

# Infrared Thermometer User Manual



Manual Ver.: V1.0  
Issuing Date: 10/04/2023

### Revision Record

<b>Document No.</b>	<b>Description</b>	<b>Software REV</b>	<b>Date</b>
<b>FRN-FC-IR109-001</b>	<b>First established</b>	<b>FC-IR109-V1.0</b>	<b>10/04/2023</b>

## **Introduction**

Thank you for purchasing this ear infrared thermometer.

After careful development, accurate, safe, and fast temperature measurement can be achieved Ear temperature.

### **1.1 Indications for Use/Intended Use**

#### 1.1 Intended for purpose

The Infrared Thermometer is intended for the measurement of human body temperatures in the home setting and medical institutes.

#### 1.2 Intended User

Intended User: Both Healthcare Professional and Lay person

Intended Use Environment: Both Hospital/Healthcare Facility and Home

#### 1.3 Indication

The infrared thermometer measures the infrared radiation exchange with the measured ear cavity and the appropriate correction value through the detector, and quickly outputs the body temperature. It is suitable for the use of acutely ill patients, the elderly, infants and young children.

#### 1.4 Contraindications

Do not use the thermometer if the ear is infected with otitis media.

**Please read these instructions carefully before using this product and keep the instructions and the thermometer in a safe place.**

## **Package Contents**

<b>No.</b>	<b>Name</b>	<b>Quantity</b>
1	Infrared Thermometer	1
2	Battery (AA, optional)	2
3	User Manual	1
4	Pouch	1
5	Earmuff	1

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## **1. WARNINGS AND PRECAUTIONS**

- 1) Keep out of reach of children under 12 years.
- 2) Never immerse the thermometer into water or other liquids (not waterproof f).  
For cleaning and disinfecting please follow the instructions in the “Care and cleaning” section.
- 3) Never use the thermometer for purposes other than those it has been intended for.  
Please follow the general safety precautions when using on children.
- 4) Keep the thermometer away from direct exposure to the sun and keep it in a dust- free, dry area, well-ventilated place at a temperature between 50°F (10°

C)-104°F (40°C). Do not use the thermometer in high humidity environment  
s. (> 95% RH)

5) Do not use the thermometer if there are signs of damage on the measuring sensor or on the instrument itself. If damaged, do not attempt to repair the instrument! Please contact dealer.

6) This thermometer consists of high-quality precision parts. Do not drop the instrument.

Protect it from severe impact and shock. Do not twist the instrument or the measuring sensor.

7) Please consult your doctor if you see symptoms such as unexplained irritability, vomiting, diarrhea, dehydration, changes in appetite or activity, seizure, muscle pain, shivering, stiff neck, pain when urinating, etc., even in the absence of fever.

8) Even in the absence of fever, those who exhibit a normal temperature may still need to receive medical attention. People who are on antibiotics, analgesics, or antipyretics should not be assessed solely on temperature readings to determine the severity of their illness.

9) Temperature elevation may signal a serious illness, especially in adults who are

old, frail, have a weakened immune system, or neonates and infants. Please seek

professional advice immediately when there is a temperature elevation and if you

are taking temperature for whom are:

- Over 60 years of age (Fever may be blunted or even absent in elderly patients)

- Having diabetes mellitus or a weakened immune system (e.g., HIV positive, cancer, chemotherapy, chronic steroid treatment, splenectomy)

- Bedridden (e.g., nursing home patient, stroke, chronic illness)

- A transplant patient (e.g., liver, heart, lungs, kidney)

10) This thermometer is not intended for pre-term babies or small-for-gestational age babies. This thermometer is not intended to interpret hypothermic temperatures.

Do not allow children to take their temperatures unattended.

11) Use of this thermometer is not intended as a substitute for consultation with

ith your physician or pediatrician. It is for household use only.

12) Clean the thermometer probe after each use.

13) The age range features is not intended for pre-term babies or small-for-gestational age babies.

14) Do not take a measurement while or immediately after nursing a baby.

15) Patients should not drink, eat or be physically active before/while taking the measurement.

16) The patient is an intended operator.

17) Warning against servicing and maintenance while the equipment is in use

18) No modification is allowed for this equipment.

19) Warning statement that addresses the HAZARDS that can result from unauthorized modification of the equipment.

