

# Fingertip Pulse Oximeter





### Jiangsu Konsung Bio-Medical Science And Technology Co., Ltd

NO.8, Shengchang West Road, Danyang Development Zone, Jiangsu Province, 212300, P.R. China

Tel: 86-511-86375968 WhatsApp: 0086-18952012596 E-mail: info@ konsung.com Website: www.konsungmedical.com



### Shanghai International Holding Corp. GmbH (Europe)

Eiffestrasse 80, 20537 Hamburg Germany Tel: +49-40-2513175 Fax: +49-40-255726 E-mail: shholding@hotmail.com

### Statement

Thanks for your purchasing Fingertip 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 holds 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.

Materials protected by the copyright law, including but not limited to confidential information such as technical information and patent information are contained in this manual, the user shall not disclose such information to any irrelevant third party.

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. Fingertip Pulse Oximeter is Class 1 LEDs product. It must be serviced by specified trained personnel.

# Responsibility of the Manufacturer

**Konsung** only considers itself responsible for any effect on safety, reliability and performance of the equipment if:

- Assembly operations, extensions, readjustments, modifications or repairs are carried out by persons authorized by Konsung, and
- The electrical installation of the relevant room complies with national standards, and
- The instrument 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 Safety

### 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

A WARNING label advises against certain actions or situations that could result in personal injury or death.

### CAUTION

A CAUTION label advises against actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure.

#### NOTE

A NOTE provides useful information regarding a function or a procedure.

### WARNING

- The pulse oximeter is not intended for treatment.Do not open the shell of pulse oximeter. Otherwise
- you may damage the pulse oximeter. All servicing and future upgrades must be carried out by the personnel trained and authorized by Konsung only.
- 3 Do not use the pulse oximeter with the defibrillator or other high-frequency equipment.
- 4 Explosion hazard: Do not use the pulse oximeter in an explosive atmosphere.
- 5 Check and change the applied site according to the different circumstances of the user while using the pulse oximeter for long-time continuous monitoring. It is recommended to check the finger after 2 hours.
- 6 Misapplication of pulse oximeter probe with excessive pressure for prolonged periods can induce pressure injury.
- 7 The measuring data displayed on the pulse oximeter are for reference only and cannot be directly used for diagnostic interpretation.
- 8 The pulse oximeter is not intended to use of infant and negnate
- 9 The presence of high ambient light may cause inaccurate SpO<sub>2</sub> measurements.
- 10 Do not use the oximeter in situations where alarms required. The oximeter does not support alarms.

  11 FUNCTIONAL TESTER cannot be used to assess
- ACCURACY.

  12 The skin temperature is initially at 35°C for each PULSE OXIMETER, the APPLIED PART temperature
- cannot exceed 41°C.

  3 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. But to some natural rubber latex sensitive user, there may be
- some allergic reactions.

  14 Disposal of the pulse oximeter and its accessories and packaging (plastic bags, foam and cartons, etc.) are subject to local laws and regulations.

### CAUTION

- Carefully read this manual about all safety information, operation and specifications before using the pulse eximeter.
- 2 To ensure patient safety, only use accessories and parts produced or recommended by Konsung. Otherwise, damage to the pulse oximeter can occur.
- Keep the operating environment clean, no vibration, no corrosion or combustible material and avoid too high or too low temperature and humidity.
- 4 Do not use the pulse oximeter near by the source of electromagnetic interference, such as mobile phones or radio transmitter.
- 5 Do not spill liquid on the oximeter. Do not immerse the oximeter in liquid. Condensation can occur from changes in temperature or exposure to humidity.
- 6 Always install or carry the pulse oximeter properly to avoid damage caused by drop, impact, strong vibration or other mechanical force
- 7 Do not use the pulse oximeter if the pulse oximeter cannot achieve satisfactory results.

