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PROFESSIONAL MEDICAL PRODUCTS

SATURIMETRO OXY-6
OXIMETER OXY-6
OXYMÈTRE OXY-6
PULSOXIMETER OXY-6
SATURÓMETRO OXY-6
MEDIDOR DE SATURAÇÃO OXY-6
ΚΟΡΕΣΤΟΜΕΤΡΟ OXY-6
مقياس التأكسج OXY-6

Manuale d'uso e manutenzione
Use and maintenance book
Instructions de foncionnement et entretien
Betriebs und wartungs anweisungen
Manual de uso y mantenimiento
Manual de uso e manutenção
Εγχειριδιο χρησης και συντηρησης
دليل الإستعمال والرعاية

ATTENZIONE: *Gli operatori devono leggere e capire completamente questo manuale prima di utilizzare il prodotto.*
ATTENTION: *The operators must carefully read and completely understand the present manual before using the product.*
AVIS: *Les opérateurs doivent lire et bien comprendre ce manuel avant d'utiliser le produit.*
ACHTUNG: *Diese Anleitung muss vor dem Einsatz des Produkts aufmerksam gelesen und vollständig verstanden werden.*
ATENCIÓN: *Los operadores tienen que leer y entender completamente este manual antes de utilizar el producto.*
ATENÇÃO: *Os operadores devem ler e entender completamente este manual antes de usar o produto.*
ΠΡΟΣΟΧΗ: *Οι χειριστές αυτού του προϊόντος πρέπει να διαβάσουν και να καταλάβουν πλήρως τις οδηγίες του εγχειριδίου πριν από την χρήση του.*
الحذر: *على العمال قراءة وفهم هذا الدليل بكامله قبل البدء باستعمال المنتج.*

REF 34285

Gima S.p.A.
Via Marconi, 1 - 20060
Gessate (MI) - Italy
Made in China

0476

M34285-M-Rev.3.03.19

Instructions to User

Read these instructions carefully before using this equipment. These instructions describe the operating procedures to be followed strictly. Failure to follow these instructions can cause measuring abnormity, equipment damage and personal injury. The manufacturer is NOT responsible for the safety, reliability and performance issues and any monitoring abnormality, personal injury and equipment damage due to user's negligence of the operation instructions. The manufacturer's warranty service does not cover such faults.

- The uncomfortable or painful feeling may appear if using the device ceaselessly, especially for the microcirculation barrier patients. It is recommended that the sensor should not be applied to the same finger for over 2 hours.
- For the individual patients, there should be a more prudent inspecting in the placing process. The device can not be clipped on the edema and tender tissue.
- The light (the infrared is invisible) emitted from the device is harmful to the eyes, so the user and the maintenance man, can not stare at the light.
- Testee can not use enamel or other makeup on the finger.
- estee's fingernail can not be too long.
- Please peruse the relative content about the clinical restrictions and caution.

1. SAFETY

1.1 Instructions for Safe Operations

- Check the main unit and all accessories periodically to make sure that there is no visible damage that may affect patient's safety and monitoring performance. It is recommended that the device should be inspected once a week at least. When there is obvious damage, stop using the oximeter.
- Necessary maintenance must be performed by qualified service engineers ONLY. Users are not permitted to maintain it by themselves.
- The oximeter cannot be used together with the devices not specified in User's Manual.

1.2 Warnings

- Explosive hazard—DO NOT use the oximeter in environment. with inflammable gas such as some ignitable anesthetic agents.
- DO NOT use the oximeter while the testee measured by MRI and CT.
- To dispose the device, the local law must be followed.

