bistos

BT-350

Fetal Monitor

Operator Manual

BT-350

P/N : OPM(BT-350E)EN, Rev.05

Proprietary Material

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Section ***1***
Safety

1.1 Instructions for the Safe Operation and Use of the BT-350E Monitor

- 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 monitor if there is any visible sign of damage.
- Only the AC line cord supplied with the BT-350E, or its equivalent, is approved for use with the Unit.
- Do not attempt to service the BT-350E monitor. Only qualified service personnel should attempt any needed internal servicing.
- The BT-350E is not specified or intended for operation during the use of defibrillators or during defibrillator discharge.
- The BT-350E is not specified or intended for operation in the presence of electrosurgical equipment.
- The BT-350E 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.
- Perform periodic safety testing to insure proper patient safety. This should include leakage current measurement and insulation testing. The recommended testing interval is once per year.
- Do not operate the BT-350E monitor if it fails to pass the power on self-test procedure.

WARNING: Be informed that it may cause serious injury or death to the patient, property damage, material losses against the "Warning" sign.

CAUTION: Be informed that it may cause no harm in life but lead to injury against the "Caution" sign.

1.2 Warnings

WARNING: EXPLOSION HAZARD — Do not use the BT-350 in a flammable atmosphere where concentrations of flammable anesthetics or other materials may occur.

WARNING: SHOCK HAZARD — The power receptacle must be a three wire grounded outlet. Never adapt the three-prong plug to fit a two-slot outlet. If the outlet has only two slots, make sure that it is replaced with a three-slot grounded outlet before attempting to operate the monitor.

WARNING: Do not connect to an electrical outlet controlled by a wall switch.

WARNING: SHOCK HAZARD — Do not attempt to connect or disconnect a power cord with wet hands. Make certain that your hands are clean and dry before touching a power cord.

WARNING: Use only patient cables and transducers supplied with the monitor. Use of any other patient cables may result in out-of-specification performance and possible safety hazards.

WARNING: Do not contact RS-232C port and patient at the same time.

WARNING: AC/DC Adaptor should use appointed product.

WARNING: SHOCK HAZARD — Do not attempt to disjoint the power adaptor exterior with no permission. It may cause electric shock. Also it has 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.

WARNING: SHOCK HAZARD — Do not touch the patient simultaneously with contacting signal connector, other equipment or ground. This can cause the electric shock to the patient or operator.

WARNING: SHOCK HAZARD — During upgrading the BT-350, do not use the BT-350 to the patient. This can cause the electric shock to the patient.

1.3 Cautions

CAUTION:
-The equipment conforms to Class A according to IEC/EN 60601-1(Safety of Electric Medical Equipment)
- This equipment conforms to Level B according to IEC/EN 60601-1-2 (Electromagnetic Compatibility Requirements)

CAUTION: The relevant law restricts this device to sale by or on the order of a physician.

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.

CAUTION: When installing the unit into a cabinet, allow for adequate ventilation, accessibility for servicing, and room for adequate visualization and operation.

CAUTION: 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.

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

CAUTION: 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 another medical devices, it must be complied with the standards IEC/EN 60601-1 and IEC/EN 60601-1-2.

CAUTION: Do not autoclave or gas sterilize the monitor or any accessories. Follow cleaning and disinfection instructions in Section 9 of this manual.

CAUTION: Do not immerse BT-350 main body and trasducers 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.

CAUTION: When washing the transducer belts, the water temperature must not exceed 60℃ (140℉).

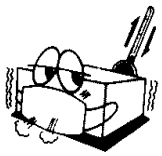
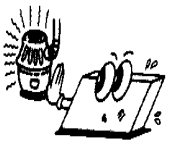
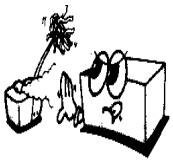
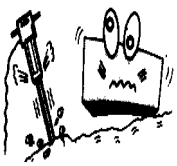
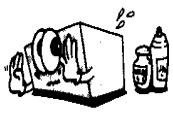
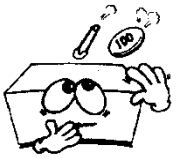
CAUTION: When loading paper, the paper must be put above the shaft. Otherwise, the paper can be biased one side.

CAUTION: If the equipment use in 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.

CAUTION: 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 the damage to the device or electric shock.

General Precaution on Environment

- Do not keep or operate the equipment under the environment listed below.

	Avoid placing in an area exposed to moisture. Do not touch the equipment with wet hand.		Avoid exposure to direct sunlight
	Avoid placing in an area where there is a high variation of temperature. Operating temperature ranges from 10°C to 40°C. Operating humidity ranges from 20% to 90%.		Avoid in the vicinity of Electric heater
	Avoid placing in an area where there is an excessive humidity rise or ventilation problem.		Avoid placing in an area where there is an excessive shock or vibration.
	Avoid placing in an area where chemicals are stored or where there is in danger of gas leakage.		Avoid dust and especially metal material into the equipment.
	Do not disjoint or disassemble the equipment. BISTOS Co., Ltd. does not take responsibility of it.		Power off when the equipment is not fully installed. Otherwise, the equipment could be damaged.

