



Attendant®

# HANDHELD PULSE OXIMETER

## Owner's Manual

*Please keep and refer to this Owner's Manual.*

Thank you for purchasing an Attendant® Handheld Pulse Oximeter from Direct Supply Equipment & Furnishings®. Please read this entire guide carefully and keep it for future reference. This guide will provide you with instructions, warnings, warranty information, and other important information about your Attendant pulse oximeter. Share this information with your housekeeping, nursing and maintenance staff to help ensure the pulse oximeter is cared for properly.

# Table of Contents

<b>Introduction .....</b>	<b>4 - 18</b>
Warnings .....	6 - 9
Symbols in the Device .....	10 - 11
Symbols on Screen .....	11 - 12
Box Contents .....	13
Front Panel Buttons .....	14 - 15
Connecting Sensor or Cable .....	16
Powered by Battery .....	17 - 18
<b>Turning on the Device .....</b>	<b>19</b>
<b>Measurement Procedure .....</b>	<b>20 - 31</b>
SpO <sub>2</sub> Measurement Procedure .....	20
Measurement Modes .....	20 - 22
Abnormal Measurement State .....	22
Data Transfer State .....	22
System Menu .....	23 - 24
Audio Paused(s) .....	25
User Maintain .....	25
Default Config .....	26
Alarm System .....	27
SpO <sub>2</sub> Alarm Setup .....	27
PR Alarm Setup .....	28 - 29
Patient ID No. Setup .....	29
Data Storage .....	29 - 30
Exit (Return) .....	31
<b>Alarms .....</b>	<b>32 - 36</b>
Alarm Categories .....	32 - 33
Alarm off Before the First Measurement .....	34
Alarm for SpO <sub>2</sub> Sensor Unconnected .....	34
Alarm for SpO <sub>2</sub> Sensor Off .....	34
Alarm for Low Battery .....	34
Higher than Hi Alarm Limit .....	35
Lower than Lo Alarm Limit .....	35
Alarm Silence .....	35
Alarm Delay .....	36
Testing Alarms .....	36

<b>Maintenance .....</b>	<b>37</b>
<b>Cleaning.....</b>	<b>38 - 39</b>
<b>Principles of Operation .....</b>	<b>40 - 44</b>
Pulse Oximetry Measurement.....	40 - 41
Wavelength .....	41
Functional vs. Fractional Saturation .....	42
Measured vs. Calculated Saturation .....	42
Performance Verification.....	42
Oximeter Performance Considerations.....	42 - 43
Sensor Performance Considerations .....	43 - 44
<b>Limited Warranty .....</b>	<b>45 - 46</b>
<b>APPENDIX I: Specification .....</b>	<b>47 - 49</b>
A1.1 Classification.....	47
A1.2 Specification .....	47
A1.2.1 Size & Weight.....	47
A1.2.2 Environment .....	47
A1.2.3 Display .....	48
A1.2.4 Batteries .....	48 - 49
A1.3 Parameters .....	49
<b>APPENDIX II: EMC Information .....</b>	<b>50 - 53</b>
A2.1 Electromagnetic Emissions – for all EQUIPMENT and SYSTEMS.....	50
A2.2 Electromagnetic Immunity – for all EQUIPMENT and SYSTEMS.....	51
A2.3 Electromagnetic Emissions – for non-Life-Supporting EQUIPMENT and SYSTEMS.....	52
A2.4 Recommended Separation Distances .....	53
<b>Appendix III Record Table .....</b>	<b>54</b>
<b>Appendix IV Abbreviations .....</b>	<b>54</b>
<b>Customer Service .....</b>	<b>55</b>

# Introduction

The Attendant Handheld Pulse Oximeter is intended for spot-checking or short-term (less than 2 hours) continuous monitoring of functional arterial oxygen saturation ( $\text{SpO}_2$ ) and pulse rate of residents in hospitals, intra-hospital transport and hospital-type facilities.

The device contains a  $\text{SpO}_2$  module, and integrates a parameter module, display and recorder output function. It can be powered by four 1.5V LR6 AA batteries or four 1.2V Ni-H rechargeable AA batteries. It clearly displays all the parameter information on an LCD screen including the  $\text{SpO}_2$  value, pulse rate value, Plethysmogram, bar graph, and related information.

## Definitions & Symbols

**NOTE:** Indicates a tip.

**CAUTION:** Indicates correct operating or maintenance procedures in order to prevent damage to or destruction of the equipment or other property.

**WARNING:** Calls attention to a potential danger that requires correct procedures or practices in order to prevent personal injury.

**DEVICE:** Your Attendant Handheld Pulse Oximeter.

**YOU and YOUR:** The facility, community or other entity that has purchased the device.

**WE, US, and OUR:** Direct Supply Manufacturing, Inc.

**⚠ Attention. Read the instructions.**

## Indications for Use

The device is intended for continuous monitoring or spot-checking of functional arterial oxygen saturation ( $\text{SpO}_2$ ) and pulse rate of adult, pediatric or neonatal residents in hospitals, intra-hospital transport and hospital-type facilities.

It is made of a main unit, batteries, sensors and silica gel protection cover.

*Additional specifications are found in the appendix to this Owner's Manual.*



*Pulse Oximeter*

## Introduction *(cont.)*

**⚠ WARNING** – Avoid explosion hazard. Do not use the device in the presence of flammable anesthetic mixtures with air, or with oxygen or nitrous oxide.

**⚠ WARNING** – Chemicals from a broken LCD display panel are toxic when ingested. Use caution when the device has a broken display panel.

**⚠ WARNING** – Routinely monitor the resident to make sure the device is functioning properly and the sensor is correctly placed.

**⚠ WARNING** – Oximetry measurements and pulse signals can be affected by certain environmental conditions, sensor application errors, and certain resident conditions.

**⚠ WARNING** – Use only sensors and extension cables approved by the manufacturer with the device. The use of accessories, sensors, and cables other than those specified may result in increased emission of electromagnetic radiation, invalid readings of the device, and/or personal injury.

