H100B/H100N

Pulse Oximeter

Version 2.7

User Manual

CE 0123

EDAN

About this Manual

P/N: 21.54.109000
MPN: 21.54.109000027
Release Date: August, 2020

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) cannot be held liable.

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Responsibility of the Manufacturer

EDAN only considers itself responsible for any effect on safety, reliability and performance of the equipment if:

Assembly operations, extensions, re-adjustments, modifications or repairs are carried out by persons authorized by EDAN, and

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

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

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

Warnings are identified by the WARNING symbol shown above.

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 Pulse Oximeter (hereinafter called 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 of covering 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.

8 The oximeter is a prescription device to be operated only by trained personnel. The oximeter is for attended measuring only.

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

WARNING

10 The oximeter is not defibrillator-proof. 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.

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 immerse or wet the sensor, as this may damage the sensor.

14 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

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

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

17 As with all medical equipment, carefully route patient cables to reduce the possibility of patient entanglement or strangulation. It is especially important for children.

18 Please avoid inhalation or swallowing of small parts.

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

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

WARNING

21 Use only EDAN permitted sensors and extension cables with the oximeter. Other sensors or extension cables may fail and/or cause improper monitor performance and/or minor personal injury.

22 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.

23 Don’t mix new and old batteries together. Don’t mix rechargeable batteries with alkaline batteries.

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

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

26 This equipment is not intended for home usage.

WARNING

27 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 oximeter and contact qualified service personnel or your local EDAN representative. Do not use the oximeter if the POST has not been finished successfully.

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

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

30 A potential hazard can exist if different alarm presets are used for the same or similar equipment in any single area, e.g. an intensive care unit or cardiac operating room.

WARNING

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

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

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 Do not service or maintain the oximeter or any accessory which is in use with the patient.

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

36 Incorrect replacement of batteries would result in unacceptable risk. The batteries shall be replaced by adequately trained personnel.

37 Operation of the equipment exceeding specified physiological signal or the operational specification may cause inaccurate results.

WARNING

38 Patient's weak pulse or disturbed SpO_2 signal may affect measurement and alarm accuracy.

39 The medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC Information provided in this user manual.

40 Portable and mobile RF communications equipment can affect medical electrical equipment; refer to the recommended separation distances provided in Appendix A2 EMC Information.

41 The use of patient cable and other accessories not supplied by the manufacturer may result in increased emissions or decreased immunity of the equipment.

42 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.

WARNING

43 The oximeter should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, you must check that normal operation is possible in the necessary configuration before you start measuring patients.

44 Only recommended rechargeable batteries and charger stand can be used for oximeter.

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

46 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.

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

48 Do not place battery in the oximeter with the (+) and (-) in the wrong way.

WARNING

49 Verification of the temperature module is necessary as frequently as dictated by your Hospital Procedures Policy. When you need to calibrate the temperature measurement, please contact the manufacturer.

50 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.

51 Do not touch accessible parts of medical or non-medical electrical equipment in the patient environment and the patient simultaneously.

52 The simultaneous use of cardiac pacemaker and other patient-connected equipment may cause safety hazard.

53 The device should keep away from pets, pests or children.

WARNING

54 Without use of data store function, the data previously measured will be cleared when the oximeter is powered off. With use of data store function, 300-hour SpO_2&PR data can be stored and transmitted to the computer.

55 During measuring, if the power supply is off, the oximeter will be off, and only the patient information and alarm settings can be saved. After reconnecting the power supply, the user should turn on the oximeter for measuring.

56 If several items of medical equipment are interconnected, pay attention to the sum of the leakage currents, otherwise it may cause shock hazard. Consult your service personnel.

57 Before using the device, the equipment, patient cable and sensors etc. should be checked. Replacement shall be taken if there is any evident defect or signs of aging which may impair the safety or performance.

WARNING

58 Correct and proper sensor application: if the sensor is too loose, it might compromise the optical alignment, and even cause the sensor to fall off. If the sensor is too tight, (such as the application site is too large or becomes too large due to edema), excessive pressure and local tissue ischemia, hypoxia and lack of nutrition may occur on the application site. Prolonged and continuous measuring may increase the risk of skin irritations or lacerations. To avoid these damages, users should periodically check surrounding skin of application site according to the patient's condition and pressure sensor, inspect if there is sign of stress-related damage in surrounding tissue, and regularly change the application site. For the patients whose fluid is easy to transfer and/or the patients with systemic or localized edema, users should inspect the skin and change application site more frequently.

WARNING

59 No modification of this equipment is allowed without authorization of the manufacturer. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe operation.

60 When serious arrhythmia is present, the SpO_2 pulse rate may differ from ECG heart rate but this does not indicate an inaccurate PR (SpO_2) value.

61 Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the oximeter, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

WARNING

62 EDAN rechargeable battery lifetime is 500 charge/discharge cycles if the battery is appropriately used and maintained. The service life of the battery depends on the service frequency and time. The service life of the battery is about two years if the battery is well maintained and stored. The service life of the battery may shorten if it is used inappropriately. If the battery life is exhausted and not replaced in time, it may cause damage or heat to the device.

1.2 Cautions

Cautions are identified by the CAUTION symbol shown above.

Cautions alert the user to exercise care necessary for the safe and effective use of the oximeter.

CAUTION

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

2 When adjusting any menu parameters, the oximeter does not display SpO_2 or PR or TEMP, but it is still recording.

3 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.

4 Oximeter will not operate with dead batteries. Install new batteries.

5 Do not run the oximeter when alkaline batteries of different types are used at the same time.

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

CAUTION

7 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 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.

CAUTION

8 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, third edition). These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

2 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 SpO_2, Pulse rate and TEMP are being reported;
- No error conditions exist.

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

4 Do not disinfect the probe with the water boiled.

5 Any residue should be removed from the probe before being disinfected, and avoid contacting corrosive solvent. Dipping 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.

6 After measuring, disinfect the probe according to the instruction described in the user manual.

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

8 A functional tester or simulator cannot be used to assess the accuracy of the pulse oximeter probe or the pulse oximeter. However, it can be used to demonstrate that a particular oximeter reproduces a calibration curve that has been independently demonstrated to meet a particular accuracy.

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

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

11 If there is independent demonstration that the particular calibration curve is accurate for the combination of a pulse oximeter and a pulse oximeter probe, then a functional tester can measure the contribution of an oximeter to the

total error of an oximeter/probe system. The functional tester can then measure how accurately a particular pulse oximeter is reproducing that calibration curve.

