BT-720 Patient monitor
Operation Manual

Keep this manual for future reference

P/N : 720-ENG-OPM-EUR-R01

Proprietary Material

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Contents

0 Safety information

Before using BT-720 Patient monitor, read this entire manual and be fully understood the following safety information to prevent injury of patient and user.

Symbols Used

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

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

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

	Used to identify safety information. Be well-known this information thoroughly before using BT-720.
	Used to identify safety information. Be well-known this information thoroughly before using BT-720
IPX1	Indicates the protection level against the ingress of liquid. IPX1 is protection against some water drops falling vertically. It correspond the device, patient monitor.
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.
	Refer to operation manual. Read manual before placing the device.
	Indicates DC power supply.
	Indicates the device is in the battery operation mode.
	Indicates nurse call interface.
	Indicates network interface.


Indicates USB interface.


Indicates power adapter polarity.


Indicates the production date.


Indicates the manufacturer.

Indicates the serial number of the device.

Indicates the authorized representative in the European Community of manufacturer.


Indicates a defibrillation-proof type BF applied part.


Indicates a defibrillation-proof type CF applied part.


Indicates CLASS II equipment.(Adapter)


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


Indicates to keep the device dry.


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


Indicates to keep upright

Indicates the maximum stacking limit.


Indicates the temperature limitation for operation, transport and storage.


Indicates the humidity limitation for operation, transport and storage.


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

Indicates the device contains natural rubber latex.(Accessories)

Indicates the packing material is recyclable.

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

0.1 General precautions, warnings and cautions

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

- Only the DC power adapter supplied with the BT-720 is approved for use with the device.

- Do not attempt to service the BT-720 patient monitor. Only qualified service personnel by Bistos Co. Ltd. should attempt any needed internal servicing.

- Perform periodic safety testing to insure proper patient safety. This should include leakage current measurement and insulation testing. The recommended testing interval is once per year.

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

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

- Do not operate the BT-720 patient monitor if it fails to pass the power on self-test procedure.

- During the operation, do not disconnect any cable.

- The BT-720 patient monitor is intended to be used by clinical professionals or trained doctors, nurses or laboratory assistant.

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

- Using the device to one patient at a time.

⚠ WARNING

- Thoroughly read and understand the manual prior to use of the BT-720. Failure to do so could result in personal injury or equipment damage.
- The device is intended for clinical patient monitoring, and only trained and qualified doctors and nurses should use the device.
- The alarm volume, upper and lower alarm limits should be set according to the actual situation of the using environment. Do not just rely on audio alarm system while monitoring the patient, because too low alarm volume or muted alarm may result in notice failure of alarm situation and endanger the patient's safety. Please pay close attention to the actual clinical status of the patient.
- Use only the power adapter supplied with monitor.
- Position the monitor where it is easy to de-energize the monitor when needed.
- Do not open the enclosure to avoid an electric shock. Any repair and upgrade of monitor should be done by service personnel trained and authorized by Bistos. Co., Ltd.
- When handling packaging materials, abide by local laws and regulations or hospital waste disposal regulations. Keep the packaging materials away from children.
- Do not use in the presence of flammable anesthetics to prevent explosion or fire.
- Install the power lines and cables of accessories carefully to avoid patient entanglement or suffocation, cables tangled or electrical interference.
- When the monitor is used together with electrosurgical devices, the user (a doctor or a nurse) should ensure the safety of the patient and instrument.
- The physiological wave, physiological parameters and alarm information displayed on the monitor are only for the doctor's reference and should not be directly used as the basis for clinical treatment.
- This is not a therapeutic device.
- For patients with pacemakers, the cardio tachometer may count the pacemaker pulse in case of a cardiac arrest or arrhythmias. Never rely solely on the cardio tachometer alarm. Closely monitor the patients with pacemaker. For the inhibition of the device on pacemaker, refers to this manual.
- Use of accessories other than those listed and approved for use with this product may result in increased emissions or decreased immunity.
- Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information

provided in this manual. In addition, portable and mobile RF communications equipment can affect medical electrical equipment.

- The equipment shall not be used adjacent to other devices unless verification of normal operation in the configuration in which it is to be used can be achieved.
- Keep matches, and all other sources of ignition, out of the room in which the patient monitor is located. Textiles, oils, and other combustibles are easily ignited and burn with great intensity in air enriched with oxygen. Personal injury or equipment damage could occur.
- A fire and explosion hazard exists when performing cleaning or maintenance procedures in an oxygen-enriched environment.
- The patient monitor has been validated with the accessories and options listed in this manual and found to comply with all relevant safety and performance requirements applicable to the device. It is therefore the responsibility of the person or organization who makes an unauthorized modification, or incorporates an unapproved attachment to the device.
- An operator may only perform maintenance procedures specifically described in this manual.
- Do not remove the covers of a BT-720 yourself to avoid damage to the equipment and unexpected electrical shock. Only qualified Bistos service engineer must repair or replace components.

⚠**CAUTION**

- Please install or carry the instrument properly to prevent damage due to falling, collision, strong vibration or other mechanical force.
- Avoid instrument splashed by water.
- Avoid high temperatures, the instrument should be used within a temperature range of 5 ℃ ~ 40 ℃。
- Avoid using instrument in the environment such as pressure is too high, poor ventilation, dusty, or contain salt, sulfur gas and chemical.
- Before using the monitor, check the monitor and accessories if there is damage that may affect patient safety. If there is obvious damage or aging, replace the parts before use. The replacement should be made with same parts of original parts.
- Before powering on the device, make sure that the power used by the device complies with the supply voltage and frequency requirements on the equipment label or in the Operator's Manual.

- Equipment should be tested at least once a year, the test should be done and recorded by trained, have security testing knowledge and experienced personnel. If there are any problems in the tests, they must be repaired.

- When the instrument and accessories are about to exceed the useful life (expected service life: 5 years), it must be treated in accordance with relevant local laws and regulations or the hospital's rules and regulations.

- Do not connect to other equipment or network which not specified in the instruction for use, in risk of external high voltage.

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

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

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

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

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

0.2 Shock hazards

⚠ **WARNING**

- Unplug the monitor from its power source prior to cleaning or maintenance to prevent personal injury or equipment damage.

- Some chemical cleaning agents may be conductive and leave a residue that may permit a build-up of conductive dust or dirt. Do not allow cleaning agents to contact electrical components and do not spray cleaning solutions onto any of these surfaces. Personal injury or equipment damage could occur.

- Do not expose the unit to excessive moisture that would allow for liquid pooling. Personal injury or equipment damage could occur.

- Do not touch the patient and signal input/output parts simultaneously

- Due to the risk of electrical shock hazard, only qualified personnel with appropriate

service documentation should service the monitor.

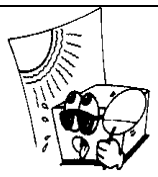
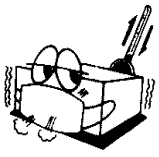
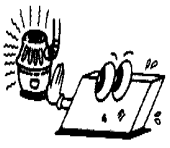
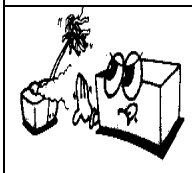
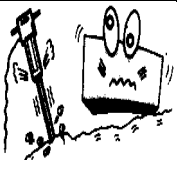
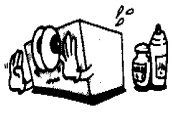
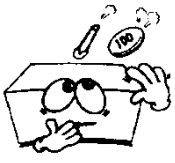
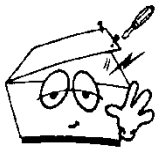
0.3 Battery warnings

⚠ **WARNING**

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

0.4 General precautions on environment

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

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

1 System basics

1.1 Intended use

The BT-720 Patient Monitors acquire the physiological signals for non-invasive blood pressure (NIBP), pulse rate (PR) and blood oxygen saturation (SpO_2). The signals are converted into digital data and processed, examines the data for alarm conditions and display the data. The monitor also provides operating control for the user. The patient monitor intend to use in hospital clinical area such as intensive care units, operating room, emergency department, to provide additional information to the medical and nursing staff about the physiological condition of the patient. The BT-720 patient monitors are intended to be used only under regular supervision of clinical personnel. It is suitable for adult and pediatric, neonate. The intended locations of use are hospitals and clinics.

1) Intended patient population

- Adult (>18 years adults) and Pediatrics (30 days < and <18 years) and Neonate (0 days＜ and ＜30days)

2) Intended user profile

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

3) Environment of use

- Hospital and clinic
- Requirements: Stable power source

4) Scope of application

This monitor is suitable for bedside monitoring of patient. This monitor enables blood oxygen saturation (SpO_2), pulse rate (PR) and monitoring. It is equipped with a replaceable built-in battery to provide convenience for the patient movement in hospital.

5) Indications and contraindications

Blood oxygen saturation (SpO_2)
Indication: - Monitoring effectives of oxygen therapy - A reading is needed to facilitate the completion of an early warning score to inform clinical assessment - Sedation or anesthesia - Transport of patients who are unwell and require oxygenation assessment - Haemodynamic instability (e.g. cardiac failure or Myocardial Infarction)

- Respiratory illness e.g. asthma, chronic obstructive pulmonary disease
- Monitoring during administration of respiratory depressant drugs, e.g. opiate epidural or patient-controlled analgesia.
- Assessing oxygen saturation during physical activity e.g. in pulmonary rehabilitation

Contraindications

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

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

Non-invasive blood pressure (NIBP)

Indication:

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

Contraindications

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

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

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

1.2 Operating principle

Refer to the chapters for every physiological parameter from chapter 5 to chapter 6.

1.3 System configurations

Basic configuration of BT-720

- Main body with 4.3” touch screen and built-in lithium-ion battery
- Adult SpO2 probe and extension cable
- AC/DC adapter

Options of BT-720

- Non-invasive blood pressure cuff

Picture	Name	Description	Qty
	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 (Option)	Measures NIBP for adult	1ea
	NIBP extension tube (Option)	Tube to connect the NIBP cuff and main body	1ea
	Adapter (Standard)	For power supply	1ea

1.4 Product outlook

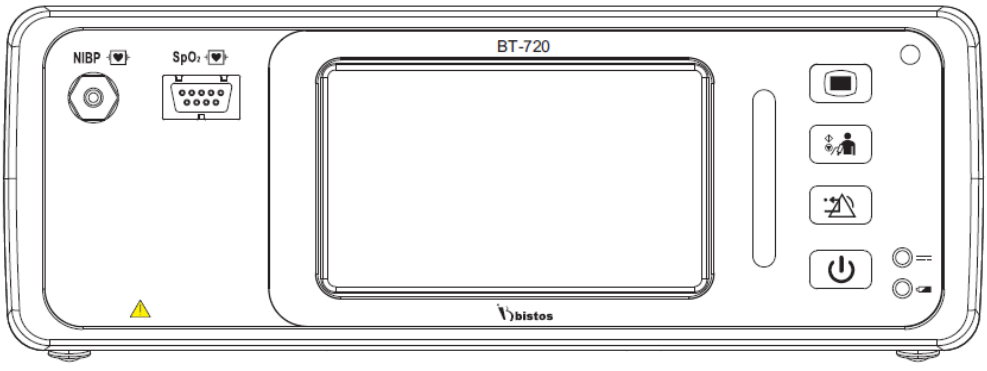


Figure1-1: Front view

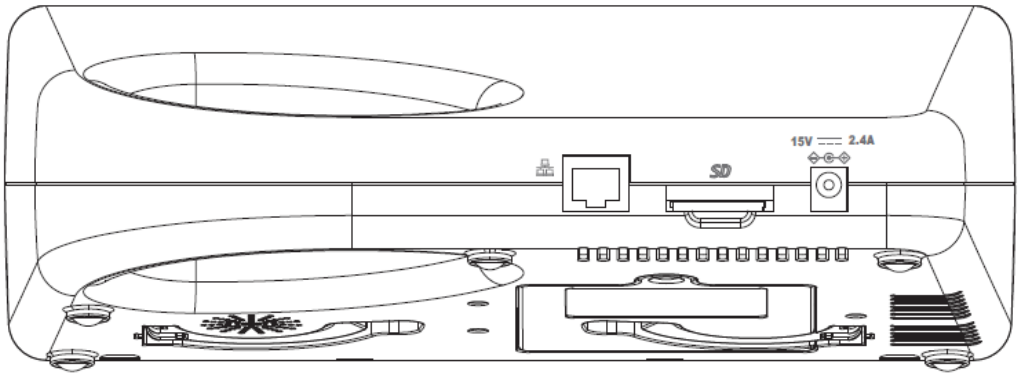


Figure1-2 : Rear view

1.5 Description of monitor

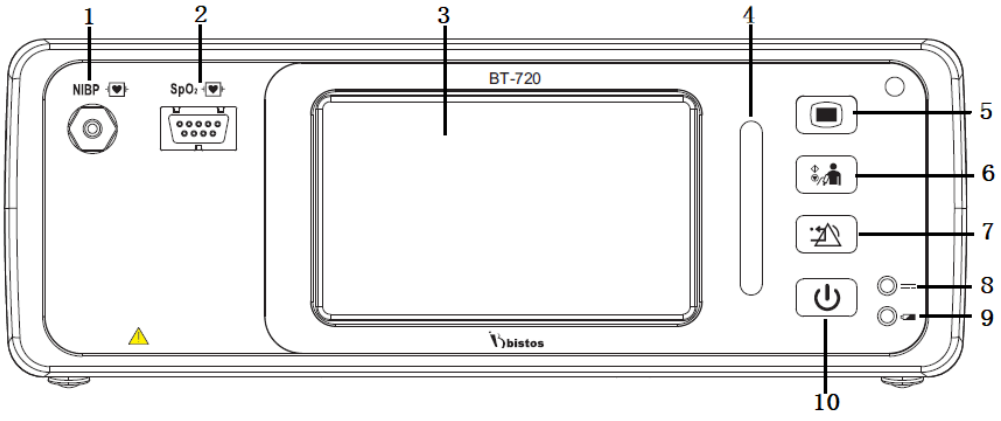


Figure1-3: Front view

	Name	Description
1	NIBP	NIBP tube interface. This is option. When you purchase the monitor only with SpO2, this interface will be blocked.
2	SpO2	SpO2 cable interface
3	Display area	Display the waveform and measured value
4	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
5	[Setting]	Enter to the setting mode. Press again to close the setting mode.
6	[NIBP]	Start and stop the non-invasive blood pressure measurement manually. This is option. When you purchase only with SpO2 this button will be deleted.
7	[Alarm reset]	To reset the alarm condition.
8	DC power indicator	Turned on when the monitor is being powered by the adapter.
9	Battery indicator	- On: The battery is being charged or has been fully charged. - Off: The battery has not been installed. - Flashing: The monitor is being powered by the battery.
10	[Power]	- Power On: Press down the key more than 2 seconds. - Power Off: Press down the keys more than 2 seconds and the system will display the alarm message “The system will shut down 3 seconds”.

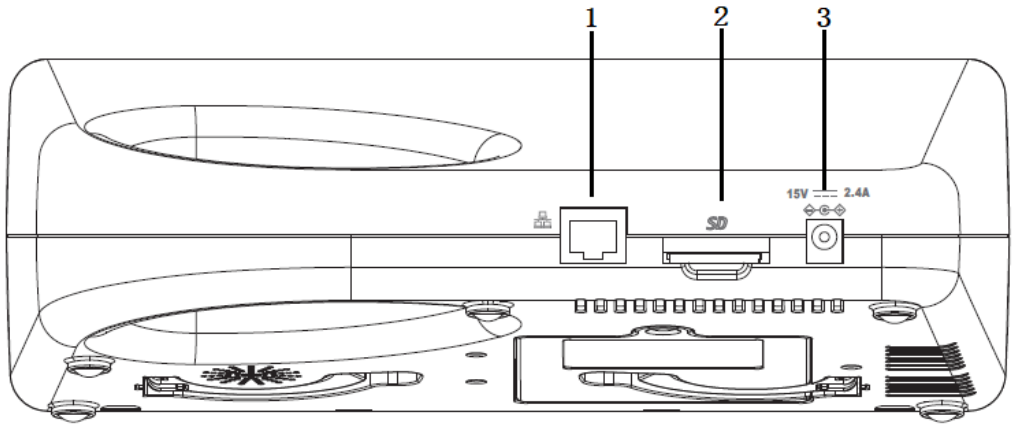


Figure1-4: Rear view

	Name	Description
1	Network port	For CMS
2	SD card interface	For software upgrade
3	Power adapter	15V, 2.4A adapter

1.6 Understanding the display

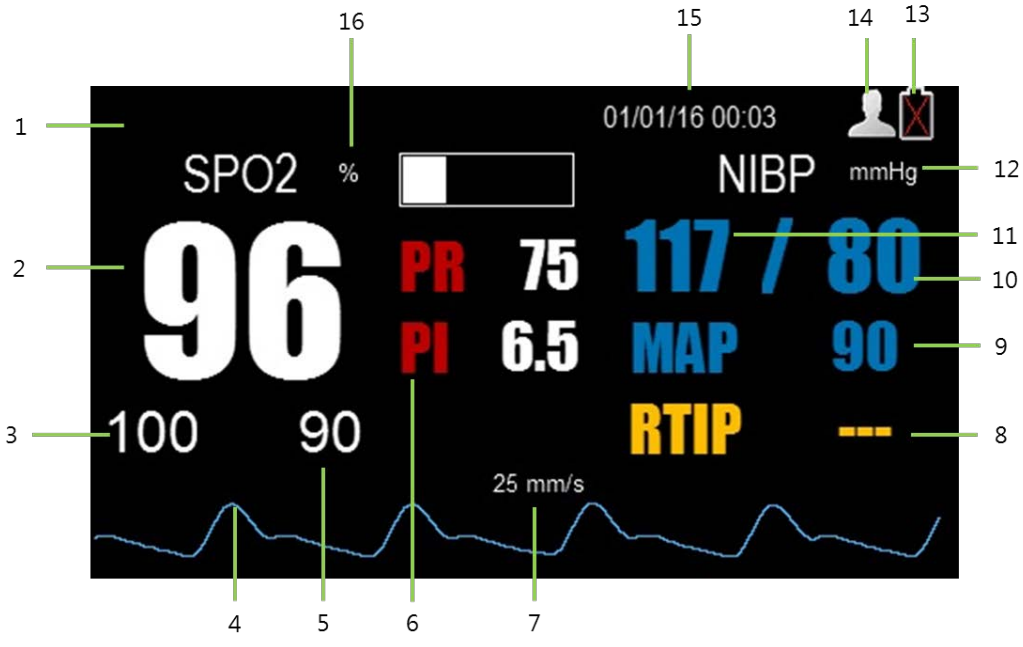


Figure 1-5: Standard display

	Description
1	Current alarm message. When an alarm occurs, this area will displayed yellow or white depending on the alarm type.
2	SpO_2 value. Display the measured SpO_2 value.
3	SpO_2 upper alarm limit. Display the user set upper alarm limit
4	SpO_2 waveform. Display the measured SpO_2 waveform.
5	SpO_2 lower alarm limit. Display the user set lower alarm limit
6	Perfusion Index. Display the measured perfusion index.
7	Sweep speed. Display the user set SpO_2 waveform speed.
8	RTIP. Display the current measured cuff pressure value.
9	MAP. Display the average pressure value.
10	Diastolic blood pressure value.
11	Systolic blood pressure value.
12	The unit of NIBP.
13	Battery status.
14	Patient type.
15	Display current time.
16	The unit of SpO_2.

1.7 Essential performance

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

2 Preparing for operations

2.1 Installation

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

⚠ WARNING

- All analog and digital devices connected to the monitor must be certified by IEC standards (e.g. IEC 60950 Data processing equipment standard and IEC 60601-1 Medical equipment standard). Furthermore, all configurations shall comply with valid version of IEC 60601-1 standard. The personnel connecting additional devices to the input / output signal ports are responsible for the compliance with IEC 60601-1 standard. If there is any question, please contact Bistos.
- If the patient cable interface and network interface are connected with multiple devices, the total electric leakage current cannot exceed the allowable value.
- The copyright of monitor software belongs to Bistos. 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 multi-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-720 patient monitor was inspected rigorously at the factory before delivery, in order to avoid being hit when transported, carried out careful packaging. Before unpacking, carefully inspect the package. If any damage, please immediately contact the Bistos. Unpack in the correct way, carefully remove the monitor and accessories from the box and check with the packing list. Check if there is any mechanical damage, the all listed are completely packed. If you have questions, please contact the marketing department of Bistos or agency.

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

2.1.2 Placement requirements

Equipment installation must meet:

- Ensure that the operating floor and the monitor have enough space for connecting the accessory wires.

2.1.3 Power requirements

- DC power supply adapter

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

  Output: D.C. 15 V, 2.5 A

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

2.1.4 Environmental requirements

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

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

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

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

⚠ WARNING

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

2.2 Connecting to power

⚠ WARNING

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

Connect to power adapter in the following steps:

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

3 Basic operations

3.1 Turn on

3.1.1 Check the monitor

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

WARNING

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

3.1.2 Start the monitor

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

Press the [Power] key and the system enters the main interface within seconds.

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

3.1.3 Connect the sensors

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

3.1.4 Start monitoring

Start monitoring in the following steps:

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

3.2 Turn off

Turn off the monitor in the following steps

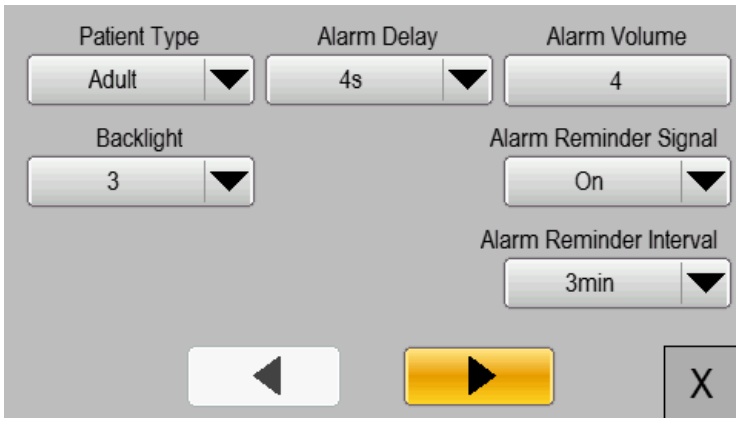
- Disconnect the cables and sensors connected to the patient.
- Press and hold the  [Power] key for 2 seconds to pop up the 3 seconds countdown window, and the monitor turns off in 3 seconds.

CAUTION

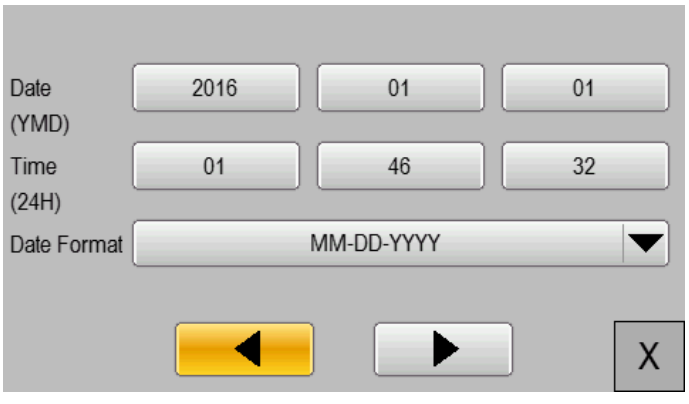
- If the monitor is not turned off properly, you can simply disconnect the power to shutdown forcibly. But the forced shutdown may cause data loss, and it is not recommended.

4 Setup the monitor

In the main screen, Press the [Setting] key enter the setup menu.



- Select “Patient Type”, you can choose “Adult” or “Pediatric” or “Neonate”.
- Select “Alarm Delay”, you can choose off, 1s, 2s, 3s, 4s, 45s, 5s, 6s, 7s or 8s.
- Select “Alarm Volume”, and enter value（Range: 0-9）.
- Select “Backlight”, and enter value（Range: 0-5）, 5 is the brightest.
- Select “Alarm Reminder Signal”, you can choose “On”, or “Off”.
- Select “Alarm Reminder Interval”, you can choose “1min”, “2min”or “3min”.



- 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.
- “Date (YMD)”: Set the year, month, and day.

- "Time (24H)": Set the hour, minute and second.

- Select "Screen Setup", set "SpO2+NIBP".
- Select "Language", and select the option as needed:

  "English": The interface language of the monitor is English.

  "Türkçe": The interface language of the pulse oximeter is Turkish.

  "Español": The interface language of the pulse oximeter is Spanish.

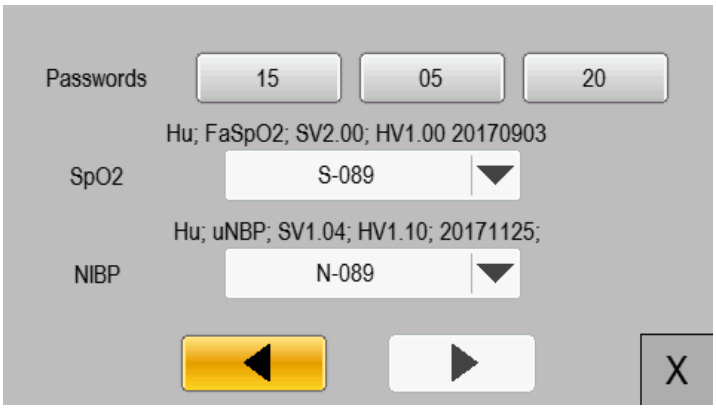
  "Français": The interface language of the pulse oximeter is French.

  "Polski": The interface language of the pulse oximeter is Polish.

  "Italiano": The interface language of the monitor is Italian.

  "Deutsch": The interface language of the monitor is German.

- Select "Network", you can choose "On", or "Off".
- Select "Default", back to the initial state.
- Select "Network Setup", set up the network.



- Select "Passwords", set Passwords.
- Select "SpO2", set "S-089".

5 SpO_2

5.1 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.

5.2 Safety information

⚠ WARNING

- Please use SpO2 sensor supplied from Bistos, operate in accordance with the Manual, and observe all warnings and precautions.
- Before monitoring, check whether the sensor cable is normal. When SpO_2 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 SpO_2 sensor; return it to the manufacturer.
- If there is carboxyhemoglobin, methemoglobin or dye diluted chemical, the SpO_2 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 SpO_2 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.
- 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.

5.3 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 finger or toe.
5. Select the appropriate alarm settings.
6. Start monitoring.

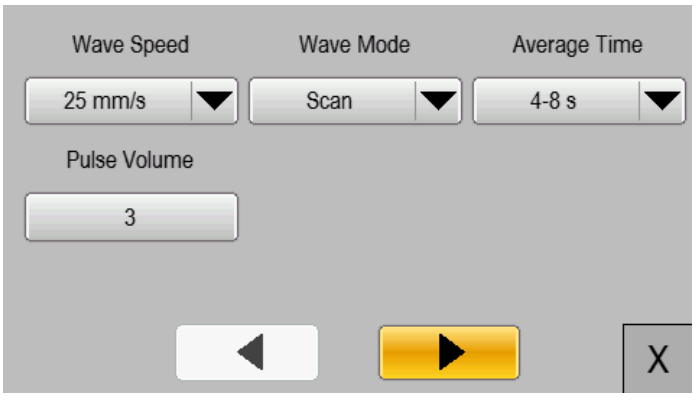
NOTE

- Turn on the monitor, plug in SpO_2 probe and connect patient's finger (or toe), monitor displays SpO_2 wave, "SpO2 Pulse Search" displayed in the technical alarm area until the monitor measured SpO_2 value and pulse rate. "SpO2 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.

5.4 Setting SpO_2

Select SpO_2 parameter area to enter the SpO2 set interface



- Select “Wave Speed” and set wave speed to “12.5mm/s” or “25mm/s”. The faster speed, the smoother wave.
- Select “Wave Mode”, and set the wave drawing mode to “Scan” or “Fill”.
- Select “Average Time”, and set the average time to “2–4s”, “4–8s”, “8–16s”.
- The user can set the pulse volume. The pulse volume can be set to 0, 1, 2, 3, 4, 5, 6, 7, 8, or 9.
- Select  key to display the following interface.

- Select “SpO2 Low Limit”, and enter value（Range: 0-99）, Adult/Pediatric/Neonate Default: 90.
- Select “SpO2 High Limit”, and enter value（Range: 1-100）, Adult/Pediatric/Neonate Default: 100/100/95.

- Select “Alarm Level”, you can choose “Mid” or “High”.
- Select “PR Low Limit”, and enter value（Adult Range: 15-299, Pediatric/Neonate Range: 15-349）, Adult/ Pediatric /Neonate default: 50/75/100
- Select “PR High Limit”, and enter value（Adult Range: 16-300, Pediatric/Neonate Range: 16-350）, Adult/ Pediatric /Neonate default: 120/160/200.
- Alarm ,Select “Default”, the alarm parameter is set to the default value
- Select “PI Low Limit”, and enter value（Range: 0.00-19.90）. Default: 0.00.
- Select “PI High Limit”, and enter value（Range: 0.10-20.00）. Default: 20.00.

5.5 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.

5.6 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.

6 NIBP (Option)

6.1 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 mode and automatic mode. Each mode shows systolic, mean and diastolic blood pressure.

- Manual mode

  Using Manual mode start to measures by hand

- Automatic mode measures

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

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

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

6.2 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 and neonate 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.

6.3 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.

6.4 Measurement procedure

6.4.1 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 (50% for neonate) 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 "ARTERIA" 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.

6.4.2 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.

6.4.3 Start/stop measurement

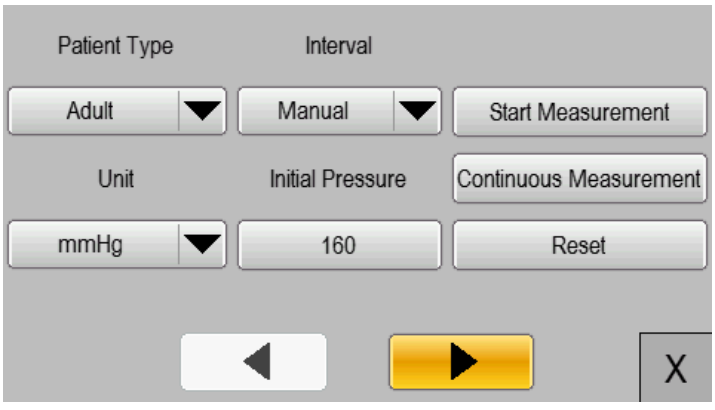
Use the  [NIBP start/stop] key on the monitor panel to start / stop the blood pressure measurement.

6.4.4 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.

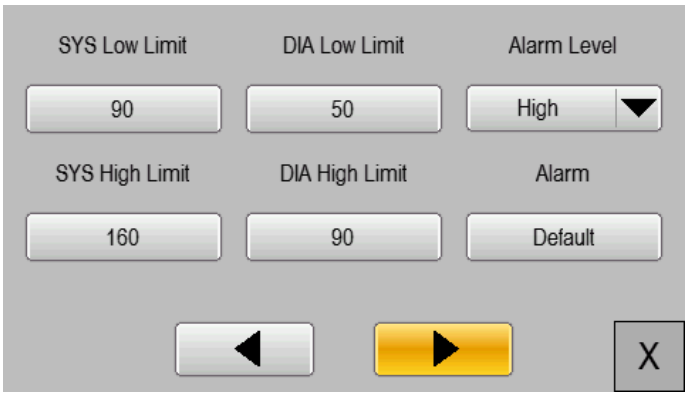
6.5 Setting NIBP



- Select “Patient Type”, you can choose “Adult” or “Pediatric” or “neonate”.
- Select “Interval”, you can choose Manual, 1min, 2min, 3min, 4min, 5min, 10min, 15min, 30min, 60min, 90min, 120min, 180min, 240min or 480min.
- Select “Unit”, and select the unit “mmHg” or “kPa”.
- 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”.
- Select “Start Measure”, starts the blood pressure measurement; select “Stop Measure”,

stop the blood pressure measurement.

- Select “Continue Measure”, continued measure pressure.
- Select “Reset”, and restore the inflation pressure of the blood pressure pump to currently configured initial settings. When the blood pressure pump is not working properly, but no warning is given, you can reset the blood pressure pump, and automatically restores the blood pressure pump.
- Select  key to display the following interface.



- Select “SYS Low Limit”, and enter value (Adult Range: 30-279, Pediatric Range: 30-229, Neonate Rang: 30-144). Adult/ Pediatric /Neonate default: 90/70/40.
- Select “SYS High Limit”, and enter value (Adult Range: 31-280, Pediatric Range: 31-230, Neonate Rang: 30-145). Adult/ Pediatric /Neonate default: 160/120/90.
- Select “DIA Low Limit”, and enter value (Adult Range: 10-219, Pediatric Range: 10-164, Neonate Rang: 10-104). Adult/ Pediatric /Neonate default: 50/40/20.
- Select “DIA High Limit”, and enter value (Adult Range: 11-220, Pediatric Range: 11-165, Neonate Rang: 11-105). Adult/ Pediatric /Neonate default: 90/70/60..
- Select “Alarm Level”, you can choose “Mid” or “High”.
- Select “Default”, the alarm parameter is set to the default value.

- Select “Calibration”, Users can not calibrate NIBP. If calibration is required, please contact your service representative. Cuff pressure sensor should be checked and calibrated at least once every two years by qualified professional service personnel.

- Select “Leak Test”, the purpose of leakage test is to detect if the sealing of the air passage is in good condition. If the leakage test passes, the alarm area displays “Leakage test Stopped”. If not passed, the alarm area displays “Cuff leak” message. NIBP leakage test shall be at least once every two years or when you think that the reading is not accurate.

6.6 Clean and disinfection method of NIBP cuff

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

6.6.1 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.

6.6.2 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

7 Review

Use the Trend screen to recall all the historical patient data in a list, including monitoring time (in 1-minute intervals), and SpO_2, PR, SYS, DIA and MAP values. The most recent measurements display at the top of the list.

