Dear Customer:

Welcome to the Proactive pulse oximeter! This manual is mainly designed to offer user operation guidance and device maintenance information. The manual explains specifications, installation, operation and safety information of the oximeter. Before use, read the manual carefully for using the oximeter properly.

Reorder Number: 20120

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1 SAFETY INFORMATION

This section contains important safety information related to general use of PROACTIVE pulse oximeter. 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.

Important! Before use, carefully read this manual, supplement directions for use, all precautionary information in boldface type and specifications.

WARNING: Proactive pulse oximeter is a prescription device and is to be operated by qualified personnel only!

WARNING: Explosion hazard. Do not use Proactive pulse oximeter in the presence of flammable anesthetics!

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

WARNING: To ensure accurate performance and prevent device failure, do not expose Proactive pulse oximeter to extreme moisture, such as rain.

Note: Proactive pulse oximeter is intended only for supplementary evaluation of patient and must be used together with combination of clinic symptom and sign.

WARNING: Proactive pulse oximeter readings and pulse signal can be affected by certain ambient environmental conditions, wrong probe operation and particular patient

WARNING: PROACTIVE pulse oximeter can not be used in MRI system. Induced current could cause burns potentially. Proactive pulse oximeter may affect MRI and MRI may affect measure accuracy of Proactive pulse oximeter.

WARNING: 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.

WARNING: 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.

WARNING: 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.

WARNING: No touching the conductive parts of the battery. No using sensor or other conductor to touch those parts, or else it may result in unexpected danger.

WARNING: Avoiding touch by children. If swallowing, immediately go to see the doctor.

Note: Ambient light, movement, electromagnetic interference, artifacts, dysfunctional haemoglobin, and certain dyes, etc may interfere the function of pulse oximeter.

Note: Do not autoclave, ethylene oxide sterilize, or immerse Proactive pulse oximeter in liquid.

Note: Proactive pulse oximeter do not provide defibrillator sync signal and can not be used with defibrillator.

Note: The Proactive pulse oximeter charger meets the international standard IEC60601-1:″Medical Equipment Part 1: General Requirement for safety″. When using, please choose the power according to the requirement of 5.18. (3).

Note: please avoid using the data communication line unless it is necessary.

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

2 INTRODUCTION

2.1 PRODUCT INTRODUCTION

- **Function**

Proactive pulse oximeter is a physiological parameter monitor to monitor pulse rate and saturation of pulse oxygen of adult, paediatric and neonates. Suitable for hospital, clinic, etc.

The product consists of main units, finger SpO2 probe and charger, etc.

Note: Proactive pulse oximeter is used only for supplementary evaluation of patient and must be used together with combination of clinic symptom and sign.

WARNING: Proactive pulse oximeter can not be used in MRI system. Induced current could cause burns potentially. Proactive pulse oximeter may affect MRI and MRI may affect measure accuracy of Proactive pulse oximeter.

- **Basic principle and condition**

Proactive pulse oximeter measures oxygen saturation in the blood quantificationally. Pulse oximeter 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 photodetector. 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 depends on light from the probe, excessive ambient light can interfere with the measurement.

WARNING: Pulse oximeter readings and pulse signal can be affected by certain ambient environmental conditions, wrong probe operation and particular patient conditions.

The above specific information about ambient environmental conditions, probe operation and patient conditions, are contained throughout this manual.

2.2 DESCRIPTION OF FUNCTIONS

Main functions of Proactive pulse oximeter:

1. Measure the saturation of oxygen in blood
2. Measure the pulse rate

3 UNPACKING AND INSTALLATION

3.1 UNPACKING

Take out main unit and accessories (SpO2 probe, charger seat, power cord, communication wire, etc.) carefully from the box. Keep the casing for transportation or preservation afterwards.

Check as below packing list. Please contact the supplier immediately if any damage or further question.

Packing list:

Pulse oximeter main unit:	one set
Operation manual:	one piece
SpO2 probe:	one piece
Wrist band:	one piece
Rechargeable battery:	four pieces
Charger pedestal	one piece
Power cord:	one piece
Communication wire and compact disc:	one of each

3.2 BATTERY INSTALLATION

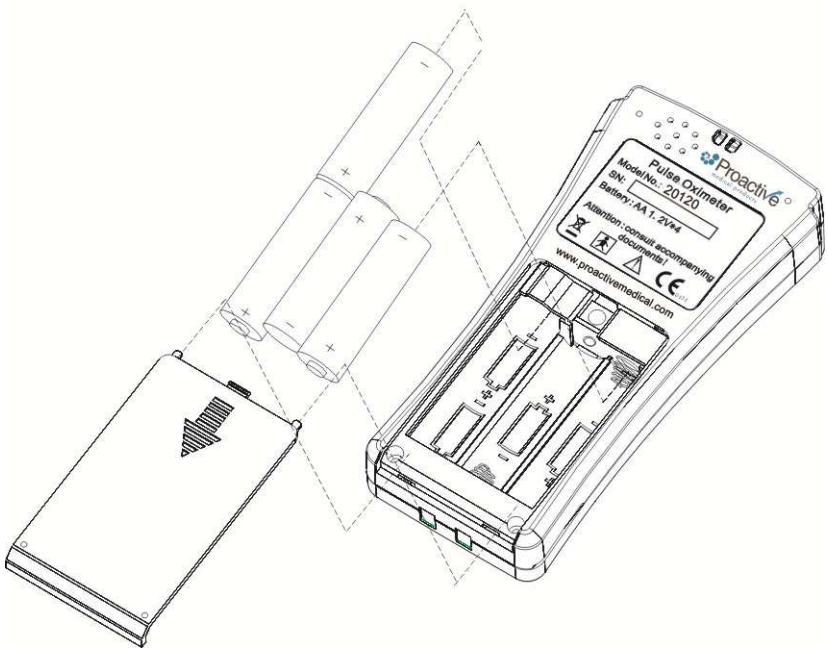


Figure 1: battery installation

Refer to figure1，Pull the battery cover latch downwards, toward the bottom of the oximeter, then take off the battery cover.

