

## Infrared thermometer

# User Manual

Mode: TH10A



Shenzhen Yolanda Technology Co., Ltd.

## Introduction

Thank you for choosing the infrared thermometer of Shenzhen Yolanda Technology Co., Ltd..

With the unique technology, the infrared thermometer TH10A of Yolanda can give the result of stable measurement. The product will self-test every time when it starts up to make sure the normal operation and accuracy.

The infrared thermometer Model TH10A can measure body temperature from the forehead and Ear of infants and adults, it can be used by consumers in household environment and by doctors in the clinic.

Please read the instructions carefully before using the product, and put it in a safe and secure place for reference.

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## **1. Product Overview**

Thank you for choosing our Infrared Thermometer. The TH10A Infrared Thermometer is used to measure objects temperature based on the relationship between temperature and measurable infrared radiation. Simply aim the unit's probe at the surface of objects to obtain a quick and accurate temperature.

To ensure proper use, please be sure to read this user manual carefully, paying close attention to the safety precautions.

- In order to use this product correctly, please read the user manual before use.
- In order to properly use this product, please carefully read the full text of this manual before using, in particular the "safety precautions" section.
- Please keep this instruction manual in a convenient place for reference.

### **Medical background**



Body temperature is one of the key indicators of human life activities. It is of great significance to measure body temperature accurately and quickly for disease diagnosis and treatment. Infrared temperature measurement provides a fast and non-contact measurement method for measuring human body temperature. Compared with the traditional mercury thermometer, this temperature measurement method has the advantages of fast response speed, short measurement time, high precision and simple use, and can be widely and effectively used for the investigation of body temperature of dense people. Non-contact infrared thermometers are effective for specific people, such as children or the elderly.

### **Basic principles:**
















All object, solid, liquid or gas, emit infrared energy by radiation. The intensity of this energy depends on the temperature of the object. The Infrared Thermometer is therefore able to measure the temperature of a person by the energy the person emits. This measurement can be carried out by a temperature probe installed on the infrared thermometer, which can permanently analyze and record the ambient temperature. Therefore, as soon as the operator holds the thermometer near the body and activates the radiation sensor, the measurement is taken instantly by detection of the infrared heat generated by the arterial blood flow or eardrum.

## 2.Warning instructions and precautions

The warning signs and graphic symbols in the manual are intended to enable you to use the product safely and correctly and to prevent harm to you and others. Warning marks and graphic symbols are described as follows:

<b>Warning/precautions symbols</b>	
 Warning	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
 caution	Means a possibility of personal injury or property damage in case of improper use.
Notes	Indicates the need for attention, if not attention may lead to incorrect use of the product or property device damage.

## 3.Symbol description

	The product should be vertically up		Pile Limit 4 layers
	Applied part of type BF		Batch code
	Serial Number		Refer to instruction manual.
	Manufacturer information: The manufacturer name and address		Manufacture date
	Keep Dry		Complies with FCC rules
	Fragile, handle with care	/	/
	Complies with the European Medical Device Regulation ( 2017/745. Notified Body is 1639.		
	Authorized representative in the European Community.		
<b>IP22</b>	The first number 2: Protected against solid foreign objects of 12.5mm diameter and greater. The second number 2: Protected against vertically falling water drops when enclosure tilted up to 15° .		
	Disposal in accordance with Directive 2002/96/EC (WEEE)		
	This device has not been tested for use in an MR environment, it should not be used in MR environments. Please keep it outside the MRI scanner room.		

## **4. Safety Precautions**



### **Warnings**

- Please put the Thermometer out of children reach.
- Do not take readings less than half an hour after a meal, exercise, a bath, take medicine or time spent in a particularly hot or cold environment.
- Do not measure the sites of scarred tissue or tissue compromised by skin disorders, because sensing body temperature from sites of scarred tissue or tissue compromised by skin disorders may be not correct.
- Do not measure the site of forehead temperature if that patient has trauma on forehead.
- For patients with external otitis and media otitis or other ear diseases, please do not use this thermometer to measure the ear temperature, which may worsen the disease or got the inaccurate measurement results.
- Do not forcibly insert the probe in the ear. If you feel uncomfortable such as pain during measurement, stop using the unit. It may injure the external auditory canal.
- Do not measure if that patient is treated with certain drug therapies, body temperature may increase if the drug is within the effort time limit.
- Do not use the unit to measure ear temperature when the external auditory canal is wet such as after swimming or a bath. It may cause measurement inaccurate.
- Do not measure when the measured sites (forehead) is exposed to direct sunlight, fireplace heat, cold compress therapies, air conditioner flow.
- In order to obtain reliable and stable results, there is a significant change in the ambient temperature due to a change of environment, you are advised each time to allow the infrared thermometer to acclimatize to this ambient temperature for 30 minutes before using it.
- In order to ensure the accuracy of measurement data, please don't take measurement of body temperature in strong electromagnetic interference environment (such as microwave, high frequency equipment operation environment).
- Portable and mobile RF communications equipment may affect the device function properly.
- Measurement may be altered when used near a TV, a microwave oven, a mobile phone or any other device with an electric field.

- Lay persons shall be note that the use of this thermometer is not intended as a substitute for consultation with your physician. It is dangerous for user to perform a self-evaluation and self-treatment based on the measuring results, consult your doctor if you suspect a fever.
- As ear wax can affect the measurement, you should clean the ear before measuring ear temperature.
- The thermometer may be used by children only under adult supervision.
- Please make sure the measuring distance of forehead is within 1~3 cm.



**Cautions:**

- This device must only be used for the purposes described in this instruction manual.
- Should a problem occur with your device, please contact your retailer. Do not attempt to repair this device yourself.
- Do not disassemble, repair, or modify the unit.
- When we measure someone's body temperature continuously, there should be at least one minute between two measurements. If you need to measure continuously in a short time, there will be some slight differences when reading the temperature, which is normal. At this time, please select the average temperature. We recommend that you measure continuously for up to three times in one time unit, because the temperature of human body will be transmitted to the thermometer, which may affect the accuracy of measurement.
- There is no absolute standard about the temperature of the human, so please try to collect the recording of Individual temperature in the usual, as a reference for having a fever or not.

**Notes:**

- Do not touch the glass of the infrared lens with your fingers.
- Do not expose the thermometer to sunlight or to water.
- Never drop and impact the thermometer.
- The patent is an intended operator. The patient can measure, read data and replace battery under normal circumstances and maintain the device according to the user manual.
- The working environment of the device is: Temperature: 15°C (59.0°F) - 40°C (104.0°F);  
Relative humidity: 15%~95% RH; Atmospheric pressure: 70-106KPa. Please measuring under these conditions.
- Do not expose this thermometer to extreme temperature conditions of  $>55^{\circ}\text{C}$  (131.0°F) or  $<-20^{\circ}\text{C}$  (-4.0°F), relative humidity of  $>95\%RH$ .
- Check the battery before use  
Replace any low-voltage battery to ensure full power supply.

- Check the sensor before use
  - If have pollution and spray, please clean it.
  - If the lens is damaged, please stop using.
- Before using, please check if the thermometer appearance is intact, if measurement function is normal. if there any abnormal, stop using.
- Forehead temperature measurement:
  - Depending on various skin types and thickness, there may be temperature difference in forehead temperature measurement.

## **5. Description of the TH10A**

### ***5.1 Intended use / Indication for use***

***Intended use / Indication for use:*** The infrared thermometer is intended for the intermittent measurement and monitoring of human body temperature through ear canal or through the center of the forehead(non-contact type) as the measurement site on people of all ages.

The thermometers can be used in clinical and home environments.

#### **[Intended users]**

1. Adult
2. Have 8 years intensive reading experience
3. Can be read and understand the user manual

#### **Contraindications:**

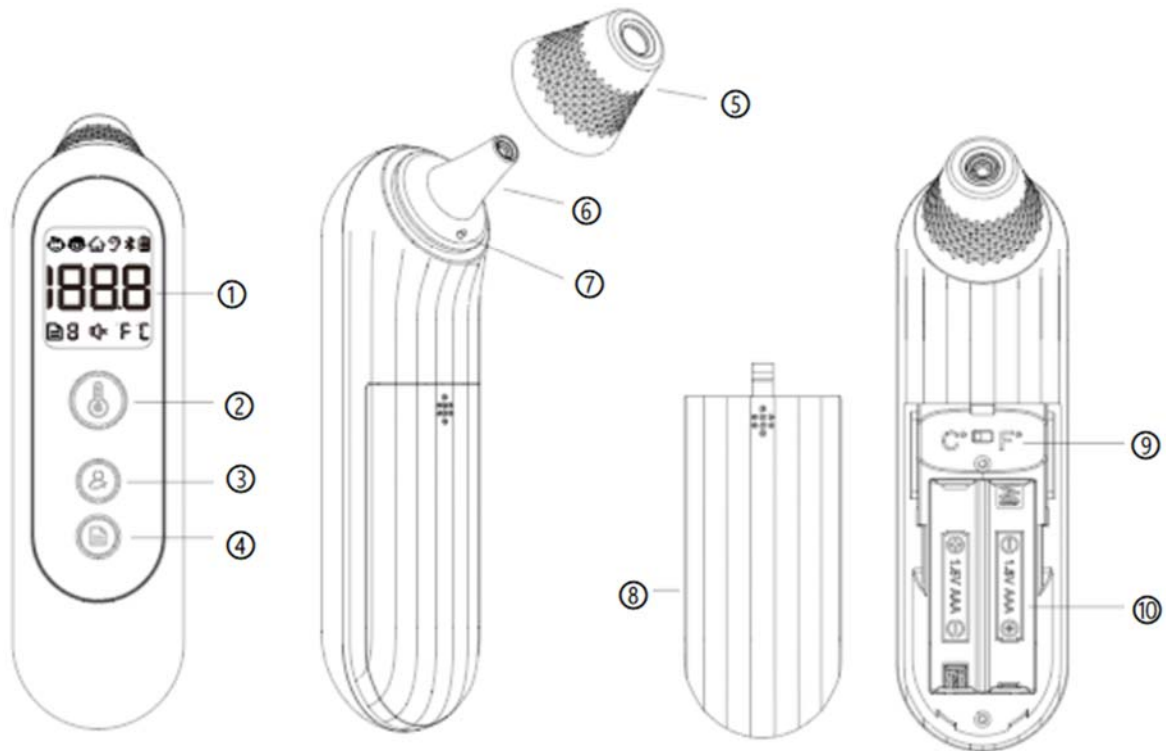
**No**

#### **Side effect:**

**No**

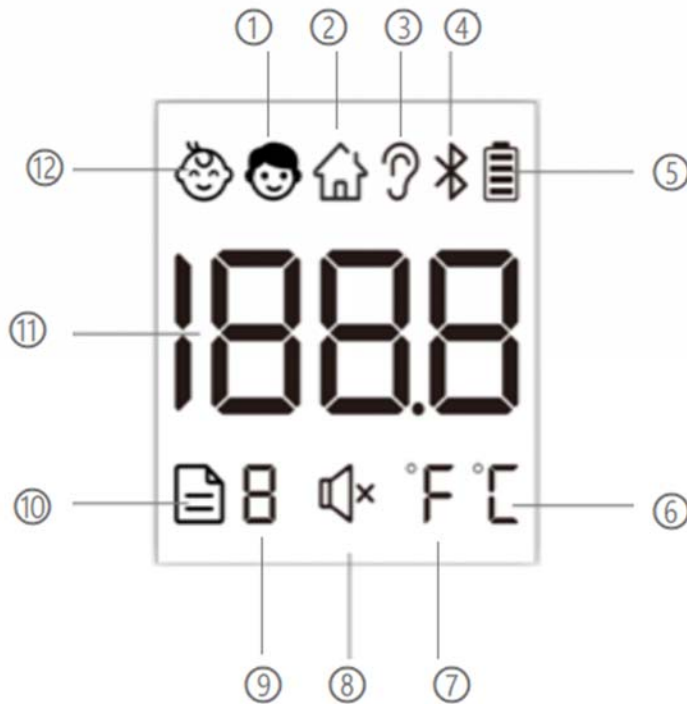
### ***5.2 Production structure***





No.	Name	No.	Name
①	LCD	⑥	Probe
②	Measuring button	⑦	Ear/forehead mode switch
③	Mode button	⑧	Battery cover
④	Memory button	⑨	Unit switch button
⑤	Forehead cap	⑩	Battery compartment

