

YT-1红外体温计英文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、不需做圆角

印后加工：六折

## 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: The Infrared thermometer is a nonsterile, reusable clinical thermometer intended for measuring the human body temperature in non-contact mode on the center of the forehead as the measurement site on people of all ages except preterm 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: Intended users: Health care professional, or lay persons at least 11 years old.

●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.

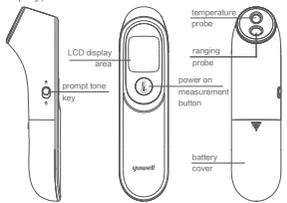
●Contraindication: None.

●The device is for professional use and consumer use.

●Patient can take measurement by themselves, or they can be taken by someone else using a thermometer. Patients can perform all the maintenance.

## 2. Device Structure And Composition

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



01

## ●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 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.

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.

02

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 to confirm that the battery is installed.

16.Please pay attention to product storage to prevent damage caused by pets and pests.

17.Due to the limited size of the label, the font is too small, please put it at a suitable location for viewing.

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

19.The thermometer shall not be serviced and maintained while in use.

20.Be careful not to fall from high, a drop may cause the sensor to loosen which will affect the accuracy of temperature measurement.

21.This thermometer is not intended to interpret hypothermic temperatures. If the device displays a temperature of 36.4°C (97.5 °F) or less, and the individual is exhibiting atypical symptoms or behaviors, contact your physician or health care professional.

⚠ 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

03

## 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 door back onto the device. Refer to the picture at right:

### ●Setting measure unit

In the shutdown state, press the measurement button "M" long for 8-12 seconds to enter the temperature unit conversion state, and then press the measurement button "C" or "F" shortly to select "C" and "F" temperature unit, then press the measurement button "M" long for final confirmation.

### ●Measure temperature of human body

1.Point the thermometer probe at the center of the eyebrows and keep a distance of 0-5 cm from the forehead (non-contact).

2.Press the measurement button "M". After about 1 second, the thermometer will have a prompt of sound and display the measurement results.

### Notes:

①When the measurement distance is more than that about 5 cm, the word "0-5" will be displayed on the screen, please close to the subject, as the picture shown at right;



[get close to measure indication]

②When the measurement distance is less than about 5 cm, the device will automatically measure, after the measurement, it will vibrate and have "di" sound, and measurement result will be displayed.

③When temperature is 37.6°C (99.7°F) or higher, the device will make three quick continuous sounds as "di-di-di" to remind.

④When the measured result is beyond device measurement range 32.0°C-43.0°C (89.6°F-109.4°F), thermometer will make three quick continuous sounds as "di-di-di" to remind, please make sure the measurement method and the external environment is normal at this time.

04

## ●Sound on/off setting

When the prompt on/off button slides to "🔊", the sound is on;  
When the prompt on/off button slides to "🔇", the sound is on.

## ●Power off

① Press the measurement button "M" for 3-5 seconds to turn off the device;  
② In the absence of any operation, the device will automatically shut down after about 30 seconds.

## 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.

How to clean sensor and probe cavity: gently wipe the inner cavity or sensor mirror with a clean soft cloth or cotton swab.

Do not wipe it with other material, otherwise it may cause lens surface of sensor abrasion or machine malfunction.

Disinfection of the product and its head: Gently wipe the surface of the product and the head used for measurement with a cotton swab dipped in a little medical alcohol (70%), it can be used until the alcohol has completely evaporated.

## ●Precaution for storage

This product should be stored in a dust-free dry place, please avoid direct sunlight; do not store in places with high temperature, humidity, dust and corrosive gas. Sensor aging may affect the measurement accuracy.

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

If the probe or the product itself has been damaged, do not continue to use it. Please do not use this product for any purposes other than its intended use. When it is used for children, please observe the general safety precautions.

We suggest to calibrate the monitor (at least once a year) according to local laws and regulations.

