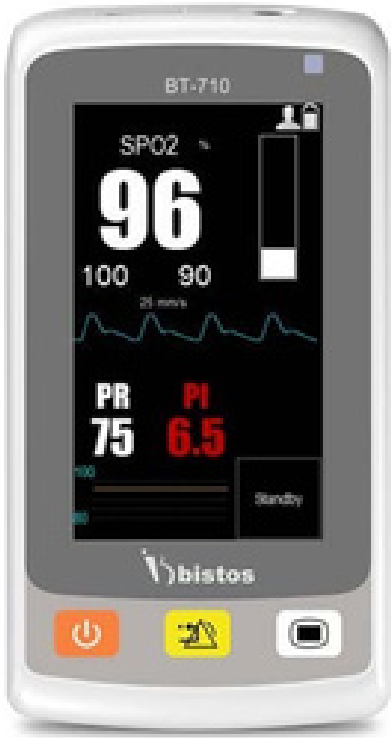
BT-710 Hand held pulse oximeter
Operation Manual



Keep this manual for future reference

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Proprietary Material

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0 Safety information

Before using BT-710 Pulse oximeter, 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 pulse oximeter. 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-710.
	Used to identify safety information. Be well-known this information thoroughly before using BT-710
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 device and the accessory for SpO2.
	Refer to operation manual. Read manual before placing the device.
	Indicates the production date.
	Indicates the manufacturer.
	Indicates the serial number of the device.
SN	Indicates the authorized representative in the European Community
EC REP	of manufacturer.
	Indicates a BF 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 temperature limitation for operation, transport and storage.
	Indicates the humidity limitation for operation, transport and storage.

	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 pulse oximeter and any accessories periodically to ensure that the cables including 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 pulse oximeter if there is any visible sign of damage.

• Only the DC power adapter supplied with the BT-710 is approved for use with the device.

• Do not attempt to service the BT-710 pulse oximeter. Only qualified service personnel by Bistos Co. Ltd. should attempt any needed internal servicing. There is no user serviceable part.

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

• During the operation, do not disconnect any cable.

• Do not operate the BT-710 pulse oximeter if it fails to pass the power on self-test procedure.

• The BT-710 pulse oximeter 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-710. Failure to do so could result in personal injury or equipment damage.

• The device is intended for measure the clinical blood oxygen saturation via

pulse oximeter, 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 pulse oximeter.
- Do not open the enclosure to avoid an electric shock. Any repair and upgrade of pulse oximeter should be done by service personnel trained and authorized by Bistos. Co., Ltd.
- When handling packaging materials and the device, abide by local laws and regulations or hospital waste disposal regulations. Keep the 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 pulse oximeter 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 pulse oximeter 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.
- Use of accessories other than 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 pulse oximeter is located. Textiles, oils, and other combustibles are easily ignited and burn with great intensity in oxygen rich environment. Personal injury or equipment damage could occur.
- A fire and explosion hazard exists when performing cleaning or maintenance procedures in an oxygen rich environment.
- The pulse oximeter has been validated with the accessories listed in this manual and found to comply with all relevant safety and performance require-

ments 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-710 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 pulse oximeter 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 pulse oximeter in the environment such as pressure is too high, poor ventilation, dusty, or contain salt, sulfur gas and chemical.
- Before using the pulse oximeter, check the pulse oximeter 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 this manual.
- Equipment should be tested at least once a year, the test should be done and recorded by trained, have safety 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 pulse oximeter. The operation or use of non-approved equipment or accessories with the pulse oximeter is not tested or supported, and pulse oximeter 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.

0.2 Shock hazards

WARNING

- Unplug the pulse oximeter 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 pulse oximeter 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 pulse oximeter.

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 pulse oximeter under the environment listed below.

	Avoid placing in an area exposed to moisture. Do not touch the pulse oximeter 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 enters into the pulse oximeter.
	Do not disjoint or disassemble the pulse oximeter. Bistos Co., Ltd. does not have liability of it.		Power off when the pulse oximeter is not fully ready to operate. Otherwise, the pulse oximeter could be damaged.

