BT-300

Fetal Monitor

OPERATION MANUAL

BT - 300

Keep this manual for future reference

P/N : 300-ENG-OPM-EUR-R12

Proprietary Material

Revision 12
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Section ***1***
Safety

1.1 Instructions for the Safe Operation and Use of the BT-300 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-300, or its equivalent, is approved for use with the Unit.

- Do not attempt to service the BT-300 monitor. Only qualified service personnel by Bistos Co., Ltd. should attempt any needed internal servicing.

- The BT-300 is not specified or intended for operation during the use of defibrillators or during defibrillator discharge.

- The BT-300 is not specified or intended for operation in the presence of electrosurgical equipment.

- The BT-300 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-300 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, and 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-300 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, possible safety hazards and electromagnetic safety problems.

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-300, do not use the BT-300 to the patient. This can cause the electric shock to the patient.

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.

WARNING: 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.

WARNING: 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.

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 sealed place, allow for adequate ventilation, accessibility for servicing, and room for adequate visualization and operation. Two side of the device is must be opened.

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-300 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-300 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-300 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.

CAUTION: When washing the transducer belts, the water temperature must not exceed 60°C (140°F).

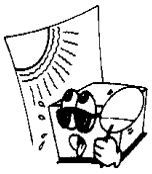
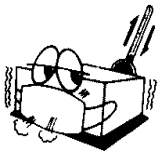
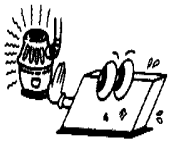
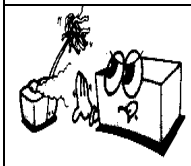
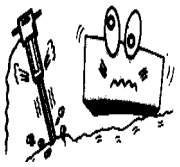
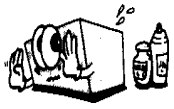
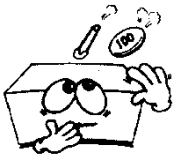
CAUTION: When loading paper, the paper must be put above the shaft. Otherwise, the paper can be biased one side.

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-300. This can cause the finger wound. Also do not prick the inside of BT-300 when the printer door is open. This can cause the damage to the device or electric shock.

1.4 General Precaution on Environment

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

	Avoid placing in an area exposed to moisture. Do not touch the equipment with wet hand.		Avoid exposure to direct sunlight
	Avoid placing in an area where there is a high variation of temperature. Operating temperature ranges from 10°C to 40°C. Operating humidity ranges from 5% to 85%.		Avoid in the vicinity of Electric heater
	Avoid placing in an area where there is an excessive humidity rise or ventilation problem.		Avoid placing in an area where there is an excessive shock or vibration.
	Avoid placing in an area where chemicals are stored or where there is in danger of gas leakage.		Avoid dust and especially metal material into the equipment.
	Do not disjoint or disassemble the equipment. BISTOS Co., Ltd. does not take responsibility of it.		Power off when the equipment is not fully installed. Otherwise, the equipment could be damaged.

1.5 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 40 minutes.)
	Operating instructions
	When disposing of some components (ex: internal Li-ion battery), do not dispose as general wastes. Adhere to all applicable laws regarding recycling.

※ According to IEC 60601-1-6 General requirements for basic safety and essential performance – Collateral Standard : Usability, the definition and using these symbols is adjusted.

Section ***2***
Introduction

2.1 General

This chapter provides a general description of the BT-300 monitor including:

- Brief Device Description
- Product Features
- Model Configurations

2.2 Brief Device Description

The BT-300 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-300 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.

> ***WARNING***: BT-350 is not intended for use during defibrillation, electro-surgery, or magnetic resonance imaging (MRI).

