BT-350 Fetal Monitor
Operation Manual



Keep this manual for future reference

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0 Safety information

This manual is for users of the BT-350 fetal monitor. It describes how to set up and use the monitor and 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 monitor.

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. Be well-known this information thoroughly before using BT-350.
	Power ON/OFF button
	Indicates the need for the user to consult the instructions for use
	External Signal IN/OUT port
IPX8	IPX8 Protected against the effects of continuous immersion in water (1 meter of water for over 40 minutes). It correspond Doppler probe and UC probe
	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.
SN	This symbol indicates the serial number of the device.
EC REP	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-350, the non-invasive fetal monitoring system provides graphical and numerical information on fetal heart rate (FHR) and maternal uterine activity (UA) to help assess fetal well-being before and during labor. FHR often exhibits decelerations and accelerations in response to uterine contractions or fetal movements; Examination of these patterns, the baseline levels, and variability characteristics can indicate the need to alter the course of labor with drugs or perform an operative delivery.
BT-350 is intended for generating alarms from fetal heart rate, for displaying, storing and recording patient data and related waveforms.

1) Intended patient population
   - Pregnant women
2) Intended user profile
   - BT-350 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-350, 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-350. Failure to do so could result in personal injury or equipment damage.
- Only properly trained personnel should use BT-350 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-350 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-350 is not intended for use during defibrillation, surgical process especially when used with high frequency surgical equipment, and magnetic resonance imaging (MRI).
- Use only the configurations including probes, transducer and AC cord, supplied with the monitor or its equivalent, is approved for use with the BT-350. 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-350 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-350 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 monitor or any accessories. Follow cleaning and disinfection instructions in Section 9 of this manual.
- Do not immerse BT-350 main body and transducers in liquid. When using solutions, use sterile wipes to avoid pouring fluids directly on the transducer. Follow cleaning and disinfection instructions in Section 9 of this manual.
- When loading paper, the paper must be put above the shaft. Otherwise, the paper can be declined on one side.
- 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.
- When the printer door is open, do not put the finger to the inside of BT-350. This can cause the finger wound. Also, do not prick the inside of BT-350 when the printer door is open. This can cause damage to the device or electric shock.
- To avoid electric interference, position the sensor cable and connector away from power cables.
- Do not unplug AC adopter or cables while the monitor is powered on. When you finish working on the device, you should turn off the device by [Power ON/OFF] button at first.

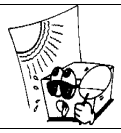
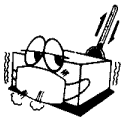
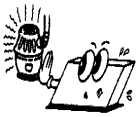
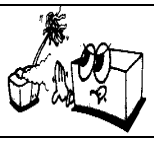
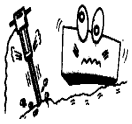
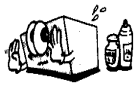
0.3 Electric safety

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 or repairing and clean the BT-350, do not use the BT-350 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-350 monitor. An operator may only perform maintenance procedures specifically described in this manual. Do not remove the covers of BT-350 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 precautions 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 a 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 ~ 40°C. Operating humidity ranges from 5% ~ 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 take responsibility for 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, heartbeat sound and fetal movement using the Doppler effect of ultrasound and measure the relative uterine contraction using the strain gauge and output the result to the printer. The two probes are equipped to detect the fetal heart rate and heartbeat sound of twins.
The detection and measurement result can be displayed on the LCD type(BT-350) or on LED type(BT-350E).

Essential performance

1) The accuracy for the FHR should be within +/- 2% at the range 30 to 240 BPM.
2) The display range of the UC is from 0 to 100.

1.2 System configurations

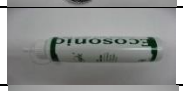
The basic configuration of BT-350

- Main body
- Two Doppler probes
- UC probe

Options of BT-350

- AST probe
- Event marker
- Li-ion Battery (14.8V, 2600mAh)

Accessory	Name	Description
	Doppler Probe	Ultrasound Transducer for Measuring FHR (IPX8: Waterproof)
	UC Probe	Pressure Sensor for Measuring Uterine contraction(UC) (IPX8: Waterproof)
	Event Marker	Used for a Fetal Movement event

Accessory	Name	Description
	Z-folded type Paper	Z-folder type thermal Paper
	Probe Belt	Used for Holding Doppler Probe and/or UC Probe
	Power Cord	AC Power cord
	Power Adaptor	Adaptor for transform AC Power (100-240V ~) to DC 18V(2.8A)
	Ultrasound Gel	Ultrasound transmission gel (Sanipia, ECOSONIC)
	AST Probe (Option)	Acoustic Stimulation Test Probe
	LI-ION Battery	14.8V, 2600mAh

1.3 Product outlook



LCD type LED type

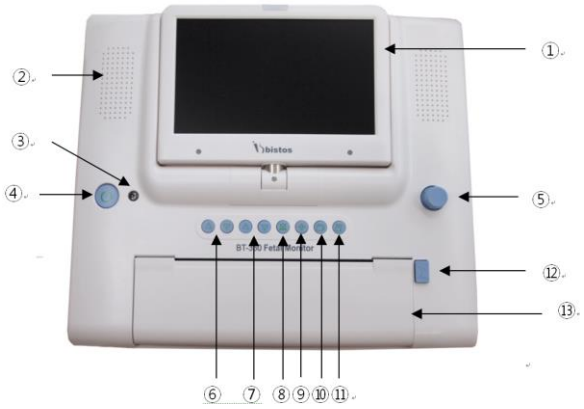
Figure1-1: Front view



Left side view Right side view

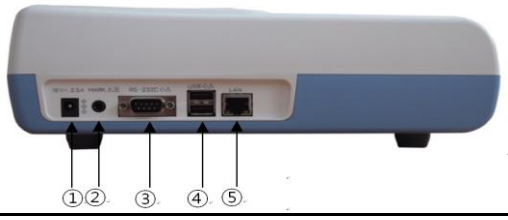
Figure1-2: Side view

1.4 Description of System components

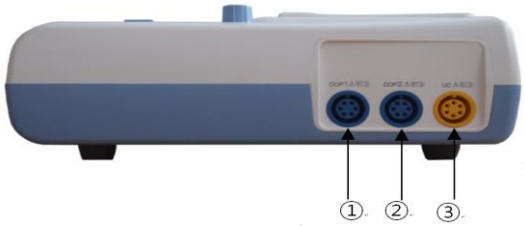




No	Name & Description	
①		TFT Color LCD
②		Speaker
③		Power indicating LED (AC: Green / Battery: Orange)
④	⏻	Power ON/OFF button: Turns the power On or Off
⑤		Control knob
⑥	1	DOP1 volume UP/DOWN button: Increase or decrease DOP1 fetal audio volume in monitoring mode
⑦	2	DOP2 volume UP/DOWN button: Increase or decrease DOP2 fetal audio volume in monitoring mode
⑧		Alarm sound ON/OFF button: Makes the alarm sound enable or disable in monitoring mode
⑨		UC reference button: Resets the UC baseline in monitoring mode
⑩		Mode change button: The monitor operating mode change
⑪		Printer ON/OFF button: Turn the printer On or Off
⑫		Print door open button
⑬		Printer door
⑭		7 segment LED Display(for LED type)



