

# HANDHELD PULSE OXIMETER

## MN 1014-B



## USER MANUAL

**MANN ELECTRONICS INDIA PVT. LTD.**

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### **Proprietary Notice**

Information contained in this document is copyrighted by the manufacturer and may not be duplicated in full or part by any person without prior written approval of the manufacturer. Its purpose is to provide the user with adequately detailed documentation to efficiently install, operate, maintain and order spare parts for the device supplied. All information contained in this document is believed to be current and accurate as of the date of publication or revision, but does not constitute a warranty.

### **Limited Warranty**

The manufacturer ("Seller") warrants to the original purchaser that the Product, not including applicable accessories, shall be free from defects in material and workmanship under normal use, if used in accordance with its labeling, for one year from the date of shipment to the original purchaser. The sole obligation of Seller warrants under this warranty will be repair or replace, at its option, products that prove to be defective during the warranty period. The foregoing shall be the sole warranty remedy. No warranty is provided if the products are modified without the express written consent of Seller warrants and seller shall not be liable in any event for incidental or consequential damage. This warranty is not assignable.

Seller warrants to the original purchaser that the reusable oximeter sensors supplied as accessories, shall be free from defects in materials and workmanship under normal use, if used in accordance with its labeling, for half year from the date of shipment to the original purchaser.

Warranties are subject to change. Please contact Seller for current warranty information.

### **Maintenance disclaimer**

This warranty is void of the product that been altered, misused, damaged by neglect or accident, not properly maintained or recharged, or repaired by persons not authorized by Seller. Misuse includes, but is not limited to, use not in compliance with the labeling or use with accessories not manufactured by Seller. This warranty does not cover normal wear and tear and maintenance items.

### **Service Support**

Repairs for devices manufactured by the manufacturer under warranty must be made at authorized repair centers. If the device needs repair, contact your local distributor or the manufacturer after-service department. When calling, have the Pulse Oximeter User and Technical Manual

device' s model and serial number ready.

Keep all original packing material, including any inserts. If you need to ship the device, use only the original packaging material, including inserts. Box and inserts should be in original condition. If original shipping material in good condition is not available, it should be purchased from the manufacturer.

If you need to ship the device, pack the device and accessories carefully to prevent shipping damage. All accessories should accompany the device. Damages occurring in transit in other than original shipping containers are the responsibility of the shipper. All costs incurred returning devices for repair are the responsibility of the shipper.

**NOTE! Shipments received without a return number will be returned to sender.**

**About this Manual**

The Operation Manual provides installation, operation, and maintenance instructions for health -care professionals and other users, trained in monitoring respiratory and cardiovascular activity.

These instructions contain important information for the safe use of the product. Read the entire contents of these Instructions For Use, including Warnings and Cautions, before using the monitor. Failure to properly follow warnings, cautions and instructions could result in death or serious injury to the patient.

The information in this manual has been carefully checked and is believed to be accurate. In the interest of continued product development, manufacturer reserves the right to make changes and improvements to this manual and the products it describes at any time, without notice or obligation.

**Using the Manual**

The monitor allows you to choose the measurement capabilities you need. A measured value refers to a derived or calculated value; a parameter refers to one or more specific measured values. For example, pulse rate and %SpO<sub>2</sub> are measurements; the monitor parameter consists of both these measured values. Operation of the monitor is the same regardless of the number of parameters you use.

If you are not familiar with the operation of this monitor, follow each chapter in the manual in order. Each chapter builds on the information from the previous chapter. If the monitor is already set up, or if you are familiar with its operation, turn to the chapter that describes the features you will use.

**Definition of Symbols**

<b>SYMBOLS</b>	<b>DEFINITION</b>	<b>SYMBOLS</b>	<b>DEFINITION</b>
	Refer to instruction manual		Defibrillation-proof type BF applied part
	indicates the the manufacturer's address		temperature limit
	Date of manufacture		humidity limitation
IP22	Dust rating is 2 and water resistance is 2 (monitor only)		Atmospheric pressure limitation

	indicates the authorized representative in the European Community		The limit of stacking layers is 3 layers
	Indicates compliance of this device to the Medical Device Directive 93/42/EEC		This way up
	Indicates separate collection for electrical and electronic equipment.		Keep away from rain
	Write and read data into and from store		Recyclable
	Caution: Consult accompanying documents		No stepping
	Fragile; handle with care		

### Warning Information

KEYWORD	DEFINITION
WARNING	Tells you something that could hurt the patient or hurt the operator.
CAUTION	Tells you something that could damage the device.
NOTE	Tells you other important information.

### Warnings

**WARNING!** Do not use this device in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.

**WARNING!** Do not use this device in the presence of magnetic resonance imaging (MR or MRI) equipment.

**WARNING!** Only Use SpO<sub>2</sub> sensors supplied with, or specifically intended for use with, this device.

**WARNING!** This device is intended for use by persons trained in professional health care. The operator must be thoroughly familiar with the information in this manual before using the device.

**WARNING!** This device must be used in conjunction with clinical signs and symptoms. This device is only intended to be an adjunct in

patient assessment.

**WARNING!** It is the operator's responsibility to set alarm limits appropriately for each individual patient.

**WARNING!** Prolonged use or the patient's condition may require changing the sensor site periodically. Change sensor site and check skin integrity, circulatory status, and correct alignment at least every 4 hours.

**WARNING!** ELECTRICAL SHOCK HAZARD when cover is removed. Do not remove covers. Refer servicing to qualified personnel.

**WARNING!** Chemicals from a broken LCD display panel are toxic when ingested. Use caution when handling a monitor with a broken display panel.

**WARNING!** In the event that earth ground integrity is lost, the performance of this device and/or other devices nearby may be affected due to excessive RF emissions.

**WARNING!** Any monitor that has been dropped or damaged should be inspected by qualified service personnel, prior to use, to insure proper operation.

**WARNING!** If the accuracy of any measurement is in question, verify the patient's vital sign(s) by an alternative method and then check the monitor for proper functioning.

**WARNING!** Remove device batteries prior to long term storage.

**WARNING!** Operation of this device may be adversely affected in the presence of strong electromagnetic sources, such as electro-surgery equipment.

**WARNING!** Operation of this device may be adversely affected in the presence of computed Computed Tomography (CT) equipment.

**WARNING!** SpO<sub>2</sub> measurements may be adversely affected in the presence of high ambient light. Shield the sensor area (with a surgical towel, for example) if necessary.

**WARNING!** Dyes introduced into the bloodstream, such as methylene blue, indocyanine green, indigo carmine, patent blue V (PBV), and

fluorescein may adversely affect the accuracy of the SpO<sub>2</sub> reading.

**WARNING!** Any condition that restricts blood flow, such as use of a blood pressure cuff or extremes in systemic vascular resistance, may cause an inability to determine accurate pulse rate and SpO<sub>2</sub> readings.

**WARNING!** Significant levels of dysfunctional hemoglobins, such as carboxyhemoglobin or methemoglobin, will affect the accuracy of the SpO<sub>2</sub> measurement.

**WARNING!** The monitor was not designed or tested to be an apnea monitor.

**WARNING!** Optical cross-talk can occur when two or more sensors are placed in close proximity. It can be eliminated by covering each site with an opaque material.

**WARNING!** Tissue damage may result from overexposure to sensor light during photodynamic therapy with agents such as verteporphin, porfimer sodium, and metatetrahydroxyphenylchlorin (mTHPC). Change the sensor site at least every hour and observe for signs of tissue damage. More frequent sensor site changes/inspections may be indicated depending upon the photodynamic agent used, agent dose, skin condition, total exposure time or other factors. Use multiple sensor sites.

