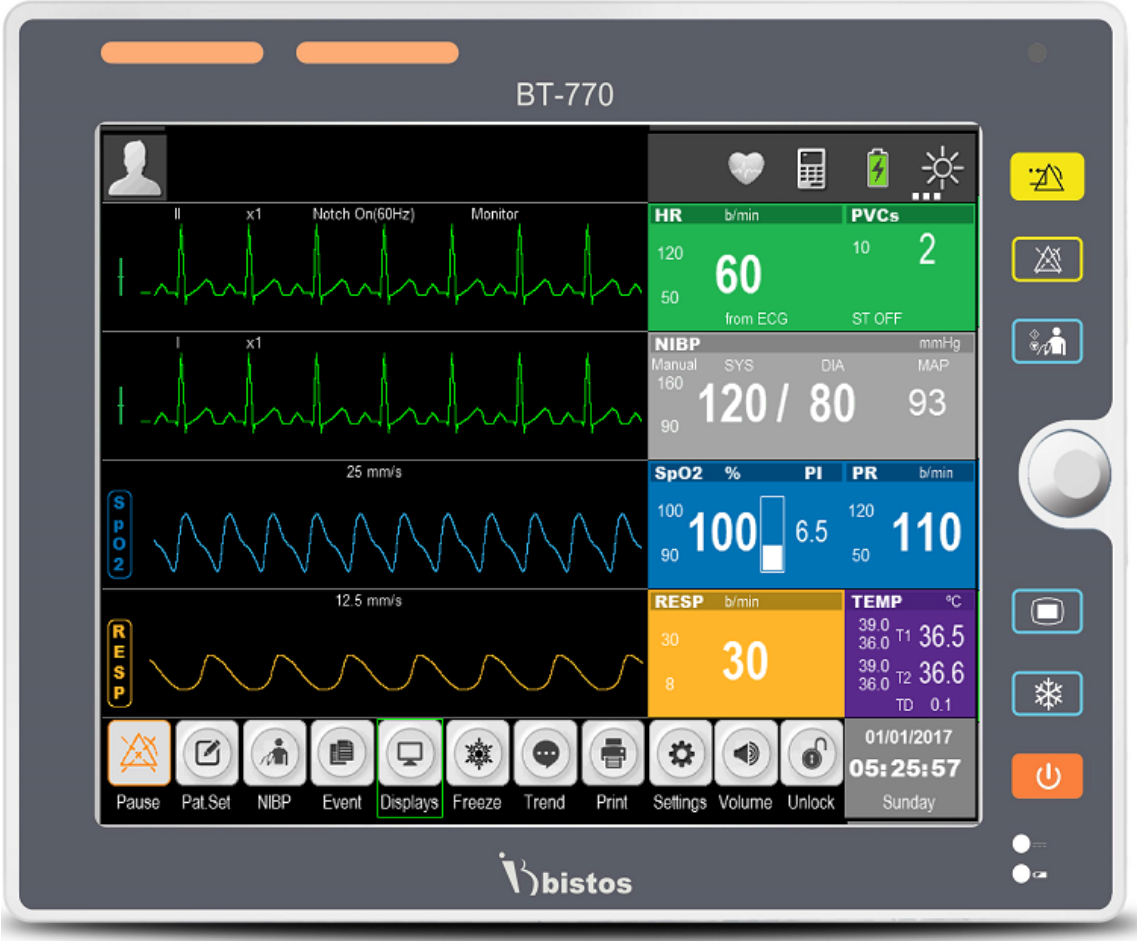
BT-770 Patient monitor
Operation Manual



Keep this manual for future reference

P/N : 770-ENG-OPM-EUR-D03

Proprietary Material

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Revision D03
May, 2018

Printed in Korea

Contents

0 Safety information

Before using BT-770 Patient monitor, read this entire manual and be fully understood the following safety information to prevent injury of patient and user.

Symbols Used

The following symbols identify all instructions that are important to safety. Failure to follow these instructions can lead to injury or damage to the patient monitor. When used in conjunction with the following words, the symbols indicate:

WARNING	Can lead to serious injury or death.
CAUTION	Can lead to minor injury or product/property damage

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

	Used to identify safety information. Be well-known this information thoroughly before using BT-770.
	Used to identify safety information. Be well-known this information thoroughly before using BT-770
IPX1	Indicates the protection level against the ingress of liquid. IPX1 is protection against some water drops falling vertically. It correspond the device, patient monitor and accessory, temperature sensor
IPX2	Indicates the protection level against the ingress of liquid. IPX2 is protection from some water drops when the device is tilted up to and including 15°. It correspond the accessories for SpO2 and ECG.
	Refer to operation manual. Read manual before placing the device.
	Indicates DC power supply.
	Indicates the device is in the battery operation mode.
	Indicates nurse call interface.
	Indicates network interface.


Indicates USB interface.


Indicates power adapter polarity.


Indicates the production date.


Indicates the manufacturer.

Indicates the serial number of the device.

Indicates the authorized representative in the European Community of manufacturer.


Indicates a defibrillation-proof type BF applied part.


Indicates a defibrillation-proof type CF applied part.


Indicates CLASS II equipment.(Adapter)


Indicates the date after which the medical device is not to be used.


Indicates to keep the device dry.


Indicates the medical device that can be broken or damaged if not handled carefully.


Indicates to keep upright

Indicates the maximum stacking limit.


Indicates the temperature limitation for operation, transport and storage.


Indicates the humidity limitation for operation, transport and storage.


Indicates the range of atmospheric pressure to which the medical device can be safely exposed.

Indicates the device contains natural rubber latex.(Accessories)

Indicates the packing material is recyclable.

Indicates to not dispose the device together with unsorted municipal waste(for EU only). The solid bar symbol indicates that mains adapter is put on the market after 13 August 2005.

0.1 General precautions, warnings and cautions

- Examine the patient monitor and any accessories periodically to ensure that the cables, adapter cords and instruments do not have visible evidence of damage that may affect patient safety or performance. The recommended inspection interval is once per week or less. Do not use the patient monitor if there is any visible sign of damage.

- Only the DC power adapter supplied with the BT-770 is approved for use with the device.

- Do not attempt to service the BT-770 patient monitor. Only qualified service personnel by Bistos Co. Ltd. should attempt any needed internal servicing.

- 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.

- If the hospital or healthcare institutions using this device fail to implement a satisfactory maintenance schedule, it will result in device failure and may endanger the patient's safety.

- Use the patient monitor under the conditions specified in this operation manual. Beyond the conditions, the patient monitor may not function properly and the measurement results may not accurate and may result in device failure or endangering the patient's safety.

- Do not operate the BT-770 patient monitor if it fails to pass the power on self-test procedure.

- During the operation, do not disconnect any cable.

- The BT-770 patient monitor is intended to be used by clinical professionals or trained doctors, nurses or laboratory assistant.

- Do not service and maintain or clean the device including accessories while in use with a patient.

- Using the device to one patient at a time.

⚠ WARNING

- Thoroughly read and understand the manual prior to use of the BT-770. Failure to do so could result in personal injury or equipment damage.

- The device is intended for clinical patient monitoring, and only trained and qualified doctors and nurses should use the device.

- The alarm volume, upper and lower alarm limits should be set according to the actual situation of the using environment. Do not just rely on audio alarm

system while monitoring the patient, because too low alarm volume or muted alarm may result in notice failure of alarm situation and endanger the patient's safety. Please pay close attention to the actual clinical status of the patient.

- Use only the power adapter supplied with monitor.
- Position the monitor where it is easy to de-energize the monitor when needed.
- Do not open the enclosure to avoid an electric shock. Any repair and upgrade of monitor should be done by service personnel trained and authorized by Bistos. Co., Ltd.
- When handling packaging materials, abide by local laws and regulations or hospital waste disposal regulations. Keep the packaging materials away from children.
- Do not use in the presence of flammable anesthetics to prevent explosion or fire.
- Install the power lines and cables of accessories carefully to avoid patient entanglement or suffocation, cables tangled or electrical interference.
- When the monitor is used together with electrosurgical devices, the user (a doctor or a nurse) should ensure the safety of the patient and instrument.
- The physiological wave, physiological parameters and alarm information displayed on the monitor are only for the doctor's reference and should not be directly used as the basis for clinical treatment.
- This is not a therapeutic device.
- For patients with pacemakers, the cardio tachometer may count the pacemaker pulse in case of a cardiac arrest or arrhythmias. Never rely solely on the cardio tachometer alarm. Closely monitor the patients with pacemaker. For the inhibition of the device on pacemaker, refers to this manual.
- Use of accessories other than those listed and approved for use with this product may result in increased emissions or decreased immunity.
- 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. In addition, portable and mobile RF communications equipment can affect medical electrical equipment.
- The equipment shall not be used adjacent to other devices unless verification of normal operation in the configuration in which it is to be used can be achieved.
- Keep matches, and all other sources of ignition, out of the room in which the patient monitor is located. Textiles, oils, and other combustibles are easily ignited and burn with great intensity in air enriched with oxygen. Personal

injury or equipment damage could occur.

- A fire and explosion hazard exists when performing cleaning or maintenance procedures in an oxygen-enriched environment.
- The patient monitor has been validated with the accessories and options listed in this manual and found to comply with all relevant safety and performance requirements applicable to the device. It is therefore the responsibility of the person or organization who makes an unauthorized modification, or incorporates an unapproved attachment to the device.
- An operator may only perform maintenance procedures specifically described in this manual.
- Do not remove the covers of a BT-770 yourself to avoid damage to the equipment and unexpected electrical shock. Only qualified Bistos service engineer must repair or replace components.

⚠CAUTION

- Please install or carry the instrument properly to prevent damage due to falling, collision, strong vibration or other mechanical force.
- Avoid instrument splashed by water.
- Avoid high temperatures, the instrument should be used within a temperature range of 5 ℃ ~ 40 ℃。
- Avoid using instrument in the environment such as pressure is too high, poor ventilation, dusty, or contain salt, sulfur gas and chemical.
- Before using the monitor, check the monitor and accessories if there is damage that may affect patient safety. If there is obvious damage or aging, replace the parts before use. The replacement should be made with same parts of original parts.
- Before powering on the device, make sure that the power used by the device complies with the supply voltage and frequency requirements on the equipment label or in the Operator's Manual.
- Equipment should be tested at least once a year, the test should be done and recorded by trained, have security testing knowledge and experienced personnel. If there are any problems in the tests, they must be repaired.
- When the instrument and accessories are about to exceed the useful life (expected service life: 5 years), it must be treated in accordance with relevant local laws and regulations or the hospital's rules and regulations.
- Do not connect to other equipment or network which not specified in the

instruction for use, in risk of external high voltage.

- Do not connect any equipment or accessories that are not approved by the manufacturer or according to IEC 60601-1 to the monitor. The operation or use of non-approved equipment or accessories with the monitor is not tested or supported, and monitor operation and safety are not guaranteed in such a case.

- Any non-medical equipment (such as the external printer) is not allowed to be used within the patient vicinity (1.5m/6ft.).

- Parts and accessories used must meet the requirements of the applicable safety standards, and/or the system configuration must meet the requirements of the medical electrical systems standard.

- Ensure that the conductive parts of electrodes and associated connectors, including neutral electrodes, do not come in contact with earth or any other conducting objects.

- Protection of ME EQUIPMENT against effects of discharge of a cardiac defibrillator depends on use of proper cables.

0.2 Shock hazards

⚠ **WARNING**

- Unplug the monitor from its power source prior to cleaning or maintenance to prevent personal injury or equipment damage.
- Some chemical cleaning agents may be conductive and leave a residue that may permit a build-up of conductive dust or dirt. Do not allow cleaning agents to contact electrical components and do not spray cleaning solutions onto any of these surfaces. Personal injury or equipment damage could occur.
- Do not expose the unit to excessive moisture that would allow for liquid pooling. Personal injury or equipment damage could occur.
- Do not touch the patient and signal input/output parts simultaneously
- Due to the risk of electrical shock hazard, only qualified personnel with appropriate service documentation should service the monitor.

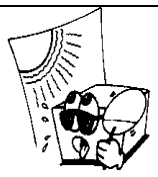
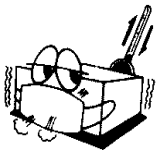
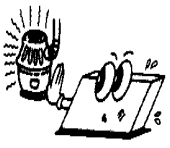
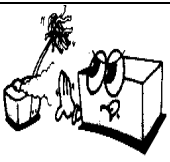
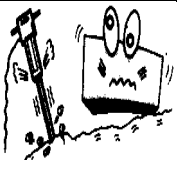
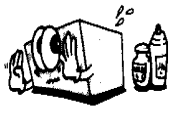
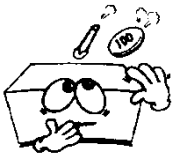
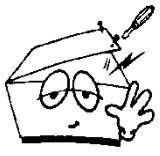
0.3 Battery warnings

⚠ **WARNING**

- Improper operation may cause the internal lithium ion battery to be hot, ignited or exploded, and it may lead to the decrease of the battery capacity. It is necessary to read the operation manual carefully and pay more attention to warning message.
- Do not open the battery compartment. Only the qualified service personnel authorized by the manufacturer can open the battery compartment and replace the battery, and batteries of same model and specification should be replaced.
- Be careful when connecting the battery with polarity.
- Do not use the battery near fire or environmental temperature exceeds 60 ℃. Do not heat or splash the battery or throw it into fire or water.
- Do not destroy the battery. Do not pierce battery with a sharp object such as a needle. Do not hit with a hammer, step on or throw or drop the battery. Do not disassemble or modify the battery. The battery can heat, smoke, deformation or burning.
- When leakage or foul smell is found, stop using the battery immediately. If your skin or cloth comes into contact with leaked liquid, cleanse it with clean water at once. If the leaked liquid splashes into your eyes, do not wipe them. Irrigate them with clean water first and go to see a doctor immediately.
- Properly dispose of or recycle the depleted battery according to local regulations.

0.4 General precautions on environment

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

	Avoid placing in an area exposed to moisture. Do not touch the equipment with wet hand.		Avoid exposure to direct sunlight
	Avoid placing in an area where high variation of temperature exists. Operating temperature ranges from 5℃ ~ 40℃. Operating humidity ranges from 30% ~ 85 %.		Avoid in the vicinity of electric heater.
	Avoid placing in an area where there is an excessive humidity rise or ventilation problem.		Avoid placing in an area where there is an excessive shock or vibration.
	Avoid placing in an area where chemicals are stored or where there is in danger of gas leakage.		Avoid dust and especially metal material enter into the equipment
	Do not disjoint or disassemble the device. Bistos Co., Ltd. does not have liability of it.		Power off when the equipment is not fully ready to operate. Otherwise, the equipment could be damaged.

1 System basics

1.1 Intended use

The BT-770 Patient Monitors acquire the physiological signals such as ECG, respiratory rate, non-invasive blood pressure (NIBP), blood oxygen saturation (SpO_2) and temperature. The signals are converted into digital data and processed, examines the data for alarm conditions and display them. The monitor also provides an operation control panel for users. The patient monitor intend to use in hospital clinical area such as intensive care units, cardiac care units, operating room, emergency department, to provide additional information to the medical and nursing staff about the physiological condition of the adult. The BT-770 patient monitors are intended to be used only under regular supervision of clinical personnel. It is suitable for adult and pediatric. The intended locations of use are hospitals and clinics.

1) Intended patient population

- Pediatrics (30 days < and <18 years) and adult (>18 years adults)

2) Intended user profile

- Doctor, physicians or nursing staff who is qualified personnel
- Basic experiences or knowledge on medical field, especially on patient monitoring
- Trained or requested to read IFU before use

3) Environment of use

- Hospital and clinic
- Requirements: Stable power source

4) Scope of application

This monitor is suitable for bedside monitoring of adults and pediatric. This monitor enables ECG, respiration (RESP), pulse rate (PR), blood oxygen saturation (SpO_2), noninvasive blood pressure (NIBP) and temperature (TEMP) monitoring. It is equipped with a replaceable built-in battery to provide convenience for the patient movement in hospital.

5) Indications and contraindications

Blood oxygen saturation (SpO_2)

Indication:

- Monitoring effectives of oxygen therapy
- A reading is needed to facilitate the completion of an early warning score to inform clinical assessment
- Sedation or anesthesia
- Transport of patients who are unwell and require oxygenation assessment
- Haemodynamic instability (e.g. cardiac failure or Myocardial Infarction)
- Respiratory illness e.g. asthma, chronic obstructive pulmonary disease
- Monitoring during administration of respiratory depressant drugs, e.g. opiate epidural or patient-controlled analgesia.
- Assessing oxygen saturation during physical activity e.g. in pulmonary rehabilitation

Contraindications

- Pulse oximetry does not give an indication of haemoglobin so if the patient is profoundly anaemic then their oxygen saturation may by normal but they may still be hypoxic

Source: NHS. "*Clinical Procedure_ Procedure for Pulse Oximetry/SPO2*". Wirral Community NHS Trust. Sep, 2013

Non-invasive blood pressure (NIBP)

Indication:

- To determine a patient's blood pressure
- Screen for hypertension
- Following the effect of anti-hypertensive treatments in a patient to optimize their management
- Assessing a person's suitability for a spot or certain occupations
- Estimation of cardiovascular risk
- Determining for the risk of various medical procedure
- Figuring out whether a patient is clinically deteriorating or is at risk.

Contraindications

- Oscillometric blood pressure devices may not be accurate in patients with weak or thready pulse
- In patients with heart beats below 50 beats/minutes, even if the rhythm is regular, some of the semi-automatic devices are unable to reduce their deflation rate sufficiently so that too rapid a falling in cuff pressure results in underestimation of systolic blood pressure and overestimation of diastolic blood pressure.
- Do not apply to limb with AV fistula, significant injury or burn, or lymph node removal post mastectomy.

Source: [1] NHS. "*Clinical Procedure_ Procedure for Blood Pressure Monitoring*". Wirral Community NHS Trust. Dec, 2013

[2] Clinical Quality& Patient Safety Unit, QAS. *Clinical Practice Procedures: Assessment/Non-invasive blood pressure*. Queensland Government, 2016. https://www.ambulance.qld.gov.au/clinical.html

Electrocardiography (ECG)

Indication:

- The electrocardiogram (ECG) has proven to be among the most useful diagnostic test in clinical medicine. It is routinely used in the evaluation of patients to detect myocardial injury, ischemia and the presence of prior infarction, in the assessment of patients with electrolyte abnormalities, drug toxicities and implanted defibrillators and pacemakers.
- In addition to its usefulness in the evaluation of ischemic coronary disease, the ECG, in conjunction with ambulatory ECG monitoring, is of particular use in the diagnosis of disorders of the cardiac rhythm and in the evaluation of syncope. Other common uses of the ECG include the assessment of metabolic disorders and side effects of pharmacotherapy, as the evaluation of primary and secondary cardiomyopathic processes, among others.

Contraindications

- No absolute contraindications to performing an ECG exist, other than patient refusal. Some patients may have allergies or, more commonly, sensitivities to the adhesive used to affix the leads; in these cases, hypoallergenic alternatives are available from various manufacturers.

Source: Tarek, A. "*Electrocardiography*",<Medscape>, Apr 17, 2017

Temperature (TEMP)

Indication:

- To obtain the baseline temperature to enable comparisons to be made with future recordings
- To enable close observation in resolving hypothermia/hyperthermia
- To observe and monitor patients for changes indicating an infection
- To monitor the effect of treatment for antimicrobial therapy for infection
- Using before and during a blood transfusion to monitor for signs of a reaction

Contraindications

- No known contraindications

1.2 Operating principle

Refer to the chapters for every physiological parameter from chapter 7 to chapter 12.

1.3 System configurations

Basic configuration of BT-770

- Main body with 12 inch touch screen and built-in lithium-ion battery
- ECG cable and electrode
- Adult SpO2 probe and extension cable
- Non-invasive blood pressure cuff
- Temperature probe
- AC/DC adapter

Options of BT-770

- External plug-in printer

Picture	Name	Description	Qty
	ECG cable and lead wire (standard)	Measures ECG	1ea
	ECG electrode (standard)	Electrode for ECG measurement	1ea
	Adult SpO2 sensor (standard)	SpO2 sensor for adult	1ea
	SpO_2 extension cord (Standard)	Cord to connect the SpO2 sensor and main body	1ea
	Adult NIBP cuff (standard)	Measures NIBP for adult	1ea
	NIBP extension tube (standard)	Tube to connect the NIBP cuff and main body	1ea
	Temperature sensor (Standard)	Measures the body temperature	1ea
	Adapter (Standard)	For power supply	1ea

1.4 Product outlook

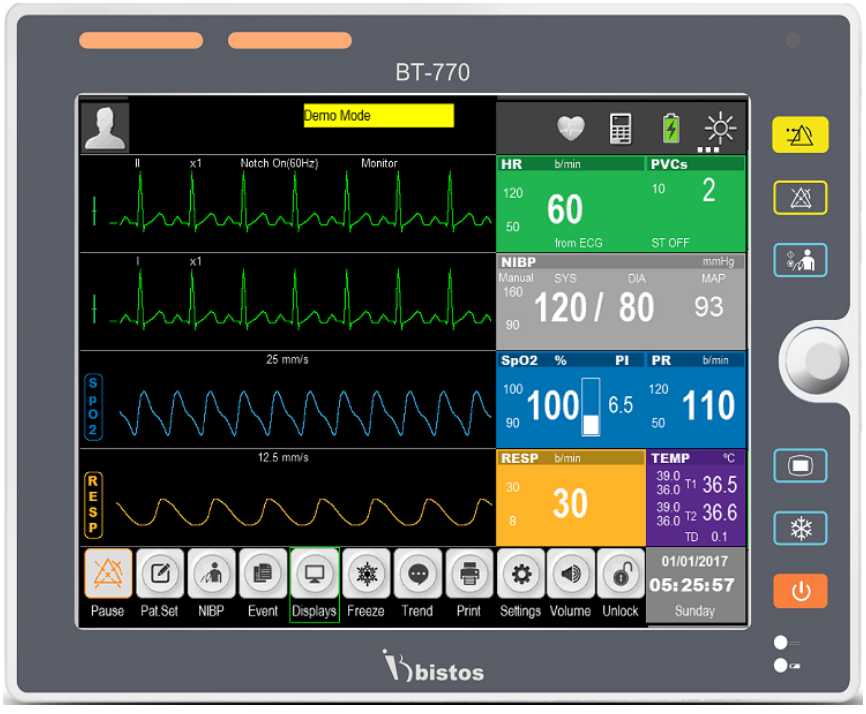


Figure1-1: Front view

Figure1-2 : Side view

Figure1-3 : Rear view

1.5 Description of monitor

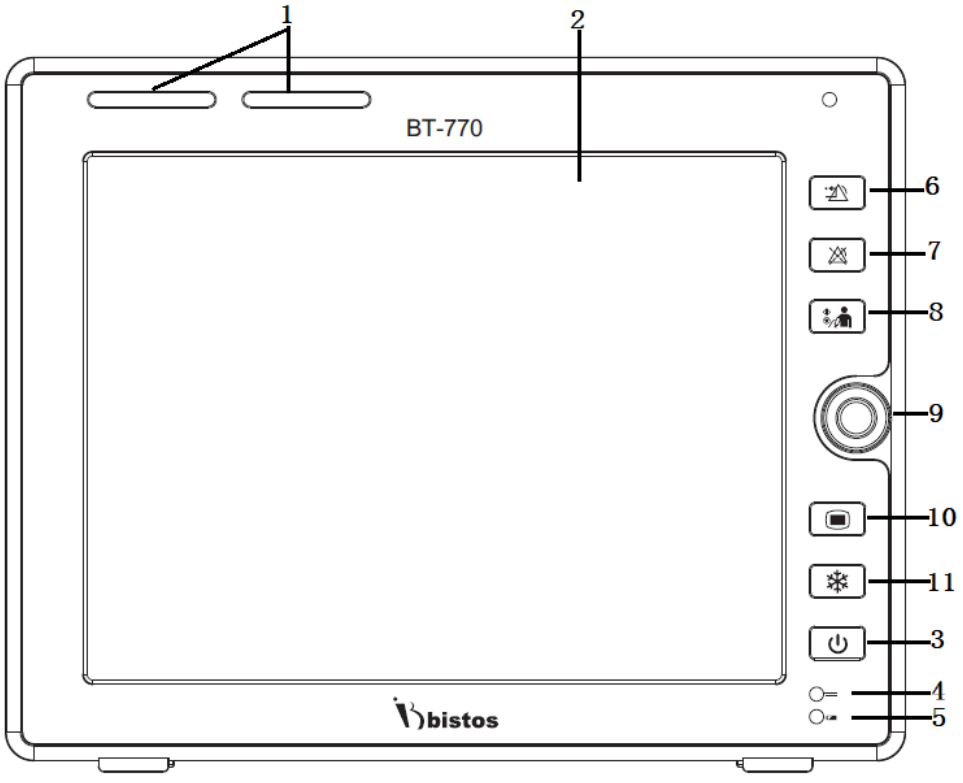


Figure1-4: Front view

	Name	Description
1	Alarm indicator	Indicates the priority of physiological alarm and technical alarms in different colors and flashing frequencies. - High priority: Red, fast flashing (1.4 - 2.8 Hz) - Medium priority: Yellow, slow flashing (0.4 - 0.8 Hz) - Low priority: Yellow, constant on
2	Display area	Display the waveform and measured value
3	[Power]	- Power On: Press down the key more than 2 seconds. - Power Off: Press down the keys more than 2 seconds and the system will display the alarm message “The system will shut down 3 seconds”.
4	Battery indicator	- On: The battery is being charged or has been fully charged. - Off: The battery has not been installed. - Flashing: The monitor is being powered by the battery.
5	DC power indicator	Turned on when the monitor is being powered by the adapter.
6	[Alarm reset]	To reset the alarm condition.

7	 [Alarm pause]	To pause the alarm sound. Alarm pause time can be set as 1 , 2, 3, 4, 5, 10, 15 minutes, and permanent. Default setting is 2 minutes.
8	 [NIBP start/stop]	Start and stop the non-invasive blood pressure measurement.
9	Control knob	Rotate: move the cursor. Press: select the menu or execute a command.
10	 [Setting]	Enter to the setting mode. Press again to close the setting mode.
11	 [Freeze]	Freeze/unfreeze the waveform.

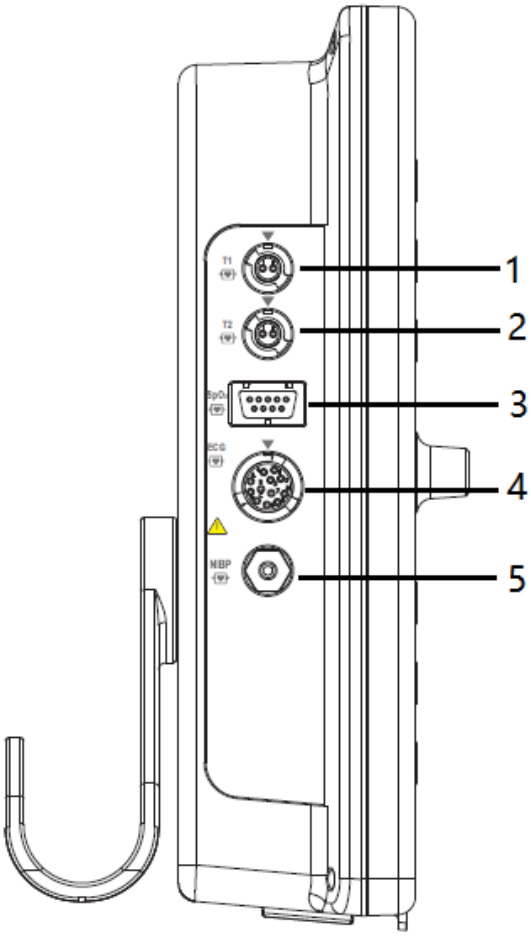


Figure1-5: Side view

	Name	Description
1	T1	Temperature probe interface
2	T2	Temperature probe interface
3	SpO2	SpO2 cable interface
4	ECG	ECG cable interface
5	NIBP	NIBP cuff interface

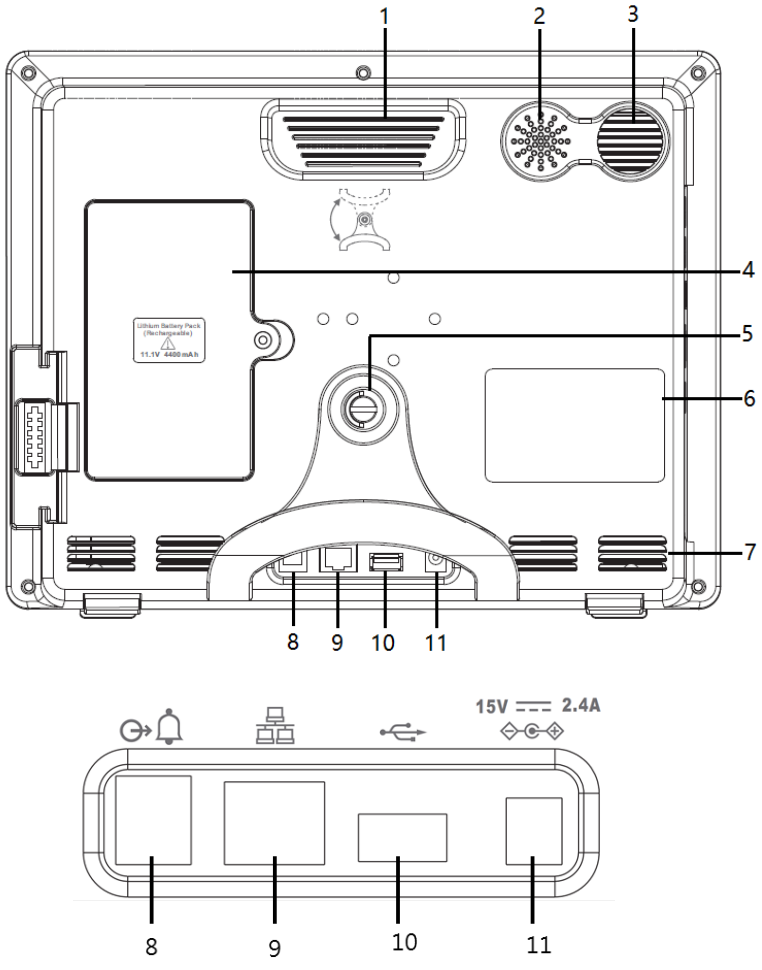


Figure1-6: Rear view

	Name	Description
1	Handle	Handle for main body transport
2	Speaker holes	For alarm and synchronizing sound
3	Air outlet	Heat dissipation
4	Battery cover	Battery compartment cover

5	Bracket	To wall mount the monitor
6	ID label	Identify the monitor information
7	Air intake	For ventilation
8	Auxiliary output interface	Nurse call
9	Network port	For CMS
10	USB port	For trend or software upgrade
11	Power adapter	15V, 2.4A adapter

1.6 Understanding the display

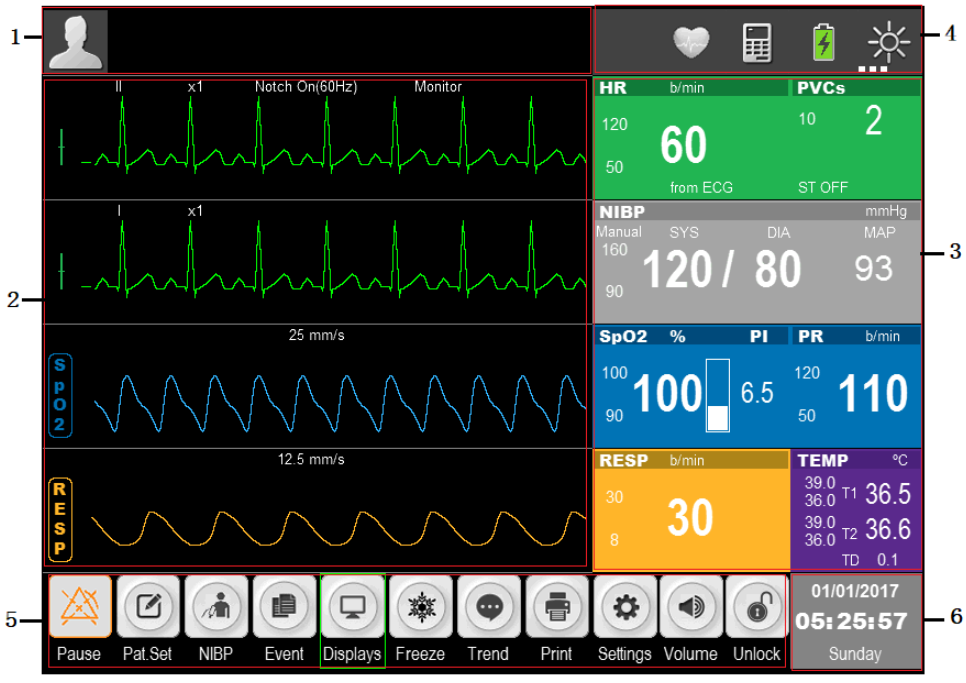


Figure 1-7: Standard display

	Name	Description
1	Information area	Include patient information, alarm status icon, physiological and technical alarms. In DEOM mode, it displays “DEMO”.
2	Waveform area	Mainly display the waves of physiological parameters with name of the parameter on the left side.
3	Parameter area	Show the corresponding parameter measured value and current upper and lower alarm limits of each parameter module. The parameters are shown in fixed position, that is, from top to bottom and from left to right: - ECG - NIBP - SpO_2 and PR - TEMP - RESP
4	Information Tip Area	Display the network status, battery status, automatic identification screen brightness icon.
5	Hot key icons	Shows the hotkeys, which are frequently used for some common operations.
6	Date and Time area	Display the current date and time.

1.7 Smart Hotkeys

Smart hotkeys are graphic hotkeys displayed at the bottom of the main screen of the monitor, and enable the user to use specific features conveniently.

Key	Name	Description
	[Pause]	Alarm pause
	[Pat. Set]	Patient information setting
	[NIBP]	NIBP measurement start and stop
	[Event]	Manual event mark
	[Displays]	Change the display format
	[Freeze]	Freeze the waveform
	[Trend]	Trend display
	[Print]	Print key
	[Settings]	Setup menu
	[Volume]	Volume setup key
	[Unlock]	Touch screen lock key

1.8 Essential performance

This device Multi-parameter Patient Monitor provides various patient vital signs such as pulse rate, ECG, respiration, blood oxygen saturation, blood pressure and temperature by placing or inserting the various sensors to the appropriate site of patient. The device is composed with display, control circuit and panel, and input part for various sensors. It detects ECG, SpO2, NIBP, etc. using ECG cable and specific probes and sensors. The detected analog signal amplifies and converted to digital. This concerted data feed to the CPU and converted to the display format as number and waveform. This device is incorporated with alarm system. The alarm generated when the detected signal range is beyond the user set alarm limits.

2 Preparing for operations

2.1 Installation

To ensure normal working of the monitor, read this chapter before use, and install as required.

⚠ WARNING

- All analog and digital devices connected to the monitor must be certified by IEC standards (e.g. IEC 60950 Data processing equipment standard and IEC 60601-1 Medical equipment standard). Furthermore, all configurations shall comply with valid version of IEC 60601-1 standard. The personnel connecting additional devices to the input / output signal ports are responsible for the compliance with IEC 60601-1 standard. If there is any question, please contact Bistos.
- If the patient cable interface and network interface are connected with multiple devices, the total electric leakage current cannot exceed the allowable value.
- The copyright of monitor software belongs to our company. Without permission, any organization or individual shall not interpolate, copy or exchange by any means or form.
- When the monitor is combined with other devices, it must comply with IEC 60601-1:2005 + A1:2012, and should not be connected with multiple socket outlet or extension cord.
- Do not connect the device on other equipment or network, to which a signal input/output part may be connected.

