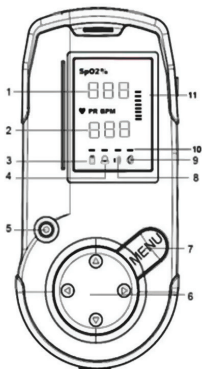# HAND HELD PULSE OXIMETER INSTRUCTION MANUAL

dynarex

Reorder No. 7089

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Contents

1 Introduction

1.1 Brief Introduction

Thank you for purchasing the Hand Held Pulse Oximeter. The device is designed to measure SpO_2 and PR, delivering visual and audio alarm, sensor off alarm, data storage and review etc. Please read this manual carefully before using it.

1.2 Safety Information

Conception of Warning, Precaution and Notice

The Warning, Precaution and Notice in this document means:

➢   **Warning** - Indicates a potential hazard or unsafe practice that, if not avoided, will result in death or serious injury.

➢   **Caution** - Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury or product/ property damage.

➢   **Notice** - Provides application tips or other useful information to ensure that you get the most from your product.

WARNINGS

- Before putting the system into operation, verify that the equipment, connecting cables and accessories are in correct working order and operating condition.

- To avoid explosion hazard, do not use the Oximeter in the presence of flammable anesthetics, vapors or liquids.

- Do not open the equipment housings; electric shock

hazard may exist. All servicing and future upgrades must be carried out by trained personnel and authorized by our company only.

- The Pulse Oximeter is specified for use by medical professionals only.

- Prolonged use of the probe/sensor or the patient's condition may require changing the sensor site periodically. Change the sensor site and check skin integrity, circulatory status, and correct alignment at least every 4 hours. Prolonged use may cause blisters, skin deterioration, and discomfort.

- When connecting this Oximeter to any instrument, verify proper operation before clinical use. Refer to the instrument's user manual for full instructions. The equipment connected to the Pulse Oximeter's data interface must be certified according to the respective IEC standards, i.e., IEC950 for data processing equipment or IEC 601-1 for medical electrical equipment. All combinations of equipment must be in compliance with IEC601-1-1 systems requirements.

- Sensor malfunction may cause inaccurate data, possibly resulting in patient injury or death, so pay close attention to the sensor and inspect it often.

- The physiological data and alarm messages displayed on the equipment are for reference only and cannot be directly used for diagnostic interpretation.

- Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to off may result in a hazard to the patient. Remember that alarm settings should be customized according

to different patient situations and always keeping the patient under close surveillance is the most reliable way for safe patient monitoring.

- Worn-out data cables may also cause inaccurate data, so if the data is used as a reference to treat a patient, pay special attention to the data cable and check it more frequently.

- When using the equipment with electrosurgical units (ESU), make sure the patient is safe.

- Do not come into contact with the patient during defibrillation. Otherwise serious injury or death could result.

- Single-use accessories should never be reused. To avoid inadvertent disconnection, route all cables in a way to prevent a stumbling hazard. Wrap and secure excess cabling to avoid risk of entanglement or strangulation by patients or personnel.

CAUTIONS

- Autoclaving, ethylene oxide sterilizing, or immersing the sensors in liquid may cause inaccurate readings.

- To ensure patient safety, use only parts specified in this manual.

- The operator must be thoroughly familiar with the information in this manual before using the device.

- Magnetic and electrical fields are capable of interfering with the proper performance of the equipment. For this reason make sure that all external devices operated in the vicinity of the equipment comply with the relevant

EMC requirements. Mobile phones, X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation.

• Unplug the sensor from the Oximeter before cleaning or disinfecting it. If liquid is accidentally spilled on the unit, clean and dry thoroughly before reuse.

• Do not try to use the SpO_2 and NIBP measurement on the same arm at the same time. This could potentially affect measurement accuracy.

• At the end of its service life, the equipment must be disposed of in compliance with the guidelines regulating the disposal of such products. If you have any questions concerning disposal of the equipment, please contact your distributor.

• Always install or carry the equipment properly to avoid damage caused by drop, impact, strong vibration or other mechanical force.

NOTES

• Put the equipment in a location where you can easily see the screen and access the operating controls.

• Keep this manual in the vicinity of the equipment so that it can be obtained conveniently when needed.

• The software was developed in compliance with IEC60601-1-4. The possibility of hazards arising from software errors is minimized.

• SpO_2 measurements may be influenced by high ambient light, especially sunlight. Shield the sensor area if necessary.

