BT-350

Fetal Monitor

Operation Manual

BT-350, BT-350E

Keep this manual for future reference

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Proprietary Material

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Section ***1***
Safety

1.1 Instructions for the Safe Operation and Use of the BT-350 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-350, or its equivalent, is approved for use with the BT-350.
- Do not attempt to service the BT-350 monitor. Only qualified service personnel by Bistos Co., Ltd. should perform any needed internal servicing.
- The BT-350 is not specified or intended for operation during the use of defibrillators or during defibrillator discharge.
- The BT-350 is not specified or intended for operation in the presence of electrosurgical equipment.
- The BT-350 is not specified or intended for operation in conjunction with any other type of monitoring equipment except the specific devices that have been identified for use in this Operator's Manual.
- 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-350 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.
⚠	**CAUTION**	Be informed that it may cause no harm in life but lead to injury.

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.
- 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-pole grounded outlet before attempting

to operate the monitor.

- Do not connect to an electrical outlet controlled by a wall switch.
- 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.
- 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.
- Do not contact RS-232C port and patient at the same time.
- AC/DC Adaptor should use appointed product.
- 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.
- 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.
- 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 I 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)
- The relevant law restricts this device to sale by or on the order of a physician.
- Keep the operating environment free of dust, vibrations, corrosive, or flammable materials, and extremes of temperature and humidity. The unit should be kept clean and free of transducer gel and other substances.
- When installing the unit into a cabinet, allow for adequate ventilation, accessibility for servicing, and room for adequate visualization and operation.
- Do not operate the unit if it is damp or wet because of condensation or spills. Avoid using the equipment immediately after moving it from a cold environment to a warm, humid location.
- Never use sharp or pointed objects to operate the front-panel switches.
- 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-

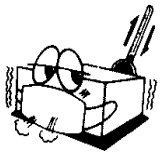
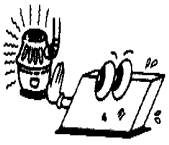
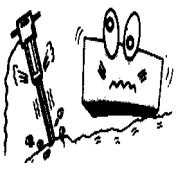
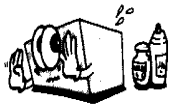
CAUTION

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.

- Do not autoclave or gas sterilize the monitor or any accessories. Follow cleaning and disinfection instructions in Section 9 of this manual.
- Do not immerse BT-350 main body and transducers in liquid. When using solutions, use sterile wipes to avoid pouring fluids directly on the transducer. Follow cleaning and disinfection instructions in Section 9 of this manual.
- When washing the transducer belts, the water temperature must not exceed 60°C (140°F).
- When loading paper, the paper must be put above the shaft. Otherwise, the paper can be biased one side.
- 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.
- 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 does not take responsibility of it.		Power off when the equipment is not fully installed. Otherwise, the equipment could be damaged.

1.4 Definitions of Symbols

Symbol	Description
	Power On/Off Button
	Indicates the need for the user to consult the instructions for use
	External Signal IN/OUT Port
	Type BF Equipment
IPX8	IPX8 Waterproof (1 meter of water for over 40 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-350 monitor including:

- Brief Device Description
- Product Features
- Model Configurations

2.2 Brief Device Description

The BT-350 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

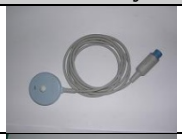
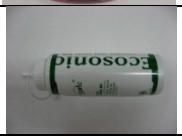
The BT-350 is a Prenatal Monitoring System for non-invasively measuring and showing graphically maternal abdominal contractions and the fetal heart rate by means of display on a non-permanent graphical display and on a strip chart recorder. This data is intended to aid in assessing the well-being of 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

<Table 2.1. BT-350 Accessories>

Accessory	Name	Description
	Doppler Probe	Ultrasound Transducer for Measuring FHR (IPX8 : Waterproof)
	UC Probe	Pressure Sensor for Measuring Uterine contraction(UC) (IPX8 : Waterproof)
	Event Marker	Used for a Fetal Movement event
	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) (BPM050S18F04, Bridge Power Corp.)
	LI-ION Battery	Type / model : 18650 Technical data : 3.7V * 4ea, 2600mA
	Ultrasound Gel	Ultrasound transmission gel (Sanipia, ECOSONIC)

Section ***3***
Installation

3.1 Description of the BT-350 Front Panel

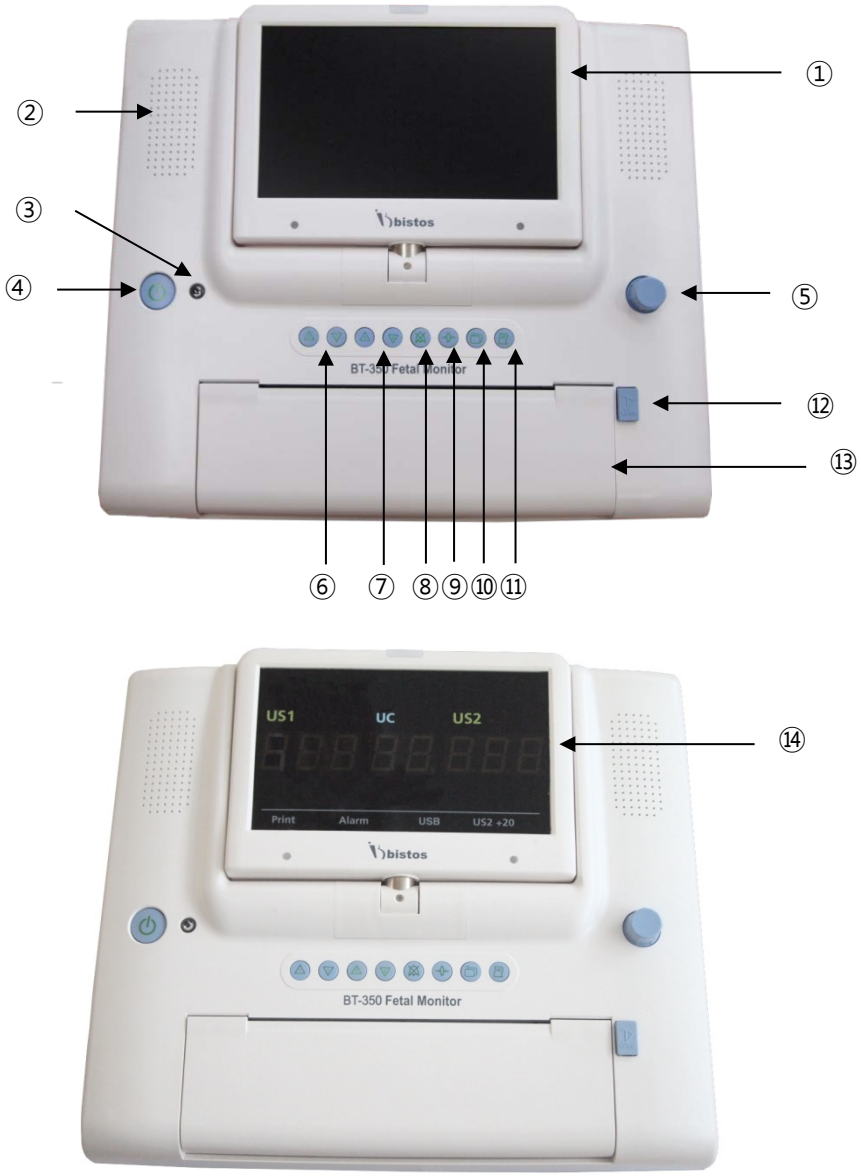


Fig. 3.1 BT-350 Front Panel

① TFT-Color LCD
② Speaker
③ Power Indicating LED (AC:Green / Battery:Orange)
④ Power On/Off Button
⑤ Control Knob
⑥ Dop1 Volume Up/Down Button
⑦ Dop2 Volume Up/Down Button
⑧ Alarm Sound On/Off Button
⑨ UC Reference Button
⑩ Mode Change Button
⑪ Printer On/Off Button
⑫ Print Door Open Button
⑬ Printer Door
⑭ 7 Segment LED display (BT-350E)

3.2 Description of the Left Panel

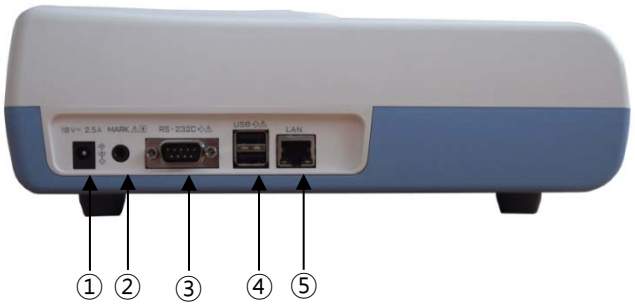


Fig. 3.2 Left Panel

① Power Adaptor Jack Connector
② Event Marker Connector
③ RS-232C Port Connector
④ USB port Connector
⑤ LAN cable Connector

