

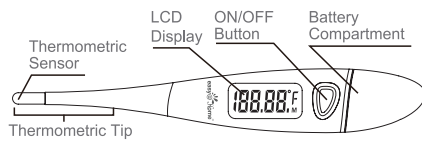
Digital Basal Thermometer

EBT-018

User Manual



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Intended Use:

The EBT-018 Digital Basal Thermometer is designed to accurately measure a person's body temperature in its regular mode. With its 1/100th Degree High Precision feature, it can assist women of childbearing age in monitoring their basal body temperature (BBT) effectively.

What is basal body temperature, and why do you need a digital basal thermometer?

Basal body temperature is your temperature when you are fully at rest. It is taken immediately upon awakening before any activity. Unlike traditional thermometers, basal body thermometers can measure with increased accuracy to easily detect your fertile window. The EBT-018 Digital Basal Thermometer is sensitive enough to measure subtle changes in body temperature with the high accuracy of $\pm 0.10^{\circ}\text{F} (\pm 0.05^{\circ}\text{C})$, and only takes about 60 seconds for the reading with proper use.

Note: It is important to record your temperature every day to identify your BBT trend for ovulation prediction.

Safety Precautions

- 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.
 - The user's temperature is below ambient temperature.
- Portable and mobile RF communications can affect the device.
- Do not use the devices in the MR environment.

Explanation of Display Error Messages

Error message	Problem	Solution
Lo	Temperature is lower than 90.00°F (32.00°C) after measurement.	Turn off, wait one minute and take a new temperature.
Hi	Temperature is higher than 109.99°F (42.99°C) after measurement.	Turn off, wait one minute and take a new temperature.
Error	The system is not functioning properly.	Remove the battery, wait for 1 minute and repower it. If the message reappears, contact customer service.
Battery icon flashing	Dead battery: Battery icon is flashing, the battery is drained.	Replace the battery.

ed to keep the thermometric sensor in mouth approximately 2 minutes regardless of beep sound. The highest measured temperature from that reading will appear on the LCD display. If the measurement is over 100.04 °F(37.80°C), the beeping will sound with a more rapid consistent buzzer sound to indicate fever. The thermometer will automatically shut off 10 minutes after the measurement is complete or you can manually shut the thermometer off with the ON/OFF button.

NOTE: Make sure to wait until the minimum measurement time is reached before reading your temperature. This is when you hear the last beep of the consecutive beeps. This is to ensure accuracy.

How do you switch between Celsius and Fahrenheit?

Turn the thermometer off; Press the ON/OFF button for 2 seconds to switch the measurement unit between °F and °C.

Memory Recall

The digital basal thermometer can only store the last measured value. The memory temperature reading may not save properly if following situations have occurred:

- Switched the measurement unit between "°F" or "°C" recently.
- The battery needs replacement.

Cleaning and Disinfecting

The best way to clean the thermometer tip is by applying a disinfectant (e.g. 75% ethyl alcohol) on a damp cloth. Do not immerse the thermometer under water or any other liquid. Never clean it with thinners, petrol or benzene.

How does your BBT help you pinpoint ovulation? What do you need to know?

Your BBT temps will likely surge right after ovulation, with a 0.40°F-1.00°F(0.20°C-0.60°C) or more shift.

What's Included:

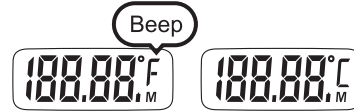
- 1 Thermometer
- 1 Manual
- 1 Protective case

Operating Instructions

- Disinfect the probe before each use with 75% ethyl alcohol on a damp cloth.
- Press the ON/OFF button to switch the device on.

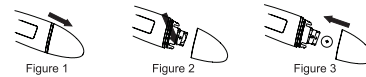
Step 1)

Initial Display: all of the symbols appear.



Battery Replacement

- Replace battery when "Lo" appears in the lower right corner of LCD display.
- Pull battery cover off as shown in Figure 1 (by sliding).
- Gently pull out plastic circuit board with battery chamber approximately 1 cm (See Figure 2)
- Use a pointed object such as a pen to remove old battery. 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 3)
- Slide battery chamber back into place and attach cover.



Battery Disposal

Please dispose of the battery in accordance with your local law and regulation.

Technical Data

Type: Digital Basal Thermometer

Measurement range: 90.00°F~109.99°F(32.00°C~42.99°C)

Measurement accuracy: $\pm 0.10^{\circ}\text{F} (\pm 0.05^{\circ}\text{C})$ during 95.90°F~100.40°F(35.00°C~38.00°C) at 64.40°F~82.40°F(18.00°C~28.00°C) ambient operating range; $\pm 0.20^{\circ}\text{F} (\pm 0.10^{\circ}\text{C})$ for other measuring and ambient operating range

Battery type:

One 1.5 V DC. button battery(size LR41or SR41, UCC 392)

Dimension: 13.9cm x 2.2cm x 1.3cm (L x W x H)

Step 2)

First Use Vs Second Use or Later-Display Differs Here.



First measurement (no past recorded temp)-Lo shows.

Any measurement after the first, recorded temp in memory shows.

