Pulse Oximeter

English

REF MD300CN310

Introduction

Oxygen binds to hemoglobin in red blood cells when moving through the lungs. It is transported throughout the body as arterial blood. A pulse oximeter uses two frequencies of light (red and infrared) to determine the percentage (%) of hemoglobin in the blood that is saturated with oxygen. The percentage is called blood oxygen saturation, or SpO_2. A pulse oximeter also measures and displays the pulse rate at the same time it measures the SpO_2 level.

Support

Our manual should provide you with all the information you need to set up & use this product. If you have a question, have a look at our troubleshooting page! For further assistance, why not contact our customer care team directly? We're here to help! Our customer care team are available from 9am - 5pm, Monday to Friday (excluding bank holidays). We promise to respond to all queries and will ensure to resolve any issue you may be having. You can reach us by...

Live Chat:

Simply visit www.kinetikwellbeing.com and send us a message.

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About Oxy-Exact™

The Kinetik Wellbeing Pulse Oximeter is expertly designed to deliver precise and reliable readings.

Our innovative Oxy-Exact™ technology provides a clear, colour-coded result that instantly indicates whether the SpO_2 reading is normal, low or very low or the Pulse Rate reading is Low, Normal, High or Very High.

Oxy-Exact™ Technology

SpO_2	SpO_2	SpO_2
≤92	93~94	≥95
Very Low	Low	Normal

PR	PR	PR	PR
≤59	60~90	91~130	≥131
Low	Normal	High	Very High

Measurement Principle

Principle of the oximeter is as follows: The pulse oximeter works by applying a sensor to a fingertip. The sensor contains a dual light source and photo detector. The one wavelength of light source is 660nm, which is red light; the other is 905nm, which is infrared-red light. Skin, bone, tissue and venous vessels normally absorb a constant amount of light over time. The photo detector in finger sensor collects and converts the light into electronic signal which is proportional to the light intensity. The arteriolar bed normally pulsates and absorbs variable amounts of light during systole and diastole, as blood volume increases and decreases. The ratio of light absorbed at systole and diastole is translated into an oxygen saturation measurement. This measurement is referred to as SpO_2.

Diagram of Operation Principle (*Figure 1)*
1. Red and Infrared-ray Detector
2. Red and Infrared-ray Light Source

Precautions For Use

1. Please read the manual carefully before use.
2. Operation of the pulse oximeter may be affected by the use of an electrosurgical unit (ESU).
3. The pulse oximeter must be able to measure the pulse properly to obtain an accurate SpO_2 measurement. Verify that nothing is hindering the pulse measurement before relying on the SpO_2 measurement.
4. Do not use the pulse oximeter in an MRI or CT environment.
5. Do not use the pulse oximeter in situations where alarms are required. The device has no alarms. It is not for continuous monitoring.
6. Do not use the pulse oximeter in an explosive atmosphere.
7. 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.
8. In order to ensure correct sensor alignment and skin integrity, the maximum application time at a single site for our device should be less than half an hour.
9. Do not sterilize the device using autoclaving, ethylene oxide sterilizing, or immersing the device in liquid. The device is not intended for sterilization.
10. Follow local ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.
11. This equipment complies with IEC 60601-1-2 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 might disrupt the performance of this device.
12. Portable and mobile RF communications equipment can affect medical electrical equipment. The portable and mobile RF communications equipment should be used no closer than 30cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
13. This equipment is not intended for use during patient transport outside the healthcare facility.
14. The patient is an intended operator. The patient can safely use all functions of the device.
15. It may be unsafe to:

- —use accessories, detachable parts and materials not described in the instructions for use.
- —interconnect this equipment with other equipment not described in the instructions for use.
- —disassemble, repair or modify the equipment.

16. The material that contact with the patient's skin has passed the ISO10993-5 Tests for invitro cytotoxicity and ISO10993-10 Tests for irritation and delayed-type hypersensitivity.
17. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
18. The use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
19. When the signal is not stable, the reading may be inaccurate. Please do not refer to it.
20. The material of the device has no nature latex.
21. The pulse oximeter equipment is calibrated to display functional oxygen saturation.
22. The waveform we provide is normalized.
23. Do not modify this equipment without authorization of the manufacturer.
24. The manufacturer will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist the user's appropriately trained personnel to repair those parts of the equipment designated by the manufacturer to be repairable.
25. Stop using and contact local service center if one of the following cases occurs:

- Any of the problems in the Possible Problems and solutions cannot be solved.
- The oximeter cannot be powered on in any case and not the reasons of battery.
- There is a crack on the oximeter or damage on the display resulting readings cannot be identified; the spring is invalid; or the key is unresponsive or unavailable.

