

yuwell



YUWELL®

YHT101

Infrared ear thermometer

User Manual And Technical Instruction

Please read the user manual carefully and follow the instructions before use. For date of manufacture, please refer to the packing.

1. Device use and working principle

●The YUWELL® Infrared ear thermometer is a non-sterile, reusable clinical thermometer. The device is to display the body temperature in the ear cavity by thermal radiation for people of all ages except preterm babies and newborns(1-29 days old).

●The YUWELL® Infrared ear thermometer is a non-contact thermometer.

●The infrared ear thermometer is equipped with an infrared sensor, which can transform the infrared light released by human ear membrane into corresponding electrical signal. The signal is corrected by the amplifier and signal processing circuit according to the internal algorithm of the instrument and the targeted emissivity, and then transformed into the temperature value of the measured human body.

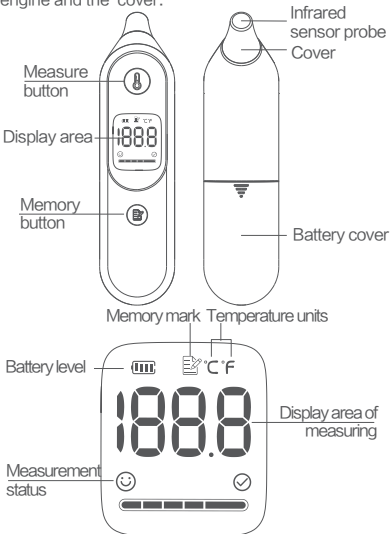
●Contraindications:

Do not use ear thermometer, if there is inflammation in the ear canal.

It is suggested to use ear thermometer after recovery of the operation or trauma of ear canal.

2. Device structure and composition

●The infrared ear thermometer consists of the main engine and the cover.




●Appendix:


ons, 2 AAA Alkaline Batteries.



3. Matters need attention

Warnings:

 The patient can use the thermometer to take the measurement by himself, or someone else can use the thermometer to measure the patient. Either way, the use and maintenance methods are the same.


 The probe lens is an infrared optical component, which is the most frequently damaged and stained part. To ensure the measurement accuracy, the cover must be worn after the measurement.

● Cleaning and disinfection


A. Before each use, check whether the probe lens is dirty. If it is dirty, wipe gently with cotton swab or soft cloth stained with a little medical alcohol(70%). Wait at least 5 minutes after disinfection before use.


Please keep the alcohol away from children.

B. Use a clean and soft cloth with medical alcohol to gently wipe the LCD screen and the shell.

 Warning: Do not immerse this product in medical alcohol or other liquids.

C. The cleaned devices shall be stored in a dust-free and dry place, please avoid direct sunlight; do not store the device in a place with high temperature, humidity, dust or corrosive gas.

 Note: The infrared ear thermometer belongs to precision equipment, do not let children play with it. Be careful not to fall from high, which will affect the accuracy of temperature measurement.

 Note: The infrared ear thermometer should not be transported without packaging, so as to avoid the influence of mechanical vibration on temperature measurement accuracy.

● If you do not use it for a long time, please take out the batteries and keep it out of the reach of children. Otherwise, it may be dangerous. In addition, if the battery is not used for a long time, it may cause breakdown due to battery leakage.

● This product contains sensitive electronic components and should be avoided in the environment with strong electromagnetic interference (such as mobile phones, microwave ovens, etc.) to prevent temporary impact on its accuracy.

● Please read this instruction manual carefully before use and confirm that the batteries are installed.

● Do not disassemble, repair or modify this device. It may cause errors in the measurement results or cause device failure.

● Please keep the probe clean before and after use. When the sensor lens becomes dirty, gently wipe it with a soft dry cloth or cotton swab. Do not wipe it with other objects, or blow the infrared sensor with your mouth. Otherwise it may cause the sensor mirror scratch or machine failure.

● If the situations cannot be solved or unexpected problem happens, please consult the local distributor.

