Ultrasound Doppler System

Operation manual

.

BT-200L, BT-200T, BT-200V

Keep this manual for future reference

200-ENG-OPM-EUR-R13

Proprietary Material

Revision 13
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Contents

1. Safety information

1.1. Instructions for the Safe Operation and Use

Symbols used:

The following symbols identify all instructions that are important to safety. Failure to follow these instructions can lead to injury or damage to the device. When used in conjunction with the following words, the symbols indicate:

⚠**WARNING**	Can lead to serious injury or product/property damage.

The following symbols are placed on product, label, packing and this manual in order to stand for the information about:

Symbol	Standard/Symbol Reference no.	Description
	ISO 15223-1, Medical Devices— Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements / 5.4.4	Used to identify safety information for caution. Be well-known this information thoroughly before using the device.
	IEC 60417 — Graphical Symbols for Use on Equipment / 5333	Indicates the BF applied part.
IPX7	IEC 60529 Degrees of protection provided by enclosures	Indicates the protection level against the ingress of solid object and liquid. IPX7 is protection against the effects of temporary immersion in water.
IPX2	IEC 60529 Degrees of protection provided by enclosures	Indicates the protection level against the ingress of solid object and liquid. IPX2 is protection against vertically falling water drops when enclosure tilted up to 15°. (See the available probe in BT-200V specification table of 2.3 Product Configuration)
	ISO 15223-1, Medical Devices— Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements / 5.1.1	Indicates the manufacturer.
	ISO 7010 — Graphical symbols — Safety colours and safety signs — Registered safety signs / M002	Refer to the operation manual. Read the manual before placing the device.
	ISO 15223-1, Medical Devices— Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements / 5.4.3	Refer to the operation manual. Indicates the need for the user to consult the instructions for use.

SN	ISO 15223-1, Medical Devices—Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements / 5.1.7	Indicates the serial number of the device.
EC REP	ISO 15223-1, Medical Devices—Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements / 5.1.2	Indicates the authorized representative in the European Community of manufacturer.
	ISO 15223-1, Medical Devices—Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements / 5.3.7	Indicates the temperature limitation for transport and storage.
	ISO 15223-1, Medical Devices—Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements / 5.3.8	Indicates the humidity limitation for transport and storage.
CE 2460	European Medical Directive 93/42/EEC	The product is in conformity with European Medical Directive 93/42/EEC. Notified body identification numbers with CE mark indicate that this has been verified by the notified body.
	Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) EN 50419 Marking of electrical and electronic equipment	This product may contain material which could be hazardous to human health and the environment. DO NOT DISPOSE of this product as unsorted municipal waste. This product needs to be RECYCLED in accordance with local regulations, contact your local authorities for more information. This product may be returnable to your distributor for recycling - contact the distributor for details.
	ASTM F2503-13 Standard practice for marking medical devices and other items for safety in the magnetic resonance environment	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.

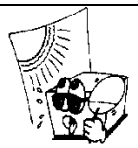
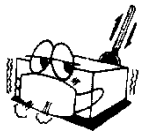
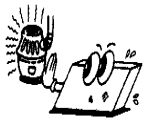
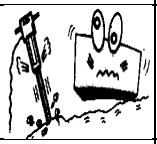
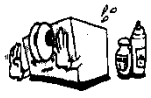
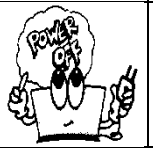
1.2. Warnings

⚠WARNING

- Do not use the device without consultation of medical professional.
- The relevant law restricts this device to sale by or on the order of a physician.
- Use the Bistos original accessories.
- Do not touch or operate the device with wet hands to avoid electric shock.
- Do not use the device during the use of defibrillators or during defibrillator discharge.
- Do not use the device in the presence of electrosurgical equipment.
- Do not use the device during the use of RF surgical equipment.
- Do not use simultaneously the device to whom that has any active implantable or body-worn medical device including pacemakers, ICDs, neurostimulators and insulin pumps.
- The device 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 Manual.
- Do not use in the out of range for humidity, temperature and atmospheric pressure environment indicated in this manual.
- Keep the operating environment free of dust, vibrations, corrosive or flammable materials and extremes of temperature and humidity.
- Do not use the device in a flammable atmosphere where concentrations of flammable anesthetics or other materials may occur.
- Do not disassemble or modify the device. The device only has the specified safety and performance when it is manufactured by the manufacturer.
- Do not attempt to repair the device. Only qualified service personnel by Bistos Co., Ltd. should perform.
- The device including probe may be broken when dropped or impacted.
- Do not use the damaged devices.
- 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 operate the device if it fails to pass the power on procedure.
- Use of accessories including probe or 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.
- Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual. 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 device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- 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.
- When disposing of the device, adhere to all applicable laws regarding recycling.
  When handling package materials, abide by local waste disposal laws and regulations.
  Properly dispose of or recycle the depleted battery in accordance with local regulations.

