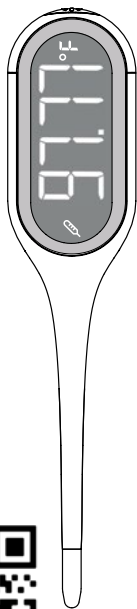


BBT-127

Basal Body Thermometer Instruction Manual



Scan for online copy or go to: iproven.com/bbt-127

Manual Version:
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Thank you for choosing iProven. Please read the instructions carefully in order to accurately and safely utilize this device.

The BBT-127 is an electronic thermometer intended for the measurement of human body temperature.

You can find the digital version of this manual on www.iproven.com/BBT-127



Professional Care Brought Home

Basal body temperature (BBT)

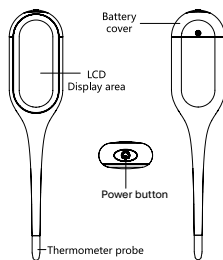
Your Basal body temperature (BBT) is your lowest body temperature in a 24-hour period. Ovulation causes a slight increase in BBT. This thermometer is sensitive enough to help you keep track of minute changes in your body temperature. By checking your basal body temperature, you can predict when you're more likely to conceive. For BBT charting, take your temperature first thing in the morning after at least three hours of uninterrupted sleep, preferably while still in bed. You can record your basal temperature using the BBT chart that you can find on www.iproven.com/BBT-chart

Special Features

The BBT-127 comes with a backlight display so that you can easily read your results even in the dark. Take your measurement and get your results in around 60 seconds. The thermometer saves up to 30 measurements in its memory. A large LCD display screen makes it easy to read your temperature. This device is medically certified for accurate and reliable results.

Components of the device

The thermometer consists of a plastic shell, thermistor, PCBA, buzzer chip, LCD display, backlight, and battery.



Display



Instructions for use

It is recommended to take your basal body temperature orally as there are different heat zones in the mouth. This is also the most convenient measurement position for daily BBT measurements. An axillary (underarm) measurement is not precise enough and a rectal measurement is inconvenient.

1. Press the power button to put on the thermometer. When the °F or °C icon blinks on the screen, place the temperature sensor of the thermometer under your tongue, far back to the left or right. Keep the thermometer tip constantly in contact with the tissue under your tongue.
2. Close your mouth and breathe evenly through your nose to prevent your measurement from being influenced by inhaled or exhaled air.
3. Once you hear a beep, the measurement is complete. Your reading will be automatically saved in the memory. The backlight will stay on for 10 seconds before the device turns off.
4. You can note the result on your copy of the iProven BBT Chart or in a smartphone app. You can also do this later using the memory function.

Memory

You can store up to 30 readings in the memory.

With the thermometer off, press and hold the power button for 3 seconds, until the screen shows --.--, and then goes blank. Then release the button to enter the memory recall mode.

The last measurement is then shown. The most recent record is shown first (number 1) followed by the previous measurements. Press the button again to skip to the next stored result, and so on. Press and hold the button for 3 seconds to exit Memory Recall mode and enter into measuring mode. Then click the button to power off.



Replacing the battery

The BBT-127 uses a CR1632 button battery which is included with your thermometer.

1. To replace the battery, turn your screwdriver counterclockwise to remove the screw on the battery cover.
2. Gently remove the battery cover, then take out the empty battery.
3. Follow the battery polarity mark in the battery compartment and put the new battery into the battery compartment. When installing, pay attention to the positive and negative polarity.
4. Reinstall the battery cover, and use a screwdriver to turn clockwise to tighten the screws.

Switching between °F or °C

1. Make sure the thermometer is off. Then hold the button for 8 seconds.
2. After 8 seconds the device will switch from to or vice versa. When the required unit is displayed, release the button and continue with your measurement.



Storage

- Do not drop or shake this device as it may cause measurement deviation or product failure.
- Do not disassemble, repair or modify the device.
- Keep this device out of reach of children to prevent the swallowing of batteries or small parts.
- Do not store the device in direct sunlight or a place with humidity, dust, close to a fire or vulnerable to vibrations.
- If the thermometer is not used for a long time, the battery should be removed to prevent leakage.
- Do not throw the thermometer and its batteries into a fire, this can cause an explosion.

