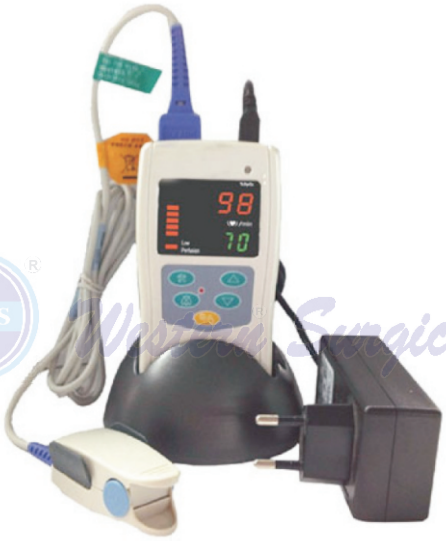
ONE STOP SHOWROOM FOR HOSPITAL & HEALTHCARE PRODUCTS.



Handheld Pulse Oximeter

USER MANUAL

WESTERN SURGICAL®

Western Surgical

AN ISO 9001 : 2008 & ISO 13485 : 2015 AC 2012 CERTIFIED COMPANY

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Email : info@westernsurgical.in Ph. : +91-281-2232871 / 2243159

Contents

* Carrying Warranty at Rajkot Office only on site warranty not provided free of cost.
* Due to constant upgradation design, price and features are subject to change any time without prior notice.

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Service Information

Dear Customer

Welcome to use HHP-201 Handheld Pulse Oximeter ! This manual is mainly designed to offer users the operation guidance and device maintenance information. The manual explains specifications, installation, use, and safety information of the Oximeter. Before use, carefully read this manual so as to use the Oximeter properly.

Note

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

Version information

This version is subject to change or upgrade without notice.
Version: 1.0
Software version: 1.0.0
Issue date: 2016-05
File's NO.: HHP-201-004

1 Safety

1.1 Safety Information

This section contains important safety information related to general use of the HHP-201. Other important safety information appears throughout the manual in sections that relate specifically to the precautionary information. Be sure to read all text surrounding all precautionary information.

Before using, read this manual carefully, accessory directions for use, all precautionary information in boldface type, and specifications.

⚠ Warning

- The HHP-201 is a prescription device and is to be operated by qualified personnel only.
- Explosion hazard. Do not use the HHP-201 handheld pulse oximeter in the presence of flammable anesthetic.
- He cover should be removed only by qualified service personnel. There are no user-serviceable parts inside.
- To ensure accurate performance and prevent device failure, do not expose the HHP-201 to extreme moisture, such as rain.
- Pulse oximetry readings and pulse signal can be affected by certain ambient environmental conditions, probe application errors, and certain patient conditions.
- Do not use the HHP-201 during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns. The HHP-201 may affect the MRI image; the MRI unit may affect the accuracy of oximetry measurements.
- If you are uncertain about the accuracy of any measurement, check the patient's vital signs by alternate means, and then make sure the Oximeter is functioning correctly.
- SpO2 measurements may be adversely affected in the presence of high ambient light. Shield the probe area (with a surgical towel, for example) if necessary.
- Tissue damage can be caused by incorrect application or duration of use of a SpO2 probe. Inspect the probe site as directed in the probe directions for use.
- Reposition the probe at least once every 4 hours to allow the patient's skin to respire.

⚠ Caution

- The HHP-201 is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.
- Ambient light, movement, electromagnetic interference, artifacts, dysfunctional hemoglobin, and certain dyes, etc. may be interfering in the pulse oximeter's functions.
- Do not autoclave, ethylene oxide sterilize. Do not immerse the HHP-201 in liquid.
- The Pulse Oximeter does not provide dfib Sync signal so it cannot be connected with a defibrillator.

1.2 Product Label

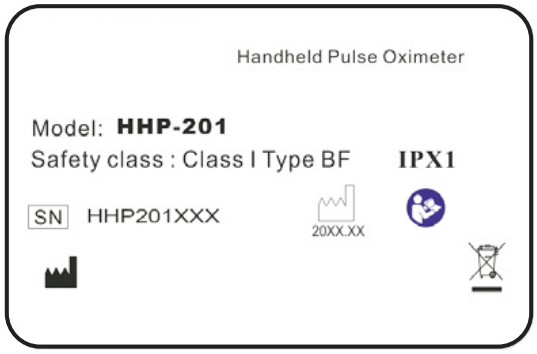


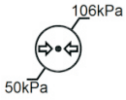
Figure1-1: Product label

1.3 Symbol

The symbols indicated on this monitor are explained below:

Symbol	Description
	Attention!
	Follow instructions for use.

Safety

	Type BF
	The sign of CE authentication
	The sign of reclaiming products
	Date of Manufacture
	Manufacturer
	Serial number
RX Only	Prescriptive device, operated by qualified personnel only!
IPX1	Drip proof
	Temperature Limit
	Humidity Limitation
	Atmospheric pressure limitation

2 Introduction

2.1 Product Introduction

❖ Intended use

The HHP-201 handheld pulse oximeter is a type of Monitor intended for measurement of pulse oxygen saturation of arterial hemoglobin (%SpO2), and pulse rate. This Oximeter can be for use on adult, pediatric, and neonatal patients.

The Pulse Oximeter contains: mainframe and probe.

