GIMA

PROFESSIONAL MEDICAL PRODUCTS

PULSOXIMETRO PEDIATRICO OXY-0
OXY-0 PEDIATRIC OXIMETER
OXY-0 OXÍMETRO PEDIÁTRIC
OXY-0 PULSOXYMETER FÜR KINDER
OXY-0 PULSOKSYMETR PEDIATRYCZNY
OXY-0 ΠΑΙΔΙΑΤΡΙΚΟ ΟΞΥΜΕΤΡΟ

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.*

ATENCIÓN: *Los operadores tienen que leer y entender completamente este manual antes de utilizar el producto.*

VORSICHT: *Bediener müssen dieses Handbuch lesen und vollständig verstehen, bevor sie das Produkt verwenden.*

UWAGA: *Operatorzy muszą przeczytać iw pełni zrozumieć niniejszą instrukcję przed użyciem produktu.*

ΠΡΟΣΟΧΗ: *Οι χειριστές αυτού του προϊόντος πρέπει να διαβάσουν και να καταλάβουν πλήρως τις οδηγίες του εγχειριδίου πριν από την χρήση του.*

REF **CMS50Q1 (GIMA 35057)**

CE 0123

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Pulse Oximeter

CMS50Q1

Instructions to User

Dear Users, thank you very much for purchasing our product.

This Manual is written and compiled in accordance with the council directive MDD93/42/EEC for medical devices and harmonized standards. The Manual is written for the current Pulse Oximeter. In case of modifications and software upgrades, the information contained in this document is subject to change without notice.

The Manual describes, in accordance with the Pulse Oximeter's features and requirements, main structure, functions, specifications, correct methods for transportation, installation, usage, operation, repair, maintenance and storage, etc. as well as the safety procedures to protect both the user and equipment. Refer to the respective chapters for details.

Please read the Manual very carefully before using this equipment. These instructions describe the operating procedures to be followed strictly, failure to follow these instructions can cause measuring abnormality, 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.

Owing to the forthcoming renovation, the specific products you received may not be totally in accordance with the description of this User Manual. We would sincerely regret for that.

This product is medical device, and can be used repeatedly. Its using life is 3 years..

WARNING:

- The uncomfortable or painful feeling may appear if using the device ceaselessly, especially for the micro-circulation 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.
- Testee's fingernail can not be too long.
- Please peruse the relative content about the clinical restrictions and caution.
- This device is not intended for treatment.

Caution: Federal law restricts this device to sale by or on the order of a physician.

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 about cables and transducers. It is recommended that the device should be inspected once a week at least. When there is obvious damage, stop using the monitor.
- 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 devices not specified in User's Manual.Only the accessory that appointed or recommendatory by manufacture can be used with this device.
- This product is calibrated before leaving factory

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.
- The person who is allergic to rubber can not use this device.
- The disposal of scrap instrument and its accessories and packings(including battery, plastic bags, foams and paper boxes) should follow the local laws and regulations.
- Please check the packing before use to make sure the device and accessories are totally in accordance with the packing list, or else the device may have the possibility of working abnormally.
- Please don't measure this device with function test paper for the device's related information.

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 or humid environment, please do not use it immediately.
- DO NOT operate keys on front panel with sharp materials.
- High temperature or high pressure steam disinfection of the oximeter is not permitted. Refer to User Manual in the relative chapter for instructions of cleaning and disinfection.
- Do not have the oximeter immerged in liquid. When it needs cleaning, please wipe its surface with medical alcohol by soft material. Do not spray any liquid on the device directly.
- When cleaning the device with water, the temperature should be lower than 60°C.
- As to the fingers which are too thin or too cold, it would probably affect the normal measure of the patients' SpO2 and pulse rate, please clip the thick finger such as thumb and middle finger deeply enough into the probe.

