

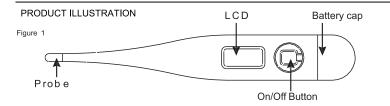


- $\underline{ \ \, } \hspace{0.1 cm} \text{Read instructions thoroughly before using digital thermometer.}$
- ⚠ Choking Hazard: Thermometer cap and battery may be fatal if swallowed. Do not allow children to use this device without
- ⚠ Do not use thermometer in ear. Designed use is for oral, rectal, and armpit (axilla) readings only
- riangle Do not place thermometer battery near extreme heat as it may explode.
- \triangle Note: Use of the probe cover may result in a 0.1 $^{\circ}$ C(0.2 $^{\circ}$ F) discrepancy from actual temperature.
- riangle It is recommended the performance should be checked every two years. riangle Remove battery from the device when not in operation for a long time.
- riangle The use of temperature readings for self-diagnosis is dangerous. Consult your doctor for the interpretation of results. Self-diagnosis may lead to the worsening of existing disease conditions. A Do not attempt measurements when the thermometer is wet as inaccurate readings may result.
- ♠ Do not bite the thermometer. Doing so may lead to breakage and/or injury. ♠ Do not attempt to disassemble or repair the thermometer. Doing so may result in inaccurate readings.
- \triangle After each use, disinfect the thermometer especially in case the device is used by more than one person. \triangle Do not force the thermometer into the rectum. Stop insertion and abort the measurement when pain is present. Failure to do so may lead to injury.
- ♠ Do not use thermometer orally after being used rectally.
- A For children who are two years old or younger, please do not use the devices orally.
- ⚠ Life time of this product is 3 years.

PLEASE READ CAREFULLY BEFORE USING

This digital thermometer provides a quick and highly accurate reading of an individual's body temperature. To better understand its functions and to provide years of dependable results, please read all instructions first.

CONTENTS 1 Thermometer, 1 Owner's Manual, 1 Storage Case



PRECAUTION

* The performance of the device may be degraded should one or more of the following occur:

- Operation outside the manufacturer s s tated te mperature a nd h umidity r ange. - Storage outside the manufacturer s s tated te mperature a nd h umidity r ange. - Mechanical shock (for example, drop test).

- Patient temperature is below ambient temperature.

* Portable and mobile RF communications can affect the device. The device needs special pre-cautions regarding EMC according to the EMC information provided in the accompany documents.

C € 0197	The product is in compliance with the requirements of MDD 93/42/EEC, "0197Vis the identification number of notify body's.	潭	Disposal of this product and used batteries should be carried ou in accordance with the national regulations forthe disposal of electronic products.
	Direct Current	LOT	Batch code
∱	Type BF Applied Part	<u>l</u>	Manufacturer
Δ	Caution, consult accompanying documents	•	Consult instruction for use
A"	Temperature Conditions	Ø	Humidity Conditions
11	Keep it uprightt	*	Keep Dry

SPECIFICATIONS

Type:	Digital Thermometer (Not Predictive)		
Range:	32.0℃—42.9℃(90.0°F-109.9°F) (℃/°F chosen by manufacturer)		
Accuracy:	± 0.1°C,35.5°C−42.0°C(± 0.2°F,95.9°F-107.6°F)		
	±0.2 °C under 35.5 °C or over 42.0 °C		
	(±0.4 °F under 95.9 °F or over107.6 °F)		
	at ambient temperature of 18 °C to 28 °C (64.4 °F to 82.4 °F)		
Display:	Liquid crystal display, 3 1/2 digits		
memory:	For storing the last measured value		
Battery:	One 1.5 V DC. button battery (size LR41or SR41, UCC 392)		
Battery life:	Approx 200 hours		
Dimentions: 12.4cm x 1.8cm x 0.9cm (L x W x H)			
Weight: Approx. 10 grams including battery			
Using environment:	Temperature: 5° C \sim 40 $^{\circ}$ C (41 $^{\circ}$ F \sim 104 $^{\circ}$ F) Atmospheric Pressure: 700hPa $^{\sim}$ 1060hPa Relative humidity: 15% \sim 95%RH		
Storage and transportation condition:	Temperature: -20°C ~55°C (-4°F \sim 131°F) Atmospheric Pressure: 700hPa $^{\sim}$ 1060hPa Relative humidity: 15% ~95%RH		
Ingress Protection Rating:	IPX0		
Classification:	Tip BF ★		

Digital Thermometer is intended to measure the human body temperature in regular mode orally, rectally or under the arm, and the device is reusable for clinical or home use on people of all ages. Not allow children to use the device without the parents supervision.