- Dyes introduced into the bloodstream, such as methylene blue, indocyanine green, indigo carmine, and fluorescein, may influence the accuracy of the SpO_2 reading.

- 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.

- Remove fingernail polish or artificial fingernails before applying SpO_2 sensors. Fingernail polish or artificial fingernails may cause inaccurate SpO_2 readings.

- 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.

- For routine equipment maintenance, please refer to the service procedures at the associated section as indicated in the manual.

- As to the other concerns for attention, please carefully look through the specific chapter in enclosed instructions.

- This manual describes all features and options. This model may not have all accessories mentioned in this manual.

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

1.3 Equipment Symbols

Symbols	Definitions
⚠	Attention! Refer to the relevant information. Read operator's manual carefully before using the Oximeter.
👤	Type BF applied part
⌂	Production date
▄▄	Manufacturer's address
⎕	Low power indicator
SN	Serial Number

1.4 Equipment Classification

Classification according to IEC-**60601**	
According to the type of protection against electrical shock	Internal electrical power source equipment
According to the degree of protection against electrical shock	Type B equipment
According to the degree of protection against harmful ingress of water	Ordinary equipment (enclosed equipment without protection against ingress of water)
According to the methods of sterilization or disinfection	Non-sterilizable: 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.	

1.5 Package Contents

1. Pulse Oximeter manual
2. Sensor manual
3. Finger Sensor w/ cable
4. USB cable
5. Software Disk

2 General Descriptions

The Hand Held Pulse Oximeter has 8-segment digital LED for displaying data. It can display the SpO_2 and pulse rate value, time & date, ID number, pulse bar as well as battery status etc.

2.1 Front Panel

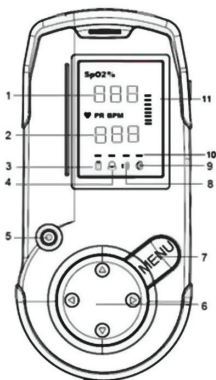Please refer to **Fig. 1**. The display in Fig. 1 is a normal screen.

Fig. 1 Front panel

Instruction of Fig. 1:

1. SpO_2: SpO_2 value

2. PR: Pulse rate

3. 🔋 Low power indicator. When the power is lower than 2.4V, the lamp indicated will be lighted, and the Oximeter will power off automatically when the power is lower than 2.3V.

4. ⬇ Alarm Indicator: When technical alarm or physiological alarm occurs, the lamp indicated will turn red.

5. Power button

6. Navigation buttons: you can select and set the different parameters. These three buttons below are also used as shortcut buttons:

  a) Press the up button, the unit will display the ID number.

  b) Press the right or left button, the unit will display the Error Code.

7. Menu button: You can return to the measurement screen or switch the main menu item by this button.

8. 𝕀⟩⟩ Reserved function.

9. 🔇 Beep off/on Indicator: When beep is off, the lamp indicated by it is on.

10. Alarm light: When there is an alarm, the associated lamp will be lighted.

11. ☰ Pulse bar: The pulse bar is in proportion to the pulse volume.

Note: This manual describes all features and options. However equipment may not have all accessories.

2.2 Rear Panel
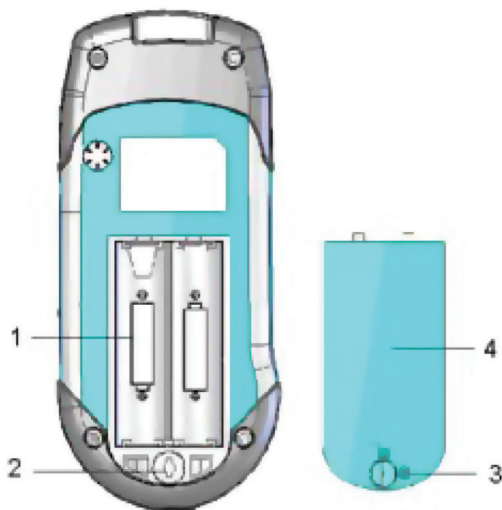
Fig. 2 Rear panel

Rear panel introduction:

1. Battery compartment – Uses 2 AA-size alkaline batteries (not included)

2. Fixing hole

3. Fixing screw

4. Battery cover

Battery Installation (Batteries Not Included):

1) Open the battery cover: Rotate the fixing screw slightly in the rear panel to the up position which is marked with " ⌒□ " and then open the cover.