**⚠ WARNING** – Failure to cover the sensor site with opaque material in high ambient light conditions may result in inaccurate measurements. The device is for attended monitoring only. Tissue damage may be caused by incorrect application or prolonged measurement using the sensor (more than 2 hours). Inspect the sensor periodically according to sensor user manual.

**⚠ WARNING** – The audio volume defaults to off. Ensure the alarm function is on and the volume is turned up if resident safety could be compromised. Ensure the speaker is clear of any obstruction and the speaker holes are not covered. Failure to do so could result in an inaudible alarm tone.

**⚠ WARNING** – The device is not defibrillator-proof. However, it can remain attached to the resident 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 device while using a defibrillator on a resident.

Disconnect the device and sensor from the resident during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns.

**⚠ WARNING** – The oximeter must be operated only by trained personnel.

**⚠ WARNING** – Do not make any clinical judgment based solely on the device. It is intended only as an adjunct in resident assessment. It must be used in conjunction with clinical signs and symptoms.

**⚠ WARNING** – Do not lift the device by the sensor or extension cable because the cable could disconnect from the device and the device may drop on the resident. Do not place the device in any position that might cause it to fall on the resident.

**⚠ WARNING** – As with all medical equipment, carefully route resident cables to reduce the possibility of resident entanglement or strangulation.

**⚠ WARNING** – Don't mix new and old batteries together. Don't mix rechargeable batteries with alkaline batteries. Periodically check the battery for corrosion. Remove batteries from the device if you do not expect to use it within one month. Dispose of batteries in accordance with local ordinances and regulations.

## Introduction *(cont.)*

**⚠ WARNING** – Do not use damaged sensor or extension cables. Do not use sensor with exposed optical components.

**⚠ WARNING** – Operating the device outside of the measurement range may cause inaccurate results.

**⚠ WARNING** – The device must be installed and put into service according to the EMC Information provided in this user manual.

**⚠ WARNING** – Portable and mobile RF communications equipment can affect the device; refer to the recommended separation distances provided in Appendix A2 EMC Information.

**⚠ WARNING** – The use of resident cable and other accessories not supplied by the manufacturer may result in increased emissions or decreased immunity of the equipment.

**⚠ WARNING** – The device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, verify normal operation is possible in that configuration before starting to monitor residents.



## **⚠ CAUTIONS**

- To ensure accurate performance and prevent device failure, do not subject the device to extreme moisture, such as direct exposure to rain. Such exposure may cause inaccurate performance and/or device failure.
- Do not spray, pour, or spill liquid onto the device and its accessories, connector, switch or opening in enclosure, as this may damage the device.
- Do not immerse or wet the sensor, as this may damage the sensor.
- There are no user-serviceable parts inside the device. The device should only be serviced by qualified service personnel.
- All combinations of equipment must be in compliance with IEC/EN 60601-1-1 system requirements.
- The sensor unconnected icon and associated alarm indicate the sensor has become disconnected or it has a wire fault. Check the sensor connection and if necessary, replace the sensor, extension cables or both.
- When adjusting any menu parameters, the device does not display SpO<sub>2</sub> or PR, but it is still recording.

# Introduction *(cont.)*

## Symbols in the Device



TYPE BF APPLIED PART



Caution



General warning sign  
Background color – yellow  
Symbol and outline color – black  
The user manual is printed in black and white.



Operating instructions



Part number



Operating instructions  
Background color – blue  
Symbol color – white  
The user manual is printed in black and white.



SERIAL NUMBER



CE marking



AUTHORISED REPRESENTATIVE IN THE  
EUROPEAN COMMUNITY



Date of manufacture



MANUFACTURER



Disposal method



Caution: Federal (U.S.) Law restricts this device to sale by or on the order of a physician.



Input/output connector



General symbol for recovery/recyclable

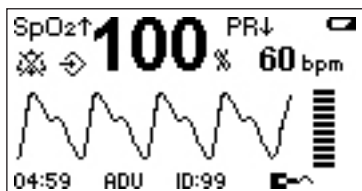
**IP22**

Ingress Protection IP22 (protected against vertically falling water drops when enclosure tilted up to 15°)

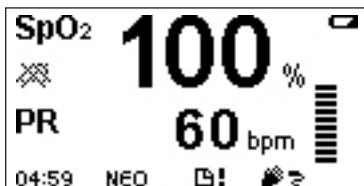


With respect to electrical shock, fire and mechanical hazards only in accordance with UL60601-1 and CAN / CSA C22.2 No. 601.1.

## Symbols on Screen















*Waveform Mode*



*Large Numeric Mode*

# Introduction *(cont.)*

## Symbols on Screen

<b>SpO<sub>2</sub></b>	SpO <sub>2</sub> value display area
<b>100%</b>	Measured SpO <sub>2</sub> %
<b>PR</b>	Pulse rate value display area
<b>60 bpm</b>	Measured pulse rate (bpm)
	Displayed when measurement value is higher than the upper alarm limit
	Displayed when measurement value is lower than the lower alarm limit
	SpO <sub>2</sub> waveform display
	Pulse amplitude display
	Low-battery icon
	Audio alarm off icon
	Alarm off icon
	Data storage icon
<b>04: 59</b>	Time display in Information area: "hour: minute"
<b>ADU/NEO</b>	Patient type in Information area: Adult or Neonate
<b>ID: 99</b>	Patient ID in Information area
	SpO <sub>2</sub> sensor unconnected icon
	SpO <sub>2</sub> sensor off
	Indicates the memory space is full
	Weak signal icon

**⚠ NOTE** – The icons for sensor unconnected, sensor off or weak signal are displayed in the lower right corner of the screen. Only one of these icons can be displayed at a time.

**⚠ NOTE** – 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.

## Box Contents

	Attendant Handheld Pulse Oximeter w/ traditional-style probe	Attendant Handheld Pulse Oximeter w/ sock-style probe
	Quantity	Quantity
Attendant Handheld Pulse Oximeter Main Unit	1	1
Traditional-Style Probe	1	
Sock-Style Probe		1
1.5V AA alkaline batteries	4	4
Protective Boot	1	1
Owner's Manual	1	1

## Optional Accessories:

Direct Supply

Part Number

- #40750** Replacement Traditional-Style Probe
- #40747** Replacement Sock-Style Probe
- #40748** Replacement Protective Boot
- #16666** Rechargeable Battery Pack & Charging Base
- #16667** Rechargeable Battery Pack

## Introduction *(cont.)*

### Front Panel Buttons

This section describes the buttons on the front panel of the device. 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.