	Name & Description
①	Power adaptor jack connector
②	Event marker connector
③	RS-232C port
④	USB port
⑤	LAN port



	Name & Description
①	DOP1/AST connector
②	DOP2/AST connector
③	UC connector

1.5 Understanding the display

1.5.1Main monitoring screen of LCD display

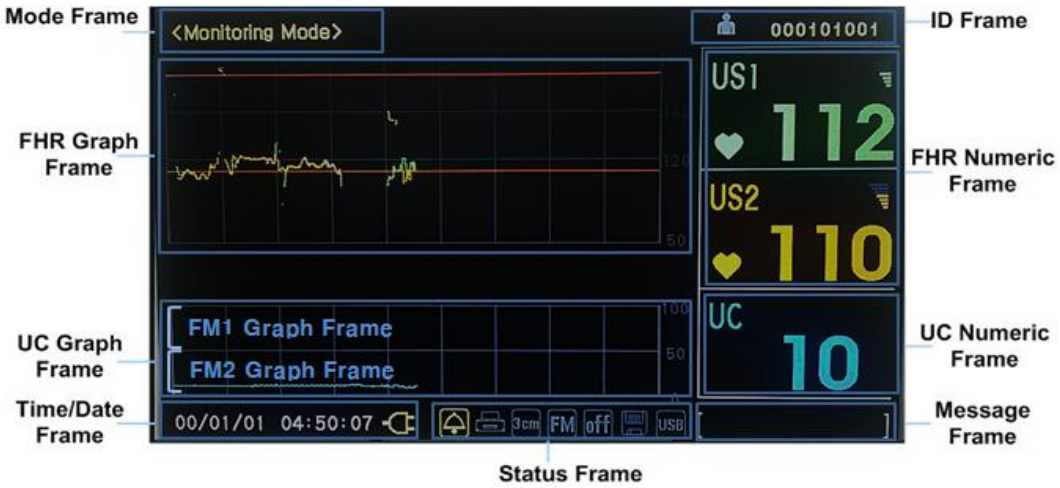


Figure 1-3 – Main monitoring screen of LCD display – Graph mode

1.5.1.1 Mode frame

The mode frame shows the current mode. There are monitoring mode, setup mode, and trend mode.

1.5.1.2 Patient ID frame

This frame displays patient identification. The monitor encodes the identification using the date to ensure no duplication of IDs. The user may enter a patient name if desired.

1.5.1.3 FHR graph frame

The FHR graph frame displays a graphical representation of the FHR. The horizontal line is scaled according to the printer paper setting (Refer to the "Printer paper select" chapter). The graph displays 4 minutes and 30 seconds of data.

This frame will show two heart rate trends when two ultrasound transducers are connected.

1.5.1.4 FHR numeric frame

The FHR numeric frame displays the fetal heart rate, a heart icon, and the volume icon. The heart rate value displays the most recently calculated fetal heart rate. When a valid heart rate is detected, the heart icon blinks at the measured heart rate interval. The volume icon indicates the current speaker volume setting.

When the second ultrasound transducer is connected, the heart rate frame "US2" will display the fetal heart rate, a heart rate icon, and the volume icon automatically. The trace-offset (DOP2 offset) icon will also appear in the FHR frame if two ultrasound transducers are connected and ultrasound trace offset (DOP2 offset) has been enabled. The trace-offset icon is either "[+10]", "[+20]", "[+30]", or "[+40]" depending on the setting.

1.5.1.5 UC (TOCO) graph frame

This frame displays the relative uterine contraction in graph form. The scale is from **zero to 100** in relative units. The graph displays 4 minutes and 30 seconds of data.

1.5.1.6 UC (TOCO) numeric frame

This frame displays the numerical value from the UC probe representing relative uterine contraction. This frame also shows the present UC baseline value. A user can reset the baseline to 10.

1.5.1.7 Time/Date frame

This frame shows the current time and date and power source. The time and date can be changed. If the device is operating using AC power then AC power icon is displayed. If the device is operating by battery power, then a battery icon is displayed. The battery icon also displays charging status. If the battery option is equipped selected, the internal

battery is used when AC power disconnected.
The battery icon will flash when the battery is low (less than 10 minutes of remaining operating time). If the battery is low (Low Battery) the printer will stop operating and the battery icon will turn to red. The AC power should be connected to the device to charge the battery. The device will operate normally while the AC power is charging the battery.

1.5.1.8 Status frame

This frame displays alarm status icon, printer status icon, printer speed set value, fetal movement set status, auto printing status, save icon, and USB icon. The alarm icon is a bell. A diagonal line on the bell indicates that alarm is disabled.

1.5.1.9 Message frame

This frame displays the error and current operation status. The error message will be displayed when the device is unable to operate properly. If this error message displayed, stop using the device and check.

Message	Description
DOP1 OPEN	DOP1 is not connected while BT-350 is monitoring
DOP2 OPEN	DOP2 is not connected while BT-350 is monitoring
DOOR OPEN	Printer door is opened while BT-350 is printing
No PAPER	Paper is not loaded while BT-350 is printing
LOW BAT	Battery's charging level is low while BT-350 is monitoring



Figure 1-4 – Main monitoring screen of LED display – Number mode

Symbol	Name	Description
	Heart Rhythm Icon	Blinking according to heart rate
	Alarm Sound Icon	Indicating of Alarm sound enable/disable
	Volume Icon	Indicating the speaker volume setting for the fetal echo sounds
	Mute Icon	In the case of volume level 0
	Print Icon	Indicating a printing status
	Save Icon	Indicating a data saving status
3cm	Print Speed Icon	Indicating print speed status
off	Auto Print Icon	Indicating of the status of the auto printing function
	AC Power Icon	Indicates the unit is operating on AC power
50%	Battery Status Icon	Indicates the battery charge status (Only when the BT-350 is operated by battery, this icon is displayed.)
USB	USB Icon	Indicating USB connection status.

1.5.2 Main monitoring screen of LED display



Figure 1-5 – Main monitoring screen of LED type

1.5.2.1 Heart Rhythm

The heart symbol is turned on according to FHR value. If FHR value is out of normal range (30 ~ 240), the heart symbol is turned off.

1.5.2.2 FHR/UC frame

The FHR frame displays the detected fetal heart rate. When the second ultrasound transducer is connected, the "US2" frame will display the fetal heart rate too.