### 5.3 LCD display instruction



①	12Y-up mode	⑦	Temperature unit: Fahrenheit
②	Calibration mode	⑧	Mute icon
③	Ear mode	⑨	Memory group number
④	Bluetooth symbol	⑩	Memory icon
⑤	Battery symbol	⑪	Temperature valuable
⑥	Temperature unit: Celsius	⑫	12Y-down mode

## 6. Specifications

Device name	Infrared thermometer
Model	TH10A
Measurement mode	Ear mode, Forehead mode; <i>Both the forehead and ear mode is adjusted mode</i> <u><i>Both the forehead and ear mode include the sub-mode of 12Y-down mode and 12Y-up mode.</i></u>
Reference body site	The forehead and ear mode is reference the oral

	temperature.
Clinical bias ( $\Delta_{cb}$ ) of ear and forehead mode	$\pm 0.1^{\circ}\text{C}$ ( $\pm 0.2^{\circ}\text{F}$ ) <i>(Calculate according to ISO 80601-2-56-2017+A1:2018)</i>
Limited of agreement (LA) of ear and forehead mode	$< 2.0^{\circ}\text{C}$ ( $< 0.4^{\circ}\text{F}$ ) <i>(Calculate according to ISO 80601-2-56-2017+A1:2018)</i>
Clinical repeatability	$\pm 0.3^{\circ}\text{C}$ ( $\pm 0.5^{\circ}\text{F}$ )
Measurement range	For ear and forehead mode: $32.0^{\circ}\text{C}$ ( $89.6^{\circ}\text{F}$ ) ~ $43.0^{\circ}\text{C}$ ( $109.4^{\circ}\text{F}$ )
Measuring accuracy (for lab. condition)	For ear and forehead mode: $\pm 0.2^{\circ}\text{C}$ ( $\pm 0.4^{\circ}\text{F}$ ): $35.0^{\circ}\text{C}$ ( $95.0^{\circ}\text{F}$ ) ~ $42.0^{\circ}\text{C}$ ( $107.6^{\circ}\text{F}$ ); $\pm 0.3^{\circ}\text{C}$ ( $\pm 0.5^{\circ}\text{F}$ ): $32.0^{\circ}\text{C}$ ( $89.6^{\circ}\text{F}$ ) ~ $34.9$ ( $94.8^{\circ}\text{F}$ ); $42.1^{\circ}\text{C}$ ( $107.8^{\circ}\text{F}$ ) ~ $43.0^{\circ}\text{C}$ ( $109.4^{\circ}\text{F}$ )
Resolution of display	$0.1^{\circ}\text{C}$ ( $0.1^{\circ}\text{F}$ )
Measuring distance for forehead mode (non-contact measurement)	1.0cm to 3.0cm
Power supply	d.c. 3V, 2 $\times$ 1.5V AAA batteries
Memory function	9 groups memory
Low battery indicator	$2.4 \pm 0.2\text{V}$
Automatic shutdown function	$10 \pm 2\text{s}$ ; <i>Remark: Under the circumstance of displaying the Bluetooth pairing code, the automatic shutdown time is <math>120 \pm 10\text{s}</math>.</i>
Operation environment	Temperature: $15.0^{\circ}\text{C}$ ( $59.0^{\circ}\text{F}$ ) ~ $40.0^{\circ}\text{C}$ ( $104.0^{\circ}\text{F}$ ); Relative humidity: 15%~95%RH; Atmospheric pressure: 70-106KPa
Storage environment	Temperature: $-20.0^{\circ}\text{C}$ ( $-4.0^{\circ}\text{F}$ ) ~ $+55.0^{\circ}\text{C}$ ( $+131.0^{\circ}\text{F}$ ); Relative humidity: $\leq 95\%$ RH; Atmospheric pressure: 70-106KPa
High temperature hint	For 12Y-up mode: $\geq 37.8^{\circ}\text{C}$ ( $100.0^{\circ}\text{F}$ ) For 12Y-down mode: $\geq 37.7^{\circ}\text{C}$ ( $99.9^{\circ}\text{F}$ )
Dimensions	$38 \times 49.5 \times 136\text{mm}$
Weight	Approximately 72g (not include batteries)
Grade of waterproof	IP22
Electric shock	Internally powered ME equipment
Applied part	Type BF applied part, including the whole unit
Mode of operation	Continuous operation
Product working life	3 years

Software version	Embedded software version of TH10A:V1.0.0 Bluetooth APP version: 1.0.1
<p><b>Note: Not intended to be sterilized.</b></p> <p><b>Not for use in an OXYGEN RICH ENVIRONMENT</b></p>	

**Remark:** 12Y-down mode is designed to measure the body temperature of people aged 12 and below, 12Y-up mode is designed to measure the body temperature of people over 12 years old.

**Note:**

If you need to monitor a patient's temperature over a period of time, due to the same person's temperature can vary at different times of the day, so it is recommended to monitor the human temperature for 3 times a day (Measure once in the morning, noon and evening respectively), and take 3 measurements for each time and take the average for reference.

**Statement:** ASTM laboratory accuracy requirements in the display range of 37 to 39°C(98 to 102°F) for IR thermometer is  $\pm 0.2^{\circ}\text{C}(\pm 0.4^{\circ}\text{F})$ , whereas for mercury-in-glass and electronic thermometers, the requirement per ASTM Standards E667-86 and E112-86 is  $\pm 0.1^{\circ}\text{C}(\pm 0.2^{\circ}\text{F})$ .

Differences in the accuracy of measurements obtained with IR thermometer versus contact thermometers (that is, mercury-in-glass and electronic thermometers) are also related to operators' technique, anatomical variations, earwax buildups, subject cooperation. Please make sure to operate in accordance with this user manual to obtain the accurate reading.

This infrared thermometer meets requirements established in ASTM Standard (E1965-98). Full responsibility for the conformance of this product to the standard is assumed by Shenzhen Yolanda Technology Co., Ltd.(Address: Room 201,Jinfulai Building, No.49-1, DabaoRoad,Dalang Area,Xinan Street,Baoan, Shenzhen, China).

**7 wireless technology**

**7.1 Summary**

The device have wireless transmission function through Bluetooth:  
Through using smart phone to download and install Bluetooth APP, and binding the APP and your thermometer, you can transfer the measurement data of the thermometer to APP for storage through data upload operation, you also can check your measurement result history on the APP.

Bluetooth is a wireless communications system that is designed to operate in short-range wireless personal area networks.

The product supports the Smart (low energy) Bluetooth protocol. It operates in the spectrum range 2.402 GHz to 2.480 GHz industrial, scientific and medical (ISM) band. Smart Bluetooth uses 40 x 2 MHz channels. Within a channel, data is transmitted using GFSK shift modulation. The bit rate is 1 Mbit/s and the maximum transmit power is 5 mW. The Smart Bluetooth protocol uses frequency hopping to counteract narrowband and interference problems.

**The specification of wireless transmission  
For Bluetooth**

Bluetooth	5.1
Valid Transmission	Up to 10 meters
Receiver	Smart phones with Bluetooth 4.0 or above version, and, Smart phones running Android 6.0 and iOS 10 or above system
Signal transmission	2.4G Bluetooth
Frequency	2.402-2.480 GHz
Output power	MAX +6dBm

**7.2 Wireless Security**

The Bluetooth App database include a Hash algorithm to protect data. Bluetooth Connections include Smart (low energy) Bluetooth protocol 5.1.

The security measures taken address:

- Embedded software
- Bluetooth wireless technology

Users should not share their login details to others. Errors in the display or integrity of the data transmit are a nuisance and will not interrupt function of the product.

**7.3 Quality of Service (QoS)**

When the product and connected device (i.e. Android 6.0 and iOS 10 or above system) are within 10m, the wireless QoS needed for effective product communication in the APP is optimized for Bluetooth. When the connected device has adequate sufficient Bluetooth connection, the wireless QoS needed for effective product communication for transferring of data to APP is optimized.

If the wireless signal is lost, the data transmission may be interrupted. Data latency and/or the probability of loss of service creates an inconvenience only and does not affect operation of the product and cannot inhibit the user's measurement.

**7.4 User actions and wireless communication delay or failure**

The function of the product is not impacted if disruption of the Bluetooth wireless communication occurs.

If the Bluetooth becomes disconnected from the product during use, remove the product from the radio frequency (RF) field and wirelessly reconnect to their device.

if the user be concerned about the Bluetooth connection for any reason, the user only need to disconnect the Bluetooth function on their smart phone.

**7.5 Wireless Coexistence**

Bluetooth connection adopts adaptive frequency hopping, which effectively alleviates the wireless interference in the same frequency band.

If Bluetooth wireless communication is interrupted, the function of the product will not be affected.

If Bluetooth is disconnected from the product during use, remove the product from the RF area and reconnect it wirelessly to the device.



**Warnings**

**Possible effects from RF sources in the vicinity of the device**



- When using infrared thermometer with a smart device, relocate the devices away from sources that may interfere with the Bluetooth. The presence of other devices that may create radio frequency interference (RFI) may result in loss of Quality of Service of the Bluetooth connection. Device may cause RFI include but are not limited to the following: other cellular telephones, wireless PC and tablets, pagers, Bluetooth devices, device with remote controls, electromagnetic security systems, RFID or other in-band transmitters.
- Please close the wireless function before used the thermometer for the persons with active implantable medical devices (e.g., pacemakers, defibrillators, etc.).
- For safety use of the device, please update the security software of smartphone timely.

\*Notes of cybersecurity:

- In order to prevent disclosure of your health condition, please do not disclose your user registration information and password to others.