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

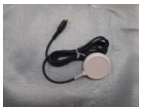
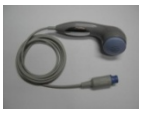
Accessory	Name	Description
	Doppler Probe	Ultrasound Transducer for Measuring FHR (IPX8 : Waterproof)
	UC Probe	Pressure Sensor (Tocotonometer) for Measuring Uterine contraction (IPX8 : Waterproof)
	Event Marker	Used for a Fetal Movement event
	AST Probe (Option)	Acoustic Stimulation Test Probe
	Z-folded 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(2.8A)
	LI-ION Battery	*14.8V, 2600mAh*
	Ultrasound Gel	Ultrasound transmission gel (Sanipia, ECOSONIC)

Table 2.1. BT-300 Accessories

Section ***3***
Installation

3.1 Description of the BT-300 Front Panel

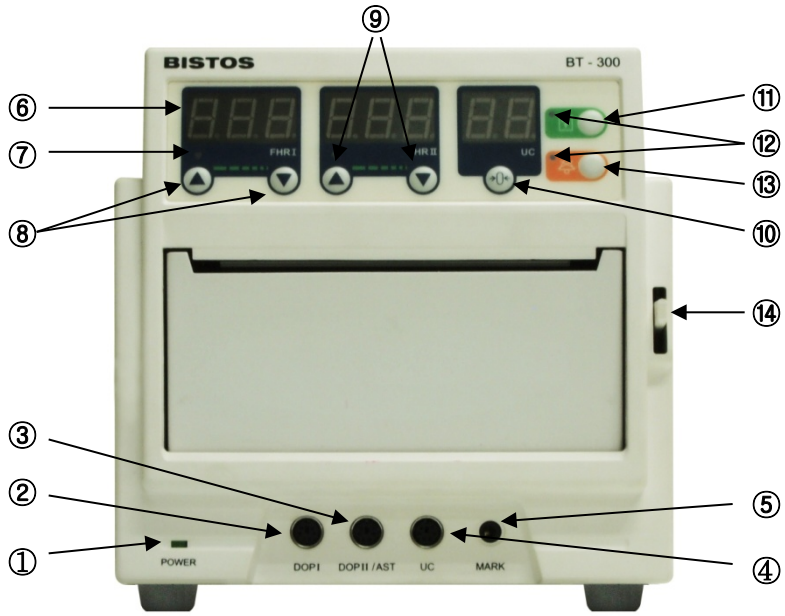


Fig. 3.1 BT-300 Front Panel

① Power Indicating LED (AC:Green / Battery:Orange)
② DOP 1 Connector
③ DOP 2 Connector(AST Connector)
④ UC Connector
⑤ Event Marker Connector
⑥ FHR & UC Value Display Panel
⑦ Heartbeat Lamp
⑧ DOP 1 Volume Up/Down Button
⑨ DOP 2 Volume Up/Down Button
⑩ UC Reference Button
⑪ Printer On/Off Button
⑫ Printer & Alarm LED
⑬ Alarm Sound On/Off Button
⑭ Print Door Open Button

3.2 Description of the Left Panel

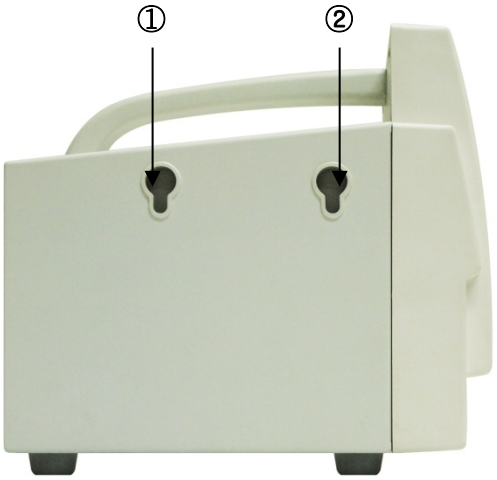


Fig. 3.2 BT-300 Left Panel

① DOP 1 Probe Holder
② DOP 2 Probe Holder(AST Probe Holder)