This frame displays the numerical value from the UC probe representing relative uterine contraction. This frame also shows the present UC baseline value. A user can reset the baseline to 10.

1.5.2.3 Status frame

This frame shows the LED type status.

Display	Description
Print	Indicating a printing status
Alarm	Indicating of Alarm sound enable/disable
USB	Indicating of USB record status
US +20	Indicating of US2 offset enable/disable

2 Operation of LCD type

2.1 System startup: Self-test

The monitor performs a self-test each time it is turned on. This process allows the monitor to check various systems for proper operation. The monitor displays the startup screen during the power-on-self-test. When the test is successfully completed the BT-350 displays the monitoring screen.

If a malfunction is detected an error message displays and an error tone is sounded. The error tone will continue until the power is turned off. If this occurs, remove the monitor from use until appropriate action is taken.

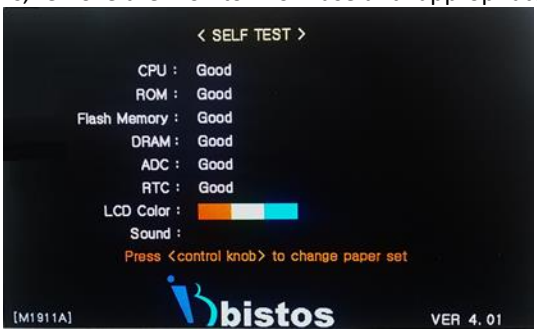


Fig. 2.1 Self-test display

2.2 Buttons

There are seven buttons located on the front panel. The buttons are activated by pushing with the finger until an audible click sound is heard.

CAUTION

- Never use sharp or pointed objects to operate the front-panel switches.

The operation of the button is as below.

Symbol	Name	Description
	Power On/Off Button	Turns the power on or off.
	Dop1 Volume Up/Down Button	Decreases or increases Dop1 fetal audio volume in monitoring mode.
	Dop2 Volume Up/Down Button	Decreases or increases Dop2 fetal audio volume in monitoring mode.
	Alarm On/Off Button	Makes the alarm sound enable or disable in monitoring mode.
	UC Reference Button	Resets the UC baseline in monitoring mode.
	Mode Button	Puts the monitor into trend scroll mode. The trend frames show historical patient data and the control knob provides navigation capability.
	Record On/Off Button	Turns the record on or off.

2.3 Control knob and system setting

Use the control knob to select the parameter to change and to adjust the parameter value selected.

Press down the knob activates the setup menu as shown in Fig.2.2. Turn the knob clockwise or counterclockwise to move the cursor and press down it to select the parameter. Turn the knob to change the value and press down to store the value. The basic operation sequence is summarized in the below table. Select “ESC” and press down the knob to save the exit setup menu.



Fig. 2.2 System setup menu

The monitor has several configuration settings that the user can change. These parameters are unaffected when the monitor is powered down. Below is the default setting value of parameters.

Parameter	Factory Default
Fetal Heart Rate Upper Alarm Limit	190 BPM
Fetal Heart Rate Lower Alarm Limit	110 BPM
Dop2 Trace Separation (Dop2 Offset)	0 BPM
FM Graph	OFF
Printing Speed	3 cm/min
Auto Printing	0 MIN
Patient Name	blank
Patient ID	Date/Sequential number
Date	YY/MM/DD
Time	HH:MM:SS
Auto Save	OFF
Language	English
Paper	FS151-90-80R-01

The basic operation of the control knob to parameter settings is as follows.

Activity	Desired Result
Press down	Enter the setup menu
Rotate	Move the cursor
Press down	Select the parameter to change.
Rotate	Change the value
Press down	Store the new value.

2.3.1 Alarm upper limit/lower limit set

The upper and lower alarm limit can be changed. The adjustable range for upper limit is [Lower limit +10] ~ 240 BPM with 5 BPM step. The adjustable range for a lower limit is 30 ~ [Upper limit – 10] BPM with 5 BPM step.

2.3.2 DOP2 offset set

The two waveforms for each Doppler transducer can be separated to prevent some confusing and enable to see the waveform clearly. When ultrasound trace separation is enabled, the trend data for ultrasound channel 2 is shifted up by either of 10, 20, 30 or 40 BPM in printing. This feature is useful when both heart rates waveforms are similar. The heart rate value shown in the numeric frame is not affected. If DOP2 offset is selected, one of [+10], [+20], [+30] or [+40] is displayed in US2 numeric frame depending on the selection.

2.3.3 Fetal movement (FM) graph

The fetal movement graph display can be turned on and off.

2.3.4 Printing speed

The printing speed can be selected among 1cm/min, 2cm/min, and 3cm/min.

2.3.5 Auto printing

The printer can be turned off automatically. If the value is set to 0, the printer will print out until the paper ended. If the value is set to 10, the printer will turn off after 10 minutes. You can choose among 0, 10, 20, 30, 40, 50, and 60.

2.3.6 Entering the patient name

You can enter a patient name if required. If you select the [NAME] item, you can see the following display to enter the name. If you want to enter the second character of the selected character set, you can press down the knob twice. For example, D requires one press down and F requires three press down.

.QZ	ABC	DEF	GHI	JKL	MNO
PRS	TUV	WXY	␣	←	ESC

2.3.7 Entering the patient ID

Patient ID is generated automatically when BT-350 has turned on. This ID is composed of YYMMDD + 3 digits serial number. The 3 digits number can be changed manually.

2.3.8 Set date and time

Set the date and time if required. Enter date in the YY/MM/DD format and time in the 24 hours format.

2.3.9 Set auto save

You can save the measured data manually or automatically. If [AUTO SAVE] function activates, all the measured data is stored from the power on. The default value for this function is OFF.

2.3.10 Set language

The default language setting is English. You can choose among English, Chinese, Spanish, German, French, Indonesian, Russian, Portuguese, Turkish, Polish, Italian, Korean, Japanese, and Serbian.

2.3.11 CMS (Central monitoring system) settings

You can change the communication channel, IP address, subnet address, gateway address, port address, and HRV (Heart Rhythm Variability) sensitivity. You can choose the communication channel between Serial and Ethernet. And you can choose the HRV sensitivity among low, middle, and high. You can enter a value for other parameters.

2.4 Printer paper select

You can use two different types of paper, FS151-90-80R-01 and M1911A, with BT-350. If you press down the control knob during the self-test, you can select the printer paper.