26. Aging infrared-ray detector or insufficient battery level may affect the equipment performance. Please follow the instructions in the manual to maintain the device.
27. Please contact the manufacturer for any question about the usage or maintenance.
28. Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

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 patient 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 intravascular line.
8. The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia.
9. The patient is in cardiac arrest or is in shock.
10. Fingernail polish or false fingernails.
11. Weak pulse quality (low perfusion).
12. Low hemoglobin.

Contraindication

Not yet found.

Product properties

1. Simple to operate and convenient to carry.
2. Small volume, light weight and low power consumption.
3. Color screen displays SpO_2, PR, PI (perfusion index), Pulse bar and waveform.
4. Level 1-10 adjustable brightness.
5. 7 display modes.
6. 2pcs AAA-size alkaline batteries; real-time battery status indication.
7. Weak or unstable signal prompt.
8. The device will automatically shut off after no operation in 8 seconds when "Finger Out" displays.
9. Multiple-patient reusability.

Intended Use

The Pulse Oximeter is a handheld non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO_2) and Pulse Rate of adult, adolescent, child and infant patients in hospitals, hospital-type facilities and homecare.

Operation Instructions

1. Install two AAA batteries according to the Battery Installation instructions.*(Figure 2*)
2. Place one of your fingers into the rubber opening of the pulse oximeter.
3. Press the switch button one time on front panel to turn the pulse oximeter on.
4. Keep your hands still for the reading. Do not shake your finger during the test. It is recommended that you do not move your body while taking a reading.
5. Read the data from the display screen.
6. The display modes are as follows. *(Figure 3*)

Notes:

- Short press the power button to switch the display modes.
- Long press the power button to adjust the brightness of the oximeter. There are 10 levels of brightness.
- Take out your finger, the screen displays "Finger Out". It means the measurement ending.

Front Panel

Notes:

1. The signal indication "?" displayed on the screen means the signal is unstable. Please keep your hands still and retry.
2. If the measurement exceeds the limit (SpO2≤92%, PR≥131bpm), the colour of the readings will become red.
3. The battery power indicator will be empty in red if the power is very low. *(Figure 4*)

Battery Installation

1. Slide the battery door cover horizontally along the arrow.
2. Install two AAA batteries into the battery compartment. Match the plus (+) and minus (-) signs in the compartment. If the polarities are not matched, damage may be caused to the oximeter.
3. Close the battery door cover.(*Figure 5*)

Notes:

- Please remove the batteries if the pulse oximeter will not be used for long periods of time.
- Please replace the battery when the power indicator starts flickering.

Using the Lanyard

1. Thread thinner end of the lanyard through the hanging hole.
2. Thread thicker end of the lanyard through the threaded end before pulling it tightly.*(Figure 6)*

Warnings!

- Keep the oximeter away from young children. Small items such as the battery door, battery, and lanyard are choking hazards.
- Do not hang the lanyard from the device's electrical wire.
- Please notice that the lanyard which is tied to the oximeter may cause strangulation due to excessive length.

Maintenance and Storage

1. Replace the batteries in a timely manner when low voltage lamp is lighted.
2. Clean surface of the oximeter before it is used in diagnosis for patients.
3. Remove the batteries if the oximeter is not operated for a long time.
4. It is best to store the product in -25˚C~+70˚C and ≤93% humidity.
5. Keep in a dry place. Extreme moisture may affect oximeter lifetime and may cause damage.
6. Dispose of battery properly; follow any applicable local battery disposal laws.

- **Cleaning and disinfecting the device**

1. It is recommended to clean and disinfect the silicone touching the finger inside of device with a soft cloth dampened with recommended alcohol of 70% isopropyl or 70% ethanol before and after each use.
2. Excessive disinfection may cause damage to the device and is therefore not recommended for this device unless otherwise indicated in your hospital's servicing schedule.
3. Do not pour or spray liquids onto the device and do not allow any liquid to enter any openings in the device. Allow the device to dry thoroughly before reuse.

Caution: Never use EtO (ethylene oxide) or formaldehyde for disinfection.
The use life of the device is five years when it is used for 15 measurements every day and 10 minutes per one measurement.