*Front Panel Buttons*



#### **On/Off Button**

Turn on or off the device.

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

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

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

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



#### **Backlight Button**

The backlight is not available during Power-On-Self-Test (POST).

After the POST is complete, the backlight button turns the backlight on and off.



### Alarm Silence Button

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

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



### 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.

If the Trend Graph is set to ON, pressing the Up Arrow button in measurement state will display the latest 10-minute SpO<sub>2</sub> 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 decrease continuously. If the Trend Graph is set to ON, pressing the Down Arrow button in measurement state will display the latest 10-minute PR trend graph.

## Introduction *(cont.)*



### Function Button

During the POST, the **Function** button is not available. Press this button in normal measurement 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.

### Button Combination

To enter Data transfer state, turn device off, then simultaneously press the **On/Off** button and the **Function** button for 1 second.

### Connecting Sensor or Cable

The SpO<sub>2</sub> sensor and cable port is located on top of the device for connecting the SpO<sub>2</sub> sensor. An extension cable can be used between the device and the SpO<sub>2</sub> sensor. Only use cables approved by the manufacturer.

The cable for connecting the device to a PC for use with the Oximeter Viewer Data Management Software also connects to this port.



*Sensor and Cable Connecting Port*



*Type BF applied part*



*Auxiliary output connector*



## SIO definition:

PIN	Name	Description
1	RSGND	The RS232 GND
2	LED+	LED drive signal, IR Anode
3	LED-	LED drive signal, Red Anode
4	RXD	RS232 RX
5	Detector Anode	Detector anode
6	Connection	Detector connection
7	AGND	Analog GND
8	TXD	RS232 TX
9	Detector Cathode	Detector cathode

## Powered by Battery

The device can be powered by four 1.5V LR6 AA alkaline batteries. A new set of batteries can provide up to 48 hours of general operation, or about 24 hours of operation with the backlight and alarm on. The device does not support built-in recharging mode.

The device can also be powered by four 1.2V Ni-H rechargeable batteries.

## Battery Installation

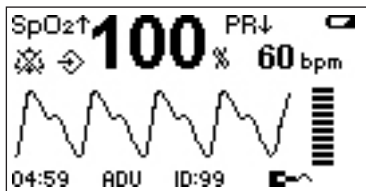
To install batteries:

1. Make sure the device has been turned off.
2. Pull the battery compartment cover downward toward the bottom of the device, and remove it.
3. Install four AA batteries according to the indications on battery compartment of the device.
4. Replace the battery compartment cover.

## Introduction *(cont.)*

### Low-Battery Icon

The low-battery icon displays and an alarm is given when a few minutes operation remains available. After the remaining minutes of operation, the device will turn off automatically. Replace the batteries.



*Low Battery Icon*

The device is compatible with Nellcor sensor and BCI DB9 sensor.

When selecting SpO<sub>2</sub> sensor, the following should be considered:

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

### Turning on the Device

The oximeter is turned on by pressing the **on/off** button. Then it will cycle through a Power-On-Self-Test (POST) before displaying valid data values. Verify all the circuitry and functions of the oximeter work properly during the POST. The device needs a few seconds to complete this verification procedure.

## Turning on the Device

**⚠ WARNING** – If the device does not function as described in this manual or functions incorrectly, **DO NOT USE THE DEVICE.**

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



While the device is cycling through POST, the Direct Supply Attendant logo and software version number is displayed as follows:



- The device enters POST (Power-On-Self-Test) immediately after power-on to confirm all the display segments and icons are shown and the speaker sounds a few seconds tone. If you do not hear the POST pass tone, it indicates the alarm system does not work well. Please do not use the Attendant hand Held Pulse Oximeter and contact qualified service personnel or your account manager and Directs Supply Equipment & Furnishings.
- If the POST is successful, the device enters the main interface.

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

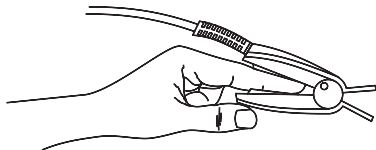
Error code	Indication
Battery Low	Indicates error for Low battery
Error 02	Indicates error for SpO <sub>2</sub> board
Error 03	Indicates error for Main control board

**⚠ NOTE** – The user can shift between waveform mode and large numeric mode by pressing the  button or  button.

# Measurement Procedure

## SpO<sub>2</sub> Measurement Procedure

1. Turn on the device.
2. Plug the SpO<sub>2</sub> sensor into the device.
3. Place the sensor on the resident's finger.



*Sensor Placement*

**⚠ WARNING** – Do not use the SpO<sub>2</sub> sensors if the packaging or the sensor is damaged. Contact Direct Supply for replacement sensors.

## Measurement Modes

There are two measurement modes: waveform mode and large numeric mode. The default measurement mode is waveform mode.

### Waveform Mode

In waveform mode, the device can measure arterial oxygen saturation and pulse rate, display oxygen saturation level and symbol (%SpO<sub>2</sub>) and PR on interface. It also displays a pulse bar graph and Plethysmogram.



*Figure 3-3 Waveform Mode*

### Large Numeric Mode

In large numeric mode, the device displays SpO<sub>2</sub>, oxygen saturation unit (%), PR, pulse rate unit (bpm), TEMP and temperature unit (°C) in a larger font.