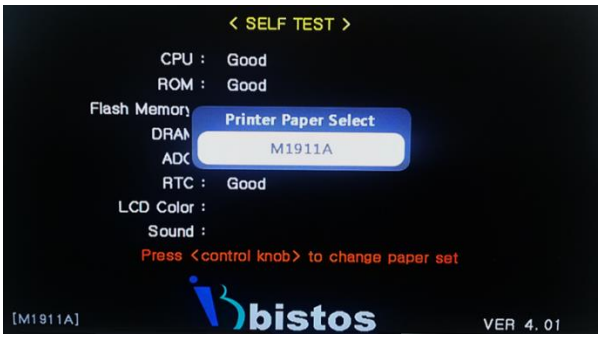


Fig. 2.3 Printer paper select

Paper	Graph Display Area	Print Area
FS151-90-80R-01	30-240 bpm	30-240 bpm
M1911A	50-210 bpm	50-210 bpm

CAUTION

- If you use a different type of paper from the selected paper type, the printed data will be incorrect. Be sure to check the selected paper type is the same with used paper.
- When paper type is changed, the alarm upper limit is changed to 190 and alarm lower limit is changed to 110.

2.5 Data saving

The measured data can be saved to the monitor itself and USB, if connected, at the same time. For each patient, up to 3 hours of data can be saved. Totally 450 hours of data can be saved. The saved data can be totally copied moved from BT-350 to USB memory later.

2.5.1 How to save data

Press down the mode button [ ] to activate the following menu.

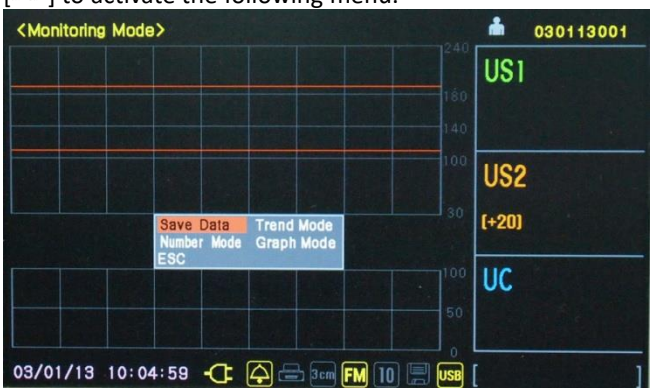


Fig. 2.4 Save Date display

Select [Save Date] item and press down the control knob to start the saving function. If the save function activated save icon [ ] is activated by yellow color and rotate. Press down the mode button [ ] to finish data saving. If the USB memory is connected, the USB icon activated by yellow color and data saved to USB memory simultaneously.

2.5.2 How to copy the saved data to USB

Press down the mode button [ ] to activate menu while USB memory has connected. Select “Trend Mode”. Turn the control knob to select USB and the USB will turn to red color. Then press down the control knob to copy the saved data to USB memory.



Fig. 2.5 Trend mode display

2.6 Trend mode

In trend mode, you can see the saved data. Press down the mode button [ ] to activate the menu shown in figure 2.4. Rotate the control knob to select the “Trend Mode”. Press down the control knob to enter the trend mode.
The data saved date and time and the relevant patient ID are displayed. You can search for data by a patient or by page and tracing saved graphic data.

Button	Function
	Searching for saved data by patient ID. Selecting Previous / Next Patient
	Searching for saved data by saved page. Selecting Previous / Next Page
	Tracing the saved graphic data

2.7 CTG (Cardiotocography) analysis function

The CTG analysis function is a computerized diagnosis of fetal heart rate and uterine contraction patterns.
When this function is activated, a CTG algorithm monitors continuous FHR and UC value for 20 minutes and analyzes FHR variability and relative FHR response to UC change.
To activate this function, press down the control knob during self-test for 4 times and then the following menu will be displayed.

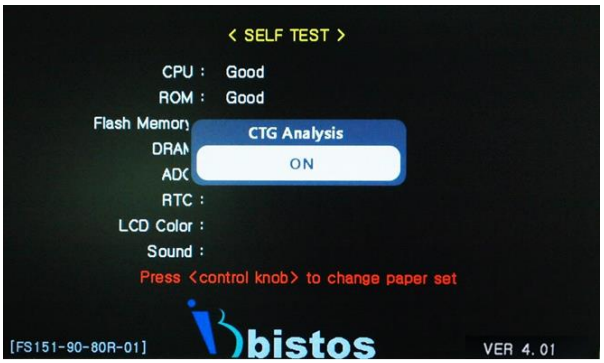


Fig. 2.6 CTG analysis function

After selecting ON the CTG analysis function, you can use this function by pressing the [Print] button in the monitoring mode. On pressing the [Print] button, the mode will change from <Monitoring Mode> to <CTG Mode> and the printing will be started. On the FHR frame, the <Baseline Value> will be displayed.

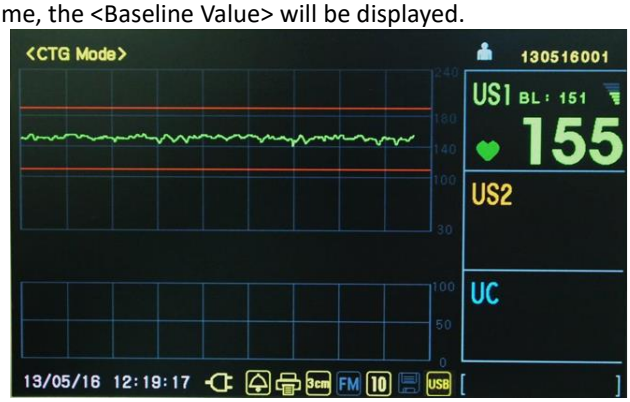


Fig. 2.7 CTG mode

When you press down the [Print] button again after more than 20 minutes elapsed, printing will be stopped and CTG analysis will be ended. The analysis result will be displayed and printed.

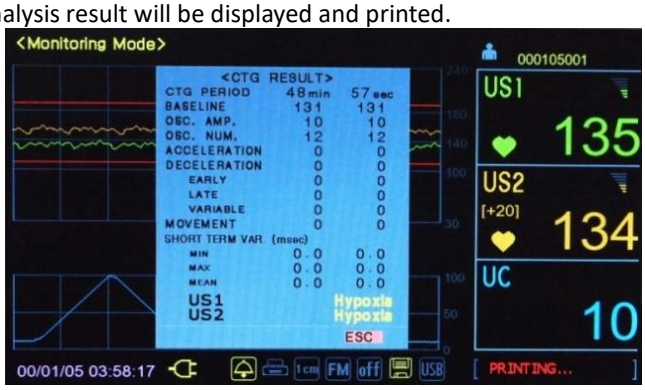


Fig. 2.8 CTG results in monitoring mode



Fig. 2.9 CTG result in trend mode

2.8 CCV (Cross-channel verification) function

When monitoring two fetuses with two Doppler probes, CCV function will compare the values from both probes and alerts when the values could be the same source (fetus).

If the difference between two probe values is within 2 bpm for more than 25 seconds during 30 seconds monitoring period, CCV alert will be generated and Ĉ icon will be displayed.

