BT-380 Fetal monitor
Operation Manual

Keep this manual for future reference

P/N : 380-ENG-OPM-EUR-R00

Proprietary Material

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Contents

0 Safety information

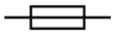
Before using BT-380 Fetal monitor, read this entire manual and be fully understood the following safety information to prevent injury of patient and user.

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 Fetal 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-380.
	Used to identify safety information. Be well-known this information thoroughly before using BT-380
IPX1	Indicates the protection level against the ingress of liquid. IPX1 is protection against some water drops falling vertically. It correspond the device, Fetal 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.
IPX8	Indicates the protection level against the ingress of liquid. IPX8 is protection against the effects of continuous immersion in water (1 meter of water for over 40 minutes) It correspond the accessories for DOP and UC probe.
	Refer to operation manual. Read manual before placing the device.
	Indicates AC power supply
	Indicates the device is in the battery operation mode.
	Fuse
	Equipotentiality
	Indicates nurse call interface.
	Indicates network interface.
	Indicates USB interface.
	Indicates the production date.
	Indicates the manufacturer.
SN	Indicates the serial number of the device.
EC REP	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 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).

0.1 General precautions, warnings and cautions

- Examine the Fetal 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 Fetal monitor if there is any visible sign of damage.
- Only the DC power cord supplied with the BT-380 is approved for use with the device.
- Do not attempt to service the BT-380 Fetal 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 Fetal monitor under the conditions specified in this operation manual. Beyond the conditions, the Fetal 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-380 Fetal monitor if it fails to pass the power on self-test procedure.
- During the operation, do not disconnect any cable.
- The BT-380 Fetal 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-380. Failure to do so could result in personal injury or equipment damage.
- The device is intended for clinical Fetal 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 cord 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 Fetal 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 Fetal 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-380 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.

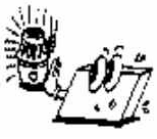
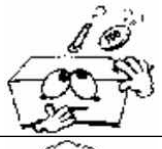
0.3 Battery warnings

⚠ **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

Fetal monitoring technology available today is not always able to differentiate a fetal heart rate (FHR) signal source from a maternal heart rate (MHR) source in all situations. Therefore, you should confirm fetal life by independent means before starting to use the fetal monitor, for example, by palpation of fetal movement or auscultation of fetal heart sounds using a fetoscrope, stethoscope, or Pinard stethoscope. If you cannot hear the fetal heart sounds, and you cannot confirm fetal movement by palpation, confirm fetal life using obstetric ultrasonography. Continue to confirm that the fetus is the signal sources for the FHR during monitoring.

Be aware that a MHR trace can exhibit features that are very similar to those of a FHR trace, even including acceleration and decelerations. Do not rely solely on trace pattern features to identify a fetal source.

It is possible to pick up maternal signal sources, such as maternal heart, aorta, or other large vessels as the FHR. Misidentification may occur when the MHR is higher than normal (especially when it is over 100bpm)

1.1 Intended use

The BT-380 Fetal monitor is intended for non-invasive monitoring of fetal heart rates and uterine activity and is intended for monitoring of maternal ECG, blood oxygen saturation (SpO2), Temperature, and non-invasive blood pressure (NiBp) also. BT-380 is intended for generating alarms from fetal heart rate, for displaying, storing and recording patient data and related waveforms.
BT-380 is intended for use by trained health care professionals.
BT-380 is intended for use in labor and delivery rooms and antepartum testing areas in the hospital environment.

1.2 Operating principle

Refer to the chapters for every physiological parameter from chapter 7 to chapter 13.

1.3 System configurations

Basic configuration of BT-380

- Main body with 10.4 inch touch screen and built-in lithium-ion battery
- Two Doppler probes
- Uterine Contraction probe
- Event marker
- ECG cable and electrode
- Adult SpO2 probe and extension cable
- Non-invasive blood pressure cuff
- Temperature probe
- Power Adaptor

Options of BT-380

- AST (Acoustic Stimulator Test) probe
- Li-ion Battery (14.8V, 4400mAh)

Picture	Name	Description	Qty
	Doppler Probe	Ultrasound Transducer for Measuring FHR (IPX8: Waterproof)	2ea
	UC Probe	Pressure Sensor for Measuring Uterine contraction(UC) (IPX8: Waterproof)	1ea
	Event Marker	Used for a Fetal Movement event	1ea
	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
	Grounding cable (Standard)	For safe using	1ea
	Z-folded type Paper	Z-folder type thermal Paper	1ea
	Probe Belt	Used for Holding Doppler Probe and/or UC Probe	1ea
	Power Cord	AC Power cord	1ea
	Power Adaptor	Adaptor for transform AC Power (100-240V ~) to DC 18V(2.8A)	1ea
	Ultrasound Gel	Ultrasound transmission gel (Sanipia, ECOSONIC)	1ea
	AST Probe (Option)	Acoustic Stimulation Test Probe	1ea
	LI-ION Battery	14.8V, 4400mAh	1ea