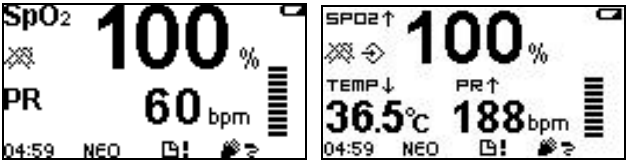
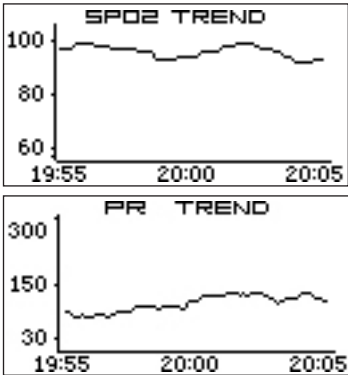


Figure 3-4 H100B & H100N Large Numeric Mode




## Measurement Procedure *(cont.)*


### Trend table:

TREND TABLE		
TIME	SPO2	PR
20:00:06	100	66
20:00:00	99	68
19:59:54	---	---
19:59:48	---	---
19:59:42	98	62

Figure 3-5 Display SpO<sub>2</sub> and PR Trend Table

### Abnormal Measurement State

If the SpO<sub>2</sub> sensor does not connect to the device, it will alarm and display  in the information area.

If the SpO<sub>2</sub> sensor falls off the finger, it will alarm and display  in the information area.

If the user leaves the device in menu or trend state for 30 seconds, the device will automatically return to measurement state.

If there are no measurement data or operations in the measurement state for 90 seconds, the device will automatically turn off.

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

### Data Transfer State

If the user sets **Data Storage** to **ON** in the menu, the device will store measured values. The SpO<sub>2</sub> and PR information can later be transferred from device to the Oximeter Viewer Data Management Software.

Data transfer procedure:

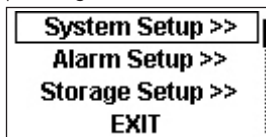
- After measurement and data storage is complete, turn off the device.
- Connect the cable between the device and computer for communicating with the Oximeter Viewer Data Management Software.
- Simultaneously press the **On/Off** button and **Function** button. After POST, the device will enter the Data Transfer State automatically. The interface displays as:



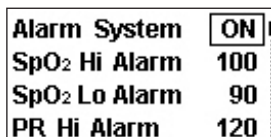
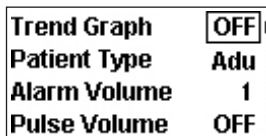
*Data Transfer State*

### System Menu

Press the **Function** button to see the main menu of device. Select items by pressing the **Up/Down** button, and confirm by pressing the **Function** button.

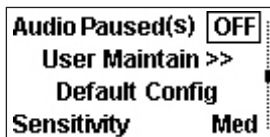


*Setup Menus*



*Alarm Setup Menus*

## Measurement Procedure *(cont.)*





System Setup Menus



Storage Setup Menu

### ⚠ NOTE

- The **SpO<sub>2</sub> Hi Alarm** and **SpO<sub>2</sub> Lo Alarm** are the upper and lower SpO<sub>2</sub> alarm limits of the device.
- The **PR Hi Alarm** and **PR Lo Alarm** are the upper and lower PR alarm limits of the device.
- Any user changes to the default value for **Lo Alarm** or **Hi Alarm** will not remain after the device is restarted.

**Trend Graph** functionality can be turned on and off from this menu. If the trend graph function is turned on, the user can shift among SpO<sub>2</sub> trend graph and PR trend graph by pressing the  button or  button.

**Patient Type** can be set to different measuring modes: **Adu** for Adult or Pediatric patient or **Neo** for Neonate patient. Set **Patient Type** to **Adu** or **Neo**, and confirm it by pressing the **Function** button.

**Alarm Volume** is used to adjust how loud the alarm is and ranges from 1 to 5. When **Alarm System** is **ON**, if Low alarm, Medium alarm or High alarm occurs, the device sounds a beep.

**Pulse Volume:** User can turn on or off the pulse volume with **Pulse Volume**, and change volume level to 1, 2, 3, 4, 5 or OFF. Press **Function** button to enter setup state, then use **Up Arrow** or **Down Arrow** button to choose, then confirm it with the **Function** button.



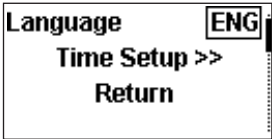
The device implements variable pulse tone whose frequency varies with the saturation.

**Audio Paused (s):** User can set the Audio Pause period for audio alarms to 30, 60, 90 or OFF.

When **Alarm System** is **ON**, pressing the **Alarm Silence** button will turn off the audio alarm. The pause period is set by the **Audio Pause** setting.

**User Maintain**

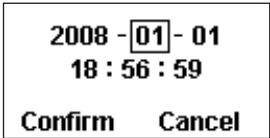
The following menu will display after pressing **User Maintain**:



*User maintain*

Language: English (ENG)

Time Setup: when this item is selected, the following interface is displayed:

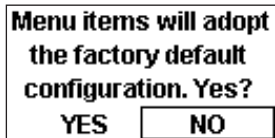


*Time Setup*

## Measurement Procedure *(cont.)*

### Default Config

If this menu item is selected, the following dialog box pops up:



*Factory Default Config*

Factory Default Configuration is as follows:

Measurement Mode:	Waveform
Trend Graph:	OFF
Patient Type:	ADU
Alarm System:	ON
Alarm Volume:	1
Pulse Volume:	OFF
Audio Alarm:	OFF
SpO <sub>2</sub> Hi Alarm:	100
SpO <sub>2</sub> Lo Alarm:	90
PR Hi Alarm:	120
PR Lo Alarm:	50
Patient ID No.:	1
Data Storage:	OFF

### Sensitivity

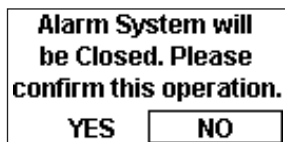
The SpO<sub>2</sub> reading is the average of data collected within a specific time. You can set the Sensitivity to Hi or Low via the menu.

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

## 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:



*Confirm to turn off alarm*

If **Alarm System** is **ON**, and an alarm occurs, the device gives a visual alarm and an audio alarm.

Pressing the **Alarm Silence** button can pause the audible alarm system for a specified amount of seconds. The audio alarm off icon will display, but the visual alarm is still active. For example, if the measured  $\text{SpO}_2$  value is higher than **SpO<sub>2</sub> Hi Alarm** or lower than **SpO<sub>2</sub> Lo Alarm**, there will be  or  icon display on screen, and the  $\text{SpO}_2$  or PR character will flash.

