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1 Introduction

1.1 Brief Introduction

Thank you for purchasing the McKesson Handheld Pulse Oximeter. The main functions of the device include SpO_2 and PR measurements, visual and audible alarm, data storage, review and transmission, etc. Please read this manual carefully before using the device.

Notes:

1. The illustrations applied in the manual may differ slightly from the actual device.
2. The specifications are subject to change without prior notice.
3. The device is designed for handheld usage. Please be sure not to turn upside down when using it.

1.2 Intended Use

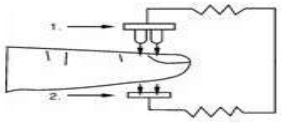
The McKesson Handheld Pulse Oximeter is intended for continuous monitoring, spot-checking of oxygen saturation (SpO_2) and pulse rate (PR) of single adult and pediatric patients in hospitals and clinics.

1.3 Measurement Principle

Principle of the oximeter is as follows: A mathematical formula is established making use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive hemoglobin(RHb) and Oxyhemoglobin (HbO_2) in glow and near-infrared zones. Operation principle of the instrument: Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning and Recording Technology, so that two beams of different wavelength of lights (660nm glow and 905nm near infrared light) can be focused onto a human nail tip through a clamping finger-type sensor. A measured signal obtained by a photosensitive element, will be shown on the oximeter's display through process in electronic circuits and microprocessor.

Diagram of Operation Principle

1. Red and Infrared-ray Emission Tube
2. Red and Infrared-ray Receipt Tube



1.4 Safety Information

Warnings, Cautions and Notes

The warnings, cautions and notes section of this document contains information to aid in user operation.

- Warnings - Indicates a potential hazard or unsafe practice that, if not avoided, will result in death or serious injury.
- Cautions - Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury or product/property damage.
- Notes - Provides application tips or other useful information to ensure that you get the most from your product.

⚠ **Warnings!**

- Before use, carefully read the manual. This device is intended for use by persons trained in professional health care. Our company will assume no warranty for using this equipment improperly.
- The pulse oximeter is to be operated by qualified personnel only.
- Operation of the pulse oximeter may be affected by the use of an electrosurgical unit (ESU).
- Sensor malfunction may cause inaccurate data possibly resulting in patient injury or death, so pay close attention to the sensor and inspect it often.
- Do not use the pulse oximeter in an MRI or CT environment.
- Although the pulse oximeter has alarms, it is not suggested for long term continuous monitoring.
- Do not use the pulse oximeter in an explosive atmosphere.
- The pulse oximeter is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
- Check the pulse oximeter sensor application site 30 minutes after application to ensure proper positioning of the sensor, and circulation and skin sensitivity of the patient.
- When linking this equipment to other peripherals, make sure you are qualified to operate and handle this device. Any peripherals should be in the light of protocol of IEC 950 and IEC 601-1-1. Any input/output device should be following the protocol of IEC 601-1-1.
- Do not sterilize the device using autoclaving, ethylene oxide sterilizing, or immersing the device in liquid. The device is not intended for sterilization.
- Follow local ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.
- This equipment complies with IEC 60601-1-2:2007 for electromagnetic compatibility for medical electrical equipment and/or systems. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare and other environments, it is possible that high levels of such interference due to close proximity or strength of a source may disrupt the performance of this device.
- Portable and mobile RF communications equipment may affect medical electrical equipment.
- You should operate the equipment according to the EMC information provided in the accompanying documents.
- This equipment should not be used adjacent to or stacked with other equipment.
- This equipment is not intended for use during patient transport outside the healthcare facility
- When connecting this device to other peripherals, make sure that you are qualified to operate this device. Any peripheral must be certified according to the protocol of IEC 950 and IEC 601-1-1. Any input/output device should follow the protocol of IEC 601-1-1.
- When using the equipment, ensure the ambient volume of the environment is not greater than 45 db.

Rx only: “Caution: Federal law restricts this device to sale by or on the order of a physician.”

Cautions:

- The pulse oximeter must be able to measure the pulse properly to obtain an accurate SpO_2 measurement. Verify that nothing is interfering with the pulse measurement before relying on the SpO_2 measurement.
- Worn-out data cables may cause inaccurate data, so if the data is used as a reference to treat a patient, pay special attention to data cable and check it more frequently.
- Do not tangle the SpO_2 cable with the wires of ES (Electrosurgery) equipment.
- Single use accessories should never be reused.
- Only use SpO_2 sensors specified by the manufacturer. Other SpO_2 sensors may cause improper performance.
- Unplug the sensor from the monitor before cleaning or disinfecting to prevent sensor or monitor from being damaged, and to prevent any unsafe conditions for the end user.
- Alarm must be set up according to individual patient needs. Make sure that audio sound can be activated when alarm occurs.
- To avoid an electrical hazard, never immerse the unit in any fluid or attempt to clean it with liquid cleaning agents. Always take out the batteries before cleaning.
- If oximeter becomes accidentally wet during use, stop operation of the oximeter until all affected components have been cleaned and permitted to dry completely. Contact your local representative if additional information is required.
- Remove the batteries from this unit or unplug the SpO_2 probe when you are not going to use it for a long period of time (approximately one month).