⚠ Caution

- The HHP-201 is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

⚠ Warning

- Do not use the HHP-201 during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns. The HHP-201 may affect the MRI image; The MRI unit may affect the accuracy of oximetry measurements.

❖ General operating principles and conditions

The HHP-201 uses pulse oximetry to measure oxygen saturation in the blood. Pulse oximetry works by applying a probe to pulsating arteriolar vascular bed, such as a finger or toe. The probe contains a dual light source and a photo 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 in an oxygen saturation measurement (SpO2).

Because a measurement of SpO2 is dependent on light from the probe, excessive ambient light can interfere with this measurement.

⚠ Warning

- Pulse oximetry readings and pulse signal can be affected by certain ambient environmental conditions, probe application errors, and certain patient conditions.
- Specific information about ambient environmental conditions, probe application, and patient conditions, is contained throughout this manual.

2.2 Description of Controls, Indicators, and Symbols

2.2.1 Overview

❖ **Front views**

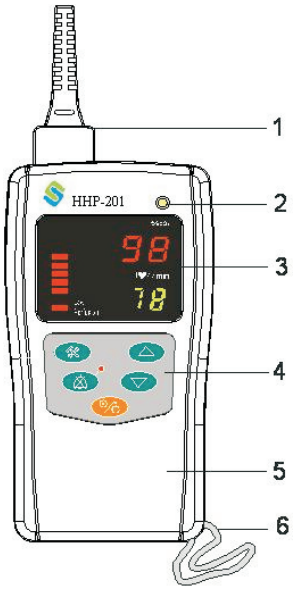


Figure 2-1：Front View

1. Probe	2. Power indicator light	3. Display Window
4. Keys	5. Front Panel	6. Wrist Tie

❖ **Stand**

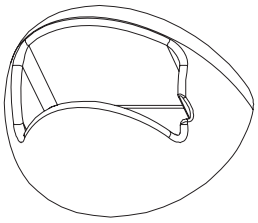


Figure 2-2：Stand

❖ **Rear view**

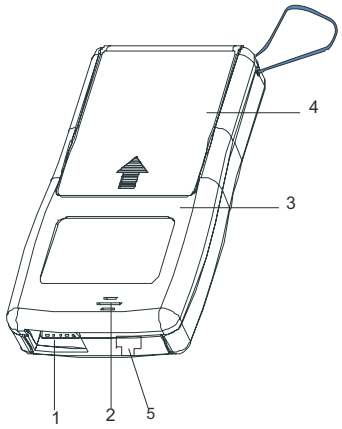


Figure 2-3: Rear view

1. Probe Socket	2. Speaker	3. Rear Panel
4. Battery Door	5.USB socket(For charging)	

2.2.2 Display

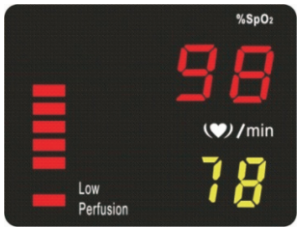


Figure 2-4：Display View

❖ **Symbols**

1. **%SpO2:** Percent oxygen saturation ,valid range is 0～100, "———"express invalid value.
2. ♥ / min: Pulse rate, Pulsation number per minute, valid range is 30～250. Unit: bpm ; "———"Express invalid value.
3. **Low Perfusion :**Low perfusion indicator. During the patient pulse strength is low, red LED will be lit.

❖ **Description of visual indicators and displays**

1. **%SpO2 display area :**Three red digital LEDs display，when invalid is displayed, "———"will blink by 1Hz frequency ; While set up Power Mode, "bAt"is displayed; Apart form that, this area is also used to show error code and software version as it is turned on.
2. **PR display area:** Three green digital LEDs display, when invalid is displayed, "———"will blink by 1Hz frequency, while set up power mode; currently set up is display.
3. **Pulse Indicator:** 8-segmant red LED, display currently pulse indication.

⚠ Note

- Pulse Indicator is a visual indication of the patient's pulse straight, not that display is proportional to the pulse volume.
- The display update period of the HHP-201 in various operating conditions is 1/60 second.

❖ **Description of audible indicators**

The following are audible indicators for which there are no accompanying symbols, keys or visual indicators.

1. Power-On---------- One tone
2. Probe disconnected--------- the first 1five beep, and after 1 double-beep every 30 seconds
3. Low Battery----------1 double–beep every 60 senconds
4. Press key volum----------during the normal press keys, 1 single –beep; invalid press keys, 1 single-beep
5. Pulse volume----------1 single-beep