1.4 Definitions and Symbols

Symbol	Description
	Power On/Off Button
	This symbol identifies a safety note. Ensure you understand the function of this control before using it. There are no noted or identified hazards by ultrasound. But there is unknown hazardous possibility by ultrasound.
	External Signal IN/OUT Port
	Type BF Equipment
IPX8	IPX8 Waterproof (1 meter of water for over 30 minutes.)
	Operating instructions
	When disposing of some components (ex: internal NiMH battery), do not dispose as general wastes. Adhere to all applicable laws regarding recycling.

Section 2
Introduction

2.1 General

This chapter provides a general description of the BT-350E monitor including:

- Brief Device Description
- Product Features
- Model Configurations

2.2 Brief Device Description

The BT-350E is a microprocessor-based fetal monitor, providing continuous monitoring, display, and recording of fetal heart rate (FHR) and uterine contraction (UC) for antepartum testing and monitoring.

2.3 Intended Use

The BT-350E is a Prenatal Monitoring System for non-invasively measuring and showing graphically maternal abdominal contractions and the fetal heart rate by means of display on a non-permanent graphical display and on a strip chart recorder. This data is intended to aid in assessing the well being of the fetus during the final trimester of pregnancy (Non-Stress Test). This device is for use only by trained medical personnel located in hospitals, clinics, doctor's offices and in the patient's home.

2.4 Product Features

The monitored data can be recorded continuously or intermittently on a strip chart recorder at the operator's discretion. The recorded information includes graphic trend data and text information of monitor hardware and software configuration, date and time, patient identification, changes to operational settings, clinician and patient event marks.

2.5 Options and Accessories

Accessory	Name	Description
	Doppler Probe	Ultrasound Transducer for Measuring FHR (IPX8 : Waterproof)
	UC Probe	Pressure Sensor (Tocotonometer) for Measuring Uterine contraction (IPX8 : Waterproof)
	Event Marker	Used for a Fetal Movement event
	AST Probe (Option)	Acoustic Stimulation Test Probe
	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(2.5A) (MW160, Bridge Power Corp.)
	GP Battery	Type / model : GP2700AAHC Technical data : 1.2V X 12ea, 2600mA (GP Batteries international Ltd.)
	Ultrasound Gel	Ultrasound transmission gel (Sanipia, ECOSONIC)

Table 2.1. BT-350E Accessories

Section 3
Installation

3.1 Description of the BT-350E Front Panel

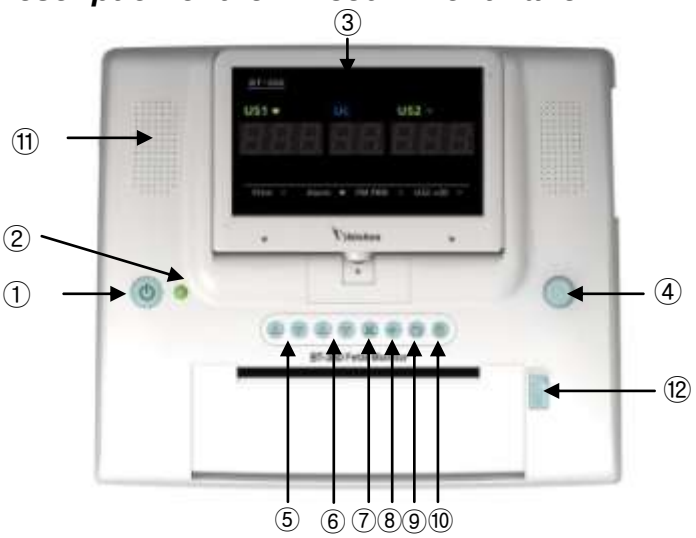


Fig. 3.1 BT-350E Front Panel

① Power On/Off Button
② Power Indicating LED (AC:Green / Battery:Orange)
③ 7Segment LED Display
④ Control Knob
⑤ Dop1 Volume Up/Down Button
⑥ Dop2 Volume Up/Down Button
⑦ Alarm Sound On/Off Button
⑧ UC Reference Button
⑨ Mode Change Button
⑩ Printer On/Off Button
⑪ Speaker
⑫ Print Door Open Button

3.2 Description of the Left Panel

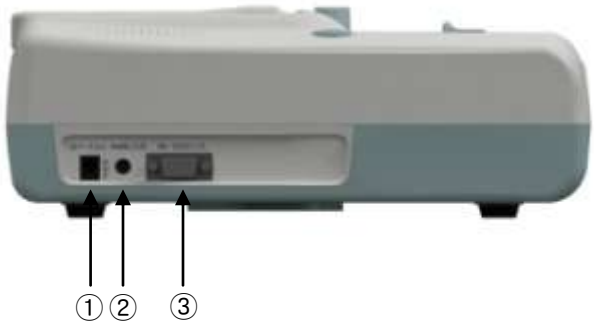


Fig. 3.2 Left Panel

① Power Adaptor Jack Connector
② Event Marker Connector
③ RS-232C Port Connector

3.3 Description of the Right Panel

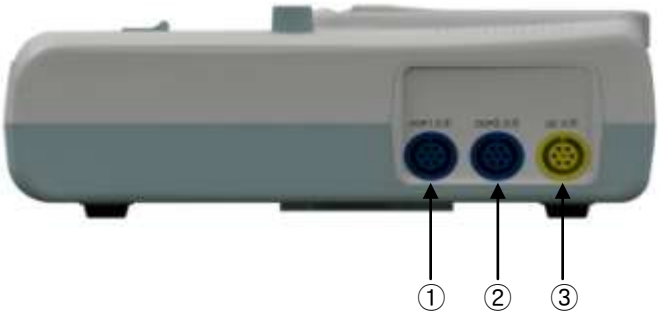


Fig. 3.3 Right Panel

① DOP1 Connector
② DOP2 Connector
③ UC Connector

3.4 Power On

When the user wants to turn BT-350E on, power adaptor is connected with power adaptor jack connector on left panel of BT-350E as shown in Figure 3.2 and power button is pressed.

