Model: THD2FE

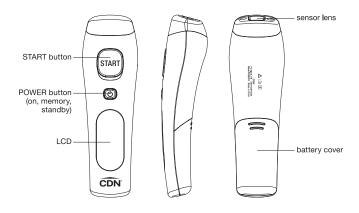


## NON-CONTACT FOREHEAD THERMOMETER

Forehead mode: 93.2 to 108°F/34 to 42.2°C Surface mode: -7.6 to +176°F/-22 to +80°C

## FOR MEASUREMENT OF HUMAN BODY TEMPERATURE IN PEOPLE OF ALL AGES

- Response Time: Forehead mode: 1 second;
   Surface mode: 0.6 second
- Forehead Measurement Distance: within 1.5 in/4 cm
- Surface mode: Distance:Spot = 1:1, emissivity: 0.95
- Accuracy: ±0.4°F/0.2°C
- · Backlit in blue
- Memory recalls 25 readings
- One-button operation
- · Battery status indication
- Temperature alert or silent
- On/Off Power button
- Auto-off after 1 minute
- ABS plastic
- Two 1.5V AAA IEC LR03 alkaline batteries, included
- FDA, RoHS, ISO 9001, ISO 13485, ASTM E1965-98, EN ISO 80601-2-56



Note: Remove label from display before initial use.

**Note:** In the following instructions, names of the control buttons are shown in CAPS. Function information that appears on the display is shown in **BOLD CAPS**.

## **USAGE**

#### **Indications for Use**

The Non-Contact Forehead Thermometer is an infrared thermometer intended for the intermittent measurement of human body temperature in people of all ages.

#### **Intended Operator:**

At least 11 years old (5 years intensive reading experience), no maximum.

#### **Ambient Temperature △**

If there is any temperature difference between the places where the device is stored and where it will be used, allow the thermometer to adjust to the room temperature where the subject is for at least 15 minutes before measurement.

#### **Points of Attention**

- 1. Forehead temperature is displayed in oral mode. This mode converts the forehead temperature to display its "oral-equivalent" value.
- 2. Before the measurement, the subject should stay in a stable environment for 5 minutes and avoid exercise or bath for 30 minutes.
- 3. Keep the forehead area clean and free from sweat, cosmetics and scars while taking the temperature.
- 4. The "Clinical Bias" is -2.5 to -3.1°F (-1.4 to -1.7°C).
- 5. The "Limits of Agreement" is 0.98.
- 6. The "Repeatability" is 0.36°F (0.20°C)

## **BEFORE WE BEGIN**

This thermometer has been designed for use in professional healthcare facility environments and home healthcare environments (as defined in 3.1 of IEC 60601-1-11 Edition 2.0 2015-01 and Guidance for Industry and Food and Drug Administration Staff: Design Considerations for Devices Intended for Home Use, Issued November 24, 2014). It is not meant to replace a visit to the doctor. Compare the measurement result to your regular body temperature. Consult with doctor if you have health concerns.

## **BATTERY INSTALLATION**

Replace battery when the Low Battery icon ( indicates the battery is low. Power off the unit before installing the batteries. A malfunction may occur if the power is on when the battery is installed. If a malfunction occurs, restart the device.

1. Remove battery cover by using the thumbs to push battery cover out.



2. Install two 1.5V AAA batteries observing polarity shown in compartment.



3. Replace the battery cover until it clicks shut.



## **OPERATING INSTRUCTIONS**

#### A. On/Off

- 1. Press the POWER button (**(b)**) to turn the thermometer on.
- 2. Forehead is the default mode. The Forehead icon (\*\*\*) appears on the display and two beeps sound when ready.
- 3. Press the POWER button (**(b)**) for 5 seconds to turn the thermometer off.
- 4. The THD2FE will automatically turn off after 1 minute of inactivity.

#### **B.** Temperature Scale

Note: When the temperature scale is changed, the memory is cleared.

To select temperature reading in Fahrenheit or Celsius:

- 1. Power off the unit.
- 2. Press and hold the START button, then press and hold the POWER button for 3 seconds.
- 3. The °F symbol changes to the °C symbol on the display or vice versa.

#### C. LCD Backlight

The backlight will turn on automatically for 2 seconds when a reading is taken.

#### D. Forehead Mode

Forehead is the default mode of the THD2FE.

- 1. Make sure that the sensor lens is clean and undamaged and that the forehead is clean.
- 2. Hold the sensor lens 1.5 inches (4 cm) or less from the center of the forehead and press the START button to get the temperature measurement.
- 3. Wait for the Forehead icon (\*\*\*) to stop flashing before taking the next measurement.

#### a. Temperature Alert

If the thermometer detects a temperature ≥99.5°F (37.5°C), three short beeps sound followed by one long beep.

#### b. Silent

- i. When the THD2FE is on, press and hold the POWER button for 3 seconds.
- ii. The silent icon ( $\mathbb{N}$ ) flashes on the display.
- iii. Release the POWER button to silence the alert.
- iv. Repeat to turn the alert on again.

