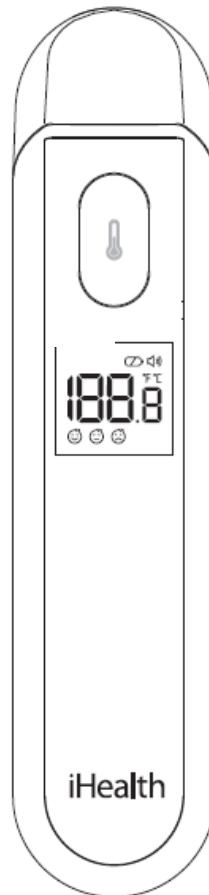

iHealth Infrared Digital No-Touch Thermometer (PT2L) User's Manual



Infrared Digital No-Touch Thermometer (PT2L)

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Product 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. The product helps you to assess you and your family members' health conditions easily and quickly.

Product Name: Infrared Digital No-Touch Thermometer

Product Model: PT2L

NOTICE

1. 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.
2. Keep the thermometer out of reach of children. For accidental swallowing of the battery or other components, please contact emergency services immediately.
3. Batteries must not be thrown into an open fire or short circuited.
4. 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.
5. 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.
6. Make sure that the forehead of the subject is free from sweat, cosmetics, dirt, or grease before measuring.
7. 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.
8. Do not take temperature measurement over scar tissue, open sores or abrasions.
9. 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.
10. Do not measure body temperature immediately after consuming a drug that raises body temperature. Temperature readings taken at this time will not be accurate.
11. 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.
12. 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.
13. 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.

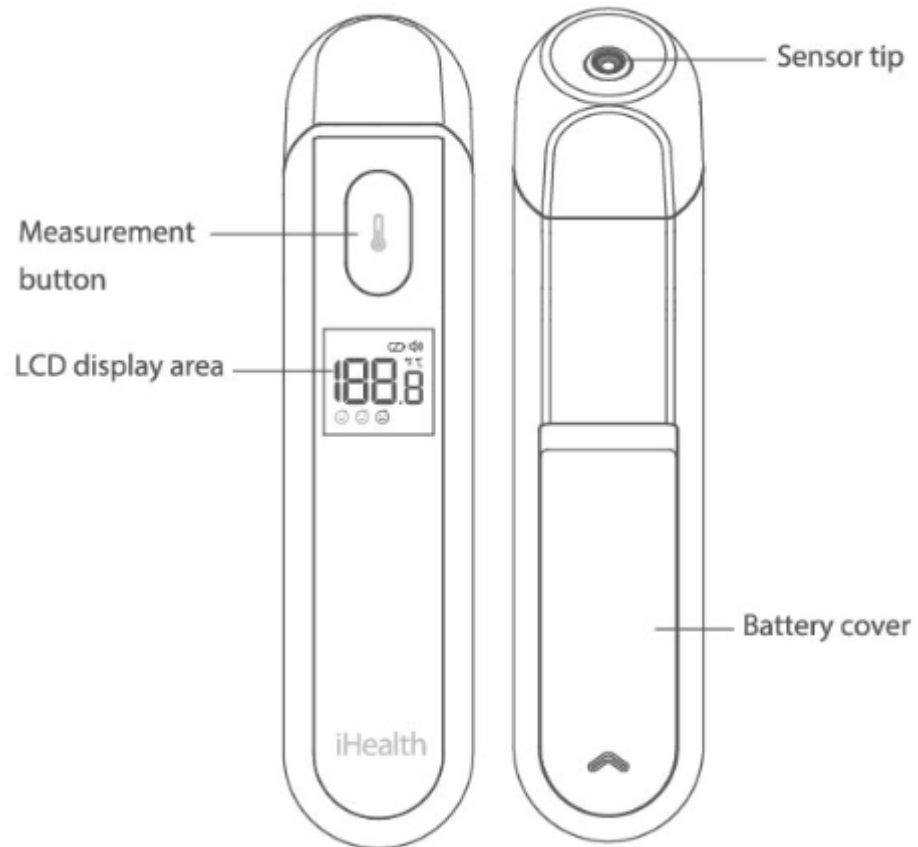
14. This product should be considered a personal device. Clean and sanitize the product properly to prevent cross contamination.

