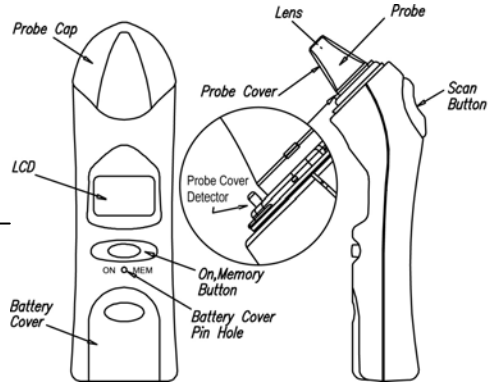
TH809 Ear-Type Thermometer



Thank you for purchasing the thermometer. This thermometer is designed with an advanced infrared and ambient temperature compensation technology for instantaneous self-diagnosis and accurate temperature measurements. Do not use this device for Live & Dead decision or Safety related applications. Please consult with doctor if you have health concerns.

Operating Instructions:

1. Gently squeeze the opposite ends of the thermometer to pull off the probe cap. Do not use force to remove the cap.
2. Always use a new and undamaged probe cover. Make sure the ear canal is clean.
3. **Install Probe Cover**
   1) Place a new probe cover on the connection ring. (*See Figure 1*)
      NOTE **：** Make sure to place the "**Adhesive Side**" of probe cover "**Upward.**"
   2) Align the probe with the center of probe cover. Insert the probe into the probe cover on the connection ring. (*See Figure 2*)
   3) Push the connection ring until the "Click" sound. This means the probe cover has been installed successfully.
      NOTE **：** If the probe cover did not connect firmly, the "▷" icon will flash on the LCD screen. Please check the setting of the probe cover again.

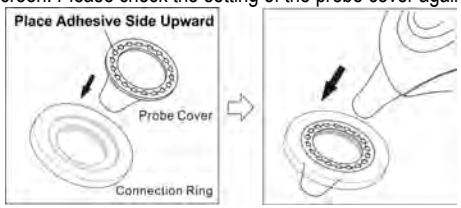


Figure 1 Figure 2

⚠ **Proper installation of the probe cover ensures accurate measurements.**

⚠ **Warning：Keep the probe covers and connection ring away from children.**

4. Press "ON/MEM" button to power on. The thermometer is ready for use after the ear icon stop flashing and two short beep sound.
5. Gently pull the ear back to straighten the ear canal and snugly position the probe into the ear canal, aiming towards the membrane of the eardrum to obtain an accurate reading. (Fig.4-1)
6. Measuring the ear temperature：Use the index finger to trigger. Press the "Scan" button until you hear a long beep. (Fig.4-2).

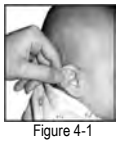


Figure 4-1

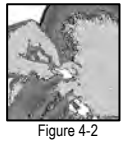


Figure 4-2

7. Power off：This device will automatically shut down after 1 minute pending to extend battery life.

NOTE **：**

a. Before the measurement, please stay in a stable environment for 5mins and avoid the exercise, bath for 30mins.

b. It is recommended that you measure 3 times with the same ear. If the 3 measurements are different, select the highest temperature.

c. To avoid the risk of cross contamination, please clean the probe according to "Cleaning and Storage" section after each use.

d. Clinical repeatability: 0.20°C (＜1 year old), 0.14°C (1~5 years old), 0.14°C (＞5 years old)

Fever Alarm:

If the thermometer detects a body temperature ≧37.5°C (or 99.5°F), three short beep sound will follow one long beep sound to warn the user for potential fever.

Switching between Fahrenheit(°F) and Celsius(°C):

In "***Power Off***" mode, press and hold the "SCAN" button, then press the "ON/MEM" button for 3 seconds, icon "**°C**" will be switched to icon "**°F**". You can also use the same process to change the LCD display from **°F** to **°C**.

Memory Function:

The reading of the thermometer is within normal temperature range between 34°C to 42.2 °C (93.2 °F to 108.0°F). After each measurement, the reading is saved into memory. Press the "ON/MEM" button again to see the temperature stored. The thermometer provides 9 sets memory for the measurements.

***** Replace the probe cover after each use to ensure an accurate reading and avoid cross contamination.***

Cleaning and Storage:

The probe is the most delicate part of the thermometer.

Use with care when cleaning the lens to avoid damage.

Storage temperature Range: It should be stored at room temperature between -20~+50°C, RH≦85%

Keep the unit dry and away from any liquids and direct sunlight.

The Probe should not submerge into any liquids.

**** If device is accidentally used without probe cover, clean the probe as follows:**

a. Please use the cotton swab with Alcohol (70% concentration) to clean the lens(on the inside of the probe).
b. Allow the probe to fully dry for at least 1 minute.

NOTE **：** Please check the device if damaged once it falls. If you can't make sure of it, please send the complete device to the nearest retailer for recalibration.

⚠ Holding the thermometer too long may cause a higher ambient temperature reading of the probe. This could make the body temperature measurement lower than usual.

Changing the Battery:

This device is supplied with one lithium cell (CR2032 x 1).

①Open the battery cover: Insert a pointed object into the battery cover pick hole. At the same time, use thumb to remove battery cover. (See Figure 1) ②Flip the battery out with a small screw driver (See Figure 2) ③ Insert the new battery under the metal hook on the left side and press the right side of the battery down until you hear a "click". (See Figure 3) ④Replace the battery cover

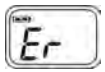
⚠ The positive (+) side **Up** and the negative (-) side pointed **Down**.

