Fingertip Pulse Oximeter
IP900AP
USER MANUAL Ver.1.0

General Description
SpO2 stands for peripheral capillary oxygen saturation. Oxygen saturation is defined as the ratio of oxyhemoglobin (HbO2) to the total concentration of hemoglobin (i.e. oxyhemoglobin + reduced hemoglobin) present in the blood. It is an important physiological parameter involved in respiration and circulation. The Pulse Oximeter feature is in small, portable, non-invasive and easy to use. The user only needs to insert a finger into the chamber to measure his/her SpO2 level and pulse rate. It has also been proven to be highly precise and reliable in clinical tests.

Measurement Principle
Oxygenated blood absorbs light preferentially at 905nm (near infrared light), whereas deoxygenated blood absorbs light preferentially at 660nm (red light). A pulse oximeter works by passing a beam of red and infrared light through a pulsating capillary bed and then measures the amount of red and infrared light emerging from the tissues via a sensor. To improve accuracy, the IP900AP uses a proprietary algorithm to collect data from pulsatile arterial blood and excludes noise from the tissues. The relative absorption of light by oxyhemoglobin (HbO2) and deoxyhemoglobin is then calculated according to the Beer-Lambert law and a quantitative measurement of the user's oxyhemoglobin status i.e. Oxygen saturation level (SpO2) is derived.

Diagram of Operation Principle
1. Red and Infrared-Emission Tube
2. Sensor

Precautions For Use
1. Please read the manual carefully before use.
2. Do not use the fingertip pulse oximeter in an MRI or CT environment.
3. This device is not for continuous monitoring.
4. Do not use the fingertip pulse oximeter in an explosive environment.
5. In order to ensure proper sensor alignment and skin integrity, the maximum application time at a single site for the device should be less than half an hour.
6. Do not sterilize the device using autoclaving, ethylene oxide sterilizing, or immersing the device in liquid. The device is not intended for sterilization.
7. Follow local ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.
8. This equipment complies with IEC 60601-1-2:2007 for electromagnetic compatibility for medical electrical equipment and 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 might disrupt the performance of this device.
9. Portable and mobile RF communications equipment can affect medical electrical equipment.
10. Do not disassemble, repair or modify the equipment.
11. It may be unsafe to use accessories, detachable parts and materials not described in the instructions for use.
12. Interconnect this equipment with other equipment not described in the instructions for use, disassemble, repair or modify the equipment.
13. The medical silicone and ABS plastic enclosure which contact the user's skin when the device has been used are assessed by and passed the ISO10993-5 Tests for in vitro cytotoxicity and ISO10993-10 Tests for irritation and delayed-type hypersensitivity.
14. The fingertip pulse oximeter is dependent on blood flow to obtain an accurate SpO2 measurement. Verify that nothing is hindering your blood flow before taking your SpO2 readings.
15. This device is not intended to diagnose or treat any medical condition or disease. It is intended for non-medical use by healthy people to monitor their pulse rate and blood oxygen levels. It is for sports and/or aviation use.
16. People who need SpO2 and pulse rate measurements because of a medical condition should not use this pulse oximeter and should consult with their physician.

Inaccurate measurements may be caused by
1. Significant levels of dysfunctional hemoglobin (such as carbonyl - hemoglobin or methemoglobin).
2. Intravascular dyes such as indocyanine green or methylene blue.
3. High ambient light. Shield the sensor area if necessary.
4. Excessive user movement.
5. High-frequency electrosurgical interference and defibrillators.
6. Venous pulsations.
7. Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravenous line.
8. The user has hypotension, severe vasoconstriction, severe anemia, or hypothermia.
9. The user is in cardiac arrest or is in shock.
10. Fingernail polish or artificial fingernails.
11. Weak pulse quality (low blood perfusion).
12. Low hemoglobin.

Product Features
1. Easy to operate. Measure your SpO2 non-invasively.
2. Small, light and portable.
3. OLED screen displays SpO2, Pulse Rate, Pulse bar, Plethysmograph and Perfusion Index (PI). Six different display options.
4. Level 1-10 adjustable brightness.
5. Pre-set alarm function.
6. 2pcs AAA-size alkaline batteries: low-battery indicator and low power consumption.
7. When no or low signal is detected, the screen will display 'Finger Out' and the device will power off automatically in about 8 seconds.

Intended Use
The IP900AP Fingertip pulse oximeter is a portable non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of children (>12 years old) and adult. The device is for sports and/or aviation use.

