

Digital Basal Thermometer

DT005

Intended Use

The Digital Basal Thermometer is intended to measure the human body temperature for people of all ages, especially for women. It has a precise digital display, it can be used in a household environment and in clinics as reference.

Warnings and precautions

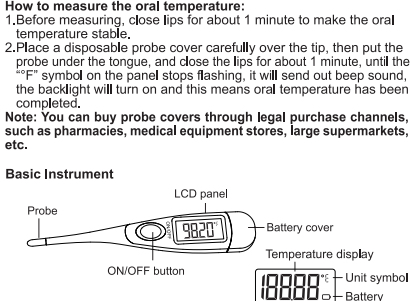
- Only use this thermometer once you have read and understood the instructions for use.
- Only use this thermometer for the specific purpose described in the instructions for use. Any misuse will void the warranty.
- This thermometer may be used for professional purposes or for personal home use.
- The probe covers should be discarded after each use.
- Using this thermometer is no substitute for consulting a doctor. Do not self-diagnose or self-medicate on the basis of the measurements without consulting your doctor. In particular, do not start taking any new medication or change the type and/or dosage of any existing medication without prior approval.
- Specially, do not take any new medication or change the type and/or dosage of any existing medication without consulting your doctor and obtaining your doctor's approval.
- Children must not be allowed to use this thermometer. Medical device is not a toy.
- Keep the product out of reach of children and newborns. Avoid small parts falling off and being swallowed.
- Keep new and used batteries out of reach of children, because a swallowed button cell can cause internal chemical burns in as little as 2 hours.
- If this thermometer is stored in a location that is cooler or warmer than where it is being used, let it sit in the patient's room for at least 15 minutes before taking the measurement.
- To ensure an accurate measurement, keep the thermometer away from direct exposure to the sun and keep it in a dust-free, dry and well-ventilated place at a temperature between 5°C (41°F) - 40°C (104°F). Do not use the thermometer in high humidity environments (>85%RH).
- Do not expose this thermometer to electric shocks.
- Do not expose this thermometer to extreme temperature conditions of greater than 55°C (131°F) or less than -20°C (-4°F).
- Do not take a measurement while or immediately after nursing a baby. Patients should not drink, eat or be physically active before/while taking the measurement.
- Avoid using thermometer with cell phones, electrocautery and MRI equipment, etc.
- This thermometer consists of high-quality precision parts. Do not drop the instrument.
- Protect thermometer from severe impact and shock. Do not twist the instrument or the probe.
- Do not use the thermometer if there are signs of damage on the probe or on the instrument itself. If damaged, do not attempt to repair the instrument! Please contact dealer.
- Clean the thermometer probe after each use.
- Never immerse the thermometer into water or other liquids (not waterproof). For cleaning and disinfecting please follow the instructions in the "Cleaning and disinfecting" section.
- The patient is an intended operator. The patient can use and maintain the device and its accessories according to the instructions for use.
- The thermometer and accessories are to be disposed of according to local regulations after their service life. Alternatively, they can be returned to the dealer or the manufacturer for recycling or proper disposal.
- Electrical components and batteries have heavy metal or chemicals which may do harm to environment, please follow the local law and regulation on its disposal.
- No modification of this thermometer is allowed.
- The thermometer is not suitability for use in an OXYGEN RICH ENVIRONMENT.
- Remove the batteries if you do not wish to use the unit for an extended period of time. Otherwise there is a danger that the batteries may leak.
- Keep the thermometer away from electromagnetic fields produced by objects such as microwave ovens, arc welders or induction heaters.
- The performance of the device may be degraded if patient temperature is below ambient temperature.
- The device should no longer be used after it reaches the expected service life (5 years, from the date of production) of the device. Please refer to "Disposal" to dispose of the device.
- Contact Berrcom ("manufacturer") or your dealer on the following issues:

- If an error occurs or if Digital Basal Thermometer is damaged. DO NOT attempt to repair the thermometer yourself, as this will void the warranty. Only have repairs carried out by authorized service partners. Berrcom will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to authorized service partners in parts repair.
- If you need assistance in setting up, using, or maintaining the thermometer. If you have unexpected operation or events to report.
- This Digital Basal Thermometer has been calibrated at the time of manufacture, and no periodic calibration is required if this product is actually operated according to these instructions. But the effects of degraded sensors that can degrade performance or cause other problems. If you doubt the accuracy of the measurement, please contact the manufacturer.
- This thermometer conforms to all of the requirements established in ASTM E1112. Full responsibility for conformance of this thermometer to the specification is assumed by Berrcom.

