



BT-200(Hi-bebe)

Fetal Doppler

Operation manual



BT-200

Keep this manual for future reference

P/N: 200-ENG-OPM-EUR-R06

Proprietary Material

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Section 1 Safety

1.1 Instructions for the Safe Operation and Use of the BT-200

- Examine the device and any accessories periodically to ensure that there is no visible evidence of damage that may affect patient safety or performance. The recommended inspection interval is once per week or less. Do not use the device if there is any visible sign of damage.
 - Do not attempt to service the HI•bebe Doppler BT-200. Only qualified service personnel by Bistos Co., Ltd. should attempt any needed service.
 - HI•bebe Doppler BT-200 is not specified or intended for operation during the use of defibrillators or during defibrillator discharge.
 - HI•bebe Doppler BT-200 is not specified or intended for operation in the presence of electrosurgical equipment.
 - HI•bebe Doppler BT-200 is not specified or intended for operation in conjunction with any other type of monitoring equipment except the specific devices that have been identified for use in this Operation Manual.
 - Do not operate the HI•bebe Doppler BT-200 if it fails to pass the power on procedure.
-

**CAUTION**

- Be informed that it may cause no harm in life but lead to injury against the “Caution” sign.
-

NOTE

- Be informed that it may cause a potential hazardous situation which, if not avoided, may result in minor or moderate injury.
-

1.2 Warnings



WARNING

- **EXPLOSION HAZARD** - Do not use the HI•bebe Doppler BT-200 in a flammable atmosphere where concentrations of flammable anesthetics or other materials may occur.
- **SHOCK HAZARD** - HI•bebe Doppler BT-200 doesn't have protection against the burn injury caused by RF Surgical equipment. Do NOT use this product along with RF Surgical equipment.
- Use of cable or accessories which do not supplied or specified by manufacturer can cause degrade of EMC characteristics or negative effect on HI•bebe Doppler BT-200.
- HI•bebe Doppler BT-200 should not be used any active implantable or body- worn medical device, including pacemakers, ICDs, neurostimulators, and insulin pumps simultaneously.
- No modification of this device is allowed. Do not modify this device without authorization of the manufacturer. If this device is modified, appropriate inspection and test shall be conducted to ensure continued safe use of device.

1.3 Cautions

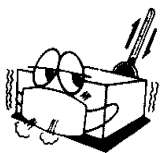
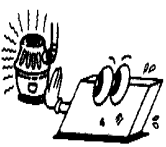
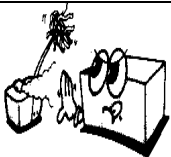
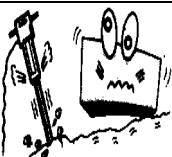
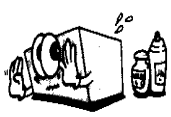
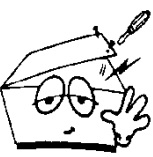


CAUTION

- The relevant law restricts this device to sale by or on the order of a physician.
- Keep the operating environment free of dust, vibrations, corrosive, or flammable materials, and extremes of temperature and humidity. The unit should be kept clean and free of transducer gel and other substances.
- HI•bebe Doppler BT-200 classified as internally powered equipment according to IEC 60601-1 Medical Electrical Equipment - Part 1: General requirements for basic Safety and essential performance
- HI•bebe Doppler BT-200 is classified as Class B according to IEC60601-1-2 Medical Electrical Equipment - Part 1-2 : General requirements for basic Safety and essential performance – Collateral standard: Electromagnetic compatibility

General Precaution on Environment

- Do not keep or operate the equipment under the environment listed below.

	Avoid placing in an area exposed to moisture. Do not touch the equipment with wet hand.		Avoid exposure to direct sunlight
	Avoid placing in an area where there is a high variation of temperature. Operating temperature ranges from 10°C to 40°C. Operating humidity ranges from 30% to 85%.		Avoid in the vicinity of Electric heater
	Avoid placing in an area where there is an excessive humidity rise or ventilation problem.		Avoid placing in an area where there is an excessive shock or vibration.
	Avoid placing in an area where chemicals are stored or where there is in danger of gas leakage.		Avoid dust and especially metal material into the equipment.
	Do not disjoint or disassemble the equipment. BISTOS Co., Ltd. does not take responsibility of it.		Power off when the equipment is not fully installed. Otherwise, the equipment could be damaged.

1.4 Definitions of Symbols

Symbol	Description
	This symbol identifies a safety note. Ensure you understand the function of this control before using it. Control function is described in the operation manual.
	Type BF Equipment
IPX2, IPX7	Degree of Waterproof
	This symbol indicates the manufacturer.
	This symbol indicates the serial number of the device.
	This symbol indicates the authorized representative in the European Community of manufacturer.
	This symbol indicates the temperature limitation for operation, transport and storage.
	This symbol indicates the humidity limitation for operation, transport and storage.
	This symbol indicates the compliance with the essential requirements and provisions of the Medical Device Directive 93/42/EEC as amended by 2007/47/EEC.
	When disposing of some components, do not dispose as general wastes. Adhere to all applicable laws regarding recycling.
	This symbol means an item is known to pose hazards in all MRI environments.