2.2.3 Keys

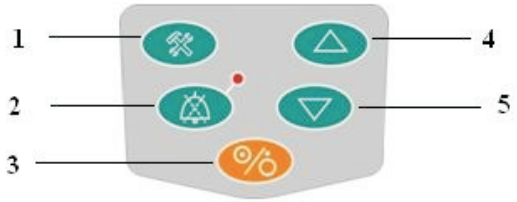


Figure 2-5: Keys

- **Choice key**：To switch between normal modes, power setting mode and SpO_2 average time set-up. In normal working condition, press and hold key to enter alarm limits and alarm silence intervals setup.
- **Silence key:** This key can control "ON" or "OFF" of pulse sound, key sound and alarm sound.
  1. Whenever press the key, it will control "ON" or "OFF" of pulse sound.
  2. When the silence interval is set for "0", press the key to control pulse sound and key sound that can not control the alarm sound.
  3. When the silence interval is set for "15, 30, 60, 90, 120"and "OFF", press the key to control pulse sound, key sound and alarm sound.
  4. f silence mode is set as "OFF", the red light will flash.
  5. In alarm limit setting, by pressing for 3 seconds, the default alarm limit for SpO2 and PR will be reset.
- Power On/Off key，press the key for 2 seconds to turn the Pulse Oximeter "On or Off".
- Up Key
  1. In power setting mode, it is to switch between "All" or "HLF". All：all-on; HLF：power-save. These are shown at Pulse Rate display area.
  2. Set SpO2 average time.
  3. Adjust alarm limit and silence interval time.
  4. If user keeps this key pressed, the value would scroll fast.
- Down Key：Similar functions as Up key.

2.3 Description of Function

HHP-201 Pulse oximeter's main function:

- Oxygen saturation of arterial hemoglobin measurement
- Pulse rate measurement
- Alarm

3 Unpackingg and Installation

3.1 Unpacking

Carefully remove the HHP-201 and its accessories form the shipping carton. Save the packing materials in case the HHP-201 must be shipped or stored.

Inspect the equipment for mechanical damage. If yes, please contact your provider promptly.

3.2 Installing the batteries

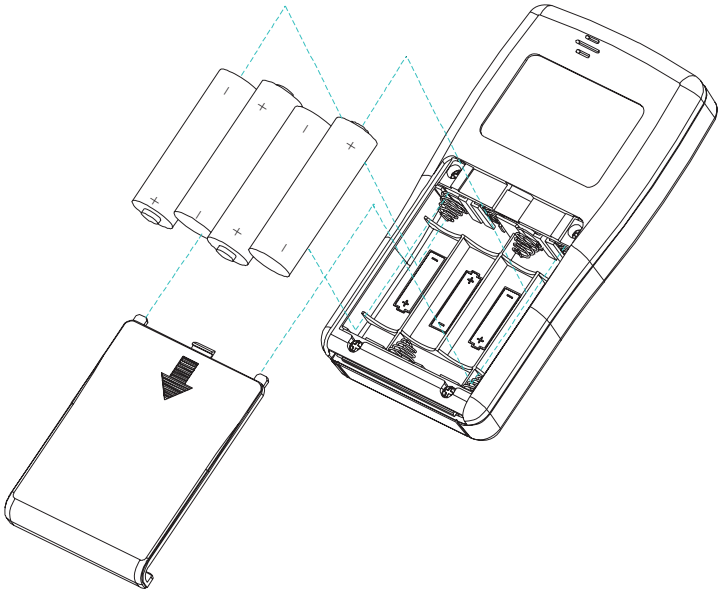


Figure3-1: Installing Batteries

1. Refer to figuer3-1，pull the battery compartment latch downward, toward the bottom of the oximeter, and remove the battery access door.
2. Install four “AA”size batteries, oriented as shown in Figure 3-1． Replace the battery access door.

To remove the batteries, reverse the installation process, removing the positive end of each battery first.

Notes

- Install the negative end of each battery first, compressing the battery terminal spring until the positive terminal clears the positive spring, and pressing the battery downward into place.
- Do not mix alkaline “AA” batteries with rechargeable batteries. When enplacing batteries, replace with four fresh (new) batteries. Do not mix used and new batteries. If don’t use HHP-201 for a period time, please take all batteries away.
- When charging the battery with power adapter, press  for 1s, the charge indicator starts blinking. It shows the battery is under charging. After charging completed the charge indicator turns off.

Warnings

- Explosion hazard. Do not use the HHP-201 handheld pulse oximeter in the presence of flammable anesthetics.
- As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.
- To ensure accurate performance and prevent device failure, do not expose the HHP-201 to extreme moisture such as rain.
- When charging the battery with power adapter, the charging time can not exceed 24 hours, otherwise the battery may be damaged or exploded

Cautions

- Check the batteries periodically for corrosion. Replace batteries if corrosion is present, otherwise damage to the monitor may occur.
- Do not use lithium batteries with the HHP-201. Lithium batteries will damage the monitor.

3.3 Installing and Using the Probe

Warnings

- Before use, carefully read the probe directions for use, including all warnings, cautions, and instructions.
- Do not use a damaged probe. Do not use a probe with exposed optical components.
- Use only Silverline sensors for SpO2 measurements. Other sensors may cause improper HHP-201 performance.

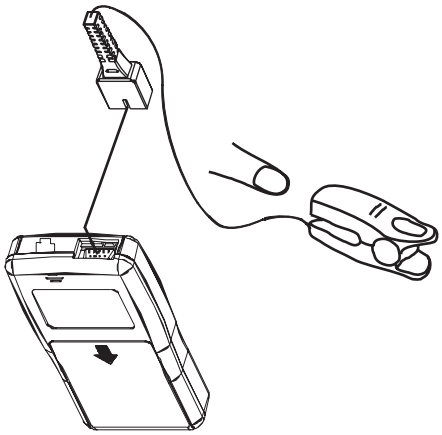


Figure 3-2：Installing and use the probe

1. Refer to Figure 3-2, Connect the Oximeter plug to pulse oximeter convex interface.
2. The probe is finger tip oximeter probe. Attach the finger probe with the light to the patient. Be sure to fully insert the patient's finger into the probe, As following:

❖ **Biocompatibility Testing**

Biocompatibility testing has been conducted on probes in compliance with ISO 10993-1, Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing. The probes have passed the recommended biocompatibility testing and are, therefore, in compliance with ISO 10993-1.