3.3 Description of the Right Panel

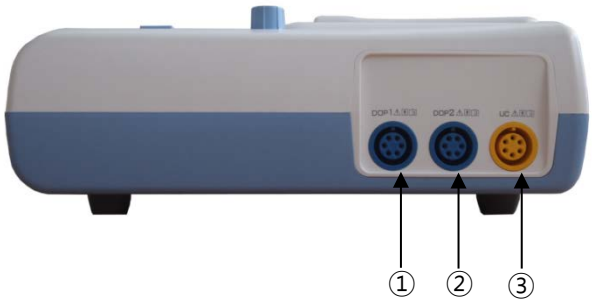


Fig. 3.3 Right Panel

① DOP1/AST Connector
② DOP2/AST Connector
③ UC Connector

3.4 Power On

When the user wants to turn BT-350 on, power adaptor is connected with power adaptor jack connector on left panel of BT-350 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-350 capable of monitoring two fetuses by connecting 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.
- Do not connect to an electrical outlet controlled by a wall switch.
- 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-350 Operation

4.1 System Startup

4.1.1 Power-on Self-test

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

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

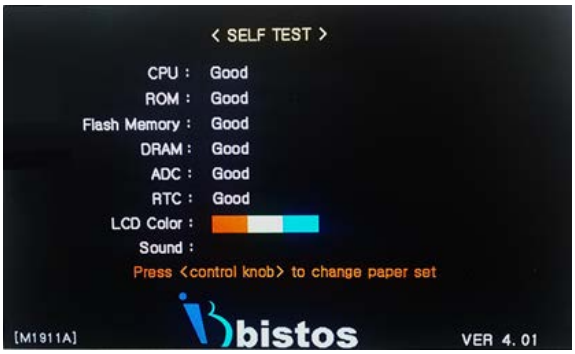


Fig. 4.1 Self-Test display

4.2 BT-350 Monitor Display Screen

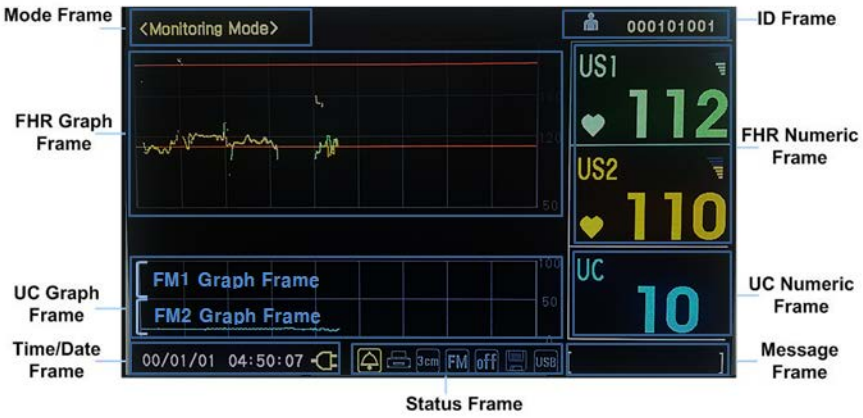


Fig. 4.2 Main Monitoring Screen – Graph Mode

Fig. 4.3 Main Monitoring Screen – Number Mode

Press mode button [ ], then the relevant menu comes out as shown Figure 4.6.
Rotate the control knob to select the ‘Number Mode” or “Graph Mode” item.
Press the Control knob to change display-mode.

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

4.2.1 Mode Frame

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

4.2.2 Heart Rate Numeric Frame (FHR Numeric Frame)

The heart rate (FHR) numeric frame displays the fetal heart rate, a heart icon, alarm status icon, and a speaker volume icon. This channel is labeled “US1.” 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.

The volume icon provides an indication of the speaker volume setting for the fetal echo sounds. This icon changes when the volume setting is adjusted. The alarm icon is a bell. A diagonal line through the bell indicates alarms are disabled. A bell missing a diagonal line indicates alarms are enabled.

When the second ultrasound transducer is connected, the heart rate frame will include additionally the fetal heart rate, a heart rate icon, alarm status icon, and a speaker volume icon for the second ultrasound channel. This channel is labeled “US2.”

The trace-offset (DOP2 offset) icon will also appear in the heart rate frame if two ultrasound transducers are connected and ultrasound trace offset (DOP2 offset) has been enabled. The trace-offset icon is “ +20”.

4.2.3 Heart Rate Graph Frame (FHR Graph Frame)

The Heart Rate (FHR) Graph Frame displays a graphical representation of the fetal heart rate. The vertical scale is labeled and corresponds to the recorder paper (30 to 240 BMP). The graph displays 4 minutes and 30 seconds of data regard less of print speed.
This frame will show two heart rate trends when two ultrasound transducers are installed.
Two or three horizontal graticules are included to make it easier for the caregiver to observe heart rate trend or heart rates that exceed limits. For the FS151-90-80R-01 paper, three graticules are indicated on 100, 140 and 180 BPM. For the M1911A paper, two graticules are indicated on 120 and 160 BPM. This graphical frame is also used to display heart rate data when scrolling through historical patient data.

4.2.4 UC Numeric 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. The UC baseline is user adjustable.

4.2.5 UC Graph Frame(TOCO Graph Frame)

The UC Graph Frame displays uterine contraction graph data. The scale is from zero to 100 in relative units. The graph displays 4 minutes and 30 seconds of data regardless of print. This graphical frame also displays uterine contraction data when scrolling through patient data.

4.2.6 Power Status Frame

This frame contains either a battery icon or an AC power connector icon. If the unit is operating on AC power then an AC power connector icon is displayed. If the monitor is operating on internal battery power then a battery icon is displayed. The battery icon also includes a scale indicating battery charge status. If AC power is disconnected, BT-350 uses the internal battery. Therefore in the case of AC power is disconnected, there is no problem to use BT-350.

The battery icon will flash when the battery is low (less than 10 minutes of remaining time). Printer will stop operation in case Low Battery and the battery icon will turn on RED.

The AC power should be connected to the monitor to charge the battery. The monitor will operate normally while the AC power is charging the battery. The battery will be fully recharged in 14 hours if the monitor is not in use, or in 14 hours while in normal use.

4.2.7 Status Frame

This frame shows printer speed set, printer operating status, zoom in status, auto printing status, and saving status.

4.2.8 Patient ID

This section displays the patient identification. The monitor uses a time and date encoded identification scheme that insures no duplication of names. The user may also enter a different name if desired.

4.2.9 Time and Date

This frame shows the current time and date for the monitor. These settings can be changed as needed.

4.2.10 Message Frame

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

4.3 BT-350 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.
	Dop1 Volume Up/Down Button	Decreases or increases Dop1 fetal audio volume in monitoring mode.
	Dop2 Volume Up/Down Button	Decreases or increases Dop2 fetal audio volume in monitoring mode.
	Alarm On/Off Button	Makes the alarm sound enable or disable in monitoring mode.
	UC Reference Button	Resets the UC baseline in monitoring mode.
	Mode Button	Puts the monitor into trend scroll mode. The trend frames shows historical patient data and the control knob provides navigation capability.
	Record On/Off Button	Turns the record on or off.

4.4 BT-350 Monitor Control Knob and system setting

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 a menu, the cursor moves throughout the items within the menu. This process is used to select a menu item for modification. The knob is then pressed to select this item for editing.

Once a menu 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.

Pressing the knob when “ESC” is selected will exit the present menu and save the changed value. The screen will back on monitoring mode when ESC is pressed on SETUP mode and relevant menu screen, and the screen will back to SETUP mode in case ESC is pressed on HELP Screen.

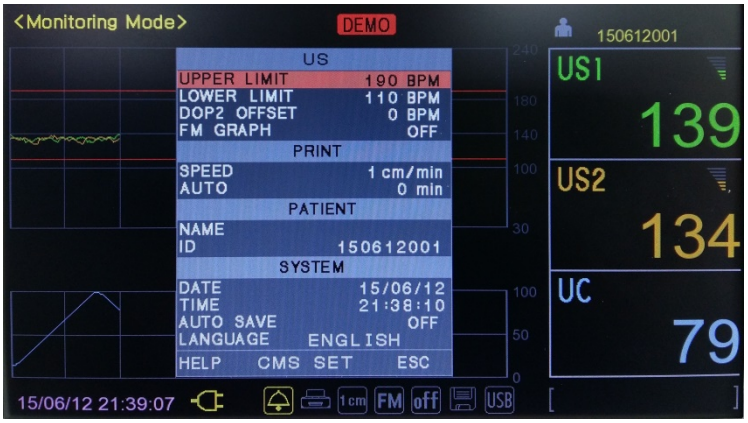


Fig. 4.4 System setup menu

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

The basic operation of control knob for configuration settings is as follows.

Activity	Desired Result
Press	Enter the configuration setting mode.
Rotate	Select the setting item
Press	Select the parameter to change.
Rotate	Change the set value
Press	Store the new value.

4.4.1 Setting Alarm Upper Limit / Lower Limit

Activity	Desired Result
Knob Rotate	Select “UPPER LIMIT” or “LOWER LIMIT”
Knob Press	Select this parameter for change.
Knob Rotate	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 step} Heart Rate Lower Limit {30 ~ (Heart Rate Upper Limit-10) BPM, 5 BPM step}
Knob Press	Store the new value.