1.3 Attentions

- Keep the oximeter away from dust, vibration, corrosive substances, explosive materials, high temperature and moisture.
- If the oximeter gets wet, please stop operating it. When it is carried from cold environment to warm and humid environment, please do not use it immediately.
- DO NOT press the keys on front panel with sharp materials.
- High temperature or high pressure steam disinfection to the oximeter is not permitted. Refer to User's Manual for instructions of cleaning and disinfection.
- DO NOT have the oximeter immerged in liquid. When it needs cleaning, please wipe its surface with disinfect solution by soft material. Do not spray any liquid on the device directly

2. OVERVIEW

The pulse oxygen saturation is the percentage of HbO_2 in the total Hb of the blood, so-called the O_2 concentration in the blood. It is an important bio-parameter to the respiration. Many of the respiration disease will cause hypoxemia, even endanger the patient's health. As a result, monitoring the SpO_2 is indispensable in the clinical rescuing. The traditional method to measure SpO_2 is to analyze the sample of the patient's blood, so can get the partial pressure of oxygen and calculate the SpO_2 by use the blood-gas analyzer. This method is inconvenient and can not be used to monitor continuously. For the purpose of measuring the SpO_2 more easily and accurately, GIMA developed the Fingertip Oximeter. The device can measure the pulse rate and blood perfusion index simultaneously.

The Fingertip Oximeter is compact, convenient to use and carry and with low power consumption. You just need to put the fingertip into the

sensor of the device, the SpO_2 value will appear on the screen immediately.

2.1 Features

- Small in size and lightweight.
- Color OLED, various display modes, display directions adjustable.
- The device can accurately measure SpO_2 value, pulse rate value and perfusion index.
- The device will automatically start measuring after putting finger into sensor.
- The device will power off automatically without signal for about 8 seconds.
- Audible & visual alarm.
- Low voltage indication.

2.2 Major Applications and Scope

This device is applicable to home, hospital (including internal medicine, surgery, anesthesia, pediatrics, emergency room etc.), oxygen bar, the community medical center, alpine area and it also can be used before or after sports, and the like. The Fingertip Oximeter can detect SpO_2, pulse rate and blood perfusion index.

This device is not appropriate to be used for continuous monitoring.

2.3 Environment Requirements

Operating Temperature: 5°C ~40°C
Operating Humidity: 30%~80%
Atmospheric pressure: 70kPa~106kPa

2.4 SpO_2 Common Knowledge

1. Meaning of SpO_2

SpO_2 is the saturation percentage of oxygen in the blood, so called O_2 concentration in the blood; it is defined by the percentage of oxyhemoglobin (HbO_2) in the total hemoglobin of the arterial blood. SpO_2 is an important physiological parameter to reflect the respiration function; it is

calculated by the following method:
SpO_2 = HbO2/ (HbO2 +Hb)×100%
HbO_2 are the oxyhemoglobins (oxygenized hemoglobin), Hb are those hemoglobins which release oxygen.

2. Principle of Measurement

Based on Lamber-Beer law, the light absorbance of a given substance is directly proportional with its density or concentration. When the light with certain wavelength emits on human tissue, the measured intensity of light after absorption, reflecting and attenuation in tissue can reflect the structure character of the tissue by which the light passes. Due to that oxygenated hemoglobin (HbO_2) and deoxygenated hemoglobin (Hb) have different absorption character in the spectrum range from red to infrared light (600nm~1000nm wavelength), by using these characteristics, SpO_2 can be determined. SpO_2 measured by this oximeter is the functional oxygen saturation - a percentage of the hemoglobin that can transport oxygen.

In contrast, hemoximeters report fractional oxygen saturation - a percentage of all measured hemoglobin, including dysfunctional hemoglobin, such as carboxyhemoglobin or metahemoglobin.

Clinical application of pulse oximeters: SpO_2 is an important physiological parameter to reflect the respiration and ventilation function, so SpO_2 monitoring used in treatment has become more popular. (For example, such as monitoring patients with serious respiratory disease, patients under anesthesia during operation and premature and neonatal infants) The status of SpO_2 can be determined in timely manner by measurement and will allow finding the hypoxemia patient earlier, thereby preventing or reducing accidental death caused by hypoxia effectively.