1 System basics

1.1 Intended use

The BT-710 pulse oximeters acquire the blood oxygen saturation (SpO2) and pulse rate (PR). The signals are converted into digital data and processed, examines the data for alarm

conditions and display the data. The pulse oximeter also provides operating control for the user. The pulse oximeter intend to use in hospital clinical area such as general ward, to provide additional information to the medical and nursing staff about the blood oxygen saturation of the patient. The BT-710 pulse oximeters 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 pulse oximeter is suitable for bedside monitoring of patient. This pulse oximeter enables the monitoring of blood oxygen saturation (SpO2) and pulse rate (PR). 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 (SpO2)
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

1.2 Operating principle

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

1.3 System configurations

Basic configuration of BT-710

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

1.4 Product outlook

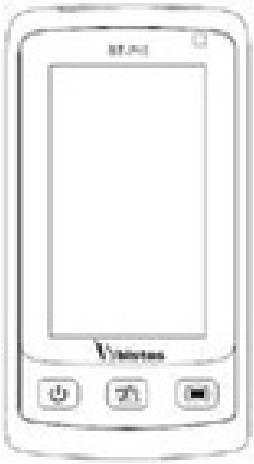

Figure1-1: Front view

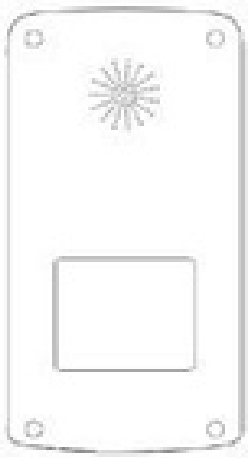

Figure1-2 : Rear view

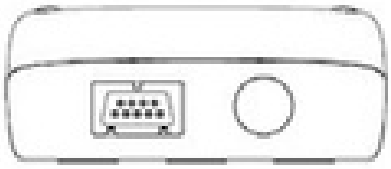

Figure1-3 : Top view

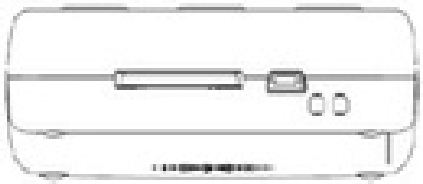

Figure1-4 : Bottom view

1.5 Description of pulse oximeter

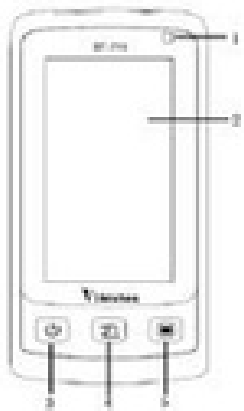

Figure1-5: Front view

	Name	Description
1	DC power indicator	Turned on when the pulse oximeter is being powered by the adapter.
2	Display area	Display the waveform and measured value
3		- Power On: Press down the key more than 2 seconds.

	[Power]	- 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	[Alarm reset]	To reset the alarm condition.
5	[Setting]	Enter to the setting mode. Press again to close the setting mode.

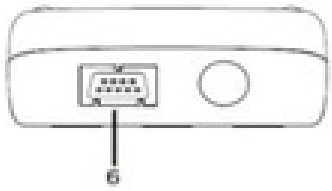

Figure1-6: Top view

	Name	Description
6	SpO2	SpO2 sensor probe interface

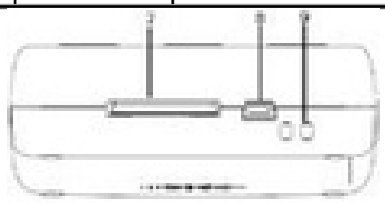

Figure1-7: Bottom view

	Name	Description
7	SD card interface	For software upgrade
8	Power adapter	5V, 2A adapter
9	Lanyard eyelet	For convenient hand held

1.6 Understanding the display

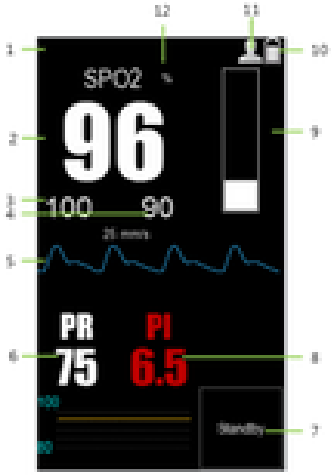

Figure 1-8: Standard display

	Description
1	Current alarm message. When an alarm occurs, this area will displayed yellow or red depending on the alarm type.
2	SpO2 value. Display the measured SpO2 value.
3	SpO2 upper alarm limit. Display the user set upper alarm limit
4	SpO2 lower alarm limit. Display the user set lower alarm limit SpO2 waveform.
5	Display the measured SpO2 waveform. The waveform is not normalized.
6	Pulse rate value. Display the measured pulse rate per minute.
7	Sleep mode. Touch this area makes the pulse oximeter to enter the sleep mode.
8	To exit "sleep mode", press [Power] or [Alarm reset] or [Setting]
9	Perfusion index. Display the measured perfusion index.
10	Pulse rhythm strength.
11	Battery Status
12	Patient type. The unit of SpO2.