To activate this function, press down the control knob during self-test for 3 times and then the following menu will be displayed.

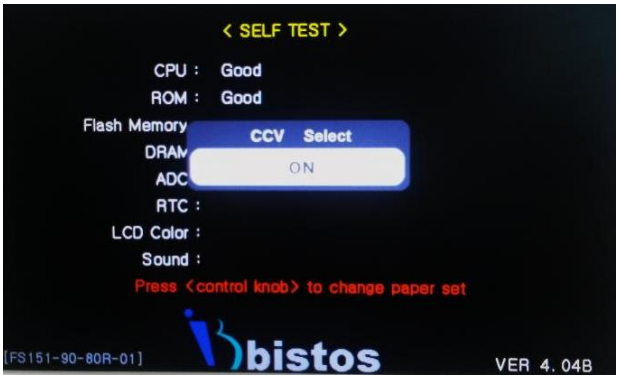


Fig. 2.10 CCV function

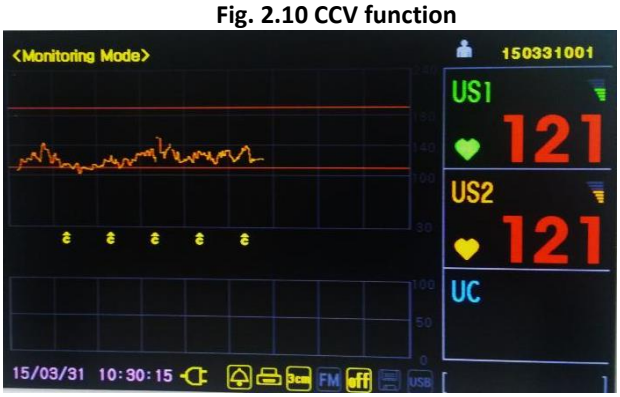


Fig. 2.11 CCV displayed

If the CCV appears during printing the data, Ĉ icon will be printed on the paper.

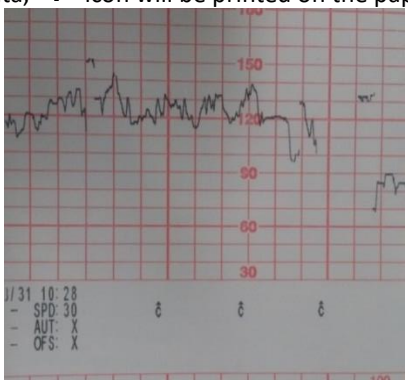


Fig. 2.12 CCV printed

3 Operation of LED type

3.1 Buttons

There are seven buttons located on the front panel. The buttons are activated by pushing with the finger until an audible click sound is heard.

CAUTION

- Never use sharp or pointed objects to operate the front-panel switches.

The operation of the button is as below.

Symbol	Name	Description
⏻	Power On/Off Button	Turns the power on or off.
1△ 1▽	Dop1 Volume Up/Down Button	Decreases or increases Dop1 fetal audio volume in monitoring mode.

Symbol	Name	Description
	Dop2 Volume Up/Down Button	Decreases or increases Dop2 fetal audio volume in monitoring mode.
	Alarm On/Off Button	Makes the alarm sound enable or disable in monitoring mode.
	UC Reference Button	Resets the UC baseline in monitoring mode.
	Mode Button	Puts the monitor into trend scroll mode. The trend frames show historical patient data and the control knob provides navigation capability.
	Record On/Off Button	Turns the record on or off.

3.2 Information messages

The following messages are displayed to indicate the error and current operation status. The error message is displayed when the monitor is unable to operate properly. If the error message is showing up, stop using LED type and take appropriate action.

Message	Description
	DOP1 OPEN. Doppler probe is not connected to DOP1 connector
	DOP2 OPEN. Doppler probe is not connected to DOP2 connector.
	DOOR OPEN. The print door is opened.
	NO PAPER. Paper is not loaded
	LOW BATTERY. Battery charging level is low

3.3 Control knob and system setting

Use the control knob to select the parameter to change and to adjust the parameter value selected.

The monitor has several configuration settings that the user can change. These parameters are unaffected when the monitor is powered down. Below is the default set of parameters.

Parameter	Factory Default
Fetal Heart Rate Upper Alarm Limit	190 BPM
Fetal Heart Rate Lower Alarm Limit	110 BPM
Dop2 Trace Separation (Dop2 Offset)	0 BPM
FM Graph	OFF
Printing Speed	3 cm/min
Auto Printing	0 MIN
Paper	FS151-90-80R-01

The basic operation of the control knob to parameter settings is as follows.

Activity	Desired Result
Press down	Enter the setup menu
Rotate	Move the cursor
Press down	Select the parameter to change.
Rotate	Change the value
Press down	Store the new value.

3.3.1 Alarm upper limit/lower limit set

The upper and lower alarm limit can be changed. The adjustable range for upper limit is [Lower limit +10] ~ 240 BPM with 5 BPM step. The adjustable range for a lower limit is 30 ~ [Upper limit – 10] BPM with 5 BPM step.



Fig. 3.1 Alarm Upper /Lower Limit

3.3.2 DOP2 offset set

The two waveforms for each Doppler transducer can be separated to prevent some confusing and enable to see the waveform clearly. When ultrasound trace separation is enabled, the trend data for ultrasound channel 2 is shifted up by either of 10, 20, 30 or 40 BPM in printing. This feature is useful when both heart rates waveforms are similar. The heart rate value shown in the numeric frame is not affected. If DOP2 offset is selected, one of [+10], [+20], [+30] or [+40] is displayed in US2 numeric frame depending on the selection.



Fig. 3.2 DOP2 offset

3.3.3 Set date and time

Set the date and time if required. Enter date in the YY/MM/DD format and time in the 24 hours format.



Fig. 3.3 Date and time

3.3.4 Printing speed

The printing speed can be selected among 1cm/min, 2cm/min, and 3cm/min.



Fig. 3.4 Printing speed

3.3.5 Auto printing

The printer can be turned off automatically. If the value is set to 0, the printer will print out until the paper ended. If the value is set to 10, the printer will turn off after 10 minutes. You can choose among off, 10, 20, 30, 40, 50, and 60.



Fig. 3.5 auto printing

3.3.6 Fetal movement (FM) graph

The fetal movement graph display can be turned on and off.



Fig. 3.6 Auto printing

3.3.7 Printer paper select

You can use two different types of paper, FS151-90-80R-01 and M1911A, with BT-350. If you press down the control knob during the self-test, you can select the printer paper.

Paper	Graph Display Area	Print Area
FS151-90-80R-01	30-240 bpm	30-240 bpm
M1911A	50-210 bpm	50-210 bpm



Fig. 3.7 Printer paper select

CAUTION

- If you use a different type of paper from the selected paper type, the printed data will be incorrect. Be sure to check the selected paper type is the same with used paper.
- When paper type is changed, the alarm upper limit is changed to 190 and alarm lower limit is changed to 110.