20) Under no circumstances should you open or repair the device yourself, as

faultless functionality can no longer be guaranteed thereafter. Failure to comply will result in voiding of the warranty.

21) If the device is not used properly, it will cause abnormal operation. The equipment temperature is not accurate.

22)

Statements shall be included in the ACCOMPANYING DOCUMENT of each PROBE, PROBE CABLE EXTENDER and PROBE COVER to the effect that

1) the operator is responsible for checking the compatibility of the thermometer or monitoring equipment, probe, probe cable extender and probe cover before use, and

2) Incompatible components can result in degraded performance.

3) a new PROBE COVER is used for each OUTPUT TEMPERATURE measurement.

## **2. Product Description**

1) Overview

Infrared Thermometer measures the body temperature based on the infrared energy emitted from the Ear. Users can quickly get measurement results after

properly scanning the Ear.

Normal body temperature is a range. The following tables show that this normal

range also varies by site. Therefore, readings from different site should not be directly

compared. Tell your doctor what type of thermometer you used to take your

temperature and on what part of the body. Also bear this in mind if you are diagnosing yourself.

	Measurements
Ear temperature	96.4°F to 100.4°F (35.8°C to 38.0°C)
Oral temperature	95.9°F to 99.5°F (35.5°C to 37.5°C)
Rectal temperature	97.9°F to 100.4°F (36.6°C to 38.0°C)
Axillary temperature	94.5°F to 99.1°F (34.7°C to 37.3°C)

## 2) Structure

The thermometer consists of a shell, an LCD, a measure button, a beeper, an infrared temperature sensor, and a Microprocessor.

## 3) Operating principle

The infrared temperature sensor collects infrared energy emitted by the skin surface.

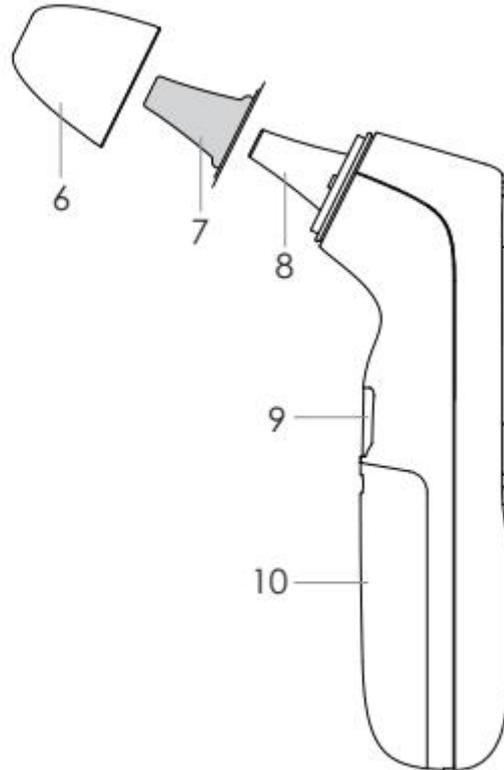
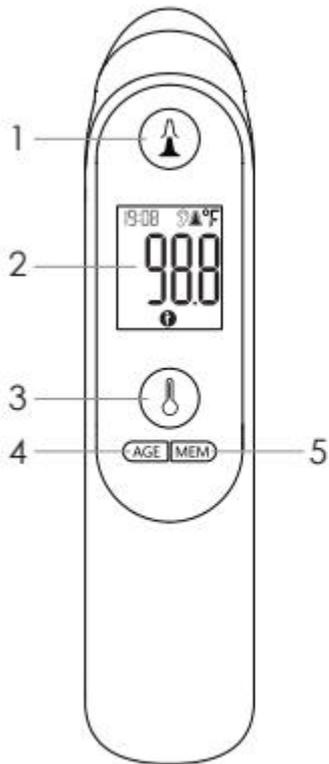
After being focused by a lens, the energy is converted into a temperature reading

by the thermopiles and measurement circuits.

