

# User's Manual

## Electrical Thermometer

Models: DT-20B、DT-20、DT-10B、DT-10



# 1. The Basics

This manual contains the instructions necessary to operate 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 and pulse rate 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 MDR 2017/745
	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 $\geq 12.5\text{mm}$ diameter, Against dripping ( $15^\circ$ tilted)
	Follow operating instructions

## 2.4 About the product

**Product name:** Electrical Thermometer

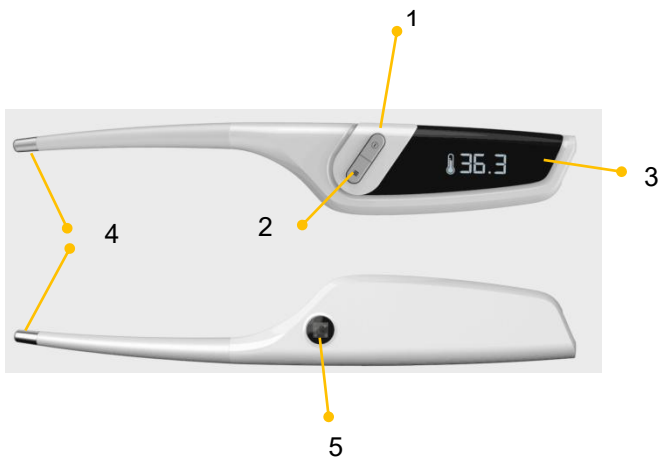
**Software release version:** V1

**Product model:**

Model and Configuration see the table below.

Function	DT-10	DT-10B	DT-20	DT-20B
Temperature	●	●	●	●
Pulse rate	△	△	●	●
Buetooth	×	●	×	●
Color	Blue	White	Blue	White

Note: ● Indicates that this function is available, × indicates that this function is not available, △ indicates optional function.



### **1. Temperature Key**

Short press the power on, and drip a sound, long press 3 seconds off;

Press to start/stop temperature measurement.

### **2. Pulse rate Key**

Short press the power on, and drip a sound, long press 3 seconds off;

Press to start/stop pulse rate measurement.

### **3. Display Screen**

It can visually display the temperature or pulse measurement results.

### **4. Probe Tip (Temperature sensor)**

By touching it, the temperature can be measured.

### **5. Pulse sensor**

Pulse rate can be measured by touching it.

Note: Type DT-10 and DT-10B have no pulse rate function.

### 3. Using the thermometer

#### 3.1 Charge the Battery

1. The device has a built-in lithium battery, which can be charged for repeated use;
2. The user connects one end of the USB cable to the power adapter, and inserts the other end into the host USB charging interface for charging. After the power is connected, charging animation will be displayed;
3. After charging, rest the screen and shut down;

*Note 1: Bluetooth is turned on when charging, and the host is in the power-on state. However, temperature and pulse rate measurement are not supported when charging.*

*Note 2: 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. Clean and disinfect the thermometer before use, and take a proper rest before measurement. If you feel unwell, you should consult your doctor immediately in addition to the measurement results of this device.
2. Please press the temperature/pulse button to start the product.
3. After starting up, the record is displayed on the screen, indicating that the value is the recent measured historical data. When the power is less than 3%, the display screen will prompt when starting up, and it will automatically shut down after 2



seconds.

### **3.3 Measurement**

Please follow the instructions below after starting the machine.

#### **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. Remain motionless, until a drops dripping sound (it takes about 20 seconds), the equilibrium temperature for prediction of the human body, if you want to get more accurate temperature value, should continue to measuring temperature, the thermometer will timely update the temperature display, until the actual human body equilibrium temperature is reached (measured temperature balance), and the process of oral general need 3-5 minutes.

#### **Measuring axillary temperature**

1. Put the temperature measuring head securely in your armpit.
2. Hold your arm down tightly at your side.
3. Remain motionless, until a drops dripping sound (it takes about 20 seconds), the equilibrium temperature for prediction of the human body, if you want to get more accurate temperature value, should continue to measuring temperature, the thermometer will timely update the temperature display, until the actual human body equilibrium temperature is reached (measured temperature balance), and the process of oral general need 5-10 minutes.

