

# **Instruction for Use**

(File No.: IFU-MIET)

Version: 01

## **Mobile Infra-red Ear Thermometer**

Zhejiang Medzone Medical Equipment Co.,Ltd

## 1 Preface

Dear Customers, thank you for purchasing the Mobile Infra-red Ear Thermometer.

This instruction for use describes the characteristics and technical requirements of the device, main structure, performance, specifications, transportation, usage, operation, maintenance and storage methods, safety measures are also included, please see specific chapters.

Please read this instruction for use carefully before you using this device, and follows this instruction. This instruction will tell you how to use the device, operations which may cause to abnormal conditions, risks to causes damages to the device and human body. Any abnormal condition or damages to the device and human body which caused by without following this instruction for use, the company will not assume responsibility for safety, reliability and performance, and will not be free of charge for such failure.

This product is a medical device that can be reused.

Please keep the instruction for use well, and refer it at any time.

## 2 Safety

### 2.1 Safety information

Danger	To remind urge dangers or unsafe operations, if not avoided, may result in death or serious personal injury or property damage.
Warning	To remind potential dangers or unsafe operations, if not avoided, may result in death or serious personal injury or property damage.
Caution	To remind potential dangers or unsafe operations, if not avoided, will lead to minor personal injury, product failure, damage or loss of property.
Attention	To emphasize important attentions, provide a description or explanation to better use this device.

#### 2.1.1 Danger

- ◆ Forbidden to use the Mobile Infra-red Ear Thermometer during charging the mobile phone, preventing from electric shock.

#### 2.1.2 Warnings

- ◆ For patients, it is danger to self-judge and self-treat according to measured results, please follow doctors guidance, self-judge may cause disease deterioration.
- ◆ If you use this product near the microwave oven, TV, X-ray equipment or other strong electromagnetic field, the measuring results may make mistakes; in order to avoid electromagnetic field effect, please stay away from the electrical measurement facilities, or to switch off the appliance before use.
- ◆ The user shall disinfect the probe before using the device to prevent from cross infection.

#### 2.1.3 Cautions

- ◆ Place the device from where children can touch, if the children use the device, may hurt their ears. If carelessly eat the battery or probe protective cover, please contact the doctor immediately.

#### 2.1.4 Attentions

- ◆ Don't touch the infra-red sensor by hand or blow it with mouth. Damaged or dirty infra-red sensor may cause incorrect measure results.
- ◆ When the infra-red sensor is dirty, it is advised to wipe softly with soft dry cloth, using sanitary paper or paper towel to wipe will hurt the infra-red sensor, which will produce incorrect measure results.
- ◆ When the ear temperature is lower than the operation temperature requirement of the device, please warm the ear firstly and then measure. Using the water pillow or water bag and just entering household in winter, the measure value may be lower than real value.
- ◆ Please DO NOT put the probe shield into the ears, and it shall immediately stop to use when feel pain and other abnormal feeling, otherwise, the ear membranes may be hurt.
- ◆ Person who suffers from otitis diseases shall not use the device, otherwise, the affected area may be deteriorated.
- ◆ Please DO NOT use when your ear is wet after such as swimming, bathing, otherwise, the ear hole may be hurt.
- ◆ If the device storage environment is different from use environment, please put the device firstly in the room temperature which is the use environment for 30 minutes, and then use to measure, otherwise, wrong measurement results may be caused.
- ◆ The device is suitable for ear temperature measurement of infants, children and adults.
- ◆ Please get out the battery when not use the device in long time (more than 3 months)
- ◆ Please pay attention to the polarity of the battery, they shall be installed correctly, otherwise it may cause damage to the product.
- ◆ The disposal of the device and its components such as battery, plastic membranes, plastic box and paper box, shall follow local regulations and laws.
- ◆ The shelf life of the device is advised 5 years, once use beyond this period, the measurement result may be inaccurate.

#### 2.2 Symbols instruction

	BF type application part		Serial number
	Recycling according to local laws		Date of manufacture
	See the Instruction		Manufacturer
	Cautions		European union representative
	Standby	IPX0	IP degree

	Temperature range		Avoid sunlight
	Humidity range		Up toward
	Keep dry		

### 3 Product brief

#### 3.1 Product characteristics

The Mobile Infra-red Ear Thermometer has a small size, low power consumption, easy to use and carry. During measurement, insert the hardware into the mobile audio port, and direct the infra-red probe facing the ear canal, the mobile screen will immediately display the measured temperature value, the device has high accuracy and repeatability.

#### 3.2 Scope

The Mobile Infra-red Ear Thermometer is intended to measure the human temperature by measuring the human ear cavity infrared radiation.

#### 3.3 Contraindications

Who has Ear deformity, external otitis, Otitis media, can not use the device.

### 4 Prepare before use

#### 4.1 Structure of the product

The Mobile Infra-red Ear Thermometer consists of the management software and measurement hardware which is composed of the infra-red temperature sensor, the micro controller (MCU), the audio port and the shell.