Install four pieces “AA” size batteries, as shown in Figure 1. Replace the battery cover.

Note: Install the negative end of each battery first, press the battery terminal spring until the positive terminal able to reach the positive spring, then pressing the battery downwards and make sure right connection.

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

WARNING: Do not mix rechargeable NiMH battery with alkaline AA battery. When replacing batteries, replace with four fresh (new) batteries. Do not make old and new batteries mix used.

WARNING: Explosion hazard! Proactive pulse oximeter cannot be used in situation of flammable anesthetic gas.

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

WARNING: As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.

WARNING: To ensure accurate performance and prevent device failure, do not expose the Proactive to extreme moisture such as rain.

Note: Please check the battery periodically for corrosion. If any corrosion, please change the batteries. Meanwhile, the corrosion may damage Proactive pulse oximeter.

Note: Do not use Proactive pulse oximeter with lithium battery. Lithium battery may cause damage to Proactive pulse oximeter.

3.3 PROBE'S INSTALLATION AND USING

WARNING: Before using Proactive pulse oximeter, read probe's instruction including all warnings, notes and introductions.

WARNING: Do not use defective probe and do not use the probe which explode optics component.

Note: Proactive pulse oximeter can only operate with its own probe. Other brand sensors may cause improper performance.

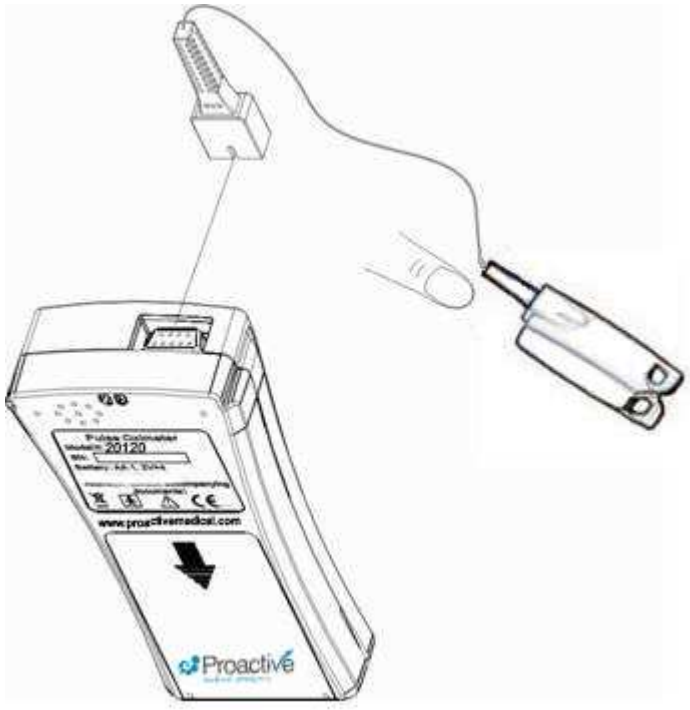


图 2: Installation and operation of probe

1. Refer to Figure 2, connect the oximeter plug to pulse oximeter convex interface;
2. The probe is digital technology finger type. Attach the finger probe with the light to the patient. Be sure to fully insert the patient's finger into the probe.

- **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 oximeter readings and pulse signal can be affected by certain ambient environmental conditions, wrong probe operation and particular 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 if the probe remains properly positioned on the patient.

WARNING: 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.

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.

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 patient and environmental conditions 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 section of installation and use.

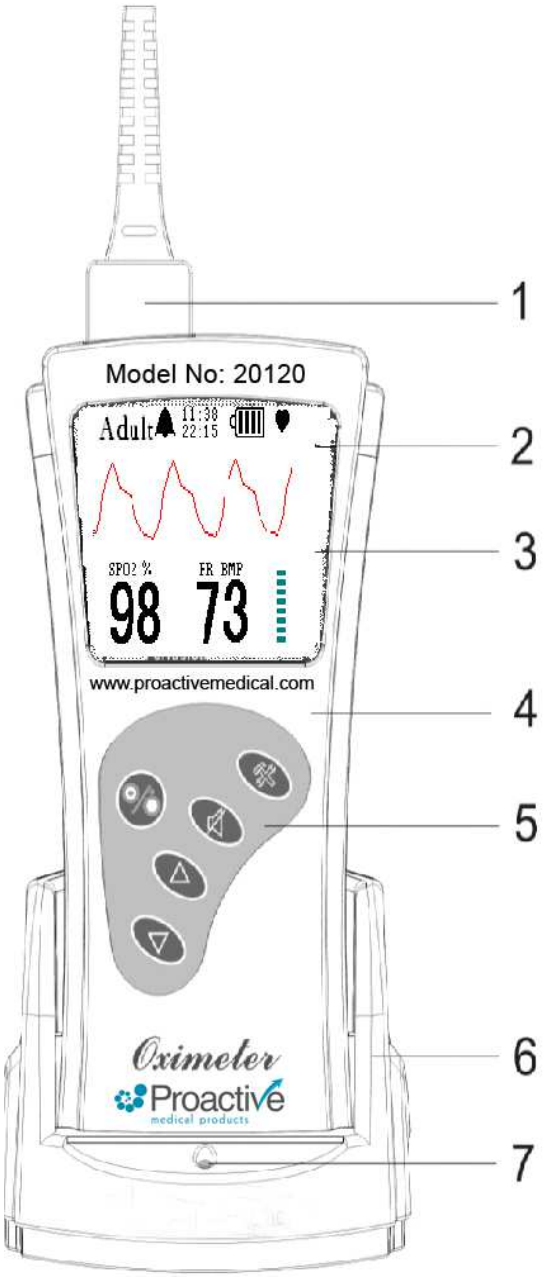
WARNING: Reposition the probe at least once every 4 hours to allow the patient's skin to respire.

