
TERMOMETRO A DISTANZA A INFRAROSSI
NON-CONTACT INFRARED BODY THERMOMETER
THERMOMÈTRE À INFRAROUGES
SANS CONTACT
TERMÓMETRO INFRARROJO
SIN CONTACTO

REF 25583

Modello / Model / Modèle / Modelo: **HTD8816C**



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 0598

IP22





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 non contact 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.

Warning

- The non contact infrared body thermometer is a medical device, and can be used repeatedly, which using life is 5 years.
- The Non Contact Infrared Body Thermometer is to be operated by consumers in the home setting and primary care setting as screening tool. This manual, accessories, Directions for Use, all precautionary information, and specifications should be read before use.
- This product is designed to measure human body temperature on the forehead. Do not use it for any other purpose.
- This product is intended in the home setting and primary care setting as screening tool.
- Do not use the thermometer if it malfunctions or has been damaged in any matter.
- 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 15°C to 40°C (59°F- 104°F).
- Remove primary batteries if equipment is not likely to be used for long time.
- This product is not waterproof, do not be immersed in water or other liquid; If cleaning and disinfection, please follow the “Care and Storage” section requirements.
- Do not touch the sensor of infrared detection with your fingers.
- If a cold compress on the forehead fever patients, or take other measures to cool down the temperature data will low, should be avoided in this case to measure body temperature.
- If measure human forehead temperature , please select “body” mode; for measure other objects, liquids, food and other temperature please select “surface” mode.
- This product must be operated in a stable environment, if the ambient environment was mutations, please should be note whether there is fog on the sensor, if any, before using accordance with the “Care and Storage” section to removing the fog.
- Do not near strong electrostatic field or strong magnetic fields, thus avoiding the impact on the accuracy of the measurement data.
- Do not mix the old and new batteries to avoid damage to the product.
- It may affect the accuracy of measurements when the forehead is covered by hair,

perspiration, cap or scarf.

- The measuring result of this product is only for your reference. If you have any doubt, please measure the temperature in other methods.



- The device should be kept out of the reach of children/pets. When not in use, store the device in a dry room and protect it against extreme moisture, heat, lint, dust and direct sunlight. Never place any heavy objects on the storage case.
- Do not throw batteries into fire.
- Only use recommended batteries. Do not use rechargeable batteries.
- This thermometer will irreplaceable the diagnostic in hospitals.
- Do not fall, disassemble or modify the device.
- Do not use this device if you think it is damaged or notice anything unusual.
- This device comprises sensitive components and must be treated with caution. Observe the storage and operating conditions described in the 'Technical Specifications' section.
- Not servicing/maintenance while the thermometer is in use.
- When using, shall not touch battery and the patient simultaneously.
- Do not use the device if it is damaged/ degraded/loosened in any way. The continuous use of a damaged unit may cause injury, improper results, or serious danger.
- Based on the current science and technology, other potential allergic reactions are unknown.
- This equipment needs to be installed and put into service in accordance with the information provided in the ACCOMPANYING DOCUMENTS.

1. Overview

Intended Use

The Non Contact Infrared Body Thermometers are designed to be used for intermittent measurement and monitoring of human body temperature by consumers in the home setting and primary care setting as screening tool.

Description of Non Contact Infrared Body Thermometer

- Device principle and introduction

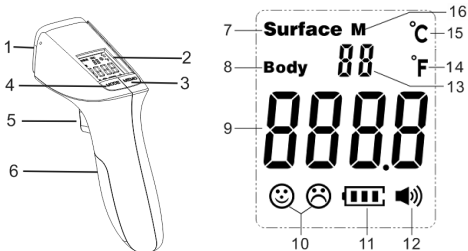
The Non contact infrared body thermometer are hand-held, reusable, battery operated devices, which can measure human body temperature on forehead, the skin temperature on one's forehead.

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 and Indicators.