If **Alarm System** is set to **OFF**, both the audio alarm and visual alarm are turned off.

**⚠ WARNING** – When the alarm system is off, the device will not give an alarm prompt. Use this function with caution as it could endanger a resident's life.

## SpO<sub>2</sub> Alarm Setup

User can choose **SpO<sub>2</sub> Hi Alarm** and **SpO<sub>2</sub> Lo Alarm** in the menu to adjust  $\text{SpO}_2$  alarm limit. Press the **Up Arrow** or **Down Arrow** buttons to increase or decrease the alarm limit.

**SpO<sub>2</sub> Hi Alarm** and **SpO<sub>2</sub> Lo Alarm** in **Neo** mode are 95 and 90 by default respectively. In **Adu** mode, they are 100 and 90 by default, respectively.

## Measurement Procedure *(cont.)*

Set the SpO<sub>2</sub> alarm limits as follows:

- Choose **SpO<sub>2</sub> Hi Alarm** in the menu; press the **Function** button to enter setup. The **SpO<sub>2</sub> Hi Alarm** box will change from a real line box to a broken line box. The adjustable range for the SpO<sub>2</sub> value is 1 to 100.
- Press **Up Arrow** or **Down Arrow** buttons to increase or decrease values.
- Choose **SpO<sub>2</sub> Lo Alarm** in the menu, press **Function** button to set up. The **SpO<sub>2</sub> Lo Alarm** box will change from a solid line to a broken line box. The adjustable range for the lower limit of SpO<sub>2</sub> Alarm is from 0 to the upper limit of SpO<sub>2</sub> Alarm minus 1.
- Press the **Up Arrow** or **Down Arrow** buttons to increase or decrease values.
- **SpO<sub>2</sub> Hi Alarm** is always higher than **SpO<sub>2</sub> Lo Alarm** by at least 1%.
- Press the **Function** button and confirm the alarm range setup.
- Press the **On/Off** button to exit menu and return to measurement state.

### PR Alarm Setup

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

In default configuration setup, the **PR Hi Alarm** and **PR Lo Alarm** limits for **Neo** mode are 200 and 100, respectively. In **Adu** mode, they are 120 and 50, respectively.

Set the PR limits per the following procedure:

- Choose **PR Hi Alarm** in the menu and press the **Function** button to enter setup. The **PR Hi Alarm** box changes from a solid line to a broken line. The adjustable range of the upper limit of the PR Alarm is 1 plus the lower limit of the PR Alarm to 250.
- Press the **Up Arrow** or **Down Arrow** buttons to increase or decrease values.

- Choose **PR Lo Alarm** in the menu and press the **Function** button to enter setup. The **PR Lo Alarm** box changes from a solid line to a broken line. The adjustable range for the lower limit of the PR Alarm is 0 to the upper limit of the PR Alarm minus 1.
- Press the **Function** button and 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 measuring state.

### Patient ID No. Setup

The device can support 100 patient IDs and 300 hours of data storage time.

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 a solid line to a broken line.

After choosing an ID, press the **Function** button to confirm the setup. If the ID exists, a dialog box will pop up to confirm to overwrite the previous data.

<b>This ID's data will be covered. Continue ?</b>	
<b>YES</b>	<b>NO</b>

*Confirm to overwrite data*


### Data Storage

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

Patient ID cannot be changed during data storage. If the user wants to change ID, he should change the **Data Storage** to **OFF**, then setup a new ID.

## Measurement Procedure *(cont.)*

Data stored in the device can be exported through the Oximeter Viewer Data Management Software. Please refer to section Data transfer procedure.

**△ NOTE** – When the memory space is full, the  icon will be displayed in the Information Area. When this occurs, the **Data Storage** function turns **OFF** automatically. When restarting the device; a dialog box will pop up, and the user should confirm to delete all the data.

**The memory space  
is full. Please delete  
all ID's Data.**

**EXIT**

*Memory space is full*

**Delete All Data** deletes all the data stored in the device. Select this item by pressing the **Function** button. A dialog box pops up as follows:

**This operation will  
delete all the ID data.  
will you continue?**

**YES**

**NO**

*Deleting all the Data*

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

***All Data Deleting...***



*All Data Deleting*

## Exit (Return)

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

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

## Using the Ni-Mh Rechargeable Battery & Charging Stand

The charger stand is intended to be used for charging the Ni-MH rechargeable battery package.

### To charge the Ni-MH rechargeable battery package:

1. Turn off the device.
2. Place the device in the charger stand.
3. Connect one end of the power cord to the charger stand.
4. Plug the other end of the power cord into an AC outlet.



A tricolor LED display indicates the charging state. Red indicates there isn't a rechargeable battery package in the device or the device isn't placed properly in the charger stand. Orange indicates the device is being charged. Green indicates the charging is complete.

**⚠ CAUTION:** Do not operate the device while the rechargeable batteries are charging.

**⚠ CAUTION:** The AC plug is used as isolation means from AC outlet. Only recharge the device in an area where the user can easily unplug the charging stand from the AC outlet.

# Alarms

## Alarm Categories

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

1. **Physiological alarms**

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

2. **Technical alarms**

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

## Alarm Levels

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

1. **High Level Alarms**

The resident is in a life-threatening situation, indicating emergency treatment is needed.

2. **Medium Level Alarms**

The resident's vital signs appear abnormal or the device system status appears abnormal, indicating prompt operator response is required.

3. **Low Level Alarms**

The resident's vital signs appear abnormal or the device system status appears abnormal, indicating operator awareness is required.

The levels for both technical alarms and physiological alarms are predefined and cannot be changed by user.



## Alarm Categories Table

	High level alarm	Medium level alarm	Low level alarm
Physiological alarm	SpO <sub>2</sub> Too High SpO <sub>2</sub> Too Low PR Too High PR Too Low		
Technical alarm		SpO <sub>2</sub> Sensor Unconnected SpO <sub>2</sub> Sensor off Low Battery	

## Alarm Indicators

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

- Character flash
- Alarm tone

High level alarms: character flashes quickly and sounds a sequence of triple + double + triple +double beeps.