Note: Do not autoclave, ethylene oxide sterilize. With a soft cloth moistened in a mild soap solution and hot water lightly wipe the surface of Proactive pulse oximeter .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 Proactive pulse oximeter openings.

4. CASING DESCRIPTION

4.1 CASING

Figure 3 through 7 shows the casing, key-press, displays, charge pedestal and rear/top views of the pulse oximeter.



1. Probe 2. Power indicator light 3. Display Window
4. Casing 5. Keys 6. Charger/pedestal 7. Charge indicator light

Figure 3：Casing View

4.2 DISPLAY

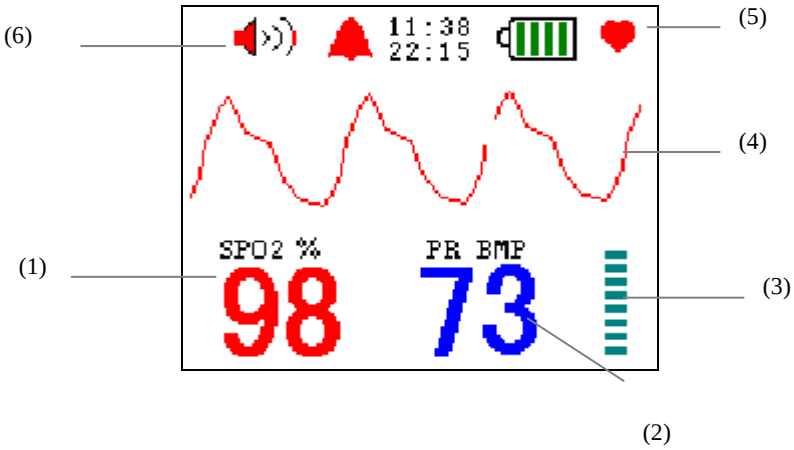


Figure 4：Display View

Symbols

SpO2%: Percent oxygen saturation ,valid range is 0～100。

PR: Pulse rate, Pulsation number per minute, valid range is 30～250. Unit: bmp 。

4.3 THE DESCRIPTION OF VISUAL PRESENTATION AND DISPLAY

1. SpO2 display area: three-digit numbers display at most, when invalid value displays, “———” will be showed;

2. PR display area: three-digit numbers display at most, when invalid value displays, “———” will be showed;

3. Indication of pulse intensity: eight bar code displays which shows the current pulse intensity.
4. Pulse curve measured currently
5. Pulse presentation: it displays on the top right corner when measuring the pulse.
6. Indication of volume : it displays on the top left corner when adjusting the volume, screen displays ----- .

4.4 DESCRIPTION OF AUDIBLE INDICATION

The following details are the audible indication which will not change with symbol,keyboard or visual indication:

Turn on	a group of 800Hz voice
Sensors off	a group of 1KHz alarming voice which lasts for 30 seconds.
SPO2/PR overrun	a group of 800Hz alarming voice which will exist when overrun
low battery	a group of 500Hz alarming voice interval, interval will be 30 seconds.
Pulse voice	a group of 160Hz-760Hz voice which lasts for 0.2 second.
voice of invalid key	a group of 300Hz voice