- | | |
|--------------------------------|-------------------------------------|
| 1. IR sensor | 9. Data indicator |
| 2. Liquid crystal display(LCD) | 10. Indicator of measurement result |
| 3. MODE button | 11. Low Battery indicator |
| 4. Memo button | 12. Voice on/off indicator |
| 5. On/Scan button | 13. Memory Number |
| 6. Battery Cover | 14. Fahrenheit |
| 7. Surface mode | 15. Celsius |
| 8. Body mode | 16. Memory indicator |

Thermometer Applications

Thermometer Style	Adult		Pediatric	
	Ear	Forehead	Ear	Forehead
Non Contact Infrared Body Thermometers		√		√



Technical Specifications

Measurement Unit	°C/°F
Operating mode	Adjusted mode (Body mode) Direct mode (surface mode)
Reference Body Site	Axillary
Rated output range	Body mode: 34.0°C~43.0°C / 93.2°F -109.4°F Surface mode: 0°C~100°C / 32°F~212°F
Output Range	Body mode: 34.0°C~43.0°C/ 93.2°F -109.4°F Surface mode: 0°C~100.0°C/ 32°F -212°F
Laboratory Accuracy	Body mode: 34.0°C~34.9°C:±0.3°C / 93.2°F-94.8°F: ±0.5°F; 35.0°C~42.0°C:±0.2°C / 95.0°F-107.6°F: ±0.4°F; 42.1°C~43.0°C:±0.3°C / 107.8°F-109.4°F: ±0.5°F; Surface mode: ±2°C/±3.6°F.
Display Resolution	0.1°C/0.1°F
Three-color Backlight (Color Alarm)	35.5-37.3°C / 95.9-99.1°F: Green (Normal Temperature); 37.4-38.0°C (Alarm point) / 99.3-100.4°F: Yellow (Slight Fever) 38.1-43.0°C / 100.6-109.4°F: Red (High Fever) Note: 1. Surface mode is always with Green backlight. 2. In body mode 34.0-35.4°C is with green backlight.
Auto Power Off Time	≤18s
Measuring Time	≤2s
Measuring Distance	1 cm -5cm (0.4 in -2in)
Memories	50
Power Supply Requirements	
Batteries	1.5V (AAA) Alkaline battery x2 (IEC Type LR03)
Adaptable Range	2.6V~3.6V



Environmental	
Operating Condition	Operating Temperature: 15°C~40°C (59°F ~104°F), Relative Humidity ≤85%, atmospheric pressure:70 Kpa -106 Kpa
Transport and Storage Condition	Storage Temperature:-20°C -55°C / (-4°F - 131°F), Relative Humidity ≤93%, Atmospheric pressure:70 Kpa -106 Kpa
Dimension and Weighting	
Weight (without batteries)	80g
Size	L:122mm X W:96mm X H:42mm
Compliance	
Item	Compliant with
Equipment classification	Safety Standards: EN 60601-1: 2006+A1:2013, EN 60601-1-2: 2015
Type of protection	Internally powered equipment (on battery power)
Degree of protection	Non Applied part
Front panel and case labeling	EN ISO15223-1:2016
Temperature	EN ISO80601-2-56:2017
Home healthcare environment	EN 60601-1-11:2015

Safety classification of ME EQUIPMENT

Protection against electric shock	Internally powered ME equipment
Applied part	Non Applied part
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

2. Operation

2.1 Battery installation

Caution: The Non Contact Infrared Body Thermometer does not operate with dead batteries and does not input outer power. Install new batteries.

1. Pull the battery downward, toward the bottom of the Non Contact Infrared Body Thermometer, and remove the battery access door;
2. Insert two pieces AAA size batteries according to the "+" and "-";
3. Close the battery cover.

2.2 How to Operate

Before Applying the Thermometer

Be sure to read and understand all warnings listed of the instructions before use.

- The thermometer is aligned with the middle of the forehead to measure body temperature (between the eyebrows above) and keep the vertical distance, press the On/Scan button, temperature display immediately, see figure 2.