3.3 Description of the Right Panel

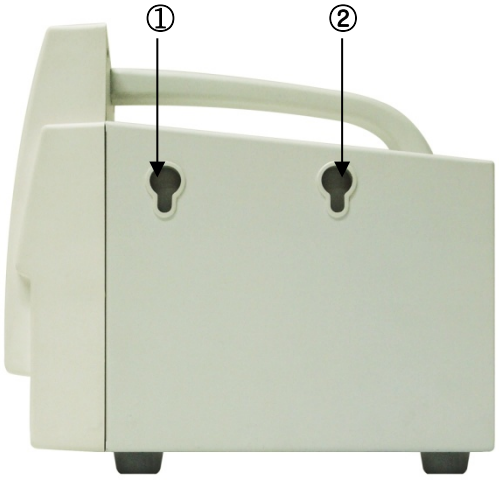


Fig. 3.3 BT-300 Right Panel

① UC Probe Holder
② Event Marker Holder

3.4 Description of the Rear Panel

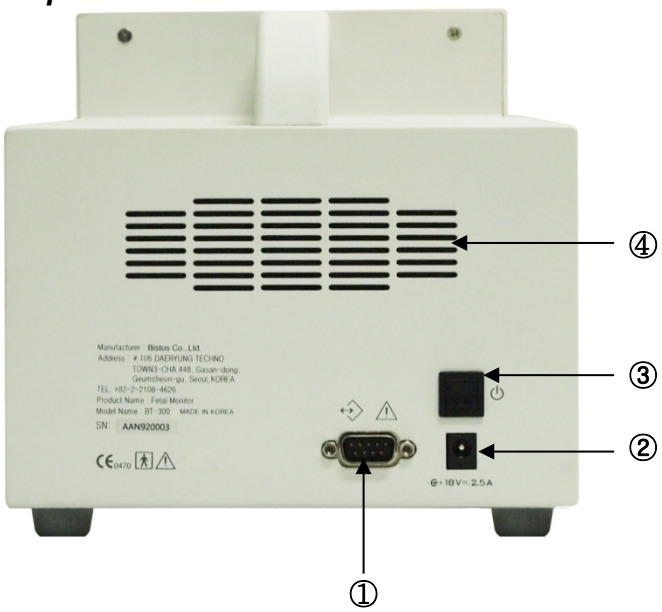


Fig. 3.4 BT-300 Rear Panel

① Power On/Off Button
② Power Adaptor Jack Connector
③ RS-232C port Connector
④ Speaker

3.5 Power On

When the user wants to turn BT-300 on, power adaptor is connected with power adaptor jack connector on Rear panel of BT-300 as shown in Figure 3.4 and power button is pressed.

3.6 Patient Cables

The ultrasound and TOCO transducer cable are connected to the front 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 front panel has a label (DOP I, DOP II/AST 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-300 capable of monitoring two fetuses by connecting this to DOP II/AST 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.

3.7 Event Marker Cable

The event marker cable is connected to the connector in the front 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-300 Operation