Prior to installation, the operator must ensure that the following space, power, environmental requirements are met.

2.1.1 Unpack and check

BT-770 patient monitor was inspected rigorously at the factory before delivery, in order to avoid being hit when transported, carried out careful packaging. Before unpacking, carefully inspect the package. If any damage, please immediately contact the Bistos. Unpack in the correct way, carefully remove the monitor and accessories from the box and check with the packing list. Check if there is any mechanical damage, the all listed are completely packed. If you have questions, please contact the marketing department of Bistos or agency.

Please keep the packing box and materials for use in future transporting or storage.

2.1.2 Placement requirements

Equipment installation must meet:

- The left and right side of the monitor should have space more than 100 cm from the wall
- Back on the monitor should have space more than 50 cm.
- Ensure that the operating floor and the monitor have enough space for connecting the accessory wires.

2.1.3 Power requirements

- DC power supply adapter

  Input: A.C. 100 V - 240 V, 50/60 Hz

  Output: D.C. 15 V, 2.5 A

- Built-in rechargeable lithium-ion battery: D.C. 11.1 V, 4400 mAh

2.1.4 Environmental requirements

The storage, transport and use of the monitor must meet the following environmental requirements.

Operating environment	Ambient temperature	5℃ ~ 40 ℃
	Relative humidity	30 % ~ 85 % (Non-condensing)
	Atmospheric pressure	700 ~ 1060 mbar (hPa)
Transportation	Prevent severe shock, vibration, rain and snow splashing during transport.	
Storage	The packaged monitor should be stored in well-ventilated room with ambient temperature -20 ℃ ~ 60℃, relative humidity 0 ~ 95 % (Non-condensing), atmospheric pressure 700 ~ 1060 mbar(hPa), and without corrosive gases.	

The operating environment of the monitor should avoid noise, vibration, dust, corrosive or flammable and explosive materials. In order to allow air flowing smoothly and achieve good heat dissipation, at least 2 inches (5cm) clearance should be kept around the device.

When the device is moved from one environment to another, the device may have condensation due to the differences in temperature or humidity. In this case, wait until the condensation disappears before using the device.

⚠ WARNING

- Ensure that the monitor is used under specified environment. Fail to do this, the technical specifications declared in this manual may not be met and it may result in damage to equipment and other unforeseen consequences.

2.2 Connecting to power

⚠ WARNING

- Do not try to open the monitor when the power is connecting.
- During the operation, do not disconnect any cable.

Connect to power adapter in the following steps:

- Make sure that the AC power supply meets the following specifications: a.c.100V-240V, 50/60Hz.
- Use the power adapter provided with the monitor. Plug the power adapter into the power connector of the monitor, and plug the other end of the power adapter into the mains (low voltage power supply network facilities) power outlet with protective earth.

3 Basic operations

3.1 Turn on

3.1.1 Check the monitor

- Before turn on the monitor, check whether there is mechanical damage to the monitor, and whether the external cables and accessories are connected correctly.
- Plug the power adapter into the AC power outlet. If using battery power, make sure the battery is fully charged.
- Check all the functions required for patient monitoring to make sure that the monitor operates properly.

WARNING

- If the monitor is damaged, or fails to work normally, do not use it for patient monitoring. Please contact the maintenance personnel or Bistos immediately.

3.1.2 Start the monitor

If finish to check the monitor, it is ready to start the monitor.

Press the [Power] key, the yellow warning lights flash once and the system enter the program reading interface; finally the system makes a “tick” sound, the boot screen disappears, and the system enters the main interface.

- If any fatal error occurs during self-test, the system will alarm. If this case persists, please stop to using the monitor and contact the maintenance personnel or Bistos.
- Check all available monitor functions to ensure that the monitor operate properly.
- If the monitor equipped with a battery, charge the battery after each use to ensure sufficient power.
- After unpacking, when use the monitor first time, the monitor should be powered with adapter.

3.1.3 Connect the sensors

Connect the required sensor to the monitor and the monitoring site of patient.

3.1.4 Start monitoring

Start monitoring in the following steps:

- Check if the patient cable and the sensor are connected properly.
- Check if the settings of the monitor are corrects, such as patient type.
- For the details of parameter measurement or monitoring, see the appropriate section.
- The operator can operate according to their own habits, standing in front, left or right of the monitor, easy to observe and operate the monitor.

3.2 Turn off

Turn off the monitor in the following steps

- Disconnect the cables and sensors connected to the patient.
- Press and hold the  [Power] key for 2 seconds to pop up the 3 seconds countdown window, and the monitor turns off in 3 seconds.

CAUTION

- If the monitor is not turned off properly, you can simply disconnect the power to shutdown forcibly. But the forced shutdown may cause data loss, and it is not recommended.

3.3 Basic operations

3.3.1 Using the control knob

Control knob can be used to perform the following operations:

- Rotate: Rotate control knob clockwise or counter clockwise to move the cursor.
- Press: Press control knob to perform an action, such as access to a menu or execute a command.

Control knob is the main control means. On the interface or the menu, the green highlighted box that moves with the knob turning is called the cursor. By turning the control knob, you can position the cursor in order to perform the desired operation.

3.3.2 Using keys

The monitor has three types of keys:

- Soft keys: Within the display these keys allow quick access to certain menus or performing certain actions, including:
    - Parameter hotkeys: Select a parameter area and enter the appropriate parameter setup menu, including drug calculation and time setup.
    - Wave hotkeys: Select a wave area and enter the appropriate parameter setup.
    - Smart hotkeys: The shortcut keys that the user can operate quickly are displayed at bottom of the screen. Refer to '1.7 Smart Hotkeys'.
- Hard keys: The physical keys on the monitor, such as the [Alarm pause] key on the front panel.
- Popup keys: Menu keys relevant to the tasks that automatically appear on the monitor screen when need, such as, the confirmation key popped up when you need to confirm the change.

3.3.3 Using the touch screen

Click on the touch screen to quickly and easily perform specific operation.

3.3.4 Using soft keyboard

If you choose a menu which needs to enter characters, the system will display the soft keyboard on the screen. If you finish entering, press [Enter] key to confirm that you have finished entering and close the soft keyboard.

3.3.5 Using menu

Select the [Settings] smart key on the monitor or press the [Setting] key on the monitor panel to open the “Settings” mode as shown below. You can set-up the monitor.

Figure 3-1: ”Setting” menu

The style of other menus is basically similar to the ″Settings″, and generally consists of the following components:

- Menu title: A title of the current menu.
- Close menu: Close the current menu. Exit the current menu or close the current menu and return to the previous menu.
- Main display area: Display options, buttons or prompt messages. The symbol ″>>″ indicates that selecting this option can enter the corresponding submenu.
- Confirmation key area: Some menus contain a confirmation key area to confirm the menu operations, including confirmation and cancel key.

3.4 Operation mode

The monitor has 2 operating modes, of which the demo mode is protected by a password.

1. Monitoring mode (operating mode)

This is the daily operating mode of patient monitoring; you can change some settings in accordance with the patients, such as alarm limits. However, when the patient is discharged, the monitor will restore these settings to default according to pre-set configuration.

2. Demo mode

This mode is protected by a password for demonstration purpose only.

- Enter the demo mode:
  - Select [Settings]Smart Hotkey or press [Setting] key on the monitor panel → "Settings";
  - Select "Demo Mode>>" → enter the password and confirm, and the monitor enters the demo mode.
- Exit demo mode:
  - Select [Settings]Smart Hotkey or press [Setting] key on the monitor panel → "Settings";
  - Select "Exit Demo >>" and the monitor exits the demo mode.

WARNING

- The demo mode is mainly used to show the monitor's performance and for user training. In actual clinical use, the demo function is prohibited in order to avoid mistaking the displayed waves and parameters as those of the patient, thus affecting patient monitoring, and delaying diagnosis and treatment.

3.5 Measurement setup

This section only describes the general settings of measuring wave in monitor mode; for other specific settings of each parameter, please refer to the appropriate section.

Select the wave area of a parameter to enter the appropriate setup menu. The setup menu defines the specific wave setup of the parameter, such as wave gain and wave speed. You may set the waves of different parameters as needed.

3.6 Freezing waves

In the patient monitoring process, you can freeze the wave on the screen, review and carefully observe the patient's condition during this time. Freeze / unfreeze the wave as follows:

Select 【Freeze】hotkey or press the [Freeze] key on the monitor panel to freeze the displayed wave of the monitor.

Select 【Freeze】hotkey or press the [Freeze] key on the monitor panel again to release the freezing state.

3.7 Other common setup

The common setup of the monitor is the general setup that defines how the monitor works, for example: alarm volume setting. They may affect the setup of multiple measurements or display interfaces.

3.7.1 Defining the monitor

When install the monitor or change the usage occasion, the monitor should be defined as follows:

- Select [Settings]Smart Hotkey or press [Setting] key on the monitor panel → "Settings".
- Select "User Maintenance >>" →enter the password and confirm → "User Maintenance" menu.
  - Select "Device Name": Enter device name through the soft keyboard on the screen.
  - Select "Department": Enter the sector and department using the device through the soft keyboard on the screen.
  - Select "Bed Number": Enter the bed number through the soft keyboard on the screen.

3.7.2 Language setup

Set the monitor language in the following steps:

- Select [Settings]Smart Hotkey or press [Setting] key on the monitor panel → "Settings".
- Select "User Maintenance >>" →enter the password and confirm →"User Maintenance" menu.
- Select "Language", and select the option as needed:
  - "English": The interface language of the monitor is English.
  - "Türkçe": The interface language of the monitor is Turkish.
  - "Español": The interface language of the monitor is Spanish.
  - "Français": The interface language of the monitor is French.

3.7.3 Date and time

Set the monitor time in the following steps:

- Select [Settings]Smart Hotkey or press [Setting] key on the monitor panel → "Settings";
- Select "User Maintenance >>" →enter the password and confirm →"User Maintenance" menu.
- Select "Time Setup >>" → enter "Time Setup>>" menu.
- Or you can enter the "Time Setup" directly by touching the time display area on the display.
- "Date (YYYY-MM-DD)": Set the year, month, and day.
- "Time (24H)": Set the hour, minute and second.
- Select "Date Format", and set the date format in accordance with custom
  - "YYYY-MM-DD": Year- Month-Day.
  - "MM-DD-YYYY": Month -Day-Year.
  - "DD-MM-YYYY": Day-Month-Year.
- "Time Format", set the time format is 24H.

3.7.4 Volume control

1. Alarm Volume
   - Select 【Volume】smart hotkey → “Volume Setup” menu.
   - Select “Alarm Volume”: Set alarm volume from 1 to 9.
2. QRS Volume
   - Select 【Volume】smart hotkey → “Volume Setup” menu.
   - Select “QRS Volume”: Set QRS volume from 0 to 9. 0 means off.
3. Pulse Volume
   - Select 【Volume】smart hotkey → “Volume Setup” menu.
   - Select “Pulse Volume”: Set pulse volume from 0 to 9. 0 means off.
4. Touch Volume
   - Select 【Volume】smart hotkey → “Volume Setup” menu.
   - Select “Touch Volume”: Set touch volume from 0 to 9. 0 means off.
5. Key Volume
   - Select 【Volume】smart hotkey → “Volume Setup” menu.
   - Select “Key Volume”: Set key volume from 0 to 9. 0 means off.

3.7.5 Setting parameter unit

You can select a preferred unit through the following operations

- Select [Settings]Smart Hotkey or press [Setting] key on the monitor panel → "Settings".
- Select “User Maintenance >>” → enter the password and confirm →“User Maintenance” menu.
- Select “Unit Setup >>” →“Unit Setup” menu.
  - Select “Height Unit”, and select the unit “cm” / “inch” as needed.
  - Select “Weight Unit”, and select the unit “kg” / “lb” as needed.

- “ST Unit” fixed as “mV”, is not optional.
- Select “Pressure Unit”, and select the unit “mmHg” / “kPa” as needed.
- Select “TEMP Unit”, and select the unit “℃” / “°F”as needed.

4 Patient information management

Connect the patient to the monitor, and the monitor will display and store the physiological data of the patient, so the patient can be monitored without admitting the patient. However, admitting the patient correctly is very important.

If the monitor has admitted the patient, it is recommended to operate the monitor to discharge the current patient before connecting to (not admitted) the next patient. Otherwise, the data of the previous patient will be stored in the data of the current patient.

⚠ WARNING

- Whether the patient is admitted or not, the system will give a default value to "Patient Type" and "Pace Maker", "Patient Type" default "Adult", "Pace Maker" default "No", and the user must confirm that the default value is appropriate for the patient being monitored.
- For patients with pacemakers, "Pace Maker" must be set to "Yes". Otherwise, the pacing pulse will be treated as normal QRS wave group, and the system is unable to detect the alarm status of "ECG Signal weak".
- For patients without a pacemaker, "Pace Maker" must be set to "No". Otherwise, the system is unable to detect the arrhythmias (including PVCs count) related to ventricular premature beats, and fails to perform ST segment analysis.

4.1 Patient setup menu

You can manage the patient through the "Patient" menu. To enter "Patient" menu, operate as follows:

Select [Settings]Smart Hotkey or press [Setting] key on the monitor panel → "Settings" → "Patient >>" → "Patient" menu;

Or

Select [Pat. Set] Smart Hotkey to enter "Patient" menu, as shown in Fig. 4-1.

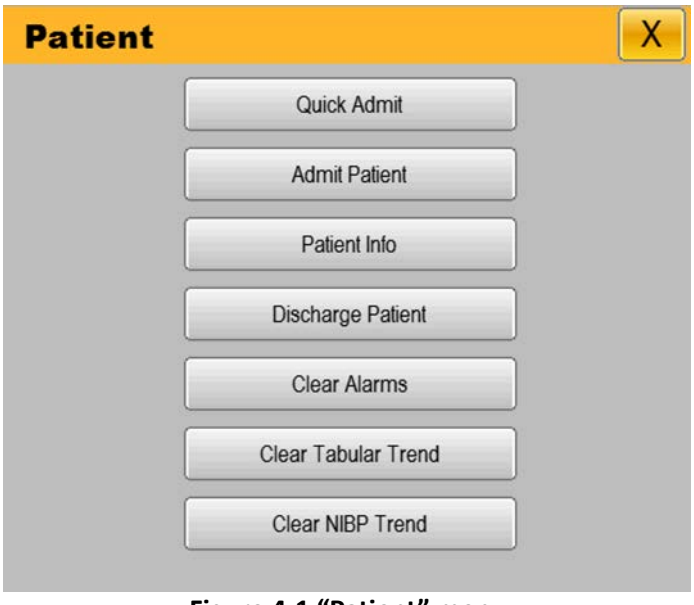


Figure 4-1 "Patient" menu

4.2 Admitting a patient

Admit a patient as follows:

In "Patient" menu, select "Quick Admit" → "Warning" message → "OK" → "Quick Admit" menu, as shown in Figure 4-2.

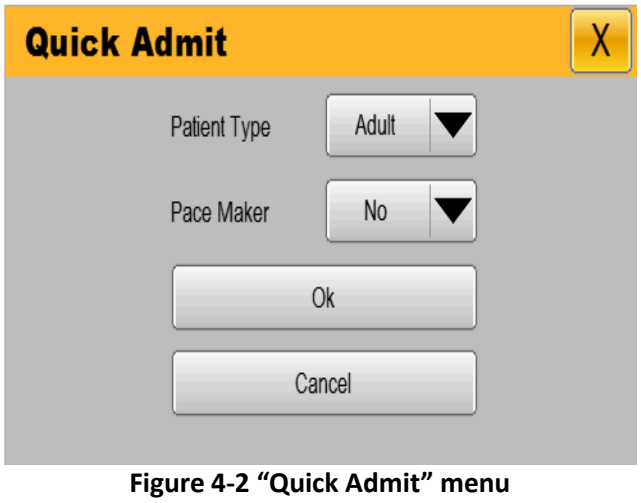


Figure 4-2 "Quick Admit" menu

- Select "Patient Type", and set the patient category as needed: "Adult" and "Pediatric".
- Select "Pace Maker", and set whether the patient wears a pacemaker according to the patient condition: "Yes" or "No".
- After setting, select "OK" to save the current setup or select "Cancel" and do not save the current setup.

4.3 Patient information

To edit patient information, operate as follows:

In the “Patient” menu, select “Patient Info”. The “Patient Info” menu as shown in Figure 4-3 will be displayed.

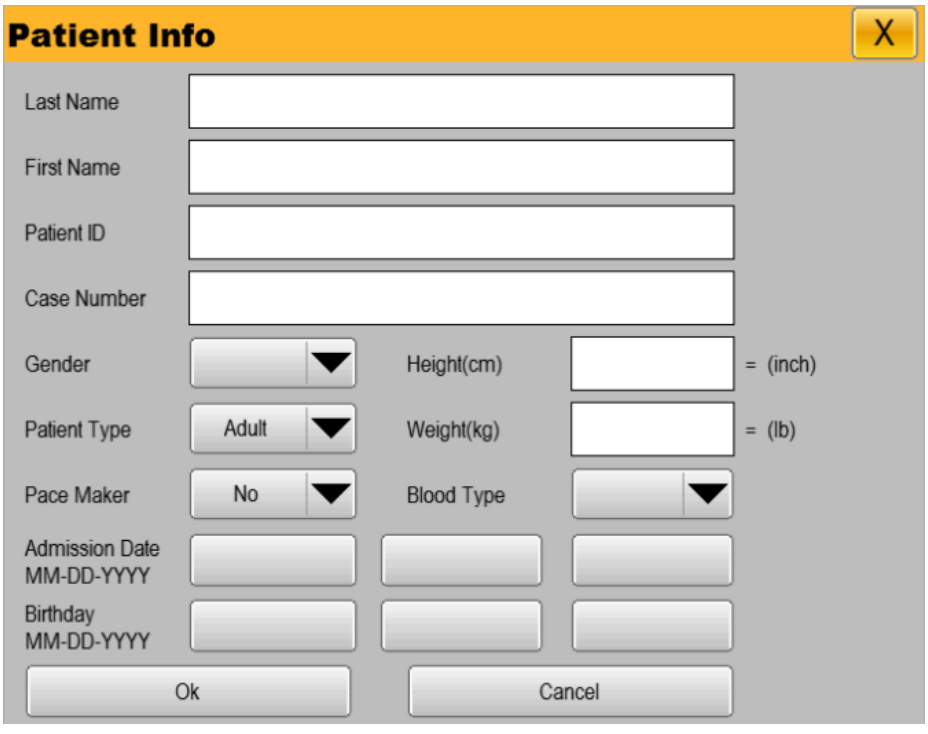


Figure 4-3. “Patient Info” menu

1. Select “Last Name”, and enter patient’s surname through the soft keyboard（Letters: not more than 20 characters）.
2. Select “First Name”, and enter patient name through the soft keyboard（Letters: not more than 20 characters）.
3. Select “Patient ID”, and enter the patient ID through the soft keyboard (Letters: not more than 20 characters).
4. Select “Case Number”, and enter the case number through the soft keyboard（Letters: not more than 20 characters）.
5. Select “Gender”, and set the patient’s gender.
6. Select “Patient Type”, and set the patient category as needed: Adult and Pediatric.
7. Select “Pace Maker”, and set whether the patient wears a pacemaker.

8. Select “Height(cm)”, and set the patient’s height via the pop-up keyboard on the screen(Range: 0 ~ 250).
9. Select “Weight (kg)”, and set the patient’s weight via the pop-up keyboard on the screen(Range: 0 ~ 350).
10. Select “Blood Type”, and set the patient’s blood type: A, B, AB or O.
11. Select “Admission Date (MM-DD-YYYY)”, and set the date of admitting the patient.
12. Select “Birthday (MM-DD-YYYY)”, and set the birth date of the patient.

After setting, select “OK” to save the current setting or select “Cancel” and do not save the current setting.

4.4 Discharging a patient

To discharge a patient, operate as follows:

In the “Patient” menu, select “Discharge Patient” → “Warning” message → “OK” to finish the operation of discharging a patient.

After the patient is discharged, all the information of the patient stored in the monitor will be cleared. Therefore, discharge the patient only when needed.

4.5 Clear alarms

To clear alarms, operate as follows:

In the “Patient” menu, select “Clear Alarms” → “Warning” message → “OK” to finish the operation of clear alarms.

After the alarm is cleared, all the information of alarms stored in the monitor will be cleared. Therefore, clear alarm only when needed.

4.6 Clear trend

To clear trend, operate as follows:

In the “Patient” menu, select “Clear Tabular Trend” → “Warning” message → “OK” to finish the operation of clear tabular trend.

After the tabular trend was cleared, all the information of tabular trend stored in the monitor will be cleared. Therefore, clear tabular trend only when needed.

4.7 Clear NIBP trend

To clear NIBP trend, operate as follows:

In the “Patient” menu, select “Clear NIBP Trend” → “Warning” message → “OK” to finish the operation of clear NIBP trend.

After the NIBP trend was cleared, all the information of NIBP trend stored in the monitor will be cleared. Therefore, clear NIBP trend only when needed.

5 Display format

The monitor has four display format, which are “Normal Screen”, “Big ECG Screen”, “Big font Screen”, and “ECG 7-Lead Full-Screen”. The user can select the display format according to needs, and get different screen information.

5.1 Selecting user interface

Select the user interface as follows:

- Select  [Displays] smart hotkey→ Screen Select;
- Select the display format according to needs:
  - “Normal Screen”: Standard interface.
  - “Big ECG Screen”: Big ECG interface.
  - “Big font Screen”: Big font interface.
  - “ECG 7-Lead Full-Screen”: ECG 7-Lead Full interface.

5.2 Display description

5.2.1 Normal display format

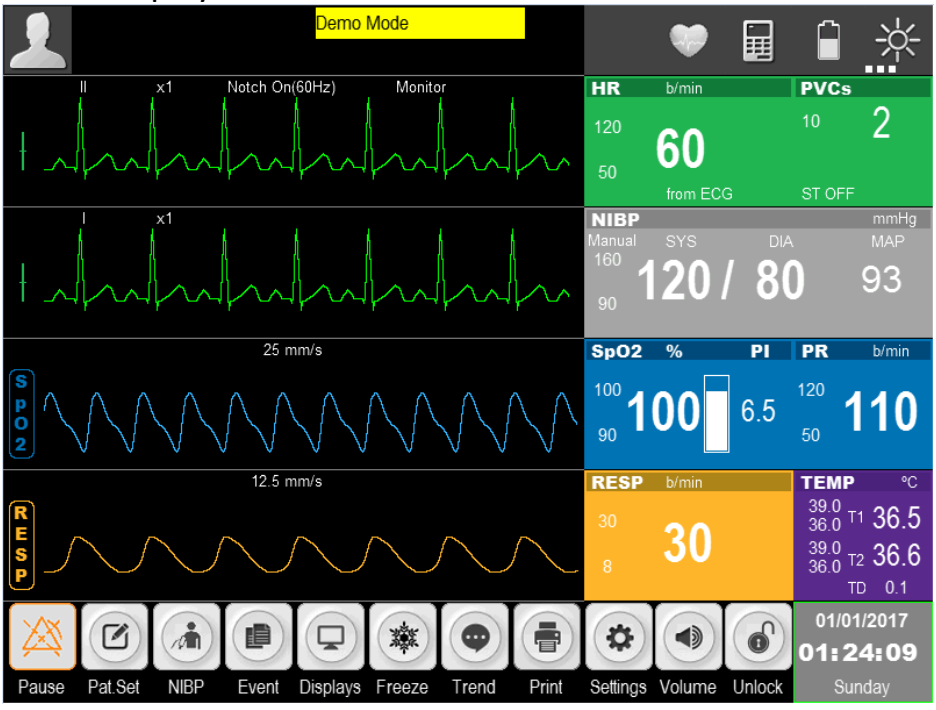


Figure 5-1: Standard Display

The normal display provides the parameter wave being monitored and the parameters displayed in the parameter area. This is the basic display of the monitor. In this display mode all parameters, two ECG waves, one blood oxygen saturation percentage wave, one respiratory wave are displayed.

5.2.2 Big ECG format

The big ECG format is as shown in Figure 5-2.

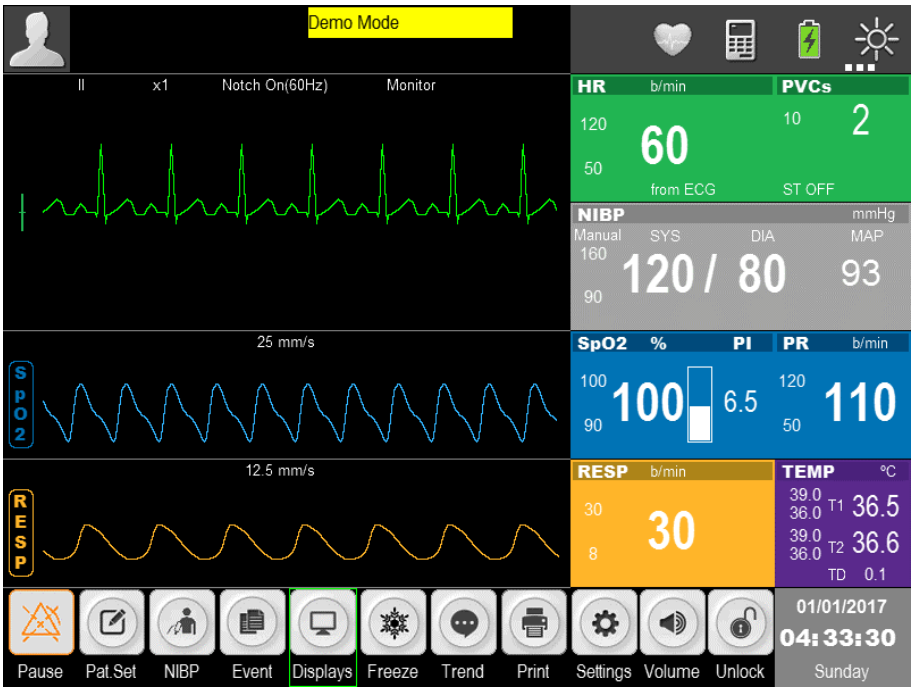


Figure 5-2: Big ECG format

5.2.3 Big font format

The big font format is as shown in Figure 5-3.

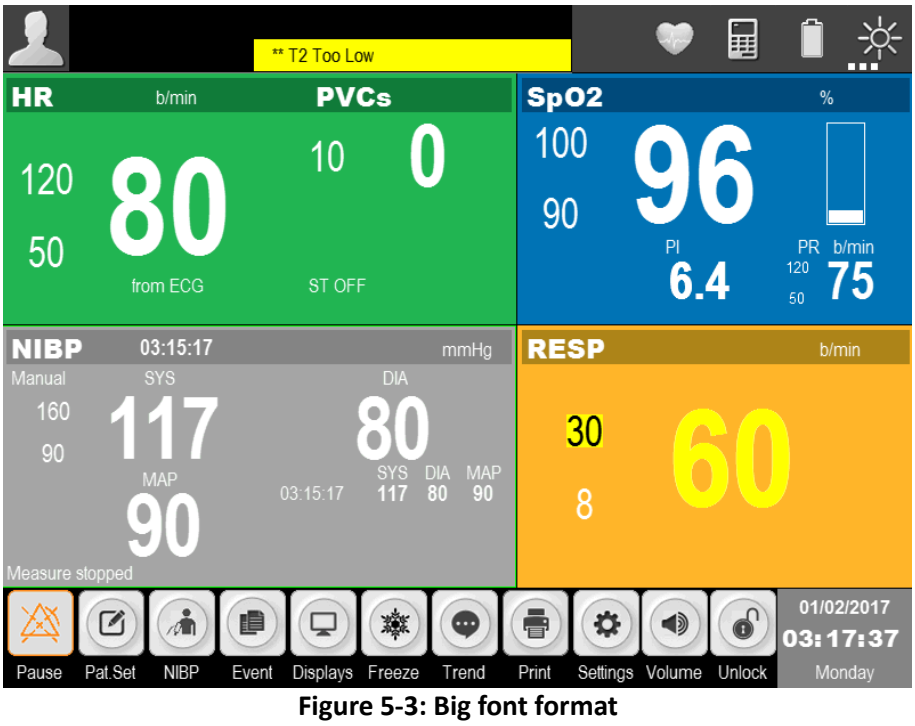


Figure 5-3: Big font format

5.2.4 ECG 7-Lead full screen format

The ECG 7-Lead full screen format is as shown in Figure 5-4.

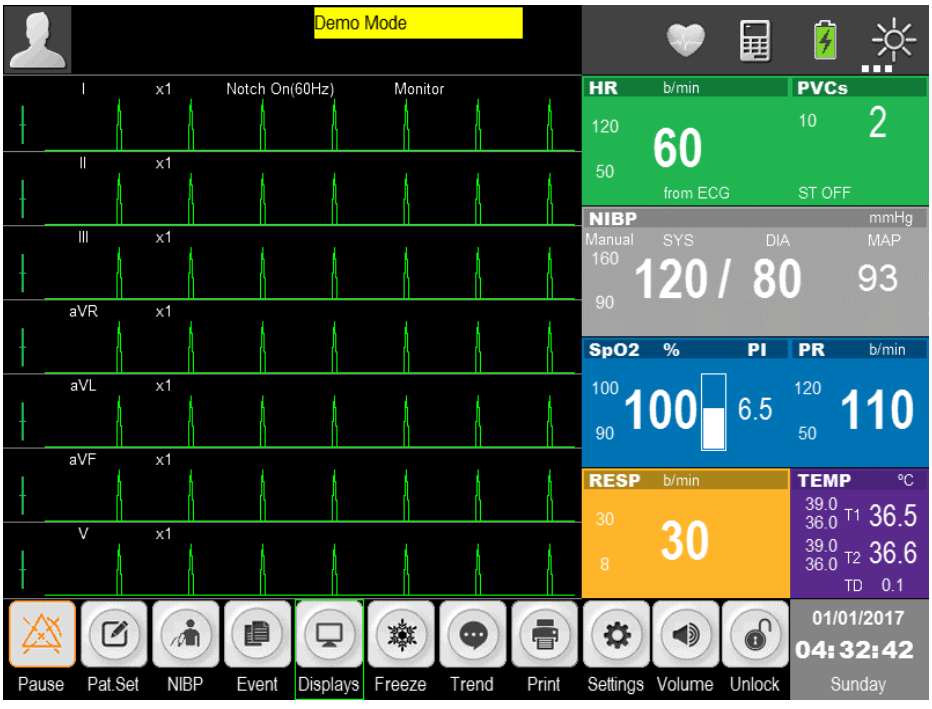


Figure 5-4: ECG 7-Lead full screen format

6 Alarm

Alarm means that the monitor prompts the medical staff through sound and light when the abnormal changes in vital signs are monitored or the monitor has a failure or is unable to monitor the patient successfully.

⚠ WARNING

- In any single region (e.g. ICU), it has potential danger if the same or similar devices use different alarm setup.

- After setting, the alarm and other parameters of the monitor won't be lost when the system is power off, unless modified manually. Connect the power again and turn on the monitor, it will resume normal working, and the alarm and other parameters remain unchanged.

6.1 Alarm types

According to the nature of the alarm, the alarms of the monitor can be divided into physiological alarms, technical alarms and prompt messages.

- Physiological alarms

  A physiological alarm is usually triggered when a physiological parameter of the patient exceeds the alarm limit or the patient has physiological abnormalities. The information of physiological alarm is displayed in the physiological alarm area on top of the screen.

- Technical alarms

  Technical alarm is also known as a system error message, which is caused by improper operation or system failure resulting in system malfunction or monitoring result distorted. The information of technical alarm is displayed in the technical alarm area on top of the screen.

- Prompt messages

  Strictly speaking, the prompt messages are not alarms. The monitor also will display some information associated with system status in addition to the physiological alarms and technical alarms, and generally such information do not involve the patient's vital signs. The prompt messages generally appear in the technical alarm area and parameters area.

6.2 Alarm condition priorities

According to the severity of the alarm conditions, the physiological alarms of the monitor can be divided into high priority, medium priority and low priority.

- High priority alarms

  The patient is in critical condition that is life-threatening, and should be immediately rescued, or the monitor has a serious mechanical failure or malfunction, causing it unable to detect the patient's critical state and endangering the patient's life.

- Medium priority alarms

  The patient's physiological signs are abnormal and appropriate measures or treatment should be taken immediately, or although it won't endanger the patient's life, the mechanical failure or disoperation of the monitor will affect the normal monitoring of key physiological parameters.

- Low priority alarms

  The patient's physiological signs are abnormal and appropriate measures or treatment may need to be taken, or certain monitoring function is invalid due to mechanical failure or disoperation, but it won't endanger the patient's life.

The priority of all technical alarms and some physiological alarms have been set in the monitor at the factory and cannot be modified by the user. The levels of some physiological alarms can be modified.

6.3 Alarm mode

When an alarm occurs, the monitor uses the following audible or visual alarm to prompt the user:

- Visual alarm
- Audible alarm
- Alarm info
- Parameter flashing

Of which, the visual alarm, audible alarm, and alarm information distinguish the alarm levels in a different manner respectively.

6.3.1 Visual alarm

When an alarm occurs, the alarm indicator will flash in different colors and frequencies to prompt the alarm priority.

- High priority alarm: Red, fast flashes.
- Medium priority alarm: Yellow, slow flashes.
- Low priority alarm: Yellow, lit without flashing.

6.3.2 Audible alarm

An audible alarm is that the monitor prompts the alarm priorities with different sound characteristics when an alarm occurs.

- High priority alarm: Beep-beep-beep--beep-beep----beep-beep-beep--beep-beep
- Medium priority alarm: Beep-beep-beep
- Low priority alarm: Beep

6.3.3 Alarm information

Alarm information displayed on the physiological or technical alarm area of the monitor indicates the corresponding alarm information when an alarm occurs. The system will distinguish the alarm priority with different background colors:

- High priority alarm: Red
- Medium priority alarm: Yellow
- Low priority alarm: Yellow

The following flags in front of physiological alarms are used to distinguish the alarm priorities.

- High priority alarm: ***
- Medium priority alarm: **
- Low priority alarm: *

6.3.4 Parameter flashing

When the physiological parameter values in the parameter area will flash once per second, and the upper limit and lower limit of the parameter will also flash at the same frequency, it indicating that the parameter exceeds the upper limit or lower limit.

6.4 Alarm states

In addition to the above alarm modes, you can also set the monitor to the following three alarm states as needed, and display different alarm icons on the screen:

- Alarm Reset
- Alarm sound off
- Alarm pause
- Alarm off

6.4.1 Alarm reset

Select button, and you can temporarily turn off the alarm sound of currently occurring physiological alarms of the monitor, but the alarm information is still retained. For technical alarms, clear the alarm state, display alarm prompt information, the alarm state icon area displays the icon. When a new physiological alarm or technical alarm occurs, the alarm reset is automatically canceled.

6.4.2 Alarm sound off

The alarm sound can be turned off through the following operations:

- Select [Settings] smart hotkey→ “Settings”.
- Select “User Maintenance >>”→enter the password and confirm →“User Maintenance” menu.
- Select “Alarm Param >>”→“ Alarm Param” menu.
- Set “Minimum Alarm Volume” to “0”. “Minimum Alarm Volume” range from 0 to 9, the default value is 1.
- Select 【Volume】smart hotkey →“Volume Setup” menu.
- Set “Alarm Volume” to “0”.

