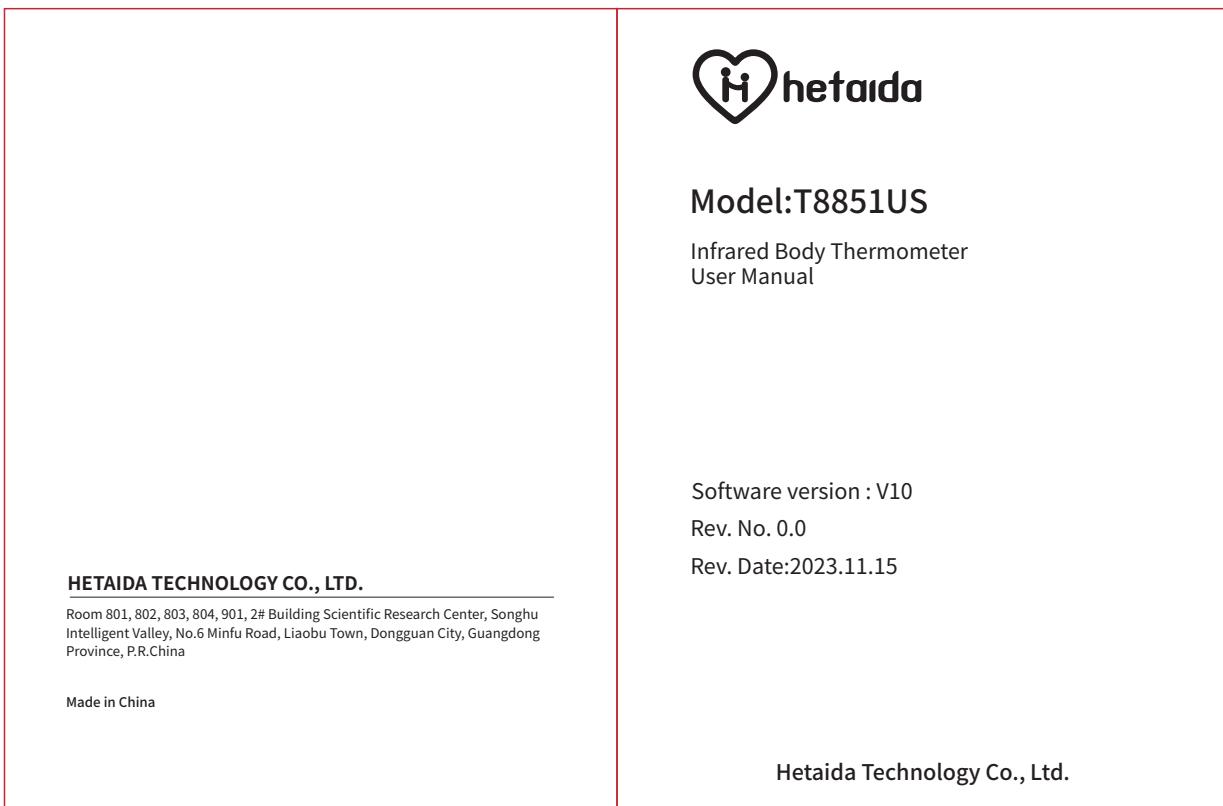


说明书印刷要求说明

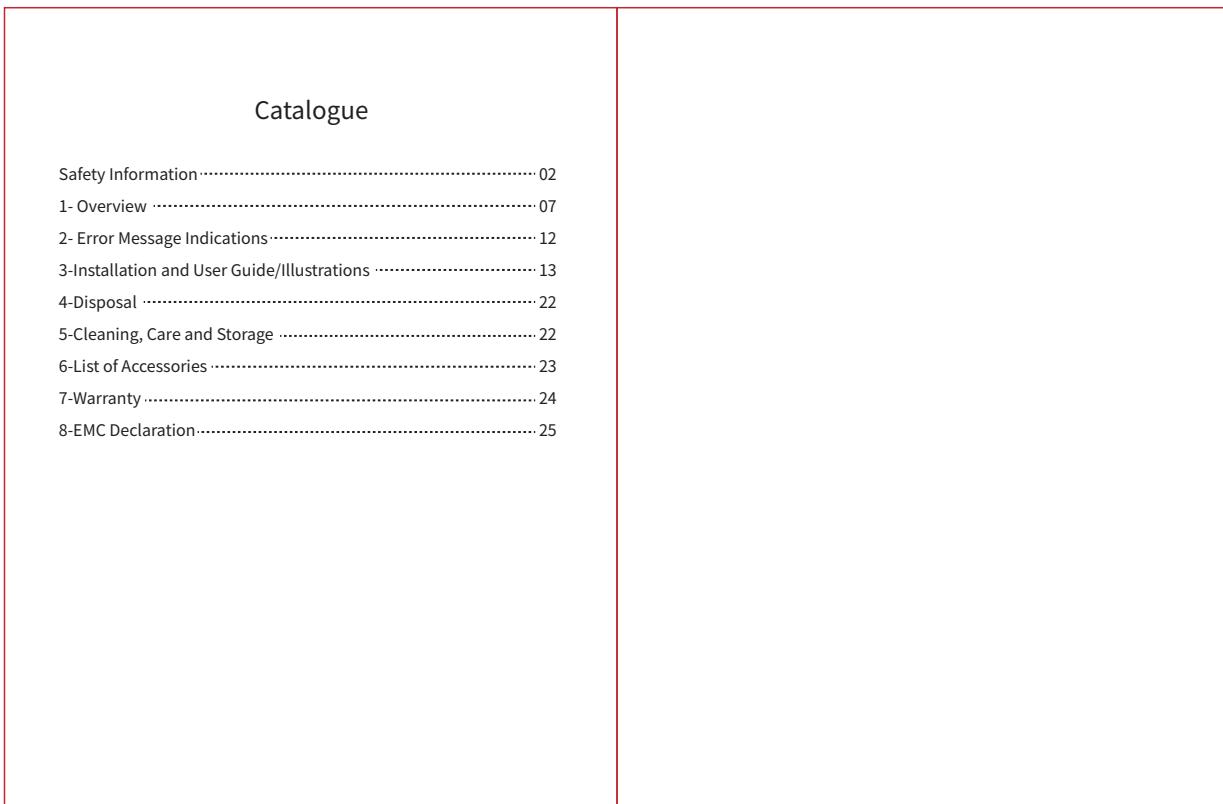
| | |
|-------|-------------------------|
| 物料名称： | Hetaida T8851US英文FDA说明书 |
| 制作时间： | 2023.11.15 |
| 版本版次： | A0 |
| 物料编号： | XX-XX-XX-XXXX-XXXX |
| 物料材质： | 105G双铜 |
| 物料尺寸： | 81x106mm |
| 页 数： | 24P |
| 装订方式： | 骑马钉装订 |
| 印刷颜色 | K(单黑) |

备注：此页非印刷页

封页正面



封页反面



Foreword

The Infrared body thermometer operating Instructions intend to provide the necessary information for proper operation of T8851US thermometer model.

General knowledge of Infrared thermometer and an understanding of the features and functions of the T8851US thermometer model are prerequisites for proper use.

The T8851US is a medical device, and can be used repeatedly with using life is 5 years. And the shelf life of T8851US is 5 years too.

Please read the manual first before using it, if not fully understand the usages, please stop using the thermometer.

Do not operate any of the models T8851US thermometer without completely reading and understanding these instructions.

Notice

Purchase or possession of this device does not carry any express or implied license to use with replacement parts which would, alone or in combination with this device, fall within the scope of one of the relating patents.

Safety Information

This device may only be used for the purposes described in these instructions. The manufacturer cannot be held liable for damage caused by incorrect application.

The infrared body thermometer is designed to minimize the possibility of hazards from errors in the software program by following sound and light engineering design processes, Risk Analysis and Software Validation.

01

Warning

Precautions:

1. Never use the thermometer for purposes other than its original design. This product is suitable for professional, medical institutions, or home use. The product can be operated correctly following its user manual without the need for additional skills or training.