**WARNING!** When connecting this monitor to any instrument, verify proper operation before clinical use. Refer to the instrument's user manual for full instructions. Accessory equipment connected to the monitor's data interface must be certified according to the respective IEC standards, i.e., IEC 60950 for data processing equipment or IEC 60601 -1 for electro medical equipment. All combinations of equipment must be in compliance with IEC 60601 -1-1 systems requirements. Anyone connecting additional equipment to the signal input port or the signal output port configures a medical system, and, therefore, is responsible that the system complies with the requirements of the system standard IEC 60601 -1-1.

**WARNING!** Failure to place the monitor away from the patient may allow the patient to turn off, reset, or damage the monitor, possibly resulting in the patient not being monitored.

**WARNING!**

Failure to carefully route the cable from the sensor to the monitor may allow the patient to become entangled in the cable, possibly resulting in patient strangulation. Route the cable in away that will prevent the patient from becoming entangled in the cable. If necessary, use tape to secure the cable.

**WARNING!**

Under certain clinical conditions, pulse oximeters may display dashes if unable to display SpO<sub>2</sub> and/or pulse rate values. Under these conditions, pulse oximeters may also display erroneous values. These conditions include, but are not limited to: patient motion, low perfusion, cardiac arrhythmias, high or low pulse rates or a combination of the above conditions. Failure of the clinician to recognize the effects of these conditions on pulse oximeter readings may result in patient injury

**WARNING!** Verify that all LEDs (light emitting diodes) on the display light up upon startup of the device.

**WARNING!** Unauthorized modification of the product may cause danger.

## **Cautions**

**CAUTION!** Do not autoclave, ethylene oxide sterilize, or immerse the monitor or sensors in liquid. Always disconnect the power source and remove all batteries before cleaning or disinfecting the monitor.

**CAUTION!** Should the device become wet, wipe off all moisture and allow sufficient time for drying before operating.

**CAUTION!** The monitor should be operated from its internal power source if the integrity of the protective earth conductor is in doubt.

**CAUTION!** Pressing front panel keys with sharp or pointed instruments may permanently damage the keypad. Press front panel keys only with your finger.

**CAUTION!** Do not allow water or any other liquid to spill onto the monitor. Unplug the external power supply from the monitor before cleaning or disinfecting the monitor. Evidence that liquid has been allowed to enter the monitor voids the warranty

**CAUTION!** Chemicals used in some cleaning agents may cause brittleness of plastic parts. Follow cleaning instructions in this manual.

### Intended Use

This Pulse Oximeter is a low cost monitor for spot checking, continuous, noninvasive monitoring or recording of functional oxygen saturation of arterial hemoglobin (SpO<sub>2</sub>), pulse rate and pulse strength. Breath rate can be calculated from SpO<sub>2</sub> and pulse rate. The monitor is a battery powered pulse oximeter. It may be used in the hospital, clinical environment, and during emergency land transportation. The oximeter works with given sensors providing SpO<sub>2</sub>, pulse rate and RR for Adult and Pediatric.

This device is intended for continuous patient monitoring with adjustable alarm limits as well as visible and audible alarm signals.

**WARNING! The monitor was not designed or tested to be an apnea monitor.**

### Features

- Provides fast, reliable SpO<sub>2</sub>, pulse rate, pulse strength, and breath rate measurements.
- Ideally suited for use in intensive care units, outpatient clinics, emergency rooms, and during emergency land transport.
- Portable and lightweight. It weighs only 265 grams, with batteries.
- Ergonomically designed to fit comfortably in the palm of your hand.
- Uses li-ion polymer battery, allow operation at +/- 30% local rated voltage.
- Standard USB interface, connect to ODMS system for data export.
- The battery can last about 15 hours after full-charge.
- Bright, easy-to-read LCD displays indicate SpO<sub>2</sub>, pulse rate and and breath rate measurements, Plethysmogram and trend table.
- Screen rotation provides upright display for vertical or horizontal monitoring positioning.
- In built exhaust for heat dissipation.
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- Screen rotation provides upright display for vertical or horizontal monitoring positioning.
- In built exhaust for heat dissipation.

## Theory of Operation

The pulse oximeter determines SpO<sub>2</sub> and pulse rate by passing two wavelengths of low intensity light, one red and one infrared, through body tissue to a photo detector. Information about wavelength range can be especially useful to clinicians. Wavelength information for this device can be found in the SpO<sub>2</sub> Specifications section of this manual.

Pulse identification is accomplished by using plethysmographic techniques, and oxygen saturation measurements are determined using spectrophotometric oximetry principles. During measurement, the signal strength resulting from each light source depends on the color and thickness of the body tissue, the sensor placement, the intensity of the light sources, and the absorption of the arterial and venous blood (including the time varying effects of the pulse) in the body tissues.

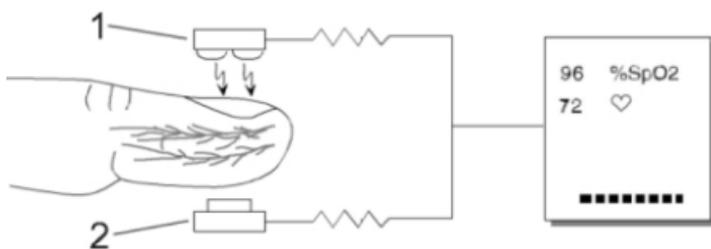


Figure 2.1: Theory of Operation

### 1. Low intensity Red and Infrared LED light sources

### 2. Detector

Oximetry processes these signals, separating the time invariant parameters (tissue thickness, skin color, light intensity, and venous blood) from the time variant parameters (arterial volume and SpO<sub>2</sub>) to identify the pulses and calculate functional oxygen saturation.

Oxygen saturation calculations can be performed because blood saturated with oxygen predictably absorbs less red light than oxygen-depleted blood.

**WARNING!** Since measurement of SpO<sub>2</sub> depends on a pulsating vascular bed, any condition that restricts blood flow, such as the use of a blood pressure cuff or extremes in systemic vascular resistance, may cause an inability to determine accurate SpO<sub>2</sub> and pulse rate readings.

**WARNING!** Under certain clinical conditions, pulse oximeters may display dashes if unable to display SpO<sub>2</sub> and/or pulse rate values. Under these conditions, pulse oximeters may also display erroneous values. These conditions include, but are not limited to: patient motion, low perfusion, cardiac arrhythmias, high or low pulse rates or a combination of the above conditions. Failure of the clinician to recognize the effects of these conditions on pulse oximeter readings may result in patient injury.

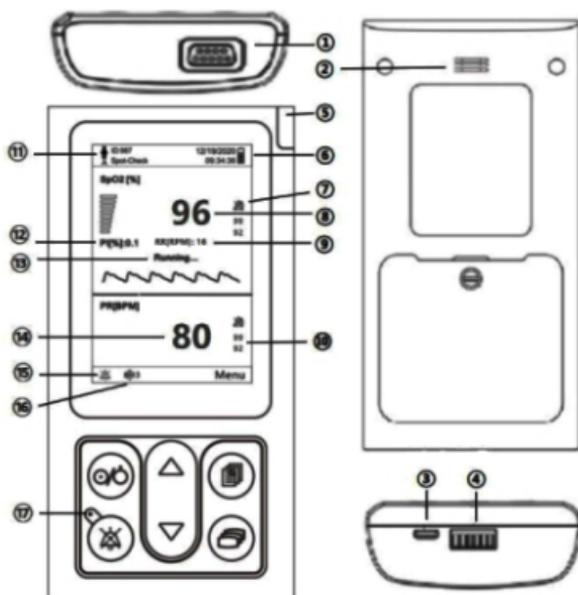
**Monitor Front Pane**


Figure 3.1: monitor appearance and structure

**1. SpO2 Sensor Connector**

The SpO2 sensor connects here, or an extension cable can be connected between the monitor and the sensor.

**2. Speaker**

It provides audible indication of alarm conditions, pulse tone and feedback for key-presses. Ensure the speaker is not covered.

