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PROFESSIONAL MEDICAL PRODUCTS

OXY-10 PULSOXIMETRO
OXY-10 PULSE OXIMETER
OXY-10 OXYMÈTRE DE POULS
OXY-10 OXÍMETRO DE DEDO
OXY-10 OXÍMETRO DE DEDO
OXY-10 FINGERPULSOXIMETER
OXY-10 PULSOKSYMETR NAPALCOWY
OXY-10 ΟΞΥΜΕΤΡΟ ΔΑΚΤΥΛΟΥ
مقياس التأكسد عن طريق الاصبع *OXY-10*

Manuale d'uso - User manual - Manuel de l'utilisateur - Guía de Uso
Guia para utilização - Gebrauchsanweisung - Instrukcja obsługi
Οδηγίες χρήσης - *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.*
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*
ACHTUNG*: Die Bediener müssen vorher dieses Handbuch gelesen und verstanden haben, bevor sie das Produkt benutzen.*
UWAGA*: przed rozpoczęciem użytkowania wyrobu operatorzy muszą przeczytać podręcznik i upewnić się, iż wszystko to, co jest w nim napisane jest dla nich jasne i zrozumiałe.*
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 35095

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

CE 0476

M35095-M-Rev.2-01.19

Instructions to User

Dear Users,
Thank you very much for purchasing our product. Please read the manual very carefully before using this device. Failure to follow these instructions can cause measuring abnormality or damage to the oximeter.

We reserve the right to improve and amend it at any time without prior notice.
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.

Warnings

- Check the device to make sure that there is no visible damage that may affect user's safety or measurement performance with regard to sensors and clips. It is recommended that the device should be inspected minimally once a week. When there is obvious damage, stop using the device.
- Special attention should be paid while the oximeter is used continuously under the ambient temperature exceeds 37°C, burning hurt may occur because of over-heating on the sensor.
- An uncomfortable or painful feeling may appear if using the oximeter continuously on the same place for a long time, especially for poor microcirculation patients.
- It is recommended that the oximeter should not be applied to the same location for longer than 2 hours. If any abnormal condition is found, please change the position of oximeter.
- Avoid placing the device on the same limb which is wrapped with a cuff for blood pressure measurement or during venous infusion.
- DO NOT clip this device on edema or tender tissue.
- The light (the infrared light is invisible) emitted from the device is harmful to the eyes, so service technician or testee should not stare at the light.
- The oximeter is not a treatment device.
- When disposing of the monitor and its accessories, the local law should be followed.

Instructions for Operation

- The finger should be put in properly and correctly.
- Do not shake the finger. Keep at ease during measurement.
- Do not put wet finger directly into sensor.
- Avoid placing the device on the same limb which is wrapped with a cuff for blood pressure measurement or during venous infusion.
- Do not let anything block the emitting light from device.
- Vigorous exercise and electrosurgical device interference may affect the measuring accuracy.
- The orientation-sensor works on the basis of the gravity. A small movable metal ball is built in the orientation-sensor for detecting the orientation of the oximeter. When you want to change the oximeter's display direction, if you move the oximeter too slowly, the movable metal ball will also move slowly because of not enough acceleration. Consequently the response of orientation detection would be delayed. Please move the oximeter with a bit of force if you want to change the display direction (such as bend/extend your finger quickly), so an acceleration is provided to the orientation-sensor for quick sensing the orientation change.
- Using enamel or other makeup on the nail may affect the accuracy of measurement, too long fingernail may casue failure of measurement or unaccuracy measurement result.
- Keep the oximeter away from dust, vibration, corrosive substances, explosive materials, high temperature and moisture.
- Existence of high intensive light sources, such as fluorescence light, ruby lamb, infrared heater or strong sunshire, etc. may cause unaccuracy of measurement result. Please put an opaque cover on the sensor or change the measuring site.
- If the first reading appears with poor waveform (irregular or not smooth), then the reading is unlikely true, the more stable value is expected by waiting for a while, or a restart is needed when necessary.

Note: Due to the working principle of orientation sensor used in oximeter, there is a small metal ball which is movable within its compartment of the orientation-sensor. Therefore you can hear a slight "clatter" sound when you wave or shake the oximeter. It is normal and not caused by unwanted part.

