HI-bebe S

Operation manual

BT-220C

Keep this manual for future reference

P/N: 220C-ENG-OPM-EUR-R06

Proprietary Material

Revision 06
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7th Fl., A Bldg., Woolim Lions Valley 5-cha, 302, Galmachi-ro
Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea

Telephone: +82 31 750 0340
Fax: +82 31 750 0344

Printed in Korea

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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. It is applicable to Doppler probe.
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.
	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.
	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.
	ISO 15223-1, Medical Devices— Symbols to be used with medical	Indicates the authorized representative in the European

	device labels, labeling and information to be supplied – Part 1: General requirements / 5.1.2	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.

※ 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

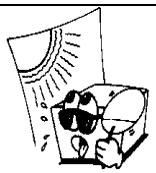
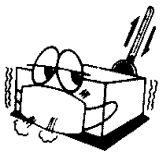
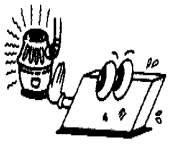
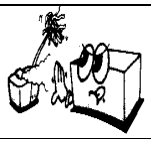
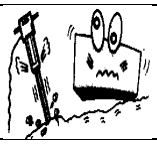
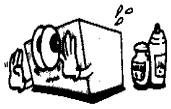
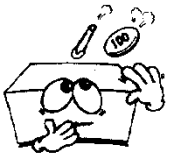
- Do not use the device without consultation of medical professional.
- The relevant law restricts this device to sale by or on the order of a physician.
- Use the Bistos original accessories.
- Do not touch or operate the device with wet hands to avoid electric shock.
- Do not use the device during 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 the device at the same time on anyone with active implantable or body-

worn medical device including pacemakers, ICDs, neurostimulators and insulin pumps.

- The device is not specified or intended to operate with any other type of monitoring equipment except for certain devices 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 repair the device.
- 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.
  Dispose of or recycle the depleted battery properly 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 S, BT-220C is a pocket-size fetal doppler intended to the detection of fetal heart rate from early gestation to delivery and as a general indication of fetal well-being. Fetal heart rate is displayed on a color LCD display, and its sound is output through a built in speaker.
There are no known contraindications.

2.2. Product description

The HI-bebe S, BT-220C is a pocket-size 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).

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-220C	2MHz probe	3MHz probe(option)
		

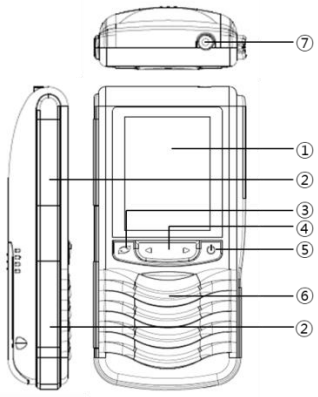
Specification table

Model		BT-220C
Display	LCD type	TFT color LCD
	Heart rate range(bpm)	30~240 ±2%
Ultrasound frequency (MHz)		2, 3
Probe Water proof		IPX7
Probe type		Detachable type
Available accessories		AY-DOP-220(2M) AY-DOP-220(3M)
Audio output		1 W speaker, 3.5mm phone jack
Auto shut off		Sound mute: 1 min. Power off: 3 min.
Power		1.5V battery *2 (AA Type)

Model	BT-220C
Battery life	240 min.

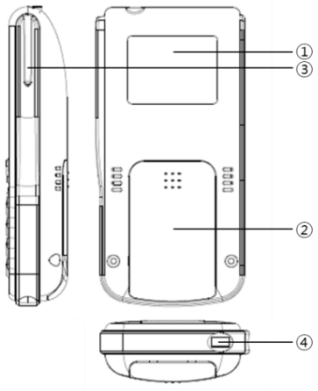
2.4. Exterior Component Designation

◎ **Front, Top & Left View**



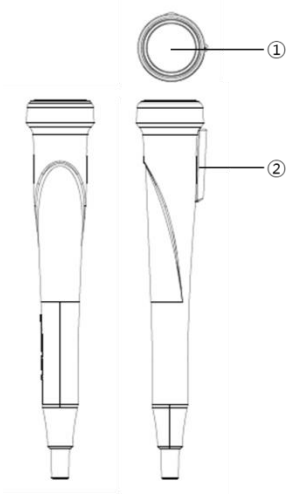
① TFT color LCD
② Electrode Plate
③ Mode button
④ Volume Up/Down button
⑤ Power On/Off button
⑥ Built-in speaker
⑦ Ear phone jack

