Pulse Oximeter

Service Manual

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Statement

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

The manufacturer holds the rights to modify, update, and ultimately explain this manual.

Responsibility on the Manufacturer

The manufacturer 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 the manufacturer, and

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

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

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

Using This Label Guide

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

Chapter 1 Safety Information

1.1 Warnings

Warnings are identified by the WARNING symbol shown above.

Warnings alert the user to potential serious outcomes, such as death, injury, or adverse events to the patient or user.

WARNING

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

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

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

4 Oximeter measurements and pulse signals can be affected by certain environmental conditions, sensor application errors, and certain patient conditions. See the appropriate sections of this manual for specific safety

information.

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

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

7 Do not silence the audible alarm, or decrease the audible 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 monitoring only.

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

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

11 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.

12 Do not use an oximeter, sensor, or cables that appear damaged.

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

14 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.

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

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

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

18 Use only sensor permitted by the manufacturer, oximeter

is compatible with Nellcor sensor and BCI DB9 sensor.

19 The oximeter readings and pulse signals can be affected by certain ambient environmental conditions, sensor application error, and certain patient conditions.

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

21 Do not use rechargeable batteries works together with alkaline batteries.

22 During the POST immediately after power-on, confirm all the display segments and icons are shown and the oximeter speaker sounds 300-millisecond tone.

23 If you do not hear the POST pass tone, please do not use the oximeter.

24 Failure to cover the oximeter with opaque materials in high ambient light conditions may leads to inaccurate measurement.

25 Users should carefully read the applicable user manual of sensor, including warning, cautions and instructions before using the sensor.

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

27 Do not immerse or wet the sensor or this may damage

the sensor.

28 Tissue damage may be caused by incorrect application or duration use of sensor (about 2hours). Inspect the sensor periodically according to sensor user manual.

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

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

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 IEC60601-1-1 requirements.

2 It is restricted that this device to sale by or on the order of a physician.

3 The institution should follow local government regulations and recycling instructions regarding disposal or recycling of the batteries and components or end of life of the oximeter.

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

5 Periodically check the battery for corrosion. Take out the batteries if the oximeter will be stored for more than one month.

6 At menu state, SpO_2 and PR will not be displayed, while the oximeter is still measuring.

7 Observe ESD (electrostatic discharge) precautions when disassembling and reassembling the oximeter and when handling any of the components of the oximeter.

1.3 Notes

NOTE:

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

2 This device has been tested and found to comply with the

limits for medical devices to the EN60601-1-2（second edition）and the Medical Device Directive 93/42/EEC. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

3 Normal operation means: The oximeter is turned on; A sensor is connected to the oximeter; The sensor is applied to the patient; The patient's %SpO_2 and pulse rate readings (BPM) are being reported; No error conditions exist.

4 Before you begin to disassemble the oximeter, remove the battery compartment door and remove the batteries.

Chapter 2 Introduction

2.1 Intended Use

The oximeter is intended for continuous monitoring or spot-checking of functional arterial oxygen saturation (SpO_2) and pulse rate of adult, pediatric or neonatal patients in hospitals, intra-hospital transport and hospital grade facilities.

2.2 General Introduction

Pulse Oximeter (hereinafter called oximeter) is one model of the series Pulse Oximeter. It displays SpO_2 value, pulse rate value, plethysmogram, bar graph, etc.

The oximeter has been installed with SpO_2 module inside. It integrates parameter module, display and recorder output functions. It can be powered by four 1.5V AA batteries or four 1.2V Ni-MH rechargeable AA batteries. It can clearly display all the parameter information on LCD.

Figure 2-1 Pulse Oximeter

For the oximeter, Oximeter Viewer Data Management Software (hereinafter called oximeter viewer) is optional.

2.3 Panel Introduction

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

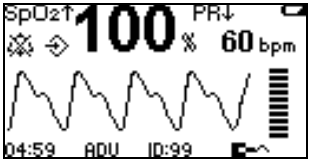


Figure 2-2 Waveform Mode

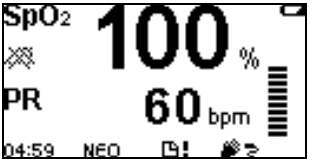


Figure 2-3 Large Numeric Mode

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)
	Displays when measurement value is higher than the upper alarm limit
	Displays when measurement value is lower than the lower alarm limit
	SpO_2 waveform display
	Pulse amplitude display

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

Chapter 3 Routine Maintenance

3.1 Maintenance Overview

Oximeter requires no routine service or calibration. The performance considerations in Chapter 4 may be used during the following repairs or routine maintenance (if required by your local institution).