## **8. Battery Installation/Replacement**

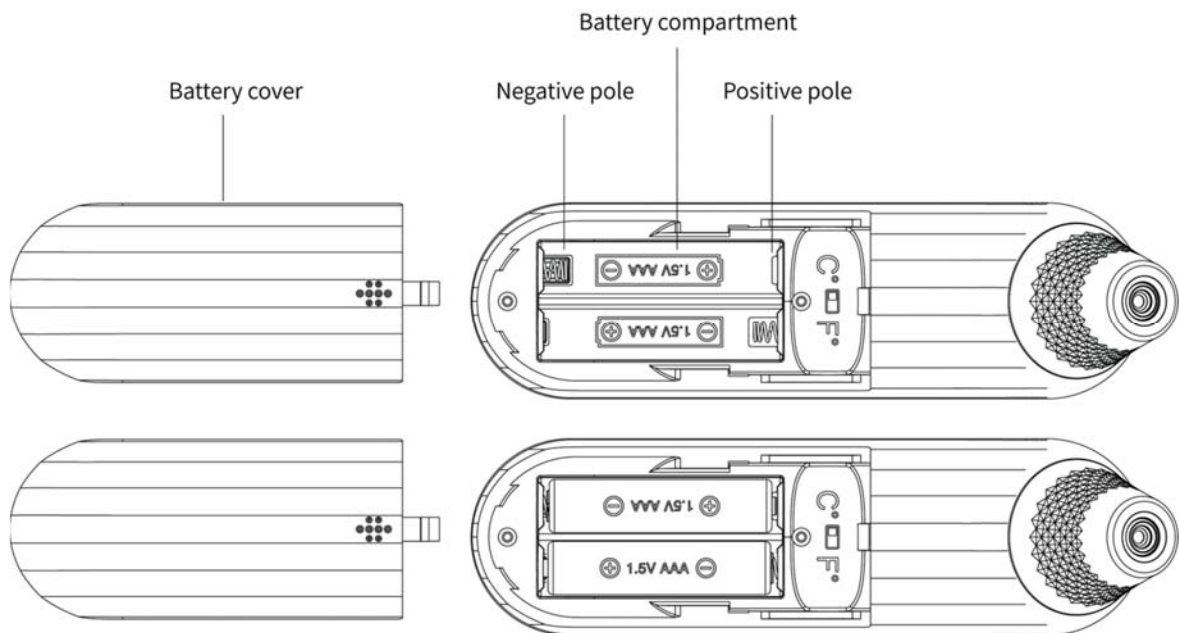
The thermometer is supplied with two 1.5V type AAA batteries. insert the batteries the to the device when initial use;

When the battery warning symbol “” appears, it means the battery is low. It is still possible to measure temperature, the batteries shall be replaced. If the battery power is too low, the battery symbol “” will flash for 3 times on the LCD, then the thermometer will switch off automatically.

- ① Pull the battery cover off downwards.
- ② Remove the used batteries, insert two new batteries in the battery compartment according to the indicated Negative pole and positive pole.

After inserting the two batteries, the LCD will self-check by full displaying for 3S, at the same time, the buzzer send out a long “bi... ..” for 3S, at the same time the backlight display “Cyan--Orange-Red” for 3S(The backlight of each color is displayed for 1s). Then the thermometer will automatically shut down.

- ③ Close the battery cover.




**Notes:**

- The two batteries supplied with the product can ensure the power consumption for at least 1000 times temperature measurements.
- When changing the batteries, use batteries of the same type and capacity.
- Always replace all batteries at the same time.
- Battery polarities should be correctly installed. The polarities are mark on the battery compartment.
- Please remove the batteries if the thermometer will not be used for a long time(over 3 months).

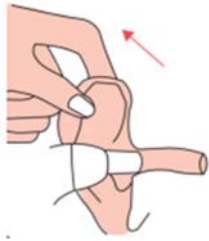
**9 Instruction for use**


**9.1 Ear temperature measurement**

Before measurement, gently clean the ear canal (earwax) with a cotton swab to ensure the measurement is accurate

- 1) Install the batteries (please refer to "8 Battery Installation/Replacement");
- 2) Take off the forehead cap to enter the ear mode(the Ear/forehead mode switch is open state) , and the LCD will show  icon to prompt if the device is powered on.
- 3) Insert the sensor tip carefully into the ear canal;

Make sure that the probe and the ear canal are clean. As the ear canal is slightly curved, please pull the ear slightly backwards before inserting the probe. This is important so that the probe can be pointed directly at the eardrum.






- 4) Press the “” button for 1 second then release the button, about 1 second later, the measured value will be appeared on the display with a “bi---” sound (If the buzzer sound is turned on).
- 5) Take out the device from the ear for reading the result, the measurement result remains on LCD for 3 seconds, then the “ — — — ” signal will be displayed on the LCD , you can make further measurement now.

If you need to make another measurement, repeat the steps above.

### Important note!

The thermometer designed with 12Y-down mode and 12Y-up mode, 12Y-down mode is used to measure the body temperature of people aged 12 and below, 12Y-up mode is used to measure the body temperature of people over 12 years old.

LCD display  means the current mode is 12Y-down mode, LCD display  icon means the current mode is 12Y-up mode. According to the age of the subjects, if your first measurement use the wrong mode, please withdraw the value, and press the “” button to select the correct mode, then perform a new measurement.



### Warnings

- The ear measurement shall not be taken in an ear affected by inflammatory disease (e.g. discharging pus or secretion), after possible ear injuries (e.g. eardrum damage) or in the healing period after operative procedures. In all of these cases, please consult your doctor.
- External factors may influence ear temperatures, including when an individual has:
  - Been laying on ear or other
  - Had their ears covered



- Been exposed to very hot or very cold temperatures, or
- Been recently swimming or bathing

In these cases, remove the individual from the situation and wait 30 minutes prior to taking a temperature.

- Do not remove the thermometer out of the ear canal until you hear beep at the end of the measurement.
- This thermometer may only be used without a disposable protective cover when measuring the ear temperature.
- Do not use ear mode to measure forehead temperature, otherwise you may get the inaccurate measurement.
- Do not use 12Y-up mode to measure the body temperature of people aged 12 and below, Do not use 12Y-down mode to measure the body temperature of people over 12 years old, otherwise the measurement results may be slightly biased.




**Cautions:**


- In order to measure the correct temperature value, make sure that the probe is aimed at the eardrum and closely matched with the ear canal.
- Use the untreated ear if prescription ear drops or others ear medication have been placed in the ear canal.
- Keep the probe tip surface clean, otherwise the measurement may not be accurate.

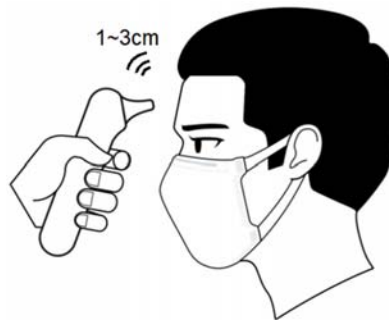
**Notes:**

- Some people produce different reading in their left and right ear. In order to record temperature changes, always measure a person's temperature in the same ear.

**9.2 Forehead temperature measurement (non-contact measurement)**

- 1) Install the batteries (please refer to "8 Battery Installation/Replacement");
- 2) Put on the forehead cap to the probe to enter the forehead mode(the Ear/forehead mode switch is closed state), there should be no obvious gap after the cap is installed, (The  icon on LCD will disappear if the thermometer is powered on, this means that the thermometer has successfully entered the forehead mode.)

- 3) Aim measuring head with the forehead cap towards the middle part of forehead, make sure that the distance between probe tip and forehead is 1~3cm. Press the “” button for about 1 seconds then release the button, about 1 second later, the measured value will appears on the display with a “bi---” sound(If the buzzer sound is turned on).









- 4) Take off the device for reading the result.

The measurement result remains on LCD for 3 seconds after finishing measurement, then the “ — — — ”signal will be displayed on the LCD , you can make further measurement now.

If you need to make another measurement, repeat the steps above.

#### Important note!

- Check if there is no  icon on LCD, if a  icon is on LCD, this means that you have not successfully entered the forehead mode. Please withdraw the measured value and recover the forehead cap to enter the forehead mode. Make sure that the LCD does not have the  icon, then measure the forehead temperature again.
- The thermometer designed with 12Y-down mode and 12Y-up mode, 12Y-down mode is used to measure the body temperature of people aged 12 and below, 12Y-up mode is used to measure the body temperature of people over 12 years old. LCD display  means the current mode is 12Y-down mode, LCD display  icon means the current mode is 12Y-up mode. According to the age of the subjects, if your first measurement use the wrong mode, please withdraw the value, and press the “” button to select the correct mode, then perform a new measurement.



#### Warnings

- Do not use 12Y-up mode to measure the body temperature of people aged 12 and below, Do not use 12Y-down mode to measure the body temperature of people over 12 years old, otherwise the measurement results may be slightly biased.

**Notes:**



- Before measuring forehead, make sure there is no hair, sweat, cosmetic, perspiration or hat on it.
- It is normal that there may be temperature difference depending on various skin types, since different skin type will reflect different voltage of infrared ray.
- Avoid any drafts (e.g. form nasal specs, air conditioning...)

**9.3 Temperature hint**

Measurement mode		Measuring temperature	Backlight	Buzzer sound	LCD display
Ear mode /Forehead mode	12Y-up mode	< 32.0°C(89.6°F)	Red	bi---	Lo
		32.0°C(89.6°F) ~ 37.7°C(99.9°F)	Cyan	bi---	Measurement value
		37.8°C(100.0°F)~39.4°C(102.9°F)	Yellow	bi-bi-bi-bi	
		39.5°C(103.1°F)~43.0°C(109.4°F)	Red	bi-bi-bi-bi	
		>43.0°C(109.4°F)	Red	bi---	Hi
	12Y-down mode	< 32.0°C(89.6°F)	Red	bi---	Lo
		32.0°C(89.6°F) ~ 37.6°C(99.7°F)	Cyan	bi---	Measurement value
		37.7°C(99.9°F)~38.5°C(101.3°F)	Yellow	bi-bi-bi-bi	
		38.6°C(101.5°F)~43.0°C(109.4°F)	Red	bi-bi-bi-bi	
		>43.0°C(109.4°F)	Red	bi---	Hi
Operation environment temperature < 15°C(59.0°F)			Cyan	bi---	Er1
Operation environment temperature >40°C(104.0°F)			Cyan	bi---	Er2


Note: The buzzer function in the table above is built when the buzzer sound is turned on.

**9.4 Voice adjustment**



On the power on status, press the “” button for 2s,the buzzer sound will be turned off, there will be no buzzer sound during subsequent operations. Pressing the “” button for 2s again, the voice function will be turned on with a “bi”sound.

**9.5 Memory mode**

This device stores the last 9 sets temperature measurements. If you want to get memory data, please following the below to get it.

- 1) At turning on status, press the “” button, to enter the memory query mode and the LCD will display the memory icon and first group of measurement data .



- 2) press the “” button repeatedly to switch a series of measurement data, memory number will start from 1, 2,3,... .
- 3) Memory mode is automatically exited by turn off the device or you can press “” button to enter the measurement mode.

Note: When the memory data is over 9 groups, the system will replace the oldest set.

The abnormal body temperature results cannot be stored too (such as Lo, Err or Hi).

All memory values will be deleted after the battery is removed.

## 9.6 Switch °C and °F

This device is shipped with Celsius(°C)temperature scale activated. If you wish to switch to Fahrenheit(°F) and/or back from Fahrenheit to Celsius, proceed as follows:

- Power on the device, remove the battery cover, move the “Unit switch button” to switch the unit between °C and °F, the LCD will display the selected unit.
- On power off status, move the “Unit switch button” can also switch the unit between °C and °F, after power on the device, the LCD will display the selected unit.

## 9.7 Power off

If no operation after  $10s \pm 2s$ , the system will be switch itself off and LCD will be blank.