How to measure the oral temperature:
1. Before measuring, close lips for about 1 minute to make the oral temperature stable.
2. Place a disposable probe cover carefully over the tip, then put the probe under the tongue, and close the lips for about 1 minute, until the "F" symbol on the panel stops flashing, it will send out beep sound, the backlight will turn on and this means oral temperature has been completed.

Note: You can buy probe covers through legal purchase channels, such as pharmacies, medical equipment stores, large supermarkets, etc.

Basic Instrument



Included

- 1pc digital basal thermometer
- 1pc instructions for use
- 1pc storage box
- 1pc button cell (DC 3.0V)

Symbol	Description of symbol		
IP22	Degree of protection against harmful ingress of water and particulate matter 2 Protected and against solid foreign objects of 12.5mm Ø and greater 2 Protection against vertically falling water drops when ENCLOSURE tilted up to 15°		
	DISPOSAL: Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treatment is necessary.		
	Refer to instructions for use		Application part, Type BF
	Direct current		Model number
	Serial number		Medical device
	Manufacturer		Country of manufacture
	Date of manufacture		Unique device identifier

Setting And Function Of Menu

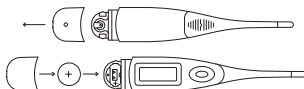
1. Choosing the temperature unit.
When the device is off, Press the "ON/OFF" button and hold down to switch units between "°F" and "°C".
2. Switch on the device
Press the "ON/OFF" button to switch on the thermometer, the screen panel displays for about 1 second.
The screen panel then displays the last 1 measurement value for about 1 second. Then displays "—°F", the symbol "°F" flashing.
3. Put the probe into the measurement site, the screen panel will display the temperature gradually rising. At the same time, "°F" symbol flashes which means the measurement is in progress. The "°F" symbol stops flashing and beep sound prompt is heard. At this moment the measurement is completed and has been recorded, the result displays on the screen panel.
4. Less than 89.60°F displays "Lo", backlight turns on and sends out one "Beep" sound, 89.60°F-109.40°F display measurement data, backlight turns on and sends out one "Beep" sound, Over 109.40°F displays "HI" backlight turns on and sends out one "Beep" sound.
5. After measuring, press the "ON/OFF" button to turn off the power. If not, it will automatically turn off in about 3 minutes.

Notes:

- To extend the battery life, it is recommended to turn off the thermometer after measurement is completed.
- Continuous measurement is not recommended. During continuous measurements, the battery voltage may drop significantly, and the low battery icon may appear. Leaving the device for 5 to 10 minutes will cause the battery voltage to correct itself back to the correct percentages.

Changing the Battery

1. The thermometer has 1pc CR1632 button cell.
2. When the screen displays and is flashing, the battery should be replaced. Remove the screws with a cross screwdriver, pull out the battery cover, and use a toothpick to pick out the battery.



3. When changing the batteries, take great care with the correct positioning.
A mistake with this could cause damage to the unit and compromise the guarantee of your Digital Thermometer.

Technical Specification

1. Normal operating condition:
Ambient temperature: 41°F - 104°F (5°C - 40°C)
Relative humidity: ≤85%RH
Pressure altitude: 700hPa - 1060hPa
2. Storage and shipping condition:
Ambient temperature: -4°F - 131°F (-20°C - 55°C)
Relative humidity: ≤95%RH
Pressure altitude: 700hPa - 1060hPa
3. Power: DC 3V (1 button cell 3.0 V CR1632 or comparable)
4. Measuring time: in 30 secs (ambient temperature 77°F, standard water bath)
5. Measuring range: 89.60°F - 109.40°F (32.00°C - 43.00°C)
6. Display resolution: 0.01°F (0.01°C)
7. Measuring precision:
89.60°F - 96.78°F (32.00°C - 35.99°C) ±0.36°F (±0.20°C)
96.80°F - 102.20°F (36.00°C - 39.00°C) ±0.18°F (±0.10°C)
102.22°F - 109.40°F (39.01°C - 43.00°C) ±0.36°F (±0.20°C)
8. Minimum time between two measurements: 60 seconds
9. Automatic power-off: About 3 minutes
10. The shelf life of the device: 5 years
11. Measuring site: oral
12. Mode of operation: Directed mode