Notes:

- Optical cross talk can occur when two or more sensors are located in adjoining areas. It can be eliminated by covering each site with opaque material. Optical cross talk may adversely affect the accuracy of the SpO_2 readings.
- Obstructions or dirt on the sensor's red light or detector may cause a sensor failure. Make sure there are no obstructions and the sensor is clean.
- Any condition that restricts blood flow, such as use of a blood pressure cuff or extremes in systemic vascular resistance, may cause a failure to determine accurate pulse rate and SpO_2 readings.
- Hazards arising from software errors have been minimized. Hazard analysis conforms to meet ISO14971: 2000 and EN60601-1-4: 1996. Significant levels of dysfunctional hemoglobin, such as carboxyhemoglogin or methhemoglobin, will spawn an affection of the accuracy of the SpO_2 measurement.
- The pulse oximeter can monitor only one patient synchronously.
- For routine equipment maintenance, please refer to the service procedures at the associated section as indicated in the manual.
- As to all other concerns requiring attention, please carefully look through the specific chapter in this instruction manual.
- All the waveforms have been uniformed.
- The materials of the device are not made with natural rubber latex.

Inaccurate measurements may be caused by:

- Significant levels of dysfunctional hemoglobin (such as carbonyl - hemoglobin or methemoglobin);
- Intravascular dyes such as indocyanine green or methylene blue;
- High ambient light. Shield the sensor area if necessary;
- Excessive patient movement;
- High-frequency electrosurgical interference and defibrillators;
- Venous pulsations;
- Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line;
- The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia;
- The patient is in cardiac arrest or is in shock;
- Fingernail polish or false fingernails;
- Weak pulse quality (low perfusion);
- Low hemoglobin;

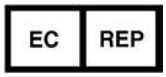
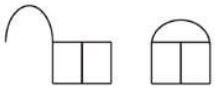
1.5 Electromagnetism Interference

This oximeter is designed and tested in compliance with the EMC standard, complying with the international standard for the EMC of the electronic medical device - IEC 60601-1-2. However, because of the proliferation of radio frequency transmitting equipment and other sources of electrical noise in the health-care and home environments (e.g. 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.

This apparatus complies with the IEC 60601-1-2 international standard. The requirements of this international standard are: CISPR11, GROP1, and CLASS B.

1.6 Explanation of Symbols

Symbol	Explanation	Symbol	Explanation
	Attention		Type BF applied part
IPX1	Protected against dripping water		Storage temperature and relative humidity
	Prevent from rain	**SN**	Serial number
SpO2	Hemoglobin Oxygen Saturation	**PR**	Pulse Rate
	The adapter is connected		Audible alarm inhibition

	USB cable is connected		Battery power indication
	Manufacturer's information		Power on/off
	European union approval		Date of Manufacture
	Authorized representative in the European community		Follow instructions for use
	The waste electrical and electronic equipment	bpm	Pulse rate
	Adpater polarity symbol		Battery cover unlock / lock
	Class II equipment		Do not discard the device and other components

1.7 Product Features

- High resolution 2.8" TFT screen display SpO2, PR, waveform and pulse bar.
- Adjustable audible and visual alarms.
- 127 ID setup; 72-hour data storage and review.
- Medview software for data analysis.
- 3 AA alkaline batteries or power adapter.
- Muti-language (Menu): English, French, German, Spanish, Italian, Japanese, Russian and Chinese

1.8 Contraindication

None

2 General Description

The McKesson Handheld Pulse Oximeter has a 2.8 inch TFT screen, which can display the SpO_2%, pulse rate, PI and other indication parameters, such as time, ID number, pulse amplitude bar and battery power status, alarm limits and the connections of probes, etc.

2.1 Appearance

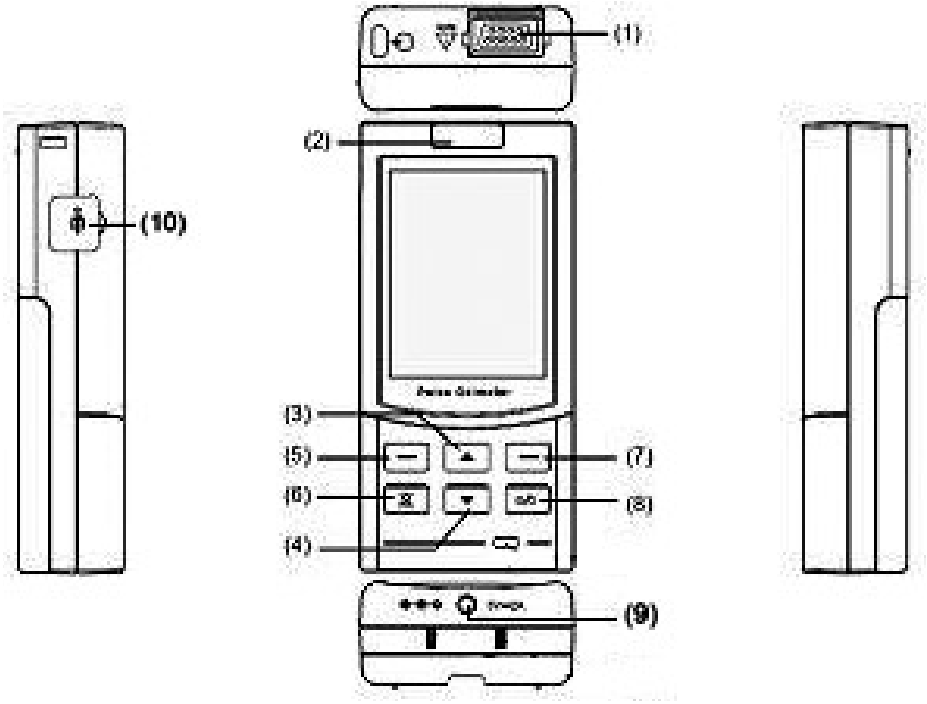


Fig.2-1

Description of these figures:

(1) SpO_2 socket: For connecting the SpO_2 probe with the pulse oximeter.

