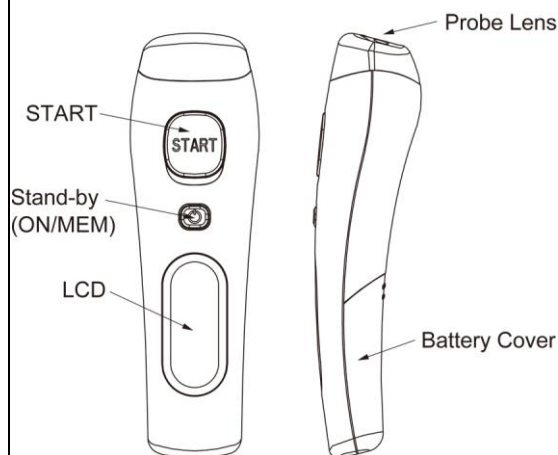


# THD2F(E) Non-contact Forehead Thermometer

**Intended use:** The infrared forehead thermometer can measure the infrared heat generated by central forehead and surrounding tissues to reflect patient's body temperature accurately.

**Intended operator:** At least 11 years old (5 years intensive reading experience), no maximum.

Specifications
<ul style="list-style-type: none"> <li>☑ Temperature measurement range: Forehead mode: 34~42.2°C (93.2~108°F) Surface mode: -22~80°C (-7.6~176°F)</li> <li>☑ Operating temperature range: 10~40°C (50~104°F), 15%~85% RH</li> <li>☑ 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%</li> <li>☑ Atmospheric pressure: 800~1013 hPa</li> <li>☑ Comply with ASTM E1965-98, EN ISO 80601-2-56, IEC/EN60601-1-2(EMC), IEC/EN60601-1(Safety) standards, ISO10993, RoHS.</li> <li>☑ Accuracy: Forehead mode: ±0.2°C (0.4 °F) within 35~42°C (95~107.6°F)(Ambient Temp: 15~35°C), ±0.3°C (0.5 °F) for other range. Surface mode: ±0.3°C (0.5°F) within 22~42.2°C (71.6~108°F), others ±4% or ±2°C (4°F) whichever is greater.</li> <li>☑ Fever indication, memory and °C/°F switch function</li> <li>☑ Battery: AAA x 2 pcs</li> <li>☑ Battery life: around 3,000 continuous readings.</li> <li>☑ Expected Service Life: 4 years</li> <li>☑ This thermometer converts the forehead temperature to display its "oral equivalent." (according to the result of the clinical evaluation to get the offset value)</li> <li>☑ E: Blue LED Backlight (optional) Blue LED Backlight will be automatically turned on after measurement, and automatically turned off after 5 seconds.</li> <li>☑ Enclosure Rating: IP22</li> <li>☑ Dimensions: 158.0 x 48.0 x 40.2 mm</li> <li>☑ Weight: 100 grams including battery</li> <li>⚠ The device should not submerge into any liquids and expose it to direct moisture.</li> <li>⚠ There is no gender and age limitation for using the infrared thermometer.</li> <li>⚠ This is not an AP or APG product.</li> </ul>