- Do not use the device on infant or neonatal patients.
- The product is suitable for children (Weight should be between 10 kg to 40kg).
- Prevent children from swallowing the product or its accessories.For children users, please use the product under the condition of adult guardianship
- The device may not work for all patients. If you are unable to achieve stable readings, discontinue use.
- The update period of data is less than 5 seconds, which is changeable according to different individual pulse rate.
- The waveform is normalized.Please read the measured value when the waveform on screen is equably and steady-going, Here this measured value is optimal value. And the waveform at the moment is the standard one.
- If some abnormal conditions appear on the screen during test process, pull out the finger and reinsert to restore normal use.
- The device has normal useful life for three years since the first electrified use.
- The hanging rope attached the product is made from Non- allergy material, if particular group are sensitive to the hanging rope, stop using it. In addition, pay attention to the use of the hanging rope , do not wear it around the neck avoiding cause harm to the patient.
- The instrument dose not have low-voltage alarm function, it only shows the low-voltage.please change the battery when the battery energy is used out.
- When the parameter is particularly, The instrument dose not have alarm function.Do not use the device in situations where alarms are required.
- Batteries must be removed if the device is going to be stored for more than one month, or else batteries may leak.
- A flexible circuit connects the two parts of the device. Do not twist or pull on the connection.

1.4 Indication for Use

The Pulse Oximeter is a non-invasive device intended for the spot-check of saturation of arterial hemoglobin(-SpO2) and the pulse rate of children in home use environments.This device is not intended for continuous monitoring.The device can be multi-used.Pulse oximeter intended for wellness use.

2 Overview

The pulse oxygen saturation is the percentage of HbO2 in the total Hb in the blood, so-called the O2 concentration in the blood. It is an important bio-parameter for the respiration. For the purpose of measuring the SpO2 more easily and accurately, our company developed the Pulse Oximeter. At the same time, the device can measure the pulse rate simultaneously.

The Pulse Oximeter features in small volume, low power consumption, convenient operation and being portable. It is only necessary for patient to put one of his fingers into a fingertip photoelectric sensor for diagnosis, and a display screen will directly show measured value of Hemoglobin Saturation.

2.1 Classification

Class II b, (MDD93/42/EEC IX Rule 10)

2.2 Features

- SpO2 value display, Pulse rate value display, bar graph display, Pulse waveform display
- The display mode can be changed
- Screen brightness can be changed
- Power consumption of the product is low and the two originally equipped AAA batteries can be operated continuously for 20 hours.
- The product will enter standby mode when no signal is in the product within 5 seconds.

2.3 Major Applications and Scope of Application

The Pulse Oximeter can be used to measure human Hemoglobin Saturation and pulse rate through finger, and

indicate the pulse intensity by the bar-display. The product is suitable for use in family, hospital (Ordinary sickroom), Oxygen Bar, social medical organizations and also the measure of saturation oxygen and pulse rate.

⚠ The product is not suitable for use in continuous supervision for patients..

⚠ The problem of overrating would emerge when the patient is suffering from toxicosis which caused by carbon monoxide, the device is not recommended to be used under this circumstance.

2.4 Environment Requirements

Storage Environment

a) Temperature: -40°C ~ +60°C
b) Relative humidity: ≤95%
c) Atmospheric pressure: 500 hPa ~ 1060 hPa

Operating Environment

a) Temperature: 10°C ~ 40°C
b) Relative Humidity: ≤75%
c) Atmospheric pressure: 700 hPa ~ 1060 hPa

3 Principle and Caution

3.1 Principle of Measurement

Principle of the Oximeter is as follows: An experience formula of data process is established taking use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive Hemoglobin (Hb) and Oxyhemoglobin (HbO2) in glow & near-infrared zones. Operation principle of the instrument is: Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning & Recording Technology, so that two beams of different wavelength of lights can be focused onto human nail tip through perspective clamp finger-type sensor. Then measured signal can be obtained by a photosensitive element, information acquired through which will be shown on screen through treatment in electronic circuits and microprocessor

