YHT101医用红外耳式体温计(CE)说明书印刷要求

尺寸：420X160mm

色彩：准确、彩色印刷，层次分明

纸张：128g铜版纸

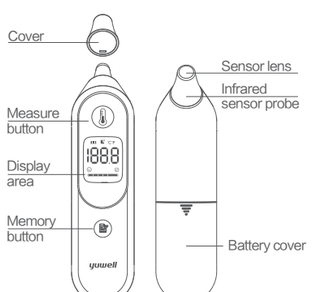
印后加工：7折

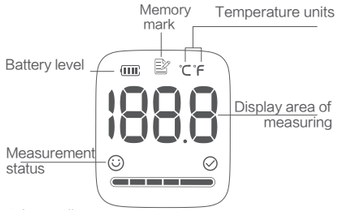
1. Device Use And Working Principle

●Intended purpose: The intended purpose of the device is to display the body temperature in the ear cavity by thermal radiation.It is intended for use on infants (except for pre−term babies or small for gestational age babies), children and adults.
●Indication: Intermittent measurement of human body temperature from ear canal, not for emergency clinical condition.
●Intended users: Lay persons, children under adult help or observation.
●Clinical benefits: The device can be used to measure body temperature so as to help to diagnose body condition. The clinical benefit associated with the device is defined as indirect, all intended patient population can experience the benefit.
●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:
Instructions, 2 AAA alkaline batteries, protective case.

3. ⚠ Matters Need Attention

Warnings:
1.The infrared ear thermometer is precise device, do not let children play with it. Be careful not to fall from high, a drop may cause the sensor to loosen which will affect the accuracy of temperature measurement.
2.The infrared ear thermometer should not be transported without packaging, so as to avoid the influence of mechanical vibration on temperature measurement accuracy.
3.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.
4.This product contains sensitive electronic compo−nents 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.
5.Please read this instruction manual carefully before use and confirm that the batteries are installed.
6.Do not disassemble, repair or modify this device. It may cause errors in the measurement results or cause device failure.
7.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.
8.Device application component materials are certified for biological compatibility.
9.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.
10. All the servicing and maintenance should be operated before or after use.
11.The thermometer shall not be serviced and maintained while in use .

12.Patient can take measurement themselves, or they can be taken by someone else using a thermometer. Patients can perform all the mainte−nance.
Caution:
1. In order to measure the correct temperature value,
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. Sleep on one side can cause the temperature of the pressed ear to rise. It is better to wait a few minutes before measuring.
5. The ear canal should be kept clean, because too much earwax in the ear canal will affect the accuracy.
6. Do not try to measure when the machine is wet, which may lead to inaccurate measurement results.
7. 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.
8. 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 measure−ment results may have errors.
9.Do not use the thermometer if there is blood or drainage in the external ear canal.
10.Use the untreated ear if prescription ear drops or other ear medications have been placed in the ear canal.
11.Patients who have deformities of the face and/or ear may not be able to have a temperature taken with the ear thermometer.
12.Complete ear canal occlusion due to cerumen (ear wax) can result in lower temperature readings.
13.Due to the limited size of the label, the font is too small, please put it at a suitable location for viewing.
14.Do not inhale or swallow small parts. Please pay attention to product storage to prevent damage caused by pets and pests.
15.Do not leave the thermometer unattended around children. Small items may become choking hazards.
16.If multiple measurements are required for the same person, remove the thermometer from the ear canal after each measurement, and follow the measurement steps to re−test.
17.Limitation: The device could not instead of rectal thermometer for rectal temperature.when measuring, please make sure that the probe is aligned with the eardrum and closely contacted with the ear canal.

4. Care And Cleaning

A.Before each use, check whether the sensor lens is

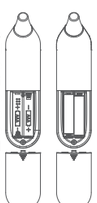
dirty. If it is dirty, wipe gently with cotton swab or soft cloth stained with clean water. Please make sure the probe is completely dry before next measurement.
B.Use a clean and soft cloth with clean water to gently wipe the LCD screen and the shell.
Warning: Do not immerse this product in medical 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. Sensor aging may affect the measurement accuracy.

5. Measurement And Transport Storage Environment

●Measurment environment:
Ambient temperature:
+10℃～+40℃(50℉～104℉)
Relative humidity: 15% to 90%, no condensation
Atmospheric pressure: 70kPa～106kPa
●Transportation and storage environment:
Ambient temperature:
−20℃～+55℃(−4℉～131℉)
Relative humidity: 15% to 90%, no condensation
Atmospheric pressure: 70kPa～106kPa

6. 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).



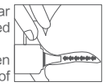
⚠ Note: The batteries attached to this device are for test use. Please replace them with new batteries when testing.