3. Factors affecting SpO_2 measuring accuracy (interference reason)

- Intravascular dyes such as indocyanine green or methylene blue.
- Exposure to excessive illumination, such as surgical lamps, bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight.
- Vascular dyes or external used color-up product such as nail enamel or color skin care.
- Excessive patient movement.
- Placement of a sensor on an extremity with a blood pressure cuff,

arterial catheter, or intravascular line.
- Exposure to the chamber with High pressure oxygen.
- There is an arterial occlusion proximal to the sensor.
- Blood vessel contraction caused by peripheral vessel hyperkinesias or body temperature decreasing.

4. Factors causing low SpO_2 Measuring value (pathology reason)

- Hypoxemia disease, functional lack of HbO_2.
- Pigmentation or abnormal oxyhemoglobin level.
- Abnormal oxyhemoglobin variation.
- Methemoglobin disease.
- Sulfhemoglobinemia or arterial occlusion exists near sensor.
- Obvious venous pulsations.
- Peripheral arterial pulsation becomes weak.
- Peripheral blood supply is not enough.

2.5 Caution

A. The finger should be placed properly (see the attached illustration of this manual), or else it may cause inaccurate measurement.
B. The SpO_2 sensor and photoelectric receiving tube should be arranged in a way with the subject's arteriole in a position there between.
C. The SpO_2 sensor should not be used at a location or limb tied with arterial canal or blood pressure cuff or receiving intravenous injection.
D. Do not fix the SpO_2 sensor with adhesive or else it may result in venous pulsation and inaccurate measure of SpO_2.
E. Make sure the optical path is free from any optical obstacles like rubberized fabric.
F. Excessive ambient light may affect the measuring result. It includes fluorescent lamp, dual ruby light, infrared heater, direct sunlight and etc.
G. Strenuous action of the subject or extreme electrosurgical interference may also affect the accuracy.
H. Testee can not use enamel or other makeup on the finger.

3. TECHNICAL SPECIFICATIONS

A. Display mode: OLED Display

B. Power supply requirement:
1.5V (AAA size) alkaline battery x 2
Battery voltage: 3VDC

C. Operating current: <50mA

D. SpO_2 Parameter Specifications:
Measuring range: 35%~100%
Accuracy: ≤3% (during 70% - 100%)

E. Pulse Rate Parameter Specifications:
Measuring range: 30bpm - 240bpm
Accuracy: ±2bpm or ±2% (which ever is greater)
Pulse Rate alarm: Upper limit: 120bpm
Lower limit: 50bpm

F. Blood Perfusion Parameter Specifications:
Measuring range: 0%~20%

G. The performance under low perfusion condition
The accuracy of SpO_2 and PR measurement still meets the specification described above when the modulation amplitude is as low as 0.6%.

H. Resistance to ambient light interference:
The accuracy of SpO_2 and PR measurement still meets the specification described above when the device is tested by SpO_2 simulator (Fluke Biomedical Index 2 series) while setting the emulating interference of sun light and 50Hz/60Hz fluorescent light.

I. Dimensions: 66 mm (L) x 36 mm (W) x 33 mm (H)
Net Weight: 60g (including batteries)

J. Classification:
The type of protection against electric shock: Internally powered equipment.
The degree of protection against electric shock: Type BF equipment.
The degree of protection against harmful ingress of water: Ordinary equipment without protection against ingress of water.
Electro-Magnetic Compatibility: Group I, Class B

