VE-H100B

Veterinary Pulse Oximeter
Version 1.8

User Manual

CE

EDAN

About this Manual

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Statement

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

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

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 Con

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 the explosion hazard. Do not use the VE-H100B Veterinary Pulse Oximeter (hereinafter called 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 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.

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

WARNING

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

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

8 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.

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

WARNING

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 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.

13 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.

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

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

WARNING

16 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.

17 Use only EDAN permitted sensors and extension cables with the oximeter. Other sensors or extension cables may be failed or cause improper monitor performance.

18 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.

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

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

21 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.

WARNING

22 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.

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

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

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

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

27 This equipment is not intended for home usage.

WARNING

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

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

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

31 Reusable sensors must be moved to a new site at least every 4 hours. Because individual skin condition affects the ability of the skin to tolerate sensor placement. It may be necessary to change the sensor site more frequently with some patients. If skin integrity changes, move the sensor to another site.

32 Do not use supplemental tape to adhere the clip and sensor directly to the site, this can restrict blood flow and cause inaccurate measurements.

33 Intravascular dyes may lead to inaccurate measurements.

WARNING

34 Performance of the sensor may be compromised by motion, particularly of a repetitive nature. If readings cannot be obtained, try another application site.

35 Do not alter or modify the sensor. Alterations or modifications may affect performance or accuracy.

36 Failure of applying the sensor properly may cause incorrect measurements.

37 Using the sensor in the presence of bright lights may result in inaccurate measurements. In such case, cover the sensor with an opaque material.

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

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

40 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 monitoring patients.

WARNIN

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

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

43 Only use EDAN approved rechargeable batteries and charger stand for the oximeter.

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

45 Setting alarm limits to extreme values may cause the alarm system to become ineffective. It is recommended to use the default settings.

46 Do not touch accessible parts of electrical equipment in the patient environment and the patient simultaneously.

47 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.

WARNING

48 Please avoid inhalation or swallowing of small parts.

49 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.

50 Do not touch accessible parts of non-medical electrical equipment and the patient simultaneously. Do not touch the signal input or output connector and the patient simultaneously.

51 The simultaneous use of cardiac pacemaker may cause safety hazard.

52 During monitoring, 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 monitoring.

53 If several medical equipments are connected to a patient, the sum of the leakage currents shouldn't exceed the limits, otherwise it may cause shock hazard.

WARNING

54 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.

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

56 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.

57 Prolonged and continuous monitoring may increase the risk of unexpected change of dermal condition such as abnormal sensitivity, rubescence, vesicle, repressive putrescence, and so on. It is especially important to check the sensor placement of neonate and patient of poor perfusion or immature dermogram by light collimation and proper attaching strictly according to changes of the skin. More frequent examinations may be required for different patients.

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 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.

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

CAUTION

5 The performance of the oximeter may degrade if the followings occur:

— Operation or storage temperature beyond the manufacturer's specified range;

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

6 For the comfort of the animal and to avoid damaging the sensor, do not pull on the cable when removing the sensor and clip from the sensor site.

7 To remove the sensor and clip from the animal, press the clip open and remove.

8 Federal law restricts this device to sale by or on the order of a veterinarian.

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

3 Normal operation means:

- The oximeter is turned on;
- A sensor is connected to the oximeter;
- The sensor is applied to the patient;
- The patient's SpO_2, Pulse rate are being reported;
- No error conditions exist.

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

5 Do not disinfect the probe with the water boiled.

6 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 r
scarfskin of the cable. Also, the connector should not be dipped.

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

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

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

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

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

12 SpO_2 waveform is not proportional to the pulse volume.

13 When the SpO_2 value is potentially incorrect, it will display “---”.

14 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.

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

16 The oximeter can only be used on one patient at a time.

17 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		Refer to User Manual (Background: blue; Symbol: white)

6	SN	SERIAL NUMBER
7	CE	CE marking
8	EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
9		Input/output connector
10		Date of manufacture
11		MANUFACTURER
12	P/N	Part Number
13		Disposal method

14	Rx Only	Caution: Federal (U.S.) Law restricts this device to sale by or on the order of a physician.
15		General symbol for recovery/recyclable
16	IPX2	Ingress Protection IPX2 (protected against vertically falling water drops when enclosure tilted up to 15°)
17		No alarm system

NOTE:

The user manual is printed in black and white.

