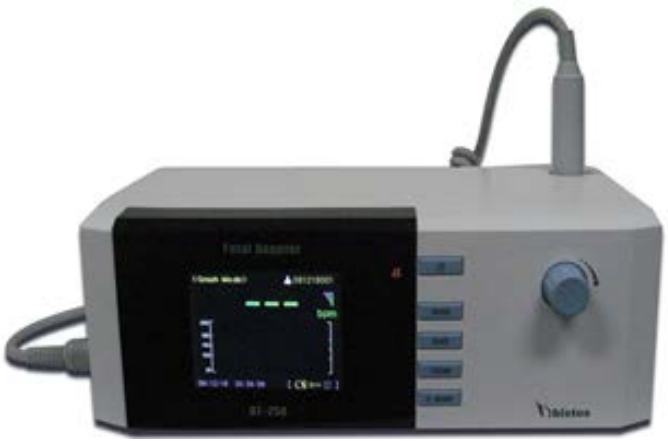
BT-250

Ultrasound Doppler System

Operation Manual



BT-250

Keep this manual for future reference

P/N: 250-ENG-OPM-EUR-R06

Proprietary Material

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Table of Contents

1 System basics

1.1 Device description & Intended Use

The BT-250 is a desktop fetal Doppler that measures the fetal heart rate, which is displayed on a LCD display, and outputs the fetal heart sound through built-in speaker. This device is for use only by trained medical personnel.

1.2 Options and Accessories

Accessory	Name	Description
	Doppler transducer (1ea)	Ultrasound transducer for measuring FHR IPX7 : Waterproof (1 meter of water for up to 30 minutes.)
	Power cord (1ea)	AC power cord
	Power adaptor (1ea)	AC/DC power adaptor Input : AC100~240 V[50/60 Hz] Output : DC 9V, 2.0A
	Ultrasound gel (1ea)	Ultrasound transmission gel

Table 1.1. BT-250 Accessories

1.3 Description of the Front Panel

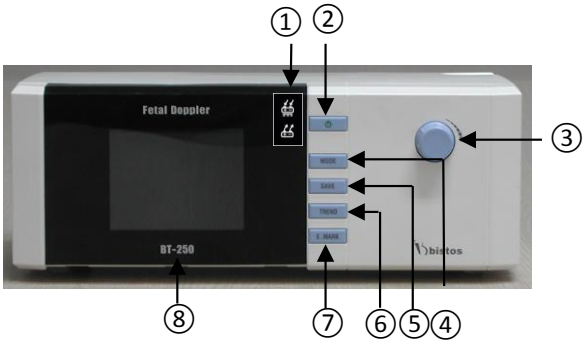


Fig. 1.1 BT-250 Front Panel

① Power Indicating LED (AC: Green / Battery: Orange)
② Power On/Off Button
③ Control knob
④ Mode change button
⑤ Save On/Off button
⑥ Trend mode Button
⑦ Event mark
⑧ TFT-Color LCD

1.4 Description of the Side Panel

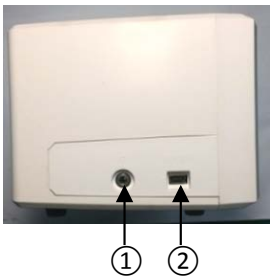


Fig. 1.2 Left Panel

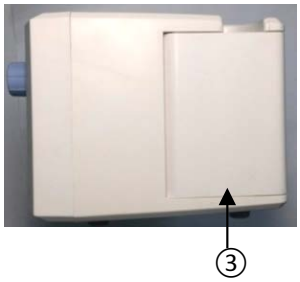


Fig. 1.3 Right Panel

① Earphone jack connector
② Doppler transducer connector
③ Doppler transducer holder