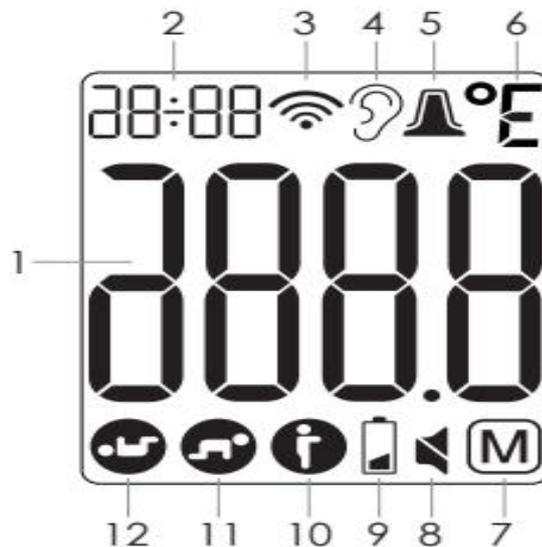
## 3. Features

- Contact design, safe and more hygienic to use.
- Quick measurement, less than 1 second
- Accurate and reliable
- Easy operation, one button design
- Ear temperature measurement
- 30 sets of memories, easy to recall
- Switching between mute and un-mute mode
- Fever alarm function, displayed in orange and red light.
- Switching between °F and °C
- Auto shut-down and power-saving

## 4. Product Structure



1. Push Ear Cover Button
  2. LCD display screen
  3. Measure button
  4. Age Precision
  5. Memory button
  6. Headcap
  7. Earmuffs
  8. Probe
  9. Back label
  10. Battery cover
- [PROBE COVER must be used](#)  
[Model: EY101](#)



- 5. Display description**
1. Temperature value
  2. Time display
  3. Wireless icon
  4. Ear temperature mode
  5. Earmuff
  6. Fahrenheit / Celsius degrees
  7. Memory mode
  8. Mute/Un-mute icon
  9. Battery level
  10. Adult mode

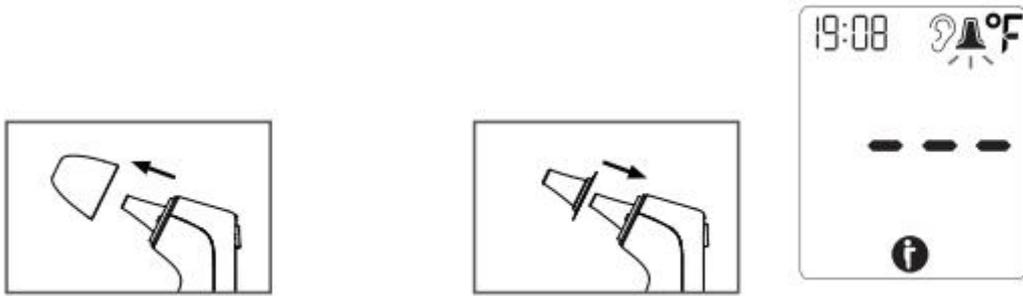
11. Baby mode
12. Neonate mode

## 6. How to use your thermometer

When using the thermometer for the first time, please insert the batteries.

### 1) Correctly wear earbuds

First remove the hood, then put the earbuds in.



Note: If you do not wear earbuds properly, you cannot measure the temperature properly.

### 2) Age mode transition

When turned on, press AGE to select the measurement mode

#### a. Neonate Mode(0-3 months baby)

When the thermometer is turned on or power off, toggle Mode button to Neonate

mode icon “

#### b. Baby Mode(3-36 months baby)

When the thermometer is turned on or power off, toggle Mode button to Baby mode

icon “

#### c. Adult Mode(over 36+ months age)

When the thermometer is turned on or power off, toggle Mode button to Adult mode

icon “

### 3) Time setting

In the power on state, press the Mem key for 3 seconds and release the button when the minute bit flashes. Press the Mem switch to switch between the minute bit and the minute bit, and press the AGE key to set the time.

Press the measurement key or exit the time setting mode without

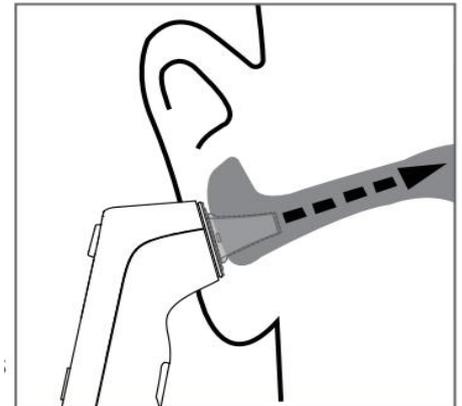


any operation for 6 seconds after the time setting is completed.