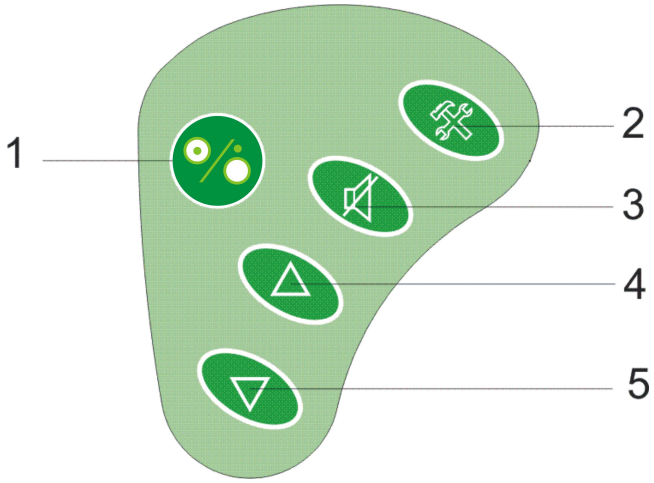


Figure 5：Keys

4.5 DESCRIPTION OF KEYS


1. Power on/off key, you need to press the button for 2 seconds for this action

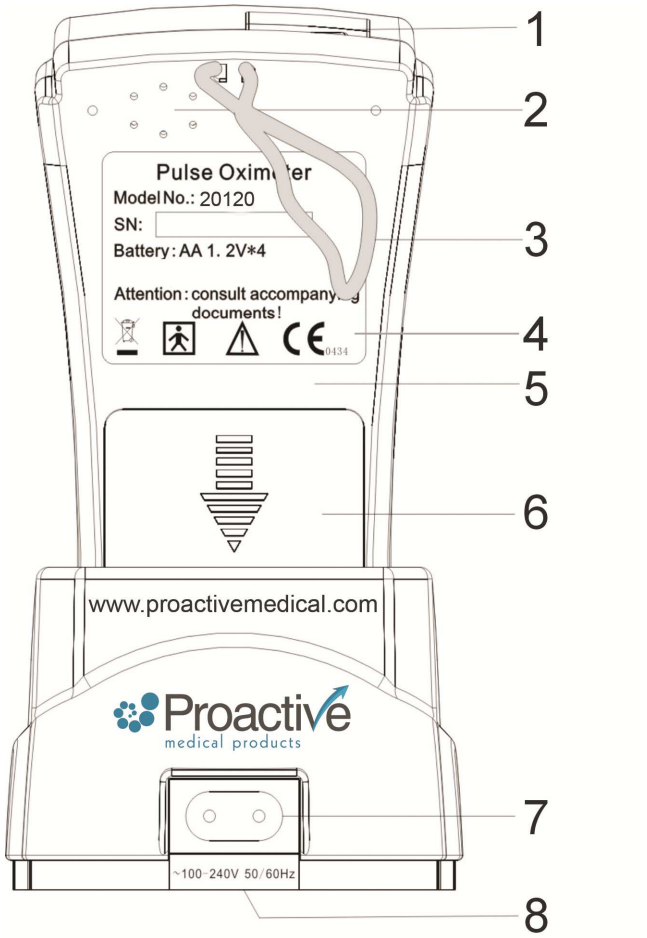

2. Menu key, turn on the menu to confirm or exit the function rapidly. (press for 2 second)


3. Alarm key, you can start or stop the voice of the alarming line by pressing the button (screen displays), you could get back to the original acquiescent setup of the alarming line by pressing the button for seconds.


4. Up key, it can adjust the volume when pressing it during working condition(screen displays ); it could adjust alarm and other upside setup when pressing it in menu condition, you could get to te upper side rapidly when pressing it for seconds.


5. Down key, same as above.

Figure 6：Pedestal View



1. Probe socket 2. Speaker 3. Wrist tie socket 4.Proactive label 5. Rear shuck 6. Battery cover 7. Power socket 8. Label of seat charger

Figure 7: Rear/Top View

5 POWER-ON AND USE

5.1 BASIC OPERATION

WARNING: The Proactive pulse oximeter is a precise device and must be operated by qualified

WARNING: Do not lift the oximeter by the probe cable because the cable could disconnect from the oximeter, which may result to the oximeter to be fall and hurt the patient.

Caution: The Proactive pulse oximeter is intended only as an adjunct in patient assessment. It must be used together with clinical signs and symptoms.

Important! Prior to using the Proactive pulse oximeter, carefully read this manual, accessory direction for use, all specification and all precautionary information in boldface.

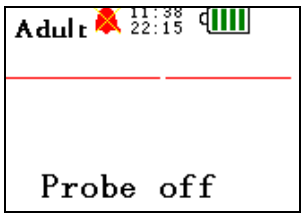
Note: Before using the Proactive pulse oximeter, remove the plastic protective sheet that covers the display, which is only for the protection purpose during the transportation. It may make it difficult to read the displayed result of measurements.

5.1.1 POWER-ON

1. Install the batteries; Proactive pulse oximeter is off state, turn on the pulse oximeter by pressing  key for 2 seconds.

Caution: If the batteries are in low power, the power indicator would turn red and blink for three seconds, and then pulse oximeter turns off automatically. If batteries are in low power or no batteries, oximeter may have no response. Please make sure the batteries have enough energy.

2. If the batteries are installed and the oximeter is turned on successfully, the indicating light of the power will turn green, and you well hear one voice “di”, and the display window will show as followed:



- Type of patient
- Display of alarming situation
- Current date(month,day,hour,minute)
- Indicating light of the power
- Pulse curve
- Situation of the sensor or value of the measurement

Make sure that you can hear sound "Dee". If not, the sound system is damaged, please do not accept it and contact your supplier or manufacturer.

If the sound is slight, make sure the holes located on the speaker are not covered. If the volume is still low， please do not accept it and contact your supplier or manufacturer.

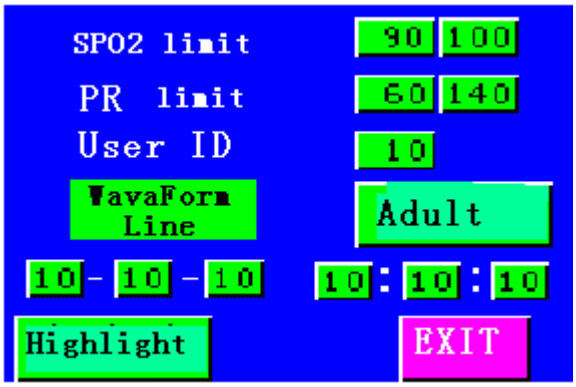
Check display content, if any display is not complete, please do not continue to use the pulse oximeter and contact your supplier or manufacturer.

3. The oximeter will have self inspection itself during the process of starting up. It will show the unusual noise and relevant error code shen something unusual happens. Please refer to the chapter of trouble removal.