2 Introduction

Intended Use/Indications for Use

The VE-H100B Veterinary Pulse Oximeter is indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (PR). It can be used for spot checking and/or continuous monitoring of canine, feline, and equine animals when attended by a veterinary professional.

2.1 General Introduction

VE-H100B Pulse Oximeter displays SpO_2 value, pulse rate value, plethysmogram, bar graph, etc.

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

Figure 2-1 VE-H100B Veterinary Pulse Oximeter

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

You may frequently use the follow functions:

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

Alarm (Refer to *Chapter 5 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

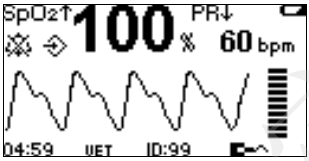


Figure 2-2 Waveform Mode

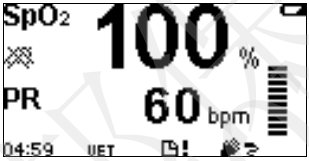


Figure 2-3 Large Numeric Mode

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"
Model	Model in Information area: Vet
ID: 99	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 POST can not 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 m

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.

Press this button in measurement state 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.

Press this button in measurement state 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

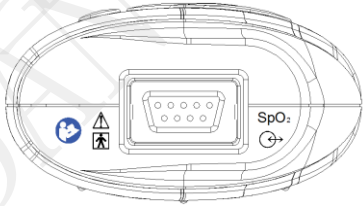


Figure 2-6 Sensor and Cable Connecting Port

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 b

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


Type BF applied part


Input/output connector

SIO definition:

PIN	Name	Description
1	RSGND	The RS232 GND
2	LED+	LED drive signal, IR Anode
3	LED-	LED drive signal, Red Anode
4	RXD	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

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 when used for general operation, or about 24 hours of operation with the backlight and alarm on.

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.

Checking the Ni-MH 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 pulse oximeter from the patient and stop all monitoring and measuring procedures.

2. Place the pulse oximeter in the charger stand and connect the AC mains. Allow the battery to be charged uninterruptedly for above 2.5 hours. For details about charging the Ni-MH battery package, please refer to section 3.4.

3. Disconnect AC mains and allow the pulse oximeter to run in the measurement state until it shuts off.

4. The operating time of a battery reflects its performance

directly. If the operating time of a l
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 few-minute operation remains available. After few-minute operation, the oximeter will turn off automatically. Replace the batteries.

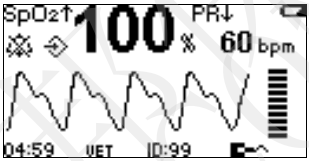


Figure 2-7 Low Battery Icon

2.5 Accessory List

Standard configuration including:

Quantity	Items	Parts No. in EDAN
1	VE-H100B Pulse Oximeter	02.06.112216
4	1.5V AA alkaline batteries (IEC LR6）	01.21.064086
1	VE-SH7 Veterinary	02.01.110498

	Pulse Oximetry Sens	
1	Carrying case	01.56.110165

Optional configuration including:

Quantity	Items	Parts No. in EDAN
1	Protective Cover	01.51.110164
1	Ni-MH rechargeable battery package	01.21.064133
1	Battery charger	02.06.112410
1	Oximeter Viewer Data management software	02.05.109016
1	Series cable	01.13.109038
1	H100 SpO_2 extension cable	01.13.110504

NOTE:

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

When selecting SpO_2 sensor, the following should be considered:

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

3 Oximeter Operation

3.1 Turning on the Oximeter

The oximeter is turned on by pressing the **on/off** button, and 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 successfu… sounds a tone and enters the main interface.

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

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

3.2 Measurement State

3.2.1 Measurement Modes

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

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.

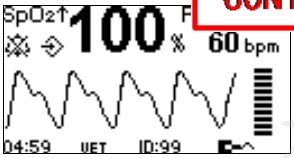


Figure 3-3 Waveform Mode

Large Numeric Mode

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

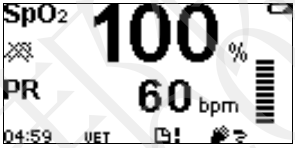
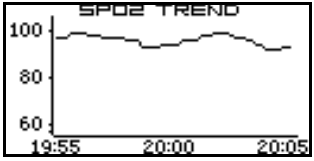


Figure 3-4 Large Numeric Mode

3.2.2 Trend Graph and Trend Table

In normal measuring state, 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.