Medium level alarms: character flashes slowly and sounds a triple beep.


Low level alarms: character displays constantly and sounds a single beep.

## Alarms *(cont.)*

### **Alarm off Before the First Measurement**


Before the first measurement, the alarm system is configured to be off. At this time, if the SpO<sub>2</sub> sensor is unconnected or the sensor is off, the device will not alarm.

### **Alarm for SpO<sub>2</sub> Sensor Unconnected**

When the SpO<sub>2</sub> sensor is disconnected, the device will give a Medium alarm, and the  icon will display in the Information area.

It displays – in the SpO<sub>2</sub> and PR value area of the LCD and gives a Medium alarm (make sure Alarm System in menu is ON).

### **Alarm for SpO<sub>2</sub> Sensor Off**


When the SpO<sub>2</sub> sensor falls off from the finger, the device will give a Medium alarm, and the  icon will display in Information Area.

It displays – in the SpO<sub>2</sub> and PR value area of the LCD and gives a Medium alarm (make sure Alarm System in menu is ON).

### **Alarm for Low Battery**

When battery is low, the device will give a Medium alarm for low battery.


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

The low-battery  icon displays on the LCD and gives a Medium alarm (make sure the Alarm System in menu is ON).

### **Higher than Hi Alarm Limit**

If the measured  $\text{SpO}_2$  or PR value is higher than the Hi Alarm (upper alarm limit), the device gives a High alarm.


Here we take PR for example:

When the measured PR value is higher than the setup PR Hi Alarm, the device gives a High alarm (make sure Alarm System in menu is ON). A  icon displays near PR, which indicates the measured value is higher than that of the PR Hi Alarm value, and it will synchronously flash with the PR value.

### **Lower than Lo Alarm Limit**

If the measured  $\text{SpO}_2$  or PR value is lower than the Lo Alarm (lower alarm limit), the device gives a High alarm.

Here we take  $\text{SpO}_2$  for example:

When the measured  $\text{SpO}_2$  value is lower than the set  $\text{SpO}_2$  Lo Alarm limit, the device gives a Low  $\text{SpO}_2$  alarm. (Make sure Alarm System in menu is ON.) A  icon displays near  $\text{SpO}_2$ , which indicates the measured value is lower than that of the  $\text{SpO}_2$  Lo Alarm, and it will synchronously flash with  $\text{SpO}_2$  value.

### **Alarm Silence**

If Alarm System in menu is ON, pressing the Alarm Silence button will result in the audio alarm being paused for a period set by the user, but the visual alarm will still active.

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

## Alarms *(cont.)*

### **Alarm Delay**

There is a delay between a physiological event at the measurement site and the corresponding alarm at the device.

There are two reasons for this delay:

1. The time between the occurrence of the physiological event and when this event is represented by the displayed numerical values. This delay depends on the algorithmic processing time and the sensitivity setting. The lower the sensitivity configured, the longer the time needed until the numerical values reflect the physiological event.
2. The time between the displayed numerical values exceeding an alarm limit and the alarm indication on the oximeter. This delay is the combination of the configured alarm delay time plus the general system delay time.

### **Testing Alarms**

For further testing of individual measurement alarms, perform the measurement on yourself or use a simulator. Adjust alarm limits and check that appropriate alarm behavior is observed. Verify the appropriate alarm text is displayed on the device screen and the alarm sounds can be heard. This indicates the visual and auditory alarm indicators are functioning correctly.

# Maintenance

## **⚠ CAUTION**

Before using the device, perform the following checks:

- Check to see if there is any mechanical damage.
- Check to see if all of the cables, inserted modules and accessories are in good condition.
- Check all the functions of the device to make sure it is in good working condition.

**⚠ WARNING** – If you find any damage to the device, **STOP USING THE DEVICE ON RESIDENTS** and contact Direct Supply Equipment & Furnishings immediately.

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

The device does not require calibration.

If service is necessary, return device to Direct Supply Equipment & Furnishings.

## **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.

None of these safety checks require opening or disassembling the device. Only qualified customer service technicians should open or disassemble the device. The safety and maintenance checks can be performed by you. If you have questions regarding service, contact Direct Supply Equipment & Furnishings.

**⚠ WARNING** – If you do not follow a satisfactory maintenance schedule, the device may become invalid, and resident health may be endangered.

# Cleaning

- Ethanol (75%)
- Isopropanol (70%)

Cleaning agents should be applied and removed using a clean, soft, non-abrasive cloth or paper towel.

## **Cleaning the Oximeter:**

To surface-clean the oximeter, follow these steps:

1. Switch off the device and take out the batteries.
2. Wipe the entire exterior surface, including the screen, of the device using a soft cloth dampened with the cleaning solution thoroughly until no visible contaminants remain (Ethanol (75%) or Isopropanol (70%)).
3. Wipe off the cleaning solution with a fresh cloth or towel, dampened with tap water after cleaning until no visible cleaning agent remains.
4. Dry the device in a ventilated and cool place.

## **Cleaning the SpO<sub>2</sub> Sensor:**

1. Wipe the surfaces of the sensor and cable using a soft cloth dampened with the cleaning solution until no visible contaminants remain.
2. Wipe the resident contact area of the sensor with the cotton swab dampened with the cleaning solution until no visible contaminants remain.
3. Wipe off the cleaning solution with a fresh cloth or towel, dampened with tap water after cleaning until no visible cleaning agent remains.
4. Wipe off with a dry cloth to remove residual moisture.
5. Leave the sensor to air-dry.

## **Disinfecting**

Clean the oximeter and reusable accessories before they are disinfected. The validated disinfectants for cleaning the oximeter and reusable accessories are:

- Ethanol (75%)
- Isopropanol (70%)
- Cidex OPA (High level disinfection of intracavitary temperature probe only)

If Ethanol or Isopropanol is used for both cleaning and disinfecting, then a new cloth is required to be used for the disinfection step.