#### 4) Measure the temperature of your ears

Hold the thermometer within fit the probe snugly into the ear canal, then push and release the start

button  .



NOTE: The **Ear** measurement is an indicative reading. The measured **Ear** temperature can fluctuate up to 1 °F/0.5 °C from your actual body temperature. Please be aware of the factors that influence the accuracy as described in the

section “Temperature taking tips” and “WARNINGS AND PRECAUTIONS” .

NS” .

 Always clean the Probe tip before use.

 Always make sure the user and the thermometer will have been in the same room for at least 30 minutes prior to the measurement.

#### 5) Take room/object temperature

When the thermometer is turned off, press and hold the "Mem" button for 3 seconds until it displays.

Then press the "Measure" button to measure. Retain the thermometer is approximately 0.4 to 1.2 inches (1-3 centimeters) above the ground Object. Press and release the 'Measure' button within 1 second You can now read the value after hearing the beep sound.



#### 6) After the measurement

Once the reading has been completed, remove the thermometer away from the **Ear** and observe temperature.

After each measurement, you can enter the recall mode and query earlier temperature readings.

Do not hold the thermometer for a long time, because it is sensitive to the ambient temperature.

 After each measurement, clean the temperature probe with a soft cloth

h, and put the thermometer in a dry and well-ventilated place.

⚠ You should wait at least 10 seconds between each measurement.

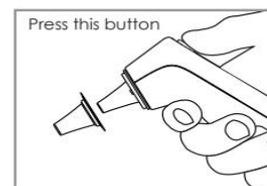
⚠ It is dangerous to make a self-diagnosis or self-treatment based on the obtained measurement results. For such purposes, please consult a doctor.

### 7) Read your temperature

The confirmation beep indicates that an accurate temperature measurement has been taken, T indicates a temperature reading.

Age range	Green Light Normal temperature	Orange Light Elevated temperature	Red Light High Temperature
0-3 Months	89.6°F ≦ T ≦ 99.4°F (32.0°C ≦ T ≦ 37.4°C)	<del>XXXXXXXXXX</del>	99.5°F ≦ T ≦ 109.2°F (37.5°C ≦ T ≦ 42.9°C)
3-36 Months	89.6°F ≦ T ≦ 99.7°F (32.0°C ≦ T ≦ 37.6°C)	99.9°F ≦ T ≦ 101.3°F (37.7°C ≦ T ≦ 38.5°C)	101.5°F ≦ T ≦ 109.2°F (38.6°C ≦ T ≦ 42.9°C)
36+ Months	89.6°F ≦ T ≦ 99.9°F (32.0°C ≦ T ≦ 37.7°C)	100.0°F ≦ T ≦ 103.0°F (37.8°C ≦ T ≦ 39.4°C)	103.1°F ≦ T ≦ 109.2°F (39.5°C ≦ T ≦ 42.9°C)

Note: In the next measurement, press the push ear cover button remove and discard the used filter, and then replace it with a new, clean filter.



### 8) Switching between mute and un-mute

When the thermometer is turned on, press the AGE button for 3 seconds to turn the sound on or off.

### 7) Check 30 sets of memory data

When the thermometer is turned on by short press the “ Mem ” button to go to the memory mode, press this button again will display the memory number , wait 0.5 seconds will display the earmuff , age precision、 measurement time and temperature.

Press the “ Mem ” button again can query the 30 sets of memories one by one. If no value, it will display “ ---M ” .

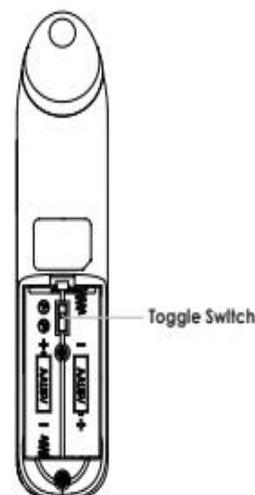


### 8) °F/°C conversion

Open the battery cover, use the toggle switch to change the °F/°C

### 9) To turn off

The unit will shut down automatically after “20 ± 1 seconds” with using. Keep pressing the Measure button for 6 seconds, it will shut down.