Functions		
<b>Forehead temperature</b>	The thermometer has been designed for practical use. It's not meant to replace a visit to the doctor. Please also remember to compare the measurement result to your regular body temperature. Please consult with doctor if you have health concerns. → Please see the "Use of the thermometer" section to learn how to measure the body temperature.	
<b>Surface temperature</b>	The surface mode shows the actual and unadjusted surface temperature which is different from the body temperature. It can help you monitor if the object temperature is suitable for the baby or patient, for example the baby's milk. → Please see the "Use of the thermometer" section to learn how to measure the object temperature.	
<b>Fever indication</b>	If the thermometer detects a temperature ≥ 37.5°C (or 99.5°F) under forehead mode, three short beep sound will follow one long beep sound to warn the user for potential fever.	
<b>Memory locations</b>	There are total 25 sets of measurement condition for body temperature. → When power on, press the "ON/MEM" button to see the temperature records with  icon.	
<b>°C / °F switch</b>	In "Power Off" mode, press and hold the "START" 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. <b>NOTE:</b> Memory clear and Celsius/Fahrenheit switch are together. When you switch Celsius and Fahrenheit, the Memory will be cleared.	
<b>Mute mode</b>	The device setting with buzzer is on, you can set buzzer on/off under Mute mode. When power on, press and hold the "ON/MEM" button for 3 seconds. The icon  will flash on the LCD screen and then release the "ON/MEM" button to set MUTE. Thus you will not hear beep sounds. You can also use the same process to turn off the Mute function. <b>NOTE:</b> If keep pressing "ON/MEM" button for 5 seconds after  icon flashing, the device will be power off WITHOUT setting Mute.	

## Use of the thermometer

**Note:** The device must stay in stable ambient (room) temperature for 15 minutes before operating.

1. Always make sure the probe lens is clean without any damage and the forehead is clean.

⚠ **Warning:** Choking from swallowing small parts and batteries by children or pets is possible, please keep small parts and batteries at places where children and pets can't reach.

2. Power on:

Press the "ON/MEM" button (see figure 1).

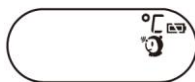


Figure 1

### 3. Measuring body temperature on the forehead:



Press the "ON/MEM" button to power on the device. **Forehead mode is the default mode.** You can see the  icon on the screen and hear two beep sounds (see figure 1). In this mode, you can hold the thermometer within 4 cm from the central forehead (Fig. 2) and press the "START" button to get the forehead measurement. The time consuming for measurement might be 1 second. After each forehead measurement, wait  icon stop flashing to be ready for next measurement.




Figure 2

#### ⚠ Points for attention:

- Forehead temperature is displayed in oral mode. This mode converts the forehead temperature to display its "oral-equivalent" value.
- Before the measurement, please stay in a stable environment for 5 minutes and avoid exercise, bath for 30mins.
- Remember to keep the forehead area clean and away from sweat, cosmetics and scar while taking temperature.
- The "Clinical Bias" is -1.4~-1.7°C.
- The "Limits of Agreement" is 0.98.
- The "Repeatability" is 0.20°C.

### 4. Measuring surface temperature:

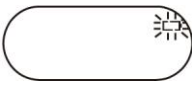



- After power on, press and hold the "ON/MEM" button, and press the "START" button one time for "Infrared thermometer" mode to see  icon on your LCD display. In this mode, you can get the target surface temperature.
- When you press the "START" button, you will get the real time temperature immediately. If you press and hold the "START" button, the reading of measurement will be continuously updated.
- Applications include temperature measurements for water, milk, cloth, skin or other objects.

**\* Note: This mode shows the actual and unadjusted surface temperature which is different from the body temperature.**







### 5. Power off:

- Device will automatically shut off if left idle for more than 1 minute to extend battery life.
- Manually power off the device by pressing the "ON/MEM" button.

### Important Notes

<p>Cleaning And Storage</p>	<p><b>Please make sure the probe is clean to ensure an accurate reading.</b></p> <p>⚠ The probe lens is the most delicate part of the thermometer. Use with care when cleaning the probe lens to avoid damage.</p> <ol style="list-style-type: none"> <li>Use the 70% alcohol swab or the soft cotton moistened with the 70% alcohol to clean the probe lens.</li> <li>Allow the probe to fully dry for at least 1 minute.</li> <li>Keep the unit dry and away from any liquids and direct sunlight.</li> <li>Storage temperature range: It should be stored at room temperature between -20~+50°C, RH ≤ 85%</li> <li>The Probe should not be submerged into liquids.</li> </ol> <p>⚠ 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.</p>
<p>Battery replacement</p> 	<p>When the "Low Battery" icon indicates the battery is low, the battery should be replaced immediately with AAA *2 pcs batteries.</p> <ol style="list-style-type: none"> <li>Open the battery cover: Use the thumbs to push battery cover out. (See Figure 1)</li> <li>Insert the new AAA *2 pcs batteries. (See Figure 2)</li> <li>Replace the battery cover. (See Figure 3)</li> </ol>   