4.4.2 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.

Activity	Desired Result
Knob Rotate	Select “DOP2 OFFSET”
Knob Press	Select this parameter for change.
Knob Rotate	Change the desired value [0/20].
Knob Press	Store the new value.

4.4.3 Setting FM(Fetal Movement) Graph

Activity	Desired Result
Knob Rotate	Select “FM GRAPH”
Knob Press	Select this parameter for change.
Knob Rotate	Change the desired value [ON/OFF].
Knob Press	Store the new value.

4.4.4 Setting Print Speed

Activity	Desired Result
Knob Rotate	Select “SPEED”
Knob Press	Select this parameter for change.
Knob Rotate	Select between ‘1cm/min’, ‘2cm/min’, and ‘3cm/min’.
Knob Press	Store the new value.

4.4.5 Setting Auto Print

Activity	Desired Result
Knob Rotate	Select “AUTO”
Knob Press	Select this parameter for change.
Knob Rotate	Change the desired value [0/10/20/30/40/50/60].
Knob Press	Store the new value.

4.4.6 Setting Patient Name

Activity	Desired Result
Knob Rotate	Select ‘NAME’.
Knob Press	Show alphabet menu. .QZ | ABC | DEF | GHI | JKL | MNO PRS | TUV | WXY | ␣ | ← | ESC
Knob Rotate	Select alphabet group to insert or delete or cancel Name change.
Knob Press	Show first character in selected alphabet group at Name menu text box. If press one more, character change to next character in a group.
Knob Rotate	Select ‘ESC’.
Knob Press	Store the new value.

4.4.7 Setting Patient ID

Patient ID is created automatically when BT-350 turns on. But This created ID can be changed manually.

Activity	Desired Result
Knob Rotate	Select “ID”
Knob Press	Select this parameter for change.
Knob Rotate	Change the desired value (0~999).
Knob Press	Store the new value.

4.4.8 Setting Time and Date

Activity	Desired Result
Knob Rotate	Select ‘TIME’ or ‘DATE’ Menu.
Knob Press	Enter Time Menu.
Knob Rotate	Change the desired value. The options for each parameter in the submenu are: Time {hours, minutes, seconds} – 24 H format Date {year, month, day} – YY/MM/DD
Knob Press	Store the new value and move to the next item.
Knob Rotate	Change the set value
Knob Press	Store the new value and move to the next item.

4.4.9 Setting Auto Save

Activity	Desired Result
Knob Rotate	Select “AUTO SAVE”
Knob Press	Select this parameter for change.
Knob Rotate	Change the desired value [ON/OFF].
Knob Press	Store the new value.

4.4.10 Setting Language

Activity	Desired Result
Knob Rotate	Select “LANGUAGE”
Knob Press	Select this parameter for change.
Knob Rotate	Select between ‘ENGLISH’, ‘CHINESE’, ‘SPANISH’, ‘GERMAN’, ‘FRENCH’, ‘INDONESIAN’, ‘RUSSIAN’, ‘PORTUGUESE’, ‘TURKISH’, ‘POLISH’, ‘ITALIAN’, ‘KOREAN’, ‘JAPANESE’.
Knob Press	Store the new value.

4.4.11 CMS(Central Monitoring System) Setting

Activity	Desired Result
Knob Rotate	Select “CMS SET”
Knob Press	The following setting menu displayed

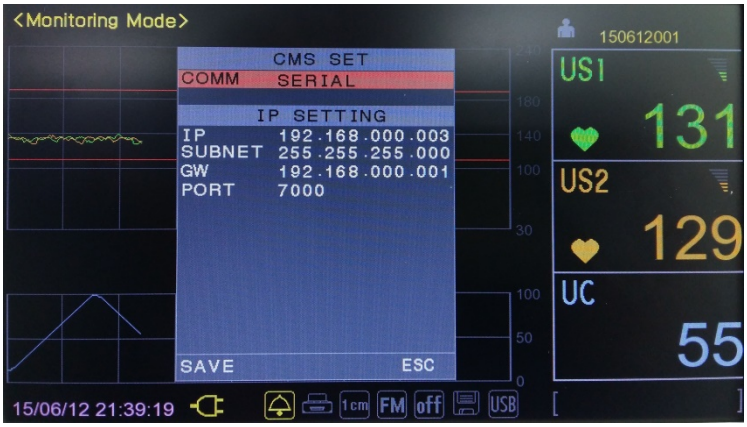


Fig. 4.5 CMS Setting configuration

Parameter	Factory Setting
COMM	SERIAL
IP	192.168.000.003
SUBNET	255.255.255.000
GW	192.168.000.001
PORT	7000

4.4.12 CMS Communication channel Setting

Activity	Desired Result
Knob Rotate	Select “COMM”
Knob Press	Select this parameter for change.
Knob Rotate	Change the desired value [SERIAL/ETHERNET].
Knob Press	Store the new value.

4.4.13 IP Address Setting

Activity	Desired Result
Knob Rotate	Select “IP”
Knob Press	Select this parameter for change.
Knob Rotate	Change IP address to the desired value.
Knob Press	Store the new value.

4.4.14 Subnet Mask Setting

Activity	Desired Result
Knob Rotate	Select “SUBNET”
Knob Press	Select this parameter for change.
Knob Rotate	Change Subnet Mask to the desired value
Knob Press	Store the new value.

4.4.15 Gateway Setting

Activity	Desired Result
Knob Rotate	Select “GW”
Knob Press	Select this parameter for change.
Knob Rotate	Change Gateway 1st bytes to the desired value.
Knob Press	Store the new value.

4.4.16 Port Number Setting

Activity	Desired Result
Knob Rotate	Select “PORT”
Knob Press	Select this parameter for change.
Knob Rotate	Change the desired value.
Knob Press	Store the new value.

4.5 Printer Paper Select

BT-350 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 4.2. Rotating control knob to choose paper type.

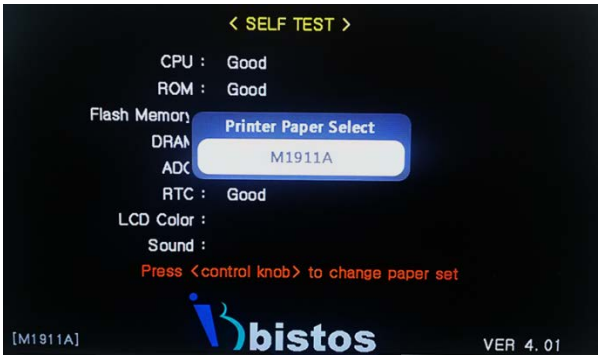


Fig. 4.6 Printer Paper Select

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

CAUTION

- If 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.
- When paper type is changed, alarm upper limit is changed to 190 and alarm lower limit is changed to 110.

4.6 Data Saving

BT-350 has a data saving function. It can save up to 450 hours. It is able to save 3 hours for each patient, so it can accommodates 150 patients. Also, the data can be stored in the USB Memory Stick.

4.6.1 How to save data

When you connect the USB Memory Stick to BT-350, USB Icon of Trend Mode and Monitoring Mode will be activated in yellow shown as bellow.

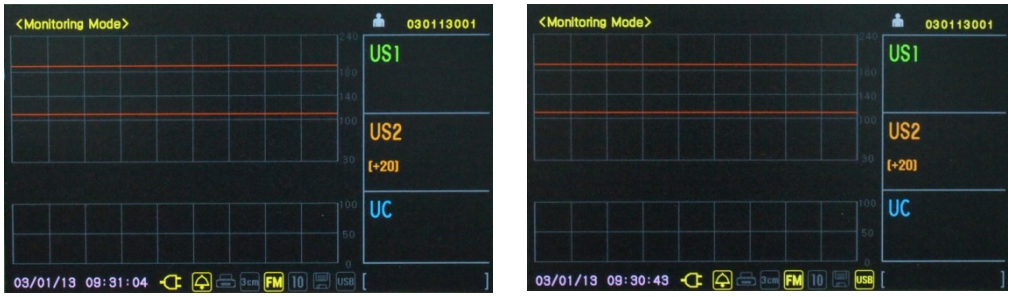


Fig. 4.7 BT-350 USB icon activation

In monitoring mode, press mode button [ ] during no data saving, then the relevant menu comes out as shown below.
Rotate the control knob to select the 'Save Data' item.
Press the Control knob to start saving. When the function is stared the save icon [ ] is activated and rotated. At that time, they are saved in USB memory stick.

Press mode button [ ] again to stop saving.

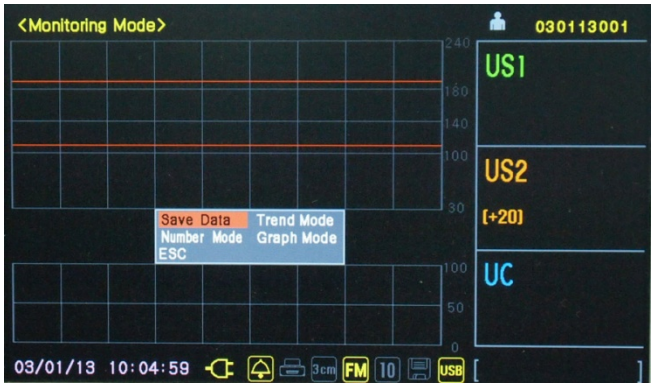


Fig. 4.8 Save Date display

For the data storage in trend mode, please refer to 4.6.