Trend graph:



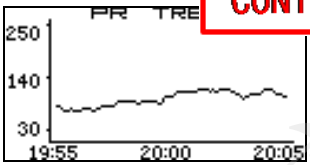


Figure 3-5 Display SpO_2 and PR Trend Graph

Trend table:

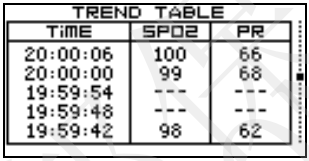


Figure 3-6 Display SpO_2 and PR Trend Table

3.2.3 Abnormal Measurement State

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

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

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.

3.2.4 Data Transfer State

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

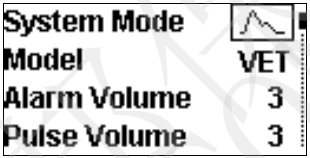
Figure 3-7 Data Transfer State

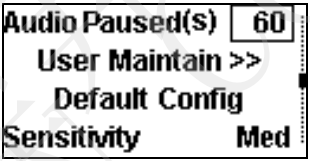
3.3 System Menu

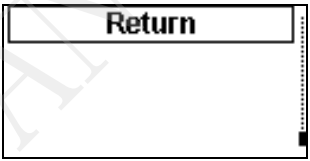
Press the **Function** button to see the following main menu of the

oximeter, select items by pressing confirm it by pressing the **Function** button.

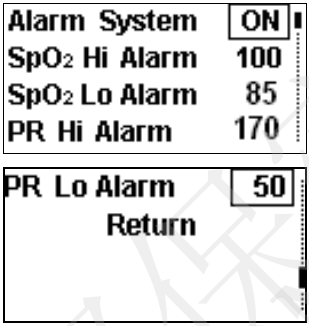
System Setup >>:







Alarm Setup >>:



Storage Setup >>:

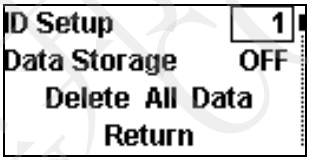


Figure 3-8 Menus

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

NOTE:

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

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

3 If the user changes the default value of **Lo Alarm** or **Hi**

Alarm, after restarting the resume to the default value for corresponding patient type.

3.3.1 System Mode

There are two items for selecting:

Waveform mode 

Large numeric mode 

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

3.3.2 Model

It indicates that the oximeter can be used by veterinary only and this item is unselectable and unmodifiable.

3.3.3 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.

3.3.4 Pulse Volume

The user can turn on or off the pulse volume by pressing **Pulse**

Volume, and change volume level to

the **Function** button to enter setup state, then use the **Up Arrow** or **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

3.3.5 Audio Paused (s)

Set the pause period for audio alarm to 30, 60, 90 or 120 seconds. When **Alarm System** is set to **ON**, pressing the **Alarm Silence** button can turn off the audio alarm, the pause period is set by the **Audio Paused (s)**.

3.3.6 User Maintain

Enter the **User Maintain** menu by inputting "819".

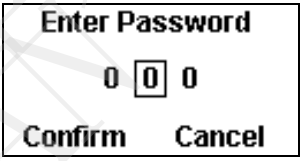


Figure 3-9 Enter Password

If the password is wrong, the followin

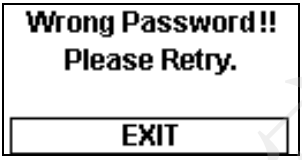


Figure 3-10 Wrong Password

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

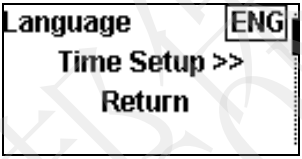


Figure 3-11 User Maintain

- Language: the user can select language to be displayed.
- Time Setup >>: select this item, the following interface displays:

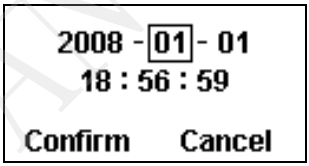


Figure 3-12 Time Setup

3.3.7 Default Config

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

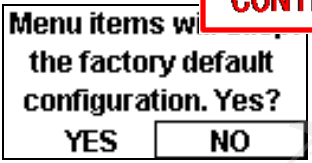


Figure 3-13 Factory Default Config

Factory Default Configuration is shown as follows:

System Mode:	
Model:	VET
Alarm System:	ON
Alarm Volume:	3
Pulse Volume:	3
Audio Paused (s):	60
SpO_2 Hi Alarm:	100
SpO_2 Lo Alarm:	85
PR Hi Alarm:	170
PR Lo Alarm:	40
Patient ID No.:	1
Data Storage:	OFF

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

3.3.9 Alarm System

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

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

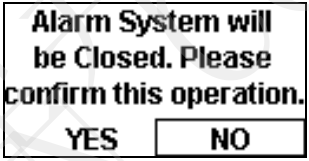


Figure 3-14 Confirm to Turn off Alarm

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 suspend the alarm system for seconds (the pause period can be set to 30, 60, 90 or 120s by the user, see section 3.3.5), the audio alarm off icon displays. But the visual alarm is still active. For example, if the measured SpO_2 value is higher than **SpO_2 Hi Alarm** or lower than **SpO_2 Lo**

Alarm, there will be ↑ or ↓ icon displa
or PR character will flash.

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

WARNING

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

3.3.10 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** are **100** and **85** 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 oxir

- 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 up 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.

3.3.11 PR Alarm Setup

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

By default, **PR Hi Alarm** and **PR Lo Alarm** are 170 and 40 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 350.
- 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.

3.3.12 Patient ID No. Setup

The oximeter can support 100 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.

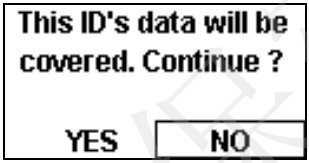


Figure 3-15 Confirm to Cover Data

3.3.13 Data Storage

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

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

Data stored in the oximeter can be exported through Oximeter Viewer Data Management Software. Please refer to section 3.2.4 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.

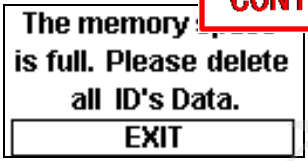


Figure 3-16 Memory Space Full

3.3.14 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:

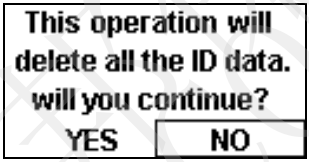


Figure 3-17 Delete All the Data

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

Figure 3-18 All Data Deleting

3.3.15 Exit (Return)

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

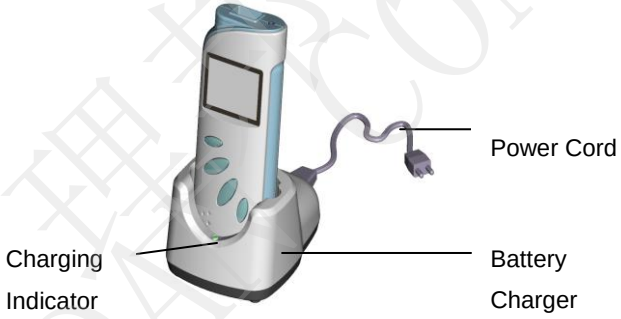
Return to the previous menu by pressi

3.4 Charging the Ni-MH 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 co

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.

3.5 Oximeter Viewer Data Management Software Introduction

Connect the oximeter to PC through the cable before running the Oximeter 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 software user manual for detailed information.