2. The thermometer is not waterproof. Do not immerse it in water or any other liquid. For cleaning and disinfection, follow the instructions in the "Maintenance and Storage" section.
3. Store the thermometer away from direct sunlight and keep it in a clean, dry place with a temperature between 5°C to 45°C and humidity below 85%.
4. Avoid touching the sensor inside the gun head with fingers or sharp objects.
5. Obstructions on the forehead such as sweat, hair, hats, or scarves may result in a lower temperature reading; thus, please use it correctly to ensure accurate measurements.
6. Do not drop, disassemble, repair, or modify the product.
7. Avoid strong electrostatic or magnetic fields to ensure measurement data accuracy. No significant risks will arise.
8. If you encounter any issues, stop using the device and contact the seller. Do not attempt to repair it yourself.
9. If the product is no longer in use, please dispose of it in accordance with local regulations to prevent environmental pollution.
10. Use the thermometer in a stable ambient temperature. If there's a sudden change in the surrounding temperature, check the sensor head for condensation. If present, follow the instructions in the "Maintenance and Storage" section to remove the condensation before using it to ensure measurement accuracy.

02

11. The thermometer is a precision instrument. If fine particles like dust or droplets fall into the probe, clean them immediately. Keeping the probe clean ensures more accurate readings. For cleaning, first wipe with a damp cotton swab, then dry with a dry cotton swab. Let it sit for 30 minutes before using. Before measuring, check the sensor head for damage or contamination to ensure accurate readings. If the sensor head is damaged, stop using it and contact the seller. Do not handle it on your own; if contaminated, clean it following the instructions in the "Maintenance and Storage" section before using.