Caution

- This product is only for monitoring and self-testing body temperature and cannot be used for disease diagnosis, so please follow the guidance of the doctor.
- To ensure the accuracy of the measurement, please set the thermometer in the normal working environment for more than 30 minutes, so that it calibrates to the ambient temperature before measuring.
- Do not measure under a strong electromagnetic interference environment (such as a working microwave oven, induction cooker, mobile phone, etc.) as this may cause incorrect measurements or inability to complete measurement.
- Taking medications prior to your measurement can cause a change in the body temperature, which may cause measurement bias.
- When measuring, please stay quiet and steady, according to the measurement method shown in the specification, so as not to cause the measurement deviation caused by improper operation.
- Continuous measuring may lead to results with a small error, which is a normal phenomenon. It is recommended that the maximum continuous measurement in a unit of time is 3 times.
- Different types and brands of temperature measuring products do not have comparative value. It is recommended to use the same temperature measuring product to observe temperature changes in order to better grasp the temperature changes.



Maintenance

- Use a soft, damp cloth to clean the device.
- Disinfect the thermometer probe regularly. You can do this by wiping the probe with a cotton ball or cloth damp with >75% medical alcohol before each measurement to prevent cross-infection.
- We recommend using the thermometer for BBT measurement for a single user. If multiple people have to use the thermometer, it is recommended to disinfect the probe before and after every measurement.
- Do not wash with water or use cleaners, diluents, or volatile liquids containing abrasives.
- At the end of the product's service life dispose of any waste in accordance with local laws and regulations.
- Please do not disassemble and adjust the thermometer.
- The thermometer has been tested and calibrated at the time of manufacture. If you have any questions about the function or measurement accuracy of the product, please contact iProven customer support.






Product Specifications

Product name	Digital Clinical Thermometer
Product model	FDTH-VO-13
Ref	BBT-127
Power supply voltage	DC 3V, 1×3.0V CR1632 batteries
Measurement type	BBT mode
Measuring site	Oral
Measuring range	32.00 °C ~ 42.90 °C (89.60 °F ~ 109.22 °F)
Measuring accuracy	(35.00 °C ~ 42.00 °C) ± 0.10 °C (95.00 °F ~ 107.60 °F) ± 0.18 °F Outside this range: ± 0.20 °C (± 0.36 °F)
Display resolution	0.01 °C (0.01 °F)
Repeatability error	≤ 0.20 °C (± 0.36 °F)
Environmental Specification	Temperature: 5 °C ~ 40 °C (41 °F ~ 104 °F) Relative humidity: 15% ~ 95%RH, No condensing Atmospheric pressure: 70 kPa ~ 106 kPa
Transportation/storage environmental conditions	Temperature: 25 °C ~ 55 °C (13 °F ~ 131 °F) Relative humidity: 15% ~ 95%RH, No condensing Atmospheric pressure: 70 kPa ~ 106 kPa
Temperature unit	°C / °F
Memory capacity	30 records
Battery life	1 year/1000 measurements
Product size	28mm × 13mm × 131mm
Net Product	17g (battery free)
Period of validity	5 years (excluding vulnerable parts)
Software version	V2.0
Grade of waterproof	IP22
Electric shock	Internally powered ME equipment
Operational mode	Continuous operation
Applied part	Type BF applied part, including the whole unit.











Display and sound patterns

Screen display	Sound patterns	Representation of information
Temperature : 32.00 °C ~ 37.59 °C (89.60 °F ~ 99.67 °F)	1 beep	Target temperature values for this measurement
Temperature : 37.60 °C ~ 42.90 °C (99.68 °F ~ 109.22 °F)	3 beeps	Target temperature values for this measurement
Err	4 beeps	Abnormal temperature rise rule (e.g. measurement process shedding)
Hi	4 beeps	The measurement temperature is higher than the maximum value of the thermometer range
Lo	4 beeps	The measured temperature is below the minimum value of the thermometer range

Troubleshooting

Fault Description	Possible causes	Solution
Battery runs out		Please replace the new battery and close the compartment
The screen does not react when the power is on or equipped with batteries.	Battery installation error	Please install the battery correctly according to the positive and negative pole mark in the battery bin.
	After reloading the battery, the screen remains blank	Please contact: iProven customer support
 All ICONS on the screen flicker	Hardware failure	Please contact: iProven customer support
 The battery icon appears on the screen and flashes	Too low battery voltage, causing failure to boot.	Please replace the new battery and restart.
 Battery icon appears on the screen	Battery power is running out.	Please replace the new battery as soon as possible.
 Abnormal temperature rise rule (e.g., measurement process shedding).	Abnormal temperature rise rule	Please restart the measurement. The thermometer should be properly placed at the measuring site according to the instructions.
 The measurement temperature is higher than the maximum value of the thermometer range.	The measurement temperature is higher than the maximum value of the thermometer range.	Please check the measurement target is correct and re-measure again.

