

## 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 SpO<sub>2</sub> sensor probe
- AC/DC adapter

## 1.4 Product outlook



Figure1-1: Front view

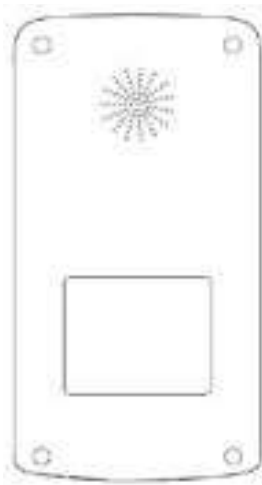


Figure1-2 : Rear view

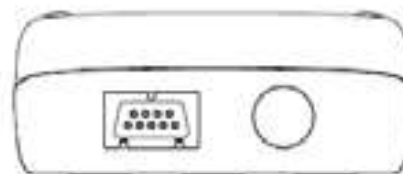


Figure1-3 : Top view

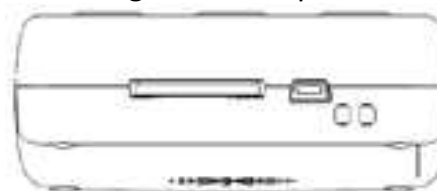


Figure1-4 : Bottom view

## 1.5 Description of pulse oximeter

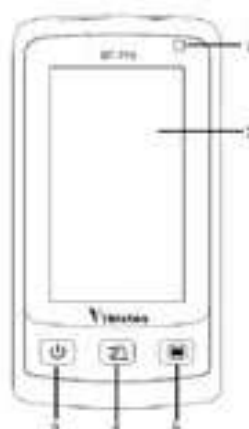


Figure1-5: Front view

|   | 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.                                                                         |

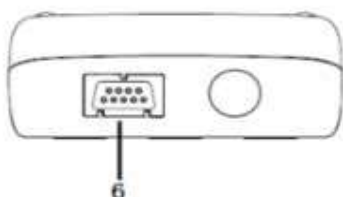


Figure1-6: Top view

|   | Name             | Description                             |
|---|------------------|-----------------------------------------|
| 6 | SpO <sub>2</sub> | SpO <sub>2</sub> sensor probe interface |

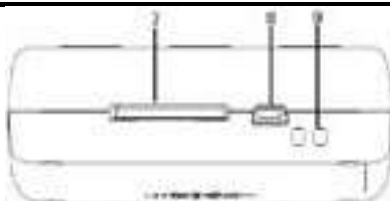


Figure1-7: Bottom view

|   | 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  | SpO <sub>2</sub> value. Display the measured SpO <sub>2</sub> value.                                                                            |
| 3  | SpO <sub>2</sub> upper alarm limit. Display the user set upper alarm limit                                                                      |
| 4  | SpO <sub>2</sub> lower alarm limit. Display the user set lower alarm limit                                                                      |
| 5  | SpO <sub>2</sub> waveform. Display the measured SpO <sub>2</sub> 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. To exit "sleep mode", press [Power] or [Alarm reset] or [Setting] |
| 8  | Perfusion Index. Display the measured perfusion index.                                                                                          |
| 9  | Pulse rhythm strength.                                                                                                                          |
| 10 | Battery Status                                                                                                                                  |
| 11 | Patient type.                                                                                                                                   |
| 12 | The unit of SpO <sub>2</sub> .                                                                                                                  |

### **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 SpO<sub>2</sub> sensors. It detects SpO<sub>2</sub> 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 °C ~ 40 °C                 |
|                       | 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 °C ~ 60 °C, 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.

## 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)<br>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 requirements |

### 12.3 Functional specifications

| SpO <sub>2</sub>                    |                     |
|-------------------------------------|---------------------|
| Standards compliant                 | ISO 80601-2-61:2011 |
| Display range                       | 0% ~ 100%           |
| SpO <sub>2</sub> display resolution | 1%                  |

|                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |             |
|------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| SpO <sub>2</sub> accuracy                      | $\pm 2\%$ (at the range 70%~100%)(adult/pediatric mode)<br>$\pm 3\%$ (at the range 70%~100%) (neonate mode)<br>not define when lower than 70% ;                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |             |
|                                                | <b>Measurement accuracy verification</b><br>The SpO <sub>2</sub> 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.<br>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.<br>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%. |             |
| SpO <sub>2</sub> alarm limit range             | Upper alarm limit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 1%~100%     |
|                                                | Lower alarm limit                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 0%~99%      |
| SpO <sub>2</sub> alarm signal generation delay | No delay when the “Alarm Delay” sets “off”.<br>If the “Alarm Delay” sets more than “1s”, the alarm generation is delayed by the set time.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |             |
| SpO <sub>2</sub> 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    | $\pm 1$ bpm                                    |
| Accuracy      | $\pm 2\%$ or $\pm 2$ bpm, whichever is greater |