Operation Instructions
1. Install two AAA batteries according to the Battery Installation instructions.
2. Place one of your fingers into the finger chamber of the pulse oximeter.
3. Press the power button on the front panel to turn the pulse oximeter on.
4. Keep your hand and finger still for the reading. It is recommended that you do not move your body while taking a reading.
5. Read the data from the display screen.
6. Press (+1 sec) the button again to toggle between six display modes (see below).
7. After turning the oximeter on, each time you press the power button, the oximeter will switch to another display mode. There are 6 display modes shown as follows:

- 66.0%
- 99.6%
- 89.6%
- 79.6%
- 69.6%
- 59.6%

Tips to getting a good reading
1. Make sure that your finger is inserted deep into the chamber so that the fingertip is placed directly in between the LED sensor and the LED light source.
2. Avoid making any body movement, especially your finger while taking measurement.
3. Long fingernails may obstruct the light sensor and prevent accurate measurement. Please keep the fingernails short while using the device.
4. Excessive ambient infrared light, especially in an overly bright lit room, can interfere with the sensor, preventing an accurate measurement.
5. Poor blood circulation can affect oximeter readings. Warm your hands and fingers before taking your measurements. Note that the pulse oximeter is measuring your SpO2 and PR based on your blood flow. If the blood flow in your finger drops below a perfusion index of 0.3, the pulse oximeter will not be able to get a reading.
6. Some people with medical conditions such as anemia, hypotension and hypothermia may experience an inaccurate reading during use. In such case, we suggest that you consult a physician.

Front Panel
The pulse bar graph, plethysmograph and perfusion index (PI) are useful features that can be used to determine the reliability of a reading. If the height of the pulse bar is less than 30%, this indicates signal inadequacy and the displayed SpO2 or pulse rate value is possibly incorrect. Adjust your finger so that it is directly between the LED lights and sensor.

Diagram of Operation Principle
1. Photoplethysmography
2. Perfusion Index

Settings
In the measuring interface, press and hold the power button to enter the settings interface. To scroll down the menu, short press (+1 sec) the power button. The ‘ – ’ icon indicates the line selected. To select an option, long press (+1 sec) the power button.

- Alm Setup to enter the Alarm Setup submenu.
- Aim to turn auditory alarm off.
- Beep to turn audible beep for pulse beat on/off.
- Brightness to adjust screen brightness from 1-10. Level 10 is the brightest.
- Reset to restore default settings.
- Exit to return to the measuring interface.

Setting the alarm parameters
When SpO2 or PR reading exceeds a defined range, an alarm will trigger and the SpO2 or PR reading will start to flash respectively. In addition, an audible alarm can be turned on by setting the ‘Beep’ under the Settings menu to on.

The upper and lower limit for the SpO2 and PR alarm can be user defined. Under the Settings menu, select ‘Aim Setup’ to enter the Alarm Setup submenu. To increase a value, ‘ + ’ should be selected. To decrease a value, ‘ – ’ should be selected. SpO2 limit can be adjusted in increment of 1%, PR limit in increment of 5bpm.

Default limits: SpO2 Alm Low 90%, PR Alm Low 80bpm
Default limit: SpO2 Alm High 100%, PR Alm High 105bpm
Default limit: SpO2 Alm Low 80%, PR Alm Low 75bpm

Exit - Press and hold the power button to return to the measuring interface.

Note: In the settings interface, if no operation is detected, device will return to the measuring interface automatically in about 8 seconds.

Product Accessories
1. One pulse oximeter
2. One lanyard
3. Two AAA batteries
4. One instruction manual

Battery Installation
1. Open the battery door cover.
2. Install two AAA batteries into the battery compartment by matching the plus (+) and minus (-) signs in the compartment.
3. Align the battery door cover and press until it snaps back in place.
4. Replace the batteries when the low battery indicator appears.
5. Dispose battery properly. Follow any applicable local battery disposal laws.

Maintenance and Storage
1. Replace the batteries when the low power indicator appears.
2. Clean the finger chamber and surface of the oximeter before use.
3. Remove the batteries if you are not planning to use the oximeter for a long period of time.
4. Store the oximeter in a cool and dry place. Extreme moisture may damage the oximeter or affect its lifespan.

Cleaning the fingertip pulse oximeter
It is recommended to clean the oximeter before and after use. To clean, use a soft cloth lightly dampened with water to wipe the finger chamber and surface of the oximeter. Allow the oximeter to dry thoroughly before use.