Figure 1 Figure 2 Figure 3

Specifications:

☑ Temperature measurement range: 34~42.2°C (93.2~108°F)
☑ Operating temperature range: 10~40°C (50~104°F)
☑ Storage temperature Range: It should be stored at room temperature between -20~+50°C , RH≦85%
Transportation temperature shall be less than 70°C, RH≦95%
☑ Comply with ASTM E1965-98, EN12470-5:2003 Clinical thermometers-Part 5:Performance of infra-red ear thermometers(with maximum device),IEC/EN60601-1-2(EMC),IEC/EN60601-1(Safety) standards.
☑ Accuracy:+/-0.2 °C (0.4 °F) within 35.5~42°C (95.9~107.6°F), +/-0.3 °C (0.5 °F) for other range.
☑ This thermometer converts the ear temperature to display its "oral equivalent." (according to the result of the clinical evaluation)
⚠ There is no gender and age limitation for using infrared thermometer.
⚠ This is not an AP or APG product.

Troubleshooting:

Error Message	Problem	Solution
	Device stabilization is in process.	Wait until stops flashing.
	Battery is low and no more measurements are possible.	Replace the battery.
	Measurement before device stabilization.	Wait until stops flashing.
	The device shows a rapid ambient temperature change.	Allow the thermometer to rest in a room for at least 30 minutes at room temperature: 10 °C and 40 °C (50 °F ~104 °F).
	The ambient temperature is not within the normal temperature range between 10 °C and 40 °C (50 °F ~104 °F).	Allow the thermometer to rest in a room at least 30 minutes at room temperature: 10 °C and 40 °C (50 °F ~104 °F).
	Error 5~9, the system is not functioning properly.	Unload the battery, wait for 1 minute and repower it. If the message reappears, contact the retailer for service.
	Temperature taken is higher than 42.2 °C (108.0 °F).	Check the integrity of the probe cover and take a new temperature measurement.
	Temperature taken is lower than 34 °C (93.2 °F).	Make sure the probe cover is clean and take a new temperature measurement.
	Device can not be powered on to the ready stage.	Change with a new battery.

Warranty :12 months

Manufacture Date ： as the serial number(please open the battery cover, it is shown on the inside of the device.)

Ex.SN:E912A000001, the first “E” is External, the second number “9” is the manufacture year 2009, the third and the fourth number “12” is the manufacture month, the others is the serial number.

Note: The thermometer is calibrated at the time of manufacture. If at any time you question the accuracy of temperature measurements, please contact the dealers or nearest service address.

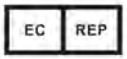
Please read the instructions for use **BF type applied part**

EC REP Medical Technology Promedt Consulting GmbH
Add: Altenhofstrasse 80, D-66386 St. Ingbert, Germany

0120

Radiant Innovation Inc.
Tel: +886 (3) 5644185 Fax: +886 (3) 5644170
E-mail: MKT@radiantek.com.tw Http://www.radiantek.com.tw
Add: 1F, No.3, Industrial East 9th Road, Science-Based Industrial Park, HsinChu, Taiwan 300.

Ref No. ： 082012

Symbol Descriptions					
CE 0120	The CE mark and Notified Body Registration Numbers, the requirement of Annex II from Medical Device Directive 93/42/EEC are met.		Indicates this device is subject to the Waste Electrical and Electronic Equipment Directive in the European Union. To protect the environment, dispose of useless device at appropriate collection sites according to national or local regulations.		Do not reuse
	Caution		Please read the instructions for use		Paper Recycling
	Manufacturer		BF type applied part		Battery Recycling
	Authorized representative in the European community				

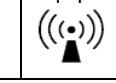
Guidance and manufacturer's declaration – electromagnetic emissions

The TH8xyz series is intended for use in the electromagnetic environment specified below. The customer or the user of the TH8xyz series should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The TH8xyz series 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.
RF emissions CISPR 11	Class B	The TH8xyz series 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.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity

The TH8xyz series is intended for use in the electromagnetic environment specified below. The customer or the user of the TH8xyz series should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not applicable	Portable and mobile RF communications equipment should be used no closer to any part of the TH8xyz series, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1{,}2\sqrt{P}$ $d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range b. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	

NOTE 1 At 80 MHz and 800 MHz, 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.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the TH8xyz series is used exceeds the applicable RF compliance level above, the TH8xyz series should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the TH8xyz series.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Guidance and manufacturer's declaration – electromagnetic immunity			
The TH8xyz series is intended for use in the electromagnetic environment specified below. The customer or the user of the TH8xyz series should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	**6 kV contact 8 kV air**	**6 kV contact 8 kV air**	**Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.**
Electrical fast transient/burst IEC 61000-4-4	2 kV for power supply lines 1 kV for input/output lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	1 kV line(s) to line(s) 2 kV line(s) to earth	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the TH8xyz series requires continued operation during power mains interruptions, it is recommended that the TH8xyz series be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Recommended separation distances between portable and mobile RF communications equipment and the ME EQUIPMENT or ME SYSTEM			
The TH8xyz series is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the TH8xyz series can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the TH8xyz series 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		
	150 kHz to 80 MHz $d = 1{,}2\ \sqrt{P}$	**80 MHz to 800 MHz** $d = 1{,}2\ \sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2{,}3\ \sqrt{P}$
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 80 MHz and 800 MHz, 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.			