Content

1. Overview

1.1 Appearance

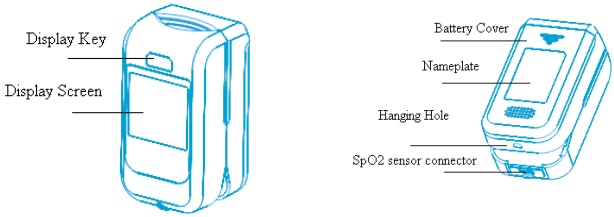

Figure 1 Front/Rear View

1.2 Name and Model

Name: Fingertip Oximeter
Model: OXY-10

1.3 Intended Use

This Fingertip Oximeter is intended for measuring the pulse rate and functional oxygen saturation (SpO_2) through patient's finger. It is applicable for spot-checking SpO_2 and pulse rate of adult and pediatric patients in homes and clinics.

1.4 Structure and Conformation

It consists of main unit and photoelectric sensor, and additional data upload connector.

1.5 Features

- Wireless data transmission can communicate with PC/mobile phone/PDA.
- External pediatric SpO_2 probe available
- Large true color OLED display of SpO_2, PR Pulse Bar, PI & Plethysmogram
- Automatic change display direction
- Automatic power on/off
- Audible & visible alarm function

- Pulse beep with pitch tone, pulse beep on/off and alarm limits can be set via setup menu.
- Shift parameter display between PR and PI
- 2AAA alkaline batteries with low power consumption
- Low battery voltage indication

2. Battery Installation

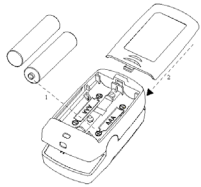

Figure 2 Battery Installation

1. Refer to Figure2, insert two AAA size batteries into the battery compartment properly.
2. Replace the cover.

⚠ Please make sure that the batteries are correctly installed, or incorrect installation may cause the device not to work.

3. Operation

3.1 Directly measurement

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 correct 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.

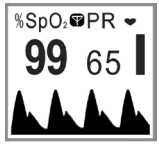

Figure4A

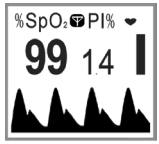

Figure4B

Screen Description:

- "**%SpO$_2$**": SpO$_2$ symbol; "**99**": SpO$_2$ value;
- "**PR**": Pulse rate icon; "**65**": Pulse rate value;
- "♥": Pulse beat symbol;
- "▮": Pulse intensity histogram.
- "**PI%**": Perfusion index icon; "1.4": Perfusion index value;
- "▽": Wireless symbol

☞ **Change display direction:**
Tilt the oximeter to change display direction. It is better for user to read value conveniently.

☞ **Shift parameter display between PR and PI during measurement:**
Short time press Display Key to shift the 4A and 4B. When shown as 4B. the display will shift 4A automatically after 20 seconds without operation.

☞ **Wireless icon "▽":**

The color of "▽"	**Definition**
"▽"displays gray	"Wireless" function is disabled
	The device fails to setup a wireless connection with the surrounding host.
"▽" flashes blue	The device is being to establish a wireless connection with the surrounding host.
"▽" long lights blue	Successful wireless connection between the device and a host is established.
No display "▽" icon	Hardware failure of wireless transmission function.

When the device fails to try establishing wireless connection within 3 minutes, the icon "" will become gray and the "Wireless" function is disabled automatically. You have to enable it next time manually.

Notes: The pulse beep has the pitch-tone feature (when SpO_2 value is higher than 90%), that means, the beeping tone changes according to the SpO_2 value.

3.2 Alarm and alarm silence

When measuring, if SpO_2 value or pulse rate value exceeds the preset alarm limit, the device will alarm automatically and the value which exceeds limit on the screen will flash. The detailed information refers to chapter 4.
Apply for belowed methods to relief alarm sound when alarm event happens:

1. When SpO_2 value and PR value get normally.
2. Press Display Key to mute. If this alarm event continues, the oximeter will resume alarm sound automatically 2 minutes later.
3. Remove the finger from the oximeter or SpO_2 probe.

