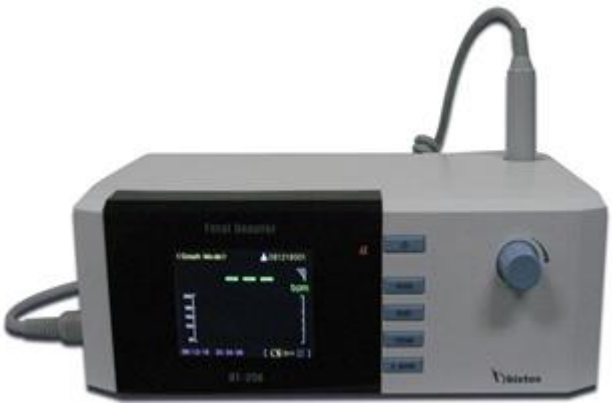
# BT-250 Fetal Doppler
# Operation Manual



**BT-250**

Keep this manual for future reference

*250-ENG-OPM-EUR-R10*

# *Proprietary Material*

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## 0 Safety information

This manual is for users of the BT-250 Fetal Doppler. It describes how to set up and use the Doppler probes. Familiarize yourself with all instructions including warnings and cautions before starting to monitor patients.

In this manual, the following symbols are used for the purpose of:

| | |
|---|---|
| **WARNING** | Alerts you to a potential serious outcome, adverse event or safety hazard. Failure to observe a warning may result in death or serious injury to the user or patient. |
| **CAUTION** | Alerts you to where special care is necessary for the safe and effective use of the product. Failure to observe a caution may result in minor or moderate personal injury or damage to the product or other property, and possibly in a remote risk of more serious injury. |

**Symbols Used**

The following symbols identify all instructions that are important for safety. Failure to follow these instructions can lead to injury or damage to the Fetal Doppler.

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

| | |
|---|---|
|  | Used to identify safety information.<br>Be well-known this information thoroughly before using BT-250.<br>During the operation, do not disconnect any cable. |
|  | Power ON/OFF button |
|  | Indicates the need for the user to consult the instructions for use |
|  | External Signal IN/OUT pservice personneort |
| **IPX7** | Protection against ingress of water and particulates<br>IPX7 Waterproof |
|  | Refer to the operation manual. Read the manual before placing the device. |
|  | Refer to the operation manual. |
|  | This symbol indicates the manufacturer. |
|  | This symbol indicates the production date. |
|  | This symbol indicates the serial number of the device. |
|  | This symbol indicates the authorized representative in the European Community of the manufacturer. |
|  | This symbol indicates a type BF applied part. |
|  | This symbol indicates to keep the device dry. |
|  | This symbol indicates the correct upright position of a package |

| | |
|---|---|
|  | This symbol indicates the device is fragile. |
|  | This symbol indicates the temperature limitation for operation, transport, and storage. |
|  | This symbol indicates the humidity limitation for operation, transport, and storage. |
|  | This symbol indicates the packing material is recyclable. |
| CE 2460 | This symbol indicates compliance with the essential requirements and provisions of the Medical Device Directive 93/42/EEC as amended by 2007/47/EEC. |
|  | In order to comply with EU Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE): 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. |

**0.1 Before using the monitor**

**Intended use**

BT-250 is a desktop ultrasonic Fetal Doppler system that measures fetal heart rate, which is displayed on an LCD display, and outputs the fetal heart sound through built-in speaker. The fetal heart rate is measured using Doppler ultrasound. The device also provides the heart sound from the heart of fetus. The heart rate of fetus can be saved in internal memory for later reference. This device is for use only by trained medical personnel.

(1) Intended patient population
- Pregnant women

(2) Intended user profile
- BT-250 is intended for use by trained health care professionals.
  Before using the device, you should be:
  - trained in the use of fetal heart rate(FHR) monitors
  - trained in the interpretation of FHR traces.
  - familiar with using medical devices and with standard fetal monitoring procedures.

