Konsung

Fingertip Pulse Oximeter Instructions for use

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Statement

Hereby, **Jiangsu Konsung Bio-Medical Science And Technology Co.,Ltd.**, declares that this **Fingertip Pulse Oximeter** is in compliance with the essential requirements and other relevant provisions of Directive 2014/53/EU.
Thanks for your purchasing SONOSAT-F series fingertip pulse oximeter of Jiangsu Konsung Bio-Medical Science And Technology Co., Ltd., (hereinafter called "**Konsung**"). Before using the pulse oximeter, please read this manual carefully for understanding the operation and maintenance of the oximeter. Konsung owns the rights to modify, update, and ultimately explain this manual. Konsung owns the copyrights of this manual. Without prior written consent of Konsung, any materials contained in this manual shall not be photocopied, reproduced or translated into other languages.
This manual will help you understand the operation and maintenance of the product better. It is reminded that the product shall be used strictly complying with this manual. User's operation failing to comply with this manual may result in malfunction or accident for which Konsung cannot be held liable. This manual is based on the maximum configuration and therefore some contents may not apply to your product.
All illustrations and settings in this manual are for reference only, and the actual product shall prevail.
Fingertip Pulse Oximeter is Class 1 LEDs product. It must be serviced by a specified trained personnel.

Responsibility of the Manufacturer

Konsung is responsible for the effects on safety, reliability and performance of this product, only if:

- All installation operations, expansions, changes, modifications and repairs of this product are conducted by Konsung authorized personnel;
- The electrical installation of the relevant room complies with the applicable national and local requirements;
- The product is used in accordance with the instructions for use.

Upon request, Konsung may provide, with compensation, necessary circuit diagrams, and other information to help qualified technician to maintain and repair some parts, which Konsung may define as user serviceable.

Part 1 SafetyPrecautions

1.1 Safety Information

The user should pay attention to and abide by the basic safety information which was referred to in this Part.

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.

NOTE
- Provides additional tips or other useful information to ensure that you get the most from your product.

WARNING

1. The oximeter is not intended as a device used for treatment purposes. Ensure that the equipment is in normal working condition and operating environment before using.
2. Do not use the measuring data displayed on the pulse oximeter as the only basis for clinical diagnosis. The oximeter is intended only as an adjunct in patient assessment. It must be used with other methods of assessing clinical signs and symptoms or physician's diagnosis.
3. Do not open the shell of instrument; otherwise you may damage the equipment. All servicing and future upgrades must be carried out by the personnel trained and authorized by our company only.
4. Misapplication of the oximeter with excessive pressure for prolonged periods can induce pressure injury, check and change the applied site according to the different circumstances of the user while using oximeter for prolonged periods. It is recommended to check and change the applied site every 2 hours.
5. Check the integrity of the subject's skin, circulatory conditions and change the applied site.
6. The oximeter is not intended to use of infant and neonate.
7. High ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight can interfere with the performance of a SpO_2 sensor.
8. Do not use the oximeter in situations where alarms required. The oximeter does not support alarms.
9. FUNCTIONAL TESTER cannot be used to assess ACCURACY.
10. The skin temperature is initially at 35°C for each PULSE OXIMETER, the APPLIED PART temperature cannot exceed 41°C.
11. The material that the pulse oximeter contacted to body is Non-toxic silica gel which meet the ISO 10993 requirements, so can be safety used. Users who are allergic to natural rubber latex cannot use this product.

CAUTION

1. To ensure user safety, only use accessories and parts produced or recommended by Konsung. Otherwise, damage to the pulse oximeter can occur.
2. Do not use the oximeter near by the source of interference, such as mobile phones, radio transmitter, radiant heater, nebuliser or steam kettle.
3. Do not use degraded or loosened sensor, which can degrade performance of the oximeter or cause other problems.
4. Keep the oximeter surface dry and clean. Keep the oximeter away from corrosive chemicals, lint, dust, high temperature and humidity environment.
5. The operating temperature of the oximeter is 5°C to 40°C. If the ambient temperature exceeds the operating temperature range, the oximeter shall be left for at least 60 minutes before use.
6. The oximeter should be appropriately placed. Keep it from falling, strong vibration, pets, pests, children or other mechanical damage.
7. Do not spill liquid on the oximeter. Do not immerse the oximeter in liquid.
8. Do not use the oximeter if the oximeter cannot achieve satisfactory results.
9. At the end or its service life, the product described in this manual, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products.