❖ **Performance Considerations**

⚠ Warning

- Pulse oximetry reading and pulse signal can be affected by certain ambient environmental conditions, probe application errors, and certain patient conditions.

Inaccurate measurements can be caused by：

❖ Incorrect application of the probe；

❖ Placement of the probe on an extremity with a blood pressure cuff, arterial catheter, or intravascular line；

❖ Ambient light；

❖ Patient movement.

Loss of pulse signal can occur for the following reasons：

- ❖ The probe is too tight；
- ❖ A blood pressure cuff is inflated on the same extremity as the one with the probe attached；
- ❖ There is arterial occlusion proximal to the probe.

Select an appropriate probe, apply it as directed, and observe all warnings and Cautions presented in the directions for use accompanying the probe. Clean and remove any substances such as nail polish from the application site. Periodically check to see that the probe remains properly positioned on the patient.

High ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight can interfere with the performance of a SpO2 probe. To prevent interference from ambient light, ensure the probe is properly applied, and cover the probe site with opaque material.

⚠ Warning

- Tissue damage can be caused by incurred application or duration of use of a SpO2 probe. Inspect the probe site as directed in the probe directions for use.

⚠ Note

- Failure to take this precaution in high ambient light conditions may result in inaccurate measurements.

If patient movement presents a problem, try one or more of the following remedies to correct the problem.

- ❖ Verify that the probe is properly and securely applied.
- ❖ Move the probe to a less active site.

⚠ Note

- The preceding section pertains to patient and environmental conditions that can be addressed by probe selection and application. For information regarding the impact of other patient and environmental conditions on oximeter performance, see “Performance Considerations” in the Power-On and Use section.

⚠ Warning

- Reposition the probe at least once every 4 hours to allow the patient's skin to respire.

Caution

- Do not autoclave, ethylene oxide sterilizes, and with a soft cloth moistened in a mild soap solution and hot water lightly wipe the surface of the HHP-201. If disinfection is required, wipe the probe surfaces with a soft cloth moistened in isopropyl alcohol. Caution, do not allow any liquid to enter any of the HHP-201 openings.

4 Power-ON and Use

4.1 Basic Operation

⚠Warnings

- The HHP-201 is a prescription device and is to be operated by qualified personnel only.
- Do not lift the monitor by the probe cable because the cable could disconnect from the monitor, causing the monitor to drop on the patient.

⚠Cautions

- The HHP-201 is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.
- If the battery were insufficient to operate, the power indicator would turn red and blink for three times. And then, HHP-201 turns itself off if the batteries are less or installing the batteries is failure. This Oximeter may have no response. Then, Please make sure the batteries have enough energy.

⚠Notes

- Before using the HHP-201, remove the plastic protective sheet that covers the display. This sheet is only on the display to protect it during shipping. Leaving it on during monitoring could make it difficult to read displayed measurements.
- Prior to using the HHP-201, carefully read this manual, accessory direction for use, all precautionary information in boldface type, and all specifications.

4.1.1 Power-On

1. Install the batteries, the Pulse oximeter would automatically power-on. If the batteries were already installed, turn on the HHP-201 by pressing  key for 2 seconds.
2. If installing the batteries or power-on is successful, the power indicator light is display green, and will generate “dee”. All displays include：
   - ❖ All segments of all numeric digits light；
   - ❖ Pulse indicator；
   - ❖ Power indicator light；
   - ❖ Low perfusion indicator.

   All display icons light, last for 1 second.

   Make sure that you can hear “dee ” sound. If inaudibility occurs, the sound system is damaged, do not continue to use it, contact your provider or manufacturer.

If the sound is slight, make sure the holes located on the speaker are not covered. After remove this instance, if the volume is low， do not continue to use the Pulse Oximeter, contact your provider or manufacturer.

Check every display content, if any display is not complete do not continue to use the

Pulse Oximeter, contact your provider or manufacturer

3. During the Power-on, the HHP-201 automatically conducts a power-on self-test .If the HHP-201 detects an internal problem, an error tone sounds and the monitor displays an Error Code and corresponding number (see Troubleshooting section for error codes).
4. If the power-on self-test is normal, the oximeter will display its software version.
5. After displaying for approximately 1 second, the Oximeter enters measurement mode.

4.1.2 Running Mode

In the normal working condition, there are four modes：

1. If no oximetry probe is inserted, SpO2 and PR display area has blink"- - -"， the Pulse Oximeter will turn off automatically in 120 seconds.
2. The oximetry probe has already been inserted, but the probe not attached to the finger, SpO2 and PR display area has blink"- - -"， At the same time, the oximeter will generate lost reminder sound in every 30 seconds. The Pulse Oximeter will be turn off automatically if this mode continues in 120 seconds.
3. Pulse search mode: If patient is connected with the probe, the oximeter attempts to search pulse. At the same time, display shows blink"- - -"in %SpO2 and PR areas. Normally the search mode process is approximately 10 seconds. If the pulse search is failed, the Pulse Oximeter continues pulse search mode for 120 second.
4. If pulse search is successful, in %SpO2 and PR area will display the patient's %SpO2 and PR. Pulse indicator will jump together with the pulse jumping. Speaker will generate "dee dee" with the pulse jumping. Feature as follows:
   - ❖ %SpO2: Express percent oxygen saturation
   - ❖ PR: In pulse beats per minute (bpm)
   - ❖ The volume of "dee dee" generated by the speaker is closely related with %SpO2. If the SpO2 value is lesser, the volume of the tone will be bigger.