When the alarm sound is turned off, the alarm state area on the screen shows the icon.

If “Minimum Alarm Volume” is larger than 0, the system will cancel alarm sound off state.

WARNING

- When the alarm is off, and the alarm reminder signal is on, the system will have alarm reminder tone.

6.4.3 Alarm pause

Press the [Pause] smart hotkey or [Alarm pause] key on the monitor panel to temporarily stop the alarm of the monitor in the following steps:

- [Pause]smart hotkey will appear magnified and reverse colored icon.
- The light alarm and audible alarm of the physiological alarms are suspended, and the alarm information is not displayed.
- The remaining time of alarm pause is displayed in the physiological alarm area.
- Alarm parameters and upper / lower limit stop flashing.
- The audible alarm and light alarm of technical alarms are suspended, but the alarm message is still displayed.

After the alarm pause is finished, the monitor will automatically cancel the alarm pause state. During the alarm pause, you can also press [Pause] smart hotkey or [Alarm pause] key on the monitor panel to cancel the alarm pause manually.

You can set the alarm pause time as follows:

- Select [Settings]Smart Hotkey or press [Setting] key on the monitor panel → "Settings".
- Select "User Maintenance >>" → enter the password and confirm →"User Maintenance" menu.
- Select "Alarm Param >>"→" Alarm Param" menu.
- Select "Alarm Pause Time", and set the alarm pause time.
  - "1min" /"2min" /"3min" /"4min" /"5min" /"10min" /"15min" "Permanent". By default, the alarm pause time is 2 minutes.
  - "Permanent" means alarm off.
  - It is recommended that the SpO2 alarm pause time shall not more than two minutes.

6.4.4 Alarm off

As shown in 6.4.3, if the “Alarm Pause Time” is set to “Permanent”, press the [Pause] smart hotkey or [Alarm pause] key on the monitor panel, and the monitor will turn off the alarm. In this case, except the alarm prompt characteristics maintained in alarm pause state:

- [Pause] smart hotkey will appear magnified icon.
- The physiological alarm area displays “Alarm Pause”.

You can press the [Pause] smart hotkey again to manually cancel the alarm off.

If the monitor is in the alarm state of suspension or high priority technical alarm is triggered, the alarm and the alarm off pause are automatically canceled.

WARNING

- When the alarm volume is set to ‘0’ or the alarm pause time is set to permanent, the monitor does not sound an alarm when an alarm occurs. Therefore, the operator should use this feature carefully.

6.5 Alarm setup

6.5.1 Setting the alarm delay time

To limit alarm of continuous measurement parameter, you can set the alarm delay time. If the alarm condition disappears during the delay period, the monitor will not generate an alarm. In "Alarm Param" menu, select "Alarm Delay" time and "ST Alarm Delay" time.

The specific operation is as follows:

- Select [Settings] smart hotkey or press [Setting] key on the monitor panel → "Settings".
- Select "User Maintenance >>" → enter the password and confirm → "User Maintenance" menu.
- Select "Alarm Param >>" → "Alarm Param" menu.
- Select "Alarm Delay", and set the alarm delay time as needed:
  - "Off": Turn off the alarm delay.
  - "1s" / "2s" / "3s" / "4s" / "5s" / "6s" / "7s" / "8s": Alarm delay time is 1 sec, 2 sec, 3 sec, 4 sec, 5 sec, 6 sec, 7 sec or 8 sec. By default, the alarm delay time is 4 seconds.
- Select "ST Alarm Delay", and set the ST alarm delay time as needed.
  - "Off": ST alarm delay is off
  - "10s" / "20s" / "30s" / "45s" / "1min" / "2min" / "3min": ST alarm delay time is 10 sec, 20 sec, 30 sec, 45 sec, 1 min, 2 min or 3 min. By default, the ST alarm delay time is 20 seconds.

6.5.2 Setting the alarm reminder signal and alarm reminder interval

The alarm reminder signal can be turned on or off. When the alarm is off and the alarm sound is off, and then the alarm reminder signal is on. You can set the alarm reminder interval as needed: "1min" / "2 min" / "3 min".

The specific operation is as follows:

- Select 【Settings】Smart Hotkey→ "Settings" .
- Select "User Maintenance >>" →enter the password and confirm → "User Maintenance" menu.
- Select "Alarm Param >>" → "Alarm Param" menu.
- Select "Alarm Reminder Signal", and set the alarm reminder signal as needed:

- "On": The alarm Reminder Signal is on.
- "Off": The alarm Reminder Signal is off.

➢ Select "Alarm Reminder Interval", and set the alarm reminder interval as needed:

- "1min" / "2 min" / "3 min": Alarm reminder interval is 1 min, 2 min or 3 min. By default, the alarm reminder interval is 3 min.

6.5.3 Setting a parameter alarm

You can set the parameter alarm for every alarm separately. For SpO_2, as an example, select "Alarm Setup >>" in the "Settings" menu and select "SpO_2" and enter the SpO_2 alarm setup menu.

1. Turn on / off alarm

➢ Select "Alarm Switch" and set the alarm switch as follows:

- "On": Turn on SpO_2 alarm; when the parameter alarm occurs, the monitor will prompt according to the set alarm level.
- "Off": Turn off SpO_2 alarm;  icon is displayed in the parameter area, and the monitor won't prompt the parameter alarm.

2. Set the alarm priority

➢ Select "Alarm Level", and set the alarm priority as follows:

- "Mid": Set the alarm priority to medium.
- "High": Set the alarm priority to high.

Note: Regulatory requirements, the parameter (ECG, blood oxygen saturation, blood pressure) can set the alarm priority high and mid.

3. Set the alarm limit

In any cases, the alarm system only allows setting the values within the effective range of the system, and the upper alarm limit must be higher than the lower alarm limit.

➢ Select "SpO_2 Low Limit" and set the lower limit of SpO_2 alarm.

➢ Select "SpO_2 High Limit" and set the upper limit of SpO_2 alarm.

➢ Select "PR Low Limit" and set the lower limit of PR alarm.

➢ Select "PR High Limit" and set the upper limit of PR alarm.

Type	Adults		Pediatric	
	Range	Default	Range	Default
SpO2 Low Limit	0-99	90	0-99	90
SpO2 High Limit	1-100	100	1-100	100
PR Low Limit	15-299	50	15-349	75
PR High Limit	16-300	120	16-350	160

4. Restore default alarm setup

➢ Select “Default”, and restore the alarm setup to the factory setup.

NOTE

- When setting the upper and lower alarm limits, confirm the patient category and set its range according to the clinical need. If the setting exceeds the alarm limits, the alarm system will fail easily.
- When the alarm limit is turned on, and the upper and lower alarm limits are manually set, the monitor will display the upper and lower alarm limits continuously, and the initial alarm preset value will not be provided additionally.

6.6 Latch alarm

Physiological alarms can be set to “Latching” or “No latching”.

➢ “Latching”: Even if the cause of physiological alarm is cleared, the system will still be “latched”, that is, continue to display the alarm information corresponding to physiological alarm, the alarm sound also continues, but the alarm mode has the following changes:

- Parameters and upper or lower alarm limit are no longer flashing.
- Display the time that the latest alarm was triggered after the alarm message in the physiological alarm area.

➢ “No latching”: After the causes of physiological alarm are cleared, the system will no longer prompt the physiological alarm.

The default alarm of the system is no-latching alarm. You can set the alarm as latching or no-latching in the following steps.

➢ Select [Settings] smart hotkey or press [Setting] key on the monitor panel → “Settings”.

➢ Select “User Maintenance >>” →enter the password and confirm → “User Maintenance” menu.

➢ Select “Alarm Param >>” → “Alarm Param” menu.

➢ Select “Latching Alarm”, and set the alarm as needed:

- “Latching”: Latching alarm.
- “No latching”: Non-latching alarm.

6.7 Manual event

In the patient monitoring process, some events may have an impact on the patient, resulting in changes of some monitoring waves or parameters. In order to assist in the analysis of these effects, you can manually record these events through the  [Event] smart hotkey, and then view it in the event review, refer to15.4 Event Review for detailed operation.

6.8 Alarm record

When the monitor's machine alarm system is powered down, all alarm records are not saved.

Physiological alarm can store 200 alarm records, if full of 200, the latest alarm records will replace the beginning of the record;

Technical alarm can store 100 alarm records, if full of 100, the latest alarm records will replace the beginning of the record.

7 ECG

7.1 Overview

Electrocardiogram (ECG) is produced by the continuous electrical activity of the patient's heart, and displayed with wave and numeric on the monitor in order to accurately assess the physiological state of the patient at the time. The ECG cable should be connected properly, so as to obtain a correct measurement value and normal display. This monitor can simultaneously display 7 ECG waves.

Patient cable consists of two parts.

- Wires connected to the monitor
- ECG electrodes connected to the patient

Connect to the monitor with five lead ECG cable, and ECG can display two different waves by adjusting the two leads. You can use the control knob to change the lead name on the left of the ECG wave on the screen and select the lead to be monitored.

The parameters displayed in the parameter area of the monitor include heart rate (HR), ST segment measurements and arrhythmia counts per minute. All these parameters can be used as alarm parameters.

The monitor is designed for defibrillation proof, so the monitor operates normally after defibrillation.

NOTE

- In the factory setup, ECG wave display in the first two waves from top in the wave area in the normal display format.

7.2 Safety information

⚠ WARNING

- To monitor ECG signal, ECG cable and ECG electrodes specified in this manual must be used.
- When connecting the electrodes or patient cable, make sure that the patient is absolutely not connected with any other conductive parts or in contact with the ground. In particular, make sure that all the ECG electrodes, including the neutral electrodes, are attached to the patient and prevent them from contact with the conductive parts or ground.
- When using electrosurgical (ES) equipment, users should put ECG electrodes at middle of the ES earthing plate and ES knives to prevent from burns. Cables of ES equipment cannot be wrapped with ECG cables together.
- During use of ES equipment, don't put electrodes near the earthing plate of such equipment, otherwise ECG signals will be much disturbed.
- For patients who wear a pace maker, pacing pulse analysis must be turned on. Otherwise, the pacing pulse may be counted as a normal QRS wave, make the ECG signal too weak to detect the alarm.
- Periodically check the skin that the electrode is placed at. If there is any sign of allergy or irritation, replace the electrode or change the placement position.
- Electrosurgical (ESU) device interference, defibrillator discharge
  - When the patient needs defibrillation, do not use non-defibrillator type ECG cables. For defibrillation protection, please use the accessories specified by manufacturer. (Refer to Chapter 17. Accessories)
  - During defibrillation, the operating personnel shall not touch the patient, tables and instrument.
  - During defibrillation, the ECG cable connected with the patient's body may be damaged. Check if the function is normal again before using these cables.
  - The monitor will recover within10 seconds after defibrillation and will not lose any stored data. During electrosurgery or defibrillation, the measurement accuracy may be temporarily reduced. This does not affect the safety of the patient or the instrument.
- Do not expose the monitor to X-ray or strong magnetic fields (e.g. MRI).

7.3 Monitoring steps

7.3.1 Preparation

Before placing the electrode, prepare the patient's skin in the following steps.

- Skin preparation: Since the skin is a poor conductor, it is very important to treat the patient's skin for electrode placement appropriately to make good contact between the electrode and the skin. Select the flat position with less muscles for the electrode placement, and refer to the method below for treatment of the skin:
  - Remove the body hair at the position for electrode placement.
  - Gently rub the skin at the position for electrode placement to remove dead skin cells.
  - Wash the skin thoroughly with soap and water (do not use ether and pure alcohol, as this will increase the skin's impedance).
  - Dry the skin completely before placing the electrode.
- Install the spring clip or stud prior to the placement of the electrodes.
- Place the electrode on the patient.
- Connect the ECG cable and ECG interface.

⚠ WARNING

- Check if the lead is adequately attached and do not have any damage before monitoring. When the ECG cable is unplugged, the screen will display "ECG Lead Off" prompt, and trigger an audible and visual alarm.

7.3.2 Selecting lead

- Select the ECG parameter area or wave area → "ECG Setup" menu.
- Select "Other Setup >>"→ "ECG Other Setup" menu.
- Select "Lead Type", and select the ECG lead as needed.
  - "3-Lead": 3-lead; ECG wave options: I, II, III.
  - "5-Lead": 5-lead; ECG wave options: I, II, III, AVR, AVL, AVF, V.

7.3.3 Lead name and corresponding color

The lead names in European standard and U.S. standard (represented with R, L, N, F, C in European Standard, and represented with RA, LA, RL, LL, V in the U.S. standard) are shown in Table 9 -1.

Table 7-1: Lead Name in European Standard and American Standard

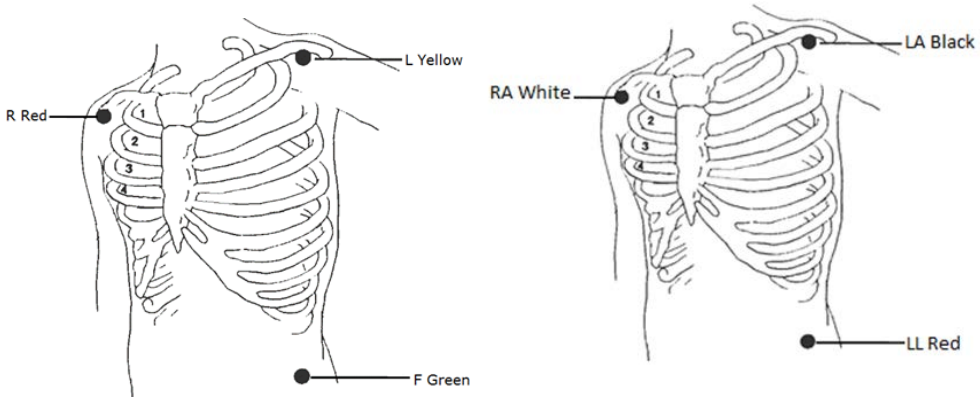
European Standard (EN)		American Standard (AHA)	
Lead Name	**Color**	**Lead Name**	**Color**
R	Red	RA	White
L	Yellow	LA	Black
F	Green	LL	Red
N	Black	RL	Green
C	White	V	Brown

7.3.4 Installing the electrodes

- 3-lead

The electrode placement position of 3-lead is shown in Fig. 7-1.

- R/RA electrode: placed below the clavicle, near the right shoulder.
- L/LA electrode: placed below the clavicle, near the left shoulder.
- F/LL electrode: placed on the left abdomen.



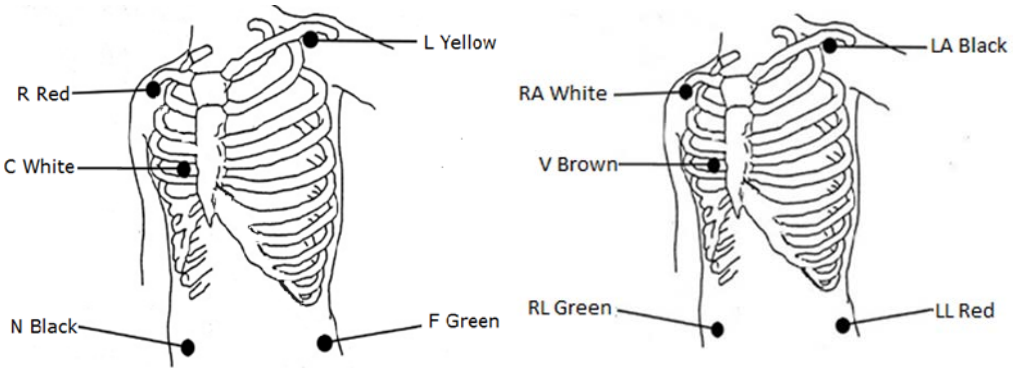
European Standard American Standard

Figure 7-1: 3-Lead placement method

➢ 5-lead

The electrode placement position of 5-lead is shown in Fig. 9-2:

- R/RA electrode: placed below the clavicle, near the right shoulder.
- L/LA electrode: placed below the clavicle, near the left shoulder.
- N/RL electrode: placed on the right abdomen.
- F/LL electrode: placed on the left abdomen.
- C/V electrode: placed on the chest wall.



European Standard American Standard

Figure 7-2: 5-Lead placement method

NOTE

- To ensure the patient safety, all leads must be connected to the patient.
- If the electrodes are attached correctly, but the ECG wave is not accurate, then replace the lead.
- Interference from ungrounded instrument near the patient and ESU may cause waveform problem.

7.3.5 Checking the pacemaker

Before ECG monitoring, it is very important to set the pace maker state of the patient properly. If the patient has a pacemaker, set “Pace Maker” to “Yes”, and the icon  displays in the patient information area. When the system detects a pacing signal, the “ | ”symbol will be marked in the top of the ECG wave.

You can change the pacing state in the following method:

- Select the patient information area to pop up the “Patient Info” menu, or select the  [Pat. Sat] smart hotkey and select “Patient Info” menu.
- Select “Yes” / “No” for “Pace Maker” as needed, indicating that the patient with or without pacemaker.

Diagnostic, Monitor, Surgery will not affect rejection of pacemaker pulses.

WARNING

- For patients with pacemakers, the cardio tachometer may count the pacemaker pulse in case of a cardiac arrest or arrhythmias. Never rely solely on the cardio tachometer alarm. Closely monitor the patients with pacemaker. For the inhibition of the device on pacemaker, refers to this manual.

7.4 ECG display

➢ **ECG wave display**

The monitor displays two ECG waves on the normal screen. Fig. 7-3 below is the monitoring interface of 5-lead, and is for reference purposes only. The graphics displayed on your monitor may be slightly different.

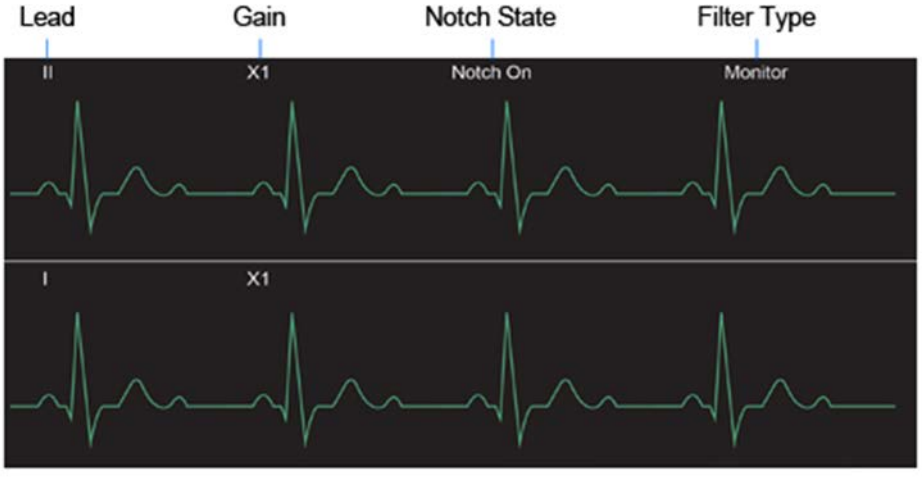


Figure 7-3: ECG wave in normal display format

In addition, when “Pace Maker” is set to “Yes”, and the patient wears a pacemaker, the “ | ”symbol will be marked in the top of the ECG wave.

➢ **ECG parameter display**

The ECG parameter area of the monitor in the normal screen is shown in Fig. 9-4:

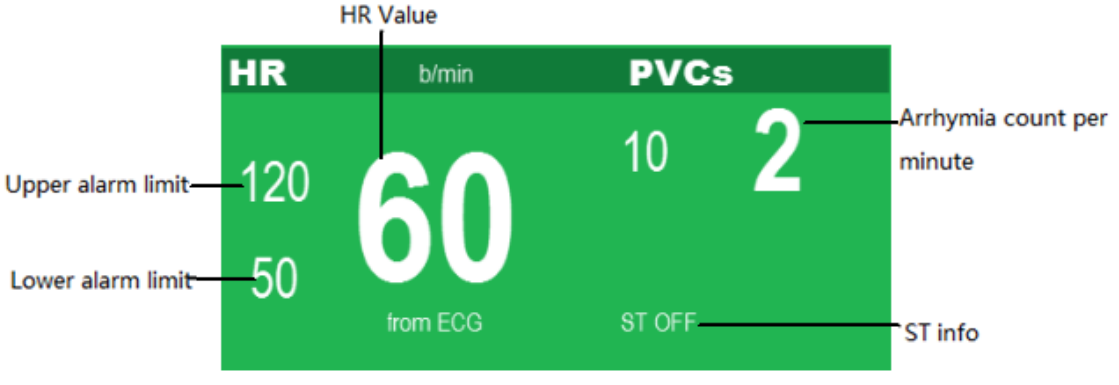


Figure 7-4: ECG parameter in standard display format

7.5 ECG setup

Select the ECG parameter area or wave ECG area or select the [Settings] smart hotkey and “Parameter Setup >>” and “ECG Setup >>” to pop up the “ECG Setup” menu, which is as shown below. You can set the ECG through the “ECG Setup” menu.

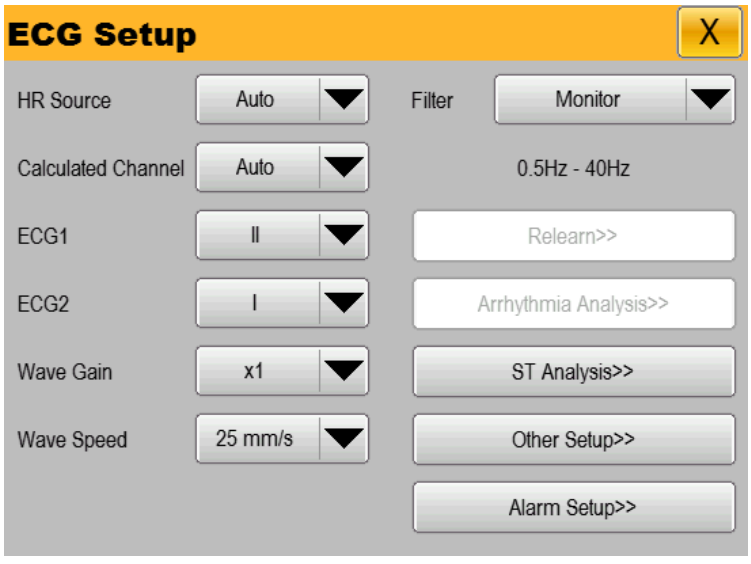


Figure 7-5: “ECG Setup” menu

- Select “HR Source”, and set the heart rate source.
  - “Auto”: Automatically select HR source.
  - “ECG”: Select ECG monitoring as the HR source.
  - “SpO2”: Select SpO2 monitoring as the HR source.
- Select “Calculated Channel” and select heart rate calculated channel.
  - “Auto”: Automatically select Heart Rate calculated Channel.
  - “I”: Select the first ECG waveform as the Heart Rate calculated Channel.
  - “II”: Select the second ECG waveform as the Heart Rate calculated Channel.
  - “V”: Select the third ECG waveform as the Heart Rate calculated Channel.
- Select “ECG1” / “ECG2” to set the display wave channel. Select “ECG1”/ “ECG2”, and set the names of upper ECG wave and lower ECG wave on the screen.
  - ECG1/ECG2 should not be the source of the same wave, source waveform can be set I/II/III/AVR/AVL/AVF/V.
- Select “Wave Gain”, and set the ECG wave gain. When the wave is shorter, increase the

wave gain factor appropriately; when the wave is high or the peak cannot be displayed, reduce the wave gain appropriately, gain can be set Auto/×0.25/×0.5/×1/×2. When Big ECG interface is selected, gain can be set Auto/×0.25/×0.5/×1/×2/×4.

- Select “Wave Speed”, and set the wave speed. The wave speed is “12.5mm/s”/“25mm/s”/“50mm/s”. The default is 25mm/s.
- Select “Filter”, and set the filter mode:
  - “Diagnostic”: Diagnostic mode
  - “Monitor”: Monitor mode
  - “Surgery”: Surgery mode
- Select “Arrhythmia Analysis>>”, and set the alarm switch, alarm level, alarm record.
- Select “ST Analysis>>”, and set the ST analysis, ST Channel, ST Alarm Setup.
  - “ST analysis”: You can set “Off” or “On”.
  - “ST Channel”: You can set “1”, “2”, “3”.
  - “ST Alarm Setup”: and set the alarm switch, alarm level, alarm record.
- Select “Other Setup>>”, and set the QRS Volume, Lead Type , Notch Filter, Pace Maker.

7.6 Alarm setup

Select “Alarm Setup >>”→ “Alarm Setup” interface to set ECG related alarms; see 6.5 Alarm Setup for the setting method.

8 RESP

8.1 Overview

Thoracic electrical bio impedance is a method used for measuring the respiration. When the patient is breathing, the thoracic impedance between two ECG electrodes changes due to thoracic activity. The monitor generates a respiratory wave on the screen by measuring the changing impedance value. The monitor calculates the respiration rate (RR) according to the wave cycle.

8.2 Safety information

NOTE

- Respiration monitoring does not apply to patient with large range of activities, as this may lead to false alarm.

⚠ **WARNING**

- Do not use anti-electric knife ECG cable for respiration monitoring.
- Respiration measurement cannot identify the apnea because it will alarm if the next respiration is not detected in the predetermined period after last respiration, and therefore it cannot be used for diagnostic purpose.

8.3 Placing electrodes for respiration monitoring

Since the skin is a poor conductor, it is very important to treat the patient's skin for electrode placement appropriately to get better respiration signals. Refer to 7.3.1.

Respiration measurement uses standard ECG cable and electrode placement method. You can use different ECG cables (3-lead or 5-lead). Respiratory signal is measured between two ECG electrodes. If standard ECG electrode position is used, the two electrodes are R (right arm) and L (left arm) electrodes of I lead or R (right arm) and F (left leg) electrode of II lead.

NOTE

- For optimal respiration wave, R and L electrodes should be placed horizontally if I lead is selected for respiration measurement. R and F electrodes should be places diagonally if II lead is selected for respiration measurement.

Figure 8-1 below shows the placement of 5-lead electrodes.

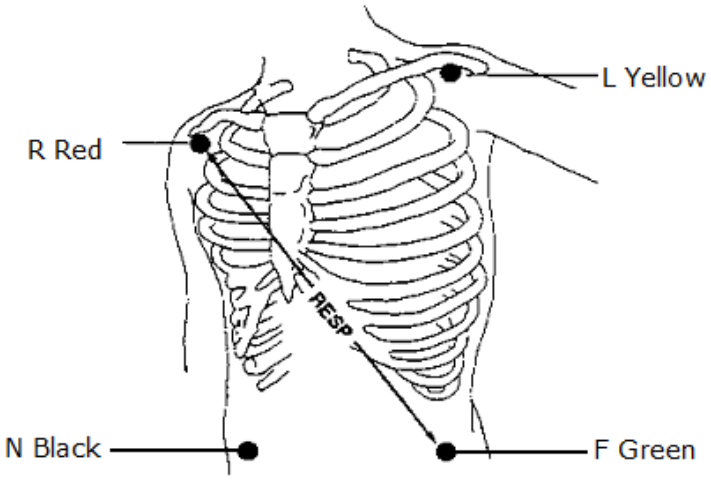


Figure 8-1: 5-lead respiration electrode placement

8.3.1 Adjusting position of respiration electrode

If you want to measure ECG and respiration simultaneously, you may need to adjust the position of the two electrodes for respiration measurement.

NOTE

- Adjusting the standard position of ECG electrodes will lead to changes in the ECG wave, and may affect the ST and arrhythmia analysis.

8.3.2 Cardiomotility superimpose

The effect of cardiomotility on the respiratory wave is called cardiomotility superimposing. When the respiration electrodes collect impedance changes caused by rhythmic blood flow, this will happen. Placing the respiration electrodes correctly will reduce this effect. The liver and ventricle should avoid the connection of respiration electrode, so that the heart or pulsating flow won't generate artifact.

8.4 Respiration display

Respiration wave is displayed as shown in Figure 8-2.

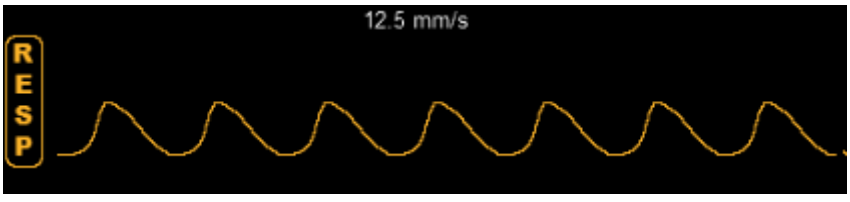


Figure 8-2: Respiration wave

Respiration parameters are displayed as shown in Figure 10-3.

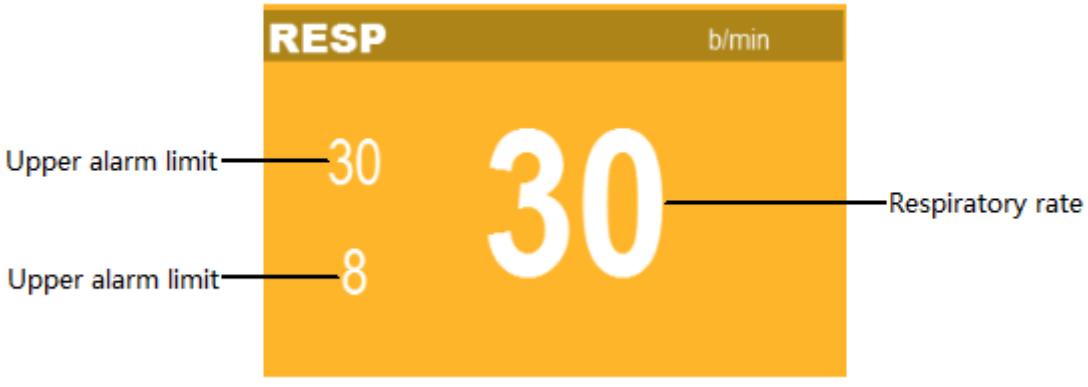


Figure 8-3: Respiration parameter display

8.5 Respiration setup

Select the RESP parameter zone or respiration wave area → “RESP Setup” menu, which is shown below. You can set respiration through “RESP Setup” menu.

Figure 8-4: “RESP Setup” menu

8.5.1 Setting apnea time

Apnea alarm is a high level alarm for monitoring the apnea. In “RESP Setup” menu, set “Apnea Delay” to an appropriate value and set the apnea alarm time. When the apnea time of the patient is longer than the set time, the monitor will trigger an alarm. Set time can be set“20s” / “25s” / “30s” / “35s” / “40s” /“45s” /“50s” /“55s” /“60s”, default apnea alarm time is 20s.

8.5.2 Adjusting wave gain

In “RESP Setup” menu, select “Wave Gain”, and set the wave gain: the greater gain, the higher wave amplitude. Gain can be set “x0.5” / “x1” / “x2”,the default is “x1”.

8.5.3 Setting sweep speed

In “RESP Setup” menu, select “Wave speed”, and set the sweep speed: the faster sweep speed, the smoother wave. The wave speed is “6.25mm/s” / “12.5mm/s” / “25mm/s”. The default is “12.5mm/s”.

8.5.4 Setting calculated channel

In “RESP Setup” menu, select “Calculated Channel”, and set the calculated channel. The calculated channels are “RA-LA”, “RA-LL”, “LA-RL” and “LL-RL”. The default is “RA-LA”.

8.5.5 Setting sensitivity

In “RESP Setup” menu, select “sensitivity”, and set the sensitivity. The sensitivity is “1” / “2” / “3” / “4” / “5”. The default is “2”.

8.6 Alarm setup

Select “Alarm Setup >>”→ “Alarm Setup” interface to set respiration related alarms; see 6.5 Alarm Setup for the setting method.

9 PR

9.1 Overview

The mechanical activity of the heart causes arterial pulsation, and PR (pulse rate) value can be obtained by measuring this pulsation. PR value can be obtained through SpO_2 measurement.

The average calculation of the heart rate is the direct average method. The refresh rate is every 1 second.

9.2 Display

The color of PR parameter area is same as SpO_2 parameter color of PR source, as shown in Fig. 9-1:

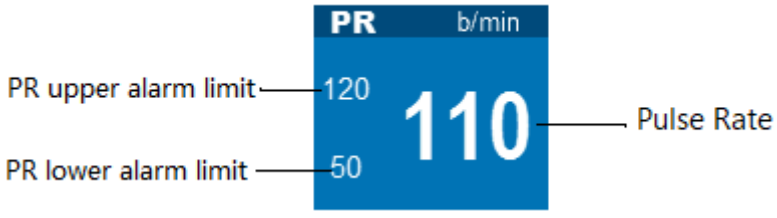


Figure 9-1: PR parameter display

9.3 Setting PR sound

Select SpO_2 parameter area or SpO_2 wave area → "SpO_2 Setup" menu;

Select "Pulse Volume" to set "Pulse Volume" to 0~9. Select 0 to turn off the pulse volume, and select 9 to set the maximum volume.

NOTE

- HR sound has higher priority than PR sound. When HR makes a sound, PR won't. When HR sound set to 0, PR can make a sound.

9.4 Alarm setup

Select PR parameter area → "SpO_2 Setup" menu → "Alarm Setup >>" to enter the "Alarm Setup" interface, and set PR alarm switch, alarm level and upper/lower alarm limit. See 6.5 Alarm Setup for detailed setting method.

10 SpO_2

10.1 Overview

Blood oxygen saturation (SpO_2) is the percentage of oxyhemoglobin (HbO2) capacity bound by oxygen in the blood in the total hemoglobin (Hb) capacity that can be combined, that is, the concentration of oxygen in the blood.

The principle for monitoring the pulse SpO_2 is to fix the probe fingerstall on the patient's finger or toe, use the finger (or toe) as a transparent container for hemoglobin, use 660nm wavelength red light and 950nm near-infrared light as the incident light, maximum output power is 300 mW, measure the light transmission intensity through the tissue bed, and calculate the concentration of hemoglobin and SpO_2.

The passing lights depend on a variety of factors, most of which are constant. However, one of these factors, the arterial blood flow, changes with time, as it is pulsating. By measuring the light absorbed during pulsating, it is possible to obtain the arterial blood SpO_2. Detection pulsation can give a "plethysmography" wave and pulse rate signal.

The main screen displays "SpO_2" value and "plethysmography" wave.

This monitor applies to measure SpO_2 of adults (>18 years) and pediatric (<18 years,>30 days). Contact SpO_2 probe to Patient's finger (or toe) to get "SpO_2" value and "plethysmography" wave.

SpO_2 function of this monitor has been calibrated in factory.

The monitor is defibrillation proof, so the monitor operates normally after defibrillation.

10.2 Safety information

⚠ WARNING

- Please use SpO2 sensor specified in this Manual, operate in accordance with the Manual, and observe all warnings and precautions.
- Before monitoring, check whether the sensor cable is normal. When SpO2 sensor cable is unplugged from the socket, the screen will display "SpO2 Sensor Off" error message, and trigger an audible and visual alarm simultaneously.
- If the sensor or sensor packaging has signs of damage, do not use this SpO2 sensor; return it to the manufacturer.
- If there is carboxyhemoglobin, methemoglobin or dye diluted chemical, the SpO2 value will have deviation.
- When the patient has a tendency to hypoxia, use the oximeter to analyze blood samples in order to fully grasp the patient's condition.