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

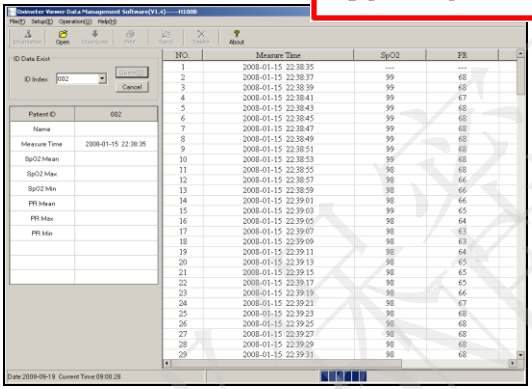


Figure 3-19 Main Interface

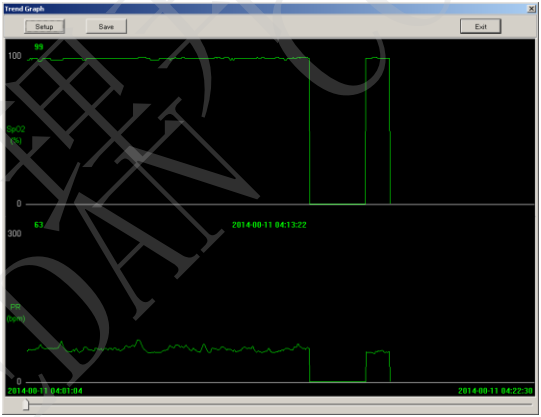


Figure 3-20 Trend Graph

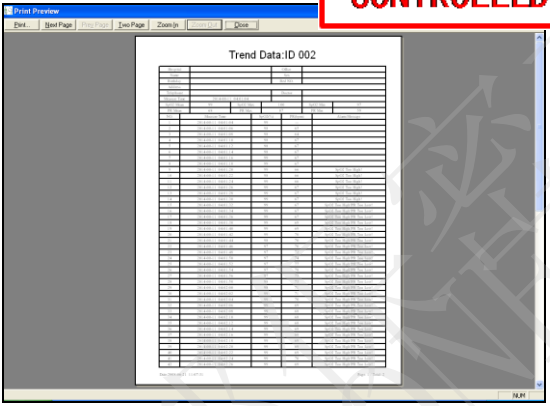


Figure 3-21 Print Preview

4 Sensor Operation

The VE-SH7 Veterinary Pulse Oximetry Sensor consists of a Multisite Pulse Oximetry Sensor (labeled M-YS) and two sensor clips that are used to apply the sensor to appropriate sensor site. There are two sizes of veterinary sensor clips: model VEC-S (small) and model VEC-L (large) which are shown in the following figure:

Figure 4-1

Reusable sensors may be used on the same site for a maximum of four hours, provided the site is inspected routinely to ensure skin integrity and correct positioning. Because individual skin condition affects the ability of skin to tolerate sensor placement, it may be necessary to change the sensor site more frequently with some patients.

1. Clean the sensor and sensor clip separately before and after each use (refer to cleaning section).
2. Nip the clamp by pressing with the thumb and forefinger.
3. Slide one of the sensor's alignment buttons along the clip slot until the sensor pad is fully engaged in the clip.
4. Slide the second sensor button along the other clip slot

until the second sensor pad is
the clip.

5. The sensor is now ready to be applied to the animal. The typical sensor application site is on the tongue, with the sensor's optical components positioned on the center of the tongue. Alternatively, the sensor and clip may be applied to the animal's lip, toe, ear, prepuce, or vulva.

NOTE:

1 If the sensor does not track the pulse reliably, it may be incorrectly positioned — or the sensor site may be too thick, thin, or deeply pigmented to permit appropriate light transmission. If any of these situations occurs, reposition the sensor or try another sensor site. If the sensor site is one that is covered with fur, try shaving the site and reapplying the sensor.

2 The sensor site too thin or dry (the typical site is on the tongue) may cause the measurement unstable. In such case, please wrap the sensor site in a piece of medical gauze moistened with normal saline and then open the sensor clip to measure again.

6. Attach the sensor as described in step 5. Be sure that the sensor cable is positioned along the side of the animal's face and body to avoid entanglement with the animal.

7. Plug the sensor into the pulse
operation.

NOTE:

To verify correct placement of the sensor on the site, manually take a pulse rate reading from another site on the animal. If the sensor is placed correctly, the manual reading should correspond to the pulse rate reading displayed on the oximeter.

WARNING

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

5 Alarm

5.1 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.

The levels for both technical alarms a
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

Technical alarms	Alarm level	Action Taken
SpO_2 Sensor Unconnected	Medium	No SpO_2 sensor was connected to the monitor.
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.