**3. Charge Port**

An optional AC power supply connects here.

**4. Dock connection port**

An optional charging base is connected here.

**5. LED Instructions**

This indicator lights steadily to inform the working status of the monitor. Green means the monitor working normally, yellow and red means alarm occurred.

## 6. Battery level Icon

This icon is displayed at the information bar and has five levels. It flashes when there is only 15 minutes left for the monitor shut down itself.

## 7. Alarm icon

The alarm icon is displayed near the parameter value and has two states:

“ ” This icon indicates that the alarm function is turned on.

“ ” This icon indicates that the alarm function is turned off.

## 8. SpO2 Display

A number shows the patient's SpO<sub>2</sub> value in percent. Dashes (- - -) mean the monitor is not able to calculate the SpO<sub>2</sub> value.

## 9. RR Display

Displays the respiratory rate calculated according to the blood oxygen pulse rate, (---) indicates that the value is empty.

## 10. Alarm limit

The large value is the upper alarm limit, and the small value is the lower alarm limit. When the displayed data is out of range, the system issues an alarm.

## 11. Information Bar

The information bar displays patient's ID/type, three measuring modes ,battery level icon, date/time.

## 12. PI Display

A number shows the SpO<sub>2</sub> Perfusion strength in percent. Dashes (- - -) mean the monitor is not able to calculate the PI value.

## 13. System Status

Display system prompt information, for example ' SpO<sub>2</sub> Sensor off ', 'Running'.

## 14. Pulse Rate Display

A number shows the patient's pulse rate value in beats per minute. Dashes (---) mean the monitor is not able to calculate the pulse rate value

## 15. Mute icon

The mute icon is displayed at the status bar and it has three statuses:

“” this icon means the normal status of alarm sound.

“” this icon is displayed during temporary 30sec, 60sec, 120sec alarm silence.

### 16. Pulse sound Icon

The Pulse sound icon has two states:

“” This icon indicates that the Pulse sound function is turned on, Currently pulse sound is level 4.

### 17. Silence Indicator

The indicator lights steadily during alarm silence.

## Monitor Operating keys

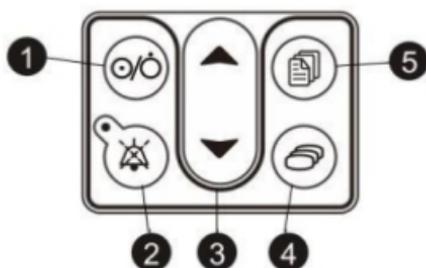


Figure 3.3: A-type and B-type Monitors Operating Keys

#### 1. ON/OFF key

Pressing this key for 3 seconds turns the monitor ON and OFF.

#### 2. Silence key

Pressing the Silence key once in turn can disable the alarm tone for 30sec, 60sec, 120sec.

Note: each pressing should be within 3 seconds.

To cancel the temporary alarm and alert tone silenced condition, press the Silence key twice. To cancel the indefinite silenced alarm, press the Silence key once. The Silence indicator will turn off.

#### 3. Up and Down Arrows

The Up and Down arrow keys are used to adjust the following settings:

- Alarm/ Pulse Volume
- Move the cursor circularly
- Increase/decrease numbers

#### 4. Mode Key

The Mode Key is used to adjust the following settings:

- Press this key to switch between the three display modes that are waveform mode, Trend-chart Display Mode, trend table Display mode.
- In the menu display interface, there is the function of confirming the selection and canceling the selection.

### 5. Menu Key

Press this key to change the settings like: patient's information, high/low alarm limits, time and date.

**WARNING! Do not use products, sensor, cables, or connectors that appear to be damaged.**

**WARNING! This device must be used in conjunction with clinical signs and symptoms. This device is only intended to be an adjunct in patient assessment.**

### Unpacking the Monitor

1. Carefully remove the monitor and its accessories from the shipping carton. Save the packing materials in case the monitor must be shipped or stored.
2. Compare the packing list with the supplies and equipment you received to make sure you have everything you'll need.

### Install the Batteries

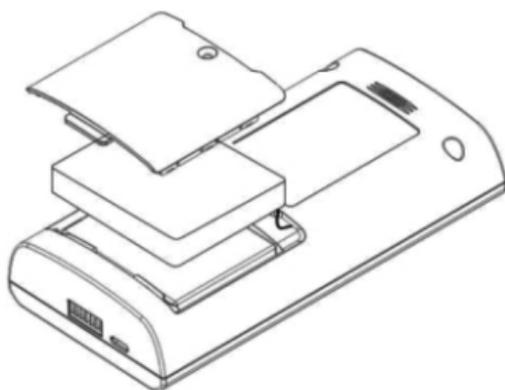


Figure 4.1: Installing the Batteries

The monitor use 4400mAh rechargeable battery to charge.

To install/replace the batteries:

1. Remove the screws, Depress the battery door and remove it downward.
2. First, insert or remove the battery terminal into the socket on the right side of the battery slot, put the battery connecting line downward into the battery, and press the battery into place.
3. Place the battery door into the slot on the rear panel of the monitor, press the battery door, and then lock the screws.

#### 4.2.1 Charging Li-ion batteries

The battery may discharge during prolonged storage or shipment. If the monitor have been in storage for more than 2 months, it is important to plug the AC power adapter into an AC outlet and allow the batteries to charge for approximately 30 minutes before attempting to operate the instrument.

To charge a low battery, connect the monitor to an AC power through the AC power adapter. A full charge of a completely discharged battery takes 4 hours while the monitor is turned off. The charging display interface is shown in Figure 4.2.

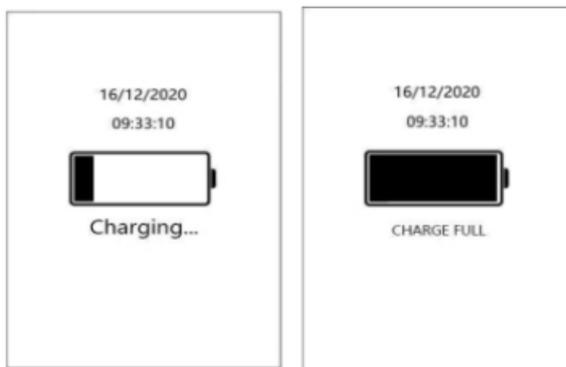


Figure 4.2: Charging interface

Note : The monitor needs to be charged and the every 2 months after storage

Note : When using AC power, the digital device is a class II device with functional earth. This earth connection is for device electromagnetic compatibility and does not provide protection to the patient or user.

#### **Attaching the Sensor to the Patient**

**WARNING! Prolonged use or the patient's condition may require changing the sensor site periodically. Change sensor site and check skin integrity, circulatory status, and correct alignment at least every 4 hours.**

Attaching the patient to the monitor requires these steps:

1. Choose the sensor.
2. Check the sensor and oximetry cable.
3. Clean or disinfect the sensor if using the reusable type (Disposable sensors are for single-patient use and do not require cleaning or disinfecting).

4. Attach the sensor to the patient.

Choosing the Sensor

**WARNING :** Before use, carefully read the sensor direction for use, including all warnings, cautions, and instruction.

Choose the appropriate sensor from the following chart.

PATIENT	SITE	DESCRIPTION
Adult > 40Kg	Finger	Sensor, Adult (reusable)
Pediatric 10-40Kg	Finger	Sensor, Pediatric (reusable)

4. Attach the sensor to the patient.

Choosing the Sensor

**WARNING :** Before use, carefully read the sensor direction for use, including all warnings, cautions, and instruction.

Choose the appropriate sensor from the following chart.

**Caring and Handling of the Sensor**

**WARNING! Misuse or improper handling of the sensor and cable could result in damage to the sensor. This may cause inaccurate readings.**

Hold the connector rather than the cable when connecting or disconnecting the sensor to the device as shown in Figure 4.3.