1.4 Product outlook

Figure1-1: Front view

Figure1-2 : Sider view

Figure1-3 : Rear view

1.5 Description of monitor

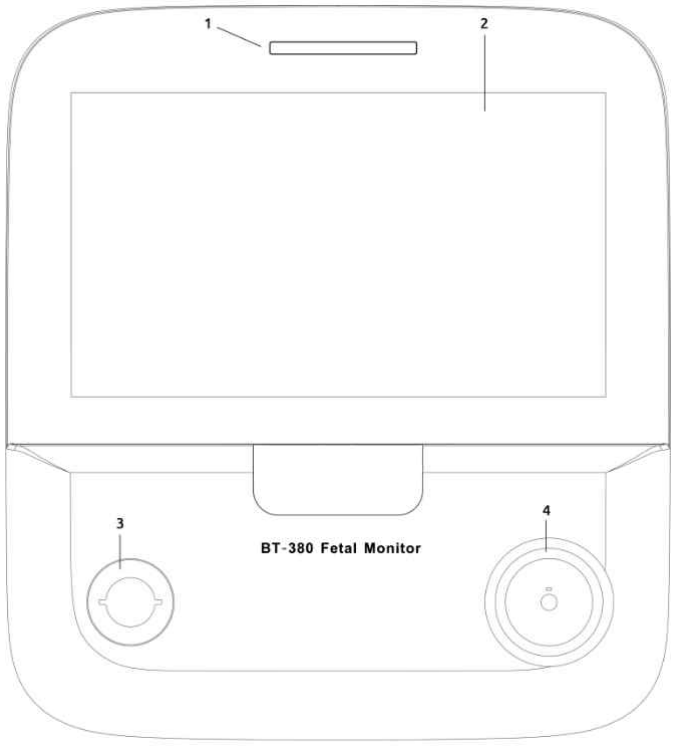


Figure1-4: Front view

	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 button	- Power On: Press down the key more than 1 second. - 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	Knob switch	Use for menu navigation and selection

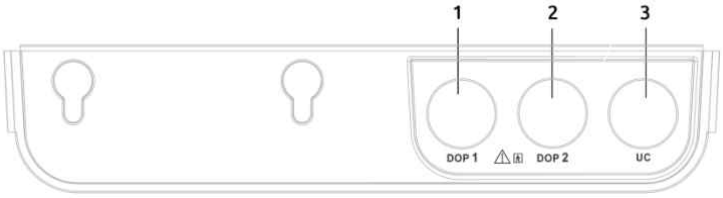


Figure1-5: Right Side view

	Name	Description
1	Doppler1	DOP1/AST cable interface
2	Doppler2	DOP2/AST cable interface
3	UC	UC cable interface

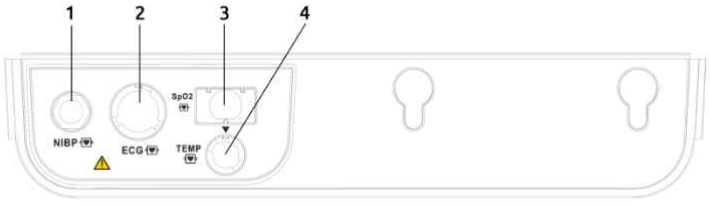


Figure1-6: Left Side view

	Name	Description
1	NIBP	NIBP cuff interface
2	ECG	ECG cable interface
3	SpO2	SpO2 cable interface
3	TEMP	Temperature probe interface

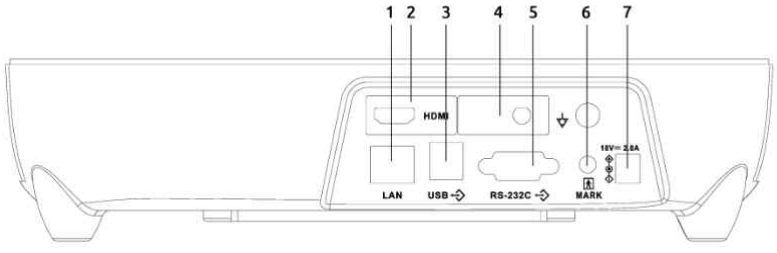


Figure1-7: Rear Side view

	Name	Description
1	Network port	For CMS
2	HDMI	Monitor interface (Optional function)
3	USB Port	USB 2.0 interface
4	Wi-Fi Antenna	For CMS (Optional function)
5	RS232	For CMS
6	Event Marker	Event marker jack interface
7	Power	18V, 2.8A adaptor interface