Caution:

1. In order to measure the accurate temperature value, when measuring, please make sure that the probe is aligned with the eardrum and closely contacted with the ear canal.
2. The temperature of left and right ears of the same person is usually slightly different. It is better to measure the same ear every time for comparison.
3. The measurement results are only for reference and cannot replace the diagnosis of doctors. Some people do not have fever when they are ill. If you feel unwell, whatever the measurement results are, it is recommended to see a doctor immediately.
4. In the following cases, it is recommended to test three times in the same ear, selecting the highest value:
 - A. 90 days old baby
 - B. Children under three years old with immune diseases
 - C. Unacquainted with the use method, resulting in obvious deviation of the measured value (the measured value tends to descend if measuring the temperature of the same ear more than three times continuously).
5. Sleep on one side can cause the temperature of the pressed ear to rise. It is better to wait a few minutes before measuring.
6. The ear canal should be kept clean, because too much earwax in the ear canal will affect the accuracy.
7. Do not try to measure when the machine is wet, which may lead to inaccurate measurement results.
8. Do not measure the body temperature within 30 minutes after exercise, bathing or eating. At these moments, the body temperature is deviated from the normal body temperature.
9. If there is a temperature difference between the device storage place and the measuring environment, the device shall be placed in the using environment for more than 30 minutes, otherwise the measurement results may have errors.
10. Do not inhale or swallow small parts. Please pay attention to product storage to prevent damage caused by pets and pests.
11. Due to the limited size of the label, the font is too small, please put it at a suitable location for viewing

4. Measurement and transport storage environment

● Measurement environment:

Ambient temperature range:

+10°C ~ +40°C (50°F ~ 104°F)

Relative humidity: 15% to 90% (non-condensing)

Atmospheric pressure: 70kPa ~ 106kPa

● Storage environment in transportation:

Ambient temperature range:

-20°C ~ +55°C (-4°F ~ 131°F)

Relative humidity: 15% to 90% (non-condensing)

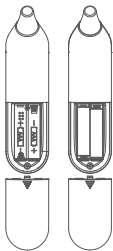
Atmospheric pressure: 70kPa ~ 106kPa

5. Installation and usage


● Installing the battery

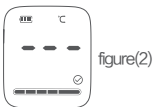
The device is supplied with 2 AAA alkaline batteries. Pry the tab down and remove the battery cover, put the battery into the battery compartment according to the instructions of the positive and negative poles in the battery compartment, and cover the battery cover (the product will carry out systematic functional self inspection such as full display).

⚠ Note: The batteries attached to this device are for test use. Please replace them with new batteries when testing.



● Product usage

1. Remove the cover, press the measure button “”, the backlight of the product will be fully displayed, as shown in figure (1), and enter the state to be tested after 1 second, as shown in figure (2).

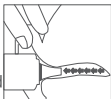



2. When the subject is testing, turn the head to one side, make the ear up, and gently pull the ear back to straighten the ear canal.



⚠ Note: The ears of children under one year old should be pulled back.

The ears of children over one year old and adults should be pulled back and up.

Please hold it correctly when measuring. Insert the probe of infrared ear thermometer into the ear canal gently and close it to ensure that the correct temperature of eardrum is measured as shown in the right figure:











Press and release measure button “”, after about 1 second, the infrared ear thermometer will beep to prompt the end of measurement and display the measurement results.


Note: when the measurement is completed, system processing busy, the device will prompt “”, When “” appears, the next measurement can be taken.


⚠ Note: Do not move while measuring

● This device has the following functions

1. Fever reminder function: When in use, if the measured temperature is over 37.5 °C, there will be a long beep followed by three short beeps to warn the user of possible fever.
2. Memory function : press memory button “  ” , memory value inquiry can be carried out. The infrared ear thermometer can store 7 groups of memory values. When the number of groups exceeds the specified number, the latest memory value will cover the earliest memory value.
3. In memory mode, press and hold the memory button “  ” for about 5s, when CLr is displayed on the screen, the memory value is cleared.
4. Automatic power off function: the product will power off automatically without any operation after 60s ± 10s
5. Manual power off function: long press measure button “  ” to turn off.
6. Battery replacement: when the screen only displays the symbol “  ” , prompt to replace the battery as soon as possible; when the symbol “  ” is displayed, replace the battery immediately.
7. Battery replacement cycle: new battery enables more than 3000 times measurements.
8. Temperature unit switching: in power off state, long press measure button “  ” for about 8s ~ 12s to enter the temperature unit switching state, short press memory button “  ” to select "°C" or "°F" temperature units, and then press the measure button “  ” to confirm.








