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Model: HB500

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## English

## Introduction

Bion non-contact temple thermometer is intended for measuring human body temperature; while is not intended as a substitute for consultation with your physician. This thermometer has been clinically tested in the hospital based on the regulatory standard protocol and proven to be safe and accurate when used in accordance to the operating instruction manual.

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- The quality of the infrared temple thermometer has been verified and conforms to the provisions of the EC council directive 93/42/EEC (Medical Device Directive) Annex I essential requirements and applied harmonized standards. Comply with ASTM E1965-98.
- This thermometer converts the temple temperature to display its "oral equivalent." (according to the result of the clinical evaluation)
- Please read the instruction manual carefully before using the product and be sure to keep this manual.

Function The thermometer has been designed for practical use. It's not meant to replace a visit Temple to the doctor. Please also remember to com-. Temperature pare the measurement result to your regular body temperature. The object mode shows the actual, unadjusted surface temperatures, which is differ-Object ent from the body temperature. It can help Mode you to measure any object other than body surface, for example the baby's milk If thermometer detects a body temperature

Fever Alarm Fever Alarm  $=> 37.5^{\circ}C(99.5^{\circ}F)$  there will be four beeps sound with flashing reading to warn the user for potential fever.



temple/object temperature 2. Hole 3. Backlight LCD Display 4. On/Off/Memory Button 5. Battery Cover



The temple temperature measurement mode
 The object temperature measurement mode
 °C/°F scale
 Battery
 Temperature display

#### How to measure temple temperature

1. Always make sure the probe is clean, and without damage.

- 2. Press "ON/OFF/Memory" button to power on the device.
- 3. Vertically aim the thermometer at the temple with a distance of less than 5 cm. If the temple is covered with hair, sweat or dirt, remove the obstacle from the temple to improve the measuring accuracy.
- 4. Press the "Start" button to take temperature. Measurement is complete when you hear a long beep sound.
- 5. Read the recorded temperature from the LCD display.
- 6. Clean the probe after each use to ensure an accurate reading and avoid cross contamination. (See the section of Care and Cleaning for details.)
- 7. Remember to put in the storage case when not in use.



### How to measure object temperature

No matter the thermometer unit is powered on or off, for changing the measuring target between the temple and Object, please open the battery cover and set the slide switch locating on the top of the battery to the corresponding measuring mode or target before the next measurement. After setting an new measuring target, the measuring site display icon will also be switched accordingly.

Note:

- 1. Applications include temperature measurements for Water, Milk, Cloth, Skin or other object.
- 2. This mode shows the actual, unadjusted object temperatures, which is different from the body temperature

 Forehead temperature
 Object temperature

 Image: Constraint of the second secon

#### Switching between Fahrenheit and Celsius

1. Make sure the device is off. (Or you can turn off the device by pressing and holding the "On/Off/Memory" button for 3 seconds.)

- 2. Hold onto the "Start" button, then press and hold the "On/ Off/Memory" button until °C appears on the LCD.
- 3. Press the "On/Off/Memory" button to select the desired scale °C or °F, once you decide the scale, wait for 5 seconds and the setting will be confirmed while you will hear 2 short beep sounds.

### **Memory function**

There are total 9 set memories for measurement records. If the reading of the thermometers is within the normal temperature range of 34 °C to 42.2 °C (93.2 °F to 108°F), when the measurement is done, the measurement data is saved into memory.

• Press " Memory" button to repeatedly to recall each temperature memory.

#### Care and cleaning

- 1. The probe is the most delicate part of the thermometer. Use with care when cleaning the lens to avoid damage.
- 2. After the measurement, please use the cotton swab with the Alcohol (70% concentration) to clean the inside of the probe, including lens and metal parts.
- 3. Allow the probe to fully dry for at least 5 minutes.
- 4. Storage temperature range: It should be stored at room temperature be-
- tween -25~+55°C, (-13°F~131°F) RH<=95% 5. Keep the unit dry and away from any liquids and direct sun-
- light.
- 6. The probe should not be submerged into liquids.
- 7. Please check the device if damaged once it falls. If you can't make sure of it, please send the complete device to the nearest retailer for re-calibration.
- 8. Holding the thermometer too long may cause a higher ambient temperature reading of the probe. This could make the body temperature measurement lower than usual. Please try not to touch the thermometer probe part for avoiding the incorrect reading.

#### **Battery Replacement**

- 1. Open the battery cover: use thumb to push battery cover out.
- 2. Hold the device and flip the battery out.
- 3. Insert the new battery down with the correct electrical polarity.
- 4. Place back the battery cover.
- 5. Keep the battery away from children.