(2) Alarm lamp: When SpO_2 or/and PR alarm occurs, It flashes.

(3) Navigation button(Up): Press this button to increase the value by one increment. Or press it and hold it down to continuously increase the value. Or select the item you want.

(4) Navigation button(Down): Press this button to decrease the value by one decrement. Or press it and hold it down to continually decrease the value. Or select the item you want.

(5) Menu/OK button: For entering main menu, or confirming the selection/setting.

(6) Alarm silence button: Press this button to silence the audible alarm for 60s/120s/180s.

(7) Back/Shift button: On the measuring screen, press it to change the display mode; On the sub-menu screen, it serves as Back button.

(8) Power switch: Press and hold for 3 seconds to power the device on, and for about 4 seconds to turn the device off.

(9) Adapter socket: For connecting the power adapter.

(10) USB socket: Used to connect the USB cable for data transmission.

2.2 Power Supply

2.2.1 Powered by batteries

Batteries Installation

1) Open the battery cover: Rotate the fixing screw slightly in the rear panel to the position which is marked with "" and then push the cover as indicated by arrowhead, as shown in Fig. 2-2.

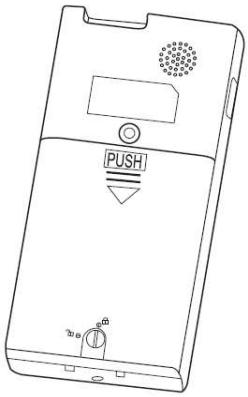


Fig.2-2

2) Install three AA Alkaline batteries as indicated by the polarity signs in battery compartment.

3) Close battery cover

Close the battery cover and rotate the screw to the position which is marked with . And the battery cover is locked.

Warning!

Make sure the polarities of the batteries are correct.

Battery life and replacement

There are five shapes for the battery life indicator: the center with 4 bars (full), 3 bars, 2 bars, 1 bar, empty and the frame in red. That the frame of indicator become red means limited battery power remains. You should replace the unit's batteries with new ones in a timely manner, or the unit will shut down.

Cautions!

- Be sure to install batteries with correct polarities.
- Only the approved (AA Alkaline) batteries are recommended to be used.
- Do not use batteries not specified for this unit.
- Do not dispose of batteries in fire.
- If battery fluid gets on your skin or clothing, rinse with plenty of clean water immediately.
- Remove the batteries from this unit when you are not going to use it for a long period of time (approximately one month).
- Do not use batteries of different types together.
- Do not use new and used batteries together.
- Dispose of batteries in accordance with the local ordinances and regulations.

2.2.2 AC Power Supply

When there are no batteries in the battery compartment, the device can be supplied by AC power by connecting the device to AC adapter.

Note: Use the AC power supply, make sure put the device in the safety and proper place and convenient to power off.

Warnings!

- Be sure to use the adapter that specified for this device.
- Plug and unplug the adapter cautiously to avoid injuries caused to your body.
- If the device suddenly power off, please take out your finger at once, and then connect power or install the batteries.
- Be sure that the AC adapter has no function of charging

3 Take a Measurement

3.1 Probe Connection

Insert the SpO_2 probe to the socket, as shown in Fig.3-1. If the SpO_2 probe is disconnected from the unit, “Probe Off” will appear in the status column.

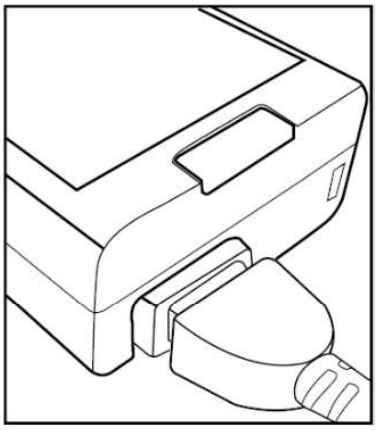


Fig.3-1

Notes:

- Please check the SpO2 probe compatibility before use, the probe should meet the ISO80601-2-61.
- Select the suitable probe in terms of type and dimension. Attach the sensor to the appropriate site of the user’s finger, refer to Fig.3-2.

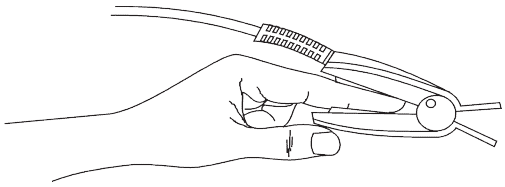


Fig.3-2 placement of the sensor

If the finger is not in the probe, “Finger off” will be shown.

3.2 Basic Operation

Press and hold the power switch for 3 seconds to power the device on. After several seconds, the measuring screen will be displayed as follows.