NOTE:
1. Check the oximeter before using. Do not use it if there is significant damage.
2. Too cold or too thin finger may affect the measurements; fully insert your finger (index, middle and ring fingers are recommended) into the oximeter during measurement.
3. Avoid measuring SpO_2 on extremities with an arterial catheter, or intravascular venous infusion line.
4. SpO_2 waveform is not proportional to the pulse volume. The SpO_2 waveform is normalized.
5. The pulse oximeter is calibrated to display functional oxygen saturation.
6. The pictures and interfaces in this manual are for reference only.
7. Fingernail polish or false fingernails may cause inaccurate SpO_2 readings.
8. Never incinerate batteries or expose them to high temperatures.

1.2 Symbol and Explanation

Symbol	Explanation	Symbol	Explanation
	Refer to instruction manual/booklet		Type BF applied part
	Caution		No alarm
	Type BF applied part		Battery indication
	Power on/off	PR	Pulse rate
SpO2	Oxygen saturation of arterial hemoglobin		WEEE symbol
SN	Serial number	P/N	Part number
LOT	Batch number	IP22	Degree protection against ingress of liquids and dust
	Date of manufacture		Manufacturer
CE 1639	The symbol indicates that the device complies with the European Council Directive 93/42/EEC concerning medical devices.	EC REP	Authorized representative in the European community

Part 2 Product Introduction

2.1 Introduction

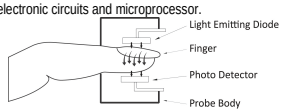
Fingertip pulse oximeter is a device that uses non-invasive method to measure the blood oxygen saturation and pulse rate. It is based on the principle of differential wavelength absorption.
The oximeter is suitable for family, clinic, oxygen bar, sports health (use before and after exercise is not recommended for use during exercise), community health and other ranges.
This product is not suitable for continuous monitoring of patients.
Oxygen saturation is an important physiological parameter that characterizes the oxygen carrying capacity of blood. Many respiratory diseases can result in low oxygen saturation in human blood. Additionally, the following factors can reduce oxygen saturation: Automatic regulation of organ dysfunction caused by Anesthesia, Intensive Postoperative Trauma, injuries caused by some medical examinations. That situation might result in light-headedness, asthenia, vomiting and other symptoms, severe cases will be life-threatening. Therefore, it is very important to know the oxygen saturation of a patient so that doctors can find problems timely.

2.2 Intended Use and Contraindication

Intended use: The fingertip pulse oximeter is intended to measure the pulse oxygen saturation of arterial hemoglobin and pulse rate of adult and child.
Contraindication: none

2.3 Working Principle

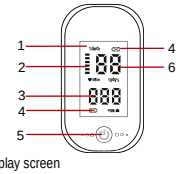
The principle is based on the different light absorption characteristics of hemoglobin and oxyhemoglobin in the blood, an experience formula of data process is established in red light and near-infrared light zones, two beams of different wavelength of lights can be focused onto human nail tip through sensor. Then measured signal can be obtained by a photosensitive element, information acquired through which will be shown on the display through process in electronic circuits and microprocessor.



Oximeter Schematic Diagram

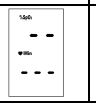
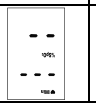
2.4 Appearance

Oximeter with digital tube screen



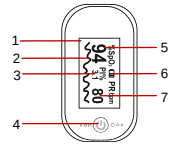
1. Display screen
2. Bar graph icon: The number of segments indicates the pulse strength.
3. Pulse rate (PR): detected pulsations per minute.
4. Battery capacity indicator
   - Low capacity: the battery icon flashes;
   - Full capacity: the battery icon is not displayed.
5. POWER button
   - Press this button to start oximeter.
   - Press this button to change the reading 180˚ after power on or during measuring.
6. SpO_2: percentage of oxygenated hemoglobin in relation to the sum of oxyhemoglobin and deoxyhemoglobin.

Display screen (2 interfaces)

Interfaces	Without data	With data
Interface 1		
Interface 2		

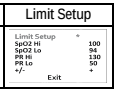
Icon description:
- "%SpO_2": means blood oxygen saturation;
- "❤/Min": means pulse rate.