3.3 Menu Screen

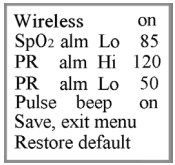

Figure 5 Menu Screen

Longtime press display key could enter the menu screen.

Menu screen description:

"**Wireless**": the wireless on-off button. Transmitting data to PC when it is on. "on" and "off" can be optional. The factory default is "on".
"**SpO_2 alm Lo**": SpO_2 alarm: Lower limit.The user can modify the value of 85~99, the step is "1", the default is 90.
"**PR alm Hi**": Pulse Rate alarm upper limit. The user can modify the value of 100~240, the step is "5", the default is 120.
"**PR alm Lo**": Pulse Rate alarm lower limit. The user can modify the value of 30~60, the step is "1", the default is 50.

"**Pulse beep**": Pulse beep button. When SpO_2 value (90~99) changes, the pitch tone changes accordingly.
"**Save, exit menu**": long time pressing this item to store and exit from the setup menu then enter the display screen.
"**Restore default**": Restore default setting. Refer to Figure 5 for each default value.

On setup menu screen:
1. Short time press Display Key to choose the setting item;
2. Longtime press Display Key to active the setting item, then short time press it to modify the setting parameter;
3. Next, longtime press Display Key to confirm the modification and exit from this setting item.
4. At last, move the setting item to "Save, exit menu", and long time pressing Display Key to store the modification and exit from the setup menu.

3.4 External SpO_2 Probe Connection

1. Connect the external SpO_2 probe to SpO_2 sensor connector in the following way. Make sure the side with "Arrow" faces upwards.

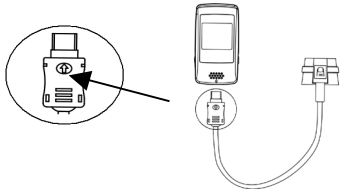

Figure 6 Probe Connection

Note: when the external SpO_2 probe is connected well, the built-in finger clip sensor will be disabled. The measurement is detected from the external SpO_2 probe.

2. The finger should be put in SpO_2 probe properly and correctly.
3. The oximeter will power on automatically 2 seconds later, then display software version number.
4. Other operation is similar to chapter 3.1 directly measurement.

3.5 Data transmission

This oximeter has the function of wireless data transmission. The user could effectively transmit the data to computer through the wireless communication module. Refer to the (Oximeter Data Manager) for detailed information.

4. Technical Specifications

A. Technique: dual-wavelength LED sensor,
LED sensor wavelength:
Red light: 663 nanometers,
Infrared light: 890 nanometers.
Maximal optical output power:
less than 1.5mW maximum average.

B. SpO_2 measurement
Measuring range: 70%~100%
Measuring accuracy:
not greater than 3% for SpO_2 range from 70% to 100%
Note: Accuracy defined as root-mean-square value of deviation according to ISO 9919.
SpO_2 alarm low limit range:
85%~99% (default 90%)

C. Pulse Rate measurement
Measuring range: 30bpm~240bpm
Measuring accuracy: ±2bpm or ±2% (whichever is greater)
Pulse Rate alarm range:
high limit: 100~240bpm (default 120bpm)
low limit: 30~60bpm (default 50bpm)

D. Perfusion Index (PI) Display
Range: 0.2%~20%

E. Audible &visual alarm function
When measuring, if SpO_2 value or pulse rate value exceeds the preset alarm limit, the device will alarm automatically and the value which exceeds limit on the screen will flash. The oximeter will shut down automatically in 8 seconds with no signal.

F. Display mode: Color OLED Display

G. Power supply requirement:
2 x LR03 (AAA) alkaline batteries
Supply voltage: 3.0VDC
Operating current: ≤40mA

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

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

J. Resistance to ambient light interference:
The accuracy of SpO2 and PR measurement still meets the specification described above when the device is tested by SpO2 simulator (Fluke Biomedical Index 2 series) while setting the emulating interference of sun light and 50Hz/60Hz fluorescent light.

K. Dimensions: 60 mm (L) × 33 mm (W) × 30 mm (H)
Net Weight: 35g (including battery)

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

5. Accessories

A. A lanyard
B. Two batteries
C. A pouch
D. An External SpO_2 Probe (optional)
E. A User Manual
F. Installation CD (optional)

Note: The accessories are subject to change. Detailed items and quantity see the Packing List.

6. Repair and Maintenance

6.1 Oximeter Maintenance

The service life (not a warranty) of this device is 5 years. In order to ensure its long service life, please pay attention to the use of maintenance.

- Please change the batteries when the low-voltage indicator lightens.
- Please clean the surface of the oximeter before use. Use soft cloth with alcohol to wipe the oximeter first, and then let it dry in air or wipe it dry.
- Please take out the batteries if the oximeter will not be used for a long time.
- The recommended storage environment of the device:
  ambient temperature: -20ºC~60ºC,
  relative humidity 10%~95%,
  atmospheric pressure: 50kPa~107.4kPa.
- The oximeter is calibrated in the factory before sale, there is no need to calibrate it during its life cycle. However, if it is necessary to verify its accuracy routinely, the user can do the verification by means of SpO_2 simulator, or it can be done by the local third party test house.
- Necessary servicing must be performed by qualified service engineers ONLY. Users are not permitted to maintain it by themselves.

⚠ **High-pressure sterilization cannot be used on the device.**
⚠ **Do not immerse the device in liquid.**

6.2 Battery Maintenance

- Keep the both sides of coin cell clean.
- Low temperature may decrease the performance of coin cell, and low battery indicator may appear early. In such case, please put coin cell into pocket for warm before use, thus bring it back to normal condition.
- Do not let any conductive metal (such as tweezers) contact both sides of coin cell simultaneously to avoid short circuit.
- Charge the coin cell for 8~10 hours each time; ambient temperature should be 5~40°C.
- If the coin cell is full after charging, but its performance decreases apparently, it means the coin cell is exhausted, please change a new one.

6.3 Cleaning and Disinfecting Instruction

- Surface-clean sensor with a soft cloth by wetting with a solution such as 75% isopropyl alcohol, if low-level disinfection is required, use a 1:10 bleach solution.
- Then surface-clean by soft cloth wet 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 sensor if it is damaged.

7. Troubleshooting

Trouble	Possible Reason	Solution
Display direction doesn't change or changes insensitively.	Maybe the oximeter is not used for a long time, the movable metal ball within the orientation-sensor can not move freely.	Please shake the oximeter with a certain force to make the movable metal ball move freely. If the problem still exists, maybe the orientation-sensor is not working properly. Please contact the local service center.
The SpO_2 and Pulse Rate display unstable	1. The finger is not placed far enough inside. 2. The finger is shaking or the patient is moving.	1. Place the finger correctly inside and try again. 2. Let the patient keep calm.
Can not turn on the device	1. The batteries are drained or almost drained. 2. The batteries are not inserted properly. 3. The device is malfunctioning.	1. Change batteries. 2. Reinstall batteries. 3. Please contact the local service center.
No display	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.
No display of the wireless icon ""	Hardware failure of wireless transmission function.	Please contact the local service center.

Appendix
A. Key of Symbols

Symbol	Description	Symbol	Description
	Type BF applied part		WEEE disposal
	Caution: read instructions (warnings) carefully		Keep away from sunlight
	Follow instructions for use		Keep in a cool, dry place
%SpO_2	The pulse oxygen saturation	CE	Medical Device complies with Directive 93/42/EEC
PR	Pulse rate (beats per minute)	REF	Product code
	Pulse rate icon	SN	Serial number
	Low battery voltage		Manufacturer
	Wireless		Date of manufacture

B. SpO_2 Common Knowledge
1. Meaning of SpO_2
SpO_2 is the saturation percentage of oxygen in the blood, so called O2 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:

$SpO_2 = HbO_2/ (HbO_2 + Hb) \times 100\%$

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

***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 manufacture'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 cycle <70% UU_T (30% dip in U_T) for 25 cycle <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	3A/m	3A/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 IEC61000-4-6	3Vrms 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 appli-cable to the frequency of the transmitter.
Radiated RF IEC61000-4-3	3V/m 80 MHz to 2.5 GHz	3V/m	**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: 

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.