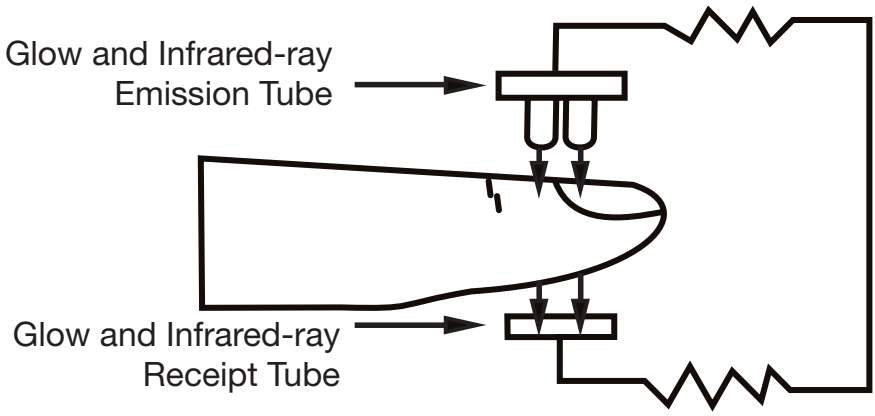


Figure 1 Operating principle

3.2 Precautions

1. The finger should be placed properly (see the attached illustration of this manual, Figure 5), or else it may cause inaccurate measurement.
2. The SpO2 sensor and photoelectric receiving tube should be arranged in a way with the subject's arteriole in a position there between.
3. The SpO2 sensor should not be used at a location or limb tied with arterial canal or blood pressure cuff or receiving intravenous injection.
4. Make sure the optical path is free from any optical obstacles like rubberized fabric.
5. Excessive ambient light may affect the measuring result. It includes fluorescent lamp, dual ruby light, infrared heater, direct sunlight and etc.
6. Strenuous action of the subject or extreme electrosurgical interference may also affect the accuracy.
7. Testee can not use enamel or other makeup.

3.3 Clinical Restrictions

1. As the measure is taken on the basis of arteriole pulse, substantial pulsating blood flow of subject is required. For a subject with weak pulse due to shock, low ambient/body temperature, major bleeding, or use of vascular contracting drug, the SpO2 waveform

(PLETH) will decrease. In this case, the measurement will be more sensitive to interference.
2. For those with a substantial amount of staining dilution drug (such as methylene blue, indigo green and acid indigo blue), or carbon monoxide hemoglobin (COHb), or methionine (Me+Hb) or thiosalicylic hemoglobin, and some with icterus problem, the SpO2 determination by this monitor may be inaccurate.
3. The drugs like dopamine, procaine, prilocaine, lidocaine and butacaine may also be a major factor blamed for serious error of SpO2 measure.
4. As the SpO2 value serves as a reference value for judgement of anemic anoxia and toxic anoxia, some patients with serious anemia may also report good SpO2 measurement.

4 Technical Specifications

1. Display Format: LCD Display; SpO2 Measuring Range: 0% ~ 100%; Pulse Rate Measuring Range: 30 bpm ~ 250 bpm; Pulse Wave Display: columniation display and the waveform display.
2. Power Requirements: 2×1.5 V AAA alkaline battery (or using the rechargeable battery instead),adaptable range: 2.6 V - 3.6 V.
3. Power Consumption: Smaller than 30 mA.
4. Resolution: 1% for SpO2 and 1 bpm for Pulse Rate.
5. Measurement Accuracy: ±2% in stage of 70% ~ 100% SpO2, and meaningless when stage being smaller than 70%. ±2 bpm during the pulse rate range of 30 bpm ~ 99 bpm and ±2% during the pulse rate range of 100 bpm ~ 250 bpm .
6. Measurement Performance in Weak Filling Condition: SpO2 and pulse rate can be shown correctly when pulse-filling ratio is 0.4%. SpO2 error is ±4%, pulse rate error is ± 2 bpm during the pulse rate range of 30 bpm ~ 99 bpm and ±2% during the pulse rate range of 100 bpm ~ 250 bpm .
7. Resistance to surrounding light: The deviation betwe-

en the value measured in the condition of man-made light or indoor natural light and that of darkroom is less than ±1%.