1.5 Description of the Rear Panel

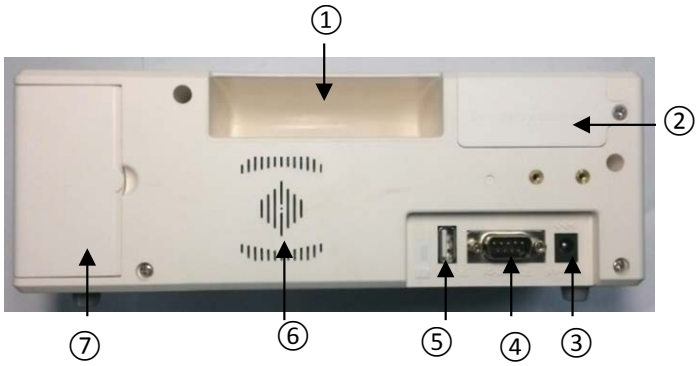


Fig. 1.4 Rear Panel

① Grip
② Battery cover
③ AC/DC adaptor connector
④ RS-232C port
⑤ USB port
⑥ Built-in speaker
⑦ Doppler transducer holder

2 Preparing to use

2.1 Place to use

Certain strong electromagnetic fields can interfere with the ultrasound transducer and cause a false heart rate reading. This interference is rare, and usually found in the vicinity of large machinery. In order to avoid the possibility of these interfering signals being analyzed as fetal heart rates, the following procedure should be followed whenever the monitor is to be used in a new location, or if it is known that electrical machinery is being operated in the vicinity.

After connecting the ultrasound Doppler transducer, turn on the monitor and observe the heart rate indications on the screen for 30 seconds while no signal input applied to the transducer surface. Intermittent display of random heart rates is acceptable. However, if there is a constant display of a heart rate lasting more than 5 seconds, this is an indication that there is a source of electromagnetic interference in the vicinity. The following steps should be taken to determine if it is possible to use the monitor in this environment.

- Move all line cords and line-powered equipment at least 6 feet (1.8 meter) away from the BT-250. Check for extension cords running behind or under the bed and equipment in adjacent rooms. If the artifact heart rate indication ceases, the monitor may be used normally.

- Remove the line cord from the monitor's power supply. If the artifact heart rate indication ceases, the monitor may be used normally.

If these measures do not result in cessation of the artifact heart rate, the monitor cannot be safely used in this environment.

2.2 AC/DC adaptor & Transducer Connection

Connect the power cord which supplied by Bistos Co., Ltd. to power outlet and power adapter receptacle. Connect the adapter plug to the BT-250 AC/DC adaptor connector as shown in Figure 2.1. Turn on the BT-250 by pressing down the power ON/OFF button about 2 seconds.

Connect the Doppler transducer cable to BT-250 as shown in the figure below.

Fig. 2.1 Power adaptor and Transducer Connection

2.3 Factory Default Setting

To enter the factory setting mode, turn on BT-250 by press down the power ON/OFF button for about 2 seconds while press down the control knob simultaneously. In factory setting mode, all configuration parameters are initialized to factory setting value. The initial factory setting values of each parameter are as below;

Setting parameter	Factory default value
Monitoring Mode	Number Mode
Graph Area	30~240
Auto Shunt Down	5
Language	English
Start Volume	3

2.4 Understanding the BT-250 Display Screen

Fig. 2.2 Main Monitoring Screen – Graph Mode

Fig. 2.3 Main Monitoring Screen – Number Mode

To change the monitoring mode between “Number Mode” and “Graph Mode”, press the [MODE] button.

2.4.1 Mode frame

The mode frame shows the current mode. There are monitoring mode (Number and Graph), setup mode and trend mode.

2.4.2 Heart Rate frame (FHR frame)

The heart rate (FHR) frame displays the fetal heart rate with a heart icon and current speaker volume setting. The heart icon blinks at the measured heart rate interval. The solid heart icon blinks when a valid rate is present and only the outline of heart icon blinks when a measured rate is unstable or weak.

The volume icon indicates the current speaker volume setting for the fetal echo sounds.

2.4.3 Heart Rate Graph frame (FHR Graph frame)

The Heart Rate (FHR) Graph frame displays a graphical representation of the fetal heart rate. The vertical scale is labeled corresponding to the recorder paper (30 to 240 BMP).

2.4.4 Status frame

This frame shows battery status and data saving status.

Symbol	Name	Description
	Battery Status Icon	Indicates the battery residual quantity
	Save Icon	Indicates the data saving status

When alarm occurs, alarm status is shown below.

Symbol	Name	Description
	Low Battery Alarm Icon	Blinking until AC/DC adapter is connected.

