YHT107医用红外耳式体温计FDA说明书印刷要求
尺寸：成品尺寸142.5x90mm，骑马订6张，单页展开尺寸142.5x180mm
色彩：准确、彩色印刷，层次分明
纸张：105g铜版纸
印后加工：骑马订

Supplier's Declaration of Conformity
47 CFR § 2.1077 Compliance Information

Trade Name: yuwell
Product name: Infrared ear thermometer
Model Number: YHT108, YHT202, YHT208

Responsible party: YUWELL MEDTECH USA LLC
Address: 2152 Serene Ct, Keller, TX 76248

Contact information
Name: Fang Zhang
Telephone number: (206) 639−1311
E−mail address: fawn.zhang@yuwell.com

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 interfer−ence that may cause undesired operation.

JIANGSU YUYUE MEDICAL EQUIPMENT & SUPPLY CO.,LTD.
No.1 Baisheng Road Development Zone, Danyang,
Jiangsu 212300 CHINA
www.yuwell.com
If you have any questions, please contact your device supplier.
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Revision date: Jan. 2025
YY−THM0108D−01(A/0)

yuwell



YUWELL®
Infrared Ear Thermometer
YHT108/YHT202/YHT208

Instructions for Use

Please carefully read and follow the instructions for use before use.
For the date of manufacture, please refer to the packaging.
See probe cover package for probe cover instructions.
The picture is for reference only; please refer to the actual product.

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I. Glossary

RF: Radio Frequency
PC: Personal Computer
°C: Celsius degree
°F: Fahrenheit degree
App: Application
DDoS: Distributed Denial-of-Service
MRI: Magnetic resonance imaging
RFID: Radio Frequency Identification Devices
FCC: Federal Communications Commission
EM environment: Electromagnetic environment
ME equipment: Medical electrical equipment
HF SURGICAL EQUIPMENT: High-frequency surgery equipment
Quality of Service (QoS): The necessary level of performance in a data communications system or other service

II. Device Description

Purpose of the device (Indications for Use and Intended Use)

Indications for Use: The infrared ear thermometer is indicated for intermittent measurement of human body temperature from the ear canal. The device can be used by people of all ages except preterm babies or babies who are small for gestational age. The thermometer is intended for use in professional settings and the home environment. It is not for emergency clinical conditions. The probe cover is used as a sanitary barrier between the infrared ear thermometer and the ear canal.

Intended Purpose: The infrared ear thermometer is a non-sterile, reusable device intended for the intermittent determination of the human's body temperature. People of all ages can use the thermometer except for pre-term babies or babies who are small for gestational age.

Intended Users: Health care professionals and lay persons at least 11 years old.

When the device should not be used (Contraindications)

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

Do not use an ear thermometer if you have not fully recovered from surgery or ear canal trauma.

Working Principle

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. The Infrared ear thermometer is a non-contact thermometer.ac-

cording to the working principle.

Risks and Benefits

●Risk: 1. Improper device use may result in harm. Always followt he provided instructions. Please do not attempt to self-diagnose or self-treat. Consult with your physician, If you feel unwell.

2. This device contains small parts that could be a choking risk if swallowed by a child. Keep small parts away from young children to prevent choking hazards.

3. As with all items applied to the skin, there is a risk of irritation and discomfort..

●Benefits: The device measures body temperature and can assist in diagnosing body conditions. The clinical benefit is considered indirect, and all intended patient populations can use it.

●Limitation: The device should not be used as a replacement for a rectal thermometer when measuring rectal temperature.

Detachable Parts and Materials for Use

Probe cover (PP), Cover (PP), Protective case (ABS), 2 AA alkaline batteries.

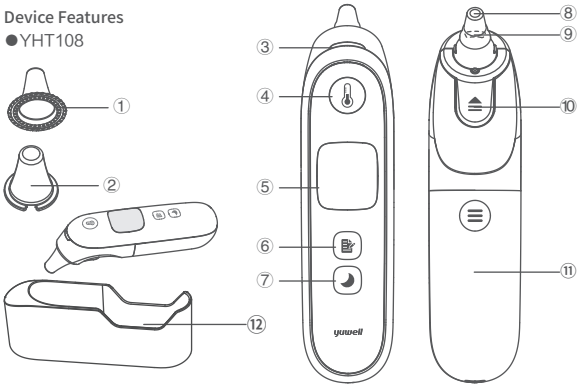
III. Device Structure and Composition

Packaging List

Infrared ear thermometer Instructions for use, 2 AA alkaline batteries, Protective case, APP Quick Guide, Probe cover (Box of 20).