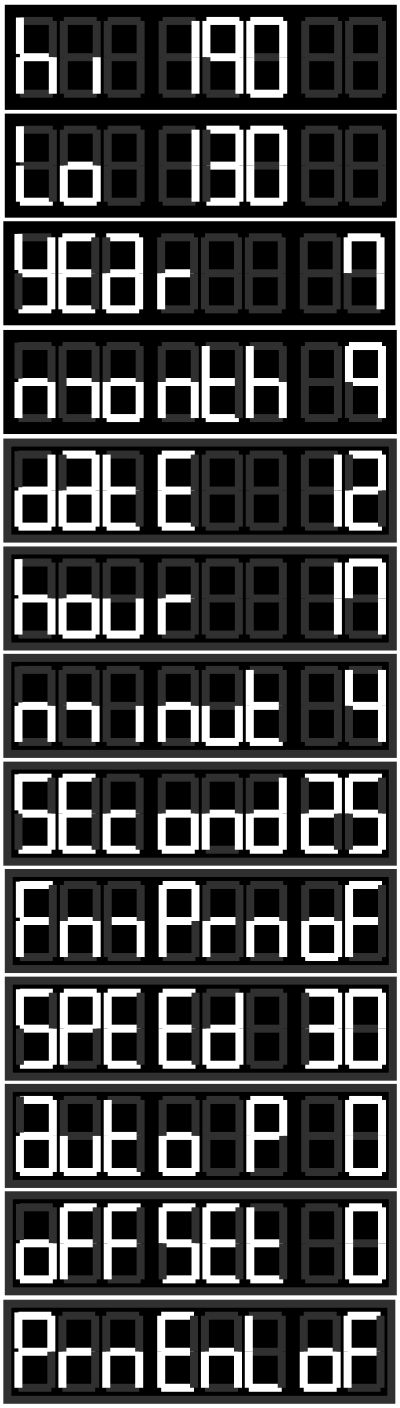
4.1 System Startup

4.1.1 Configuration Settings

The monitor has several configuration settings that the user can change. Some of these settings are reset to the default value each time the monitor is powered down. Other parameter settings are saved in the monitor until the next time they are changed. These parameters are unaffected when the monitor is powered down. A complete list of these parameters is shown below.

Configuration parameter	Mode Key	Factory Default
Fetal Heart Rate Upper Alarm Limit	Alarm	190 BPM
Fetal Heart Rate Lower Alarm Limit		130 BPM
Record Paper Speed	UC Reference	30 mm/min
Fm Prn (Fetal Movement Graph Print)		OFF
Auto Print		0
(Dop2) Offset		0
Prn EnL(Zoom Function)		OFF

Item	Mode Key	Setup Menu	Details
Alarm & Date	Alarm	hi	Heart Rate Upper Alarm Limit
		Lo	Heart Rate Lower Alarm Limit
		yEar	Year
		month	Month
		datE	Date
		hour	Hour
		minut	Minute
		SEcond	Second
Print	UC Reference	SPEEd	Record Speed (10, 20, 30mm/min)
		Fm Prn	Fetal Movement Print
		auto P	Auto Print
		oFFSEt	Dop2 Offset (+20 bpm recording)
		Prn EnL	Record Enlarge(Zoom)



Turn on the monitor and keep the alarm button depressed until the setup items appear in the FHR display. Pressing the DOP1 volume button, you can change the setup menu and using by DOP2 volume button, you can change the setup value.
Pressing the DOP2 volume button for more than 2 seconds causes the setting value and display to increment (or decrement) continuously for as long as the button is pressed. When the parameter is set, press the printer button to save and exit the setup mode. If you press the alarm button for more than two seconds, you can set the alarm range and date values. If you press the DOP2 volume up/down button, you can change the alarm high limit value. The alarm range is 35 ~ 235bpm and, if the upper limit value(or the lower limit value) is lower(or greater) than the lower limit value(or the upper limit value), the setting values do not change. If you press the DOP1 volume down button, enter the next menu year, month, date, hour, minute, second sequentially. And you can change the value by pressing the DOP2 volume button.

If you press the UC Reference pushbutton for more than two seconds, you can set the print values. In print setting menu, you can change the record speed to one of the three choices, 10, 20, 30mm/minute. The “Fm Prn” function is activated, the fetal movement graph is printed on the paper. In “auto P” menu, you can change the record auto-printing period to one of the 7 choices, 0(Continuous), 10, 20, 30, 40, 50, 60 minutes. When you want to measure twin’s heart rates simultaneously, because the FHR patterns are in the same range, it makes you trouble to distinguish the FHR patterns. By enabling the “oFFSEt” function, the Dop2 heart rates will be printed plus by 20bpm. Next the “Prn EnL” functions, you can activate a zoom in function that printed 74 ~ 200 bpm range.

4.1.2 Understanding and Setting Alarms

The BT-300 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 5 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.
Pressing the alarm button on the monitor's keypad can silence the alarm tone.
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. The following section describes the procedure used to set alarm parameters for ultrasound heart rates.

Activity	**Desired Result**
[]Button Press	To enter the setup menu over 2 seconds.
[] FHR1Button Press	To select "UPPER LIMIT," "LOWER LIMIT."
[] FHR2Button Press	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) ~ 235 BPM, 1 BPM increments} Heart Rate Lower Limit {35 ~ (Heart Rate Upper Limit-5) BPM, 1 BPM increments}
[]Button Press	To save and exit setup menu.

4.1.3 Setting [Print Speed / Fetal Movement Print / Auto Print / Dop2 Offset / Record Enlarge]

This section describes the procedure used to set the paper speed and auto stop time.
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. When fetal movement is enabled, fetal movement graph is printed. FM1 graph is printed 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.