If performance of the instrument may be adversely affected should one or more of the following occur:

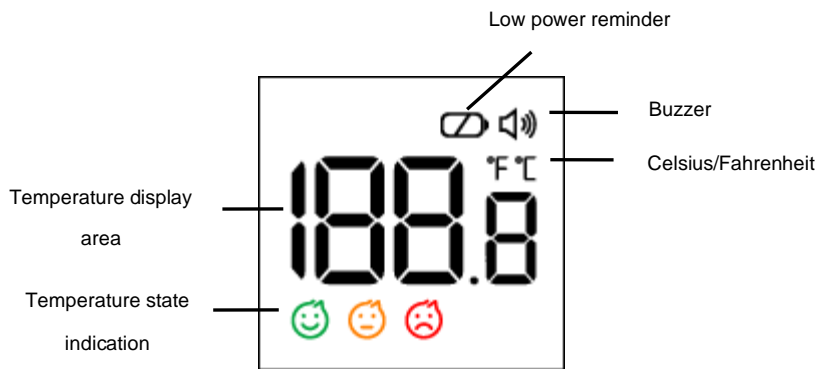
- 1) Operation outside of the manufacturer-specified subject temperature range.
 - 2) Operation outside of the manufacturer-specified operating temperature and humidity ranges.
 - 3) Storage outside of the manufacturer-specified ambient temperature and humidity ranges.
 - 4) Mechanical shock.
 - 5) Manufacturer-defined soiled or damaged infrared optical components.
15. 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).
16. If you are allergic to plastic/rubber, please don't use this device.
17. The materials 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.
18. The patient is an intended operator.
19. 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.
20. 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.
21. Forehead temperature readings on this device are equivalent to oral readings.

Overall Description

The thermometer is mainly comprised of a plastic housing, IR temperature sensor, LCD display screen and batteries.




LCD screen instructions



Device dimensions: Approx 141mm × 32mm × 48mm (5.55in×1.26in×1.89in)

Product weight: Approx 53 g (exclude batteries)

Product performance

1. Measurement position: Centre of the forehead surface
2. Forehead Measurement distance: ≤3 cm(1.18in)
3. Power source: DC 3V; 2 x 1.5V  AAA batteries
4. Measurement range: 34.0°C-43.0°C(93.2°F-109.4°F)
5. Measurement precision: ±0.2°C (±0.4°F) within 35.0°C-42.0°C(95°F-107.6°F), outside this measurement range: ±0.3°C (±0.5°F).
6. Resolution:0.1°C (0.1°F)
7. Measurement units: Celsius (°C) or Fahrenheit (°F)
8. Clinical repeatability: Within ±0.3°C(±0.5°F)
9. Operating conditions:
 - Temperature: 15°C-40°C(59°F-104°F)
 - Humidity: ≤95%RH, non-condensing
 - Atmospheric Pressure: 70KPa~106KPa
10. Transportation / storage conditions
 - Temperature: -25°C-55°C(-13°F-131°F)
 - Humidity: ≤95%RH, non-condensing
 - Atmospheric Pressure: 70KPa~106KPa
11. Display: LCD display
12. Operation mode: adjusted mode; reference body site: oral.
13. Expected service life: 5 years
14. Interval between 2 measurements: at least 5 seconds.
15. Battery life: approx. 3000 times measurements

Intended use

The Infrared Digital No-Touch Thermometer is intended for the intermittent measurement of body temperature from central forehead skin surface on people of all ages. It can be used by consumers in the household environment and by healthcare providers.


Contraindications

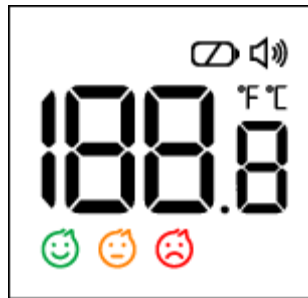



It is not recommended for people whose measuring part has local lesions, such as inflammation, trauma, postoperative, etc.