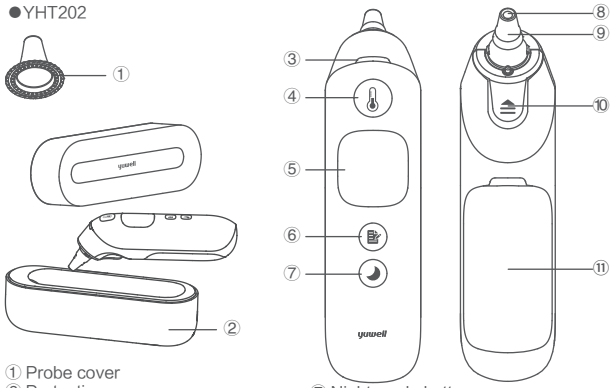
Device Features

●YHT108



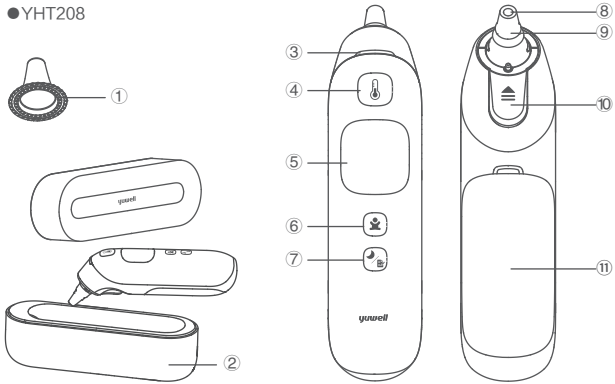
① Probe cover
② Cover
③ Indicator light
④ Measure button
⑤ Display area
⑥ Memory button
⑦ Night mode button
⑧ Sensor lens
⑨ Probe
⑩ Probe cover replacement button
⑪ Battery cover
⑫ Protective case

●YHT202



① Probe cover
② Protective case
③ Indicator light
④ Measure button
⑤ Display area
⑥ Memory button
⑦ Night mode button
⑧ Sensor lens
⑨ Probe
⑩ Probe cover replacement button
⑪ Battery cover

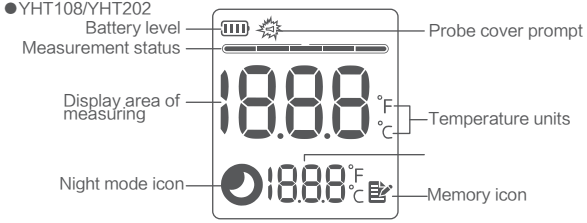
●YHT208



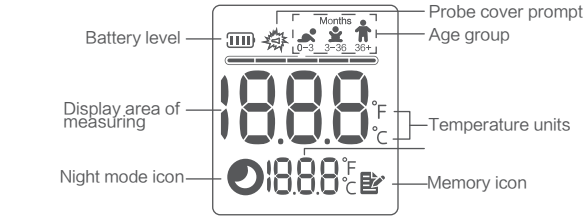
① Probe cover
② Protective case
③ Indicator light
④ Measure button
⑤ Display area
⑥ Age select button
⑦ Memory/night mode button
⑧ Sensor lens
⑨ Probe
⑩ Probe cover replacement button
⑪ Battery cover

Device Display

●YHT108/YHT202



●YHT208



IV. ⚠Warnings and Precautions

Proper use is critical for obtaining accurate temperatures. Please ensure you read the instructions for use carefully and thoroughly.

Safety Warnings and Cautions

WARNING: Do not use in areas filled with flammable gases, such as anesthetics, oxygen, oxygen enriched environments, or nitrous oxide, to prevent fire risk.
WARNING: Do not use the device during magnetic resonance imaging (MRI) or in an MRI environment.
WARNING: Do not use damaged, perforated, dirty, or poor fitting probe covers to avoid inaccurate or unavailable temperature measurements.
WARNING: Use only with YUWELL certified probe covers for accurate readings.
CAUTION: Due to the limited size of the label, the font is too small. Please put it in a suitable location for viewing.
CAUTION: Please pay attention to device storage to prevent damage caused by pets and pests.
CAUTION: Do not reuse the probe cover to avoid cross-infection.
CAUTION: Do not leave the thermometer unattended around children. Small

items, such as probe covers, may pose a choking hazard.