4. If the power-on self-test is ok, the oximeter will display its software version. After displaying about 2 seconds, the pulse oximeter enters measurement mode.

5.1.2 MENU APPEARANCE

You will get to menu mode when you press the  one time under normal working condition, the screen shows: SPO2 alarming line, PR alarming line, user ID, measuring object, current date(year,month,day,hour,minute), high luminance, back to the picture as followed: (refer to 5.1.5 button operation)



5.1.3 TIME SETTING

The time of the oximeter may not be correct after the installation of batteries, it will cause the wrong time of the trend data, so it’s necessary to set up the right time, there is total two ways to set up the time:

1. Set the time by the computer RS-232 port (refer to 5.1.9 “output of data”)

2. Set the time by Key-press (Refer to 5.1.5 “Operation of Key-press”)

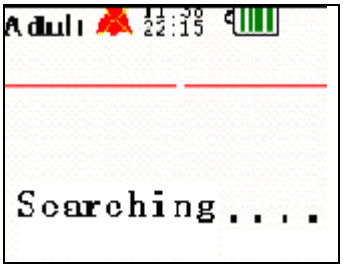
5.1.4 RUNNING MODE

In the normal working condition, with four modes:

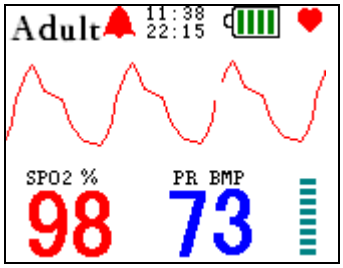
1. If probe is disconnected, display area of SpO2 and PR will blink and the pulse oximeter will turn off automatically after 120 seconds.

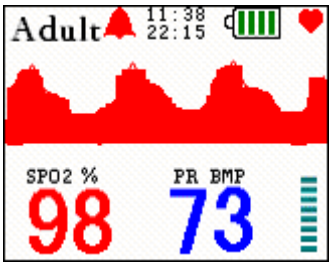
2. If the probe is connected, but the probe is not attached to the finger, the SpO2 % and PR display area will blink "Sensor off", meanwhile the oximeter will generate lost hint sound every 30 seconds. The pulse oximeter will turn off automatically if this mode lasts 120 seconds.

3. Pulse search mode: If patient is connected to the probe, the oximeter try to find the pulse and display blink "Searching…" As the figure below:



4. If it searches the pulse succeed, the SPO2 and PR of the patient will show on the screen as the figure below:





The pulse strength indicator with pulse and the horn will make the sound "Di Di" with the pulse. The characteristics as follows:

- SpO2%: Means percent oxygen saturation
- PR: Pulse beats per minute (bmp)
- The volume of "Dee Dee" generated by the speaker is closely related with SpO2. The

lower SpO2 value, the higher sound frequency.

- Pulse wave（Waveform Line or Waveform Fill）
- Pulse strength indicator: 8 codes, which reflect the strength of current pulse

5.1.5 KEY'S OPERATION

When the machine is under normal working condition, press  and  to adjust the volume. If your press the keys when the volume has reached the maximum/ minimum valve, it will sent an invalid voice.

- Press  could turn on/ off the alarm line function and press 2 seconds to restore the default alarm line.
- Press  enters the menu directly. And after entering the menu, this key can be used to identify and quickly exit the function (long press for 2 seconds)
- Press  more than 2 seconds to turn off the machine.

When the machine is under normal working condition, press  could enter any setting you like. Press  or  select and set up after press  to confirm the setting, and then select "back" press  again to exit the alarm line setting. Return to normal operation (long press  2 seconds to exit)

5.1.6 ALARM SETUP

Under normal working state, long press  enter into menu setting, which could set the alarm high limit and low limit for the SPO2 and PR by  or  . Then press  to confirm the setting, select "back" and press  to exit the setting. Return to normal working conditions (long press  for two seconds quick exit).

Alarm On/ Off setting: Under normal working state, press  could turn on / off alarm voice of the alarm line.

5.1.7 USER ID SETTING

User ID is the unique number that made by the machine automatically to distinguish the different users' trend data. Each time when you choose the user ID will add one automatically.

5.1.8 PULSE WAVE SETTING

Pulse wave setting is used to select the type of Waveform Line or WaveForm Fill.

5.1.9 MEASUREMENT OBJECT SETTING

Measurement object is used to select the type of patient, respectively for adult, pediatric and neonate.

5.1.10 TIME SETTING

Time setting is used to set the time and date.

5.1.11 LIGHT SETTING

Light setting is used to select the state of brightness of screen, for example: "high light" "mid-light" "low light" "light"。 Select the state of "high light" or "mid-light", the screen brightness will turn to lowest afer 20 minutes when there is no key's operation; select the type of "light", under normal working state, the screen will last light long time。

5.1.12POWER SUPPLY MODE

If the sensor doesn't connect with the patient and there is no key operation, the pulse oximeter will turn off after 120 seconds automatically. Press  more than 2 seconds to turn on the machine..

5.1.13 TURN OFF

The pulse oximeter will turns off after pressing  keys for 2 seconds. Pulse oximeter turns itself off automatically when the batteries are weak.