4.1.3 Keys Operation

In normal working condition, at this time, press  and  keys adjust pulse volume, invalid press key volume comes out when it reaches the Max. /Min. value ；By press 

key turn on or off silencing function ; Press once enters power manager setup; twice enters SpO2 average time setup; third return to the normal working situation. Please press key for two seconds, the oximeter will turn off.

In order to prolong battery's using time, the Pulse oximeter has two power modes: All-on mode and Power-saved mode.

In all-on mode, it has no Power-save function. More power could be consumed. When it is in power-save mode, if no key is pressed for 40 seconds, the brightness of the screen will be less; If no key is pressed for 15 minutes, displays will be off automatically. Then if any key is pressed or there is reminder, display will resume.

Whether in All-on mode or in Power-save mode, if no patient is connected with the probe and no key is operated, the Pulse Oximeter will turn off automatically in 120 seconds. If the user needs to continue to use it, please press for two seconds, the oximeter will be turned on again. When there is not enough power in battery, the oximeter will be turned off by itself too. Please change the battery in time.

In normal working condition, press and keys to adjust pulse volume.

In normal working condition, please press once to set power mode. In SpO2 % area in the screen "bAt"is on .In PR area"All" and "HLF"are on;

No change is showed in pulse indicator area. "All" indicates all-on mode is on;"HLF"indicates power-save mode is on. or could be pressed to switch the power mode. After setting, please press twice to exit mode setting. Besides, even in all-on mode, if the power volume is less than a certain value, the oximeter will switch to power-save mode by itself.

In normal working condition, press twice to set SpO2 average time. AVE will be shown in SpO2 area. In PR area there are three numbers in terms of SpO2 average time: 4, 8, 16. Press or to select. After setting, press once to exit mode setting and return to the normal working situation.

4.1.4 Turn Off

The Pulse Oximeter turns itself off automatically after pressing keys for 2 seconds. The HHP-201 turns itself off automatically when the batteries are weak.

4.1.5 Charge

❖ **Specification**

a) There is a USB socket on the pulse oximeter top left corner, that's for charger plug. The other side of charger connect AC100-240V 50/60Hz power, battery start charging when connects with power.

b) When battery power is not enough, the indicator light would blink in Red. Means battery need be charged.

c) Charging during machine is ON, pulse oximeter indicator light. Blink in Green. When battery charged full, indicator light in Green.

d) Charging during machine is OFF, pulse oximeter indicator light blink in Green.When battery charged full, indicator light turn off.

❖ **Attention**

a) Pulse oximeter charger socket is same with normal USB interface, but oximeter charger socket is special for charging, only match with original charger. Do not connect with computer or other device.

b) Only use original charger charge battery, otherwise would damage battery, even damage oximter or take place danger.

c) Only use Ni-MH battery during charging. Do not use commonly dry battery or alkaline battery.

d) New battery first time charge should be charged enough full by original charger before use. Otherwise would bring important influence to the battery efficiency.

e) If don't use pulse oximter in long time, battery should be take out of it.

f) Oximeter would generate much heat during charging. Oximeter couldn't covered by anything. Do not have on carrying pouch during charging

4.1.6 Storage

Remove the batteries from the HHP-201 before long-term storage, or if the device won't be used for 6 months or more. This protects the device from damage due to batteries leaking acid.

Store the device in its original shipping carton and packing materials to help protect the device from damage during storage.

4.1.7 Environment of Protection

For minimizing risks, discard the used-up batteries and HHP-201 according to your local government organization rules, ROHS （2002/95/EC） and WEEE （2002/96/EC） .

4.2 Impact of Performance Consideration

Inaccurate measurements can be caused by:

❖ Excessive patient movement;

❖ Venous pulsations;

❖ Intravascular dyes, such as indocyaninegreen or methylene blue;

❖ Significant levels of dysfunctional hemoglobins

❖ Defibrillation.

Ambient environmental conditions and probe application errors, which can affect pulse oximetry readings, are discussed in the Probe section of this manual and in the probe directions for use.

The effects of electromagnetic interference on oximetry reading is discussed in the Troubleshooting and Maintenance section of this manual

5 Alarm Functions

5.1 On/Off Function

In the normal condition, press key three times enter alarm function on/off setup, screen SpO_2 area display “ALA” ;PR area display “ON”or “OFF”。Press or key switch it, press key go back to the normal state after setting. If the alarms set “OFF”, user can’t enter alarm setting option.

5.2 Alarm Limit Setup

In the normal condition, press key three seconds，enter alarm limit setup, screen SpO2 area would display “SPH”（SpO2 high limit ）.Press key choice the setting parameter “SPH”（SpO2 high limit)、“SPL”（SpO2 low limit)、“PRH” (pulse high limit）or “PRL” （pulse low limit）；PR area displays the value of the current parameter setting. Press or key adjusts the value. If user keeps the key pressed, the number will scroll fast.

