User Manual

EDAN

# H100N

Pulse Oximeter

Release 1.3 with Software Revision 1.3

CE 0123

# About this Manual

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# Statement

This manual will help you understand the operation and maintenance of the product better. It is reminded that the product shall be used strictly complying with this manual. User's operation failing to comply with this manual may result in malfunction or accident for which EDAN INSTRUMENTS, INC. (hereinafter called EDAN) can not be held liable.

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The electrical installation of the relevant room complies with national standards, and

The instrument is used in accordance with the instructions for use.

Upon request, EDAN may provide, with compensation, necessary circuit diagrams, and other information to help qualified technician to maintain and repair some parts, which EDAN may define as user serviceable.

## Terms Used in this Manual

This guide is designed to give key concepts on safety precautions.

**WARNING**

A **WARNING** label advises against certain actions or situations that could result in personal injury or death.

**CAUTION**

A **CAUTION** label advises against actions or situations

that could damage equipment, produce inaccurate data, or invalidate a procedure.

**NOTE**

A **NOTE** provides useful information regarding a function or a procedure.

# Table of Contents

# 1 Safety Information

## 1.1 Warnings

A **WARNING** label advises against certain actions or situations that could result in personal injury or death.

**WARNING**

1 Avoid explosion hazard. Do not use the oximeter in the presence of flammable anesthetic mixtures with air, or with oxygen or nitrous oxide.

2 Chemicals from a broken LCD display panel are toxic when ingested. Use cautions when the oximeter has a broken display panel.

3 Routinely monitor the patient to make sure the oximeter is functioning and the sensor is correctly placed.

## WARNING

4 Oximetry measurements and pulse signals can be affected by certain environmental conditions, sensor application errors, and certain patient conditions.

5 The use of accessories, sensors, and cables other than those specified may result in increased emission of electromagnetic radiation and/or invalid readings of the oximeter.

6 Failure to cover the sensor site with opaque material in high ambient light conditions may result in inaccurate measurements.

7 Do not silence the audio alarm function, or decrease the audio alarm volume, if patient safety could be compromised.

## WARNING

8 H100N Pulse Oximeter is a prescription device to be operated only by trained personnel. The oximeter is for attended monitoring only.

9 Dispose of batteries in accordance with local ordinances and regulations.

10 The oximeter is not defibrillator-proof. However, it may remain attached to the patient throughout defibrillation or while an electrosurgical unit is in use. The measurements may be inaccurate throughout the defibrillation, or use of an electrosurgical unit, and shortly thereafter. To avoid shock, the caregiver should not hold the oximeter while using a defibrillator on a patient.

## WARNING

11 Disconnect the oximeter and sensor from the patient throughout magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns.

12 To ensure accurate performance and prevent device failure, do not subject the oximeter to extreme moisture, such as direct exposure to rain. Such exposure may cause inaccurate performance or device failure.

13 Do not lift the oximeter by the sensor or extension cable because the cable could disconnect from the oximeter and the oximeter may drop on the patient.

## WARNING

14 Do not make any clinical judgment based solely on the oximeter, and it is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

15 To ensure patient safety, do not place the oximeter in any position that might cause it to fall on the patient.

16 As with all medical equipment, carefully route patient cables to reduce the possibility of patient entanglement or strangulation.

17 Ensure that the speaker is clear of any obstruction and that the speaker holes are not covered. Failure to do so could result in an inaudible alarm tone.

## WARNING

18 Use only Nellcor-approved OxiMax Sensors and extension cables with the H100N Pulse Oximeter. Other sensors or extension cables may cause improper monitor performance or minor personal injury.

19 H100N Pulse Oximeter readings and pulse signals can be affected by certain ambient environmental conditions, sensor application error, and certain patient conditions. See the appropriate sections of the manual for specific safety information.

20 Don't mix new and old batteries together. Don't mix rechargeable batteries with alkaline batteries.

21 Periodically check the battery for corrosion. Remove the batteries from the oximeter if you do not expect to use it within one month.

## WARNING

22 The device enters POST (Power-On-Self-Test) immediately after power-on. During the POST, confirm all the display segments and icons are shown and the speaker sounds a few seconds tone. Do not use the H100N Pulse Oximeter if you do not hear the POST pass tone. Do not use the oximeter if the POST has not been finished successfully.

23 Before using it, the user should carefully read the applicable user manual of sensor, including warnings, cautions and instructions.

24 Do not use damaged sensor or extension cables, do not use sensor with exposed optical components.

## WARNING

25 Tissue damage may be caused by incorrect application or prolonged measurement duration using the sensor (more than 2 hours). Inspect the sensor periodically according to sensor user manual.

26 Do not immerse or wet the sensor, as this may damage the sensor.

27 There are no user-serviceable parts inside the oximeter, the cover should only be removed by qualified service personnel.

28 Do not spray, pour, spill liquid to H100N Pulse Oximeter and its accessories, connector, switch or opening in enclosure, as this may damage the oximeter.

## WARNING

29 Before cleaning the oximeter or the sensor, make sure that the equipment is switched off and disconnected from the power line.

30 Setting the alarm limits to extreme values can cause the alarm system useless.

31 Do not use the charger stand when the alkaline battery is depleted or no battery is installed.

32 Do not monitor the patient while the battery is being charged.

33 Do not disassemble batteries, or dispose of them in fire, or cause them to short circuit. They may ignite, explode, leak, or cause personal injury.

34 Only use EDAN approved rechargeable batteries and charger stand for H100N pulse oximeter.

## WARNING

35 The temperature sensor should be disinfected after each measurement. The probe must not be sterilized in steam. Only detergents containing no alcohol can be used for disinfection.

36 The temperature sensor should not be heated above 100℃ (212℉). It should only be subjected to temperatures from 80℃ (176℉) to 100℃ (212℉).

37 The calibration of the temperature module is necessary for every two years (or as frequently as dictated by your Hospital Procedures Policy). When you need to calibrate the temperature measurement, please contact the manufacturer.

**WARNING**

38 Take the TEMP probe and cable carefully. If you do not use them for a long time, you should coil up the probe and cable into a loose circle. If the wire inside the cable is tensely pulled, it may cause mechanical damage to the probe and the cable.

## 1.2 Cautions

A **Caution** label alerts the user to exercise care necessary for the safe and effective use of the H100N Pulse Oximeter.

**CAUTION**

1 All combinations of equipment must be in compliance with IEC/EN 60601-1-1 system requirements.

## CAUTION

2 The device and accessories are to be disposed of according to local regulations after their useful lives. Alternatively, they can be returned to the dealer or the manufacturer for recycling or proper disposal. Batteries are hazardous waste. Do NOT dispose of them together with house-hold garbage. At the end of their life hand the batteries over to the applicable collection points for the recycling of waste batteries. For more detailed information about recycling of this product or battery, please contact your local Civic Office, or the shop where you purchased the product.

3 H100N Pulse Oximeter will not operate with dead batteries. Install new batteries.

## CAUTION

4 The sensor unconnected icon and associated alarm indicate the sensor has disconnected or wire fault. So check the sensor connection and, if necessary, replace the sensor, extension cables or both.

5 When adjusting any menu parameters, the oximeter does not display SpO2, PR or TEMP, but it is still recording.

6 The performance of the oximeter may be degraded if the following occur:

— Operation or storage temperature and humidity outside the manufacturer's stated range;

— Mechanical shock (for example, it drops from the table).

— Patient temperature is below ambient temperature (For measurement body temperature).

## 1.3 Notes

**NOTE:**

Notes are identified by the symbol shown above. Notes contain important information that may be overlooked or missed.

**NOTE:**

1 This device has been tested and found to comply with the limits for medical device in IEC/EN60601-1-2 (International standard for EMC testing of Medical Electrical Equipment, second edition). These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

2 Sensor LED light emissions fall within Class 1 level, according to IEC 60825-1:2001. No special safety precautions are required.

3 Normal operation means:

— The oximeter is turned on;

— A sensor is connected to the oximeter;

— The sensor is applied to the patient;

— The patient's SpO2, Pulse rate or Temperature readings are being reported;

— No error conditions exist.

4 Wash the probe with clean water after disinfecting it to remove any remaining solution. The probe can only be reused after being dried thoroughly.

5 Do not disinfect the probe with the means of water boiled.

6 Any residue should be removed from the probe before being disinfected, and avoid contacting corrosive solvent. Dip the cable into alcohol or alkalescent solvent for a long time, may reduce the flexibility of the scarfskin of the cable. Also, the

connector should not be dipped.