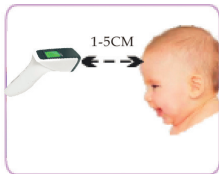


Figure 2-Measuring position and distance

- 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 15°C to 40°C.
- The ambient temperature around the test person should be stable, should keep away from the larger flow fan, air-conditioning vents and so on.
- When people moving from one place of lower temperature to another place of higher temperature, should at least remain in the test environment more than 5 minutes, to be consistent with the ambient temperature after the re-measurement.
- Wait at least 1 second for the next measurement. If the continuous measurement of five times, it is recommended to wait at least 30 seconds and then continue measurement.



- You cannot use the thermometer in place where the sun is strong.
- If for some reason the low forehead temperature measurement can try to align behind the ears. See figure 3.

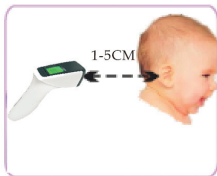


Figure 3- Align behind the ears to measurement

General Setup and Use

Start measuring

1. Turn on the thermometer by pressing the On/Scan button. The thermometer will perform self-test with all segments displayed for 2 seconds.
2. Align staff forehead to keep the distance, and then press the On/Scan button to start the measurement, read the data.

Note: 1) After full display over, you will hear a rattle or “beep beep beep” three times, which means that the measurements have been completed, while the target value of the measured temperature is displayed on the LCD, while backlit display according to the appropriate setting among the three colors red, green, yellow one of. And the Green means ready for next measurement. When 37.4°C-38.0°C, it's yellow ,means slight fever warning. Please pay attention to body temperature. When the body temperature is above 38.1°C, it's red, means high fever. Please take action to cool down or go for a doctor.

- 2) To ensure the accuracy of the measurement, wait at least 30 seconds after 5 consecutive measurements.

Mode conversion

When the device is running, pressing the MODE button to cycle conversion between “body” mode and “surface” mode.

“body” mode is used for measuring human body temperature, the “surface “ mode is used to measure the surface temperature. (The factory default is “body” mode).

Recalling and Erasing Memory Data

The last temperature taken before the thermometer powers off is stored in memory, up to 50.

As below step:

1. In the boot or shutdown state, short press the MEMO button to view the history of measured values.
2. An empty memory cell shows “---°C” or “---°F”.
3. Temperature readings can be stored in memory. Up to 50 temperature readings can be stored into the memory cells and automatically overwrite historical data.
4. In boot mode, press the MEMO button until the LCD display “CLR”, which means that all stored data is cleared completely.

Parameter settings

This product can be set according to the subjects of different colors and different environments data to meet the different characteristics of populations or individuals.

As below step:

1. Unit Set-F1

Under the boot mode, long press the MODE button to enter F1, press the “MODE” or “MEMO” button to switch Celsius and Fahrenheit temperature units, press the On/Scan button to confirm the unit settings (factory default is Celsius).

2. Fever alert set-F2

Under F1 state, press On/Scan button to enter the F2, press the “MODE” button to plus 0.1 °C, press the “MEMO” button decrease 0.1 °C, long press to accelerate the speed of temperature regulation, and finally press the On/Scan button to save. (The factory default is 38.1°C).

3. Prompt sound settings-F3

Under F2 state, press On/Scan button to enter F3, press MODE button or MEMO button to set voice switch, and press the On/Scan button to confirm the settings. (The factory default is the voice Prompt to open).

4. Exit setting mode

In the F3 mode, press the On/Scan button will automatically turn off the screen, exit setting.

Prompt sound settings ON/OFF function








Under the boot mode, short press power on/off button, at the same time press the MODE button to take on or take off the Prompt sound function.


Restore to factory setting function

Under the boot mode, short press power on/off button, at the same time press the MEMO button. Until LCD display “rst”. Two seconds later, former F1-F3 parameter back to factory setting.