12 SpO_2 waveform is not directly proportional to the pulse volume.

13 When there's measurement beyond range, invalid measurement or no measurement value, it will display “---”.

14 The reference body site temperature is the same as the temperature of the measuring site.

15 Ensure the volume is properly set up. When the sound pressure of audible alarm is below or equivalent to the ambient noise, it may be difficult for the operator to distinguish the audio alarm.

16 Ensure that the environment in which the oximeter is used is not subject to any sources of strong electromagnetic interference, such as radio transmitters, mobile telephones, microwaves, etc.

17 The oximeter can only be used on one patient

at a time.

18 The device is calibrated to display functional oxygen saturation.

1.4 Symbols in the Oximeter

1		TYPE BF APPLIED PART
2		Caution
3		Warning (Background: yellow; Symbol and outline: black)
4		Operating instructions
5	P/N	Part Number

6		Refer to instruction manual/booklet (Background: blue; Symbol: white)
7	SN	Serial Number
8	CE 0123	CE marking
9	EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
10		Date of manufacture
11		Manufacturer
12		Disposal method

13	Rx Only	Caution: Federal (U.S.) Law restricts this device to sale by or on the order of a physician.
14		Input/output connector
15		General symbol for recovery/recyclable
16	IP22	Ingress Protection IP22 (Protected against access to hazardous parts with a finger; Protected against solid foreign objects of 12.5 mm Ø and greater; Protected against vertically falling water drops when enclosure tilted up to 15°)
17	ETL CLASSIFIED Intertek 4005997 (H100B)	Conforms to UL Std. 60601-1 Certified to CSA Std. C22.2 No 601.1

18		No alarm system
19		This way up
20		Fragile, handle with care
21		Keep dry
22		Use-by date

NOTE:

The user manual is printed in black and white.

2 Introduction

Intended Use/Indications for Use

The H100B Pulse oximeter is intended for spot-checking of functional arterial oxygen saturation (SpO_2) and pulse rate of single adult, pediatric or neonate patient in hospitals, intra-hospital transport and hospital type facilities.

H100N Pulse Oximeter (hereinafter called oximeter) is one model of H100 series Pulse Oximeter. The oximeter is intended for 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

H100B&H100N are models of H100 series Pulse Oximeter. They display SpO_2 value, pulse rate value, plethysmogram, bar graph, temperature (only for

H100N), etc.

H100B is installed with EDAN SpO_2 module inside. H100N is installed with Nellcor SpO_2 module and the manufacturer's TEMP module inside. They both integrate parameter module, display and data output functions. They can be powered by four 1.5 V AA batteries or four 1.2 V Rechargeable Ni-MH AA batteries. They can clearly display all the parameter information on LCD.

Figure 2-1 H100B&H100N Pulse Oximeter

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

You may frequently use the follow functions:

SpO_2 measuring (Refer to *Chapter 3 Oximeter Operation* for more information.)

Alarm (Refer to *Chapter 4 Alarm* for more information.)

2.2 Panel Introduction

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

2.2.1 Symbols on Screen

Figure 2-2 Waveform Mode

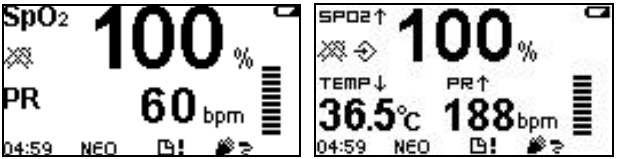


Figure 2-3 H100B&H100N Large Numeric Mode

Icons on the screen and their meanings:

SpO_2	SpO_2 value display area
100%	Measured SpO_2%
PR	Pulse Rate value display area
60 bpm	Measured Pulse rate (bpm)
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, Ped, Neo	Patient type in Information area: Adult, Pediatric 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 one second, the oximeter will enter data transfer state.

In the **Menu** state, press this button to return to the 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) cannot be silenced.
When **Alarm System** in menu is setup to **ON**, pressing the **Alarm Silence** button can turn off the 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 the menu to turn off the alarm. A Pop-up dialog box will display to confirm alarm setting. See details in 3.3.8.

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 one second to repeat the increment continuously.

When **Trend Review** is set to **ON**, press this button to enter the latest 10-minute SpO_2 or PR 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 one second to repeat the decrement continuously.

When **Trend Review** is set to **ON**, press this button to enter the latest 10-minute SpO_2 and PR trend table.

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 the **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 one 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 one second, the oximeter will enter Data transfer state.

2.2.3 Rear Panel

Figure 2-5 Rear Panel

2.3 Connecting Sensor or Cable

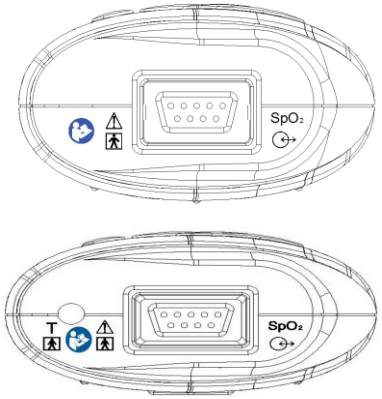


Figure 2-6 Sensor and Cable Connecting Port

SpO_2 Sensor and cable port is at the top of the oximeter. An extension cable can be used between the oximeter and the SpO_2 sensor. Use only the cable permitted by EDAN.

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

The temperature sensor port is only configured for H100N.

SIO definition:

H100B		
PIN	Name	Description
1	RSGND	The RS232 GND
2	LED+	LED drive signal, IR Anode
3	LED-	LED drive signal, Red Anode
4	RXD	H100 RS232 RX
5	Detector Anode	Detector anode
6	Connection	Detector connection
7	AGND	Analog GND
8	TXD	H100 RS232 TX
9	Detector Cathode	Detector cathode
H100N		
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 1.5 V LR6 AA alkaline batteries. It will operate for 48 hours 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 the Ni-MH rechargeable battery package.

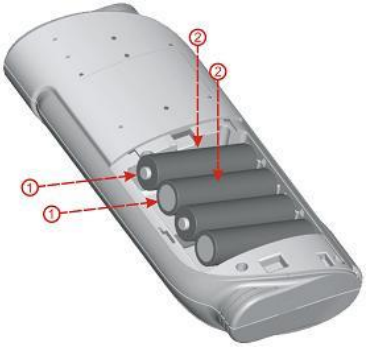
Battery Installation

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 Ni-MH rechargeable 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.

WARNING

In order to avoid safety hazards, do not disassemble the battery pack or use battery pack with signs of wear, otherwise it may lead to a fire.