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;

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

5.2 Alarm Conditions

5.2.1 Alarm off Before the First Measurement

Before the first measurement, the alarm system is configured to be off. At this time, if the SpO_2 sensor is unconnected or the sensor is off, the oximeter will not give an alarm.

5.2.2 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.)

5.2.3 Alarm for SpO_2 Sensor

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.)

5.2.4 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 **Alarm System** in menu is ON.)

5.2.5 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.

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.

5.2.6 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.

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 **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.

5.2.7 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.

5.2.8 Turning off Alarm System

After the alarm system is turned off, the oximeter can not 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.

5.2.9 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.

5.2.10 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.

5.2.11 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.

6 Performance Considerations

6.1 Performance Verification

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

6.2 Oximeter Performance Considerations

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

- Dysfunctional Hemoglobins

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

- Anemia

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

- Saturation

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

- Pulse rate

The oximeter displays pulse rate between 25 and 350 beats per minute (bpm). The sensor accuracy ranges do not apply to pulse rates above 350 bpm.

- Data update period

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

6.3 Sensor Performance Considerations

Inaccurate measurements can be caused by:

- Incorrect application of the sensor.
- Placement of the sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.
- Excessive patient activity.
- 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 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 the sensor are:

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

- Bilirubin lamps.
- Fluorescent lights.
- Infrared heating lamps.
- Direct sunlight.

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

6.4 SpO_2 Functional Test

This test checks the function of the SpO_2 measurement.

Tools required: SpO_2 simulator.

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 valu
configuration. The value should be 85% ±2%.

6.5 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:

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

7 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 te 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 patient's health may be endangered.

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. Wipe off the cleaning solution with a fresh cloth or towel, dampened with tap water after cleaning until no visible cleaning agent remains.
4. Dry the 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. Wipe off the cleaning solution with a fresh cloth or towel,

dampened with tap water after cleani
agent remains.

4. Wipe off with a dry cloth to remove residual moisture.
5. 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%)

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

WARNING

The oximeter and reusable accessories shall be disinfected to avoid 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

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. Maintenance should be taken half a year for continuous use if service life exceeds 5 years.

8 Principles of Operation

VE-H100B Pulse Oximeter adopts non-invasive double wavelength to measure SpO_2 and PR. It can perform spot and continuous measurement for a short time.

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

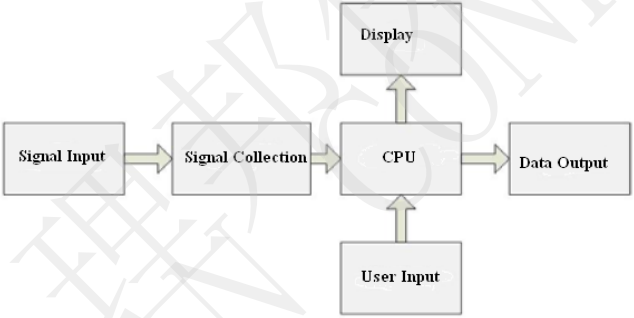


Figure 8-1 System Principle

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

8.1 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 vascul
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 infr
is related to hemoglobin oxygen saturation. To identify the oxygen saturation of arterial hemoglobin, the oximeter uses the pulsatile nature of arterial flow.

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

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

Wavelength

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

8.2 Functional Versus Fractional Saturation

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

dysfunctional hemoglobin, such as carboxyhemoglobin and 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.

8.3 Measured Versus Calculated Saturation

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

9 Warranty and Service

9.1 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.

9.2 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 Specificat

A1.1 Classification

Type of Protection	Internally powered equipment
Degree of Protection	Type BF-Applied part
Ingress Protection	IPX2
Mode of operation	Continuous
Degree of Safety in Presence of Flammable Gases	Not suitable for use in presence of flammable gases
Compliant with Safety Standards:	IEC 60601-1:2005+A1:2012, EN 60601-1:2006+A1:2013, IEC 60601-1-2:2007, EN 60601-1-2:2007; ISO 80601-2-61:2011

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	0 °C ~ + 40 °C (32 ℉~104 ℉)
Storage	-20 °C ~ + 55 °C (-4 ℉~131 ℉)
Humidity	