◎ **Rear, Bottom & Right View**



① Product label
② Battery compartment with cover
③ Groove joint for holding probe
④ Connection part to probe

◎ **Probe**



① Sensor cover

② Tongue for holding probe

3. Operation

3.1. Operation requirements

- The ambient temperature and humidity of the HI-bebe S should be 10°C～40°C 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?

- Press the power button to turn on the device.
- Apply a liberal amount of ultrasound gel to the face of the probe (end of the probe).
- Place the probe 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.

⚠ CAUTION

- Please power off the device before connecting or disconnecting the doppler probe.

NOTE

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

3.2.1. HI-bebe S Controls and Indicators

3.2.1.1. Button

Button	Description
	Mode change or menu select
	Volume Down
	Volume Up
	Power On/Off

3.2.1.2. Symbol

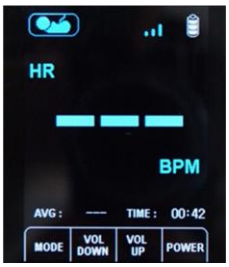
Symbol	Description
	Battery indicator
	Doppler volume indicator
	Doppler volume mute indicator
	Low battery indicator

3.2.1.3. Mode

Symbol	Description	
	FHR Number	This mode displays fetal heart rate and heart rhythm with heart sound
	FHR Graph	This mode displays fetal heart rate, heart rhythm and change of heart rate with heart sound
	BMI calculation	This mode displays the BMI
	BMI trend	This mode displays saved data of BMI
	Unit setting	This mode set the unit of height, weight, and start mode.

3.2.2. HI-bebe S Mode

- BT-220C has totally four modes. You can select the mode by pressing  button for a short time.



FHR Number mode

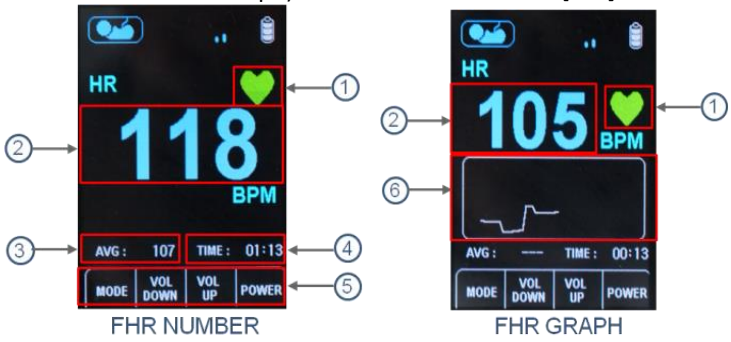
FHR Graph mode

BMI mode

BMI trend mode

3.2.2.1. FHR(Fetal Heart Rate) Mode

- 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.
- Mode change (FHR Number → FHR Graph): Press the mode button [ ].

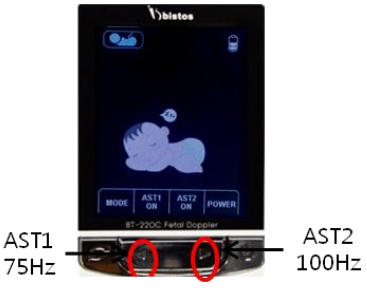


① Heart rhythm indicator ② Heart rate (HR) value
③ Average HR value ④ Operating time of FHR
⑤ Function of button ⑥ Graph of HR

When the the input signal is not stable, only the outline of heart rhythm indicator will flash. 'AVG' represents the average value of the stable heart rate and 'TIME' represents listening time of heat beat.
The bold lines in graph region represent the stable heart rate.

- To control the volume: Press the button to adjust volume (1 ~ 4 levels). The current volume setting is displayed as an icon on the upper right corner of screen.