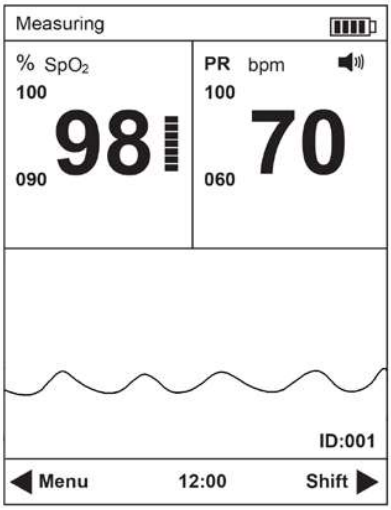


Fig.3-3 Wave display

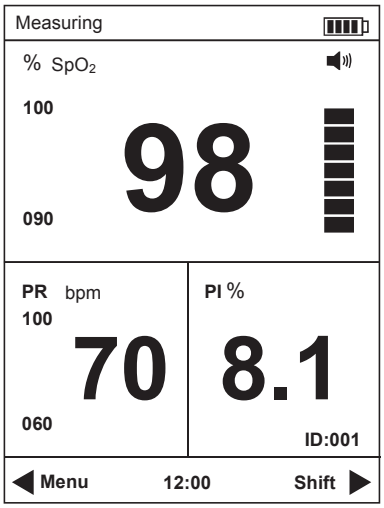


Fig.3-4 Digital display

Description of measurement screens:

1. **Measuring:** The pulse oximeter is in the status of measuring.
   - It shows "Finger off" when there is no finger inserted or no signal is detected.
   - It shows "Probe off" when the probe is not connected to the pulse oximeter.
2. **%SpO_2:** SpO_2 display area
   - It shows the oxygen saturation level of functional hemoglobin during normal measurement.
   - The color of the SpO_2 value will become red when the SpO_2 is beyond the alarm limits.
   - It shows two dashes throughout probe off and finger out conditions.
3. **100:** SpO_2 high alarm limit; 90: SpO_2 low alarm limit.
4. : Pulse bar
5. **100:** PR high alarm limit; 060: PR low alarm limit.
6. **PRbpm:** PR area of display
   - It shows the pulse rate in beats per minute during normal measurement.
   - The color of the PR value will become red when the PR is beyond the alarm limits.
   - It shows three dashes throughout probe off and finger out conditions.
7. **ID:** 001, the ID number of the current patient is 001.
8. **12:00:** The current time.
9. PI%: Perfusion indicator display area.

Note: When no signal is detected or no operation, one minute later the pulse oximeter will automatically turn off the screen display and enter into standby status.

3.3 Factors that may affect the measurement

Warnings!

• The measurement would not be performed if the following instances come across in operation:

1) Shock
2) Low temperature of hand
3) Have taken vascular activity medicine
4) Anemia
5) Carboxyhemoglobin
6) Methemoglobin
7) Methylene blue
8) Indigo carmine

• Do not use the SpO_2 probe with exposed optical components.

• Tissue damage can be caused by incorrect application or use of probe, for example by wrapping the probe too tightly. Inspect the probe site to ensure skin integrity and correct positioning and adhesion of the probe. More frequent inspections should be made to meet individual patients' needs when necessary.

• Inaccurate measurements may be caused by:

1) Incorrect application or use of probe
2) Significant levels of dysfunctional hemoglobin (such as carboxyhemoglobin or methemoglobin)
3) Intravascular dyes such as indocyanine green or methylene blue
4) Exposure to excessive illumination, such as surgical lamps (especially ones with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight
5) High-frequency electrosurgical interference and defibrillators
6) Venous pulsations
7) Placement of a probe on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.
8) The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia
9) There is arterial occlusion proximal to the probe
10) The patient is in cardiac arrest or is in shock

• Loss of pulse signal can occur in any of the following situations:

1) The probe is too tight
2) There is excessive illumination from light sources such as a surgical lamp, a bilirubin lamp, or sunlight
3) A blood pressure cuff is inflated on the same extremity as the one to which an SpO_2 probe is attached

Note: SpO_2 probe should be kept from the light source, e.g. radial lamp or infrared lamp.

3.4 Alarm

ALARM PRIORITY:

There are two-level priorities for selection.

High priority: indicates the patient is in a very dangerous situation.

Low priority: indicates the technical alarm caused by the device itself.
Alarms of the oximeter include technical and physiological alarms. Both priorities are divided by built-in module and cannot be changed by user.

Assignment of priority:

	High	Low
Paramter	SpO_2	/
Value	Red	Yellow
Alarm lamp	Flashing	Yellow
Lamp Frequency	1.5Hz	/
Audiblesound	Di- Di – Di ----- Di - Di	Di
Alarm cycle	3 seconds	20 seconds
Alarm info	SpO_2 too high/low PR too high/low Battery power low	Probe off/Finger out

Notes:
1. The alarm will occur if the measurement value is out of range.
2. The alarm will sound until alarm disappears or is turned off.
3. After silencing the alarm, the corresponding indicator will indicate this.
4. The low power alarm: the corresponding indicator light will be flashing red.

AUDIBLE ALARM INHIBITION:

Short press the  button to silence the audible alarm for 60 seconds/120 seconds, the audible alarm indicator will be displayed as  , together with the countdown, short press it again, to cancel alarm inhibition;

⚠ Warnings!
- When an alarm occurs, check patient's condition immediately.
- Check the parameter which is alarming.
- Check patient's condition.
- Search for the source of the alarm.
- Mute the alarm, if necessary.
- Check the alarm when no warning is apparent.

After measurement

After measurement, please remove the patient's finger and press and hold the power button to turn off the device.
Remove the batteries from this unit or unplug the SpO_2 probe when you are not going to use it for a long period of time (approximately one month).

Alarm delay

The alarm condition delay and alarm signal generation delay: less than 1 second.