1.7 Essential performance

This device Pulse oximeter provides patient vital signs such as pulse rate, blood oxygen saturation and perfusion index by placing the sensors to the appropriate site of patient. The device is composed with display, control circuit and panel, and input part for SpO2 sensors. It detects SpO2 and PR using specific sensors. The detected analog signal amplified and converted to digital. This converted 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 pulse oximeter, read this chapter before use, and install as required.

WARNING

- All analog and digital devices connected to the pulse oximeter 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.

- The copyright of pulse oximeter software belongs to Bistos. Without permission, any organization or individual shall not interpolate, copy or exchange by any means or form.
- When the pulse oximeter 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.

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

2.1.1 Unpack and check

BT-710 pulse oximeter 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 pulse oximeter and accessories from the box and check with the packing list. Check if there is any mechanical damage, and the all listed components 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 Power requirements

- DC power supply adapter (Model: UE10WCP1-050200SPA)
  Input: A.C. 100 V ~ 240 V, 50/60 Hz
  Output: D.C. 5 V, 2.0 A
- Built-in rechargeable lithium-ion battery: D.C. 3.7 V, 3000mAh (Model: JHY605085)

2.1.3 Environmental requirements

The storage, transport and use of the pulse oximeter 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 pulse oximeter 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 pulse oximeter 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 pulse oximeter 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 pulse oximeter when the power is connecting.

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 pulse oximeter. Plug the power adapter into the power connector of the pulse oximeter, and plug the other end of the power adapter into the mains (low voltage power supply network facilities) power outlet.

NOTE

• The operation of pulse oximeter after the supply mains has been interrupted and is restored after a period of time that is longer than 30s.

3 Basic operations

~~3.1 Turn on~~

3.1.1 Check the pulse oximeter

- Before turn on the pulse oximeter, check whether there is mechanical damage to the pulse oximeter, 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 to make sure that the pulse oximeter operates properly.

WARNING

• If the pulse oximeter is damaged, or fails to work normally, do not use it. Please contact the maintenance personnel or Bistos immediately.

3.1.2 Start the pulse oximeter

If finish to check the pulse oximeter, it is ready to start the pulse oximeter.

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

- Once the power is supplied, the system performs a power-on self test to check the functions before start-up. If any fatal error occurs during boot up, the system will alarm. If this case persists, please stop to using the pulse oximeter and contact the maintenance personnel or Bistos.
- Check all available pulse oximeter functions to ensure that the pulse oximeter operate properly.

- If the pulse oximeter equipped with a battery, charge the battery after each use to ensure sufficient power.
- After unpacking and use the pulse oximeter at first time, the pulse oximeter should be powered with adapter.

3.1.3 Connect the sensors

Connect the SpO2 sensor probe to the pulse oximeter and the monitoring site of patient.

3.1.4 Start monitoring

Start monitoring in the following steps:

- Check if the patient cable is connected properly.
- Check if the settings of the pulse oximeter 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 pulse oximeter in the following steps

- Disconnect the sensor probe connected to the patient.
- Press and hold the [Power] key for 2 seconds to pop up the 3 seconds countdown window, and the pulse oximeter turns off in 3 seconds.

⚠CAUTION

• If the pulse oximeter 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 pulse oximeter

In the main screen, Press the key enter the setup menu.

- Select “Patient Type”, you can choose “Adult” or “Pediatric” or “Neonate”. According to patient type, the settable PR alarm limit and default are changed. Select “Alarm Delay”, you can choose “off”, “1s”, “2s”, “3s”, “4s”, “5s”, “6s”, “7s” or “8s”. It sets the time from the occurrence of a trig- gering event either in the patient, for physiological alarm conditions to when the alarm system determines that an alarm condition exists. Technical alarm conditions are not delayed.
- Select “Backlight”, and enter value （Range: 0-5）. It can set brightness of the background according to needs of use. “5” is the brightest.
- Select “Alarm Volume”, which is alarm tone volume and settable among （Range: 0-9）. “0” is alarm sound off.
- Select “Alarm Reminder Signal”, you can choose “On”, or “Off”. It is periodic signal that reminds the operator that the alarm system is in an alarm signal inactivation for both physiological alarm conditions

and technical alarm conditions.