1.3 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.

2. Introduction

2.1. Intended use

The HI•bebe, BT-200L/T, and HI•dop, BT-200V are pocket-size fetal Doppler intended to the detection of fetal heart rate from early gestation thru delivery and as a general indication of fetal well-being; and output the sound of fetal heart beat through built-in speaker.
There are no known contraindications.

2.2. Device description

The HI•bebe, BT-200L/T, and HI•dop, BT-200V are 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 heart rate information of fetus can be obtained through the abdomen of the mother by using the Doppler effect. There are two ultrasonic sensors at the end of the probe, and one ultrasonic sensor generates ultrasonic waves using the piezoelectric inverse effect (when a voltage is applied, the piezoelectric material causes shape deformation), and the reflected signal is obtained from another ultrasonic sensor using piezoelectric direct effect (when the pressure is applied to the piezoelectric material, an electric potential is generated). The intended application site may vary depending on which probe frequency is used.

2.3. Product Configuration

The ultrasound Doppler system consists of the following. Unpack the package and check out the following items. Also be sure to check any damage of the monitor, probe and accessories.

① The monitor and probe (Refer to the below table)
② 1.5V Battery(2EA)
③ User's manual (1EA)
④ Carrying case (pouch, 1EA)

BT-200L	BT-200T	BT-200V	
			
Mono LCD: 2 MHz	Mono LCD: 3MHz	Mono LCD: 2,4,5,8 MHz	
			
2MHz	3MHz	2MHz	4, 5, 8MHz

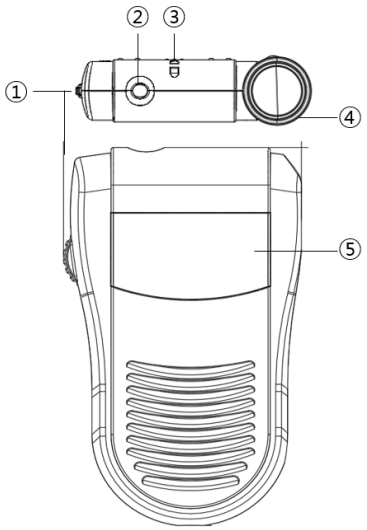
Variant's comparison table

Series		BT-200L	BT-200T	BT-200V
Display	LCD type	Mono LCD	Mono LCD	Mono LCD
	Heart rate range(bpm)	50~240 ±2%	50~240 ±2%	50~240 ±2%
Ultrasound frequency (MHz)		2	3	2, 4, 5, 8
Probe Water proof		IPX7	IPX7	IPX2
Probe type		Integral type	Integral type	Detachable type
Available accessories		Non-detachable, AY-DOP-200L(2M)	Non-detachable, AY-DOP-200T (3M)	Detachable, AY-DOP-200V(2M); AY-DOP-200V(4M); AY-DOP-200V(5M); AY-DOP-200V(8M);
Audio output		1.2W speaker, 3.5mm phone jack	1.2W speaker, 3.5mm phone jack	1.2W speaker, 3.5mm phone jack
Auto shut off		Sound mute: 1min. Power off: 5min.	Sound mute: 1min. Power off: 5min.	Sound mute: 1min. Power off: 5min.

Series	BT-200L	BT-200T	BT-200V
Power	1.5V battery *2 (AA Type)	1.5V battery *2 (AA Type)	1.5V battery *2 (AA Type)
Battery life	280min.	280min.	280min.