Technology specification:

- **SpO2**

  Alarm High limit: 0～100% （default：99%）

  Alarm Low limit: 0～100% （default：92%）

  The low limit of SpO_2 can’t lower than SpO_2 default value.

- **Pulse rate**

  Alarm Upper limit: 0 ～ 255bpm （default: 130）

  Alarm Lower limit: 0 ～ 255bpm （default: 50）

- **Alarm setting precision can’t lower than test precision,**

  SpO2：1%，Pulse rate：1bpm

- **Alarm High limit can’t less than alarm Low limit**

5.3 Alarm mute time interval setup

In the alarm limit setting，continuous press key，screen SpO2 area circular display “SPH”Æ“SPL”Æ“PRH”Æ“PRL”Æ“INT”Æ“SPH”，the “INT” is correspond the alarm mute time，valid setting is 0sec、15sec、30sec、60sec、90sec、120sec、OFF, press or key choice it. Long press key go back to the normal condition.

When there is no alarm ，press key mute the PR volume ;when the alarm is start，press key mute the alarm volume，have several instance ,as following:

- INT setting as 0 sec，press key can’t mute alarm volume;
- INT setting as “OFF”,press key can mute the alarm volume. Until appear more badly alarm condition, or patient’s SpO2 and PR from no alarm to start alarm;
- INT setting as other values, press key, will mute corresponding time.

Others: when alarm volume is mute, press key on-off PR volume

6 Troubleshooting and Maintenance

⚠Warnings

- If you are uncertain about the accuracy of any measurement, check the patient's vital signs by alternate means; then make sure the Oximeter is functioning correctly.
- The cover should be removed only by qualified service personnel. There are no user-serviceable parts inside.

If you experience a problem while using the HHP-201 and are unable to correct it, contact qualified service personnel or representative. The HHP-201 service manual, which is for use by qualified service personnel, provides additional troubleshooting information.

6.1 Troubleshooting and Solutions (Refer to Table)

Problem	Possible Reason	Suggestion
No pulse shown on the bar graph.	Probe is disconnected from HHP-201 ; Probe is incorrectly positioned on the patient ; Poor patient perfusion ; Defective probe	Check probe connection to the patient and cable to the HHP-201 ; Reposition the probe ; Try a new probe or contact your authorized repair center for help.
Pulse rate is erratic, intermittent, or incorrect ; %SpO_2 value is erratic, intermittent, or incorrect.	Probe incorrectly positioned ; Poor patient perfusion ; Patient motion.	Reposition the probe ; Patient must remain still to obtain an accurate measurement.
HHP-201 doesn't turn on.	Batteries weak ; Batteries not installed or batteries incorrectly installed ; Internal fuse blown.	Replace the batteries ; Ensure the batteries are installed correctly ; Incorrectly installed batteries may cause an internal fuse to blow. In that case, the HHP-201 must be sent to an authorized repair center.
HHP-201 turn off unexpectedly.	The HHP-201 turns itself off automatically two minutes after the probe is	None Replace the batterie

	removed from the patient or after the probe is disconnected from the HHP-201； Batteries are weak or dead.	
"E01" appears on the Display.	Internal fuse damage.	Contact technical service department.

6.2 Obtaining Technical Assistance

For technical information and assistance, or to order parts or a service manual, contact Technical Services Department or your local representative .The service manual includes block diagrams and a parts list required by qualified personnel when servicing the HHP-201.

The software version appears on the display screen immediately after the power-on self-testis completed. Write the number down and have it available whenever requesting technical assistance.

6.3 Returning

ContactTechnical Services Department or your local representative for shipping instructions including a Returned Goods Authorization number. Remove the batteries for shipping, and unplug the probe. Pack the HHP-201 in its original shipping carton .If the original carton is not available; use a suitable carton with appropriate packing material to protect it during shipping.

6.4 Service

⚠Warning

- The cover should be removed only by qualified service personnel. There are no user-service-able parts inside.

6.4.1 Pulse Oximeter

If cleaning is required, wipe the Pulse Oximeter's surfaces with a soft cloth moistened with commercial nonabrasive cleaner. Do not allow any liquid to enter any of the Pulse Oximeter openings.

⚠Warnings

- Turn off the Pulse Oximeter before cleaning.

- Do not autoclave, ethylene oxide sterilize, or immerse the Pulse Oximeter in liquid. If disinfection is required, wipe the Pulse Oximeter's surfaces with a soft cloth moistened with commercial nonabrasive cleaner. Do not allow any liquid to enter any of the Pulse Oximeter's openings.

6.4.2 Probe

The probe is the only part touching the patient. Every time the probe is used, it must be cleaned. Refer to the directions for use enclosed with the probe for cleaning directions.

6.5 Periodic Safety Checks

The following safety checks should be performed every 24 months by a qualified person who has adequate training, knowledge, and practical experience to perform these tests.

- Inspect the equipment for mechanicaland functional.
- Inspect the safety relevant labels for legibility.
- Verify that the device functions properly as described in this operator's manual.