Performance Warnings and Cautions

WARNING: Avoid dropping the thermometer from a height, as damage to the probe may affect the accuracy of the measurement.
WARNING: The ear thermometer should not be transported without packaging to avoid mechanical vibrations impacting temperature measurement accuracy.
WARNING: This device contains sensitive electronic components and should not be used in environments with strong electromagnetic interference (e.g., mobile phones, microwave ovens, etc.) to prevent temporary impacts on its accuracy.
CAUTION: To ensure an accurate temperature reading, Please ensure the probe is properly aligned with the eardrum and in close contact with the ear canal when measuring.
CAUTION: The temperature in each ear of the same person may vary slightly. For consistency, measuring the same ear each time for comparison is recommended.
CAUTION: The measurement results are for reference only and cannot replace a doctor's diagnosis. Some people may not have a fever when they are ill. If you feel unwell, regardless of the measurement results, it is recommended to see a doctor immediately.
CAUTION: The ear canal temperature may increase after lying on one side. Wait ten minutes before measuring, or alternatively, measure the other ear.
CAUTION: Keep the ear canal clean, as excess earwax can affect the accuracy of the measurement.
CAUTION: Do not measure when the device is wet, which may lead to inaccurate measurement.
CAUTION: Avoid measuring body temperature within 30 minutes after exercise, bathing, or eating, as these activities can temporarily alter the normal body temperature.
CAUTION: Do not use the thermometer if there is blood or drainage in the external ear canal.
CAUTION: Use the untreated ear if prescription ear drops or other ear medications have been placed in the ear canal.
CAUTION: Patients with deformities of the face and/or ear may be unable to use the ear thermometer.
CAUTION: Complete occlusion of the ear canal due to cerumen (ear wax) may result in lower temperature readings.
CAUTION: If there is a temperature difference between the device's storage location and the measuring environment, the device should be placed in the measuring environment for at least 30 minutes to avoid inaccurate measurement.
CAUTION: 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 retest.

CAUTION: When using the thermometer with a smart device, keep both devices within the recommended range of each other (see Specifications for details); moving outside of this range may cause a loss in connection with the smart device.

CAUTION: When using the thermometer with a smart device, keep the devices away from sources that may interfere with the Bluetooth connection. Other devices may cause radio frequency interference (RFI), which may result in a loss of quality of service (see Specifications for details) for the Bluetooth connection. Devices that may cause RFI include but are not limited to: electro-cautery equipment, diathermy equipment, other cellular telephones, wireless PC and tablets, pagers, RFID devices, MRI, and electromagnetic security systems.

Cleaning, Disinfection and Care Warnings and Cautions

WARNING: Do not immerse this device in medical alcohol or other liquids.

WARNING: Avoid contact between liquid and the device's metal parts.

WARNING: Cleaned devices should be stored in a dust-free and dry place. Please avoid direct sunlight and not store the device in an area with high temperatures, humidity, dust, or corrosive gases.

WARNING: This device is suitable for multiple people to use. A new probe cover must be used before each measurement to prevent cross-infection. Clean the device before use for optimal performance.

WARNING: The sensor lens is a delicate infrared optical component and is the most frequently damaged and stained part. To maintain measurement accuracy, always cover the sensor after use.

WARNING: Patients can take their temperature or have someone assist them. The use and maintenance methods are the same in both situations.

WARNING: All the servicing and maintenance should be performed before or after use. While the ME equipment is in use, servicing and maintenance must not be performed.

WARNING: Please remove the battery if the thermometer is not used for an extended period. Keep the battery out of children's reach.

WARNING: Please keep the probe clean before and after use. If the sensor lens becomes dirty, gently wipe it with a soft dry cloth or cotton swab. Do not use other objects to clean it or blow on the infrared sensor. It may scratch the sensor mirror or cause device failure.

WARNING: This device contains batteries and recyclable electronic components. To protect the environment, do not dispose of it with household waste. Dispose of used batteries at an appropriate collection location following national or local regulations.

CAUTION: Store thermometer and probe covers in a dry location, free from dust and contamination and away from direct sunlight.

CAUTION: Do not expose the thermometer to extreme temperatures below −20℃ (−4°F) or above +55℃ (131°F), nor to excessive humidity and desiccation (> 90 % RH, < 15% RH).

CAUTION: When the ambient temperature is 20℃ (68°F), the thermometer requires approximately 4 hours to stabilize if transitioning from the maximum or the minimum storage temperatures before it is ready for use.

Compliance Warnings and Cautions

WARNING: Do not modify the device without authorization from the manufacturer. If the probe is damaged, return the device to the manufacturer or distributor for service.

WARNING: Dispose of thermometer, accessories, and battery per local laws and regulations.

NOTE: 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, according 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.
- Consult the dealer or an experienced radio/TV technician for help.

V. Setup and Use

Installing the AA Batteries

1. Remove the battery cover, as shown in figure 1 or figure 2.
2. Insert two new AA alkaline batteries, ensuring they match the labels (+ and −) inside the battery compartment. (The device will perform internal self-check, the display shows all segments as shown in figure 6 or figure 7.)

NOTE: The thermometer will not work if the batteries are inserted incorrectly.

3. Secure the battery cover by snapping it into place.

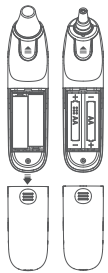


Figure 1

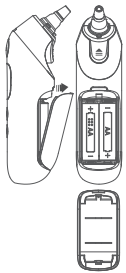


Figure 2

NOTE: The batteries included with this device are for trial use. Please replace them with new batteries when measuring.

4.Battery Reminder

The status of the internal electrical power source will be indicated by different icons depending on the battery capacity. When the screen only displays the symbol "▭", replace the battery as soon as possible; when the symbol "▭" appears, replace the battery immediately. To replace batteries, slide open the battery cover and remove the old batteries. Insert two new AA batteries, ensuring they align correctly with the (+) and (−) markings inside the battery compartment. Ensure the batteries are properly installed before closing the cover.