1.6 Understanding the display

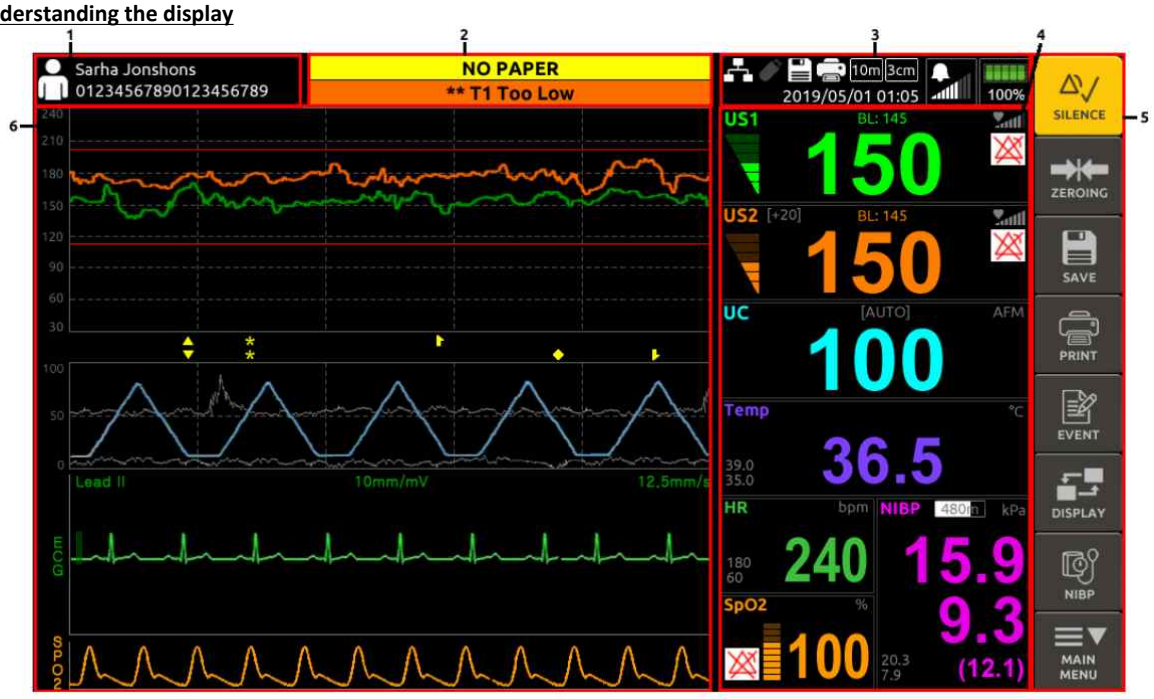


Figure 1-8: Standard display

	Name	Description
1	Patient Information	Show patient Name and ID
2	Alarm status	Show alarm status with corresponding alarm level color, physiological and technical alarms. In DEOM mode, it displays “DEMO”.
3	Information area	Shows current time, network status, USB connection status, Save indicator, Print indicator and so on.
4	Parameter area	Show the corresponding parameter measured value and current upper and lower alarm limits of each parameter module. - US1, US2, UC, TEMP, ECG, NIBP, SpO_2
5	Hot key icons	Shows the hotkeys, which are frequently used for some common operations.
6	Waveform area	Mainly display the waves of physiological parameters with name of the parameter on the left side

1.7 Smart Hotkeys

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

Key	Name	Description
	[Alarm]	Alarm pause
	[Zeroing]	UC manual zeroing button
	[Save]	Saving start and stop
	[Print]	Printer start and stop
	[Event]	Record clinical event mark or clinical event message.

	[View mode]	Change view mode from “Graphic mode” to “Numeric mode”
	[NIBP]	NIBP measurement start and stop
	[Main Menu]	Shows all configurable setting menus

1.8 Essential performance

This device Multi-parameter Fetal monitor provides not only FHR and UC parameter but also various maternal vital signs such as pulse rate, ECG, 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 and control circuit, and input part for various sensors. It detects FHR, UC, ECG, SpO2, NIBP, etc. using Doppler probe, ECG cable and specific probes and sensors. The detected analog signal amplifies and converted to digital. This converted data feed to the CPU and processed by some FHR algorithm, and then 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-380 Fetal 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 adaptor
  Input voltage: AC. 100 V - 240 V,
  Input current: 2.0A
  Frequency: 50/60 Hz
- Built-in rechargeable lithium-ion battery: DC. 14.8V, 4400mAh

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 cord in the following steps:

- Make sure that the AC power supply meets the following specifications: a.c.100V-240V, 50/60Hz.
- Use the power cord provided with the monitor. Plug the power cord into the power connector of the monitor, and plug the other end of the power cord 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 Fetal 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 Fetal 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] button, 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] button 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 keys

The monitor has two 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 time 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’.
- 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.

3.3.2 Using the touch screen

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

3.3.3 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.

3.3.4 Using menu

Select the [Main Menu] smart key on the monitor to open the “Main Menu” mode as shown below. You can set-up the monitor.

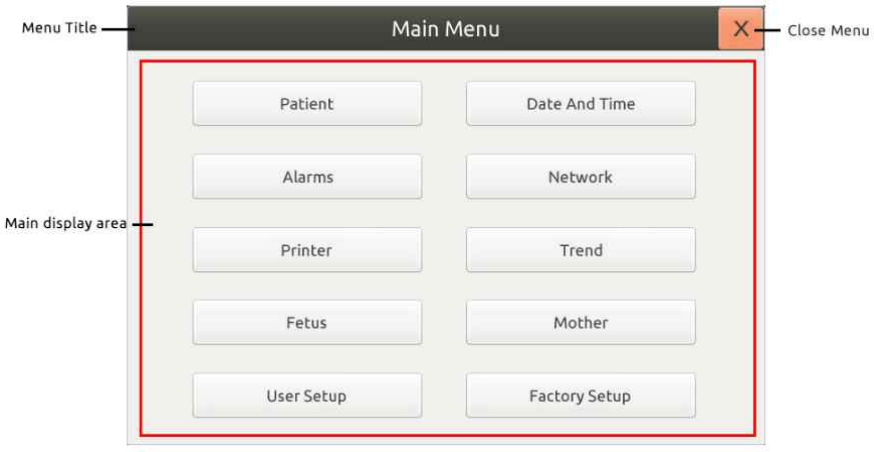


Figure 3-1: “Setting” menu

The style of other menus is basically similar to the “Settings” mode as shown below. You can set-up the monitor screen if you need.

- 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.

3.4 Operation mode

The style of other menus is basically similar to the mode is protected by a password. “User Setup” and “Factory Setup” contains a password key area to access the operations, including confirmation and cancel key.

1. Monitoring mode (operating mode)

This is the daily operating mode of fetal monitoring; you can change some settings in accordance with the patients, such as alarm limits.

2. Demo mode

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

- Enter the demo mode:
  - Select [Main Menu] Smart Hotkey → “Main Menu”;
  - Select “Factory Setup”;
  - Toggle “Demo Mode” and the monitor enter the demo mode.
- Exit demo mode:
  - Select [Main Menu] Smart Hotkey → “Main Menu”;
  - Select “Factory Setup”;
  - Toggle “Demo Mode” 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 Fetal 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 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.

3.6.1 Language setup

Set the monitor language in the following steps:

- Select [Main Menu] Smart Hotkey → “Main Menu”.

- Select “Factory Setup >>” →enter the password and confirm →“General” menu.
- Select “Language”, and select the option as needed:
  - “English”: The interface language of the monitor is English.
  - “French”: The interface language of the monitor is French.
  - “German”: The interface language of the monitor is German.

3.6.2 Date and time
Set the monitor time in the following steps:

- Select [Main Menu] Smart Hotkey → “Main Menu”.
- Select “Date And Time” → enter “Date and Time” menu.
- Or you can enter the “Date and Time” 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.

3.6.3 Sound Effect
Enable or disable the sound effect in the following steps:

- Select [Main Menu] Smart Hotkey → “Main Menu”.
- Select “User Setup” → enter “User Setup General” menu.
- Set the switch for the sound effect of “Start-up”, “Key Touch”, and “Print Ending”.

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.