7 After monitoring, disinfect the probe according to the instruction described in the user manual.

8 The materials with which the patient or any other person can come into contact conform with the standard of ISO10993.

9 The pictures and interfaces in this manual are for reference only.

10 A functional tester cannot be used to assess the accuracy of the pulse oximeter probe or the pulse oximeter monitor.

11 If there is independent demonstration that the particular calibration curve is accurate for the combination of a pulse oximeter monitor and a pulse oximeter probe, then a functional tester can measure the contribution of a monitor to the total error of a monitor/probe system. The functional tester can then measure how accurately a particular

pulse oximeter monitor is reproducing that calibration curve.

12 The operating time of the Ni-MH rechargeable battery package depends on the configuration and operation of the pulse oximeter.

## 1.4 Symbols in the oximeter

| | |
|---|---|
|  | This symbol indicates that the instrument is IEC/EN 60601-1 Type BF equipment. |
|  | Symbol for Caution |
|  | Consult Instructions for Use |
| SN | Serial Number |
| CE 0123 | CE Mark |

| | |
|---|---|
|  | Date of Manufacture |
|  | Manufacturer |
| **P/N** | Part Number |
| **IPX1** | Ingress Protection Degree |
|  | Recycle |
|  | The symbol indicates that the device should be sent to the special agencies according to local regulations for separate collection after its useful life. |
|  | Auxiliary Output Connector |

# 2 Introduction

## Intended Use

H100N Pulse Oximeter (hereinafter called oximeter) is one model of H100 series Pulse Oximeter. The oximeter is intended for continuous monitoring or spot-checking of functional arterial oxygen saturation ($SpO_2$), pulse rate and for oral, axillary and rectal temperature measurement. It is intended to be used on adult, pediatric or neonatal patient in hospitals, intra-hospital transport and hospital type facilities.

# 2.1 General Introduction

It displays $SpO_2$ value, pulse rate value, plethysmogram, bar graph, temperature, etc.

The oximeter has been installed Nellcor $SpO_2$ module and the manufacturer's TEMP module inside. It integrates parameter module, display and recorder output

functions. It can be powered by four 1.5V AA batteries or four 1.2V Rechargeable Ni-MH AA batteries. It can clearly display all the parameter information on LCD.


Figure 2-1 H100N Pulse Oximeter

For the oximeter, PatientCare Viewer Data Management Software is optional.

# 2.2 Panels Introduction

This section identifies the symbols, controls, displays, and buttons on the front panel and rear panel of the oximeter.

## 2.2.1 Symbols on Screen

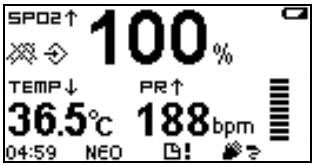



Figure 2-2 Large Numeric Mode

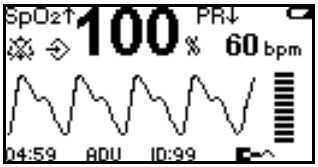



Figure 2-3 Waveform Mode

Icons on display screen and their meanings:

| | |
|---|---|
| $SpO_2$ | $SpO_2$ value display area |
| PR | Pulse Rate value display area |
| TEMP | Temperature value display area |
|  | Displays when measurement value is higher than the upper alarm limit |
|  | Displays when measurement value is lower than the lower alarm limit |
|  | $SpO_2$ waveform display |
|  | Pulse amplitude display |
|  | Low battery icon |
|  | Audio alarm off icon |

| | |
|---|---|
|  | Alarm off icon |
|  | Data storage icon |
| 04: 59 | Time display in Information area: “hour: minute” |
| ADU/NEO | Patient type in Information area: Adult or Neonate. |
| ID: 99 | Patient ID in Information area |
|  | $SpO_2$ sensor unconnected icon |
|  | $SpO_2$ sensor off |
|  | Indicates the memory space is full |
|  | Weak signal icon |

**NOTE:**

1 The icons for sensor unconnected, sensor off or weak signal are displayed on the right of Information area. Only one of them can be displayed at a time.

2 The ID icon and the icon that indicates the memory space is full are displayed in the Information Area. Only one icon can be displayed at a time.

## 2.2.2 Front Panel Buttons

This section describes the buttons on the front panel of the oximeter. The controls are activated by pressing the button that corresponds to that control. For example, press the **Alarm Silence** button to control the audio alarm.

Figure 2-4 Front Panel buttons

**On/Off Button**

Turn on or off the oximeter.

On: Press and hold the **On/Off** button for one second.

Off: Press and hold the **On/Off** button for two seconds.

When the oximeter is off, synchronously press the **On/Off** button and the **Function** button for 1 second, the oximeter will enter Data transfer state.

In the menu state, press this button to return to measurement state.

**Backlight Button** 

During the POST, the backlight is not available.

In the normal measurement, press this button to turn on or off the backlight.

**Alarm Silence Button** 

Alarms that occur during the Power-On-Self-Test (POST) can not be silenced.

When **Alarm System** in menu is set to **ON**, pressing the **Alarm Silence** button can turn off audio alarm. The pause period can be set to 30, 60, 90 or 120 seconds. Although the audio alarm is off, the visual alarm is still active. After the pause period is over, the audio alarm is reactivated.

Set **Alarm System** to **OFF** in menu to turn off the alarm. A pop-up dialog box will display to confirm alarm setting. See details in 3.3.3.

**Up Arrow Button** 

In the menu state, press the **Up Arrow** button to choose different items, and increase the value of some parameters. Press it repeatedly to make a parameter increase by more than one. Press and hold this button for more than 1 second to repeat the increment continuously.

Press this button in measurement state to display the latest 10-minute $SpO_2$ trend graph.

**Down Arrow Button** 

In the menu state, pressing the **Down Arrow** button can choose different items, and decrease the value of some parameters. Press it repeatedly to make a parameter decrease by more than one. Press and hold the button for more than 1 second to repeat the decrement continuously.

Press this button in measurement state to display the latest 10-minute PR trend graph.

**Function Button** 

During the POST, the **Function** button is not available;

Press this button in normal measuring state to enter function choice or setup menu;

In the menu state, this button is also used as the **Enter** button. Choose one item in menu using the cursor button (the **Up Arrow** button and **Down Arrow** button), and press the **Function** button to confirm, then increase or decrease the value using cursor button.

When the oximeter is off, synchronously press the **On/Off** button and the **Function** button for 1 second, the oximeter will enter Data transfer state.

### Button Combination

When the oximeter is off, synchronously press the **On/Off** button and the **Function** button for 1 second, the oximeter will enter Data transfer state.

## 2.2.3 Rear Panel

Figure 2-5 Rear Panel

# 2.3 Connecting Sensor or Cable

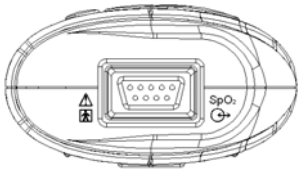



Figure 2-6 Sensor and Cable Connecting Port

$SpO_2$ Sensor and cable port is on the top of the oximeter for connecting the $SpO_2$ sensor. An extension cable can be used between the oximeter and the $SpO_2$ sensor. Use only the cable permitted by the manufacturer.

The cable for connecting the oximeter and PC with the PatientCare Viewer Data Management Software is also connected to this port.

The temperature sensor port is only configured for H100N.

Symbol for caution

Type BF applied part

Auxiliary output connector

SIO definition:

| PIN | Name | Description |
|---|---|---|
| 1 | GND | GND |
| 2 | LED+ | LED drive signal, IR Anode |
| 3 | LED- | LED drive signal, Red Anode |
| 4 | TXD / Sensor Memory Return | UART Tx / DigiCAL communication signal return signal return |

| | | |
|---|---|---|
| 5 | Detector Anode | Detector anode connection |
| 6 | Inner Shield | Detector shield to GND |
| 7 | Outer Shield | Outer cable shield to GND |
| 8 | RXD / Sensor Memory Data | UART Rx /DigiCAL communication signal |
| 9 | Detector Cathode | Detector cathode connection |

## 2.4 Powered by Battery

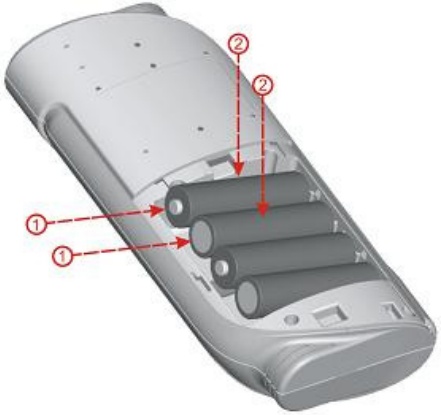
The oximeter can be powered by four 1.5V LR6 AA alkaline batteries. It will operate for 48 hours when used for general operation, or about 24 hours of operation with the backlight and alarm on. The oximeter does not support built-in recharging mode.