4. ACCESSORIES

A. A hanging cord
B. Two batteries
C. A pouch
D. A User Manual

5. INSTALLATION

5.1. Front view

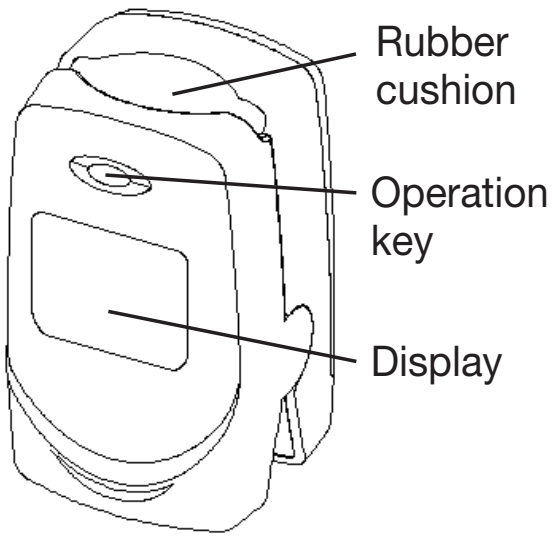


Figure 1

5.2. Rear view

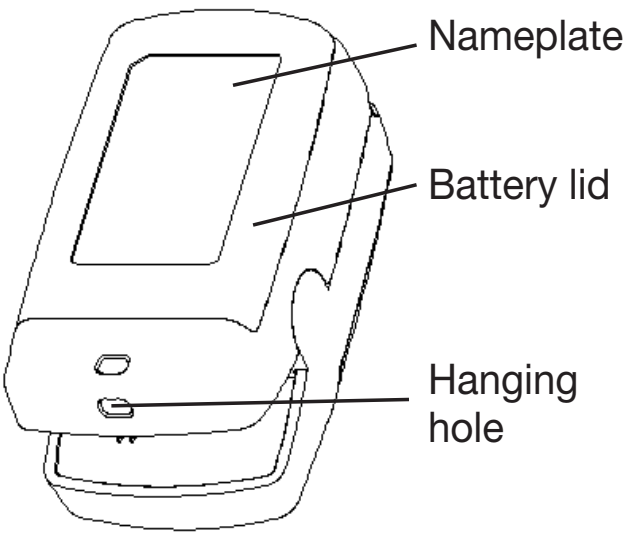
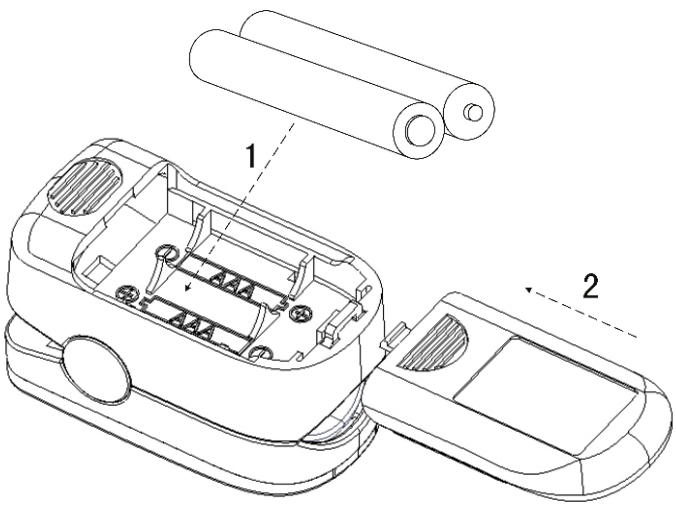


Figure 2

5.3. Battery

Refer to the figure, and insert the two AAA size batteries properly in the right direction.
Replace the cover.

- Please take care when you insert the batteries for the improper insertion may damage the device.



6. OPERATION

1. Open the clip as shown in Figure 3.

Figure 3 Put Finger into the Oximeter

2. Put finger into the rubber cushions of the clip (make sure the finger is in the right position), and then clip the finger.
3. The device will power on automatically in 2 seconds, and start to display software version number.
4. Next enter into data display screen (as shown in Figure 4). User can read the values and view the waveform from display screen.
   "**%SpO2**": SpO2 symbol; "**99**": SpO2 value;
   "**PR**": Pulse rate icon; "**65**": Pulse rate value;
   " ♥ ": Pulse beat symbol;
   " ▌ ":Pulse intensity histogram

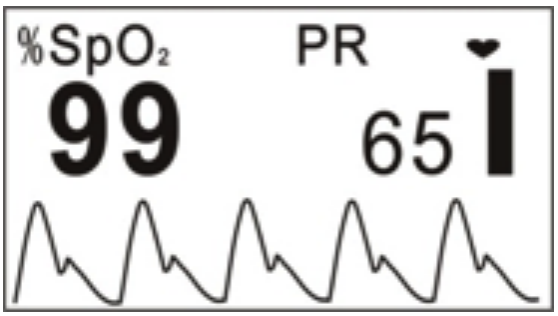


Figure 4

5. When the display is shown as Figure 4, press Display Key to switch display screen:
   - Press Display Key once, display screen (as shown in Figure 4) will be flipped 180°.
   - Press Display Key twice, display screen will be changed as Figure 5.