- Do not put the sensor on limbs with arterial duct or intravenous tube.
- Do not intertwine electrosurgical equipment cable with the sensor cable.
- Avoid using the monitor and sensors while using the NMR equipment, in order to avoid severe burns to the patient as a result of induced currents.
- During long time continuous monitoring of a patient, check the position of SpO2 sensor once every 2 hours, and move properly when the skin changes or every four hours. Some patients may require more frequent inspection, such as patients with perfusion disorders or sensitive skin, because persistent and prolonged monitoring may increase unpredictable skin changes, such as allergies, redness, blistering or pressure necrosis.
- When the measured pulse rate is not complete, then the "---".
- Before using, verify compatibility between the monitor, probe and cable, otherwise it may cause injury to the patient.
- Functional testers cannot be used to evaluate the accuracy of pulse oximetry and pulse oximetry.
- SpO2 low alarm limit cannot be less than 85.

NOTE

- Do not put the oxygen probe and blood pressure cuff on the same limb, because blood flow occlusion during blood pressure measurement will affect the SpO_2 readings.
- The monitor cannot be used to verify the accuracy of SpO_2 probe and SpO_2 equipment.

10.3 Monitoring steps

1. Select the appropriate SpO_2 sensor according to the patient.
2. Turn on the monitor, and connect the SpO_2 lead wire to the monitor.
3. Clean the measurement site, such as finger with nail polish.
4. Put the SpO_2 sensor probe on the patient's body.
5. Select the appropriate alarm settings.
6. Start monitoring.

NOTE

- Turn on the monitor, plug in SpO_2 probe and connect patient's finger (or toe), monitor displays SpO_2 wave, "SpO_2 Pulse Search" displayed in the technical alarm area until the monitor measured SpO_2 value and pulse rate. "SpO_2 Search Timeout" displayed in the technical alarm area until the monitor measured pulse rate. Check the sensor mounting position, whether the sensor is damaged or sensor type. Reconnect the sensor or use new sensor.

10.4 Display

SpO2 parameter area is as shown in figure 10-1.

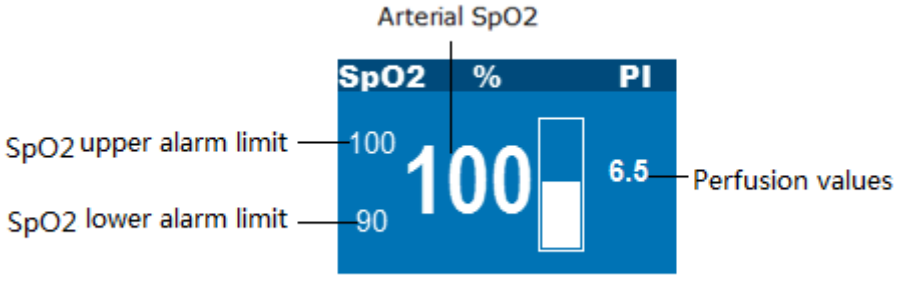


Figure 10-1: SpO_2 parameter display

SpO2 wave is as shown in figure 10-2.

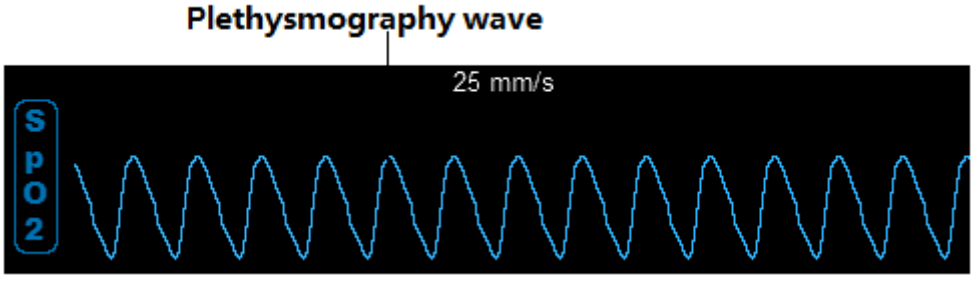


Figure 10-2: SpO_2 wave

10.5 Setting SpO_2

Select SpO_2 parameter area or SpO_2 wave area → "SpO_2 Setup" menu, which is shown below. You can set SpO_2 through "SpO_2 Setup" menu.

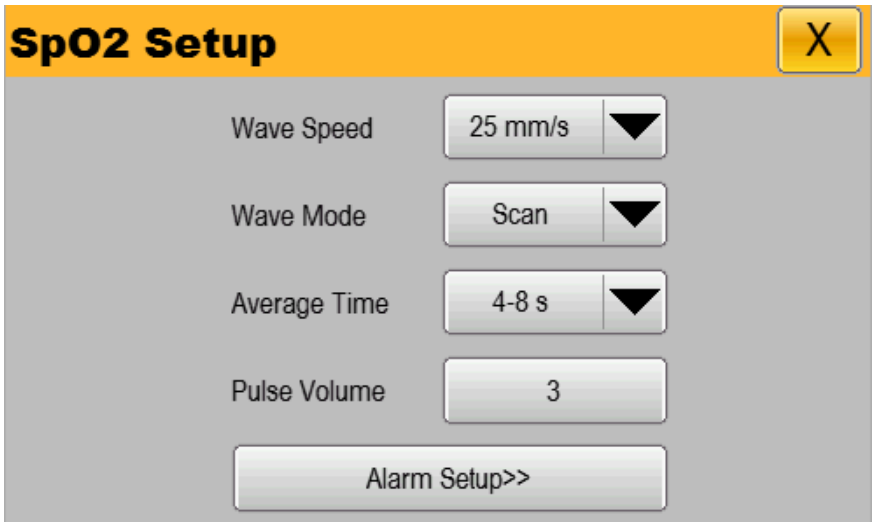


Figure 10-3: "SpO2 Setup" menu

10.5.1 Setting wave speed

- Select "Wave Speed" and set wave speed to "12.5mm/s" or "25mm/s"; the faster speed, the smoother wave.

10.5.2 Setting wave mode

- Select "Wave Mode", and set the wave drawing mode
  - "Scan": Scan mode.
  - "Fill": Fill mode.

10.5.3 Setting average time

- Select "Average Time", and set the average time to "2-4s", "4-8s" , "8-16s".

10.5.4 Pulse volume

- The user can set the pulse volume. The pulse volume can be set to 0, 1, 2, 3, 4, 5, 6, 7, 8, or 9. By default, the pulse volume is set to 3.

10.6 Measuring influencing factors

During operation, the following factors can affect the accuracy of SpO_2 measurement:

- High-frequency radio wave interference, such as interference generated by the host system or interference from electrosurgery instrument connected to the system.
- Intravenous dye.
- Too frequent movement of the patient.
- External light radiation.
- Sensor is improperly installed or improperly in contact with the patient.
- Sensor temperature.
- The sensor is placed on limbs with blood pressure cuff, arterial duct or lumen tube.
- Concentration of non-functional hemoglobin such as carboxyhemoglobin (COHb) and methemoglobin (MetHb).
- Shock, anemia, hypothermia, and the application of vasoconstrictor drugs may reduce the arterial blood flow to a level that cannot be measured.
- The measurement also depends on the absorption of specific wavelengths of light by oxyhemoglobin and reduced hemoglobin. If there is any other substance that absorbs the same wavelength, the measurement may have false or low SpO_2 values, such as: carbon hemoglobin, methemoglobin, methylene blue, and indigo carmine.
- SpO_2 probe described in Annex is recommended.
- Operating environment limit: Operating temperature range: 5 ~ 40℃, Humidity range:30%~85% (non-condensing) Atmospheric pressure: 700hPa ~ 1060hPa.

10.7 Alarm setup

In "SpO_2 Setup" menu, select "Alarm Setup >>" to enter "Alarm Setup" interface, and set SpO_2 alarm switch, alarm level, upper and lower alarm limit. See 6.5 Alarm Setup for detailed setting method.

10.8 Technical description

- Accessories have passed the biocompatibility test and meet the requirements of ISO 10993-1.
- Fluke's index 2XL Oxygen Analyzer can be used to check the function of the monitor and can be used to assess the accuracy of the pulse rate but cannot be used to assess the accuracy of blood oxygen.
- Functional testers cannot be used to evaluate the accuracy of pulse oximetry probe and pulse oximetry.
- Measure the maximum temperature between the oxygen probe and the tissue contact surface：Measured as described in Annex BB of ISO 80601-2-61,the temperature is less than 41 ° C.

11 NIBP

11.1 Overview

The monitor uses oscillometric method to measure noninvasive blood pressure (NIBP).

The oscillometric method for measuring blood pressure is to inflate a cuff with a certain amount of pressure until the arterial blood flow has been completely blocked. As applied pressure decreases, the arterial blood flow which was completely occluded gradually opened, and completely opened. Then, the pulsation of the arterial vascular wall will generate a shock wave in the cuff. SBP, MAP, and DBP are obtained by measuring and analyzing cuff pressure oscillations when deflating.

- Produce first most clear signal - reflect SBP
- Oscillation amplitude reaches the peak - reflect MAP
- When the cuff pressure is suddenly lowered - reflect DBP

Measuring mode: manual, cycle, and continuous. Each mode shows systolic, mean and diastolic blood pressure.

- Manual mode

  Using Manual mode start to measures by hand

- Automatic mode measures

  Use manual mode to open automatic mode, then the measure will automatically turn to automatic mode after a certain time. During measurement, any error will stop the current automatic measurement, but not affect next automatic measurement unless the time interval less than 30s. If the time interval less than 30s, should delay the next automatic measurement, keep the interval more than 30s.

  The time interval can be choose In Automatic mode as 1, 2, 3, 4, 5, 10, 15, 30, 60, 90, 120, 180, 240, 480 minutes.

- Continuous mode

  Choose continuous mode, 5 seconds after complete a measurement start the next measurement, continue 5 minutes then stop. During measurement, any error will stop the continuous measurement. If the first measurement time is over 4 minutes and 40 seconds but less than 5 minutes, the continuous mode will stop before 5 minutes, if the first measurement time is over 5 minutes, the continuous mode will stop after 5 minutes.

The monitor is defibrillation proof, so the monitor operates normally after defibrillation.

11.2 Safety information

⚠ WARNING

- Do not carry out non-invasive blood pressure measurement on patients with sickle cell disease and skin damage or any expected damage. Do not measure NIBP on traumatic body part. This may cause further injury.
- When pediatric patients are measured, in order to ensure the cuff pressure does not exceed its maximum measurement range of patient types (Adult mode: 300mmHg and Pediatric mode: 240mmHg), you must ensure that you have selected the correct patient type (see patient information menu settings). Using the wrong type of pattern is likely to endanger the patient to patient safety, as higher blood pressure levels for adults does not apply to pediatric.
- For patients with severe coagulation disorder, determine if the automatic blood pressure measurement is carried out according to the clinical evaluation, since the friction of body and cuff may produce hematoma.
- Do not install a cuff on the limbs with intravenous infusion or duct, because it may lead to tissue damage around the duct when the cuff is inflated and makes the infusion slow down or be blocked.
- The inflatable tube connecting the blood pressure cuff and the monitor should be smooth without entanglement. The pressure generated by being kinked connection tubing may cause blood flow interference.
- For patients with severe thrombotic disorders, determine whether to carry out automatic blood pressure measurement according to the clinical situations, since the limb bundled with a cuff may produce hematoma.
- Measure blood pressure frequently will affect the distribution of blood flow, May endanger the safety of patients.
- Check the patient's physiological condition before measure blood pressure, in order to ensure that long time measure will not damage the circulation of patients
- For mastectomy patients, applying the NIBP cuff on the surgery side arm can cause lymphedema. Measure blood pressure on opposite side arm.
- Pressurization of the cuff can temporarily cause loss of function of simultaneously used monitoring device on the same limb.
- Measurement results may be affected by posture and mental state of the patient.
- If there are doubts on the measurement results, please use other blood pressure measurements and compare, if necessary, contact the Equipment Division.

11.3 Measurement limits

According to the patient's condition, the oscillometric method has some limitations. This measurement is to look for the regular pulse waves generated by arterial pressure. If the patient's condition makes this detection method difficult, the measured value becomes unreliable, and pressure measurement time increases. The user should be aware that the following conditions may interfere with measurement method, making the pressure measurement unreliable or extend the time. In this case, the patient's condition does not allow measurement.

- Patient movement

  If the patient is talking, moving, shaking or cramping, the measurement will be unreliable or even impossible, as these may interfere with the detection of arterial pressure pulse, and extend the pressure measurement time.

- Arrhythmia

  If the patient shows arrhythmia which results in irregular heartbeat, the measurement will be unreliable and even cannot be done, and the pressure measurement time will be extended.

- Use of an artificial heart-lung machine

  If a patient is connected to an artificial heart-lung machine, the measurement will be impossible.

- Pressure changes

  If the arterial pressure pulse is being analyzed to obtain a measured value at a certain time and the blood pressure of the patient changes rapidly, the measurement will be unreliable or impossible.

- Severe shock

  If the patient is in severe shock or hypothermia, the pressure measurement will not be reliable, because the decrease of blood flow to the periphery would cause decrease in arterial pulsation.

- Limit heart rate

  If the heart rate is below 40bpm (beats / min) or above 240bpm (beats / min), the blood pressure measurement is impossible.

- Obese patients

  A thick layer of fat around a limb blocks the arterial oscillation so that it cannot reach the cuff. The accuracy is lower than normal.

- Environmental Requirements

  Measuring blood pressure should meet the environment range as follow:

ambient humidity 30% ~ 85%, no condensing,

ambient temperature 5 ~ 40℃,

Atmospheric pressure: 700hPa ~ 1060hPa.

NIBP performance and measurement accuracy will be affected beyond the range.

11.4 Measurement procedure

11.4.1 Prepare the measurement

1. Turn on the monitor, and check if it works properly.
2. Verify the patient category, and make changes if improper. Depending on the current patient type, the patient type is selected in the patient information interface.
3. Connect the blood pressure cuff extension tube to the monitor.
4. Select the cuff in accordance with the following method, make sure that the cuff is completely deflated, and then tie it to the upper arm or thigh of the patient.
   - Determine the limb circumference of the patient.
   - Select the appropriate cuff (marked with appropriate limb circumference). Cuff width should be 40% of the limb circumference or 2/3 of the upper arm length. The length of the inflated part of the cuff should be sufficient for 50%~80% around the limb.
   - Place the cuff on the upper arm or thigh of the patient, and ensure that the marking ϕ is located just above the appropriate artery. Make sure that the cuff does not wrap too tight around the limb, or it may cause distal discoloration or even ischemia.

11.4.2 Patient posture requirements during measurement

1. Sit comfortable or lie down relaxedly.
2. No crossing legs.
3. Back and elbow should be supported.
4. The center of NIBP cuff and the right atrium are at in the same level.
5. Remind patients, no talking during measurement and try to relax.

NOTE

- When have doubt about blood pressure measuring result, re-measure after the patient sit-in about 5 minutes. If still have doubt, replace the blood pressure measuring equipment and measure again.
- The operator should be in the position where he/she can readily operate the sphygmomanometer.

11.4.3 Start/stop measurement

Use the  [NIBP start/stop] key on the monitor panel or  [NIBP] smart hotkey on the display to start / stop the blood pressure measurement.

11.4.4 Correcting measurement results

The position of limb blood pressure measurement should be in the same horizontal position of the patient's heart. Otherwise, correct the measurement results with the following correction method.

- If the cuff is above the heart level position, increase 0.75mmHg (0.10kPa) per centimeter of gap to the measured results.
- If the cuff is below the heart level position, subtract 0.75mmHg (0.10kPa) per centimeter of gap from the measured results.
- If the patient is obese or clothes are too thick, subtract 5mmHg ~ 10mmHg (0.65kPa ~ 1.3kPa) from the measured results.

11.5 NIBP display

NIBP measurement has no waveform display, and only displays NIBP measurement results in the parameter area, as shown in Fig. 11-1. The figure below is for reference only. The graphics displayed on the monitor may be slightly different.

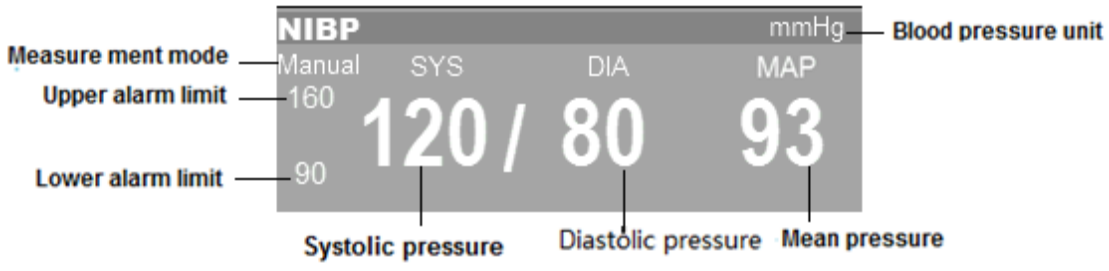


Figure 11-1: NIBP parameter display

11.6 Setting inflation pressure

If necessary, you can manually set the initial cuff inflation pressure as follows.

- Select the NIBP parameter area → “NIBP Setup” menu;
- Select “Initial Pressure”, and set the appropriate cuff pressure value. When the patient is adult, the pressure can be select from “140”, ”160” , ”180”. The default cuff pressure value is “160”.
- Select “Initial pressure”, and set the appropriate cuff pressure value. When the patient is pediatric, the pressure can be select from “140”, ”160”. The default cuff pressure value is “140”.

11.7 NIBP reset

Select NIBP parameter area → “NIBP Setup” menu → Select “Reset”, and restore the inflation pressure of the blood pressure pump to currently configured initial settings. When the blood pressure pump is not working properly, but no warning is given, you can reset the blood pressure pump, and automatically restores the blood pressure pump.

11.8 Clean and disinfection method of NIBP cuff

If necessary, NIBP cuff and NIBP extension tube can be cleaned and disinfected together without separated

11.8.1 Cleaning method

1. Prepare enzyme cleaning agent, distilled water and 10% solvent, respectively in different spray bottle.
2. Sprinkle cleaning agent on NIBP cuff, connector and extension tube, keep 1 minute for the dry stains.
3. Use a soft cloth to wipe smooth face. Use soft hair brush to brush visible stain and irregular surface
4. Rinsed with copious amounts of distilled water.

NOTE

- Please be especially careful to clean the air ball and control valve of whole air system. Do not allow any liquid entering into reversing valve and saturated valve.
- Don’t use a soft cotton ball and fiber to clean this accessory because they will stick on the cuff and extension tube.

11.8.2 Disinfection method

1. Sprinkle bleach solution (Formula: the proportion of water and bleaching powder to 1:10) then keep 5 minutes
2. Wipe off excess bleach solution and elute with distilled water again
3. Natural dry cuff

11.9 Alarm setup

In “NIBP Setup” menu, select “Alarm Setup >>” to enter “Alarm Setup” interface, and set NIBP alarm switch, alarm level, upper and lower alarm limit. See 6.5 Alarm Setup for detailed setting method.

12 TEMP

12.1 Overview

The monitor has two temperature measurement channels; the temperature sensor will measure the body temperature, and calculate the difference between the body temperature data.

The monitor is designed for defibrillation proof, so the monitor operates normally after defibrillation.

12.2 Safety information

⚠ WARNING

- Before monitoring, check if the probe cable is normal. Unplug the temperature probe cable from the jack, the screen will display “TEMP1 Sensor Off” and “TEMP2 Sensor Off” prompt and make an alarm sound.
- Calibrate the temperature measuring instrument at least once every two years (or according to hospital procedures). When calibration is required, please contact Bistos.

12.3 Measurement steps

Please refer to the following steps:

1. Turn on the monitor and check if it works normally.
2. Select the appropriate temperature probe according to the patient category and measurement needs.
3. Insert the probe lead wire into the temperature probe interface.
4. Attach the probe to the patient properly.
5. Make sure that the alarm settings apply to the patient.

When measuring body temperature, temperature probe can be attached to body surface such as the neck, armpits, ears and other locations.

12.4 Measurement requirements

The normal measuring range of monitor is 0℃~50℃, and the accuracy is consistent in this range.

The environmental temperature range for body temperature measuring is 5℃~40℃. Get the right temperatures for the shortest measurement time is 40s, and the measuring interval is 1s.

⚠ WARNING

- Please measure the body temperature in the specified environment temperature range, or else it may be dangerous.

12.5 Temperature display

The monitor can display the body temperature of two channels (T1 and T2) and the alarm limits, difference between the two temperature (TD) and temperature units. Select Temp parameter area and open the [Temp Setup] menu.

Temperature display area is as shown below:

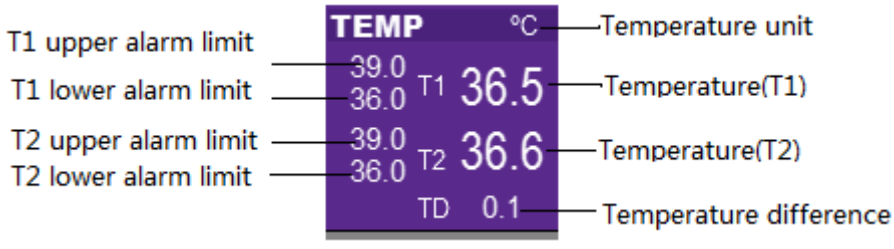


Figure 12-1: TEMP parameter display

⚠ WARNING

- The operator, prior to use, need to check the compatibility of the probe and thermometer. If the temperature value displayed by the monitor has significant difference from the body temperature under normal condition, please check if the probe resistance of the monitor matches the resistance set in the monitor system; if not, please replace a probe with appropriate resistance or adjust the monitor and select the appropriate resistance. Incompatible probe will affect the critical properties.

12.6 Setting temperature unit

-You can define your favorite temperature unit as follows:

- Select TEMP parameter area → “TEMP Setup” menu.

In the “TEMP Setup” menu, set “Unit” to “℃” or “℉”

12.7 Alarm setup

In “TEMP Setup” menu, select “Alarm Setup >>” to enter “Alarm Setup” interface, and set TEMP alarm switch, alarm level, upper and lower alarm limit. See 6.5 Alarm Setup for detailed setting method.

12.8 Technical description

Accessories have passed the biocompatibility test and meet the requirements of ISO 10993-1.

13 Review

The monitor provides up to 168 hours trend data review of all monitoring parameters, 1000 groups of NIBP measurement data and 200 physiological alarm events, 100 technical alarm events. The user can select trend chart or trend table to view trend change; or view the latest wave.

13.1 Reviewing trend chart

Select [Trend] smart hotkey to enter [Trend] menu, and select [Graphic] to enter the following window.

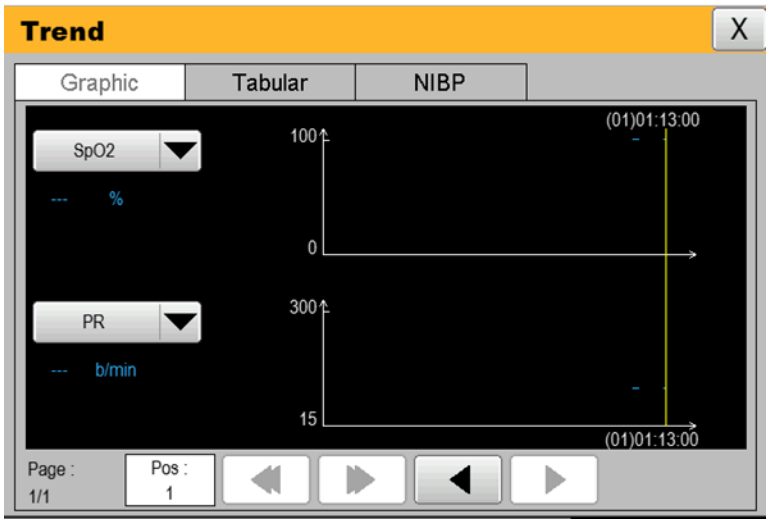


Figure 13-1: Trend chart

- In the trend chart, use the following method to select the parameter to be reviewed:
  - Select the parameter box, rotate the shuttle to select the parameters to be reviewed, press the shuttle, and set the parameter box as the parameter to be reviewed.
- Browse the trend chart in the following method:
  - Select and to move the trend cursor.
  - Select and to turn pages to left or right and move the trend chart.
  - The cursor top displays the current time corresponding to the current cursor position, and the left of the trend chart window displays the parameter values of the time, which will change automatically with the move of trend cursor.

13.2 Reviewing trend table

Select [Trend] smart hotkey to enter “Trend” menu, select “Tabular” and enter the following window.

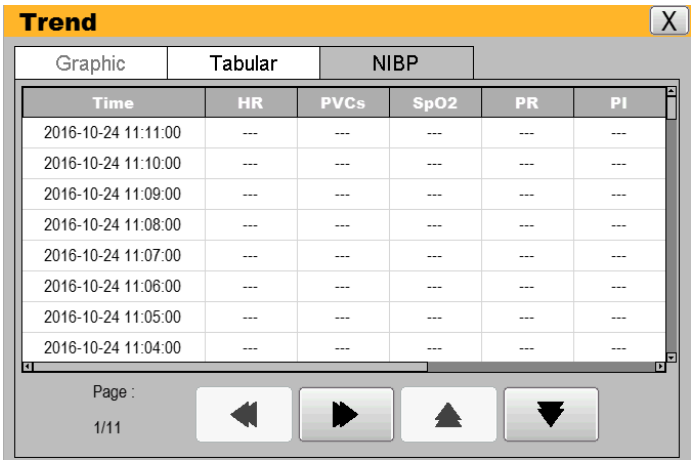


Figure 13-2: “Trend” table

- Browse the trend table in the following method:
  - Select and to turn pages to left or right and move the trend table to observe the target parameters.
  - Select and to turn pages up or down and move the trend table to observe more data.

13.3 NIBP measurement review

Select 【Trend】 smart hotkey to enter “Trend” menu, and select “NIBP” to enter the following window

Figure 13-3: NIBP measurement review

This window shows the measurement time of noninvasive blood pressure, systolic blood pressure “SYS”, diastolic blood pressure “DIA”, mean blood pressure “MAP” and pulse rate “PR”. The monitor can store 1000 sets of NIBP measurements in total.

- NIBP viewing method is as follows:
  - Select and to turn pages up or down and move the trend table to observe more data.

14 Battery

14.1 Overview

The monitor has a built-in rechargeable battery to ensure that the monitor can also be used normally in case of patient transfer or power failure. When the monitor is connected to an DC power source, it will charge the battery no matter whether the monitor is turned on or not. In the case of power failure, the system will automatically use the battery to power the monitor to avoid interrupting the monitor working.

The battery icon on the screen indicates the battery status:

 Battery is working properly and is fully charged.

 Battery is working properly and the green part indicates the battery power.

 Battery power is low, and requires charging immediately, or else the pulse oximeter will turn off automatically.

 Battery is not installed.

 Battery is properly installed and being charged.

The battery power can only maintain for some time. Low battery voltage will trigger a high level technical alarm “Battery Low”; in this case, connect the monitor to DC power and charge the battery.

14.2 Battery usage guide

Battery life depends on the frequency and time of use. If the battery maintenance and storage are proper, the lithium battery life is three years. If you do not use the battery properly, its life may be shortened. It is recommended to replace the lithium battery once every three years.

In order to ensure the maximum capacity of the battery, please note the following usage guide:

- Do not drop the battery.
- Check the battery performance once every two years. Before servicing the monitor or you suspect that the battery is the fault source, also check the battery performance.

⚠ WARNING

- Keep the battery out of the reach of children.
- Use only the designated battery.
- If the battery is damaged or leaks, replace it immediately. Do not use a defective battery for the monitor.
- Do not open the battery compartment. Only the qualified service personnel authorized by the manufacturer can open the battery compartment and replace or check the battery, and when it needs replacement, the replacement should be same model with established battery.
- Do not disassemble the battery, throw it in fire, or short-circuit it. Battery fire, explosion and leakage may lead to personal injury. Do not touch the leaking battery with bare hand directly.

14.3 Checking battery performance

Please refer to the following steps to check the battery performance:

- Disconnect the monitor from the patient and stop all monitoring or measurement.
- Connect DC power to the monitor, and charge the battery for more than 4 hours uninterruptedly.
- Disconnect the DC power and power the monitor with battery until the monitor is turned off.
- Battery duration reflects the battery performance.

If the battery operating time is significantly shorter than the time stated in specifications, please contact our service personnel for replacing the battery.

⚠ WARNING

- Do not open the battery compartment. Only the qualified service personnel authorized by the manufacturer can open the battery compartment and replace or check the battery, and when it needs replacement, the replacement should be same model with established battery.

14.4 Battery recycling

If the battery has visible damage or cannot store power, it should be replaced and recycled properly. Follow the appropriate regulations to dispose of used batteries.

⚠ WARNING

- Do not disassemble the battery, throw it in fire, or short-circuit it. Battery fire, explosion and leakage may lead to personal injury. Do not touch the leaking battery with bare hand directly.

15 Caring and cleaning

15.1 Overview

In the using process, please make sure that there is no dust on or near your device. To prevent damage, please use the diluted detergents and disinfectants specified in this Manual, and use the lowest possible concentration. For the damage or accident caused by using other materials or methods, our company does not assume any responsibility.

15.2 Cleaning

The device should be cleaned regularly. In the heavily polluted environment, increase the frequency of cleaning. Before cleaning, please consult the hospital about device cleaning requirements.

Below are available cleaning agents:

- Diluted ammonia
- Diluted sodium hypochlorite (washing bleach)
- Diluted formaldehyde
- Hydrogen peroxide (3%)
- Ethanol (70%)
- Isopropanol (70%)

Before cleaning:

- Turn off the monitor and disconnect the power.
- Use a soft cotton ball to adsorb appropriate amount of cleaning agent and wipe the display screen.
- Use a soft lint-free cloth to adsorb appropriate amount of cleaning agent and wipe the surface of the device.
- If necessary, use a clean, dry, lint-free cloth to remove any excess detergent.
- Dry the device naturally in a ventilated cool environment.

⚠ **WARNING**

- Before cleaning the monitor or sensor, turn off the power and disconnect the DC power.

- The monitor should be kept clean. It is recommended to regularly clean the enclosure surface and the display screen. Cleaning the enclosure with non-etching cleaner such as soap and water.

⚠**CAUTION**

- To avoid damaging the monitor:
  - Do not use strong solvents such as acetone.
  - Most cleaners must be diluted before use. Diluting should be according to the manufacturer's instructions.
  - Do not use abrasive materials (such as steel wool).
  - Do not allow any liquid entering into the enclosure, and never immerse any part of the device into liquid.
  - Do not leave any cleaning solution on the surface of any part of the device.

NOTE

- Wipe the monitor and sensor surface with medical alcohol, dry it naturally or with clean, dry, lint-free cloth.
- Bistos is not liable for effectiveness of using these chemicals for infectious disease control. Please consult the infectious disease control officers or experts of the hospital for advice.

15.3 Disinfection

In order to avoid damage to the product, we recommend that the product is disinfected only when it is deemed necessary by the hospital maintenance procedures. We also recommend that the instrument to be disinfected must first be cleaned.

⚠**CAUTION**

- To prevent damage to the monitor, do not disinfect the monitor with gas (EtO) or formaldehyde.

16 Maintenance

⚠ WARNING

- If the hospitals or institutions using this instrument can't implement a satisfactory maintenance schedule, it will result in device failure and may endanger human health.

16.1 Checking

Check the following basic items before each using the monitor:

- Check for any mechanical damage.
- Check all exposed wires, insertions and accessories.
- Check all instrument functions that may be used for patient monitoring and ensure that the instrument is in good working condition.

If the instrument function has any sign of damage, do not use this monitor for any patient monitoring. Please contact the hospital's professional maintenance personnel or our customer service personnel.

Every 6-12 months or after each repair, a comprehensive examination must be performed by trained and qualified technical service personnel, including functional safety checks; the specific inspection items are as follows:

- Environment and power meet the requirements.
- Device and accessories have no mechanical damage.
- The power supply has no wear, and the insulation is good.
- Specified accessories are used.
- Alarm system is functioning correctly.
- Battery performance meets the requirements.
- Monitoring functions are in good working condition.
- Ground impedance and leakage current meet the requirements.

If the instrument function has any sign of damage, do not use this monitor for any patient monitoring. Please contact the hospital's professional maintenance personnel or our customer service personnel.

All checks that require disassembling the instrument must be performed by qualified service personnel. Safety and maintenance checks may also be carried out by the Company's personnel.

16.2 Viewing software version information

You can view the software version through the following steps:

- Select 【Settings】Smart Hotkey→ “Settings” Menu;
- Select “Monitor Info>>”→ “Monitor Info” menu;
- “Monitor Info” menu displays the software version information of the monitor.

16.3 Maintenance plan

The following tasks can only be done by qualified service personnel of Bistos. When the following maintenance is needed, please contact your service representative. Before testing or maintenance, clean and disinfect the device.

Inspection / Maintenance Item	Frequency
Check the safety according to IEC 60601-1	At least once every two years, after replacing the power supply or the monitor falls down.
Check all monitoring or measuring functions not listed	At least once every two years, or when you suspect that the measured value is not accurate.
NIBP leakage test	At least once every two years, or follow hospital regulations
NIBP calibration	At least once every two years, or follow hospital regulations

16.4 ECG calibration

In the process of using the monitor, the displayed ECG signals may be inaccurate due to hardware or software problems, mainly shown as waveform amplitude becoming larger or smaller. At this moment, you need to calibrate ECG.

Prepare the following instruments before testing:

- ECG simulator
- ECG cable
- Vernier caliper

The calibration method is as follows:

- Connect the ECG cable to the monitor.
- Connect the ECG electrodes to the ECG simulator.
- Select  【Settings】Smart Hotkey→ “Settings” Menu;
- Select “User Maintenance >>” →enter the password and confirm → “User Maintenance” menu.
- Select “Module Maintenance >>” → “Module Maintenance” menu.
- Select “ECG ”→ “ECG Maintenance” menu, and select “Calibration” to calibrate the ECG.
- Measure the wave amplitude with a caliper; in different filtering modes, ×0.25 is 2.5 ± 5% (mm), ×0.5 is 5.0 ±% 5 (mm), ×1 is 10.0 ±% 5 (mm), and ×2 is 20.0 ±% 5 (mm). Comparing the amplitude of the square wave with the ruler, the error range should be within 5%.
- When calibration is complete, select “Stop Calibration” to exit.

17 Accessories

⚠ WARNING

- Use the accessories specified in this manual. Using other accessories may damage the monitor, or cannot reach the safety and performance claimed in this manual.
- The operating and storage environment of the monitor should meet the requirements of the accessories. Please refer to the manual of the accessories for these requirements.
- Disposable accessories can only be used once, because repeated use can cause performance degradation.
- If the packaging or accessories have any sign of damage, do not use such accessories.
- For ECG Cables, SpO_2 Sensor, Blood Pressure Cuff and Temperature Sensor, the normal life time is two years. Please replace in time.