- Select “Alarm Reminder Interval”, when the “Alarm Reminder Signal” sets “On”, you can choose alarm interval to “1min”, “2min”or “3min”.
- Select key to display the following interface.

- Select “Year”, “Month”, “Day”, “Hour”, “Minute” and “Second”, and set the current date.
- Select “Date Format”, and set among the below date formats in accordance with custom.
  “YYYY-MM-DD”: Year- Month-Day.
  “MM-DD-YYYY”: Month -Day-Year.
  “DD-MM-YYYY”: Day-Month-Year.
- Select key to display the following interface.

- Select “Displays”, set “SpO2”.
- Select “Language”, and select the option as needed:
  “English”: The interface language of the pulse oximeter 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 “Default”, clears all the setting except the date and time and go back to the initial factory setup.
- Select key to display the following interface.

5 SpO_2

5.1 Overview

Blood oxygen saturation (SpO2) 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 SpO2 is to fix the probe fingerstall on the patient’s finger, use the finger as a transparent container for hemoglobin, use 660nm wavelength red light and 905nm 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 SpO2.

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 SpO2. Detection pulsation can give a “plethysmography” wave and pulse rate signal.

The main screen displays “SpO2” value and “plethysmography” wave. While the monitor gets and displays the physiological signal from a patient, the pulse tone which is the auditory information signal. The volume of this pitch tone is user adjustable.

This pulse oximeter applies to measure SpO2 of adults (>18 years), pediatric (<18 years,>30 days), neonate (<30 days). Contact SpO2 probe to Patient’s finger to get “SpO2” value and “plethysmography” wave.

SpO2 function of this pulse oximeter has been calibrated in factory.

NOTE

- Information about wavelength range can be especially useful to clinicians.

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 probe is normal. When SpO2 sensor probe is unplugged from the socket, the screen will display “SpO2 No Sensor connected” 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 patient cable.
- Avoid using the pulse oximeter 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.
- Before using, verify compatibility between the monitor and probe, otherwise it may cause injury to the patient.
- Functional testers cannot be used to evaluate the accuracy of pulse oximetry.

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 SpO2 readings.

•The pulse oximeter cannot be used to verify the accuracy of SpO2 probe and SpO2 equipment.

5.3 Monitoring steps

(1)Act the appropriate SpO2 sensor according to the patient.
(2)Turn on the pulse oximeter, and connect the SpO2 sensor probe to the pulse oximeter.
(3)Clean the measurement site, such as finger with nail polish.
(4)Put the SpO2 sensor probe on the patient's finger.
(5)Select the appropriate alarm settings.
(6)Start monitoring.

NOTE

•When you turn on the pulse oximeter, plug in SpO2 probe and connect patient's finger (or toe), monitor displays SpO2 wave, "SpO2 Pulse Search" displayed in the technical alarm area until the monitor measured SpO2 value and pulse rate. "SpO2 Search Timeout" displayed in the technical alarm area until the pulse oximeter measured pulse rate. Check the sensor mounting position, whether the sensor is damaged or sensor type. Reconnect the sensor or use new sensor.

•The alarm message for signal inadequacy such as "SpO2 No Sensor connected", "SpO2 Sensor Off", "SpO2 Search Timeout", "SpO2 Signal Unstable", "SpO2 Sensor Error" and low priority alarm and indication for signal instability like "---" are meaning that the value of SpO2 or PR might be inaccurate.

5.4 Setting SpO2

Select the main screen 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”. This displays a wave as line graph or filled line graph.
- Select “Average Time”, and set the average time to “2-4s”, “4-8s”, “8-16s”. According to the selected option, the module displays the average of data collected within that time. The shorter the averaging time is, the quicker the monitor responds to changes in the patient’s oxygen saturation level.
- Select “Pulse Volume”, and set the volume for auditory information signal for pulse rate (Range: 0-9).
- Select “Sensitivity”, and you can choose “1”, “2”, “3”. It is responding speed for changes of parameter setup. It is faster when setting value is higher.
- Select key to display the following interface.