Activity	**Desired Result**
[]Button Press	To enter the setup menu over 2 seconds.
[] FHR1Button Press	To select "Print Speed", "Fetal Movement Print", "Auto Print", "DOP2 OFFSET", "Record Enlarge"
[] FHR2Button Press	The list below shows the values that are available for each parameter: Print Speed {10, 20, 30 mm/minute} Fetal Movement Print {ON or OFF} Auto Print{0, 10, 20, 30, 40, 50, 60 minute} Dop2 Offset {0 BPM," or "20 BPM.} Record Enlarge {ON or OFF}
[]Button Press	To save and exit setup menu.

4.1.4 Setting Time and Date

This section describes the procedure used to change the time and date settings of the monitor.

Activity	**Desired Result**
[ ]Button Press	To enter the setup menu over 2 seconds.
[ ] FHR1Button Press	To select Time Menu.
[ ] FHR2Button Press	To change the desired value. The list below shows the values that are available for each parameter: Year {1 ~ 99 Year} Month {1 ~ 12 Month} Date {1 ~ 31 Date} Hour {0 ~ 23 Hour} Minute {0 ~ 59 Minute} Second {0 ~ 59 Second}
[ ]Button Press	To save and exit setup menu.

4.2 BT-300 Monitor Display Screen

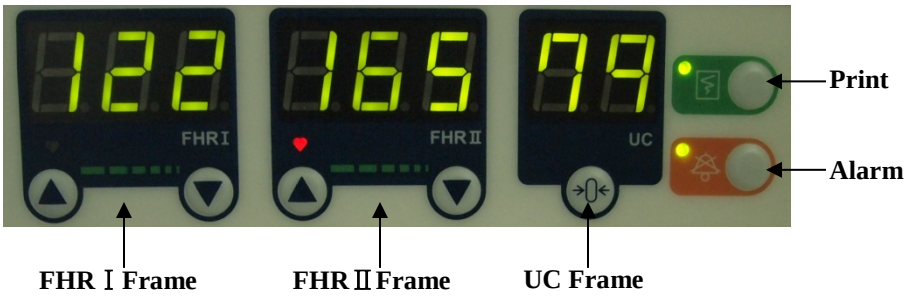


Fig. 4.3 FHR & UC value display panel

Symbol	Name	Description
	Heart Rhythm Icon	Blinking according to heart rate
	Alarm Sound Icon	Indicating of Alarm sound enable/disable
	Print Icon	Indicating of a printing status

4.2.1 FHR I & II Frame (Fetal Heart Rate Numeric Frame)

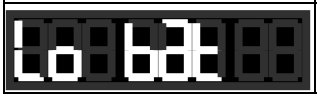
FHR I & II frames display the fetal heart rate and heart icon. And in this frame, the volume buttons are provided to change speaker volume for setting for the fetal echo sounds. Using these buttons, user can change speaker volume. This channel is labeled “FHR I” and “FHR II”. The heart rate value shows the most recent calculated fetal heart rate. The heart rate icon blinks at the measured heart rate interval when a valid rate is present.

4.2.2 UC Frame (TOCO Numeric Frame)

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

4.2.3 The error and current operation message display

FHR I & II and UC frames show 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 is not connected while BT-300 is monitoring
	DOP2 is not connected while BT-300 is monitoring
	Print door is opened while BT-300 is printing
	Paper is not loaded while BT-300 is printing
	Battery's charging level is low while BT-300 is monitoring

4.3 BT-300 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 buttons.

The operation of the buttons is summarized below.

Symbol	Name	Description
	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.
	UC Reference Button	Resets the UC baseline in monitoring mode.
	Alarm On/Off Button	Makes the alarm sound enable or disable in monitoring mode.
	Record On/Off Button	Turns the record on or off.

Section ***5***
Recorder Operation

5.1 Loading Paper

The paper is loaded by pulling down 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.

