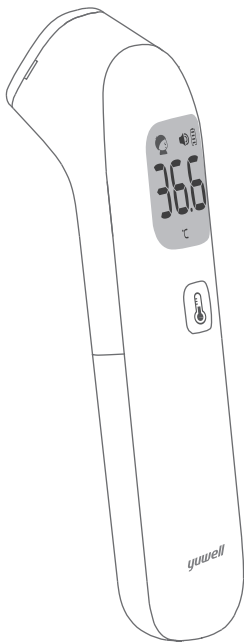


# yuwell



## YHW-5/YHW-6 Infrared Thermometer

### User Manual And Technical Instruction

Service life: 5 years. Please read the user manual carefully and follow the instructions before use. For date of manufacture, please refer to the packaging.

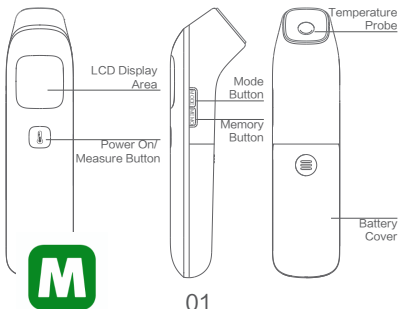
The picture is for reference only, please refer to the actual product.

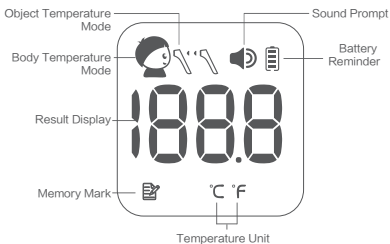
## 1. Device Use And Applicant Scope

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





● Appendix:

Instructions, 2 AAA alkaline batteries,  
APP Quick Guide(for YHW-6).

### 3. Warnings and Precautions

**WARNING:** 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.

**WARNING:** Please put the battery out of the reach of children, otherwise it is dangerous.

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

**WARNING:** 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.

**WARNING:** 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.

**WARNING:** 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.

**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.

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


**WARNING:** If the situations cannot be solved or unexpected problem happens, please consult the local

distributor.

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

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

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

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

**CAUTION:** 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.

**CAUTION:** 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.

**CAUTION:** 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.

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

**CAUTION:** Please read this instruction carefully before use and confirm that the battery is installed.

**CAUTION:** Do not move while using.

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

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

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

**CAUTION:** Due to the limited size of the label, the font is too small, please put it in the appropriate position to watch.

**CAUTION:** 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% non-condensing relative humidity).

**CAUTION:** 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% non-condensing relative humidity).

**CAUTION:** To avoid dust entering the probe cavity resulting in inaccurate measurements, install the cover after each use.

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

**CAUTION:** 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.

**CAUTION:** Do not mix old and new batteries.

**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: electrocautery equipment, diathermy equipment, other cellular telephones, wireless PC and tablets, pagers, RFID devices, MRI, and electromagnetic security systems.

**CAUTION:** The user is cautioned that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment

**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.

#### 4. Measurement And Transport Storage Environment

##### ● Measurement 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:

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

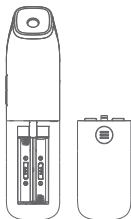
Relative humidity: 15% to 90% (no condensation)

Atmospheric pressure: 70kPa to 106kPa


#### 5. Setup and Use

##### ● 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 the forehead (non-contact).

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 Body temperature mode:

22.0°C~43.0°C(71.6°F~109.4°F); the thermometer will make one quick continuous sounds as "di-di-di" to prompt, at the same time, "Hi," or "Lo" appears on the display interface, accompanied by an orange backlight.

When body temperature is 37.6 °C(99.7°F) or higher, the device will make sounds as "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 Object temperature mode:

0.0°C~60.0°C(32.0°F~140.0°F), the thermometer will make sounds as "di-di-di" to prompt, at the same time, "Hi" 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 32 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

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

## 6. 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

Inspect 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.



















## 7. Troubleshooting Instructions

Phenomenon of breakdown	Possible cause	Trouble shooting methods
The screen display "Lo"	In the body temperature mode, the measurement result is $< 22.0^{\circ}\text{C}$ ( $71.6^{\circ}\text{F}$ ) or in the object temperature mode, the measurement result is $< 0.0^{\circ}\text{C}$ ( $32.0^{\circ}\text{F}$ )	Please remeasure following the product instruction
The screen display "Hi"	When in body temperature mode, the measurement result is $> 43.0^{\circ}\text{C}$ ( $109.4^{\circ}\text{F}$ ) or when in the object temperature mode, the measurement result is $> 60.0^{\circ}\text{C}$ ( $140.0^{\circ}\text{F}$ )	