2) Install 2 batteries as indicated by the polarity sign.

   Note: Be sure to insert the batteries in the correct polarity, as indicated by polarity markings (+ and -) inside the battery cover.

3) Close battery cover: Close the battery cover and rotate the screw to the 🔒 position, and the batteries are locked.

⚠ **Make sure that the polarity of the batteries is correct, otherwise the unit cannot operate normally.**

Battery Life And Replacement

When the low-power indication lamp is lighted, please replace the batteries with new ones as needed.

   ♦ Always turn the unit off before replacing the batteries.

   ♦ Dispose of the used batteries according to the applicable local regulations.

⚠ **Warnings!**

If battery contents should get into your eyes, immediately rinse with plenty of clean water. Consult a doctor immediately.

Cautions!

   ♦ Do not use batteries not specified for this unit.

♦ Do not insert the batteries with the polarities in the wrong direction.

♦ Do not dispose of batteries in fire.

♦ If battery contents should get on your skin or clothing, immediately rinse with plenty of clean water.

♦ Remove the batteries from this unit when you are not going to use it for a long period of time (approximately three months or more).

♦ Do not use batteries of different types together.

♦ Do not use new and used batteries together.

2.3 Product Features

♦ Rubber grip design offers special protection.

♦ Compact, light-weight design for simple, one-hand operation.

♦ High brightness LED displays SpO_2, pulse rate and pulse bar.

♦ Up to 99 patients' ID and 72-hour record storage.

♦ Visual & audio alarm, low battery alarm.

♦ Data transfer to PC for storage or printing.

♦ Convenient 2 AA-size alkaline batteries (not included).

2.4 Intended Use

The Hand Held Pulse Oximeter is intended for continuous monitoring, spot-checking of functional pulse oxygen saturation (%SpO_2) and pulse rate (PR) of single adults, pediatric patients in hospitals and home care.

3. Getting Started

3.1 Unpacking and Checking

Before unpacking, examine the packing case carefully for damage. If any damage is detected, contact your distributor. Open the package and remove the equipment and accessories carefully. Check all materials as per the packing list and check for any mechanical damage.

NOTE

Save the packing case and packaging material as they can be used if the equipment must be reshipped.

WARNINGS

- Keep the packing material out of children's reach. Disposal of the packaging material should observe the applicable waste control regulations.

- Before use, please verify whether the packages, especially the package is intact. In case of any damage, do not apply the Pulse Oximeter to the patient.

3.2 Environmental Requirements

The operating environment of the equipment must meet the requirements specified in this manual.

When the equipment is moved from one place to another, condensation may occur as a result of temperature or humidity difference. In this case, never start the system before the condensation disappears.

Warning: Make sure that the operating environment of the equipment meets the specific requirements. The equipment may not meet the specifications defined in this manual and unexpected consequences, e.g. may result in damage to the equipment

3.3 Connect The Sensor

1. Before use, check the Pulse Oximeter for mechanical damage.

2. Install the alkaline batteries and ensure that the batteries have sufficient power.

3. Plug the SpO_2 extension cable in the multifunctioning connector on top of the Oximeter, as shown in Fig. 3 Ensure that the sensor is firmly plugged in.
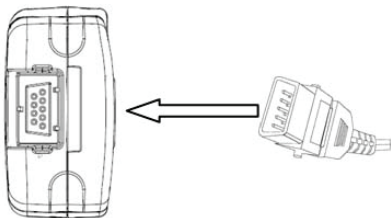
Fig. 3

Note: The connector is also applied to upload data to Med-View software for reviewing. Detailed information is referred to MedView software operator's manual.

3.4 Starting or Shutting Off the Oximeter

To start the Pulse Oximeter:

1. Press and hold the Power button for about 3 seconds. The LED and alarm lamp flashes, and then goes out. The system gives a beep and displays the startup screen. The startup screen displays the version number of software.

2. The startup screen disappears and normal screen appears.

To shut off the Pulse Oximeter:

1. Confirm that the patient measurement is finished.

2. Disconnect the SpO_2 extension cable from the Pulse Oximeter.

3. Press and hold the Power button for 4 seconds.

WARNING
Do not use the Pulse Oximeter if you suspect it is not working properly, or if it is mechanically damaged. Contact your distributor immediately.

4 Setting ID, Date and Time

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

Check and make sure the date and time are correct

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

4.1 Date & Time Setting

Press the menu button four times under the screen to enter time setup.