Specifications

1. Display Type: LCD display

2. SpO_2
Display range: 0%~100%
Measurement range: 70%~100%
Accuracy: 70%~100%±2%;0%~69% no definition
Resolution: 1%
Note: 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%~100%. Accuracy data is calculated using the root-mean-squared (Arms value) for all subjects, per ISO 80601-2-61, 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 Pulse Oximeter is reproducing the specified calibration curve and the PR accuracy.
The model of functional tester is Index2 FLUKE simulator and the version is 2.1.3.

Pulse oximeter equipment measurements are statistically distributed, only about two-thirds of Pulse oximeter equipment measurements can be expected to fall within Arms of the value measured by a co-oximeter.

3. Pulse Rate
Display range: 30bpm~250bpm
Measure range: 30bpm~250bpm
Accuracy: 30bpm~99bpm, ±2bpm; 100bpm~250bpm, ±2%
Resolution: 1bpm

4. Perfusion Index
Display range: 0.1%~20.0%
Measure range: 0.3~20.0%
Resolution: 0.1%

5. Probe LED Specifications(Note: The information about wavelength range can be especially useful to clinicians.)

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

6. Power Requirements: Two AAA alkaline Batteries
Power consumption: Less than 40mA
Battery Life: Two AAA 1.5V, 1200mAh alkaline batteries could be continuously operated as long as 20 hours.

7. Environment Requirements
Operation Temperature: 0℃ ~40℃
Storage Temperature: -25℃ ~+70℃
Ambient Humidity: 15%~93% no condensation in operation; ≤93% no condensation in storage/transport
Atmosphere pressure: 70kPa~106kPa
Note: When the ambient temperature is 20°C, it is required 6 hours for the equipment to warm from the minimum storage
temperature or 4 hours to cool from the maximum storage temperature between uses until it is ready for its intended use.

8. Equipment data update period: the average data update period is 8 seconds.

9. Classification
According to the type of protection against electric shock: Internally powered equipment
According to the degree of protection against electric shock: Type BF applied part (applied part: the rubber hole of the device)
According to the degree of protection against ingress of water: IP22
According to the mode of operation: Continuous operation

Clinical Study Summary

There were no adverse events during the study. The subject demographics included a total of 11 subjects, 6 females and 5 males. The subject ages ranged from 20 to 42 years. The subject weights ranged from 52 to 70kg. The subject height ranged from 154 to 176cm. The skin tones included in the study were as follows: 1 subject with light skin tone of Caucasians, 3 subjects with dark pigmentation, the remaining subjects with yellow skin tones of China origins.
The following details 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 of data are shown as follows:

ARMS Value Analysis Statement

Item	70–100	90–100	80–<90	70–<80	70-<90
#pts	225	89	81	55	136
Bias	0.62	0.10	1.10	0.76	0.96
ARMS	1.75	0.96	1.93	2.35	2.11

Bland-Altman Plot Graphic (*Figure 7)*

Possible Problems and Solutions

Problems	Possible reason	Solution
SpO_2 or PR can not be shown normally	1. Finger is not inserted correctly 2. Patient's Oxyhemoglobin value is too low to be measured	1. Retry by inserting the finger 2. There is excessive illumination 3. Try some more times. If you can make sure no problem exist in the product, please go to a hospital timely for exact diagnosis
SpO_2 or PR is shown unstably	1. Finger might not be inserted deep enough 2. Excessive patient movement	1. Retry by inserting the finger 2. Be calm
The oximeter can not be powered on	1. No battery or low power of battery 2. Batteries might be installed incorrectly 3. The oximeter might be damaged	1. Please replace batteries 2. Please reinstall the batteries 3. Please contact with local customer service center
Indication lamps are suddenly off	1. The product is automatically powered off when no signal is detected longer than 8 seconds 2. The battery power is too low to work	1. Normal 2. Replace the batteries
"Err7" is displayed on screen	Err 7 means all the emission LED or reception diode is damaged	Please contact customer support