4.7 Trend Mode

Press mode button [ ], then the relevant menu comes out as shown in Fig. 4.7. Rotate the control knob to select the 'Trend Mode' item. Press the control knob to enter the Trend mode. And, you can search saved data.

USB Icon will RED in case data saving is ON. And 'Data Saving' will display on Message frame. When data saving is completed USB Icon will turn to yellow and sound 'ding-dong'.

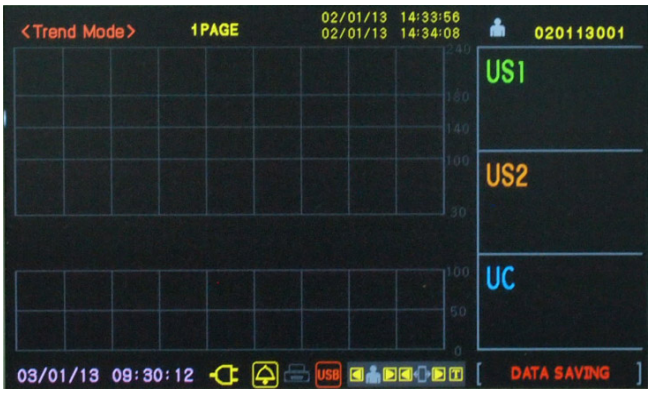


Fig. 4.9 Trend Mode display

4.7.1 Saved Time/Date Frame

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

4.7.2 ID Frame

This frame shows the saved patient name and ID.

4.7.3 Data Searching Frame

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

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

4.8 CTG(Cardiotocography) Analysis Function

4.8.1 CTG Analysis Method

At self-test, press the control knob, then, paper selection menu appears. After selecting the paper and demo mode of next step, selection screen of the CTG analysis appears. Select the ON / OFF by rotating the control knob.

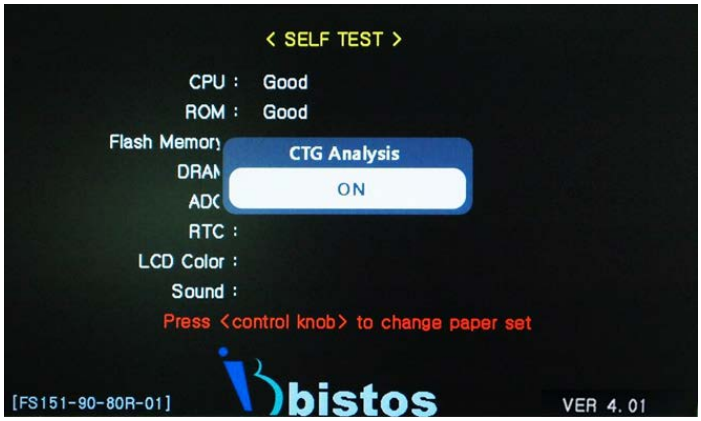


Fig. 4.10 CTG Analysis Function

After selecting ON the CTG analysis function, when you press the print button in monitoring mode, printing is started and CTG analysis is going on at the same time. At this time, <Monitoring Mode> will be changed to <CTG Mode>, the baseline value is displayed on the FHR frame shown as below.

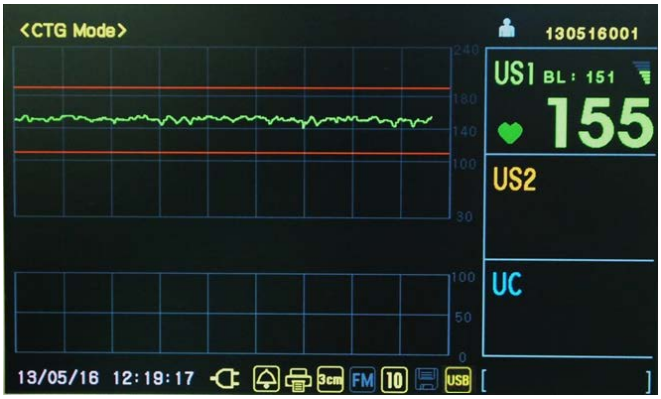


Fig. 4.11 CTG Mode

When you press the print button again, printing is completed and CTG analysis is also ended, analysis result screen is displayed. After the end of printing, CTG analysis results are printed in addition, the message "Printing..." is displayed in the warning frame. During printing, Key operation is disabled.

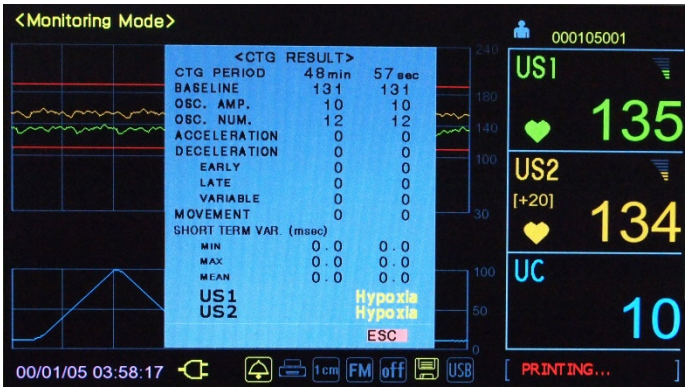


Fig. 4.12 CTG Result in Monitoring mode

If CTG analysis time, that is printing time, is less than 10 minutes, the results analysis is not printed and displayed.

In trend mode, CTG analysis results are displayed on the last page of the each patient's data. When you press the print button, the stored data is printed. Then CTG analysis data are also printed.

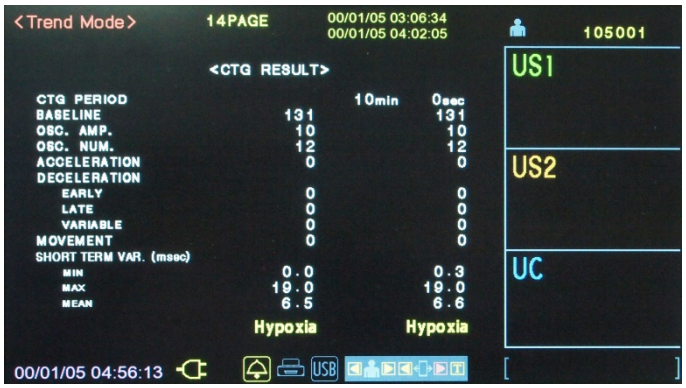


Fig. 4.13 CTG Result in Trend Mode

4.9 CCV(Cross-channel Verification) Function

4.9.1 CCV Function Setting

During Self-Test, press Control Knob 3 times then, there will be pop up message “CCV Select”. Rotate the control knob to Left/Right way then, it is available to change On/Off mode for CCV Function.

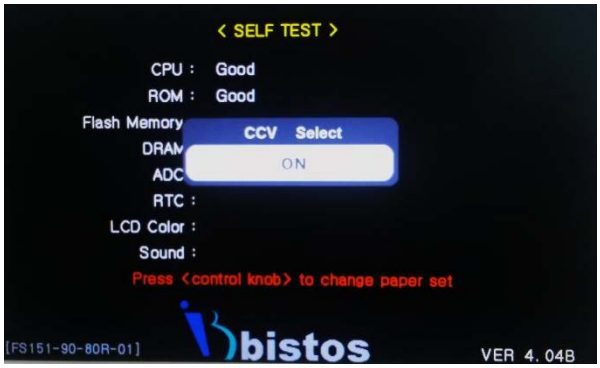


Fig. 4.14 CCV Function

Once CCV function is set, the function will be maintained when restart the equipment.

After setting CCV Function, please know button 3 times then, the equipment will be restarted.

When 1st fetal heart rate is the same with 2nd fetal heart rate (CCV) during using 2ea Doppler to the patient, icon will be appeared and alarm will be activated. (If one probe is removed or it is not CCV, alarm will be stopped and the equipment will work normally.)