(3) Environment of use
- Hospital environment (birthing center, delivery rooms or examination rooms)
- Requirements: Stable power source

Fetal monitoring technology available today is not always able to differentiate a fetal heart rate (FH) signal source from a maternal heart rate (MHR) source in all situations. Therefore, you should confirm fetal life by independent means before starting to use the fetal monitor, for example, by palpation of fetal movement or auscultation of fetal heart sounds using a fetoscope, stethoscope, or Pinard stethoscope. If you cannot hear the fetal heart sounds, and you cannot confirm fetal movement by palpation, confirm fetal life using obstetric ultrasonography.
Continue to confirm that the fetus is the signal source for the FHR during monitoring. Be aware that a MHR trace can exhibit features that are very similar to those of a FHR trace, even including acceleration and decelerations. Do not rely solely on trace pattern features to identify a fetal source.
It is possible to pick up maternal signal sources, such as maternal heart, aorta, or other large vessels as the FHR. Misidentification may occur when the MHR is higher than normal (especially when it is over 100 bpm).

**0.2 General precautions, warnings and cautions**

Before using BT-250, read all section of this manual carefully because there are additional warnings and cautions which relate to specific features of the monitor.
The warnings and cautions in this section relate to the equipment in general and apply to all aspects of the monitor. The listed order does not imply any order of importance.

**WARNING**

- Thoroughly read and understand the manual prior to use of BT-250. Failure to do so could result in personal injury or equipment damage.
- Only properly trained personnel should use BT-250 as directed by an appropriately qualified attending physician aware of currently known risks and benefits.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. The BT-250 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 Operator's Manual. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally
- Do not use in the presence of flammable anesthetics. Personal injury or equipment damage could occur.
- BT-250 is not intended for use during defibrillation, surgical process especially when used with high frequency surgical equipment, and magnetic resonance imaging (MRI).
- Use of accessories other than those listed and approved for use with this product may result in increased emissions or decreased immunity.
- Use only the configurations including probes and AC cord, supplied with the device or its equivalent, is approved for use with the BT-250. Using any other cables may result in out-of-specification performance and possible safety hazards. This device has been validated with the accessories and options listed in this manual and found to comply with all relevant safety and performance requirements applicable to the device. It is, therefore the responsibility of that person or organization who makes an unauthorized modification or incorporates an unapproved attachment to the device.

**CAUTION**

- 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 before use.
- 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.
- General-purpose personal computers and modems are not designed to meet the electrical safety requirements of medical devices. The RS-232C connector on the BT-250 is electrically isolated to permit safe connections to non-medical devices, which should be connected with a cable of sufficient length to prevent the non-medical equipment from contacting the patient. If the BT-250 have to be connected with other medical devices, it must comply with the standards IEC/EN 60601-1 and IEC/EN 60601-1-2.
- Do not autoclave or gas sterilize the device or any accessories. Follow cleaning and disinfection instructions in Section 4 of this manual.
- Do not immerse BT-250 main body and Doppler in liquid. When using solutions, use sterile wipes to avoid pouring fluids directly on the Doppler. Follow cleaning and disinfection instructions in Section 4 of this manual.
- If the equipment is used in the area where the integrity of the external protective conductor in the installation or its arrangement is in doubt, equipment shall be operated from its internal electrical source when the optional battery is selected.