If the oximeter is not functioning properly or fails any of the above tests, do not attempt to repair the oximeter. Please return the oximeter to the manufacturer or to your distributor for any required repairs.

7 Appendix

7.1 Principles of Measurement

Pulse oximetry is based on two principles: 1. that oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light(i . e. ,Spectrophotometry), and that the volume of arterial blood in tissue(and hence, light absorption by that blood)changes during the pulse(i .e. ,plethysmography). A pulse oximeter determines SpO2 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 (LEDs) in the oximetry probe serve as light sources; a photodiode 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 bemoglobin, the monitor uses the pulsatile nature of arterial flow.

During systole, a new pulse of arterial blood volume and light absorption increase.

During diastole, blood volume and light absorption reach their lowest point .The monitor bases its SpO2 measurements on the difference between maximum and minimum absorption (i.e., Measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of nonpulsatile absorbers such as tissue, bone, and venous blood.

The Pulse oximeter determines SpO2 and pulse rate by passing two wavelengths of light, one red and one infrared, through body tissue to a photodetector. During measurement, the signal strength resulting from each light source depends on the color and thickness of the body tissue, the probe placement,The intensity of the light sources, and the absorption of the arterial and venous blood (including the time varying effects of the pulse) in the body tissue (Refer To Figure 8)

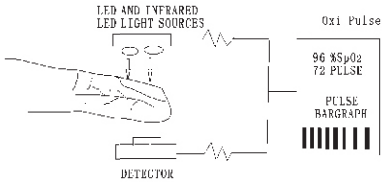


FIGURE 8: SpO2 THEORY OF OPERATION

The Pulse Oximeter processes these signals, separating the time invariant parameters (tissue thickness, skin color, light intensity, and venous blood) from the time variant parameters (arterial volume and SpO2) to identify the pulse rate and calculateoxygen saturation. Oxygen saturation calculations can be performed because oxygen saturated blood predictably absorbs less red light than oxygen depleted blood.

7.2 HHP-201 Standard Packaging

①Main unit; ② Adult SpO2 finger sensor; ③Wrist Tie; ④Oximeter Base; ⑤four dry alkaline batteries

Available SpO2 Sensors for replacement orders

SN	PN	Description (1.6m cable length)	Icon	Manufacturer
1	S400A	Adult SpO2 finger sensor		Silverline Medical Technology,Inc.
2	S400P	Pediatric Finger SpO2 Sensor		Silverline Medical Technology,Inc.
3	W400AN	Neonatal Digital SpO_2 Wrap sensor		Silverline Medical Technology,Inc.

8 Guarantee

The company warrants HHP-201 handheld Pulse oximeter at the time of its original purchase and for the subsequent time period of twelve months for the original purchaser. The company warrants SpO2 Probe free of defects at the time of its original purchase and for the subsequent time period of three months.

The warranty does not cover the followings:

- The monitor series number label is teared off or can not be recognized.
- Damage to the monitor resulting from misconnection with other devices.
- Damage to the monitor resulting from accidents.
- Changes performed by users without the prior written authorization of the company.

9 Technical Specification

9.1 Performance Index

%SpO2

- Measurement Range： 0 ～ 100%;
- Measurement Accuracy：at 70% ～ 100% ±2%
  a0% ～ 69% unspecified
- Alarm High limit: 0～100% (default：99%)
- Alarm Low limit: 0～100% (default：92%)

Pulse Rate

- Measurement Range： 30 bpm ～ 250 bpm
- Measurement Accuracy：1 bpm or ±2%，take the bigger one as standard.
- Alarm Upper limit: 0 ～ 255bpm (default: 130)
- Alarm Lower limit: 0 ～ 255bpm (default: 50)

9.2. Probe Standard type:

Silverline S400A

- LED red wavelength：660nm
- LED infrared wavelength：880~940nm

9.3. Environmental Requirements

Working Conditions：

- Ambient Temperature：(0 ～ +40) ℃
- Relative Humidity Range: ≤95 %, no condensing
- Atmospheric Pressure：(70 ～ 106) kPa

Transport/Storage Conditions:

- Ambient Temperature：(- 20 ～ +55) ℃
- Relative Humidity Range: ≤95 %, no condensing
- Atmospheric Pressure：(50 ～ 106) kPa

9.4. Power Requirements

Four standard "AA"size high energy alkalescence batteries are applied on HHP-201.

9.5. Fuse Specification

- Manufacturer: FUZETEC
- Model: FSMD160-1812
- Specification: 1.6A, 6V.

9.6. Size and Weight

- Size：130mm(L)×69mm(W)×22mm(H)
- Weight (with batteries installed)：195g
- (without batteries installed)：100g

9.7. The equipment classifications

- Type of Protection：Internally Powered
- Degree of Protection：Type BF
- Harmful liquid material proof degree: IPX1.
- Operation Mode:continuous operation

10 EMC (Electro-Magnetic Compatibility)

⚠ Caution

- The Oximeter complys with the limits for medical devices to IEC601-1-2: 2007, EN60601-1-2: 2007, Medical Device Directive 93/42/EEC, and this oximeter has been tested for CISPR 11 class A.