Fig. 4.15 CCV Mode

If CCV is appeared during printing the data, alarm on LCD will be activated and Ĉ icon will be printed in the paper

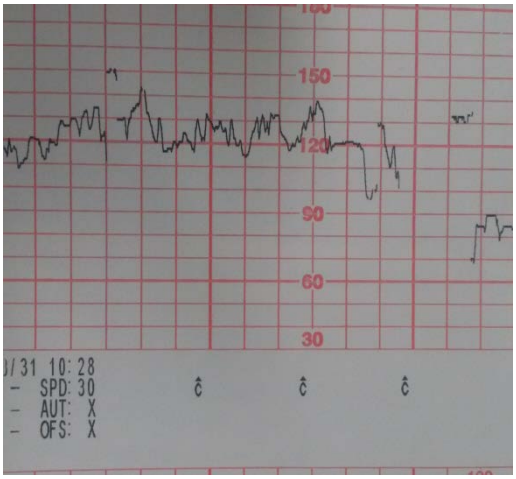


Fig. 4.16 CCV Result in Paper

Section 5
BT-350E Operation

5.1 System Startup

5.1.1 Power on

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

5.1.2 Factory Setting

The monitor has a function to return the setting values to the default value. BT-350 LED 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
CCV On/Off	OFF
CMS Comm. Channel	SERIAL
IP	192.168.0.3
Subnet Mask	255.255.255.0
Gateway	192.168.0.1

Fig. 5.1 Factory Mode

5.2 BT-350E Monitor Display Screen

Fig. 5.2 Main Monitoring Screen

5.2.1 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.

5.2.2 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.

5.2.3 Status Frame

This frame shows BT-350 LED status.

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

5.3 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.
	Alarm On/Off Button	Makes the alarm sound enable or disable in monitoring mode.
	UC Reference Button	Resets the UC baseline in monitoring mode.
	USB Record On/Off Button	Turns the USB record on or off when USB memory stick is being inserted.
	Record On/Off Button	Turns the record on or off.

5.3.1 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-350 LED is monitoring 
DOP2 OPEN	DOP2 is not connected while BT-350 LED is monitoring 
DOOR OPEN	Print door is opened while BT-350 LED is printing 
No PAPER	Paper is not loaded while BT-350 LED is printing 
LOW BAT	Battery's charging level is low while BT-350 LED is monitoring 

5.4 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.

5.5 System Setting

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

Activity	Desired Result
Knob Press	Enter the setup mode.
Knob Rotate	Select setting value.
Knob Press	Select this parameter for change.
Knob Rotate	Change the desired value.
Knob Press	Store the new value.

5.5.1 Setting Alarm Upper Limit / Lower Limit

Fig. 5.3 Alarm Upper /Lower Limit

Activity	Desired Result
Knob Rotate	Select “hi” or “Lo”
Knob Press	Select this parameter for change.
Knob Rotate	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	Store the new value.

5.5.2 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. 5.4 Dop2 Offset

Activity	Desired Result
Knob Rotate	Select “oFS”
Knob Press	Select this parameter for change.
Knob Rotate	Change the desired value [on/oFF].
Knob Press	Store the new value.

5.5.3 Setting Time and Date

Fig. 5.5 ***Time and Date***

Activity	Desired Result
Knob Rotate	Select ‘rtc’ Menu.
Knob Press	Enter Time Menu.
Knob Rotate	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	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.)	

5.5.4 Setting Print Speed

Activity	Desired Result
Knob Rotate	Select “SPd”
Knob Press	Select this parameter for change.
Knob Rotate	Change the desired value [10/20/30].
Knob Press	Store the new value.

Fig. 5.6 ***Print Speed***

5.5.5 Setting Auto Print

Fig. 5.7 ***Auto Print***

Activity	Desired Result
Knob Rotate	Select “aut”
Knob Press	Select this parameter for change.
Knob Rotate	Change the desired value [oFF/10/20/30/40/50/60].
Knob Press	Store the new value.

5.5.6 Setting FM(Fetal Movement) Graph

Activity	Desired Result
Knob Rotate	Select “Fm”
Knob Press	Select this parameter for change.
Knob Rotate	Change the desired value [on/oFF].
Knob Press	Store the new value.

Fig. 5.8 ***FM Graph***

5.5.7 Printer Paper Select

BT-350 LED 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. 5.9 ***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.
- When paper type is changed, alarm upper limit is changed to 190 and alarm lower limit is changed to 110.

5.5.8 CMS(Central Monitoring System) Communication Channel Select

Activity	**Desired Result**
Knob Rotate	Select “con”
Knob Press	Select this parameter for change.
Knob Rotate	Change the desired value [SEr/Eth].
Knob Press	Store the new value.

Fig. 5.10 ***CMS Comm. Channel Select***

5.5.9 IP Address Setting

Activity	Desired Result
Knob Rotate	Select “IP”
Knob Press	Select this parameter for change.
Knob Rotate	Change IP 1st bytes to the desired value [0~255].
Knob Press	Store the new value.
Knob Rotate	Change IP 2nd bytes to the desired value [0~255].
Knob Press	Store the new value.
Knob Rotate	Change IP 3rd bytes to the desired value [0~255].
Knob Press	Store the new value.
Knob Rotate	Change IP 4th bytes to the desired value [0~255].
Knob Press	Store the new value.

Fig. 5.11 ***IP Address Setting***

5.5.10 Subnet Mask Setting

Activity	Desired Result
Knob Rotate	Select “Sub”
Knob Press	Select this parameter for change.
Knob Rotate	Change Subnet 1st bytes to the desired value [0~255].
Knob Press	Store the new value.
Knob Rotate	Change Subnet 2nd bytes to the desired value [0~255].
Knob Press	Store the new value.
Knob Rotate	Change Subnet 3rd bytes to the desired value [0~255].
Knob Press	Store the new value.
Knob Rotate	Change Subnet 4th bytes to the desired value [0~255].
Knob Press	Store the new value.

Fig. 5.12 ***Subnet Mask Setting***

5.5.11 Gateway Setting

Activity	Desired Result
Knob Rotate	Select “gat”
Knob Press	Select this parameter for change.
Knob Rotate	Change Gateway 1st bytes to the desired value [0~255].
Knob Press	Store the new value.
Knob Rotate	Change Gateway 2nd bytes to the desired value [0~255].
Knob Press	Store the new value.
Knob Rotate	Change Gateway 3rd bytes to the desired value [0~255].
Knob Press	Store the new value.
Knob Rotate	Change Gateway 4th bytes to the desired value [0~255].
Knob Press	Store the new value.

Fig. 5.13 ***Gateway Setting***

5.5.12 Port Number Setting

Activity	Desired Result
Knob Rotate	Select “Pot”
Knob Press	Select this parameter for change.
Knob Rotate	Change the desired value [0~65535].
Knob Press	Store the new value.

Fig. 5.14 ***Port Number Setting***

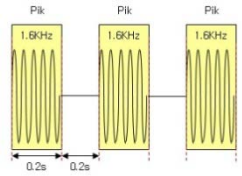
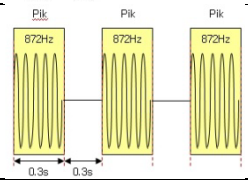
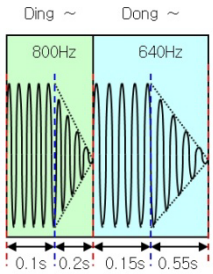
5.6 Understanding Alarms

The BT-350 LED 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-350 LED is monitoring. 3. Paper is out while BT-350 is printing. 4. Door is opened while BT-350 is printing. 5. Battery's charge level is low while BT-350 LED is monitoring. 6. Complete auto printing

5.7 USB Data Saving

BT-350 LED has a data saving function. The data can be stored in the USB Memory Stick.

After connecting the USB Memory Stick to a device, press mode button [ ]. Then, data saving start and indicating in status frame is enable shown as below.

Fig.5.15 ***USB Data Saving Indication***

If you press mode button [ ] again, data storage is over with "ding- dong" sound.

5.8 CCV(Cross-channel verification) function

CCV compares all fetal heart rates continuously and indicates when multiple transducer are picking up the same signal.

5.8.1 CCV Function Setting

1. In the set-up menu, turn the knob 8 times in the clockwise direction to show the “ccV on/oFF’.
2. Press down the knob and turn to change the ccv setting between on ↔ off.

3. Press down the knob to set the value. The flashing is terminated. The set value is remained.

5.8.2 CCV Operation

1. When the DOP1 and DOP2 are differ less that ±2 BPM error occurred and the FHR value are displayed alternately and alarm initiated.

2. When the DOP1 and DOP2 values differ more than ±2 BPM more than 5 seconds the alarm stopped and equipment work normally.
3. When the printing operated, the coincidence indicator ( ) will be printed in the 30 minutes interval.

Section 6
Recorder Operation

6.1 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.