Periodic Safety Checks

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

- Inspect the devices for mechanical and functional damage
- Inspect the safety labels for legibility.

Cleaning

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

To surface-clean the oximeter:

- Use a soft cloth dampened with either a commercial, nonabrasive cleaner, or a solution of 70% alcohol in water.
- Lightly wipe the surfaces of the oximeter.

To disinfect the oximeter:

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

3.2 Battery Maintenance

When inserting the positive end of each battery, be cautious not to damage the small coiled spring contact.

The oximeter could be damaged by batteries that are left in the oximeter and begin to leak.

The batteries should be replaced whenever a low battery icon is displayed on the screen.

When batteries have been replaced, dispose of the old batteries following local ordinances.

Chapter 4 Performance Considerations

4.1 Performance Verification

Qualified service personnel should do performance verification before the oximeter is used for the first time in a clinical setting.

Before performance verification, fresh batteries should be installed in the oximeter. If any of the required observations can not be obtained, please refer to Chapter 6, Troubleshooting. If the problems still exist, return the oximeter to service personnel authorized by the manufacturer.

When the oximeter is turned on, POST automatically tests the oximeter circuitry and functions.

Press the **On/Off** button to turn on the oximeter. The backlight remains on throughout the POST.

After POST, the backlight is then turned off, and normal measuring interface is displayed.

Turn on or off the backlight

Backlight turns off approximately 5s after powered on. When the oximeter is turned on, press **Backlight** button to turn on or off the backlight.

Sensor attached

Please pay attention to the beep tone while using the oximeter. If it does not beep for each pulse, it indicates one of the following:

- Pulse beep volume is off.
- Speaker/audio has malfunction.
- Signal is corrupted.
- The oximeter has stopped functioning.

No Sensor attached

If the oximeter does not connect to a sensor or the sensor is off, the oximeter will give medium alarm, meanwhile the sensor unconnected icon shows.

After successful POST, the oximeter sounds 300-millisecond tone.

4.2 Performance Considerations

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

- Dysfunctional Hemoglobins

Dysfunctional hemoglobins, such as carboxyhemoglobin, methemoglobin, and sulfhemoglobin, are unable to carry oxygen. SpO_2 readings may appear normal; however, a patient may be hypoxic because less hemoglobin is available to carry oxygen. Further assessment beyond oximeter is recommended.

◆ Anemia

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

◆ Saturation

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

◆ Pulse rate

The oximeter displays pulse rate between 30BPM and 255BPM (beats per minute). The sensor accuracy ranges do not apply to pulse rates above 250 BPM. Detected pulse rates less than 20 are shown as 0.

4.3 Sensor Performance Considerations

Inaccurate measurements can be caused by:

◆ Incorrect operation of sensor.

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

◆ Excessive patient activity.

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

◆ Externally applied coloring, such as nail polish or pigmented

cream.

- Failure to cover sensor site with opaque materials in high ambient light conditions.
- Venous pulsation.
- Dysfunctional hemoglobin.
- Low perfusion.

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

- The sensor is applied too tightly.
- Defibrillation.
- A blood pressure cuff is inflated on the same extremity as the one with the sensor attached.
- There is arterial occlusion proximal to the sensor.
- Poor peripheral perfusion.
- Loss of pulse/cardiac arrest.

To use the sensor:

- Select an appropriate sensor.
- 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.

High ambient light sources that can interfere with the performance of an SpO_2 sensor are:

- Surgical lights (especially those with a xenon light source).
- Bilirubin lamps.
- Fluorescent lights.
- Infrared heating lamps.
- Direct sunlight.

To prevent interference from ambient light, ensure that the 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 another site.
- Use an adhesive sensor.
- Use a new sensor with fresh adhesive backing.
- Keep the patient still, if possible.