2.4.5 Patient ID frame

This flame displays the patient identification number. The BT-250 uses time and date information to generate the part of ID number (6 digits). The last 3 digits used for the individual patient ID. Default ID number is YYMMDD001 when YYMMDD is the current date information. To change the individual ID number (3 digits) enter [Setup mode] by pressing control knob button. (Refer to '4.4 BT-250 Control Knob' section)

2.4.6 Time and Date

This frame shows the current time and date saved. These settings can be changed as needed. (Refer to '4.4 BT-250 Control Knob' section)

2.5 Button description

There are 5 buttons located on the front panel. The operation of the buttons is summarized below.

CAUTION 	● Never use sharp or pointed objects to operate the front-panel buttons

Symbol	Description
	Turns power on or off.
MODE	Display mode Change [Graph Mode ↔ Number Mode]
SAVE	Start and stop the save function.
TREND	To enter into or exit from Trend mode. The trend frames shows historical patient data and the control knob provides navigation capability.
E.MARK	Marking event

2.6 BT-250 Control Knob

In monitoring mode, the control knob decrease and increase the fetal heart audio volume.
In Trend mode, use Control Knob to search the stored data to recall. After selecting the stored data, press down the Knob to see the data.
In the Setup mode, use Control Knob to adjust parameters. Press down the control knob in monitoring mode to enter Setup mode. Rotate the knob to select the item and press down the knob for editing. Rotate the knob again to change the value and press knob after change.

CAUTION

- Pressing the knob on 'Delete All Memory' item makes the all saved data is deleted.

To save the changed value and exit from Setup mode, select 'ESC' and press the knob. The BT-250 will return to monitoring mode after storing the changes values.

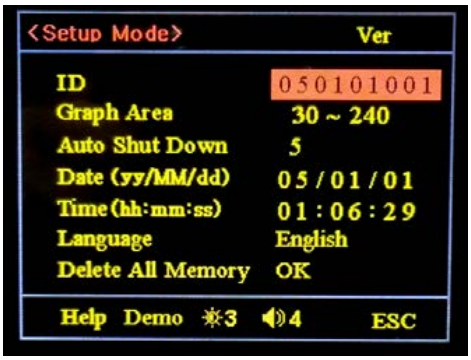


Fig. 4.3 System setup menu

Configuration parameter	Available List
ID (Last 3 digits)	001 ~ 999
Graph Area	30~240/100~180
Auto Shut Down (minutes)	5/10/15/30/off
Date	YY/MM/DD
Time	HH:MM:SS
Language	English/Spanish
Bright	1~5
Start Volume	1~7

2.7 Data Saving

BT-250 has a data saving function. It can save up to 4 hours (10 minutes for one time, total 25 times).

Press [SAVE] button to start saving. When the function is stared, the save icon [ ] is activated and rotated.
Press [SAVE]button again to stop saving.

2.8 Trend Mode (Data Tracing Mode)

Press [TREND] button to enter the Trend mode. In trend mode, the saved data is displayed.

Fig. 4.4 Trend Mode display

Rotate the control knob to select the saved data and press it to see the saved data.

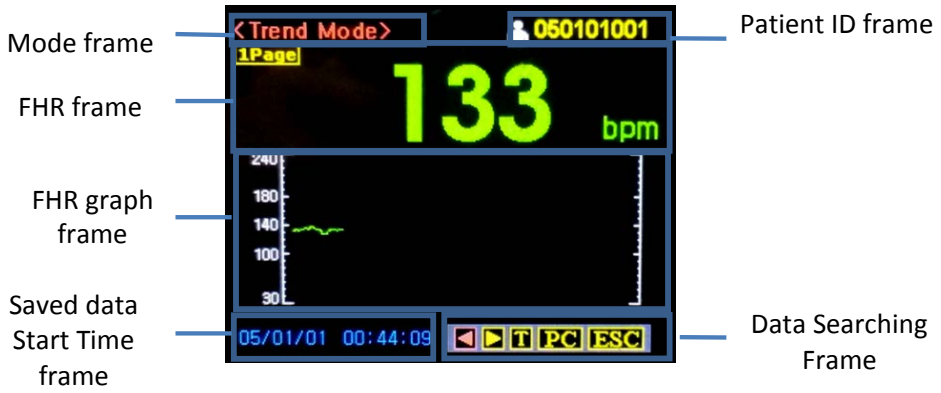


Fig. 4.5 Saved Data Tracing Mode display

2.8.1 Saved Data Start Time Frame

This frame shows the date and start time of data saving.