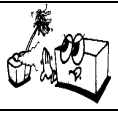
**0.3 Shock hazards**

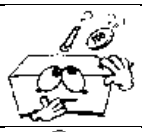
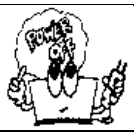
**WARNING**

- Do not attempt to connect or disconnect a power cord with wet hands. Make sure that your hands are clean and dry before touching a power cord.
- Do not to position to make it difficult to operate the disconnection plug.
- Do not attempt to disassemble the power adaptor with no permission. It may cause an electric shock. Also, it has a low possibility of reaching to death. In the case of you have some problems with the power adaptor, we recommend that you have to contact to us first of all.
- During upgrading the BT-250, do not use the BT-250 on the patient. This can cause an electric shock to the patient.
- Unplug the unit from its power source prior to cleaning or maintenance to prevent personal injury or equipment damage.
- If there is smoke or a strange sound, immediately turn off the power of the main body, and then be sure to disconnect the power plug from the outlet.
- Some chemical cleaning agents may be conductive and leave a residue that may permit a build-up of conductive dust or dirt. Do not allow cleaning agents to contact electrical components and do not spray cleaning solutions onto any of these surfaces. Personal injury or equipment damage could occur.
- To ensure grounding reliability, plug the AC power cord only into a properly grounded 3-wire hospital-grade or hospital-use outlet. Do not use extension cords. If any doubt exists as to the grounding connection, do not operate the equipment. Personal injury or equipment damage could occur.
- Do not expose the unit to excessive moisture that would allow for liquid pooling. Personal injury or equipment damage could occur.
- Do not touch the patient and signal input/output parts simultaneously
- Do not attempt to service the BT-250 Fetal Doppler. An operator may only perform maintenance procedures specifically described in this manual. Do not remove the covers of BT-250 yourself to avoid damage to the equipment and unexpected electric shock. Only qualified service personnel by Bistos Co., Ltd. should perform any needed internal servicing.

**0.4 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 ready to operate. Otherwise, the equipment could be damaged. |

# 1 System basics

### 1.1 Operating principle

The device detects the fetal heart rate and heartbeat sound using the Doppler effect of ultrasound and output the result to the LCD.

### 1.2 Essential performance

The accuracy for the FHR should be within ±2% at the range 30 to 240BPM.

### 1.3 System configurations

The basic configuration of BT-250

- Main body
- Doppler probe

Options of BT-250

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

Table 1.1. BT-250 Accessories

### 1.4 Description of the Front Panel

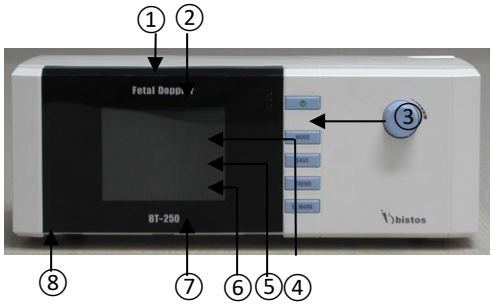


Fig. 1.1 BT-250 Front Panel

| | | | |
|---|---|---|---|
| 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 |

**1.5 Description of the Side Panel**

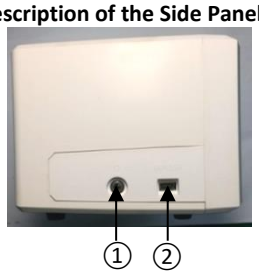



Fig. 1.2 Left Panel

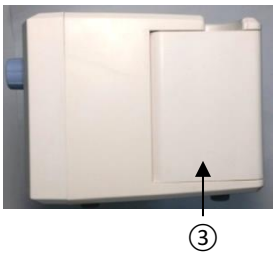



Fig. 1.3 Right Panel

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

**1.6 Description of the Rear Panel**

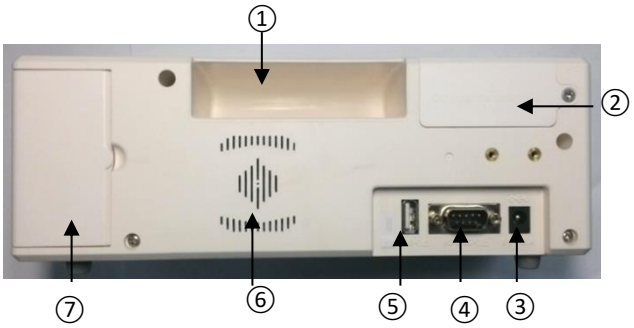



Fig. 1.4 Rear Panel

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

**1.7 Essential performance**

The accuracy for the FHR should be within ±2% at the range 30 to 240BPM.