**⚠ WARNING** – The oximeter and reusable accessories shall be disinfected to avoid resident cross-infection.

### **Disinfecting the Device:**

**⚠ WARNING** – Before disinfecting the device, make sure the oximeter is switched off and batteries are taken out.

To disinfect the device, follow these steps:

1. Switch off the device and take out the batteries.
2. Wipe the display screen using a soft, clean cloth dampened with the disinfectant solution.
3. Wipe the exterior surface of the device using a soft cloth dampened with the disinfectant solution.
4. Wipe off the disinfectant solution with a dry cloth after disinfection if necessary.
5. Dry the device for at least 30 minutes in a ventilated and cool place.

### **Disinfecting the SpO<sub>2</sub> Sensor:**

1. Wipe the surfaces of the sensor and cable using a soft cloth dampened with the disinfection solution.
2. Wipe the resident contact area of the sensor with the cotton swab dampened with the disinfection solution.
3. Wipe off the disinfection solution with a dry cloth.
4. Leave the sensor to air-dry for at least 30 minutes.

**⚠ WARNING** – Sterilization may cause damage to the equipment and is therefore not recommended for this device.

**⚠ CAUTION** – Never use EtO or formaldehyde for disinfection.

The replacement of accessories, such as cables, sensors, etc., should be made based off of actual usage. It is recommended to replace accessories once a year.

# Principles of Operation

The device adopts a noninvasive double wavelength to measure  $\text{SpO}_2$  and PR. It can perform spot measuring and continuous measuring for a short time.

The system consists of a Central Processing Unit, Signal Collection, Signal Input, Data Output, Display and User Input module, shown as follows:



*System Principle*

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

## **Pulse Oximetry Measurement**

The device uses oximetry to measure functional oxygen saturation in the blood. Pulse oximetry works by applying a sensor to a pulsating arteriolar vascular bed, such as a finger or 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 ( $\text{SpO}_2$ ). Because a measurement of  $\text{SpO}_2$  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 device determines  $\text{SpO}_2$  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 device 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 device bases its  $\text{SpO}_2$  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 absorbers such as tissue, bone and venous blood.

## **Wavelength**

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

## Principles of Operation *(cont.)*

### **Functional vs. Fractional Saturation**

This device 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:

### **Measured vs. Calculated Saturation**

When saturation is calculated from a blood gas partial pressure of oxygen (PO<sub>2</sub>), the calculated value may differ from the SpO<sub>2</sub> measurement of a device. This usually occurs because the calculated saturation was not appropriately corrected for the effects of variables that shift the relationship between PO<sub>2</sub> and pH, the partial pressure of carbon dioxide (PCO<sub>2</sub>), 2,3-DPG and fetal hemoglobin.

### **Performance Verification**

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

### **Oximeter Performance Considerations**

There are some resident conditions that can affect the device's measurements.

### 1. **Dysfunctional Hemoglobins**

Dysfunctional hemoglobins, such as carboxyhemoglobin, methemoglobin and sulfhemoglobin, are unable to carry oxygen. SpO<sub>2</sub> readings may appear normal, but a resident may be hypoxic because less hemoglobin is available to carry oxygen. Further assessment beyond the use of a pulse oximeter is recommended.

### 2. **Anemia**

Anemia causes decreased arterial oxygen content. Although SpO<sub>2</sub> readings in an anemic resident may appear normal, the resident may be hypoxic. Correcting anemia can improve arterial oxygen content. The device may fail to provide an SpO<sub>2</sub> reading if hemoglobin levels fall below 5 gm/dl.

### 3. **Saturation**

The device displays a saturation level between 1% and 100%.

### 4. **Pulse Rate**

The device displays a pulse rate between 30 and 254 beats per minute (bpm). The sensor accuracy ranges do not apply to pulse rates above 254 bpm.

## **Sensor Performance Considerations**

Inaccurate measurements may be caused by:

- Incorrect use of the sensor
- Placement of the sensor on an extremity with a blood pressure cuff, arterial catheter or intravascular line
- Excessive resident activity
- Intravascular dyes, such as indocyanine green or methylene blue
- Externally applied coloring, such as nail polish or pigmented cream
- Failure to cover the sensor site with opaque materials in high ambient light conditions
- Venous pulsation
- Dysfunctional hemoglobin
- Low perfusion

## Principles of Operation *(cont.)*

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

- The sensor is applied too tightly
- Defibrillation
- 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
- Poor peripheral perfusion
- Loss of pulse/cardiac arrest

To use the sensor:

- Select an appropriate sensor.
- Clean and remove any substances, such as nail polish, from the application site.
- Apply the sensor as directed, and observe all warnings and cautions presented in the sensor user manual.
- Periodically check to ensure the sensor remains properly positioned on the resident.

High ambient light sources that can interfere with the performance of the 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 the sensor is properly applied, and cover the sensor site with opaque material.

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

- Verify the sensor is properly and securely applied.
- Move the sensor to another site.
- Use an adhesive on the sensor.
- Use a new sensor with fresh adhesive backing.
- Keep the resident still, if possible.

## Limited Warranty

We offer to you, as the original purchaser, a warranty for the Attendant Handheld Pulse Oximeter. Our warranty applies for the limited warranty period stated below. If any device or device part listed below is defective in material or workmanship during the applicable limited warranty period, we will repair or replace it at our cost. Please note that the decision to repair or replace a device or device part will be at our discretion. Our warranty applies only if the device is properly maintained by the original purchaser for normal, indoor use and does not cover normal wear and tear, modification of the device, or damage caused by abuse, improper use, failure to maintain, use which exceeds the published device limitations, or the combination of any device with another product. In addition, our warranty does not cover fading, colorfastness, stains, spills, or exposure to chemicals, odors, heat or light. In certain cases, we may provide you repair or adjustment instructions and/or replacement parts, and ask you to perform a repair or adjustment or replace a defective part.

Our warranty gives you specific legal rights, and you may also have other rights, which vary, from state to state. Please note that our limited warranty period begins when we ship the device to you. The limited warranty period and our obligations under the warranty end once you transfer the device to someone else, or at the end of the applicable limited warranty period identified below, whichever is earlier.