12. Before measuring, inspect the product's appearance to ensure it hasn't been dropped or externally damaged, which could lead to inaccurate readings. If damaged, stop using.

13. When powering on, ensure it displays measurement data correctly. If errors related to the "Error Message Information" are shown, check according to the corresponding method. If the problem persists, cease use.

14. When connecting the thermometer to external devices, it can only be connected to devices approved by our company (specific requirements are in Chapter 7 of the user manual), and only to those without external voltage risks, complying with safety standards IEC 60601-1 and IEC 60601-1-2.

15. The measurement results of this product cannot replace a physician's diagnosis.

16. A rise in body temperature could indicate a severe illness, especially in newborns and infants, frail elderly individuals, and adults with weakened immune systems. If the following individuals exhibit a rise in body temperature, seek medical attention promptly:

- Newborns and infants under three months (if their temperature exceeds 37.5°C, seek immediate medical attention).
- Individuals over 60 years of age (elderly individuals may exhibit subtle or even no fever symptoms).

03

▪ Patients with diabetes or those with compromised immune systems (e.g., individuals with a positive HIV status, undergoing cancer chemotherapy, on chronic steroid therapy, or those who have had a splenectomy).

▪ Those who are bedridden for extended periods (e.g., patients in care homes, individuals with stroke or chronic illnesses, and those in post-operative recovery).

▪ Organ transplant recipients (e.g., liver, heart, lung, or kidney transplants).

17. If you experience unexplained restlessness, vomiting, diarrhea, dehydration, changes in appetite or behavioral patterns, seizures, muscle pain, shivering, stiff neck, or pain during urination, even without fever, seek medical attention promptly.

18. Never allow children to measure their body temperature unsupervised.

19. If the thermometer's storage location is colder or hotter than the place of use, let it sit in the room where the individual's temperature will be measured for more than 10 minutes before starting the measurement.

20. Even individuals with normal body temperatures, showing no signs of fever, may still require medical attention. Individuals taking antibiotics, pain relievers, or fever reducers should not solely rely on temperature readings to determine the severity of their condition.

21. The patient is the anticipated operator. This product is used by the operator under the guidance of the instruction manual. The operator can be a maintenance personnel who, following the manual, performs preventative checks and maintenance on the product.

22. This product's casing is made from biocompatible ABS material. When in contact with human skin, it does not cause any irritation or allergic reactions.

04

23. Before use, check the product's expiration date. If the product is used past its expiration date, it may yield inaccurate readings. Do not use expired products.

⚠️ Keep the thermometer out of reach of children.

⚠️ Do not throw the thermometer into fire.

⚠️ Do not charge the lithium battery for more than 12 hours; doing so can damage the battery and even pose a risk.

⚠️ Use the dedicated power adapter and avoid touching the power socket with wet hands to prevent the risk of electric shock or injury.

⚠️ Do not use a damaged USB cable to avoid risks of electric leakage, shock, or fire.

⚠️ Using the thermometer does not replace seeking medical advice.

⚠️ Measurements may be inaccurate on inflamed, injured, or post-surgical areas.

05

1- Overview

Indication for use:

The Infrared Body Thermometer, Model: T8851US, is an electronic clinical thermometer using an infrared sensor to detect body temperature from the forehead in people of all ages for home setting use.

Description of Infrared Body Thermometer

• Device principle and introduction

The HeTaiDa Infrared body thermometer are hand-held, reusable, battery operated devices, which can measure human body temperature on forehead, the skin temperature on one's forehead.

The operation principle is based on Infrared Sensor technology. The IR sensor can output different signal when measuring different object temperature or in different ambient temperature, and the ASIC can turn the signal from IR Sensor to a digital value and display it on the LCD.

• Description on Controls, Indicators, and Symbols, as shown in Fig 1:

1. Distance Measuring Sensor
2. Passive Infrared Sensor
3. Measuring site indicator light
4. Vibration Function Button
5. Memory Function Button
6. Battery charging terminal
7. Settings Function Button
8. Age Function Button
9. Measurement Result Indicator Light
10. LED Display
11. Power/Measurement Button

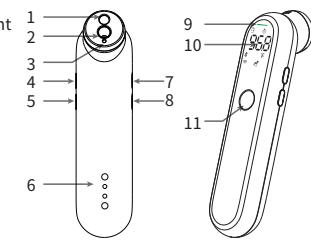


Fig 1

06

Explanation of Button Functions and Icons:

💡 : Power/Measurement Button: Press to turn on or begin measurement.

⚙️ : Settings Button: Enter settings mode.

⌚ : Mode Button: Switch between age and temperature modes.

⚡ : Vibration Switch: Toggle between turning vibration mode on and off.

📅 : Memory Function: Press the button to check historical test results.