Checking the Ni-MH Rechargeable Battery Package

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

1. Disconnect the oximeter from the patient and stop all measuring procedures.

2. Place the oximeter in the charger stand and connect the AC mains. Allow the battery to be charged uninterruptedly for above 2.5 hours. For details about charging the Ni-MH rechargeable battery package, please refer to *section 3.5*.
3. Disconnect AC mains and allow the 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 Ni-MH rechargeable 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 there isn't sufficient battery energy. Replace the batteries.

Figure 2-7 Low Battery Icon

2.5 Accessory List

Standard configuration including:

Items	P/N
H100B Pulse Oximeter Main Unit	02.06.109006
H100N Pulse Oximeter	02.06.110185
1.5V AA alkaline batteries (IEC LR6)	01.21.064086
SH1 Adult Reusable SpO_2 Sensor (H100B)	02.01.210120
Nellcor Reusable Adult SpO_2 Sensor (DS-100A OxiMax) (Weak Perfusion Resistance) (H100N)	01.15.30043
Skin Temperature Probe (H100N)	01.15.040188
Carrying case	11.56.110165

Optional configuration including:

Items	P/N
Protective Cover	01.51.110164
Battery charger (H100N)	02.06.112410

Items	P/N
EDAN SH3 Neonate Wrap Sensor (reusable) (H100B)	02.01.210673
EDAN SH4 Adult Silicone Soft-tip SpO_2 Sensor (DB9, Only compatible with EDAN SpO_2 module and EDAN SpO_2 extension cable) (H100B)	02.01.210122
Nellcor Reusable Adult/Neonate SpO_2 Sensor (OXI-A/N OxiMax) (Weak Perfusion Resistance)	01.15.40096
H100 SpO_2 extension cable	01.13.110504
Rectal/Oral Temperature Probe	01.15.040424
Oximeter Viewer Data management software	02.05.109016
USB to series cable (For H100N)	01.13.110200
Series cable (For H100B)	01.13.109038
Charger stand	83.60.112409
Charger stand	83.60.316030
4.8 V Ni-MH rechargeable battery	21.21.064164
MAX-FAST, Adult/Pediatric, RoHS, OxiMax	01.57.040436

Items	P/N
OXI-P/I, Pediatric/Infant, RoHS, OxiMax	01.57.040437
D-YS, Multisite, RoHS, OxiMax	01.57.040438
MAX-A/MAX-AL, Adult, RoHS, OxiMax	01.57.040440
MAX-N, Neonatal/Adult, RoHS, OxiMax	01.57.040441
MAX-I, Infant, RoHS, OxiMax	01.57.040442
MAX-P, Pediatric, RoHS, OxiMax	01.57.040445

NOTE:

The part name may vary depending on context, but the part number is constant.

H100N 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 measuring.

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 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 EDAN LOGO is shown.

Figure 3-1 EDAN LOGO

- Secondly the product model is displayed.

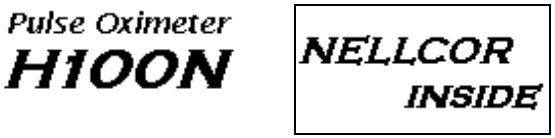


Figure 3-2 Model

- If the POST is successfully finished, the oximeter sounds a tone and enters the waveform interface.

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

H100B	
Error code	Indication
Battery Low	Indicates error for low battery
Error 02	Indicates error for SpO_2 board
Error 03	Indicates error for main control board
H100N	
Error code	Indication
Battery Low	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 Procedure

3.2.1 SpO_2 Measurement Procedure

Select the correct patient category setting (adult/pediatric and neonatal), as this is used to optimize the calculation of the SpO_2 and pulse numerics.

During measurement, ensure that the application site:

– has a pulsatile flow, ideally with a good circulation perfusion.

– has not changed in its thickness, causing an improper fit of the sensor.

1. Switch on the oximeter.
2. Attach the sensor to the appropriate site of the patient.

Before Applying the Sensor:

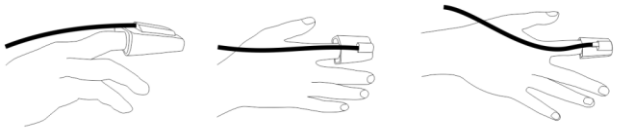
Be sure to understand all warnings listed in the previous section before applying any sensor to a patient. Also, check the sensor as follows:

- Check the sensor outside and inside. To inspect the inside, gently open the sensor cavity and check splits on or next to the transparent silicone that covers the optical elements.

- Any sensor showing signs of damage or alteration must not be used for further patient measuring; instead, dispose of it using proper disposal procedures.

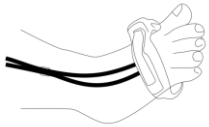
Applying Finger/Soft-tip Sensors:

- Nip the clamp, and choose a site that is well perfused and restricts a conscious patient's movements least. The ring finger of the non-dominate hand is preferred. Alternatively, the other fingers on the non-dominate hand may be used.
- The big toe or long toe (next to the big toe) may be used on restrained patients or patients whose hands are unavailable.
- Place the finger into the sensor according to the direction of the symbol on the sensor. Adjust the finger to ensure that the pad of the finger completely covers the sensor detection window.
- Orient the sensor so that the cable will be running towards the top of the patient's hand.
- Connect the sensor with the oximeter (or with the extension cable if needed).



Applying Neonatal Finger (or Toe) Wrap Sensors:

- When you perform the measurement, position the sensor over the hand or foot with optical components opposite each other.
- Hold the sensor, and insert stretched strap into slot, hold it there while threading end through latch. If strap is too long, thread it through second latch.
- Connect the sensor with the oximeter (or with the extension cable if needed).



3. Plug the connector of the sensor extension cable into the SpO_2 socket.

WARNING

1 Inspect the application site every two to three hours to ensure skin quality and correct optical alignment. If the skin quality changes, move the sensor to another site. Change the application site at least every four hours. For neonate, change the measuring site every 20 minutes.

2 Do not use the SpO_2 sensors if the packaging or the sensor is damaged and return them to the vendor.

3 If the SpO_2 sensor cannot work properly, please reconnect the sensor or change a new one.

NOTE:

1 Avoid placing the sensor on extremities with an arterial catheter, intravascular venous infusion line, or inflated NIBP cuff.

2 If the surrounding temperature increases, the operator should pay attention to the site of poor perfusion, and increase the frequency of checking the skin and changing the

measurement site to prevent burns. If the initial skin temperature is less than 35°C, the temperature of all the listed sensors on the skin will not exceed 41°C during working.

