

This infrared thermometer meets requirements established in ASTM Standard E 1965-98. Full responsibility for the conformance of this product to the standard is assumed by JIANGSU YUYUE MEDICAL EQUIPMENT & SUPPLY CO.,LTD. ASTM laboratory accuracy requirements in the display range of 37 °C to 39 °C (98 °F to 102 °F) for IR thermometers is ±0.2 °C (±0.4 °F), whereas for mercury-in-glass and electronic thermometers, the requirement per ASTM Standards E667-86 and E1112-86 is ±0.1 °C (±0.2 °F).

FCC Radiation Exposure Statement:
Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment .

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, you can contact us at the following phone number or email.
Contact number: (86-511) 8690 0890
E-mail: yuwellsales@yuyue.com.cn / sales@yuyue.com.cn

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YY-THM0107D-01(A/0)

3.Physical Characteristics

ITEM	PARAMETER
Dimensions	153 mm×59 mm×37.5 mm
Weight without battery	About 80 g

4.Bluetooth Technology Information

Frequency Range	2402 MHz-2480 MHz
Bandwidth	1 MHz, 2 MHz
Modulation	GFSK
Frequency characteristics	UHF
Max Conducted TX Power	3.12 dBm
Recommended Range	~10 feet (~3 meters) line-of-sight
FCC ID	2A2JJ-YHT107

5.Environment

ITEM	DESCRIPTION
Operating temperature range	+10°C--+40°C (50°F-104°F)
Transport and storage temperature range	-20°C--+55°C (-4°F-131°F)
Humidity	15% to 90%, no condensation
Atmospheric pressure	70kPa-106kPa

6.Clinical accuracy

The clinical thermometer uses adjusted mode.
The clinical accuracy 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, 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_{CL})	0.14°C	0.28°C	0.00°C
LIMITS OF AGREEMENT (Δ_{L})	0.76°C	1.06°C	0.88°C
CLINICAL REPEATABILITY(σ_{CL})	0.16°C	0.19°C	0.19°C
REFERENCE BODY SITE		Oral	
Measuring site of infrared ear thermometer		Ear canal	

7.Compliance

EQUIPMENT CLASSIFICATIONS PER IEC 60601-1	
Degree of protection against electric shock	Internally powered ME equipment Type bf applied part, 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

IX. Symbols

SYMBOL	DEFINITION
	Type BF applied part
	Caution
	Refer to instructions manual (Background: Blue; Symbol: White)
	Waste from electrical and electronic equipment (WEEE)
	Safety and environmental protection use period for 10 years
	MR Unsafe (Background color: white; Circular frame and diagonal bar: red; Letters 'MR': black)

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°
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	This way up
	Fragile, handle with care

	Bluetooth
	Manufacturer
	Recyclable
	Medical device
	Batch code
	Unique device identifier
	Keep dry
	Serial number
	Date of manufacture

X. After-sales Service

1. From the date of purchase, the device will enjoy a free one-year warranty with the purchase invoice. During warranty service, if you need to be provided with circuit diagram, components, necessary materials and electrical circuit maintenance, please contact the manufacturer.
2. The infrared ear thermometer is calibrated initially when manufactured. There is no need for readjustment if it is used according to the instruction. If anytime you question the accuracy of the temperature measurement, please contact the manufacturer.
3. Free warranty service will not be provided for faults caused by the following personal reasons:
●The following conditions are not covered by the warranty:
A. Vulnerable and consumable parts: cover, battery and probe cover;
B. Breakdown caused by unauthorized disassembly and assembly of the device;
C. Breakdown caused by operation not in accordance with the instructions;
D. Breakdown caused by lack of reasonable maintenance;
E. Fault caused by device falling carelessly;

F. Damage caused by external force;
4. Maintenance services beyond the scope of warranty will be charged according to regulations.
5. If the situations cannot be solved or unexpected problem happens, please consult the local distributor.

Warranty card
Product name:
Infrared ear thermometer
Model:
YHT107

XI. Guidance and manufacturers declaration on EMC

EMC compliance

1.This device has been tested and found to comply with the Class B limits for medical devices according to the IEC 60601-1-2.
2.The thermometer is suitable to be used in professional use environment and home use environment except for near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging.
3.The essential performance of the thermometer is measurement range 34.0°C-42.2°C (93.2°F-108.0°F).Within the temperature display range of 35.0°C-42.0°C (95.0°F-107.6°F), it is ± 0.2°C (± 0.4°F); beyond the temperature display range of 35.0°C-42.0°C (95.0°F-107.6°F), it is ± 0.3°C (± 0.5°F). When used directly near strong electromagnetic interference (for example: near mobile phones, microwave ovens, etc.), it may be temporarily inaccurate. If so, please keep the product away from interfering devices.
4.**WARNING:** Use of the thermometer adjacent to or stacked with other equipment should be avoided because it could result in improper operation.
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 _r ; 0.5 cycle, 0 % U _r ; 1 cycle, 70 % U _r ; 25/30 cycles Voltage interruptions: 0 % U _r ; 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 ^{a)} ± 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				

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.

) For some services, only the uplink frequencies are included.

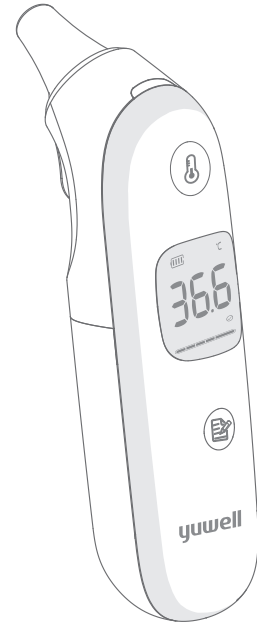
The carrier shall be modulated using a 50 % duty cycle square wave signal.

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.

XII. Abbreviations Definition

RF	Radio Frequency	EM environment	Electromagnetic environment
PC	Personal Computer	ME equipment	Medical electrical equipment
°C	Celsius degree		
°F	Fahrenheit degree	HF SURGICAL EQUIPMENT	High-frequency surgery equipment
App	Application		
MRI	Magnetic resonance imaging		
RFID	Radio Frequency Identification Devices		
FCC	Federal Communications Commission		

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YUWELL®
Infrared ear thermometer
YHT107

Instructions for Use

Please read the instructions for use 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.