LED Display Explanation, as shown in Fig 2:

1. Measurement Result Indicator Light

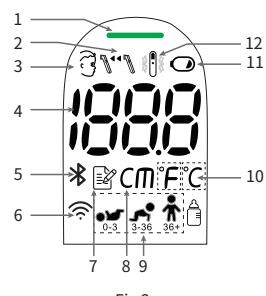


Fig 2

Thermometer Applications

| Thermometer Model Number | Thermometer Style | Adult | | Pediatric | |
|--------------------------|----------------------------|-------|----------|-----------|----------|
| | | Ear | Forehead | Ear | Forehead |
| T8851US | Infrared Body Thermometers | | ✓ | | ✓ |

07

Equipment Symbols

| | | | |
|--|--|--|--|
| | Warning | | Restriction of Hazardous Substances |
| | Non sterile packaging | | Batch code |
| | Consult instructions for use | | Compliance with WEEE Standard |
| | Operating Temperature | | DO NOT THROW AWAY Intended for multiple use |
| | Operating Humidity | | Operating atmospheric pressure |
| | This device complies with Part 15 of FCC(Federal Communications Commission) Rules. | | Serial number |
| | Manufacturer | | This symbol means type BF applied part. |
| | IP22: The first number 2: Protected against solid foreign objects of Ø 12.5 mm and greater. The second number: Protected against vertically falling water drops when enclosure tilted up to 15°. | | |

08

Technical Specifications

| Measurement Range | |
|-----------------------|---|
| Body Temperature Mode | 32.0°C ~43.0°C/89.6°F~109.4°F |
| Laboratory Accuracy | 32.0~34.9°C: ±0.3°C/89.6°F~94.8°F: ±0.5°F; 35.0~42.0°C: ±0.2°C/95.0°F~107.6°F: ±0.4°F; 42.1~43.0°C: ±0.3°C/107.8°F~109.4°F: ±0.5°F; |
| Operating Mode | Adjusted mode (Body mode) |
| Measurement Unit | °C/°F |
| Display Resolution | 0.1°C/0.1°F |
| Measuring distance | 1-3cm/0.4in-1.2in |
| Measurement Method | Spot measurement or scan measurement |
| Memories | 50 |
| Measurement Time | |
| Spot Measurement | ≤2s |
| Scanning Measurement | ≤4s |
| Operating Condition | |
| Ambient Temperature | 5.0°C~40.0°C/41°F~104°F |
| Relative Humidity | ≤85% (non-condensing) |
| Atmospheric Pressure | 60kPa to 106kPa |
| Batteries | DC 3.7V (Rechargeable lithium battery) |
| Weight | 76g |
| Size | 151 mm x 37 mm x 38 mm (Length x Width x Height) |

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Notification Function

Alarm of Indicator Light (In Body Mode)

| | |
|---------------------|--|
| 0-3 months | 32.0°C~35.8°C/89.6°F~96.5°F: None 35.9°C~37.5°C/96.6°F~99.6°F: Green light 37.6°C~38.1°C/99.7°F~100.7°F: Yellow light 38.2°C~43.0°C (100.8°F~109.4°F): Orange light |
| 3-36 months | 32.0°C~35.6°C/89.6°F~96.2°F: None 35.7°C to 37.4°C/96.3°F~99.4°F: Green light 37.5°C to 38.0°C/99.5°F~100.5°F: Yellow light 38.1°C~43.0°C (100.6°F~109.4°F): Orange light |
| More than 36 months | 32.0°C~35.4°C/89.6°F~95.8°F: None 35.5°C to 37.3°C/95.9°F~99.2°F: Green light 37.4°C to 38.0°C/99.3°F~100.5°F: Yellow light 38.1°C~43.0°C (100.6°F~109.4°F): Orange light |

Note: All the light color indications are based on temperature ranges.

| | |
|----------------------------|------------------------|
| Auto Power Off Time | ≤5 mins |
| Measurement Site | Forehead |
| Reference Body Site | Oral |
| Storage and Transportation | -20°C~55°C/-4°F~131°F, |
| Relative Humidity | ≤93% (non-condensing) |
| Atmospheric Pressure | 60kPa to 106kPa |

If necessary, our company can provide circuit diagrams, component lists, and other materials for professional technicians to use for repairs.

Note: This manual includes both user instructions and technical specifications and is not provided in electronic format.