5.1.14 OUTPUT OF DATA

History data of the pulse oximeter can be stored for about 24 hours and can be transferred to computer by equipped communication cable, as below process:

1. Turn off pulse oximeter;
2. Pull down the probe of pulse oximeter;
3. Plug the communication cable to the probe socket of pulse oximeter;
4. Plug the other end of the communication cable to the RS-232 port of the computer;
5. Turn on pulse oximeter;

6. Install and run the trend analysis software on the computer and select the corresponding RS-232 port, press “Acquire tendency data” key;
7. Data upload is ok when the schedule bar on the screen reaches 100%.

Caution: Please make sure pulse oximeter is off state when plug on or pull off the communication cable.

You may set the date and time of the pulse oximeter by trend analysis software, please refer to the attached small CD for the detailed operation of software.

5.1.15 CHARGING BATTERIES

Please check whether the batteries for pulse oximeter are rechargeable NiMH AA type before charge and then follow below steps:
1. Put pulse oximeter into the pedestal;
2. Connect power cord to the pedestal;
3. Plug the other end of the power cord to 100～240 V AC 50/60Hz.
Then it’s ready for charge, yellow light indicates it’s during the process of charge, green light means the batteries full charged

Caution 1: Please confirm the batteries for the pulse oximeter are rechargeable NiMH AA type, otherwise will result in unpredictable result.

Caution 2: There would be problem if both the lights off, please contact the supplier immediately.
Caution 3: Please replace with new batteries if the old batteries working time is very shorten.
Caution 4: In order to prolong the batteries lifespan, please store the batteries in cool, dry environment.
Caution 5: Don’t use pulse oximeter while charging.

5.1.16 STORAGE

Remove the batteries from the pulse oximeter if long-term storage, or if the device won't be used for 2 months or more. This will protect the device from damage due to battery leakage.

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

5.1.17 PROTECTION OF ENVIRONMENT

For minimizing risks, please do not discard the used-up batteries of pulse oximeter, handle it according to your local government organization rules and regulation of RoHS（2002/95/EC）and WEEE（2002/96/EC）.

5.2 IMPACT OF PERFORMANCE CONSIDERATION

Inaccurate measurements can be caused by:

- Excessive movement of patient;
- Venous pulsations;
- Intravascular dyes ,such as indocyanine green or methylene blue;

- Significant levels of dysfunctional hemoglobins;
- Defibrillation.

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

The effects of electromagnetic interference on oximeter reading are discussed in the Troubleshooting and Maintenance section of this manual.

6 TROUBLESHOOTING AND MAINTENANCE

WARNING: If you are uncertain about the accuracy of any measurement, check the patient's vital signs by alternate means; then make sure the monitor is functioning correctly.

WARNING: 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 Proactive pulse oximeter and are unable to correct it, please stop use it and do not try to correct it by yourself, contact qualified service personnel or appointed representative. Proactive pulse oximeter service manual, which is for use by qualified service personnel, provides additional troubleshooting information.

6.1 TROUBLESHOOTING AND SOLUTIONS (REFER TO TABLE)

Problem	Possible Cause	Corrective Action	remark
No pulse shown on the bar-graph.	Probe is disconnected from pulse oximeter. Probe is incorrectly Positioned on the patient Poor patient perfusion. Defective probe.	Check probe connections to patient and to pulse oximeter. Reposition the probe. Try a new probe or contact your authorized repair center for help.	Chapter 5
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 peaceful to obtain accurate measurement.	Chapter 5
Pulse ox can not be turned on	Batteries weak. Batteries not installed or installed incorrectly. Internal fuse blown.	Recharge the batteries. Ensure the batteries are installed correctly. Incorrectly installed batteries may cause an internal fuse to blow. In that case, send pulse ox to an authorized repair center.	Chapter 5
Pulse oxs turned off unexpectedly.	The pulse oximeter turns itself off automatically two minutes after the probe is removed from the patient or after the probe is disconnected from the pulse oximeter. Batteries are weak or dead.	None Recharge the batteries or change new battery	Chapter 5
E01 appears on the Display.	Internal fuse damaged.	Contact technical services department.	Chapter 5

6.2 EMC（ELECTRO-MAGNETIC COMPATIBILITY）

Caution: The oximeter complies with the limits for medical devices to IEC60601-1-2: 2007, Medical Device Directive 93/42/EEC, and this oximeter has been tested for CISPR 11 class B.

Guidance and manufacturer's declaration-electromagnetic emissions-

for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration-electromagnetic emission		
Proactive pulse oximeter is intended for use in the electromagnetic environment specified below. The customer user of pulse oximeter should assure that it is used in such environment.		
Emission test	**Compliance**	**Electromagnetic environment-guidance**
RF emissions CISPR 11	Group 1	Proactive 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 B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacture's declaration-electromagnetic immunity –

for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration-electromagnetic immunity			
Proactive pulse oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of Proactive Pulse Oximeter should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**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%.
Electrical fast Transient/burst IEC 61000-4-4	± 2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	＜5 % UT (＞95 % dip in UT) for 0, 5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles ＜5 % UT (＞95 % dip in UT) for 5 sec	＜5 % UT (＞95 % dip in UT) for 0, 5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles ＜5 % UT (＞95 % dip in UT) for 5 S	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Model 004 Image Intensifier requires continued operation during power mains interruptions. It is recommended that the Model 004 Image intensifier be powered from an uninterruptible power supply or a battery.