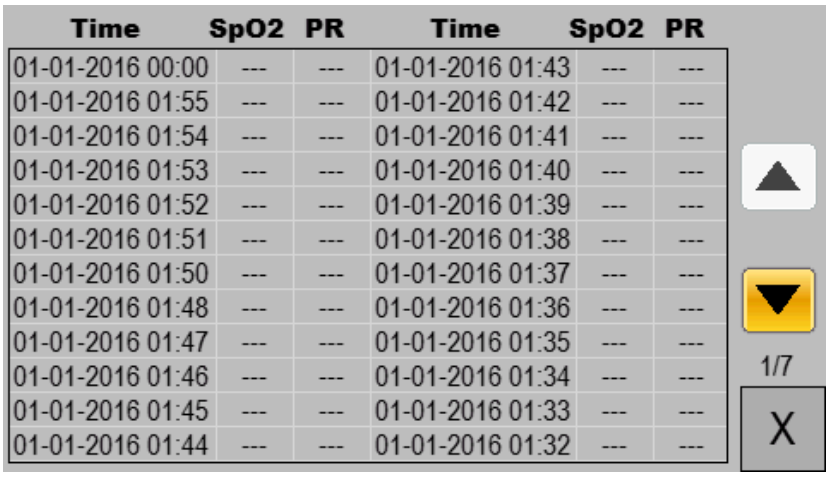


Figure 7-1: SpO2 trend (1)

To view historical data:

- Press the [Setting] key twice to display the Trend screen.
- Select or key to page up and down to view patient data.
- Press X key to exit the Trend screen and display the Main screen or press the [Setting] key to see the trend graph.

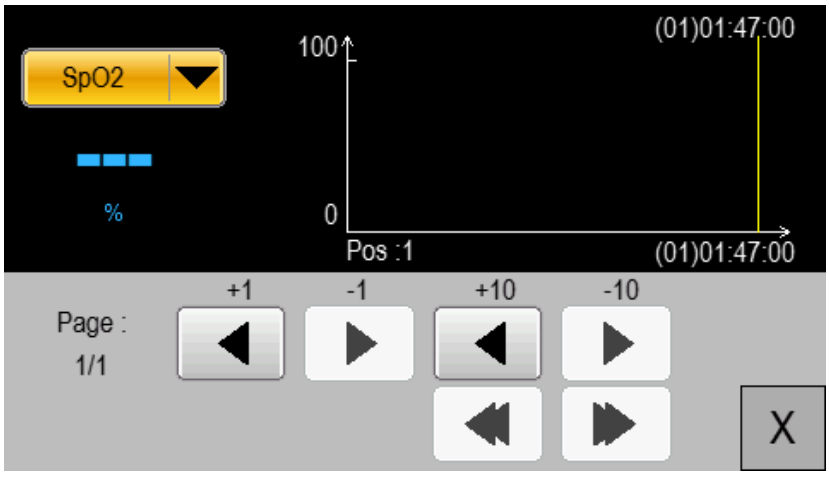
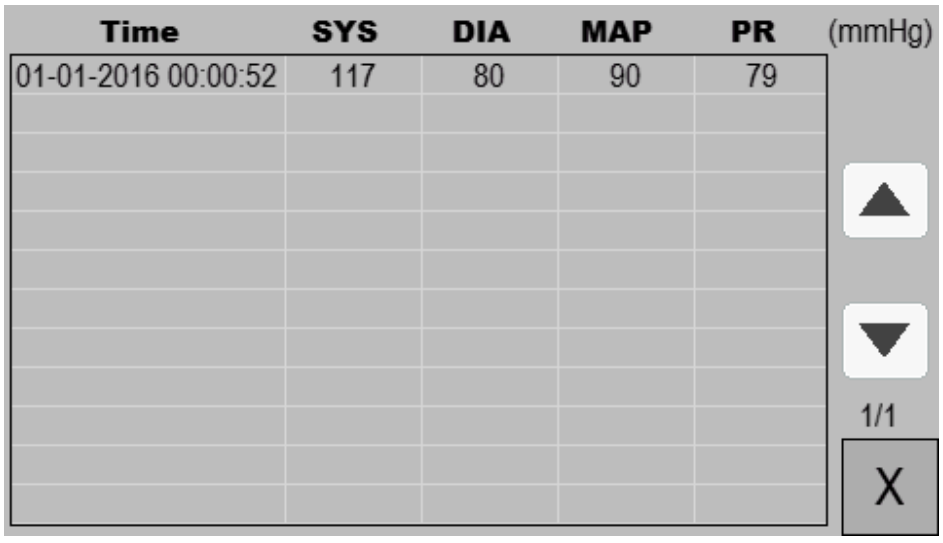


Figure 7-2: SpO2 trend (2)

- Select 'SpO2', 'PR' or 'PI' to see.
- Press X key to exit the Trend screen and display the Main screen or press the [Setting] key to see the NIBP Trend.



- Select ▲ or ▼ key to page up and down to view patient data.

8 Alarm

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

- Physiological alarm information.

Source	Alarm message
SpO_2	SpO_2 Too High
	SpO_2 Too Low
	PR Too High
	PR Too Low
NIBP	Systolic Too High
	Systolic Too Low
	Mean pressure Too High
	Mean pressure Too Low
	Diastolic Too High
	Diastolic Too Low

- Technical alarm information.

Source	Alarm message
SpO_2	SpO_2 Communication Stop
	SpO_2 Communication Error
	SpO_2 No Sensor
	SpO_2 Sensor Off
	SpO_2 Search Timeout
	SpO_2 Search Pulse
NIBP	NIBP Communication Stop
	NIBP self-check error
	Cuff type error
	Cuff loose or no cuff
	Cuff leak
	Air pressure error
	NIBP signal weak
	NIBP over range
	NIBP signal unstable
	NIBP over pressure
	NIBP signal saturated
	NIBP system error
	Measurement timeout

9 Battery

9.1 Overview

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

The battery icon on the screen indicates the battery status:

 Battery is working properly and is fully charged.

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

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

 Battery is not installed.

 Battery is properly installed and being charged.

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

9.2 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.

9.3 Checking battery performance

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

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

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

⚠ WARNING

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

9.4 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 naked hand directly.

10 Caring and cleaning

10.1 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.

10.2 Cleaning

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

Below are available cleaning agents:

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

Before cleaning:

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

⚠ WARNING

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

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

⚠**CAUTION**

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

NOTE

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

10.3 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.

11 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.

11.1 Checking

Check the following basic items before using the monitor:

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

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

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

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

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

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

11.2 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

12 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 SpO_2 Sensor and Blood Pressure Cuff, the normal life time is two years. Please replace in time.