4.1 Patient setup menu

You can manage the patient through the “Patient” menu. To enter “Patient” menu, operate as follows:
Select [Main Menu] Smart Hotkey → “Main Menu” → “Patient” → “Patient” menu;

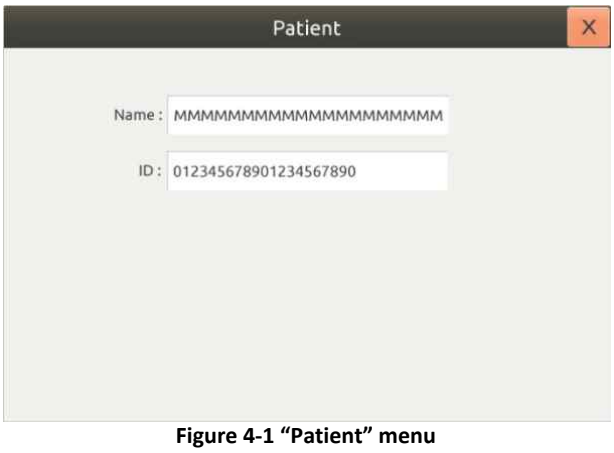


Figure 4-1 “Patient” menu

4.2 Patient information

To edit patient information, operate as follows:

1. Select “ Name”, and enter patient’s name through the soft keyboard（ Letters: not more than 20 characters）.
2. Select “ ID”, and enter the patient ID through the soft keyboard (Letters: not more than 20 characters).

After setting, select “Close menu” to save the current setting.

5 Display format

The monitor has two display formats, which are “Graphic mode” and “Numeric mode”. 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 [View Mode] Smart Hotkey
- Change view mode from “Graphic Mode” to “Numeric Mode” or vice versa.

5.2 Display description

5.2.1 Graphic mode

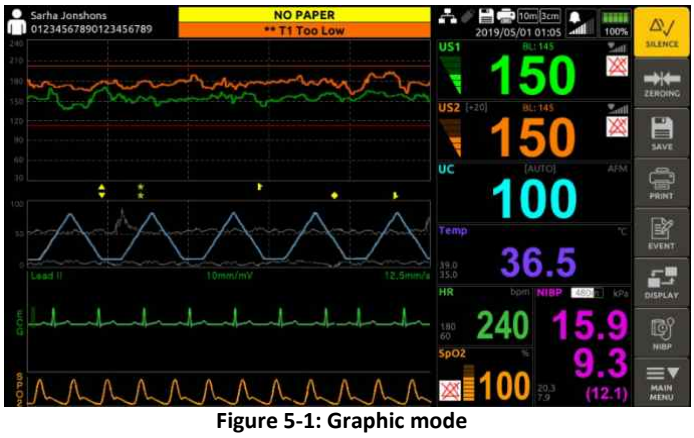


Figure 5-1: Graphic mode

The Graphic mode 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 FHR waves, one UC wave, one ECG wave, and one blood oxygen saturation percentage wave is displayed.

5.2.2 Numeric mode

The Numeric mode is as shown in Figure 5-2.

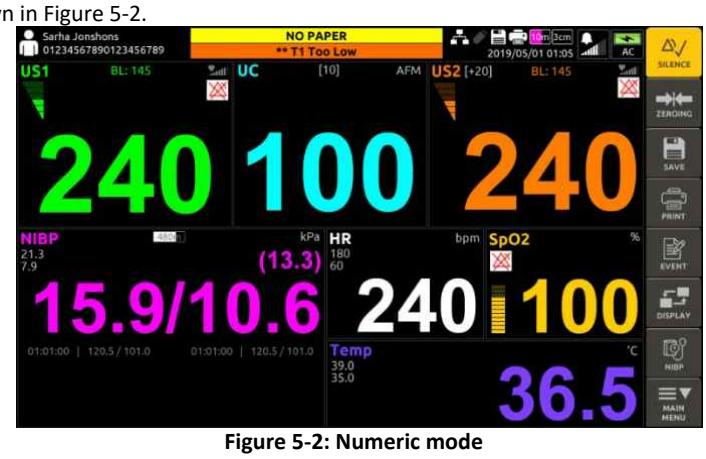


Figure 5-2: Numeric mode

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 volume 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 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  [Main Menu] Smart Hotkey → "Main Menu".
➢ Select "Alarm" → "Alarms" menu.
➢ Select "General" tab → Select "Alarm Volume" → "Alarm Volume" sub menu.
➢ Set "Alarm Volume" to "Off".

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  [Alarm] smart hotkey to temporarily stop the alarm of the monitor in the following steps:

➢  [Alarm] 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  [Alarm] smart hotkey to cancel the alarm pause manually.
You can set the alarm pause time as follows:

➢ Select  [Main Menu] Smart Hotkey → "Main Menu".
➢ Select "Alarm" → "Alarms" menu.
➢ Select "General" tab → Select "Alarm Reminder" → "Alarm Reminder Time" menu.
➢ Select "Alarm Reminder Time" and set.
  - "Off"/ "1min" /"2min" /"3min". By default, the alarm reminder time is 2 minutes.
  - It is recommended that the SpO2 alarm pause time shall not more than 2 minutes.

6.4.4 Alarm off

As shown in 6.4.3, if the "Alarm Reminder Time" is set to "Off", press the  [Alarm] smart hotkey and the monitor will turn off the alarm. In this case, except the alarm prompt characteristics maintained in alarm pause state:

➢  [Alarm] smart hotkey will appear magnified  icon.
➢ The physiological alarm area displays "Alarm Pause".

You can press the  [Alarm] 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 a parameter alarm

You can set the parameter alarm for every alarm separately. For SpO_2, as an example, select "Alarm" in the "Main Menu" menu and select "HR/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 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 "Low Limit" and set the lower limit of SpO_2 alarm.
- Select "High Limit" and set the upper limit of SpO_2 alarm.

Type	Range	Default
SpO2 Low Limit	0-99	90
SpO2 High Limit	1-100	100

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 Manual event

In the Fetal 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  [zeroing] smart hotkey, and then view it in the event review, refer to15.4 Event Review for detailed operation.