Character Definitions:

∏ : Is the minute. The setting range is: 0-59

H : Is the hour. The setting range is: 0-23

d : Is the date. The setting range is: 1-31

∏□ : Is the month. The setting range is: 1-12

Ч : Is the year. The setting range is: 0-20

Press the left or the right button to select different date & time parameters; Press the up or down button to set your suitable time & date.

Year setting for example:

1) Press the power button for 3 seconds to turn on the unit.

2) Hit the menu button four times to enter into the time setting screen shown as **Fig. 4**. Press the up or down button to set the suitable year, and then press the left or right button to enter into the other date and time parameter setting pictures.

4.2 ID Number Setting

1. After powering on, hit the menu button two times. You can enter into the ID setting screen.

    Press the up or down button to set the ID number and then press the menu button to confirm your setting. It will turn to the normal screen if there is no button pressed for 10 seconds. The setting range of ID number is: 1-99.

2. In normal screen, press the up button, the digital LED shows the current ID number. It will automatically turn back to normal screen.

Fig. 4

Fig. 5

5 Take A Measurement

SpO$_2$ measuring is a non-invasive technique used to measure the amount of oxygenated hemoglobin and pulse rate by measuring the absorption of selected wavelengths of light. The light emitted by the red infrared light-emitting diodes passes through the tissue and is converted into electrical signals by a photodiode.

After finishing the time and the ID number setting, plug your finger into the sensor as indicated in the picture below:
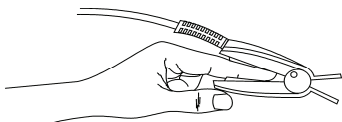
Fig. 6 placement of the sensor

Select the suitable sensor in terms of type and dimension.

Clip the sensor in the right position of the patient finger and ensure that the patient's nail surface is facing upward.

Fig. 7

Plug sensor into SpO2 port on top panel of Pulse Oximeter.
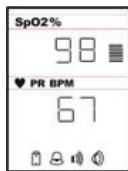
Note: To maintain the highest degree of accuracy, it is recommended that the finger and the Oximeter sensor/ probe is kept as still as possible.

Description of Fig. 7:

SpO2: SpO2 value (displayed value is 98%)

PR: Pulse rate (displayed value is 67 bpm)

5.1 Factors That May Affect The Measurement

During operation, the accuracy of oximetry readings can be affected by the following factors:

5.1.1

Instrument performance depends on the pulsatile character of the artery. The display would not be considered reliable and accurate if the following conditions are present during measurement.

- Shock or cardiac arrest
- Temperature of the unit
- After the administration of a cardiovascular drug
- Anemia
- Evidence of ventilation-perfusion mismatch

5.1.2

Instrument performance depends on the wavelength absorption for oxyhemoglobin and deoxyhemoglobin. If there are substances absorbing the same wavelength, this would induce false or low SpO_2 values. The following may affect these values:

- carboxyhemoglobin
- methemoglobin
- methylene blue
- Indigo carmine

5.1.3

Extremely high illumination could affect the SpO_2 measurement. Use a semi-translucent or opaque cover to shield the sensor.

5.1.4 Other factors

a) High-frequency electrosurgical interference from external devices, including defibrillators.

b) Placement of a sensor on an extremity that currently has installed a blood pressure cuff, arterial catheter, or intravascular line;

c) The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia;

d) An arterial occlusion proximal to the sensor.

⚠ WARNING!

• Use only SpO$_2$ sensors provided by manufacturer. Other SpO$_2$ sensors may cause improper performance.

• Do not use an SpO$_2$ sensor with exposed optical components.

• Excessive patient movement may cause inaccurate measurements.

• Tissue damage can be caused by incorrect operation or misusing sensor. Inspect the sensor site to ensure the skin's integrity and the adhesion position of the sensor is correct. More frequent inspection should be taken if necessary.

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

a) The sensor is too tight.

b) There is excessive illumination from light sources such as a surgical lamp, a bilirubin lamp, or sunlight.

c) A blood pressure cuff is inflated on the same extremity as the one to which an SpO$_2$ sensor is attached.

NOTES:

- ➢ Pulse sensor should obviate the light source, e.g. radial lamp or infrared lamp.
- ➢ Set the upper limit of SpO_2 alarm to 100% means cut off the upper alarm. High density of oxygen will cause adverse affection to the neonate. So the upper limit of SpO_2 alarm must be selected prudently according to the 6 History Data Reviewing.