- ※ According to IEC 60601-1-6 General requirements for basic safety and essential performance
– Collateral Standard: Usability, the definition and using these symbols is adjusted.



CAUTION

Federal law restricts this device to sale by or on the order of a physician.

Section 2 Introduction

2.1 Intended use

HI•bebe Doppler BT-200 is a pocket-size fetal Doppler that measures the fetal heart rate and outputs the fetal heart sound through built-in speaker. Measuring the FHR gives an indication of fetal well-being.

2.2 Indications for Use

The HI•bebe Doppler BT-200 is a pocket sized ultrasonic fetal monitor that measures heart rate, which is displayed on an LCD display, and outputs fetal heart sounds through a built in speaker. The fetal heart rate is measured using Doppler ultrasound.

2.3 Product Configuration

HI•bebe Doppler BT-200 consists of the following. Unpack the package and check out the following items. Also be sure to check any damage of main body, probe and accessories.

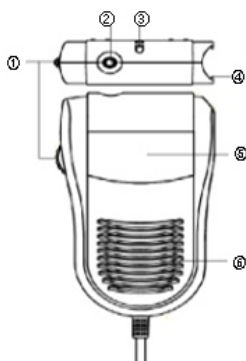
- ① BT-200 main body and probe(Refer to the below table)
- ② 1.5V Battery(2EA)
- ③ Ultrasound transmission gel (1EA)
- ④ User's manual (1EA)
- ⑤ Carrying case(pouch, 1EA)

BT-200 series comparison table

Series		200S	200L	200T	200C
Display	LCD type	None	Mono LCD	Mono LCD	Color LCD
	Heart rate range(bpm)	Not displayed	50~240 ±2%	50~240 ±2%	50~240 ±2%
Ultrasound frequency (MHz)		2	2	3	2
probe Water proof		IPX7	IPX7	IPX7	IPX7
Probe type		Non-detachable	Non-detachable	Non-detachable	Non-detachable

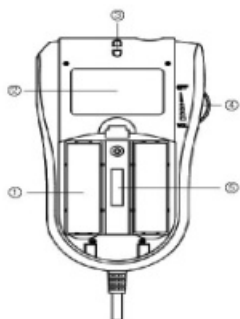
2.4 Exterior Component Designation

◎ Front View & Top View



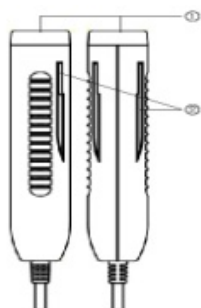
- ① Power and Volume Switch
- ② Ear phone jack
- ③ Ring for necklace
- ④ Probe holder
- ⑤ LCD display

◎ Rear View



- ① Battery compartment
- ② Label
- ③ Ring for necklace
- ④ Power and Volume Switch

◎ Probe



- ① Transducer
- ② Groove joint

Section 3 Operation

3.1 Operation requirements

- The ambient temperature and humidity of the HI • bebe BT-200 should to be 10℃ ~ 40℃ and 30% ~ 85%.
- Handle with care.
- Avoid dust or flammable materials.
- When changing the batteries, make sure the batteries are inserted correctly.
- When detaching the probe from the main body, slide the probe upwards to prevent damage.

3.2 How to use?

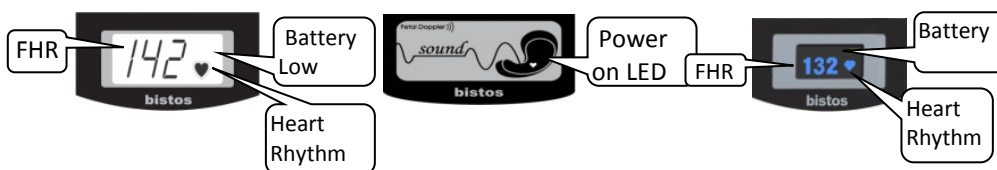
- Turn the power and volume switch counterclockwise to turn the device on and adjust the volume level.
- Apply a liberal amount of ultrasound gel to the face of transducer (end of the probe).
- Place the transducer directly against the abdomen, just above the point where the pelvic bones meet.
- Search for the fetal heart by slowly moving the probe around until the fetal heart sounds are heard.
- Search for the position which can get the clearest heart sound.

3.2.1 HI • bebe BT-200 LCD

- When the input signal is good and stable, FHR will appear on the screen and the solid heart rhythm indicator will flash as shown in Figure.
- When the input signal is not stable, the outline heart rhythm indicator will flash.
- If the voltage level of battery is lower than the required level, the battery low message "bat Lo" will appear. In this case, the unit will not functional correctly and the batteries should be replaced.

3.2.2 HI • bebe BT-200 Sound

- FHR measuring method : Calculate the FHR for 1 minute.



3.3 Basic clinical information

- The fetal heart rate range is normally between 120 – 160 BPM (beats per minute).
- When the fetal heart rate remains outside of this normal range for an extended period, please seek advice from your obstetrician.