3 When a trend toward patient deoxygenation is indicated, analyze the blood samples with a laboratory co-oximeter to completely understand the patient's condition.

4 Injected dyes such as methylene blue or intravascular dyshemoglobins such as methemoglobin and carboxyhemoglobin may lead to inaccurate measurements.

5 Inspect the sensor to ensure that the light emitter and receiver are aligned with each other and there is no gap between the sensor and the finger. All the light emitted by the light emitter must pass through the patient's tissue.

3.2.2 TEMP Measurement Procedure

TEMP Measurement Procedure

1. With a reusable TEMP probe you can plug the probe directly into the TEMP connector.
2. Apply the TEMP probes securely to the patient.

3. Switch on the oximeter.

It takes 5 minutes for the temperature measurement to stabilize.

The patient is an intended operator. Follow the steps above for measurement.

3.3 Measurement State

3.3.1 Measurement Modes

There are two measurement modes which are waveform mode and large numeric mode. By default, H100B configuration is waveform mode and H100N configuration is 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.

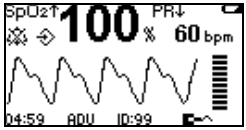


Figure 3-3 Waveform Mode

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.

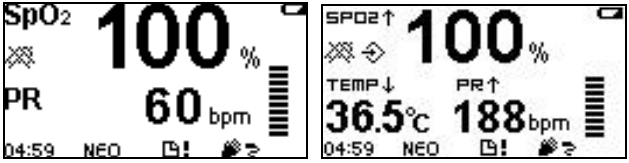
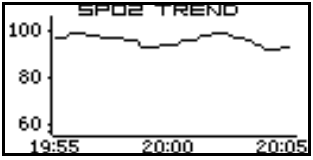


Figure 3-4 H100B&H100N Large Numeric Mode

3.3.2 Trend Graph and Trend Table

When **Trend Review** is set to **ON**, press the **Up Arrow** button to enter the latest SpO_2 or PR trend graph, and press the **Down Arrow** button to enter latest 10-minute SpO_2 and PR trend table. Shift the pages by pressing the **Up Arrow** or **Down Arrow** button. In trend review interface, the oximeter does not store trend data.

Trend graph:



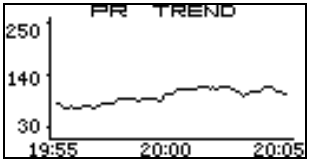


Figure 3-5 Display SpO_2 and PR Trend Graph

Trend table:

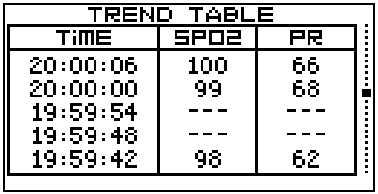


Figure 3-6 Display SpO_2 and PR Trend Table

3.3.3 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 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 any responsible signals for 10 minutes, it will turn off automatically.

3.3.4 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 Oximeter 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 the communication between the oximeter and the Oximeter Viewer Data Management Software;
- Synchronously press the **On/Off** button and the

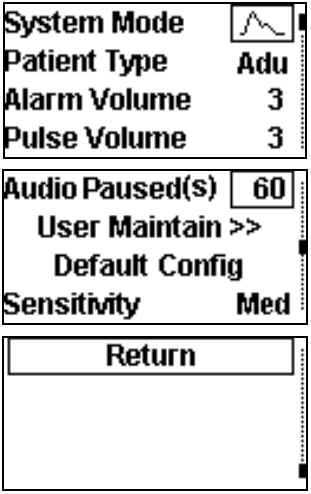
Function button, after POST, the oximeter enters Data Transfer State automatically. The interface displays as below:

Figure 3-7 Data Transfer State

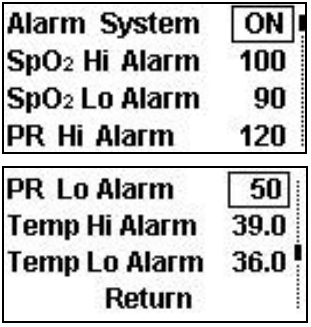
3.4 System Menu

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

System Setup >>:



Alarm Setup >>:



Storage Setup >>:

Figure 3-8 Menus

The menus are shown above and the details for each item will be introduced in the following sections.

NOTE:

1 **SpO_2 Hi Alarm** and **SpO_2 Lo Alarm** stand for the upper and lower alarm limits of SpO_2 respectively.

2 **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 the corresponding patient type.

3.4.1 System Mode

There are two items for selecting:

Waveform mode 

Large numeric mode 

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

3.4.2 Patient Type

Patient Type can be set to different measurement modes.

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

NOTE:

When **patient type** is changed to **Neo**, please use the Neonate SpO_2 Sensor for accurate measurement.

3.4.3 Alarm Volume

The **Alarm Volume** button is used to adjust alarm volume and its range is from one to five.

When **Alarm System** is setup to **ON**, if a low alarm, a

medium alarm or a high alarm occurs, the oximeter sounds beep.

3.4.4 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, then use the **Up Arrow** or the **Down Arrow** button to choose, then confirm it by pressing the **Function** button.

The oximeter implements variable pulse tone and its frequency varies with the saturation. Beat frequency of pulse has positive correlation with measurement value.

3.4.5 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 the **Audio Paused (s)**.

3.4.6 User Maintain

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

Figure 3-9 Enter Password

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

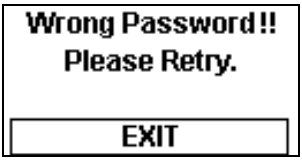


Figure 3-10 Wrong Password

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

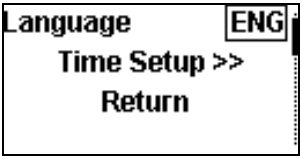


Figure 3-11 User Maintain

- 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:

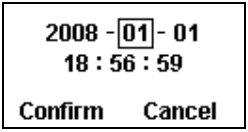


Figure 3-12 Time Setup

● Trend Review: the user can choose whether to turn on or off the trend review function.

NOTE:

1 If the system is not used for a longer period of time, its system time may be inaccurate. In this case, readjust the system time after powering on.

2 If the system time cannot be saved and resumes the default value after restart, contact the service department of EDAN to replace the button cell in main board.