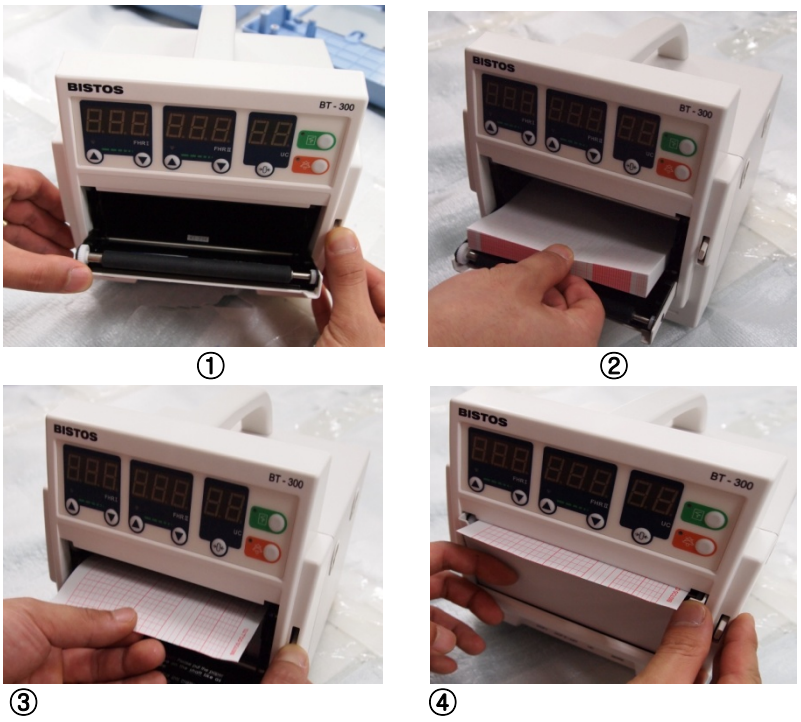


Fig. 5.1 Loading Paper

5.2 Operation

Print On/Off button — A single press and release of [] button will toggle the recorder mode between printing and nonprinting.
The printer LED in on when the paper is loaded correctly and the printer is operating. The printer LED is off when the printer is off. If there is no paper, “no paper” alarm will be displayed and alarm sounds.

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.
The below is shown the printing parameters.

Symbol	Description	Source of mark	Possible events
	Event Mark	Press Event marker (by pregnant woman)	When pregnant woman feels fetus movement
	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 display 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-300. 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-300, 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 display is normal. 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 battery status to determine whether the battery has sufficient charge to complete the monitoring session. Use the AC power if the “low battery” alarm is displayed.

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 display 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 display are blinking at the measured heart rate.

CAUTION: The material safety data sheet of ultrasound gel is provided by the manufacturer of ultrasound gel. Therefore using the gel is safe for the patient. But unexpected side effects can be caused by different patients. To minimize unexpected side effects, please do not use the gel for many hours.

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 rear 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 I" or "DOP II/AST".

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.

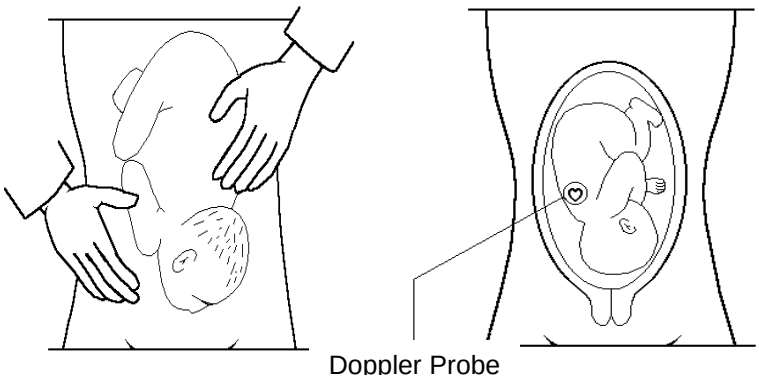


Figure 6.1 the direction of Doppler Probe

⑪ If the printer is not already activated, press the [ ] button located on the front panel of the monitor. The recorder plots the FHR on the paper strip chart.