6.7 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 FHR

7.1 Electromagnetic interface

Strong electromagnetic fields can interfere with the ultrasound transducer and cause a false heart rate reading that does not originate from the fetus. This interference is rare and usually found in the vicinity of large machinery. In order to avoid the possibility of these interferences, the following procedure should be followed whenever the monitor is to be used in a new location, or if it is known that electrical machinery is being operated in the vicinity.

After connecting the ultrasound transducer(s), turn on the monitor and observe the heart rate indications on the screen for 30 seconds. Intermittent display of random heart rate is acceptable. However, if there is a constant display of a physiological heart rate lasting more than 5 seconds, this is an indication that there is a source of electromagnetic interference in the vicinity. The following steps should be taken to determine if it is possible to use the monitor in this environment.

- Move all line cords and line-powered equipment at least 200 cm away from the monitor. Check for extension cords running behind or under the bed and equipment in adjacent rooms. If the artifact heart rate indication ceased, the monitor may be used normally.
- Remove all the line cord from the monitor's power supply. If the artifact heart rate indication ceased, the monitor may be used normally.

If these measures do not result in cessation of the heart rate artifact, the monitor can't be safely used in this environment.
Fetal heart rate is measured by placing the ultrasound transducer on the maternal abdomen and by processing the received Doppler echo signal to produce a heart rate and an audio representation of the echo signal.

CAUTION

- The cable of the Doppler probe is not intended to contact the patient. To prevent such contact, please cover the patient's abdomen section which has a possibility of contacting by the cable with clean gauze or fabric.

7.2 Monitoring sequence overview

Step 1: Preparing the monitor

- Turn the monitor on and verify that the normal monitoring screen appears on the display. Stop using the monitor if an error occurs.
- Check whether the monitor is powered from the internal battery or AC power. If the monitor is powered from the internal battery, check the power status from on the display to determine whether the battery has sufficient charge to complete the monitoring session. Use the AC power if the battery is too low.
- Check the ultrasound transducer to verify proper attachment to the monitor. For monitoring twins, make sure the second ultrasound transducer is properly connected.

- Adjust channel one speaker volume to the middle level. Adjust channel two speaker volume to zero if monitoring twins.
- Apply ultrasound gel to the face of the transducer.

Step 2: Acquiring the fetal heart signal

- Determine the location of the fetal heart using palpation or a fetoscope. Place the transducer on the maternal abdomen and listen to the fetal heart signal. Reposition the transducer for the loudest fetal heart sound.
- Secure the ultrasound transducer with the elastic belt. Make sure that the transducer is still positioned for the loudest fetal heart signal.
- Verify the monitor is displaying fetal heart rate values and that the heart shape icon on the screen is blinking at the measured heart rate.

Step 3: Acquiring twin's heart rate

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

Step 4: Monitor adjustment

- Readjust the volume settings for the desired loudness.

7.3 Detail procedure

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

CAUTION

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

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

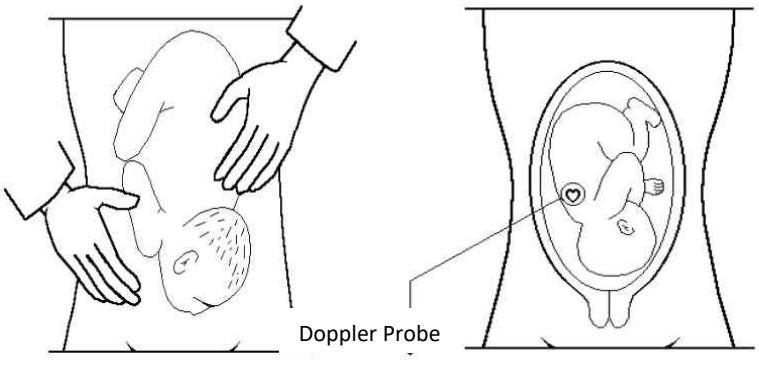


Fig. 7.1 The position of the Doppler probe

8 UC (Uterine Contraction)

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

CAUTION

- The cable of the UC probe is not intended to contact the patient. To prevent such contact, please cover the patient's abdomen section which has a possibility of contacting by the cable with clean gauze or fabric.

8.1 Monitoring sequence overview

Step 1: Preparing the monitor

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

Step 2: Acquiring the uterine contraction data

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

8.2 Detail procedure

- Explain the procedure to the patient.
- Place a probe belt under the patient
- Turn the monitor on.
- Connect the UC probe to the “UC” connector.
- Press the [zero] smart key to set the UC baseline at 10.

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

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

CAUTION

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

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

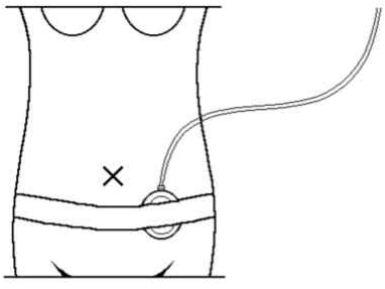


Fig. 8.1 The position of UC probe

9 Event marker

9.1 Overview

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

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

9.2 Clinical event marker

When an important event, like a fetus movement, occurs, the clinical event marker is used. If necessary, the doctor will press down [clinical event] button. Then the marker is recorded.

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

10 ECG

10.1 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.

10.2 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).

10.3 Monitoring steps

10.3.1 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.

10.3.2 Selecting lead

- Select the ECG parameter area → "ECG Setup" menu.
- 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.