3. Troubleshooting

MESSAGE	SITUATION	SOLUTION
Body °C 	Temperature taken in not within Typical human temperature range. (34.0~43.0°C or 93.2°F~109.4°F).	Make sure the forehead thermometer is for forehead measurement, not other human body site.
Body °C 		
Body °C 	Measured over the distance 1-5 cm (0.4-2in).	Optimum measurement distance is 1cm.
	Incorrect test position.	See figure 2 Measuring position and distance.
	Subjects forehead hair, Antipyretic stickers, head with sweat, etc.	Subjects sit quietly 5-10 minutes before the test.
	Some people's body temperature is lower than the general population.	The main concern fever temperature,
Body °C 	Operating temperature exceeds the range of specified temperature.	Move to a room within the operating range wait 30 minutes before taking temperature.
	The screen flicker, automatic turn off.	Replace battery or the product has been damaged, needs repairs.
	Battery capacity is too low. Taking temperature is not allowed.	Install a new battery
	Ambient temperature changes too fast.	Wait until the ambient temperature is stably.

	<ol style="list-style-type: none"> 1) Power is off. 2) Improper battery installation. 3) The battery is exhausted. 4) Display remains blank. 	<ol style="list-style-type: none"> 1) Press ON button again. 2) Check the battery polarity. 3) Replace with a new battery. 4) Contact the retailer or service center.
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4. Replacing the Battery

1. Open and release battery cover following indicator on the surface of battery cover. Before changing the battery be sure the system is already power off.
2. Remove the battery and replace with 2 new one, type AAA, Make sure align properly as indicated inside the battery cover.
3. Slide the battery cover back in until it snaps in place.
4. Do not dispose of used batteries in household waste. Take them to special local collection sites.
5. In case, if system is latched up after changing battery. You may not follow up the process of rule one. Just take off battery, waiting 30 sec, then load battery again.



Warning

Do not recharge, disassemble or dispose of in fire.

1. The typical service life of the new and unused batteries is 2000 measurements for the operation time is 18s.
2. Only use the recommended batteries, do not recharge non-rechargeable batteries and do not burn them.
3. Remove the batteries if the thermometer is not to be used for a long period.

5. Cleaning, Care and Storage

- The lens is very delicate.
- It is very important to protect the lens from dirt and damage.
- Use a clean, soft cloth to clean the surface of the device and LCD. Do not use solvents or immerse the device into water or other liquids.
- Always keep the thermometer a within the storage temperature and humidity range as specified.
- It is recommended to store the thermometer in a dry location free from dust.

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 15°C to 40°C.

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

Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The Non Contact Infrared Body Thermometer use 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 emission CISPR 11	Class B	The Non Contact Infrared Body Thermometer is suitable for use in all establishments, other than domestic 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	


Guidance and manufacturer's declaration – electromagnetic immunity


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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±15 kV air	±6 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Non Contact Infrared Body Thermometer requires continued operation during power mains interruptions, it is recommended that the Non Contact Infrared Body Thermometer be powered from an uninterruptible power supply or a battery.
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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

**Guidance and manufacturer's declaration – electromagnetic immunity**

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 10V/m 80 MHz to 2.5 GHz	Not applicable 10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Non Contact Infrared Body Thermometer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80MHz to 800MHz $d = 2.3 \sqrt{P}$ 80MHz to 800MHz 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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol: 

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 Non Contact Infrared Body Thermometer is used exceeds the applicable RF compliance level above, the Non Contact Infrared Body 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 Non Contact Infrared Body Thermometer.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Non Contact Infrared Body Thermometer.

The Non Contact Infrared Body Thermometer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Non Contact Infrared Body Thermometer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Non Contact Infrared Body 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)		
	150KHz to 80MHz $d = 1.2 \sqrt{P}$	80MHz to 800MHz $d = 1.2 \sqrt{P}$	800MHz to 2.5GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for 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.



	Caution: read instructions (warnings) carefully		Follow instructions for use
	Manufacturer		Date of manufacture
REF	Product code	LOT	Lot number
IP22	Covering Protection rate		Authorized representative in the European community
	WEEE disposal		Medical Device complies with Directive 93/42/EEC
	Recyclable PVC		Recyclable
FC	This device complies with Part 15 of FCC(Federal Communications Commission) Rules		Restriction of Hazardous Substances
	Temperature limitation		Moisture limitation
	Atmospheric pressure limitation	SN	Serial number



Disposal: *The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment.*

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies.