected. If battery capacity is low but adequate for measurements, the low power symbol [] will be displayed with the measurement results. However, if the battery capacity is too low for measurements, the screen will

display a single, flashing [] icon and automatically switch OFF after 8 seconds. To continue using the device, old batteries must be replaced.

(6) Replacing batteries

1. Press down and hold the battery cover with the finger and apply some force to slide the cover backwards to open the battery compartment.
2. Remove the old batteries and install the new batteries.
3. Refer to the battery polarity symbols to orient the batteries properly during installation. Make sure that the new batteries are tightly inserted into the battery compartment and make sure that the polarity is not reversed during installation.
4. Return the battery cover to close the battery compartment.
 - Comply with relevant national laws and regulations when disposing of the used batteries.
 - Do not dispose of batteries directly into the trash bag.
 - Remove the batteries if the device will not be used more than one month.
 - When using, shall not touch battery and the patient simultaneously.
 - Do not throw batteries into fire.
 - The typical service life of the new and unused batteries is 300 measurements for the operation time are 60s.



Sync Time and Results Via Bluetooth

Prior to first use, scan the QR code to install the iHealth App.



Note: The App works with both iOS and Android device. For a complete list of compatible devices, visit our support on page on www.ihealthlabs.eu.

Connect to iOS Device Via Bluetooth

1. Launch the iHealth App from your iOS device.
2. Enable Bluetooth on your iOS device: Slide gently upward the iPhone screen from  to open the Control Center, and click on the .
3. Once the thermometer is off, press the button to start one measurement or sync the results.
4. When a connection has been established, the Bluetooth indicator will always light up, if not, the Bluetooth indicator will be off.
5. Please repeat these steps when you switch to another iOS device with the thermometer.

Connect to Android Device via Bluetooth

1. Press the button to turn on the thermometer or start one measurement.
2. Enable Bluetooth on your Android device.

- When using the thermometer for the first time, you should pair the thermometer to the Android device. Go into your device's setting to pair it with your Android device. Check the Bluetooth menu for the model name of your thermometer (PT3SBT) to appear, and then select it to pair.
- Launch the iHealth app to sync with your thermometer.
- When a connection has been established, the Bluetooth indicator will always light up, if not, the Bluetooth indicator will be off.
- Please repeat these steps when you switch to another Android device with the thermometer.





Update the firmware of PT3SBT

If a new version of the PT3SBT's firmware is released, the iHealth App will inform user to update when the PT3SBT is connected to the smart device with Bluetooth. User can choose whether to update this version of the PT3SBT's firmware, but it is strongly recommended to do this updating to get a better experience.

Note: During the upgrade process, the Bluetooth icon on the thermometer is always on and the three horizontal bars are displayed in cycles.



Product Errors and Troubleshooting

Problem	Item to detect	Solution
	<ul style="list-style-type: none"> Battery depleted 	Replace old batteries with new ones
	<ul style="list-style-type: none"> Batteries have been installed with the wrong polarity Batteries are not installed properly 	Take out the batteries and re-install them correctly.
	<ul style="list-style-type: none"> Unable to carry out measurement as current battery capacity is too low. 	Replace the batteries
	<ul style="list-style-type: none"> Measurement distance too long Target temperature is beyond range of measurements 89.6°F-109.2°F(32°C-42.9°C) Environment temperature either exceeds the design range 32°F-104°F(0°C-40°C) or is unstable 	Follow the instruction manual and repeat the measurements



· Current state: All symbols are flashing on the screen. The product is not usable.

Please contact customer services.



· Current battery capacity is too low.

Replace the battery as soon as possible.

· The application cannot find the product.

· There may be a problem with the Bluetooth connection

Restart the device. Turn off and turn on the Bluetooth of the smart device.

Body Temperature

- Body temperature varies from person to person and fluctuates during the course of the day. For this reason, it is suggested to know one's normal, healthy forehead temperature to correctly determine the temperature.
- Body temperature runs approximately from 95.9°F to 100°F (35.5°C - 37.8°C). To determine if one has a fever, compare the temperature detected with the person's normal temperature. A rise over the reference body temperature of 1.8°F/1°C or more is generally an indication of fever.
- Different measurement sites (rectal, axillary, oral, frontal, auricular) will give different readings. Therefore it is wrong to compare the measurement taken from different sites.
- The following are typical temperatures for adults, based on different measurement sites:

Rectal	97.9°F-100.4°F	36.6°C to 38°C
Axillary	94.5°F-99.1°F	34.7°C to 37.3°C
Oral	95.9°F-99.5°F	35.5°C to 37.5°C
Auricular	96.4°F-100.4°F	35.8°C to 38°C

Cleaning and Care

The thermometer is mainly for home use, if use for multiple patients, please clean the device in between uses with the following steps:

- ① Use an alcohol swab or cotton tissue moistened with alcohol (70% Isopropyl) to clean the thermometer casing thoroughly, The wiping process preferably lasts 15 seconds.
- ② Allow at least 5 minutes drying time before taking a temperature.
- ③ After cleaning, if the device is not visually clean when observed with magnification and adequate lighting, please repeat the clean steps above.

Note 1. The cleaning steps above has been validated according to the FDA Guidance, "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling".

Note 2. Ensure that no liquid enters the interior of the device. Never use abrasive cleaning agents, thinners or benzene for cleaning and never immerse the device in water or other cleaning liquids.

Care the Probe

1. The probe (comprising a temperature sensor and a distance sensor) is the most intricate part of the thermometer, and should be kept clean and intact to acquire accurate readings. Use the following method to clean the probe: Gently swab the surface of the probe using a cotton bud soaked in 70% Isopropyl.
2. If the probe (sensor) is broken, please contact customer services.
3. The product is not waterproof. Do not clean the device with detergents. Do not soak the thermometer in water or other liquids.

Maintenance

1. This company has not authorized any agency or individual to carry out product repairs or maintenance. Do not attempt to disassemble or modify the thermometer if you suspect functional issues with the device.
2. The IR thermometer is an extremely precise instrument. Any improper maintenance, disassembly, or modification may lead to inaccuracies of the product measurements.
3. If you suspect any product issues during the warranty period, please contact customer services for subsequent handling.

Disposal



Dispose of the battery in accordance with the regulation applicable at the place of operation. Dispose of at public collection point in the EU countries – 2002/96/EC WEEE Directive.

If you have any queries, please refer to the local authorities responsible for waste disposal.

Notes

- Please act according to local laws for disposal of used batteries.
- Take out the battery if you are not going to use the unit for a long time.



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

Dispose of at public collection point in the EU countries – 2006/66/EC Directive.

Operating, Shipping, and Storage Conditions

(1) Operating conditions

Range of operating environments

Temperature: 32°F-104°F(0°C- 40°C)

Humidity: 15-95%RH, non-condensing

Atmospheric Pressure: 70kPa~106kPa

(2) Transportation / storage conditions

Temperature: -4°F~131°F(-20°C~ 55°C)

Humidity: 15-95%RH, non-condensing

Atmospheric Pressure: 70kPa~106kPa

Accessories

Use only accessories provided by the original manufacturer, and check for any missing accessories.

1 IR Thermometer

2 AAA batteries

1 Instruction manual

1 Quick user guide

Standard Icons



Symbol for "THE OPERATION GUIDE MUST BE READ"

The sign background color: blue.

The sign graphical symbol: white.



The batteries and electronic instruments must be disposed of in accordance with the locally applicable regulation, not with domestic waste.



Symbol for "MANUFACTURER"



Symbol for "WARNING"



Symbol for "SERIAL NUMBER"



Symbol for "EUROPEAN REPRESENTATIVE"

IP22

IP code of the device: this device's grade of against ingress of solid foreign objects – \geq 12.5mm diameter (and the against access to hazardous parts with finger); the grade of waterproof is dripping (15° tilted).