10.3.3 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

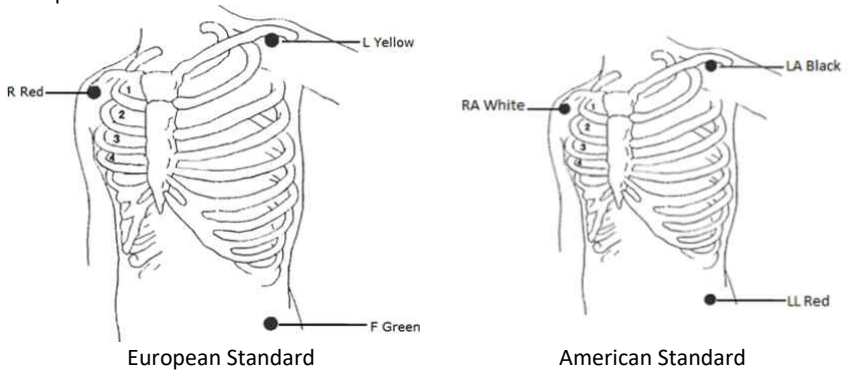
European Standard (EN)		American Standard (AHA)	
Lead Name	**Color**	**Lead Name**	**Color**
R	Red	RA	White
L	Yellow	LA	Black
F	Green	LL	Red
N	Black	RL	Green
C	White	V	Brown

10.3.4 Installing the electrodes

- 3-lead

The electrode placement position of 3-lead is shown in Fig. 10-1.

- 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.



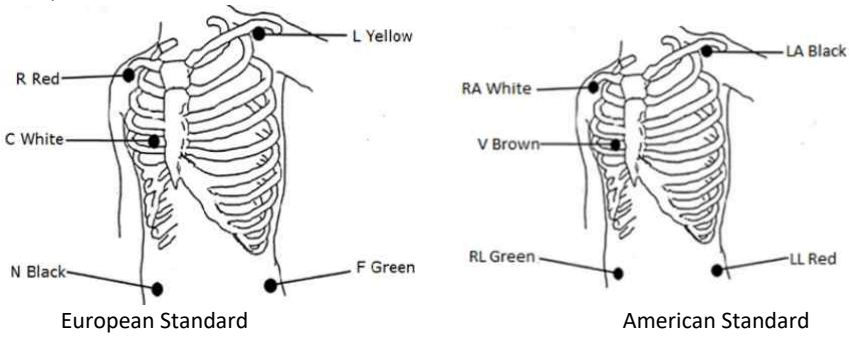
European Standard American Standard

Figure 10-1: 3-Lead placement method

- 5-lead

The electrode placement position of 5-lead is shown in Fig. 10-2:

- 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 10-2: 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.

10.4 ECG display

- **ECG wave display**

The monitor displays two ECG waves on the normal screen. Fig. 10-3 below is the monitoring interface of 5-lead, and is for reference purposes only. The graphics displayed on your monitor may be slightly different.

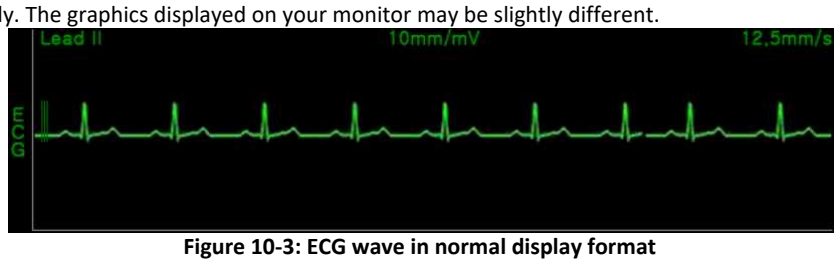


Figure 10-3: ECG wave in normal display format

- **ECG parameter display**

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

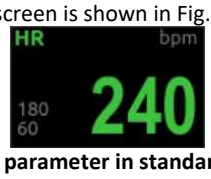


Figure 10-4: ECG parameter in standard display format

10.5 ECG setup

Select the ECG parameter area or select the [Main Menu] Smart Hotkey and "Mother" to pop up the "Mother" parameter setting menu, which is as shown below.

Figure 10-5: "Mother" menu

- Select "ECG 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 2.5mm/mV, 5mm/mV, 10mm/mV, and 20mm/mV.
- Select "ECG Speed", and set the wave speed. The wave speed is "12.5mm/s", "25mm/s", "50mm/s". The default is 25mm/s.
- Select "ECG Beep", and set the QRS Volume

10.6 Alarm setup

Select "Alarm"→ "HR/SPO2" tab to set ECG related alarms; see 6.5 Alarm Setup for the setting method.

11 SpO_2

11.1 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), neonate (<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.

11.2 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.

11.3 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.

11.4 Display

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

Figure 11-1: SpO_2 parameter display

SpO2 wave is as shown in figure 11-2.

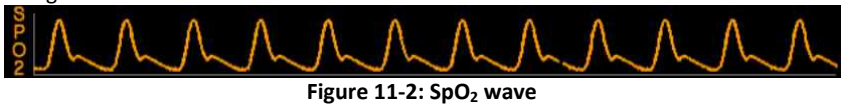


Figure 11-2: SpO_2 wave

11.5 Setting SpO_2

Select the SpO2 parameter area or select the [Main Menu] Smart Hotkey and “Mother” to pop up the “Mother” parameter setting menu, which is as shown as **Figure 10-5.**

11.5.1 Pulse volume

- The user can set the pulse volume. The pulse volume can be set to Off, 1, 2, or 3. By default, the pulse volume is set to Off.

11.6 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.

11.7 Alarm setup

In “Alarm” menu, select “HR/SPO2” tab to enter “SpO2 Alarm” interface, and set SpO_2 alarm switch, upper and lower alarm limit. See 6.5 Alarm Setup for detailed setting method.

11.8 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.

12 NIBP

12.1 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 chosen 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.

12.2 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, Neonate mode: 150mmHg), 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 and neonate.
- 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.

12.3 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.

12.4 Measurement procedure

12.4.1 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.

12.4.2 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.

12.4.3 Start/stop measurement

Use the  [NIBP] smart hotkey on the screen to start / stop the blood pressure measurement.

12.4.4 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.

12.5 NIBP display

NIBP measurement has no waveform display, and only displays NIBP measurement results in the parameter area, as shown in Fig. 12-1. The figure below is for reference only. The graphics displayed on the monitor may be slightly different.