Under the circumstance of displaying the Bluetooth pairing code, if no operation after  $120 \pm 10s$ , the system will be switch itself off and LCD will be blank.

## **10. Wireless transmission function operation guide**

### **10.1 APP Download and Installation**

If you want to use the Bluetooth function, you can download the free App from the Apple App Store and Google Play:

--- For iPhone with iOS 10 or above system, enter the “Runcobo note” under Apple APP store, then search and install the Bluetooth APP.

--- For Android phones with Android 6.0 or above, enter the “Runcobo note” under Google Play, then search and install the Bluetooth APP.

The installed Bluetooth App icon on the smart phone, as shown on below picture:



### **10.2 Registration**

If you using the App for the first time, you need to sign up for the user account:

- 1) click the Bluetooth App icon and enter the Fig.1 interface, click the “sign up now”, it will jump to Fig.2 interface.
- 2) Please enter the user information(as shown on Fig.2), then click the small circle next to “ <User License Agreement> and <Privacy Protection Agreement>”,
- 3) Click the "Sign up" button to create new account and password. After successful sign-up, the APP will automatically jump back to the Fig.1 interface.

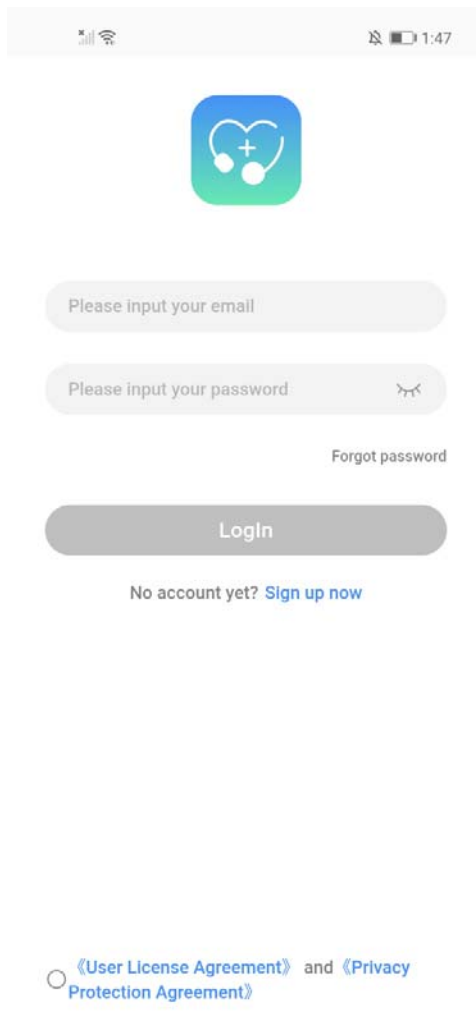


Fig. 1

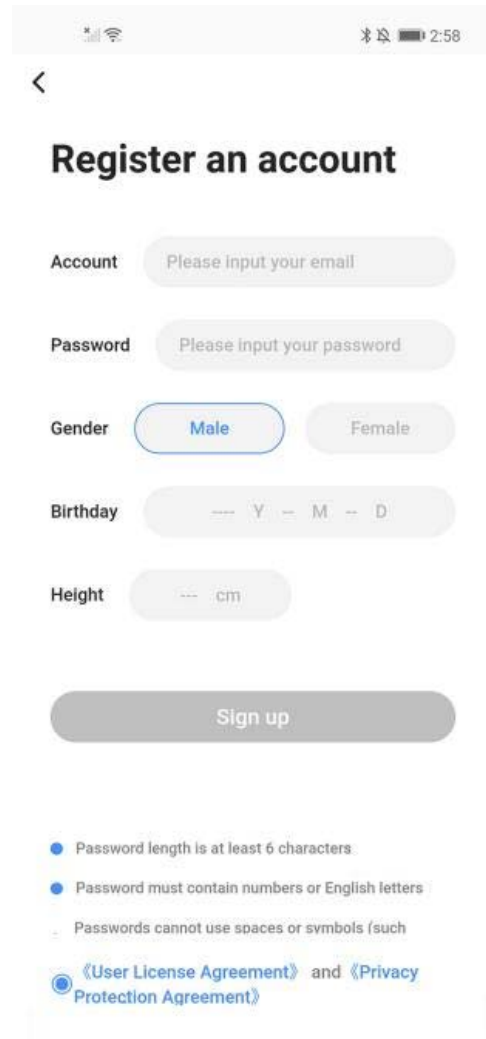
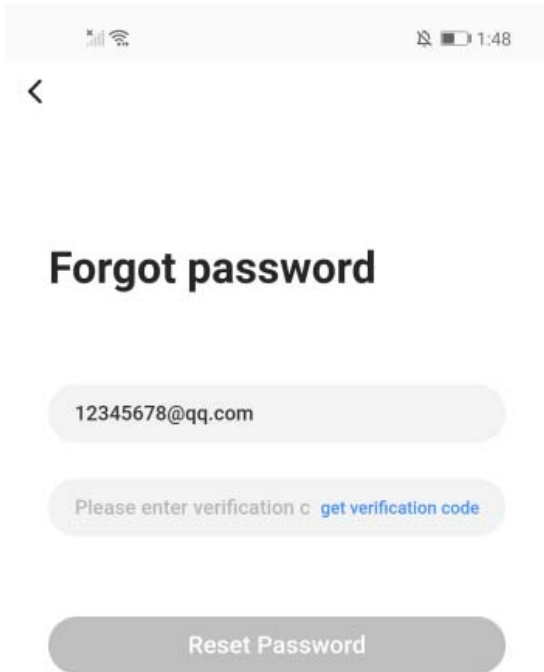


Fig. 2

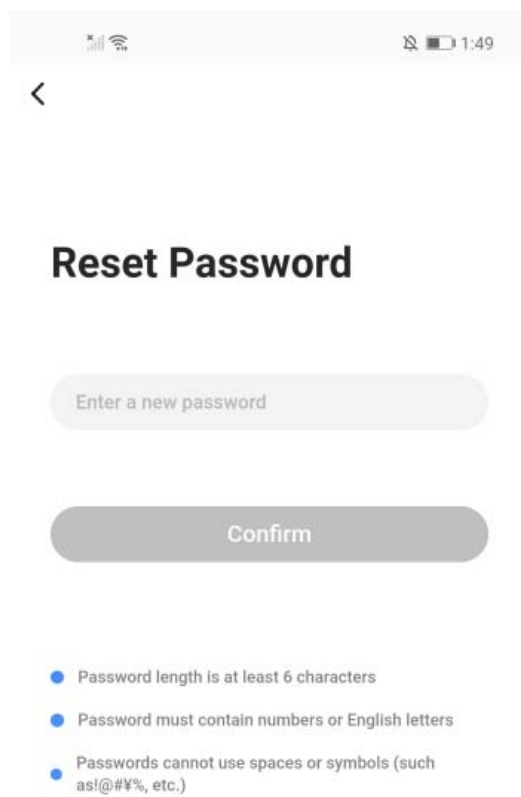
### Reset password

If you forget your password, you can reset the password by doing the following:

- 1) In the login interface (Fig.1), click “forgot password”, then it will jump to Fig. 3 interface.
- 2) Enter your email address(i.e. the user account), then click the “get verification code”, the verification code will send to your email.
- 3) Log in to your email to check the verification code and fill the verification code in the verification code box.
- 4) Click the “Reset Password”, it will jump to the Fig. 4 interface.
- 5) Enter a new password and click "Confirm". When the password is reset successfully, the APP will automatically jump to Fig.1 Interface.



**Fig. 3**



**Fig.4**

## 10.2 Binding of APP and you thermometer

If this is your first time to use the Bluetooth APP function ,you shall binding the APP and you thermometer:

- 1) Turn on your phone's Bluetooth function.
- 2) Click the Bluetooth App icon on your smart phone, the APP will jump to the Fig. 1 interface, enter your account number and password, the click “login”, the APP will jump to the Fig.5 interface.
- 3) Click “Click Add thermometer” on Fig.5, it will jump to Fig.6 interface, the interface indicates that the APP is looking for a nearby thermometer.

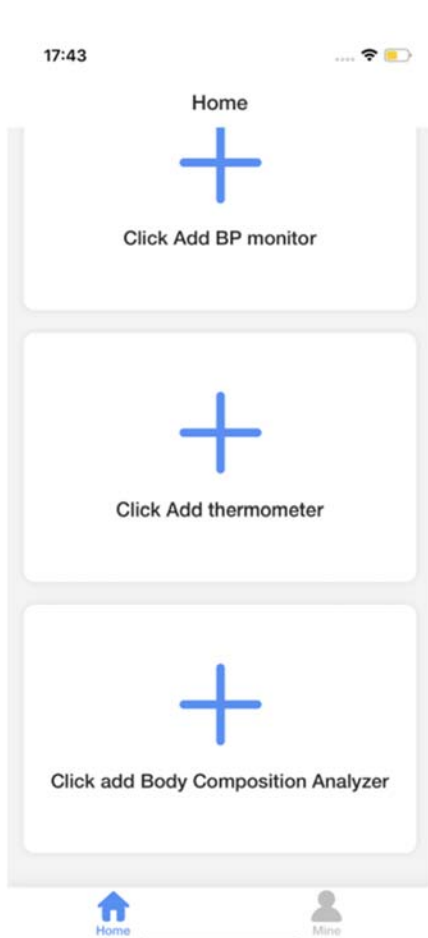


Fig.5

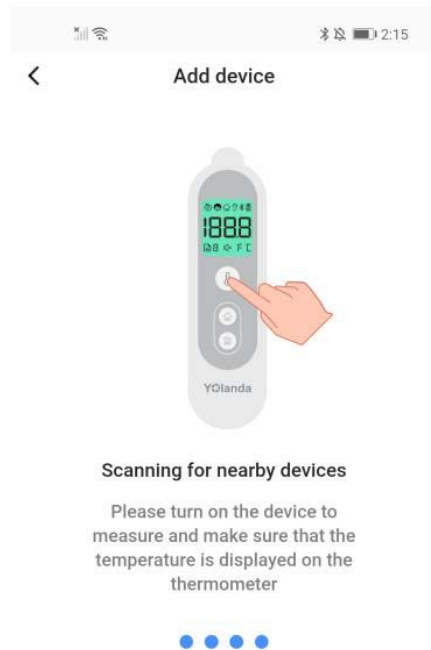



Fig.6

- 4) At this time, please follow the interface prompt of Fig.6, press the “” button on your thermometer to start up and measure temperature until the temperature value is displayed on the thermometer, then app can successfully search your thermometer. When the app searches for your thermometer, the APP will display as Fig.7.
- 5) Click the “Waiting for binding” on Fig.7 interface, it will jump to Fig.8 interface
- 6) Click “PAIR”, the APP will send out a command to your thermometer, at the same time, the APP will jump to Fig.10 interface, the LCD of your thermometer will display pairing code (a pairing code include Six digits, see Fig.9) after your thermometer receiving the command.