The oximeter can also be powered by 4 1.2V Ni-MH rechargeable batteries.

## Battery Installation

To install the alkaline batteries:

1. Make sure the oximeter is turned off.
2. Press the battery compartment latch and remove the battery access door.
3. Place four AA batteries as shown in the following figure, first push it oriented as shown in ①, then press it oriented as shown in ②.
4. Install the battery compartment cover.



To install the rechargeable Ni-MH battery package:

1. Make sure the oximeter is turned off.

2. Press the battery compartment latch and remove the battery access door.

3. Place the Ni-MH rechargeable battery package as shown in the follow figure, first push it oriented as ①, then press it oriented as ②.

4. Install the battery compartment cover.

## Checking the Ni-MH Battery Package

The performance of a rechargeable Ni-MH battery package may deteriorate. To check the performance of the battery, follow the procedures below:

1. Disconnect the pulse oximeter from the patient and stop all monitoring and measuring procedures.
2. Place the pulse oximeter in the charger stand and connect the AC mains. Allow the battery to be charged uninterruptedly for above 2.5 hours.
3. Disconnect AC mains and allow the pulse oximeter to run in the measurement state until it shuts off.

The operating time of a battery reflects its performance directly. If the operating time of a rechargeable Ni-MH battery package is noticeably shorter than that stated in the specifications, replace it or contact your service personnel.

### Low Battery Icon

The low battery icon displays and an alarm is given when 15 minutes operation remains available. After 15 minutes operation, the oximeter will turn off automatically. Replace the batteries.


Figure 2-7 Low Battery Icon

## 2.5 Accessory List

Standard configuration including:

| Quantity | Items | Parts No. |
|---|---|---|
| 1 | H100N Pulse Oximeter | MS8-110185 |
| 4 | 1.5V AA alkaline batteries (IEC LR6） | M21R-064086 |

| | | |
|---|---|---|
| 1 | Nellcor Reusable Adult $SpO_2$ Sensor (DS-100A OxiMax) (Weak Perfusion Resistance) | MS2-30043 |
| 1 | Skin Temperature Probe | M15R-040156 |
| 1 | H100N Pulse Oximeter User Manual | MS1R-110221 |
| 1 | H100N Pulse Oximeter Reference Card | MS1R-110222 |
| 1 | Carrying case | MS1-110165 |

Optional configuration including:

| Quantity | Items | Parts No. |
|---|---|---|
| 1 | H100N Pulse Oximeter Service Manual | MS1R-110223 |
| 1 | H100N Protective Cover | MS1-110164 |
| 4 | Rechargeable Ni-MH battery package | M21R-064133 |
| 1 | Battery charger | MS8-112410 |
| 1 | Nellcor Reusable Adult $SpO_2$ Sensor (DS-100A OxiMax)<br>(Weak Perfusion Resistance) | MS2-30043 |

| | | |
|---|---|---|
| 1 | Nellcor ReusableAdult/Neonate $SpO_2$ Sensor (OXI-A/N OxiMax)<br>(Weak Perfusion Resistance) | M15-40096 |
| 1 | Rectal / Oral Temperature Probe | M15R-040157 |
| 1 | H100N Patient Information management accessory package<br>(include 1xCD、USB cable、User manual) | |

The oximeter is compatible with Nellcor-approved OxiMax Sensors and extension cables.

When selecting $SpO_2$ sensor, the following should be considered:

- Patient weight and activity.
- Adequacy of perfusion.
- Available sensor sites.
- Anticipated duration of monitoring.

# 3 Oximeter Operation

## 3.1 Turning on the Oximeter

The oximeter is turned on by pressing the **on/off** button, it will cycle through a Power-On-Self-Test (POST) before displaying valid data values. Verify that all the circuitry and functions of the oximeter work properly during the POST. It needs a few seconds to complete the verification procedure POST. If it functions incorrectly, do not use the oximeter.

Press the **On/Off** button for one second to turn on the oximeter.

- At first the Logo EDAN is shown.

◆ And then the Logo for product model is shown.

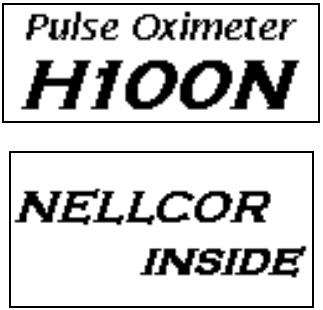



Figure 3-1 Model

◆ If the POST is successfully finished, the oximeter sounds a tone and enters the main interface.

If there is an error during the POST, the following error codes will display on the screen:

| Error code | Indication |
|---|---|
| Error 01 | Indicates error for Low battery |
| Error 02 | Indicates error for $SpO_2$ board |

| | |
|---|---|
| Error 03 | Indicates error for Temp board |
| Error 04 | Indicates error for main control board |

# 3.2 Measurement State

## 3.2.1 Measurement Modes

There are two measurement modes which are waveform mode and large numeric mode. By default, the configuration is waveform mode.

**Large Numeric Mode**

The oximeter can display $SpO_2$, oxygen saturation unit (%), PR, pulse rate unit (bpm), TEMP and temperature unit (℃) in large numeric mode.

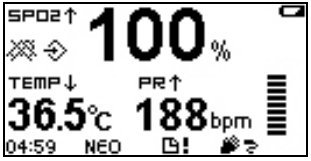



Figure 3-2 Large Numeric Mode

**Waveform Mode**

In the normal measurement state, oximeter can measure arterial oxygen saturation and pulse rate, display oxygen saturation level and symbol（%$SpO_2$）and PR on interface. Besides, it can also display pulse bar graph and Plethysmogram.

In waveform mode, oximeter displays $SpO_2$ and PR information, and the TEMP value is not displayed on the screen.

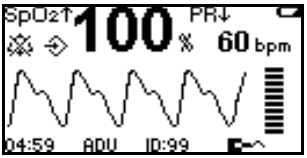



Figure 3-3 Waveform Mode

## 3.2.2 Trend Graph

In normal measurement state, press the **Up Arrow** button to display $SpO_2$ trend graph; press the **Down Arrow** button to display 10-minute PR trend graph as follows:

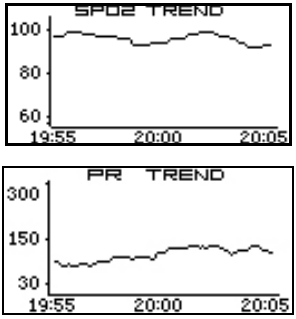



Figure 3-4 Display SpO2 and PR Trend Graph

### 3.2.3 Abnormal Measurement State

If the $SpO_2$ sensor does not connect to the oximeter, it will give a medium alarm, and display in the Information area.

If the $SpO_2$ sensor falls off from the finger, it will give a medium alarm, and display in the information area.

If the Temp sensor is abnormal, it will give a low alarm, and display --- in TEMP parameter area.

In menu state or trend graph state, if there is no operation for 30 seconds, the oximeter will return to measurement state.

In measurement state, if there is no measurement data and no operation for 10 minutes, the oximeter will turn off automatically.

In Data transfer state, if the oximeter does not receive responsible signals for 10 minutes, it will turn off automatically.

### 3.2.4 Data Transfer State

Set **Data Storage** in menu to **ON**, the measurement value will be stored in the oximeter. The $SpO_2$ and PR information can be transferred from oximeter to PatientCare Viewer Data Management Software.

Data transfer procedure:

◆ After the measurement and storage are all finished, turn off the oximeter;

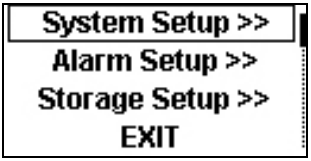
◆ Connect the oximeter and the computer with a cable for communication between the oximeter and PatientCare Viewer Data Management Software;

◆ Synchronously press the **On/Off** button and the **Function** button, after POST, the oximeter enters Data Transfer State automatically. The interface displays as follows:

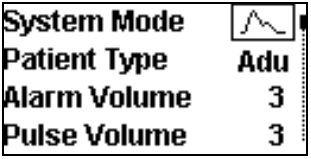

Figure 3-5 Data Transfer State

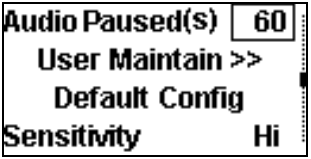
## 3.3 System Menu

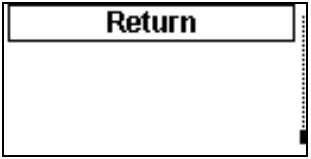
Press the **Function** button to see the following main menu of oximeter, select items by pressing the **Up/Down** button, and confirm it by pressing the **Function** button.