Note:

1. The pulse rate correspondence with the user's pulse rate is based on the user's actual pulse rate.
2. Use the alarm setting in different areas can be potentially dangerous.
3. The alarm settings can recover if the power outage time less than 30 seconds.
4. Set the high parameter value with simulator to test the efficiency of the alarm system.
5. DO NOT set the parameter value out of range, or the alarm system will fail.
6. The device can preserve alarm settings if a power outage occurs.

4 Settings

4.1 Password: Modify Settings & Sounds

Always set the date and time before using the unit for the first time. Set different ID numbers for different users.

Check the date and time are correct before using the unit, and reset them if necessary. The date and time are important indicators when a measurement is taken.

Before setting, please enter passoword (1234) to set the parameter. Or you can direct access to check the parameter but not to change.

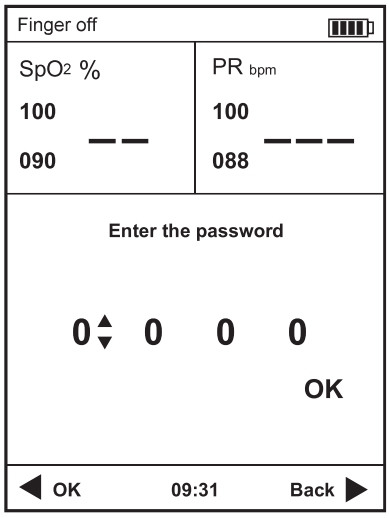


Fig.4-1

How do you input passwords?

1. Press the Navigation button to change the numbers.
2. Press the OK button to confirm your selection.
3. Press the Navigation button to switch to the next number.
4. Repeat steps one through three until four numbers are selected.

Notes:

1. The read-only password is 0000. Use this password to check the parameter. No Changes can be made when read-only password is used.

2. The make-changes password is 1234, enter this password to set the parameters.

3. If you forget your password, please contact the service center.

4.2 Date & Time Settings

Set the correct time according to the following steps:

1) Press the power switch for 3 seconds to power on the oximeter and then press the menu button to enter the main menu, refer to the Fig.4-2.

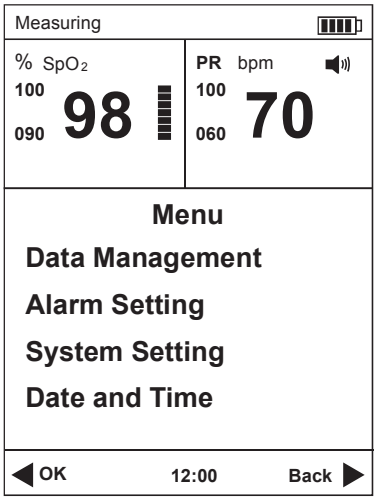


Fig.4-2

2) Press the Navigation button to select “Date and Time", and then press the OK button to enter the time setup screen, refer to Fig.4-3.

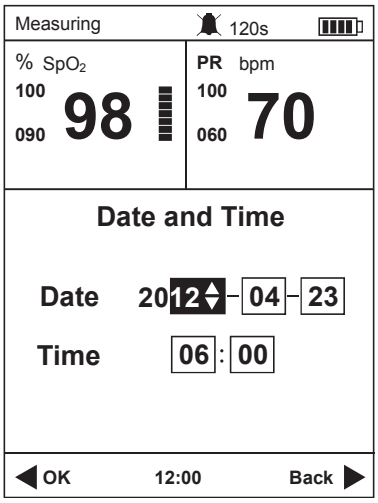


Fig.4-3

Press the Navigation button to select it and then press the OK button to confirm. Press the Navigation button to adjust the value, and then press the OK button to confirm the value.

The date is displayed in the order of Year-Month-Day and Time in Hour-Minute

4.3 About the User ID

Every time, when you insert your finger, the ID number will increase automatically.

4.4 Alarm Setting

From the main menu, select and enter the “Alarm setting” screen, refer to Fig.4-4.

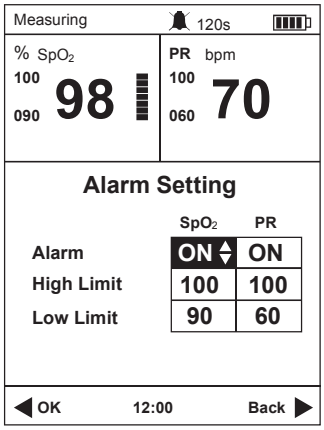


Fig.4-4

You can select the Alarm on or off.
High limit SpO_2 range is71~100
Low Limit SpO_2 range is 70~99
High Limit PR range is 31~250
Low Limit PR_2 range is30~249

4.5 Data Management

From the main menu screen, select and enter the “Data Manage” screen, refer to Fig.4-5.

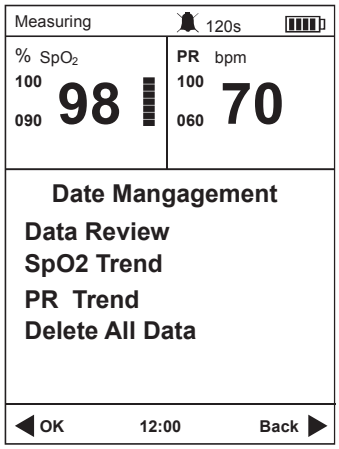


Fig.4-5

Press the Navigation button to select the sub-item to set, and then press the OK button to confirm or Back button to return to the previous screen.