 Caution

1. All memory records will be lost when you uninstall or reinstall the batteries.
2. All settings will come to default when you uninstall the batteries. If you need to adjust the settings, please turn on the device and make the new settings.

10) Replace the battery.

Press the battery button on the back bottom of the thermometer to open the battery compartment. Put two AA batteries correctly into the compartment.

 Remove the batteries, if the thermometer will not be used for more than two months.

Disposal:

- For environmental reasons, do not dispose of the device in the household waste at the end of its useful life. Dispose of the unit at a suitable local collection or recycling point.

- Observe the local regulations for material disposal.

- Please dispose of the device in accordance with EC Directive – WEEE (Waste

Electrical and Electronic Equipment). If you have any questions, please contact the

local authorities responsible for waste disposal.

- Batteries must not be disposed of with household waste. As a consumer, you are required by law to re-cycle used batteries. You can re-cycle your old batteries at public collection points in your community or wherever batteries of the relevant type are sold.

- The codes below are printed on batteries containing harmful substances:

Pb = Battery contains lead, Cd = Battery contains cadmium, Hg = Battery contains

Mercury. The batteries in this device do not contain any pollutants.

## 7. Temperature taking tips

1) It is important to know each individual's normal temperature when they are well.

This is the only way to accurately diagnose a fever. Record readings twice a day (early morning and late afternoon). Take the average of the two temperatures to calculate normal equivalent temperature. Always take the temperature in the same location, since the temperature readings may vary from different locations on

the Ear.

2) A child's normal temperature can be as high as 99.9 ° F (37.7°C) or as low as 89.6 ° F (32.0°C). Please note that this unit reads 0.9 ° F (0.5°C) lower than a rectal digital thermometer.

3) Holding the thermometer for too long in the hand before taking a measurement

can cause the device to warm up. This means the measurement could be incorrect.

4) Patients and the thermometer should stay in steady-state room condition for at least

30 minutes.

5) Before placing the thermometer sensor onto the Ear, remove dirt, hair, or sweat from the Ear area. Wait 10 minutes after cleaning before taking measurement.

6) Use an alcohol swab to carefully clean the sensor and wait for 5 minutes before

taking a measurement on another patient. Wiping the Ear with a warm or cool cloth may impact your reading. It is advised to wait 10 minutes before taking a reading.

7) In the following situations it is recommended that 3-5 temperatures in the same

location be taken and the highest one taken as the reading:

- Newborn infants in the first 100 days.
- Children under three years of age with a compromised immune system and for whom the presence or absence of fever is critical.
- When the user is learning how to use the thermometer for the first time until he/she has familiarized himself/herself with the instrument and obtains consistent readings.

## 8. Care and cleaning

1) Cleaning and user maintenance must not be performed by children unless supervised.

2) Cleaning the device use an alcohol swab or cotton swab moistened with 95% alcohol to clean the thermometer case and the measuring probe.

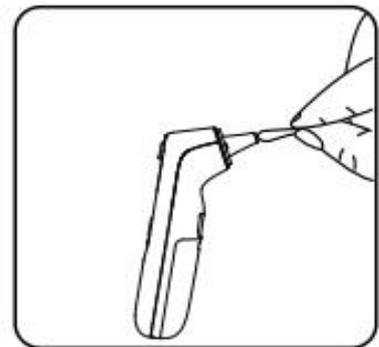
3) After the alcohol has completely dried out, you can take a new measurement (minimum of 10 minutes).

4) Ensure that no liquid enters the interior of the thermometer.

5) Never use abrasive cleaning agents, thinners or benzene cleaning and never immerse the instrument in water or other cleaning liquids.

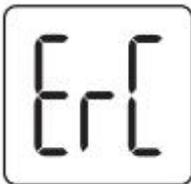
6) Take care not to scratch the surface of the LCD screen.

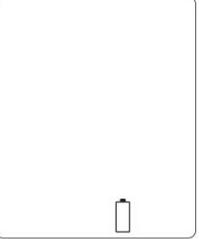
7) Remove the batteries from the device before cleaning.