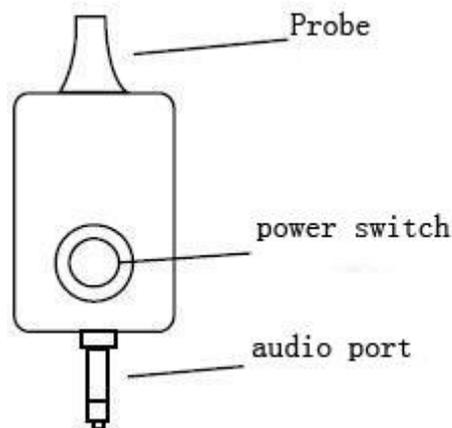


Diagram 1 Measurement hardware structure

#### 4.2 How to install and change the battery

4.2.1 To press the battery cover groove, slip outward and open the battery cover;

4.2.2 To refer the battery cover reed polarity direction, insert into one 3V button battery;

4.2.3 Close the battery cover.

**Warnings:** When the oxygen terminal appears low voltage, please change the battery in time. If it is not used for a long time, remove the battery, so as to avoid battery leakage.

**4.2 Installation and use of the Mobile Infra-red Ear Thermometer management software, see “Rapid use manual of mobile Mobile Infra-red Ear Thermometer”**

## 5 Method of use

5.1 Correctly install the battery and the mobile APP software.

5.2 Press the power switch of the infra-red ear thermometer hardware, the blue power indicator lamp will be light.

5.3 Open the mobile APP software into the measurement interface.

5.4 Insert the hardware into the mobile audio port according to guidance in the software, and then insert the probe into ear canal.

5.5 Click the mobile screen to start measurement, when hear the buzzer sound, the measurement is finished, get out the probe, and the measurement results will be displayed in the mobile screen.

5.6 The infra-red ear thermometer hardware will automatically shutdown in absence of new order.

## 6 Maintenance and repair

6.1 Don't fall or strongly collide the device.

6.2 Avoid high temperature or exposure to the sun!

6.3 When clean the shell or rubber pad, firstly turn off the power, use soft cotton fabric dipped in a little neutral detergent gently wipe the surface, and dry naturally, it is prohibited high temperature baking! It is recommended to clean monthly.

6.4 This product is strictly forbidden water!

6.5 Please take out the battery if long term not to use, so as to avoid battery leakage!

6.6 Do not disassemble the product body!

6.7 It is forbidden to use this product for other purposes!

6.8 The shelf life of the product is 5 years. To ensure the service life of the device, please pay attention to the device's maintenance.

## 7 Troubleshooting

Abnormal phenomenon	Reason of analysis	Troubleshooting
Abnormal measurement values happen	The depth of the probe into the ear was not enough, the membrane temperature was not successful measured.	Adjust the direction and depth of the probe into the ear canal, and then measure again.

	Too low or high environment temperature	Use the device on required environment
	Interference happen or wrong operation	Leave the interference source, use according to IFU
	Earwax is too thick	Clean the ear canal, and measure again.
The software can not connect to the hardware	Orange lamp flashing, Low battery voltage	Change the battery
	The hardware may enter hibernation, or automatic shutdown	Press the power key and reconnect
	Mobile phone bluetooth function does not open	Open the mobile phone bluetooth function
No display after pressing power button	Battery energy is completely consumed, or no battery	Change the battery
Orange lamp flashing after pressing power button	Low battery voltage	Change the battery

## 8 Specifications

Unit	°C	
Temperature range	32.0~42.0°C	
Accuracy	35.0°C~42.0°C	±0.2°C
	35.0°C~42.0°C	±0.3°C
Power	Internal d.c rated value: 3±10% V	
Battery	CR1632 3V button battery	
Work environment	Environment temperature	16°C~35°C
	Relative humidity	≤85%
	Air pressure	70KPa~106KPa
Storage and transport environment	Environment temperature	-5°C~50°C
	Relative humidity	15%~85%RH, Non condensing
	Air pressure	50KPa~107.4 KPa
	No corrosive gas and well ventilated indoor.	

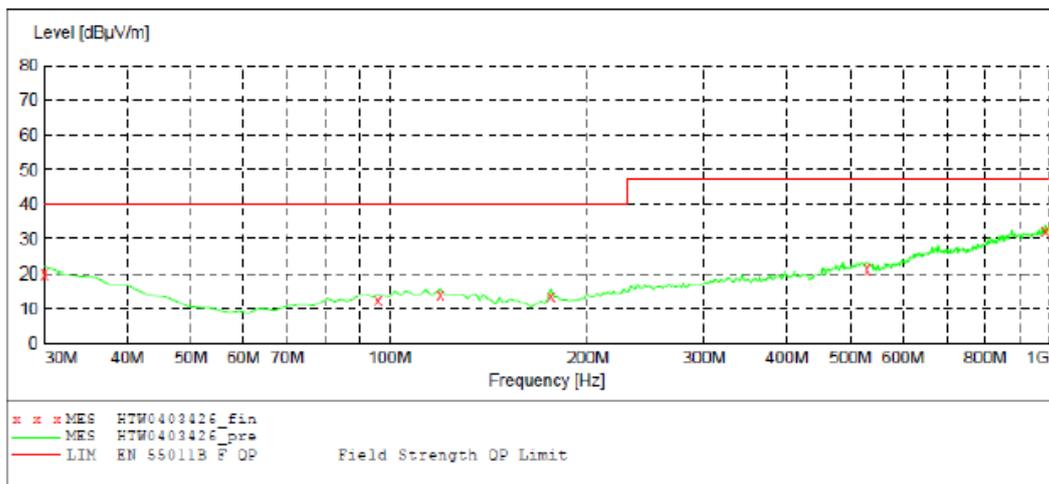
Equipment information	Classification of electric shock type: internal power supply equipment
	Classification of electric shock degree: BF type
	Protection against liquid: IPX0
	Running mode: continuous operation
	Safety classification of using with flammable anesthetic gas or flammable anesthetic gas mixed with oxygen or nitrous oxide: Non AP/APG