Explanation of standardized symbols

	Complies with the European Medical Device Directive (93/42/EEC), Notified Body is SGS Belgium NV.
	Authorized representative in the European Community.
	Attention: see Instructions for use!
	Caution! Consult accompanying documents.
	Type BF applied parts
	Batch code
	Serial number
	Manufacturer information:
	IP code of the device: this device's grade of against ingress of solid foreign objects
	Disposal in accordance with Directive 2002/96/EC (WEEE)

Electromagnetic Compatibility Information

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.

Not use of accessories, transducers and cables other than those specified or provided by the manufacturer of this BBT-127 could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the BBT-127, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. Guidance and manufacturer's declaration – electromagnetic emission – for all EQUIPMENT AND SYSTEMS


The BBT-127 is intended for use in the electromagnetic environment specified below. The customer or the user of BBT-127 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The BBT-127 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 BBT-127 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	Class A	
Voltage fluctuations flicker emissions IEC 61000-3-3	Complies	

The BBT-127 is intended for use in the electromagnetic environment specified below. The customer or the user of the BBT-127 should assure that it is used in such an environment.

Immunity test	IEC 60601	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 ± 1 kV for input/output lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U _n ; 0,5 cycle U _n ; At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U _n ; 1 cycle and 70 % U _n ; 25/30 cycles Single phase: at 0° 0 % U _n ; 250/300 cycle	0 % U _n ; 0,5 cycle U _n ; At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U _n ; 1 cycle and 70 % U _n ; 25/30 cycles Single phase: at 0° 0 % U _n ; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the BBT-127 requires continued operation during power mains interruptions, it is recommended that the BBT-127 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_n is the a.c. mains voltage prior to application of the test level.

The BBT-127 is intended for use in the electromagnetic environment specified below. The customer or the user of the BBT-127 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	3 Vrms 150 kHz to 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz	3V 150 kHz to 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the BBT-127 (including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{12}{V_1} \right] \sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	$d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P}$ 800 MHz to 2.7 GHz where p is the maximum output power rating of the transmitter in watts (W) according to the 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. ³⁾ Interference may occur in the vicinity of equipment marked with the following symbol: 

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

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

a. The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 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. 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 BBT-127 is used exceeds the applicable RF compliance level above, the BBT-127 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the BBT-127 .

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

Recommended separation distances between portable and mobile RF communications equipment and the BBT-127				
R a t e d maximum output of transmitter W	Separation distance according to frequency of transmitter m			
	150 kHz to 80 MHz outside ISM and amateur radio bands $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$	150 kHz to 80 MHz in ISM and amateur radio bands $d = \left[\frac{12}{V_1} \right] \sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$	800 MHz to 2.7 GHz $d = \left[\frac{7}{E_1} \right] \sqrt{P}$
0.01	0.12	0.20	0.035	0.07
0.1	0.38	0.63	0.11	0.22
1	1.2	2.00	0.35	0.70
10	3.8	6.32	1.10	2.21
100	12	20.00	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.

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.

Standard List	
BBT-127 complies with the following standards	
IEC 60601-1	Medical electrical equipment Part 1: General requirements for basic safety and essential performance.
IEC 60601-1-2	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.
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.
ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
E N I S O 15232-1	Medical device – symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements.
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.

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This Limited Warranty covers any defects in materials or workmanship under normal use during the Warranty Period. iProven will either replace the product or repair the product at no charge, using new or refurbished replacement parts. The Warranty Period of this iProven product is 2 years from the date of purchase. A replacement product or product part assumes the remaining warranty of the original product purchase. This Limited Warranty does not cover batteries and packaging, nor any problem that is caused by conditions, malfunctions, or damage not resulting from defects in material or workmanship.

If for any reason you are unsatisfied with our product, feel free to reach out to iProven directly. We offer a refund or will replace the product for free within 100 days from your purchase.

Contact us: support@iproven.com



Manufactured for iProven
Burg. de Raadtsingel 67b
3311 JG Dordrecht
The Netherlands