3.4.7 Default Config

Choose this item to resume factory default configuration. A dialog box pops up:

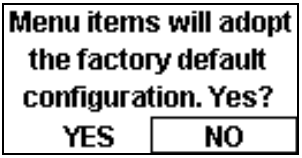


Figure 3-13 Factory Default Config

Factory Default Configuration is shown as follows:

System Mode:	 (H100B)
	 (H100N)
Patient Type:	Adu
Alarm System:	ON
Alarm Volume:	3
Pulse Volume:	3
Audio Paused (s):	60
SpO_2 Hi Alarm:	100
SpO_2 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
Trend Review:	OFF

3.4.8 Sensitivity

The SpO_2 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.

3.4.9 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:

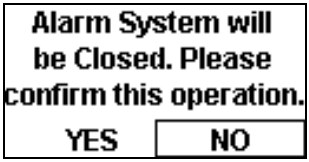


Figure 3-14 Confirm to Turn off Alarm

If **Alarm System** is **ON** and an alarm occurs, the oximeter will give a visual alarm and an audio alarm.

Pressing the **Alarm Silence** button can pause the alarm system for seconds (the pause period can be set to 30, 60, 90 or 120s by the user, see section *3.4.5*), 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.

3.4.10 SpO_2 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, 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 SpO_2 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 SpO_2 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 SpO_2 Alarm - 1". If the value of SpO_2 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, confirm the alarm range setup.
- Press the **On/Off** button to exit the menu, and return to measurement state.

WARNING

High oxygen levels may predispose a premature infant to retrolental fibroplasia. If this is a consideration do NOT set the high alarm limit to 100%, which is equivalent to switching the high limit alarm off.

3.4.11 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 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.

3.4.12 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.

3.4.13 Patient ID No. Setup

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

When entering 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.

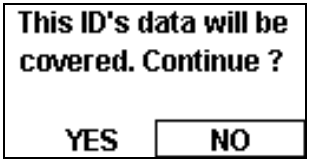


Figure 3-15 Confirm to Cover Data

3.4.14 Data Storage

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

During the data storage, patient ID cannot 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 Oximeter Viewer Data Management Software. Please refer to *section 3.3.4* for Data transfer procedure.

When the memory space is full, an icon will be displayed 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 3-16 Memory Space Full

3.4.15 Delete 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:

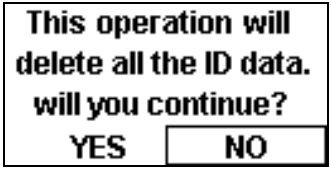


Figure 3-17 Delete All the Data

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

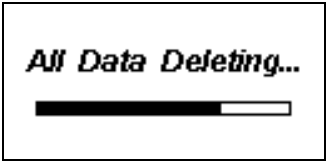


Figure 3-18 All Data Deleting

3.4.16 Exit (Return)

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

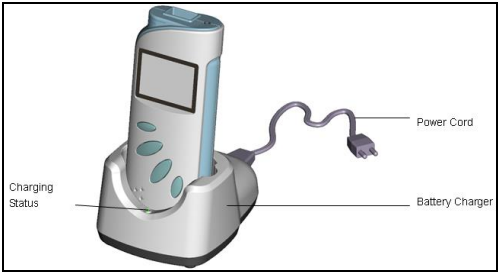
Return to the previous menu by pressing **Return** in the menu.

3.5 Charging the Ni-MH Rechargeable Battery Package

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 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 isn't placed properly.
Orange indicates the device is being charged.
Green indicates that the charging is complete.

CAUTION

1 When the device is being charged, it cannot be operated.
2 The mains plug is used as isolation means from supply mains. Position the oximeter in a location where the operator can easily access the disconnection device.

3.6 Oximeter 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.

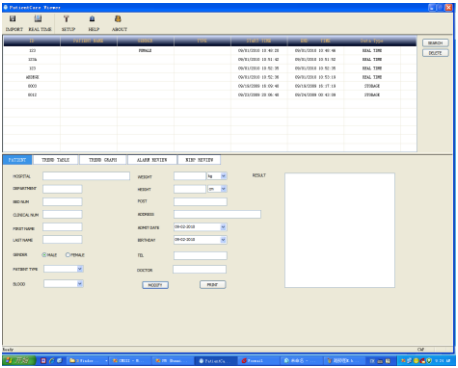


Figure 3-19 Main Interface

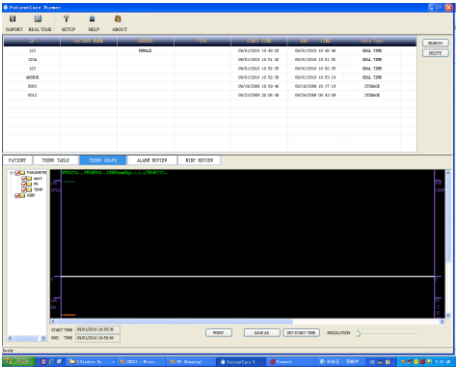


Figure 3-20 Trend Graph

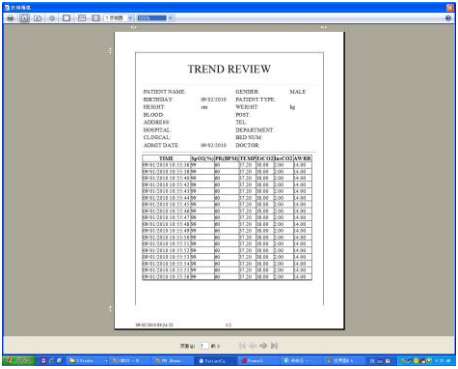


Figure 3-21 Print Preview

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 two categories: high level alarms and medium 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

Physiological alarms	Alarm level
SpO_2 Too High	High
SpO_2 Too Low	High
PR Too High	High
PR Too Low	High
Temp Too High	Medium
Temp Too Low	Medium

Technical alarms	Alarm level	Action Taken
SpO_2 Sensor Unconnected	Medium	No SpO_2 sensor was connected to the oximeter.
SpO_2 Sensor off	Medium	Make sure the sensor is well connected to the patient's finger or other parts. Make sure the oximeter and cables are well connected.
Low Battery	Medium	Replace the batteries.
Temp Sensor Abnormal	Low	Make sure that the cable is properly connected.

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.

The sound pressure range for auditory alarm signal is from 45 dB to 85 dB.

4.2 Alarm Conditions

The alarm system is **ON** by default. When the oximeter is turned on and no measurement is started, if the SpO_2 or TEMP sensor is unconnected or off, the oximeter will not give an alarm.

4.2.1 Alarm for SpO_2 Sensor Unconnected

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

information area.

SpO_2 and PR value area display "---", and give a medium alarm. (Make sure the alarm system in menu is ON.)