2.8.2 Patient ID Frame

This frame shows the saved patient ID.

2.8.3 Data Searching Frame

This frame is consisted of control buttons for searching saved data. The description of each button is shown below:

Button	Description
	Searching for saved data in previous page.
	Searching for saved data in next page.
	Tracing the saved data

3 Monitoring fetal heart rate

Fetal heart rate is measured by placing an ultrasound Doppler transducer on the maternal abdomen and by analyzing the echo signal to calculate a heart rate and an audible sound.

Step 1: Preparing the Monitor

Turn the monitor on and verify that the normal monitoring screen appears on the display. Do not use the BT-250 if an error occurs.

Check whether the monitor is powered from the internal battery or AC power. If operating on the internal battery, check the power status frame on the display to determine whether the battery has sufficient charge to complete the monitoring session. Use the AC power if the battery is too low.

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.

Detail Procedure

① Explain procedure to the patient.

② Turn the monitor power on. The power button is located on the front panel.

③ Determine the position of the fetus using Leopold's maneuvers. The strongest fetal heart tones are heard through the fetal back.

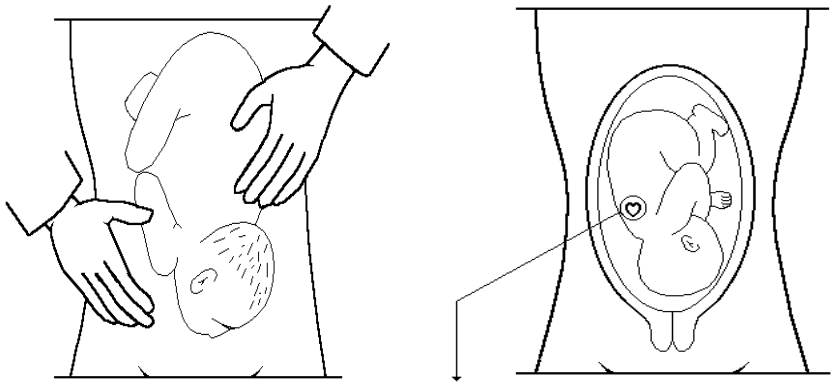
④ Plug the ultrasound transducer cable into the connector labeled "DOP."

⑤ Apply a small amount of ultrasonic transmission gel to the face of the transducer.

⑥ Place the transducer face down on the maternal abdomen over the area determined to be the fetal back.

⑦ Volume Up/Down may be used to adjust the volume.

⑧ Reposition the transducer as necessary until the clearest heart sound is heard. Three to five seconds after a clear heart beat sound is heard, the heart icon will flash synchronously with the sound. This indicates that the received signal is stable.



[Figure 3.1 Direction of Doppler Transducer]

4 Cleaning and disinfection

The BT-250 requires proper care and preventive maintenance. This ensures consistent operation and maintains the high level of performance necessary in monitoring procedures.
All exterior parts and transducer should be cleaned and/or disinfected as necessary or between uses. Clean each compartment to remove any surface particles.

4.1 Monitor

Turn off the monitor prior to clean.

Use a clean gauze pad or lint-free cloth, lightly moistened with a mild detergent, to wipe the surface of monitor. Ensure that cleaning solution does not seep into the monitor. Be careful not to power on the monitor during cleaning.
After cleaning, use a clean, lint-free cloth to dry the surface.

WARNING	●	Unplug the monitor from the AC power source and detach all accessories before cleaning. Do not immerse the unit in the water or allow liquids to enter the case.

CAUTION 	●	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 Transducers

WARNING	●	To avoid electrical shock and damage to the monitor, disconnect the transducer prior to cleaning and disinfecting.

CAUTION 	●	Transducers are sensitive instruments – irreparable damage may occur if they are dropped, knocked against other objects, cut, or punctured. Do not attempt to repair to alter any part of a transducer.
	●	Do not autoclave or EO gas sterilize.