**Note:**

- *The six digit pairing code will be displayed by thermometer’s LCD for twice. First, the first three pairing codes will be displayed for 2.5S, and then the last three pairing codes will be displayed for 2.5S. In this way, it will be switched in turn until the binding is successful or the thermometer is automatically turned off. (under the status of displaying the pairing codes, the thermometer will automatically shut down if there is no operation of 120s ±10s.)*
- *“Allow access to your contacts and call history” in Fig. 8 and Fig.10 , the “PIN contains letters or symbols” and “you may also need to enter this PIN on the other device” in Fig.10, All of these are automatically ejected by the Bluetooth system of mobile phone. Different*



mobile phones may eject different contents. Please don't care. You don't need to click. It won't affect the pairing of Bluetooth and thermometer.



Fig.7

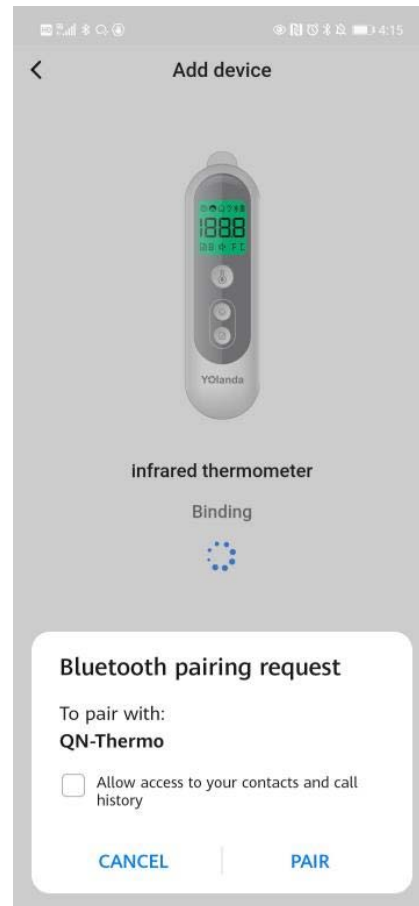


Fig.8



Fig.9 Pairing code displayed by LCD

- 7) At the Fig.10 interface, fill in the six-digit pairing code shown on the thermometer's LCD.
- 8) Click "OK", the APP will jump to Fig.11 interface, the APP is binding the thermometer now.
- 9) After successfully binding the thermometer, the APP will jump to the Fig.12. Click the "return" on Fig.12, the interface will return to home page Fig.13.

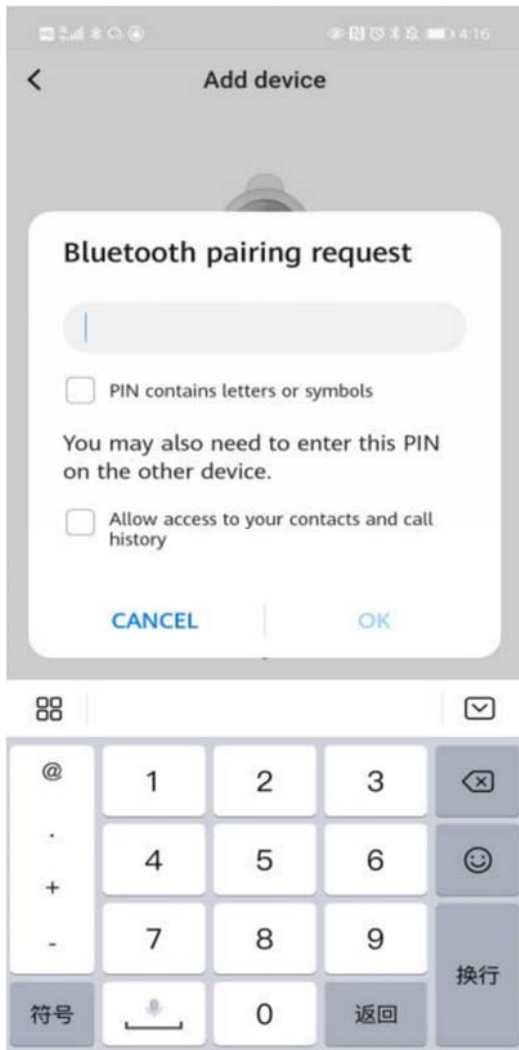


Fig.10



Fig. 11



Fig.12

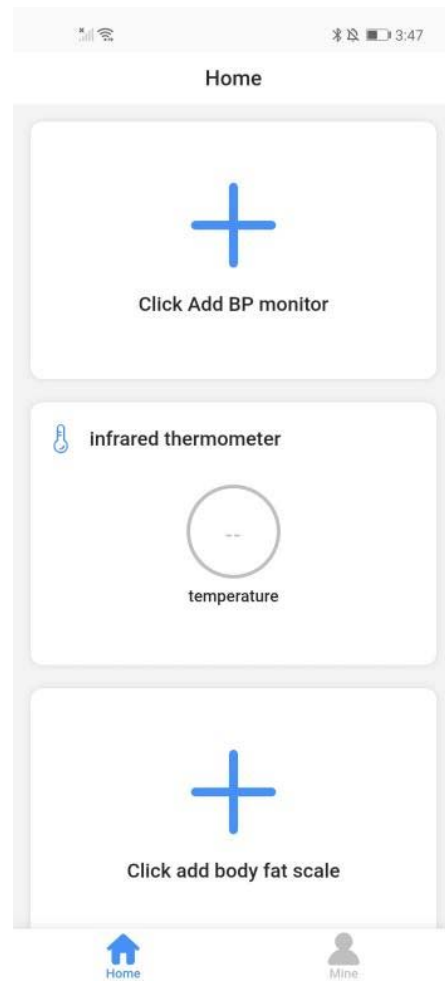


Fig.13

### 10.3 Measurement and data transmission

- 1) Please make sure that you have logged in to your account and click the app icon to enter the Fig.13 interface. If you don't log in, please enter your account and password to login first.
- 2) Click the "O" next to "temperature" on Fig.13, it will jump to Fig.14 interface.

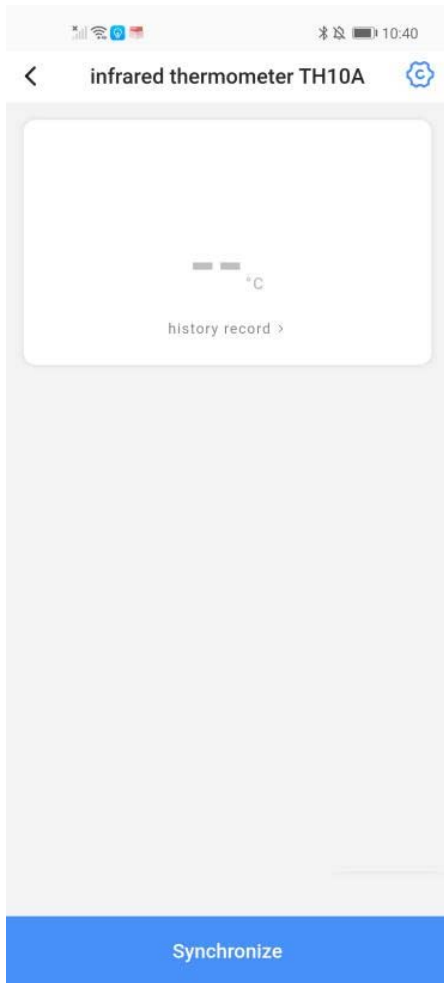


Fig.14

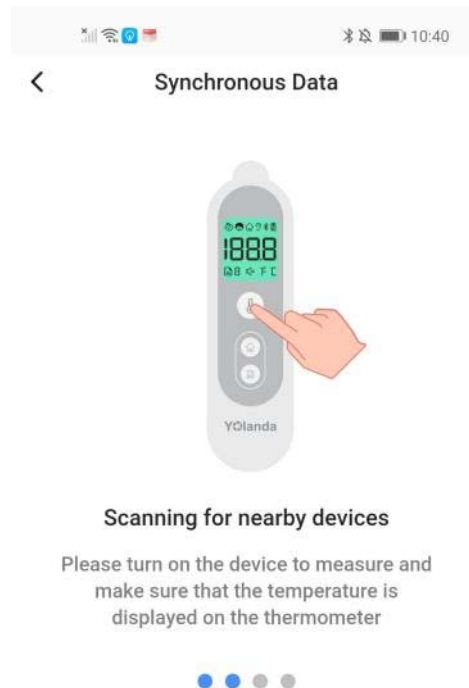


Fig.15

- 3) Click "Synchronize" on Fig.14 and wait for the device to connect. The connection status is as shown in Fig.15
- 4) Power on your thermometer and measure the temperature according to the Fig.15 prompts. When the temperature value is displayed on your thermometer after the measurement, the app will automatically search your thermometer, the APP will jump to Fig.16 if it successfully connect to the your thermometer(at the same time, the LCD will display the Bluetooth icon).
- 5) Click the“waiting for synchronization”in Fig.16, at this time, the measured data is being transferred from the thermometer to the app. Please keep the thermometer in the power on state.

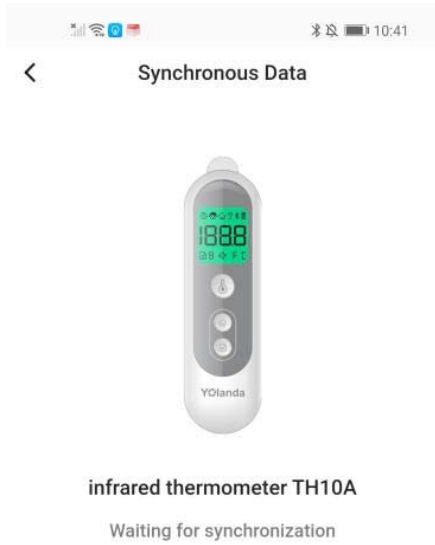


Fig.16

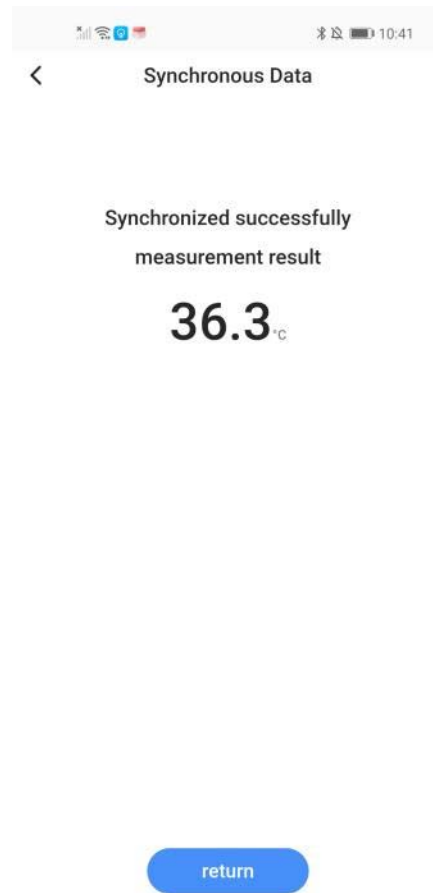


Fig.17

- 6) After the data is successfully transmitted to the APP, the APP will display the measurement results, see Fig.17.
- 7) Click the "return" on Fig.17, it will jump to Fig.18 interface.
- 8) If you need to re-measure and transfer the measurement results to the APP again, you can click the "Synchronize " on Fig. 18 and follow the above method to perform another measurement.