### Trouble shooting:

Error Message	Problem	Solution
	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.
	Measurement before device stabilization.	Wait until all the icons stop flashing.
	The ambient temperature is not within the range between 10°C and 40°C (50°F ~104°F).	Allow the thermometer to rest in a room for at least 15 minutes at room temperature: 10°C and 40°C (50°F ~104°F).
	(1) In forehead mode: Temperature taken is higher than +42.2°C (108°F) (2) In surface mode: Temperature taken is higher than +80°C (176°F)	Please select the target within specifications. If a malfunction still exists, please contact the nearest retailer.
	(1) In forehead mode: Temperature taken is lower than +34°C (93.2°F) (2) In surface mode: Temperature taken is lower than -22°C (-7.6°F)	
	Device cannot be powered on to the ready stage.	Change with a new battery.

### Warranty:

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:E512A000001, the first "E" is External, the second number "5" is the last number of manufacture year, 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.**

⚠ **Warning: No modification of this equipment is allowed.**

 Please read the instructions for use  BF type applied part











 Radiant Innovation Inc.  
 Http://www.radiantek.com.tw  
 Add: 1F, No.3, Industrial East 9th Road,  
 Science-Based Industrial Park, HsinChu, Taiwan 300.




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



Ref No. : 122016

Symbol Descriptions					
	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.		Authorized representative in the European community
	Caution		Please read the instructions for use		Manufacturer
	BF type applied part		Battery Recycling		Paper Recycling
IP22	Classification for water ingress and particulate matter.		Stand-by		

Guidance and manufacturer's declaration – electromagnetic emissions		
The THD2F(E) is intended for use in the electromagnetic environment specified below. The customer or the user of the THD2F(E) should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The THD2F(E) 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 THD2F(E) 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 THD2F(E) is intended for use in the electromagnetic environment specified below. The customer or the user of the THD2F(E) 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 THD2F(E), including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  <b>Recommended separation distance</b> $d = 1,2 \sqrt{P}$ $d = 1,2 \sqrt{P}$ 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 THD2F(E) is used exceeds the applicable RF compliance level above, the THD2F(E) should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the THD2F(E).
- 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 THD2F(E) is intended for use in the electromagnetic environment specified below. The customer or the user of the THD2F(E) 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 %.
<b>Electrical fast transient/burst</b> IEC 61000-4-4	<b>2 kV for power supply lines</b> <b>1 kV for input/output lines</b>	<b>Not applicable</b>	<b>Mains power quality should be that of a typical commercial or hospital environment.</b>
<b>Surge</b> IEC 61000-4-5	<b>1 kV line(s) to line(s)</b> <b>2 kV line(s) to earth</b>	<b>Not applicable</b>	<b>Mains power quality should be that of a typical commercial or hospital environment.</b>
<b>interruptions and voltage variations on power supply input lines</b> 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	<b>Not applicable</b>	<b>Mains power quality should be that of a typical commercial or hospital environment. If the user of the THD2F(E) requires continued operation during power mains interruptions, it is recommended that the THD2F(E) be powered from an uninterruptible power supply or a battery.</b>
<b>Power frequency (50/60 Hz) magnetic field</b> IEC 61000-4-8	<b>3 A/m</b>	<b>3 A/m</b>	<b>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</b>

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 THD2F(E) is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the THD2F(E) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the THD2F(E) 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	N/A	0,12	0,23
0,1	N/A	0,38	0,73
1	N/A	1,2	2,3
10	N/A	3,8	7,3
100	N/A	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.