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Compliance

| Item | Compliant with |
|-------------------------------|--|
| Equipment classification | Safety Standards: ANSI AAMI ES60601-1: 2005/(R)2012 and A1:2012+A2:2021, IEC 60601-1-2: 2014+A1:2020 |
| Type of protection | Internally powered equipment (on battery power) |
| Degree of protection | Type BF |
| Front panel and case labeling | ISO 15223-1:2021 |
| Temperature | ASTM E1965-98 (reapproved 2016) |
| Home healthcare environment | IEC 60601-1-11:2015+A1:2020 |

Calculated values of the indicators according to ASTM E1965-98

| Indicators | Forehead mode | | | Forehead Scan mode | | |
|-------------------------------|----------------------|------------------------|-----------------------|----------------------|------------------------|-----------------------|
| | Group I (Infants) | Group II (Children) | Group III (Adults) | Group I (Infants) | Group II (Children) | Group III (Adults) |
| Clinical Bias \bar{x}_d | 0.18 | 0.17 | 0.17 | 0.16 | 0.16 | 0.15 |
| Uncertainty | ±0.11 | ±0.10 | ±0.10 | ±0.09 | ±0.08 | ±0.08 |
| Clinical repeatability, S_r | 0.13 | | | 0.12 | | |

Note: the above value is calculated from clinical data of HTD8823US.

Safety classification of ME EQUIPMENT

| | |
|---|---------------------------------|
| Protection against electric shock | Internally powered ME equipment |
| Applied part | Type BF |
| Protection against harmful ingress of water or particulate matter | IP22 |
| Mode of operation | Continuous operation |

Note: Not intended to be sterilized. Not for use in an OXYGEN RICH ENVIRONMENT

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2. Error Message Indications

| Display/Issu | Displayed Meaning | Possible Causes and Troubleshooting |
|--------------|--|--|
| | Measured Temperature Too High | Body Temperature Mode: Target temperature exceeds 43.0°C/109.4°F |
| | Measured Temperature Too Low | Body Temperature Mode: Target temperature is below 32.0°C/89.6°F |
| | Environment Temperature Out of Range | The thermometer's ambient temperature is below 5.0°C/41°F or above 40.0°C/104°F |
| | Scanning Too Quickly or Exceed Measurement Range | Do not shake rapidly during scanning tests and measure within the specified distance range. |
| | Exceed the range of measuring distance | Distance too far, beyond measurement range. Place the thermometer closer to the forehead, positioning it 1~3cm away. |

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| | | |
|--|------------------------------|---|
| | Function Error Indication | System detected an error during self-check; all indicators flash, and an orange light illuminates. |
| | Battery Depletion Indication | When the battery is critically low, a “” symbol will flash on the screen until it turns off. Please charge immediately. |
| | Low Battery Indication | For a low battery alert, a “” symbol will appear on the screen. Please charge as soon as possible. |

3. Installation and User Guide/Illustrations

I. Charging instructions:

T8851C has two charging methods:

1. Use the charging base, as shown in Fig 3:



Fig 3

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a. Connect the charging base and charging cable, then connect the power adapter to the power socket.

b. Place the device on the charging base, ensuring the thermometer aligns with the base until a charging icon flashes on the thermometer's screen, as indicated in Fig 4.

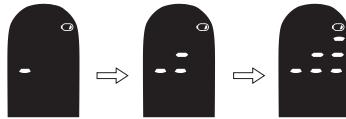


Fig 4

c. Once the device is fully charged, the charging icon will stop flashing, as shown in Fig 5.



Fig 5

2. Use the portable charging cable, as illustrated in Fig 6:



Fig 6

a. Connect the portable charging cable to the power adapter and then plug the power adapter into an electrical socket.

b. Align the charging prongs on the device with the magnets on the charging cable, ensuring the thermometer adheres to the portable charging cable until a charging icon flashes on the screen.

c. Once the device is fully charged, the charging icon will stop flashing.

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Precautions:

1. Ensure the charging interface is dry and clean before charging to prevent short-circuiting or other risks.
2. Since the charging base contains magnets, it can inevitably attract metallic objects. Be sure to clean it thoroughly before use and avoid exposing the charging base to prolonged high temperatures, which could lead to demagnetization and other anomalies.
3. If the thermometer is not in use for extended periods, to prolong the battery life, it is recommended to charge it every 2-3 months.

II. Preparing for Measurement:

Correct usage is essential for accurate readings; otherwise, it may result in measurement errors. For accurate temperature readings, please follow the guidelines below:

Precautions:

1. During measurement, ensure the individual's forehead is free from obstructions like hair, sweat, cosmetics, or hats. Ensure the probe's surface is clean.
2. The individual should remain in the testing environment for more than 5 minutes, allowing their body temperature to stabilize before measurement.
3. Avoid measuring if the individual's forehead has been cooled with a compress or other cooling measures, as it can cause the reading to be lower than actual.

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4. Ensure a stable ambient temperature around the individual and avoid measuring near large airflows such as fans or air conditioner vents.

5. If the thermometer has been moved from a location with a significant temperature difference, let it sit in the new environment for at least 10 minutes before using.