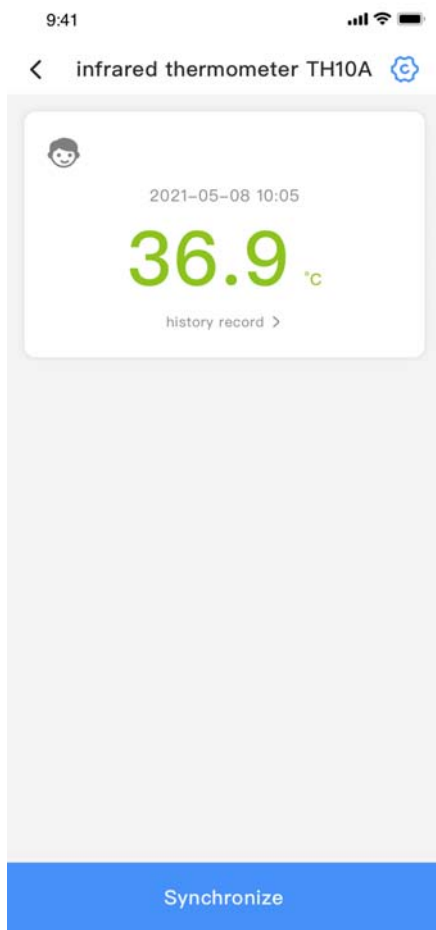


Fig.18

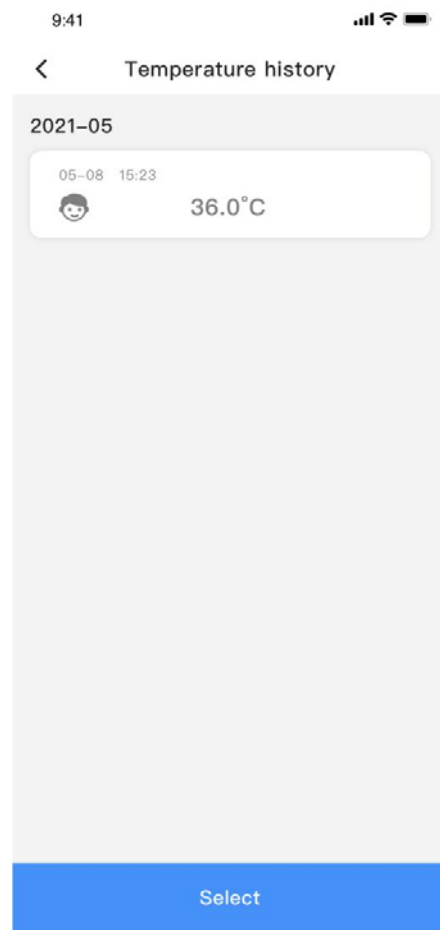


Fig.19

- 9) If you need to view historical data, click "History record >" on the Fig.18 to enter the history interface, as shown in Fig.19.
- 10) Click the record group you need to query in Fig.19, and the APP will display the measurement results, as shown in Fig. 20.
- 11) If you want to delete the history record, Click the "select" on Fig.19, it will jump to Fig.21.

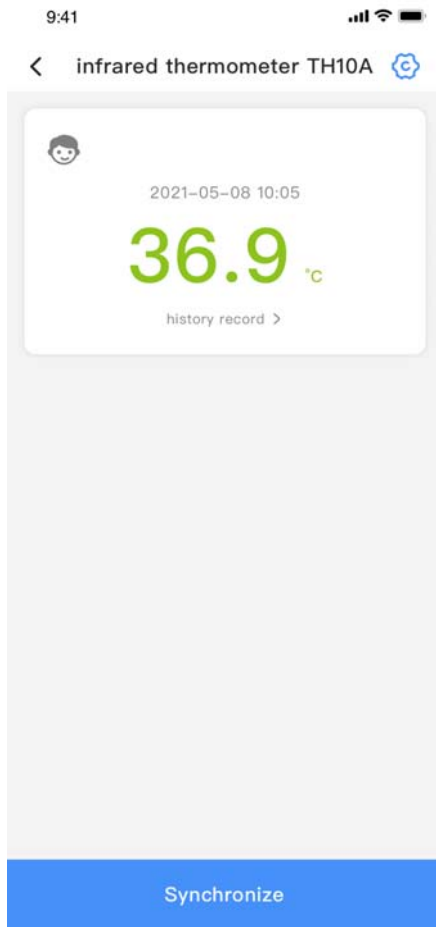


Fig.20

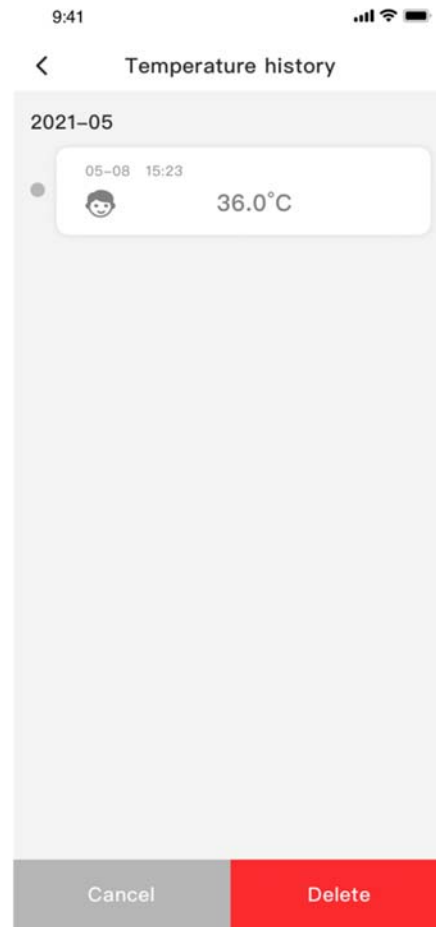


Fig.21

12) Select the history record that you want to delete, then click the “Delete” on Fig.21, then the selected history record will disappear from the interface. If you delete all the history record, the APP interface will be shown as Fig.22.

13) Click the “<” on upper left corner can return to the previous interface.

*Note: Deleting the historical data of the APP will not cause the historical data of the thermometer itself to be deleted.*

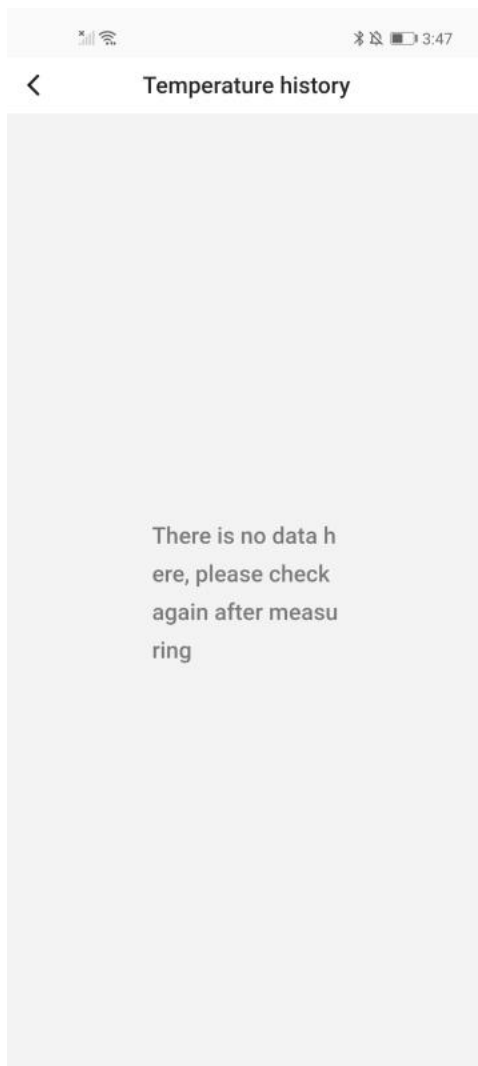


Fig.22

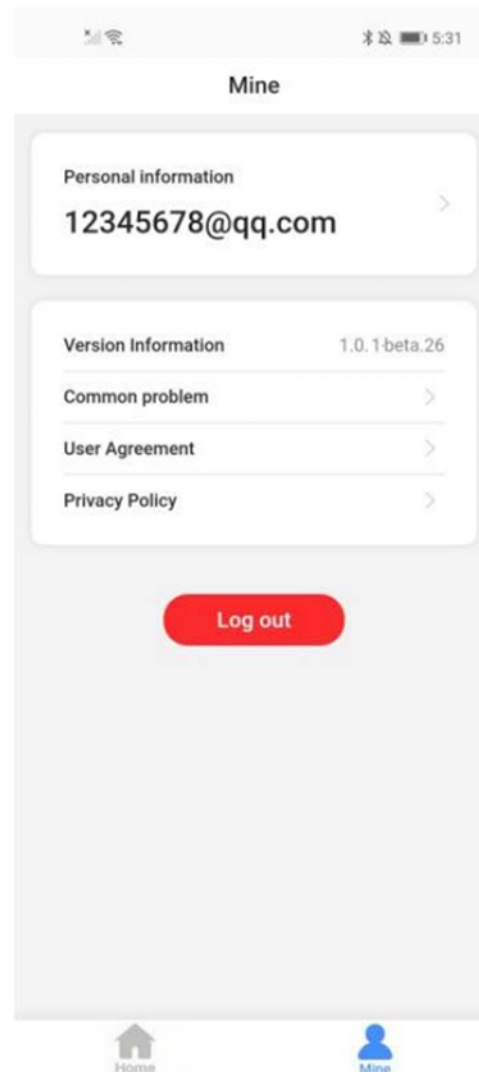


Fig.23

#### 10.4 FAQ helping of APP

1) How to find the FAQ on APP?

Click the “mine” in Fig.13 interface, you will find the APP version as shown on Fig.23, click the common problem, you will see the FAQ as shown in Fig.24, slide down the smartphone and you will see the content of Fig.25