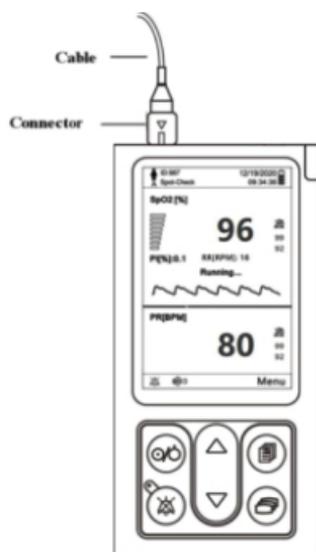


Figure 4.3: Disconnecting or connect the sensor

**NOTE :** Please plug the SpO<sub>2</sub> sensors on its own connectors correctly. Otherwise, the device may work abnormal.

Do not use excessive force or unnecessary twisting when connecting, disconnecting, storing, or when using the sensor.

**Placing the adult/pediatric SpO<sub>2</sub> sensor:**

When placing the sensor on the patient, allow the cable to lay the back of hand as shown in Figure 4.4.

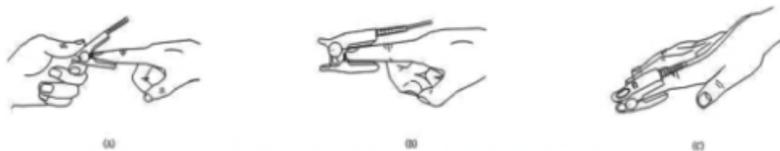


Figure 4.4: Positioning the cable of the finger sensor

**Checking the SpO<sub>2</sub> Sensor**

Follow these instructions each time before you attach the sensor to the patient. This helps ensure the SpO<sub>2</sub> sensor are working properly.

**WARNING! Using a damaged sensor may cause inaccurate readings. Inspect each sensor. If a sensor appears damaged, do not use it. Use another sensor or contact your authorized repair center for help**

1. Carefully inspect the SpO<sub>2</sub> sensor to make sure it does not appear damaged.
2. Connect the SpO<sub>2</sub> sensor to the monitor. Push the connector firmly into the monitor.
3. If the monitor is not already on, press the On/Off key to turn on the monitor.  
**WARNING! If any of the integrity checks fail, do not attempt to monitor the patient. Use another sensor or oximetry cable, or contact the equipment dealer for help if necessary.**
4. Before the sensor is attached to the patient, check the integrity of the sensor, oximetry cable, and oximeter as follows:
  - a. Make sure the red light in the sensor is illuminated.
  - b. Obstructions or dirt on the sensor's red light or detector may cause the checks to fail. Make sure there are no obstructions and the sensor is clean.
5. You are now ready to attach the sensor to the patient.

**Cleaning or Disinfecting the Sensor**

Clean or disinfect reusable sensor before attaching to a new patient.

**WARNING:** Do not autoclave, ethylene oxide sterilize, or immerse the sensor in liquid.

**CAUTION:** Unplug the sensor from the monitor before cleaning or disinfecting.

For cleaning and disinfection methods, please refer to the description in section 7.2.2.

**Performance Considerations**

**WARNING!** Pulse oximetry readings and pulse signal can be affected by certain ambient environmental conditions, sensor application errors, and certain patient conditions.

Inaccurate measurements can be caused by:

- Incorrect application of the sensor
- Placement of the sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line
- Ambient light
- Prolonged patient movement

Loss-of-pulse signal can occur for the following reasons:

- The sensor is too tight
- A blood pressure cuff is inflated on the same extremity as the one with the sensor attached
- There is arterial occlusion proximal to the sensor

Select an appropriate sensor, apply it as directed, and observe all warnings and Cautions presented in the directions for use accompanying the sensor. Clean and remove any substance such as nail polish from the application site. Periodically check to ensure that the sensor remains properly positioned on the patient.

**WARNING!** Tissue damage can be caused by incorrect application or duration of use of a SpO<sub>2</sub> sensor. Inspect the sensor site as directed in the sensor directions for use.

High ambient light source such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight can interfere with the performance of a SpO<sub>2</sub> sensor. To prevent interference from ambient light, ensure that the sensor is properly applied, and cover the sensor site with opaque material.

**NOTE:** Failure to take this precaution in high ambient light conditions may result in inaccurate measurements.

If patient's movement present a problem, try one or more of the following remedies to correct the problem:

- \* Verify that the sensor is properly and securely applied
- \* Move the sensor to a less active site.

### **Turning On the Monitor**

**WARNING!** To ensure patient safety, do not place the monitor in any position that might cause it to fall on the patient.

**WARNING!** As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.

**WARNING!** Ensure that the speaker is clear of any obstruction. Failure to do so could result in an inaudible alarm tone.

1. To turn on the monitor, press and held the ON/OFF key for about three seconds. When turned ON, the monitor does the following:

- The monitor starts a power-on self test (POST) quickly.
- The monitor's software revision is momentarily displayed.
- The Power Indicator illuminates green.

2. Upon successful completion of the POST, the device sounds a one-second tone indicating that the monitor has passed the test.

3. If the SpO<sub>2</sub> sensor is connected to the monitor and the patient, a blood oxygen waveform will appear in about 3 seconds, and the pulse rate and blood oxygen level can be measured in about 8 seconds.

4. The monitor will use the default ID or the last ID of the current patient.

6. Monitor the patient.

**WARNING!** Verify that the power indicator lights up and you can hear the POST pass tone upon startup of the device. If not, do not use the monitor.

**WARNING!** The oximeter will automatically be powered off when no finger is in the device and no operation for longer than five minutes in the Spot-check and Monitoring measuring modes. The screen brightness will be decreased when no

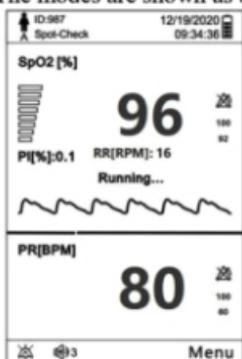
finger is in the device and no operation for longer than three minutes in the Recording measuring modes.

### Three Display Modes

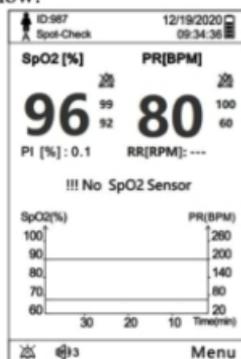
There are four Display Modes of the monitor, you can switch between them by pressing the Mode Key.

In the trend-table display mode, touch the screen to select the data of the trend table. You can view the data recorded by the trend table by moving the cursor by pressing the up / down keys or sliding the slider. The trend table can record up to 120 sets of data. After filling 120 sets of data, the newly stored data will replace the oldest data.

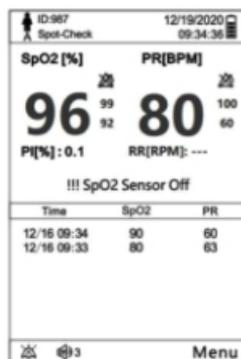
The modes are shown as below:



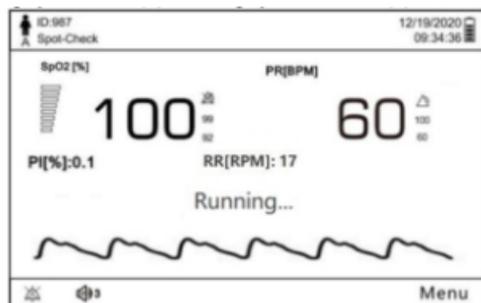
(A) Waveform Display Mode



(B) Trend display mode



(C) Trend-table Display Mode



(D) Landscape Display Mode

Figure 4.5: Three Display Modes

### Three Measuring Modes

There are three Measuring Modes: Spot-Check, Continuous Monitor, Record. Their differences are compared in to below table:

Modes	Spot-Check	Monitor	Record
Way of Measurement	intermittently	continuously	continuously
Data Saved or not	NO	YES	YES
Energy-save or not	NO	YES	YES
Alarm or not	YES	YES	NO
Volume Adjustable or not	YES	YES	NO

In any measurement mode, if you do not press any key within 3 minutes, the display will enter the power saving mode to save energy.