Instruction For Use

1. Installing the product

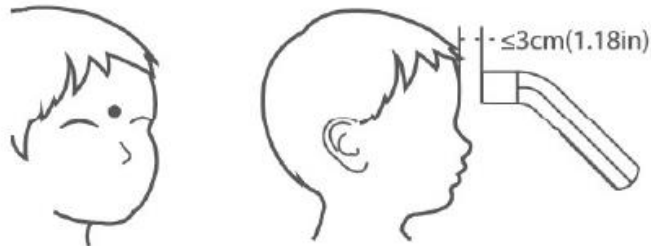
Insert the two batteries into the battery compartment at the back of the device. The thermometer will initiate a self-check, LCD displaying the following picture, then beep once and power off automatically (if the LCD displays , then replace the batteries to ensure ample power supply).




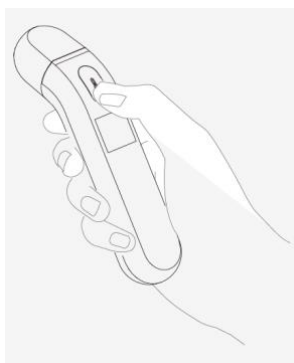
Note:  The batteries and electronic instruments must be disposed of in accordance with the locally applicable regulation, not with domestic waste.


2. Measurement process

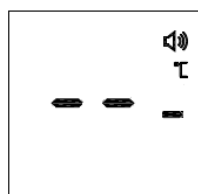
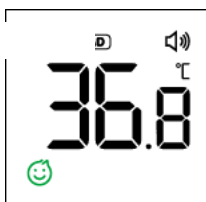
1) Aim the thermometer probe at the center of the forehead and keep the probe no more than 3cm (1.18in) away from the forehead (the optimal distance is about the width of an adult's index finger). Do not touch the forehead with the probe.



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



3) The buzzer will beep once a reading is obtained (Buzzer switch function is optional, please refer to "4. Buzzer prompt switch" for settings). The reading will be displayed on the screen. If the measurement is failed, the beeper will not beep and the screen displays [] instead.



Possible reasons for measurement errors include:

- A. Environment temperature does not meet measurement requirements or there is an excessively large temperature difference;
- B. 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. Buzzer Prompt Switch

- 1) Under the power off state, press and hold the measurement button until the buzzer symbol "🔊" appears alternately on the screen.
- 2) Release the button when "🔊" appears, buzzer function open;
- 3) Release the button when "🔊" disappears, buzzer function close;
- 4) After setting the buzzer prompt switch, the screen displays the current temperature unit, and automatically shuts down in 4s.

5. Unit switching

- 1) After setting the buzzer prompt switch in 4. above, the LCD display the current temperature unit. Press and hold the button immediately then enter the unit setting state, At this point, the unit symbols of °C and °F appear alternately.

-
- 2) Release the button when "°C" appears, the unit set as °C ;
 - 3) Release the button when "°F" appears, the unit set as °F.

6. Indication of temperature status

- 1) When the measured temperature $T < 37.5^{\circ}\text{C}$ (99.5°F), "😊" appears on the LCD.
- 2) When the measured temperature $37.5^{\circ}\text{C} \leq T < 38.0^{\circ}\text{C}$ ($99.5^{\circ}\text{F} \leq T < 100.4^{\circ}\text{F}$), "😬" appears on the LCD.
- 3) When the measured temperature $T \geq 38.0^{\circ}\text{C}$ (100.4°F), "😞" appears on the LCD.




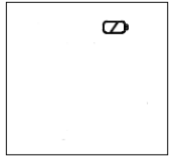
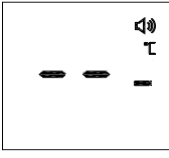

7. Low power reminder function

When switched ON for use, the thermometer will automatically detect remaining battery capacity. 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.

8. 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.