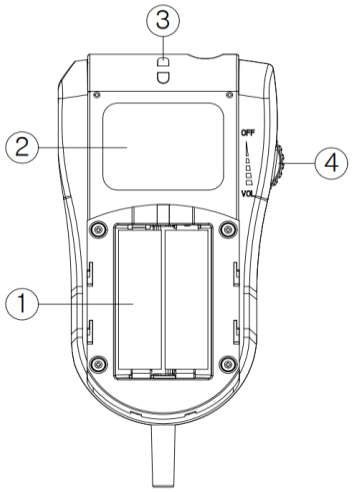
2.4. Exterior Component Designation

◎ **Front View & Top View**



① Power and Volume Switch
② Ear phone jack
③ Ring for necklace
④ Probe holder
⑤ LCD display
⑥ Built in speaker

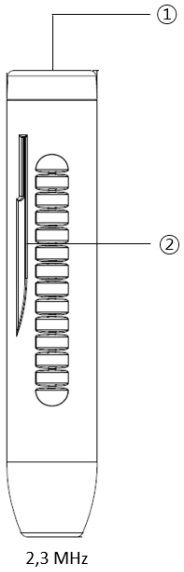
◎ **Rear View**



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

◎ **Probe**

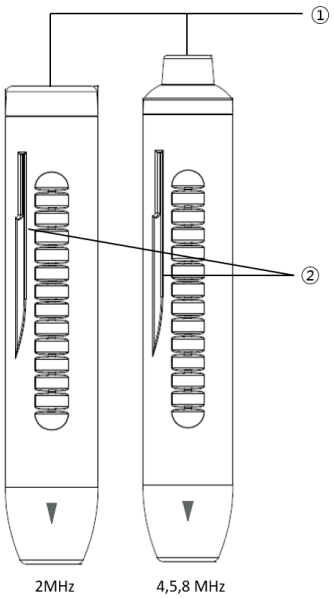
(1) BT-200L, BT-200T



① Transducer

② Groove joint

(2) BT-200V



③ Transducer

④ Groove joint

NOTE

- Connect the device in the direction of the arrow indicated on the probe.

3. Operation

3.1. Operation requirements

- The ambient temperature and humidity of the HI • bebe 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 monitor, 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).
- If use 4,5,8MHz probe of BT-200V, hold the probe softly against the measurement area at an angle of approximately 45 degrees to the skin surface (see figure 1). Place the probe on the skin and move slowly to locate the point where maximum Doppler sounds are heard.

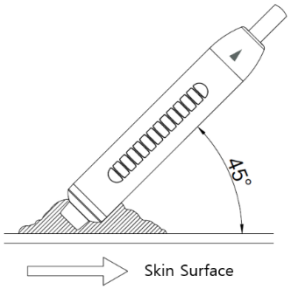


Figure 1. BT-200V 4MHz, 5MHz, 8MHz Probe

- If use 2,3 MHz probe of BT-200L, BT-200T and BT-200V, place the probe on the measurement area at a 90-degree angle (see figure 2 and 2-1.) and move slowly to locate the point where fetal heart sounds are at the maximum. Or place the transducer directly against the abdomen, just above the point where the pelvic bones meet.

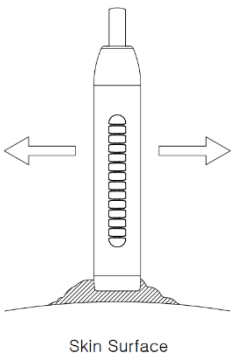


Figure 2. BT-200L, BT-200T Probe

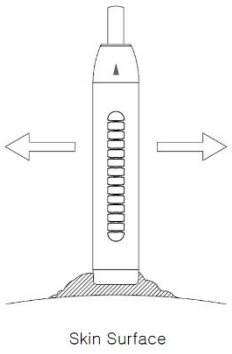


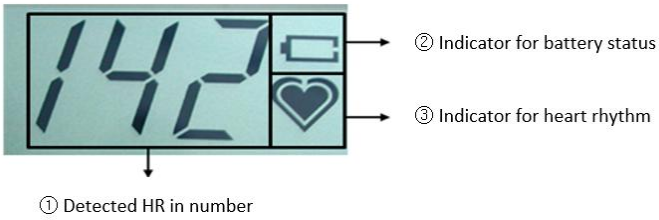
Figure 2-1. BT-200V 2MHz Probe

- 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.

NOTE
- Use the device with the ultrasound gel that has CE MARK

3.2.1. Display

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



3.3. 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. Monitoring sequence overview

➢ ***Step 1: Preparing the device.***
- Turn the monitor on and verify that the normal monitoring screen appears on the display. Do not use the device if an error occurs.
- Check is powered from the AA battery.
- Apply ultrasound gel to the face of the transducer.

