User's Manual

Bluetooth Clinical Electrical Thermometer

Model DT1/DT2



1. The Basics

This manual contains the instructions necessary to oper ate the product safely and in accordance with its function and intended use. Observance of this manual is a prerequisite for proper product performance and correct operation and ensures patient and operator safety. Professionals, non-professionals, and patients can operate medical device in accordance with the instructions.

1.1 Safety

- Get medical attention if you have high fever or prolonged fever, especially young children. Read carefully and follow the instructions to ensure accurate temperature measurement.
- Keep out of reach of unsupervised children. Components may be harmful if swallowed.
- This device is designed for oral, rectal, or axillary use only.
- Please note that temperature measuring are affected by many factors, including strong physical activity before the test, drinking hot or cold drinks, and measurement methods.
- Avoid taking temperature for 30 minutes after physical exercise, bathing, dining, or drinking hot or cold beverages.
- Stop using the thermometer if it operates erratically or if the display malfunctions.
- Allow the thermometer to warm naturally to room temperature before using. Performance may be affected if operated or stored outside stated temperature and humidity ranges or if the patient's temperature is below the ambient (room) temperature.
- Please note that the use of this product in high temperature or humidity may cause inaccurate temperature measurement results.
- Do not boil, bite, bend, drop, or disassemble the

thermometer.

- Do not share the thermometer with more than one person without disinfection, or it may cause cross-infection.
- Do not try to sterilize by immersing the thermometer head in alcohol or hot water (water temperature exceeds 50° C).
- Do not use force to squeeze the product. If the appearance is damaged, stop using it immediately.
- Precision components are used in the construction of this device. Extremes in temperature, humidity, direct sunlight, shock or dust should be avoided.
- Clean the device with a dry, soft cloth or a cloth dampened with water and a neutral detergent. Never use alcohol, benzene, thinner or other harsh chemicals to clean the device.
- Measurements may be distorted if the device is used close to television, microwave oven, cellular telephone, X-ray or other devices with strong electrical fields.
- Used equipment, parts and battery are not treated as ordinary household waste, and must be disposed of according to the applicable local regulations.
- Please keep the thermometer close to the skin when measuring. If it is loose, the temperature measurement result could be inaccurate.
- During the measurement, please avoid strenuous activity,eating or strong emotional ups and downs, and use this product in a relatively stable indoor environment.
- When reusing the device, confirm that the device is clean.
- Do not modify the device. It may cause accidents or damage to the device.
- Do not self-diagnose the measurement results and start treatment by yourself. Always consult your doctor for evaluation of the results and treatment.

- Adults are required to shaving the skin before measuring their temperature. Make sure that the skin that is in contact with the thermometer is flat and wrinkle-free.
- Do not use the device where flammable gases such as anesthetic gases are present. It may cause an explosion.
- Please note that the use of this product in high temperature or humidity may cause inaccurate temperature measurement results.
- The effective wireless transmission distance of this
 product in a barrier-free environment is 10 meters. If
 the distance exceeds this limit, this product may not
 work properly. Please use this product in the effective
 wireless transmission distance.
- The battery inside this product cannot be replaced.
- All the illustrations provided in this manual are for reference only.
- Please refer to the actual product.
- When the device is abnormal or damaged, please do not use the device again, you can contact the manufacturer.
- If necessary, to obtain information on the use and maintenance of the equipment or to report abnormal conditions, please contact the manufacturer.

2. Introduction

2.1 Intended Use

The product is used to measure body temperature in the home and in the medical sector.

2.2 Contraindications

 Those who are allergic to stainless steel or PC plastic should not use this product.

2.3 Symbols

Symbol	Meaning		
*	Application part type BF		
***	Manufacturer		
CE0197	In conformity with Directive 93/42/EEC		
EC REP	European Representative		
	Symbol for "ENVIRONMENT PROTECTION – Waste electrical products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local authority or retailer for recycling advice".		
IP22	Against ingress of solid foreign objects ≥12.5mm diameter, Against dripping(15° tilted)		
(3)	Follow operating instructions		

2.4 About the product

Product name: Bluetooth Clinical Electrical Thermometer

Software release version: V1

Product model:

Model and Configuration see the table below.

No.	Model	Temperat ure measure ment function	Bluetooth transmissio n function
1	DT1		
2	DT2	√	×



1. On/Off button

On/Off: long press it to achieve this function.

When you want to take your temperature again, shortly press it to re-measure your temperature.

2. Display screen It visually displays the temperature measurement results.

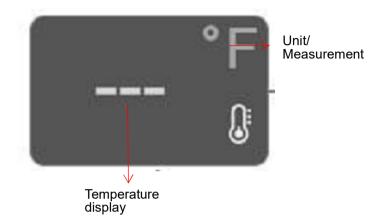
3. Indicator light

Green light: it means your body temperature is normal. Yellow light: it means you have a moderate fever. Red light: it means you have a ultra high fever.

4. Probe tip

It can measure the temperature.