6. Do not use this thermometer in direct sunlight.

7. It's recommended to take at least three readings and consider the highest one.

8. If, for any reason, the forehead temperature appears to be low, you can try measuring near the ear.

III. Starting the Measurement:

1. Press the power/measure button. Once the LED screen fully lights up and self-check is complete, the thermometer will vibrate, indicating it's ready for measurement.

2. In the ready state, the LED screen displays a waiting prompt.

Precautions:

1. If the scanning distance exceeds 3cm during the process, a distance prompt will be displayed, as shown in Fig 7.

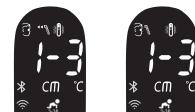


Fig 7

2. If left inactive, the thermometer will automatically shut off after 5 minutes.

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Measurement

1. Automatic Measurement: Upon entering the measurement interface, approach the forehead. The measurement starts automatically when the distance is less than 3cm. The display during measurement is as shown in Fig 8.

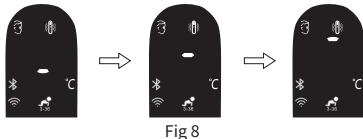


Fig 8

2. Spot Measurement: During measurement, aim the thermometer at the center of the forehead (above the brow) and keep it vertical, maintaining a distance of 1-3cm. Press the power/measure button, and the position indicator light will show the measurement spot. When the thermometer vibrates, it indicates that the measurement is complete, and the reading along with the corresponding indicator light will be displayed, as illustrated in Fig 9.

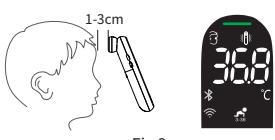


Fig 9

3. Scanning Measurement: To measure body temperature, aim the thermometer at the center of the forehead (above the brow) keeping it vertical and 1-3cm away. Press and hold the power/measure button, then scan the thermometer across the forehead from left to right or right to left. When the thermometer vibrates, it indicates that the measurement is complete, displaying the reading and the corresponding indicator light, as depicted in Fig 10.

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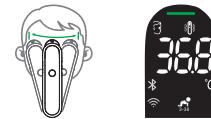


Fig 10

Precautions:

1. If the indicator light doesn't illuminate, it means the measurement is too low, and a retest is recommended.
2. If the green indicator light is on, it indicates the temperature is within a normal range.
3. If the yellow indicator light is on, it suggests the person may have a mild fever.
4. If the orange indicator light is on, it suggests the person may have a high fever.
5. If the measurement value is below 32.0°C, "Lo" will be displayed, as shown in Fig 11.
6. If the measurement value exceeds 43.0°C, "Hi" will be displayed, as illustrated in Fig 12.
7. If it's outside the ambient temperature range, "Err" will be displayed, as seen in Fig 13.



Fig 11



Fig 12



Fig 13

18

IV. Operational Features:

Switching Measurement Modes

Upon startup, it defaults to "Body Temperature Mode". Hold the age function key for an extended time to toggle between "Body Temperature" and "Object Surface Temperature" modes.

1. Body Temperature Mode: Used for measuring human body temperature.
2. Object Surface Temperature Mode: For measuring the temperature of object surfaces, as shown in Fig 14.



Fig 14

Switching Age Group

Briefly press the age function key to toggle between age groups.
a. 0-3 months (Fig 15); b. 3-36 months (Fig 16); c. Over 36 months (Fig 17).



Fig 15



Fig 16



Fig 17

Unit Switching

The interface of the thermometer offers two units: Fahrenheit and Celsius. When powered on, press and hold the settings button to switch units and return to the measurement interface.

Vibration Switch

In the powered-on state, press the vibration switch to activate or deactivate the vibration alert feature.

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Viewing Memory Values

When powered on (excluding during measurement): Press the memory function key to enter memory mode. The screen will sequentially display the memory sequence number and the stored value. Use the vibration/memory key to scroll up or down.

Clearing Memory Values

When powered on, hold the memory function key to clear all stored data.

Restoring factory settings

In the power-on state, press and hold the Setup key for 10 seconds: factory settings are restored.

V. Data Transfer Feature

Bluetooth and WIFI Connectivity

- After powering on, Bluetooth and WIFI automatically initiate connection. During the connection process, the Bluetooth and WIFI icons blink. Once successfully connected, the blinking stops, and the icons remain continuously illuminated, as shown in Fig 18.



Fig 18

- If the Bluetooth and WIFI are turned on but not connected to any devices, the icons will continue to blink, as shown in Fig 19.



Fig 19

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Bluetooth and WIFI Switch

After turning on the device, press and hold the settings button. The Bluetooth icon will flash, indicating entry into the Bluetooth settings mode, as illustrated in Fig 20.



Fig 20

a. Briefly press the age button to turn Bluetooth on or off, as displayed in Fig 21.



Fig 21

b. Press the settings button briefly, and the WIFI icon will flash, indicating you've entered the WIFI switch settings, as shown in Fig 22.



Fig 22

Again, briefly press the age button to turn the WIFI on or off, as shown in Fig 23.