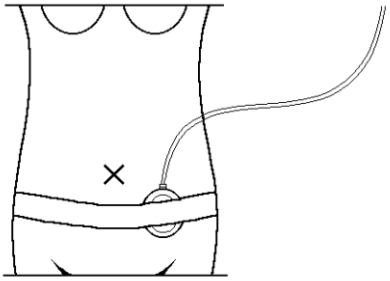


Figure 6.2 Positioning of UC Probe

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-300, 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 display is normal. 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 battery status to determine whether the battery has sufficient charge to complete the monitoring session. Use the AC power if the "low battery" alarm is displayed.

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 the printer is not already activated, depress the [ ] button 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. The event marker icon by patient's press is an upward pointing arrow. A strip chart printout of the patient record will also show this mark.

Section **9**
Cleaning and Disinfection

This chapter contains instructions for the care and cleaning of the BT-300 unit and its accessories.

The BT-300 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. Does not gas or 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°C (140°F).

9.4 Contacting components and characteristics

Contacting component	Material	Usage	Disinfection
DOP enclosure	ABS AV20F	Reusable	Must be cleaned and disinfected prior to use
UC enclosure	ABS AV20F + Polyurethane ESTANE S385A-46N	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°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.

Section ***10***
Specifications

BT-300 Monitor Specifications:

Physical Characteristics

Dimensions – 19.1 cm H x 18.7 cm W x 20.1 cm D
Weight - approx. 5.0 kg

Safety

Complies with IEC 60601-1, IEC 60601-1-2, IEC 60601-2-37
Class I Equipment & Internal Powered Equipment
Continuous Operation
Type BF applied parts
Doppler / UC Probe : IPX8

Power

External:	Power Adaptor	Input : AC (100-240V), 50~60Hz Output: DC(18V), 2.8A
Internal:		Li-ion, rechargeable battery
Power	AC -powered:	80 W, maximum
Dissipation:	Battery -powered	80 W, maximum 1-hour battery operation when fully charged at 25℃

Environmental

Operating Temperature:	10 °C to 40 °C (50 °F to 104 °F)
Operating Humidity	5 to 85% non-condensing
Storage Temperature:	- 20 °C to 60 °C (-4 °F to 140 °F)
Storage Humidity:	0 to 95% non-condensing
Altitude:	0 -2000m (0 -6,561.68 ft)
Pressure	70kPa ~ 106kPa

Doppler Ultrasound FHR Monitoring

Parameter	**Value**
FHR 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:	130 mm x 120 mm x 20 mm
End-of-Pack:	Mark along paper edge
Loading:	Front-door, slide-in
Paper Detectors:	Paper Out Loading Door Open

Paper Speeds

Normal: 1, 2, and 3 cm/min ±1%
High-Speed: 50 cm/min

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

Acoustic Output Reporting Non-Auto scanning Mode

Operating Mode : PW Mode

Acoustic Output			MI	$I_{SPTA.3}$ (mW/cm^2)	$I_{SPPA.3}$ (mW/cm^2)
Global Maximum Value			0.04	17.6	0.396
Associated Acoustic Parameter	$P_{r.3}$ (MPa)		0.063685		
	W_0 (mW)			16.7*	16.7*
	f_c (MHz)		0.985	0.985	0.985
	Z_{sp} (cm)		2	2	2
	Beam dimensions	x_{-6} (cm)		0.6	0.6
		y_{-6} (cm)		1.3	1.3
	PD (μsec)		128		128
	PRF (Hz)		3472		3470
	EBD	Az.(cm)		1.1	
		Ele.(cm)		1.1	
Operating Control Conditions	Control 1		Default Mode	Default Mode	Default Mode
	Control 2				
	Control 3				
	Control 4				
	Control n				

- *Measured values were multiplied by nine to account for nine elements in the transducer.*

- Ultrasonic Power = 16.7 mW
- Ultrasonic element diameter = 1.1cm

- 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 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 User Test

The user has to check the monitor performances each time the unit is turned on.

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 LED window. If an error occurs , 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 front panel.

2. Turn on the monitor.

3. Adjust the speaker volume to an audible level.

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

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 front.

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°F. 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-300.