#### **Measuring rectal temperature**

1. Lubricate the probe tip with a water-soluble jelly for easier insertion;
2. 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

1. When the buzzer emits a beep sound (*Beep-short sound*), it indicates that the temperature measurement is finished. The display " $^{\circ}\text{C}/^{\circ}\text{F}$ " stops blinking, and the displayed temperature value is the result of the current body temperature.

2. Turn off the thermometer: press and hold ( $> 0.5$  seconds) to switch the thermometer off.

3. 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.

### 3.5 Pulse measurement

1. Place your finger on the pulse sensor and gently touch the pulse sensor for 30 seconds.

2. After the finger continues to contact the pulse rate probe for 10 seconds or more, the finger leaves the pulse rate probe to display the average pulse rate. At this time, the measurement results do not flicker, but emit drip-drip sound to save the data.

3. The measurement will automatically end after 1 minute. At this time, the measurement results will not flicker, but emit three beeps to save the data.

**Note 1:** Do not press the device too tightly against the skin as this may cause measurement errors.

**Note 2:** The pulse rate measurement range is 40Bpm-200Bpm. When the measured value is not within this range, the heart icon will flash and the pulse rate will be displayed. There is no

*indicator light, data will not be saved, and the voice will prompt the long drop for 3 seconds.*

**Note 3:** *User's finger was detected touching the pulse probe. Mode switching is not allowed.*

## **3.6 Data storage**

1. The host can save a total of 60 sets of data (pulse rate 30 + temperature 30).

2. During the measurement process, temperature and pulse rate will be stored in the host machine. Users can export the stored data through Bluetooth or device interface.

● Steps for data export by Bluetooth method:

It automatically turns on Bluetooth broadcast when the device is turned on, which supports users to transmit the host data of the thermometer to mobile devices (mobile phone /iPad) through Bluetooth communication for viewing and storage.

(1) Name of Bluetooth broadcast: Model + last four SN codes, such as DT-20T 8888

(2) Bluetooth connection mechanism: when the Bluetooth function and APP are opened at the same time, APP will automatically search and display the product model and SN number. Click the host with the corresponding Bluetooth broadcast name on APP to automatically connect.

(3) Data transmitted includes: Time information Power information Pulse rate/Body temperature measurement data

*Note :DT-10 and DT-20 are wired without Bluetooth function*

● Steps to realize data export:

1) Connect the small-end interface of the data cable to the charging interface of the thermometer.

2) Connect the other end of the data cable to the USB interface of the PC .

3) Implemented data export according to the instructions of the PC.

*Note: The data cable is a dedicated cable, please purchase additionally.*

## **3.7 Time Management**

1. The device supports Real-Time Clock function, so the device Clock will work correctly when the host is powered.
2. Time will be lost after absolute shutdown and then boot up after absolute shutdown.
3. The host time will become the time stored by the hardware on the host.

## **4. Cleaning and Disinfecting**

Do not use corrosive detergent to clean the unit.

Clean and disinfect the thermometer before and after each use.

### **4.1 Cleaning Process**

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

### **4.2 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

<b>Problem</b>	<b>Possible Cause</b>	<b>Recommended Action</b>
Can not boot	Very low battery	Please charge it according to the instruction
	The ambient temperature exceeds 40°C or below 5°C.	Please use within the working environment temperature range (5°C-40°C)
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.	Check whether the thermometer is placed in the correct position as described in "Using the thermometer".
	Thermometer moves while measuring temperature.	
	The measured position is not kept closed while the temperature measurement	

	is being performed.	
	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°C or below 30°C.	Please use within the measuring temperature range (30°C43.9°C)

## 6. Accessories

Model	Description
540-00240-00	MICRO USB charge cable

## 7. Specifications

<b>Classifications</b>		
EC Directive	MDR, 2017/745	
	RED, 2014/53/EU	
	ROHS 2.0, 2011/65/EU	
Degree protection against electrical shock	Type BF	
<b>Environmental</b>		
<b>Item</b>	<b>Operating</b>	<b>Storage</b>
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	
<b>Physical</b>		
Size	147mm× 24mm ×11.3mm(main unit)	
Weight	Less than 20 g (main unit)	
Wireless connectivity	Built-in Bluetooth 4.0 BLE	
Expected service life	5 years	
<b>Power Supply</b>		
Charge input	Micro USB, DC4.5V-5.5V	
Battery type	Rechargeable lithium-polymer battery	
Battery life	Temperature mode: no less than 9 hours (full) Pulse rate mode: not less than 10 hours (full mode)	
Charge time	2~3 hours.	