Using Infrared Ear Thermometer

1. Take the infrared ear thermometer out of the protective case, as shown in figure 3 or figure 4. If the model is equipped with a cover, remove the cover.

2. Attach probe cover.

Place a new, clean probe cover onto the probe, ensuring the centers are aligned, and insert it firmly until properly attached, as shown in figure 5.

NOTE: Please only use the designated probe cover to ensure the accuracy of the measurement. Please contact the manufacturer or an authorized seller to purchase the genuine probe covers.

NOTE: Probe covers are single-use. Always use a new, clean, undamaged probe cover before each measurement. Before attaching the probe cover, please ensure the sensor lens is clean and intact.

3. Press the measure button " 🌡 " to power on the device.

Infrared ear thermometer YHT108/ YHT202

The thermometer will perform an internal self-check, displaying all segments on the screen, as shown in figure 6. After self-check, the screen will display the pending test status as shown in Figure 8, with the indicator light on.

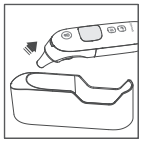


Figure 3



Figure 4

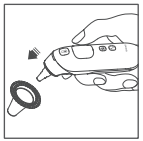


Figure 5

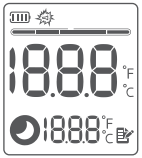


Figure 6

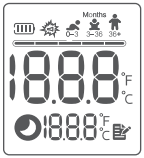


Figure 7

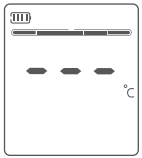


Figure 8

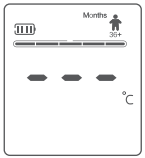


Figure 9

Infrared ear thermometer YHT208

The thermometer will perform an internal self-check, displaying all segments on the screen, as shown in figure 7 . After self-check, the screen will display the pending test status as shown in Figure 9, with the indicator light is on (Please select the age group when measuring for the first time after installing the batteries.).



figure 10



figure 11

4. Gently pull on the patient's ear, then insert the probe snuggly into the ear canal.

For patients over one year old, pulled the ear back and up, as shown in Figure 10;

For patients under one year old, pulled the ear back and up, as shown in Figure 11.

NOTE: Do not move while measuring.

5. Press and release the measure button " 🌡 ", the device will beep after about one second to indicate the completion of the measurement, and the measurement reading will be displayed.

NOTE: When the indicator light is on, the next measurement can be taken. The time interval between each measurement will be less than 12 seconds.

6. To take another temperature measurement, press the probe cover replacement button to remove and discard the used cover. Attach a new, clean, and undamaged probe cover before measuring.

7. If another measurement is unnecessary, remove the used probe cover, put the cover on the thermometer, and store the thermometer in the protective case.

VI. Device Functions

1. High Temperature Reminder

When in use, if the temperature measurement is exceeds 37.5℃ (99.5°F), device will play a long beep followed by three short beeps to remind the user.

Age Group	White Backlight Normal Temperature	Orange Backlight Evaluated Temperature	Red Backlight High Temperature
0–3 Months	≥34.0–≤37.5℃ (≥93.2–≤99.5°F)		>37.5℃ (>99.5°F)
3–36 Months	≥34.0–≤37.5℃ (≥93.2–≤99.5°F)	>37.5–≤38.5℃ (≥99.5–≤101.3°F)	>38.5℃ (>101.3°F)
36 Months–Adult	≥34.0–≤37.5℃ (≥93.2–≤99.5°F)	>37.5–≤39.4℃ (≥99.5–≤102.9°F)	>39.4℃ (>102.9°F)

2. Memory Mode

Infrared ear thermometer YHT108/YHT202

Press the memory button " 📝 " memory value inquiry can be carried out. To clear the previous stored memory value, press and hold the memory button"📝" for approximately 5s until “CLr” appears on the screen.

Infrared ear thermometer YHT208

Long press the memory/night mode button "" access to memory page, short press to query memory value. To clear the previous stored memory value, press and hold the age select button " " for approximately 5s until "CLr" appears on the screen.

NOTE: When the number of groups exceeds the specified number, the latest memory value will cover the earliest memory value.

3. Power Off

Manual power off: Press and hold the measure button " " to turn off the device.

Automatic power off: The device will automatically turn off after 60s ± 10s of inactivity.

4. Switching Temperature Unit

Infrared ear thermometer YHT108/YHT202

In power off state, press and hold the measure button " " for approximately 8s-12s to enter the temperature unit switching state, press the memory button " " to select "℃" or "°F" temperature units, then press the measure button " " to confirm your selection.

Infrared ear thermometer YHT208

In power off state, press and hold the measure button " " for approximately 8s-12s to enter the temperature unit switching state, press the age select button " " to select "℃" or "°F" temperature units, then press the measure button " " to confirm your selection.