●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 the 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, will prompt " ☺ ".
When " ▬▬ " appears，the next measurement can be taken.
⚠ Note: Do not move while measuring
●This device has the following functions
1. High temperature reminder function: when in use, if the temperature measurement is over 37.5 ℃, there will be a long beep followed by three short beeps to remind the user.
2. Memory function : press the 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 the 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 the Measure button " 🌡 " for about 8s ~ 12s to enter the temperature unit switching state, short press the Memory button " 🗎 " to select "℃" or "℉" temperature units, and then press the Measure button " 🌡 " to confirm.

7. 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.
3.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.

8. Trouble Shooting 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
	Battery not correctly installed	Check whether the battery is installed correctly
	The batteries were wearing out	Replace with new batteries
	Screen is still blank	Please contact the dealer for repair
Er1	Operating temperature is lower than the set value	Put the ear thermometer at room temperature (10℃~40℃), (50℉～104℉) and let it stand for 30 minutes before use
Er2	Operating temperature is higher than the set value	Put the ear thermometer at room temperature (10℃~40℃), (50℉～104℉) and let it stand for 30 minutes before use
Er4	SENSOR serious error	Please contact the dealer for repair.
Hi	The temperature of the testedobject is higher than the measuring range of the device	Please measure again according to the instructions
Lo	The temperature of the measured object is lower than the measuring range of the device	Please measure again according to the instructions

⚠ Note: When the equipment is operated over the

specified normal ambient temperature, Er1 and Er2 errors will occur, and the device cannot work normally.

9. The Symbols Related To Safety Requirements In This Device And Their Meanings

Symbols	Implication
	Type BF applied part
	Caution
	Recyclable
	Manufacturer
EC REP	Authorized representative in the European Community/European Union
	Refer to instructions manual
	Symbol for the marking of electrical and electronic devices according to Directive 2012/19/EU
10	Safety and environmental protection use period for 10 years
IP22	Protection from ingress of particulates than ≥ 12.5mm. Dripping water falling within 15° of vertical will not have a harmful effect on the infrared ear thermometer per IEC 60529
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	This way up
	Fragile, handle with care
	Keep dry
CE 0297	This device fulfils the provisions of regulation (EU) 2017/745 (Medical Device Regulation).
SN	Serial number
	Date of manufacture
MD	Medical device
yuwell	Manufacturer mark
LOT	Batch code
UDI	Unique device identifier
MR	MR Unsafe

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Revision date: June 2024
YY-THM0101C-01(B/3)

10. Product Technical Parameters

●Power supply:
DC 3V(2 x 1.5V AAA alkaline batteries)
●Measurement range:
34.0℃～42.2℃ (93.2℉～108.0℉)
●Temperature units: ℃/℉
●Minimum discernible value: 0.1℃(0.1℉)
●Accuracy:
within the temperature display range of 35.0℃～42.0 ℃(95.0℉～107.6℉), it is ± 0.2 ℃(±0.4℉); beyond the temperature display range of 35.0℃～42.0℃(95.0℉～107.6℉), it is ± 0.3℃(±0.5℉)
●Time interval between each measurement≤12s
●Automatic power off time: 60s±10s
●Measurement duration≤2s
●Electrical safety belongs to internal power supply equipment category
●Type BF applied part is the probe.
●Degrees of protection provided by enclosures (IP code): IP22
●Operation mode: continuous operation
●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: 145 mm × 37 mm × 57 mm
●Product weight: about 62g (excluding Batteries)
●Service life: 5 years (excluding vulnerable and consumable parts)
●This device is suitable for multiple people.
Clean 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 clinical thermometer uses adjusted mode.
●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℃	−0.11℃	−0.13℃
LIMITS OF AGREEMENT (L_A)	0.71℃	0.67℃	0.73℃
CLINICAL REPEATABILITY(σ_r)	0.14℃	0.13℃	0.13℃
Measuring site of infrared ear thermometer	Ear canal		

REFERENCE BODY SITE	Oral measurement

11. 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℃~37.5℃ / 95.9℉~99.5℉
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℃. Please use it carefully.

12. 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. If at anytime you question the accuracy of the temperature measurement, please contact the manufacturer. Adjusted mode is for general public; calibration mode is for after-sale person only.
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;
5.If the situations cannot be solved or unexpected problem happens, please consult the local distributor.

6.Any serious incident that has occurred in relation to the device please report to the manufacturer and the competent authority of the Member State.

13. Warranty Card

Warranty card
Product name:
Infrared ear thermometer
Model:
YHT101

14. 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 adequateprotection to radio-frequency communicationservices. 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

Phenomenon	Compliance level
ELECTROSTATIC DISCHARGE IEC 61000-4-2	± 8 kV contact ± 15 kV air
RATED power frequency magnetic fields 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; CMDA 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.

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 packaging. The picture is for reference only, please refer to the actual product.