2.5 Screen display information



3. Using the thermometer

3.1 Charge the Battery

Use the USB cable to charge the product. Connect the USB cable to a USB charger or to the PC. There will be a battery logo flash on the device when charging. When the battery is low, the display screen will display a low power prompt.

Note: The device cannot be used during charging. When charging, you must use a class *II* adapter conforming to IEC/EN 60601-1, and the output is DC 5V 1A. If it is not followed, there may be a risk of electric shock.

3.2 Before Measurement

- 1. Please long press the on key to start the product.
- 2. Display history

The history record appears on the screen,indicating that the value is the last measured temperature.

3.3 Measurement

Note:

Before measuring temperature, please clean the temperature measuring head with or rubbing alcohol. Rinse it with cool water.

The thermometer supports measuring temperature of multiple body parts.

For the infants under 3 months old, it is recommended to measure rectal temperature.

Please follow the below instructions.

Measuring oral temperature

- 1. With your mouth open, put the temperature measuring head under your tongue.
- 2. Close your lips gently around the thermometer.
- 3. Keep the thermometer under your tongue until the digital thermometer beeps.

Measuring axillary temperature

- 1. Put the temperature measuring head securely in your armpit.
- 2. Hold your arm down tightly at your side.
- 3. Keep the thermometer in your armpit until the digital thermometer beeps.

Measuring rectal temperature

1. Lubricate the probe tip with a water-soluable jelly for easier insertion; do not use petroleum jelly,as it may cause an inaccurate reading. Gently insert the probe tip no more than 1/2 inch into the rectum.

3.4 After Measurement

 When the buzzer emits a beep sound(Beep-short sound), it indicates that the temperature measurement is finished. The display "° C/ F" stops blinking, and the displayed temperature value is the result of the current body temperature.

Note:

When the temperature measured by the device is lower than 35 $\mathcal C$ or 95 $\mathcal F$, the screen will display "LOW"with beep-long sound.

When the temperature measured by the device is higher than 41 ${\mathcal C}$ or 105.8 ${\mathcal F}$, the screen will display "HIGH" with beep-long sound.

- 2. Turn off the thermometer: press and hold (> 0.5 seconds) to switch the thermometer off.
- If no operation is performed for more than 3 minutes, the thermometer will automatically turn off. It is recommended to manually turn off the thermometer after the temperature measurement to extend the battery life.

4. Cleaning and Disinfecting

Do not use corrosive detergent to clean the unit. Clean and disinfect the thermometer before and after each use.

Cleaning Process

1. Wipe probe with a cloth dipped in a disinfectant solution such as 70% isopropyl (rubbing) alcohol or soap and water. 2.Rinse off disinfectant residue.

Care and Storage

- Do NOT drop or crush; this device is not shock proof.
- · Do NOT dismantle or modify device.
- Do NOT store the device in an extreme environment with direct sunlight or high temperatures.
- Store the unit in the protective case while not in use.

5. Trouble Shooting

Problem Possible Cause Recommended				
Problem	Possible Cause	Recommended Action		
Can not boot	Very low battery	Please charge it according to the instruction		
	The ambient tem perature exceeds 40℃ or below 5℃.	Please use within the working environment temperature range (5℃-40℃)		
The monitor cannot be connected to other devices	Other devices have Bluetooth turned off	Turn on the devices Bluetooth from the setting menu.		
	Other devices don't support the Bluetooth 4.0 BLE	Change to a compatible one.		
Inaccurate measured value	The temperature measuring heads are placed in different positions, resulting in different readings. Thermometer moves while measuring temperature. The measured position is not kept closed while the temperature measurement is being performed.	Check whether the thermometer is placed in the correct position as described in "Using the thermometer".		

The device has not been placed for more than 30 minutes from the colder environment to the measuring environment.	Measurements should be taken before they are left in the measuring environment for more than 30 minutes.
The device has not been placed for more than 30 minutes from the warmer environment to the measuring environment.	Measurements should be taken before they are left in the measuring environment for more than 30 minutes.
The measurement temperature exceeds 43.9℃ or below 30℃.	Please use within the measuring temperature range (30 °C 43.9 °C)

6. Accessories

Model	Description
540-00240-00	MICRO USB charge cable

7. Specifications

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Classifications				
	MDD, 93/42/E	MDD, 93/42/EEC		
EC Directive	RED, 2014/53/	EU		
	ROHS 2.0, 201	1/65/EU		
Degree protection against electrical shock	Type BF			
Environmental				
Item	Operating	Storage		
Temperature	5 to 40°C	-20 to 50°C		
Relative humidity (noncondensing)	15% to 85%	15% to 85%		
Barometric	700 to 1060 hPa	700 to 1060 hPa		
Degree of dust & water resistance	IP22	IP22		
Physical				
Size	160mm×22mm×10mm(main unit)			
Weight	Less than 30 g (main unit)			
Wireless connectivity	Built-in Bluetooth 5.0 BLE			
Expected service life	5 years			
Power Supply				
Charge input	Micro USB, DC5V			
Battery type	Rechargeable lithium-polymer battery			
Battery life	Operating:12-14hours for typical use Storage:5 years			