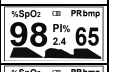
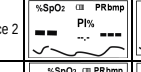
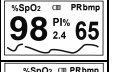
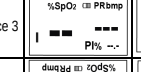
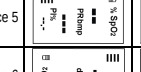
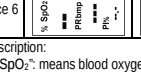
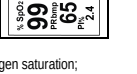
Oximeter with OLED screen



1. Two-color OLED display
2. Pleth waveform: visual indication of patient's pulse.
3. Perfusion index (PI): gives the numerical value for the pulsatile portion of the measured signal caused by arterial pulsation. PI is an indicator of the pulsatile strength. You can also use it to assess the quality of SpO_2 measurement.
4. POWER button
   - Press this button to start oximeter.
   - Press this button to change the reading 90˚ after power-on or during measuring.
   - Press this button 2 seconds to enter the setting interface when the oximeter is on.
   - In the setting interface, press this button to switch Settings.
   - In the Setting interface, press and hold this button 2 seconds to confirm the setting.
5. SpO_2: percentage of oxygenated hemoglobin in relation to the sum of oxyhemoglobin and deoxyhemoglobin.
6. Battery capacity indicator
   - Full capacity, the middle part indicates the capacity.
   - Battery extremely low, change new battery.
7. Pulse rate (PR): detected pulsations per minute.

Display screen (6 interfaces)

	Remind Setup	Limit Setup
Setting interface		

Measure interface	Without data	With data
Interface 1		
Interface 2		
Interface 3		
Interface 4		
Interface 5		
Interface 6		

Icon description:
- "%SpO_2": means blood oxygen saturation;
- "PR bpm"means pulse rate;
- "PI%": means perfusion index;
- "": bar graph icon;
- "": pulse intensity histogram.

Part 3 Unpacking and Storage

3.1 Open-case inspection

Before unpacking, examine the packing case carefully for signs of damage. If any damage is detected, contact the carrier or us. If the packing case is intact, open the package and remove the oximeter and accessories carefully. Do not use it if the oximeter has mechanical damage.
Check whether there is any damage to the surface of the oximeter such as notches, dents, abrasions and so on. Check whether the components are missing according to packing list.

3.2 Storage

The oximeter is manufactured with precision parts. Do not place the oximeter in the following places:

- Easy to splash;
- With Direct sunlight, high temperature, humidity, dust, and corrosive gas;
- Tilt, generate vibration and impact;
- Store chemicals or corrosive gases.

Part 4 Operation Instructions

4.1 Using Oximeter

1. Remove the battery cover, and insert the two AAA batteries following polarity markings indicated inside of the battery compartment, then reposition the cover.

2. Hold the oximeter clamp, place your finger into the oximeter as shown below. For best results, make sure the finger is centered within the oximeter.

3. Press the ON/OFF button to turn the oximeter on. The measure interface is shown.
4. The measured value is displayed after completing the test.

NOTE:
1. Index finger, middle finger or ring finger is recommended for measurement.
2. The screen shows '---' if oximeter is faulty or the signal quality is poor.
3. The user's hand should be relaxed (e.g. lying on a flat surface), and do not shake the finger, hand or body during the measuring.
4. Tape or other light obstructions around the applied site may affect the accuracy of SpO_2 and pulse rate.
5. Cold hands/fingers could affect reading accuracy.
6. The oximeter will shut down if no any actions within 10 seconds after it turning on.
7. If a reading does not appear within 10 seconds, remove the user's finger slightly, or twist and/or shift the finger and try again.
8. If a second try is unsuccessful, repeat the measuring process on a smaller finger.

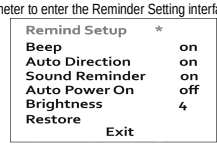
The following factors may influence the accuracy of measurements:
- Ambient light (including photodynamic therapy)
- Physical movement (patient and imposed motion)
- Diagnostic testing
- Low Perfusion;
- Electromagnetic interference, such as MRI environment
- HF surgical equipment
- Dysfunctional hemoglobin, such as carboxyhemoglobin (COHb)and methemoglobin (MetHb)
- Presence of certain dyes, such as methylene and indigo carmine
- Inappropriate positioning of the SpO_2 sensor, or use of incorrect SpO_2 sensor.
- Drop of arterial blood flow to immeasurable level caused by shock, anemia, low temperature or vasoconstrictor.

4.2 Reminder Function

For the oximeter with OLED screen: when the SpO2 or PR value exceeds the set limit, the measured value flashes to remind the user that the SpO_2 or PR is abnormal.
For the oximeter with digital tube screen: when the SpO2 is less than 90%, PR is less than 50bpm or greater than 140bpm, the measured value flashes to remind the user that the SpO_2 or PR is abnormal.

4.3 Settings (only for oximeters with OLED screen)

Reminder Setting
Press and hold POWER button 2 seconds after turning on the oximeter to enter the Reminder Setting interface.