3.5 Patient Cables

The ultrasound and TOCO transducer cable are connected to the right panel. Each transducer has a label (DOP or UC) to insure proper connection to the exact connector on the monitor. Also each connector in the right panel has a label (DOP1 or UC) to insure proper cable connection.

The cables are connected or removed by putting into the connector tightly or pulling out of the connector. There is no connector locking mechanism.

Another ultrasound transducer is supplied with the BT-350E capable of monitoring two fetuses by inserting this to DOP2 connector.

WARNING: Use only patient cables and transducers supplied with the monitor. Use of any other patient cables may result in out-of-specifications performance and possible safety hazards.

3.6 Event Marker Cable

The event marker cable is connected to the connector in the left panel. The label on the housing shows the location of the connector. The cable is connected by putting into the connector tightly. There is no connector locking mechanism.

WARNING: SHOCK HAZARD — Power receptacle must be a three -slot grounded outlet. If the outlet has only two slots, make sure that it is replaced with a three-slot grounded outlet before attempting to operate the monitor.

WARNING: Do not connect to an electrical outlet controlled by a wall switch.

WARNING: SHOCK HAZARD — Do not attempt to connect or disconnect a power cord with wet hands. Make certain that your hands are clean and dry before touching a power cord.

Section 4
BT-350E Operation

4.1 System Startup

4.1.1 Power on

To operate BT-350E, please push Power On/Off button slightly. According to the probe connection, BT-350E displays FHR and UC.

4.1.2 Factory Setting

The monitor has a function to return the setting values to the default value. BT-350E enters <Factory Mode> when the monitor is powered on, while control knob is pressed. Factory setting reset configuration settings to the default value.

Configuration parameter	Factory Default
Fetal Heart rate Upper Alarm Limit	190 BPM
Fetal Heart rate Lower Alarm Limit	110 BPM
Dop2 Offset	0 BPM
FM Graph	OFF
Record Paper Speed	3 cm/min
Auto Printing	0 MIN
Paper	FS151-90-80R-01

Fig. 4.1 Factory Mode

4.2 BT-350E Monitor Display Screen

Fig. 4.2 Main Monitoring Screen

4.2.1 Heart Rhythm

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

4.2.2 FHR/UC Frame

The heart rate (FHR) numeric frame displays the fetal heart rate. This channel is labeled “US1.” When the second ultrasound transducer is connected, the heart rate frame will include additionally the fetal heart rate for the second ultrasound channel. This channel is labeled “US2.” The heart rate value shows the most recent calculated fetal heart rate.

This frame contains the numeric value from the UC transducer representing uterine contraction. This frame also shows the present UC baseline value. The UC baseline is user adjustable.

4.2.3 Status Frame

This frame shows BT-350E status.

Display	Description
Print	Indicating of a printing status
Alarm	Indicating of Alarm sound enable/disable
FM PRN	Indicating of Fetal Movement Graph enable/disable
US +20	Indicating of US2 offset enable/disable

4.3 BT-350E Monitor Controls and Indicators

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

> ***CAUTION***: Never use sharp or pointed objects to operate the front-panel switches.

The operation of the buttons is summarized below.

Symbol	Name	Description
	Power On/Off Button	Turns power on or off.
	US1 Volume Up/Down Button	Decreases or increases US1 fetal audio volume in monitoring mode.
	US2 Volume Up/Down Button	Decreases or increases US2 fetal audio volume in monitoring mode.
	UC Reference Button	Resets the UC baseline in monitoring mode.
	Alarm On/Off Button	Makes the alarm sound enable or disable in monitoring mode.
	Mode Button	Puts the monitor into trend scroll mode. The trend frames shows historical patient data and the control knob provides navigation capability.
	Record On/Off Button	Turns the record on or off.

4.3.1 Information Message

This frame shows the error and current operation status. The error message will be displayed when the monitor is unable to operate properly. If this error message shows, discontinue use of monitor.

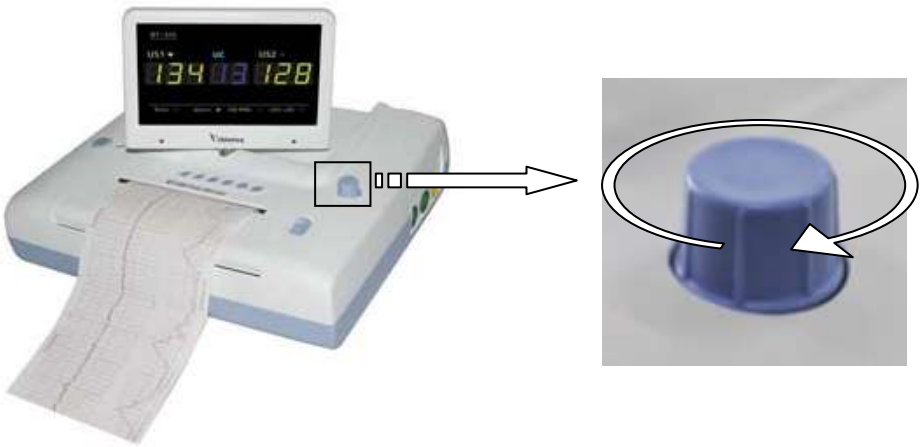
Message	Description
DOP1 OPEN	DOP1 is not connected while BT-350E is monitoring 
DOP2 OPEN	DOP2 is not connected while BT-350E is monitoring 