Charge time	$2\sim$ 3 hours.		
Temperature measurement			
Measurement method	Direct mode		
Measurement site	Mouth,Axilla,Rectum		
REFERENCE BODY SITE	Mouth,Axilla,Rectum		
Temperature Unit	Celsius($^{\circ}$ C) or Fahrenheit($^{\circ}$ F)		
Temperature range	32.0 − 43.9°C (89.6-111.0°F)		
Measurement accuracy	Less than 35.8° C, $\pm 0.3^{\circ}$ C.(Less than 96.4° F, $\pm 0.5^{\circ}$ F.) 35.8° C to less than 37° C, $\pm 0.2^{\circ}$ C.(96.4° F to less than 98.0° F, $\pm 0.3^{\circ}$ F.) 37.0° C to 39.0° C, $\pm 0.1^{\circ}$ C.(98.0° F to 102.0° F, $\pm 0.2^{\circ}$ F.) Greater than 39.0° C to 41.0° C, $\pm 0.2^{\circ}$ C.(Greater than 102.0° F to 106.0° F, $\pm 00.3^{\circ}$ F.) Greater than 41.0° C, $\pm 0.3^{\circ}$ C.(Greater than 106.0° F, $\pm 0.5^{\circ}$ F.)		
Bluetooth RF			
Frequency range	2.402 – 2.480 GHz		
Max RF power	-14 dBm		

8. Electromagnetic Compatibility

The device meets the requirements of EN 60601-1-2.

riangle Warnings and Cautionary Advices

- Using accessories other than those specified in this manual may result in increased electromagnetic emission or decreased electromagnetic immunity of the equipment.
- The device or its components should not be used adjacent to or stacked with other equipment.
- The device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.
- Other devices may interfere with this device even though they meet the requirements of CISPR.
- When the inputted signal is below the minimum amplitude provided in technical specifications, erroneous measurements could result.
- Portable and mobile communication equipment may affect the performance of this device.
- Other devices that have RF transmitter or source may affect this device (e.g. cell phones, PDAs, and PCs with wireless function).

The device is intended for use in the electromagnetic environment enecified below

Guidance and Declaration - Electromagnetic Emissions

The customer or the user of the device should assure that it is used in such an environment.			
Emission tests	Complianc	Electromagnetic environment -	
	е	guidance	
RF emissions CISPR 11	Group 1	The device 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 device is suitable for use in all establishments, including domestic	
Harmonic emissions IEC61000-3-2	Class A	establishments and those directly connected to the public low-voltage	

Voltage Fluctuations /	Complies	power supply network that supplies
Flicker Emissions IEC		buildings used for domestic purposes.
61000-3-3		

Guidance and 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	IEC60601 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	± 2 kV for power supply lines ± 1 kV for input/output lines	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	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	
Voltage dips, short 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	<pre><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</pre>	Mains power quality should be that of a typical commercial or hospital environment. If the user of our product requires continued operation during power mains interruptions, it is recommended that our product be powered from an uninterruptible power supply or a

	UT) for 5 s	<5 % UT (>95 % dip in UT) for 5 s	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: U_T is the AC mains voltage prior to application of the test level.

Guidance and Declaration - Electromagnetic Immunity

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

Immunity	IEC60601	Complia	Electromagnetic environment -
test	test level	nce level	guidance
Conduced RF IEC61000-4 -6	3 Vrms 150 kHz to 80 MHz outside ISM bands	3 Vrms 150 kHz to 80 MHz outside ISM bands	Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter. Recommended separation distances: $\frac{1}{d} = \frac{1}{2} \sqrt{F}$
Radiated RF IEC61000-4 -3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	Recommended separation distances: 80 MHz \sim 800 MHz: $_{d=1.2}$ $_{\sqrt{P}}$ 800MHz-2.5GHz: $_{d=2.3}$ $_{\sqrt{P}}$ 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 $^{\rm a}$, 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:

Note 1: At 80 MHz to 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.

- ^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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.
- ^b Over frequency range 150kHz to 80MHz. For Resp field strength should be less than 1V/m

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 monitor as recommended below, according to the maximum output power of the communications equipment.

Rated max. output power	Separation distance according to frequency of the transmitter (m)			
of transmitter (W)	150 kHz - 80 MHz $d = 1.2\sqrt{P}$	80 MHz - 800 MHz $d = 1.2\sqrt{P}$	800 MHz - 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	1.20	1.20	2.30	
10	3.80	3.80	7.30	
100	12.00	12.00	23.00	

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 absorption and reflection from structures, objects and people.

FCC Warnning:

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

- (1) This device may not cause harmful interference, and
- (2) this device must accept any interference received, including interference that may cause undesired operation.

 Note: This equipment has been tested and found to comply

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no quarantee that interference will not occur in a particular installation. If this equipment does cause interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- -Reorient or relocate the receiving antenna.
- -Increase the separation between the equipment and receiver.
- -Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- -Consult the dealer or an experienced radio/TV technician for help.

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.



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