Standard accessories are as follows:

No.	Description	QTY	Type-number
1	ECG Cables and lead-wires ECG electrodes(5)	1	Manufacturer: Shenzhen Launch Electronics Tech CO., Ltd
			98ME01AC009(AHA standard) or 98ME01EC009(IEC standard)
2	Adult Finger Clip SpO_2 Sensor	1	Manufacturer: Unimed Medical Supplies,Inc
3	SpO2 extension cable		U403-01
4	Adult Non-Invasive blood pressure cuff	1	Manufacturer: Shenzhen Med-link Electronics Tech Co.,Ltd
			Y000A1
5	NIBP extension tube	1	Manufacturer: XIAMEN CONJOIN ELECTRONICS TECHNOLOGY CO., LTD
			CJP37-C12B1
6	Temperature Sensor	1	Manufacturer: Shenzhen taijia electronic Co., Ltd
			SPT4520010N
7	Power Adapter	1	Manufacturer: DONGGUAN SHILONG GUHUA ELECTRONIC CO., LTD
			UE36LCP1-150240SPA

18 Specifications

18.1 Safety specifications

18.1.1 Product category

In accordance with classification specified in the European Medical Device Directive 93/42/EEC, this monitor is Class IIb device. The monitor is classified as follows in accordance with IEC 60601-1:

Category Name	Specification
Type of electric shock protection	Class II and internally powered equipment When you question the integrity of the external protective earthing or protective ground conductor parameter of the equipment, the device must be powered by the internal power supply (battery).
Electric shock protection grade	Type CF applied part (defibrillation proof)
Explosion protection grade	Common equipment, no explosion protection
Liquid inlet protection grade	IPX1
Operating mode	Continuous mode
Movement	Portable equipment

18.1.2 Power

Power	
Adapter	Input: AC 100 - 240V (50/60 Hz) Output: DC 15V / 2.4A
Rechargeable Battery	11.1V Li-ion battery 4400 mA
	Operating Time(When it fully charged): 5 hours
	Charging Time(Fully): 4 hours

18.2 Hardware specifications

Physical Characteristics	
Dimensions	Main Unit: 320(W) X 250(H) X 65(D)
Weight	<= 2.8 Kg for standard configuration

Display	
Type	Color TFT touch screen LCD
Size and resolution	12”, 800 X 600 pixels

Audio	
Speaker	Alarm sound (45 ~ 85 dB), key pressing sound
	QRS sound, PR sound
	Alarm sound meet the IEC 60601-1-8 standard requirements

Alarm signal	
Alarm delay	Off, 1s, 2s, 3s, 4s, 5s, 6s, 7s, 8s, depending on the setup Default is 4s
Pause duration	1min, 2min, 3min, 4min, 5min, 10min, 15min or permanent, depending on the setup Default is 2 minutes.

Data storage	
Trend	168 hours. Resolution: 1 min
Alarm event	200 physiological alarm events, 100 technical alarm events
NIBP measurement result	1000 groups

Environment		
	Operation	**Transport and storage**
Temperature	5~ 40°C (41°F~104°F)	–20 ~ 60°C (-4°F~140°F)
Humidity	30~ 85% non-condensing	0 ~ 95 % non-condensing
Atmospheric pressure	70~106 kPa	70~106 kPa

18.3 Functional specifications

18.3.1 ECG/TEMP/RESP

ECG		
Lead Type	3 lead	I, II, III
	5 lead	I, II, III, aVR, aVL, aVF, V
Display sensitivity	Auto, 2.5mm/mV(x0.25), 5 mm/mV(x0.5), 10mm/mV(x1.0), 20mm/mV(x2.0), 40mm/mV(x4.0)	
Wave sweep speed	12.5 mm/s, 25 mm/s, 50 mm/s	
Band width	Diagnostic mode	0.05 - 100 Hz
	Monitor mode	0.5 - 40 Hz
	Surgery mode	1 - 25 Hz
CMRR	>100 dB	
Notch	50/60 Hz notch filter can be set to on or off	
Differential input impedance	> 5 MΩ	
Electrode polarization voltage range	± 400 mV	
Baseline recovery time	<5s after defibrillation (in monitor and surgery mode)	
Calibration signal	1 mV (peak – peak), accuracy ± 3%	
Lead-off detection current	Measuring electrode: < 0.1 uA Drive electrode: < 1uA	

Pacing pulse	
Pulse identification	For PACE MAKER pulses that meet the criteria below, pacing pulse will be marked on the screen. Detection range(Amplitude): ± 2 mV ~ ± 700 mV Pulse width: 0.2ms ~ 2.0 ms
Average HR	Calculate from 15s data
Interval of HR refreshing	Calculate once every second
HR change response time	Time from 80 bpm to 120 bpm: ≤ 10 sec Time from 80 bpm to 40 bpm: ≤ 10 sec
Tall T-wave suppression	For T-wave with 100ms QRS wave, 350ms QT period, 180ms duration and 1.2mV amplitude, the HR calculation will not be affected
Without overshoot rejection of pacemaker pulses	Amplitudes (ap) from ±2 mV to ±700 mV and pulse widths from 0.1 ms to 2.0 ms.
Tall T-wave rejection capability	2mV

HR		
Measuring range	Adult: 15 ~ 300 bpm Pediatric: 15 ~ 350 bpm	
Resolution	1 bpm	
Heart rate measurement error	± 1 bpm or ± 1%, whichever is greater	
Heart rate measuring accuracy and response to irregular rhythm	Ventricular bigeminy	80 ± 1 bpm
	Slow alternating ventricular bigeminy	60 ± 1 bpm
	Rapid alternating ventricular bigeminy	120 ± 1 bpm
	Bidirectional systoles	90 ± 2 bpm
Time to alarm for tachycardia	1 mV, 206 bpm Ventricular tachycardia	<10 s
	0.5 mV, 206 bpm Ventricular tachycardia	<10 s
	2 mV, 206 bpm Ventricular tachycardia	<10 s
	2 mV, 195 bpm Ventricular tachycardia	<5 s
	1 mV, 195 bpm Ventricular tachycardia	<5 s
	4 mV, 195 bpm Ventricular tachycardia	<5 s

HR Alarm	
HR upper limit	Adult: 16 ~ 300, 1 bpm step Pediatric: 16 ~ 350, 1 bpm step
HR lower limit	Adult: 15 ~ 299, 1 bpm step Pediatric: 15 ~ 349, 1 bpm step

TEMP	
Standard compliance	ISO 80601-2-56:2009
Measurement method	Thermistor
Operating mode	Direct mode
Measuring range	0 ℃ ~ 50.0 ℃ (32 ℉ ~ 122.0 ℉)
Resolution	0.1 ℃
Measurement accuracy	± 0.3 ℃
Number of channel	2

TEMP Alarm	
T1/T2 upper limit	0.1 ℃ ~ 50.0 ℃, 0.1℃/℉ step
T1/T2 lower limit	0 ℃ ~ 49.9 ℃, 0.1℃/℉ step
TD upper limit	0 ℃ ~ 50.0 ℃, 0.1℃/℉ step

RESP	
Measurement method	Thoracic electrical bio impedance method
Measuring range	Lead RA-LA, RA-LL,LA-RL,LL-RL
Wave gain	X0.5, x1, x2
Respiratory impedance range	0.2 ~ 3 Ω
Base line impedance	500 ~ 2 000 Ω
Scan speed	6.25 mm/s, 12.5 mm/s, 25 mm/s
Measurement accuracy	± 2 rpm
Measurement range	0 ~ 120 rpm

RR Alarm	
RR upper limit	Adult: 7 ~ 120 Pediatric: 7 ~ 150
RR lower limit	Adult: 6 ~ 119 Pediatric: 6 ~ 149

18.3.2 NIBP

NIBP				
Standards compliant	IEC 80601-2-30:2009/A1:2013			
Measurement method	Automatic oscillometric method			
Operating mode	Manual, automatic, continuous			
Useful life	100, 000 times			
Measurement interval in automatic mode	1/2/3/4/5/10/15/30/60/90/120/180/240/480min			
Typical measurement time	20~40s			
Normal mode measuring range (mmHg)			Adult	Pediatric
	Systolic blood pressure		40-270	40-200
	Mean blood pressure		20-230	20-175
	Diastolic blood pressure		10-210	10-162
Measurement accuracy	Maximum average error: ±5mmHg Maximum standard deviation: 8mmHg			
Resolution	1mmHg			
Initial inflation pressure		Default	Pressure setting range	
	Adult	160mmHg	140mmHg, 160mmHg, 180mmHg	
	Pediatric	140mmHg	140mmHg, 160mmHg,	
Overpressure protection point (software)	Adult: 300mmHg			
	Pediatric: 240mmHg			
Overpressure protection point (hardware)	Adult: 320~330mmHg			
	Pediatric: 265~275mmHg			
Static Pressure accuracy	±3mmHg			

NIBP Alarm			
		Adult	Pediatric
NIBP upper limit (mmHg) 1 mmHg step	SYS	31 ~ 280	31 ~ 230
	MAP	11 ~ 240	11 ~ 175
	DIA	11 ~ 220	11 ~ 165
NIBP lower limit (mmHg) 1 mmHg step	SYS	30 ~ 279	30 ~ 229
	MAP	10 ~ 239	10 ~ 174
	DIA	10 ~ 219	10 ~ 164

NIBP Electrical characteristics	
Supply voltage	10V~14V DC
Maximum power consumption	3.6w
Quiescent current	50mA
Maximum current during measurement	180mA
Maximum current during inflation	300mA

18.3.3 SpO_2

SpO_2		
Standards compliant	ISO 80601-2-61:2011	
Measurement accuracy verification The SpO_2 accuracy has been verified in human experiments by Comparing with arterial blood sample reference measured with a CO-oximeter. Pulse oximeter measurements are statistically distributed and about two-thirds of the measurements are expected to come within the specified accuracy range compared to CO- oximeter measurements. The accuracy of the oximeter has been validated by a clinical trial involving 12 healthy adult subjects - 4 women and 8 men. Among them medium skin are 4 subjects, light skin are 5 subjects, dark skin are 3 subjects, the age from 21 to 28. Overall accuracy was determined by calculating the root mean square error across all samples and is 1.56%".		
Display range	0% ~ 100%	
SpO_2 display resolution	1%	
SaO_2 checking accuracy	±2% (70%~100%); not define when lower than 70% ;	
SpO2 alarm limit range	Upper alarm limit	1%~100%
	Lower alarm limit	0%~99%
SpO_2 alerting signal generates a delay	No delay	
SpO_2 value refresh period	1s/time	
Average period	Low sensitivity	6 ~ 8s
	Intermediate sensitivity	4 ~ 6s
	Advanced sensitivity	2 ~ 4s
Alarm condition delay period	Low sensitivity	＜8s
	Intermediate sensitivity	＜6s
	Advanced sensitivity	＜4s
Alarm sign generates delay period	0s	

PR	
Measuring range	25~250bpm
Resolution	1% bpm
Accuracy	±2% or ±2bpm, whichever is greater

PR alarm	
Upper limit	Adult: 16 ~ 300 Pediatric: 16 ~ 350
Lower limit	Adult: 15 ~ 299 Pediatric: 15 ~ 349

19 Alarm information

This chapter lists some important physiological and technical alarm information, and some alarms are not necessarily listed.

Note that in this chapter: P column indicates the default alarm priority: H indicates high priority, M indicates middle priority, L indicates low priority, and "*" indicates priority set by the user.

Corresponding countermeasures are listed for each alarm message. If you operate in accordance with the countermeasures but the problem persists, contact your service personnel.

19.1 Physiological alarms

Source	Alarm message	P	Causes and countermeasures
ECG	HR Too High	M*	HR value is higher than the upper alarm limit or lower than the lower alarm limit. Check the patient's physiological condition, and check if the patient category and alarm limit settings are appropriate for the patient.
	HR Too Low		
	PVCS Too High	M*	PVCs value is higher than the upper alarm limit or lower than the lower alarm limit. Check the patient's physiological condition, and check if the patient category and alarm limit settings are appropriate for the patient.
	Asystole	H	The patient has arrhythmia. Check the patient's condition, electrodes, cables and lead wires.
	VF/VTA	H	
	R on T	M*	
	Frequent PVC	M*	
	Couplet PVC	M*	
	Single PVC	M*	
	PVC Bigeminy	M*	
	PVC Trigeminy	M*	
	Tachycardia	M*	
	Bradycardia	M*	
	Miss Beat	M*	
	Pacemaker Not Capture	H	Pacemaker works abnormally; check the pacemaker.
	Pacemaker Not work	H	
	ECG Signal weak	H	The patient ECG signal is too weak, and the system can't analyze. Check the patient's condition, electrodes, cables and leads.
	ST-I Too High	M*	ST value is higher than the upper alarm limit or
	ST-I Too Low		

Source	Alarm message	P	Causes and countermeasures
	ST-II Too High		lower than the lower alarm limit. Check the patient's physiological condition, and check if the patient category and alarm limit settings are appropriate for the patient.
	ST-II Too Low		
	ST-III Too High		
	ST-III Too Low		
Resp	RR Too High	M*	Patient PR value is higher than the upper alarm limit or lower than the lower alarm limit. Check the patient's physiological condition, and check if the patient category and alarm limit settings are appropriate for the patient.
	RR Too Low		
	Apnea(RESP)	H	The patient's respiratory signal is too weak, and the system can't analyze. Check the patient's condition, electrodes, cables and leads.
	RESP ARTIFACT	H*	Respiration heartbeat interference
Temp	T1 Too High	M*	T1/T2 value is higher than the upper alarm limit or lower than the lower alarm limit. Check the patient's physiological condition, and check if the patient category and alarm limit settings are appropriate for the patient.
	T1 Too Low		
	T2 Too High		
	T2 Too Low		
	TD Too High		TD value is higher than the upper alarm limit or lower than the lower alarm limit. Check the patient's physiological condition, and check if the patient category and alarm limit settings are appropriate for the patient.
SpO_2	SpO_2 Too High	M*	SpO_2 value is higher than the upper alarm limit or lower than the lower alarm limit. Check the patient's physiological condition, and check if the patient category and alarm limit settings are appropriate for the patient.
	SpO_2 Too Low		
	PR Too High		PR value is higher than the upper alarm limit or lower than the lower alarm limit. Check the patient's physiological condition, and check if the patient category and alarm limit settings are appropriate for the patient.
	PR Too Low		
NIBP	NIBP signal weak	M*	NIBP value is higher than the upper alarm limit or lower than the lower alarm limit. Check the patient's physiological condition, and check if the patient category and alarm limit settings are appropriate for the patient.
	NIBP-Sys Too High		
	NIBP-Sys Too Low		
	NIBP-Mean Too High		
	NIBP-Mean Too Low		
	NIBP-Dia Too High		

19.2 Technical alarms

Source	Alarm message	P	Causes and countermeasures
System	Battery Low	H	Connect to AC power supply, and charge the battery, and power with the battery as needed after fully charged.
ECG	ECG Comm. Stop	H	ECG module failure, or communication failure between the module and the host; please restart the device.
	ECG Comm. Error	H	
	ECG Config Error	H	
	ECG Selfcheck Error	H	
	ECG Lead Off	M*	The electrodes are not connected to the patient firmly or fall off, or lead wires and the main cable fall off. Check the connection of electrodes and lead wires.
	ECG YY OFF (YY is a lead name)	M*	
Temp	TEMP1 Sensor Off	L	The temperature sensor falls off from the patient. Check the sensor connection.
	TEMP2 Sensor Off	L	
SpO_2	SpO_2 Comm. Stop	H	SpO_2 module failure, or communication failure between the module and the host; please restart the device.
	SpO_2 Comm. Error	H	
	SpO_2 No Sensor	L	SpO_2 sensor falls off from the patient or monitor, malfunctions, or sensor other than specified in this Manual is used. Check the sensor mounting position, whether the sensor is damaged or sensor type. Reconnect the sensor or use new sensor.
	SpO_2 Sensor Off	L	
	SpO_2 Search Timeout	L	
	SpO_2 Search Pulse	L	Sensor signal is poor or too weak. Check the patient's condition, and place the sensor in a suitable position. If the failure persists, replace the sensor.
NIBP	NIBP Comm. Stop	H	NIBP module failure, or communication failure between the module and the host; please restart the device.
	NIBP Comm. Error	H	
	NIBP Selfcheck error	H	
	NIBP CFG Error	H	
	NIBP system error	H	If failure occurs during measurement, the system can’t analyze and calculate. Check the patient's condition, check the connections or replace the cuff, and then re-test.
	Measurement timeout	L	
	Cuff type error	L	The used cuff does not match the set patient category. Verify the patient category and replace the cuff.
NIBP	Cuff loose or no cuff	L	NIBP cuff isn’t placed or connected properly, or there is gas leak.
	Cuff leak	L	Check cuff and inflation tube.
	Air pressure error	L	Ambient atmospheric pressure is abnormal. Confirm that the environment complies with the

Source	Alarm message	P	Causes and countermeasures
			monitor's specifications, and check whether there are special reasons affecting ambient pressure.
	NIBP over range	L	The measured blood pressure of the patient exceeds the measuring range.
	NIBP signal weak	L	Patient’s pulse may be weak or cuff is too loose. Check the condition of the patient, and place the cuff in a suitable position. If the failure persists, replace the cuff.
	NIBP signal unstable	L	Excessive movement may result in too much motion artifact or interference in the signal during measurement.
	NIBP signal saturated	L	Motion signal amplitude is too large due to movement and other reasons.
	NIBP over pressure	L	Cuff overpressure, and gas blockage may occur; check the gas path, and then re-measure.
	Module reset failed	L	NIBP module reset error; check the gas path is blocked, and then restart the measurement.

20 Default parameter configuration

This chapter lists the important factory default settings of different departments in monitor configuration mode. Users can not change the default configuration, but can modify the settings as required and save as user-defined configuration.

Module	Option			Module defaults	
				Adult	Pediatric
ECG	Alarm level			Mid	Mid
	Alarm record			Off	Off
	Lead type			5-lead	5-lead
	Calculation channel			Auto	Auto
	Power frequency suppression			On	On
	Alarm limits			50~120 on	75~160 on
	ST segment analysis	ST segment analysis		Off	Off
		Alarm level		Mid	Mid
		Alarm record		Off	Off
		Alarm limits		-0.2~0.2 on	-0.2~0.2 on
	Arrhythmia analysis	Alarm level		Mid	Mid
		Alarm record		Off	Off
		Alarm limits		0~10 on	0~10 on
		ARR alarm settings	Alarm switch	On	On
			Alarm level	Mid	Mid
			Alarm record	Off	Off
	Gain			x1	x1
	Wave velocity			25.0mm/s	25.0mm/s
	Filter mode			Monitor	Monitor
	Wave color			Green	Green
	Wave style			Color scale	Color scale
NIBP	Alarm level			Mid	Mid
	Alarm record			Off	Off
	Pressure unit			mmHg	mmHg
	Measurement mode			Adult	Pediatric
	Interval			Manual	Manual
	Display color			White	White
	Pre-inflation value			150	100
	Systolic blood pressure limit			90~160 on	70~120 on
	Mean blood pressure limit			60~110 on	50~90 on
	Diastolic blood pressure limit			50~90 on	40~70 on
SpO_2	Alarm level			Mid	Mid
	Alarm record			Off	Off
	Alarm limits			90~100 on	90~100 on
	Wave velocity			25.0	25.0
	Wave color			Cyan	Cyan
	Wave style			Line	Line
RESP	Alarm level			Mid	Mid
	Alarm record			Off	Off
	Apnea alarm			20 sec	20 sec

Module	Option	Module defaults	
		Adult	Pediatric
	Alarm limits	8~30 on	8~30 on
	Gain	x1	x1
	Wave velocity	12.5	12.5
	Wave color	Yellow	Yellow
	Wave style	Line	Line
PR	Alarm source	SpO_2	SpO_2
	Alarm level	Mid	Mid
	Alarm record	Off	Off
	Alarm limits	50~120 on	75~160 on
TEMP	Alarm level	Mid	Mid
	Alarm record	Off	Off
	Display color	White	White
	Temperature unit	℃	℃
	T1 alarm limits	36.0~39.0 on	36.0~39.0 on
	T2 alarm limits	36.0~39.0 on	36.0~39.0 on
	TD alarm limits	0.0~2.0 on	0.0~2.0 on

21 Common faults and maintenance

The following table shows the common faults on the operation, and the solution.

Faults	Solution
Blank Screen	Connects the monitor to check the screen and screen line whether normal.
The system time is not correct	1. Set up error, can be reset through the system User Maintenance menu. 2. The button battery on main control board is run out, please change the button battery.
No ECG waveform	1. See the ECG cable and lead-wires whether in good condition, disconnected or electrode rusting result in connection fail. 2. Look at whether the ECG cable and lead type are consistent.
Unable to do ST analysis	1. Check the ECG Setup→ ST Analysis→ ST Analysis is set to “On”. 2. Check the ECG Setup→ Other Setup→ Paced whether be set to “On”. If Paced is set to “On”, means the patient have a pacemaker; in this case the machine is not doing the ST analysis.
No SpO_2 waveform or value	Check whether the SPO2 Sensor is connected and in good condition.
Blood pressure does not start	1. Check whether the pump is broken. 2. Check whether the trachea is broken. 3. Check whether the blood pressure plate is normal.
Blood pressure started, but couldn't measure the value	1. Check whether the blood pressure cuff is leakage. 2. Check whether the NIBP extension tube and machine connect is well. 3. Check whether the deflating valve on blood pressure plate is normal. 4. Check whether the pressure sensor is normal.

If the above doesn't solve the problem, please contact Bistos after-sales department or dealers.

22 Manufacturer's declaration on EMC

BT-770 needs special precautions regarding EMC (Electromagnetic compatibility) and needs to be used according to the EMC information provided in this user manual. Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect the BT-770 and should be kept at least 1 m away from the equipment.

NOTE

- Using unqualified accessories, sensors and cables will increase the electromagnetic emission and reduce the electromagnetic immunity of the device.
- Do not put the device close to other devices or stack together. When necessary, observe the device closely to ensure that it runs normally in the environment.
- The device requires special EMC protection, and it is necessary to install and maintain it in the environment that meets the following EMC information.
- Even if other devices comply with CISPR emission requirements, they may also cause interference to this device.
- When the input signal amplitude is smaller than the minimum amplitude specified in the technical specifications, it may result in inaccurate measurements.
- Mobile communication devices or wireless network devices may have an impact on the device.

22.1 Electromagnetic emissions

<table>
<tr><td colspan="3">The BT-770 is intended for use in the electromagnetic environment specified below.
The customer or the user of the BT-770 should assure that it is used in such an environment.</td></tr>
<tr><td>Emissions test</td><td>Compliance</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The BT-770 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.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class A</td><td rowspan="3">The BT-770 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-770 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-770 or shielding the location.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations / flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

22.2 Recommended separation distances between portable and mobile RF communications equipment and BT-770

The BT-770 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BT-770 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BT-770 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter [W]	Separation distance according to frequency of transmitter [m]		
	150 kHz to 80 MHz $d = 3.5\sqrt{p}$	80 MHz to 800 MHz $d = 3.5\sqrt{p}$	800 MHz to 2.5 GHz $d = [\frac{7}{3}]\sqrt{p}$
0.01	0.35	0.35	0.23
0.1	1.11	1.11	0.74
1	3.5	3.5	2.34
10	11.07	11.07	7.38
100	35	35	23.24

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.

22.3 Electromagnetic immunity

The BT-770 is intended for use in the electromagnetic environment specified below. The customer or the user of the BT-770 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 61000-4-2:2009	±8 kV Contact ±15 kV air	±8 kV Contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4:2004	±2 kV for power supply lines ±1 kV for input/output lines (>3m)	±2 kV for power supply lines ±1 kV for input/output lines (>3m)	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5:2006	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	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 IEC 61000-4-11:2004	< 5 % U_T (> 95 % dip in U_T) for 0.5 cycles 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (> 95 % dip in U_T) for 5 s	< 5 % U_T (> 95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (> 95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the BT-770 requires continued operation during power mains interruptions, it is recommended that the BT-770 be powered from an uninterruptible power supply.
Power frequency (50 Hz and 60 Hz) magnetic field IEC 61000-4-8:2010	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

The BT-770 is intended for use in the electromagnetic environment specified below.
The customer or the user of the BT-770 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level
Conducted RF IEC 61000-4-6:2009	3 Vrms 150 kHz to 80 MHz	3 Vrms
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m

Electromagnetic environment - guidance
Portable mobile RF communications equipment should be used no closer to any part of the BT-770, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance

$d-1.2\sqrt{p}$ ($d-3.5\sqrt{p}$)

$d-1.2\sqrt{p}$ (Resp: $d-3.5\sqrt{p}$) 80 to 800MHz

$d-1.2\sqrt{p}$ 800M to 2.5GHz

where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m).

Field strengths from fixed RF transmitters, as deter-mined 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-770 is used exceeds the applicable RF compliance level above, the BT-770 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-770.

[b] Over the frequency range 150 kHz to 80MHz, field strengths should be less than 3 V/m**.**

Product Warranty

Product Name	Patient Monitor
Model Name	BT-770
Serial No.	
Warranty Period	2 Years
Date of Purchase	
Customer	Hospital: Address: Name: Telephone:
Sales Agency	
Manufacture	Bistos Co., Ltd.

※ Thank you for purchasing BT-770.
※ This product is manufactured and passed through strict quality control and inspection.
※ Compensation standard concerning repair, replacement, refund of the product complies with "**Framework Act on Consumers**" noticed by Fair Trade Commission of Republic of Korea.

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BT-350

Fetal Monitor

Operation Manual

BT-350, BT-350E

Keep this manual for future reference

P/N : 350-ENG-OPM-EUR-R10

Proprietary Material

Revision 10
August 2017

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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-

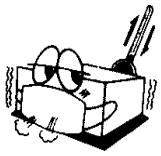
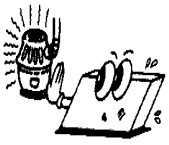
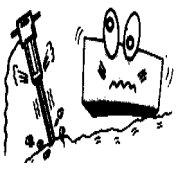
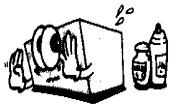
CAUTION

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

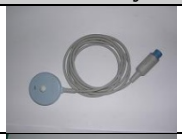
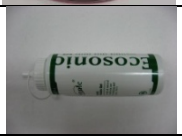
The BT-350 is a Prenatal Monitoring System for non-invasively measuring and showing graphically maternal abdominal contractions and the fetal heart rate by means of display on a non-permanent graphical display and on a strip chart recorder. This data is intended to aid in assessing the well-being of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

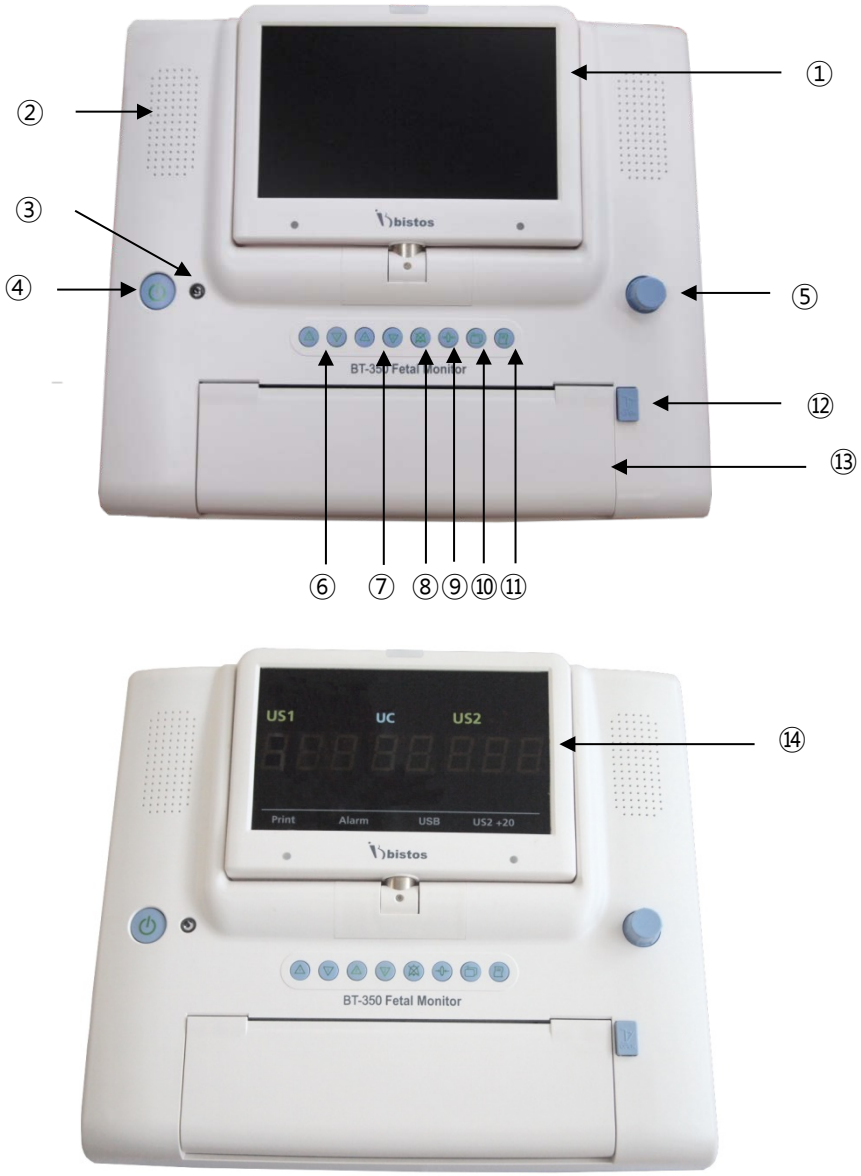


Fig. 3.1 BT-350 Front Panel

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

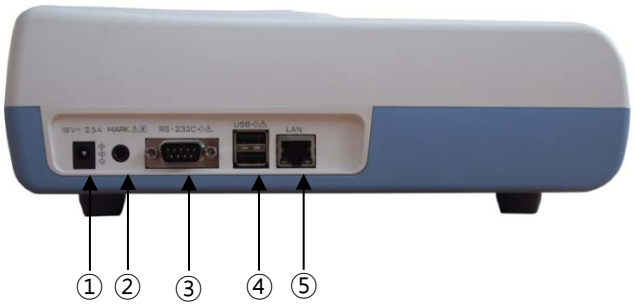


Fig. 3.2 Left Panel

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

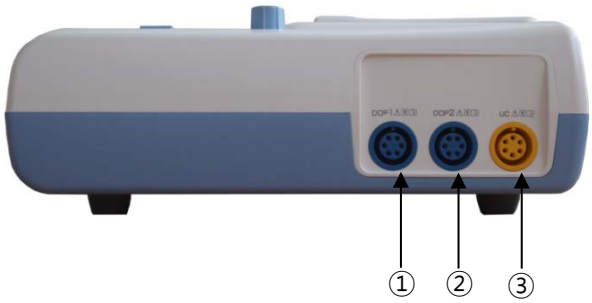


Fig. 3.3 Right Panel

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.

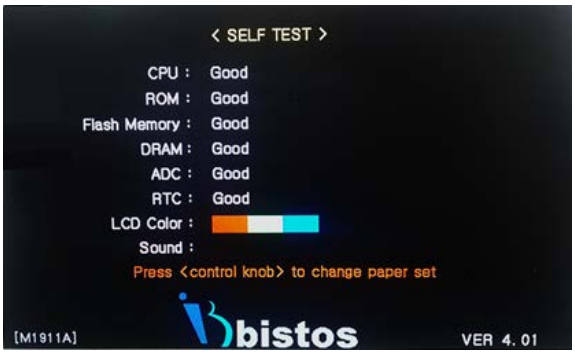


Fig. 4.1 Self-Test display

4.2 BT-350 Monitor Display Screen

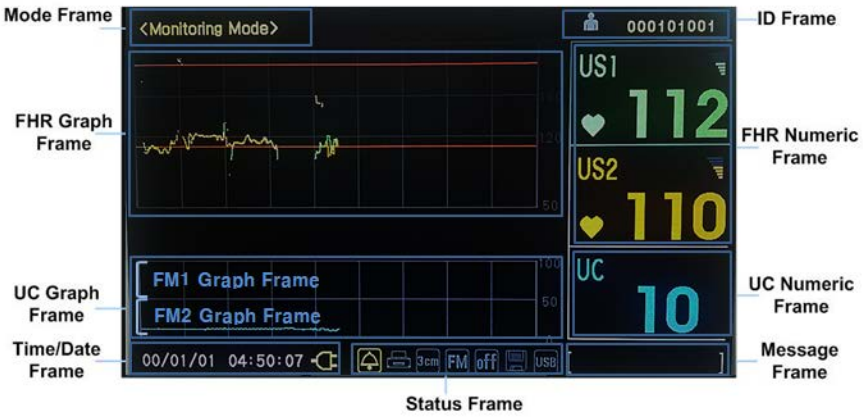


Fig. 4.2 Main Monitoring Screen – Graph Mode

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.

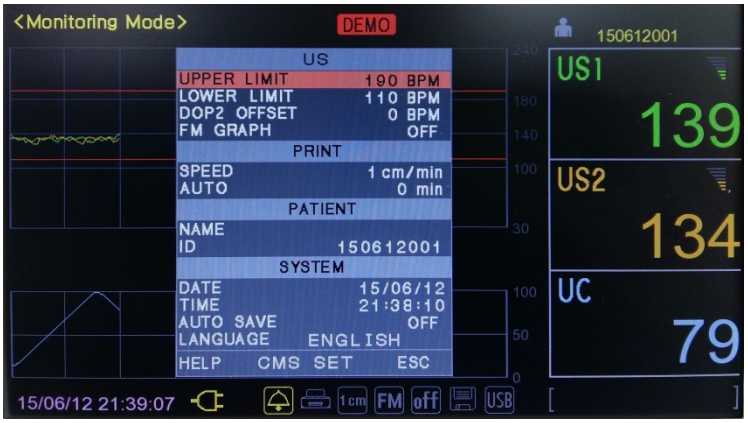


Fig. 4.4 System setup menu

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

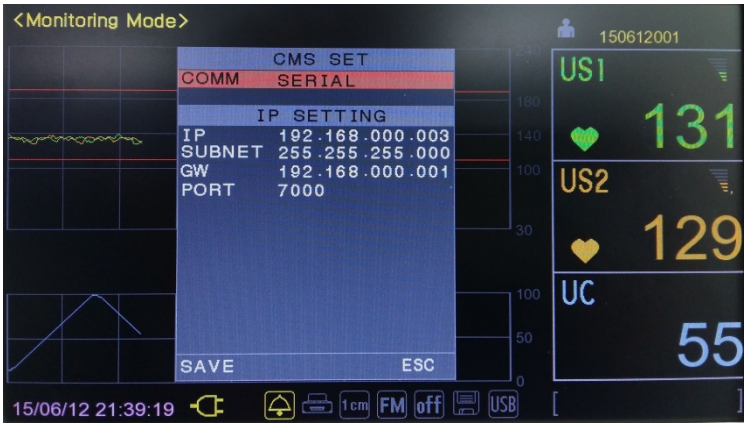


Fig. 4.5 CMS Setting configuration

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.

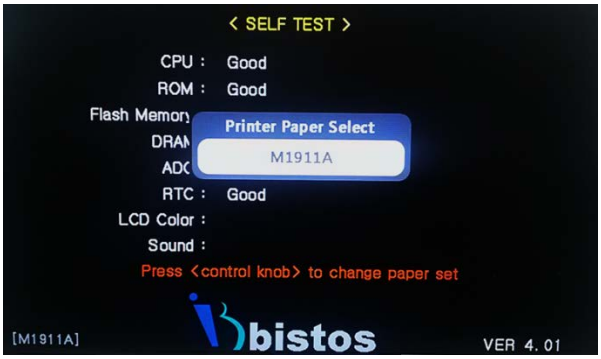


Fig. 4.6 Printer Paper Select

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.