DOOR OPEN	Print door is opened while BT-350E is printing 
No PAPER	Paper is not loaded while BT-350E is printing 
LOW BAT	Battery's charging level is lowwhile BT-350E is monitoring 

4.4 Control Knob

The Control Knob is the primary method of adjusting parameters and navigating through the menu system. If the knob is rotated to the CW (clockwise) or CCW (counterclockwise) while in system setting, the setting display will be changed. This process is used to select a setting item for modification. The knob is then pressed to select this item for editing.

Once a setting item has been selected for editing, the knob is rotated to scan through the available choices for this parameter. Pressing the knob stores the new value temporarily.



4.5 System Setting

The following section describes the procedure used to set alarm parameters and system setting.

Activity	**Desired Result**
[ ]Button Press	To enter the setup mode.
Knob Rotate	To select setting value.
Knob Press	To select this parameter for change.
Knob Rotate	To change the desired value.
Knob Press	To store the new value.
[ ]Button Press	To exit setup menu.

4.5.1 Setting Alarm Upper Limit / Lower Limit

Fig. 4.3 Alarm Upper /Lower Limit

Activity	**Desired Result**
Knob Rotate	Select “hi” or “Lo”
Knob Press	To select this parameter for change.
Knob Rotate	To change the desired value. The list below shows the values that are available for each parameter: Heart Rate Upper Limit { (Heart Rate Lower Limit +10)–240 BPM, 5 BPM increments} Heart Rate Lower Limit {30–(Heart Rate Upper Limit-10) BPM, 5 BPM increments}
Knob Press	To store the new value.
[ ]Button Press	To exit setup menu.

4.5.2 Setting Dop2 Offset

When ultrasound trace separation is enabled, the trend data for ultrasound channel 2 is shifted up by 20 BPM in printing. This feature is provided to clearly see separate heart rate trends when both heart rates are similar. The heart rate value shown in the numeric frame is not affected. If dop2 offset is selected, led of [US2 +20] in status frame is on.

Fig. 4.4 Dop2 Offset

Activity	**Desired Result**
Knob Rotate	Select “oFS”
Knob Press	To select this parameter for change.
Knob Rotate	To change the desired value [on/oFF].
Knob Press	To store the new value.
[ ]Button Press	To exit setup menu.

4.5.3 Setting Time and Date

Fig. 4.5 ***Time and Date***

Activity	**Desired Result**
Knob Rotate	To select Time Menu.
Knob Press	To enter Time Menu.
Knob Rotate	To change the desired value. The options for each parameter in the submenu are: Time {hours, minutes, seconds} - 24-hour format Date {year, month, day} – YY/MM/DD
Knob Press	To store the new value and move to the next item. (YEa → mo → dat → hou → mi → SEc → rtc)

(When the item is returned to “rtc”, the setting procedure is completed.)

[ ]Button Press	To exit setup menu.

4.5.4 Setting Print Speed

Fig. 4.6 ***Print Speed***

Activity	**Desired Result**
Knob Rotate	Select “SPd”
Knob Press	To select this parameter for change.
Knob Rotate	To change the desired value [10/20/30].
Knob Press	To store the new value.
[ ]Button Press	To exit setup menu.

4.5.5 Setting Auto Print

Fig. 4.8 ***Auto Print***

Activity	**Desired Result**
Knob Rotate	Select “aut”
Knob Press	To select this parameter for change.
Knob Rotate	To change the desired value [oFF/10/20/30/40/50/60].
Knob Press	To store the new value.
[ ]Button Press	To exit setup menu.

4.5.6 Setting FM(Fetal Movement) Graph

This graph is displayed on UC graph Frame. FM1 graph is displayed in upper area(50~100 in UC graph Frame), and FM2 graph is in lower area(0~50 in UC graph Frame). When follow the steps below to change the US graph separation setting.

Fig. 4.7 ***FM Graph***

Activity	**Desired Result**
Knob Rotate	Select “Fm”
Knob Press	To select this parameter for change.
Knob Rotate	To change the desired value [on/oFF].
Knob Press	To store the new value..
[ ]Button Press	To exit setup menu.

4.5.7 Printer Paper Select

BT-350E is able to use two different types of papers. If you press control knob during self test, you can see paper select menu as shown Figure 4.8. Rotating control knob to choose paper type.

Fig. 4.8 ***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 the inserted paper is different from the selected paper type, the printed data will be incorrect. Be sure to check the selected paper type is same as inserted paper.