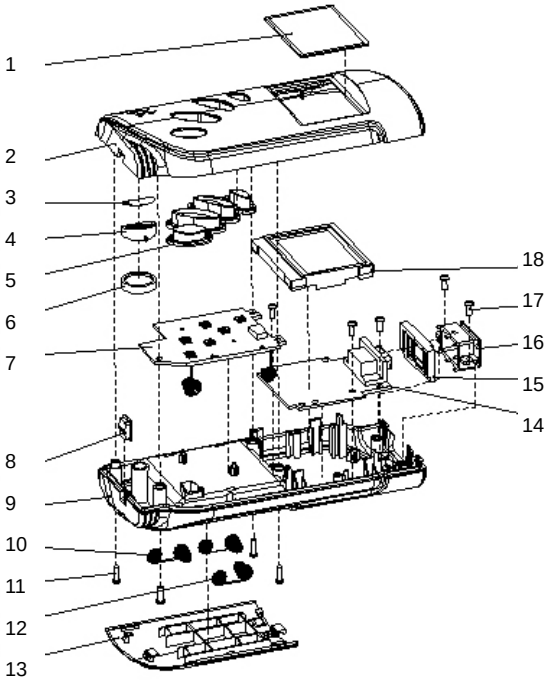
Chapter 5 Disassembly Guide

5.1 Introduction

The oximeter can be disassembled into five assemblies:

- Case top/ Front panel keypad;
- Case bottom;
- Main control board PCB;
- LCD module;
- Battery compartment door.

The oximeter disassembly graphics indicated the product structure as follows.



1	Protection screen	2	Front panel
3	Speaker dustproof	4	Speaker circle
5	Silica gel key	6	Speaker
7	Main control board	8	Charge insulated
9	Back panel	10	Battery spring ②

11	Cross recessed pan head screw M2.5X8	12	Battery spring ①
13	Battery compartment door	14	Function board
15	Socket silica gel holster	16	Socket holster
17	Cross recessed pan head screw M2.5X6	18	White backlight LCD module

Figure 5-1 Pulse Oximeter Disassembly Guide

5.2 System Disassembly and Reassembly

Use the following procedure to disassembly the oximeter. Reassemble the oximeter in reverse order and, if the oximeter is to be returned to service, install batteries when reassembly is complete and replace the battery compartment door. The manufacturer recommends that you follow this disassembly procedure in the order presented.

1 Place the oximeter on a nonabrasive surface so that the back of the oximeter is up and the bottom of the oximeter is closest to you.

2 Remove the four screws holding the case together as indicated in figure 5-1.

When reassembling the oximeter, tighten by hand the screws that hold the oximeter case together. Over tightening could

cause the screws to strip out of the screw-holes in the top case, rendering it unusable.

3 When holding the case together, turn the oximeter over with the Front panel up and the bottom of the oximeter closest to you.

4 Carefully separate the case top from the bottom case and rotate it, in case break off the speaker cable.

5 Unlock connector on main control board PCB, remove the connecting cable between LCD screen and main control board, then remove the connecting cable between main control board and function board.

NOTE:

1 When inserting connector for reassembling, exert pressure equally on both ends, in case the small socket breaks the inserting pins.

2 Observe carefully how the connectors and pins are arranged, so it can be reassembled correctly.

6. Synchronously remove the main control board and LCD module.

7. To separate the main control board PCB and the LCD module, grasp the main control board PCB in one hand and the LCD module in another. Rotate the ends of the two modules as

shown in figure 5-1 until the two assemblies separate at the connecting point.

NOTE:

When reassembling the oximeter, be sure to align all pins on the main control board with all sockets on the LCD module. Then fit the two modules together.

5.3 Spare Parts

Spare parts are shown in figure 5-1, which shows the replaceable components.

If some of the components need to be changed, please contact service personnel authorized by the manufacturer.

Chapter 6 Troubleshooting

This chapter contains troubleshooting for the oximeter and PC Patient Information Management Software.

6.1 Pulse Oximeter Troubleshooting

1. There is no response to the On/Off button.

- Ensure the power button is fully depressed.
- The batteries may be missing, discharged, or oriented incorrectly. Install new batteries.
- The sensor is defective.
- The front panel keypad is defective.
- Flex circuit between front panel and main control board is disconnected.
- main control board PCB component has failed.