Press the POWER button to select the setting item, * will jump to the current item, you can select Beep, Auto Direction, Sound Reminder, Brightness, Restore or Exit. Press the POWER button to switch options, and press and hold POWER button to confirm the setting. On means open, Off means closed.

Turn on/off Beep
In Reminder Setting interface, press POWER button to select Beep, * appears on Beep, then press and hold POWER button to switch between On and Off. The default is Off.

Turn on/off Auto Direction
In Reminder Setting interface, press POWER button to select Auto Direction, * appears on Auto Direction, then press and hold POWER button to switch between On and Off. The default is On.

Turn on/off Sound Reminder
In Reminder Setting interface, press POWER button to select Sound Reminder, * appears on Sound Reminder, then press and hold POWER button to switch between On and Off. The default is On.

Turn on/off Auto Power On
In Reminder Setting interface, press POWER button to select Auto Power On, * appears on Auto Power On, then press and hold POWER button to switch between On and Off. The default is Off. On means the oximeter will turn on automatically if it detects the finger insertion.

Screen Brightness Setup

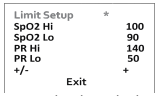
In Reminder Setting interface, press POWER button to select Brightness, * appears on Brightness, then press and hold POWER button to set brightness level.
Brightness level is adjusted from 1 to 10, the default is 4.

Restore the initial settings

In Reminder Setting interface, press POWER button to select Restore, * appears on Restore, then press and hold POWER button to restore all initial settings.

Limit Setup

Press and hold power button to enter the Remind Setting interface after turning on the oximeter, and press the power button again to enter the Limit Setup interface, as shown below.



Press power button to select the setting item, * will jump to the current item, you can select SpO2 Hi (high limit of SpO_2), SpO2 Lo (low limit of SpO_2), PR Hi(high limit of PR), PR Lo (low limit of PR), +/- (value increase/ value decrease), or Exit.
Press the POWER button to switch options, and press and hold POWER button to confirm the setting.

Exit Setting

In the setting interface, press the switch button to select Exit, * appears on Exit, press and hold power button to save settings and exit the setting interface.
In the setting interface, if there is no operation within 30 seconds, the oximeter will automatically save the setting and exit the setting interface.

4.4 Data transmission (only for oximeter with Bluetooth module)

Some oximeters with OLED screen are configured Bluetooth module, which can send measurement data to the mobile phone through Bluetooth transmission, and users can install an APP on the mobile phone to view the measurement data.

Part 5 Accessories

Use only accessories specified in this manual. Using other accessories may cause damage to the pulse oximeter. Or the performance of pulse oximeter cannot meet the specifications claimed in this specification.
The accessory material that contacts the user or other personnel has undertaken the bio-compatibility test and is verified to be in compliance with ISO 10993-1.

- One lanyard
- One User Manual
- One Quality Certificate

Part 6 Maintenance

The oximeter can be used for 5 years. Keep the oximeter and accessories free of dust and dirt, and follow these rules:

1) Please clean the equipment before use according to Part 7; Remove the batteries inside the battery cassette if the equipment will not be operated for more than 30 days.
2) Battery polarities should be correctly installed, otherwise, damage may be caused to the oximeter.
3) Replace the batteries when the low battery indicator says it is necessary.
4) Battery may leak or explode if used or disposed of improperly.
5) It is recommended that the oximeter should be kept in a dry environment with no corrosive gases and good ventilation. Storing the oximeter improperly will affect its lifespan and damage the equipment.
6) It is best to preserve the product in a place where the temperature is between -20°C to 60°C and the relative humidity is less than 95%.
7) The packed equipment can be transported by ordinary conveyance. The equipment may not be transported with toxic, harmful, or corrosive materials.
8) Dispose of the oximeter in accordance with local environment and waste disposal laws and regulations.

NOTE:

1 Do not attempt to disassemble the oximeter or repair it unless you are trained personnel.
2 Necessary maintenance or calibration must be performed by qualified service personal ONLY.
3 Users are NOT permitted to maintain the equipment by themselves.
4 There are NO replaceable components in the equipment.

Part 7 Cleaning and Disinfection

7.1. Cleaning

The recommended cleaning agent is water.

1. Shut down the oximeter and remove the batteries.
2. Clean the oximeter with cotton or a soft cloth moistened with water.
3. After cleaning, wipe off the water with a soft cloth.
4. Allow the oximeter to air dry.