5.Night Mode

Infrared ear thermometer YHT108/YHT202

Press the night mode button " " to enter the night mode.

Infrared ear thermometer YHT208

Pressing the memory/night mode button " " to enter the night mode .

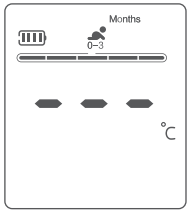
In night mode, all audible beeps are muted, the night mode icon is displayed on the screen and night-light will turn on. Secondary press of night mode button turns night mode off both sound on and night-light off.

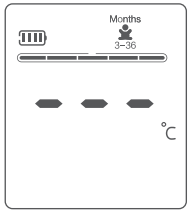
6. Age Selection Function (Infrared ear thermometer YHT208)

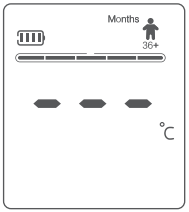
Select age with the age select button. Press button to toggle through each age group.

NOTE: Please select the age group when measuring for the first time after installing the batteries.

NOTE: When the device is switched on again, it defaults to the age group selected last time. If the patient's age group is different from the default age group, please select the age again.







7. Bluetooth (Optional)

(1) Download & Install Yuwell HealthCare+ app

Method 1: Search for the Yuwell HealthCare+ app in the App Store or Google Play store and download it.

Method 2: Scan the QR codes below to download and install.

(2) Measurement

Launch the Yuwell HealthCare+ app and choose the temperature measurement interface. Ensure the Bluetooth is enabled on the smart device. Attach a new, clean probe cover to the thermometer and take a measurement.

NOTE: When powered on, the thermometer will automatically search for and connect to your smart device.

NOTE: Keep the thermometer and smart device within the recommended range. (see Bluetooth technology information section for details); Outside of this range may result in a lost connection with the smart device

(3) Measurement Records

Click the "Data" on the main interface of the Yuwell HealthCare+ app to open the history records. Temperature records and curve are available.

NOTE: Bluetooth communication is only available with smart devices using the Yuwell HealthCare+ app. The thermometer can only connect to a single smart device at a time to minimize the risk of unauthorized access.

Support version iOS 10.0 and above

Support version Android 5.0 and above

VII. Cleaning and Disinfection

Manual Cleaning Procedure

1. Use a clean and dry soft cloth or cotton swab to gently wipe the sensor lens for a minimum of 30 seconds.
2. Thoroughly wipe the device surfaces with a non-linting cloth dampened (not dripping) with soap solution for at least three (3) minutes. And wipe the device surface with a non-linting cloth dampened (not dripping) with bottled water for at least three (3) minutes.

NOTE: Prepare the cleaning solution according to the detergent manufacturer's instructions. (e.g., Alconox® Powdered Precision Cleaner, 10 g/L)

NOTE: Pay extra attention to the device's cracks, crevices, and hard-to-reach areas.

3. Dry the device thoroughly with a soft, clean, non-linting cloth.

Post-cleaning inspection

IInspect the device visually after cleaning for cleanliness, damage, and missing or illegible device labeling or markings:

1.If any visible dirt or residue remains, repeat the cleaning procedure.

2.Any damaged device should be removed from use. Damage may include, but is not limited to, corrosion, discoloration, excessive scratches, flaking, cracks, and wear.

3. Remove any device with missing, illegible device labeling or marking from use.

Disinfection Procedure

1. Clean the device before disinfection.
2. With the probe facing down, wipe the device surfaces with a non-linting cloth dampened (not dripping) with 70% Isopropyl Alcohol (IPA).
3.Allow all surfaces to remain wet for at least two (2) minutes. If necessary, use additional wipes to ensure the surfaces remain wet for the full duration.
4.Dry thoroughly with a soft, clean, non-linting cloth.
5. Allow at least five (5) minutes of drying before taking a temperature reading. Make sure the probe lens is clean and dry before use.

VIII.Troubleshooting Instructions

Error Message	Situation	Solution
	Low power unable to use.	Replace with new batteries.
Blank screen	Thermometer has been automatically turned off.	Restart
	Battery is not correctly installed.	Check if the battery is correctly installed.
	The batteries were wearing out	Replace with new batteries.
	Screen is still blank.	Please contact the authorize reseller for repair.
	No probe cover is attached, or probe cover is not in place.	Attach the probe cover in place.
Er 1	The operating temperature is below the set value.	Place the thermometer at room temperature, 10℃-40℃ (50°F-104°F) for 30 minutes before use.
Er2	The operating temperature is exceeds the set value.	Place the thermometer at room temperature, 10℃- 40℃ (50°F -104°F) for 30 minutes before use.
Er3	The operating environment temperature has changed significantly compared to the storage temperature.	Place the thermometer at the operating environment temperature for 30 minutes before use.
Er4	Sensor error	Please contact the local distributor or manufacture.
Hi	The measured temperature is above the device's measuring range.	Please measure again following the instructions.
Lo	The measured temperature is below the device's measuring range.	Please measure again following the instructions.
POS	The thermometer probe was not positioned securely in ear canal. An accurate measurement was not possible	Take care that the positioning of the probe is correct and remains stable. Replace probe cover and reposition. Press measuring button to begin a new measurement.