4.2.2 Alarm for SpO_2 Sensor off

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

SpO_2 and PR value area display "---", and give a medium alarm. (Make sure the alarm system in menu is ON.)

4.2.3 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.

4.2.4 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 the alarm system in menu is **ON**.)

4.2.5 Higher than Hi Alarm Limit

If the measured SpO_2 or PR 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:

If the measured PR value is higher than the setup **PR Hi Alarm**, the oximeter gives a high alarm (Make sure alarm system in menu is **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.

4.2.6 Lower than Lo Alarm Limit

If the measured SpO_2 or PR 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:

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

A ↓ icon displays near SpO_2 value, 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.

4.2.7 Alarm Silence

If **Alarm System** in menu is **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 the **Alarm Silence** button to reactivate the audio alarm function.

4.2.8 Turning off Alarm System

After the alarm system is turned off, the oximeter cannot give a visual or 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.

4.2.9 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.

If the pulse beep and audio alarm sound at the same time, the oximeter will only give an alarm sound.

4.2.10 Alarm Delay

There is a delay between a physiological event at the measurement site and the corresponding alarm at the oximeter. This delay has two components:

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.

4.2.11 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. You must check that the character flashes and beep sound can be heard. This indicates that the visible and auditory alarm indicators are functioning correctly.

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.

◆ Nonfunctional Hemoglobins

Nonfunctional hemoglobins, such as carboxyhemoglobin, methemoglobin, and sulfhemoglobin, are unable to transport oxygen for tissue, so SpO_2 may not be in proportion to the actual oxyhemoglobin in human body. 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

H100B: The oximeter displays pulse rate between 25 and 300 beats per minute (bpm). The sensor accuracy ranges do not apply to pulse rates above 300 bpm.

H100N: The oximeter displays pulse rate between 20 and 300 beats per minute (bpm). The sensor accuracy ranges do not apply to pulse rates above 250 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. It takes 5 minutes for the temperature measurement to stabilize.

◆ Data update period

The data update period is one second typically, and 10 seconds in extreme conditions.

Certain patient conditions can affect the measurements or cause the loss of the pulse signal.

Inaccurate measurements can be caused but not limited by:

- Incorrect application of the sensor.
- High levels of ambient light sources, such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight.
- Placement of the sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.
- Excessive or violent patient movement.
- Intravascular dyes, such as indocyanine green or methylene blue.
- Externally applied coloring, such as nail polish or pigmented cream.
- Failure of covering the sensor site with opaque materials in high ambient light conditions.
- Venous pulsation.
- Dysfunctional hemoglobin.

- Low peripheral perfusion.
- Defibrillation.
- Electromagnetic interference.

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

- The sensor is applied too tightly.
- 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.
- Low peripheral perfusion.

To use the sensor:

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

To prevent interference from ambient light, ensure that the sensor is properly applied, and cover the 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 sensor is properly and securely applied.
- Move the sensor to a less active site.
- Use an adhesive to the sensor.
- Use a new sensor with fresh adhesive backing.
- Keep the patient still, if possible.

For H100N, 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.

NOTE:

Adjacent SpO_2 sensors may interfere with each other (eg, multiple SpO_2 measurements in the same patient). Be sure to cover the sensor with opaque material to reduce cross-interference.

5.3 SpO_2 Functional Test

This test checks the function of the SpO_2 measurement.

Tools required: SpO_2 simulator (Provided with a calibration curve approved by EDAN).

Procedure:

1. Connect the oximeter and the SpO_2 simulator with a SpO_2 cable.
2. Switch on the oximeter and the simulator.
3. Set the simulator to the following configuration:

- SpO_2 = 85%.

Check the displayed SpO_2 value against the simulator configuration. The value should be 85% ±2%.

5.4 Assessing the Validity of a SpO_2 Reading

You can check the quality of the pleth wave and the stability of the SpO_2 values to assess whether the sensor functions properly and whether the SpO_2 readings are valid. Always use these two indications simultaneously to assess the validity of a SpO_2 reading.

Generally, the quality of the SpO_2 pleth wave reflects the quality of the light signals obtained by the sensor. A wave of poor quality manifests a decline of the signal validity. On the other hand, the stability of the SpO_2 values also reflects the signal quality. Different from varying SpO_2 readings caused by physiological factors, unstable SpO_2 readings are resulted from the sensor's receiving signals with interference. The problems mentioned above may be caused by patient movement, wrong sensor placement or sensor malfunction. To obtain valid SpO_2 readings, try to limit patient movement, check the placement of the sensor, measure another site or replace the sensor.

NOTE:

1 The SpO_2 accuracy has been validated in controlled human studies against arterial blood sample reference measured with a CO-oximeter. SpO_2 measurements are statistically distributed, only about two-thirds of the measurements can be expected to fall within the specified accuracy compared to CO-oximeter measurements. The volunteer

population in the studies composed of healthy men and women from age 19 to 37 (for H100B), from age 18 to 50 (for H100N), with various skin pigmentations. Note that the study population was healthy adults and not in the actual intended use population.

2 The pulse rate accuracy is obtained by comparison to the pulse rate generated with an arterial oxygen simulator (also an electronic pulse simulator).

3 During measuring, if the oximeter's reading differs significantly from the patient's physiological condition, it indicates that the signal may be disturbed, resulting in an inaccurate reading. In this case, the artifact can disguise as a similar reading, causing the oximeter to fail to send an alarm. In order to ensure reliable measuring, it is necessary to regularly check whether the sensor is wearing properly and the signal quality is good.

6 Maintenance

Maintenance shall be carried out at least once every two years, or as specified by local regulations.

The oximeter does not require calibration.

If service is necessary, contact qualified service personnel or your local EDAN 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 patient, and contact the biomedical engineer of the hospital or Customer service immediately.

Periodic Safety Checks

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

- Inspect the devices for mechanical and functional damage
- Inspect the relevant labels for legibility

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 personnel 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

1 The maintenance operations like software upgrade of the device can only be completed by EDAN-qualified service professionals.

2 Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Cleaning

If the device or accessory has been in contact with the patient, then cleaning and disinfection is required after every use. If there has been no patient contact and there is no visible contamination then daily cleaning and disinfection is appropriate.

The validated cleaning agents for cleaning the oximeter and reusable accessories are:

- Mild near neutral detergent
- Ethanol (75%)
- Isopropanol (70%)

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

Cleaning the Oximeter:

WARNING

Before cleaning the oximeter or the sensor, make sure that the oximeter is switched off and batteries are taken out.