Figure 12-1: NIBP parameter display

12.6 Setting inflation pressure

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

- Select the NIBP parameter area → "Mother" 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".
- Select "Initial pressure", and set the appropriate cuff pressure value. When the patient is neonate, the pressure can be select from "100","120". The default cuff pressure value is "100".

12.7 Clean and disinfection method of NIBP cuff

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

12.7.1 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.

12.7.2 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

12.8 Alarm setup

In "Mother" menu, select "NiBp/Temp" tab to enter "Nibp Alarm" interface, and set NIBP alarm switch, upper and lower alarm limit. See 6.5 Alarm Setup for detailed setting method.

13 TEMP

13.1 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.

13.2 Safety information

WARNING

- Before monitoring, check if the probe cable is normal. Unplug the temperature probe cable from the jack, the screen will display "TEMP 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.

13.3 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.

13.4 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.

13.5 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 13-1: 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.

13.6 Setting temperature unit

-You can define your favorite temperature unit as follows:

➢ Select TEMP parameter area → “Mother” menu.
In the “Mother” menu, set “Temp Unit” to “℃” or “°F”

13.7 Alarm setup

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

13.8 Technical description

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

14 Review

The monitor provides up to 150 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.

14.1 Reviewing trend chart

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

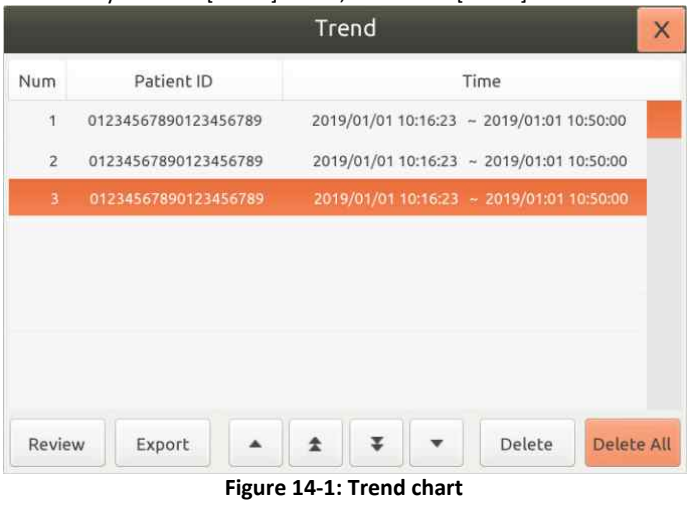


Figure 14-1: Trend chart

➢ In the trend list, 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.

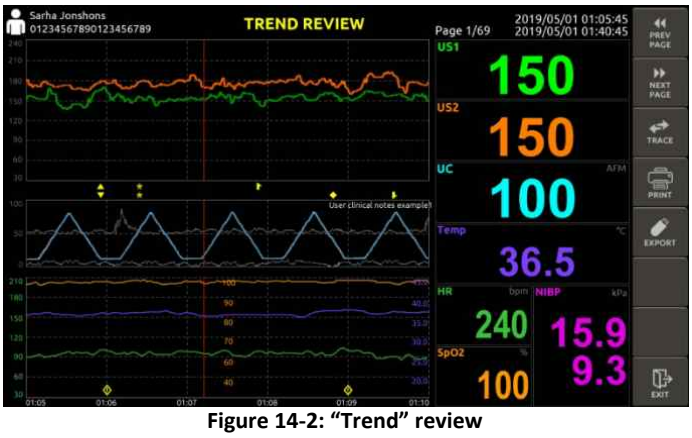


Figure 14-2: “Trend” review

15 Battery

15.1 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 a 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 not installed and operate using AC power source.

Battery is properly installed and charging status will be shown.

Battery is working properly and is fully charged.

Battery is working properly and remain battery capacity will be shown.

Battery is working properly and remain battery capacity is too low.

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 power and charge the battery.

15.2 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.

15.3 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 power to the monitor, and charge the battery for more than 4 hours uninterruptedly.
- Disconnect the 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.

15.4 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.

16 Caring and cleaning

16.1 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.

16.2 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 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.

16.3 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.

17 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.

17.1 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 Fetal 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 Fetal 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 Fetal 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.

17.2 Viewing software version information

You can view the software version through the following steps:

- Select  [Main Menu] Smart Hotkey→ "Main Menu" Menu;
- Select "Factory Setup"→ "Factory Setup" menu;
- "Version" tab displays the software version information of the monitor.

17.3 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

17.4 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  [Main Menu] Smart Hotkey→ "Main Menu" Menu;
- Select "Factory Setup" →enter the password and confirm → "Factory Setup" menu.
- Select "Calibration" → "Calibration" menu.
- Select "ECG 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.

18 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

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: SHENZHEN CONNECTOR TECHNOLOGY CO.,LTD
			N4520027N
6	Temperature Sensor	1	Manufacturer: Shenzhen taijia electronic Co., Ltd
			SPT4520010N
7	Grounding cable	1	Manufacturer: SHENZHEN CONNECTOR TECHNOLOGY CO.,LTD
			F002M
8	Power Cord	1	Manufacturer: BIZLINK INVESTMENTS LIMITED
			BP370L-BC313

19 Specifications

19.1 Safety specifications

19.1.1 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

19.1.2 Power

Power	
Power adapter	Input voltage: AC 100 - 240V, 50/60Hz
	Input current: 2.0A
	Output: DC 18V, 2.8A
Rechargeable Battery	14.8V Li-ion battery 4400mAh
	Operating Time(When it fully charged): 5 hours
	Charging Time(Fully): 4 hours

19.2 Hardware specifications

Physical Characteristics	
Dimensions	Main Unit: 296.98(W) X 327.99H) X 83.75(D)
Weight	<= 6.5 Kg for standard configuration
Display	