8. It is equipped with a function switch: The product will enter standby mode when no signal is in the product within 5 seconds.
9. Optical Sensor:
   Red light (wavelength is 660 nm, 6.65 mW) Infrared (wavelength is 880 nm, 6.75 mW)

5 Accessories

One hanging rope;
Two batteries(optional)
One User Manual.

6 Installation

6.1 View of the Front Panel

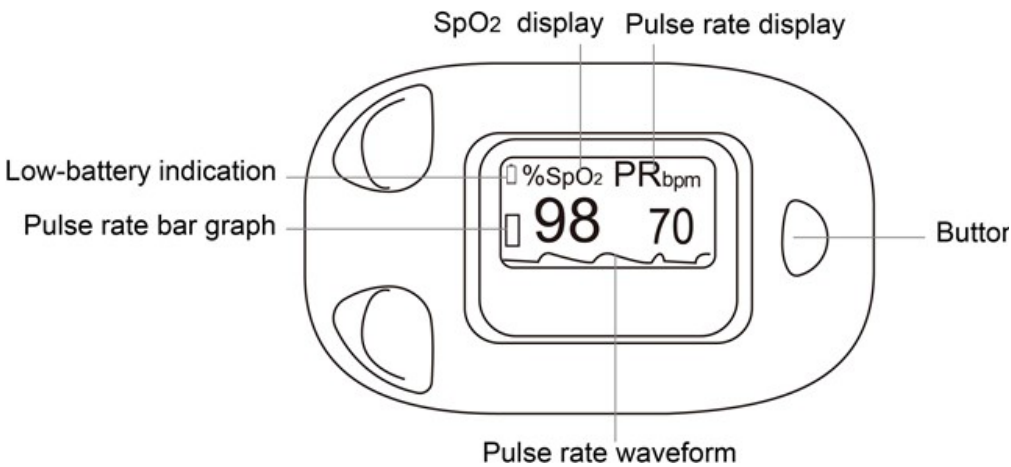


Figure 2 Front view

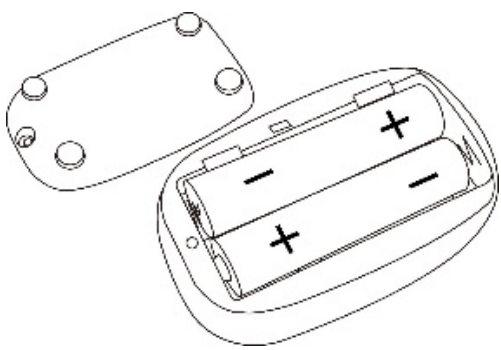


Figure 3 Batteries installation

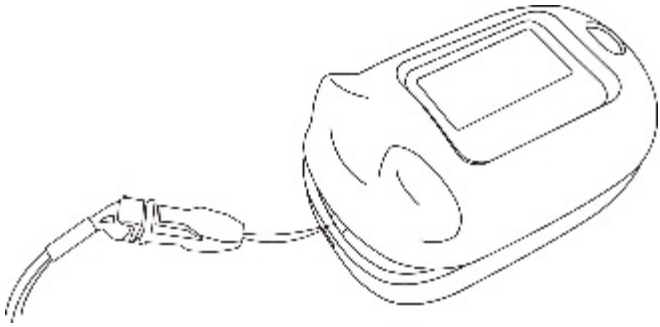


Figure 4 Mounting the hanging rope

6.2 Battery

Step 1. Refer to Figure 3. and insert the two AAA size batteries properly in the right direction.
Step 2. Replace the cover, turn the screw.