6. Replacing the batteries

1. Battery replacement: When “  ” symbol is displayed, replace with 2 new AAA alkaline batteries, slide to open the battery cover and remove old batteries. Replace the batteries being sure to align properly as indicated inside the battery compartment.
2. Remove the batteries from the product if it is not required for extended periods of time in order to avoid damage to the thermometer resulting from a leaking battery.







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















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.

7. Troubleshooting instructions

Phenomenon of breakdown	Possible cause	Troubleshooting methods
	Low power unable to use	Replace with new batteries
 Blank screen	Ear thermometer has been turned off automatically	Restart the thermometer
	Battery not correctly installed	Check whether the battery is installed correctly
	The batteries run out.	Replace with new batteries
	Screen is still blank	Please contact the dealer for repair
	Operating temperature is lower than the set value	Put the ear thermometer at room temperature (10°C~40°C), (50°F~104°F) for 30 minutes before use
	Operating temperature is higher than the set value	Put the ear thermometer at room temperature (10°C~40°C), (50°F~104°F) for 30 minutes before use
	Sensor error	Please contact the dealer for repair.
	The temperature of the tested object is higher than the measuring range of the device	Please measure again according to the instructions
	The temperature of the measured object is lower than the measuring range of the device	Please measure again according to the instructions


8. The symbols related to safety requirements in this device and their meanings:

Symbols	Implication
	Equipment with type BF applied parts
	Warnings and precautions
	Recyclable
	Manufacturer
	Follow instructions for use
	Symbol for the marking of electrical and electronics devices according to Directive 2002/96/EC

	Safety and environmental protection use period for 10 years
IP22	Protection from ingress of particulates than $\geq 12.5\text{mm}$. Dripping water falling within 15° of vertical will not have a harmful effect on the infrared ear thermometer per IEC 60529.
	Temperature range
	Humidity range
	Atmospheric pressure range
	This side up
	Fragile
	Non-rainproof
	This device fulfils the provisions of EC directive 93/42/EEC(Medical Device Directive).
	See instruction for use
	Date of manufacture
	MR Unsafe items should not enter the MRI scanner room.
	Serial Number
	Date of effective use of the product
	Batch code

9. Product technical parameters

- Power supply:
DC 3V(2 x 1.5V AAA alkaline batteries)
- Measurement range:
34.0°C ~ 42.2°C (93.2°F ~ 108.0°F)
- Temperature units: °C/°F
- Minimum discernible value: 0.1°C(0.1°F)
- Measuring site: ear canal
- Maximum allowable error of temperature measurement:
34.0°C~34.9°C(93.2°F~94.8°F), $\pm 0.3^\circ\text{C}$ ($\pm 0.5^\circ\text{F}$)
35.0°C~42.0°C(95.0°F~107.6°F), $\pm 0.2^\circ\text{C}$ ($\pm 0.4^\circ\text{F}$)
42.1°C~42.2°C(107.7°F~108.0°F), $\pm 0.3^\circ\text{C}$ ($\pm 0.5^\circ\text{F}$)
- Time interval between each measurement $\leq 12\text{s}$
- Automatic power off time: 60s $\pm 10\text{s}$
- Measurement duration $\leq 2\text{s}$

- Electrical safety belongs to internal power supply equipment category
 - Electrical protection is type BF application part 
 - Degrees of protection provided by enclosures (IP code): IP22
 - Running mode: continuous running
 - Device type: Non-AP/APG device (cannot be used in the presence of flammable anesthetic gas mixed with air or flammable anesthetic gas mixed with oxygen or nitrous oxide)
 - Product size: 145x37x57mm
 - Product weight: about 62g (excluding batteries)
 - Service life: 5 years (excluding vulnerable and consumable parts)
 - This device is suitable for multiple people.
- Clean and disinfect the thermometer after use to prevent cross-infection of patients.
- This product will not cause allergic reaction and harm to human body during normal use
 - The device uses the adjusted mode in measuring
 - The clinical validation was conducted according to the requirements of ISO 80601-2-56. Take the result measured by mercury thermometer from oral cavity as the reference. Test three groups: 0 to 1 year old, older than 1 year and younger than 5 years, older than 5 years. The minimum number of subjects in an age group shall be at least 35. The test results are shown in the table below:

	Less than 1 year of age	Aged 1-5 years	Older than 5 years
CLINICAL BIAS(Δ_{cb})	-0.16°C	-0.11°C	-0.13°C
LIMITS OF AGREEMENT (L_A)	0.71°C	0.67°C	0.73°C
CLINICAL REPEATABILITY(σ_r)	0.14°C	0.13°C	0.13°C
According to EN 12470-5, clinical repeatability shall not exceed $\pm 0.3^\circ\text{C}$.			
REFERENCE BODY SITE	Oral measurement		

10. Temperature sense

The normal body temperature of people is a range, different people's normal body temperature varies, and individual body temperature will change at different times.