#### **Troubleshooting:**

Error Message	Problem	Solution	
<b>EE</b>	The system is not functioning properly.	Unload the battery, wait for 1 minute and re- power it. If the message reappears, contact the retailer for service.	
<b>E</b>	Exceeding operating temperature range	Allow the thermometer to rest in a room for at least 30 minutes at room temperature: 15~40°C (59~104°F).	
H,	<ol> <li>In Temple mode: Temperature taken is higher than +42.2°C (108°F)</li> <li>In Object mode: Temperature taken is higher than 99.9°C (199.9°F)</li> </ol>	Please select the target within specifications. If a malfunction still exists, please contact the near- est retailer.	
Lo	<ul> <li>(1) In Temple mode: Temperature taken is lower than +34°C (93.2°F)</li> <li>(2) In Object mode: Temperature taken is lower than 0°C (32°F)</li> </ul>	Please select the target within specifications. If a malfunction still exists, please contact the near- est retailer.	
	Device cannot be powered on to the ready stage.	Change with a new bat- tery.	

#### Specification

Temperature measurement range	Temple mode: 34~42.2°C (93.2~108°F) Object mode: 0~99.9°C (32~199.9°F)
Accuracy	For temple mode :+/-0.3°C (0.5°F) dur- ing 34~42.2°C (93.2~108°F). For object mode :+/- 1°C or +/- 2°F when measuring the object tem- perature between 0~99.9°C (or 32~199.9°F)
Operating condi- tion	Temple mode :15~40°C (59~104°F), RH<=95%; 700~1060 hPa Object mode :10~40°C (50~104°F), RH<=95%; 700~1060 hPa
Storage and trans- portation condi- tion	-25~55°C (-13~131°F), RH<=95%; 700~1060 hPa
Memory	9 set
Display resolution	0.1
Battery	CR2032 x 1
Weight (without battery)	65 g (without battery)
Size	13.5 cm(L) x 3.55 cm(w) x 4.2 cm(H)
Auto shutdown	60 sec.
Battery life	3000 consecutive measurements or 1 year with 1-2 measurements per day including stand-by mode.
Safety classification	Type BF equipment
IP Classification	IP22 Protection against water and dust

\*Dispose of device and batteries according to local regulations

#### Caution

- 1. Only use the device once you have read and understood these instructions for use. Keep the instruction manual for use.
- 2. The thermometer and patient needs to stay in the room in which the measurement is taken for at least 30 minutes before use.
- It is recommend that you always take the temperature in the same location, since temperature readings may vary according to the locations.
- 4. It is recommended that three temperatures are taken and the highest one taken as the reading if:
- a) New born infants
- b) Children with a compromised immune system and for whom the presence or absence of fever is critical.
- c) When the user is learning how to use the thermometer for the first time until he/she has familiarized himself/ herself with the instrument and obtains consistent readings.
- d) The reading is extremely low.
- Do not take a measurement while drinking, eating, sweating or exercising.
- 6. Do not take measurement while or immediately after nursing.
- Children is not allowed to use the device. Medical products are not toys.
- 8. Influences on body temperature
- a) A person's individual metabolism
- b) Age: Greater temperature fluctuations occur faster and more often in children. Normal body temperature decreases with age.
- c) Clothing
- d) Outside temperature
- e) Time of day: Body temperature is lower in the morning and increases throughout the day towards evening.
- f) Activities: Physical and, to a lesser extent, mental activities increase body temperature.
- 9. This device is not shock-protected. Do not drop or expose to heavy shock this device.
- 10. Do not bend the device.
- 11. Do not disassemble or make modifications the device.
- 12. Please do not dispose of the product in the household waste at the end of its useful life. Disposal can take place at your local retailer or at appropriate collection points provided in your country.
- 13. Do not boil the probe.
- 14. Do not use the device if it operates irregularly or any error massage showed.
- 15. Do not use thinner or benzene to clean the device.
- 16. Wipe the device clean before storing.
- 17. When take the device from storage at below or above 15~40°C(59~104°F), place it in 15~40°C(59~104°F) temperature range for at least 30 minutes before use.
- 18. Remove the battery if the device will not be used for a long time.
- 19. If this device is used according to the operation instruction, periodic re-calibration is not required. If you still have questions, please send the complete device to dealers.

- 20. Do not use this device for diagnosis or treatment of any health problem on disease. Measurement results are for reference only. Contact your physician if you have or suspect any medical problems. Do not change your medications without the advice of your physician or healthcare professional.
- 21. This device may not meet its performance specification if stored or used outside temperature and humidity ranges specified in specifications.
- 22. Battery should not be charged or placed into extreme heat as it may explode.
- 23. The thermometer contains small parts (ex: battery, etc.) that can be swallowed by children. Therefore never leave the thermometer unattended to children.
- 24. Be sure to consult a doctor if you feel that your health is in poor condition.
- 25. Do not judge your health only on the presence or absence of a fever.