➢ **Step 2: Acquiring the Fetal Heart Signal**
- Determine the location of the fetal heart using palpation or a fetoscope. Place the transducer on the maternal abdomen and listen for the fetal heart signal. Reposition the transducer for the loudest fetal heart signal and verify the heart icon on the screen is blinking at the fetal heart rate.
- Secure the ultrasound transducer. Make sure the transducer is still positioned for the loudest fetal heart signal.
- Verify the monitor is displaying fetal heart rate values and that the heart icon on the screen is blinking at the measured heart rate.

➢ **Step 3: Monitor Adjustments**
- Readjust the volume settings for the desired loudness.

4. Cleaning and disinfection

The Ultrasound Doppler System requires proper control and preventive maintenance. This ensures consistent operation and maintains the high level of performance necessary in monitoring procedures.

4.1 Monitor

Keep the external surface clean and free of dust, dirt, and residual liquids. Clean with a damp cloth using mild soap and water or hospital approved nonabrasive disinfectants.

⚠ **WARNING**

- Do not immerse the unit and transducer in water or allow liquids to enter the case. When using solutions, use sterile wipes to avoid pouring fluids directly.
- Take extra care when cleaning display surface, which are sensitive to rough handling. Rub the lens that covers them with a soft, dry cloth.

4.2 Probe

To avoid damage to the transducers, clean and disinfect according to the following instructions.

⚠ **WARNING**

- Do not autoclave. Do not gas sterilize.
- Do not immerse in liquid. When using solutions, use sterile wipes to avoid pouring fluids directly on the transducer.
- Clean the probe after each use. Turn off the device when cleaning.
- The probe should be kept clean and free of transducer gel and other substances except when used.

(1) Wipe the device with a sterile wipe soaked in enzymatic detergent safe for use with metal instruments. Wipe the exterior of the device three times. Prepare the detergent according to the manufacturer's recommendations.
(2) Scrub the transducer with enzymatic detergent using a soft bristled brush for five (5) minutes.
(3) Wipe the transducer three (3) times with sterile water to remove soap residue.
(4) Wipe the transducer with a sterile wipe soaked in Cidex™. Wipe all exterior surfaces of the transducer three (3) times.
(5) Wipe the transducer three (3) times with sterile water to remove Cidex™ residue.
(6) Dry the device thoroughly with a sterile soft towel or gauze surgical sponge.
(7) Wrap the dry transducer with a fresh sterile soft towel or transparent sterile wrap for storage until next use.

4.3 Contacting components

Contacting component	Material	Disinfection
DOP enclosure	ABS AV20F	Must be cleaned and disinfected prior to use

4.4 Description of Cidex™

(1) Cidex™ is FDA-cleared for use in the United States. Therefore, we suggest that the disinfection effect using Cidex™ is valid.

(2) FDA-Cleared Sterilants and High Level Disinfectants with General Claims for Processing Reusable Medical and Dental Devices – March 2015 (https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices-information-manufacturers/fda-cleared-sterilants-and-high-level-disinfectants-general-claims-processing-reusable-medical-and)

Manufacturer	Active Ingredient	Sterilant Contact Conditions	High Level Disinfectant Contact Conditions
K924434 Cidex™ Activated Dialdehyde Solution			
Johnson & Johnson Medical Products	2.4% glutaraldehyde	10 hrs at 25°C 14 days Maximum Reuse Contact conditions based on AOAC Sporicidal Activity Test only.	45 min at 25°C 14 days Maximum Reuse Contact conditions based on literature references.

5. Troubleshooting and maintenance

Observe all precautions to ensure the safety of the patient and those near the instrument.

- Examine the monitor and any accessories periodically to ensure that the cables, line cords, transducers, and instruments do not have visible evidence of damage that may affect patient safety or monitoring performance. The recommended inspection interval is once per week or less. Do not use the device if there is any visible sign of damage.
- The device and accessories do not require periodic calibration or adjustment.
- Perform periodic safety testing to ensure proper patient safety. This should include leakage current measurement and insulation testing. The recommended testing interval is once per year.
- Do not operate the device if it fails to pass the power on self-test procedure.
- When the displayed condition is not stable, check the battery and replace them.

5.1 Ultrasound transducer test

To test the ultrasound transducer:

(1) Connect the transducer to the monitor.
(2) Turn on the monitor.
(3) Adjust the speaker volume to an audible level.
(4) Hold the transducer on one hand and tap on the transducer face with the other hand. The tapping sound should be heard from the speaker.
(5) The transducer is operating properly if you can hear the sound from the speaker. If no sound is heard, please stop using the transducer and call for the service.

5.2 Battery

The capacity of the battery is gradually decreased over time and usage. Consequently, the operating time with the battery can be reduced. If the operation time is not long enough, please changing the battery.

