124mm

320mm

BUBBLES DIGITAL THERMOMETER - BUE4320

OWNER'S MANUAL

Warning :

⚠ 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 parental supervision.
⚠ Do not use thermometer in ear. Designed use is for oral, rectal, and armpit (axilla) readings only.
⚠ Do not place thermometer battery near extreme heat as it may explode.
⚠ Note: Use of the probe cover may result in a 0.1℃(0.2℉) discrepancy from actual temperature.
⚠ Remove battery from the device when not in operation for a long time.
⚠ 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.
⚠ 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.
⚠ After each use, disinfect the thermometer especially in case the device is used by more than one person.
⚠ 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.
⚠ For children who are two years old or younger, please do not use the devices orally.
⚠ If the unit has been stored at temperatures over 5℃～40℃(41℉～104℉), leave it in 5℃～40℃ (41℉～104℉) ambient temperature for about 15 minutes before using it.

PLEASE READ CAREFULLY BEFORE USING

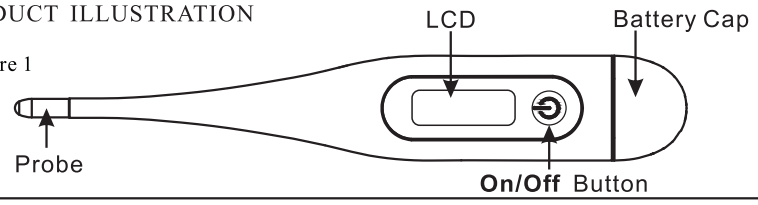
This digital thermometer provides a quick and highly accurate reading of an individual's body temperature. The digital thermometer is intended to measure the human body's temperature in regular mode orally, rectally or under the arm, and the device is reusable for clinical or home use on people of all ages. To better understand its functions and to provide years of dependable results, please read all instructions first.
This appliance conforms to the following standards:
EN 12470-3 Clinical thermometers —Part 3: Performance of compact electrical thermometers (non-predictive and predictive) with maximum device,
ISO 80601-2-56 Medical electrical equipment —Part 2-56:Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement,
EN 60601-1-11 Medical electrical equipment —Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment and complies with the requirements of EN 60601-1-2(EMC), IEC/EN60601-1(Safety) standards. And the manufacturer is ISO 13485 certified.

CONTENTS

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

PRODUCT ILLUSTRATION

Figure 1



PRECAUTION

* The performance of the device may be degraded should one or more of the following occur:
- Operation outside the manufacturer's stated temperature and humidity range.
- Storage outside the manufacturer's stated temperature and humidity range.
- Mechanical shock (for example, drop test) or degraded sensor.
- 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.

SYMBOL EXPLANATION

⎓	Direct Current	LOT	Batch Code
	Type BF Applied Part		Manufacturer
	Consult Accompanying Documents	-20℃ 55℃	Storage and Transportation Temperature Limit: -20℃~55℃ (-4℉～131℉)

SPECIFICATIONS

Type:	Digital Thermometer (Not Predictive)
Measure Range:	32.0℃—42.9℃(90.0℉-109.9℉)(℃/℉ chosen by manufacturer)
Accuracy:	±0.1℃(±0.2℉) during 35.5℃~42.0℃(95.9℉~107.6℉) at 18℃~28℃ (64.4℉~82.4℉) ambient operating range ±0.2℃(±0.4℉) for other measuring and ambient operating range
Operating mode:	Direct Mode
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. 200hours of continuous operation or 1 year with 3 measurements per day
Dimension:	13.8cm x 2.2cm x 1.2cm (L x W x H)
Weight:	Approx. 12 grams including battery
Expected service life:	Three years
Ambient operating range:	Temperature: 5℃～40℃(41℉～104℉) Relative humidity: 15%~95%RH Atmospheric Pressure : 700hPa ~ 1060hPa
Storage and transportation condition:	Temperature: -20℃~55℃(-4℉～131℉) Relative humidity: 15%~95%RH Atmospheric Pressure : 700hPa ~ 1060hPa
Ingress Protection Rating:	IP 27
Classification:	Type BF

℃/℉ SWITCHABLE

Temperature readings are available in the Celsius or Fahrenheit scale (℃/℉; located in the upper right corner of LCD.) With the unit off, press and hold the On/Off Button for approximately 2 seconds to change the current setting.