CE 0197

Symbol for "COMPILES WITH MDD93/42/EEC REQUIREMENTS"

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Calibration

The thermometer is initially calibrated at the time of manufacture. If this thermometer is used according to the use instruction, periodic re-adjustment is not required. If any time your question the accuracy of measurement, please contact distributor or manufacturer, the contact information is on the last page.

Storage



- (1) Do not put the thermometer under direct sunlight, high temperature, or moist environments. Do not allow it to come into contact with fire or harsh vibrations.
- (2) Take out the battery if the device is not used for a long period of time.

Other Standards and Compliances

The Wireless No-Touch Forehead Thermometer corresponds to the following standards: IEC 60601-1:2005 +A1:2012(E)/EN 60601-1:2006/A1: 2013 (Medical electrical equipment – Part 1: General requirements for basic safety and essential performance), IEC 60601-1-2:2014(Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and Tests), ISO 80601-2-56:2017/AC:2018(Medical Electrical Equipment – Part 2-56: Particular Requirements For The Basic Safety And Essential Performance Of clinical thermometers for body temperature measurement), ASTM E1965-98:2016(Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature).

The SAR limit of USA (FCC) is 1.6 W/kg averaged over one gram of tissue. Device has also been tested against this SAR limit.

Electronic Compatibility Information

This product is applicable to the equipment and system requirements for the purpose of receiving radio frequency energy for the purpose of the work, Bluetooth low energy receive bandwidth 2M. This product can also be used to include RF transmitter equipment and system requirements and emission frequency of 2.4GHz ISM band, BLE modulation types: GFSK, effective radiated power: < 0dBm .

Table 1 - Emission limits per environment

Phenomenon	Compliance	Electromagnetic environment
Conducted and radiated RF emissions	CISPR 11 Group 1, Class B	The device is intended to be used in home healthcare environment.
Harmonic distortion	IEC 61000-3-2 NA	The device is powered by battery.
Voltage fluctuations and flicker	IEC 61000-3-3 NA	The device is powered by battery.

Table 2 - Enclosure Port

Phenomenon	Basic EMC standard	Immunity test levels
		Home Healthcare Environment
Electrostatic Discharge	IEC 61000-4-2	±8 kV contact ±2kV, ±4kV, ±8kV, ±15kV air
Radiated RF EM field	IEC 61000-4-3	10V/m 80MHz-2.7GHz 80% AM at 1kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Refer to table 3
Rated power frequency magnetic fields	IEC 61000-4-8	30A/m 50Hz or 60Hz

Table 3 - Proximity fields from RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Immunity test levels
		Professional healthcare facility environment
385	380-390	Pulse modulation 18Hz, 27V/m
450	430-470	FM, ±5kHz deviation, 1kHz sine, 28V/m
710	704-787	Pulse modulation 217Hz, 9V/m
745		
780		
810	800-960	Pulse modulation 18Hz, 28V/m
870		
930		
1720	1700-1990	Pulse modulation 217Hz, 28V/m
1845		
1970		
2450	2400-2570	Pulse modulation 217Hz, 28V/m
5240	5100-5800	Pulse modulation 217Hz, 9V/m
5500		
5785		

Warranty

Please contact your dealer or the device center in case of a claim under the warranty. If you have to send in the unit, enclose a copy of your receipt with clear statement of defect description.

The warranty terms as below:

1. The warranty period for device is one year from date of delivery. In case of a warranty claim, the date of delivery has to be proven by means of the sales receipt or invoice.
2. Repairs under warranty do not extend the warranty period.
3. The following cases are excluded under the warranty
 - All damage which has arisen due to improper treatment, e.g. nonobservance of the user instruction.
 - All damage which is due to repairs or tampering by the customer or unauthorized third parties.
 - Damage which has arisen during transport from the manufacturer to the consumer or during transport to the service centre.
 - Accessories which are subject to normal wear and tear.
4. Liability for direct or indirect consequential losses caused by the unit is excluded even if the damage to the unit is accepted as a warranty claim.

Manufactured for iHealth Labs, Inc.

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EC	REP
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