## 9 Guidance and manufacturer's declaration-electromagnetic emissions

### 9.1 Emission

Band width: 120kHz; Frequency range: 30MHz to 1000MHz

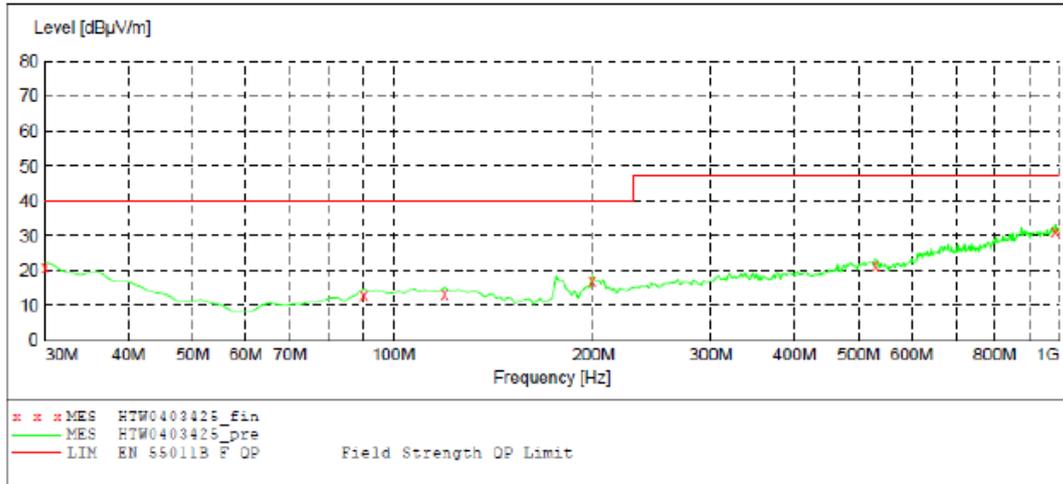
Result: Fulfilled



#### MEASUREMENT RESULT: "HTW0403426\_fin"

4/3/2015 4:59PM

Frequency MHz	Level dBµV/m	Transd dB	Limit dBµV/m	Margin dB	Det.	Height cm	Azimuth deg	Polarization
30.000000	19.90	-10.0	40.0	20.1	QP	100.0	21.00	HORIZONTAL
96.090000	12.50	-18.5	40.0	27.5	QP	300.0	103.00	HORIZONTAL
119.410000	14.00	-17.8	40.0	26.0	QP	100.0	196.00	HORIZONTAL
175.790000	13.90	-21.0	40.0	26.1	QP	100.0	228.00	HORIZONTAL
529.570000	21.40	-11.1	47.0	25.6	QP	100.0	346.00	HORIZONTAL
986.390000	31.90	-3.2	47.0	15.1	QP	300.0	51.00	HORIZONTAL



**MEASUREMENT RESULT: "HTW0403425\_fin"**

4/3/2015 4:51PM

Frequency MHz	Level dBµV/m	Transd dB	Limit dBµV/m	Margin dB	Det.	Height cm	Azimuth deg	Polarization
30.000000	20.80	-10.0	40.0	19.2	QP	100.0	314.00	VERTICAL
90.260000	12.90	-18.8	40.0	27.1	QP	100.0	50.00	VERTICAL
119.410000	13.40	-17.8	40.0	26.6	QP	100.0	196.00	VERTICAL
199.110000	16.90	-19.7	40.0	23.1	QP	100.0	75.00	VERTICAL
529.570000	21.60	-11.1	47.0	25.4	QP	100.0	242.00	VERTICAL
986.390000	31.30	-3.2	47.0	15.7	QP	100.0	293.00	VERTICAL

**9.2 Immunity**

Test frequency: 50Hz, 60Hz; Continuous field: 3 A/m; Test duration: 5m; Antenna factor: 0.917A/m; Axis: X, Y, Z.

Test results: No degradation of function, comply with EN 60601-1-2:2007+AC:2010, ISO 80601-2-56:2009 Clause 202, EN 60601-1-11:2010 Clause 12.