#### EMC guidance and manufacturer's declaration

	Guidance	and manufacturer	's declaration-electromagnetic emissions
The HB500 is in	tended for use in the	electromagnetic e	environment specified below. The customer or the user of the HB500
should assure th	nat it is used in such a	an environment.	
Em	ission test	Compliance	Electromagnetic environment-guidance
RF emissions CI	SPR 11	Group 1	The HB500 uses RF energy only for its internal function. Therefore,
			its RF emissions are very low and are not likely to cause any inter-
			ference in nearby electronic equipment.
RF emissions Cl	SPR 11	Class B	The HB500 is suitable for use in all establishments, including
Harmonic emiss	sions IEC 61000-3-2	Not applicable	domestic establishments and those directly connected to the public
Voltage fluctuat	tions/flicker emission	is Not applicable	low-voltage power supply network that supplies buildings used for
IEC 61000-3-3			domestic purposes.
	Cuidanca		/
	Guidance	and manufacturer	's declaration-electromagnetic immunity
The HR200 is in	tended for Use in the	electromagnetic e	nvironment specified below. The customer of the user of the hbouu
should assure th	Tal ILIS USED IN SUCH (	an environment.	The second section of the second section of the second sec
immunity test	IEC 6060 I test level	Compliance level	Electromagnetic environment-guidance
			Portable and mobile RF communications equipment should be
			used no closer to any part of the HBSUU, including capies, than the
			recommended separation distance calculated from the equation
	21/		applicable to the frequency of the transmitter.
Conducted KF	3 Vrms	Matanalisahla	Kecommended separation distance:
IEC 6 1000-4-6	150 KHz to 80 MHZ	Not applicable	$a = 1,2 \sqrt{P}, a = 1,2 \sqrt{P}$ 80MHz to 800 MHz, $a = 2,3 \sqrt{P}$ 800MHz to 2,5 GHz
Radiated RF	3 V/m	3 V/m	Where P is the maximum output power rating of the transmitter in
IEC 61000-4-3	80MHz to 2,5 GHz		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, <sup>a</sup> should be less than the compliance level in each fre-
			quency range. <sup>b</sup> Interference may occur in the vicinity of equipment
			marked with the following symbol: (😭)
NOTE1: At 80 M	Hz and 800 MHz, the	e higher frequency	range applies.
NOTE2: These g	uidelines may not ap	oply in all situation	<ul> <li>Electromagnetic propagation is affected by absorption and reflec-</li> </ul>
tion fron	n structures, objects a	and people.	
a. Field strengt	hs from fixed transm	nitters, such as bas	e stations for radio (cellular/cordless) telephones and land mobile
radios, amateu	r radio, AM and FM	radio broadcast a	and TV broadcast cannot be predicted theoretically with accuracy.
To assess the e	lectromagnetic envir	ronment due to fix	ed RF transmitters, an electromagnetic site survey should be con-
cidorod If the r	mancurad field strand	ath in the location	in which the URSOO is used exceeds the applicable PE compliance

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 HB500 is used exceeds the applicable RF compliance level above, the HB500 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the HB500. b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

	Guidance and manufacturer's declara	ation-electromagn	etic immunity
The HB500 is intended	for use in the electromagnetic environm should assure that it is used	ent specified belov in such an environ	v. The customer or the user of the HB500 ment.
Immunity test	IEC 60601 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 tran- sient/burst IEC 61000- 4-4	± 2kV for power supply lines ± 1kV for input/output lines	Not applicable Not applicable	Mains power quality should be that of a typical commercial or hospital environ- ment.
Surge IEC 61000-4-5	± 1kV differential mode ± 2kV common mode	Not applicable Not applicable	Mains power quality should be that of a typical commercial or hospital environ- ment.
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	Not applicable Not applicable Not applicable Not applicable	Mains power quality should be that of a typical commercial or hospital environ- ment. If the user of the HB500 requires continued operation during power mains interruptions, it is recommended that the HB500 be powered from an uninterruptible power supply or a bat- tery.

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

Recommended separation distance between portable and mobile RF communications equipment and the HB500 The HB500 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the HB500 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the HB500 as recommended below, according to the maximum output power of the communications equipment.

ted maximum output	Separation distance according to frequency of transmitter / m			
wer of transmitter / W	150 kHz to 80 MHz / d=1,2√P	80 MHz to 800 MHz / d=1,2√P	800 MHz to 2,5 GHz / d=2,3	
0,01	0,12	0,12	0,23	
0,1	0,38	0,38	0,73	
1	1,2	1,2	2,3	
10	3,8	3,8	7,3	
100	12	12	23	

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 sower rating of the transmitter in watts (W) according to the transmitter manufacturer.

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

#### Warranty Terms & Conditions (www.bionmedicalgroup.com/warranty)

 Product is entitled to 3 years off-site warranty coverage against manufacturing defects from the date of purchase, with the original invoice/receipt as proof of purchase.

• This warranty does not cover damages or defects arising from accident, misuse, mishandling, improper installation, any manner of tampering, usage of wrong electrical supply/voltage, corrosion/fungus, rusting or stains, any unauthorized repair or modification to the product, act of god, fire, civil unrest and consequential damages.

This warranty does not cover normal wear and tear.Batteries are not covered under this warranty.

•This warranty shall be null and void in the event that the serial number on the product has been altered or removed.

 WARNING: The symbol on this product means that it's an electronic product and following the European directive 2012/19/EU the electronic products have to be dispose on your local recycling centre for safe treatment.

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