- 8) Clean the device after use with a soft, slightly damp cloth. If they are very dirty, you can also moisten the cloth with a mild soapy solution.
- 9) Ensure that no water enters the device. If this happens, only use the device again once it has fully dried out.

## 9. Error and Troubleshooting

Symptom	Possible Cause	Description & Solution
Failed to power on.	The battery level is too low.	Replace with a new battery
	Polarities of the batteries are reversed.	Ensure the batteries are in the right position.
	The thermometer is damaged.	Contact dealer.
The reading is too low	The lens of the probe is dirty.	Clean the lens with a cotton swab.
	The distance of the item and target is too far.	Keep the thermometer in contact with Ear.
	You have just come from a cold environment.	Stay in a warmer room for at least 30 minutes before taking a reading.
The reading is too high	You have just come from a hot environment.	Stay in an adequately cool room for at least 30 minutes before taking a reading.
	The ambient temperature is not in range.	3 short beeps and red indicator light 3 seconds. Take a measurement under an ambient temperature between 50.0 ° F (10 ° C ) and 104 ° F (40 ° C).
	Memory Error	3 short beeps and red indicator light for 3 seconds. Contact dealer.

	In <b>Ear</b> mode, T > 109.2 ° F (42.9 ° C)	3 short beeps and red in dicator light for 3 second s.
	In <b>Ear</b> mode, T < 89.6°F (32°C)	3 short beeps and red in dicator light for 3 second s.
	$2.6V \pm 3\% \leq \text{power voltage}$ $< 2.7V \pm 3\%$	The battery level is low, it suggests you to replace thebattery, but you can c ontinue to use it.
	The power voltage is lower than $2.5V \pm 3\%$ .	It will turn off automaticall yafter 10 seconds. Please replace with a new batte ry.

#### 10. Specifications:

Product name	Infrared thermometer
Power supply	DC1.5V × 2
Measurement range	32.0°C-42.9°C (89.6 ° F-109.2 ° F)
Accuracy (Laboratory)	95 ° F-102.2 ° F (35°C-39°C) ± 0.4 ° F/± 0.2 ° C Outside this range: ± 0.5 ° F/± 0.3 ° C
Display resolution	0.1 ° F/0.1 ° C
Measuring distance	0 -1.2 inches (0-3cm)
Automatic shutdown	10s ± 1s
Memory	30 groups of measured temperature.
Battery	2*AA, can be used for more than 3000 times
Weight & Dimension	76.5g (without battery),35*156*67mm
Operating conditions	Operating environment: 50 ° F-104 ° F (10°C-40 ° C), ≤85%RH Relative Humidity: ≤85% moisture condensati

	on Atmospheric pressure: 70 - 106kPa
Storage	Temperature: -4 ° F-131 ° F (-20°C~55°C) Relative Humidity: ≤95% moisture condensati on Atmospheric pressure: 70 - 106kPa
Device Life	5 Years

## 11. Symbols:

### SYMBOLS USED IN THIS INSTRUCTION MANUAL



Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.



Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property.



Please read this instruction manual thoroughly before using the unit.

Please keep for future reference.

For specific information about your own blood pressure, CONSULT YOUR DOCTOR.



Transport package shall be kept away from rain.



Keep away from sunlight.



Fragile, handle with care.



AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY



Refer to instruction manual/booklet



Unique device identifier



MANUFACTURER



Date of manufacture



Made in China



SERIAL NUMBER



Model number



Medical device

 Type BF applied part	 Importer	 CE mark
 The marking of electrical and electronics devices according to Directive 2002/96/EC. The device accessories and the packaging have to be disposed of waste correctly at the end of the usage. Please follow Local Ordinances or Regulations for disposal.		
 Device used within the Magnetic Resonance (MR) environment is prohibited.		
IP22	2 Protected against solid foreign objects of 12,5 mm Ø and greater; 2 If keep the thermometer in 15 degree angle, it still can prevent the water drop.	
LOT	Batch number	

## 12. EMC information

**IEC 60601-1-2:** 2014 ME EQUIPMENT and ME SYSTEMS identification, marking and documents for Class B product The ME EQUIPMENT or M E SYSTEM is suitable for home healthcare environments and so on.

**Warning:** Don't use device near HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

**Warning:** Use of this equipment adjacent to or stacked with other equipments 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.

