

YHW-5 ( ce ) 红外体温计说明书印刷要求

尺寸：480 × 160mm

色彩：准确、单色，层次分明

纸张：128g铜版纸、不需做圆角

印后加工：八折

## 1. Device Use And Applicant Scope

● The thermometer uses an infrared sensor, which can sense the ambient temperature and the infrared heat radiation emitted by the human body. Referring to the corresponding parameter table, the best core algorithm is used to calculate the accurate temperature.

● Intended purpose: This device is used to measure the forehead temperature of the human body. It is intended for use on people of all ages except pre-term babies or very small (small for gestational age) babies.

● Indication: Intermittent measurement of human body temperature from forehead, not for emergency clinical condition.

● Intended users: Health care professional, or 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.

● Contraindication: None.

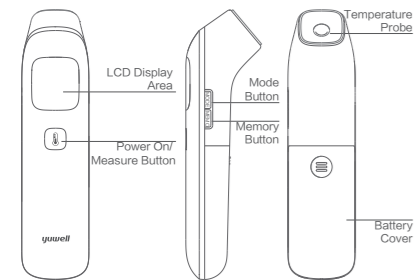
● The device is for professional use and consumer use.

● The device is used in professional healthcare facility environment and home healthcare environment.

## 2. Device Structure And Composition

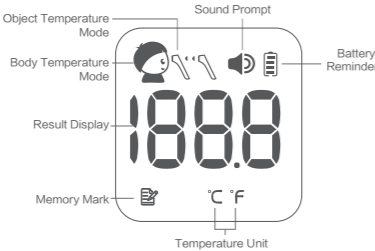
● Device main structure and composition  
The thermometer consists of a housing, a sensor, a display and a circuit board.

Detachable parts and materials for use: cover, 2 AAA alkaline batteries



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## ● LCD area



## ● Appendix:

Instructions, 2 AAA Alkaline Batteries.

## 3. Matters Need Attention

Warnings:

1. The measurement result is only for reference, which is not a substitute for a physician's diagnosis. It is very dangerous to self-judge and treat only based on the measurement result. Please follow the doctor's instructions.

2. Please put the battery out of the reach of children, otherwise it is dangerous.

3. When the product is not used for a long time (more than 3 months), remove the battery from device to prevent the battery leakage.

4. If there is a temperature difference between the environment of the storage and that of the measurement, place the device in the measuring environment for more than 30 minutes, otherwise there may be errors in the measurement results.

5. It is forbidden to immerse the infrared thermometer in any liquid, and it is forbidden to use it for a long time under too high or low temperature condition. No collisions, drops and mixing with sharp objects.

6. Do not put the battery close to the fire or into the fire to avoid the battery explosion. Do not use the battery when it leaks or molds. When discarding batteries or this product, follow local regulations to avoid contamination.

7. This product contains sensitive electronic components which could be temporarily inaccurate while using directly near strong electromagnetic interference.

8. Do not modify this equipment without the authorization of the manufacturer, which may lead to measurement error or machine malfunction.

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

⚠ Caution:

10. Do not try to measure when the device is wet, which may cause measurement results inaccurate.

11. Before measurement, please make sure that there is no sweat, cosmetics or oil stains on the forehead of subject. Please make sure that the subject does not take a bath, exercise or have a meal within 30 minutes, and the body is measured at a steady state.

12. During measurement, do not let the subject directly face sunlight, heater or the air outlet of air conditioner, which will change the temperature of the forehead. Please conduct measurement in a stable environment as far as possible.

13. When the product gets wet due to contact with steam, do not use until it get dry or be gently wiped with a soft, dry cloth or cotton balls, otherwise it will cause measurement errors.

14. For patients measuring their own temperature, it is recommended to measure close to the forehead.

15. Please read this instruction carefully before use and confirm that the battery is installed.

16. Do not move while using.

17. Under the combined effects of the environment and the frequency of use, temperature of the product's housing may exceed 41°C. Please use it carefully.

18. Please pay attention to product storage to prevent damage caused by pets, pests or children.

19. This product is a high-precision device, please do not drop the device! Avoid drastic collisions and jolts and other adverse possibilities for transport.