To clean a transducer,

1. Disconnect the transducer from monitor.
2. Moisten a clean gauze pad with water and wipe the transducer to remove any gel or particles remaining on the transducer. If water is not effective, then you can use an approved pre-cleaner or low-level disinfectant.
3. Carefully wipe the entire transducer, including the cable and connector.
4. After cleaning, use a clean cloth to dry the transducer.

To disinfect a transducer,

1. Disconnect the transducer from the monitor.
2. Thoroughly clean, rinse, and dry the transducer.
3. Take care to keep the cable strain relief and the connector of the transducer dry while immersing the transducer in an approved disinfectant.
4. Carefully follow the disinfectant manufacturer's instructions for disinfections or high-level disinfection.
5. After disinfecting or high-level disinfecting, use a clean cloth to dry the transducer.

The following high-level disinfectant agents have been approved for use with transducers.

- Cidex OPA
- Cidex Plus

5 Troubleshooting and maintenance

5.1 Transducer

To test an ultrasound transducer:

1. Properly connect the transducer to the side of 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 monitor speaker if the transducer operating properly. The transducer is operating properly if you can hear noise from the speaker. Do not use the transducer if no sound is heard or until the proper cause is identified and repaired.

5.2 Battery Disposal and Handling

Be sure to follow the applicable regulations and/or laws regarding recycling when dispose the internal Li-ion battery. Avoid storing battery above 60°C (140 °F). If cloth or skin comes in contact with material from inside the battery, immediately wash with plenty of clean water.

5.3 Maintenance

To maintain the safety and functionality of the BT-250, maintenance must be performed every 12 months. Electrical safety tests must also be performed at regular intervals as specified by local safety regulations.

6 Safety and regulatory information

You should make sure to comply with the following safety precautions during all phase of operation. If you fail to comply with these safety precautions or specific warnings in this manual, you violate safety standards in terms of design, manufacture, and intended use of this monitor. Bistos Co., Ltd. does not have liability for your failure to comply with these requirements.

Safety Notice

WARNING	A WARNING notice indicates a hazard. You need to observe an operating procedure, practice, or conducts like that. If you do not correctly perform this notice, it could result in personal injury or death.

CAUTION 	A CAUTION notice indicates a hazard. You need to observe an operating procedure, practice, or conducts like that. If you do not correctly perform this notice, it could result in damage to the system or less of important data.

6.1 Warnings

WARNING

- EXPLOSION HAZARD — Do not use the BT-250 in an explosive atmosphere.
- SHOCK HAZARD —Do NOT use BT-250 with RF Surgical equipment.
- SHOCK HAZARD — Do not attempt to connect or disconnect a power cord with wet hands.
- Always use accessories and cables supplied or appointed by Bistos Co., Ltd.
- Do not contact RS-232C port and patient at the same time.
- Use only AC/DC Adaptor supplied or appointed by Bistos Co., Ltd.
- Do not use stacking and location close to other equipment.
- Do not remove the covers of a monitor yourself to avoid damage to the monitor and unexpected electrical shock. Only qualified Bistos service engineer must repair or replace components.

- Before cleaning up and disinfecting the monitor, always make sure turn off the monitor and unplug the power cord from the power outlet.
- Do not allow water or liquids on or above the monitor. Dripping water or liquids into the monitor may cause electrical shock and damage to the monitor.
- Always use accessories approved by Bistos. You must secure connect the accessories to the monitor.
- Do not modify the monitor such as components, or software. When you modify the monitor, it may cause safety hazards. Only qualified Bistos service engineer must modify the monitor.
- Always use the monitor properly to avoid serious injury. Before using the monitor, you must read the instructions for use carefully.
- Always use transducers approved or supplied by Bistos.
- When you observe that the monitor causes any malfunction, you must stop operating the monitor and contact to Bistos service engineer.
- Always make sure that you do not use the monitor in an explosive atmosphere.
- You should use the monitor after few hours when the monitor is in a high humidity place.
- Using spray cleaners on the monitor drips cleaning fluid into the monitor. It damages component in the monitor.
- Do not use aerosol spray cleaners on the monitor to prevent electrical shock and damage to the monitor.
- Do not use damaged or defective transducer to prevent monitor damage and serious patient injury.
- Use only approved or supplied ultrasound transmission gel. Using unapproved gels may damage the transducer and void the warranty.
- Do not drop the transducer. Always keep the transducer secure in transducer holder when you do not use it.