### NOTE:

- Too cold or too thin finger may affect the measurements; thicker finger (recommended index finger, middle finger, or ring finger) should insert into the cover fully.
- 2 SpO<sub>2</sub> waveform is not proportional to the pulse volume. The waveform is normalized.
- 3 Avoid placing the sensor on extremities with an arterial catheter, or intravascular venous infusion line.
- Check the pulse oximeter before using. Do not use it if there is significant damage.
- The pulse oximeter is calibrated to display functional oxygen saturation. It is not necessary to have a SpO<sub>2</sub> calibration when the pulse oximeter is in use.
- 6 The pictures and interfaces in this manual are for reference only.
- 7 Fingernail polish or false fingernails may cause inaccurate SpO<sub>2</sub> readings.
- 8 Never incinerate batteries or expose them to high temperatures.

### 1.2 Symbols

1.2 Sym	IDOIS
Symbols	Definition of symbols
<b>③</b>	Refer to instruction manual/booklet
$\triangle$	Caution
$\bowtie$	No alarm
橑	Type BF Applied Part
<u></u>	Power on/off
	Battery indication
SpO <sub>2</sub>	Oxygen saturation of arterial hemoglobin
PR	Pulse Rate
Ø	WEEE symbol
	The symbol indicates that the device
C € <sub>1639</sub>	complies with the European Council
C C1639	Directive 93/42/EEC concerning medical
	devices.
EC REP	Authorized representative in the
	European community
SN	Serial Number
P/N	Part Number
LOT	Batch number
•••	Manufacturer
~	Manufacturer  Date of manufacture
M IPX1	

# Part 2 The Basics

### 2.1 Introduction

This fingertip pulse oximeter is a kind of innovated detection device with non-invasive and continuous features for artery  $SpO_2$  and PR detection. It is portable and easy to measure the  $SpO_2$  and PR value quickly and precisely.

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. It's for ages from 15 to 60 years old users.

The oximeter is not suitable for continuous monitoring of patients.

The pulse oxygen saturation is the percentage of  $HbO_2$  in the total Hb in the blood, so-called the  $O_2$  concentration in the blood. It is an important bioparameter for respiration. A number of diseases relating to the respiratory system may cause the decrease of  $SpO_2$  in the blood, furthermore, some other causes such as the malfunction of the human body's self-adjustment, damages during surgery, and the injuries caused by some medical checkups would also lead to the difficulty of oxygen supply in human body. The corresponding symptoms would appear as a consequence, such as vertigo, impotence, vomit etc.

Some symptoms may be serious enough to cause significant harm. Therefore, prompt information concerning the patients SpO<sub>2</sub> can help doctors discover potential problems, and is of great importance in the clinical and medical field.

# 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 adults and pediatrics in home care and medical outpatient environment.

Contraindication: none

### 2.3 Principle

The Principle of the oximeter is as follows: an experience formula of data process is established making use of the Lambert Beer law according to Spectrum Absorption Characteristic of Reductive hemoglobin (Hb) and oxyhemoglobin (HbO2) in glow & near-infrared zones. The operation principle of the device is: Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning Recording Technology, so that two beams of different wavelengths of light can be focused onto human nail tip through perspective clangs finger-type sensor. Then measured signal can be obtained by a photosensitive element, information acquired through which will be shown on two groups of LED through process in electronic circuits and microprocessor



### 2.4 Applications

- This pulse oximeter is suitable for the following people: People with vascular disease, such as: coronary heart disease, hypertension, hyperlipidemia, cerebral thrombosis;
- People with respiratory diseases, such as: asthma, trachitis, chronic bronchitis, chronic cor pulmonale, chronic obstructive pulmonary disease;
- Old people above 60 years old;
- People who works more than 12 hours a day;
- People works on extreme exercise or under the alpine hypoxic environment;
- Long-term alcohol people.