- Speaker test operation (FHR graph → AST): Press the button shortly.



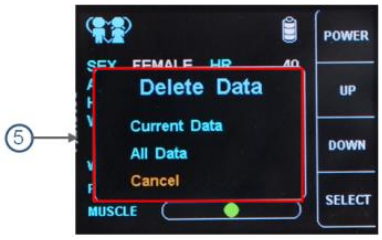
< AST Operation>

Use the button for generating sound. The sound is generated only at speaker. AST1 has 75 Hz and AST2 has 100 Hz frequency.

3.2.2.2. BMI(Body mass index) Mode

- BT-220C displays BMI(Body Mass Index) using the weight and height.
- Mode Change (FHR mode → BMI mode): Press the button for a short time.

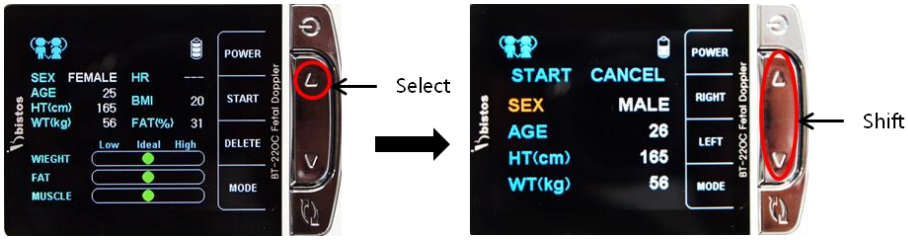
BMI mode



Delete data

① Function of button
② Last measured data
③ Entered information
④ Body composition graph
⑤ Pop-up window for deleting data

- Information Setting: Press the button to enter the start menu.
  - Item Select: Press the button to select item (Sex, Age, HT, WT)
  - Change Value : Use the button to change the value.
    (Information of age, height, and weight is not cleared)



① Function of button
② Start/Cancel
③ Entered information

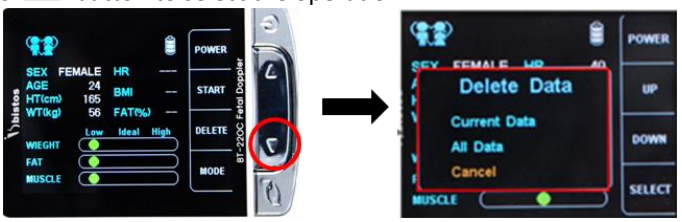
If all information has been modified or changed press mode button to select [START/CANCEL] menu.

- Start Measurement: when the cursor is on [START CANCEL], press the button to start measurement or press the button to cancel (return to BMI mode).
-

<Ready> <Processing>

After pressing start, touch the metal electrode on the left side on main body with both thumbs. Then measurement begins automatically. If the contact area is small, the measurement may be inaccurate Information of setting age, height, weight will be saved automatically.
Automatically measured HR, BMI, FAT is stored (up to 10).

- Delete Data : Press the ▼ button to delete data. Use the ◄ ► button to select the menu and press ↻ button to select the operation.



3.2.2.3. BMI TREND

① Function of button ② Measured data
③ Last entered information ④ Graph of stored data

- Mode Change: Press the ↻ button shortly to change the mode to FHR numeric mode.
- Stored Data Review: Press the ◄ ► button to see the stored data.

3.2.2.4. UNIT Setting

① Unit set value ② Function of buttons

- To enter unit setting menu, press down the button about 2 seconds.
- Item select: Press the button shortly
- Value Change: Press the button.
- The following items can be changed:
  - DISP: Default display when power ON. Dop(N): Doppler Normal, Dop(G): Doppler Graph, Bmi(M): Bmi measurement, Bmi(T): Bmi trend.
  - HT: The unit of height for BMI. cm/ft
  - WT: The unit of weight for BMI. kg/lb
- To exit unit setting and return to the current operating mode, press down the button about 2 seconds.

3.3. Basic clinical information

- The fetal heart rate range is normally between 110 – 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 probe.