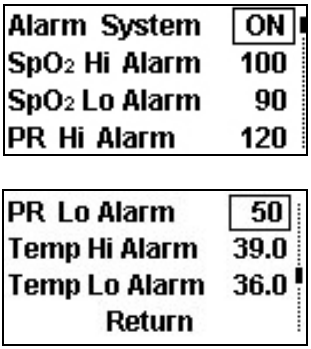

System Setup >>:



Alarm Setup >>:




Storage Setup >>:

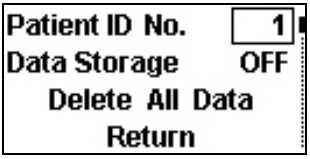



Figure 3-6 Menus

**NOTE:**

1 The **$SpO_2$ Hi Alarm** and **$SpO_2$ Lo Alarm** stand for the upper and lower alarm limits of $SpO_2$

respectively.

2 The **PR Hi Alarm** and **PR Lo Alarm** stand for the upper and lower alarm limits of PR respectively.

3 The **Temp Hi Alarm** and **Temp Lo Alarm** stand for the upper and lower alarm limits of Body temperature respectively.

4 If the user changes the default value of **Lo Alarm** or **Hi Alarm**, after restarting the oximeter, the value will resume to the default value for corresponding patient type.

### 3.3.1 System Mode

There are two items for selecting:

Large numeric mode 

Waveform mode 

Then confirm the selection by pressing the **Function**

button.

### 3.3.2 Patient Type

**Patient Type** can be set to Adult (Adu) or Neonate (Neo) for different measurement modes.

Set **Patient Type** to **Adu** or **Neo**, and confirm it by pressing the **Function** button.

### 3.3.3 Alarm Volume

**Alarm Volume** is used to adjust alarm volume and its range is from 1 to 5.

When **Alarm System** is **ON**, if a low alarm, a medium alarm or a high alarm occurs, the oximeter sounds beep.

### 3.3.4 Pulse Volume

The user can turn on or off the pulse volume by pressing **Pulse Volume**, and change volume level to 1, 2, 3, 4, 5 or OFF. Press the **Function** button to enter setup state and use the **Up Arrow** or **Down Arrow** button to choose

the volume, and confirm it by pressing the **Function** button.

The oximeter implements variable pulse tone and its frequency varies with the saturation.

### 3.3.5 Audio Paused (s)

Set the pause period for audio alarm to 30, 60, 90 or 120 seconds.

When **Alarm System** is **ON**, pressing the **Alarm Silence** button can turn off the audio alarm, the pause period is set by pressing **Audio Paused (s)**.

### 3.3.6 User Maintain

Enter the **User Maintain** menu by inputting “819”.


Figure 3-7 Enter Password

If the password is wrong, the following dialog box will pop up:

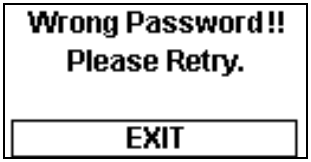



Figure 3-8 Wrong Password

If the password is right, the following menu will display:

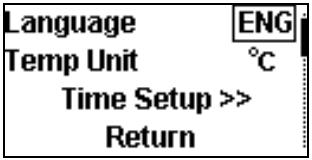



Figure 3-9 User Maintain

- Language: the user can select language to be displayed.
- Temp Unit: the user can set the temperature unit to ℃ or ℉.
- Time Setup >>: select this item, the following

interface displays:

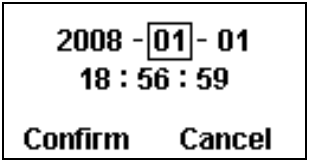



Figure 3-10 Time Setup

## 3.3.7 Default Config

Choose this item to resume factory default configuration.

A dialog box pops up:

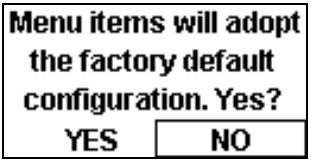



Figure 3-11 Factory Default Config

Factory Default Configuration is shown as follows:

System Mode: 

Patient Type: ADU

| | |
|---|---|
| Alarm System: | ON |
| Alarm Volume: | 3 |
| Pulse Volume: | 3 |
| Audio Paused (s): | 60 |
| SpO2 Hi Alarm: | 100 |
| SpO2 Lo Alarm: | 90 |
| PR Hi Alarm: | 120 |
| PR Lo Alarm: | 50 |
| Temp Hi Alarm: | 39 |
| Temp Lo Alarm: | 36 |
| Patient ID No.: | 1 |
| Data Storage: | OFF |

### 3.3.8 Sensitivity

The SpO2 reading is the average of data collected within a specific time. You can set the **Sensitivity** to **Hi** or **Low** via the menu. The higher the sensitivity is, the quicker

the pulse oximeter responds to the changes in the patient's oxygen saturation level. Contrarily, the lower the sensitivity is, the slower the pulse oximeter responds to the changes in the patient's oxygen saturation level, but the measurement accuracy will be improved. When a critical patient is monitored, selecting high sensitivity will help to understand the patient's state.

### 3.3.9 Alarm System

Set **Alarm System** to **ON** or **OFF** to turn on or off the alarm system.

If **Alarm system** is set to **OFF**, a dialog box pops up as follows:

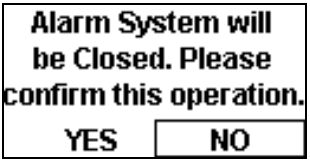



Figure 3-12 Confirm to Turn off Alarm

If **Alarm System** is **ON**, when an alarm occurs, the

oximeter gives a visual alarm and an audio alarm.

Pressing the **Alarm Silence** button can suspend the alarm system for seconds (the pause period can be set to 30, 60, 90 or 120s by the user, see section 3.3.5), the audio alarm off icon displays. But the visual alarm is still active. For example, if the measured $SpO_2$ value is higher than **$SpO_2$ Hi Alarm** or lower than **$SpO_2$ Lo Alarm**, there will be ↑or ↓ icon displayed on screen, and the $SpO_2$ or PR character will flash.

If **Alarm system** is set to **OFF**, all audio alarms and visual alarms are turned off.

**WARNING**

When the Alarm system is off, the oximeter will not give an alarm prompt. In order to avoid endangering the patient's life, the user should use this function cautiously.

## 3.3.10 SpO2 Alarm Setup

The user can choose **$SpO_2$ Hi Alarm** and **$SpO_2$ Lo Alarm** in menu to adjust $SpO_2$ alarm limit. Press the **Up Arrow** button or **Down Arrow** button to increase or decrease alarm limit.

By default, **$SpO_2$ Hi Alarm** and **$SpO_2$ Lo Alarm** in **Neo** mode are set to **95** and **90** respectively; while they are **100** and **90** in **Adu** mode respectively.

Set the $SpO_2$ alarm limits as follows:

◆ Choose **$SpO_2$ Hi Alarm** in the menu, and press the **Function** button to enter setup. The **$SpO_2$ Hi Alarm** box will change from real line box to broken line box. The adjustable range for upper limit of $SpO_2$ is from "1 + the lower limit of $SpO_2$" to 100. If the value of SpO2 Hi Alarm is set to less than 85, it will restore to default value after the oximeter is turned on again. In the NEO mode, if the value of SpO2 Hi Alarm is set to higher than 95, it will restore to 95 after the oximeter is turned

on again.

◆ Press the **Up Arrow** or **Down Arrow** button to increase or decrease values.

◆ Choose **$SpO_2$ Lo Alarm** in the menu, press the **Function** button to set it. The **$SpO_2$ Lo Alarm** box will change from real line box to broken line box. The adjustable range for the lower limit of $SpO_2$ Alarm is from 0 to "the upper limit of SpO2 Alarm - 1". If the value of SpO2 Lo Alarm is set to less than 85, it will restore to 85 after the oximeter is turned on again.

◆ Press the **Up Arrow** or **Down Arrow** button to increase or decrease values.

◆ **$SpO_2$ Hi Alarm** is always higher than **$SpO_2$ Lo Alarm** by at least 1%.

◆ Press the **Function** button, and confirm the alarm range setup.

◆ Press the **On/Off** button to exit the menu, and return to measurement state.