# 2.5 Appearance



- 1. Two colors OLED display
- Oxygen saturation of arterial blood (SpO<sub>2</sub>): percentage of oxygenated hemoglobin in relation to the sum of oxyhemoglobin and deoxyhemoglobin.
- 3. Battery capacity Indicator
- Full capacity, the middle part indicates the capacity.
- Capacity is seriously empty, change batteries immediately.
- Pulse rate (derived from pleth wave): detected pulsations per minute.
- Power button
- Press this button to turn on the oximeter.
- Press this button to adjust the display screen direction according to the users observation data needs.
- \_ Press and hold this button 2 seconds to

- enter Setting interface.
- In Setting interface, press this button once to switch setting items.
- In Setting interface, press and hold this button 2 seconds to confirm setting.
- Pleth waveform: visual indication of patient's pulse.
- Perfusion index (PI): gives the numerical value for the pulsatile portion of the measured signal caused by arterial pulsation.

Pl is an indicator of the pulsatile strength. You can also use it to assess the quality of SpO<sub>2</sub> measurement. Above 1 is optimal, between 0.3 and 1 is acceptable. Below 0.3 indicates low perfusion; reposition the SpO<sub>2</sub> sensor or find a better site. If low perfusion persists, choose another method to measure oxygen saturation if possible.

# 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. Take out all bulk packaging from the carton. If the packing case is intact, open the package and remove the equipment and accessories carefully. 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

### 3.2 Storage

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

Easy to splash;

missing according to packing list.

- 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

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



Hold the oximeter with the display facing toward you, slide your finger into the opening probe of the device as shown below, until the fingertip touches the built-in stop guide. For best results, make sure the finger is centered within the finger guide.





- Press the POWER button to turn on the oximeter. The measurement interface will appear in 3 seconds.
- The measurement result will appear on the screen within 10 seconds.

The pulse oximeter will power off in 15 seconds if no signal in screen, or there is finger for detection and without operation.

# NOTE:

1 We recommend using the index finger, middle finger, or ring finger as suitable positions for the monitor. It is

- intended for spot-checking or attended-care monitoring in home health care and medical facilities
- The displayed parameters will show invalid indicator as '---' if signal quality is very low.
- 3 The displayed parameters will show invalid
- indicator as '---' if oximeter fault occurs.

  4 Finger cannot apply nail polish and other cosmetics.
- 5 Do not shake the finger, hand or body during the

pulse rate.

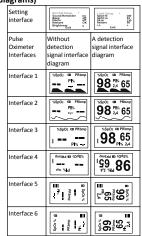
- measuring.

  6 Tape or other light obstructions around the applied site may affect the accuracy of SpO₂ and
- 7 The oximeter will shut down if no any actions within 15 seconds after it turning on.
- 8 Battery polarities should be correctly installed, otherwise, damage may be caused to the equipment.
- 9 Please remove the batteries if the oximeter will be stored for more than 30 days.
- 10 Battery may leak or explode if used or disposed of improperly.

The following factors may influence the accuracy of measurement:

- 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<sub>2</sub> sensor, or use of incorrect SpO<sub>2</sub> sensor.
- Drop of arterial blood flow to immeasurable level caused by shock, anemia, low temperature or vasoconstrictor.

# 4.2 Display Description (6 interface diagrams)



Screen Description:

"%SpO<sub>2</sub>": SpO<sub>2</sub> symbol;
"PR bpm": Pulse rate icon;
"Pl%": Perfusion index icon;

" = ": Bar graph icon;

" : Pulse intensity histogram.

### Part 5 Included 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 hiocompatibility test and is verified to be in compliance with ISO 10993-1.

- One lanyard
- One User Manual
- ◆ One Quality Certificate

### Part 6 Maintenance

### 6.1 Maintenance

The oximeter's design life expectancy is about two years, keep your equipment 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) Replace the batteries when the low battery indicator says it is necessary
- 3) It is recommended that the equipment should be kept in a dry environment with no corrosive gases and good ventilation. Storing the pulse oximeter improperly will affect its lifesnan and damage the equipment
- 4) It is best to preserve the product in a place where the temperature is between -20°C to 55°C and the relative humidity is less than
- 5) The packed equipment can be transported by ordinary conveyance. The equipment may not be transported with toxic, harmful, or corrosive materials

If any damage or abnormality is found, please do not use the oximeter and contact local Customer Service Center.