<b>Product/Part</b>	<b>Warranty (Parts)</b>	<b>Anticipated Usable Device Life</b>
Attendant Handheld Pulse Oximeter (excluding batteries and accessories)	3 years	3 years
Attendant Handheld Pulse Oximeter probes	1 year	1 year

## Limited Warranty *(cont.)*

Anticipated Usable Device Life is based on normal use with proper maintenance, cleaning and storage. You should still inspect, monitor and care for the device as described in this guide, as the device may need to be replaced sooner than anticipated in particular situations.

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# 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	IP22
Mode of operation	Continuous measuring and spot checking
Compliance with safety standards:	IEC 60601-1:2005, +A1:2012 EN 60601-1:2006, +A1:2013 IEC 60601-1-2:2007, EN 60601-1-2:2007; ISO 80601-2-56:2009, ISO 80601-2-61:2011

## A1.2 Specification

### A1.2.1 Size & Weight

Size	160mm (L)×70mm (W)×37.6mm (H)
Weight	165 (g) (without battery)

### A1.2.2 Environment

Temperature	
Working	+32°F - +104°F
Storage	-4°F - +131°F
Humidity	
Working	15% - 95% (non condensing)
Storage	15% - 95% (non condensing)
Atmospheric pressure	
Working	70 kPa - 106 kPa
Transport and storage	70 kPa - 106 kPa





## Appendix I: Specification *(cont.)*

### A1.2.3 Display

Screen Type	128×64 dot-matrix LCD, with white LED backlight
Large Numeric Mode	SpO <sub>2</sub> , PR, and Bar graph displayed
Waveform Mode	SpO <sub>2</sub> , PR, Bar graph and Plethysmogram displayed

### A1.2.4 Batteries

Battery status symbols on screen

Battery power level	symbol
Level 1	 (Batteries are almost depleted and need to be replaced immediately. The device will turn off after 15 min. when battery low symbol appears.)
Level 2	
Level 3	
Level 4	

Alkaline batteries

Quantity	4
Total rated voltage	6 V
Capacity	2600 mAh
Typical operation time	48 hrs. or longer (At 25°C, with new fully charged batteries, SpO <sub>2</sub> measurement in use, backlight set to off, pulse volume set to 3, alarm volume set to 3 (without alarm triggered))



### Ni-MH rechargeable battery package

Charge/discharge cycle	≥500 times
Quantity	1
Total rated voltage	4.8 V
Capacity	1800 mAh
Typical battery life	36 hrs. or longer (At 25°C, with new fully charged batteries, SpO <sub>2</sub> measurement in use, backlight set to off, pulse volume set to 3, alarm volume set to 3 (without alarm triggered))
Charge time	No more than 2.5 hrs. to 80%
	No more than 4 hrs. to 100%
Quantity	1
Total rated voltage	4.8 V
Capacity	1500 mAh

### A1.3 Parameters

#### Measurement Range

SpO <sub>2</sub>	0% - 100%
PR	25 bpm - 300 bpm

#### Alarm Range

SpO <sub>2</sub>	0% - 100%
PR	0 bpm - 300 bpm

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

Saturation	
Adult and Pediatric	± 2% (70% - 100%) Undefined (0% - 69%)
Neonate	± 3% (70% - 100%) Undefined (0% - 69%)

#### Pulse Rate Accuracy

25 bpm ~ 300 bpm	± 2 bpm
------------------	---------

#### Resolution

SpO <sub>2</sub>	1%
Bpm	1 bpm

# Appendix II: EMC Information

## Guidance and Manufacturer'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

<b>Guidance and manufacturer's declaration – electromagnetic emissions</b>		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should ensure it is used in such an environment.		
<b>Emissions test</b>	<b>Compliance</b>	<b>Electromagnetic environment -guidance</b>
RF emissions CISPR11	Group 1	The device 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	
Harmonic emissions IEC/ EN61000-3-2	N/A	
Voltage fluctuations/ flicker emissions IEC/ EN61000-3-3	N/A	The device is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purpose.

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

<b>Guidance and manufacturer's declaration – electromagnetic immunity</b>			
The oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the oximeter should ensure it is used in such an environment.			
<b>Emissions test</b>	<b>Compliance</b>	<b>Compliance level</b>	<b>Electromagnetic environment - guidance</b>
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 ±1kV for input/output lines (>3m)	N/A	Mains power quality should be that of a typical commercial or hospital/Skilled Nursing environment.
Surge IEC/EN61000-4-5	±1kV for power differential mode ±2kV common mode	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  40% UT (60% dip in UT) for 5 cycles  70% UT (30% dip in UT) for 25 cycles  <5% UT (>95% dip in UT) for 5s	N/A	Mains power quality should be that of a typical commercial or hospital/Skilled Nursing environment. If the user of the device requires continued operation during power mains interruptions, it is recommended 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/Skilled Nursing environment.

## A2.3 Electromagnetic emissions for non-Life-Supporting 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 ensure it is used in such an environment.

Immunity test	IEC/EN 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC/EN 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the oximeter (including cables) than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  <b>Recommended separation distance</b> $d = 1.2 \sqrt{P}$ 150 kHz to 80 MHz $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz 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).
Radiated RF IEC/EN 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

**NOTE 1** At 80 MHz and 800 MHz, the 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.

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 $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.74
1	1.2	1.2	2.3
10	3.8	3.8	7.4
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance  $d$  in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where  $P$  is the maximum output power rating of the transmitter in watts (W) – according to the transmitter manufacturer.

**NOTE 1** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

**NOTE 2** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

## Appendix III Record Table

ID No.	Name	Time	SpO <sub>2</sub>	PR	NOTE

## Appendix IV Abbreviations

Abbr	English Full Name/Description
CISPR	International Special Committee on Radio Interference
EEC	European Economic Community
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 <sub>2</sub>	Arterial Oxygen Saturation From Pulse Oximeter

## Customer Service

Our promise to you is that you will have a convenient and easy ordering experience, receive a quality pulse oximeter, and enjoy outrageous customer service. If you have any questions about the pulse oximeter you have purchased or would like to request warranty service, please contact:

**Direct Supply Equipment & Furnishings®**,  
1-800-634-7328, 6767 North Industrial Road, Milwaukee, WI  
53223, SalesSupport@DirectSupply.com



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