## 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.

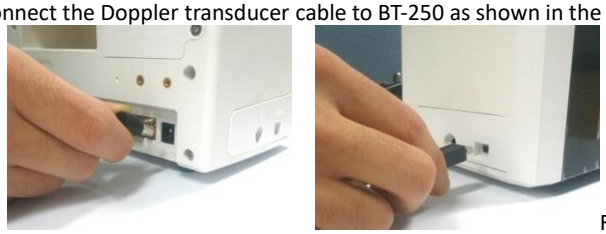


Fig. 2.1 Power adaptor and Transducer Connection

**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**

(1) Graph Mode

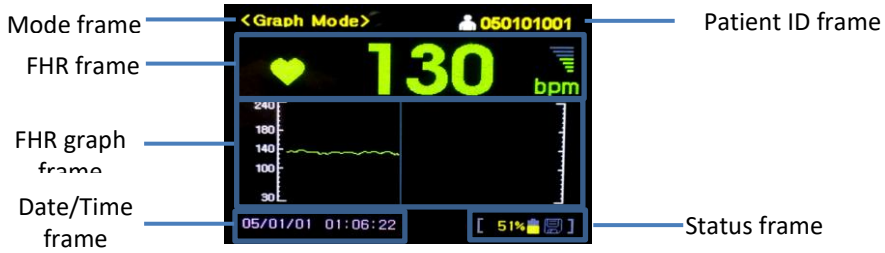



Fig. 2.2 Main Monitoring Screen – Graph Mode

(2) Number Mode

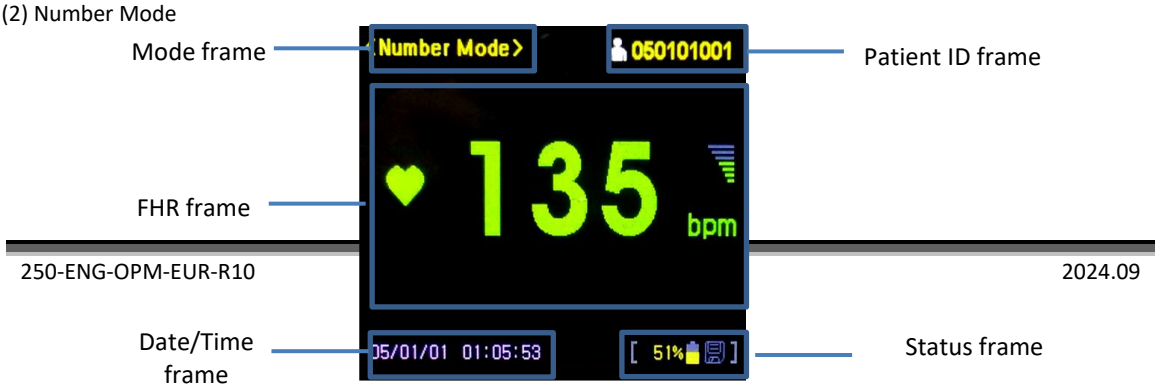


Fig. 2.3 Main Monitoring Screen – Number Mode

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

| ` | 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. 2.4 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. 2.5 Trend Mode display