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

6.3 Mounting the Hanging Rope

Step 1. Put the end of the rope through the hole.
Step 2. Put another end of the rope through the first one and then tighten it..

7 Operating Guide

1) Insert the two batteries properly to the direction, and then replace the cover.
2) Open the clip as shown in Figure 5.

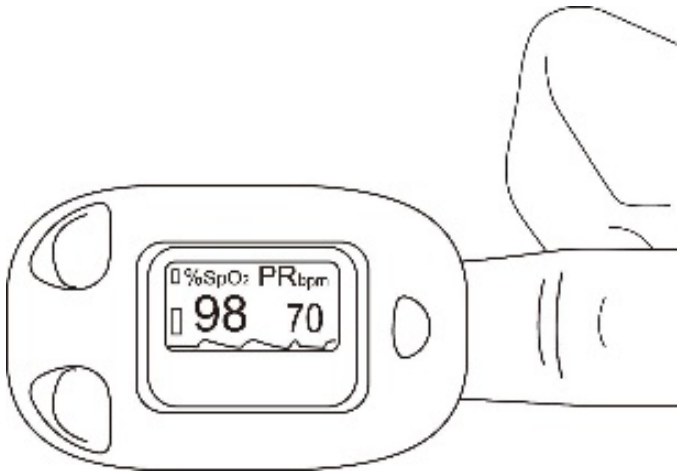


Figure 5 Put finger in position

3) Let the patient's finger put into the rubber cushions of the clip (make sure the finger is in the right position), and then clip the finger.
4) Press the button once on front panel.
5) Do not shake the finger and keep the patient at ease during the process. Meanwhile, human body is not recommended in movement status.
6) Get the information directly from screen display.
7) The button has two functions.When the device is in standby mode, pressing the button can exit it; When the device is in operation status, pressing the button long can change brightness of the screen.
8) The device could change display direction according to the handing direction.

⚠ Fingernails and the luminescent tube should be on the same side.

8 Repairing and Maintenance

- Please change the batteries when the low-voltage displayed on the screen.
- Please clean the surface of the device before using. Wipe the device with medical alcohol first, and then let it dry in air or clean it by dry clean fabric.
- Using the medical alcohol to disinfect the product after use, prevent from cross infection for next time use.
- Please take out the batteries if the oximeter is not in use for a long time.
- The best storage environment of the device is -40 ºC to 60 ºC ambient temperature and not higher than 95% relative humidity.
- Users are advised to calibrate the device termly (or according to the calibrating program of hospital). It also can be performed at the state-appointed agent or just contact us for calibration.

⚠ High-pressure sterilization cannot be used on the

device.

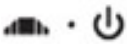
Do not immerse the device in liquid.

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.

9 Troubleshooting

Problem	Possible cause	Solution
The SpO2 and Pulse Rate can not be displayed normally	1. The finger is not properly positioned. 2. The patient's SpO2 is too low to be detected.	1. Place the finger properly and try again. 2. Try again; Go to a hospital for a diagnosis if you are sure the device works all right.
The SpO2 and Pulse Rate are not displayed stably	1. The finger is not placed inside deep 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 be turned on	1. The batteries are drained or almost drained. 2. The batteries are not inserted properly. 3. The malfunction of the device.	1. Change batteries. 2. Reinstall batteries. 3. Please contact the local service center.
The display is off suddenly.	1. The product will enter standby mode when no signal is in the product within 5 seconds 2. The batteries are almost drained.	1. Normal. 2. Change batteries

10 Key of Symbols

	Type BF applied part
	Follow instructions for use
%SpO2	The pulse oxygen saturation (%)
PR bpm	Pulse rate (bpm)
	The battery voltage indication is deficient (change the battery in time avoiding the inexact measure)
	1. No finger inserted 2. An indicator of signal inadequacy
	Battery positive electrode
	Battery cathode
	1. Change brightness of the screen. 2. Exit standby mode
SN	Serial number
	Alarm inhibit
	WEEE disposal
IP22	Covering Protection rate
CE	Medical Device complies with Directive 93/42/EEC
	Manufacturer
	Date of manufacture
	Temperature limit