20. Due to label layout restrictions, the font cannot be enlarged, please watch the label at a proper distance to make sure that you can see the content clearly.

21. Do not store this thermometer in temperature extremes below -20°C (-4°F) or over +55°C (131°F) or in excessive humidity (below 15% or above 90% no condensation relative humidity).

22. Do not use this thermometer in temperature extremes below 10°C (50°F) or over 40°C (104°F) or in excessive humidity (below 15% or above 90% no condensation relative humidity).

23. To avoid dust entering the probe cavity resulting in inaccurate measurements, install the cover after

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each use.

24. Do not use non-specified detachable parts and materials, otherwise the product may not work properly.

25. Do not leave the thermometer unattended around children. Small items such as battery may become choking hazards.

⚠ 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.

## 4. Measurement And Transport Storage Environment

● Measurement environment:

Environment temperature: 10°C (50°F) to 40°C (104°F)

Relative humidity: 15% to 90%, no condensation

Atmospheric pressure: 70kPa to 106kPa

● Transportation and storage environment:

Environment temperature: -20°C (-4°F) to +55°C (131°F)

Relative humidity: 15% to 90%, no condensation

Atmospheric pressure: 70kPa to 106kPa

## 5. Installation And Usage

● Installing the battery

The device is supplied with 2 AAA alkaline batteries. Push the battery cover downward and load the battery into the battery compartment. At this time, the device will start self-inspection. Pay attention to the positive and negative poles instruction in the battery compartment and snap the battery cover back onto the device. Refer to the picture at right:

● Setting measure unit

In the shutdown state, long press the Mode Button until the unit symbol flashes, then short press the Mode Button to select the temperature units "°C" and "°F", and press the Power On/ Measure Button "⏻" to confirm.

● Body temperature mode (Measure temperature of human body)

1. Point the infrared thermometer probe at the center of the eyebrows and keep a distance of 0-3 cm from

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the forehead.

2. Press the Power On/ Measure Button "⏻". After about 1 second, the infrared thermometer will have a prompt of sound and display the measurement results.

When the measured result is beyond device measurement range 22.0°C~43.0°C (71.6°F~109.4°F) in body temperature mode, the thermometer will make one quick continuous sounds as "di di-di-di" to prompt, at the same time, "H" or "Lo" appears on the display interface, accompanied by orange backlight.

When body temperature is 37.6°C (99.7°F) or higher, the device will make sounds as "di di-di-di" to prompt.

● Object temperature mode (Measure temperature of object)

Short press the Mode Button in the power-on state, and the display icon flashes to switch between body temperature mode "👤" and object temperature mode "🌡". After selecting "🌡" (object temperature mode), approach the object to be measured and press the Power On/ Measure Button "⏻" to display the measurement result.

When the measured result is beyond device measurement range 0.0°C~60.0°C (32.0°F~140.0°F) in object temperature mode the thermometer will make sounds as "di di-di-di" to prompt, at the same time, "H" or "Lo" appears on the display interface. Notes: Please make sure the measurement method and the external environment is normal at this time.

● Memory function: Press Memory Button, memory value inquiry can be carried out. Thermometer can store 20 groups of memory values. When the number of groups exceeds the specified number, the latest memory value will cover the earliest memory value.

● In memory mode, press and hold Memory Button, when CLr is displayed on the screen, the memory value is cleared.

● Sound switch setting

Step 1: In the shutdown state, long press the Mode Button until the temperature unit flashes.

Step 2: Then short press Memory Button to switch to sound setting.

Step 3: Press Mode Button to select sound on "🔊" or sound off "🔇".

Step 4: Press the Power On/ Measure Button "⏻" to confirm.

● Power off

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In the absence of any operation, the device will automatically shut down within 2 minutes.

## 6. Product Maintenance And Upkeep Method

As the product is a reusable device, please pay attention to cleaning and disinfection after use.

If the product is dirty, please keep the sensor and probe cavity clean, otherwise the measurement accuracy will be affected.

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 medical alcohol (70%). Please keep the medical 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.

D. This device is suitable for multiple people. In order to prevent cross-infection. It is recommended to clean and disinfect this product before use.