3.4 Maintenance and cleaning

- To keep clean, wipe the body and probe regularly with an alcohol based clinical wipe.
- Do not use the following agents: lacquer, thinner, ethylene or an oxidizing agent as these could damage the device.
- Do not under any circumstances immerse the device in cleaning fluid.

Section 4 General information and specifications

- Turn the power off after use. If you do not turn the power switch off, 1 minute later, the sound will be muted automatically. In this case, a single “beep” sound will be heard. 3 minutes later, the system will go to sleep mode. In this case two “beep” sounds will be heard. The display will be turned off. In this mode power very little power is consumed. If you want to wake up the device from sleep mode, turn the power off and then 1 second later turn the switch on by turning the switch counterclockwise.
- 1.5V × 2(AA Type) Batteries are used for the system power. Do not use any other type of battery. Use of the wrong battery type may damage the equipment.
- Do not open the device cover or disassemble the device. Refer servicing to qualified personnel of Bistos Co., Ltd.

General		
Ultrasound center frequency	Refer to the comparison table on page 7	
Intensity	<10 mW/cm ²	
Heart rate range	50~240 bpm	
FHR accuracy	±2% of range	
Sensitivity	10 ~ 12 weeks onward	
Physical characteristics		
Main body	(L)75 mm×(H)128 mm×(D)26 mm	
Probe	200S/C/L/T: (L)27.8 mm X (H)160.25 mm X (D)27.8 mm	
	200V : (L)25 mm X (H) 131/139 mm X (D) 25 mm	
Weight(Main body with probe)	190 g	
Electrical safety		
Compliance with IEC 60601-1, IEC 60601-1-2		
Ultrasound Doppler system according to IEC 60601-2-37		
Internally powered equipment		
Type BF applied parts		
Probe waterproof Level IPX7 ,IPX2		
Power		
Battery	1.5V X 2 (AA type) About 280 minutes for continuously use	
Environmental conditions		
	Operation	Storage
Temperature	10℃(50°F) ~ 40℃(104°F)	-20℃(14°F) ~ 60℃(131°F)
Relative Humidity	30% ~ 85% non-condensing	
Atmospheric pressure	79.051 kPa ~ 101.325 kPa	

Section 5 Declaration on EMC

5.1 Electromagnetic emissions

The BT-200 is intended for use in the electromagnetic environment specified below. The customer or the user of BT-200 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The BT-200 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 BT-200 is suitable for use in all establishments by using a battery.
Harmonic emission IEC61000-3-2	Not applicable	
Voltage fluctuations /flicker emissions IEC61000-3-3	Not applicable	

5.2 Recommended separation distances between portable and mobile RF communications equipment and the BT-200

The BT-200 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BT-200 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BT-200 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 80MHz $d = 1,2\sqrt{P}$	80 MHz to 800 MHz $d = 1,2\sqrt{P}$	800 MHz to 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	1.2	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 meters (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.			

5.3 Electromagnetic immunity

The BT-200 is intended for use in the electromagnetic environment specified below. The customer or the user of the BT-200 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	±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 transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not applicable	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	< 5 % U_T (> 95 % dip in U_T) for 0.5cycle 40 % U_T (60 % dip in U_T) for 5 cycle 70 % U_T (30 % dip in U_T) for 25 cycle <5 % U_T (> 95 % dip in U_T) for 5 s	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the BT-200 image intensifier requires continued operation during power mains interruptions, it is recommended that the BT-200 image intensifier be powered from a battery.
Power frequency (50 Hz and 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 a.c. mains voltage prior to application of the test level.			

The BT-200 is intended for use in the electromagnetic environment specified below.
The customer or the user of the BT-200 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	$3 V_{rms}$ 150 kHz ~ 80 MHz	3 V/m	Portable mobile RF communications equipment should be used no closer to any part of the BT-200, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz ~ 2.5 MHz	3 V/m	Recommended separation distance $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P} \quad 80 \text{ MHz} \sim 800 \text{ MHz}$ $d = 2,3\sqrt{P} \quad 800 \text{ MHz} \sim 2.5 \text{ GHz}$ 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,^a should be less than the compliance level in each frequency range.^b 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 propagation is affected by absorption and reflection from structures, objects and people.

^a 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 BT-200 is used exceeds the applicable RF compliance level above, the BT-200 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the BT-200.

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

Product Guarantee

Product Name	Ultrasound Doppler System
Model Name	HI•bebe Doppler BT-200
Approval No.	
Approval Date	
Serial No.	
Warranty Period	1 Years (Probe excluded)
Date of Purchase	
Customer	Hospital: Address: Contact Name: Telephone:
Sales Agency	
Manufacture	Bistos Co., Ltd.

- ※ Thank you for purchasing HI•bebe Doppler BT-200.
- ※ This product is manufactured and passed through strict quality control and inspection.
- ※ Compensation standard concerning repair, replacement, refund of the product complies with “**Framework Act on Consumers**” noticed by Fair Trade Commission of Republic of Korea

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