3.3.8 CCV On/Off

When monitoring two fetuses with two Doppler probes, CCV function will compare the values from both probes and alerts when the values could be the same source (fetus).

If the difference between two probe values is within 2 bpm for more than 25 seconds during 30 seconds monitoring period, CCV alert will be generated and ĉ icon will be displayed.

This CCV function can be on and off.



Fig. 3.8 CCV function select

3.3.9 CMS (Central monitoring system) communication channel

CMS communication channel can be selected between serial and Ethernet.



Fig. 3.9 CMS communication channel

3.3.10 IP address set

Set the IP address as required.



Fig. 3.10 IP address set

3.3.11 Subnet mask set

Set the subnet mask as required.



Fig. 3.11 Subnet mask set

3.3.12 Gateway set

Set the gateway as required.



Fig. 3.12 Gateway set

3.3.13 Port number set

Set the port number as required.



Fig. 3.13 Port number set

3.3.14 HRV (Heart Rate Variability) sensitivity set

Set the HRV sensitivity as required.



Fig. 3.14 HRV sensitivity set

3.4 Data saving

The measured data can be saved to the USB memory.

After co**nnecti**ng USB memory to LED type, press down the mode button [ ] to activate the data saving function. The USB data saving indicator will be lit and the “ding-dong” sound will be generated.



Fig. 3.15 USB data saving function activated

Press down the mode button [] to finish data saving. The USB data saving indicator will be turned off and the "ding-dong" sound will be generated.

3.5 CCV (Cross-channel verification) function

When monitoring two fetuses with two Doppler probes, CCV function will compare the values from both probes and alerts when the values could be the same source (fetus).
If the difference between two probe values is within 2 bpm for more than 25 seconds during 30 seconds monitoring period, CCV information sound will be generated



When the difference between two probe values is more than 2 bpm for more than 5 seconds, the CCV information sound will be turned off and LED type will be operating normally.
If the CCV appears during printing the data, ĉ icon will be printed on the paper.

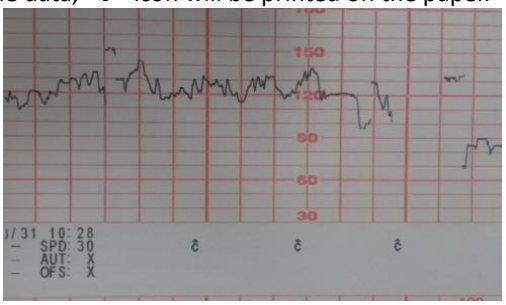
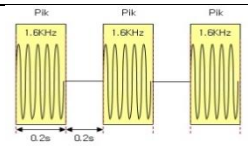
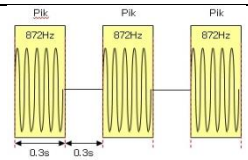
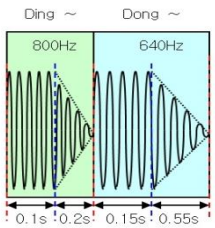


Fig. 3.16 CCV printed

4 Understanding alarms

The monitor will generate an alarm when the FHR exceeds the set alarm limits. But these limits have no significant meaning in clinical uses.
One time exceeding the limits will not generate the alarm. If the alarm condition (exceeding the limits) endures for more than 20 seconds the alarm sound will be generated and the red led is flashing with the heart rate value on display will be blinking as long as the alarm condition persists or alarm is disabled by the user. Pressing the alarm button on the monitor's keypad can silence the alarm tone.
Alarms are enabled or disabled by pressing the alarm button on the keypad.

Classification		Frequency/Sound	Repetition Interval	Situation
Alarm Sound	Upper alarm sound		3 seconds	When FHR exceeds Upper Limit value over 20 seconds
	Lower alarm sound		3 seconds	When FHR goes down Lower Limit over 20 seconds
Information sound			2 seconds	1. Power on 2. DOP1 or DOP 2 is disconnected while BT-350 is monitoring. 3. Paper is out while BT-350 is printing. 4. Printer door is opened while BT-350 is printing. 5. Battery's charge level is low while BT-350 LED is monitoring. 6. Complete auto printing

5 Printer

5.1 Loading paper

Open the printer door by pressing down the [Printer door open button]. Unwrap a pack of paper and put it into the paper tray.

A page from the top of the paper pack should drape forward over the shaft of the printer. The orientation of the paper is with the printed grid facing up (unfolding from the top of the pack) and the UC grid area is the right side.

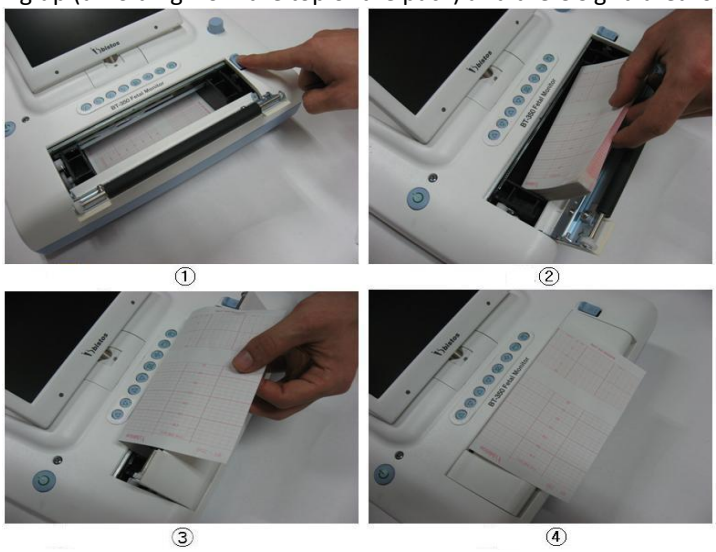


Fig. 5.1 Loading paper

5.2 Printing

Print On/Off button — Press the print button [] to start printing. Press again to stop printing.
Paper Advance — Press and hold the print button [] to fast-forward the paper.