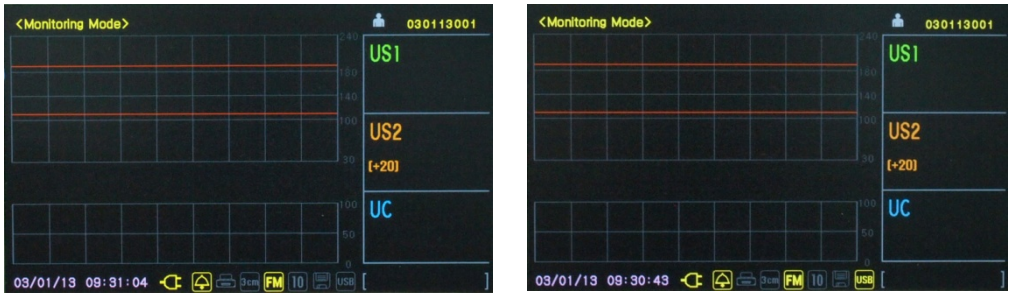


Fig. 4.7 BT-350 USB icon activation

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.

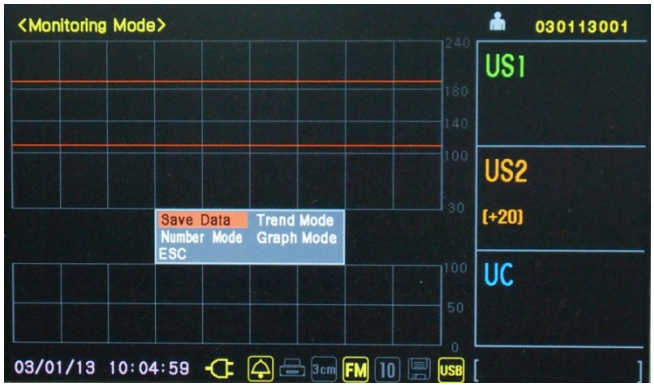


Fig. 4.8 Save Date display

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'.

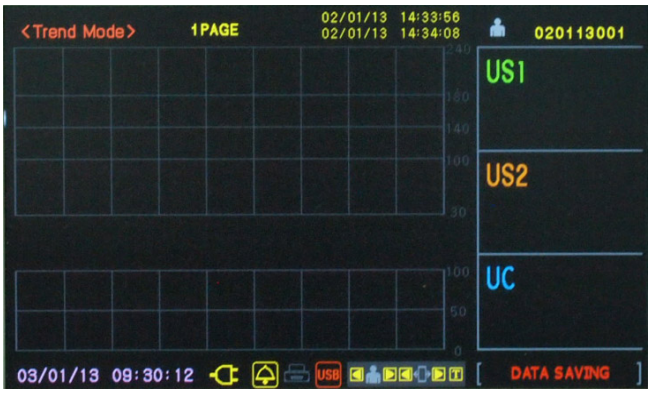


Fig. 4.9 Trend Mode display

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.

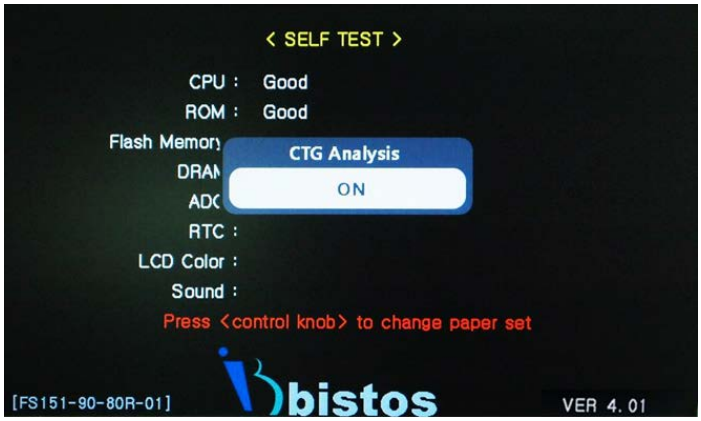


Fig. 4.10 CTG Analysis Function

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.

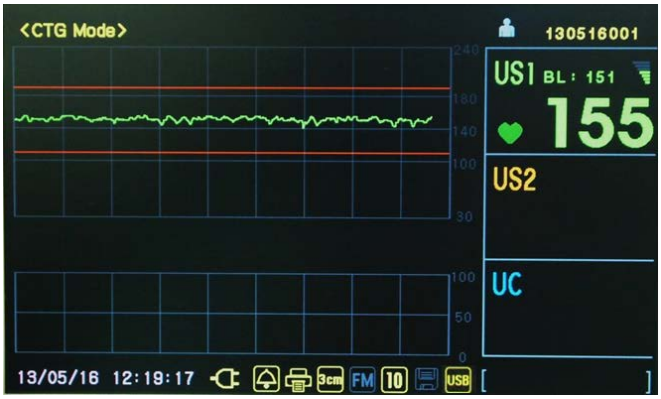


Fig. 4.11 CTG Mode

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.

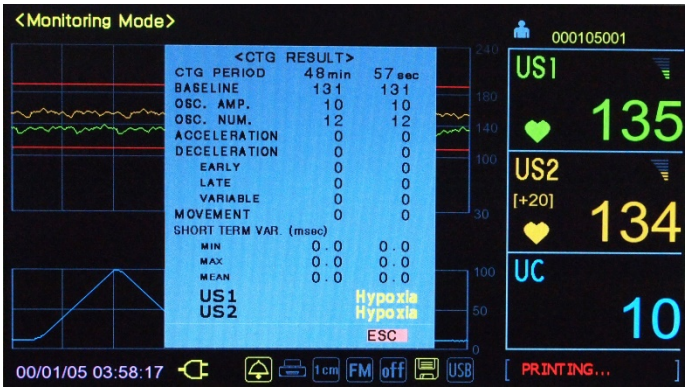


Fig. 4.12 CTG Result in Monitoring mode

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.

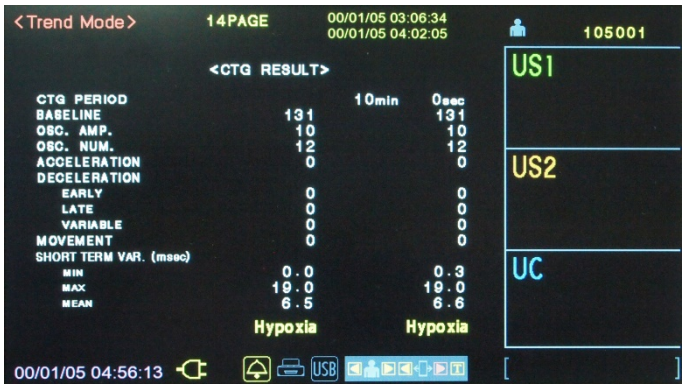


Fig. 4.13 CTG Result in Trend Mode

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.

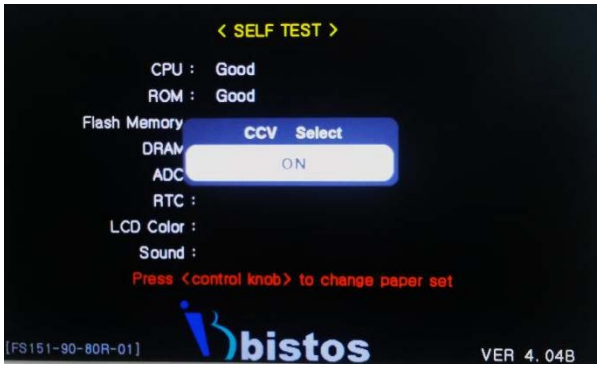


Fig. 4.14 CCV Function

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

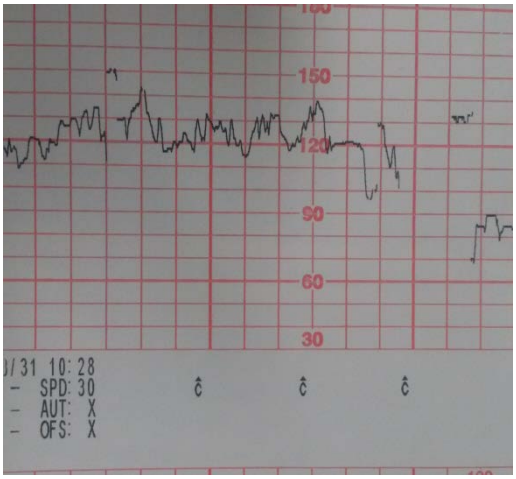


Fig. 4.16 CCV Result in Paper

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***

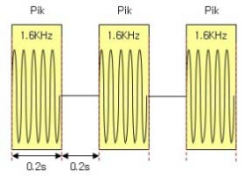
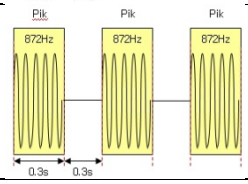
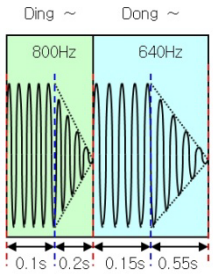
5.6 Understanding Alarms

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.

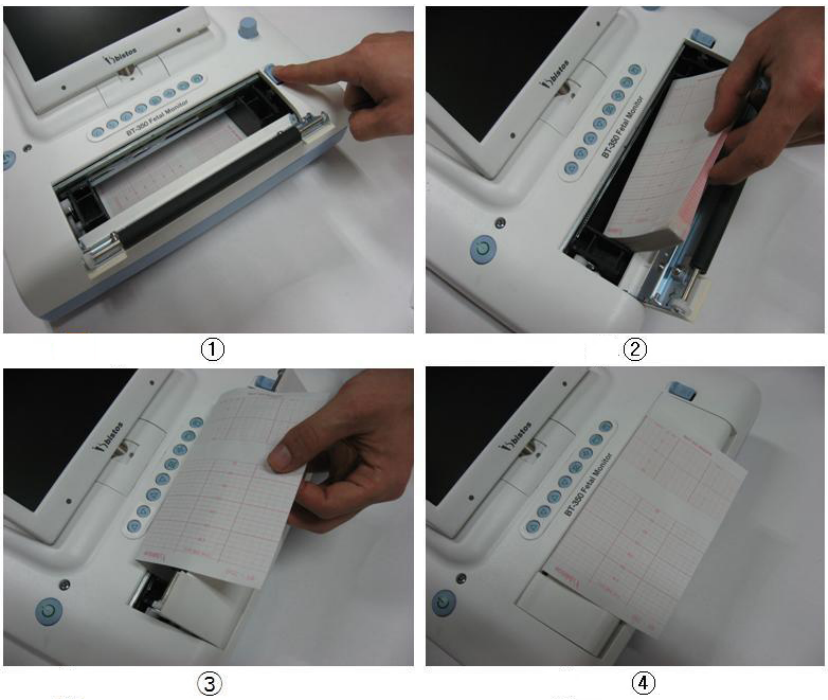


Fig. 6.1 Loading Paper

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.

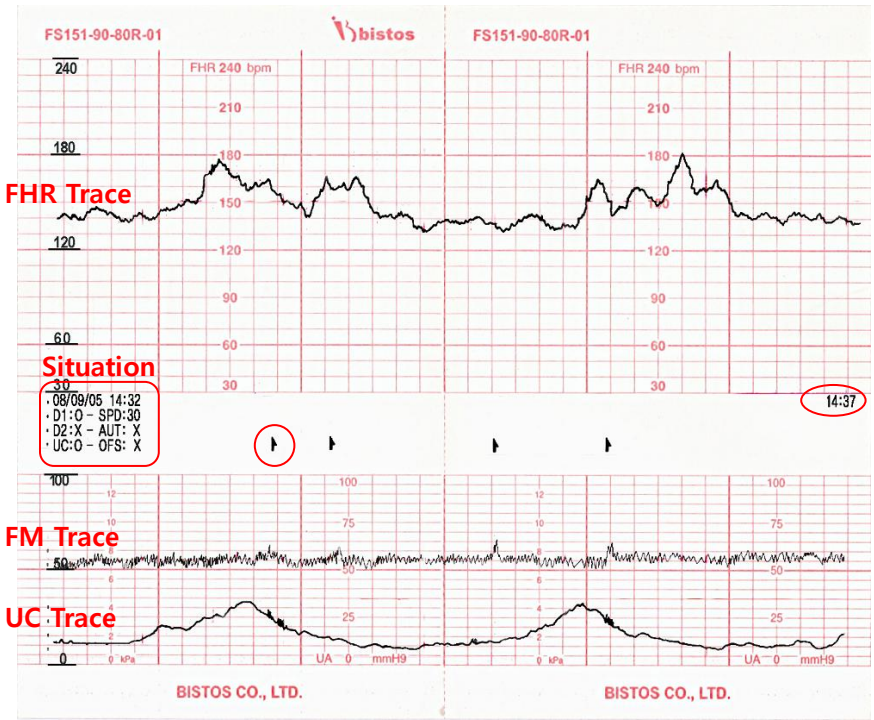


Fig. 6.2 Printing Paper [FS151-90-80R-01]

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.

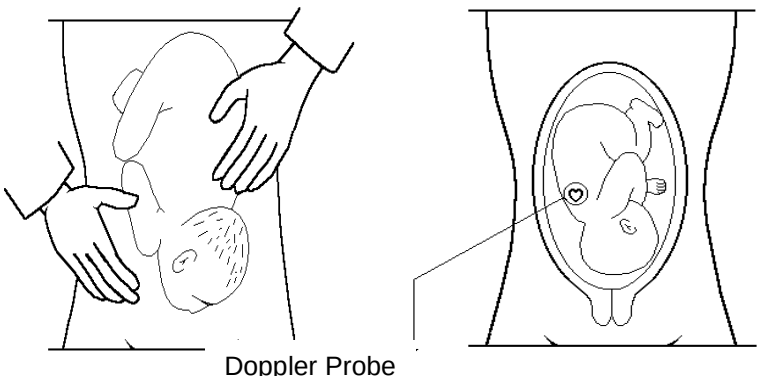


Figure 7.1 the direction of Doppler Probe

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.

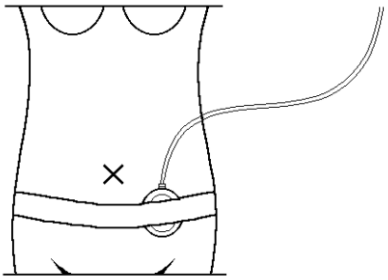


Figure 7.2 Positioning of UC Probe

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

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bistos

CE 2460

bistos
Bistos Co.,Ltd

BT-500

Infant incubator

Service Manual

BT-500

P/N : 500-ENG-SVM-EUR-R03

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Revision 03
Mar, 2018

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Table of Contents

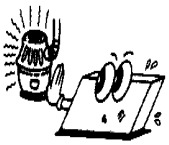
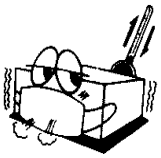
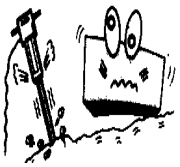
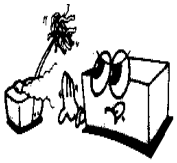
Section 1
Safety

1.1 Instructions for the Safe Operation and Use of the BT-500 Infant incubator

- Examine the incubator and any accessories periodically to ensure that the cable and batteries do not have visible evidence of damage that may affect patient safety or performance. The recommended inspection interval is once per week or less. Do not use the incubator if there is any visible sign of damage.
- Only the AC line cord supplied with the BT-500 is approved for use with the device.
- Do not attempt to service the BT-500 incubator. Only qualified service personnel by Bistos Co., Ltd. should attempt any needed internal servicing training.
- BT-500 is not specified or intended for operation during the use of defibrillators or during defibrillator discharge.
- BT-500 is not specified or intended for operation in the presence of electrosurgical equipment.
- BT-500 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 the Operation Manual.
- Perform periodic safety testing to insure proper patient safety. This should include leakage current measurement and insulation testing. The recommended testing interval in once per year.
- Do not operate the BT-500 if it fails to pass the power on procedure.

WARNING	Can lead to serious injury or death.
CAUTION	Can lead to minor injury or product/property damage
NOTE	Can lead a potential hazardous situation which, if not avoided, may result in minor or moderate injury

1.2. General Precaution on Environment

	Avoid placing in an area exposed to moisture. Do not touch the equipment with wet hand.		Avoid in the vicinity of electric heater
	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 30% to 85%.		Avoid placing in an area where there is an excessive shock or vibration.
	Avoid placing in an area where there is an excessive humidity rise or ventilation problem.		Avoid dust and especially metal material into the equipment.

1.3. Definition of Symbols

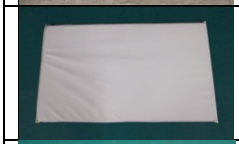
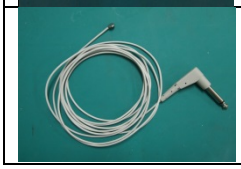
Symbol	Description
	Used to identify safety information. Be well-known this information thoroughly before using BT-500. During the operation, do not disconnect any cable.
	Indicate the warning for hot surface.
	Type BF Applied part
	Refer to operation manual. Read manual before placing the device.
	Skin temperature sensor #1, to be connected to infant's abdomen for baby (controlled) mode
	Skin temperature sensor #2, to be connected to other than infant abdomen
IPX0	IPX0 Non-protected against ingress of water with harmful effects. (Device)
IPX1	IPX1 Protected against the vertically dripping water (Skin temperature sensor_2EA)
IPX2	IPX2 Protected against the dripping water (SpO_2 sensor)
IPX6	IPX6 Protected against the powerful jetting (Foot switch_2EA)
	Indicates the weight limit

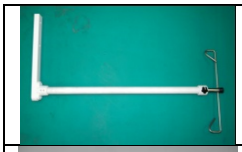
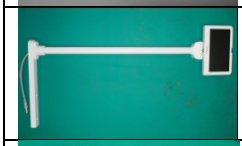
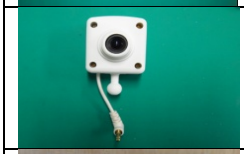
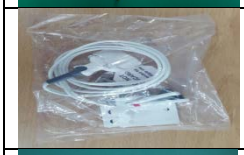
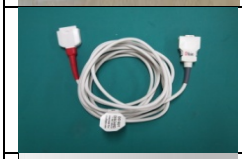
Section 2
Introduction

2.1 Product overview

BT-500 is an infant incubator. It supports the best temperature, humidity and clean air to a premature baby or a precocious baby under 2kgs. Also BT-500 measures SpO2 and the weight of an infant and displays the measured value, temperature and humidity. And BT-500 has an alarm function.

2.2 Options and accessories

Picture	Name	Description	Qty
	Control shell (Standard)	Hold up the hood and be composed with instruments and parts that control the temperature and humidity	1ea
	Hood (Standard)	Made of double framed clear acrylic panel to watch inside, and to minimize heat loss	1ea
	Fixed Stand (Standard)	Movable incubator cradle with wheels	1ea
	Basket (Optional)	Storage of medical equipment and items which infant needs	1ea
	Basket Partition (Optional)	Partition of Basket	1ea
	Sensor module (Standard)	Measures temperature and humidity inside the hood and infant's body temperature	1ea
	Mattress tray (Standard)	Baby desk with X-ray tray	1ea
	mattress (Standard)	Accommodate infant stably with bouncy mattress	1ea
	Skin temperature sensor (Standard)	Measures infant's skin temperature	2ea

	IV-pole (Optional)	IV hanger.	1ea
	AC power code (Standard)	AC Power cord(AC Power cord for operating the equipment)	1ea
	External LCD Monitor (Optional)	Displays measured values from the control and video of infant inside the hood.	1ea
	CCD Camera (Optional)	Takes video of infant inside the hood	1ea
	Masimo SpO2 sensor probe (Optional)	Measures infant's SpO2	1ea
	Masimo Extension for SpO2 sensor (Optional)	Extend sensor cable	1ea
	IV plate (Optional)	Plate to place items which infant needs	1ea
	Shelf (Optional)	Plate to place items which infant needs	1ea
	Lift Stand (Optional)	Movable incubator cradle with wheels (VHA- Variable Height Adjustable)	1ea
	Weighting Scale (Optional)	Measures Infant's weight	1ea

2.3 Appearance of BT-500

2.3.1 BT-500 Front View

Figure 2-1. BT-500 Front view

① Control Shell	② Hood
③ Sensor module	④ Moving Stand
⑤ Basket	⑥ IV pole
⑦ IV plate	⑧ External monitor

2.3.2 BT-500 Front View Detail

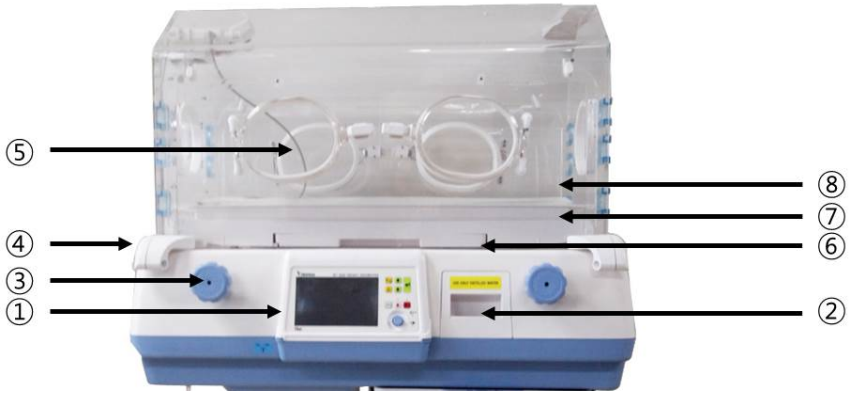


Figure 2-2. BT-500 Front view details

① Console box
② Water tank draw
③ Tilting mechanism handle
④ Hood handle
⑤ Front access door
⑥ Baby desk with X-RAY Tray
⑦ Weighing scale
⑧ Compatible mattress

2.3.3 BT-500 Rear view

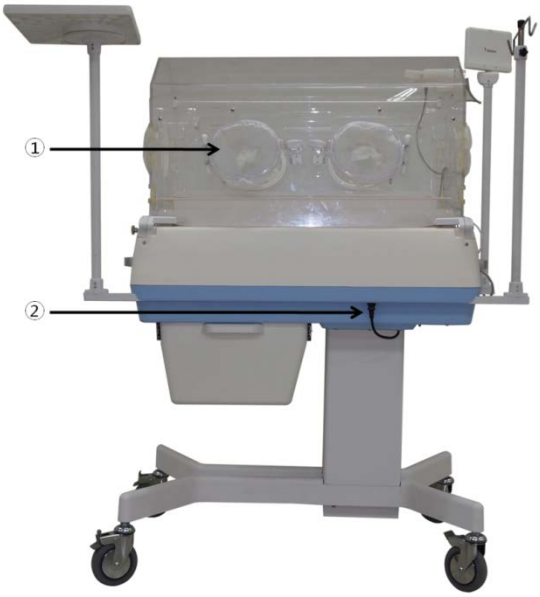


Figure 2-3. BT-500 Rear view

① Rear Access Door
② AC power cord & Connector

2.3.4 BT-500 Side view

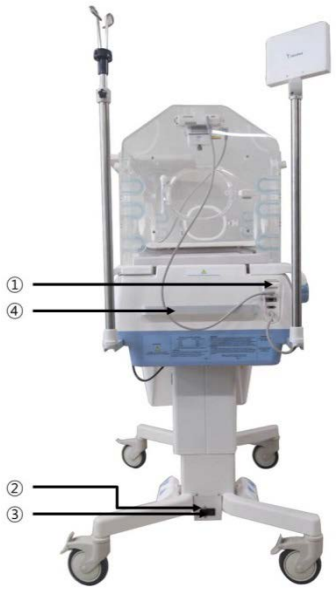


Figure 2-4. BT-500 Left view

① Sensor Module, SpO2 sensor & External Communication port
② Main power switch
③ Main power AC connector
④ Incubator handle

Figure 2-5. BT-500 Right view

2.4 Description of each part

BT-500 is composed with several parts. The control shell is the part which controls the entire device. To measure the infant's environment, the sensor module is needed. The hood is used to protect an infant from the external environment and maintain the internal environment of hood to best condition.

2.4.1 Control shell

The control shell part consists of console box and water tank.

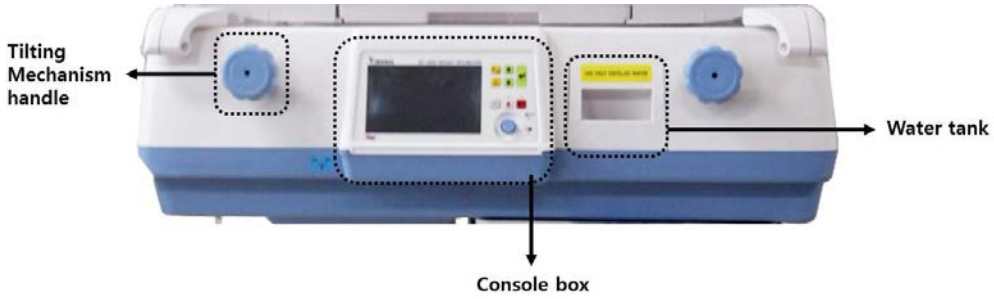


Figure 2-6. Control Shell

The water tank has a 1 Liter capacity. The reservoir permits visual inspection of the water level. It is located in a drawer in the front of the shell. When the drawer is closed and the latching handle is engaged, the reservoir is connected to manifold.
For more information about how to clean, see "Chapter 6 cleanliness and maintenance"

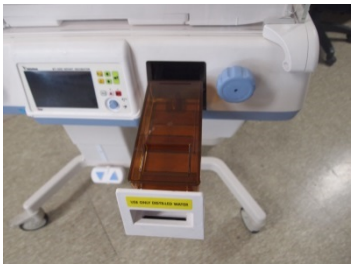


Figure 2-7. Water Tank

2.4.2 Hood

The hood of BT-500 is an acrylic material. There is Access door in the front, rear and both sides of hood.

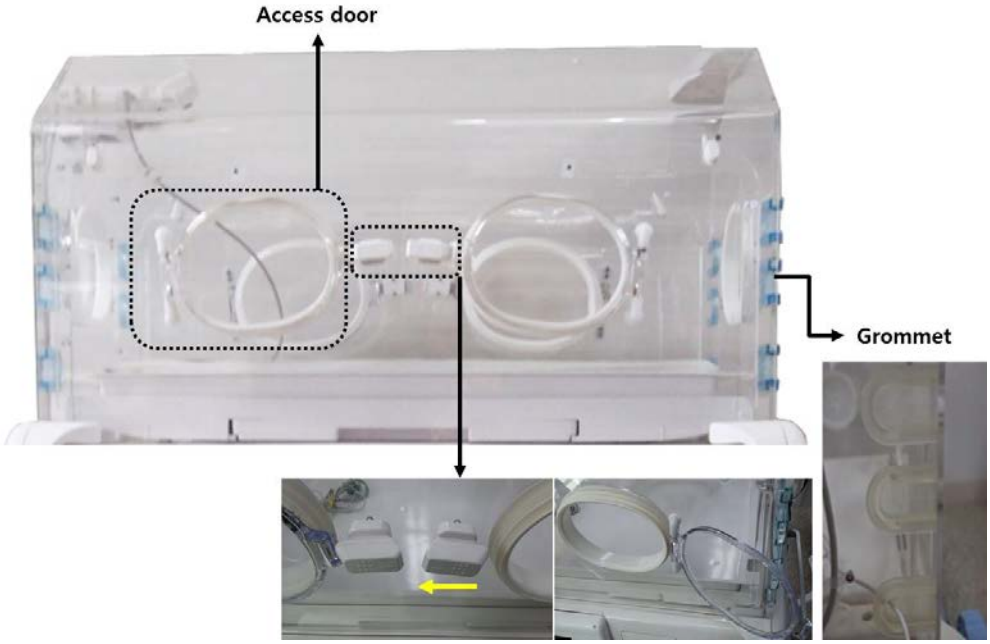


Figure 2-8. Hood front view & Access door / side function

2.4.3 Stand

BT-500 has two types of stand as fixed and lifting. Following figure show the fixed stand.

Figure 2-9. Fixed Stand (Standard)

In case of lifting type, you are able to adjust the vertical height using two sets of up/down arrow on footswitch. (VHA - Variable Height Adjustable) This type is optional. The height of the stand can be adjusted if necessary by stepping on an appropriate side of the pedal for height adjustment.

Figure 2-10. Lifting Stand (Optional)

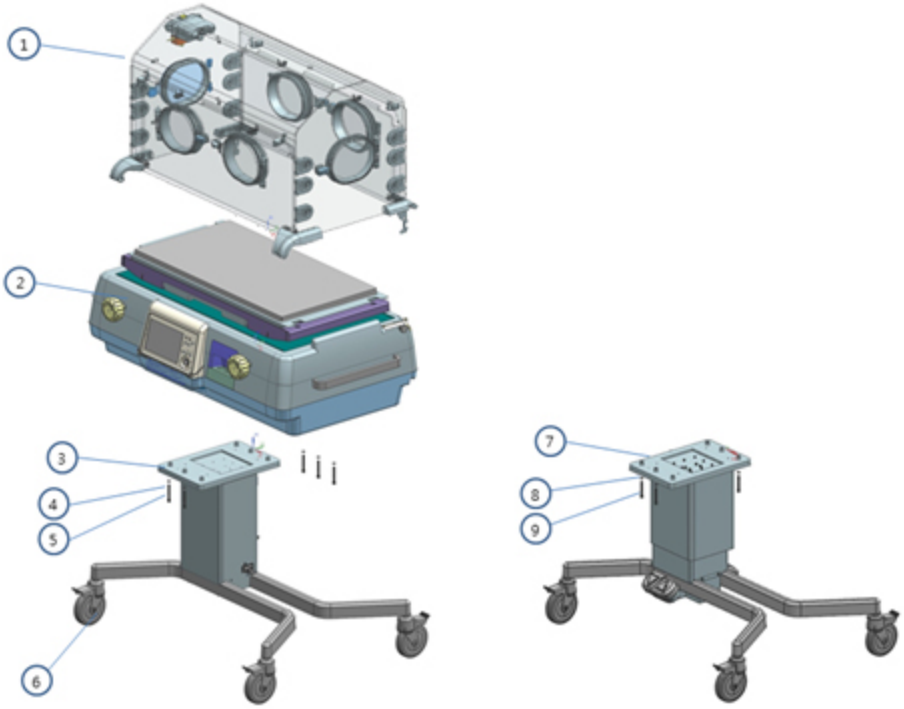
WARNING 	•	When raising or lowering the incubator, the operator should ensure that both equipment and appendages are clear of the unit's travel path. Patient and incubator connections must also be checked before adjusting the incubator height. Never place any objects on top of the drawer assembly and always check before lowering the VHA that there is sufficient clearance between the incubator and stand assembly. Do not raise or lower the unit while installing or removing medical gas tanks from the tank holder assembly. Failure to do so could result in personal injury of equipment damage.

Section 3
Assemble & Disassemble

This manual contains technical details for the BT-500 Infant Incubator. It provides a technical foundation to support effective troubleshooting and repair. It is not a comprehensive, in-depth explanation of the product architecture or technical implementation. It offers enough information on the functions and operations of the equipment so that engineers who repair them are better able to understand how they work.
Only qualified service personnel should attempt to install the equipment, disassemble the Incubator, remove or replace any internal assemblies.

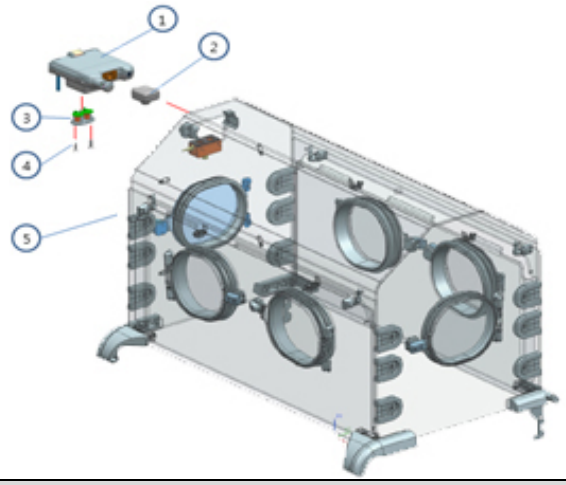
Remember to store all screws and parts in a safe place for later refitting.

3.1. Main Assembly & Disassembly



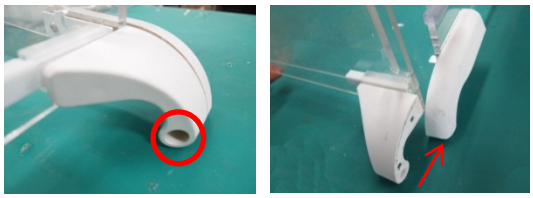
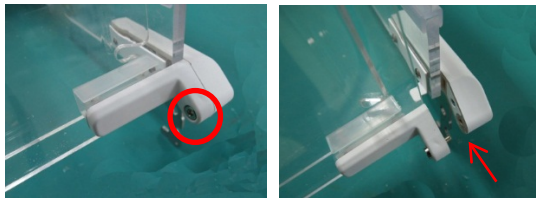
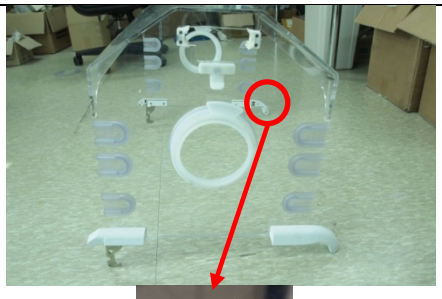
No.	Qty	Description
①	1ea	Hood Ass'y
②	1ea	Shell Ass'y
③	1ea	Fixed Stand Ass'y
④	5ea	Lock washer, M6 , stain-less steel
⑤	5ea	Screw, M6x50, Hex wrench, stain-less steel, (Hexagon wrench 5 mm)
⑥	4ea	Caster 5" lock
⑦	1ea	Lifting Stand Ass'y (Option)
⑧	5ea	Lock washer, M6 , stain-less steel
⑨	5ea	Screw, M6x50, Hex wrench, stain-less steel, (Hexagon wrench 5 mm)

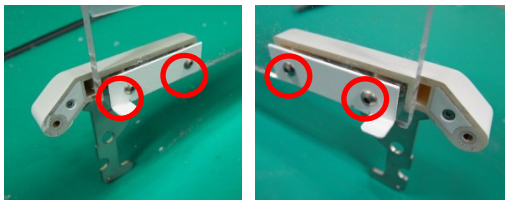
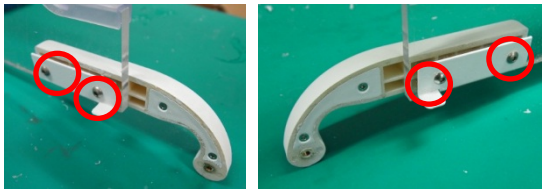
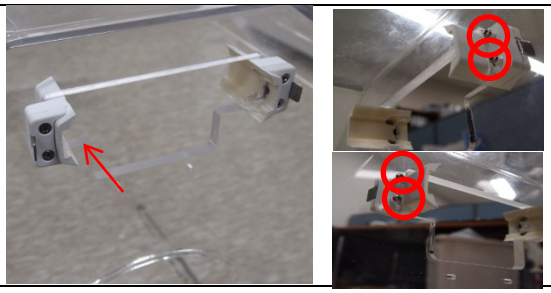
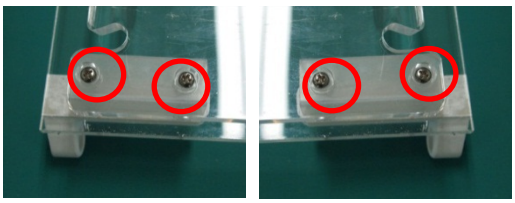
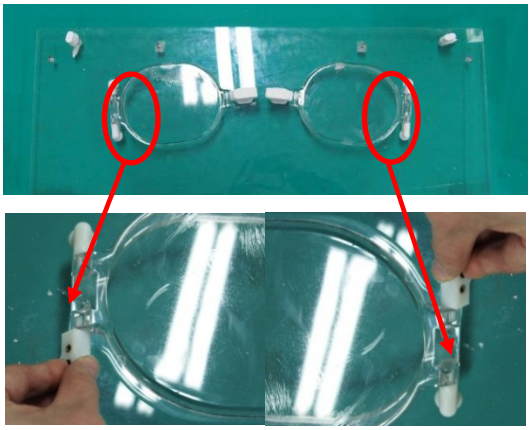
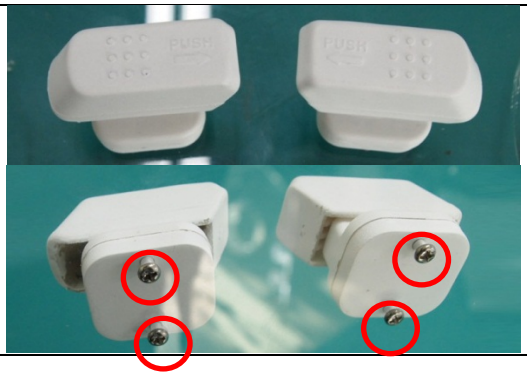
3.2. Hood Assembly & Disassembly



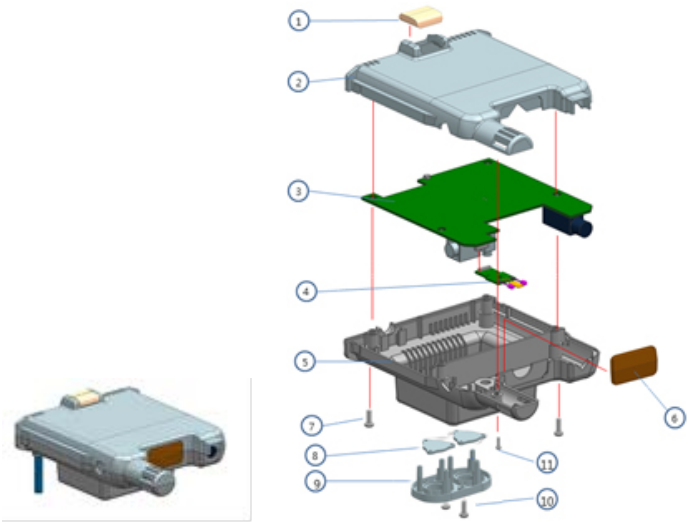
No.	Qty	Description
①	1ea	Sensor Module Ass'y
②	1ea	Camera Ass'y (Option)
③	1ea	O2 Sensor Ass'y (Option)
④	2ea	Screw, M3x10 , stain-less steel
⑤	1ea	Hood Ass'y

3.2.1. Hood Disassemble

Step	Picture	Description
1		Loose the hinge bolt from both side and disassemble hood body and hood front panel assay.
2		Loose the hinge bolt from both side and disassemble hood body and hood rear panel assay.
3	 	To replace the cable guide, disassemble nut from the opposite side of cable guide and remove a bolt.