4.4.1 Data Review

Select and enter the “Data review” interface as shown in Fig.4-6. Press the Navigation button to review the records page by page.

The pulse oximeter can record the alarming parameter marked with red color. Press the Back button and the pulse oximeter returns to the previous interface.

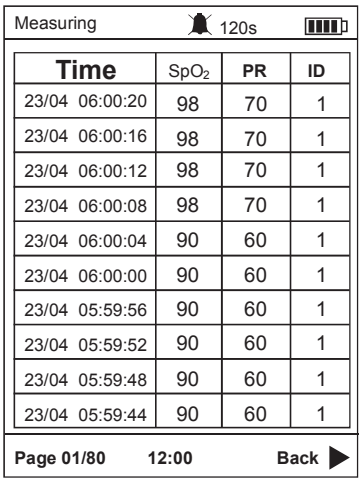


Fig.4-6

4.4.2 SpO_2 Trend

Select and enter the “SpO_2 Trend” interface as shown in Fig.4-7. Press the Navigation button to review the records page by page. Press the Back button and the pulse oximeter returns to the previous interface.

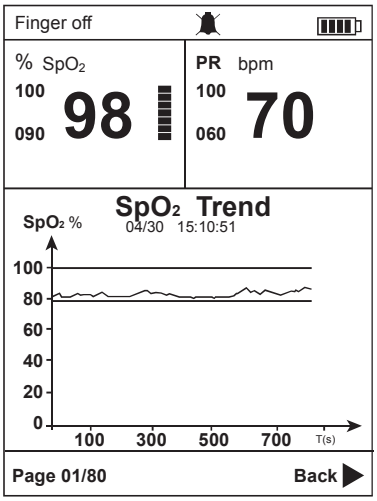


Fig.4-7

Above the trend, the date and time of the first item are displayed, with year-month-day; hour: minute: second.

4.4.3 PR Trend

Select and enter the “PR Trend” interface as shown in Fig.4-8. Press the Navigation button to review the records page by page. Press the Back button and the pulse oximeter returns to the previous interface.

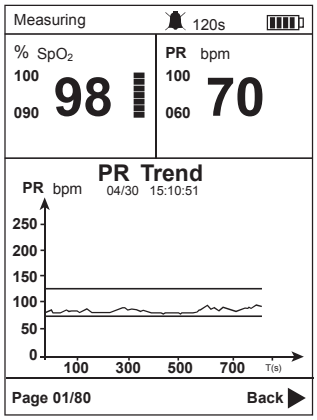


Fig.4-8

4.4.4 Delete all data

Select and enter the “Delete all data” interface as shown in Fig.4-9. You can select “Yes” or “No” by pressing the Navigation button. Press the OK button to confirm your selection.

Note: Please take caution with the deletion of data; you will never get the data back once deleted.

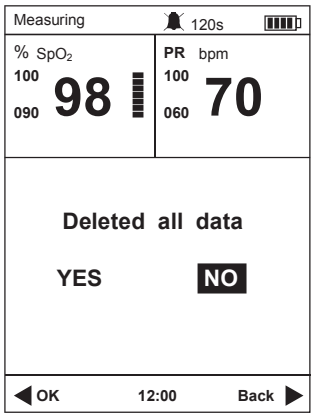


Fig.4-9

4.5 System Setting

Select and enter the [System Setting] interface from the main menu. And then press the Navigation button to browse, adjust and select different item settings.

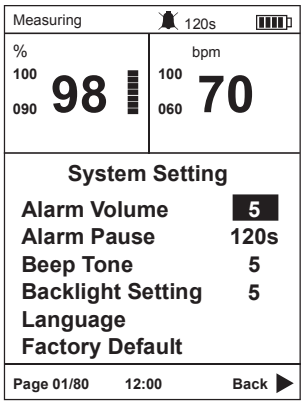


Fig.4-10

Alarm Volume: You can adjust the value of alarm volume, there are 7 levels, and the default level is 1.
Alarm Pause: There are three modes: 60 seconds, 120 seconds and Permanent (always on). The default mode is 120 seconds.
Beep Tone: Levels from 0 to 7. The default level is 0.
Backlight Setting: Levels of brightness from 1 to 7. The default level is 3.
Language: English, French, German, Spanish, Italian, Japanese, Russian and Chinese.
Note: After changing the batteries, the settings may return to the default settings.

5 Data Transmission

Use USB cable to transmit the measurements to PC for further review and analysis.

Before data transmission, be sure to turn the device on and connect it with a computer by way of the attached USB cable. The operations refer to the User Manual of the data transmission Software.

6 Maintain and Repair

⚠ Warnings!

The advanced circuit inside the oximeter does not require periodic calibration and maintenance, except replacing the batteries.

Don’t open the cover of oximeter or attempt to repair electronic circuits. This may cause damage to the device and annulment of the warranty.

6.1 Maintenance

Replace the batteries in a timely manner when low voltage indication appears.
Clean surface of the oximeter before it is used in diagnosis for patients.
Remove the batteries if the oximeter is not operated for a long time.
It is best to store the product in -20℃~+70℃ and ≤93% humidity.
Keep in a dry place. Extreme moisture may affect oximeter lifetime and may cause damage.
Dispose of batteries properly; follow any applicable local battery disposal laws.

6.2 Cleaning and Disinfecting

Cleaning

Please use medical alcohol to clean the silicone touching the finger inside of SpO_2 probe with a soft cloth dampened with 70% isopropyl alcohol. Also clean the patient's finger using alcohol before and after each test.