7.2 Disinfection

Recommended disinfectants are Ethanol 75%, isopropanol 70%.

1. Shut down the oximeter and remove the batteries.
2. Clean the pulse oximeter as instructed in section 7.1.
3. Disinfect the oximeter with cotton or soft cloth moistened with one of the recommended disinfectants.
4. After disinfection, be sure to wipe off the disinfectant left on the oximeter with a soft cloth moistened with water.
5. Allow the oximeter to air dry.

CAUTION

1 Never immerse or soak the pulse oximeter.
2 It is recommended that the pulse oximeter be cleaned and disinfected after every use as determined by your hospital's policy to avoid long term damage to the pulse oximeter.
3 Never use cleaning agents/disinfectants other than the types recommended.
4 The sensor component is not cleaned and disinfected during testing.
5 Do not disinfect the oximeter with high temperature, high pressure, gas vapor or liquid immersion. Clean and disinfect the oxygen meter according to the manufacturer's requirements.
6 Oximeter's regular calibration and maintenance should be taken by qualified professionals.

NOTE:

1 If you spill liquid on the equipment or accessories, wipe it clean immediately. If the oximeter does not work properly, contact us or your service personnel.
2 Never use EtO or formaldehyde for disinfection.

Part 8 Product Specification

Safety Specifications (classified according to IEC60601-1)	
Electric shock protection	External battery power supply device
Degree of protection against electrical shock	Type BF applied part
Degree of protection against ingress of liquid:	IP22
Operating mode	Continuous

Measurement Specifications	
SpO_2 displayed range	0%～-100%
SpO_2 accuracy[1]	70% -100%, ±2%; 0% - 69%: Not specified.
PR displayed range	18bpm - 250bpm
PR accuracy	25bpm -250bpm, ±3bpm; 18bpm - 24bpm, Not specified.
PI displayed range	0% - 20%
PI resolusion	0.1%
Data update period	<30s
Data average time	8s
SpO_2 sensor peak wavelength range[2]	Red light: 660±3nm; Infrared light: 940±5nm
Maximum photic output power	<30mW

[1] Sensor accuracy was obtained by performing controlled hypoxia studies on healthy, non-smoking adult volunteers (according to ISO 80601-2-61). The SpO_2 readings have been compared to CO-oximeter measurements on arterial blood saturation. To represent the general population, data from at least 10 subjects (male and female) with a wide range of skin color was taken to validate SpO_2 accuracy.
[2] The information about wavelength range and maximum optical output power of the light emitted by the oximeter sensor can be especially useful to clinicians, for example, clinicians performing photodynamic therapy.
Note: Only 2/3 of measurements are expected to fall within the DECLARED RANGE of SpO_2 ACCURACY.

Physical Specifications		
Dimension	70 x40 x 30mm(L x W x H)	
Weight	≤ 60g (without battery)	
Hardware specifications		
Display screen	Digital tube, 1.1"	
	OLED, 0.96"	
Display content	Oximeter with digital tube screen	SpO_2, PR, battery icon, bar histogram
	oximeter with OLED screen	SpO_2, PR, battery icon, bar histogram, wavelength, PI

Environmental Specifications	Working	Transport and Storage
Temperature	5°C～40°C	-20°C～60°C
Relative humidity (non-condensing)	30%～80%	10%～95%
Atmospheric pressure	70～106kPa	70～106kPa
Power supply specification		
Battery	2 AAA alkaline batteries	
Voltage	3.0V	
Operating time	≥20 hours (2 new Nanfu batteries)	

Network and RF	
Hardware Configuration	CPU: HC32L130J8TA Operating system: no Memory: 64KB Flash, 8KB RAM
Software Environment	Keil uVision5
Software environment update	N/A
Data interface	Transmission protocol: BLE 4.2 specification and custom communication protocol
Bluetooth frequency range	2402-2480MHz
Maximum RF power	< 10dBm

Model and configuration table

Model	Screen	Function
Oximeters with digital tube screen	Digital tube / two direction	SpO2, PR, Bar histogram, low battery prompt, automatic shutdown, over-limit reminder, pulse beep
Oximeters with OLED screen	OLED/ four direction	SpO2, PR, Bar histogram, low battery prompt, automatic switch on/off, Pulse beep,PI, Reminder setting, Limit setting, over-limit reminder, auto direction, Bluetooth
Remarks: Some functions and displays may not be applicable to your oximeter, refer to the actual product.		