Corrective action:

- Open the battery compartment door and if the batteries are missing, install new batteries. If the batteries are not installed correctly, reinstall them.
- If the sensor is defective, replace the sensor. If the front panel buttons are defective, take out the main control board, find out the causes for failures using an ohmmeter. Check if there is short-circuit. If all keys function correctly, replace

main control board PCB.

- Insert the flex circuit between the front panel and the main control board PCB and reconnect them if loose.
- Inspect the main control board PCB components and circuit board for cracking, burning, or damage, and replace the main control board PCB if any are found. If any failed components are observed, replace main control board PCB. Replace the main control board PCB with a known good PCB.

2. One or more keys on the front panel keypad do not work.

- The front panel keypad is defective.
- Flex circuit between front panel and main control board PCB is disconnected.
- A main control board PCB component has failed.
- Main control board PCB has failed.

Corrective action for corresponding errors:

- Open the oximeter, find out causes using an ohmmeter and other professional tools. If necessary, replace case top or main control board PCB.

  Unlock latch before attempting to remove flex circuit conductor.
- Inspect the flex circuit between the front panel and the main

control board PCB and reconnect them if loose.

- Inspect the main control board PCB components and circuit board for cracking, burning, or damage and replace the main control board PCB if any are found.
- Replace the main control board PCB with a known good PCB.

3. One or more display segments do not work.

- An LCD PCB component has failed.
- Flex circuit between main control board and LCD PCB has come loose.

Corrective action for corresponding errors:

- Insert the LCD PCB components and circuit board for cracking, burning, or damage and replace the LCD PCB if any is found.
- Inspect the flex circuit between the main control board and LCD PCB has come loose, replace the LCD PCB if loose.
- Replace the LCD PCB with a known good PCB.

4. Beeper does not beep for pulse indication or no sound can be heard from the beeper.

- The beeper has been turned off or its volume is turned down too low to hear.

- The holes for the beeper on the back of the oximeter are blocked.
- The external output port on the main control board PCB has failed.
- The connecting point between the beeper and main control board is defective.

Corrective action for corresponding errors:

- Turn the beeper back on.
- Clear the holes for the beeper on the back of the oximeter.
- Replace the beeper with a known good one.

5. Pulse rate or SpO_2 value is not displayed when the oximeter is on.

- The SpO_2 sensor is not connected properly.
- The SpO_2 sensor has failed.
- A component on the LCD PCB has failed.
- A component on the main control board PCB has failed.

Corrective action for corresponding errors:

- Connect the SpO_2 sensor to the oximeter.
- Replace the SpO_2 sensor with a known good SpO_2 sensor.
- Replace the LCD PCB with a known good PCB.
- Replace the main control board PCB with a known good PCB.

6. LCD backlight is not on when the backlight key is pressed.

- The backlight key on the front panel keypad is defective.
- The backlight LEDs on the LCD PCB have failed.

Corrective action for corresponding errors:

- See item 2 above “one or more keys on the front panel keypad does not work”.
- Replace the LCD PCB with a known good PCB.

7. The oximeter shuts off when the LCD backlight is turned on.

- The batteries are at or near a voltage too low for the oximeter to operate.

Corrective action for corresponding errors:

- Install new batteries.

8. EMI (electromagnetic interference)

Due to proliferation of radio-frequency transmitting equipment and other sources of electrical noise in health care environments, it is possible that high levels of such interference due to close proximity, or strength of a source, may result in disruption of performance of this device. Examples of noise sources in healthcare environments that could cause electromagnetic interference are:

- Electrosurgical units
- Cellular phones
- Mobile two-way radios
- Electrical appliances
- High-definition television

The oximeter is designed for use in environment in which the pulse can be obscured by electromagnetic interference. During such interference, measurements may seem inappropriate or the oximeter may not seem to operate correctly.

Disruption may be evidenced by erratic readings, cessation of operation, or other incorrect functioning. If this occurs, the site of use should be surveyed to determine the source of this disruption, and the following actions taken to eliminate the source:

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

The oximeter generates, uses, and can radiate radio frequency energy. If it is not installed and used in accordance with these instructions, the oximeter may cause harmful interference with other devices in the vicinity.