<b>Temperature measurement</b>	
Measurement method	Direct mode
Measurement site	Mouth,Axilla,Rectum
REFERENCE BODY SITE	Mouth,Axilla,Rectum
Temperature Unit	Celsius( $^{\circ}\text{C}$ ) or Fahrenheit( $^{\circ}\text{F}$ )
Temperature range	32.0 – 43.9 $^{\circ}\text{C}$ (89.6-111.0 $^{\circ}\text{F}$ )
Measurement accuracy	<p>Less than 35.8<math>^{\circ}\text{C}</math>, <math>\pm 0.3^{\circ}\text{C}</math>.(Less than 96.4<math>^{\circ}\text{F}</math>, <math>\pm 0.5^{\circ}\text{F}</math>.)</p> <p>35.8<math>^{\circ}\text{C}</math> to less than 37<math>^{\circ}\text{C}</math>,<math>\pm 0.2^{\circ}\text{C}</math>.(96.4<math>^{\circ}\text{F}</math> to less than 98.0<math>^{\circ}\text{F}</math>,<math>\pm 0.3^{\circ}\text{F}</math>.)</p> <p>37.0<math>^{\circ}\text{C}</math> to 39.0<math>^{\circ}\text{C}</math>, <math>\pm 0.1^{\circ}\text{C}</math>.(98.0<math>^{\circ}\text{F}</math> to 102.0<math>^{\circ}\text{F}</math>, <math>\pm 0.2^{\circ}\text{F}</math>.)</p> <p>Greater than 39.0<math>^{\circ}\text{C}</math> to 41.0<math>^{\circ}\text{C}</math>,<math>\pm 0.2^{\circ}\text{C}</math>.(Greater than 102.0<math>^{\circ}\text{F}</math> to 106.0<math>^{\circ}\text{F}</math>,<math>\pm 0.3^{\circ}\text{F}</math>.)</p> <p>Greater than 41.0<math>^{\circ}\text{C}</math>,<math>\pm 0.3^{\circ}\text{C}</math>.(Greater than 106.0<math>^{\circ}\text{F}</math>,<math>\pm 0.5^{\circ}\text{F}</math>.)</p>
<b>Pulse Rate measurement</b>	
Pulse Rate range	40 to 200 bpm
Pulse Rate accuracy	$\pm 2$ bpm or $\pm 2\%$ , whichever is greater
<b>Bluetooth RF</b>	
Frequency range	2.402 – 2.480 GHz
Max RF power	-10 dBm



## 8. Electromagnetic Compatibility

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

### **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).

<b>Guidance and Declaration - Electromagnetic Emissions</b>		
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.		
<b>Emission tests</b>	<b>Compliance</b>	<b>Electromagnetic environment - guidance</b>
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 establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC61000-3-2	Class A	
Voltage Fluctuations / Flicker Emissions IEC 61000-3-3	Complies	

**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.

<b>Immunity test</b>	<b>IEC60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment - guidance</b>
Electrostatic discharge (ESD) IEC 61000-4-2	$\pm 8$ kV contact $\pm 2$ kV, $\pm 4$ kV, $\pm 8$ kV, $\pm 15$ kV air	$\pm 8$ kV contact $\pm 2$ kV, $\pm 4$ kV, $\pm 8$ kV, $\pm 15$ 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 %.
Electrical fast transient/burst IEC 61000-4-4	$\pm 2$ kV for power supply lines $\pm 1$ kV for input/output lines	$\pm 2$ kV for power supply lines $\pm 1$ kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	$\pm 1$ kV line(s) to line(s) $\pm 2$ kV line(s) to earth	$\pm 1$ kV line(s) to line(s) $\pm 2$ 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 UT) for 5 s	$<5$ % 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 s	
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 test	IEC60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted 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: $d = 1.2 \sqrt{P}$
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~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 <sup>a</sup> , should be less than the compliance level in each frequency range <sup>b</sup> . 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.			
<sup>a</sup> 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.			
<sup>b</sup> 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 of transmitter (W)	Separation distance according to frequency of the transmitter (m)		
	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 Warning:**

FCC ID: 2AD XK-7611

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 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 guarantee that interference will not occur in a particular installation. If this equipment does cause harmful 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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