IX.Technical Specification

1. Configuration

Model	REF/Catalog Number	Description
YHT108	YHT108001	No Wireless Communication
	YHT108002	Communication (Bluetooth)
YHT202	YHT202001	No Wireless Communication
	YHT202002	Communication (Bluetooth)
YHT208	YHT208001	No Wireless Communication
	YHT208002	Communication (Bluetooth)

2. Displayed Temperature Range and Accuracy

ITEM	PARAMETER
Displayed temperature range	34.0℃–42.2℃ (93.2°F–108.0°F)
Temperature units	℃/°F
Display resolution	0.1℃ (0.1°F)
Accuracy for displayed temperature range	±0.2℃ (±0.4°F), 35.0 ℃–42.0℃ (95.0°F–107.6°F); ±0.3℃ (±0.5°F), 34.0℃–34.9℃ (93.2°F–94.8°F), 42.1℃–42.2℃ (107.8°F–108.0°F)

NOTE: In accordance with ISO 80601–2–56.
The rated output range: 34.0℃–42.0℃ (93.2°F–107.6°F).
The rated extended output range: 42.1℃–42.2℃ (107.6°F –108.0°F).

NOTE: Body temperature varies based on the measurement site, age, individual differences, and time of day. The typical tympanic temperature for most people is: 35.5℃–37.5℃ (95.9°F–99.5°F); this is for reference only.

NOTE: This thermometer meets ASTM Standard E 1965–98 requirements. Full responsibility for the conformance of this device to the standard is assumed by JIANGSU YUYUE MEDICAL & SUPPLY CO.,LTD..
ASTM laboratory accuracy requirements for infrared ear thermometer in the display range of 37℃–39℃ (98°F–102°F) is ±0.2℃ (±0.4°F), while for mercury–in–glass and electronic thermometers, the requirement, according to ASTM Standards E667–86 and E1112–86 is ±0.1℃ (±0.2°F).

3. Battery Life

ITEM	DESCRIPTION
Power supply	DC 3V (2 x 1.5V AA alkaline batteries)
Battery life	New battery enables more than 600 times measurements.

4.Physical Characteristics

MODEL	DIMENSIONS	WEIGHT WITHOUT BATTERY
YHT108	6" ×2.3"×1.5" 153 mm×59 mm×37.5 mm	About 0.176 lbs. (80g)
YHT202	5.9" ×2.1"×1.5" 150 mm×54 mm×38 mm	About 0.165 lbs. (75g)
YHT208	5.8" ×2.1"×1.5" 148 mm×54 mm×38 mm	About 0.187 lbs. (85g)

5. Bluetooth Technology Information

Frequency Range	2402 MHz–2480 MHz
Bandwidth	1 MHz, 2 MHz
Modulation	GFSK
Frequency characteristics	UHF
Max Conducted TX Power	2 dBm
Recommended Range	~10 feet (~3 meters) line–of–sight
FCC ID (YHT108)	2A2JJ–YHT108
FCC ID (YHT202)	2A2JJ–YHT202
FCC ID (YHT208)	2A2JJ–YHT208
Quality of Service (QoS)	Delay <10 seconds

6. Environment

ITEM	DESCRIPTION
Operating Temperature Range	+10℃–+40℃ (50°F–104°F)
Transport and Storage Temperature Range	–20℃–+55℃ (–4°F–131°F)
Humidity	15% to 90%, no condensation
Atmospheric Pressure	70kPa–106kPa

7. Service Life

ITEM	DESCRIPTION
Service Life	5 years (excluding vulnerable and consumable parts)

8. Clinical Accuracy

The clinical thermometer operates in adjusted mode.

Clinical accuracy was tested according to ISO 80601-2-56. The mercury thermometer measurement from the oral cavity is used as the reference. Three groups were tested, with a minimum of 35 subjects per age. The results are shown in the table below.