6 History Data Reviewing

6.1 Character Definition:

- H5o : The user's SpO_2.
- HP : The user's pulse rate.
- HId : The user's ID number.
- HΠI : The minute of the history data.
- HH : The hour of the history data.
- Hd : The date of the history data.
- HΠo : The month of the history data.
- HЧ : The year of the history data.

6.2 Reviewing Operation:

On normal screen, after hitting the menu button one time, you can enter the data reviewing screen shown as the Fig 8. By the up or down button, you can review the new measure of a single group of data including SpO_2, pulse rate, ID number, data and time.
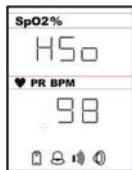
Fig.8

By the right or down button, you can review the next or last group of measured data.

If "S" displays on the screen after pressing the left button continuously, it means the last group is the newly measured data. And, if "E" displays on the screen after pressing the right button continuously, it means the last group is the previous measured data .

7 Alarm Setting

7.1 Alarm Priority

There are three-level priorities for selection.

<u>High priority</u>: the highest level alarm, indicates the patient is in a very dangerous situation.

<u>Medium priority</u>: indicates the warning should be paid

attention to.

<u>Low priority</u>: indicates the technical alarm caused by the

device itself.

Alarm of this Oximeter includes technical and physiological alarm.

All three priorities are divided by a built-in module and can not be changed by a user.

Visual Alarm Indicators:

If the alarm is activated through over limitation of physiological alarm, corresponding data area is flashing. If the alarm is activated by more than one physiological alarm, each parameter will be displayed when flashing.

Audible Alarm Indicators:

Audible alarms can be heard in a quiet environment. The audible alarm has different tone pitch and on-off beep patterns for each alarm priority.

- High priority: SpO_2 alarm "du-du-du ---------- du-du", beeps every 8 seconds.

- Medium priority: PR alarm "du-du-du". beeps every 8 seconds.

- Low priority: Sensor off or finger out "du-", beeps every 20 seconds.

7.2 Character Definition:

SHI: High alarm of SpO_2

SLo: Low alarm of SpO_2

PHI: High alarm of pulse rate

PLo : Low alarm of pulse rate

ALA: Turn on or turn off the Alarm

Fig. 9

7.3 SpO_2 Alarm Setting:

SHI SpO_2 high alarm: Turn on the Pulse Oximeter and hit the menu button three times, and you will see the screen showing high alarm of SpO_2 (**refer to Fig. 9**). Press the up or down button to increase or decrease the number. Press the right button to select other alarms for setting or press menu button save the alarm setting(s) and enter into another parameter item. The high alarm (SpO_2) setting range is: 71-100(%)

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�️SLo SpO₂ Low alarm: After finishing the high alarm setting, press the right button and you will see on the screen the low alarm of SpO₂ setting **(refer to Fig. 10)**. Press the up or down button to adjust the number. The low alarm (SpO₂) setting range is 70-99(%).
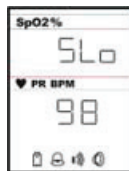
Fig. 10

7.4 PR Alarm Setting:

After SpO₂ low alarm setting, press the right button, and you will see the screen shown as **Fig. 11** for setting PR high alarm. The high alarm (PR) setting range is: 31-254 (bpm).

Press the up or down button to adjust the number. Then press the right button for setting the low PR alarm **(refer to Fig. 12).** The low alarm (PR) setting range is: 30-253(bpm).
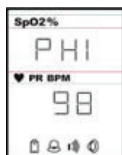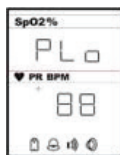
Fig. 11   Fig. 12

7.5 Alarm on/off

After PR alarm setting, press the right button, you will see the alarm on/off setting screen. Press the up or down button to set the alarm on or off.
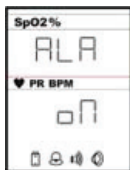
Fig. 13
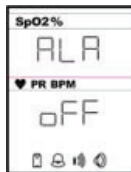
Fig. 14

7.6 Alarm Activation

Alarm will be activated with the following conditions:

Physiological alarm:

- The alarm will work when the SpO_2 value or pulse rate gets beyond the high-limit or goes below the low-limit. The difference is their priority; the SpO_2 has the high priority while the pulse rate has the medium.
- Technical alarm (error code):

a) Error Definitions

E 1: Program memory is damaged.