DIRECTIONS

1. Press the On/Off Button next to LCD display. A tone will sound as the screen shows 188.8℉, followed by last recorded temperature. After showing the self-test temperature, the thermometer is now in the testing mode.
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 by inhaled/exhaled air. Normal temperature between 35.7℃ and 37.3℃ (96.3℉ and 99.1℉).

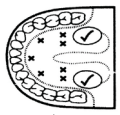


Figure 2

   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℃ and 37.7℃ (97.2℉ and 99.9℉).
   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℃ (95.4℉ and 98.1℉).
3. The degree sign flashes throughout the testing process. When flashing stops an alarm 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. So that in order to achieve better body temperature 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- " ; Alarm beeps more rapidly when temperature reaches 37.8℃ (100℉) 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.

TROUBLESHOOTING

Error message	Problem	Solution
Lo	Temperature taken is lower than 32.0°C(90.0°F)	Turn off, wait one minute and take a new temperature via close contact and sufficient rest.
Hi	Temperature taken is higher than 42.9°C(109.9°F)	Turn off, wait one minute and take a new temperature via close contact and sufficient rest.
Err	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.
▮	Dead battery: Battery icon is flashing, can't be measurable.	Replace the battery.

BATTERY REPLACEMENT

1. 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 "+" polarity facing up. (See Figure 5)
5. Slide battery chamber back into place and attach cover.

Figure 3

Figure 4

Figure 5

CALIBRATION

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. Turn on the thermometer and insert into the water bath and then check the laboratory accuracy of thermometer. Please send the complete device to the dealers or manufacturer.
The above recommendations do not supersede the legal requirements. The user must always comply with legal requirements for the control of the measurement, functionality, and accuracy of the device which are required by the scope of relevant laws, directives or ordinances where the device is used.

CLEANING AND DISINFECTION

Wipe the thermometer with a soft clean cloth.
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.
For disinfection, 75% Ethanol or Isopropyl alcohol can be used.
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 attempt to disinfect the sensing section (tip) of the thermometer by immersing in alcohol or in hot water (water over 50℃(122℉)).
-Do not use ultrasonic washing to clean the thermometer.

Disposal of this product and used batteries should be carried out in accordance with the national regulations for the disposal of electronic products.

CE 0197 The product is in compliance with the requirements of MDD 93/42/EEC, "0197" is the identification number of notify body.

124mm

254mm

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 declaration of manufacturer-electromagnetic emissions		
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.		
Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device 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	N/A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A	

Table 2

Guidance and declaration of manufacturer-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 environm entguidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ±2 kV,±4 kV, ±8 kV, ±15 kV air	± 8 kV contact ±2 kV,±4 kV, ±8 kV, ±15 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 %.
Electrostatic transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	N/A	
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	N/A	
Voltage dips, short interrupti-ons and voltage variations on p-ower supply in-put lines IEC 61000-4-11	< 5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycle 70% UT (30% dip in UT) for 25 cycle <5% UT (>95% dip in UT) for 5 secretary	N/A	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m; 50Hz or 60Hz	30 A/m; 50Hz or 60Hz	Power frequency magnetic fields should be at levels charactertic of a typical location in a typical comme-rcial or hospital environment.

Table 3

Guidance and declaration of manufacturer-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 environmentguidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 Mhz	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.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 Ghz	10 V/m	Recommended seperation distance $d=[\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d=[\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2.7 Ghz
RF Wireless Communication Equipment IEC 61000-4-3	380MHz, 27V /m 450MHz, 28V /m 710MHz,745 MHZ,780MHz 9V/m 810MHz,870 MHZ,930MHz 28V/m 1720MHz,1845 MHZ,1970MHz 28V/m 2450MHz, 28V /m 5240MHz,5500 MHZ,5785MHz 9V/m	380MHz, 27V /m 450MHz, 28V /m 710MHz,745 MHZ,780MHz 9V/m 810MHz,870 MHZ,930MHz 28V/m 1720MHz,1845 MHZ,1970MHz 28V/m 2450MHz, 28V /m 5240MHz,5500 MHZ,5785MHz 9V/m	where P is the maximum output power rating of the transmitter in watts (W) according to the transm-itter 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. Interference may occur in the vicinity of equipment marked with the following symbol:

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 therefore 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 communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m	
	80 MHz to 800 MHz $d=[\frac{3.5}{E_1}]\sqrt{P}$	800 MHz to 2.7 GHz $d=[\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.23
0.1	0.38	0.73
1	1.2	2.3
10	3.8	7.3
100	12	23

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.

NOTE1 At 80 MHz and 800 MHz, the separation distance for the higer frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.