### Turning Off the Monitor

After monitoring is complete, remove the sensor from the patient and store or dispose of the sensor according to governing rules.

Turn off the monitor when you are not monitoring a patient. To turn off the monitor, press and held the On/Off key for about three seconds.

### Managing the Patient's Information

Please write down the information of the patient who is going to be monitored like: Patient's ID (from 000 to 999), Sex (Male or Female), Type (Adult/ pediatric) and Mode (Spot-Check/Record/Monitor). As shown in Figure 5.1.

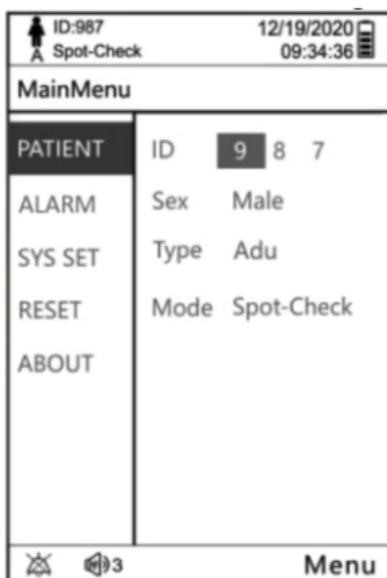


Figure 5.1 Managing the patient's information

**Key operation mode:**

1. Press the Menu key to enter the main menu interface.
2. Press the Up/Down key to choose the "PATIENT" sub-menu , and press the mode key to enter the "PATIENT" sub-menu.
3. Press the Up/Down keys to select items you want to change.
4. Press the mode key for the first time to confirm the change item, press the Up/Down keys to change the current setting, and press the mode key for the second time to confirm the change and exit.
5. Press the Menu key to close the menu interface.

**WARNING! There is no alarm in the Record Measuring Mode. Please set the appropriate measurement mode according to the actual situation of the patient.**

**Changing the Alarm Limits**

Alarms are audio and visual indicators generated by the monitor to alert doctors and nurses. These alarms occur when the vital signs of the patients being monitored become abnormal, or the monitor itself malfunctions and could not perform the monitoring task.

**Changing the SpO<sub>2</sub> and Pulse Rate Alarm Settings**

You can turn on or off the blood oxygen alarm switch. If the blood oxygen alarm switch is turned on, the alarm will be activated when the measured value exceeds the blood oxygen alarm limit. If the blood oxygen alarm is off, the alarm will not start when the measured value exceeds the blood oxygen alarm limit. The blood oxygen Upper is 100 and Lower is 1. The pulse rate Upper is 250 and Lower is 25. When the alarm is turned on, the upper limit of blood oxygen or pulse rate exceeds your set value or the lower limit of blood oxygen or pulse rate is below your set value. The blood oxygen priority be set to H , and the pulse rate priority be set to M . As shown in Figure 5.2.

ID:987		12/19/2020	
Spot-Check		09:34:36	
<b>MainMenu</b>			
PATIENT	SpO <sub>2</sub>	PR	
<b>ALARM</b>	Alarm	<b>On</b>	ON
SYS SET	Upper	99	100
RESET	Lower	92	60
ABOUT	Priority	H	M
		<b>Menu</b>	

Figure 5.2 SpO<sub>2</sub> and PR alarm parameter settings

**Key operation mode:**

1. Press the Menu key to enter the main menu interface.
2. Press the Up/Down keys to choose the "ALARM" sub-menu, and press the the Mode key to enter the "ALARM" sub-menu.
3. Press the Up/Down keys to select items you want to change.
4. Press the Mode key for the first time to confirm the change item, press the Up/Down keys to change the current setting, and press the Mode key for the second time to confirm the change and exit.
5. Press the Menu key to close the menu interface.

**System settings**

The system setting menu can set time and date, system language, backlight brightness, pulse prompt volume and alarm volume. You can set it according to your preference, as shown in Figure 5.3: The following is the introduction of setting range:

**Date setting:** 2019-1-1 to 2050-12-31.

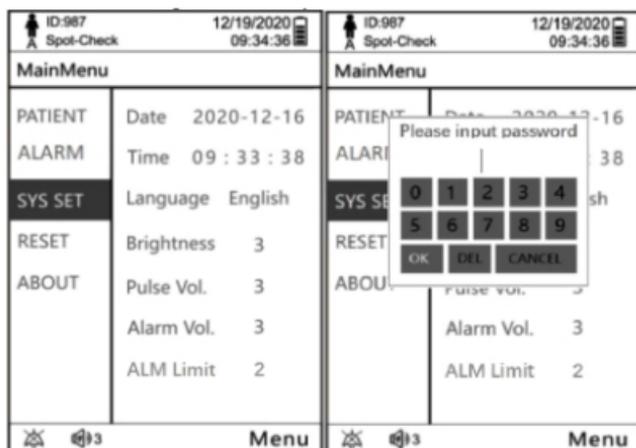
**Language setting:** After you set the language, you need to restart to take effect.

**Brightness setting:** The brightness of the backlight can be adjusted in six levels (0-5). Set the backlight brightness by pressing the "up or down key".

**Pulse vol. setting:** A " beep " sound will be emitted every pulse. There are five levels of beep volume (1-5). Set the volume by pressing the "up or down keys".

**Alarm vol. Setting:** There are five levels of "beep-beep-beep beep-beep" volume (2-5). Set the volume by pressing the "up or down" key.

**ALM Limit:** The sound pressure level range of the alarm volume can be set after entering the correct password. The lower limit of sound pressure level can be set to 1-5. After confirming the setting, your alarm volume lower limit level depends on the lower limit of sound pressure level you set.



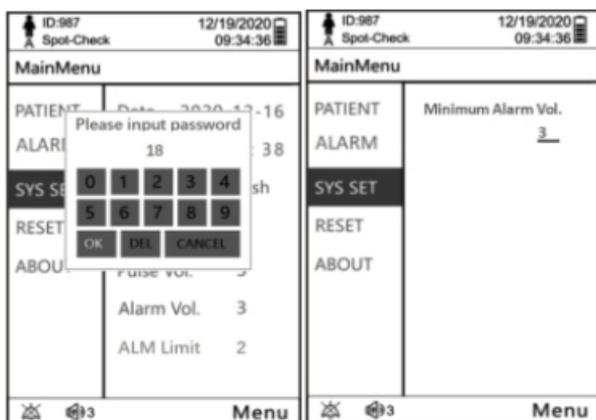


Figure 5.3 System settings

**Key operation mode:**

1. Press the Menu key to enter the main menu interface.
2. Press the Up/Down keys to choose the "SYS SET" sub-menu, and then press the Mode key to enter the "SYS SET" sub-menu..
3. Press the Up/Down keys to select items you want to change.
4. Press the Mode key for the first time to confirm the change item, press the Up/Down keys to change the current setting, and press the Mode key for the second time to confirm the change and exit.
5. When setting the alarm volume, if you need to set a lower lower limit, you need to enter the Maintenance, enter the correct password, and set the lower limit you need.
6. Press the Menu key to close the menu interface.