### 3.3.11 PR Alarm setup

The user can use **PR Hi Alarm** and **PR Lo Alarm** in menu to adjust pulse rate alarm limits.

By default, **PR Hi Alarm** and **PR Lo Alarm** in **Neo** mode are **200** and **100** respectively; while they are **120** and **50** in **Adu** mode respectively.

Set the PR limits as follows:

◆ Choose **PR Hi Alarm** in the menu, press the **Function** button to enter setup. The **PR Hi Alarm** box changes from real line to broken line. The adjustable range of the upper limit of PR Alarm is from "1 + the lower limit of PR Alarm" to 300.

◆ Press the **Up Arrow** or **Down Arrow** button to increase or decrease values.

◆ Choose **PR Lo Alarm** in menu, press the **Function** button to enter setup. The **PR Lo Alarm** box changes from real line to broken line. The adjustable range for

the lower limit of PR Alarm is from 0 to "the upper limit of PR Alarm – 1".

◆ Press the **Function** button, confirm the alarm range setup.

◆ **Hi Alarm** is always higher than **Lo Alarm** by at least 1 bpm.

◆ Press the **On/Off** button to exit the menu, and return to measurement state.

### 3.3.12 Temp Alarm Setup

The user can use **Temp Hi Alarm** and **Temp Lo Alarm** in menu to adjust body temperature alarm limits.

By default, the **Temp Hi Alarm** and **Temp Lo Alarm** are set to **39.0**℃ and **36.0**℃respectively in both **Neo** and **Adu** modes.

Set the Temp limits as follows:

◆ Choose **Temp Hi Alarm** in the menu, press the

**Function** button to enter setup. The **Temp Hi Alarm** box changes from real line to broken line. The adjustable range of the upper limit of Temp Alarm is from "0.1℃ + the lower limit of Temp Alarm" to 50.0℃.

◆ Press the **Up Arrow** or the **Down Arrow** button to increase or decrease values.

◆ Choose **Temp Lo Alarm** in menu, and press the **Function** button to enter setup. The **Temp Lo Alarm** box changes from real line to broken line. The adjustable range for the lower limit of Temp Alarm is from 0 to "the upper limit of Temp Alarm - 0.1℃".

◆ Press the **Function** button, and confirm the alarm range setup.

◆ **Hi Alarm** is always higher than **Lo Alarm** by at least 1℃.

◆ Press the **On/Off** button to exit the menu, and return to measurement state.

## 3.3.13 Patient ID No. setup

The oximeter can support 100 patient IDs, and 300-hour data storage.

When entering the menu, press the **Function** button to set ID (valid range is from 1 to 100). The ID display box on the interface will change from real line to broken line.

After choosing ID, press the **Function** button to confirm the setup. If the ID exists, the following confirmation dialog box will pop up.

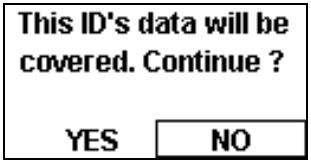



Figure 3-13 Confirm to cover data

## 3.3.14 Data Storage

Choose **Data Storage**, and set it to **ON**, then the measurement data can be stored.

During the data storage, patient ID can not be changed. If the user wants to change ID, he should change **Data Storage** to **OFF**, then set a new ID.

Data stored in the oximeter can be exported through PatientCare Viewer Data Management Software. Please refer to 3.2.3 for Data transfer procedure.

When the memory space is full, an icon displays in Information Area. Meanwhile **Data Storage** changes to **OFF** automatically. Restart the oximeter and a dialog box pops up. The user should confirm it to delete all the data.

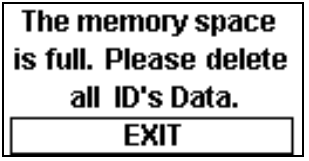



Figure 3-14 The Memory space is full

## 3.3.15 Deleting All Data

**Delete All Data** is used to delete all the stored data. Choose this item by pressing the **Function** button, a dialog box pops up as follows:

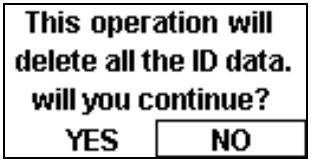



Figure 3-15 Deleting all the data

If you choose **YES** to delete all the data, the deleting progress shows:

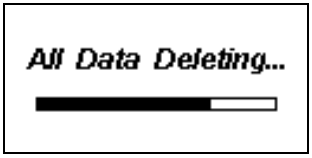



Figure 3-16 All Data Deleting

## 3.3.16 Exit (Return)

Exit menu by pressing **Exit** in the menu.

Return to the previous menu by pressing **Return** in the menu.

## 3.4 Charging the Ni-MH Battery Package

To charge the rechargeable Ni-MH battery package:

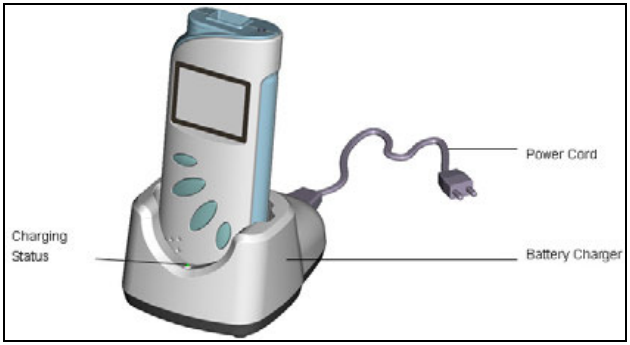
1. Turn off the device.
2. Place the pulse oximeter in the charger stand.
3. Connect the power cord.
4. Plug the power cord into the AC mains.

A tricolor LED display indicates the charging state.

Red indicates no rechargeable battery package in the machine or the device is not placed properly.

Yellow indicates the device is being charged.

Green indicates that the charging is complete.




## 3.5 PatientCare Viewer Data Management Software Introduction

Connect the oximeter to PC through the cable before running the PatientCare Viewer Data Management Software. This Software implements the following functions:

1. Query or save the oximeter's data based on the patient ID.

2. Edit and manage patient information.

3. Review each ID's data in trend graph format.

4. Print all data information via PC

Refer to the PatientCare Viewer Data Management Software user manual for detailed information.

The following figures demonstrate the main interface, trend graph and print preview.

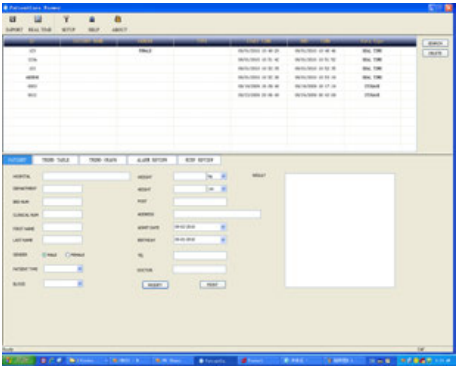


Figure 3-17 Main Interface

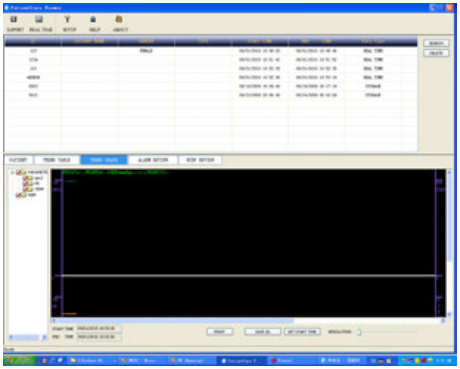


Figure 3-18 Trend Graph

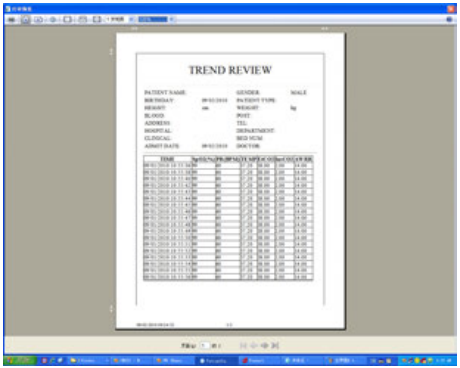



Figure 3-19 Print Preview

# 4 Alarm

## 4.1 Alarm Categories and Levels

### Alarm Categories

The oximeter's alarms can be classified into two categories: physiological alarms and technical alarms.

1. Physiological alarms

   Physiological alarms, also called patient status alarms, are triggered by a monitored parameter value that violates setup alarm limits or an abnormal patient condition.

2. Technical alarms

   Technical alarms, also called system status alarms, are triggered by a device malfunction or a patient data distortion due to improper operation or system problems.