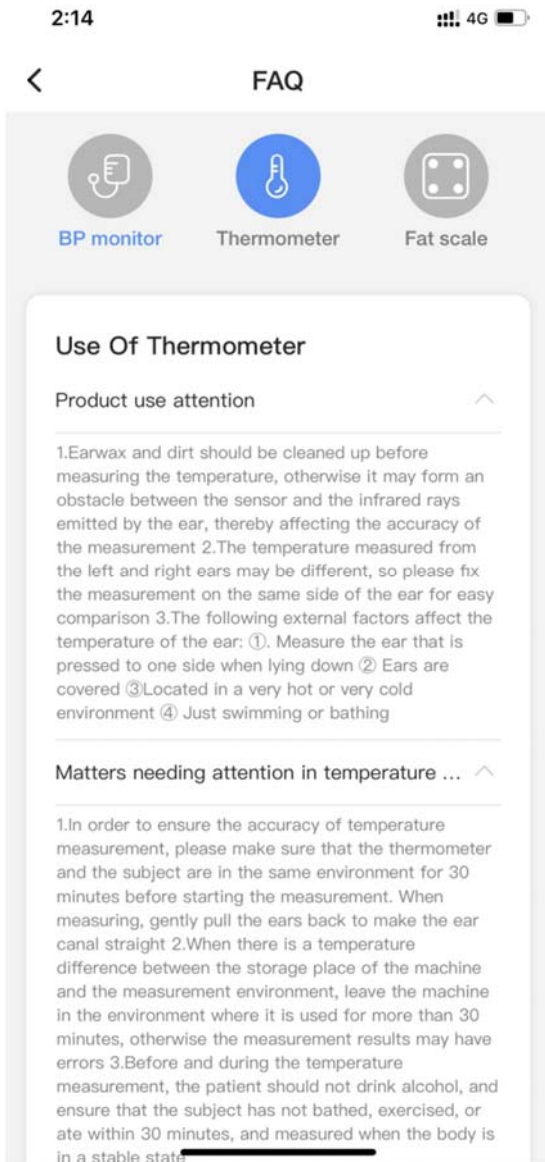


Fig.24

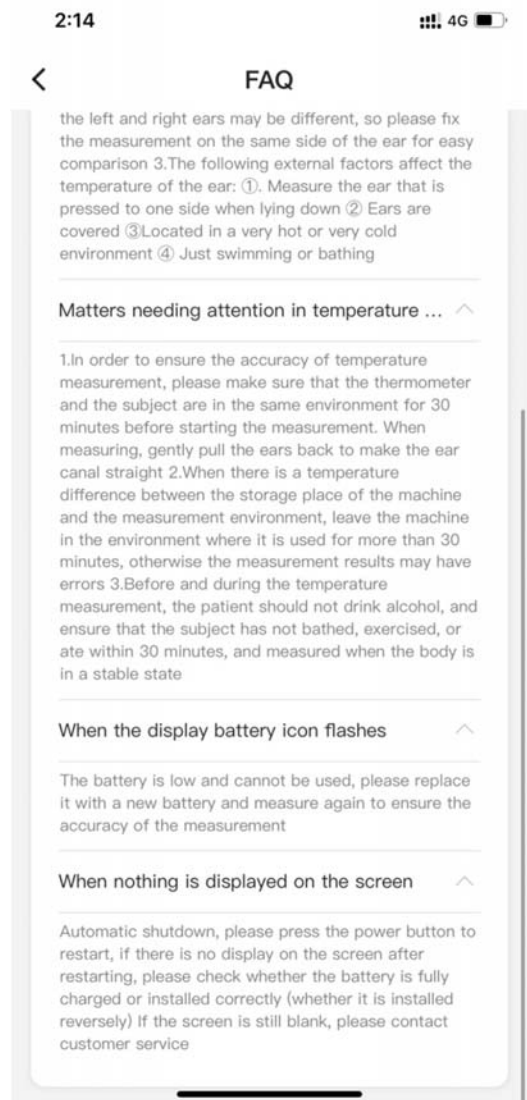


Fig.25

2) How to unbind the thermometer from the APP?

Click "⚙️" in the upper right corner of Fig.20, then it will jump to Fig.26, click the "delete device", it will jump to Fig.27, click the "confirm" to unbind the thermometer, the APP will automatically jump to Fig.5, unbind successfully.

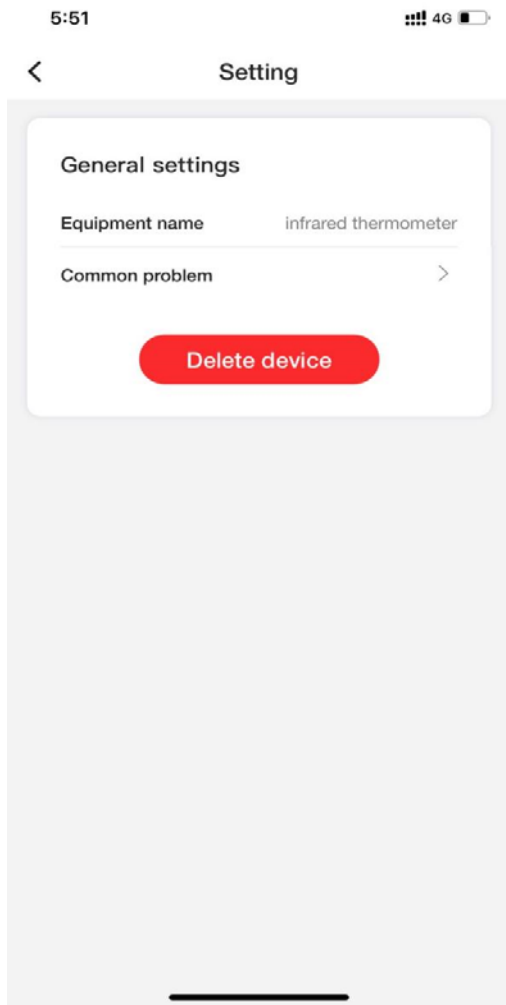


Fig.26

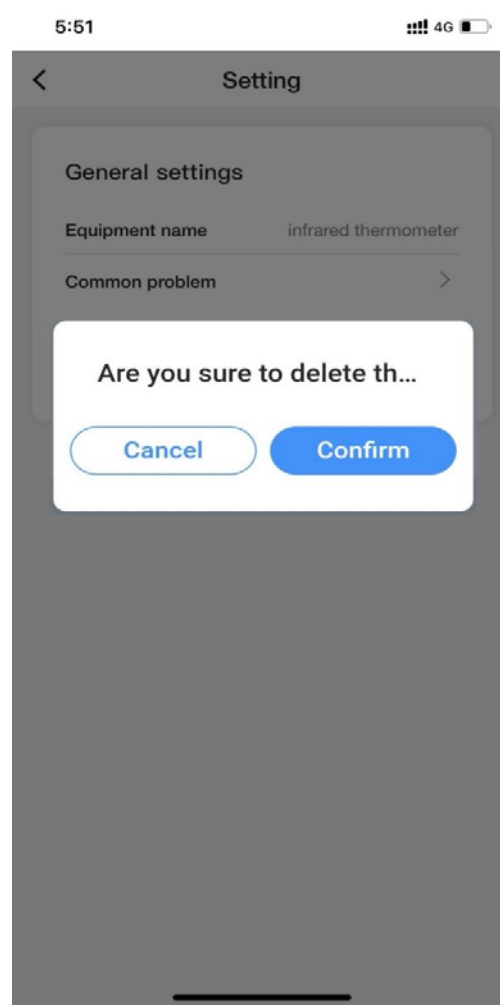


Fig.27

### 10.5 App updates

If there is any update to the APP, we will send you an update notice via email. When you receive the update notice of APP, please follow the steps in Section 10.1 to download and install the APP again.

## **11. Cleaning/disinfection and Care**

After use, the device surface (include the forehead cap, surface of probe, probe tip and enclosure) should be thoroughly cleaned and should be disinfected. Cleaning and disinfecting the thermometer at room temperature(under 10.0°C(50.0°F) - 40.0°C (104.0°F)) as below:

### 11.1. Cleaning:

11.1.1 Before performing this cleaning procedure, wash your hands with hand sanitizer first.

11.1.2 Remove all residual foreign matters from the transducer using clean soft cloth immediately after use.

11.1.3 Take a piece of clean soft cloth soaked with 70% isopropyl alcohol to swab on the surface of the device until no visible contaminants remain.

11.1.4 Use a piece of clean soft cloth soaked with sterile water to wipe off the cleaning reagent on the surface until no visible cleaning agent remain.

11.1.5 Wipe off with a dry and clean soft cloth to remove residual moisture.

11.1.6 The device should be thoroughly cleaned, inspect the device surface to ensure the device has no visible dirt. If there is still dirt, repeat the steps from 11.1.3 to 11.1.5 until the device is free of dirt.

11.1.7 Check whether there are cracks on the device surface. If there is any damage, contact the distributor.

## **11.2. Disinfection:**

11.2.1 Clean and dry the device according to the methods in section 11.1 Cleaning.

11.2.2 Take a piece of clean soft cloth soaked with 70% isopropyl alcohol to swab on the surface of the device for 20s, or follow the disinfectant manufacturer's recommended contact time and mode.

11.2.3 Use a piece of clean soft cloth soaked with sterile water to wipe off the disinfectant solution on the surface until no visible disinfectant solution remain.

11.2.4 Wipe off with a dry and clean soft cloth to remove residual moisture.

11.2.5 Check whether there are cracks on the device surface. If there is any damage, contact the distributor.

## **NOTES:**

- After cleaning and disinfection, the thermometer should be placed at room temperature for at least 30min then can be used for measuring.
- Do not use abrasive cleaning reagent or disinfectant solution.
- Don't use other non-recommended methods to perform cleaning and disinfection.
- Don't use the abrasive cleaner to clean the product, don't drop the thermometer in the water or other liquids.
- If the probe tip is damaged, contact the distributor.

## **11.3 Guarantee**

From the date of purchase, the product will enjoy a one-year free warranty with the purchase invoice. If the circuit diagram, components, necessary materials and electrical circuit maintenance are required during warranty service, please contact the manufacturer. Free warranty service will not be provided for failures caused by the following users' personal reasons:

- A. Wearable and consumable parts: covers and batteries;
- B. Failure caused by unauthorized disassembly, assembly and modification of products;
- C. Failure caused by not operating according to the requirements of the manual;
- D. Failure caused by lack of reasonable maintenance;
- E. Failure caused by product falling carelessly;
- F. Damage caused by external force;
- G. Maintenance services outside the warranty scope will be charged according to regulations.

#### **11.4 Storage**

- Always store the thermometer with forehead cap on.
- Please store the thermometer within the temperature of  $-20^{\circ}\text{C}(-4.0^{\circ}\text{F})\sim+55^{\circ}\text{C}(131.0^{\circ}\text{F})$  ; and make sure the relative humidity is  $\leq 95\%RH$ ; the Atmospheric pressure: 70-106KPa
- Avoid moisture, high temperature, falling, dust, sun exposure, vibration, chemicals or corrosive gas, etc.

#### **12 Calibration**


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 measuring accuracy, please contact our service representative(see last page for contact information). The service life of the thermometer is 3 years. Once the service life of thermometer was exceeds 3 years, if users want to continue to use, please return the thermometer to manufacturer for re-calibration. Or change a new thermometer.

##### **Calibration method**

*Note: This function is mainly used for professional calibration. Users please do not operate it, otherwise it may affect the accuracy of measurement*

Set the ambient temperature within the  $25^{\circ}\text{C}\pm 1^{\circ}\text{C}(77.0^{\circ}\text{F}\pm 1.8^{\circ}\text{F})$ :

1. Hold down the mode button, at the same time, install the batteries, the thermometer will

enter the factory calibration mode and the LCD display “”.

2. Set the black body to 35.00°C(95.00°F), measure for 3 times, the measurement result shall be within 35±0.2°C(95.00 ± 0.4°F), otherwise, the thermometer is inaccurate.

3. Set the black body to 37.00°C(98.60°F), measure for 3 times, the measurement result shall be within 37±0.2°C(98.60 ± 0.4°F), otherwise, the thermometer is inaccurate.

4. Set the black body to 39.00°C(102.00°F), measure for 3 times, the measurement result shall be within 39±0.2°C(102.00 ± 0.4°F), otherwise, the thermometer is inaccurate.

After finishing calibration, remove the battery to exit the calibration mode.