E 2: Data memory is damaged.

E 3: Signal strength is too weak to be detected.

E 4: Sensor is unplugged.

E 5: No finger is inserted or sensor goes wrong.

E 6: The Oximeter can not detect for pulse.

E 7: It takes too long to search for pulse.

E 8: Pulse alarm is malfunctioning.

E 9:   The SpO$_2$ value is lower than the low limit.

E 10: The SpO$_2$ value is higher than the high limit.

E 11: The value of pulse rate is lower
        than the low limit.

E 12: The value of pulse rate is higher
        than the high limit.

E 13: Power supply is insufficient.

When E9, E10, E11 or E12 occurs, the value of parameter will flash.

- Check the error code.
- Press the right key under normal screen, it will indicate an error code. To return to normal screen please press menu button again.

⚠ WARNING!

When alarm occurs, DO as follows:

- Check which type of alarm is on.
- Check patient's condition if parameter alarm is on.
- Make the alarm mute if necessary.
- Check whether the alarm is in proper condition in case of no warning.

8 Beep on/off

Press the menu key five times under the normal screen to enter access to this function, the associated screen will be displayed. Press up or down key to set the pulse beep on/off.

9 Maintain and Cleaning

Use only the substances approved and methods listed in this chapter to clean or disinfect your equipment. Warranty does not cover damage caused by unapproved substances or methods. We make no claims regarding the efficacy of the listed chemicals or methods as a means for controlling infection. For methods to control infection, consult your hospital's Infection Control Officer or Epidemiologist. Keep your equipment free of dust and dirt. To avoid damage to the equipment, follow these rules:

- Always dilute according to the manufacturer's instructions or use lowest possible concentration.
- Do not immerse any part of the equipment into liquid.
- Do not pour liquid onto the equipment or any accessories.
- Do not allow liquid to enter the case.
- Never use abrasive materials (such as steel wool or silver polish), or erosive cleaners (such as acetone or acetone-based cleaners).

CAUTION:

If you spill liquid on the equipment or accessories, contact the manufacturer.

Note: To clean or disinfect reusable accessories, refer to the instructions provided.

9.1 Safety Checks

Before every use, or after your Pulse Oximeter has been used for 6 to 12 months, or whenever your Pulse Oximeter

is repaired or upgraded, a thorough inspection should be performed by qualified service personnel to ensure its reliability. Follow these guidelines when inspecting the equipment:

- Make sure that the environment and power supply meet the requirements.

- Inspect the equipment and its accessories for mechanical damage.

- Make sure that only specified accessories are applied.

- Inspect if the alarm system functions correctly.

- Make sure that the batteries meet the performance requirements.

- Make sure that the Pulse Oximeter is in good working condition.

In case of any damage or abnormality, do not use the Pulse Oximeter. Contact your hospital's biomedical engineers or your service personnel immediately.

Cleaning

Your equipment should be cleaned on a regular basis. If there is heavy pollution or lots of dust and sand in your location, the equipment should be cleaned more frequently. Before cleaning the equipment, consult your hospital's regulations for cleaning the equipment.

Recommended cleaning agents are:

- Mild soap (diluted)

- Ammonia (diluted)

- Sodium hypochlorite bleach (diluted)

- Hydrogen peroxide (3%)
- Ethanol (70%)
- Isopropanol (70%)

To clean your equipment, follow these instructions:

1. Shut down the Pulse Oximeter and take the batteries out of the battery cover.

2. Clean the display screen with soft, clean cloth dampened with a glass cleaner.

3. Clean the exterior surface of the equipment with soft cloth dampened with proper cleaner.

4. Wipe off all the cleaning solution with a dry cloth after cleaning if necessary.

5. Dry your equipment in a ventilated, cool place.

Disinfecting

Disinfection 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 before disinfecting it.

The recommended disinfectants include: ethanol 70%, isopropanol 70%, glutaraldehyde-type 2% liquid disinfectants.

CAUTION: Never use autoclaving, EtO or formaldehyde for disinfection.

9.2 Calibration and Verification

The performance should be checked every year and after any kind of maintenance and repairing.

Required Test Equipment: SpO_2 signal simulator.

Notice: The simulator cannot be used to assess the accuracy of a Pulse Oximeter probe or a Pulse Oximeter.

9.2.1 Control Key Verification

Press Menu key to display the history data.