- Select “Patient Type”, you can choose “Adult” or “Pediatric” or “Neonate”. According to patient type, the settable PR alarm limit and default are changed. Select “SpO2 Low Limit”, and set the SpO2 alarm
- low limit value (Range: 0-99), Adult/Pediatric/Neonate default: 90. The input cannot enter higher than the SpO2 alarm upper limit. Select “SpO2 High Limit”, and set the SpO2 alarm upper limit value (Range: 1-
- 100), Adult/Pediatric/Neonate default: 100/100/95. The input cannot enter less than the SpO2 alarm low limit. Select “PR Low Limit”, and set the RP alarm low limit value (Adult
- Range: 15-349), 15-299, Pediatric/Neonate Range: Adult/Pediatric/Neonate default: 50/75/100. The input cannot enter higher than the PR alarm upper limit.
- Select “PR High Limit”, and set the PR alarm upper limit value (Adult Range: 16-350), 16-300, Pediatric/Neonate Range: Adult/Pediatric/Neonate default: 120/160/200. The input cannot enter less than the PR alarm low limit.
- Select “PI Low Limit”, and set the PI alarm low limit value (Range: 0.00-19.90). Default: 0.00.
- Select “PI High Limit”, and set the PI alarm upper limit value (Range: 0.10-20.00). Default: 20.00.
- Select “Alarm Level”, you can choose “Mid” or “High” of priority level for the physiological alarm.
- Alarm, Select “Default”, the alarm parameter is set to the default value.

NOTE

- Setting values including alarm settings are stored and does not changed even when the power supply interrupted.

5.5 Measuring influencing factors

During operation, the following factors can affect the accuracy of SpO2 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 SpO2 values, such as: carbon hemoglobin, methemoglobin, methylene blue, and indigo carmine.
- SpO2 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

- The SpO2 sensor probe (specified in Chapter 11) material which contacts patients or other staff has 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 pulse oximeter 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.
- The PR accuracy shall be stated as the root-mean-square (rms) difference between paired pulse rate data recorded pulse oximeter equipment and with a reference method (E.G, an electronic pulse simulator, ECG heart rate, palpated pulse, thoracic auscultator or a second pulse equipment which has been qualified by comparison to one of these references).

6 Review

Use the trend screen to recall all the historical patient data in a list, including monitoring time (in 1-minute intervals), and SpO2 and PR values. The most recent measurements display at the top of the list.

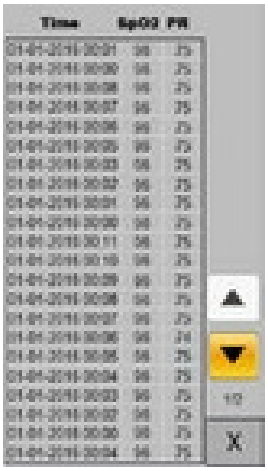

Figure 6-1: SpO2 Trend (1)

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 key to exit the Trend screen and display the Main screen or press the [Setting] key to see the trend graph.

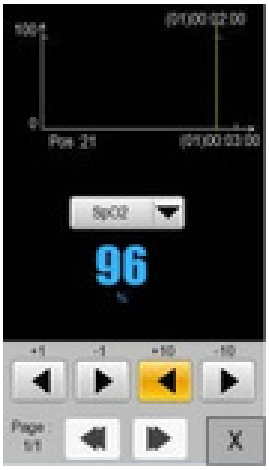

Figure 6-2: SpO2 Trend (2)

- Select 'SpO2', 'PR' or 'PI' to see.
- Press key to exit the Trend screen and display the Main screen.

7 Alarm

Alarm means that the pulse oximeter prompts the medical staff through sound and light when the abnormal changes in vital signs are monitored or the pulse oximeter has a failure or is unable to monitor the patient successfully. For better viewing those alarms, it is recommended to look straight at the display when using the monitor.

WARNING

- In any single area (e.g. intensive care unit), it can be a potential danger if there are the same or similar devices using different alarm preset.

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.

7.1 Alarm types

According to the nature of the alarm, the alarms of the monitor can be divided into physiological alarms, technical alarms, alarm reminder signal 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.

- Alarm Reminder Signal

  Alarm Reminder Signal is periodic signal that reminds the operator that the alarm system is in an alarm signal inactivation for both physiological alarm conditions and technical alarm conditions.

- 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.

7.2 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.

- 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 deactivation of the monitor will affect the normal monitoring of key physiological parameters.

- Low priority alarms

  The certain monitoring function is invalid due to mechanical failure or deactivation, but it won’t endanger the patient’s life.

The levels of some physiological alarms can be modified. But, 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.