Disinfecting the fingertip pulse oximeter
It is recommended to clean the oximeter before and after use. To clean, use a soft cloth lightly dampened with water to wipe the finger chamber and surface of the oximeter. Allow the oximeter to dry thoroughly before use.

Note: Please remove the batteries if the pulse oximeter will not be used for a long period of time.

Note: Please replace the batteries when the low power indicator appears.

Using the Lanyard
1. Thread the thin end of the lanyard through the lanyard hole on the device.
2. Thread the thin end of the lanyard through the thin loop (threaded in step 1) and pull to tighten.

Warning!
- Keep the oximeter away from young children. Small items such as the battery door, battery, and lanyard are choking hazards. That is when you should take the reading. The pulse oximeter can function with a PI reading as low as 0.3. If your PI is below 0.3, this means that your blood perfusion is too low for a reliable read. Warm your hands to improve blood flow and rotate your measurement. In general, a higher PI will give you a more reliable reading.

Note: The user is in cardiac arrest or is in shock.

Diagram of Operation Principle
1. Red and Infrared-Emission Tube
2. Sensor
Specifications

1. Display Type
   OLED display

2. SpO2
   Accuracy: 70%~100%
   Measurement range: 70%~100%

3. Power Requirements
   - Atmosphere pressure: 70kPa
   - The PR accuracy.
   - The CO-oximeter samples measured over the 2; 80% to 100% range of 70%~100%. 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.
   - A functional tester is used to measure how accurately FingerTip Pulse Oximeter is reproducing the specified calibration curve and the PR.
   - The model of functional tester is Index2 FLUKE simulator and the version is 2.1.3.

4. Probe LED Specifications
<table>
<thead>
<tr>
<th>Wavelength</th>
<th>Radiant Power</th>
</tr>
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<tbody>
<tr>
<td>RED</td>
<td>660 ± 3nm</td>
</tr>
<tr>
<td>IR</td>
<td>905 ± 10nm</td>
</tr>
</tbody>
</table>

5. Environment Requirements
   - Temperature: 0°C ~ 40°C
   - Storage Temperature: -25°C ~ 70°C
   - Humidity: 10% ~ 90% non-condensation in storage/transport
   - Atmosphere pressure: 70kPa ~ 106kPa

6. Equipment data update period
   - Resolution: 10s
   - Perfusion Index:
     - Measurement range: 0.2% ~ 20.0%

7. Probe Specifications
   - The oximeter automatically powered off when no signal is detected for more than 8 seconds
   - The oximeter fails to display SpO2 and/or PR when abnormal performance is observed, additional measurements may be necessary, such as reorienting of the relocating the Pulse Oximeter (IP900AP).

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

9. Classification
   - According to the degree of protection against electric shock: INTERNALLY POWERED EQUIPMENT:
     - Group 1
   - According to the degree of protection against electric shock: TYPE BF APPLIED PART.
     - Applied part: the rubber hole of the device; B: Basic insulation

10. Probe LED Specifications
    - The oximeter fails to display SpO2 and/or PR when abnormal performance is observed, additional measurements may be necessary, such as reorienting of the relocating the Pulse Oximeter (IP900AP).

Clinical Study Summary

The following data are provided to disclose actual performance observed in the clinical validation study of healthy adult volunteers. The ARMS value analysis statement and Bland-Altman plot data of a shown as following:

ARMS Value Analysis Statement

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<th>90–100</th>
<th>80–90</th>
<th>70–80</th>
<th>60–70</th>
<th>50–60</th>
<th>40–50</th>
<th>30–40</th>
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<tr>
<td>Bias</td>
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<td>-2.46</td>
<td>-3.46</td>
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<td>-5.46</td>
</tr>
</tbody>
</table>

Declaration

Guidance and Manufacturer’s declaration – electromagnetic emissions
For all EQUIPMENT and SYSTEMS

Guidance and Manufacturer’s declaration – electromagnetic immunity
For all EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and Manufacturer’s declaration – electromagnetic immunity
For all EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the equipment or SYSTEMS - For all EQUIPMENT and SYSTEMS - For all INTERFERENCE - For all INTERFERENCE - For all INTERFERENCE

Symbol Definitions

Table of Symbols

Applicable Models

Notes

The illustrations used in this manual may differ slightly from the appearance of the actual product.

The specifications are subject to change without prior notice.

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