To clean your equipment, follow these rules:

1. Shut down the pulse oximeter and take the batteries out of the battery wharf.
2. Clean the display screen using a soft, clean cloth dampened with a glass cleaner.
3. Clean the exterior surface of the equipment using a soft cloth dampened with the cleaner.
4. Wipe off all the cleaning solution with a dry cloth after cleaning, if necessary.
5. Dry the equipment in a ventilated, cool place.

Do not pour or spray liquids onto the oximeter, and do not allow any liquid to enter any openings in the device. Allow the oximeter to dry thoroughly before reuse.

All device parts that come in contact with the patient's body are required to be disinfected once after each use. The recommended disinfectants include: ethanol 70%, isopropanol 70%, glutaraldehyde-type 2% liquid disinfectants.
Disinfection using non-recommended disinfectants may cause damage to the equipment and is therefore not recommended for this pulse oximeter unless otherwise indicated in your hospital's servicing schedule. Clean the pulse oximeter (per the "cleaning" instructions listed above in section 6.2, steps 1-5) before disinfecting it.

CAUTION: Never use EtO or formaldehyde for disinfection.

6.3 Calibrating

A functional tester cannot be used to assess the accuracy of a pulse oximeter monitor or sensor. Clinical testing is used to establish the SpO_2 accuracy. The measured arterial hemoglobin saturation value (SpO_2) of the sensors is compared to arterial hemoglobin oxygen (SaO2) value, determined from blood samples with a laboratory CO-oximeter. The accuracy of the sensors in comparison to the CO-oximeter samples measured over the SpO_2 range of 70–99%. Accuracy data is calculated using the root-mean-squared (Arms value) for all subjects, per ISO 9919:2005, Medical Electrical Equipment–Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.

6.4 Troubleshooting

a) The oximeter can't be powered on

Please check the batteries. If you use an external power supply, please check if the power supply is connected with oximeter properly.

b) "Probe off" alarm

Please check if the probe is connected with the oximeter correctly. If the sensor is used with extension cable, please check if the extension cable is connected with the sensor correctly.

c) "No finger" alarm

Please check whether the sensor is correctly connected with patient's finger.

6.5 Warranty and Repair

6.5.1 Maintenance and Product Support

a) Maintenance and Product Support: Call 1-800-777-4908 from 9:00 a.m. to 5:30 p.m. Eastern standard time, Monday to Friday (except Holidays), or e-mail mckessonbrands@mckesson.com.

b) Spare Parts: Our company changes parts if it is necessary free of charge in the warranty period. User should send the part(s) back to our compnay if not specified.

6.5.2 Exempt and Limitation

a) Our company isn't responsible for such damage caused by force majeure. For example: fire, thunder flash, flood, cyclone, hail, earthquake, house collapse, commotion, plane failing and traffic accident, deliberate damage, lack of fuel or water, labor and capital bother, strike and stop-working etc.

b) Non-service items

- The corresponding charge and insurance charge of disassembling, refurbishing, repackaging and moving the oximeter or the part of it.
- The damage caused by the third company not commended by our company to adjust, install replace the parts of the oximeters.
- The damage and failure caused by the users incorrect operations not complying with the operator's manual.

c) Our company will not provide the free maintenance in the warranty if the oximeter is installed or connected with the external devices which are not permitted by Our company, e.g. printer, computer, cable and lead to oximeter failure. Our company will charge for the maintenance.

d) Responsibility limitation

During the period of warranty, if user changes the parts manufactured by the third party without our company permission, our company is entitled to stop contract.

6.5.3 Satisfaction Guarantee

a) Please read user manual carefully before operation.

b) Please operate the oximeter in accordance with the requests made in this manual and perform the required maintenance.

c) Please guarantee the power supply and the working environment of monitor.

6.5.4 Non-guarantee principle

●There is physical damage on oximeter and its accessory.

APPENDIX A Specifications

Notes:

- Specifications may be changed without prior notice.
- The circuit diagrams, the list of components, the illustration of diagrams, and the detailed rules of calibration, are provided exclusively to professional personnel authorized by our company.
- The equipment has been calibrated, users do not need to calibrate. In order to ensure the accuracy of the probe, please change the probe once a year. Make sure to use the type of probe specified in this manual.

Specifications:

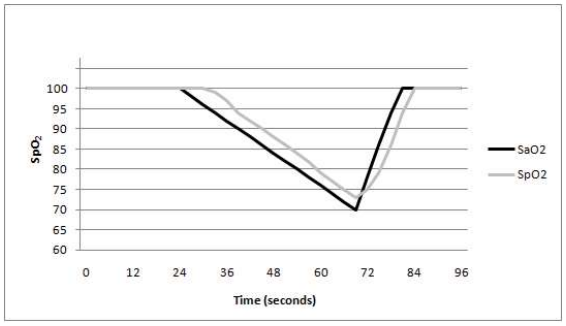
Display:

Data: SpO_2%, PR, PI, pulse bar

Others: connection status of probe and other alarm information.

Equipment data update period

As shown in the following figure. Data update period of slower average is 8s.