9.2.2 Sound Verification

  a. Set the Pulse Oximeter sound ON.

  b. You hear the simulated heart beep sound.

9.2.3 SpO_2 & Pulse Rate Measurement Value Verification

  a) Connect SpO_2 Probe to the SpO_2 connector on the Oximeter.

  b) Insert the operator's finger into the finger sensor, the SpO_2 measured value of a healthy person should be from 95% to 99%, and the pulse rate is the same as a heart rate.

  c) If SpO_2 Simulator is available, verify the accuracy of Oxygen Saturation Value with probes as follows:

  Oxygen Saturation Tolerance

96%	±2%
86%	±2%
70%	±3%

9.2.4 SpO$_2$ & Pulse Rate Alarm Verification

a) Connect SpO$_2$ Probe to the SpO$_2$ connector on the Oximeter.

b) Insert the operators finger into the finger sensor, the SpO$_2$ measured value of a healthy person should be more than 96%.

c) Set the SpO$_2$ high limit as 90 and low limit as 80.

d) Verify the SpO$_2$ visual and auditory alarms, the background color of the SpO$_2$ data should be red and "du-du" voice should be heard.

9.3 Trouble Shooting

• Can't power on the Oximeter

Please check the batteries voltage.

• "SEn oFF" alarm

Please check if the probe was connected with the Pulse Oximeter correctly or the finger is inserted fully. If the sensor is with extension cable please check if the extension cable is connected with the sensor correctly.

• "E1, E2, E8, E14" alarm

Please contact our service department.

• "E3, E6, E7" alarm

Check the patient's condition. For other please contact our service department.

9.4 Warranty

9.4.1 Exempt and Limitations (one year warranty):

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

b) No-service offer

  • The cost and insurance charge of disassembling, refurbishing, repackaging and conveying of the Pulse Oximeter or the part of it.

  • Damage or loss sustained due to inspected or repaired by other institutions that is not covered.

  • The damage and failure caused by user or its representative who isn't authorized to use the device according to the operator's manual.

c) The damage or loss sustained due to connection to peripheral equipment (such as printer, computer etc.), that are not provided by our company are not covered by the warranty.

d) Responsibility limitation: In the duration of the one year warranty, if user changes the parts manufactured by other manufacturers without our company permission, the warranty is null and void.

9.4.2 User Guarantees

a) Please read user manual carefully before operation.

b) Please operate and make daily maintenance as requested by the manual and warranty.

c) Power supply and environment must be maintained under manual specifications.

9.4.3 What's not Covered by Warranty

• The device does not remain in original condition.

• The shell of the device is broken or cracked.

• Evidence of water damage.

• Accessories or appearance of unit is physically abused.

• Evidence of crushing damage to the probe.

• Original package is not used during transportation.

• Non authorized service is performed on Oximeter.

• Damage to a product as a result of not conforming to manual specifications.

• The work environment is not eligible.

• Any smear or marks that do not belong to the instrument and cannot be removed from the outside surface of the instrument.

• The circuit is shorted and damaged due to liquid or other substances in the instrument or its fittings.

• All Probe and its accessories are not eligible for free replacement.

• If any code label of parts are damaged or missing, this warranty shall become null and void.

- Damage of probe caused by mechanical force doesn't apply for free replacement.

- During measurement of SpO_2, principle leads to measuring value difficultly or inaccurate measurement.

- Maintenance seal of Pulse Oximeter is not opened.

9.4.4 User's Special Request for Warranty

As indicated, according to the relevant electronic regulation of country, the warranty period is one year, limited warranty. The sensor's warranty period is three months.

Storage and Transportation

Storage: Storage Temperature -20°C~55°C (-4°F~131°F). Relative Humidity ≤ 90%, no condensation.

Transportation: Transport by airline, train or vessel after packing according to request.

APPENDIX A Specifications

Display

Data: SpO_2%, PR

Others: connection status of probe and other alarm information.

Alarm

Alarm: SpO2% and pulse rate value, probe off, battery exhausted

Alarm mode: audio alarm, visual alarm and error code

Alarm limits range: 70%-100%

Default limits: High 99%: low 90%

SpO₂

Display range: 0%~100%

Measurement range: 70%~100%

Resolution: 1%

Accuracy: ±3% (70-100%) Unspecified (0-69%)

Measurement Wavelengths and Output Power

Red 660nm @ 3mw nominal

Infrared 940nm @ 3mw nominal

Pulse Rate

Display range: 0~254bpm

Measurement range: 30~235bpm

Resolution: 1bpm

Accuracy: 30~99bpm: ±2bpm; 100~235bpm: ±2%

Operation Environment

Operating temperature: 5℃~40℃

Relative humidity: ≤ RH80%, no condensation

Atmosphere pressure: 86kPa ~106kPa

Power supply: Two AA alkaline batteries (not included).