The normal body temperature of most people is

provided as follows, just for reference (The measurement of yuwell thermometer refers to ear canal)

Tympanic temperature:
35.5°C~37.5°C / 95.9°F~99.5°F

Caution:

1. Do not move while using.
2. Under the combined effects of the environment and the frequency of use, the product's shell temperature may exceed 41°C. Please use it carefully.

11. After-sales service

1. From the date of purchase, the product will enjoy a free one-year warranty with the purchase invoice. During warranty service, if you need to be provided with circuit diagram, components, necessary materials and electrical circuit maintenance, please contact the manufacturer.

2. The infrared ear thermometer is calibrated initially when manufactured. There is no need for readjustment if it is used according to the instruction. However, it is still recommended to calibrate the product once a year or when something goes wrong with the clinical accuracy.

3. Free warranty service will not be provided for faults caused by the following personal reasons:

● The following conditions are not covered by the warranty:

- A. Vulnerable and consumable parts: cover and battery;
 - B. Breakdown caused by unauthorized disassembly and assembly of the device;
 - C. Breakdown caused by operation not in accordance with the instructions;
 - D. Breakdown caused by lack of reasonable maintenance;
 - E. Fault caused by device falling carelessly;
 - F. Damage caused by external force;
4. Maintenance services beyond the scope of warranty will be charged according to regulations;

12. Warranty card

Warranty card

Product name:

Infrared ear thermometer

Model:

YHT101

13. Electromagnetic compatibility information

⚠ 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, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

⚠ This equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

⚠ When the instrument is in use, never put it near other instruments or stack it on other instruments. If you have to put it near other instruments or stack it on other instruments, please inspect and verify if the instrument could run normally.

There is the potential risk of radio frequency interference between the device and other devices. If there is, please find out the problems and take the following measures:

- (1) Turn off the device, and turn on again.
- (2) Change the direction of the device.
- (3) Keep the product away from the interferential devices.

Table 1–Compliance information for Emission test

Emission test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B

Table 2–Compliance information for Immunity test

Immunity test	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air
Power frequency(50Hz) magnetic field IEC 61000-4-8	30A/m 50Hz or 60Hz
Radiated RF EM fields IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80% AM at 1kHz

Table 3–Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band ^{a)} (MHz)	Service ^{a)}	Modulation ^{b)}
385	380-390	TETRA 400	Pulse modulation ^{b)} 18 Hz
450	430-470	GMRS 460, FRS 460	FM ^{c)} ± 5 kHz deviation 1 kHz sine
710	704-787	LTE Band 13,17	Pulse modulation ^{b)} 217 Hz
745			
780			
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation ^{b)} 18 Hz
870			
930			
1720	1700-1990	GSM 1800; TETRA 1900; GSM 1900; DECT; LTE Band 1,3, 4,25; UMTS	Pulse modulation ^{b)} 217 Hz
1845			
1970			
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n RFID 2450, LTE Band 7	Pulse modulation ^{b)} 217 Hz

5240	5100–5800	WLAN 802.11 a/n	Pulse modulation ^{b)} 217 Hz
5500			
5785			
Test frequency (MHz)	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	1,8	0,3	27
450	2	0,3	28
710	0,2	0,3	9
745			
780			
810	2	0,3	28
870			
930			
1720	2	0,3	28
1845			
1970			
2450	2	0,3	28
5240	0,2	0,3	9
5500			
5785			

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

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

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

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



Manufacturer: JIANGSU YUYUE MEDICAL
EQUIPMENT & SUPPLY CO.,LTD.

Manufacturing Address:
No.1 Baisheng Road Development Zone,
Danyang, Jiangsu 212300 CHINA

www.yuwell.com

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