Fig 23

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Visual Inspection: After cleaning, there should be no visible blotches and soil stains on the device under natural light, if there is still blotches and/or soil stains existed, repeat the cleaning steps mentioned above until there is no visible blotches and soil stains.

Disposing the device if there is corrosion, discoloration, pitting or cracked seals after cleaning, enquire about the options for environment-friendly and appropriate disposal. Take local regulations into account.

Reuse Life: 5 years.

Care:

The lens is very delicate. It is very important to protect the lens from dirt and damage. Do not touch or use tools to press it. Must be carefully protected otherwise it will affect the accuracy of the measurement.

Storage:

Always keep the thermometer within the storage temperature and humidity range as specified.

It is recommended to store the thermometer in a dry location free from dust.

Always keep the thermometer within the storage temperature range (-20°C to 55°C or -4°F to 131°F) and humidity range (< 93% non-condensing).

It is recommended to store the thermometer in a dry location free from dust. Do not expose the thermometer to direct sunlight, high temperature/ humidity or any extreme environment, otherwise the function will be reduced.

When the ambient temperature of the thermometer changes too much, such as moving the thermometer from one place of lower temperature to another place of higher temperature, allow the thermometer to remain in a room for 30 minutes where the temperature is between 5°C to 40°C.

6. List of Accessories

Instruction Manual 1 Copy

Charging dock (optional): 1 unit

Portable charging cable (optional): 1 piece

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4-Disposal

Used batteries should not be disposed of in the household rubbish. Used batteries should be deposited at a collection point.

At the end of its life, the appliance should not be disposed of in household rubbish. Enquire about the options for environment-friendly and appropriate disposal. Take local regulations into account.

5-Cleaning, Care and Storage

Cleaning:

Purpose: This thermometer is for reuse to measure body temperature, you may clean the surface of thermometer since which can be contaminated during use with organic soil and microorganisms carried by human hands immediately after each use.

Cleaning Agent: 70% isopropyl alcohol wipe.

Method of Cleaning: To thoroughly clean the device, immediately after each use, rubbing device (including markings) such as the position lamp, shell, button and LCD screen by hands without undue pressure with 70% isopropyl alcohol wipes for 15s and lens of thermometer (which is in the center of device top surrounded by ABS case) for 3s immediately after each measurement, as seen in Fig 16.

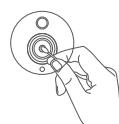


Fig 16

Note: Ensure that no liquid enters the interior of the thermometer, never use abrasive cleaning agents, thinners or benzene for cleaning and never immerse the instrument in water or other cleaning liquids. Wait 10 minutes after cleaning, allowing the thermometer to air-dry before taking a temperature measurement.

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7. Warranty

Our company warrants Non Contact Infrared Body Thermometer at the time of its original purchase and for the subsequent time period of one year.

The warranty does not cover the following:

The device series number label is torn off or cannot be recognized.

Damage to the device resulting from misconnection with other devices.

Damage to the device resulting from accidents.

Changes performed by users without the prior written authorization of the company.

Batteries and packaging are not covered under warranty.

When asked to provide warranty service, you must have a purchase date and purchase stamp dealers (including dealers name and address) of the warranty card. Be sure to ask the dealer to purchase this product signature on the warranty card. When asked to provide warranty service, please put the product to get our distribution points for repair. Products outside the warranty expires, will be charged accordingly.

Note:

1. If you have any problems with this device, such as setting up, maintaining or using, please contact with SERVICE PERSONNEL of HeTaiDa Technology Co., Ltd. Don't open or repair the device by yourself.

2. Please report to HeTaiDa Technology Co., Ltd. if any unexpected operation or events occur.

3. The 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 us timely.

4. The patient is an intended operator. The patient can measure and change battery. Under normal circumstances and maintain the device and its accessories according to the user manual.

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8-EMC Declaration

1. This equipment needs to be installed and put into service in accordance with the information provided in the ACCOMPANYING DOCUMENTS;

This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.

2. Caution: Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.

3. Caution: This unit has been thoroughly tested and inspected to assure proper performance and operation!

4. Caution: this machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used.

Guidance and manufacturer's declaration - electromagnetic emission

The Forehead&Ear Infrared Body Thermometer is intended for use in the electromagnetic environment specified below. The customer or the user of the Infrared Body Thermometer should assure that it is used in such an environment.

| Emission test | Compliance |
|--|----------------|
| RF emissions CISPR 11 | Group 1 |
| RF emission CISPR 11 | Class B |
| Harmonic emissions IEC 61000-3-2 | Not applicable |
| Voltage fluctuations/flicker emissions IEC 61000-3-3 | Not applicable |