- Press Display Key three times, display screen (as shown in Figure 5) will be flipped 180°.
- Press Display Key four times, display screen will back to the screen as shown in Figure 4.
- Press Display Key circularly, display screen will be switched between the two screens (as shown in Figure 4 and Figure 5), and four directions display alternately.

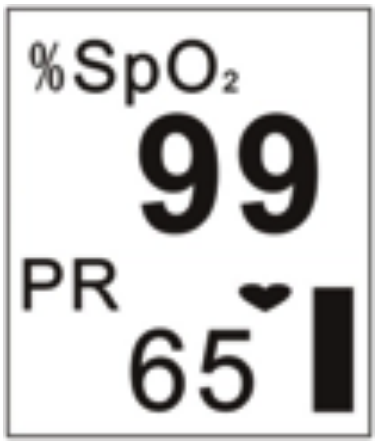


Figure 5

6. Longtime press Display Key (about 2 seconds), display screen will be shown as Figure 6. Differences between Figure 6 and Figure 4 are as follows:
   - In Figure 4, SpO2 and pulse rate are being monitored and displayed on the screen.
   - In Figure 6, SpO2 and perfusion index are being monitored and displayed on the screen.

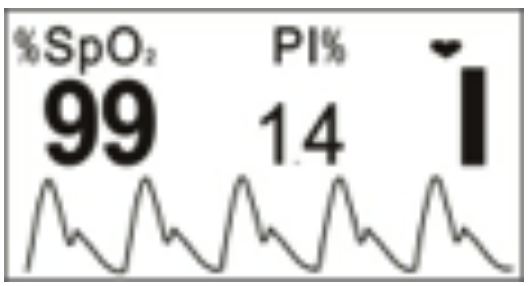


Figure 6

7. When the screen displays as shown in Figure 6, press Display Key circularly, the display screen will be switched between the two screens (as shown in Figure 6 and Figure 7), and four directions display alternately.

8. Display screen (as shown in Figure 6 or Figure 7) will return to the screen as shown in Figure 4 or Figure 5 if without operation in 10 seconds.

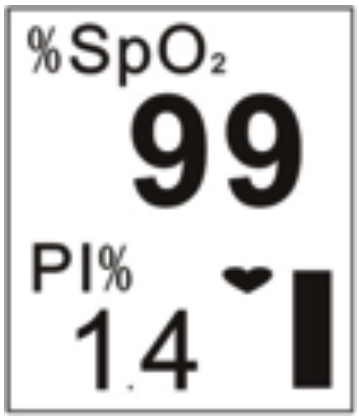


Figure 7

9. Alarm Indicator
When measuring, if SpO2 value and pulse rate value exceeds the preset alarm limits, the device will alarm automatically and the value on the screen exceeding limit will blink; at this time press Display Key to shut down the alarm. Exceeding pulse rate alarm limit: sound twice as an interval;
Preset alarm range:
SpO2 alarm: Low limit: 90%
Pulse Rate alarm: High limit 120bpm - Low limit: 50bpm.

7. REPAIR AND MAINTENANCE

A. Please change the batteries when the low-voltage indicator lightens.
B. Please clean the surface of the device before using. Wipe the device with alcohol first, and then let it dry in air or wipe it dry.
C. Please take out the batteries if the oximeter will not be used for a long time.
D. The best storage environment of the device is -20ºC to 55ºC ambient temperature and less than 95% relative humidity.
The expected useful life (not guaranteed) of this device is 5 years.

High-pressure sterilization cannot be used on the device.
Do not immerse the device in liquid.
It is recommended that the device should be kept in a dry environment. Humidity may reduce the useful life of the device, or even damage it.