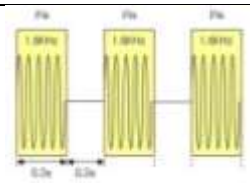
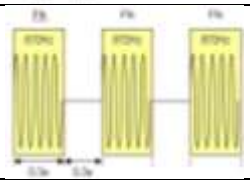
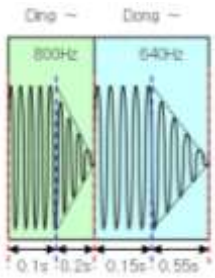
CAUTION: When paper type is changed, alarm upper limit is changed to 190 and alarm lower limit is changed to 110.

4.6 Understanding Alarms

The BT-350E monitor has the capability to alert the caregiver in the event a heart rate goes above or below an alarm limit for a preset time delay.

The limit values are configurable. These limit values have no significant meaning in clinical uses. To prevent overwrapping of limit value, there is an apartness of upper or lower limit by 10 bpm. The purpose of setting for the limit values is to give accommodation to user. But the delay from onset to alert is fixed to 20 seconds. If alert situation is continued over 20 seconds, an alarm event results in an audible tone and blinking of the heart rate value on the display. Pressing the alarm button on the monitor's keypad can silence the alarm tone. The blinking heart rate will continue as long the alarm condition persists or until alarms are disabled.

Alarms are enabled or disabled by pressing the alarm on/off button. If alarms are disabled then all alarms are off. If alarms are enabled then all alarms are on.

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

Section 5
Recorder Operation

5.1 Loading Paper

The paper is loaded by pushing the lever to open the door. Unwrap a pack of paper and put it into the paper tray.

Several pages from the top of the pack of paper should drape forward over the shaft of the recorder. The orientation of the paper is with the printed grid facing up (unfolding from the top of the pack) and the UC grid area right side. The recorder is now ready for use.

> ***CAUTION***: When loading paper, the paper must be put side upward. Otherwise, the paper will not be printed.

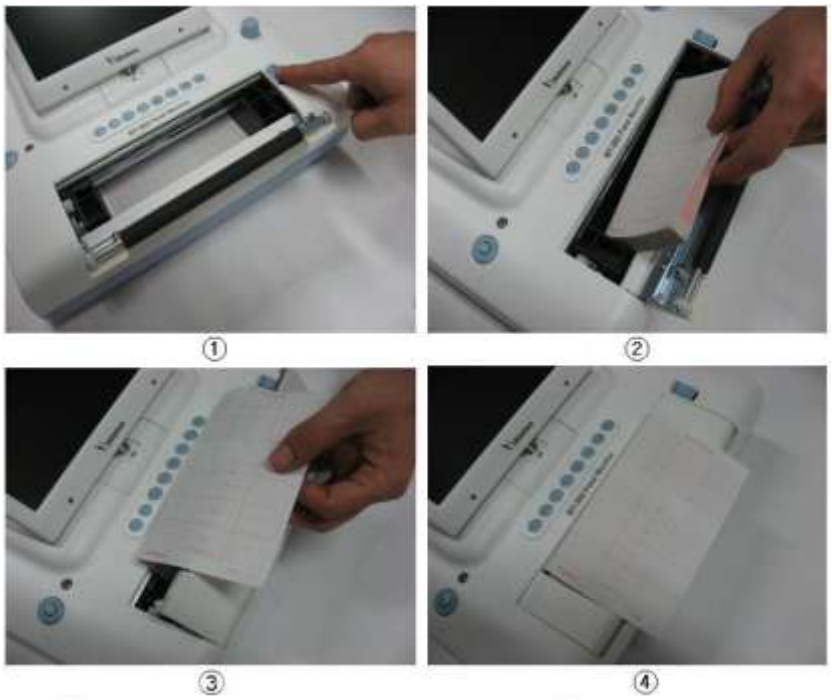


Fig. 5.1 Loading Paper

5.2 Operation

Print On/Off button — A single press and release of [ ]button will toggle the recorder mode between printing and nonprinting.
The relevant message is displayed at message frame when printing is enabled and when disabled.

Paper Advance — [ ] button is also used to fast-forward the recorder paper. A press and hold of this button will advance the recorder paper at high speed until the button is released. The recorder will resume its original activity when the button is released. This function is ignored during recording. When the record is finished, the paper feeding function is performed automatically during short time. In Fig.5.2, BT-350E prints many parameters such as FHR, FM, UC and the situation information.

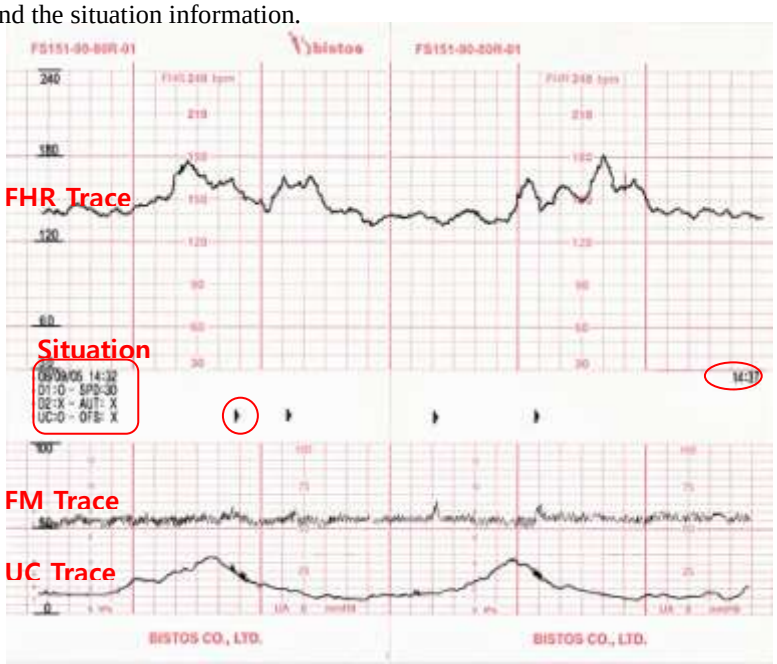


Fig. 5.2 Printing Paper [FS151-90-80R-01]