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.
NOTE: UT is the AC. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration-electromagnetic immunity-

for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration-electromagnetic immunity			
Proactive pulse oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of Proactive 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 150kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of Proactive pulse oximeter. including cables and less than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = $\left[\frac{3.5}{V1}\right]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	d = $\left[\frac{3.5}{E1}\right]\sqrt{P}$ d= 80 MHz to 800 MHz d = $\left[\frac{7}{E1}\right]\sqrt{P}$ d=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 and 800 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 Proactive pulse oximeter is used exceeds the applicable RF compliance level above, Proactive pulse oximeter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating Proactive pulse oximeter. b Over the frequency range 150 kHz to 80MHz. Field strengths should be less than 3 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 PROACTIVE pulse ox meter

Proactive pulse oximeter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of Proactive pulse oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Proactive 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 $d = \left[\frac{3.5}{V1}\right]\sqrt{P}$	80 MHz to 800 MHZ $d = \left[\frac{3.5}{E1}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{E1}\right]\sqrt{P}$
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.

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.

Proactive pulse oximeter under the using environment, the function may be destroyed temporarily by the electromagnetic interruption. During some period of interruption, it will take place that the testing result is not proper or pulse oximeter can’t work normally.

Proactive pulse oximeter 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 our technical services department or your local representative.

6.3 OBTAINING TECHNICAL ASSISTANCE

For technical information and assistance, or to order parts or a service manual, contact our technical services department or your local representative. Please tell the software version number of pulse oximeter to maintenance representative.

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

6.4 RETURNING

Contact our technical services department or your local representative for shipping instructions including a Returned Goods Authorization number. Remove the batteries for shipping, and unplug the probe. And probe is not necessary to be returned. Pack the pulse oximeter 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.

6.5 SERVICE

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

6.5.1 PULSE OXIMETER

If cleaning is required, wipe the pulse oximeter 's surfaces with a soft cloth. Do not allow any liquid to enter any opennings of the pulse oximeter.

WARNING: Turn off the pulse oximeter before cleaning.

WARNING: 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 openings on the pulse oximeter.

WARNING: Do not allow any abrasive, instrument and coarse material to brush or touch the pulse oximeter display

6.5.2 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.

6.6 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 in mechanical and functional aspects.
- Inspect the safety relevant labels for legibility.
- Verify that the device functions properly as described in this operator's manual.

The numeral must be recorded on the record of equipment. 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 oximeter is based on following principles: oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (i. e., Spectrophotometry), and 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 (LED) in the ox meter 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 haemoglobin, 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 SpO2measurements 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 non-pulsatile 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)

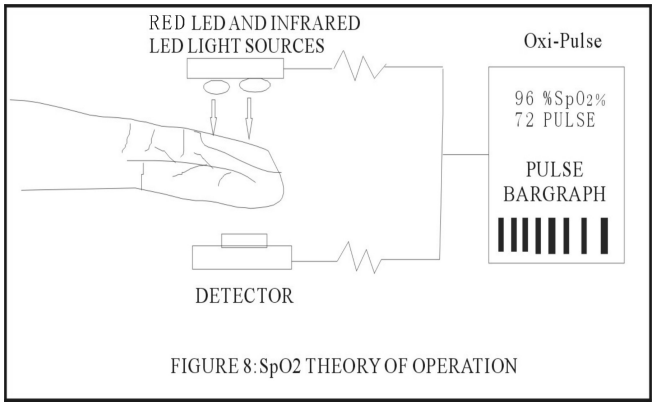


FIGURE 8:SpO2 THEORY OF OPERATION

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 calculate oxygen saturation. Oxygen saturation calculations can be performed because oxygen saturated blood predictably absorbs less red light than oxygen depleted blood.

7.2 PRODUCT LABEL

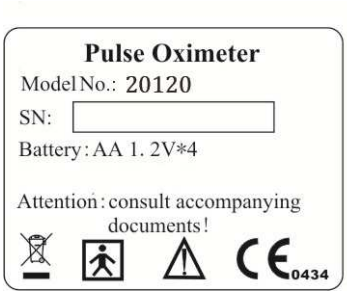


Figure 9: Product label

Meanings of the symbols are:

	Caution! To signify caution. Please read the instructions carefully before operating the product.
	Type BF applied part
SN	Manufacture's serial number
	Waste Electrical and Electronic Equipment Directive 2002/96/EC (WEEE Directive) after over the valid term within 4 years, the machine should be treated on local law or regulation requirement. To avoid hurt users and pollute environment.
	The equipment bears CE mark CE_{0434} indicating its conformity with the provision of Council Directive 93/42/EEC concerning medical devices, and fulfils the essential requirement of Annex I of this directive.

7.3 THE CONTROL SOFTWARE IN PROACTIVE

The Control software in Proactive pulse oximeter is performed risk analysis according to ISO 14971 /EN 1441, and the possibility of hazards arising from errors in the software program is minimized.

7.4 ADULT REUSABLE SPO2 FINGER SENSOR DIRECTIONS FOR USE

Intended Use

When used with compatible oximeter, this sensor is intended to be used for continuous, non-invasive functional arterial oxygen saturation (SpO2) and pulse rate monitoring for patients weighing greater than 40kg.

Contraindications

This sensor is contraindicated for use on active patients or for prolonged use.

Instructions for Use

1. With the upper and lower jaws open, place an index finger evenly on the base of the clip. Push the finger tip against the stop so that it is over the sensor window (A). If an index finger cannot be positioned correctly, or is not available, other fingers can be used.

Note: When selecting a sensor site, priority should be given to an extremity free of an arterial catheter, blood pressure cuff, or intravascular infusion line.