	Less than 1 year of age	Aged 1-5 years	Older than 5 years
CLINICAL BIAS($\mathbf{d_{cb}}$)			
LIMITS OF AGREEMENT (L_A)			
CLINICAL REPEATABILITY(σ_r)			
REFERENCE BODY SITE		Oral	
Measuring site of infrared ear thermometer		Ear canal	

9. Compliance

EQUIPMENT CLASSIFICATIONS PER IEC 60601-1	
Degree of Protection against Electric shock	Internally powered ME equipment Type BF applied part, The applied part is the probe.
Degree of Protection from Liquid Ingress	IP22
Mode of Operation	Continuous operation
Environment	Not for use in an OXYGEN RICH ENVIRONMENT
The MAX. temperature of applied part not exceed 48℃	

X. Symbols

SYMBOL	DEFINITION	SYMBOL	DEFINITION
	Temperature limit	REF	Catalogue number
	Humidity limitation		Manufacturer
	Atmospheric pressure limitation		Recyclable
	This way up	MD	Medical device
	Fragile, handle with care	UDI	Unique device identifier
	Keep dry	SN	Serial number

LOT	Batch code		Bluetooth
	Type BF applied part		
	Caution		
	Follow instructions for use		
	Date of manufacture		
	Do not re-use		
	Waste from electrical and electronic equipment (WEEE)		
	Safety and environmental protection use period for 10 years		
	MR Unsafe. Not appropriate for use in MR environment (i.e., inside the MR magnet room)		
IP22	Protected against solid foreign objects of 12.5 mm ϕ and greater. Protection against vertically falling water drops when enclosure tilted up to 15° .		

XI. After-sales Service

1. YUYUE provides a 12-month warranty to the original end-user purchaser from the original purchase date. Please contact the manufacturer if you require a circuit diagram, components, necessary materials, or electrical circuit maintenance during the warranty period.
2. The infrared ear thermometer is calibrated at the time of manufacture. No recalibration is necessary if used as instructed. However, YUYUE recommends an annual calibration check if clinical accuracy is uncertain.

If you are concerned about the accuracy of the temperature, please contact the manufacturer.

Calibration mode: Press and hold the measure button, then insert the battery, and the screen will display “CAL”.

Adjusted mode is for general use; calibration mode is for after-sales service only.

3. The warranty does not cover:
A. Vulnerable and consumable parts: cover, battery and probe cover;
B. Damage caused by unauthorized disassembly and assembly;
C. Damage caused by improper use contrary to the instructions;
D. Damage caused by lack of proper maintenance;
E. Damage caused by device drops;
F. Damage caused by external force;
4. Maintenance services beyond the warranty scope will be charged as per regulations.
5. If issues cannot be resolved or unexpected problems arise, please contact the local distributor.

Warranty card
Product name:
Infrared Ear Thermometer
Model:
YHT108/YHT202/YHT208

XII. Guidance and Manufacturers Declaration on EMC

Electromagnetic Compatibility (EMC) Compliance

1.This device has been tested and complies with the Class B limits for medical devices according to the IEC 60601−1−2.

2.The thermometer is suitable for both professional and home use, except near active HF SURGICAL EQUIPMENT or in RF shielded magnetic resonance imaging (MRI) rooms.

3.The thermometer measure ranges between 34.0℃−42.2℃ (93.2°F−108.0°F). Accuracy is ±0.2℃ (±0.4°F) within 35.0℃−42.0℃ (95.0°F−107.6°F), ±0.3℃ (±0.5°F) beyond this range. When using the device near strong electromagnetic interference (e.g., cell phones, microwaves, etc.), it may temporarily affect accuracy. Please keep the device away if necessary.

4.**WARNING:** Do not place the thermometer near or stack it with other medical devices to avoid potentially inaccurate measurements.

5.**WARNING:** 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 of the thermometer. Otherwise, degradation of the performance of the thermometer could result.

Table 1. Electromagnetic Emissions

Phenomenon and Standard	Limit	Test Result
RF Emissions CISPR 11	Class B Group 1	PASS
Harmonic Current Disturbance IEC 61000−3−2	Class A	Not applicable
Voltage Fluctuations & Flicker IEC 61000−3−3	−	Not applicable

Table 2. Electromagnetic Immunity

Phenomenon and Standard	Immunity Test Levels		Test Result
	Professional Healthcare Facility Environment	Home Healthcare Environment	
Electrostatic discharge IEC 61000−4−2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air		PASS
Radiated RF EM Fields IEC 61000−4−3	3 V/m 80 MHz − 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz − 2,7 GHz 80 % AM at 1 kHz	PASS
Proximity Fields from RF Wireless Communications Equipment IEC 61000−4−3	Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment		PASS
Electrical Fast Transient/burst IEC 61000−4−4	± 2 kV 100 kHz repetition frequency		Not applicable
Surge IEC 61000−4−5	± 0,5 kV, ± 1 kV (Line−to−line) ± 0,5 kV, ± 1 kV, ± 2 kV (Line−to−ground)		Not applicable
Conducted Disturbances Induced by RF IEC 61000−4−6	3 V 0,15 MHz − 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz − 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	Not applicable
Power Frequency Magnetic Field IEC 61000−4−8	30 A/m 50 Hz and 60 Hz		PASS
Proximity Magnetic Fields IEC 61000−4−39	8 A/m for 30 kHz, 65 A/m for 134.2 kHz,75 A/m for 13.56 kHz		PASS
Voltage Dips, Short Interrupts ,and Voltage Variations on Power Supply Input Lines IEC 61000−4−11	Voltage dips: 0 % U_T; 0,5 cycle, 0 % U_T; 1 cycle, 70 % U_T; 25/30 cycles Voltage interruptions: 0 % U_T; 250/300 cycle		Not applicable
Electrical Transient Conduction Along Supply Lines ISO 7637−2	−		Not applicable