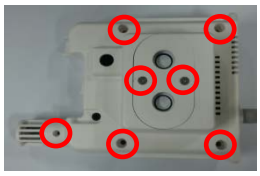
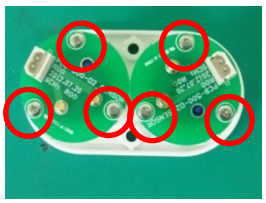
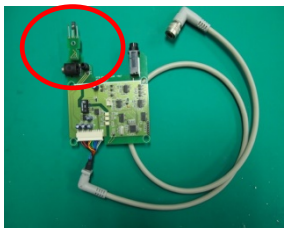
4		Loose bolts inside of hood hinge rear assay.
5		Loose bolts inside of hood hinge front assay.
6		Loose bolts of sensor module guide from inside. A magnet sensor indicated by the arrow must in position.
7		Loose bolts of hinge heat plates.
8		Loose bolts inside of hood pivot hinge and disassemble hood door.
9		Loose bolts of hood door latch and disassemble hood door latch. Be careful of the direction hood door latch.

3.3. Sensor Module Assembly & Disassembly

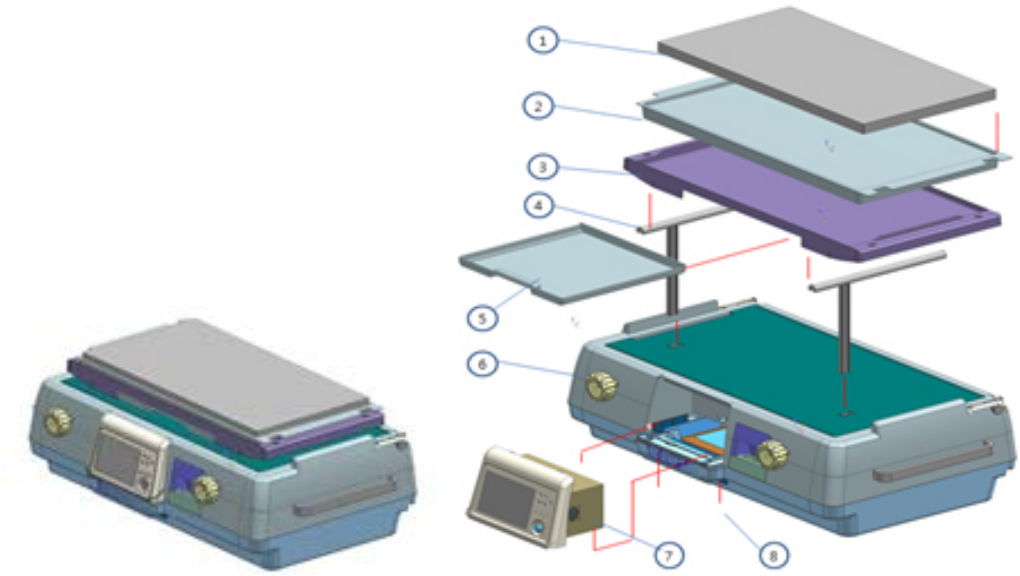


No.	Qty	Description
①	1ea	Alarm Indicator
②	1ea	Sensor Module Top
③	1ea	Sensor Board Ass'y
④	1ea	Sensor Sub Board Ass'y
⑤	1ea	Sensor Module Bottom
⑥	1ea	Camera Bracket Standard
⑦	4ea	Screw, M3x16 , stain-less steel
⑧	1ea	Sensor Module O2 Sensor Cap
⑨	1ea	Sensor Module O2 Sensor Cover
⑩	2ea	Screw, M3x10 , stain-less steel
⑪	1ea	Screw, M2.5x10 , stain-less steel

3.3.1. Sensor Module Disassemble

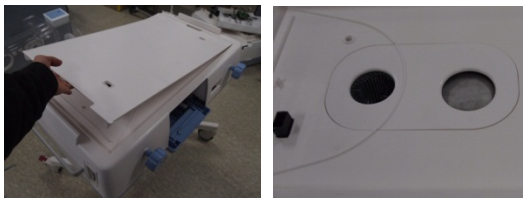
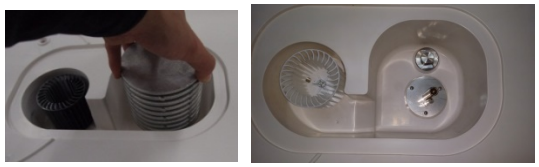
Step	Picture	Description
1		Loose seven screws on the front panel and disassemble the top and bottom.
2		Disassemble the top and bottom case and take out the oxygen sensor, sensor board.
3	 	Detach O2 sensor after unplug 2 pin cable and remove bolts in the red circles
4		Detach sub board from sensor board.

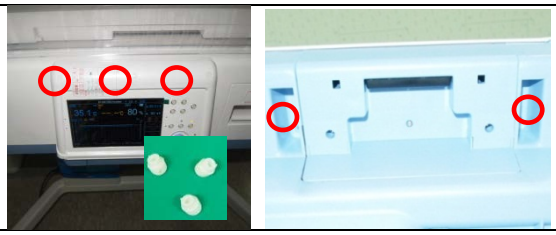
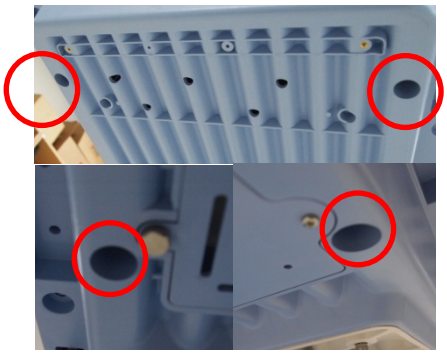
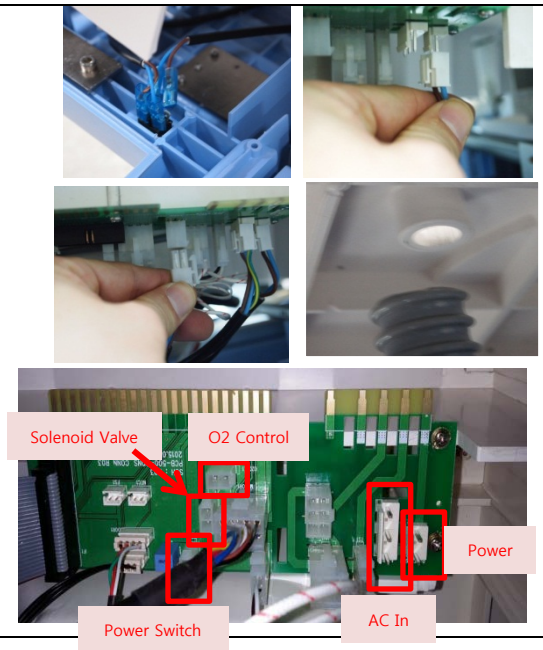
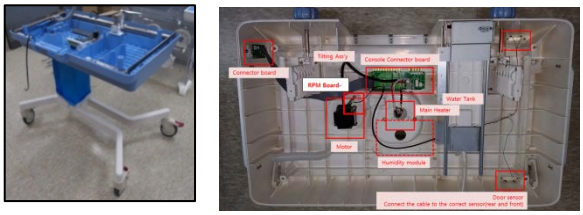
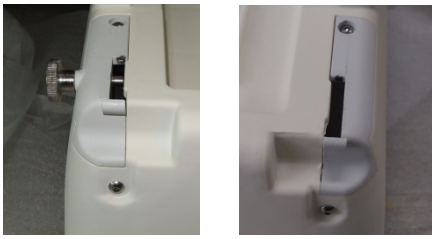
3.4. Shell Assembly & Disassembly

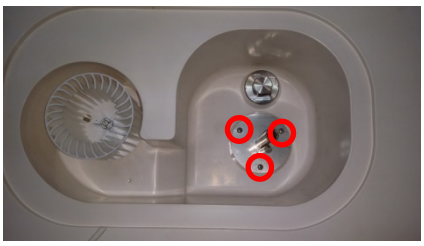
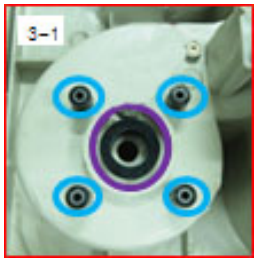
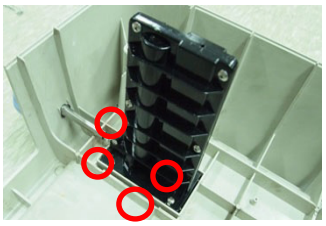
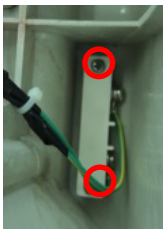
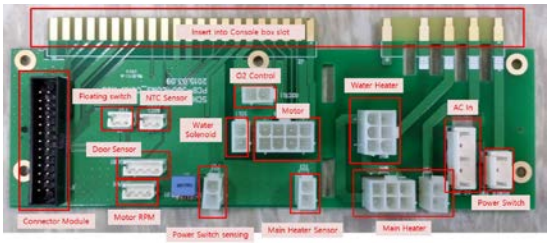


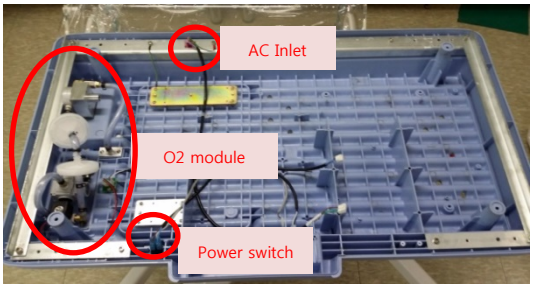
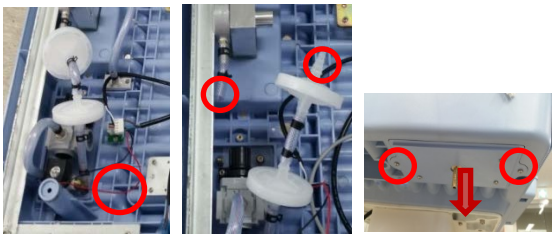
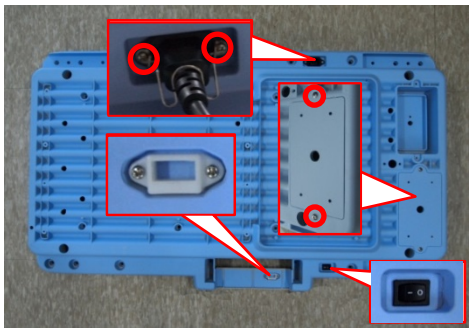
No.	Qty	Description
①	1ea	Mattress
②	1ea	Scale
③	1ea	Tray-Mattress
④	2ea	Tilt lift Ass'y
⑤	1ea	X-Ray Tray
⑥	1ea	Shell Ass'y
⑦	1ea	Control Ass'y
⑧	2ea	Screw, M3x16 , stain-less steel

3.4.1. Shell Module Disassembly

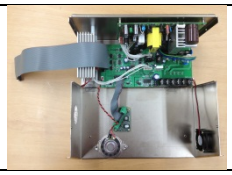
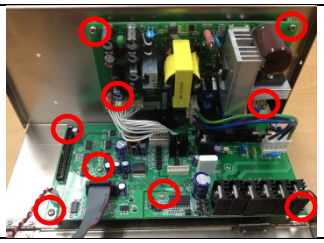
Step	Picture	Description
1		Remove shell desk and scroll cover.
2		Remove radiator heater from shell module.

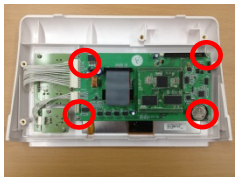
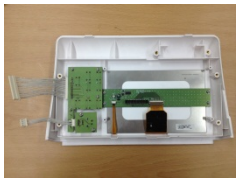
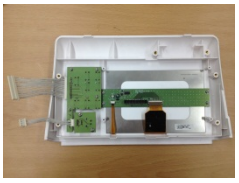
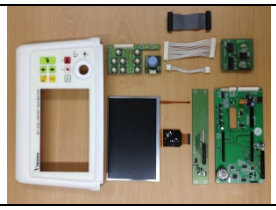
3		Remove three caps from upper part of control box and loose bolts. Then, loose two bolts from the shell bottom and disassemble the control box.
4		Loose four bolts of shell bottom module from the bottom side.
5		After lifting shell top cover a little bit, remove the cable referred to a picture and below cables. - Power socket (3pin) - Power button cable - Solenoid cable - Humidity power cable - O2 Control Cable - Air hose
6		Disassemble shell top cover.
7		Loosen two bolts from shell bracket pivot R Ass'y and shell bracket pivot L.

8	  	Loosen three bolts which is fixed to the cartridge heater and disassemble cartridge heater and cartridge packing.
9	 	Loosen four wrench bolts which are fixed to motor and disassemble the motor. After then, disassemble vibration proof rubber by turning it with the hands.
10	 	Loosen four screws which are fixed to tilt ass'y. After then, remove E-ring which is fixed to tile handle.
11	 	Loosen a screw which is fixed to connector module and pull out. Disconnect the cable to the main board and disassemble entire connector board.
12	  	Loosen two screws which are fixed to both magnetic sensors.
13		Left picture shows how to connect cables to the console connector board.

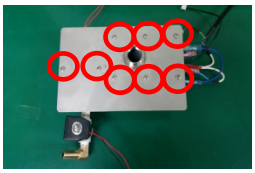
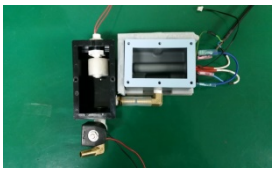
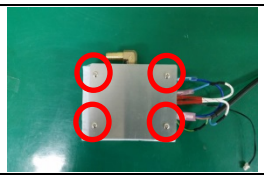
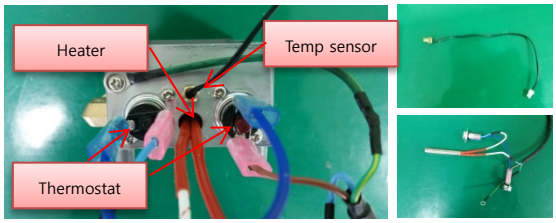
14		Remove hose tongs which is fixed to impeller by nipper then, disassemble hose tongs and impeller.
15		Release the humidity cap using spanner and disassemble the humidity module from shell top.
16		O2 module sit on the shell bottom.
17		Pull out the solenoid cable from O2 sub board. Remove tube clip from the tube between O2 check valve and O2 filter. Release 2 screws under the shell bottom and pull out entire O2 module.
18		Loosen the screws which are fixed to the material and disassemble it. From left upper side in a clockwise direction, there are Power Soket IEC Innet, Shell Pneumatc Module Cover, Power Switch, Humidity Lock Guide.

3.4.2. Control box Disassembly

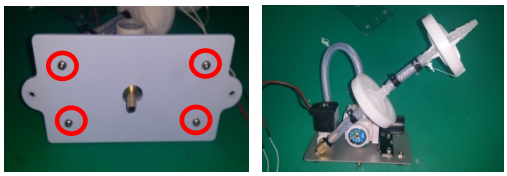
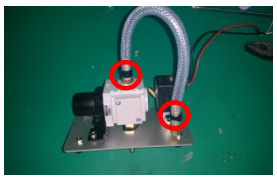
Step	Picture	Description
1		Disassemble control box from BT-500 main body.
2		Loosen four screws in the bottom side of control box.
3	 	Disassemble front cover.
4	 	Loosen two screws from both side of the control box.
5		Disassemble control box into upper and lower part.
6		Loosen two screws from the upper side of control box then, disassemble O2 control board.
7		Loosen six screws in the bottom side of control box then, disassemble main board. After then, loosen four screws in the upper part and disassemble SMPS board.
8		Loosen four screws in the right side of control box and disassemble pan.

9	 	Loosen four screws from front cover then, disassemble control board.
10	 	Loosen eleven screws from key board, knob board and LCD board then, disassemble boards.
9~10		The picture is shown the parts of front cover.

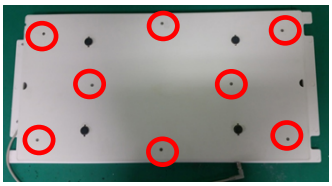
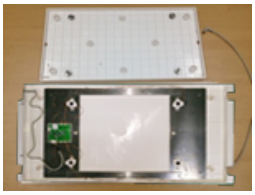
3.4.3. Humidity Module Disassembly

Step	Picture	Description
1	 	Loosen eight screws on the Humidity plate.
2		Remove a tube between Plate body and Heater body and separate them.
3		Release 4 screws on the Bracket to take apart the melamine foam from Heater body.
4		Remove the temp. sensors, heater and thermostat assembly from the Heater body.
5		Disassemble the Solenoid valve and the Floating switch. (Keep “DAS” on the floater to be upward when reassemble)

3.4.4. Oxygen module Disassembly

Step	Picture	Description
1		Loosen 4 screws from the shell pneumatic module cover.
2		Remove the hose clip and disassemble the control module.
3		Remove 2 hose clips and take apart the hose.
4		Release 4 screws to disassemble the Regulator and Solenoid assemblies.

3.4.5. Scale Module Disassembly

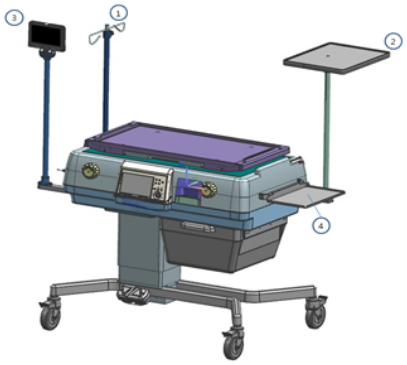
Step	Picture	Description
1		Loosen eight screws in the bottom of scale module then, disassemble top and bottom cover.
2		Check scale board and four load cell sensors.

3.5. Accessories & Options

3.5.1. IV pole Assembly & Disassembly

The IV poles can be mounted as below.

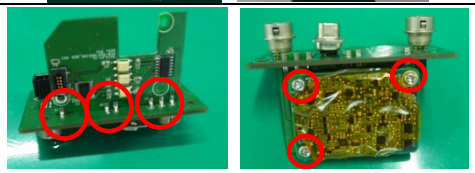
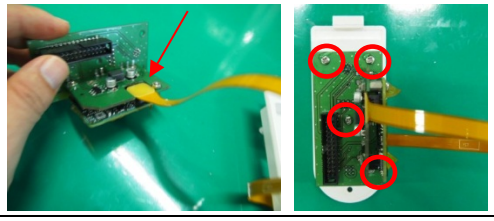
- **IV External monitor**



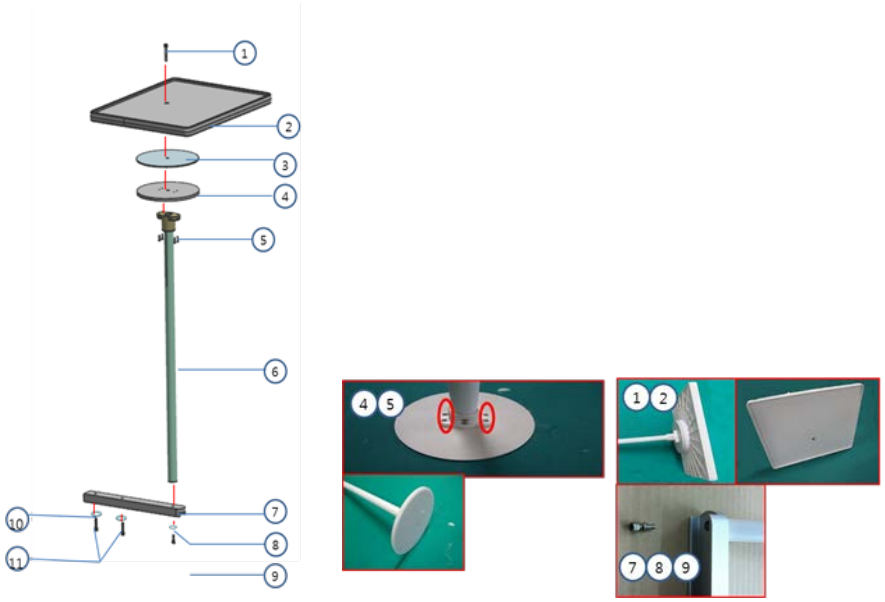
No.	Part name
①	IV ringer pole Assembly
②	IV plate Assembly
③	IV External monitor Assembly
④	shelf

No.	Qty	Description
①	1ea	LCD Monitor Ass'y
②	3ea	Machine Screw, M5x5 , stripper , stain-less steel , (Hexagon wrench 2.5 mm)
③	1ea	IV LCD PIPE , 25.4mm , stain-less steel
④	4ea	Machine Screw, M3x12 , pan head , stain-less steel
⑤	1ea	IV LCD FRAME
⑥	2ea	Lock washer, M6 , stain-less steel
⑦	2ea	Screw, M6x25 , Hex wrench , stain-less steel , (Hexagon wrench 5 mm)
⑧	1ea	LCD Monitor Ass'y Cable

- **Masimo Module Disassembly**

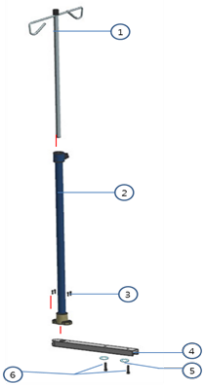
Step	Picture	Description
1		Put felex instrument cable into connector bracket and tighten two screws.
2		Solder Maimo gender board to connector board and tighten three screws.
		Connect flexible instrument cable to Masimo board and fix connector board to connector bracket with four screws.

- **IV plate**



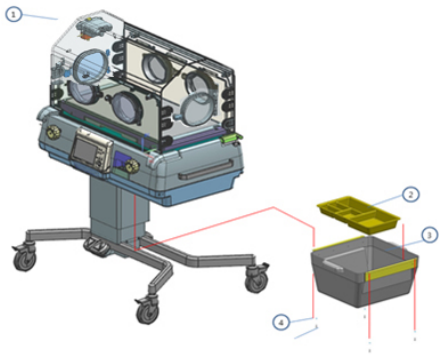
No.	Qty	Description
①	1ea	IV PLATE BOLT , Hex wrench , stain-less steel
②	1ea	IV PLATE
③	1ea	IV PLATE BUSHING 2T
④	1ea	IV PLATE SUPPORT 6T
⑤	4ea	Machine Screw, M3x12 , pan head , stain-less steel
⑥	1ea	IV PLATE POLE ,25mm , aluminum
⑦	1ea	IV PLATE FRAME
⑧	1ea	Lock washer, M5 , stain-less steel
⑨	1ea	Screw, M5x15 , Hexagon head bolt, stain-less steel (Hexagon wrench 4 mm)
⑩	2ea	Lock washer, M6 , stain-less steel
⑪	2ea	Screw, M6x25 , Hexagon head bolt , stain-less steel (Hexagon wrench 5 mm)

- **IV ringer pole**



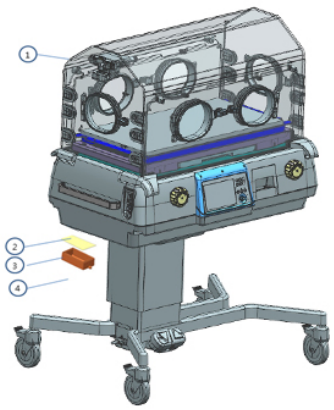
No.	Qty	Description
①	1ea	Ringer Pole
②	1ea	IV Ringer pipe, 25.4mm , stain-less steel
③	4ea	Machine Screw, M3x12 , pan head , stain-less steel
④	1ea	IV LCD FRAME

3.5.2. Basket Assembly & Disassembly



No.	Qty	Description
①	1ea	Main Ass'y
②	1ea	Basket Partition
③	1ea	Basket Ass'y
④	4ea	Spring Washer, M4 , stain-less steel ,
⑤	4ea	Screw, M4x10 , stain-less steel

3.5.3. Filter Assembly & Disassembly

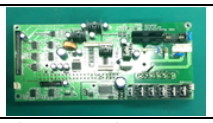
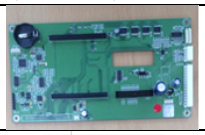
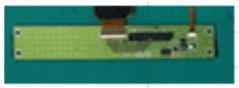
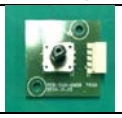


No.	Qty	Description
①	1ea	Total Ass'y
②	1ea	Micro Filter
③	1ea	Filter Cover
④	2ea	Filter Cover Bolt

WARNING
- Air filter exchange period is once in 3 months. Please check frequently and carefully that it is not dirty.

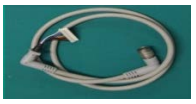
Section 4
Part List

4.1. Control box Parts

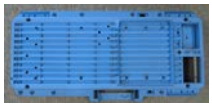
No	Part Number	Part Name	Picture
1	AY-500-CONTROL	CONTROL BOX Ass'y	
2	BD-500-MAIN R01	MAIN Board Ass'y	
3	BD-500-CONTROL SMPS R00	SMPS Board	
4	BD-500-CPU _CTRL R01	Control Board	
5	BD-350-CPU-R01	CPU Board	
6	BD-500-LCD-R00	LCD Board	
7	BD-500-KNOB R00	Control Knob Board	
8	BD-500-KEY R00	Key Board	
9	BD-500-O2CTL R00	Oxygen Control board Ass'y	
10	LCD-LTP700WV-F01-0	LCD	
11	500-MP-FNT-03R02	Shell Control Front	
12	BAT-LI-3R70-2201	Battery	
13	WH-500-23	MPS-8000 AC Power 03pin Cable Ass'y (1X1)	
14	WH-500-19	KNOB 4pin Cable Ass'y (1X1)	
15	WH-500-24	MPS-8000 Interface 12pin Cable Ass'y (1X1)	

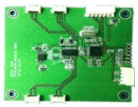
16	WH-500-20	Main 22 X 02 (44) pin Cable Ass'y (1X1)	
17	FAN-MFB40H-12L	Fan	

4.2. Sensor Module Parts

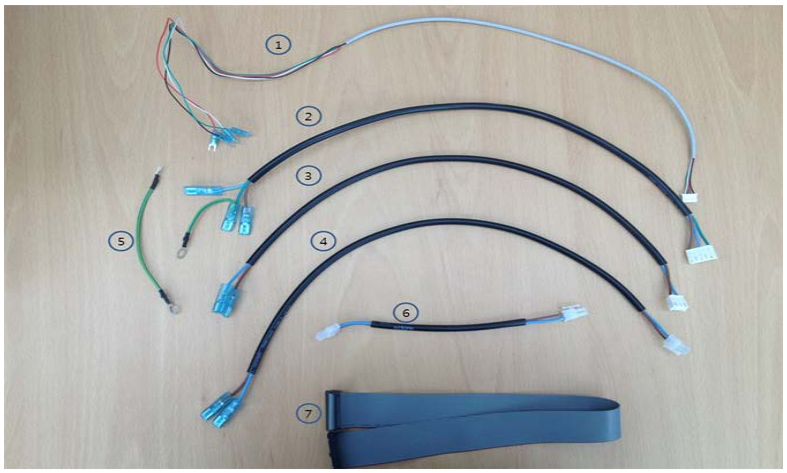
No	Part Number	Part Name	Picture
1	AY-500-SENSOR MODULE	Sensor Module Ass'y	
2	BD-500-SENSOR R01	Sensor board	
3	Sensor Module Cable	Sensor Module Cable	
4	BD-500-SENSOR SUB R00	Sensor Module Sub board	
5	SEN-HIH4021-002	Humidity Sensor	
6	SEN-CIG-103F397-S3	Temperature Sensor	
7	SEN-SS1118	O2 Sensor	
8	AY-500-CAMERA MODULE	Camera	
9	SEN-YSI 400	Skin Temperature Sensor	

4.3. Internal Shell Parts

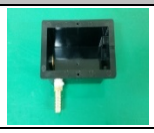
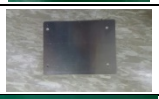
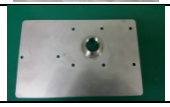
No	Part Number	Part Name	Picture
1	Shell Module Ass'y	Shell Module Ass'y	
2	500-MP-TOP-01R02	Shell Top Cover	
3	500-MP-BTM-01R00	Shell Bottom Covfer	

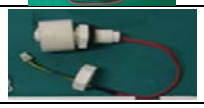
4	500-DA-RDT-01R00	Radiator heater machining	
5	500-MP-COV-01R00	SHELL SCROLL COVER	
6	500-MP-DEK-01R00	Shell Desk	
7	AY-500 TILF LIFT	TILT LIFT Ass'y	
8	AY-500-TRAY MATTRES	TRAY MATTRES Ass'y	
9	AY-500- SCALE	Scale Ass'y	
10	BD-500-SCALE R00	Scale Board	
11	LOA-FX1901-0001-0025L	Load cell	
12	HEA-HEATER240V400W	Cartridge Heater	
13	500-DA-PVT-01R00	SHELL BRACKET PIVOT_R Ass'y	
14	500-DA-PVT-02R00	SHELL BRACKET PIVOT_L Ass'y	
15	AY-500-TILT	TILT Ass'y	
16	AY-500-TILT HANDLE	Tilt Handle Ass'y	
17	MOT-B60Q-H24051-R4	BLDC Motor	
18	500-RQ-RUB-01R00	Vibration Proof Rubber	
19	BD-500-RPM R00	RPM Board	

20	BD-500-CONS_CONNR	Conlse Connector Board Ass'y	
21	SEN-AMS-39(N.O)	Magnetic Sensor	
22	BD-500-CONNECTOR R01	Connector Board	
23	BD-500-MASIMO MODULE R00	Masimo Module	
24	500-MP-IMP-01R01	Impeller	
25	SW-PWR-RL3-4-G-2	Power Switch	
26	SOCD-SS-7B-VDE-4.8-3	Power Soket Innet	
27	500-MP-GID-08R02	Humidity Lock Guide	
28	500-MP-COV-04R00	Shell Pneumatc Module Cover	
29	Water Box Guide Ass'y	Water Box Guide Ass'y	
30	HT 1230	Water Box Hose Ass'y	
31	AY-500-CHECK VALVE	Check Valve Ass'y	
32	AY-500-WATER BOX	Water Box	
33		Internal Cables	Following image

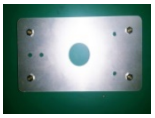
34			
	34-1	WH-500-07	Door Sensor 04pin Cable Ass'y
	34-2	WH-500-04	AC IN Power Socket 03pin Cable Ass'y
	34-3	WH-500-05	Power Switch1 02pin Cable Ass'y
	34-4	WH-500-06	Power Switch2 02pin Cable Ass'y
	34-5	WH-500-30	Ground 01pin Cable Ass'y
	34-6	WH-500-06	Power Switch2 02pin Cable Ass'y
	34-7	WH-500-01	Connector Bracket 13 X 02 (26)pin Cable Ass'y(1X1)

4.4. Humidity Module Parts

No	Part Number	Part Name	Picture
1	500-MP-BOD-02R00	Humidity Float body	
2	500-DA-BOD-01R00	Humidity heater Body	
3	AY-500-SPONGE	Melamine module Ass'y	
4	500-PA-BRT-03R00	Melamine Foam Bracket	
5	500-PS-PLT-03R00	Humidity plate	
6	SEN-NTC-103F397F-LI220	Temperature Sensor	
7	THE-MR-1-N150	Thermostat(manual)	

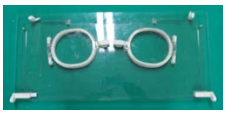
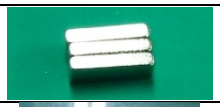
8	THE-MS-1-N120	Thermostat(Auto)	
9	HEA-HEATER220V250W HEA-HEATER110V250W	Water Heater	
10	WH-500-33	Humidity cable	
11	VAL-121S432KS-I-1S-C2-U	SOLENOID VALVE Ass'y	
12	SW-FLT-DM-F30	Float Switch	
13	500-PS-CAP-03R00 - 500-PS-CAP-03R00 - 500-AP-BUS-10R00	Humidity Cap - Humidity cap - Huidity cap bushing - Humidity guiding bushing	

4.5. Oxygen Module Parts

No	Part Number	Part Name	Picture
1	4250 (50mm POLYPROPYLENE GAS FILTER) x 2	Control module assembly	
2	VAL-121S432KS-I-1S-C2-U	Solenoid Valve	
3	PR2-02BG	Regulator	
4	500-PA-PLT-03R00	O2 plate	
5	HO-080120070	Hose	