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

Section ***6***
Monitoring Fetal Heart Rate

6.1 Electromagnetic Interference

Certain strong electromagnetic fields can interfere with the ultrasound transducer and cause a false heart rate reading that does not originate from the patient. This interference is rare, and usually found in the vicinity of large machinery. In order to avoid the possibility of these interfering signals being misinterpreted 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 transducer(s), turn on the monitor and observe the heart rate indications on the screen for 30 seconds. Intermittent display of random heart rates 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 6 feet away from the BT-350E. 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 heart rate artifact, the monitor cannot be safely used in this environment.

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

> ***CAUTION***: During the using BT-350E, we do not intend that the cable of DOP sensor contacts to the patient. To prevent that the cable contacts to the patient, please cover the patient's abdomen section which have a possibility of contacting by the cable with cleaned gauze or fabric.

Step 1: Preparing the Monitor

Turn the monitor on and verify that the normal monitoring screen appears on the display. Remove the monitor from service 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.

Check the ultrasound transducer to verify proper attachment to the monitor. For twins monitoring, make sure the second ultrasound transducer is properly connected.

Adjust heart rate channel one speaker volume to mid level. Adjust channel two speaker volume to off if monitoring twins.

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 shape icon on the screen is blinking at the fetal heart rate.

Secure the ultrasound transducer with the elastic belt. 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 shape icon on the screen is blinking at the measured heart rate.

Step 3: Acquiring Twins' Heart Rates

Follow the steps outlined in step 2 above to acquire the heart rate for the first fetus.

Adjust the ultrasound audio volume for channel one down and channel two up so that the second heart sounds can be heard.

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. Adjust the position of the transducer to find the fetal signal and to maximize its loudness.

Secure the ultrasound transducer with the elastic belt. Make sure the transducer

is still positioned for the loudest fetal heart signal. Also verify the position of transducer one has not changed.

Verify the monitor is displaying fetal heart rate values for both fetuses and that the heart shape icons both on the screen are blinking at the measured heart rate.

Step 4: Monitor Adjustments

Readjust the volume settings for the desired loudness.

6.2 Detail Procedure

① Explain procedure to the patient.

② Place a probe belt under the patient.

③ Turn the monitor power on. The power switch is located on the front panel. The green indicator located on the front panel when the power on.

④ Determine the position of the fetus using Leopold's maneuvers. The strongest fetal heart tones are heard through the fetal back.

⑤ Plug the ultrasound transducer cable into the connector labeled "DOP."

⑥ Apply a small amount of ultrasonic coupling gel to the face of the transducer.

⑦ Place the transducer face down on the maternal abdomen over the area determined to be the fetal back.

⑧ Secure the transducer comfortably in the place by inserting the transducer button through the buttonholes on each end of the belt.

⑨ Volume Up/Down button may be used to adjust the volume.

⑩ 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 shaped indicator will flash synchronously with the sound. This indicates signal acceptance and recording.

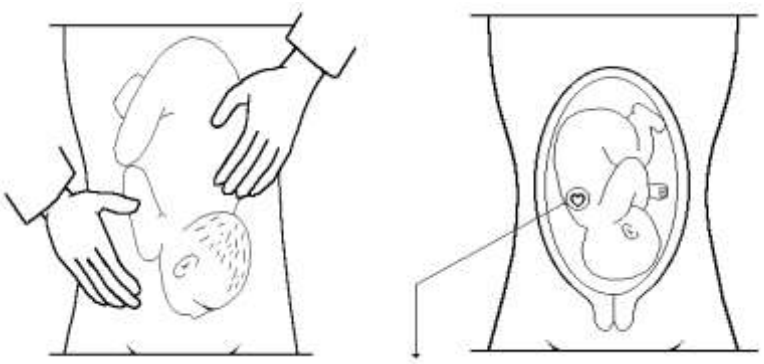


Figure 6.1 the direction of Doppler Probe

⑪ If not already activated, depress the [ ] pushbutton located on the front panel of the monitor. The recorder plots the FHR on the paper strip chart.

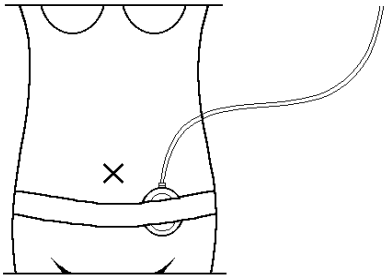


Figure 6.2 Positioning of UC Probe

Section 7
Uterine Contraction (UC)

Uterine contraction is measured externally by placing a pressure sensitive device (Tocotonometer) on the maternal abdomen and recording relative pressure changes.