Standard accessories are as follows:

No.	Description	QTY	Type-number
1	Adult Finger Clip SpO_2 Sensor	1	Manufacturer: Unimed Medical Supplies,Inc
2	SpO2 extension cable		U403-01
3	Power Adapter	1	Manufacturer: DONGGUAN SHILONG GUHUA ELECTRONIC CO., LTD
			UE36LCP1-150240SPA

Optional accessories list is as follows:

No.	Description	QTY	Type-number
1	Adult Non-Invasive blood pressure cuff	1	Manufacturer: Shenzhen Med-link Electronics Tech Co.,Ltd
			Y000A1
2	NIBP extension tube	1	Manufacturer: XIAMEN CONJOIN ELECTRONICS TECHNOLOGY CO., LTD
			CJP37-C12B1

13 Specifications

13.1 Safety specifications

13.1.1 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

13.1.2 Power

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

13.2 Hardware specifications

Physical Characteristics	
Dimensions	Main Unit: 254(W) X 90(H) X 185(D)
Weight	< 1.5 Kg

Display	
Type	Color TFT touch screen LCD
Size	4.3”, 480 x 272 pixels

LED	
Alarm Indicator	Yellow & Red
Adapter power indicator	1 green
Battery status indicator	1 green

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

Alarm signal	
Alarm delay	Off, 1s, 2s, 3s, 4s, 5s, 6s, 7s, 8s, depending on the setup

Data storage	
Trend	168 hours. Resolution: 1 min

Environment		
	Operating	**Transport and storage**
Temperature	5℃~40℃(41°F~104°F)	-20℃~60℃(-4°F~140°F)
Relative Humidity	30~85% RH, Non-condensing	0 ~ 95 % RH, Non-condensing
Atmospheric pressure	70kPa~106kPa	70kPa~106kPa

13.3 Functional specifications

13.3.1 SpO_2

SpO_2		
Standards compliant	ISO 80601-2-61:2011	
Display range	0% ~ 100%	
SpO_2 display resolution	1%	
SaO_2 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	＜2s
Alarm sign generates delay period	0s	

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

13.3.2 NIBP

NIBP				
Standards compliant	IEC 80601-2-30:2009			
Measurement method	Automatic oscillometric method			
Operating mode	Manual, automatic			
Useful life	100, 000 times			
Measurement interval in automatic mode	1/2/3/4/5/10/15/30/60/90/120/180/240/480min			
Typical measurement time	20~40s			
Normal mode measuring range (mmHg)		Adult	Pediatric	Neonate
	Systolic blood pressure	40-270	40-200	40-130
	Mean blood pressure	20-230	20-175	20-100
	Diastolic blood pressure	10-210	10-162	10-90
Measurement accuracy	Maximum average error: ±5mmHg Maximum standard deviation: 8mmHg			
Resolution	1mmHg			
Initial inflation pressure		Default	Pressure setting range	
	Adult	160mmHg	140mmHg, 160mmHg, 180mmHg	
	Pediatric	140mmHg	140mmHg, 160mmHg,	
	Neonate	100mmHg	100mmHg, 120mmHg,	
Overpressure protection point (software)	Adult: 300mmHg			
	Pediatric: 240mmHg			
	Neonate: 150mmHg			
Overpressure protection point (hardware)	Adult: 320~330mmHg			
	Pediatric: 265~275mmHg			
	Neonate: 160~165mmHg			
Static Pressure accuracy	±3mmHg			

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

14 Common faults and maintenance

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

Faults	Solution
Not power on	Check the battery. If the battery is low, please contact to Bistos.
Blank Screen	Check the screen and screen line.
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 contact to Bistos.
No SpO_2 waveform or value	1. Is the red light on the finger sensor flashing? If not there might be poor contact. Check the extension cable and the connector. 2. Is the patient's arm under pressure? Never take blood pressure and SpO2 measurements on the same arm. 3. Is the environmental temperature too low? Never expose the patient's arm to cold air since this can affect the readings. 4. Has all patient nail polish, especially blue or purple been removed?
SpO2 value turn on and off during monitoring	During long term monitoring, patient movement might result in SpO2 interruption. Keep the patient stabilized. SpO2 interruptions due to patient hand motion are normal.
Blood pressure measurement 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 leak. 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.

15 Manufacturer's declaration on EMC

BT-720 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-720 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.

15.1 Electromagnetic emissions

<table>
<tr><td colspan="3">The BT-720 is intended for use in the electromagnetic environment specified below.
The customer or the user of the BT-720 should assure that it is used in such an environment.</td></tr>
<tr><td>Emissions test</td><td>Compliance</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The BT-720 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class A</td><td rowspan="3">The BT-720 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-720 is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the BT-720 or shielding the location.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations / flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

15.2 Recommended separation distances between portable and mobile RF communications equipment and BT-720

The BT-720 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BT-720 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BT-720 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.

15.3 Electromagnetic immunity

The BT-720 is intended for use in the electromagnetic environment specified below. The customer or the user of the BT-720 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment -guidance**
Electrostatic discharge (ESD) IEC 61000-4-2:2009	±8 kV Contact ±15 kV air	±8 kV Contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4:2004	±2 kV for power supply lines ±1 kV for input/output lines (>3m)	±2 kV for power supply lines ±1 kV for input/output lines (>3m)	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5:2006	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11:2004	< 5 % U_T (> 95 % dip in U_T) for 0.5 cycles 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (> 95 % dip in U_T) for 5 s	< 5 % U_T (> 95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (> 95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the BT-550 image intensifier requires continued operation during power mains interruptions, it is recommended that the BT-720 be powered from an uninterruptible power supply.
Power frequency (50 Hz and 60 Hz) magnetic field IEC 61000-4-8:2010	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

The BT-720 is intended for use in the electromagnetic environment specified below.
The customer or the user of the BT-720 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-550, 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-720 is used exceeds the applicable RF compliance level above, the BT-550 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-720.

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

Product Warranty

Product Name	Patient Monitor
Model Name	BT-720
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-720.
※ 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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