  Note: If the POWER button is pressed for 5 seconds after the silent icon has begun flashing, the device will power off without setting the alert to silent.

#### c. Memory

Recall up to 25 readings.

Note: As the memory gets full, the newer readings will replace the older readings.

- i. When the THD2FE is on, press the POWER (**(b)**) button to see the temperature records in memory.
- ii. The memory icon ( appears on the display.
- iii. Press the Power button again to cycle through all of the previous readings starting with the most recent.

#### E. Surface Mode

**Note:** 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.

- 1 Turn the thermometer on
- 2. Press and hold the POWER button and press the START button once to enter Surface mode.
- 3. The surface icon ( ) appears on the display.
- 4. Aim the sensor lens at the target and press the START button to display the surface temperature.
- Press and hold the START button to get continuous measurements.
   Note: Applications include temperature measurements for

**Note:** 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.

Important: HAND WASH AND DRY. DO NOT IMMERSE IN LIQUID.

#### F. Trouble Shooting

Error Message	Problem	Solution		
Er	Error 5-9, the system is not functioning properly.	Unload the battery, wait for 1 minute and repower it. If the message reappears, contact CDN for further assistance.		
Er 1	Measurement before device stabilization.	Wait for "Er1" to disappear.		
Er3	The ambient temperature is not within the range between 50 to 104°F (10 to 40°C).	Allow the thermometer to rest in a room for at least 15 minutes at room temperature: 50 to 104°F (10 to 40°C).		
H,	Forehead mode: Temperature taken is higher than 108°F (+42.2°C) Surface mode: Temperature taken is higher than 176°F (+80°C)	Select the target within specifications. If a malfunction still exists, contact CDN for further assistance.		
Lo	Forehead mode: Temperature taken is lower than 93.2°F (+34°C) Surface mode: Temperature taken is lower than -7.6°F (-22°C)			
(88.8¥2)	Device cannot be powered on to the ready stage.	Replace batteries with new batteries.		

#### E. Battery Status

The thermometer incorporates visual battery status indication:

- 1. Battery OK: measurements are possible
- 2. E3 Battery Low: replace battery with two 1.5V AAA alkaline cells; measurements are possible
- 3. **Battery Exhausted:** replace battery; measurements are not possible

## **CARE OF YOUR PRODUCT A**

- The sensor lens is the most delicate part of the thermometer and should be kept clean at all times.
   Take care when cleaning the lens. Use only a soft cloth or cotton swab with water or rubbing alcohol. Allow the lens to dry fully for at least 1 minute before using the thermometer.
- Do not submerge any part of the thermometer in liquids. Keep it dry and away from any liquids and direct sunlight. Wipe clean with a damp cloth.
- Store the thermometer at room temperature between -4 to +122°F/-20 to +50°C, RH ≤85%.
- Avoid holding the thermometer too long. This could cause the body temperature measurement to be lower than usual.

## **PRECAUTIONS A**

- Dispose of used batteries promptly and keep away from children.
- Keep the thermometer and batteries away from children.
- Do not clean the case with abrasive or corrosive compound, which may scratch the plastic and corrode the electronic circuits.
- Do not subject the unit to excessive force shock, dust, temperature or humidity, which may result in malfunction, shorter electronic life span, damaged battery and distorted parts.
- Do not tamper with the unit's internal components.
   Doing so will invalidate the warranty on the unit and may cause unnecessary battery damage and distorted parts.
- Do not subject the unit to excessive exposure to direct sunlight. The unit is not waterproof — do not immerse it into water or expose to heavy rain.
- To avoid deformation, do not place the unit in extreme temperatures.
- Do not use the thermometer in a microwave oven.
- Always read the user manual thoroughly before operating.

## **SPECIFICATIONS**

Measurement Range	Forehead mode: 93.2 to 108°F/34		
	to 42.2°C; Surface mode: -7.6 to		
	+176°F/-22 to +80°C		
Unit of Measure	°F/°C		
Resolution	0.1°F/0.1°C		
Water Resilience	IP22: protected from solids bigger		
	than 12.5 mm (e.g. fingers); dripping		
	water when enclosure tilted up to 15°		
Accuracy	Forehead mode: 95 to 107.6°F/35		
	to 42°C: ±0.4°F/0.2°C, otherwise		
	±0.5°F/0.3°C;		
	Surface mode: 71.6 to 108°F/22 to		
	42.2°C: ±0.5°F/0.3°C, otherwise		
	±4% or ±4°F/2°C whichever is		
	greater		
<b>Measurement Distance</b>	Within 1.5 in/4 cm		
Distance:Spot	Surface mode: 1:1		
Emissivity	Surface mode: 0.95		
Operating Range	50 to 104°F/10 to 40°C, 15% to 85%		
Storage Range	-4 to +122°F/-20 to 50°C, RH ≤85%		
Transportation	Shall be less than 158°F/70°C,		
Temperature	RH≤95%		
Power Supply	Two AAA 1.5V IEC LR03 alkaline		
	batteries, included		
<b>Product Dimensions</b>	1.89 W x 6.22 H x 1.58 D (in)/		
	4.8 W x 15.8 H x 4.02 D (cm)		
Weight	3.5 oz / 100 g (including battery)		