7.3 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.

7.3.1 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
- Medium and Low priority alarm: Yellow

7.3.2 Audible alarm

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

Audible alarm pattern:

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

7.3.3 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: *

7.3.4 Parameter flashing

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

7.4 Alarm state

7.4.1 Alarm reset

Select button, and you can temporarily turn off the alarm sound of currently occurring physiological alarms of the pulse oximeter, 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.

7.4.2 Alarm sound off

When “Alarm Volume” sets “0”, the alarm state area on the screen shows the icon.
If “Alarm Volume” sets bigger 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.

7.5 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 configurable priority 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.

Physiological alarm information.

Source	SpO2			
Parameter	**Alarm message**	**Default**		**Causes and countermeasures**
		Value (Adult/ Pediatric/ Neonate)	**P**	
SpO2 High Limit	SpO2 Too High	100/100/95	M *	SpO2 value is higher than the settled upper alarm limit or lower than the settled lower alarm limit. Check the patient's physiological condition, and check if the patient category and alarm limit settings are appropriate for the patient.
SpO2 Low Limit	SpO2 Too Low	90		
PR High Limit	PR Too High	120/160/200		PR value is higher than the settled upper alarm limit or lower than the settled lower alarm limit. Check the patient's physiological condition, and check if the patient category and alarm limit settings are appropriate for the patient.
PR Low Limit	PR Too Low	50/75/100		

PI High Limit	PI Too High	0.00		PI value is higher than the settled upper alarm limit or lower than the settled lower alarm limit. Check the patient's physiological condition, and when the PI alerts the clinician to consider another monitoring site.
PI Low limit	PI Too Low	20.00		
-	No Pulse	-	H	The physiological signal shows a potentially life-threatening drop in oxygen saturation. Check the patient's physiological condition.

□ Technical alarm information.

Source	Alarm message	P	Causes and countermeasures
SpO2	SpO2 No Sensor connected	L	Indicates the condition that SpO2 sensor cable is unplugged from the socket.
	SpO2 Search Timeout	L	When you turn on the monitor, plug in SpO2 probe and connect patient's finger (or toe), monitor displays SpO2 wave, "SpO2 Pulse Search" displayed in the technical alarm area until the monitor measured SpO2 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.
	SpO2 Sensor Off	L	SpO2 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.
Battery	Battery Low	M	Connect to DC power supply, and charge the battery, and power with the battery as needed after fully charged.
	System will shutdown	N/A	Press down the keys more than 2 seconds and the system will display the alarm message "The system will shut down 3 seconds"

8 Battery

~~8.1 Overview~~

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

8.2 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:

- Before using the battery, please read this manual and labels on the battery surface carefully.
- Do not drop the battery.
- If it won’t be used for a long time (over three months), please store the battery properly. Charge the battery to 50%, and wrap the battery with non-conductive material in order to avoid direct contact with metal, resulting in damage. Keep the battery in a cool dry place.
- Check the battery performance once every two years. Before servicing the pulse oximeter or you suspect that the battery is the fault, 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.

8.3 Checking battery performance

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

- Disconnect the pulse oximeter from the patient and stop the monitoring or measurement.
- Connect DC power to the monitor, and charge the battery for more than 4 hours uninterruptedly.
- Disconnect the DC power and power the pulse oximeter with battery until the pulse oximeter 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.

8.4 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.

9 Caring and cleaning

~~9.1 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.

9.2 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 pulse oximeter, disconnect the power cord.
- 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 pulse oximeter or sensor, turn off the power and disconnect the DC power.
- The pulse oximeter 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 pulse oximeter:
- 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 pulse oximeter 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.

9.3 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 pulse oximeter, do not disinfect the pulse oximeter with gas (EtO) or formaldehyde.

10 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.

10.1 Checking

Check the following basic items before using the pulse oximeter:

- Check for any mechanical damage.
- Check all wires and accessories.
- Check all instrument functions that may be used for pulse oximeter and ensure that the instrument is in good working condition.

If the instrument function has any sign of damage, do not use this pulse oximeter. 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.

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 Bistos personnel.