• Infectious diseases • Certain inflammatory conditions such as rheumatoid arthritis • A malignant tumor • Some medications, such as antibiotics • Other causes such as dehydration, vaccine reactions
Target users are the patients who indicated with above mentioned situations.
Contraindications:

Contraindications:
- Contraindication of oral temperature: • Unconscious patients • Inflammation or surgery of mouth • Persistent frequent coughing

 Mouth breathing patients.
 Contraindication of axillary temperature: • Skin disease • Axillary operation Contraindication of rectal temperature: • Patients with surgical operation in the rectum or perineal region
 Disease or inflammation of the rectum • Diarrhea.

There is no side effect related with digital thermometer. These devices are for measuring and monitoring purposes.

DIRECTIONS Press the *On/Off* Button next to LCD display. A tone will sound as the "DDB" as the screen shows

followed by last recorded temperature. After showing the self-test temperature, the thermometer is now in the testing * Note: If the measured temperature is less than 32 $^\circ$ C or 90 $^\circ$ F, the LCD will display Lo, if the measured temperature is higher than 42.9 $^\circ$ C or 109.9 $^\circ$ F, the LCD will display Hi.

2. Position thermometer in desired location (mouth, rectum, or armpit.) a) Oral Use: Place thermometer under tongue as indicated by "\"



position shown in Figure 2. Close your mouth and breathe evenly through the nose to prevent the measurement from being influenced b) Rectal Use: Lubricate silver probe tip with petroleum jelly for easy insertion. Gently insert

sensor approximately 1cm (less than 1/2" into rectum. Normal temperature between 36.2°C and 37.7 °C (97.2°F and 99.9°F). c) Armpit Use: Wipe armpit dry. Place probe in armpit and keep arm pressed firmly at side.

From a medical viewpoint, this method will always provide inaccurate readings, and should not be used if precise measurements are required. Normal temperature between 35.2℃ and 36.7℃

3. The degree sign flashes throughout the testing process. When flashing stops the device will beep for approximately 10 seconds. The measured reading will appear on the LCD simultaneously. The minimum measurement time until the signaling tone (beep) must be maintained without exception. The measurement continues even after the buzzer notification. The displayed temperature will not change when thermometer is removed from its testing position.

measurement result, recommend to keep the probe in mouth and rectum about 2 minutes, or in armpit about 5 minutes regardless of the beep sound and at least 30 seconds measurement interval should be maintained. * Note: Normally the buzzes are "Bi-Bi-Bi-Bi-"; The device beeps more rapidly when temperature reaches 37.8 °C (100 °F) or higher ,and the buzzes are "Bi-Bi-Bi------- Bi-Bi-Bi------- Bi-Bi-Bi"

4. To prolong battery life, press the On/Off Button to turn unit off after testing is complete. If no action

is taken, the unit will automatically shut off after around10 minutes. 5. Store the thermometer in its protective case.

BATTERY REPLACEMENT

Replace battery when " appears in " | " the lower right corner of LCD display.

2. Pull battery cover off as shown in Figure 3.

3. Gently pull out plastic circuit board with battery chamber approximately 1 cm (slightly less than1/2" (See Figure 4)

4. Use pointed object such as a pen to remove old battery. Discard battery lawfully. Replace with new 1.5V DC button type LR41 or SR41,UCC392, or equivalent. Be sure battery is installed with "+" $^{\prime\prime}$ polarity facing up. (See Figure 5) 5. Slide battery chamber back into place and attach cover







CLEANING AND DISINFECTION Wipe the thermometer with a soft clean cloth.

-Do not use ultrasonic washing to clean the thermometer.

For stubborn stains, wipe the thermometer with a cloth that has been dampened with water or a neutral detergent solution and then wring thoroughly. Finish by wiping with a soft dry cloth.

Observe the following to prevent damage to the thermometer.

-Do not use benzene, thinner, gasoline or other strong solvents to clean the thermometer -Do not soak the sensing section in alcohol for long periods of time or attempt to sterilize it using hot water (water at a temperature of 50 $^{\circ}\mathrm{C}(122~^{\circ}\mathrm{F}$) or higher).

The thermometer is initially calibrated at the time of manufacture. If the thermometer is used according to the use instruction, periodic readjustment is not required. However, we recommend checking calibration every two years or whenever clinical accuracy of the thermometer is in question at the authorised laboratories.

LIMITED WARRANTY

The thermometer is guaranteed for 2 years from the date of purchase. If the thermometer does not function properly due to defective components or poor workmanship, we will repair or replace it free of charge. All components are covered by this warranty excluding the battery. The warranty does not cover damages to your thermometer due to improper handling. To obtain warranty service, an original or copy of the sales receipt from the original retailer is required.