Product errors and troubleshooting

Problem	Item to detect	Solution
	Battery depleted	Replace old batteries with new ones
	Batteries have been installed with the wrong polarity Batteries are not installed properly	Take out the batteries and re-install them correctly.
	Unable to carry out measurement as current battery capacity is too low.	Replace the batteries
	Measurement distance too long Target temperature is beyond range of measurements Environment temperature either exceeds the design range 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.

Body temperature

- Body temperature runs approximately from 35.5°C-37.8°C (95.9°F to 100°F). 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°C(1°F) 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-99.1°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

Care and Cleaning

1. The probe (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:
 - 1) Gently swab the surface of the probe using a cotton bud soaked in > 95% medical alcohol.
 - 2) Allow at least 1 minute for the probe to fully dry.
2. If the probe (sensor) is broken, please contact customer services.
3. Use a piece of soft, dry cloth to clean the display screen and external surface of the thermometer. If the thermometer is very dirty, the cloth can be moistened with some medical alcohol to clean the device.
4. 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. Please check the device if damaged after it is dropped. If unsure, please contact customer services for having the device checked.
4. 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 during the warranty period, please contact customer services.
5. No component can be maintained by user in the monitor. circuit diagrams, component part lists, descriptions, calibration instructions, or other information which will assist the user's appropriately qualified technical personnel to repair those parts of equipment which are designated repairable can be supplied.
6. The method for verifying the clinical accuracy can be requested, please contact customer services.
7. The device must not be stored or used at an excessively high or low temperature or humidity (see technical data), in sunlight, in association with an electrical current or in dusty locations. Avoid dropping or subjecting the product to external forces. Otherwise inaccuracies can occur.
8. 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.
9. The monitor requires 4 hours to warm from the minimum storage temperature between uses until the monitor is ready for its INTENDED USE when the ambient temperature is 20 °C (68°F).
10. The monitor requires 4 hours to cool from the maximum storage temperature between uses until the monitor is ready for its INTENDED USE when the ambient temperature is

20 °C (68°F).

Included in delivery

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

1 Infrared Digital No-Touch Thermometer

2 x 1.5 V AAA batteries

1 instruction manual

Signs and symbols

The following symbols appear in these instructions for use and on the device:



Symbol for "THE OPERATION GUIDE MUST BE READ"
(The sign background color: blue. The sign graphical symbol: white.)



Symbol for "ENVIRONMENT PROTECTION –Waste electrical products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local Authority or retailer for recycling advice".



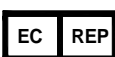
Symbol for "MANUFACTURER"



Symbol for "CAUTION"



Symbol for "SERIAL NUMBER"



Symbol for "EUROPEAN REPRESENTATIVE"

IP22 The first characteristic numeral symbol for "Degrees of protection against access to hazardous parts and against solid foreign objects". The second characteristic numeral symbol for "Degrees of protection against ingress of water"



Symbol for "Application part, type BF"

CE 0197 Symbol for "COMPLIES WITH MDD93/42/EEC REQUIREMENTS"

OTHER STANDARDS AND COMPLIANCES

This device complies with the EU Directive 93/42/EEC concerning medical products, IEC 60601-1 (Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance), IEC 60601-1-2(Medical electrical equipment -- Part 1-2:

General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and Tests), IEC 60601-1-11 (Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment), the ASTM (American Society for Testing and Materials) E 1965 - 98 , ISO 80601-2-56 (Medical Electrical Equipment -- Part 2-56: Particular Requirements For The Basic Safety And Essential Performance Of clinical thermometers for body temperature measurement). Please note that portable and mobile HF communication systems may interfere with this unit.

This infrared thermometer meets requirements established in ASTM Standard (E1965-98) except of clause 5.2.2. It's display range is 34.0°C-43.0°C(93.2°F-109.4°F).the Full responsibility for the conformance of this product to the standard is assumed by manufacturer.

ELECTROMAGNETIC COMPATIBILITY INFORMATION

Table 1 – Emission

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, ± 5 kHz 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 center.
 - 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.

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Date of issue: May 28, 2020