## **SYMBOL DESCRIPTIONS**

$\triangle$	Caution
<b>沐</b>	BF type applied part
IP22	Classification for water ingress and particulate matter
Ţ <u>i</u>	Please read the instructions for use
<b>也</b>	Power, standby
<b>③</b>	Paper recycling

#### MANUFACTURER'S DECLARATION ELECTROMAGNETIC EMISSIONS

The THD2FE is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the THD2FE should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment – Guidance (for home healthcare environment)		
EIIIISSIOIIS TEST	Compliance	(for nome nearthcare environment)		
RF emissions CISPR 11	Group 1	The THD2FE 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 THD2FE 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.		

## MANUFACTURER'S DECLARATION ELECTROMAGNETIC IMMUNITY

The THD2FE is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the THD2FE should assure that it is used in such an environment.

			Electromagnetic Environment – Guidance
Immunity Test	IEC 60601 Test Level	Compliance Level	(for home healthcare environment)
Electrostatic discharge (ESD) IEC 61000-4-2	Contact:±8 kV Air±2 kV,±4 kV,±8 kV,±15 kV	Contact:±8 kV Air±2 kV,±4 kV,±8 kV,±15 Kv	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50, 60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz and 60 Hz	The THD2FE power frequency magnetic fields should be at levels characteristic of a typical location in a typical home healthcare environment.

#### MANUFACTURER'S DECLARATION ELECTROMAGNETIC IMMUNITY

The THD2FE is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the THD2FE should assure that it is used in such an environment.

	IEC 60601		Electromagnetic Environment –		
Immunity Test	IEC 60601 Test Level	Compliance Level	Guidance (for home healthcare environment)		
Immunity Test Radiated RF IEC 61000-4-3	Test Level 10 V/m 80 MHz - 2,7 GHz 80 % AM at 1 kHz	Compliance Level 10 V/m 80 MHz - 2,7 GHz 80 % AM at 1 kHz	(for home healthcare environment) Recommended separation distance: $d=1,2 \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \$		

OTE 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.

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 THD2FE is used exceeds the applicable RF compliance level above, the THD2FE should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the THD2FE.

# RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE THD2FE

The THD2FE is intended for use in an electromagnetic environment (for home healthcare) in which radiated RF disturbances are controlled. The customer or the user of the THD2FE can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the THD2FE 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			
	150 kHz to 80 MHz $d = 1,2 \sqrt{P}$	80 MHz to 800 MHz $d = 1,2 \sqrt{P}$	<b>800 MHz to 2,7 GHz</b> $d = 2,3 \sqrt{P}$	
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.

## MANUFACTURER'S DECLARATION ELECTROMAGNETIC IMMUNITY

## TEST SPECIFICATIONS FOR ENCLOSURE PORT IMMUNITY TO RF WIRELESS COMMUNICATIONS EQUIPMENT

The THD2FE is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the THD2FE should assure that it is used in such an environment.

Test frequency	Band <sup>a)</sup>			Maximum power	Distance	Immunity Test Level	Compliance Level (V/m)
(MHz)	(MHz)	Service a)	Modulation b)	(W)	(m)	(V/m)	(for home healthcare)
385	380-390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0.3	27	27
450	430-470	GMRS 460,	FM ©	2	0,3	28	28
		FRS 460	±5 kHz deviation 1 kHz sine				
710			Pulse modulation b)				
745	_ 704–787	LTE Band 13,17	217 Hz	0,2	0,3	9	9
780			217 112				
810		GSM 800/900, TETRA	Pulse modulation b)				
870	800-960	800, iDEN 820, CDMA	18 Hz	2	0,3	28	28
930		850, LTE Band 5	10 П2				
1720		GSM 1800; CDMA 1900;	Dulas madulation h				
1845	1700–1990	GSM 1900; DECT; LTE	Pulse modulation b)	2	0,3	28	28
1970		Band 1, 3, 4, 25; UMTS	217 Hz		,		
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation <sup>b)</sup> 217 Hz	2	0,3	28	28
5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation <sup>b)</sup> 217 Hz	0,2	0,3	9	9

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.

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1-Year Limited Warranty: Any instrument that proves to be defective in material or workmanship (excluding batteries) within one year of original purchase will be repaired or replaced without charge upon receipt of the unit prepaid at: CDN, PO Box 10947, Portland, OR 97296-0947 USA. This warranty does not cover damage in shipment or failure caused by failure to adhere to the accompanying instructions, inadequate maintenance, normal wear and tear, tampering, accident, misuse, unauthorized modification, obvious carelessness or abuse. CDN shall not be liable for any consequential or incidental damages whatsoever.

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