6.2 Oximeter Viewer Troubleshooting

There are some failure types for Oximeter Viewer Data Management Software.

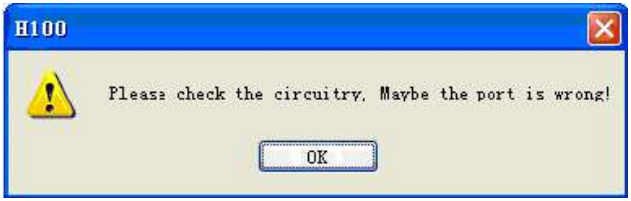
6.2.1 Communicate Failures with the Oximeter

(1) Possible Causes

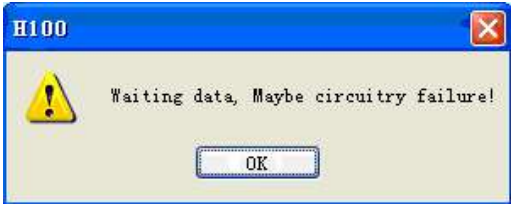
- Oximeter viewer has not been connected to the oximeter.
- The special serial port inner circuitry for the oximeter has error, or it is not special for the oximeter.
- The serial port cable which is connected to oximeter viewer is loose or offline.
- The oximeter has not been switched on, so the corresponding data can not be gained from it.
- The oximeter did not enter communication state.
- When the oximeter is powered by batteries, it is switched off for using up batteries.
- During communication, the software chooses incorrect serial port codes.
- Other unknown reasons.

(2) According as judgment

- After the software has run 2 seconds, the prompt pops up to display “Please check the circuitry, Maybe the port is wrong!”, see as follows:



- When performing data export, inquiry or other operations, there is no data displaying but the prompt pops up displaying "Waiting data, Maybe circuitry failure!".



(3) Solutions

- First the user should make sure to use special serial port circuitry for the oximeter.
- Check the connection state of serial port circuitry between oximeter viewer and the oximeter to make sure there is no physical damage in transmitting circuitry, so it can be the medium of data transmission.
- Check the port between the oximeter and oximeter viewer to see if it is loose or disconnected, make sure it is connected

stably.

- Check if the oximeter has been switched on, and make sure it is at data transmission state.
- Make sure the oximeter has not been switched off for low power supply or other unknown reasons, which stops the data from being gained.
- Check if the battery was used up, change the battery if necessary, and switch on the oximeter, then check if it can communicate with the software.
- Make sure the serial port code for software running is in accordance with that of the oximeter connected to the oximeter viewer.
- If the oximeter viewer still can not communicate with oximeter after all solutions above are carried out, please restart the software and perform data export again to find out failure types.
- Try the solutions above, if the failures still can not be solved, please contact developer as soon as possible.

6.2.2 Software Abnormal

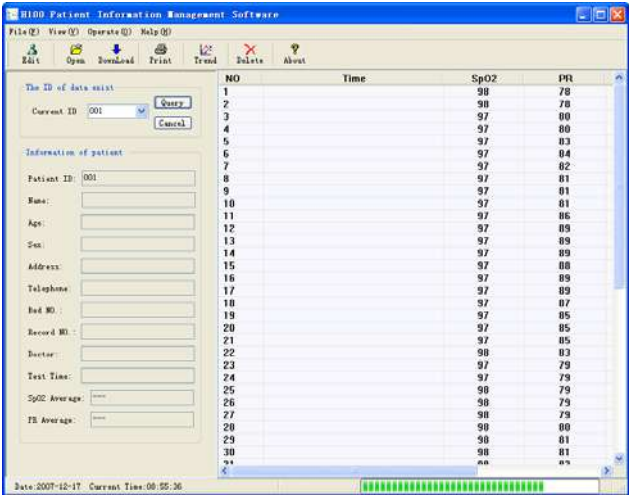
(1) Possible causes

- Abnormal state during startup.
- Software is abnormal during data export.

(2) According as judgment

- The software can not be opened, and the prompt pops up which displays “The port is not found or occupied by other equipment!”.