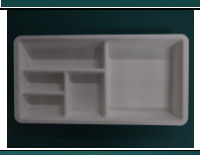
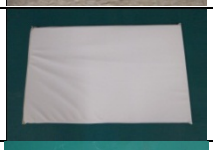
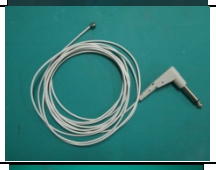
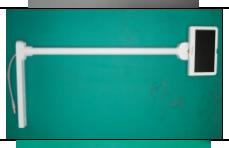
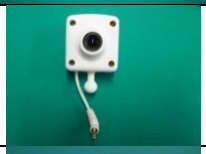
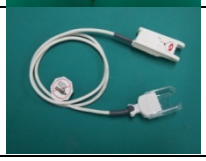
4.6. Hood Ass'y Shell Parts

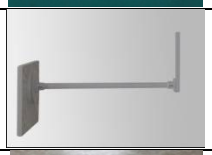
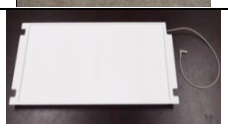
No	Part Number	Part Name	Picture
1	Hood Hinge Rear Ass'y	Hood Ass'y	
2	Hood Hinge Panel Front Ass'y	Hood Hinge Panel Front Ass'y	

3	Hood Hinge Panel Rear Ass'y	Hood Hinge Panel Rear Ass'y	
4	500-MP-GID-05R00	Cable Guide	
5	Hood Hinge Rear Ass'y	Hood Hinge Rear Ass'y	
6	Hood Hinge Front Ass'y	Hood Hinge Front Ass'y	
7	Hood S_Module Guide	Hood S_Module Guide	
8	500-MP-DOR-01R00	Hood Door	
9	AY-500-HOOD DOOR LATCH	Hood Door Latch Ass'y	
10	500-MP-PLT-04R00	Hood Hinge Heat Plate	
11	NM4-1005-02	Square Neodymium Magnet	
12	500-RQ-GSK-01R01	Hood Door Gasket	
13	500-MU-REG-01R00	Hood Ring Retaining	
14	500-MP-POT-01R00	Hood Ring Port	
15	500-MP-FNG-01R00	Hood Ring Flange	
16	500-MU-GOM-01R00	Hood Grommet	

4.7. Accessory & Option Parts

	Picture	Name	Description	Qty
1		Control shell (Standard)	Hold up the hood and be composed with instruments and parts that control the temperature and humidity	1ea
2		Hood (Standard)	Made of double framed clear acrylic panel to watch inside, and to minimize heat loss	1ea

3		Moving stand(no lift) (Standard)	Movable incubator cradle with wheels	1ea
4		Basket (Standard)	Store medical equipment and items which infant needs	1ea
5		Basket Partition	Partition of Basket	1ea
6		Sensor module (Standard)	Measures temperature and humidity inside the hood and infant's body temperature	1ea
7		Mattress tray (Standard)	Baby desk with X-ray tray	1ea
8		Compatible mattress (Standard)	Accommodate infant stably with bouncy mattress	1ea
9		Skin temperature sensor (Standard)	Measures infant's skin temperature	2ea
10		IV-pole (Standard)	IV hanger.	1ea
11		AC power code (Standard)	AC Power cord(AC Power cord for operating the equipment)	1ea
12		External 7" Color TFT LCD Monitor (Optional)	Displays measured values from the control and video of infant inside the hood.	1ea
13		CCD Camera (Optional)	Takes video of infant inside the hood	1ea
14		Masimo SpO2 sensor probe (Optional)	Measures infant's SpO2	1ea

15		Masimo Extension for Spo2 sensor (Optional)	Extend sensor cable	1ea
16		IV-plate (Optional)	Plate to place items which infant needs	1ea
17		Shelf plate (Optional)	Plate to place items which infant needs	1ea
18		BT-500 Moving lift Stand (Optional)	Movable incubator cradle with wheels (VHA- Variable Height Adjustable)	1ea
19		BT-500 Weighing module (Optional)	Measures Infant’s weight	1ea

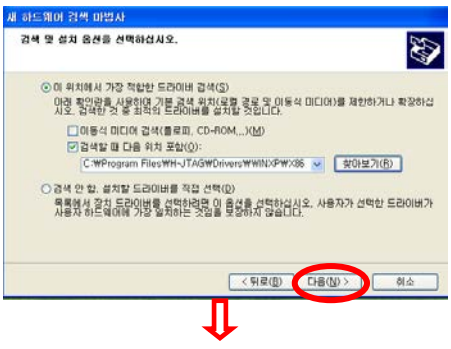
Section 5
Firmware Download

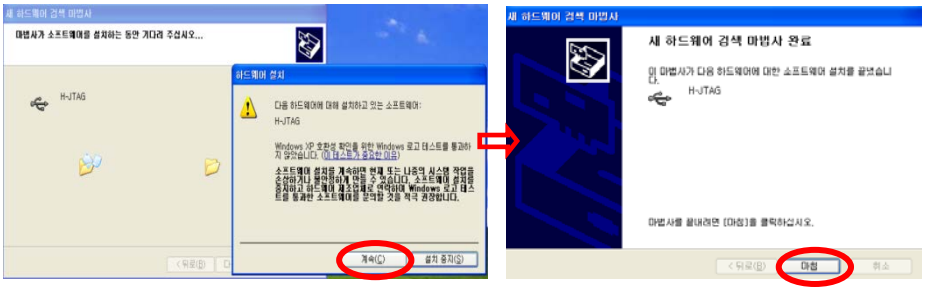
Bistos supports “Software upgrade function” for algorithm or user interface upgrade of BT-500. Software upgrade function must be operated by authorized service engineer. Follow the below sequence to use the software upgrade function.

5.1. How to do S3C2410 flash fusing

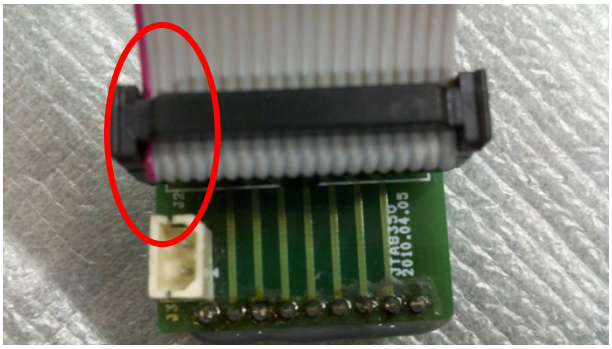
① Open http://www.hjtag.com/download.html
② Download H-JTG V1.1 RELEASE (Build 20100601)
③ Open compressed file, and install program file.
④ Connect H-JTAG to PC, and install USB Drivers.

⑤ Select red round above. Then find and select the folder which is accordance with your system. (you can find this folder generally “C:\Program Files\H-JTAG\Drivers”)





⑥ Connect the connecter to the cable of JTAG. You can see ‘J2’ on the connecter. It could be a reference for proper connection.



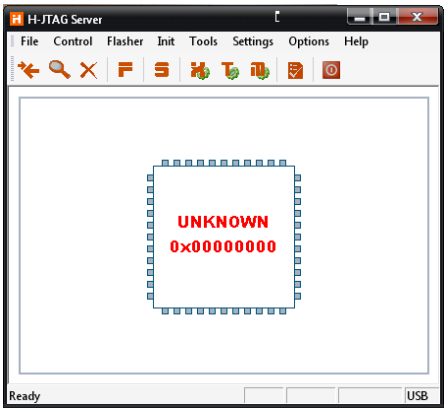
⑦ Connect JTAG dongle(left hand side of second image below) to J3 on BT-500 CPU module (S3C2410 CPU module) and connect USB Jack(right hand side of second image below) to PC.

BT-500 CPU module

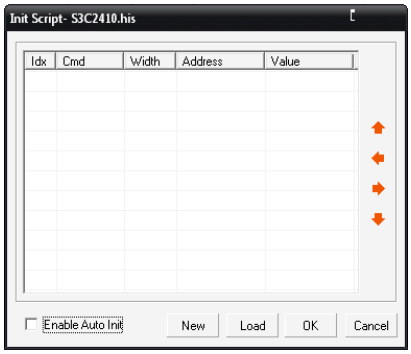
PC

⑧ Run H-JTAG

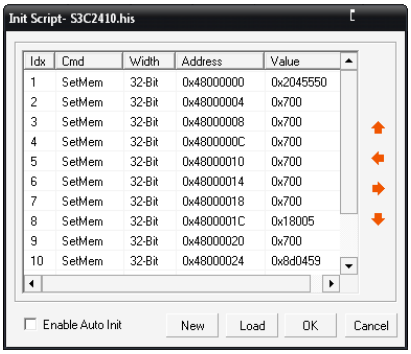
You can see below on the screen. Then turn on the device(Fetal monitor). TGT of JTAG lights. (If you see “ARM920T” already on the screen, pls. proceed from no. 13)



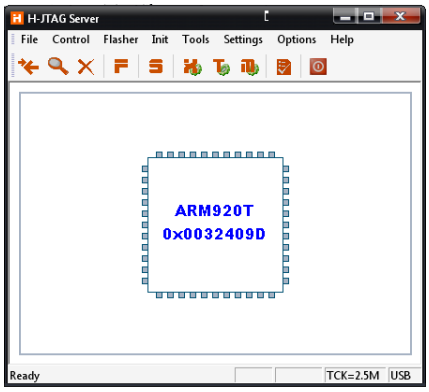
⑨ Click “Init” of red round above.
Init → Init script



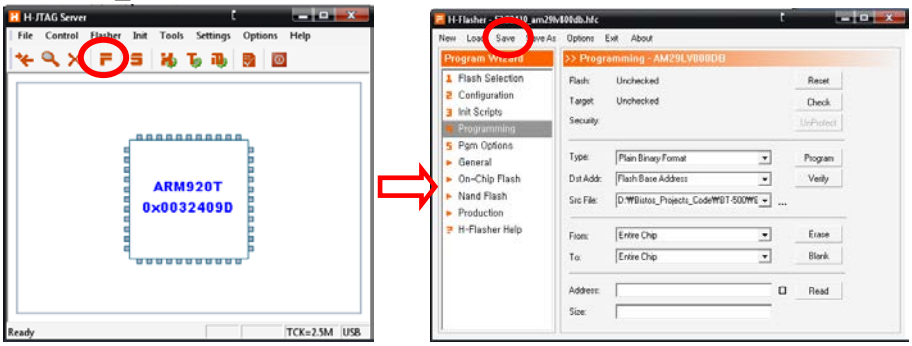
Click “Load” and select “S3C2410.his”file, then click “OK”.
Click “Init” – “Auto init” and confirm “V” mark.



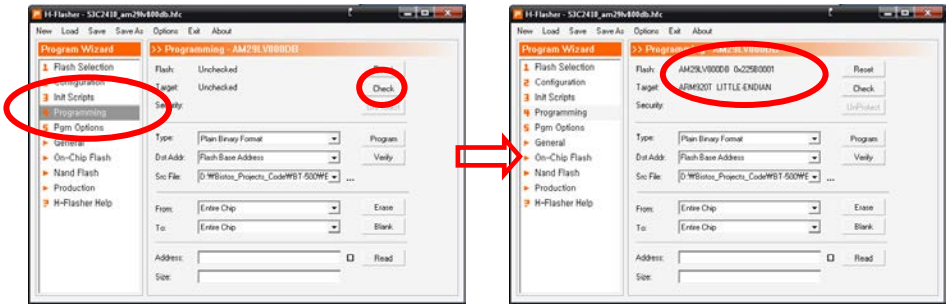
⑩ Click the icon in red round below image and confirm ARM920T is shown as follows.



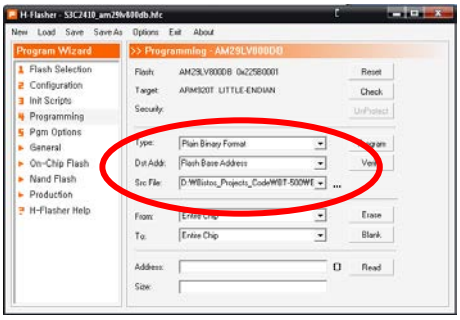
⑪ Click “F” icon of red round below. Then you can see the right screen. Click “Load” and select “S3C2410_am29lv800db.hfc” file.



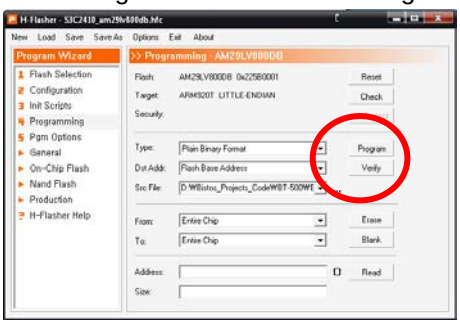
⑫ Select “Programming”, and Click “Check” of Target.

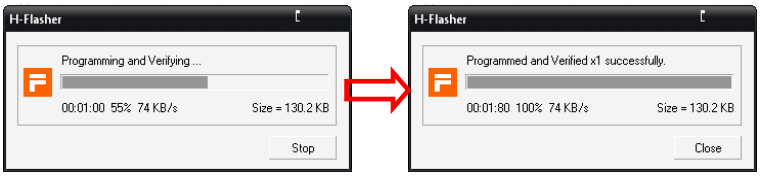


Confirm you see “AM29LV800DB 0x225b0001” and select as below.
Type : Plain Binary Format
Dst Addr : Flash Base Address
Src : XXX.bin (provided file)



Click “Program” and do flash fusing.





Turn off and disconnect H-JTAG. Connect Jumper and run factory set up.

Section 6
Maintenance & Conservation

This chapter contains instructions for the care and cleaning of the BT-500 unit and its accessories.

The BT-500 requires proper care and preventive maintenance. This ensures consistent operation and maintains the high level of performance necessary in the environmental for the early born infant.

6.1. Hood

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

- Turn off the BT-500 and unplug the BT-500 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.
- Do not use alcohol for cleaning. Alcohol can cause crazing of the clear acrylic hood.

6.2. Shell, Sensor module, Scale module, basket

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

- Be careful not to have a burn when clean the radiator of shell. Check the temperature of the radiator before cleaning.

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.

6.3. Humidity module, water tank

Keep inside of water tank and humidity module clean and free of fur, dirt. Clean with a damp cloth using mild soap and water or hospital approved, nonabrasive disinfectants.

6.4. Skin temperature sensors and SpO2 sensors.

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

6.5. 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.

6.6. Battery Disposal and Handling

The capacity of 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

- The internal battery must be handled by the qualified service engineer only. Do not attempt to open the BT-500.
- When disposing of internal Li-ion battery, adhere to all applicable laws regarding recycling. Avoid storing battery above 60℃ (140˚F). If cloth or skin come into contact with material from inside the battery, immediately wash with plenty of clean water.

6.7. Maintenance

The BT-500 incubator and accessories require no periodic calibration or adjustment. The recommended interval for performing leakage testing is once per year.

6.8. Disposal of the BT-500

When disposing of the BT-500, adhere to all applicable laws regarding recycling. If you are not able to dispose the BT-500or you need a help for disposing the BT-500, please contact us. In the case of there are no appropriate ways to dispose, we will pick up the BT-500.

6.9. 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-500 does not work properly, please contact us and change the corresponding parts. Note that the replacement costs can be occurred.

Section 7
Troubleshooting

If there is trouble with the equipment, check the possible cause in the below.

7.1. General Checking

When the following problems are happened, before contact the head office, please check following measures.

When the device is not turned on
- Please check that the power cable is securely connected to the AC power

When values are not displayed
- Please check that sensor and extension cables are properly connected to sensor connector.
- Please check that sensor works properly after connect cables.

When values are not in proper range
- Please check if the hood in closed well.
- Please check the probe is attached properly.
- When setting the scale to zero or measuring weight, please check if any object is placed on the measuring plate.

7.2. Alarm Message Checking

① After the monitor power on, Self-testing mode will be appeared.

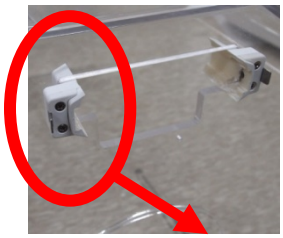
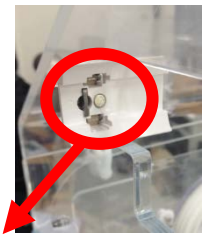
② If the BT-500 has some problem for operation, alarm messages will be displayed as follows.

Alarm Messages	Cause	Solution
Fan power failure	Failure of fan power system.	Replace Main board. Replace the control box according to 3.4.2.
Air circulation failure	Failure of impeller operation.	Check the impeller and replace it. (Break, distortion) Replace the impeller according to 3.4.1. RPM Board or Main Board broken. Replace the RPM board and main board according to 3.4.1 and 3.4.2.
Motor Failed	Failure of motor driver	Check U12 of Main board /replace it. Or replace main board according to 3.4.2.
Over-burned Heater	Overheating of cartridge heater and pan motor. Malfunction of servo control of temperature or malfunction (break) of impeller.	Stop using BT-500 and contact the distributor or Bistos office.
Humidity Heater failed	Malfunction of inserted heater from humidity module or failure of humidity heater control part.	Check F1 fuse of Main board. If F1 is broken, replace F1. If it is normal, replace inserted heater of humidity module. Replace the humidity heater according to 3.4.3.

Heater system failed	Malfunction of cartridge inside of Shell module or failure of main heater control part.	Check F1 fuse of Main board. If F1 is broken, replace F1. If it is normal, replace Main board or Shell module of cartridge heater. Replace the cartridge heater according to 3.4.1.
O2 mod power fail	Oxygen module power fail	Replace O2 board in the console box following to 3.4.2.
Stuck key	Key button or knob button is stuck	Check key button and knob switch are pressed. If it is normal, replace U3 of control board.
Air sensor failure	Failure of air temperature sensor	Replace sensor sub board or air temperature sensor following the 3.3.1
Humidity sensor failure	Failure of humidity sensor	Replace sensor sub board or air temperature sensor following the 3.3.1
Skin Probe Disconnect	Failure of disconnection skin temperature sensor from sensor module in skin mode.	Check skin senor is inserted in the proper position of sensor module. Check it is skin mode.
O2 sensor failure	Failure of O2 sensor. (Life cycle : 1.5 ~2 year)	Replace O2 sensor following the 3.3.1.
Sensor mod disconnected	Failure of connecting sensor module to shell module. The sensor module connector of connector board can be broken.	Check sensor module is connected with shell module properly. Check the sensor module connector of connector board. If the connector has broken replace the connector board following 3.4.1.
Sensor module not in position	The sensor module is not positioned to Hood properly.	Check sensor module is placed in the proper position of hood and shell module is connected. If it is normal, check magnet is placed in hood properly. Refer to 7.3
Temperature does not go up	Main board failure or heater cartridge failure	Replace the main board or heater cartridge. Refer to 7.3.
Humidity instable	Humidity sensor failure	Replace the humidity sensor Replace the sensor sub-board according to 3.3.1.
Humidity cannot be controlled.	SSR1 of main board shorted.	Replace the SSR1 of main board according to 3.4.2.
Humidity increasing continuously	SSR1 of main board shorted.	Check pin 2 and 3 of SSR1 in main board has been shorted. Replace SSR or main board. Refer to 3.4.2.
Self Test error (RAM Check error etc.)	CPU board failure	Replace CPU board. Refer to 3.4.2.
Key button failure(Button not operation)	Control board failure	Check whether the CPU board is correctly inserted to the control board. If the board is connected correctly replace the control board according to 3.4.2.
O2 Sensor Power failure	O2 control board failure.	Replace O2 control board. Refer to 4.3.2.

7.3. Technical Descriptions

<Magnetic sensors>
There are several sensors using magnets in BT-500. It is explained in the below picture.

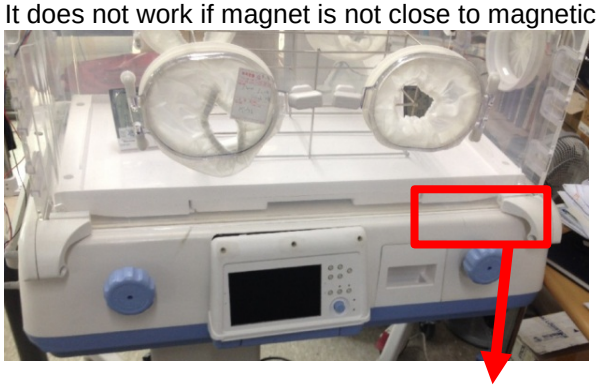



Neodymium
Magnetic

Magnetic
sensor

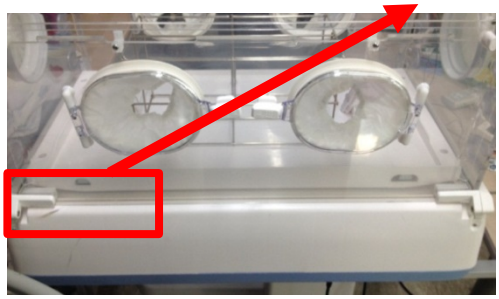
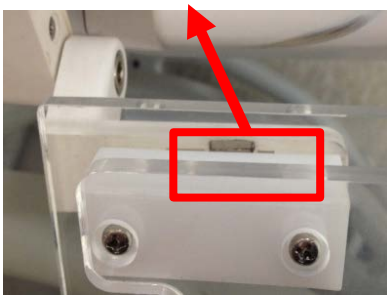
When the message “Sensor Mod Not in Position” displayed, check the magnet is in the correct position.

It does not work if magnet is not close to magnetic sensor referring to the picture.



Magnetic
sensor

Neodymium
Magnetic

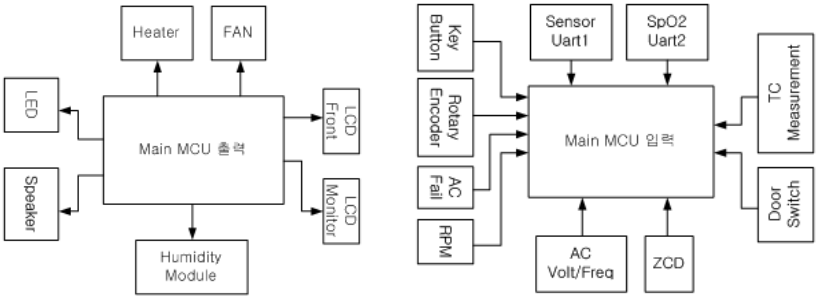
When there is a problem with the hood door sensor, check the position of magnet referring to the above picture.

<Water Leakage>
If water leak is founded or occurred during operating BT-500, it should be stopped to use. It will be the cause of all malfunctions. When there is water leak, it is required to find the place and cause of water leak. (Humidity module, water tank, main body fitting parts, etc.) If the cause of water leak is founded, it is required to replace the related module or spare part.
Water leak can be occurred if water tank is not inserted in the main body completely or not positioned properly. All the time, check if the module is inserted properly.

<Fuses>
There are 3 fuses in BT-500. When there are failures such as Heater system failure or Humidity heater failed, the electric circuit such as main board is protected by the fuse.
The way how to check if the system operates properly is that fuse should be connected when

checking the both ends of conduction test from fuse by tester. The both ends is not conducted, there is problem with the fuse. (Where there are failures of Heater system failure, Humidity Heater failed, Motor Failed, it is required to check the fuse certainly.)
Also, check if thermostats are overheated. The power will be shut off when main cartridge heater is overheated over 120 °C. The humidity module has one temperature sensor (NTC sensor) and 2 thermostats. Thermostat 1 will be shut off the power when the water heated over 120 °C, and thermostat 2 will be shut off at 150 °C. NTC sensor will monitor the water temperature and the MCU will control the water heater to keep the water temperature between 92℃(Normal) and 110℃(Humidifying).

<Abnormal Humidity or Air/Skin temperature>
If the value of humidity is displayed high (Max) or "---", humidity sensor or sensor sub board are required to be displaced. If humidity value is decreased or changed suddenly even though humidity status is increased or maintained, there is the failure of humidity sensor. In this case, breathe the humidity sensor then, check it. (Humidity value should be increased when breathing to the humidity sensor)
Also, check if hood door open sensor works properly. When hood door is displayed as open status, the humidity value could be decreased. If a value of air and skin temperature is not accurate, check hood door open sensor operation. If it is open, close hood door and check the value again.
If there is no problem with hood door status, it is caused by the temperature sensor so, replace the temperature sensor. If the cause of inaccuracy for the temperature is made by temperature sensor, it could be the problem with cartridge heater. Check a resistance value of the cartridge heater by tester. The resistance of the cartridge heater should be 130~150ohm(220v) or 30~40 ohm(110v) If this value is not displayed, it is required to replace main cartridge heater.



[System output signal] [System input signal]

When air and skin temperature operate together, the currently selected mode from two modes is controlled only. (The selected mode is temperature control mode, the unselected mode is monitoring mode) The inaccuracy of the temperature value for the unselected mode is not trouble.

<Boards>
There are 4 important boards in BT-500. Each boards perform their own functions.
- SMPS board : Make main power required for BT-500 circuit.
- Main board : Motor driver(control), Humidity control, Oxygen control, AC control.
- Control board: I/O Interface, Display.
- Sensor board: Measure the temperature/humidity/O2, scale, camera.

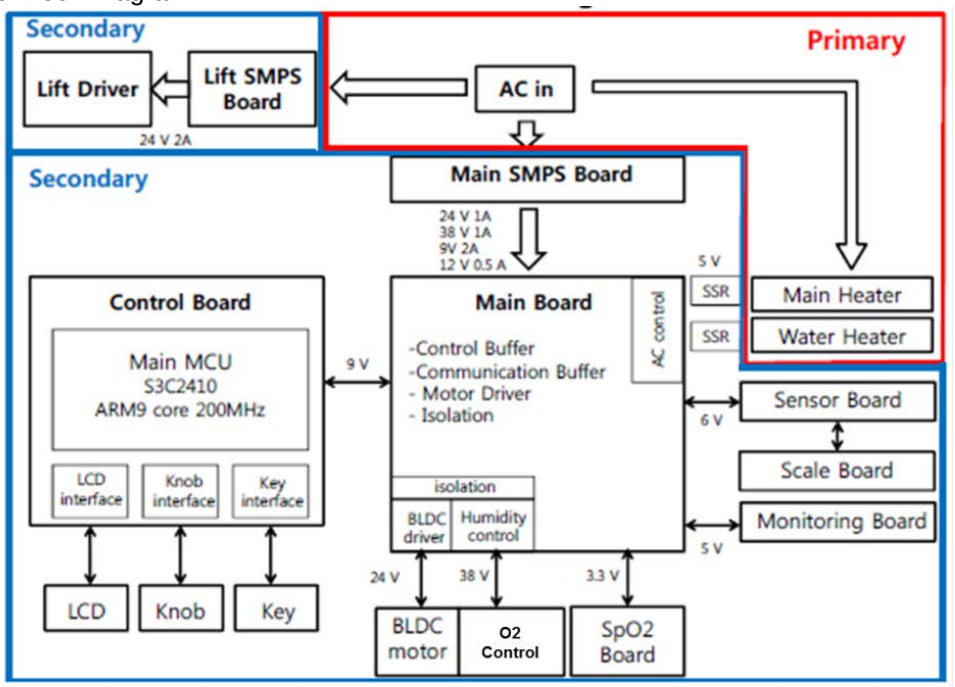
<System>
BT-500 Software is consisted according to input and output connects. For Input, there are key button, rotary encoder, AC fil input to control AC, RMP input to measure the speed of main motor, AC Volt/Freq to control the duty value by AC frequency, ZCD(Zero crossing detector) to decide heater output, Door switch and TC measure for the device operation status.

After getting the input above, it is available to predict the device status and the value is applied to the control system. The required output signal for the control is referred to the below picture. There are LED output to display the alarm status, Speaker output, humidity output to control the humidity inside of hood, LCD to display whole device status, heater to circulate the internal

environment and fan output signal etc.

BT-500 is built in system so, there is no detachable storing device. The program data required to operate the system is consisted 3 parts and they are saved in Flash. Each part is recognized as the module and it is divided according to function/expandability/portability. Each module is explained as below.
Bootloader module is operated firstly after power is input and it performs system initialization process and copy as SDRAM of saved application code.
Monitor Module observes the system status and performs process allocation through system timer, interface of input/output device.
Application module performs servo control of temperature/humidity and GUI. The memory area is as below in the status of save/operation.

<BT-500 Block Diagram>



Service Telephone and Fax. Numbers

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

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

www.bistos.co.kr
bistos@bistos.co.kr

EC REP ***Obelis s.a***
Bd. Général Wahis 53
1030 Brussels, BELGIUM
Telephone: + (32) 2. 732.59.54
Fax.: + (32) 2.732.60.03

CE 2460

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

Notified Body Confirmation Letter Reference: C615266

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, DNV Product Assurance AS, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number NB 2460 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Bistos Co., Ltd.
7th Fl., A Bldg., Woolim Lions Valley 5-cha, 302, Galmachi-ro,
Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea
SRN Number (if available): KR-MF-000035951

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

Place and date:
Høvik, 2023.08.22

For the issuing office:
DNV Product Assurance AS – Notified Body 2460
Veritasveien 1, 1363 Høvik, Norway

Menaka Singh
Management Representative

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Fetal monitor (BT-350, FM20) / 88000123MEFM03009A	Class IIb	N/A	- Certificate number: 243269-2017-CE-KOR-NA-PS (Rev. 5.0); - NB number NB: 2460; - Expiry date: 01 Sep 2023
Neonatal Phototherapy unit (BT-400) / 88000123MEPU0400G9	Class IIa	N/A	- Certificate number: 243269-2017-CE-KOR-NA-PS (Rev. 5.0); - NB number NB: 2460; - Expiry date: 01 Sep 2023
Pulse Oximeter (BT-710) / 88000123MEPO710BV	Class IIb	N/A	- Certificate number: 243269-2017-CE-KOR-NA-PS (Rev. 5.0); - NB number NB: 2460; - Expiry date: 01 Sep 2023
Patient Monitor (BT-720) / 88000123MEPM0700DY	Class IIb	N/A	- Certificate number: 243269-2017-CE-KOR-NA-PS (Rev. 5.0); - NB number NB: 2460; - Expiry date: 01 Sep 2023
Patient Monitor (BT-740, BT-770, BT-780) / 88000123MEPM0701E2	Class IIb	N/A	- Certificate number: 243269-2017-CE-KOR-NA-PS (Rev. 5.0); - NB number NB: 2460; - Expiry date: 01 Sep 2023
Fetal monitor (BT-300, Biocare FM-1) / 88000123MEFM03009A	Class IIb	N/A	- Certificate number: 243269-2017-CE-KOR-NA-PS (Rev. 5.0); - NB number NB: 2460; - Expiry date: 01 Sep 2023
Ultrasound Doppler system with Probes ▪ BT-200L - AY-DOP-200L (2M) ▪ BT-200C - AY-DOP-200C (2M) ▪ BT-200S - AY-DOP-200S (2M) ▪ BT-200T	Class IIa	N/A	- Certificate number: 243267-2017-CE-KOR-NA-PS (Rev. 2.0); - NB number NB: 2460; - Expiry date: 27 May 2024

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
- AY-DOP-200T (3M) ▪ BT-200V - AY-DOP-200V (2M) - AY-DOP-200V (4M) - AY-DOP-200V (5M) - AY-DOP-200V (8M) ▪ Flux200 diaped® - AY-DOP-200V (2M) - AY-DOP-200V (4M) - AY-DOP-200V (5M) - AY-DOP-200V (8M) ▪ F10 - AY-2MHZDOP-010 / Basic UDI DI : 88000123MEFD020062			
Ultrasound Doppler system with Probes ▪ BT-220L - AY-DOP-220 (2M) - AY-DOP-220 (3M) ▪ BT-220C - AY-DOP-220 (2M) - AY-DOP-220 (3M) / Basic UDI DI : 88000123MEFD022068	Class IIa	N/A	- Certificate number: 243267-2017-CE-KOR-NA-PS (Rev. 2.0); - NB number NB: 2460; - Expiry date: 27 May 2024
Ultrasound Doppler system with Probes ▪ BT-250 - AY-DOP-250 (2M) / Basic UDI DI : 88000123MEFD02506H	Class IIa	N/A	- Certificate number: 243267-2017-CE-KOR-NA-PS (Rev. 2.0); - NB number NB: 2460; - Expiry date: 27 May 2024
Electric Breast Pump (BT-100) / Basic UDI DI : 88000123MEBP01008D	Class IIa	N/A	- Certificate number: 243267-2017-CE-KOR-NA-PS (Rev. 2.0); - NB number NB: 2460; - Expiry date: 27 May 2024
Electric Breast Pump (BT-150, BT-150L, BT-150B, BT-150S) / Basic UDI DI : 88000123MEBP01508U	Class IIa	N/A	- Certificate number: 243267-2017-CE-KOR-NA-PS (Rev. 2.0); - NB number NB: 2460; - Expiry date: 27 May 2024
Infant warmer (BT-550) / Basic UDI DI : 88000123MEWM0550GY	Class IIb	N/A	- Certificate number: 243267-2017-CE-KOR-NA-PS (Rev. 2.0); - NB number NB: 2460; - Expiry date: 27 May 2024

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Infant incubator (BT-500) / Basic UDI DI : 88000123MEIN0500B6	Class IIb	N/A	- Certificate number: 243267-2017-CE-KOR-NA-PS (Rev. 2.0); - NB number NB: 2460; - Expiry date: 27 May 2024

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A			

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/08/22	C615266	Initial issue

Lack of fulfilment of conditions

The following may render this letter of confirmation invalid:

- Lack of compliance to the requirements of Regulation (EU) 2023/607
- Significant changes to design or intended purpose of the devices
- Changes in the quality system affecting production
- Periodical audits not held within the timeframe

EC CERTIFICATE

Full Quality Assurance System

Certificate No.: 243267-2017-CE-KOR-NA-PS Rev. 2.0 Project No.: PRJC-533956-2015-MSL-KOR Valid Until: 27 May 2024

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:

Ultrasound Doppler System with Foetal Doppler System Probes, Electric breast pump, Infant warmer, and Infant incubator

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

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

Place and date:
Høvik, 17 March 2021

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

Eugenie Winger Husebye
Technical Reviewer

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 EU1012401, Rev 3.0 (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	**Recertification (Certificate no. 215934-2017-CE-KOR-NA-PS has been merged after the recertification audit completed)**	**17 March 2021**

Products covered by this Certificate:

Product Description	Product Name	Class
Ultrasound Doppler system with Probes	▪ BT-200L - AY-DOP-200L (2M) ▪ BT-200C - AY-DOP-200C (2M) ▪ BT-200S - AY-DOP-200S (2M) ▪ BT-200T - AY-DOP-200T (3M) ▪ BT-200V - AY-DOP-200V (2M) - AY-DOP-200V (4M) - AY-DOP-200V (5M) - AY-DOP-200V (8M) ▪ F-10 - AY-2MHZDOP-010 ▪ BT-220L - AY-DOP-220 (2M) - AY-DOP-220 (3M) ▪ BT-220C - AY-DOP-220 (2M) - AY-DOP-220 (3M) ▪ BT-250 - AY-DOP-250 (2M)	IIa
Electric Breast Pump	▪ BT-100 ▪ Milk Genie ▪ BT-150, BT-150L, BT-150B, BT-150S	IIa

Infant warmer	▪ BT-550	IIb
Infant incubator	▪ BT-500	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, Galmachiro, 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