

1. Device use and applicant scope

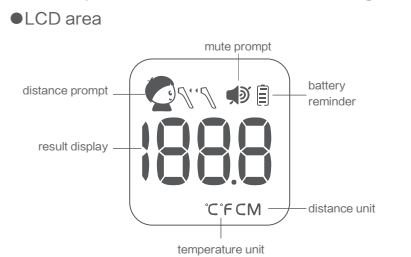
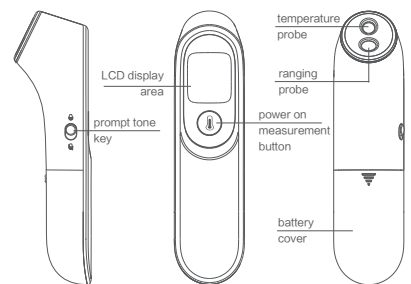
●The infrared thermometer has an infrared sensor, which can read the ambient temperature and the infrared energy radiation emitted by the human body. Referring to the corresponding parameter table, the best core algorithm is used to calculate the accurate temperature.

●Intended use and application scope: The YUWELL® 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.

●Contraindication: None.

2. Device structure and composition

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



●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 the measuring environment is different from the storage environment, place the device in the measuring environment for more than 30 minutes, otherwise The measurement results may be incorrect.

5.It is forbidden to immerse the infrared thermometer in any liquid, and use it for a long time in too high or low temperature environment. Collisions, dropping and mixing with sharp objects are not allowed.

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 the local regulations to avoid contamination.

7.This product contains sensitive electronic components which could be temporarily inaccurate while using under 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. Cautions:

10.Do not 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. The body should be 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 may 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.

⚠️ 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%RH (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%RH (no condensation)

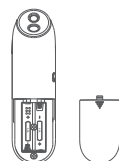
Atmospheric pressure: 70kPa to 106kPa

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

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



●Measure temperature of human body
1.Point the infrared thermometer probe at the center of the eyebrows and keep a distance of 0~5cm away from the forehead.

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

Notes:

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



[get close to the subject 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 alarm.

④When the measured result is beyond device measurement range 32.5 °C~43 °C(90.5 F~109.4 F), thermometer will make three quick continuous sounds as "di-di-di" to alarm, Please make sure the measurement method is right and the external environment is normal .

●Sound on/off setting

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

●Power off

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

6. Care and Cleaning

The product is a re-usable device. The end user should clean the device until the device is visually clean before use.

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

The way 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%). Wait at least 5 minutes after disinfection before use.

●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 or corrosive gas.

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.

7. Common failures and troubleshooting methods

Phenomenon of breakdown	Possible cause	Troubleshooting methods
The screen display "Lo"	The measurement temperature is lower than 32.5°C(90.5°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 "□"	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 cell, or contact the dealer

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

Symbols	Implication
	Equipment with type BF applied parts
	Warnings and precautions
	Recyclable
	Manufacture
	Follow instructions for use
	Symbol for the marking of electrical and electronics devices according to Directive 2002/96/EC
	Safety and environmental protection use period for 10 years
IP22	Protection from ingress of particulates than ≥12.5mm. Dripping water falling within 15° of vertical will not have a harmful effect on the infrared thermometer per IEC 60529
	Temperature range
	Humidity range
	Atmospheric pressure range
	This side up
	Fragile
	Non-rainproof
	This device fulfils the provisions of EC directive 93/42/EEC(Medical Device Directive).
	See instruction for use
	Date of manufacture
	MR Unsafe items should not enter the MRI scanner room.

9. Product technical parameters

●Power source: DC 3V(2 AAA alkaline batteries)
●Measurement range: 32.5°C ~ 43.0°C(90.5°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 32.5°C ~ 34.9°C(90.5°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

●Applied part: Type BF applied parts is the probe

●Running mode: continuous running

●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

●Product size: 149×38×42(mm)

●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 device is a clinical/infrared thermometer for temperature measurement.

●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 _b)	-0.09°C	-0.17°C	-0.10°C
LIMITS OF AGREEMENT (Δ _a)	0.62°C	0.95°C	0.95°C
CLINICAL REPEATABILITY(σ _r)	0.13°C	0.21°C	0.22°C

According to EN 12470-5, clinical repeatability shall not exceed ±0.3°C.

REFERENCE BODY SITE	Oral measurement

10. Temperature sense

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

The normal body temperature of most people is provided as follows, just for reference.

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. Battery replacement: When "  " symbol is displayed, replace with 2 new AAA batteries, push the battery cover downward and remove old batteries. Replace the batteries and make 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 your authorized service center.

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.

13. Electromagnetic compatibility information

 Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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

 When the instrument is in use, never put it near other instruments or stack it on other instrument. If you have to put it near other instrument or stack it on other instruments, please inspect and verify if the instrument could run normally. There is the potential risk of radio frequency interference between the device and other devices. If there is, please find out the problems and take the following measures:

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

Table 1—Compliance information for Emission test

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

Table 2—Compliance information for Immunity test

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

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

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

5240	5100-5800	WLAN 802.11 a/n	Pulse modulation ^{b)} 217 Hz
5500			
5785			
Test frequency (MHz)	Maximum power (MHz)	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.

14. Warranty card

Warranty card

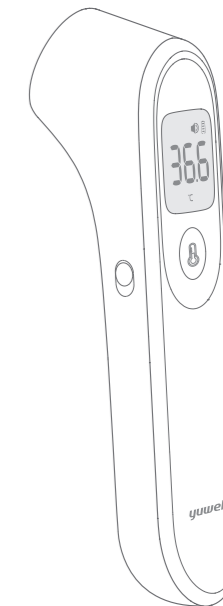
Product name:

Infrared thermometer

Model:

YT-1

yuwell



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 packing.

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

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

http://www.yuwell.com

Revision date: Dec. 2020

1730211-1A 