- The software stay at the exporting state, the progressing bar indicating data transmission is stopped without prompt, it looks like deadlock of computer.



- The software displays LOGO for a while, and then prompts communication overtime or other errors.

(3) Solutions

- If it prompts the serial port was not found, the user should at first check if the oximeter viewer has serial port. If oximeter viewer has no serial port, check if the driver for changing USB port to serial port has been installed, and check if the line for changing USB port to serial port has been inserted.

  The default port for software to open is serial port 1, if it is occupied, the dialog box pops up to prompt serial port can not

be found. Choose the unoccupied serial port code, so the software can be opened.

- The condition described in (2) b. may be caused by communication error between the oximeter and the software. Restart the oximeter and enter data exporting state, then the oximeter can recover to normal state.
- If the software can not enter interface for a long time, the user should press **Ctrl+Alt+Del**, choose **Task Management**, then choose **.exe** file and press **Alt+E** to close it, then restart the software again.
- If problems still exist after all solutions above are carried out, the user should reinstall the relative software.

6.2.3 Printing Abnormal

(1) Possible causes

- Printer is damaged.
- The power supply of printer is off.
- Cables between printer and server oximeter viewer is loose or the cables is abnormal.
- The printer driver is abnormal.
- The paper size setup for printer is not accordant with default setup.

(2) According as judgment

- After pressing Print key, the printer does not start up and no printing process appears.
- After restarting the unresponsive printer, it automatically prints former data.
- Restart printer for few times, but it still unavailable.
- On the printout, the words overlap with each other.

(3) Solutions

- Check if the printer has powered on.
- Check if the printer is damaged, including if cables is available, and if the cables between oximeter viewer and printer is loose.
- Sometimes data jam may happen to printer. When it happens, restarting the printer can solve the problem.
- If printing is unavailable, reinstall printer driver, and try printing again.
- Make sure the paper size setup is A4, direction is Lengthways.

6.2.4 Other Failures

Solutions: Please contact developer in time for solutions.

Chapter 7 Technical Supplement

This chapter provides a description of the principles of pulse oximetry, a block diagram level theory of operation discussion, and a schematic theory of operation discussion.

7.1 Pulse Oximetry Principles

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 toe. The sensor contains a dual light source and a photonic detector.

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

Pulse oximetry is based on two principles:

- Oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (spectrophotometry).
- The volume of arterial blood in tissue (hence light absorption by the blood) changes during the pulse (plethysmography).

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

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

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

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

The oximeter measures functional saturation-oxygenated hemoglobin expressed as a percentage of the hemoglobin that can transport oxygen. It does not detect significant amounts of

dysfunctional hemoglobin, such as carboxyhemoglobin or methemoglobin.

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

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

$$\text{Functional saturation} = \frac{\text{Fractional saturation}}{100-(\%\text{carboxyhemoglobin}+\%\text{methemoglobin})} \times 100$$

7.2 Circuit Principle Analysis

This section provides an explanation theory of operation using block diagrams and schematic diagrams. The oximeter adopts modules structure, so it is convenient for update. The oximeter consists of three modules:

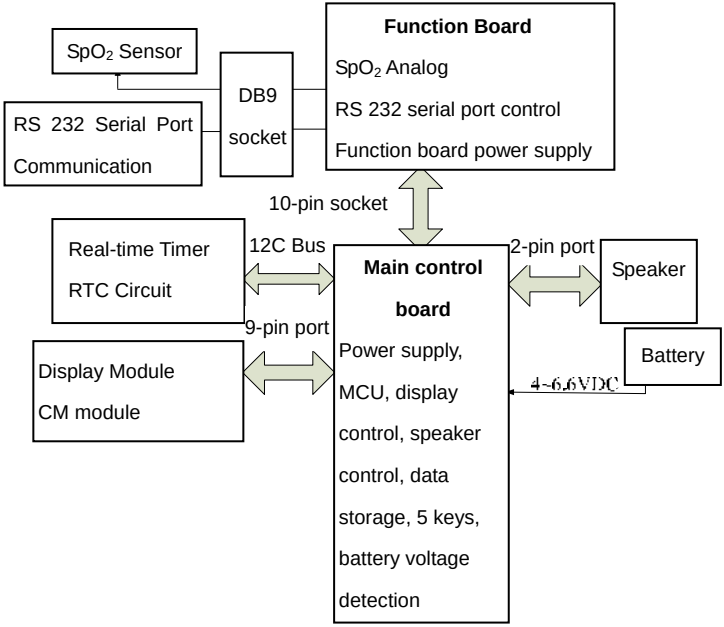


Figure 7-1 Overall Schematic diagram

(1) Function board

It collects, converts, amplifies, and processes SpO_2 and pulse signals. The measuring method is dual-wavelength measuring, it can be an independent SpO_2 function board module.