The screen display " E1 "	The operating environment temperature is lower than 10°C (50.0°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 dealer and send it to the factory for repair
The screen display " E2 "	The operating environment temperature is higher than 40°C(104.0°F)	
The screen display " E3 "	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.
The screen display " E4 "	Infrared sensor sampling error	Please contact the dealer and send it to the factory for repair
The screen display " □ "	The power of batteries is shortage	Replace with new batteries
No display	The positive and negative poles of the batteries are reversed or the device is abnormal	Reinstall the batteries, or contact the dealer
	The batteries are not installed well	Check if the batteries are installed upside down
	Low battery	Replace with new batteries
	The screen is still blank	Please contact the dealer and send it to the factory for repair

## 8. Symbols

Symbols	Implication
	Manufacturer mark
	Caution
	Recyclable
	Manufacturer

	Non-ionizing radiation
	Symbol for the marking of electrical and electronic devices according to Directive 2012/19/EU
	Safety and environmental protection use period for 10 years
	Bluetooth
	Unique device identifier
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	Fragile, handle with care
	Keep dry
	This way up
	Serial number
	Date of manufacture
	Medical device
	Batch code
<b>IP22</b>	Protection from ingress of particulates than $\geq 12.5\text{mm}$ . Dripping water falling within $15^\circ$ of vertical will not have a harmful effect on the thermometer per IEC 60529
	Catalogue number
	MR Unsafe. Not appropriate for use in MR environment (i.e.: inside the MR magnet room)
	Refer to instruction manual

## 9. Technical Specification

- 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:  $\pm 0.2^\circ\text{C}$  ( $\pm 0.4^\circ\text{F}$ ) in the range of 35.0°C ~ 42.0°C (95.0°F ~ 107.6°F);  $\pm 0.3^\circ\text{C}$  ( $\pm 0.5^\circ\text{F}$ ) 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
  - Operation mode: continuous operation
  - Temperature units: °C/°F
  - Body temperature mode measuring site: forehead
  - Time interval of each measurement  $\leq 1$ s.
  - Measurement time:  $\leq 1$ s.
  - 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: 6" × 1.5" × 1.7"  
(152mm × 38mm × 43mm)
  - Product weight: About 0.15 lbs. (70g) (not including battery)
  - Number of memory groups: 32 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
  - Wireless connection: Bluetooth
  - Frequency range: 2.400 GHz~2.4835 GHz
  - Modulation mode: GFSK
  - Transmitting power:  $\leq 20$ dBm
  - FCC ID: 2A2JJ-YHW-6
- Recommended Range: ~10 feet (~3 meters) line-of-sight
- Quality of Service (QoS): Delay <10 seconds
- 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 thermometer in the display range of 37°C -39°C (98°F -102°F) is  $\pm 0.2^\circ\text{C}$  ( $\pm 0.4^\circ\text{F}$ ), while for mercury-in-glass and electronic thermometers, the requirement, according to ASTM Standards E667-86 and E1112-86 is  $\pm 0.1^\circ\text{C}$  ( $\pm 0.2^\circ\text{F}$ ).
- 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. After-sales Service

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.

### 13. Warranty Card

Warranty card

Product name:

Infrared thermometer

Model:

YHW-5/YHW-6

### 14. Connect To HealthCare+

For details, please refer to the APP Quick Guide.

1.To ensure that the measurement results can be transmitted through Bluetooth, please keep the distance between the device and the mobile phone no more than 10 meters.

2.If you want your body temperature measurements to be sent to your phone via Bluetooth, get a phone that supports Android 5.0 and above or IOS 10.0 and above to download Yuwell HealthCare+.

## 15. 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 °C- 42.2°C (93.2°F-108.0°F). Accuracy is  $\pm 0.2^{\circ}\text{C}$  ( $\pm 0.4^{\circ}\text{F}$ ) within 35.0°C- 42.0°C (95.0°F-107.6°F),  $\pm 0.3^{\circ}\text{C}$  ( $\pm 0.5^{\circ}\text{F}$ ) 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

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	$\pm 8$ kV contact $\pm 15$ 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

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; CMDA 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

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.

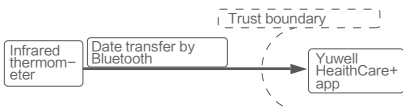
## 16. Cybersecurity

### 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	Bluetooth
Interface functionality	Transmit measured body temperature values
Attribute	Outgoing
Approved Destination End-points	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.

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

Trade Name: **yuwell**

Product name: Infrared thermometer

Model Number: YHW-6

Responsible party: YUWELL MEDTECH USA LLC

Address: 2152 Serene Ct, Keller, TX 76248

## Contact information

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## 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 interference that may cause undesired operation.

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