Guidelines

This device complies with the ISO 80601-2-56 and the EN60601-1-2 and is subject to particular precautions with electromagnetic compatibility. This thermometer conforms to all of the requirements established in ASTM E1112. Full responsibility for conformance of this thermometer to the specification is assumed by Berrcom.

Cleaning and disinfecting

The thermometer only needs routine cleaning and disinfection, and period or times can depend on user's need. It is recommended to clean and disinfect once a week.
It is recommended, the probe is cleaned and disinfected before and after each use.
The method of cleaning and disinfecting is as follows:
①.Cleaning method: take a piece of nonwoven material or cloth saturated with distilled water to clean the surface of the probe and enclosure back and forth, until there's no visible soil and contamination,
②. Disinfection method: After cleaning, take another piece of nonwoven material or cloth saturated with 70% isopropyl alcohol to swab on the surface of the probe and enclosure back and forth. The nonwoven material or cloth saturated with 70% isopropyl alcohol should remain on the device at least for 15s,
After cleaning and disinfecting, the thermometer should dry at room temperature for 15s before use.

Troubleshooting

When message E shows on the screen, the sensor has failed, the thermometer cannot work. When message "  " shows on the screen, you need to change the battery.
Should a problem occur with your device, please contact you retailer. Do not attempt to repair this device yourself.

EMC Declaration

The ME EQUIPMENT or ME SYSTEM is suitable for home healthcare and clinic environments.
Warning: Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.
Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 inches (30 cm) to any part of the equipment DT005, including cables specified by the manufacturer. Otherwise the performance of this instrument could result in degradation:
1.All necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the accepted service life. Portable and mobile RF communication equipment may affect the performance of the DT005, avoiding strong electromagnetic interference when used, such as near mobile phones, microwave ovens, etc.
2.Guidance and manufacturer's declaration -electromagnetic emissions and Immunity.

Guidance and manufacturer's declaration -electromagnetic emissions and Immunity

Guidance and manufacturer's declaration - electromagnetic emissions	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Not applicable
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable

Table 2

Guidance and manufacturer's declaration - electromagnetic Immunity		
Immunity Test	IEC 60601-1-2 Test level	Compliance level
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
Electrical fast transient/burst IEC 61000-4-4	Not applicable	Not applicable
Surge IEC 61000-4-5	Not applicable	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Not applicable	Not applicable
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conducted RF IEC61000-4-6	Not applicable	Not applicable
Radiated RF IEC61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
NOTE UT is the a.c. mains voltage prior to applicable of the test level.		

Table 3

Guidance and manufacturer's declaration - electromagnetic immunity						
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	Test Frequency (MHz)	Band (MHz)	Service	Modulation	Modulation	Distance (m)
	385	380–390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3
	450	430–470	GMR5 460,FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3
	710	704–787	LTE Band 13,17	Pulse modulation 217 Hz	0.2	0.3
	745					
	780					
	810	800–960	GSM 800/900, TETRA 800, IDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3
	870					
	930					
	1720	1700–1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3
	1845					
	1970					
	2450	2400–2570	Bluetooth, WLAN,802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3
	5240	5100–5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3
	5500					
	5785					

Disposal

Observe the applicable regulations when disposing of the thermometer and batteries.
This thermometer must not be disposed of together with domestic waste. All users are obliged to hand in all electrical or electronic devices, regardless of whether or not they contain toxic substances, at a municipal or commercial collection point so that they can be disposed of in an environmentally acceptable manner.
Please remove the batteries before disposing of the thermometer. Do not dispose of old batteries with your household waste, but at a battery collection station at a recycling site or in a shop.

THE MANUFACTURER RESERVES THE RIGHT TO ALTER THE SPECIFICATIONS OF THE PRODUCT WITHOUT PRIOR NOTIFICATION.