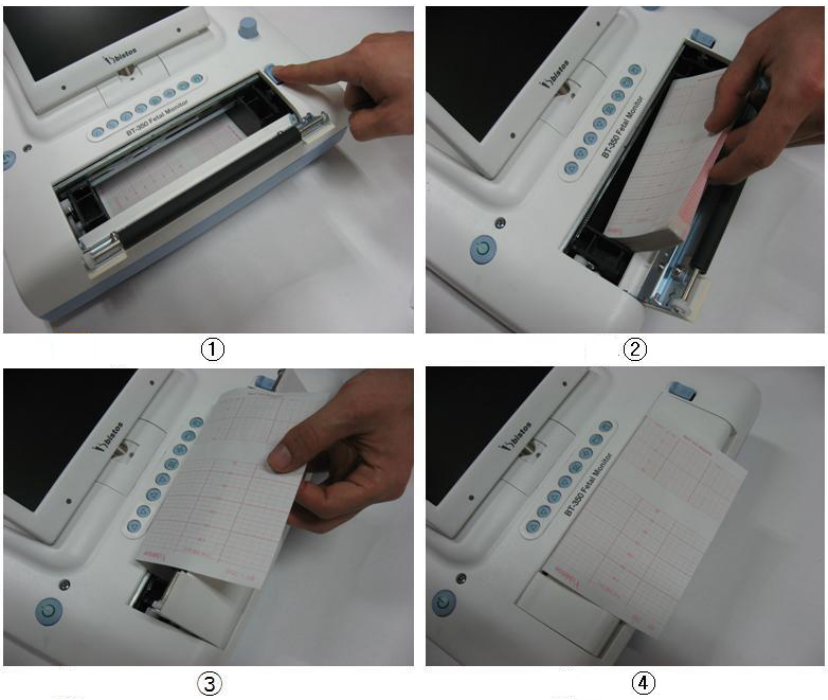


Fig. 6.1 Loading Paper

6.2 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-350 prints many parameters such as FHR, FM, UC and the situation information. These parameters are displayed in LCD monitor. Especially to display FM Trace, BT-350 needs to be set FM graph is on.

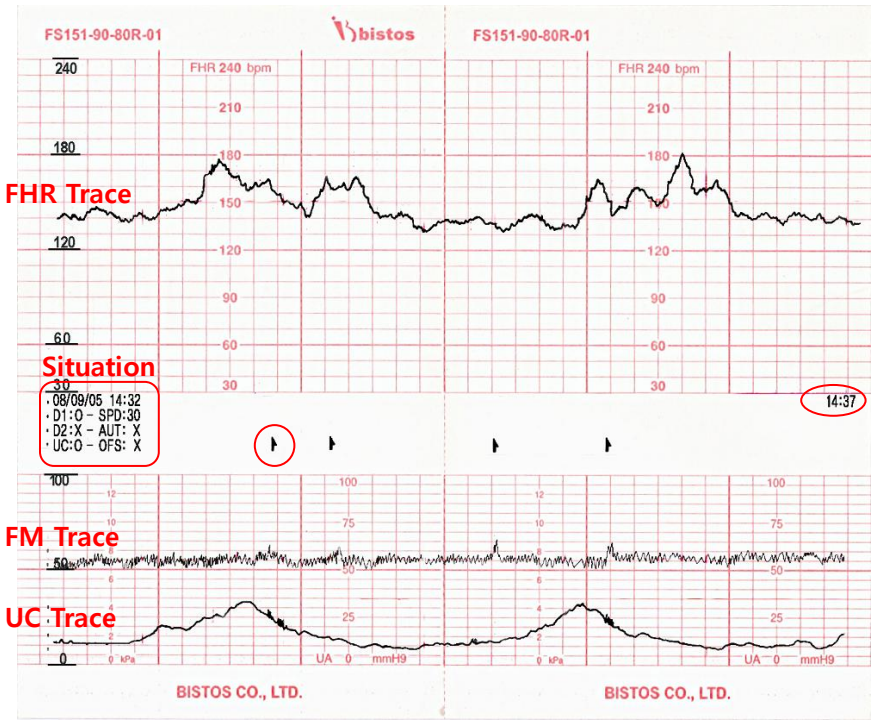


Fig. 6.2 Printing Paper [FS151-90-80R-01]

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 7
Monitoring Fetal Heart Rate

7.1 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-350. 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-350, 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 middle 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.

7.2 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.

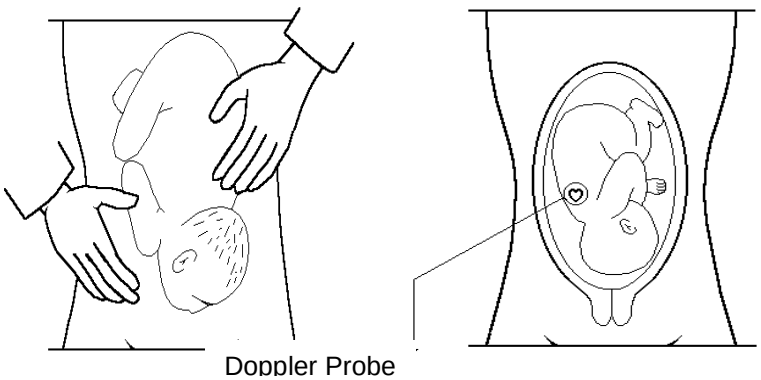


Figure 7.1 the direction of Doppler Probe

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.

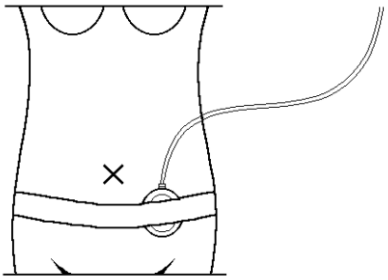


Figure 7.2 Positioning of UC Probe

Section ***8***
Uterine Contraction (UC)

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

⚠ CAUTION

- During the using BT-350, 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.

8.1 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 UC probe 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 UC probe 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 ***9***
Event Marker

9.1 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 monitor.

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

9.2 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. The monitor will display this downward pointing arrow in the information frame of the display. A strip chart printout of this event will also show this mark.

Section ***10***
Cleaning and Disinfection

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

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

10.1 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.

10.2 Probes

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

CAUTION

- Do not autoclave. Do not gas sterilize.
- Do not immerse in liquid. When using solutions, use sterile wipes to avoid pouring fluids directly on the transducer.

1. Wipe the device with a sterile wipe soaked in enzymatic detergent safe for use with metal instruments. Wipe the exterior of the device three times. Prepare the detergent according to the manufacturer's transducer recommendations.
2. Scrub the transducer with enzymatic detergent using soft bristled brush for five (5) minutes.
3. Wipe the transducer three (3) times with sterile water to remove soap residue.
4. Wipe the transducer with a sterile wipe soaked in Cidex™. Wipe all exterior surfaces of the transducer three (3) times.
5. Wipe the transducer three (3) times with sterile water to remove Cidex residue.
6. Dry the device thoroughly with a sterile soft towel or gauze surgical sponge.
7. Wrap the dry device in a fresh sterile soft towel or transparent sterile wrap for storage until next use.

10.3 Belts

Wash soiled belts with soap and water.

> ⚠ **CAUTION**
>
> - The water temperature must not exceed 60°C (140°F).

10.4 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	Estane S385A TPU	Reusable	Must be cleaned and disinfected prior to use

10.5 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 ***11***
Specifications

Physical Characteristics	
Dimensions	9.6cm(H) x 32.6 cm(W) x 27.6cm(D)
Weight	Approx. 5.5 kg

Safety	
Standard	EN 60601-1, EN60601-2
Classification	Class I, Internal Powered Equipment
Mode of Operation	Continuous operation
Protection against electric shock	Type BF applied part
Protection against ingress of water	IPX8(Dop/UC probe)

Power		
External	Power adapter	Input: AC 100 ~ 240 V, 50/60 Hz Output: DC 18V, 2.8A
Internal	Battery	14.8V, Li-ion
Power Dissipation	AC-powered	80 VA, maximum
	Battery powered	80 VA, maximum

Environment	
Operating temperature	10°C ~ 45°C (50°F ~ 110°F)
Operating humidity	5 ~ 85%, Non condensing
Storage temperature	-20°C ~ 60°C (-4°F ~ 140°F)
Storage humidity	0 ~ 95%, non-condensing
Altitude	0 ~ 2 000 m(0 ~ 6 561.68 ft)
Pressure	79.051 kPa ~ 101.325 kPa

Doppler ultrasound FHR monitoring	
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	
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	
Speed	Normal	1, 2 and 3 cm/min ± 1%
	High-speed	10 cm/min (only in Trend mode)
Tracking accuracy	± 1% (exclusive of paper accuracy)	

Acoustic output information for the transducer assembly

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				

- 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 ***12***
Troubleshooting and Maintenance

12.1 Self-Test

The monitor performs a self-test 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 main monitoring screen. If an error occurs the monitor will display the error message.
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.

12.2 Ultrasound Transducer Test

To test an ultrasound transducer:

1. Properly connect the transducer to the rear 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.

12.3 UC(TOCO) Test

To test the UC(TOCO) transducer:

1. Properly connect the transducer to the rear 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.

12.4 Battery Disposal and Handling

The capacity of internal battery is gradually decreased over time and usage. 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.

⚠ CAUTION

- When disposing of internal Li-ion 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.
- The internal battery must be handled by the company's technician only. Do not attempt to open the BT-350.

12.5 Maintenance

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

12.6 Disposal of the BT-350

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

Product Guarantee

Product Name		Fetal Monitor
Model Name		BT-350
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-350.
※ This product is manufactured and passed through strict quality control and inspection.
※ Compensation standard concerning repair, replacement, refund of the product complies with "**Framework Act on Customer**" noticed by Fair Trade Commission of Republic of Korea.