To surface-clean the oximeter, follow these steps:

1. Switch off the oximeter and take out the batteries.
2. Wipe the entire exterior surface, including the

screen, of the equipment using a soft cloth dampened with the cleaning solution thoroughly until no visible contaminants remain.

3. After cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.

4. Dry the oximeter in a ventilated and cool place.

Cleaning the SpO_2 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 patient contact area of the sensor with the cotton swab dampened with the cleaning solution until no visible contaminants remain.

3. After cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.

4. Wipe off residual moisture with a dry cloth.

5. Leave the sensor to air dry.

Cleaning the TEMP Sensor:

1. Wipe the patient contact area with a soft cloth dampened with the cleaning solution until no visible

contaminants remain.

2. After cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.
3. Wipe off residual moisture with a dry cloth.
4. Leave the sensor to air dry.

Disinfecting

For devices or accessories that have been in contact mucosal surface, High Level disinfection must occur, for all other accessories, low level disinfection is appropriate. 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.

CAUTION

1 Do not use any disinfectant containing additional active ingredients other than those listed, such as disinfectant didecyl dimethyl ammonium bromide which contains quanternary ammonium salt.

2 Although the oximeter chemically resistant to most common hospital cleaners, disinfectants and non-caustic detergents, different cleaners or disinfectants are not recommended and may stain the oximeter, such as disinfectant didecyl dimethyl ammonium bromide which contains quanternary ammonium salt.

WARNING

The oximeter and reusable accessories shall be disinfected to avoid patient cross infection.

Disinfecting the Oximeter:

WARNING

Before disinfecting the oximeter, make sure that the oximeter is switched off and batteries are taken out.

To disinfect the oximeter, follow these steps:

1. Switch off the oximeter 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 equipment 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 oximeter for at least 30 minutes in a ventilated and cool place.

Disinfecting the SpO_2 Sensor:

1. Wipe the surfaces of the sensor and cable using a soft cloth dampened with the disinfection solution.
2. Wipe the patient contact area of the sensor with the cotton swab dampened with the disinfection solution.
3. Wipe off the disinfection solution with a dry cloth

after disinfection.

4. Leave the sensor to air dry for at least 30 minutes.

Disinfecting the TEMP Sensor:

The intracavitary TEMP sensors should be reprocessed by high-level disinfection before and after use on each new patient. Cidex OPA is the validated agent for high level disinfection. Refer to the instructions of the disinfectant for the methods of disinfection. High level disinfection has been validated with a 12 minute soak. Rinse and dry according to the labeled instructions of Cidex OPA. Do not dampen the sensor connector.

For the skin TEMP sensors, disinfect them as follows using ethanol or isopropanol only:

1. Wipe the patient contact area with a soft cloth dampened with the disinfectant solution (ethanol or isopropanol).
2. Wipe off the disinfectant solution with a dry cloth after disinfection.
3. Leave the sensor to air dry.

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.

The replacement of accessories, such as cables, sensors etc., should be taken according to actual usage. It is recommended to replace accessories once a year. Please refer to installation methods in relevant chapters for replacement.

Production date can be found on labels. The service life for main machine (not including replaceable accessories or parts) is 5 years when working time is 8 hours per day.

7 Principles of Operation

H100 Series Oximeters adopt non-invasive double wavelength to measure SpO_2 and PR. They can perform spot and continuous measurement for a short time. H100N 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, shown as follows:

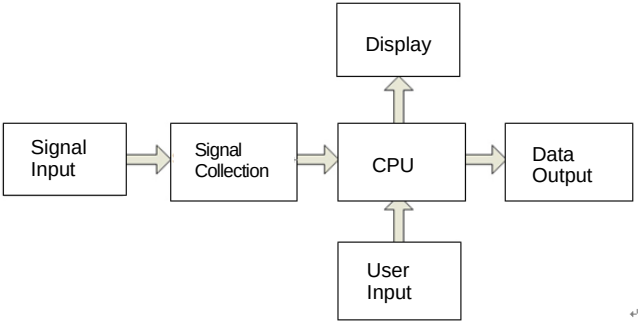


Figure 7-1 System Principle

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 the 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 0oxygen 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.

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.

7.2 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, the partial pressure of carbon dioxide (PCO_2), 2,3-DPG, and fetal hemoglobin.

8 Warranty and Service

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 is void in cases of:

a) damage caused by mishandling 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 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
Degree of Protection	Type BF-Applied part
Ingress Protection (H100B/H100N)	IP22
Mode of operation	Continuous
Degree of Safety in Presence of Flammable Gases	Not suitable for use in presence of flammable gases
Compliant with Standards:	IEC 60601-1:2005+A1:2012, EN 60601-1:2006+A1:2013, IEC 60601-1-2: 2014, EN 60601-1-2: 2015, ISO 80601-2-56:2017+A1:2018, ISO 80601-2-61: 2017

A1.2 Specification

NOTE:

The performance of the equipment with ☆ mark is determined to be essential performance.

A1.2.1 Size and Weight

Size	160 mm(L) ×70 mm(W) ×37.6 mm(H)

Weight (H100B)	165 g (without battery)
Weight (H100N)	185 g (without battery)

A1.2.2 Environment

Temperature

Working	0 ℃ ~ + 40 ℃ (32 ℉~104 ℉)
Storage	-25 ℃~ +70 ℃ (-13 ℉~158 ℉)

Humidity

Working	15%RH~95%RH (non-condensing)
Storage	15%RH~95%RH (non-condensing)

Atmospheric pressure

Working	70 kPa ~ 106 kPa
Storage	70 kPa ~ 106 kPa

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

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 h or longer (At 25 °C, with new fully charged batteries, SpO_2 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	1500 mAh
Typical battery life	30 h or longer (At 25 °C, with new fully charged batteries, SpO_2 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 h to 80%
	No more than 4 h to 100%

A1.2.5 Charger Stand

Model	CS-01
Input voltage	(100 to 240) VAC, 50 Hz/60 Hz, 0.4 A - 0.15 A
Output voltage	6 VDC
Output current	0.8 A
Output power	4.8 W

A1.2.6 Data Storage

Data Storage	300 hours

A1.3 Parameters

☆Measurement Range

☆SpO_2	0% ~ 100%
SpO_2 Resolution	1%
Bpm Resolution	1 bpm
☆PR (H100B)	25 bpm ~ 300 bpm
☆PR (H100N)	20 bpm~ 300 bpm

☆SpO_2 Accuracy (H100B)

☆Adult and Pediatric	±2% (70%~ 100%) Undefined (0%~ 69%)
☆Neonate	±3% (70%~ 100%) Undefined (0%~ 69%)