Type	Color TFT touch screen LCD	
Size and resolution	10”, 1024*600 pixels	
Audio		
Speaker	Alarm sound (45 ~ 85 dB), key pressing sound	
	Doppler sound, QRS sound, PR sound	
	Alarm sound meet the IEC 60601-1-8 standard requirements	
Alarm signal		
Pause duration	Off, 1min, 2min, 3min, depending on the setup Default is Off.	
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

19.3 Functional specifications

19.3.1 FHR/UC

FHR	
Measuring range	30 ~ 240 bpm
Resolution	1 bpm
Heart rate measurement error	± 2 bpm or ± 1%, whichever is greater
FHR Acoustic Output Level	
MI and TI	Does not exceed 1.0
I_{spta}	< 10mW/cm^2
FHR Alarm	
FHR upper limit	31 ~ 240, 1 bpm step
FHR lower limit	30 ~ 239, 1 bpm step
UC	
Measuring range	0 ~ 100 relative units
Resolution	1 Count

19.3.2 ECG/TEMP/RESP

ECG		
Standard compliance	IEC 60601-2-27:2012	
Lead Type	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	0.5 - 40 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/Neonate: 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	16 ~ 300, 1 bpm step	
HR lower limit	15 ~ 299, 1 bpm step	
TEMP		
Standard compliance	ISO 80601-2-56:2018	
Measurement method	Thermistor	
Operating mode	Direct mode	
Measuring range	0 ℃ ~ 50.0 ℃ (32 ˚F ~ 122.0 ˚F)	
Resolution	0.1 ℃	
Measurement accuracy	± 0.3 ℃	
Number of channel	2	
TEMP Alarm		
T1 upper limit	0.1 ℃ ~ 50.0 ℃, 0.1℃/˚F step	
T1 lower limit	0 ℃ ~ 49.9 ℃, 0.1℃/˚F step	

19.3.3 NIBP

NIBP		
Standards compliant	IEC 80601-2-30:2018	
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
	Systolic blood pressure	30-280
	Mean blood pressure	10-240
	Diastolic blood pressure	10-220
Measurement accuracy	Maximum average error: ±5mmHg Maximum standard deviation: 8mmHg	
Resolution	1mmHg	
Initial inflation pressure	Default	Pressure setting range
	160mmHg	140mmHg, 160mmHg, 180mmHg
Overpressure protection point (software)	300mmHg	
Overpressure protection point (hardware)	320~330mmHg	
Static Pressure accuracy	±3mmHg	

NIBP Alarm		
NIBP upper limit (mmHg) 1 mmHg step	SYS	31 ~ 280
	MAP	11 ~240
	DIA	11 ~ 220
NIBP lower limit (mmHg) 1 mmHg step	SYS	30 ~ 279
	MAP	10 ~ 239
	DIA	10 ~ 219
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	

19.3.4 SpO_2

SpO_2		
Standards compliant	ISO 80601-2-61:2017	
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%) (adult/pediatric mode); ±3% (70%~100%) (neonate mode); 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	

20 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.

20.1 Physiological alarms

Source	Alarm message	P	Causes and countermeasures
FHR	FHR Too High	M*	FHR 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.
	FHR Too Low		
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

Source	Alarm message	P	Causes and countermeasures
	HR Too Low		check if the patient category and alarm limit settings are appropriate for the patient.
	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.
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		
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		
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-Dia Too High		
	NIBP-Dia Too Low		

20.2 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.
FHR	US1 Open	M	DOP1 probe are not connected to the socket during measurement.
	US2 Open	M	DOP2 probe are not connected to the socket during measurement.
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.
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 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

Source	Alarm message	P	Causes and countermeasures
			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.

21 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
US1	Alarm Limit	30 ~ 240bpm
	Alarm	Off
	Volume	Off
	Color	Green
US2	Alarm Limit	30 ~ 240bpm
	Alarm	Off
	Volume	Off
	Color	Orange
	Offset	Off
UC	Auto Zeroing	Off
	AFM	Off
	UC Baseline	10
	Color	Cyan
ECG	Alarm record	Off
	Lead type	5-lead
	Calculation channel	Auto
	Power frequency suppression	On
	Alarm limits	50~120 on
	Gain	x1
	Wave velocity	25.0mm/s
	Filter mode	Monitor
	Wave color	Green
	Wave style	Color scale
NIBP	Alarm record	Off
	Pressure unit	mmHg
	Measurement mode	Adult
	Interval	Manual
	Display color	White
	Pre-inflation value	150
	Systolic blood pressure limit	90~160 on
	Mean blood pressure limit	60~110 on
	Diastolic blood pressure limit	50~90 on
SpO_2	Alarm record	Off
	Alarm limits	90~100 on
	Wave velocity	25.0
	Wave color	Orange
	Wave style	Line
TEMP	Alarm record	Off
	Display color	White
	Temperature unit	℃
	T1 alarm limits	36.0 ~ 39.0 on

Module	Option	Module defaults
	T2 alarm limits	36.0 ~ 39.0 on

22 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.

23 Manufacturer's declaration on EMC

BT-380 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-380 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.

23.1 Electromagnetic emissions

The BT-380 is intended for use in the electromagnetic environment specified below. The customer or the user of the BT-380 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The BT-380 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The BT-380 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-380 is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

		operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the BT-380 or shielding the location.

23.2 Recommended separation distances between portable and mobile RF communications equipment and BT-380

The BT-380 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BT-380 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BT-380 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.

23.3 Electromagnetic immunity

The BT-380 is intended for use in the electromagnetic environment specified below.
The customer or the user of the BT-380 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.
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. If the user of the BT-380 requires continued operation during power mains interruptions, it is recommended that the BT-380 be powered from an uninterruptible power supply.
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	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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-380 is intended for use in the electromagnetic environment specified below.
The customer or the user of the BT-380 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-380, 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-380 is used exceeds the applicable RF compliance level above, the BT-380 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-380.

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

Product Warranty

Product Name	Fetal monitor
Model Name	BT-380
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-380.
※ 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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