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-300 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-300

When disposing of the BT-300, adhere to all applicable laws regarding recycling. If you are not able to dispose the BT-300 or you need a help for disposing the BT-300, please contact us. In the case of there are no appropriate ways to dispose, we will pick up the BT-300 for you.

11.7 Request a service for general problems

If the main body or accessories are damaged by excessive mechanical forces, narrow cracks or separation of internal ultrasonic sensor can be happened. These can be checked through visible or auditory decision. These can cause malfunction some times. But these do not cause unacceptable risks. If the BT-300 does not work properly, please contact us and change the corresponding parts. Note that the replacement costs can be occurred.

Section ***12***
Manufacturer's Declaration

12.1 Electromagnetic emissions

The BT-300 is intended for use in the electromagnetic environment specified below. The customer of the user of the BT-300 should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The BT-300 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-300 is intended for use in the electromagnetic environment specified below. The customer or the user of the BT-300 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	± 8 kV contact ± 15kV air	± 8 kV contact ± 2kV, ± 4kV, ± 8kV, ± 15kV 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 ± 1kV 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	± 1kV power differential mode ± 2kV power common mode ± 2kV input / output signal lines	± 0.5kV, ± 1kV power differential mode ± 0.5kV, ± 1kV, ±2kV power common mode ± 2kV input / output signal lines	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines (50/60Hz) IEC 61000-4-11	70%U_T for 25cycle (50Hz) 70%U_T for 30cycle (60Hz) 0%U_T for 0.5cycle 0% U_T for 1cycle	70%U_T for 25cycle (50Hz) 70%U_T for 30cycle (60Hz) 0%U_T for 0.5cycle 0% U_T for 1cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the [ME Equipment or ME System] requires continued operation during power mains interruptions, it is recommended that the [ME Equipment or ME System] be

	0% U_T for 250cycle (50Hz) 0% U_T for 300cycle (60Hz)	0% U_T for 250cycle (50Hz) 0% U_T for 300cycle (60Hz)	powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note U_T is the a.c. mains voltage prior to application of the test level.			

The BT-300 is intended for use in the electromagnetic environment specified below. The customer or the user of the BT-300 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80MHz (AM 80%, 1kHz sine-wave)	3 Vrms 150 kHz to 80MHz (AM 80%, 1kHz sine-wave)	Portable and mobile RF communications equipment should be used no closer to any part of the BT-300, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
	6 Vrms 150 kHz to 80MHz (AM 80%, 1kHz sine-wave)	6 Vrms 150 kHz to 80MHz (AM 80%, 1kHz sine-wave)	**Recommended separation distance.** $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz (AM 80%, 1kHz sine-wave)	3 V/m 80 MHz to 2.7 GHz (AM 80%, 1kHz sine-wave)	$d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m).
	9 ~ 28 V/m 385MHz to 6GHz (FM, ±5kHz deviation 1kHz sine) (PM, 50% 18/217Hz)	9 ~ 28 V/m 385MHz to 6GHz (FM, ±5kHz deviation 1kHz sine) (PM, 50% 18/217Hz)	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol : 

NOTE 1) At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the BT-300 is used exceeds the applicable RF compliance level above, the BT-300 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-300.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V / m.

12.3 Recommended separation distances between portable and mobile RF communications equipment and the BT-300

Rated maximum output power of transmitter [W]	Separation distance according to frequency of transmitter [m]			
	150 kHz to 80 MHz $d = [\frac{3,5}{V_1}]\sqrt{P}$		80 MHz to 800 MHz $d = [\frac{3,5}{E_1}]\sqrt{P}$	800 MHz to 2.5 GHz $d = [\frac{7}{E_1}]\sqrt{P}$
	V1 = 3Vrms	V2=0.1Vrms	E1=3V/m	E1=3V/m
0.01	0.12	3.50	0.12	0.23
0.1	0.37	11.06	0.37	0.74
1	1.17	35.00	1.17	2.33
10	3.69	110.67	3.69	7.38
100	11.66	350.00	11.66	23.33
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m)can be estimated using the equation applicable to the frequency of the transmitter, where *p* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1) At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.				

Product Guarantee

Product Name	Fetal Monitors
Model Name	BT-300
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-300.
※ 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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