Guidance and Manufacturer's Declaration-Electromagnetic Emissions

For all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration-electromagnetic emission		
The *HHP-201 Handheld Pulse Oximeter* is intended for use in the electromagnetic environment specified below. The customer of the user of the *HHP-201 Handheld Pulse Oximeter* should assure that it is used in such environment.		
Emission test	**Compliance**	**Electromagnetic environment-guidance**
RF emissions CISPR 11	Group 1	The *HHP-201 Handheld Pulse Oximeter* uses RF energy only for its internal function. Therefore its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class A	The *HHP-201 Handheld Pulse oximeter* is suitable for use in all establishments other than domestic.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacture's declaration-electromagnetic immunity

For all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration-electromagnetic immunity
The *HHP-201 Handheld Pulse Oximeter* is intended for use in the electromagnetic environment specified below. The customer or the user of *HHP-201 Handheld Pulse Oximeter* should assure that it is used in such an environment.

Immunity test	IEC 60601 testlevel	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge(ESD) IEC 61000-4-2	±6 kV Contact ±8 kV air	±6 kV Contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50Hz) magnetic field IEC 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.

Guidance and manufacturer's declaration-electromagnetic immunity

For EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration-electromagnetic immunity

The *HHP-201 Handheld Pulse Oximeter* is intended for use in the electromagnetic environment specified below. The customer or the user of *HHP-201 Handheld Pulse Oximeter* should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	1V	Portable and mobile RF communications equipment should be used no closer to any part of the *HHP-201 Handheld Pulse Oximeter*, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	1V/m	$\mathbf{d} = \left\lvert \frac{3.5}{V1} \right\rvert \sqrt{P}$

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			$\mathbf{d} = \left\lvert \frac{3.5}{E1} \right\rvert \sqrt{P}$ 80 MHz to 800 MHz $\mathbf{d} = \left\lvert \frac{7}{E1} \right\rvert \sqrt{P}$ 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 transmitter as determined by an electromagnetic site survey [a] should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the following symbol. 

NOTE 1 At 80 MHz. 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.

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 HHP-201 Handheld Pulse Oximeter is used exceeds the applicable RF compliance level above, the HHP-201 Handheld Pulse Oximeter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the HHP-201 Handheld Pulse Oximeter.

b.Over the frequency range 150 kHz to 80MHz. Field strengths should be less than 1 V/m.

Recommended separation distances between portable and mobile RF RF communications equipment and the EQUIPMENT or SYSTEM- For EQUIPMENT or SYSTEM that are not LIFE-SUPPORTING

Recommended separation distances between Portable and mobile RF communications equipment and the *HHP-201 Handheld Pulse Oximeter*

The *HHP-201 Handheld Pulse Oximeter* is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *HHP-201 Handheld Pulse Oximeter* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *HHP-201 Handheld Pulse 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 $d = \left\lvert \frac{3.5}{V1} \right\rvert \sqrt{P}$	80 MHz to 800 MHZ $d = \left\lvert \frac{3.5}{E1} \right\rvert \sqrt{P}$	800 MHz to 2.5 GHz $d = \left\lvert \frac{7}{E1} \right\rvert \sqrt{P}$
0.01	0.35	0.35	0.70

0.1	1.11	1.11	2.21
1	3.5	3.5	7.0
10	11.1	11.1	22.1
100	35	35	70

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.

Note1: At 80 MHz and 800 MHz, the separation distance for the higher 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.

These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in the health-care and home environments (for example, cellular phones, mobile two-way radios, electrical appliances), 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.

The HHP-201 generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with these instructions, may cause harmful interference with other devices in the vicinity. 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 actions taken to eliminate the source:

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

If assistance is required, contact Technical Service Department or your local representative

7.3 WARRANTY CERTIFICATE

western surgical product is warranted to be free from electrical and mechanical defects in material and workmanship, under normal use. The western surgical product must not have been moved from the site of original installation. A new or remanufactured part to replace the defective part will be provided without charge for the part itself, through an authorized western surgical service dealer. The replacement part assumes the unused portion of the warranty.

WESTERN SURGICAL WILL NOT BE RESPONSIBLE FOR:

1. Damage or repairs required as a consequence of faulty installation or application by others.
2. Damage or repairs needed as a consequence of any misapplication, negligent handling, improper servicing, unauthorized alteration, or improper operations.
3. Failure to start due to voltage conditions, blown fuses, open circuit breakers or other damages due to the inadequacy or interruption of electrical service.
4. Damage as a result of floods, winds, fires, lightning, accidents, corrosive atmosphere, or other conditions beyond the control of western surgical
5. Parts not supplied or designated by western surgical.

Date of Installation	**Installed By**
Model No.	**Serial No.**
Warranty Period	
Name of Doctor & Address :	

Customer Sign. With Stamps

Marketed By: Western Surgical
Sign. With Stamps

No Claim Warranty :

1) Any Defect Througut Power Supply

2) Any Physical Damage

3) Under Warranty Standby Unit Not Provide

4) Under Warranty When Company Send Parts or Machine we Imidiat send to Buyer.

* Carrying Warranty at Rajkot Office only on site warranty not provided free of cost.
* Due to constant upgradation design, price and features are subject to change any time without prior notice.

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Ph. : +91-281-2232871 / 2243159

OUR OTHER PRODUCTS RANGE

* Carrying Warranty at Rajkot Office only on site warranty not provided free of cost.
* Due to constant upgradation design, price and features are subject to change any time without prior notice.

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