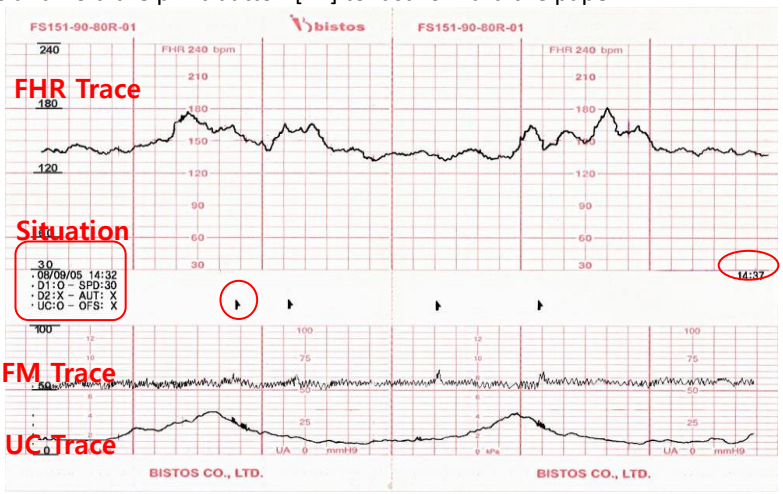


Fig. 5.2 Printing result

Symbol	Description	Source of mark	Possible events
▶	Event Mark	Press Event marker (by a pregnant woman)	When a pregnant woman feels fetus movement
▶	Clinical Event Mark	Press [] button over 2 seconds (by a doctor)	When doctor judges fetus movement happens
▲	FM1 Detection Mark	FM1 Trace (by algorithm and automatic)	When the system detects fetus movement(FM1)
▼	FM2 Detection Mark	FM2 (by algorithm and automatic)	When the system detects fetus movement(FM2)
✱	AST Mark	AST (by a doctor)	When the system detects AST signal

6 Monitoring fetal heart rate

6.1 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.

6.2 Monitoring sequence overview

Step 1: Preparing the monitor

- Turn the monitor on and verify that the normal monitoring screen appears on the display. Stop using the monitor if an error occurs.
- Check whether the monitor is powered from the internal battery or AC power. If the monitor is powered from the internal battery, check the power status from on the display to determine whether the battery has sufficient charge to complete the monitoring session.
- Check the ultrasound transducer to verify proper attachment to the monitor. For monitoring twins, make sure the second ultrasound transducer is properly connected.
- Adjust channel one speaker volume to the middle level. Adjust channel two speaker volume to zero if monitoring twins.
- Apply ultrasound gel to the face of the DOP 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 to the fetal heart signal. Reposition the transducer for the loudest fetal heart sound.
- Secure the ultrasound transducer with the elastic belt. Make sure that the transducer is still positioned for the loudest fetal heart signal.
- Verify the monitor is displaying fetal heart rate values and that the heart shape icon on the screen is blinking at the measured heart rate.

Step 3: Acquiring twin's heart rate

- Follow step 2 above to acquire the heart rate for the first fetus.
- Decrease the channel one speaker volume and increase the channel two speaker volume to hear the second heart sound.
- Determine the location of the second fetal signal using palpation or fetoscope.
- Apply gel to the second ultrasound transducer and place it on the maternal abdomen where the second fetal signal was located. Reposition the transducer for the loudest fetal heart sound.
- Secure the ultrasound transducer with the elastic belt. Make sure that the transducer is still positioned for the loudest fetal heart signal.
- Verify the monitor is displaying fetal heart rate values and that the heart shape icon on the screen is blinking at the measured heart rate.

Step 4: Monitor adjustment

- Readjust the volume settings for the desired loudness.

6.3 Detail procedure

- Explain the procedure to the patient.
- Place a probe belt under the patient
- Turn the monitor on.
- Connect the ultrasound probe to the “DOP” connector.
- Apply a small amount of ultrasound coupling gel to the face of the transducer.
- Determine the position of the fetus using Leopold’s maneuvers. The strongest fetal heart tones are heard through the fetal back.
- Place the transducer face down on the maternal abdomen over the area determined as the fetal back.
- Secure the transducer comfortable in the place by inserting the transducer button through the button holes on each end of the belt.

CAUTION

- The probe belt may cause allergy or skin side effects to the patient if it is used so long time.

- Adjust the volume as required.
- Press the print button [ ] to activate the printer.

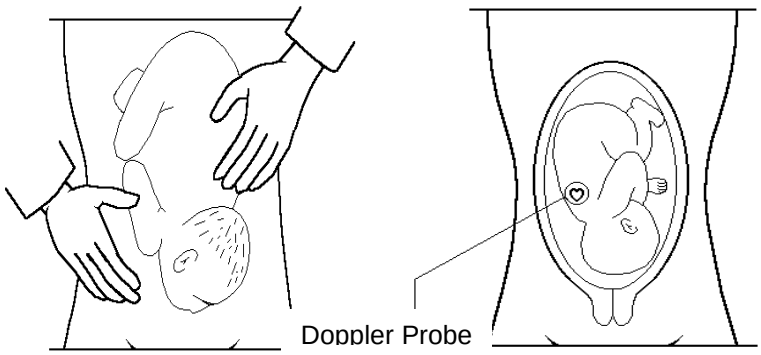


Fig. 6.1 The position of the Doppler probe

7 Uterine contraction (UC)

Uterine contraction is measured externally by placing a pressure sensor (UC sensor) on the maternal abdomen and measure the relative pressure change.

CAUTION

- The cable of the UC 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.

7.1 Monitoring sequence overview

Step 1: Preparing the monitor

- Turn the monitor on and verify that the normal monitoring screen appears on the display. Stop using the monitor if an error occurs.
- Check whether the monitor is powered from the internal battery or AC power. If the monitor is powered from the internal battery, check the power status from on the display to determine whether the battery has sufficient charge to complete the monitoring session.
- Check the UC probe to verify proper attachment to the monitor.
- Press the UC reference button to adjust the values to the baseline.

Step 2: Acquiring the uterine contraction data

- Place the face (button side) of the UC probe on the fundus on the uterus when contractions are not occurring. No gel is required.
- Secure the UC probe with the elastic belt. The uterine contraction reading at this point should be greater than 30 and less than 90 units. If the readings fall outside of this range, the belt may be too tight or too loose. If the belt is overtightened, the contraction peaks may have a flat-top at less than on the UC scale. If the belt is under tightened, the sensor can move and cause unstable readings. Readjust the belt pressure as needed.

7.2 Detail procedure

- Explain the procedure to the patient.
- Place a probe belt under the patient
- Turn the monitor on.
- Connect the UC probe to the "UC" connector.
- Press the UC reference button [ ] to set the UC baseline at 10.

Note: After connecting or re-connecting the UC probe to the UC connector, you must wait at least 10 seconds before pressing the UC reference button [ ].

- Position the UC probe on the maternal abdomen over the uterine fundus or where there is the least maternal tissue and the contractions are strongly palpated.
- Secure the UC probe comfortable in the place by inserting the transducer button through the button holes on each end of the belt.

CAUTION

- The probe belt may cause allergy or skin side effects to the patient if it is used so long time.

- Between contractions, press the UC reference button [ ] again. This sets UC baseline to 10.
- Press the print button [ ] to activate the printer.