## Alarm Levels

In terms of severity, the oximeter's alarms levels can be classified into three categories: high level alarms, medium level alarms and low level alarms.

1. High level alarms

   Indicate that the patient is in a life threatening situation and an emergency treatment is demanded.

2. Medium level alarms

   The patient's vital signs appear abnormal or the oximeter system status appears abnormal, indicate that prompt operator response is required.

3. Low level alarms

   The patient's vital signs appear abnormal or the oximeter system status appears abnormal, indicate that operator awareness is required.

The levels for both technical alarms and physiological alarms are predefined and can not be changed by the user.

## Alarm Categories Table

| | High Level Alarm | Medium Level Alarm | Low Level Alarm |
|---|---|---|---|
| Physiological alarm | $SpO_2$ Too High<br>$SpO_2$ Too Low<br>PR Too High<br>PR Too Low | Temp Too High<br>Temp Too Low | |
| Technical alarm | | $SpO_2$ Sensor Unconnected<br>$SpO_2$ Sensor off<br>Low Battery | Temp Sensor Abnormal |

### Alarm Indicators

When an alarm occurs, the oximeter will indicate it through the following indications:

- Character flash
- Alarm tone

High level alarms: character flashes quickly and sounds triple + double + triple +double beep.
Medium level alarms: character flashes slowly and sounds triple beep.
Low level alarms: character display constantly and sounds a single beep.

## 4.2 Alarm Conditions

### 4.2.1 Alarm Off Before the First Measurement

Before the first measurement, the alarm system is

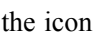
configured to be off. At this time, if the $SpO_2$ or Temp sensor is unconnected or the sensor is off, the oximeter will not give an alarm.

### 4.2.2 Alarm for SpO2 Sensor Unconnected

When the $SpO_2$ sensor is disconnected, the oximeter gives a medium alarm. The icon  displays in Information area.

It displays --- in $SpO_2$, PR area of LCD, and gives a medium alarm. (Make sure **Alarm System** in menu is set to **ON**.)

### 4.2.3 Alarm for SpO2 Sensor off

When the $SpO_2$ sensor falls off the finger, the oximeter will give a medium alarm, and the icon  displays in information Area.

It displays --- in $SpO_2$, PR display area, and gives a medium alarm. (Make sure **Alarm System** in menu is **ON**.)

### 4.2.4 Alarm for Abnormal State of Temp Sensor

In the measurement state, if the Temp sensor falls off the oximeter, it will display --- in the TEMP display area and give a low alarm. (Make sure **Alarm System** in menu is set to **ON**.)

If the measured value is below 0℃ or above 50℃, the oximeter will give a low alarm.

If the Temp sensor is damaged, the oximeter will give a low alarm.

### 4.2.5 Alarm for Low Battery

When the battery is too low, the oximeter gives a medium alarm for low battery.

After the low battery alarm occurs, the oximeter can still be operated for a few minutes before it turns off automatically.

The low battery icon  displays on LCD, and gives a medium alarm. (Make sure **Alarm System** in menu is set to **ON**.)

### 4.2.6 Higher than Hi Alarm Limit

If the measured value is higher than the **Hi Alarm** (upper alarm limit), the oximeter gives a high alarm for $SpO_2$ or PR, and gives a medium alarm for TEMP.

Here we take PR for example:

When the measured PR value is higher than the set **PR Hi Alarm**, the oximeter gives a high alarm (Make sure **Alarm System** in menu is set to **ON)**. A ↑ icon displays near PR, which indicates that the measured value is higher than that of **PR Hi Alarm**, it will synchronously flash with PR value.

### 4.2.7 Lower than Lo Alarm limit

If the measured value is lower than the **Lo Alarm** (lower

alarm limit), the oximeter gives a high alarm for $SpO_2$, PR, and gives a medium alarm for TEMP.

Here we take $SpO_2$ for example:

When the measured $SpO_2$ value is lower than the set **$SpO_2$ Lo Alarm**, the oximeter gives a low $SpO_2$ alarm. (Make sure **Alarm System** in menu is set to **ON**.)

A ↓ icon displays near $SpO_2$, which indicates the measured value is lower than that of **$SpO_2$ Lo Alarm**, it will synchronously flash with $SpO_2$ value.

Likewise, when measured $SpO_2$ is lower than **$SpO_2$ Lo Alarm**, or measured Temp is lower than **Temp Lo Alarm**, it will also give an alarm.

### 4.2.8 Alarm Silence

If **Alarm System** in menu is set to **ON**, pressing the **Alarm Silence** button, the audio alarm will be off for the pause period set by the user, but the visual alarm is still active.

When the audio alarm is off, press **Alarm Silence** button to reactivate the audio alarm function.

### 4.2.9 Turning off Alarm System

After **Alarm system** is turned off, the oximeter can not give a visual and an audio alarm except for low battery icon alarm.

Set **Alarm system** to **ON**, the alarm system will be active. It will give an audio alarm and a visual alarm if an alarm occurs.

### 4.2.10 Alarm Priority

Only one kind of alarm can be given at once. For example, if a medium alarm and a high alarm occur at the same time, the high alarm will take priority.

# 5 Performance Considerations

## 5.1 Performance Verification

Qualified service personnel are responsible for performance verification procedures before the oximeter is used for the first time in a clinical setting.

## 5.2 Oximeter Performance Considerations

There are some patient conditions that can affect the oximeter's measurements.

◆ Dysfunctional Hemoglobins

Dysfunctional hemoglobins, such as carboxyhemoglobin, methemoglobin, and sulfhemoglobin, are unable to carry oxygen. $SpO_2$ readings may appear normal; however, a

patient may be hypoxic because less hemoglobin is available to carry oxygen. Further assessment beyond pulse oximeter is recommended.

◆ Anemia

Anemia causes decreased arterial oxygen content. Although $SpO_2$ readings may appear normal, an anemic patient may be hypoxic. Correcting anemia can improve arterial oxygen content. The oximeter may fail to provide $SpO_2$ if hemoglobin levels fall below 5 gm/dl.

◆ Saturation

The oximeter displays saturation level between 1% and 100%.

◆ Pulse rate

The oximeter displays pulse rate between 20 and 300 beats per minute (bpm). The sensor accuracy ranges do not apply to pulse rates above 300 bpm. Detected pulse rates less than 20 are shown as 0.

◆ Temperature

The oximeter normally displays temperature from 0℃ to + 50℃, there are abnormal state if the temperature is out of the range.

## 5.3 OxiMax Sensor Performance Considerations

Inaccurate measurements can be caused by:

◆ Incorrect application of the OxiMax sensor.

◆ Placement of the OxiMax sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.

◆ Excessive patient activity.

◆ Intravascular dyes, such as indocyanine green or methylene blue.

◆ Externally applied coloring, such as nail polish or

pigmented cream.

◆ Failure to cover the OxiMax sensor site with opaque materials in high ambient light conditions.

◆ Venous pulsation.

◆ Dysfunctional hemoglobin.

◆ Low perfusion.

Loss-of-pulse signal occurs for the following reasons:

◆ The OxiMax sensor is applied too tightly.

◆ Defibrillation.

◆ A blood pressure cuff is inflated on the same extremity as the one with the OxiMax sensor attached.

◆ There is arterial occlusion proximal to the OxiMax sensor.

◆ Poor peripheral perfusion.

◆ Loss of pulse/cardiac arrest.

To use the OxiMax sensor:

◆ Select an appropriate OxiMax sensor.

◆ Apply the OxiMax sensor as directed, and observe all warnings and cautions presented in the OxiMax sensor user manual.

◆ Clean and remove any substances, such as nail polish, from the application site.

◆ Periodically check to ensure that the OxiMax sensor remains properly positioned on the patient.

High ambient light sources that can interfere with the performance of the OxiMax sensor are:

◆ Surgical lights (especially those with a xenon light source).

◆ Bilirubin lamps.

◆ Fluorescent lights.

◆ Infrared heating lamps.

◆ Direct sunlight.

To prevent interference from ambient light, ensure that the OxiMax sensor is properly applied, and cover the OxiMax sensor site with opaque material.

If interference due to patient activity presents a problem, try one or more of the following to correct the problem:

◆ Verify that the OxiMax sensor is properly and securely applied.

◆ Move the OxiMax sensor to another site.

◆ Use an adhesive to the OxiMax sensor.

◆ Use a new the OxiMax sensor with fresh adhesive backing.

◆ Keep the patient still, if possible.