Part 9 Troubleshooting

Trouble	Possible Causes	Solution
The oximeter can not enter to measure mode.	The batteries are completely exhausted.	Replace new battery
	Battery installation is incorrect.	Check and correct the batteries installation.
	The oximeter may be broken.	Contact the local distributor.
The display is suddenly off.	The oximeter will turn into sleep mode automatically if there is no signal in 10 seconds.	Press power ON/OFF button to restart the oximeter.
	The batteries are completely exhausted.	Replace new battery
The SpO2 and Pulse Rate readings are unstable.	The luminescent or photoelectric window is sheltered by some object.	Check the luminescent and photoelectric window.
	Excessive movement.	Stop moving finger, hand and body.
	The finger is not placed inside deep enough.	Place the finger properly and try again.
	Finger size is not within the recommended range.	Change to another finger.
	Excessive ambient light.	Avoid the excessive light.
	Pulse rate value of the cyclical fluctuations.	The measurement is normal, and the patient has arrhythmia.
The SpO2 and PR are not displayed normally.	Finger might not be inserted properly	Place the finger properly and try again.
	The patient's SpO2 is too low to be detected.	Try again, go to a hospital for a diagnosis if you are sure the oximeter works properly.

Part 10 Warranty and Service

The materials and processes used of manufacturing equipment meet the requirements. Konsung's obligation or liability under this warranty does not include any transportation or other charges or liability for direct, indirect or consequential damages or delay resulting from the improper use or application of the product or the use of parts or accessories not approved by Konsung or repairs by people other than Konsung authorized personnel.

The products are free to enjoy after-sales service within warranty period. But please beware, even during the warranty period, due to the following reasons the product needs repair, Konsung will be charged maintenance services, you need to pay for maintenance and parts costs:

- Damage caused by mishandling during shipping.
- Subsequent damage caused by improper use or maintenance.
- Damage caused by alteration or repair by anyone not authorized by Konsung.
- Damage caused by non-normal use beyond the prescribed conditions;
- Original serial number tag or manufacturer logo is removed or replaced;

Konsung can continue to provide toll maintenance services after the warranty expires. If you do not pay or delay the payment of maintenance costs, Konsung will temporarily suspend maintenance until you pay.
If any questions in equipment operation, please contact the manufacturer or local agency.

Part 11 EMC

11.1 Electromagnetic Emissions-for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic emission		
The oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the oximeter should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment – guidance
RF(Radio frequency) emissions CISPR 11	Group 1	The oximeter uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF(Radio frequency) CISPR 11	Class B	The oximeter is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC/EN 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC/EN 61000-3-3	Complies	

11.2 Electromagnetic Immunity-for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic immunity			
The oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the oximeter should assure that it is used in such an environment.			
Immunity test	IEC/EN 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC/EN 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient /burst IEC /EN 61000-4-4	±2kV for power supply lines ±1 kV for input /output lines	N/A	N/A
Surge IEC / EN 61000-4-5	±1 kV differential mode ±2 kV common mode	N/A	N/A
Power frequency (50/60Hz) magnetic field IEC /EN 61000-4-8	30A/m	30A/m, 50/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC/EN 61000-4-11	0 % U_T, for 0.5 cycle (100% dip in U_T) 0 % U_T, for 1 cycle (100% dip in U_T) 70 % U_T, for 25/30 cycles (30% dip in U_T) 0 % U_T, for 250/300 cycles (100% dip in U_T)	N/A	N/A
NOTE: U_T is the AC mains voltage prior to application of the test level.			

11.3 Electromagnetic Immunity-for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacture's declaration – electromagnetic immunity			
The oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of oximeter should assure that it is used in such an environment.			
Immunity test	IEC/EN 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC/EN 61000-4-6	3 Vrms 150 kHz to 80 MHz	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the Oximeter, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz-800 MHz $d = 2.3\sqrt{P}$ 800 MHz-2.7 GHz Where: Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF 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:
Radiated RF IEC/EN 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	
NOTE 1:At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Oximeter is used exceeds the applicable RF compliance level above, the Oximeter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Oximeter. b Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.			

11.4 Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the oximeter			
The oximeter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the oximeter as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter(m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3\sqrt{P}$
0.01	N/A	0.12	0.23
0.1	N/A	0.38	0.73
1	N/A	1.2	2.3
10	N/A	3.8	7.3
100	N/A	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1: At 80MHz and 800MHz, the separation distance for the higher frequency range applies. NOTE 2:These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

FCC Statement

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

WARNING: Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.