Note: According to this cleaning and disinfection method, there will be no impact on device performance. Do not use strong solvents such as acetone. Do not use abrasive materials (e.g. steel wool) to clean the device surface.

To avoid dust entering the probe cavity, install the cover after each use.

## 7. Common Failures And Troubleshooting Methods

| Phenomenon of breakdown   | Possible cause                      | Troubleshooting methods         |
|---------------------------|-------------------------------------|---------------------------------|
| The screen display "Er 4" | Infrared sensor sampling error.     | Please contact the distributor. |
| The screen display "□"    | The power of batteries is shortage. | Replace with new batteries.     |

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|                                |   |   |
|--------------------------------|---|---|
| The screen display "Lo"        | In the body temperature mode, the measurement result is <22.0°C (71.6°F) or in the object temperature mode, the measurement result is <0.0°C (32.0°F).            | Please re-measure following the product instruction.  |
| The screen display "H" or "Lo" | When in body temperature mode, the measurement result is > 43.0°C (109.4°F) or when in the object temperature mode, the measurement result is > 60.0°C (140.0°F). | Place the infrared thermometer at an ambient temperature of 10°C to 40°C (50°F to 104°F) and let it stand for 30 minutes before measuring. If the problem persists, please contact the distributor. |
| The screen display "Er 1"      | The operating environment temperature is lower than 10°C (50.0°F).  |   |
| The screen display "Er 2"      | The operating environment temperature is higher than 40°C (104.0°F).  |   |
|                                | The positive and negative poles of the batteries are reversed or the device is abnormal.  | Reinstall the batteries, or contact the distributor.  |
| No display                     | The batteries is not installed well.  | Check if the batteries is installed upside down.  |
|                                | Low battery.  | Replace with new batteries.   |
|                                | The screen is still blank.  | Please contact the distributor.   |

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

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

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|  |  |
|--|--|
|  | MR Unsafe (Background color: white; Circular frame and diagonal bar: red; Letters 'MR': black) |
|--|--|

## 9. Product Technical Parameters

- Power source: DC 3V (2 × 1.5V AAA alkaline batteries)
- Measurement range in body temperature mode: 22.0°C ~ 43.0°C (71.6°F ~ 109.4°F)
- Display resolution: 0.1°C (0.1°F)
- Measurement accuracy in body temperature mode: ± 0.2°C (± 0.4°F) in the range of 35.0°C ~ 42.0°C (95.0°F ~ 107.6°F); ± 0.3°C (± 0.5°F) in the range of 22.0°C ~ 34.9°C (71.6°F ~ 94.8°F) and 42.1°C ~ 43.0°C (107.8°F ~ 109.4°F)
- According to ISO 80601-2-56, Rated output range: 34.0°C to 42.0°C (93.2°F to 107.6°F). Rated extended output range: 22.0°C to 33.9°C (71.6°F to 93.0°F) and 42.1°C to 43.0°C (107.6°F to 109.4°F)
- Electric shock protection: the device is supplied by internal power
- Applied part: Type BF applied part is the probe
- Operation mode: continuous operation
- Temperature units: °C/°F
- Body temperature mode measuring site: forehead
- Time interval of each measurement ≤ 1s.
- Measurement time: ≤ 1s.
- Degrees of protection provided by enclosures (IP code): IP22
- Safety classification: the device that cannot be used in the presence of flammable anesthetic gases mixed with air or oxygen or nitrous oxide
- Product size: 152mm × 38mm × 43mm
- Product weight: about 70g (not including cell)
- Number of memory groups: 20 groups
- Service life: 5 years
- The thermometer uses an adjusted mode when measuring the body temperature.
- Battery replacement cycle: use the new battery for no less than 3000 measurements
- 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 ( $\Delta_{cb}$ )        | -0.09°C                 | -0.17°C        | -0.10°C            |
| LIMITS OF AGREEMENT ( $L_A$ )          | 0.62°C                  | 0.95°C         | 0.95°C             |
| CLINICAL REPEATABILITY ( $\sigma_r$ )  | 0.13°C                  | 0.21°C         | 0.22°C             |
| Measuring site of infrared thermometer | Forehead                |                |                    |
| 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.