# NOTE:

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

### 6.2 Disposal

Dispose of the pulse oximeter in accordance with local environment and waste disposal laws and regulations

# Part 7 Cleaning/Disinfection

The recommended cleaning agent is water.

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

### 7.2 Disinfection

The recommended disinfectants include: ethanol (75%), isopropanol (70%).

- 1. Shut down the pulse oximeter and remove the
- 2. Clean the pulse oximeter as instructed above.

- 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 pulse oximeter to air dry.

### CAUTION

- 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 methods such as high temperature, high pressure, gas fumigation or liquid immerse. Follow the manufacturer's instructions of cleaning and disinfection for pulse oximeter.
- 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 the oximeter immediately and dry the oximeter. If the oximeter cannot work normal please contact us or your service personnel.
- 2 Never use EtO or formaldehyde for disinfection

# Part & Specification

i art o specification			
Safety specifications (classified according to IEC60601-1)			
Electric shock protection	Internal power supply device		
Degree of protection against electrical shock	Type BF applied part		
Degree of protection against ingress of liquid	IPX1, non AP/APG type		
Operating mode Continuous			

Measurement Specifications				
SpO₂ Displayed Range		35%-10	35%-100%	
SpO <sub>2</sub> Accuracy <sup>1</sup>	±2% in the range of 70%-100% Other scope is not defined			
PR Displayed Range		30bpm - 240bpm		
PR accuracy		±3bpm		
Data update period		0.25s -2s		
SpO₂/PR averaging time		8s		
Peak wavelength range <sup>2</sup>		500nm	- 1000nm	
Maximum optical output p		ower	15mW	
1 Sensor accurac	v was oht	ained h	nerforming	

controlled hypoxia studies on healthy, nonsmoking adult volunteers (according to ISO 80601-2-61). The SpO<sub>2</sub> 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 SpO2 accuracy. The information about wavelength range and maximum ontical output nower of the light emitted by the oximeter sensor can be especially useful to clinicians, for example, clinicians performing photodynamic therapy.

Physical Specifications		
Length x Width x Height	64 x 39 x 36 mm	
Weight	≤55g (excluding batteries)	

Hardware specifications		
Display screen two color OLED, 0.96"		
Display Content SpO <sub>2</sub> %, Pulse rate, Battery		

	indicator, Bar graph, Pulse waveform, PI%		
Environmental Specifications	Working	Transport and Storage	
Temperature (°C)	5 ~ 40	-20 ~ 60	

30% ~ 80%

70~106

10% ~ 95%

70~106

Relative humidity

(non condensing)

Atmospheric

Pressure (KPa)				
Power Requirements				
Specification of alkaline batteries	Two AAA			
Operating current	Less than 30mA			
Power dissipation	in normal measurement, less than 40mA; in power off state, less than 50µA			

# **Part 9 Troubleshooting** Trouble Possible Reason Solution

rouble	Possible Reason	Solution	
The	The batteries are	Please replace	
oximeter	completely	the batteries.	
can't turn	exhausted.		
to measure	An incorrect	Verify and correct	
mode.	battery installation.	the batteries	
		installation.	
	The oximeter may	Please contact	
	be broken.	local service.	
The display	The device will turn	Press the POWER	
is off	into sleep mode	button again to	
suddenly.	automatically if	reactivate the	
Juduciny.	there is no signal in	oximeter.	
	15 seconds.	DAIIII CCCII	
	The batteries are	Please replace	
	completely	the batteries.	
	exhausted.	the batteries.	
Th - C-O		Charletha	
The SpO <sub>2</sub> and Pulse	The luminescent or photoelectric	Check the luminescent and	
Rate	window is	photoelectric	
	sheltered by some	window.	
readings are	object.	willuow.	
unstable.		C1	
unstable.	Excessive	Stop moving	
	movement.	finger, hand and	
		body.	
	The finger is not	Place the finger	
	placed inside deep	properly and try	
	enough.	again.	
	Finger size is not	Change to	
	within the	another finger.	
	recommended		
	range.		
	Excessive ambient	Avoid the	
	light.	excessive light.	
	Pulse rate value of	The	
	the cyclical	measurement is	
	fluctuations.	normal, and the	
		patient has	
		arrhythmia.	
The SpO <sub>2</sub>	The finger is not	Place the finger	
and PR are	properly	properly and try	
not	positioned.	again.	
displayed	The patient's SpO <sub>2</sub>	Try again, go to a	
normally.	is too low to be	hospital for a	
	detected.	diagnosis if you	
		are sure the	
		device works	
		properly.	