Working	15%RH ~ 95
Storage	15%RH ~ 95%RH (non-condensing)
Atmospheric pressure	
Working	86 kPa ~ 106 kPa
Transport and Storage	70 kPa ~ 106 kPa

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 operation time	48 hours or longer (At 25 ℃, 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

Quantity	1
Total rated voltage	4.8 V
Capacity	1800 mAh
Typical battery life	36 hours 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 hours to 80%
	No more than 4 hours to 100%

Quantity	1
Total rated voltage	4.8 V
Capacity	1500 mAh
Typical battery life	30 hours 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 hours to 80%
	No more than 4 hours to 100%

A1.2.5 Charger Stand

Model	CS-01
Input voltage	100 to 240 VAC, 50/60 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	25 bpm ~ 350 bpm
Accuracy Tolerance	
Saturation	
Normal condition	±2% (70%~ 100%)
Pulse Rate	
Normal condition	±2 bpm
Resolution	
SpO_2	1%
Bpm	1 bpm
Sensor	
Red Light	(660±3) nm
Infrared Light	(905±10) 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).

Appendix II EMC Information

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		
VE-H100B and charger stand are intended for use in the electromagnetic environment specified below. The customer or the user of the VE-H100B and charger stand should assure that they are used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment -guidance**
RF emissions CISPR11	Group 1	VE-H100B and charger stand 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	VE-H100B and charger stand 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	Pulse oximeter: N/A Charger stand :Class A	
Voltage fluctuations /flicker emissions IEC/EN61000-3-3	Pulse oximeter: N/A Charger stand: Complies	

A2.2 Electromagnetic Immunity

For pulse oximeter:

Guidance and manufacturer's declaration – electromagnetic immunity			
VE-H100B is intended for use in the electromagnetic environment specified below. The customer or the user of VE-H100B should assure that it is used in such an environment.			
Emissions test	**Compliance**	**Compliance level**	**Electromagnetic environment - guidance**
	±6kV contact	±6kV contact ±8kV air	Floors should be wood,

Electrostatic discharge(ESD) IEC/EN61000-4-2	±8kV air		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	<5%UT(>95 % dip in UT)for 0.5	N/A	N/A

power supply input lines IEC/EN61000-4-11	cycle 40%UT(60 % dip in UT)for 5 cycles 70%UT(30 % dip in UT)for 25 cycles <5%UT(>95 % dip in UT)for 5s		
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

			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.			
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

			humidity should be at least 30%.
Electrical Fast Transient/Burst IEC/EN61000-4-4	±2kV for power supply lines	±2kV 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 ±2 kV line to ground	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	<5%UT(>95% dip in UT)for 0.5 cycle	<5% UT (>95% dip in UT) for 0.5 cycle	Mains power quality should be that of a typical commercial or

IEC/EN61000-4-11	40%UT(60% dip in UT)for 5 cycles 70%UT(30% dip in UT)for 25 cycles <5%UT(>95% dip in UT)for 5s	40 (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5s	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	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a

			commercial or hospital environment
NOTE UT is the a.c. mains voltage prior to application of the test level.			

A2.3 Electromagnetic emissions

For pulse oximeter and charger stand:

Guidance and manufacturer's declaration – electromagnetic immunity			
VE-H100B and charger stand are intended for use in the electromagnetic environment specified below. The customer or the user of VE-H100B 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**
			Portable and mobile RF communications equipment

			no closer to any part of VE-H100B 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
Conducted RF IEC/EN 61000-4-6	3 Vrms 150KHz to 80MHz	3 Vrms	

Radiated RF IEC/EN 61000-4-3	3 V/m 80 MHz to 2.5GHz	3 V/m	80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where *p* is the maximum output power rating of the transmitter in watts(W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an

			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 pre 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

For pulse oximeter and charger stand:

Recommended separation distances between portable and mobile RF communications equipment and the VE-H100B and charger stand
VE-H100B and charger stand is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of VE-H100B and charger stand can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the oximeter as recommended below, according to the maximum output power of the

communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	**0.12**	**0.12**	**0.23**
0.1	**0.38**	**0.38**	**0.73**
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	Arterial Oxygen Saturation From Pulse Oximeter

P/N: 01.54.110263
MPN: 01.54.110263018

受控文件
CONTROLLED FILE

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EC REP

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