## 7. Common Failures And Troubleshooting Methods

Phenomenon of breakdown	Possible cause	Troubleshooting methods
The screen display "Lo"	The measurement temperature is lower than 32°C (89.6°F), which is beyond the measurement range	Please re-measure following the product instruction
The screen display "Hi"	The measurement temperature is higher than 43°C (109.4°F), which is beyond the measurement range	Please re-measure following the product instruction
The screen display "Err"	The environment temperature is too high or too low	Please measure under the 10°C (50°F) to 40°C (104°F) environment temperature
The screen display "E"	The power of cell is shortage	Replace with new batteries
No display or abnormal display	The positive and negative poles of the cell are reversed or the device is abnormal	Re-install the battery, or contact the dealer

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

Symbols	Implication
	Manufacturer mark
	Caution
	Recyclable
	Manufacturer
	Authorized representative in the European Community/European Union
	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

06

	This way up
	Fragile, handle with care
	Keep dry
	This device fulfills the provisions of regulation (EU) 2017/745 (Medical Device Regulation).
	Serial number
	Date of manufacture
	Medical device
	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
	MR Unsafe
	Refer to instructions manual

## 9. Product Technical Parameters

●Power source: DC 3V( 2 AAA alkaline batteries)

●Measurement range: 32.0°C ~ 43.0°C (89.6°F ~ 109.4°F)

●Display resolution: 0.1°C (0.1°F)

●Measurement accuracy: ± 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 32.0°C ~ 34.9°C (89.6°F ~ 94.8°F) and 42.1°C ~ 43.0°C (107.8°F ~ 109.4°F)

●Electric shock protection: the device is supplied by internal power

●Operation mode: continuous operation

●Temperature units: °C/°F

●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

07

05

- Product size: 149mm × 38mm × 42mm
- Product weight: about 68g (not including cell)
- Service life: 5 years
- The device uses the adjusted mode in measuring.
- 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(Δ <sub>cl</sub> )	-0.09℃	-0.17℃	-0.10℃
LIMITS OF AGREEMENT (Δ <sub>A</sub> )	0.62℃	0.95℃	0.95℃
CLINICAL REPEATABILITY(σ <sub>r</sub> )	0.13℃	0.21℃	0.22℃
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℃ ~ 37.4℃/96.8 F ~ 99.32 F

Oral temperature:

36.3℃ ~ 37.2℃/97.34 F ~ 98.96 F

Rectal temperature:

36.9℃ ~ 37.9℃/98.42 F ~ 100.22 F

08

### 11. Replacing The Batteries

1. Battery replacement: When "  " symbol is displayed, 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. The 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 and calibration mode is for after-sale person only.
2. This product provides free maintenance service for one year. If you need to provide circuit diagram, necessary materials and maintenance of electrical circuit for any problem, please contact the manufacturer.
3. No free warranty service will be provided for the faults caused by the following use:
  - 1) Failure caused by unauthorized disassembly and modification of products.
  - 2) Failure caused by product drop.
  - 3) Failure caused by failure to operate according to the instructions.
  - 4) Failure caused by lack of reasonable maintenance.
  - 5) Damage caused by external force.
4. This product will not cause allergic reaction and harm to human body during normal use.
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.

09

### 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 communications 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 ± 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

10

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

11

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			
5500			
5785	0,2	0,3	9

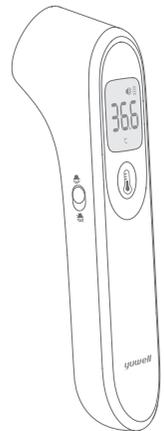
NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.  
a) For some services, only the uplink frequencies are included.  
b) The carrier shall be 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.

### 14. Warranty Card

Warranty card  
Product name:  
Infrared thermometer  
Model:  
YT-1

12

yuwell



YT-1  
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 packaging. The picture is for reference only, please refer to the actual product.