Table 3. Test Specifications for ENCLOSURE PORT IMMUNITY to RF Wireless Communications Equipment

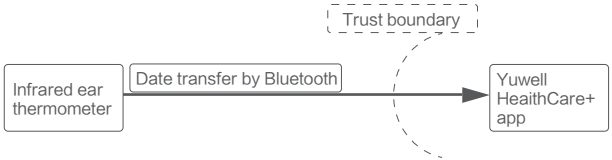
Test Frequency (MHz)	Band[a] (MHz)	Service[a]	Modulation[b]	IMMUNITY Test LEVEL (V/m)
385	380–390	TETRA 400	Pulse modulation[b] 18 Hz	27
450	430–470	GMRS 460, FRS 460	FM[c] ± 5 kHz deviation 1 kHz sine	28
710	704–787	LTE Band 13,17	Pulse modulation[b] 217 Hz	9
745				
780				
810	800–960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation[b] 18 Hz	28
870				
930				
1720	1700–1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation[b] 217 Hz	28
1845				
1970				
2450	2400–2570	Bluetooth, WLAN, 802.11 b/g/n RFID 2450, LTE Band 7	Pulse modulation[b] 217 Hz	28
5240	5100–5800	WLAN 802.11 a/n	Pulse modulation[b] 217 Hz	9
5500				
5785				

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, the carrier may be pulse modulated using a 50 % duty cycle square wave signal at 18 Hz. While it does not represent actual modulation, it would be worst case.

XIII. Cybersecurity

1.Cybersecurity Controls and Product Specification Description
(1) The device and the App communicate via Bluetooth, ensuring secure communication through a private protocol.
(2) Please ensure that your network environment has installed and updated firewall and antivirus software to protect against malicious software and virus intrusions.
2. Detailed Cybersecurity Implementation Diagram



3. Network Interface and Port Description

Interface	Interface functionality	Attribute	Approved Destination End-points
Bluetooth	Transmit measured body temperature values	Outgoing	Yuwell HealthCare+ application

4. Support Infrastructure Requirements
(1) Users should only pair the device with their mobile phones in a secure and trusted environment; for example:
- Encrypted broadband networks
- Dedicated network lines
- WIFI Personal portable Wi-Fi

(2) Place the device as far away as possible from other electronic devices that may cause interference. For instance, maintain a certain distance from other Bluetooth devices, Wi-Fi routers, and microwave ovens.
(3) It is recommended that users protect their mobile phones to prevent unauthorized access to personal data by:
- Setting an automatic keyboard lock on the phone to prevent unauthorized use;
- Configuring a personal device PIN or password to unlock the keyboard;
- Installing security protection software on the phone to guard against viruses, trojans, and other intrusions.

(4) Please do not install or use the APP on rooted or jailbroken devices.
5.Software Bill of Materials (SBOM): An international standard Software Bill of Materials (SBOM) in SPDX format has been generated, supporting conversion

to other international and industry-standard SBOM formats such as CycloneDX and SWID. If required, users can send an email to request the latest SBOM list.

6. Software and Firmware Download

(1) The App is distributed exclusively through the Google Play Store and Apple Store. Downloading software updates from unauthorized channels increases the risk of cybersecurity vulnerabilities. Our company bears no responsibility for any consequences that may arise from such actions.

(2) Users should regularly check and perform available updates for the APP software to promptly address potential security vulnerabilities.

7. Security Event Response Design

The device operates fully localized, without communication to the cloud, and does not handle sensitive personal data. Data transmission is based on Bluetooth protocol.

8. Critical Function Protection

The device operates fully localized without networking. Its core functions remain unaffected even if the device is partially damaged and unusable.

9. Backup and Restore Features

No such function

10. Retention and Recovery of Device Configuration

The device operates fully offline and uses Bluetooth for communication. There is no risk of network-based attacks (e.g., DDoS attacks, etc.), and neither the device nor the app requires security configurations.

11. Secure configuration of device

The device and app do not have security configurations. Bluetooth communication is used, and the manufacturer has closed all service ports to prevent attacks, as confirmed by security testing.

12. Capture of Forensic Evidence

The app does not generate log files because internet connectivity is absent to transmit log files.

13. Information Concerning Device Cybersecurity End of Support and End of Life

During the valid service period of the device, our company will provide continuous tracking and repair of any security issues that exist with the device. If the device exceeds its service life, our company cannot guarantee reasonable software update services for users. Continued use of the device after support has ended may pose certain security risks to users, and it is recommended that users discontinue use of the device.

14.Information on Securely Decommissioning Devices

The device does not contain sensitive, confidential, or proprietary data or software; users can delete all measurement data on the device and in the app.