Axillary temperature:  
36.0°C ~ 37.4°C / 96.8°F ~ 99.32°F

Oral temperature:  
36.3°C ~ 37.2°C / 97.34°F ~ 98.96°F

Rectal temperature:  
36.9°C ~ 37.9°C / 98.42°F ~ 100.22°F

## 11. Replacing The Batteries

1. The state of the internal electrical power source will display a different icon depending on the battery capacity. 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. Replace with 2 new AAA batteries, slide 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 battery 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 empty

batteries at appropriate collection sites according to national or local regulations.

## 12. Product Warranties

1. This product has been calibrated at the time of manufacture. If used according to the use instructions, periodic calibration is not required. If at any time you question the accuracy of the temperature measurement, please contact the distributor. Adjusted mode is for general public and calibration mode is for after-sale person only.
2. If you need to provide circuit diagram, necessary materials and maintenance of electrical circuit for any problem, please contact the distributor. This product has a 1 year limited warranty.
3. This warranty will not be honored if any of the following conditions apply:
  - Unauthorized disassembly and modification of product.
  - Dropping product.
  - Not following the IFU instructions for operations and maintenance.
  - Damage caused by external force.
4. This product will not cause allergic reaction and harm to human body during normal use.
5. Maintenance personnel should be authorized by manufacturer or participate training organized by the manufacturer.
6. If the situations cannot be solved or unexpected problem happens, please consult the local distributor.
7. 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 thermometer  
Model:  
YHW-5

## 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 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

| Phenomenon  | Compliance level                              |
|---|---|
| ELECTROSTATIC DISCHARGE IEC 61000-4-2               | ± 8 kV contact<br>± 15 kV air                 |
| RATED power frequency magnetic fields IEC 61000-4-8 | 30A/m<br>50Hz or 60Hz                         |
| Radiated RF EM fields IEC 61000-4-3                 | 10 V/m<br>80 MHz to 2.7 GHz<br>80% AM at 1kHz |

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

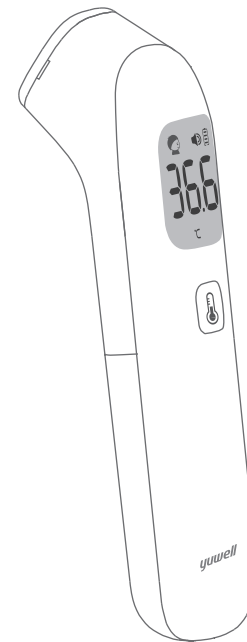
| Test frequency (MHz) | Band <sup>(a)</sup> (MHz) | Service <sup>(a)</sup>   | Modulation <sup>(b)</sup>                            |
|----------------------|---------------------------|--|--|
| 385                  | 380-390                   | TETRA 400  | Pulse modulation <sup>(b)</sup><br>18 Hz             |
| 450                  | 430-470                   | GMRS 460, FRS 460  | FM <sup>(c)</sup><br>± 5 kHz deviation<br>1 kHz sine |
| 710                  | 704-787                   | LTE Band 13,17   | Pulse modulation <sup>(b)</sup><br>217 Hz            |
| 745                  |                           |  |  |
| 780                  |                           |  |  |
| 810                  | 800-960                   | GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5         | Pulse modulation <sup>(b)</sup><br>18 Hz             |
| 870                  |                           |  |  |
| 930                  |                           |  |  |
| 1720                 | 1700-1990                 | GSM 1800; C/MDA 1900; GSM 1900; DECT; LTE Band 1,3, 4,25; UMTS | Pulse modulation <sup>(b)</sup><br>217 Hz            |
| 1845                 |                           |  |  |
| 1970                 |                           |  |  |
| 2450                 | 2400-2570                 | Bluetooth, WLAN, 802.11 b/g/n<br>RFID 2450, LTE Band 7         | Pulse modulation <sup>(b)</sup><br>217 Hz            |
| 5240                 | 5100-5800                 | WLAN 802.11 a/n  | Pulse modulation <sup>(b)</sup><br>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 | 0,2 | 0,3 | 9  |
| 5240 |     |     |    |
| 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**



YHW-5  
Infrared 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.