☆SpO_2 Accuracy (H100N)

☆Adult	(70%~ 100%) ±2%
☆Neonate	(70%~ 100%) ±3%
Low Perfusion	(70%~ 100%) ±2%

☆Pulse Rate Accuracy (H100B)

25 bpm ~300 bpm	±2 bpm

☆Pulse Rate Accuracy (H100N)

20 bpm to 250 bpm	±3 bpm

Alarm Range (H100B)

SpO_2	0% ~ 100%
PR	0 bpm ~ 300 bpm

Perfusion Range(H100N)

Measurement range	0.03% ~ 20%

SpO_2 Sensor (H100B)

Red Light	(660±3) nm
Infrared Light	(905±10) nm
Emitted Light Energy	< 15 mW

SpO_2 Sensor (H100N)

Wave length	approximately 660 nm and 900 nm
Emitted light energy	<15 mW

NOTE:

The information about wavelength range can be especially useful to clinicians (for instance, when photodynamic therapy is performed).

TEMP

☆Measurement range	0 ℃ ~ 50 ℃ (32 ℉ ~ 122 ℉)
☆Accuracy	(25 ℃ ~ 45 ℃) ±0.1 ℃ (0 ℃ ~ 25 ℃ and 45 ℃ ~50 ℃) ±0.2 ℃
Resolution	0.1 ℃
Position	Skin, oral cavity, rectum
Measuring mode	Direct mode
Refresh time	Every 1 s to 2 s
Self-test	At an interval of (5-10) min
Transient response time	≤ 30 s

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 pulse oximeter and charger stand:

Guidance and manufacturer's declaration – electromagnetic emissions		
H100B&H100N and charger stand are intended for use in the electromagnetic environment specified below. The customer or the user of H100B&H100N and charger stand should assure that they are used in such an environment.		
Emissions test	Compliance	Electromagnetic environment -guidance
RF emissions CISPR11	Group 1	H100B&H100N and charger stand use RF energy only for their internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

RF emissions CISPR11	Class A	H100B&H100N and charger stand are 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 purposes.
Harmonic emissions IEC/EN61000-3-2	H100B&H100N :N/A Charger stand: N/A	
Voltage fluctuations /flicker emissions IEC/EN61000-3-3	H100B&H100N:N/A Charger stand: Complies	

NOTE:

The EMISSIONS characteristics of H100B&H100N make them suitable for use in industrial areas and hospitals (CISPR 11 class A). If they are used in a residential environment (for which CISPR 11 class B is normally required) H100B&H100N might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

A2.2 Electromagnetic Immunity

For pulse oximeter:

Guidance and manufacturer's declaration – electromagnetic immunity
H100B&H100N are intended for use in the electromagnetic environment specified below. The customer or the user of H100B&H100N should assure that they are used in such an

environment.			
Immunity test	IEC/EN 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge(ESD) IEC/EN61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC/EN61000-4-4	±2kV for power supply lines ±1kV for input/output lines (>3m)	N/A	N/A
Surge IEC/EN61000-4-5	±1 kV line to line ±2 kV line to ground	N/A	N/A
Voltage dips, short interruptions, and voltage variations on	0 % $U_{T;}$ 0.5 cycle At 0°, 45°,	N/A	N/A

power supply input lines IEC/EN61000-4-11	90 °; 135 °; 180 °; 225 °; 270 ° and 315 ° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles) Single phase: at 0 ° 0 % U_T; 250/300 cycle		
Power Frequency(50/60 Hz)Magnetic Field IEC/EN 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment

For charger stand:

Guidance and manufacturer's declaration – electromagnetic immunity			
The CS-01 Battery Charger Stand is intended for use in the electromagnetic environment specified below. The customer or the user of CS-01 Battery Charger Stand should assure that it is used in such an environment.			
Immunity test	IEC/EN 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge(ESD) IEC/EN61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC/EN61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.

Surge IEC/EN61000-4-5	±1 kV line to line ±2 kV line to ground	±1 kV line to line	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC/EN61000-4-11	0 % $U_{T;}$ 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles) Single phase: at 0° 0 % U_T; 250/300 cycle	0 % $U_{T;}$ 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles) Single phase: at 0° 0 % U_T; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the CS-01 requires continued operation during power mains interruptions, it is recommended that the CS-01 be powered from an uninterruptible power supply.

Power Frequency(50/60 Hz)Magnetic Field IEC/EN 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
NOTE UT is the a.c. mains voltage prior to application of the test level.			

A2.3 Electromagnetic Immunity

For pulse oximeter and charger stand:

Guidance and manufacturer's declaration – electromagnetic immunity			
H100B&H100N and charger stand are intended for use in the electromagnetic environment specified below. The customer or the user of H100B&H100N and charger stand should assure that they are 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 6Vrms[c] in ISM bands between 0.15 MHz and 80 MHz	3 Vrms 150 kHz to 80 MHz 6Vrms[c] in ISM bands between 0.15 MHz and 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the H100B&H100N and charger stand, including cables, than the recommend separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ 150 kHz to 80 MHz

Radiated RF IEC/EN 61000-4-3	3 V/m 80 MHz to 2.7 GHz See Table 1	3 V/m 80 MHz to 2.7 GHz Comply with Table 1	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz $d = 6\sqrt{P}/\mathrm{E}$ at RF wireless communications equipment bands (Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the oximeter, including cables specified by the manufacturer). 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). 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. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE1 At 80 MHz and 800 MHz, 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.

a. Field strengths from fixed transmitters, such as base stations for radio(cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Complies is used exceeds the applicable RF compliance level above, the H100B&H100N and charger stand should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating H100B&H100N and charger stand.

b. The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

Table 1 Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM [c] ±5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28
870						
930						

1720 1845 1970	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
2450	2400-2570	Blueto oth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28
5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

A2.4 Recommended Separation Distances

For pulse oximeter and charger stand:

Recommended separation distances between portable and mobile RF communications equipment and H100B&H100N and charger stand

H100B&H100N and charger stand are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the H100B&H100N and charger stand can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the H100B&H100N and charger stand 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 2.7 GHz $d = 2.3\sqrt{P}$

0.01	**0.12**	**0.12**	**0.23**
0.1	**0.38**	**0.38**	**0.73**
1	**1.2**	**1.2**	**2.3**
10	**3.8**	**3.8**	**7.3**
100	**12**	**12**	**23**

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in 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	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_2	Pulse Oxygen Saturation

P/N: 21.54.109000
MPN: 21.54.109000027

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