6.2 Cautions

CAUTION

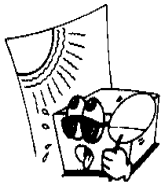
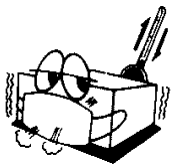
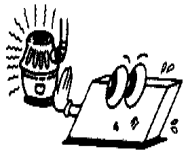
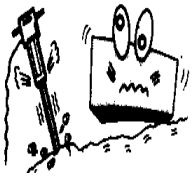
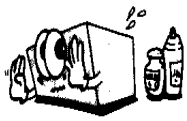
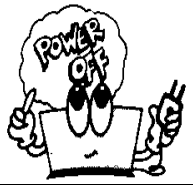
- The relevant law restricts this device to sale by or on the order of a physician.
- Keep the operating environment free of dust, vibrations, corrosive or flammable materials and extremes of temperature and humidity. The unit should be kept clean and free of transducer gel and other substances.
- When installing the unit into a cabinet, allow for adequate ventilation, accessibility for servicing, and room for adequate visualization and operation.
- Do not operate the unit if it is damp or wet because of condensation or spills. Avoid using the equipment immediately after moving it from a cold environment to a warm, humid location
- Never use sharp or pointed objects to operate the front-panel switches.
- Always connect the certified equipment with relevant International standards (e.g. IEC 60950 for IT equipment and IEC 60601-1 for medical equipment) to RS-232C and USB connector.
- Do not autoclave or gas sterilize the BT-250 or any accessories. Follow cleaning and disinfection instructions in Section 6 of this manual.
- Do not immerse transducers in liquid. Follow cleaning and disinfection instructions in Section 6 of this manual.
- When washing the transducer belts, the water temperature must not exceed 60°C (140°F).
- When operating the device by external power supply, noise can be appeared on the sound output due to the instability of power supply. In this case, operate the device by internal battery.
- Examine the device main body 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 often. Do not use the device if there is any visible sign of damage.
- Only the AC line cord supplied with the BT-250, or its

equivalent, is approved for use with the device.

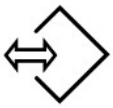
- Do not tamper the BT-250. Only qualified service personnel should attempt any needed internal servicing.
- The BT-250 is not specified or intended to use with defibrillators or during defibrillator discharge.
- The BT-250 is not specified or intended to use with electrosurgical equipment.
- The BT-250 is not specified or intended to use with any other type of monitoring equipment except the specific devices that have been identified for use in this Operator's Manual.
- Perform periodic safety testing to insure proper patient safety. This should include leakage current measurement and insulation testing. The recommended testing interval is once per year.

6.3 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 high variation of temperature exists. Operating temperature ranges from 10 ℃ to 40 ℃. 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 enter into the equipment
	Do not disjoint or disassemble the device. Bistos Co., Ltd. does not have liability of it.		Power off when the equipment is not fully installed. Otherwise, the equipment could be damaged.

6.4 Symbols

Safety Symbol	Description
	Power On/Off Button
	This symbol identifies a safety note. Ensure you understand the function of this control before using it. Control function is described in the operating manual.
	External Signal IN/OUT Port
	Patient applied part meets the isolation requirements for the type BF equipment
IPX7	Protection against ingress of water and particulates IPX7 Waterproof

6.5 Compliance to the standards

The BT-250 ultrasound Doppler system conforms to the following classifications, in accordance with the EN 60601-1

- Type of protection against electrical shock : Class II, internally powered equipment
- Degree of protection against electrical shock (Patient connection) : Type BF equipment
- Degree of protection against harmful ingress of water : ultrasound transducer IPX7
- Mode of operation : Continuous operation

The BT-250 ultrasound Doppler system conforms to the following standards;

- EN 60601-1:2006 + A11:2011
- EN 60601-1-2:2007/AC:2010
- EN 60601-2-37:2008+A11:2011
- EN 60601-1-6:2010
- EN 62304:2006
- EN 62366:2008
- IEC 60529:2013
- EN 1041:2008
- EN ISO 14971:2012
- EN 980:2008
- EN ISO 10993-1:2009
- EN ISO 10993-5:2009
- EN ISO 10993-10:2013

6.6 Guidance and manufacturer's declaration - Electromagnetic emissions

This system is suitable for use in the following environment. The user must assure that it is used only in the electromagnetic environment as specified.