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

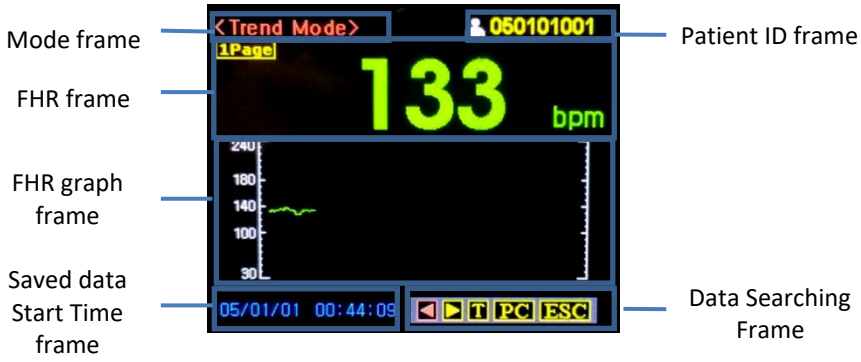



Fig. 2.6 Saved Data Tracing Mode display

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 |

### 2.9 Power off

2.9.1. For the safe power-off of BT-250, follow the below .

- Turn off the power by pressing the power button.
- Remove the power cord after power off.

## 3 Monitoring fetal heart rate

### 3.1 Electromagnetic interference

Strong electromagnetic fields can interfere with the ultrasound transducer and cause a false heart rate reading that does not originate from the fetus. This interference is rare and usually found in the vicinity of large machinery. In order to avoid the possibility of these interferences, 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 transducer(s), turn on the monitor and observe the heart rate indications on the screen for 30 seconds. Intermittent display of random heart rate is acceptable. However, if there is a constant display of a physiological 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 200 cm away from the monitor. Check for extension cords running behind or under the bed and equipment in adjacent rooms. If the artifact heart rate indication ceased, the monitor may be used normally.
- Remove all the line cord from the monitor's power supply. If the artifact heart rate indication ceased, the monitor may be used normally.

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

Fetal heart rate is measured by placing the ultrasound transducer on the maternal abdomen and by processing the received Doppler echo signal to produce a heart rate and an audio representation of the echo signal.

**⚠CAUTION**

- The cable of the Doppler probe is not intended to contact the patient. To prevent such contact, please cover the patient's abdomen section which has a possibility of contacting by the cable with clean gauze or fabric.

### 3.2 Monitoring sequence overview

- ***Step 1: Preparing the Fetal Doppler***
  - 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.
  - 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.

**3.3 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.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.

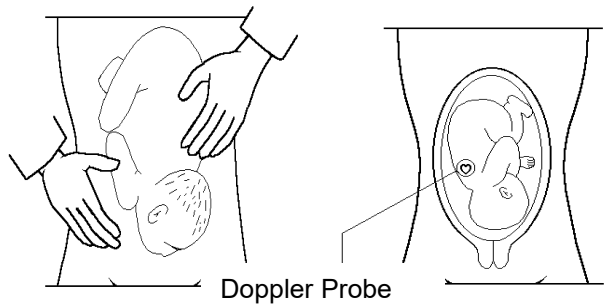



Fig. 3.1 The position of the Doppler probe

**⚠CAUTION**

- When using the product, use a distance of at least 30cm from the speaker and use the cumulative exposure time within 6 hours a day.

## 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.

### 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**

- Unplug the monitor from the AC power source and detach all accessories before cleaning.
- 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

**⚠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 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.

(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<br>14 days Maximum Reuse<br>Contact conditions based on AOAC Sporicidal Activity Test only. | 45 min at 25°C<br>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.
- BT-250 Fetal Doppler 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 BT-250 monitor if it fails to pass the power on self-test procedure.

#### 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 contact the service center and change the battery.

**⚠ WARNING**

- Improper operation may cause the internal lithium-ion battery to be hot, ignited or exploded, or it may lead to a decrease of the battery capacity.
- Do not open the battery compartment. Only the qualified service personnel authorized by the manufacturer can open the battery compartment and replace the battery, and batteries of same model and specification should be replaced. Where incorrect replacement would result in risks such as excessive temperatures, fire or explosion.
- If it won't be used for a long time (over three months), please store the battery properly.
- 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.
- Properly dispose of or recycle the depleted battery in accordance with local regulations.

## 6 Manufacturer's declaration on EMC

BT-250 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-250 and should be kept at least 1 m away from the equipment.