Electromagnetic Compatibility Information

The device satisfies the EMC requirements of the international standard IEC 60601-1-2. The requirements are satisfied under the conditions described in the table below. The device is an electrical medical product and is subject to special precautionary measures with regard to EMC which must be published in the instructions for use. Portable and mobile HF communications equipment can affect the device. Use of the unit in conjunction with non-approved accessories can affect the device negatively and alter the electromagnetic compatibility. The device should not be used directly adjacent to or between other electrical equipment. Table 1

Guidance and manufacturer's declaration - electromagnetic emission

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

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions	Correct 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and
CISPR 11	Group 1	are not likely to cause any interference in nearby electronic equipment.
RF emissions		The device is suitable for use in all
CISPR 11	Class B	establishments, including domestic establishments and those directly connected to the public low-voltage power
Harmonic emissions		supply network that supplies buildings used for domestic
	Not applicable	purposes.
IEC 61000-3-2		
Voltage fluctuations / flicker emissions	Not applicable	
IEC 61000-3-3	11	

Table 2

Guidance and manufacturer's declaration - electromagnetic immunity

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance	
Electrostatic discharge (ESD)	± 8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV	± 8 kV contact ±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	
IEC 61000-4-2	air	air	should be at least 30 %.	
Electrostatic transient / burst IEC 61000-4-4 # 2 kV for power supply lines 100 kHz repetition frequency ± 1 kV for input/output lines		N/A	N/A	
Surge IEC 61000-4-5	± 0.5 kV, ± 1 kV differential mode line-line	N/A	N/A	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT (100 % dip in UT) for 0.5 cycle at 0°, 45°, 90°, 135°,180°, 225°, 270°, and 315° 0 % UT (100 % dip in UT) for 1 cycle at 0° 70 % UT (30 % dip in UT) for 25/30 cycles at 0° 0 % UT (100 % dip in UT) for 25/30 cycles at 0°	N/A	N/A	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m, 50/60Hz	30 A/m, 50/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.	

			ion – electromagnetic immunity
			nent specified below. The customer or the user of the
Immunity test	at it is used in such an IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms 150 kHz to 80 MHz outside ISM bandsa	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3.5}{V_1}\right] \sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	$d = \left[\frac{3.5}{E_{\rm i}}\right] \sqrt{P} \text{80MHz to 800MHz}$
			$d = \left[\frac{7}{E_1}\right] \sqrt{P} 800 \text{MHz to } 2.7 \text{GHz}$
			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 metres(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:
			transmitter manufacturer and d is th recommended separation distance in Field strengths from fixed RF transs determined by an electromagnetic s should be less than the compliance frequency range b Interference may occur in the vicini

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.

The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The mateur radio hands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,7 GHz are ications equipment could cause interference if it is inadvertently brough ntended to decrease the likelihood that mobile/portable comm nto patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the nended separation distance for transmitters in these frequency ranges

c Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur adio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the elecation in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal ration. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

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

Table 4

Recommended separation distances between

portable and mobile RF communications equipment and the device The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters' and the device as recommended below, according to the maximum output power of the communication

equipment.					
	Separation distance according to frequency of transmitter				
	m				
Rated maximum	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.7 GHz		
output of transmitter	$d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	$d = \left[\frac{7}{E_1}\right]\sqrt{P}$		
W					
0.01	0.12	0.04	0.07		
0.1	0.37	0.12	0.23		
1	1.17	0.35	0.7		
10	3.7	1.11	2.22		
100	11.7	3.5	7.0		

For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (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 absorptiand reflection from structures, objects and people.

Table 5

Recommended separation distances between RF wireless communications equipment

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimu distance between RF wireless communications equipment and the device as recommended below, according to the maximum output power of the communications equipment.

Frequency MHz	Maximum Power W	Distance	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
385	1.8	0.3	27	27	RF wireless communication equipment should be used no closer to any part of the device including cables, than the
450	2	0.3	28	28	
710		0.3		9	recommended separation distance calculated from the
745	0.2		9		equation applicable to the frequency of the transmitter. Recommended separation distance
780					
810					$E = \frac{6}{d} \sqrt{P}$
870	2	0.3	28	28	Where P is the maximum output power rating of the
930					ransmitter in watts (W) according to the transmitter
1720					manufacturer and d is the recommended separation
1845	2	0.3 28	28	28 28	distance in meters (m). Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey should be less than the compliance level in each
1970					
2450	2	0.3	28	28	
5240					frequency range. Interference may occur in the vicinity of
5500	0.2	0.3	9	9	equipment marked with the following symbol:
5785	1				((·•))

WARNINGS!

• This device should not be used in the vicinity or on the top of other electronic equipment such as cell phone, transceiver or radio control products. If you have to do so, the device should be

observed to verify normal operation.

reflection from structures, objects and people.

• The use of accessories and power cord other than those specified, with the exception of cables sold by the manufacturer of the equipment or system as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment or

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