**Warning:** Use of accessories, transducers and cables 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.

**Warning:** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used not closer than 30 cm (12 inches) to any part of the Infra-red Thermometer (FC-IR109), including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

**If any:** A list of all cables and maximum lengths of cables (if applicable),

transducers and other ACCESSORIES that are replaceable by the RESPONSIBLE ORGANIZATION and that are likely to affect compliance of the ME EQUIPMENT or ME SYSTEM with the requirements of Clause 7 (EMISSIONS) and Clause 8 (IMMUNITY). ACCESSORIES may be specified either generically (e.g. shielded cable, load impedance) or specifically (e.g. by MANUFACTURER and EQUIPMENT OR TYPE REFERENCE).

**If any:** The performance of the ME EQUIPMENT or ME SYSTEM that was determined to be ESSENTIAL PERFORMANCE and a description of what the OPERATOR can expect if the ESSENTIAL PERFORMANCE is lost or degraded due to EM DISTURBANCES (the defined term “ESSENTIAL PERFORMANCE” need not be used).

**Technical description:**

1. All necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the expected service life.
2. Guidance and manufacturer’s declaration -electromagnetic emissions and Immunity.

Table 1

Guidance and manufacturer’s declaration - electromagnetic emissions	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	N/A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A

Table 2

Guidance and manufacturer’s declaration - electromagnetic Immunity		
Immunity Test	IEC 60601-1-2 Test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 1	± 8 kV contact ± 2 kV,

	5 kVair	$\pm 4$ kV, $\pm 8$ kV, $\pm 15$ kVair
Electrical fast transient/ Burst IEC 61000-4-4	Power supply lines: $\pm 2$ kV input/output lines: $\pm 1$ kV 100 kHz repetition frequency	N/A
Surge IEC 61000-4-5	line(s) to line(s): $\pm 1$ kV. line(s) to earth: $\pm 2$ kV.	N/A
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% 0.5 cycle At $0^\circ$ , $45^\circ$ , $90^\circ$ , $135^\circ$ , $180^\circ$ , $225^\circ$ , $270^\circ$ and 315° 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 0% 250 cycle	N/A
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conducted RF IEC61000-4-6	150KHz to 80MHz: 3Vrms 6Vrms (in ISM and amateur radio bands) 80% Am at 1kHz	N/A
Radiated RF IEC61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
NOTE UT is the a.c. mains voltage prior to application of the test level.		

Table 3

Guidance and manufacturer' s declaration - electromagnetic Immunity							
Radiated RF	Test Frequency (MHz)	Band (MHz)	Service	Modulation	Modulation (W)	Distance (m)	IMMUNITY TEST LEVEL

IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	Hz)						EL (V/m)
	385	380 – 390	TETRA 400	Pulse modulation 18 Hz	1,8	0.3	27
	450	430 – 470	GMRS 460, FRS 460	FM ± 5 kHz Deviation 1 kHz sine	2	0.3	28
	710	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0.3	9
	745						
	780						
	810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	0,2	0.3	28
	870						
	930						
	1720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
	1845						
1970							
2450	2 400 – 2 570	Bluetooth, WLAN, 802.11	Pulse modulation 217 Hz	2	0.3	28	

			b/g/n, RFID 2450, LTE Ba nd 7				
	5240	5 100	WLAN	Pulse	0.2	0.3	9
	5500	–	802.11	modula			
	5785	5 800	a/n	tion 217 Hz			

### 13. Warranty and After-Sale Service

The device is under warranty for 12 months from the date of purchase. The batteries, packing and any damage caused by improper use are not covered by the warranty.

Excluding the following user-caused failures:

- 1.Failure resulting from unauthorized disassembly and modification.
- 2.Failure resulting from an unexpected dropping during application or transportation.
- 3.Failure resulting from not following the instructions in the operating manual.

Product Name: Infrared Thermometer

Model: FC-IR109

U.S. Agent:

CTI U.S. Inc.

Suite 230,1455 Cti U.S. Inc.

Lincoln Parkway, Atlanta, Ga, 30346



RIOMAVIX S.L.

Calle de Almansa 55, 1D, Madrid,

28039 Spain

Manufacturer:



Shenzhen Finicare Co., Ltd.

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