(2) Main control board

It mainly controls general functions, including battery power

conversion function, button function, sound alarm function, display output function, data storage function, oximeter viewer communication, real-time timer function, extension function, etc.

(3) Display module

Oximeter adopts LCM display module (including LCD screen and corresponding driver circuit board).

7.3 Main Control Board Introduction

The oximeter can be powered by 4 1.5V LR6 AA Alkaline batteries, or 1.2V Ni-H rechargeable batteries. Oximeter do not support built-in recharge. Most of the Power conversion circuits are on main control board PCB, some of them are on function board.

Oximeter power supply schematic diagram is shown in figure 7-2, there are 4 circuits.

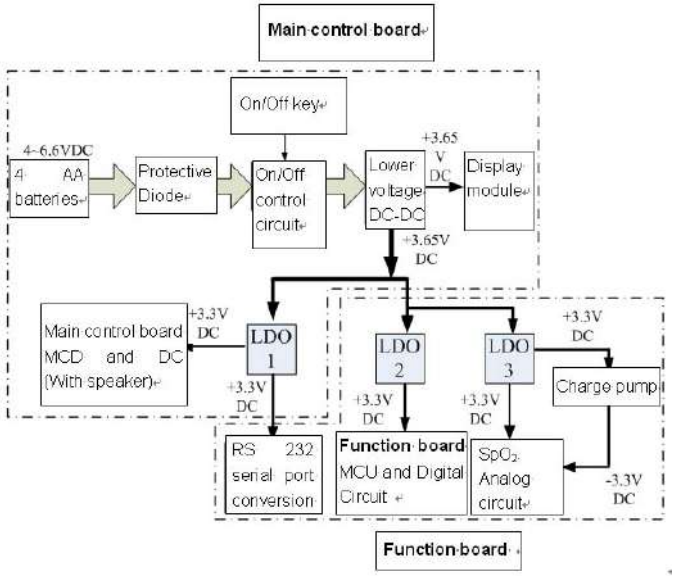


Figure 7-2 Main control board Schematic Diagram

The +4V ~ +6.6V battery voltage is connected to on-off control circuit by anti-reverse protection diode. The on-off control circuit and on-off key controls to lower voltage DC-DC function which then output stable voltage +3.65 VDC, and the voltage is divided into 3 ways:

(1) One way to LCM display module to drive backlight;

(2) One way to LD01 main control board;

(3) The other way to LD02 and LD03 function board.

LD01 main control board output stable voltage +3.3 VDC, it is divided into two ways: one way to main control board d MCU and digital circuit (with speaker), another way to function board MCU and digital board through 9-pin socket.

LD02 function board output stable voltage +3.3 VDC to function board MCU and digital circuit.

LD03 function board output stable voltage +3.3 VDC which is then divided into 2 ways: one way directly output to SpO_2 analog circuit (including power sensor), another way output to Charge pump which can convert +3.3 VDC to -3.3 VDC, then output to analog circuit.

Chapter 8 After-Sales Service

If you have any question about maintenance, technical specifications or malfunctions of devices, contact the manufacturer.