⚠ **WARNING**

- User can open the battery compartment to replace the battery, and use 2 of AA 1.5V batteries.
- Do not mix batteries of different types, such as alkaline or manganese. Use only batteries of the same type.
- Do not mix old and new batteries.
- The incorrect battery replacement could be caused danger such as excessive temperatures, fire or explosion.
- If it won't be used the device for a long time (over three months), please store the device with the battery removed.
- When leakage or foul smell is found, stop using the battery immediately, If your skin or cloth comes into contact with leaked liquid, cleanse it with clean water at once. If the leaked liquid splashes into your eyes, do not wipe them. Irrigate them with clean water first and go to see a doctor immediately.

6. 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	
MI and TI values do not exceed 1.0.	
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	
Monitor	(L)75 ㎜×(H)128 ㎜×(D)26 ㎜
BT-200L/T Probe (2, 3MHz)	(L)27.8 ㎜ X (H)160.25 ㎜ X (D)27.8 ㎜
BT-200V Probe (2/4, 5, 8MHz)	(L)25 ㎜ X (H) 131/139 ㎜ X (D) 25 ㎜
Total Weight (monitor with probe)	190 g

Electrical safety
Compliance with IEC 60601-1, IEC 60601-1-2, IEC 60601-2-37

Internally powered equipment
Type BF applied parts
BT-200L/T Probe waterproof Level IPX7
BT-200V Probe waterproof Level 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)	-10℃(14˚F) ~ 60℃(140˚F)
Relative Humidity	30% ~ 85% non-condensing	
Atmospheric pressure	79.051 ㎪ ~ 101.325 ㎪	

7. Declaration on EMC

The Ultrasound Doppler System needs special precautions regarding EMC (Electromagnetic compatibility) and needs to be used according to the EMC information provided in this user manual. Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect the BT-200 series and should be kept at least 1 m away from the equipment.

⚠ **WARNING**

- Use of accessories including probe 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.
- Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual. 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 device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- 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.
- The device makes a beef sound when an abnormal signal input is provided.

7.1. Electromagnetic emissions

The BT-200 series 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

RF emissions CISPR 11	Group 1	The device 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 device is suitable for use in all establishments by using a battery.
Harmonic emission IEC61000-3-2	Not applicable	
Voltage fulctuations /flicker emissions IEC61000-3-3	Not applicable	

7.2. Recommended separation distances between portable and mobile RF communications equipment and the BT-200 series

The BT-200 series is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BT-200 series can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BT-200 series as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter [W]	Separation distance according to the 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.

7.3. Electromagnetic immunity

The BT-200 series is intended for use in the electromagnetic environment specified below. The customer or the user of the BT-200 series 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 %.
Electrical fast transient/burst IEC 61000-4-4	Not applicable	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	Not applicable	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	Not applicable	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the BT-200 series 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	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.

The BT-200 series is intended for use in the electromagnetic environment specified below. The customer or the user of the BT-200 series should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Conducted disturbances, induced by RF fields IEC 61000-4-6	3 Vrms 150㎑ to 80㎒ 6 Vrms in ISM bands between 0.15㎒ and 80 ㎒	3 Vrms 150㎑ to 80㎒ 6 Vrms in ISM bands between 0.15㎒ and 80 ㎒	Portable mobile RF communications equipment should be used no closer to any part of the BT-200 series, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Radiated RF electromagnetic field IEC 61000-4-3	10 V/m 80㎒ to 2.7 G㎐ 80%, 2㎐ AM RF Wireless Comm	10 V/m 80㎒ to 2.7 G㎐ Other 2Hz RF Wireless Comm	Recommended separation distance $d = 1{,}2\sqrt{P}$ $d = 1{,}2\sqrt{P}$ 80 ㎒ ~ 800 ㎒ $d = 2{,}3\sqrt{P}$ 800 ㎒ ~ 2.5 ㎓ 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 : 
Radiated disturbance CISPR 11 2015+AMD1:2016+AMD 2:2019 CSV	Group 1, Class A	Group 1, Class B	

NOTE 1) At 80 ㎒ and 800 ㎒, 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 series is used exceeds the applicable RF compliance level above, the BT-200 series 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 series.

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

Product Guarantee

Product Name	Ultrasound Doppler System
Brand Nam	HI•bebe / HI•dop
Model Name	BT-200L, BT-200T, BT-200V
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 and HI•dop.

※ 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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