Step 3)

Calibration temperature 97.70°F ~ 99.50°F(36.50°C ~ 37.50°C) with flashing "°F" or "°C" is displayed in both instances.



Step 4)

When the "°F" or "°C" symbols flashes with Lo sign, the temperature is ready for use. If ambient or baseline temperature is over 90.00°F (32.00°C), that real temperature will be displayed instead without a flashing "°F" or "°C". In both cases, you can now measure.



Step 5)

Temperature measurement will commence and the "°F" or "°C" symbol will flash.



Step 6)

The "°F" or "°C" symbol will stop flashing and stay on when the reading is ready.



- Place the thermometer tip under the tongue and close your mouth.

The thermometer tip should remain in constant contact with the tissue under the tongue, and the mouth should remain closed during measuring. The average measuring time is 60 seconds.

NOTE: Avoid eating or drinking just before measuring the temperature, as this will result in an inaccurate temperature reading.

- Consecutive beeps for approximately 10 seconds indicate that the measurement is complete.

Also, the "°F" or "°C" symbol will stop flashing when the measurement is completed. The displayed temperature can increase slightly if the measurement continues after the beep. So it is recommend-

Weight: Approx. 11 grams including battery

Service life: Three years

Ambient operating range:

41°F~104°F(5°C~40°C),15%~95%RH

Storage and transportation condition:

-4°F~131°F (-20°C~55°C),15%~95%RH

Explanation of Symbols

--	Direct Current		Manufacturing date
	Type BF Applied Part	REF	Catalog Number
	Refer to instruction manual		WEEE (Waste Electrical and Electronic Equipment)
	Storage and Transportation Humidity Limitation: 15% ~ 95% RH		Storage and Transportation Temperature Limit: -4°F~131°F(-20°C~55°C)
LOT	Batch Code	IP27	Ingress Protection Rating
	Recyclable		

FCC Information

Caution: Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user authority to operate the equipment.

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. 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 and correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the distance between the equipment and the receiver.
- Connect the equipment to an outlet on a circuit different from that to which the receiver is connected.
- Consult the manufacturer or an experienced electronic technician for help.

Standards

- ASTM E1112 Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature.
- 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.
- IEC 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 therequirements of IEC 60601-1-2(EMC), AAMI/ANSI ES60601-1(Safety) standards. And the manufacturer is ISO 13485 certified.

Warning

- Read instructions thoroughly before using digital thermometer.
- 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.
- If the unit has been stored at temperatures outside 41°F~104°F(5°C~40°C), leave it in 41°F~104°F (5°C~ 40°C) ambient temperature for about 15 minutes before using it.
- Contraindication: None.
- Do not use the thermometer in ear.
- Do not place the thermometer battery near extreme heat as it may explode.
- 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.
- After each use, disinfect the thermometer especially in case the device is used by more than one person.
- Keep new and used batteries out of the reach of children, to seek immediate medical attention if a battery is ingested, and to follow any other consensus medical advice.
- Choking Hazard-Small parts not for children under 3 years or any individuals who have a tendency to place inedible object in their mouths.

Calibration

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

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a 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 27,263 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands 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.

b 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 intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended 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 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.

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

Warranty

This product is warranted by the manufacturer for one year from the date of retail purchase. It does not cover damages or wear resulting from an accident, misuse or abuse, commercial use, or an unauthorized adjustment or repair of the product.

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 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		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.7GHz
	$d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$	$d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$	$d = \left[\frac{7}{E_1} \right] \sqrt{P}$
0.01	0.12	0.04	0.07
0.1	0.37	0.12	0.25
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.

NOTE1 At 80 MHz and 800 MHz, the separation distance for the 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.

Table 1

Guidance and manufacturers declaration - electromagnetic emission


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
Radiated emission 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.
Conducted emission 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	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

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 minimum distance between RF wireless communications equipment and the device as recommended below, according to the maximum output power of the communications equipment.

Frequency MNz	Maximum Power W	Distance	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
385	1.8	0.3	27	27	RF wireless 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 $E = \frac{6}{d} \sqrt{P}$ 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 metres (m). Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
450	2	0.3	28	28	
710	0.2	0.3	9	9	
745					
780					
810	2	0.3	28	28	
870					
930					
1720	2	0.3	28	28	
1845					
1970					
2450	2	0.3	28	28	
5240					
5900	0.2	0.3	9	9	
5785					

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.
- 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 system.

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 environment -guidance
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 100 kHz repetition frequency ± 1 kV for input/output lines	N/A	N/A
Surge IEC 61000-4-5	± 0.5 kV, ± 0.1 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 250/300 cycles at 0.	N/A	N/A
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m; 50Hz	30 A/m; 50Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: UT is the a. c. mains voltage prior to application of the test level.

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 environment -guidance
Conducted RF IEC 61000-4-6	3Vrms 150kHz to 80 MHz 6 Vrms 150 kHz to 80 MHz outside ISM handsa	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 $d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$ 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 metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000- 4-3	10 V/m 80 MHz to 2.7 GHz	10V/M	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, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1At 80 MHz and 800 MHz, the higher frequency range applies.

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