Symbol Definitions

Symbol	Definition	Symbol	Definition
	Type BF applied part.	-70℃ max, -25℃ min, RH ≤ 93% non-condensing	Storage temperature and relative humidity
	Caution		Manufacturer's information
CN	Date of Manufacture / Made in China	IP22	The degree of protection against ingress of dust and water
%SpO_2	Oxygen saturation	CE 0123	European union approval
PR bpm	Pulse rate (BPM)	EU REP	Authorized European representative
	Low power indication		Follow instructions for use
SpO_2	No SpO_2 Alarm	SN	Serial No.
	Conformity to WEEE Directive	?	Indicate the signal is not stable
	Importer's information	MD	Medical Device
PI%	Perfusion index		Power Switch
REF	Catalogue Number / Model Number		Importer
LOT	Lot Number		Recyclable
UDI	Unique Device Identifier		

Figure 1/ Figure 2

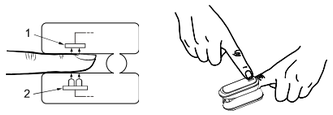


Figure3

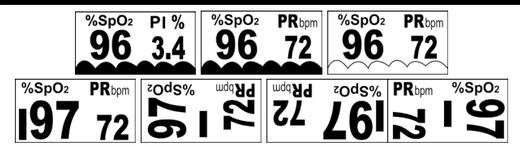


Figure 4

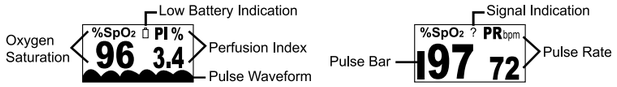


Figure 5/ Figure 6

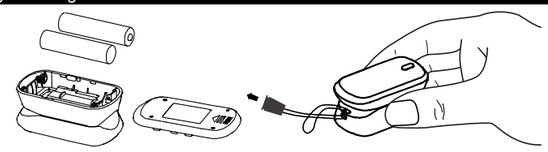
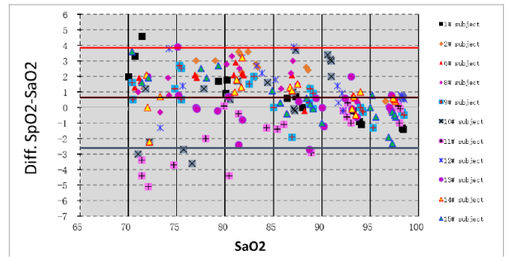


Figure 7



Electromagnetic Compatibility

The device conforms to IEC60601-1-2 Electromagnetic Compatibility (EMC) standard.
Essential performance is defined as SpO2 accuracy and pulse rate accuracy or an indication of abnormal operation. Accuracies may be affected as a result of exposure to electromagnetic disturbances that are outside of the environments listed in the intended use. If issues are experienced, move the device away from the source of electromagnetic disturbances.

Table 1: Electromagnetic Emissions Limits and Compliance

Emissions Test	Compliance
RF Emissions CISPR 11	Group 1, Class B
Note : Harmonic Emissions (IEC 61000-3-2), Voltage Flicker Emissions (IEC 61000-3-3) are not applicable.	

Table 2: Electromagnetic Immunity

Immunity Test	Compliance	
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	
Rated power Frequency Magnetic Fields IEC 61000-4-8	30 A/m 50Hz and 60 Hz	
Radiated RF IEC 61000-4-3	80 MHz – 2.7 GHz	10 V/m 80% AM 1kHz
	380 – 390 MHz	27 V/m Pulse mod. 18Hz
	430 – 470 MHz	28 V/m FM±5Hz deviation 1kHz sine
	704 – 787 MHz	9 V/m Pulse mod. 217Hz
	800 – 960 MHz	28 V/m Pulse mod. 18Hz
	1.7 – 1.99 GHz	28 V/m Pulse mod. 217Hz
	2.4 – 2.57 GHz	28 V/m Pulse mod. 217Hz
	5.1 – 5.8 GHz	9 V/m Pulse mod. 217Hz
Note: Electrical Fast Transients (IEC 61000-4-4), Surge (IEC 61000-4-5), Voltage dips (IEC 61000-4-11), Conducted Immunity (IEC 61000-4-6) are not applicable.		

Test frequency	Modulation	IMMUNITY TEST LEVEL (A/m)
30 kHz a)	CW	8
134.2 kHz	Pulse modulation b) 2.1kHz	65 c)
13.56 MHz	Pulse modulation b) 50kHz	7.5 c)
a) This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT. b) The carrier shall be modulated using a 50% duty cycle square wave signal. c) r.m.s., before modulation is applied.		

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CE 0123
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Pack contains:
Kinetik Wellbeing MD300CN310 Pulse Oximeter, Instruction Manual, Quick Start Guide, Lanyard, 2 x AAA Batteries