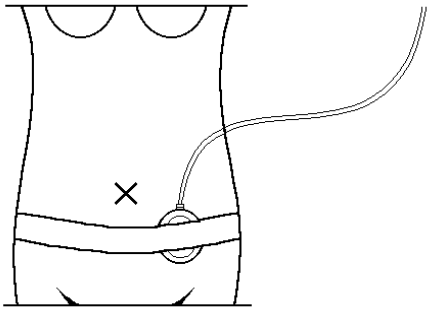


Fig. 7.1 The position of UC probe

8 Event marker

8.1 Event marker

The event marker arrow is provided so that the patient can record the time of important events. The patient merely presses the marker button at the time an event occurs. This marker time is recorded in the monitor.

The patient marker icon is an upward pointing arrow [ ]. The monitor will display this arrow in the information frame of the display. A strip chart printout of the patient record will also show this marker.

8.2 Clinical event marker

When an important event, like a fetus movement, occurs, the clinical event marker is used. If necessary, the doctor will press down and hold the mode button [ ] for more than 2 seconds. Then the marker is recorded.

The clinical event marker icon is a downward pointing arrow [ ]. The monitor will display this arrow in the information frame of the display. A strip chart printout of the patient record will also show this marker.

9 Cleaning and disinfection

BT-350 requires proper care and preventive maintenance. This ensures consistent operation and maintains a high level of performance necessary in monitoring procedures.

9.1 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 the display surfaces, which are sensitive to rough handling. Rub them with a soft, dry cloth.

9.2 Probes

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.

9.3 Belt

Wash soiled belts with soap and water.

CAUTION

- The water temperature must not exceed 60°C (140°F).

9.4 Contacting components

Contacting component	Material	Disinfection
DOP probe	ABS AV20F	Must be cleaned and disinfected prior to use
UC probe	ABS AV20F + Polyurethane ESTANE S385A-46N	Must be cleaned and disinfected prior to use

9.5 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.

10 Specifications

Physical Characteristics	
Dimensions	9.6cm(H) x 32.6 cm(W) x 27.6cm(D)
Weight	Approx. 5.5 kg
Display type	LCD(TFT Color LCD) or LED(7 segment LED)

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	IPX8(Dop/UC probe)

Power		
External	Power adapter	Input: AC 100 ~ 240 V, 50/60 Hz Output: DC 18V, 2.8A
Internal	Battery	14.8V, 2600mAh (Li-ion) Operating Time: 120 min Charging Time (100%) : 150 min Maximum charge-discharge cycles: 300 cycles
Power Dissipation	AC-powered	80 VA, maximum
	Battery powered	80 VA, maximum

Environment	
Operating temperature	10°C ~ 40°C (50°F ~ 104°F)
Operating humidity	5 ~ 85%, Non condensing
Operating atmosphere	80kPa ~ 106kPa
Storage temperature	-20°C ~ 60°C (-4°F ~ 140°F)
Storage humidity	0 ~ 95%, non-condensing
Storage atmosphere	70kPa ~ 106kPa

Doppler ultrasound FHR monitoring	
MI and TI values do not exceed 1.0.	
BPM Range	30 ~ 240 BPM
Accuracy	± 2% of range
Leakage	<10 μA @ 264 VAC applied to the transducer
Isolation	>4 kV RMS, Type BF applied part

Uterine Contraction (TOCO) monitoring	
UC range	0-100 relative units
Resolution	1 Count
Leakage	<10 μA @ 264 VAC applied to the transducer
Isolation	>4 kV RMS, Type BF applied part

Acoustic Stimulator	
Acoustic output:	75db ± 5db (1m dist.)
Frequency:	75hz ± 5hz

Paper		
Pack Style	Z-Fold.	
Pack Size	150 mm x 90 mm x 15 mm	
End-of-Pack	Mark along the paper edge	
Loading	Open-door, slide-in	
Paper Detectors	Paper Out	
	Loading door open	
Speed	Normal	1, 2 and 3 cm/min ± 1%
	High-speed	10 cm/min (only in Trend mode)
Tracking accuracy	± 1% (exclusive of paper accuracy)	

11 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-350 monitor 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-350 monitor if it fails to pass the power on self-test procedure.

11.1 Self-test

The monitor performs self-test each time it turns on.

1. Make sure the monitor power is properly connected.
2. Check the printer paper and printer door closed.
3. Connect the probe to the monitor
4. Turn on the monitor.

Check that the monitor successfully powered on and is displaying the main monitoring screen. If an error occurs the monitor will display the error message.

11.2 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.

11.3 UC (TOCO) probe test

To test the UC (TOCO) probe:

1. Connect the probe to the monitor.
2. Turn on the monitor.
3. Gently apply pressure to the button centered on the face of the probe.
4. The change of pressure should be displayed on the screen if the probe operating properly. If there are no changes, please stop using the probe and call for the service.

11.4 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.

12 Manufacturer's declaration on EMC

BT-350 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-350 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

12.1 Electromagnetic emissions

The BT-350 is intended for use in the electromagnetic environment specified below. The customer or the user of the BT-350 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The BT-350 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 A	**NOTE**: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). The BT-350 is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: **Warning:** This BT-350 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, such as re-orienting or relocating the BT-350 or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

12.2 Electromagnetic immunity

The BT-350 is intended for use in the electromagnetic environment specified below. The customer or the user of the BT-350 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	±2 kV for power supply lines ±1 kV for input/output lines	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	±1 kV line(s) to line(s) ±2 kV 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	< 5 % U_T (> 95 % dip in U_T) for 0.5cycle	< 5 % U_T (> 95 % dip in U_T) for 0.5cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the BT-350 requires continued operation

input lines IEC 61000-4-11	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	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	during power mains interruptions, it is recommended that the BT-350 image intensifier be powered from an uninterruptible power supply.
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.
Conducted RF IEC61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable mobile RF communications equipment should be used no closer to any part of the BT-350, 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 ~ 800 MHz $d = 2.3\sqrt{P}$ 800 MHz ~ 2.7 MHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol : 
Radiated RF IEC61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	
NOTE 1) U_T is the a.c. mains voltage prior to application of the test level. NOTE 2) At 80 MHz and 800 MHz, the higher frequency range applies. 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 BT-350 is used exceeds the applicable RF compliance level above, the BT-350 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-350. [b]Over the frequency range 150 kHz to 80MHz, field strengths should be less than **3 V/m.**			

Product Warranty

Product Name	Fetal Monitor
Model Name	BT-350
Serial No.	
Warranty Period	2 Years (Probe excluded)
Date of Purchase	
Customer	Hospital: Address: Name: Telephone:
Sales Agency	
Manufacture	Bistos Co., Ltd.

※ Thank you for purchasing BT-350.

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

※ Compensation standard concerning the repair, replacement, refund of the product complies with "**Framework Act on Consumers**" noticed by Fair Trade Commission of the Republic of Korea.

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