**WARNING :** When the "pulse Vol." or "Alarm Vol." is zero, the monitor will remain quit.

**NOTE :** If you change the "Alarm vol.", the "Alarm vol." will be reset after you turn off the monitor.

**NOTE :** If you change the "AIM Limit", The "Alarm Vol." Setting range will be limited by the lower limit you set.

**NOTE :** The password is 18

**Resetting**

Restore the personality settings of the monitor to the factory default state, such as upper and lower limit of blood oxygen, upper and lower limit of pulse rate, backlight brightness, alarm priority, alarm switch, pulse prompt tone, etc. to the factory settings, but the stored data will not be deleted.

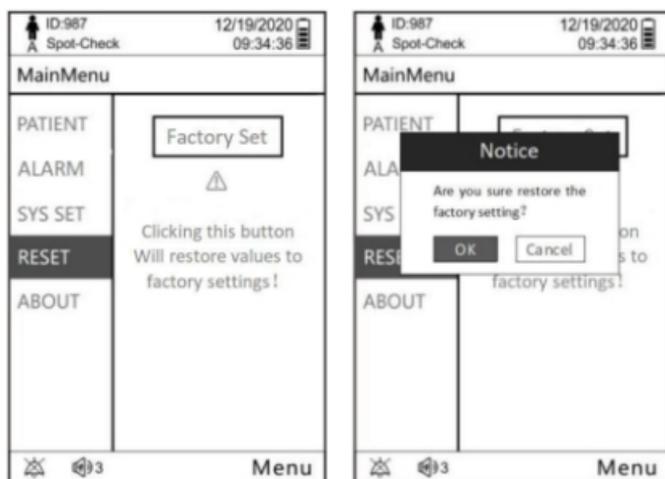


Figure 5.4 Restoring default settings

**Key operation mode:**

1. Press the Menu key to enter the main menu interface.
2. Press the Up/Down keys to choose the "RESET" , and then press the Mode key to enter the "RESET" sub-menu.
3. Press the Mode key to select " Factory Set", press the Mode key to enter the notification menu, and then press the Up/Down keys to select "OK" or "Cancel" and press the Mode key to confirm.
4. Press the Menu key to close the menu interface.

**NOTE :** If you choose to reset your settings, all settings will be restored to the Factory Default Setting except the Date and Time.

**About**

In the "About" option, you can query the specifications of this device, such as Model, OXI version, and Firmware version.

**Key operation mode:**

- 1, Press the Menu key to enter the main menu interface.
- 2, Press the Up/Down keys to select the "About" , get the information you need.
- 3, Press the Menu key to close the menu interface.

**WARNING!** In any single area (such as the intensive care unit or heart operating room), the same or similar equipment using different alarm presets is potentially dangerous.

**WARNING!** The alarm settings of different monitoring equipment in the same area may be different in order to adapt to the condition of the patient being monitored. It should be checked whether the alarm settings are suitable for the patient being monitored, these necessary alarm limits should always be turned on, and it should be ensured that the alarm limit settings are suitable for the patient being monitored.

**NOTE!** When the alarm system is powered off, the pulse oximeter will save the alarm before the power failure. The stored alarm information will not change with the power-off time.

### **Alarm type and level**

This pulse oximeter has two kinds of alarms: physiological alarm and technical alarm. Physiological alarms are usually caused by the patient's blood oxygen saturation or pulse rate physiological parameters exceeding the set alarm upper and lower limits, or the patient's physiological abnormalities. Technical alarms are also called system error messages, which refer to the system not working properly or providing wrong parameter information due to improper operation or system failure.

The level of physiological alarm is divided into two levels: High priority alarm and Medium priority alarm

The level of technical alarm is divided into two levels: High priority alarm, prompt information

The advanced alarm indicates that the measured object is in danger or the oximeter has serious problems, and belongs to the highest level of alarm.

Intermediate alarms are indicated as warnings.

The prompt information does not belong to the alarm, but the system status information that should be paid attention to.

The level of the alarm system is set by the system and cannot be changed by the user.

### **Alarm mode**

When an alarm occurs, the pulse oximeter will remind the user in the following ways:

Alarm sound: According to different alarm levels, the horn emits different beat sounds to prompt.

Alarm lights: The alarm light flashes in different colors and frequencies according to different alarm levels.

Alarm information: In the middle of the screen, text messages are output according to the alarm conditions. High priority alarms are shown in red text, Medium priority alarms are displayed in yellow text.

Parameter flashing: The parameters that have alarmed will be displayed flashing.

**NOTE!** The overall performance of each alarm corresponds to the level of the alarm .

#### Alarm sound

The pulse oximeter distinguishes different alarm levels by the following sound methods. The alarm sound pressure level range is 45~85dB(1 meter away from the operator).

Alarm priority	Voice performance
High priority alarm	•Two groups of "beep-beep-beep---beep-beep" •Cycle: 10 secs
Medium priority alarm	•One groups of "beep-beep-beep" •Cycle: 18 secs

#### Alarm light

Alarm priority	Light performance
High priority alarm	The LED and alarm message flash red. The flashing frequency is approximately 1.5Hz.
Medium priority alarm	The LED and alarm message flash yellow. The flashing frequency is approximately 0.625Hz.

#### Alarm Setting

##### General alarm settings

The alarm volume of the system can be set through the menu "Main Menu→ System Settings→ Alarm Volume, Can choose: 1, 2, 3, 4, 5 levels.

##### Pause the audible alarm

Short press the "🔔" button on the operation key panel to turn off all alarm sounds. The alarm sound pause time is 30 seconds, 60 seconds, or 120 seconds, so that the system enters the "alarm pause" state. The remaining time of the alarm pause is displayed after the alarm pause icon.

Press the "🔔" button again to switch back to the normal state. After the alarm pause time timer expires or a newly triggered alarm can also be released from the "pause" state, And the "🔔" symbol changes back to "🔔".

**WARNING :** Adjusting the alarm sound to a lower volume will prevent the operator from recognizing the alarm state and cause the patient to be in danger.

**NOTE :** After returning to the normal state, the existence of an alarm depends on whether the alarm conditions are met.

##### Alarm condition delay

Delay is the time from the occurrence of an alarm event to the alarm system confirming the existence of the alarm state. The trigger conditions are physiological alarms and technical alarms. For example, when the blood oxygen saturation drops from 98% to 92% and a visual alarm and audible alarm are generated, there will be a 500ms delay: the data update cycle is 500ms;

Alarm condition delay	Delay time
Maximum alarm state delay	500ms
Maximum alarm signal delay	5s
Average alarm state delay	200ms
Average alarm signal delay	1s

### Alarm countermeasures

**NOTE! When an alarm occurs, check the patient's condition first.**

Check the alarm information displayed on the screen, correctly identify the alarm, and deal with the alarm reasonably according to the cause of the alarm.

1. Check the patient's condition
2. Identify the parameter that is alarming or the category of the alarm
3. Find the cause of the alarm
4. If necessary, suppress the alarm
5. After the alarm condition is removed, check whether the alarm is working properly.

### Alarm Information :

Prompt information	Cause	Alarm level
!!! SpO2 Too High	The measured value of blood oxygen saturation is higher than the set alarm upper limit	High
!!! SpO2 Too Low	The measured value of blood oxygen saturation is lower than the set alarm lower limit	High
!! PR Too High	The measured value of pulse rate is higher than the set alarm upper limit	Middle
!! PR Too Low	The measured value of pulse rate is lower than the set alarm lower limit	Middle

#### Technical alarm:

Prompt information	Cause	Alarm level
!!! Finger off	SpO2 sensor comes off the patient's finger	High
!!! SpO2 Sensor off	SpO2 sensor falls off the pulse oximeter	High
!!! No Pulse	The blood oxygen saturation and pulse rate search time is too long or cannot be detected	High
!!! Sensor Faultly	The sensor not specified in this manual is used, or the sensor is damaged or not installed properly	High
!!! SpO2 Module Error	SpO2 board failure	High
!!! Battery low	The battery is too low	High
!! Data Full	Data is full	Middle

Prompt information:

Prompt information	Cause	Alarm level
Running...	SpO2 module is searching for pulse	No alarm

### Accessories

CAT.NO	DESCRIPTION
1	Adult Finger SpO <sub>2</sub> Sensor
2	Power Adapter
3	Power Cord/ USB Cable

### Optional Accessories

CAT.NO	DESCRIPTION
1	Reusable sensor Pediatric, Finger Spo2 sensor Neonates
2	Charging dock
3	Adaptor
4	Protective cover

The products have been designed to operate continuously for long periods without maintenance.