> ***CAUTION***: During the using BT-350E, we do not intend that the cable of UC sensor contacts to the patient. To prevent that the cable contacts to the patient, please cover the patient's abdomen section which have a possibility of contacting by the cable with cleaned gauze or fabric.

Step 1: Preparing the Monitor

Turn the monitor on and verify that the normal monitoring screen appears on the display. Remove the monitor from service if an error occurs.

Determine whether the monitor is powered from the internal battery or the 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.

Check the UC transducer to verify proper attachment to the monitor.

Check for the proper setting for UC baseline. Adjust as needed.

Step 2: Acquiring Uterine Contraction Data

Place the face (button side) of the UC probe on the fundus of the uterus when contractions are not occurring. No gel is required.

Secure the UC probe with the belt. The uterine contraction reading at this point should be greater than 30 and less than 90 units. If the readings fall outside this range, the belt may be too tight or too loose. If the belt is over tightened, the contraction peaks may have a flat-top at less than 100 on the UC scale. If the belt is under tightened, the position of the transducer may wander and cause unusable readings. Readjust the belt pressure as needed.

Step 3: Monitor Adjustments

Press the UC reference button on the front panel to adjust the values to the baseline. This must be done during non-contraction intervals.

7.1 Detail Procedure

① Explain procedure to the patient.

② Place a probe belt under the patient

③ Turn the monitor power on. The power switch is located on the rear panel. The green indicator located under the left side of the printer door illuminates when the power on.

④ Connect the transducer plug to "UC" connector located on the underside of the front cover.

> ***Note***: When connector or re-connecting the tocotransducer to the monitor's UC connector, you must wait at least 10 seconds before depressing the UC reference [→0←] button.

⑤ Briefly depress the UC reference [→0←] pushbutton to set the UC baseline at 10.

⑥ Position tocotransducer on the maternal abdomen over the uterine fundus or where there is the least maternal tissue and the contractions are strongly palpated.

⑦ Connect each end of the belt to the transducer by inserting the transducer button through a buttonhole on the strap. Select a buttonhole that ensure a comfortable fit and holds the transducer securely in the place.

⑧ Between contractions, depress the UC reference [→0←] button again. This set UC baseline to 10. The monitor is now ready to begin monitoring.

⑨ If not already activated, depress the [] pushbutton located on the front panel of the monitor. The recorder plots the UC on the paper strip chart.

> ***CAUTION***: The probe belt may cause allergy or skin side effects to patient, if it is used so long time.

Section ***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 located on the end of the marker cable at the time an event occurs. This marker time is recorded in the patient record in the strip chart.

The event marker icon is an upward pointing arrow. A strip chart printout of the patient record will show this mark.

8.2 Clinical Event Marker

When an important event occurs like a fetus movement, the clinical event marker is used. If necessary, the doctor will press [ ] button over 2 seconds. Then the doctor can check the important event.

The icon is downward pointing arrow. A strip chart printout of this event will show this mark.

Section ***9***
Cleaning and Disinfection

This chapter contains instructions for the care and cleaning of the BT-350 unit and its accessories.

The BT-350E requires proper care and preventive maintenance. This ensures consistent operation and maintains the 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 in water or allow liquids to enter the case.

CAUTION: Take extra care when cleaning the display surfaces, which are sensitive to rough handling. Rub the lens that covers them with a soft, dry cloth.

9.2 Transducers

Cleaning and Disinfecting the Tocotonometer and Ultrasound Transducer

To avoid damage to the transducers, clean and disinfect only according to the following instructions. Care MUST be taken to preserve both the Tocotonometer label and the Tocotonometer cable label. DO NOT remove, conceal or deface Tocotonometer labels.

CAUTION: Do not autoclave. Do not gas sterilize.

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 transducer recommendations.

2. Scrub the transducer with enzymatic detergent using soft bristled brush for five (5) minutes..

CAUTION: Do not immerse in liquid. When using solutions, use sterile wipes to avoid pouring fluids directly on the transducer.

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 device in a fresh sterile soft towel or transparent sterile wrap for storage until next use.

9.3 Belts

Wash soiled belts with soap and water.

CAUTION: The water temperature must not exceed 60℃ (140℉).

9.4 Contacting components and characteristics

Contacting component	Material	Usage	Disinfection
DOP & UC Housing	ABS AF-302	Reusable	Must be cleaned and disinfected prior to use
Strain gauge sensor housing	RTV664	Reusable	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 2009 ***(www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofSingle-UseDevices/UCM133514)***

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℃ 14 days Maximum Reuse Contact conditions based on AOAC Sporicidal Activity Test only.	45 min at 25℃ 14 days Maximum Reuse Contact conditions based on literature references.