<table>
<tr><td colspan="3">The BT-250 is intended for use in the electromagnetic environment specified below. The customer of the user of the BT-250 should assure that it is used in such an environment.</td></tr>
<tr><td>Emission test</td><td>Compliance</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The BT-250 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.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class B</td><td rowspan="3">The BT-250 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations / flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

6.7 Guidance and manufacturer's declaration - electromagnetic immunity

<table>
<tr><td colspan="4">The BT-250 is intended for use in the electromagnetic environment specified below. The customer or the user of the BT-250 should assure that it is used in such an environment.</td></tr>
<tr><td>Immunity Test</td><td>IEC 60601
Test level</td><td>Compliance level</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td>Electrostatic discharge (ESD)
IEC
61000-4-2</td><td>± 6 kV contact
± 8kV air</td><td>± 6 kV contact
± 8kV air</td><td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.</td></tr>
<tr><td>Electrical fast transient/ burst
IEC 61000-4-4</td><td>± 2 kV for power supply lines
± 1kV for input / output lines</td><td>± 2 kV for power supply lines
± 1 kV for input / output lines</td><td>Mains power quality should be that of a typical commercial or hospital environment.</td></tr>
</table>

Surge IEC 61000-4-5	± 1 kV Line(s) to line(s) ± 2kV Line(s) to earth	± 1 kV Line(s) to line(s) ± 2kV Line(s) to earth	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 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5s	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5s	Mains power quality should be that of a typical commercial or hospital environment. It is recommended to be powered by the internal battery if it is needs to operate when the supply of main power is cut.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be meet the level of a typical commercial area or hospital environment.
Note U_T is the a.c. mains voltage prior to application of the test level.			

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 150 kHz to 80 MHz 3 V/ms 80 MHz to 2.5 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the BT-250, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance.**

			$d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 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 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 EUT is used exceeds the applicable RF compliance level above, the EUT should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the EUT. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

6.8 Recommended separation distances between portable and mobile RF communications equipment and the BT-250

The BT-250 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BT-250 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BT-250 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 80 MHz $d = 1.2\sqrt{P}$	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
NOTE: The application range of high frequency is from 80 MHz and 800 MHz. NOTE: However, it does not mean that these guidelines are applied to every situation without an exception; electromagnetic waves are affected by absorption and reflection from structures, objects and people.			

7 Specifications

Physical Characteristics	
Main body	90 mm(H) x 250 mm(L) x 118 mm(D)
Transducer	29.7mm(Ø) x 145 mm(H)
Weight	approx. 1.5 kg

Power	
Internal	3.7V, Li-ion, rechargeable
	4 hours Fast Charge
	Continuously 5 hours operating
External	AC/DC Adaptor
	Input : AC100~240 V[50/60 Hz]
	Output : DC 9 V, 2.0 A
Power dissipation	18VA, maximum

Environmental	
Operating Temperature	10°C to 40°C (50°F to 104°F)
Transfer & Storage Temperature	–20°C to 60°C (–4°F to 140°F)
Relative Humidity	20% to 90% non-condensing
Altitude	0 - 3048m (0 -10,000 ft)

Doppler Ultrasound FHR Monitoring	
I_{spta}	< 94 ㎽/㎠
Entrance beam dimensions	20 mm, circular
Ultrasonic frequency	2 MHz
BPM Range	30-240 BPM
Accuracy	±2% of range
Leakage	<10 μA @ 264 VAC applied to transducer
Isolation	>4 kV RMS, Type BF applied part

Product Guarantee

Product Name		Fetal Doppler
Model Name		BT-250
Approval No.		
Approval Date		
Serial No.		
Warranty Period		2 Years (Transducer excluded)
Date of Purchase		
Customer	Hospital: Address: Name: Telephone:	
Sales Agency		
Manufacture		Bistos Co., Ltd.

※ Thank you for purchasing BT-250.

※ This product is manufactured and passed through strict quality control and inspection.

※ Compensation standard concerning repair, replacement, refund of the product complies with "**Consumer's protection law**" noticed by Economic Planning Dept.