However, in order to ensure a continued high level of performance and safety of operation, you must observe the routine maintenance information in this section. Perform on-site routine maintenance daily; a summarized schedule and full details are contained in this section.

The Pulse Oximeter User and Technical Manual also contains the circuit diagrams, parts lists, and descriptions required for carrying out repairs and disposing of batteries. The Service Manual is available on request from Mann Electronics India Pvt. Ltd or your local agent.

**Schedule of Maintenance**

MAINTAIN THIS ITEM	HOW OFTEN	BY DOING THIS
Battery	When Battery Level icon is flashing, and/or audible alarm sounds.	Follow the instructions for installing the batteries.
Disinfecting the reusable sensor.	Before attaching the sensor to the patient.	Follow the instructions for cleaning the reusable sensor.
Disinfecting the monitor.	When necessary.	1, Remove the batteries from the unit. 2, Wipe the surfaces of the monitor with a soft, clean cloth dampened in isopropyl alcohol. Use only a cloth that is dampened, not wet.

**CAUTION!** Do not allow isopropyl alcohol or water to enter any of the openings on the monitor. Evidence that liquid has been allowed to enter the monitor voids the warranty.

**Cleaning the Monitor and Sensor**

**WARNING!** Do not autoclave, ethylene oxide sterilize, or immerse the monitor in liquid.

**CAUTION!** Do not allow water or any other liquid to be spilled onto the monitor. Unplug the AC power cord from the monitor before cleaning or disinfecting.

**CAUTION!** Where the equipment has accidentally gotten wet, it should be wiped dry externally and allowed to dry thoroughly before use.

**CAUTION!** Unplug the sensor from the monitor before cleaning or disinfecting.

**NOTE!** Do not clean the screen with glutar aldehyde. These liquids can scratch the screen. Use only water or a mild soap solution to clean the screen.

**Recommended Cleaning Materials**

- Soft cloth
- Pure water
- 75% medical alcohol

**Expected service life of the me equipment :** 5 years for Main unit, 1 year for accessories

**Clean the surfaces of the monitor**

1. To avoid possible shock, remove the sensor from the patient, turn off the monitoring system.
2. Dampen a soft cloth with pure water or 75% medical alcohol. If the cloth becomes soaked with liquid, start again with a dry cloth.
3. Gently wipe all surfaces of the monitoring system.
4. Allow the monitoring system to dry

**Clean the surfaces of the monitor**

1. To avoid possible shock, remove the sensor from the patient, turn off the monitoring system.
2. Dampen a soft cloth with pure water or 75% medical alcohol. If the cloth becomes soaked with liquid, start again with a dry cloth.
3. Gently wipe all surfaces of the monitoring system.
4. Allow the monitoring system to dry



Figure 7.1 Cleaning or Disinfecting the Sensors

**WARNING! To ensure accurate performance and prevent device failure, do not subject This products to extreme moisture such as direct exposure to rain. Such exposure may cause inaccurate performance or device failure.**

Whenever possible, the monitor should be stored at room temperature in a dry environment.

If it is necessary to store the monitor for an extended period of time, the unit should be packed in its original shipping container. Storing the monitor for a long period of time may degrade the battery capacity. Batteries should be removed from the monitor before storing. Storage specifications are as follows:

Temperature:	-20 °C to +55 °C
Relative Humidity:	≤95 % (non-condensing)

**Troubleshooting**

<b>PROBLEM</b>	<b>POSSIBLE CAUSE</b>	<b>CORRECTIVE ACTION</b>
No pulse shown on the bargraph.	<ul style="list-style-type: none"> <li>•Patient cable or sensor is disconnected from the oximeter.</li> <li>•Sensor is incorrectly positioned on the patient.</li> <li>•Poor patient perfusion.</li> <li>•Defective sensor or patient cable.</li> </ul>	<ul style="list-style-type: none"> <li>•Check sensor connections to the patient cable and to the oximeter.</li> <li>•Reposition the sensor.</li> <li>•Change a new sensor or contact your authorized repair center for help.</li> </ul>
No Pulse	<ul style="list-style-type: none"> <li>•Pulse signal is too weak</li> </ul>	<ul style="list-style-type: none"> <li>•Check signal source.</li> </ul>
Pulse rate is erratic, intermittent, or incorrect.	<ul style="list-style-type: none"> <li>•Sensor incorrectly positioned.</li> <li>•Patient motion</li> </ul>	<ul style="list-style-type: none"> <li>•Reposition the sensor.</li> <li>•Patient must remain still to obtain an accurate measurement.</li> </ul>
SpO <sub>2</sub> value is erratic, intermittent, or incorrect.	<ul style="list-style-type: none"> <li>•Poor patient perfusion.</li> <li>•Patient motion.</li> </ul>	<ul style="list-style-type: none"> <li>•Reposition the sensor.</li> <li>•Patient must remain still to obtain an accurate measurement.</li> </ul>
No PR and SpO <sub>2</sub> values.	<ul style="list-style-type: none"> <li>• Defective sensor or patient cable or monitor.</li> </ul>	<ul style="list-style-type: none"> <li>•Change a new sensor or contact your authorized repair center for help.</li> </ul>
Battery Abnormal	<ul style="list-style-type: none"> <li>•Batteries incorrectly installed.</li> <li>•There are no batteries.</li> </ul>	<ul style="list-style-type: none"> <li>• Reposition batteries correctly.</li> <li>•Equip with oximeter with batteries.</li> </ul>
The oximeter doesn't turn on.	<ul style="list-style-type: none"> <li>•Batteries weak.</li> <li>•Batteries not installed or batteries incorrectly installed.</li> </ul>	<ul style="list-style-type: none"> <li>•Replace the batteries.</li> <li>•Ensure the batteries are installed correctly.</li> </ul>
The oximeter turns off unexpectedly.	<ul style="list-style-type: none"> <li>•Batteries are weak or dead.</li> </ul>	<ul style="list-style-type: none"> <li>•Replace the batteries.</li> </ul>
Sensor off	<ul style="list-style-type: none"> <li>•Patient cable or sensor is disconnected from the oximeter.</li> <li>•Sensor is incorrectly positioned on the patient.</li> <li>•Poor patient perfusion.</li> <li>•Defective sensor or patient cable</li> </ul>	<ul style="list-style-type: none"> <li>•Check sensor connections to the patient cable and to the oximeter.</li> <li>•Reposition the sensor.</li> <li>•Try a new sensor or contact manufacturer Service Department for help.</li> </ul>

## 9.1 Display

3.5"-inch TFT LCD

Resolution: 320 × 480 pixels

### Indicators

LEDs: Work Status LED

Alarm Silence LED

### Alarm Volume

45dBA to 85 dBA at 1 meter distance (adjustable)

### Keys/User controls

- On/Off Key
- Up Key
- Down Key
- Alarms silence Key
- Mode Key
- Menu Key

### Equipment Classification

Type of Protection Against Electric shock:	Belongs to Class II ordinary equipment with internal power supply or ordinary equipment using internal power supply
Mode of operation:	Continuous
Degree of Protection Against ingress of Liquids:	IP22
Degree of Mobility:	Handheld
Degree of Protection Against Electric Shock:	Type BF
Safety Requirements:	IEC 60601-1

### SpO<sub>2</sub>

SpO <sub>2</sub> Range:	(0 to 100) %
SpO <sub>2</sub> Accuracy:	(70 to 100)%, Motionless: ± 2 %; Motion: ± 3 %; Low Perfusion: ± 2 %; < 70 % unspecified
Resolution:	1 %
Wavelength information:	Red light 660 nm Infrared 905 nm
	Maximum output power <90 mW, The use of different wavelengths of the LED will lead to erroneous measurement data.