Section ***10***
Specifications

BT-350E Monitor Specifications:

Physical Characteristics

Dimensions – 9.6 cm H x 32.6 cm W x 27.6 cm D
Weight - approx. 5.5 kg

Safety

Complies with IEC/EN 60601-1, IEC/EN 60601-1-2
Class I Equipment & Internal Powered Equipment
Continuous Operation
Type BF applied parts
Dop / UC Probe : IPX8

Power

External:	Power Adaptor	Input : AC (100-240V ~), 50~60Hz,1.2A Output: DC(18V), 2.5A
Internal:		NiMH, rechargeable battery 14 hours to full recharge during monitoring 14 hours to full recharge when monitor is off.
Power Dissipation:	AC -powered:	80VA, maximum
	Battery -powered	80VA, maximum Dop1/2 On[Vol4], **Print On**[3cm/min, FM Print On] : about 30minutes Dop1/2 On[Vol4], **Print Off** : about 2Hours

Environmental

Operating Temperature:	10℃ to 40℃ (50℉ to 104℉)
Storage Temperature:	–20℃ to 60℃ (–4℉ to 140℉)
Relative Humidity:	20% to 90% non-condensing
Altitude:	0 -2000m (0 -6,561.68 ft)
Pressure	79.051kPa – 101.325kPa

Doppler Ultrasound FHR Monitoring

Parameter	**Value**
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

Uterine Contraction (TOCO) Monitoring

Parameter	**Value**
UC Range:	0-99 relative units
Resolution:	1 Count
Accuracy:	±1% relative unit
Leakage:	<10 µA @ 264 VAC applied to transducer
Isolation:	>4 kV RMS, Type BF applied part

Paper

Pack Style:	Z-Fold.
Pack Size:	150 mm x 90 mm x 15 mm
End-of-Pack:	Mark along paper edge
Loading:	Open-door, slide-in
Paper Detectors:	Paper Out
	Loading Door Open

Paper Speeds

Normal: 1, 2, and 3 cm/min ±1%

Paper Tracking Accuracy: ±1% (exclusive of paper accuracy)

Acoustic output information for the transducer assembly

ISATA @ Transducer Face	1.95 mW / cm^2
Entrance beam dimension	8.54865 cm^2
Center frequency	0.985 Mhz
Pulse duration	128 μsec
Pulse repetition frequency	3472 Hz
Measurement uncertainty for ISATA	+/- 19%
Measurement uncertainty for ultrasonic power	+/- 19%
Measurement uncertainty for center frequency	+/- 4.5%

- Ultrasonic Power for the transducer assembly = 16.7 mW

- Ultrasonic element diameter = 1.1 cm
  (9 ultrasonic elements are used in the transducer assembly.)

- Duty Factor(DF) =Pulse Duration x Pulse Repetition Frequency = 128 x 10^{-6} x 3,472 = 0.444416

- Area corresponding to entrance beam dimensions = 9(the number of ultrasonic element in the transducer assembly) x 3.14 x 0.55^2 = 8.54865 cm^2

- I_{SATA} @ Transducer Face = Ultrasonic Power / Area Corresponding to entrance beam dimensions = 16.7 / 8.54865 = 1.95352482555725 ≒ 1.95 mW/cm^2

- I_{SAPA} @ Transducer Face = I_{SATA} @ Transducer Face / DF = 1.95 / 0.444416 ≒ **4.4 mW/cm^2**

Section 11
Troubleshooting and Maintenance

11.1 General Test

1. Make sure the monitor power is properly connected.

2. Check the recorder for paper and door open.

3. Connect the transducers to the monitor.

4. Turn on the monitor.

Check that the monitor successfully powered on and is displaying the FHR amd UC. If an error occurs the monitor will not turn on or operate with abnormal status. The unit should be removed from service if this occurs.

Check that the recorder is feeding paper and the power on test pattern printed properly. Remove from service if this does not occur.

11.2 Ultrasound Transducer Test

To test an ultrasound transducer:

1. Properly connect the transducer to the right panel of the monitor.

2. Turn on the monitor.

3. Adjust the speaker volume to an audible level.

4. Hold the transducer on one hand and tap on the transducer face with the other hand. The tapping should be heard from the monitor.

The transducer is operating properly if you can hear noise from the speaker. Remove from service if no noise is heard or until the proper cause is identified and repaired.

11.3 UC(TOCO) Test

To test the UC(TOCO) transducer:

1. Properly connect the transducer to the right panel of the monitor.

2. Turn on the monitor.

3. Gently apply pressure to the button centered on the face of the transducer.

The display and printout should show a change in pressure if the transducer is operating properly. Remove from service if this does not occur.

11.4 Battery Disposal and Handling

CAUTION: When disposing of internal Ni-MH battery, adhere to all applicable laws regarding recycling. Avoid storing battery above 140℉. If clothing or skin comes in contact with material from inside the battery, immediately wash with plenty of clean water.

CAUTION: The internal battery must be handled by the company's technician only. Do not attempt to open the BT-350E.

The internal battery is consumables. Therefore the operation time by the battery can be decreased. If the operation time is not long enough, please contact service center and change the battery. If this system is used with not sufficient operating time by the internal battery, it is possible to be shut down the system because of the lack of the internal battery's capacity. This situation can cause not intended stop of measuring and monitoring function..

11.5 Maintenance

The BT-350E monitor and accessories require no periodic calibration or adjustment. The recommended interval for performing hipot and leakage testing is once per year.

11.6 Disposal of the BT-350E

When disposing of the BT-350E, adhere to all applicable laws regarding recycling. If you are not able to dispose the BT-350E or you need a help for disposing the BT-350E, please contact us. In the case of there are no appropriate ways to dispose, we will pick up the BT-350E for you.

Product Guarantee

Product Name		Fetal Monitors
Model Name		BT-350E
Approval No.		
Approval Date		
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-350E.

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

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

Service Telephone and Fax. Numbers

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