Service Telephone and Fax. Numbers

Telephone: +82 31 750 0340
Fax: +82 31 750 0344

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bistos@bistos.co.kr

EC REP Medical Econet Gmbh
Im Erlengrund 20 D-46149 Oberhausen/Germany
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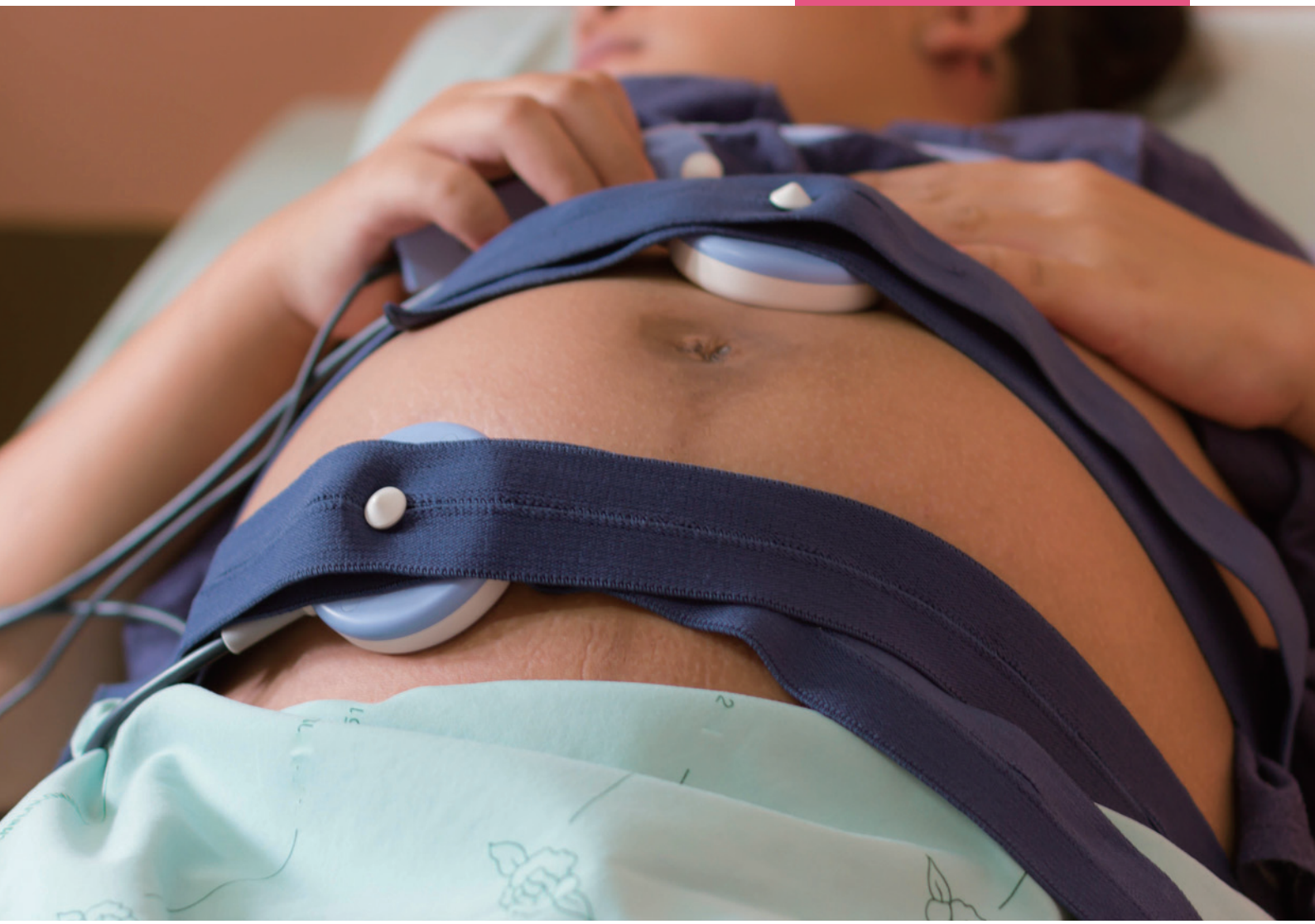
Fax: +49 (0)208 377 890 55

bistos

CE 2460



Fetal Monitor

BT-300

BT-350 LED

BT-350 LCD

bistos

Fetal Monitor

BT-350

Advanced Fetal Monitor dedicated to Fetal health monitoring

Wall mount

Carrying bag

Fetal Monitor

BT-350 LCD Graphic mode

BT-350 LED

BT-350 LCD Number mode

USB port for data export

BT-350 LCD

displays trace and numbers. Stored data can be reviewed afterward.

BT-350 LED

displays numbers only.
Large and bright LED is visible from a distance.

CTG Analysis*

calculates important data suchas baseline, Acceleration, Deceleration, fetal movement.

Various Paper Selection

BT-350 can use two most usual papers in the market (30-240bpm / 50-210bpm)

Cross Channel Verification

prevent the FHR is miscalculated by twin fetus by alarm.

USB Data Save

FHR and UC trend data can be exported to USB memory stick and it can be managed by BCM-350 Central Monitoring Software

Multi Language Support*

13 languages including English, Chinese, Spanish, German, Russian, Portuguese and more languages are available.

Central Monitoring Software

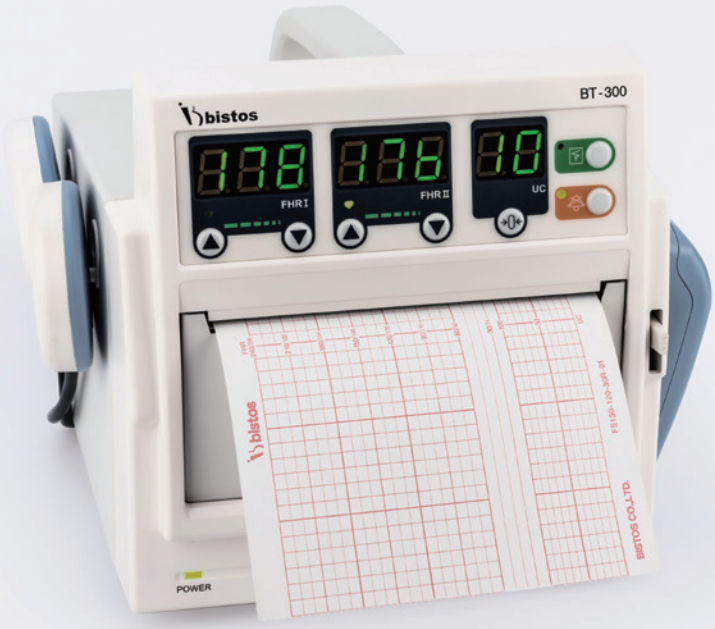
Works on BCM-350 software along with other Fetal monitors by wire or wireless.

Built-in Quick Guide*

Quick guide in the menu screen helps the user get to understand how to use and maintain the monitor properly.

*BT-350 LCD only

Fetal Monitor



BT-300

Portability
Compact design with built-in handle enable portable use especially to midwives.

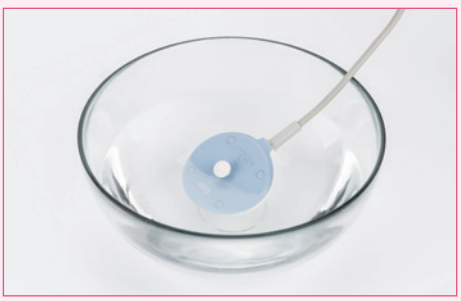
Rechargeable Battery*
Li-ion battery enable BT-300 can operate without AC power up to 3 hours.

Waterproof probe
All probes are waterproof and ready for water birth (IPX8).

Zoom-in Function
Enlarge FHR graph scale on the paper to examine the trend with more dynamics by focusing FHR range to most frequent area.

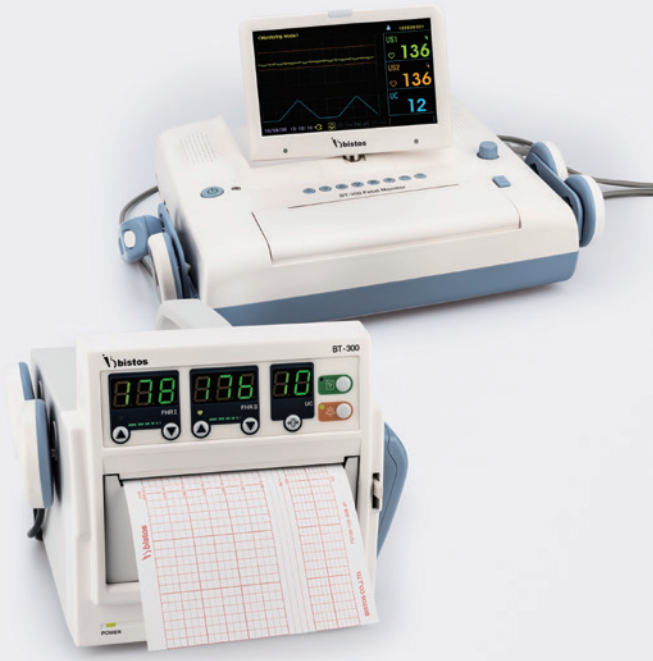
Offset DOP2 FHR
This function makes DOP2 FHR 20 bpm higher to enhance DOP2 trend easy to read.