Working time: work for 30 hours continuously

Store and replay

Store and replay 72-hour SpO₂% and Pulse rate value, the time interval is 4 seconds.

Abbreviations

CISPR	International Special Committee on Radio Interference
EEC	European Economic Community
EMC	Electromagnetic Compatibility
ID	Identification
IEC	International Electrotechnical Commission
LED	Light Emitting Diode
PR	Pulse Rate
RF	Radio Frequency
SpO_2	Arterial Oxygen Saturation from Pulse Oximeter

Units

A	ampere	bpm	beats per minute
°C	centigrade	g	gram
kHz	kilohertz	MHz	megahertz
GHz	Gigahertz	h	hour
Hz	hertz	K	kilo
kg	kilogram	kPa	kilopascal
m	meter, minute	M	mega
min	minute	mm	millimeters
mW	milliwatt	s	second
nm	nanometer	V	volt

Symbols

–	minus; negative	©	copyright
%	percent	/	per; divide; or
+	plus	=	equal to
<	less than	>	greater than
≤	less than or equal to	≥	greater than or equal to
±	plus or minus	×	multiply

APPENDIX B

<table>
<tr><td colspan="4" align="center">Guidance and manufacturer's declaration - electromagnetic immunity</td></tr>
<tr><td colspan="4">The Hand Held Pulse Oximeter is intended for use in an electromagnetic environment specified below. The customer or the user of the Pulse Oximeter should assure that it is used in such an environment.</td></tr>
<tr><td>Immunity Test</td><td>IEC 60601 Test level</td><td>Compliance Level</td><td>Electromagnetic environment guidance</td></tr>
<tr><td>Electro-static Discharge (ESD) IEC61004-2</td><td>6kV contact 8kV air</td><td>6kV contact 8kV air</td><td>Floors should be wood, concrete or ceramic tile. If floor are convert-ed with Synthetic material, the relative humidity should be at least 30%</td></tr>
</table>

Guidance and manufacture's declaration - Electromagnetic Immunity for Equipment and Systems that are not Life-Supporting		
61000-4-6 Radiated RF IEC **61000-4-3**	**3**V/m **80**Hz to **2.5 GHz**	d= $\dfrac{3.5}{V_1}\sqrt{P}$ 80MHz to 800MHz d= $\dfrac{3.5}{E_1}\sqrt{P}$ 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, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol.
NOTE1 At 80MHz and 800MHz, the higher frequency range applies.		
NOTE2 These guideline may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		
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 Hand Held Pulse Oximeter is used exceeds the applicable RF compliance level above, the Hand Held Pulse Oximeter should be observed.		

<table>
<tr><td colspan="4" align="center">

Recommended separation distances between portable and mobile RF communications equipment and the

Hand Held Pulse Oximeter

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<tr><td colspan="4">

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

</td></tr>
<tr>
<td rowspan="2">Rated maximum output power of transmitter (W)</td>
<td colspan="3">Separation distance according to frequency of transmitter (m)</td>
</tr>
<tr>
<td>150KHz to 80 MHz
$d=\frac{3.5}{V_1}\sqrt{P}$</td>
<td>80MHz to 800 MHz
$d=\frac{3.5}{E_1}\sqrt{P}$</td>
<td>800MHz to 2.5 GHz
$d=\frac{7}{E_1}\sqrt{P}$</td>
</tr>
<tr><td>0.01</td><td>0.1167</td><td>0.1167</td><td>0.2334</td></tr>
<tr><td>0.1</td><td>0.3689</td><td>0.3689</td><td>0.7378</td></tr>
<tr><td>1</td><td>1.1667</td><td>1.1667</td><td>2.3334</td></tr>
<tr><td>10</td><td>3.6893</td><td>3.6893</td><td>7.3786</td></tr>
<tr><td>100</td><td>11.6667</td><td>11.6667</td><td>23.3334</td></tr>
<tr><td colspan="4">

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.

</td></tr>
</table>

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