If interference due to poor perfusion presents a problem, consider using the MAX-R OXIMAX sensor or the MAXFAST OXIMAX sensor. The MAX-R OXIMAX sensor obtains measurements from the nasal septal anterior ethmoid artery, an artery supplied by the internal carotid. These OXIMAX sensors may obtain measurements when peripheral perfusion is relatively poor.

# 6 Maintenance

The oximeter does not require calibration.

If the service is necessary, contact qualified service personnel or your local the manufacturer representative.

Before using the oximeter, do the following:

- Check if there is any mechanical damage;
- Check if all the outer cables, inserted modules and accessories are in good condition;
- Check all the functions of the oximeter to make sure that the oximeter is in good condition.

If you find any damage on the oximeter, stop using the oximeter on the patient, and contact the biomedical engineer of the hospital or Customer service immediately.

The overall check of the oximeter, including the safety check, should be performed only by qualified personnel once every 6 to 12 months, and each time after fix up.

All the checks that need to open the oximeter should be performed by qualified customer service technician. The safety and maintenance check can be conducted by persons from this company. You can obtain the material about the customer service contract from the local company's office.

If the hospital or agency that is responding to using the oximeter does not follow a satisfactory maintenance schedule, the oximeter may become invalid, and the human health may be endangered.

**WARNING**

Before cleaning the oximeter or the sensor, make sure that the oximeter is switched off.

## Periodic Safety Checks

It is recommended that the following checks be performed every 24 months:

◆ Inspect the devices for mechanical and functional damage

◆ Inspect the relevant labels for legibility

## Cleaning

You can surface-clean and disinfect the oximeter and sensor.

To surface-clean the oximeter:

◆ Use a soft cloth dampened with either a commercial, nonabrasive cleaner, or a solution of 70% alcohol in water.

◆ Lightly wipe the surfaces of the oximeter.

To disinfect the oximeter:

◆ Use a soft cloth saturated with a solution of 10% chlorine bleach in tap water.

## Cleaning reusable TEMP probes:

1 The TEMP probe should not be heated above 100℃ (212℉). It should only be subjected briefly to temperatures between 80℃ (176℉) and 100℃ (212℉).

2 The probe must not be sterilized in steam.

3 Only detergents containing no alcohol can be used for disinfection.

4 To clean the probe, hold the tip with one hand and with the other hand rubbing the probe down in the direction of the connector using a moist lint-free cloth.

## Disinfecting

Clean the pulse oximeter before disinfecting it.

The recommended disinfectants include: ethanol 70%, isopropanol 70%, glutaraldehyde-type 2% liquid disinfectants.

**WARNING**

Sterilization may cause damage to the equipment and is therefore not recommended for this pulse oximeter unless otherwise indicated in your hospital's servicing schedule.

**CAUTION**

Never use EtO or formaldehyde for disinfection.

# 7 Principles of Operation

H100N Pulse Oximeter adopts non-invasive double wavelength to measure $SpO_2$ and PR. It can perform spot measuring and continuous measuring for a short time. It can also measure TEMP by a thermistor probe (a semiconductor whose resistance changes with temperature).

The system consists of Central Processing Unit, Signal Collection, Signal Input, Data Output, Display and User Input module, as shown in figure 7-1:

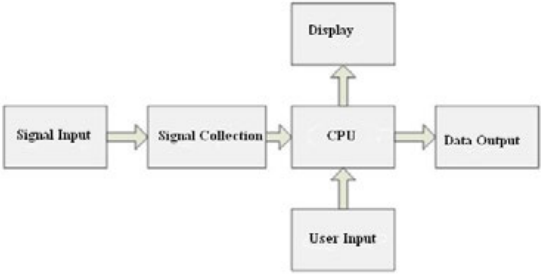



Figure 7-1 System Principle

The oximeter communicates with external devices through RS-232 interface.

## 7.1 Pulse Oximetry Measurement

The oximeter uses oximetry to measure functional oxygen saturation in the blood. Pulse oximetry works by applying sensor to a pulsating arteriolar vascular bed, such as a finger or a toe. The sensor contains a dual light source and a photonic detector.

Bone, tissue, pigmentation, and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable amounts of light during the pulsations. The ratio of light absorbed is translated into a measurement of functional oxygen saturation ($SpO_2$). Because a measurement of $SpO_2$ is dependent upon light from the sensor, excessive ambient light can interfere with this measurement.

Pulse oximetry is based on two principles:

◆ Oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (spectrophotometry).

◆ The volume of arterial blood in tissue (hence light absorption by the blood) changes during the pulse (plethysmography).

The oximeter determines $SpO_2$ by passing red and infrared light into an arteriolar bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared low-voltage light-emitting diodes (LED) serve as light sources; a photonic diode serves as the photo detector.

Because oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by blood is related to hemoglobin oxygen saturation. To identify the oxygen saturation of arterial

hemoglobin, the oximeter uses the pulsatile nature of arterial flow.

During systole, a new pulse of arterial blood enters the vascular bed, and blood volume and light absorption increase. During diastole, blood volume and light absorption reach their lowest point.

The oximeter bases its $SpO_2$ measurements on the difference between maximum and minimum absorption (measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of non-pulsatile absorbs such as tissue, bone and venous blood.

**Wavelength**

The Oximax sensor contains LEDs that emit red light at a wavelength of approximately 660 nm and infrared light at a wavelength of approximately 900 nm.

The total optical output power of the sensor LEDs is less

than 15 mW. This information may be useful to clinicians, such as those performing photodynamic therapy.

## 7.2 Functional Versus Fractional Saturation

This oximeter measures functional saturation-oxygenated hemoglobin expressed as a percentage of the hemoglobin that can transport oxygen. It does not detect significant amounts of dysfunctional hemoglobin, such as carboxyhemoglobin or methemoglobin.

In contrast, hemoximeter such as the IL482 report fractional saturation-oxygenated hemoglobin expressed as a percentage of all measured hemoglobin, including measured dysfunctional hemoglobins.

To compare functional saturation measurements to those from an instrument that measures fractional saturation, fractional measurements must be converted as follows:

## 7.3 Measured Versus Calculated Saturation

When saturation is calculated from a blood gas partial pressure of oxygen ($PO_2$), the calculated value may differ from the $SpO_2$ measurement of a pulse oximeter. This usually occurs because the calculated saturation was not appropriately corrected for the effects of variables that shift the relationship between $PO_2$ and pH, temperature, the partial pressure of carbon dioxide ($PCO_2$), 2,3-DPG, and fetal hemoglobin.

# 8 Warranty and Service Policy

## 8.1 Warranty

EDAN warrants that EDAN's products meet the labeled specifications of the products and will be free from defects in materials and workmanship that occur within warranty period. The warranty period begins on the date the products are shipped to distributors.

The warranty is void in cases of:

a) damage caused by handling during shipping.

b) subsequent damage caused by improper use or maintenance.

c) damage caused by alteration or repair by anyone not authorized by EDAN.

d) damage caused by accidents.

e) replacement or removal of serial number label and manufacture label.

If a product covered by this warranty is determined to be defective because of defective materials, components, or workmanship, and the warranty claim is made within the warranty period, EDAN will, at its discretion, repair or replace the defective part(s) free of charge. EDAN will not provide a substitute product for use when the defective product is being repaired.

## 8.2 Service Policy

All repairs on products must be performed or approved by EDAN. Unauthorized repairs will void the warranty. In addition, whether or not covered under warranty, any product repair shall be exclusively be performed by EDAN certified service personnel.

If the product fails to function properly or if you need

assistance, service, or spare parts, contact EDAN's service center. A representative will assist you troubleshooting the problem and will make every effort to solve it over the phone or Email, avoiding potential unnecessary returns.

In case a return can not be avoided, the representative will record all necessary information and will provide a Return Material Authorization (RMA) form that includes the appropriate return address and instructions. An RMA form must be obtained prior to any return.

***Freight policy:***

Under warranty: the service claimer is responsible for freight & insurance charges when a return is shipped to EDAN for service including custom charges. EDAN is responsible for freight, insurance & custom charges from EDAN to service claimer.

Out of warranty: the service claimer is responsible for

any freight, insurance & custom charges for product.

***Contact information:***

If you have any question about maintenance, technical specifications or malfunctions of devices, contact your local distributor.

Alternatively, you can send an email to EDAN service department at: support@edan.com.cn.