Acoustic Stimulator*
Stimulate sleeping fetus to speed up the test or to facilitate further evaluation of non-stress test (NST).



*Option

Central Monitoring Software

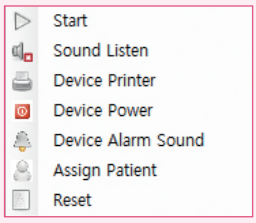


Connection

Maximum connection: 16 monitors
Wire connection : RS-232C, LAN*
Wireless connection : Bluetooth (optional) *BT-350 only

Remote Control

BCM-350 is not only monitoring Fetal Monitors at central station but it can control monitors remote for basic function.

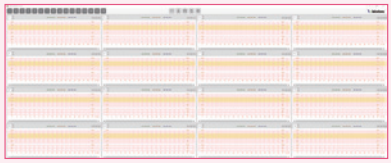


Database

BCM-350 is store data from the BT-300/350 by network connection and by USB memor y. Stored data in internal memor y of BT-350 can be exported to USB memor y and it can be managed by BCM-350

Multi-language Support

BCM-350 is multi-lingual software and friendly to many non-English speaking users.



Various Bed Display mode

Various style of Bed display can satisfy ever y users with their own preference.

BISTOS Fetal Monitors Technical Specification

Model	BT - 300	BT - 350	
Order code	300	350E	350L
Dual DOP Probe	●	●	●
FHR Range (BPM)	30 ~ 240	30 ~ 240 / 50 ~ 210	30 ~ 240 / 50 ~ 210
DOP2 Offset (20BPM)	●	●	●
Auto FM Detection	●	●	●
FM Graph Print	●	●	●
DOP Signal Quality Indicator	●	●	●
UC Probe	External type		
UC Range	0 - 99	0 - 99	0 - 99
Waterproof Probe (IPX8)	●	●	●
Display Type	LED	Large LED	7" Color LCD
Wall Mount		○	○
Trend Display			●
Trend Data Save			450 Hours
Alarm Sound Level		2 levels	2 levels
Alarm Sound	Tachycardia, Bradycardia		
Information Sound	Probe Disconnection, Printer door open, No Paper, Low Battery		
Printer Speed	1, 2, 3cm/minute, 10cm/min(Trend mode only)		
Thermal Paper (Z-fold)	130mm(W) x 20.5m(L)	150mm(W) x 13.5m(L)	150mm(W) x 13.5m(L)
Auto Print	10, 20, 30, 40, 50, 60minute		

● Standard ○ Option

Model	BT - 300	BT - 350	
Order code	300	350E	350L
Paper Select (30-240/50-210)		●	●
Patient ID/Name Print			●
Cross Channel Verification		●	●
CTG Interpretation			●
Data Save to USB Memory		●	●
Multi Langage Support			●
On-Screen Quick Guide			●
PC Interface	RS-232C	RS-232C / Ethernet	RS-232C / Ethernet
BCM-350 CMS	●	●	●
Power	AC100-240V (50/60Hz) DC18V/2.5A		
Weight (Kg)	5	2.8	2.8
Dimensions (HxWxD) - mm	190 x 190 x 200	240 x 405 x 360	240 x 405 x 360
Carrying Bag		○	○
Rechargeable Battery	○	○	○
Battery Life (h)	3	5	5
Acoustic Stimulator	○	○	○
Cart	○	○	○
External Bluetooth Connector	○	○	○
Warranty (Main unit)	2 year	2 year	2 year

BIO SIGNAL TOTAL SOLUTION

Bistos Co., Ltd. (Headquarter)

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11417 W Bernardo Ct Ste D, San Diego, CA 92117, USA
Tel. +1-868-433-6689
Fax. +1-888-391-5153

EC CERTIFICATE
Full Quality Assurance System

Certificate No.: 243269-2017-CE-KOR-NA-PS Rev. 5.0 Project No.: PRJC-533956-2015-MSL-KOR Valid Until: 01 September 2023

This is to certify that the quality system of:

Bistos Co., Ltd.

7th Fl., A Bldg., Woolim Lions Valley 5-cha, 302, Galmachi-ro, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea

For design, production and final product inspection/testing of:

Monitoring devices of vital physiological parameters and Utilising non-ionizing radiation

Has been assessed with respect to:

The conformity assessment procedure described in Annex II excluding section 4 of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply

Place and date:
Høvik, 30th April 2021

Check Validity

For the issuing office:
Notified Body 2460
DNV Product Assurance AS

Hazem Tinawi
Technical Reviewer

Further details of the product(s) and conditions for certification are given overleaf.

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Replaces certificate EU1308401, Rev2.0 (NB 0470) following transfer of Notified Body functions to DNV GL Nemko Presafe AS (NB 2460)	01 September 2017
1.0	EU Rep change	13 April 2018
2.0	Re-certification for Fetal monitor and Neonatal Phototherapy unit (BT-300, BT-350, FM-20, Biocare FM-1, BT-400) Scope extension for pulse oximeter and patient monitor (BT-710, BT-720, BT-740, BT-770) The accessories (Feotal Doppler system probe and Cardiotocograph transducers) are removed (AY-DOP-300, AY-DOP-350, AY-UC-300, AY-UC-350)	01 September 2018
3.0	Editorial change	13 February 2020
4.0	Scope extension to new model (BT-780)	26 April 2021
5.0	**Editorial change in model name (typo error)**	**30th April 2021**

Products covered by this Certificate:

Product Description	Product Name	Class
Fetal monitor	▪ **BT-300** ▪ BT-350 ▪ FM-20 ▪ Biocare FM-1	IIa
Neonatal Phototherapy unit	▪ BT-400	IIa
Pulse Oximeter	▪ BT-710	IIb
Patient Monitor	▪ BT-720 ▪ BT-740 ▪ BT-770 ▪ BT-780	IIb

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Bistos Co., Ltd.	7th Fl., A Bldg., Woolim Lions Valley 5-cha, 302, Galmachi-ro, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea

EU Representative

OBELIS S.A, Bd. General Wahis, 53, 1030 Brussels, Belgium

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. the Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.

End of Certificate

No. DOC - 350 - 16

EC Declaration of Conformity

We, Bistos Co., Ltd., (7th Fl., A Bldg., Woolim Lions Valley 5-cha, 302, Galmachi-ro, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea) hereby declare that medical device described hereafter:

Product : Fetal monitor

Model No. : BT-350

GMDN Code: 43958, Foetal cardiac monitor

Accessories : Fetal Doppler system probes, AY-DOP-350 (GMDN Code: 41917) and Cardiotocograph Transducers, AY-UC-350 (GMDN Code: 37258)

Classification: IIa (according to Rule 10 of Annex IX of Council Directive 93/42/EEC as amended by 2007/47/EC)

EC Representative : Obelis s.a. (Bd. Général Wahis 53 1030 Brussels / BELGIUM**)**

- is in conformity with the essential requirements and provisions of Council Directive 93/42/EEC as amended by 2007/47/EC.
- is subject to the procedures set out in Annex II excluding section 4 of Council Directive 93/42/EEC as amended by 2007/47/EC under the supervision of Notified Body 2460, DNV Product Assurance AS: Veritasveien 3 1363 Høvik Norway. (Certificate no.: 243269-2017-CE-KOR-NA-PS Rev. 5.0)
- is in conformity with the harmonized standards.

This declaration is supported by following Quality Management System certification:

Certification No. 243275-2017-AQ-KOR-NA-PS Rev.3.0

- is complies ISO 13485:2016/NS-EN ISO 13485:2016 requirements
- is issued by DNV Product Assurance AS (Veritasveien 3, N-1363 Høvik, Norway)

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Place of Issue: Gyeonggi-do, Korea
Date of Issue: May 3, 2021

Signed for and behalf of Bistos Co., Ltd

정혜선

Hyesun Jeong, RA

Management System Certificate

Certificate No.:	Project No.:	Initial Certification Date:	Valid Until:
243275-2017-AQ-KOR-NA-PS Rev. 2.0	**PRJC-533956-2015-MSL-KOR**	**12 August 2004**	**09 SEPTEMBER 2021**

This is to certify that the management system of:

Bistos Co., Ltd.

7th Fl., A Bldg., Woolim Lions Valley 5-cha, 302, Galmachi-ro, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea

Complies with the requirements of:

ISO 13485:2016/NS-EN ISO 13485:2016

The Certificate is valid for the following scope:

Design, manufacturing, Sales, Distribution, and servicing of Ultrasound Doppler system, Fetal monitor, Phototherapy, Patient Monitor, Pulse Oximeter, Incubator, Head-worn light, Infant Warmer and Electric Breast Pump.

Place and Date:
Høvik, 12 September 2018

NORWEGIAN ACCREDITATION
MSYS 018

For:
DNV GL PRESAFE AS

Tone Kolpus

Tone Elise Kolpus

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info