# Part 10 Warranty and Service Policy 10.1 Warranty

Konsung warrants that Konsung's products meet the labeled specifications of the products and will be free from defects in materials and workmanship that occur within

warranty period

The warranty is void in cases of:

- damage caused by mishandling during shipping.
- subsequent damage caused by improper use or
- · damage caused by alteration or repair by anyone not authorized by Konsung.
- damage caused by accidents.
- · replacement or removal of serial number label and manufacture label.

If a product covered by this warranty is determined to be defective hecause of defective materials, components, or workmanshin, and the warranty claim is made within the warranty period. Konsung will, at its discretion, repair or replace the defective part(s) free of charge. Konsung will not provide a substitute product for use when the defective product is being repaired.

### 10.2 Contact Information

If any questions in equipment operation, please contact the manufacturer or local agency. Jiangsu Konsung Bio-Medical Science And Technology Co...

Address: No. 8, Shengchang West Road, Danyang

Development Zone, Jiangsu Province, China Tel: +86-511-86375968 Fax: +86-511-86371668 E-mail: info@konsung.com

### Part 11 EMC

# 11.1 Electromagnetic Emissions-for all **EQUIPMENT and SYSTEMS**

Guida		ufacture's declaration – gnetic emission
environment s	pecified below	r use in the electromagnetic w. The customer or the user of that it is used in such an
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
Harmonic emissions IEC/EN 61000- 3-2	Class A	and those directly connected to the public low-voltage power supply network that supplies buildings used for
Voltage fluctuations/ flicker	C	domestic purposes.

# 11.2 Electromagnetic Immunity-for all FOUIPMENT and SYSTEMS

Complies

emissions

IEC/EN 61000-

EQUIT WILLY WING STOTE WIS				
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	Electromagnet ic environment - guidance	

Immunity test	IEC/EN 60601 test level	Compliance level	ic environment - guidance
Electrostati c 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 differenti al mode 2 kV common mode	N/A	N/A
Power frequency (50/60Hz) magnetic field IEC /EN 61000-4-8	30A/m	30A/m,50/60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dibps, short tinterruptions and voltage variations on power supply input lines IEC/EN 61000-4-11	$0 \% U_{T_r}$ for $0.5$ cycle $(100\% \operatorname{dip} \operatorname{in} U_{T})$ $0 \% U_{T_r}$ for $1$ cycle $(100\% \operatorname{dip} \operatorname{in} U_{T})$ $70 \% U_{T_r}$ for $25/30$ cycles $(30\% \operatorname{dip} \operatorname{in} U_{T})$ $0 \% U_{T_r}$ for $25/30 \odot \operatorname{cycles}$ $(100\% \operatorname{dip} \operatorname{in} U_{T})$	N/A	N/A
NOTE: U <sub>T</sub> 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 use of oximeter should assure that it is used in such an

IEC/EN

mmunity est	60601 test level	Compliance level	environment - guidance
Conducted RF EC/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
Radiated RF EC/EN 51000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2\sqrt{P}$ 80 MHz-800 MHz

	2.5 1			
	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, <sup>a</sup> 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:			
	(( <u>(•</u> ))			
	` <b>`</b> A''			
At 80 MHz and 800 MHz, the higher				
frequency range applies.				

 $d = 2.3\sqrt{P} 800 \text{ MHz}$ 

NOTE 1

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.
- 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 equipmen 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

ipment.						
ated maximum utput power of	Separation distance according to frequency of transmitter(m)					
transmitter (W)		80 MHz to 800 MHz	800 MHz to 2.7 GHz			
	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$			
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 senaration 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 transmitte 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.