# Appendix Ⅰ Specification

## A1.1 Classification

| | |
|---|---|
| Type of Protection | Internally powered equipment |
| EMC Compliance | Class B |
| Degree of Protection | Type BF-Applied part |
| Ingress Protection | IPX1 |
| Mode of operation | Continuous measuring and spot measuring |
| Compliant with Safety Standards | IEC 60601-1:1988+A1+A2, EN 60601-1:1990+A1+A2, IEC/EN 60601-1-2:2001+A1, ISO 9919, EN 12470-4 |

## A1.2 Specification

### A1.2.1 Size and Weight

| | |
|---|---|
| Size | 160 mm (L) × 70 mm (W) × 37.6 mm (H) |

| | |
|---|---|
| Weight | 185 g (without battery) |

## A1.2.2 Environment

**Temperature**

| | |
|---|---|
| Working | + 5 °C ~ + 40 °C |
| Storage | -20 °C ~ + 55 °C |

**Humidity**

| | |
|---|---|
| Working | 25% ~ 80% (No coagulate) |
| Storage | 25% ~ 93% (No coagulate) |

**Atmospheric pressure**

| | |
|---|---|
| Working | 860 hPa ~ 1060 hPa |
| Transport and Storage | 700 hPa ~ 1060 hPa |

## A1.2.3 Display

| | |
|---|---|
| Screen Type | 128×64 dot-matrix LCD, with white LED backlight |
| Large Numeric Mode | $SpO_2$, PR, TEMP and Bar graph displayed |

| | |
|---|---|
| Waveform Mode | $SpO_2$, PR, Bar graph and Plethysmogram displayed |

## A1.2.4 Batteries

**Alkaline batteries**

| | |
|---|---|
| Quantity | 4 |
| Total rated voltage | 6 V |
| Capacity | 2600 mAh |
| Typical battery life | 48 hours |

**Ni-MH rechargeable battery package**

| | |
|---|---|
| Quantity | 1 |
| Total rated voltage | 4.8 V |
| Capacity | 1800 mAh |
| Typical battery life | 36 hours |
| Charge time | 2.5 hours to 80% |
| | 4 hours to 100% |

## A1.2.5 Charger Stand

| | |
|---|---|
| Input voltage | 100 to 240 VAC, 50/60Hz |
| Output voltage | 8 VDC |
| Output current | 0.8 A |
| Output power | 6.4 W |

# A1.3 Parameters

**Measurement range**

| | |
|---|---|
| $SpO_2$ | 1 % ~ 100 % |
| PR | 20 bpm ~ 300 bpm |
| Perfusion range | 0.03 % ~ 20 % |
| TEMP | 0 ℃~ 50 ℃ |

**Accuracy Tolerance**

| | |
|---|---|
| Saturation | |
| Adult | 70 %~ 100 % ± 2digits |
| Neonate | 70 %~ 100 % ± 3digits |
| Low Perfusion | 70 %~ 100 % ± 2digits |

**Pulse Rate**

| | |
|---|---|
| Adult and Neonate | 20 bpm ~ 300 bpm ± 3digits |
| Low Perfusion | 20 bpm ~ 300 bpm ± 3digits |
| Data Update Period | 7 seconds |

| | |
|---|---|
| TEMP | 25 ℃~ 45 ℃ ± 0.1℃ |

| | |
|---|---|
| | 0 ℃~ 25℃ and 45 ~50℃ ± 0.2℃ |

**Resolution**

| | |
|---|---|
| $SpO_2$ | 1 % |
| Bpm | 1 bpm |
| TEMP | 0.1 ℃ |

# Appendix II EMC Information

***Guidance and Manufacture's Declaration***

Refer to the following tables for specific information regarding this device's compliance to IEC/EN 60601-1-2.

## A2.1 Electromagnetic Emissions - for all EQUIPMENT and SYSTEMS

| **Guidance and manufacturer's declaration – electromagnetic emissions** | | |
|---|---|---|
| The oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the oximeter should assure that it is used in such an environment. | | |
| **Emissions test** | **Compliance** | **Electromagnetic environment -guidance** |

| | | |
|---|---|---|
| RF emissions CISPR11 | Group 1 | The oximeter 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 CISPR11 | Class B | The oximeter is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply net work that |
| Harmonic emissions IEC/EN61000-3-2 | N/A | |
| Voltage fluctuations | N/A | |

| | | |
|---|---|---|
| /flicker emissions IEC/EN61000-3-3 | | supplies buildings used for domestic purpose. |

## A2.2 Electromagnetic Immunity - for all EQUIPMENT and SYSTEMS

| **Guidance and manufacturer's declaration – electromagnetic immunity** | | | |
|---|---|---|---|
| The oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the oximeter should assure that it is used in such an environment. | | | |
| **Emissions test** | **Compliance** | **Compliance level** | **Electromagnetic environment - guidance** |
| Electrostatic discharge(ESD) IEC/EN61000-4-2 | ±6kV contact ±8kV air | ±6kV contact ±8kV 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/EN61000-4-4 | ±2kV for power supply lines<br>±1kV for input/output lines (>3m) | N/A | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC/EN61000-4-5 | ±1kV for line to line<br>±2kV for line to ground | N/A | |

| | | | |
|---|---|---|---|
| Voltage dips, short interruptions, and voltage variations on power supply input lines IEC/EN61000-4-11 | <5%UT(>95% dip in UT)for 0.5 cycle<br><br>40%UT(60% dip in UT)for 5 cycles<br><br>70%UT(30% dip in UT)for 25 cycles<br><br><5%UT(>95% dip in UT)for | N/A | Mains power quality should be that of a typical commercial or hospital environment. If the user of the product requires continued operation during power mains interruptions, it is recommend |

| | | | |
|---|---|---|---|
| | 5s | | that the product be powered from an uninterruptible power supply or a battery. |
| Power Frequency( 50/60 Hz)Magnetic Field IEC/EN 61000-4-8 | 3A/m | 3A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment |

## A2.3 Electromagnetic emissions-for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

| **Guidance and manufacturer's declaration – electromagnetic immunity** | | | |
|---|---|---|---|
| The oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the oximeter should assure that it is used in such an environment. | | | |
| **Immunity test** | **IEC/EN 60601 test level** | **Compliance level** | **Electromagnetic environment - guidance** |
| Conducted RF IEC/EN | 3Vrms 150KHz to | 3V | Portable and mobile RF communications |

| | | | |
|---|---|---|---|
| 61000-4-6<br><br>Radiated RF IEC/EN 61000-4-3 | 80MHz<br><br>3V/m<br>80 MHz to 2.5GHz | 3V/m | equipment should be used no closer to any part of the oximeter, including cables, than the recommend separation distance calculated from the equation applicable to the frequency of the transmitter.<br>**Recommended separation** |

| | | | |
|---|---|---|---|
| | | | **distance**<br>$d = \frac{3.5}{3}\sqrt{P}$<br>$d = \frac{3.5}{3}\sqrt{P}$<br>80 MHz to 800 MHz<br>$d = \frac{7}{3}\sqrt{P}$<br>800 MHz to 2.5 GHz<br>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 metres (m).<br><br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each |

| | | | |
|---|---|---|---|
| | | | frequency range.<br><br>Interference may occur in the vicinity of equipment marked with the following symbol:<br><br>  |

**NOTE1** At 80MHz and 800MHz, the frequency range applies.

**NOTE2** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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 oximeter is used exceeds the applicable RF compliance level above, the oximeter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the oximeter.

## A2.4 Recommended Separation Distances

| **Recommended separation distances between portable and mobile RF communications equipment and the oximeter** |
| --- |
| The oximeter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the oximeter 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** $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ | **80 MHz to 800 MHz** $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ | **800 MHz to 2.5GHz** $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ |
| 0.01 | **0.12** | **0.12** | **0.23** |
| 0.1 | **0.37** | **0.37** | **0.74** |
| 1 | **1.2** | **1.2** | **2.3** |
| 10 | **3.7** | **3.7** | **7.4** |
| 100 | **12** | **12** | **23** |

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

# Appendix Ⅲ Record Table

| ID No. | Name | Time | $SpO_2$ | PR | Temp | NOTE |
|---|---|---|---|---|---|---|
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

# Appendix Ⅳ Abbreviations

| Abbr | English Full Name/Description |
|---|---|
| CISPR | International Special Committee on Radio Interference |
| EMC | Electromagnetic Compatibility |
| ID | Identification |
| IEC | International Electrotechnical Commission |
| LCD | Liquid Crystal Display |
| LED | Light Emitting Diode |
| MDD | Medical Device Directive |
| PC | Personal Computer |
| PR | Pulse Rate |
| RF | Radio Frequency |
| $SpO_2$ | Arterial Oxygen Saturation From Pulse Oximeter |

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