	Humidity limit
	Atmospheric pressure limit
	This side up
	Fragile; maneggiare con cura
	Keep away from sunlight
	Keep away from sunlight
REF	Product code
LOT	Lot number
	Caution: read instructions (warnings) carefully
EC REP	Authorized representative in the European community

11 Function Specification

Display Information	Display Mode
The Pulse Oxygen Saturation (SpO2)	LCD
Pulse Rate (PR)	LCD
Pulse Intensity (bar-graph)	LCD bar-graph display
Pulse wave	LCD
SpO_2 Parameter Specification	
Measuring range	0% ~ 100%, (the resolution is 1%).

Measuring range	0% ~ 100%, (the resolution is 1%).
Accuracy	70% ~ 100%: ±2%, Below 70% unspecified.
Optical Sensor	Red light (wavelength is 660 nm) Infrared (wavelength is 880 nm)
Pulse Parameter Specification	
Measuring range	30 bpm ~ 250 bpm (the resolution is 1 bpm)
Accuracy	±2 bpm or ±2% select larger
Pulse Intensity	
Range	Continuous bar-graph display, the higher display indicate the stronger pulse.
Battery Requirement	
1.5 V (AAA size) alkaline batteries × 2 or rechargeable battery	
Battery Useful Life	
Two batteries can work continually for 20 hours	
Dimensions	59(L) × 37(W) × 35(H) mm
Weight	About 50g (with the batteries)

Appendix

Guidance and manufacture's declaration-electromagnetic emission
for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration –electromagnetic emission
The CMS50Q1 Pulse Oximeter is tended for use in the electromagnetic environment specified below. The customer of the user of the CMS50Q1 Pulse Oximeter should assure that it isused in such an environment.

Emission test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The CMS50Q1 Pulse Oximeter uses RF energy only for their internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The CMS50Q1 Pulse Oximeter is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emission IEC 61000-3-3	Not applicable	

Guidance and manufacture's declaration-electromagnetic immunity for all EQUIPMENT and SYSTEMS

The CMS50Q1 Pulse Oximeter is intended for use in the electromagnetic environment specified specified below. The the user of CMS50Q1 Pulse Oximeter should assure that it is used in such an environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6KV contact ±8KV air	±6KV contact ±8KV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.

Power frequency (50Hz) 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.

Guidance and manufacture's declaration-electromagnetic immunity for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacture's declaration-electromagnetic immunity			
The CMS50Q1 Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of CMS50Q1 Pulse Oximeter should assure that it is used in such an environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment -guidance

Radiated RF ICE 61000-4-3	3V/m 80MHz to 2.5GHz	3 V/m	Portable and mobile RF communication equipment should be used no closer to any part of the CMS50Q1 Pulse Oximeter, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. recommended separation distance $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80MHz to 800MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 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 meters (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: 

NOTE 1 At 80MHz and 800MHz, 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 broadcastcannot 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 CMS50Q1 Pulse Oximeter is used exceeds the applicable RF compliance level above, the CMS50Q1 Pulse Oximeter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the CMS50Q1 Pulse Oximeter. b. Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3V/m.

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM for EQUIPMENT or SYSTEM that not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the CMS50Q1 Pulse Oximeter
The CMS50Q1 Pulse Oximeter is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CMS50Q1 Pulse Oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CMS50Q1 Pulse 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 $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	800 MHz to 2,5 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0,12	0,12	0,23
0.1	0,37	0,37	0,74
1	1,17	1,17	2,33
10	3,69	3,69	7,38
100	11,67	11,67	23,33

For transmitters rated at a maximum output power not listed above, the recommended separation distanced in meters (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.

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

GIMA WARRANTY TERMS
The Gima 12-month standard B2B warranty applies