➢ **Step 2: Acquiring the Fetal Heart Signal**
- Determine the location of the fetal heart using palpation or a fetoscope. Place the probe on the maternal abdomen and listen for the fetal heart signal. Reposition the probe for the loudest fetal heart signal and verify the heart rhythm indicator on the screen is solid and blinking at the fetal heart rate.
- Secure the ultrasound probe. Make sure the probe is still positioned for the loudest fetal heart signal.
- Verify the monitor is displaying fetal heart rate values and that the heart rhythm indicator on the screen is solid and 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 probe 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 is sensitive to rough handling. Rub the display surface with a soft and dry cloth.

4.2 Probe

To avoid damage to the probes, 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 probe.
- Clean the probe after each use. Turn off the device when cleaning.
- The probe should be kept clean and free of ultrasound 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 probe with enzymatic detergent using a soft bristled brush for five (5) minutes.
(3) Wipe the probe three (3) times with sterile water to remove soap residue.
(4) Wipe the probe with a sterile wipe soaked in Cidex™. Wipe all exterior surfaces of the probe three (3) times.
(5) Wipe the probe 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 prove 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, probes, 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 probe test

To test the ultrasound probe:

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

⚠ WARNING

- User can open the battery compartment to replace the battery, and use 2 of AA type 1.5V batteries.

- The incorrect battery replacement could cause danger such as excessive temperatures, fire or explosion.
- When not using 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	2, 3 MHz
Intensity	<94 mW/cm^2
Heart rate range	30~240 bpm
FHR accuracy	±2% of range

Physical characteristics	
Monitor	(L)132 mm×(H)66 mm×(D)27.6 mm
Probe (AY-DOP-220(2M), AY-DOP-220(3M))	(L)162 mm X (H)29.3 mm X (D)27.8 mm
Total Weight (monitor with probe)	200 g

Electrical safety
Compliance with IEC 60601-1, IEC 60601-1-2, IEC 60601-2-37
Internally powered equipment
Type BF applied parts
Probe waterproof Level IPX7

Power	
Battery	1.5V X 2 (AA type) About 240 minutes for continuously use

Environmental conditions		
	Operation	Storage
Temperature	10°C(50°F) ~ 40°C (104°F)	-10°C (14°F) ~ 60°C (140°F)
Relative Humidity	30% ~ 85% non-condensing	
Atmospheric pressure	79.051 kPa ~ 101.325kPa	

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 Hi-bebe S 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.

7.1. Electromagnetic emissions

The HI-bebe S 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-220C

The BT-220C is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BT-220C can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BT-220C 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.

7.3. Electromagnetic immunity

The BT-220C is intended for use in the electromagnetic environment specified below. The customer or the user of the BT-220C 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-220C image intensifier requires continued operation during power mains interruptions, it is recommended that the BT-220C 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-220C is intended for use in the electromagnetic environment specified below.
The customer or the user of the BT-220C 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-220C, 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 $d = 1{,}2\sqrt{P}$ $d = 1{,}2\sqrt{P}$ 80 MHz ~ 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz ~ 2.5 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 deter-mined 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-220C is used exceeds the applicable RF compliance level above, the BT-220C 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-220C.

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

Product Guarantee

Product Name	HI-bebe S
Model Name	BT-220C
Approval No.	
Approval Date	
Serial No.	
Warranty Period	1 Year (Probe excluded)
Date of Purchase	
Customer	Hospital: Address: Contact Name: Telephone:
Sales Agency	
Manufacture	Bistos Co., Ltd.

※ Thank you for purchasing HI-bebe S.

※ 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

Service Telephone and Fax. Numbers

Telephone: +82 31 750 0340
Fax: +82 31 750 0344

Bistos Co., Ltd.
7th FL., A Bldg., Woolim Lions Valley 5-cha, 302, Galmachi-ro,
Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea

www.bistos.co.kr
bistos@bistos.co.kr

EC REP ***Obelis s.a***
Bd. Général Wahis 53
1030 Brussels, BELGIUM
Telephone: + (32) 2. 732.59.54
Fax.: + (32) 2.732.60.03

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