**Pulse Rate**

Pulse Rate Range	30 bpm to 250 bpm
Pulse Rate Accuracy:	Motionless : $\pm 2$ bpm; Motion: $\pm 3$ bpm ; Low Perfusion: $\pm 2$ bpm
Resolution:	1 bpm

**Breath rate**

RR Range	3 rpm to 150 rpm
RR Accuracy:	$\pm 3$ rpm;
Resolution:	1 rpm
Perfusion Index (PI)	0.02% - 20%
Pleth variable index (PVI)	0-100%

**Default Settings of Alarms Limits**

Factory Default Settings:				
PATIENT	<b>ID</b>		987	
	<b>Sex</b>		Male	
	<b>Type</b>		Adult	
	<b>Mode</b>		Spot-Check	
SPO <sub>2</sub> , PR ALM (default)			<b>SPO2</b>	<b>PR</b>
	<b>Alarm</b>		On	On
	<b>Upper</b>		99	100
	<b>Lower</b>		92	60
	<b>Priority</b>		H	M
SYS SET	<b>Date</b>		No reset	
	<b>Time</b>		No reset	
	<b>Language</b>		English	
	<b>Brightness</b>		3	
	<b>Pulse vol.</b>		3	
	<b>Alarm vol.</b>		3	
	Default values of High Alarm Limits		Default values of Low Alarm Limits	
	Adu.	Ped.	Adult	Ped.
<b>SpO<sub>2</sub>(%)</b>	99	99	92	92
<b>PR(bpm)</b>	100	110	60	70

**Power Requirements**

Power Adapter:	INPUT: AC 100 V to 220 V, 50/60 Hz, 0.6 A to 0.2 A OUTPUT: DC 5 V, 2 A
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**Battery**

Li-ion polymer Battery:	3.7 V / 4400 mAh(16.28 Wh)
Battery power duration:	more than 15 hours

**Dimensions**

Width:	78.5 mm (3.09 inch)
Height:	158 mm (6.22 inch)
Depth:	31.5 mm (1.24 inch)
Weight:	258 g (without batteries installed)

**Environmental Specification**

Temperature:	(+5 to +45) °C (Operating) (-20 to +55) °C (Storage) (-40 to +55) °C (Shipping)
Relative Humidity(non-condensing):	≤ 85 % (Operation) ≤ 95 % (Storage) ≤ 95 % (shipping)
Atmospheric pressure:	700 hPa to 1060 hPa

**CAUTION!** This device has been tested and found to comply within the limits for medical devices to EN 60601-1-2:2014. Medical Device Directive 93/42/EEC. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

**CAUTION!** This product needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile radio frequency (RF)

The monitor is designed for use in environments in which the signal can be obscured by electromagnetic interference. During such interference, measurements may seem inappropriate or the monitor may not operate correctly.

The monitor generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with these instructions, may cause harmful interference with other devices in the vicinity. Disruption may be evidenced by erratic readings, cessation of operation, or other incorrect function. If this occurs, the site of use should be surveyed to determine the source of this disruption, and actions taken to eliminate the source:

- Turn equipment in the vicinity off and on to isolate the offending equipment.
- Reorient or relocate the other receiving device.
- Increase the separation between the interfering equipment and this equipment.

**Guidance and manufacturer's declaration-electromagnetic emissions - For all EQUIPMENT and SYSTEMS**

Guide and manufacturer's declaration-electromagnetic emissions		
The product is intended for use in the electromagnetic environment specified below. The customer or the user of the product should assure that it is used in such an environment.		
Launch test	Compliance	Electromagnetic environment-guidance
RF missions CISPR11	Group 1	The product 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 missions CISPR11	Class B	The product is suitable for use in all establishments, including domestic
Harmonic emissions	N/A	establishments and those directly connected to

IEC61000-3-2		the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuation / flicker emission	N/A	
IEC61000-3-3		

**Guidance and manufacturer's declaration - electromagnetic immunity- For all EQUIPMENT and SYSTEMS**

Guidance and manufacturer's declaration-electromagnetic immunity			
The product is intended for use in the electromagnetic environment specified below, The customer or the user of the product should assure that it is used in such an environment			
Immunity test	IEC60601 test level	Coincidence level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC61000-4-2	± 8 kV contact ± 15 kV Air	± 8 kV contact ± 15 kV Air	floors should be wood, concrete or tile, if floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrostatic transient/ burst IEC61000-4-4	± 2 kV for power supply lines ± 1 kV for input / output lines	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	± 1 kV Differential mode ± 2 kV Common mode	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	<5% UT (>95% dip in UT for 0.5 cycle) 40% UT f (60% dip in UT for 5 cycles) 70% (30 % dip in U for 25 cycles) <5% UT (>95 %dip in UT for 5 sec)	N/A	Mains power quality should be that of a typical commercial or hospital environment If the user of the Non-contact infrared thermometer requires continued operation during power mains interruptions, it is recommended that the Non- contact infrared thermometer be powered from an uninterruptible power supply or a battery
Power frequency (50/60HZ) magnetic field IEC61000-4-8	30A/m	30A/m.	Power frequency magnetic fields should have power frequency magnetic field level characteristics typical of typical locations in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level			

**Guidance and manufacturer's declaration -electromagnetic immunity - For EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING**

Guidance and manufacturer's declaration-electromagnetic immunity			
The product is intended for use in the electromagnetic environment specified below. The customer or the user of the product should assure that it is used in such an environment			
Immunity test	IEC60601 test level	Coincidence level	Electromagnetic environment-guidance
Conducted RF	3Vrms	N/A	<p>Portable and mobile RF communications equipment should not be used closer to any part of the product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = \left[ \frac{3.5}{\sqrt{p}} \right] \sqrt{P}$ <p><b>80 MHz to 800 MHz</b></p> $d = \left[ \frac{3.5}{\sqrt{E1}} \right] \sqrt{P}$ <p><b>800 MHz to 2.7 GHz</b></p>
IEC 61000-4-1	150KHz to 80MHz	N/A	<p>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).</p>
Radiation RF	10V/m	10V/m	<p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.</p>
IEC 61000-4-3	80 MHz to 2.7 GHz	80 MHz to 2.7 GHz	<p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>Note 1: At 80 MHz and 800 MHz, the higher frequency band formula is used.</p> <p>Note 2: These guidelines may not be suitable for all situations. Electromagnetic wave propagation is affected by absorption and reflection from buildings, objects and people</p> <p>a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, 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 Non-contact infrared thermometer is used exceeds the</p>			

applicable RF compliance level above, the non-contact infrared thermometer should be observed to verify normal operation. If abnormal performance is observed additional measures may be necessary, such as reorienting or relocating the Non-contact infrared thermometer

b. Over the entire frequency range of 150KHz ~ 80MHz, the magnetic field should be lower than 3V / m.

### Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM-for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the Non-contact infrared thermometer

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

Rated maximum output of transmitter / W	Separation distance according to frequency of transmitter		
	150KHz to 80MHz $d = \left[ \frac{3.5}{\sqrt{1}} \right] \sqrt{P}$	80MHz to 800MHz $d = \left[ \frac{7}{\sqrt{1}} \right] \sqrt{P}$	80 MHz to 2.7 GHz $d = \left[ \frac{7}{\sqrt{1}} \right] \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above the recommended separation distance  $d$  in (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.