10.2 Trouble shootings

Problem	Solution
Device not power on	Check the battery. If the battery is low, it should be promptly charged.
SpO2 waveforms or	Is the red light on the finger sensor flashing? If not, there

values do not displayed on the screen	might be poor contact. Check the patient cable and the connector.
	Is the patient's arm under pressure? Never take blood pressure and SpO2 measurements on the same arm
	Is the environmental temperature too low? Never expose the patient's arm to cold air since this can affect readings.
	Has all patient nail polish, especially blue or purple, been removed?
SpO2 values turn on and off during SpO2 monitoring	During long term monitoring, patient movement might result in SpO2 interruptions. Keep the patient stabilized. SpO2 interruptions due to patient hand motion are normal.

10.3 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 pulse oximeter 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.

11 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.

• If the packaging or accessories have any sign of damage, do not use such accessories.

• For SpO2 Sensor, 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 Probe	1	Manufacturer: Unimed Medical Supplies,Inc U403-01

12 Specifications

12.1 Safety specifications 12.1.1 Product category In accordance with classification specified in the European Medical Device Directive 93/42/EEC, this pulse oximeter is Class IIb device. The pulse oximeter is classified as follows in accordance with IEC 60601-1:

Category Name	Specification
Type of electric shock protection	Class II and internally powered equipment
Electric shock protection grade	Type BF applied part
Explosion protection grade	Common equipment, no explosion protection
Liquid inlet protection grade	IPX2
Operating mode	Continuous mode
Movement	Hand-held equipment

12.1.2 Power

Power	
Adapter	Input: AC 100 ~ 240V (50/60 Hz) Output: DC 5V / 2.0A
Rechargeable Battery	3.7V Li-ion battery 3000 mA
	Operating Time(When it fully charged): 5 hours
	Charging Time(Fully): 4 hours

12.2 Hardware specifications

Physical Characteristics	
Dimensions	Main Unit: 84(W) X 158.5(H) X 34.5(D)
Weight	< 1.5 Kg for standard configuration
Display	
Type	Color TFT touch screen LCD
Size	4.3”
Audio	
Speaker	Alarm tone (45 ~ 85 dB)
	Pulse tone
	Alarm sound meet the IEC 60601-1-8 standard require-ments

12.3 Functional specifications

SpO2	
Standards compliant	ISO 80601-2-61:2011
Display range	0% ~ 100%
SpO2 display resolution	1%

SpO2 accuracy	±2% (at the range 70%~100%)(adult/pediatric mode) ±3% (at the range 70%~100%) (neonate mode) not define when lower than 70% ;	
	Measurement accuracy verification The SpO2 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. Over the range of 70% to 100%, overall accuracy was determined by calculating the root mean square error across all samples and is 1.44%.	
SpO2 alarm limit range	Upper alarm limit	1%~100%
	Lower alarm limit	0%~99%
SpO2 alarm signal generation delay	No delay when the “Alarm Delay” sets “off”. If the “Alarm Delay” sets more than “1s”, the alarm generation is delayed by the set time.	
SpO2 value refresh period	The data update period is 1s/time	
Data averaging	Low sensitivity (when sensitivity sets 1)	Within 6.8s
	Intermediate sensitivity (when sensitivity sets 2)	Within 3.4s
	Advanced sensitivity (when sensitivity sets 3)	Within 3.4s
Alarm condition delay	Select “Alarm Delay”, you can choose “off”, “1s”, “2s”, “3s”, “4s”, “5s”, “6s”, “7s” or “8s”.	

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

13 Manufacturer's declaration on EMC

BT-710 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-710 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.

13.1 Electromagnetic emissions

The BT-710 is intended for use in the electromagnetic environment specified below.
The customer or the user of the BT-710 should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The BT-710 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-710 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-710 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-710 or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

13.2 Recommended separation distances between portable and mobile RF communications equipment and BT-710

The BT-710 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BT-710 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BT-710 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 $d=3.5$	80 MHz to 800 MHz $d=3.5$	800 MHz to 2.5 GHz $d=7$
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.

13.3 Electromagnetic immunity

The BT-710 is intended for use in the electromagnetic environment specified below.
The customer or the user of the BT-710 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	< 5 % U_T (> 95 % dip in U_T) for 0.5 cycles	< 5 % U_T (> 95 % dip in U_T) for 0.5 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user

voltage variations on power supply input lines IEC 61000-4-11:2004	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	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	of the BT-550 image intensifier requires continued operation during power mains interruptions, it is recommended that the BT-710 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-710 is intended for use in the electromagnetic environment specified below.
The customer or the user of the BT-710 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-710 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-710.

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

Product Warranty

Product Name	Pulse oximeter
Model Name	BT-710
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-710.
※ 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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