**⚠ WARNING**

- Use of accessories, transducers 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

### 6.1 Electromagnetic emissions

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.

| Emission test | Compliance | Electromagnetic environment - guidance |
|---|---|---|
| RF emissions<br>CISPR 11 | Group 1 | 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. |
| RF emissions<br>CISPR 11 | Class B | 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.<br>⚠ **Warning:** This BT-250 is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, |
| Harmonic emissions<br>IEC 61000-3-2 | Class A | |
| Voltage fluctuations / flicker emissions<br>IEC 61000-3-3 | Complies | |

| | | |
|---|---|---|
| | | such as re-orienting or relocating the BT-250 or shielding the location. |

**6.2 Electromagnetic immunity**

| 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. | | | |
|---|---|---|---|
| Immunity Test | IEC 60601<br>Test level | Compliance<br>level | Electromagnetic environment - guidance |
| Electrostatic discharge (ESD)<br>IEC 61000-4-2 | ± 6 kV contact<br>± 8kV air | ± 6 kV contact<br>± 8kV 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<br>IEC 61000-4-4 | ± 2 kV for power supply lines<br>± 1kV for input / output lines | ± 2 kV for power supply lines<br>± 1 kV for input / output lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge<br><br>IEC 61000-4-5 | ± 1 kV Line(s) to line(s)<br>± 2kV Line(s) to earth | ± 1 kV Line(s) to line(s)<br>± 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<br>IEC 61000-4-11 | <5% $U_T$<br>(>95% dip in $U_T$) for 0.5 cycle<br>40% $U_T$<br>(60% dip in $U_T$) for 5 cycles<br>70% $U_T$<br>(30% dip in $U_T$) for 25 cycles<br><5% $U_T$<br>(>95% dip in $U_T$) for 5s | <5% $U_T$<br>(>95% dip in $U_T$) for 0.5 cycle<br>40% $U_T$<br>(60% dip in $U_T$) for 5 cycles<br>70% $U_T$<br>(30% dip in $U_T$) for 25 cycles<br><5% $U_T$<br>(>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<br>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. |
| Conducted RF<br>IEC 61000-4-6<br><br>Radiated RF IEC 61000-4-3 | 3 Vrms<br>150 kHz to 80 MHz<br><br>3 V/m<br>80 MHz to 2.5 GHz | 3 Vrms<br>150 kHz to 80 MHz<br><br>3 V/ms<br>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.<br>**Recommended separation distance.**<br>$d = 1.2\sqrt{P}$<br>$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz<br>$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz<br>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).<br>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]<br>Interference may occur in the vicinity of equipment marked with the following symbol :<br> |
| NOTE 1) $U_T$ is the a.c. mains voltage prior to application of the test level.<br>NOTE 2) At 80 MHz and 800 MHz, the higher frequency range applies.<br>NOTE 3) 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.<br>[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m. | | | |

**6.3 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.<br>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 |

| **Safety** | |
|---|---|
| Standard | EN 60601-1, EN 60601-1-2, EN 60601-2-37 |
| Classification | Class I, Internal Powered Equipment |
| Mode of Operation | Continuous operation |
| Protection against electric shock | Type BF applied part |
| Protection against ingress of water | IPX7(Doppler) |

| **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) |
| Operating humidity | 5 ~ 85%, Non condensing |
| Operating atmosphere | 80kPa ~ 106kPa |
| Storage temperature | –20°C to 60°C (–4°F to 140°F) |
| Storage humidity | 20% to 90% non-condensing |
| Storage atmosphere | 70kPa ~ 101.325kPa |

| **Doppler Ultrasound FHR Monitoring** | |
|---|---|
| MI and TI values do not exceed 1.0. | |
| $I_{spta}$ | < 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 Warranty

| | |
|---|---|
| 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:<br>Address:<br>Name:<br>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 "**Framework Act on Consumers**" noticed by Fair Trade Commission of Republic of Korea.

## Service Telephone and Fax. Numbers

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