Cleaning and Disinfecting Instruction

Surface-clean sensor with a soft cloth damped with a solution such as 75% isopropyl alcohol, if low-level disinfection is required, use a mild bleach solution.

Then surface-clean by soft cloth damped ONLY with clean water and let air dry or wipe it dry.

Caution: Do not sterilize by irradiation steam, or ethylene oxide.

Do not use the Pulse Oximeter if it is damaged visually.

8. TROUBLESHOOTING

Trouble	Possible Reason	Solution
The SpO_2 and Pulse Rate display instable.	1. The finger is not placed inside enough. 2. The finger is shaking or the patient is moving	1. Place the finger properly and try again. 2. Let the patient keep calm.
The device can not turn on.	1. The batteries are drained or almost drained. 2. The batteries are not inserted properly. 3. The device's malfunction.	1. Change batteries. 2. Reinstall batteries. 3. Please contact the local service center.
The indicator light is off suddenly.	1. The device will power off automatically when it gets no signal for 8 seconds. 2. The batteries are almost drained.	1. Normal. 2. Change batteries.

Declaration of Conformity:
The manufacturer hereby declares that this device complies with the following standards:
-IEC 60601-1:2005+A1: 2012,
-IEC60601-1-2:2014,
-IEC60601-1-11:2010, ISO 80601-2-61:2011 and follows the provisions of the council directive MDD93/42/EEC.

9. KEY OF SYMBOLS

Symbol	Description	Symbol	Description
	Type BF applied part		WEEE
	Read instructions carefully		Keep away from sunlight
	Please read instructions carefully		Keep in a cool, dry place
%SpO2	The pulse oxygen saturation	CE	Product complies with European Directive
PI	Perfusion Index	REF	Product code
hpm	Pulse rate (beats per minute)	LOT	Lot number (see box / package)
	Low battery voltage		Manufacturer
SN	Serial number		Date of manufacture

***Disposal**: The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment. For further information on recycling points contact the local authorities, the local recycling center or the shop where the product was purchased. If the equipment is not disposed of correctly, fines or penalties may be applied in accordance with the national legislation and regulations.*

GIMA WARRANTY CONDITIONS

Congratulations for purchasing a GIMA product. This product meets high qualitative standards both as regards the material and the production.
The warranty is valid for 12 months from the date of supply of GIMA.
During the period of validity of the warranty, GIMA will repair and/or replace free of charge all the defected parts due to production reasons.
Labor costs and personnel traveling expenses and packaging not included.
All components subject to wear are not included in the warranty.
The repair or replacement performed during the warranty period shall not extend the warranty. The warranty is void in the following cases: repairs performed by unauthorized personnel or with non-original spare parts, defects caused by negligence or incorrect use. GIMA cannot be held responsible for malfunctioning on electronic devices or software due to outside agents such as: voltage changes, electro-magnetic fields, radio interferences, etc. The warranty is void if the above regulations are not observed and if the serial code (if available) has been removed, cancelled or changed.
The defected products must be returned only to the dealer the product was purchased from. Products sent to GIMA will be rejected.

Guidance and manufacturer's declaration – electromagnetic emission

The Fingertip Oximeter is intended for use in the electromagnetic environments specified below, the customer or the user of the Fingertip Oximeter should assure that it is used in such an environment.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT GUIDANCE
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	N/A	N/A
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	N/A	N/A
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 cycle <40% U_T (60% dip in U_T) for 5 cycles <70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	N/A	N/A
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity

The Fingertip Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Fingertip Oximeter should assure that it is used in such an electromagnetic environment.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT GUIDANCE
Conducted RF IEC 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 Fingertip Oximeter, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80MHz to 800MHz $d = 2.3\sqrt{P}$ 800MHz to 2.5GHz 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).[b] 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 61000-4-3	3 V/m 80 MHz to 2.5 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 Fingertip Oximeter is used exceeds themapplicable RF compliance level above, the Fingertip Oximeter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.