Appendix Ⅰ Specification

A1.1 Classification

Type of protection	Internally powered equipment
EMC compliance	Class B
Degree of protection	Type BF-Applied part
Ingress protection	IPX2
Mode of operation	Continuous measuring and spot checking
Compliant with safety standards	IEC60601-1:1988+A1+A2, EN60601-1:1990+A1+A2, IEC/EN60601-1-2:2001+A1, ISO 9919

A1.2 Specification

A1.2.1 Size and Weight

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

A1.2.2 Environment

Temperature	
Working	+5 °C ~ +40 °C
Transport and storage	-20 °C ~ +55 °C
Humidity	
Working	25% ~ 80 % (no condensing)
Transport and storage	25% ~ 93 % (no condensing)

Altitude	
Working	860hPa ~ 1060hPa
Transport and storage	700hPa ~ 1060hPa

A1.2.3 Display

Screen type	128×64 dot-matrix LCD, with white LED backlight
Big numeric mode	SpO_2, PR and Bar graph displayed
Waveform mode	SpO_2, PR, Bar graph and Plethysmogram displayed

A1.2.4 Batteries

Alkaline batteries	
Quantity	4
Total rated voltage	6 V
Capacity	2600 mAh
Typical battery life	48 hours
Ni-MH rechargeable battery	
Quantity	1
Total rated voltage	4.8 V
Capacity	1800 mAh
Typical battery life	36 hours
Charge time	2.5 hours to 80%; 4 hours to 100%

A1.2.5 Charger Stand

Input voltage	100 V-240 V~, 50 Hz /60 Hz

Output voltage	8 VDC
Output current	0.8 A
Output power	6.4 W

A1.3 Parameters

Measurement range	
SpO_2	0 % ~ 100 %
PR	30 bpm ~ 254 bpm
Saturation	
Adult and Pediatric	± 2digits (70 %~ 100 %)
Neonate	± 3digits (70 %~ 100 %)
Pulse Rate	
Adult and Pediatric	± 3digits
Neonatal	± 3digits
Resolution	
SpO_2	1 %
Bpm	1 bpm

Appendix Ⅱ EMC Information

-Guidance and Manufacture's Declaration

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

A2.1 Electromagnetic Emissions - for all EQUIPMENT and SYSTEMS

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

RF emissions CISPR11	Class B	The device is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply net work that supplies buildings used for domestic purpose.
Harmonic emissions IEC/EN61000-3-2	N/A	
Voltage fluctuations /flicker emissions IEC/EN61000-3-3	N/A	

A2.2 Electromagnetic Immunity - for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration – electromagnetic immunity			
The oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the oximeter should assure that it is used in such an environment.			
Emissions test	**Compliance**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge(ESD) IEC/EN61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors should be wood, concrete or ceramic tile. If

			floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC/EN61000-4-4	±2kV for power supply lines ±1kV for input/output lines (>3m)	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC/EN61000-4-5	line to line line to ground	N/A	
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC/EN61000-4-11	<5%UT(>95% dip in UT)for 0.5 cycle 40%UT(60% dip in UT)for 5 cycles	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user

	70%UT(30% dip in UT)for 25 cycles <5%UT(>95% dip in UT)for 5s		of the product requires continued operation during power mains interruptions, it is recommend that the product be powered from an uninterruptible power supply or a battery.
Power Frequency(50/60 Hz)Magnetic Field IEC/EN 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment

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

Guidance and manufacturer's declaration – electromagnetic immunity			
The oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the oximeter should assure that it is used in such an environment.			
Immunity test	**IEC/EN 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC/EN 61000-4-6 Radiated RF IEC/EN 61000-4-3	3Vrms 150KHz to 80MHz 3V/m 80 MHz to 2.5GHz	3V 3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the oximeter, including cables, than the recommend separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**

			$d = \frac{3.5}{3}\sqrt{P}$ $d = \frac{3.5}{3}\sqrt{P}$ 80 MHz to 800 MHz $d = \frac{7}{3}\sqrt{P}$ 800 MHz to 2.5GHz 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 80MHz and 800MHz, the frequency range applies.

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

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

A2.4 Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the oximeter			
The oximeter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the oximeter as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	**80 MHz to 800 MHz** $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	**0.12**	**0.12**	**0.23**
0.1	**0.37**	**0.37**	**0.74**
1	**1.2**	**1.2**	**2.3**
10	**3.7**	**3.7**	**7.4**

100	**12**	**12**	**23**

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

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

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

Appendix Ⅲ 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	Arterial Oxygen Saturation From Pulse Oximeter

Appendix Ⅳ Record Table

ID No.	Name	Time	SpO_2	PR	NOTE