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| Guidance and manufacturer's declaration - electromagnetic immunity | | |
|---|--|------------------|
| The Infrared Body Thermometer is intended for use in the electromagnetic environment specified below. The customer or the user of Infrared Body Thermometer should assure that it is used in such an environment. | | |
| Anti-interference detection | IEC 60601-1 test level | Compliance level |
| Electrostatic discharge (ESD) IEC 61000-4-2 | Contact: ± 8 kV Air: ± 2 , ± 4 , ± 8 , ± 15 kV | Same as the left |
| Electrical fast transient/burst IEC 61000-4-4 | The input a.c. power ports: ± 2 kV The input d.c. power ports: ± 2 kV Signal input/output ports: ± 1 kV | Not applicable |
| Surge IEC 61000-4-5 | Input power ports: $+0.5$, $+1.0$ kV Signal input/output: ± 2.0 kV | Not applicable |
| Voltage dips IEC 61000-4-11 | 0.5 cycles for $> 95\%$ (sync angle (degrees):0, 45, 90, 135, 180, 225, 270, 315) 1 cycles for $> 95\%$ UT (sync angle (degrees):0) 25 (50Hz)/30 (60Hz) cycles for 30% UT (sync angle (degrees):0) | Not applicable |
| Voltage interruption IEC 61000-4-11 | 250 (50Hz)/300 (60Hz) cycles for $> 95\%$ UT (sync angle (degrees):0) | |
| Powerfrequency (50Hz/60Hz) magnetic field IEC 61000-4-8 | 30A/m | Same as the left |

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

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Guidance and manufacturer's declaration - electromagnetic immunity

The Infrared Body Thermometer is intended for use in the electromagnetic environment specified below. The customer or the user of the Infrared Body Thermometer should assure that it is used in such an environment.

| Immunity test | IEC 60601 test level | Compliance level |
|----------------------------|--|--|
| Conducted RF IEC 61000-4-6 | 3 Vrms 150 kHz to 80 MHz | Not applicable |
| Radiated RF IEC 61000-4-3 | Professional healthcare environment: 3 V/m Home healthcare environment: 10 Vm 80 MHz to 2700 MHz | Same as the left. ( |

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Infrared Body Thermometer is used exceeds the applicable RF compliance level above, The Forehead&Ear Infrared Thermometer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Infrared Body Thermometer.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

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Guidance and manufacturer's declaration - RF wireless communication equipment immunity

| Test frequency (MHz) | Band ^{a)} (MHz) | Service ^{a)} | Modulation ^{b)} | Maximum power (W) | Distance (m) | NIVEAU DU TEST D'IMMUNITE (V/m) |
|----------------------|--------------------------|---|---|-------------------|--------------|---------------------------------|
| 385 | 380 - 390 | TETRA 400 | Pulse modulation ^{b)} 18 Hz | 1,8 | 0,3 | 27 |
| 450 | 430 - 470 | GMRS 460, FRS 460 | FM ^{c)} ± 5 kHz deviation 1 kHz sine | 2 | 0,3 | 28 |
| 710 | | | | | | |
| 745 | 704 - 787 | LTE Band 13, 17 | Pulse modulation ^{b)} 217 Hz | 0,2 | 0,3 | 9 |
| 780 | | | | | | |
| 810 | | | | | | |
| 870 | 800 - 960 | GSM 800, TETRA 800, IDEN 820, CDMA 850, LTE Band 5 | Pulse modulation ^{b)} 18 Hz | 2 | 0,3 | 28 |
| 930 | | | | | | |
| 1720 | | | | | | |
| 1845 | 1700 - 1990 | GSM 1800, CDMA 1900, GSM 1900, DECT: LTE Band 1, 3, 4, 25, UMTS | Pulse modulation ^{b)} 217 Hz | 2 | 0,3 | 28 |
| 1970 | | | | | | |
| 2450 | 2400 - 2570 | Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7 | Pulse modulation ^{b)} 217 Hz | 2 | 0,3 | 28 |
| 5240 | | | | | | |
| 5500 | 5100 - 5800 | WLAN 802.11 a/n | Pulse modulation ^{b)} 217 Hz | 0,2 | 0,3 | 9 |
| 5785 | | | | | | |

^{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.

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FCC COMPLIANCE STATEMENT:

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.

Note: 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.

Warning: Changes or modifications to this unit not expressly approved by the part responsible for compliance could void the user's authority to operate the equipment.

Radiation Exposure Statement

The product complies with the FCC portable, RF exposure limits set forth for an uncontrolled environment in accordance with FCC rule part 2.1093 and KDB 447498 D01.

The exposure standard for wireless device employs a unit of measurement known as the Specific Absorption Rate, Mobile Point of Sales terminal and meets FCC RF exposure guidelines when used with an accessory that contains no metal and that positions the product a minimum of 0 mm from the body. Use of other accessories may not ensure compliance with SAR. The SAR limit set by the FCC is 1.6W/kg. For body worn operation, this has been tested FCC RF exposure guidelines