### **13 Maintenance**

- 1) We do not authorize any institutions or individuals to maintain and repair of the product. If you suspect that the products have any questions, please contact the manufacturer or distributor to handle the case.
- 2) The user must not attempt any repairs to the device or any of its accessories. Please contact the retailer for repair.
- 3) Opening of the equipment by unauthorized agencies is not allowed and will terminate any claim to warranty.
- 4) Cleaning/disinfecting the device after each use, detail method see the chapter 11  
Cleaning/disinfection and Care


**WARNING: No modification of this equipment is allowed!**

### **14.Packing list**

Quantity	Parts	Part No.
1pc	Infrared Thermometer(main unit)	TH10A
2PCS	2 AAA batteries	AAA
1PC	Forehead cap(Installed on main unit)	TH10ASMGW
1PC	Battery cover(Installed on main unit)	TH10AASDCW
1pc	User Manual	/
1pc	Certificate of qualification	/

### **15.Trouble-shooting**

Troubles or error message	Checklists or situation	Countermeasures or solution
---------------------------	-------------------------	-----------------------------

The LCD is blank	No batteries installed	Install the batteries
	Batteries used up?	Replace new batteries
	Batteries in wrong polarity?	Take out battery, adjust batteries to proper polarity
	The thermometer power off automatically	Power on the device again
LCD shows Lo or Hi	<p>Exceed measurement range</p> <p>Body mode:</p> <p>&lt; 32.0°C (89.6°F) display Lo;</p> <p>&gt; 43.0°C (109.4°F) display Hi.</p>	<p>1 Make sure the probe tip and the forehead cap is clean and there is no obstruction prior to taking a temperature</p> <p>2 Make sure there is no air flux as this could interfere with the infrared system.</p> <p>3 Make sure the measuring distance is not too far during forehead measure mode measurement, distance should be within 1.0cm to 3.0cm.</p> <p>4 Ensure that the ear canal is clean and the probe tip and ear canal are closely matched when measuring ear temperature.</p>
LCD shows Er1	Ambient temperature too low	Allow the device to remain in a room for 30 minutes where the temperature is range from 15°C (59.0°F) to 40°C (104.0°F)
LCD shows Er2	Ambient temperature too high	
LCD shows Er3	Ambient temperature changes too quickly	
LCD shows Er4	IR sensor or other hardware failure	Turn off the device, then turn on again, if still unable to use please contact the factory
 flash on LCD	The battery power is low and the device can't be used	Replace 2 new AAA batteries

Inaccurate measurement	Waiting time is not enough.	Wait at last 30 minutes.
	The measurement method is not correct. Use the wrong measurement mode.	According to the requirements of the user manual to measuring.
	The surface of the probe tip or forehead cap is dirty.	According to the requirements of the user manual to cleaning.
	In forehead measure mode, the measuring distance is not correct .	Please respect the measuring distance shall be within 1.0cm to 3.0cm.
	In ear measure mode, the probe tip isn't aimed at the eardrum and/or isn't closely matched with the ear canal	Ensure that the ear canal is clean and the probe tip and ear canal are closely matched when measuring ear temperature.
The Bluetooth connection failed	The Bluetooth module of the thermometer failed to initialize	Remove the battery from the thermometer and reinstall it to reinitialize
	The distance between the thermometer and the Bluetooth APP is too large	Make sure the distance between thermometer and Bluetooth APP is within 10 meters

**Remark:** If the above methods still do not solve the problem, please contact the manufacturer, contact information see the last page.

## **16. Standard List**

Shenzhen Yolanda Technology Co., Ltd. declares that the TH10A complies with following applicable standards:

IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11, ASTM E 1965-98, ISO 10993-1, ISO 10993-5, ISO 10993-10 and IEC 62304, ISO 1497, ISO 80601-2-56, EN 1401, ISO 15223-1.

## **17. Disposal**



Dispose of the device in accordance with the regulations applicable at the place of operation.

Dispose of at public collection point in the EU countries – 2002/96/EC WEEE Directive.

If you have any queries, please refer to the local authorities responsible for waste disposal.

**NOTES:**

- Handing of battery and wastes method, please act according to the native law to proceed to handle.




To protect the environment, dispose of empty battery at your retail store or at appropriate collection sites according to national or local regulations.

## **18 RF STATEMENT/ FCC statement**

### **RF STATEMENT**

Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the following section.

Interference may occur in the vicinity of equipment marked with the following symbol . Portable and mobile RF communication equipment (e.g. cell phones) can affect Medical Electrical Equipment. The use of accessories and cables other than those specified may result in increased emissions or decreased immunity.

The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.

Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Any other accessories, transducers and cables may result in increased emissions or decreased immunity and EMC performance.

The device should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, it should be observed in order to verify normal operation in the configuration in which it will be used.

Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the following.

Portable and mobile RF communication equipment (e.g. cell phones) can affect Medical Electrical Equipment. The use of accessories and cables other than those specified may result in increased emissions or decreased immunity of the unit.



## FCC 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.

Attention that changes or modification not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Note: This product has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This product 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 product 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.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

## **19.EMC DECLATION**

The thermometer needs special precautions regarding EMC and needs to be installed and put into service according to the below EMC information.

### **Statement:**

The equipment with following ESSENTIAL PERFORMANCE is intended used in Home healthcare environment and professional healthcare facility environment.

### **Essential Performance:**

The measurement range and measurement accuracy shall be meet the below requirement:

Measurement range	For ear and forehead mode: 32.0°C (89.6°F)~43.0°C(109.4°F)
Measurement accuracy	For ear and forehead mode: $\pm 0.2^{\circ}\text{C}(\pm 0.4^{\circ}\text{F})$ : 35.0°C(95.0°F)~42.0°C(107.6°F); $\pm 0.3^{\circ}\text{C}(\pm 0.5^{\circ}\text{F})$ : 32.0°C(89.6°F)~34.9(94.8°F); 42.1°C(107.8°F) ~ 43.0°C(109.4°F)

If Essential Performance is lost or degraded due to electromagnetic disturbances, this may result in inaccurate measurement and lead to mislead patients , please read below important information before to avoid possible electromagnetic disturbances.

**Warning :**

- Using cell phone or microwave oven, HF surgical equipment, magnetic resonance imaging or other radio radiant equipment near this product may cause malfunction or lead to loss of essential performance, which means that the measurement accuracy will be affected.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- 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 this equipment could result.
- Use of accessories, transducers other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

**Caution:**

- Security, anti-theft, and radiofrequency identification (RFID) devices. Some electromagnetic anti-theft systems and metal detectors such as those used at entrances or exits of department stores, libraries, and other public places, and airport security screening devices may affect the thermometer. Additionally, RFID devices, which are often used to read identification badges, as well as some tag deactivation devices, such as those used at payment counters at stores and loan desks at libraries, may also affect the thermometer. Please do not use thermometer near these places. If you have to go through one of these devices, turn off your thermometer. Before each usage, checking the status of your thermometer to ensure it can operating normally.
- Using short-wave diathermy, microwave diathermy, or therapeutic ultrasound diathermy (all now referred to as diathermy) and electrocautery devices near this product may cause malfunction or lead to loss of essential performance, please do not use thermometer near these equipment. Before each usage, observing the device to verify that they are operating normally.

<b>Guidance and manufacture's declaration – electromagnetic emissions</b>		
The Infrared thermometer is suitable for use in the specified electromagnetic environment (s) and it has meets the following standard's emission requirements.		
Phenomenon	Profession healthcare facility environment	Home healthcare environment
Radiated RF emissions	CISPR 11, Group 1, Class B	CISPR 11, Group 1, Class B

<b>Guidance and manufacturer's declaration — electromagnetic immunity</b>
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Phenomenon	Basic EMC standard or test method	Professional healthcare facility environment	Home healthcare facility environment
Electrostatic discharge	IEC 61000-4-2	+/- 8 kV contact +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV air	
Radiated RF EM fields	IEC 61000-4-3	3V/m 80MHz-2.7GHz 80%AM at 1kHz or 2Hz	10V/m 80MHz-2.7GHz 80%AM at 1kHz or 2Hz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See the RF wireless communication equipment table in "Recommended minimum separation distances".	
Rated power frequency magnetic fields	IEC 61000-4-8	30A/m; 50 Hz or 60Hz	

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>	Maximum power (W)	Distance (m)	Immunity Test Level (V/m)
385	380-390	TETRA 400	Pulse modulation <sup>b)</sup> 18Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM <sup>c)</sup> ±5kHz deviation 1kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation <sup>b)</sup> 217Hz	0.2	0.3	9
745						
780						
810	800-960	GSM800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation <sup>b)</sup> 18Hz	2	0.3	28
870						
930						
1720	1700-	GSM1800;	Pulse	2	0.3	28

1845	1990	CDMA 1900; GSM 1900; DECT; LTE Band 1,3, 4,25; UMTS	modulation <sup>b)</sup> 217Hz			
1970						
2450	2400- 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation <sup>b)</sup> 217Hz	2	0.3	28
5240	5100- 5800	WLAN 802.11 a/n	Pulse modulation <sup>b)</sup> 217Hz	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.						

**Recommended separation distances between portable and mobile RF communication equipment and thermometer**

The thermometer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the devices can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the thermometer as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter/ W.	Separation distance according to frequency of transmitter/m		
	150kHz ~ 80MHz $d = 1.2\sqrt{P}$	80MHz ~ 800MHz $d = 1.2\sqrt{P}$	800MHz ~ 2.5GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance  $d$  in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where  $P$  is the maximum output power rating of the transmitter in watts(W) according to the transmitter manufacturer.

NOTE 1 At 80MHz and 800MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

## **20.Reporting adverse events**

### **For the users/patients/customer in US**

MedWatch is the Food and Drug Administration's (FDA) program for reporting serious reactions, product quality problems, therapeutic inequivalence/failure, and product use errors with human medical products, including drugs, biologic products, medical devices, dietary supplements, infant formula, and cosmetics.

If you think you or someone in your family has experienced a serious reaction to a medical product, you are encouraged to take the reporting form to your doctor. Your health care provider can provide clinical information based on your medical record that can help FDA evaluate your report.

However, we understand that for a variety of reasons, you may not wish to have the form filled out by your health care provider, or your health care provider may choose not to complete the form. Your health care provider is NOT required to report to the FDA. In these situations, you may complete the Online Reporting Form yourself.

You will receive an acknowledgement from FDA when your report is received. Reports are reviewed by FDA staff. You will be personally contacted only if we need additional information.

### **Submitting Adverse Event Reports to FDA**

Use one of the methods below to submit voluntary adverse event reports to the FDA:

1) **Report**

**Online** at: [www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home](http://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home)

2) **Consumer Reporting Form FDA 3500B**. Follow the instructions on the form to either fax or mail it in for submission. For help filling out the form, see *MedWatchLearn*. The form is available at: [www.fda.gov/downloads/aboutFDA/reportsmanualsforms/forms/ucm349464.pdf](http://www.fda.gov/downloads/aboutFDA/reportsmanualsforms/forms/ucm349464.pdf)

3) **Call FDA at 1-800-FDA-1088** to report by telephone

a) **Reporting Form FDA 3500** commonly used by health professionals. The form is available at: [www.fda.gov/downloads/aboutFDA/reportmanualsforms/forms/ucm163919.pdf](http://www.fda.gov/downloads/aboutFDA/reportmanualsforms/forms/ucm163919.pdf)

### **For the users/patients/customer in EU countries:**

If users/patients/customer think that they or someone in they family has experienced a serious incident that has occurred in relation to the device, users/patients/customer are encouraged to report the incident to the manufacturer and the competent authority of the Member State in which the users/patients/customer is established

## **21. Manufacturer and European Authorized Representative Information**



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