Alarm:

Alarm: SpO_2% and pulse rate value, probe off, battery exhausted

Alarm mode: audible alarm, visual alarm and information

Alarm limits range: SpO_2 70%-100%, PR 30-250 bpm

Default limits: SpO2 High 100%, low 90%; PR High 100 bpm, low 60 bpm

SpO_2

Measurement range: 70%~100%

Resolution: 1%

Accuracy: 70%~100% : ±2%; <70% unspecified

Pulse Rate

Measurement range: 30~250 bpm

Resolution: 1 bpm

Accuracy: ±2 bpm or 2%(The larger)

PI

Measurement range: 0.1%~20%

Accuracy: 0.1%~1.0% ±0.2%；1.1%~20% ±20%

Probe

Emitter: OL660905HM2-2(H2)-C
Receiver: OP30TMF-3

Probe LED Specifications:

	Wavelength	Radiant Power
RED	660±3nm	3.2mW
IR	905±10nm	2.4mW

Environment Requirements

Operation temperature:	0℃~40℃
Operation humidity:	≤80%,no condensation
Storage / transport temperature:	-20℃~+70℃
Storage / transport humidity:	≤93%, no condensation
Power supply:	Three AA alkaline batteries or adapter
Working time:	more than 10 hours
Atmosphere pressure:	86kPa~106kPa

AC adapter(optional)

Input Voltage: AC 100~240V
Input Frequency: 50~60Hz
Output Voltage: DC 5V±5%
Output Current: 2A MAX

Fuse

Type: 1206L050

I(hold)0.5A, I(trip)1A, V(max)15V

Store and Replay

Store and replay 72 hours SpO_2% and Pulse rate value, the time interval is 4 seconds.

Outline of Product

Dimension: 125mmX60mmX30mm
Weight: 195g (excluding the batteries)

Equipment Classification

Classification according to IEC-60601-1	
According to the type of protection against Electrical shock	Internal electrical power source equipment and Class II equipment
According to the degree of protection against Electrical shock	Type BF equipment
According to the degree of protection against harmful ingress of water.	IPX1

According to the methods of sterilization or disinfection.	Non-sterile: Use of Liquid surface disinfectants only.
According to the mode of operation.	Continuous operation
Equipment not suitable for use in the presence of a flammable anesthetic mixture air or with oxygen or nitrous oxide.	

Note: the applied part of the device: the SpO_2 probe.
Box contents:

1. Reuseable Sp02 sensor(adult or pediatric)
2. Three AA alkaline batteries
3. Software CD
4. USB Cable
5. User's Manual
6. Hanging Strap

APPENDIX B Statement of Manufacturer

Guidance and manufacturer's declaration - Electromagnetic emission---- for all EQUIPMENT AND SYSTEMS

1	Guidance and manufacturer's declaration- electromagnetic emission		
2	The McKesson Pulse Oximeter is intended for use in the electromagnetic enviroment specified below. The customer or the user of the McKesson Pulse Oximeter should assure that it is used in such an environment.		
3	Emissions test	Compliance	Electromagnetic environment-guidance
4	RF emissions CISPR11	Group 1	The McKesson 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.
5	RF emissions CISPR11	Group B	
6	Harmonic emissions IEC 61000-3-2	Class A	
7	Voltage fluctuations/ IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - Electromagnetic Immunity-
For all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration - electromagnetic immunity			
The McKesson Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the McKesson 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	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrostatic transient/burst IEC 61000-4-4	±2kV for power supply lines ±1kV for input/ output lines	±2kV for power supply lines ±1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode ±2kV 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 cycles 40% UT (60%dip in UT) for 5 cycles 70% UT (30%dip in UT) For2 5 cycles <5% UT (>95%dip in UT) for 5 sec	<5% UT (>95%dip in UT) for 0.5 cycles 40% UT (60%dip in UT) for 5 cycles 70% UT (30%dip in UT) For2 5 cycles <5% UT (>95%dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the McKesson Pulse Oximeter requires continued operation during power main interruptions, it is recommended that the McKesson Pulse Oximeter be powered from an uninterruptible power supply or a battery.
Power frequency(50/60Hz) 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 a.c. 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			
The McKesson Pulse Oximeter is intended for use in the electromagnetic specified below. The customer of the user of the McKesson 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 Radiated RF IEC 61000-4-3	3Vrms 150kHz to 80MHz 3V/m 80MHz to 2.5GHz	3V 3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the McKesson Pulse Oximeter, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=[\frac{7}{E_1}]\sqrt{P}$ $d=1.2\sqrt{P}$ 80MHz to 800MHz $d=2.3\sqrt{P}$ 800MHz to 2.5GHz Where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacture and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE1 At 80MHz and 800MHz, 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.

a Field strengths from fixed transmitters, such as base situation 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 McKesson Pulse Oximeter is used exceeds the applicable RF compliance level above, the Pulse Oximeter should be observed to verify normal operation. If abnormal performance is observed, the additional measures may be necessary, such as reorienting or relocating the McKesson Pulse Oximeter.
b Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.

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

Recommended separation distances between portable and mobile RF communications equipment and the McKesson Pulse Oximeter

The McKesson Pulse Oximeter is intended for use in an electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of the McKesson Pulse Oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the McKesson Pulse Oximeter as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output of transmitter(W)	Separation distance according to frequency of transmitter (m)		
	150KHz to 80 MHz $d=[\frac{7}{E_1}]\sqrt{P}$	80MHz to 800 MHz $d=1.2\sqrt{P}$	800MHz to 2.5 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance in meters (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 80MHz and 800MHz, the separation distance for the higher frequency range applies.
NOTE2 These guidelines may not apply in all situations. Electromagnetic interference is affected by absorption and reflection from structures, objects and people.