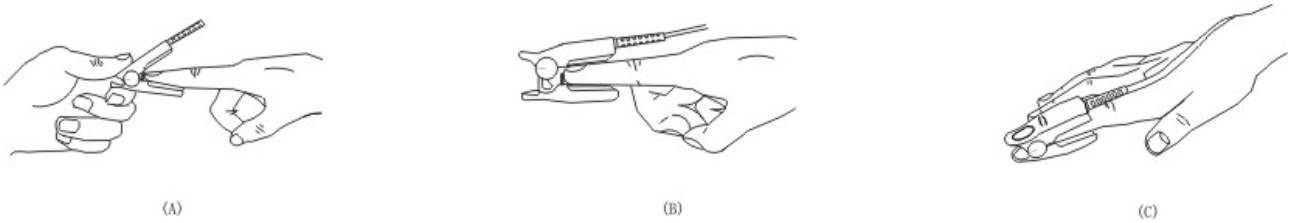
2. Spread open the rear tabs of the sensor to provide even force over the length of the pads (B).

3. The sensor should be oriented in such a way that the cable is positioned along the top of the hand (C).

4. Plug the sensor into the oximeter and verify proper operation as described in the oximeter operator's manual.

5. Inspect the monitoring site every 4 hours for skin integrity.

6. After use, surface-clean sensor and cable with a soft gauze pad by saturating it with a solution such as 70% isopropyl alcohol. If low-level disinfection is required, use a 1:10 bleach solution.



Caution: Do not sterilize by irradiation steam, or ethylene oxide.

Warnings

1. **Some factors may affect the accuracy of saturation measurements. Such factors include: excessive patient motion, fingernail polish, use of intravascular dyes, excessive light, poorly perfuse finger, extreme finger sizes or improper placement of the sensor.**
2. **Using the sensor in the presence of bright lights may result in inaccurate measurements. In such cases, cover the sensor site with an opaque material.**
3. **The sensor 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.**
4. **Do not apply tape to secure the sensor in place or to tape it shut; venous pulsation may lead to inaccurate saturation measurements.**
5. **Do not use the sensor or other oximeter sensors during MRI scanning.**
6. **Carefully route cables to reduce the possibility of patient entanglement or strangulation.**
7. **Do not alter or modify the sensor. Alterations or modifications may affect performance or accuracy.**
8. **Do not use the sensor if it is damaged.**

If you have any questions regarding to any of this information, contact your local distributor.

Warranty

The manufacturer offers a 12-month warranty against manufacturing defects for this product in its undamaged condition.

8 GUARANTEE

In order to protect the customers interest and achieve a better service, please read the following carefully.

i The content and period that need to be warranted:

1. **The content:** Manufacturer/Supplier will be responsible for defects in workmanship & materials and the problem is due the quality of the product if the user use product exactly according to the manual and in the period of warranty. Manufacturer/Supplier's obligation under this warranty is limited to repair, any part that upon Manufacturer/Supplier's examination proves defective.
2. **The period:** 18months (12 months for accessories) from shipment date.

ii In the following cases, Manufacturer/Supplier do not provide quality warranty of our product

1. Not operate product according to the manual.
2. Beyond the warranty period.
3. Caused by modification or repair by anyone except Manufacturer/Supplier or Manufacturer/Supplier designated person; from which Manufacturer/Supplier's original serial number tag or product identification markings have been altered or removed.
4. Use the parts that were not manufactured by Manufacturer/Supplier.
5. Without the permission of Manufacturer/Supplier, restructure the product.
6. Product is damaged due to typhoon, flood, fire, earthquake, war and other force, which cannot be resisted by human power.

iii The method of validity

If find any problem, please contact the sales who is appointed to service you. The sales are responsible for informing the problem to Manufacturer/Supplier's technical department and it will valid after the technician conform it.

iv Return and Freight

Be sure confirmed with Manufacturer/Supplier before any return machine and/or parts, to avoid problem.

1. Within Warranty: The customer is responsible for freight & insurance charges, includes custom charges when the equipment and/or parts is shipped to Manufacturer/Supplier for service. Manufacturer/Supplier is responsible for the freight & insurance charges from Manufacturer/Supplier's to the customer.

Contact Proactive 855-237-7622

9 TECHNICAL SPECIFICATION

1. Performance Index

SpO_2%

Measurement Range: 0 ～ 100%;

Measurement Accuracy: ±2 % at 70% ～ 100%;
No indication at 0% ～ 69%

Pulse rate

Measurement Range: 30 bpm ～ 250 bpm

Measurement Accuracy: ±1 bpm or ±2%; whichever is greater

2. Probe type:

LED red wavelength: 660nm

LED infrared wavelength: 880~940nm

3. Environmental Requirements

Temperature Range:

Operating: （-10 ～ + 40）℃

Transport/Storage: （- 40 ～ + 55）℃

Relative Humidity (noncondensing):

Operating: 0 ～ 93 %

Transport/Storage: 0 ～ 95 %

4. Power Requirements

Battery: Four standard “AA” size rechargeable NiMH batteries are applied on PROACTIVE,
(Such as GPI INTERNATIONAL LIMITED GP200AAH)

Input voltage: 100~240V AC 50/60Hz

Input power: 14VA

5. Continuous operating time

Internal power operating time: ≥10h

6. Size and Weight

Size: 135mm(L)×67mm(W)×31mm(H)

Weight (with batteries installed): 430g

(without batteries installed): 314g

7. Equipment classification

Protection model: CLASS II EQUIPMENT /
INTERNALLY POWERED EQUIPMENT

Protection degree: BF type

Outside surface protection degree: IPX0

Operating model: continuous