QOCA

Pulse Oximeter

Model : o2c

目錄

SAFEY NOTES

- QOCA pulse oximeter is to be used for clinical assessment only.
- QOCA pulse oximeter could be used by layperson. No race and skin color limited.
- QOCA pulse oximeter consists entirely of sophisticated medical electrical parts. Maintenance can only be carried out by professional technicians. Unauthorized disassembly of the device by the user is not allowed.
- Do not use the device in flammable anesthetics or flammable gas environments. Do not allow the connectors or contacts on the devices to come into contact with any kind of power source during use.
- Do not use the device with MRI / X-ray room /AED equipment together.
- Do not use on infant.

- Do not immerse the machine in liquids or expose the machine to extremely high humidity.
- Do not wash hands with probe on finger.
- QOCA pulse oximeter measurement will be influenced by environment, usage errors or patient conditions.
- It is recommended to use the index finger, middle finger and ring finger for measurement。 For long-term use, please change the use position every 4 hours, and check the patient's status regularly. Please avoid injury, disability, or other medical conditions that may cause abnormal test results。
- Keep still and stable during the measurement. Do not move or shake your body or hand so as not to affect the measurement。
- Avoid using QOCA PULST OXIMETER with the following conditions as these will affect the accuracy. Examples：contrast media, nail polish, artificial nails, anemia, weak pulse signal,

circulatory embarrassment, carboxyhemoglobin, oxyhemoglobin, abnormal environment light (overbright), low perfusion...etc.

- Please make sure that the indicator lights of the machine can be clearly identified in the operating environment。
- The measurement information cannot be provided in an error action.
- The device will automatically stop the measuring process when battery is out of energy. Please use the compatible model of charging cable and adaptor for battery charging.
- When the QOCA pulse oximeter is working, please avoid using any instruments or equipment that will affect measurement accuracy (eg, the sphygmomanometer will affect blood flow and cause incorrect measurement values).
- When QOCA pulse oximeter is working, please avoid using other electronic equipment nearby. If it must be used with other electronic equipment

at the same time, please confirm that the device still maintains the normal measuring operation.

- Do not replace or connect other batteries in device. This may cause the QOCA pulse oximeter to burst。
- Please avoid the environment of electromagnetic interference during measuring and avoid products that can cause electromagnetic interference (e.g., electric blankets).
- Please be careful of the device impact or fall.
- Do not clean the device with corrosive or abrasive cleaning agents.
- Pay attention to ensure that the device is not swallowed by pets or children.
- Do not expose device to extreme temperatures, extremely moist environments, dust, or direct sunlight.
- If SpO2 value is lower than 95% during the measuring, please contact a doctor for confirmation.

- A function tester cannot be used to assess the accuracy of a pulse oximeter device.
- Please consult with your doctor if you have any question about the measured SpO2 and pulse rate.
- Please do not use any other cables or accessories not approved by the manufacturer in this manual to avoid negative influence on electromagnetic compatibility.
- The portable RF communications equipment can affect medical electrical equipment. We recommend a safety distance no closer than 30 cm (12 inches) to any part of the QUOCA PULSE OXIMETER and at least 1 meter for sensitive equipment.
- The QOCA PULSE OXIMETER is to be used for clinical assessment and personal reference only.

PRODUCT OVERVIEW

Intended use

The QOCA Pulse Oximeter is a non-invasive device intended to do continuous or spot check of SpO2 and pulse rate measurement in non-motion status. The device is intended for use in hospitals, healthcare institutes, or home environments. It displays SpO2 and pulse rate on the dedicated software.

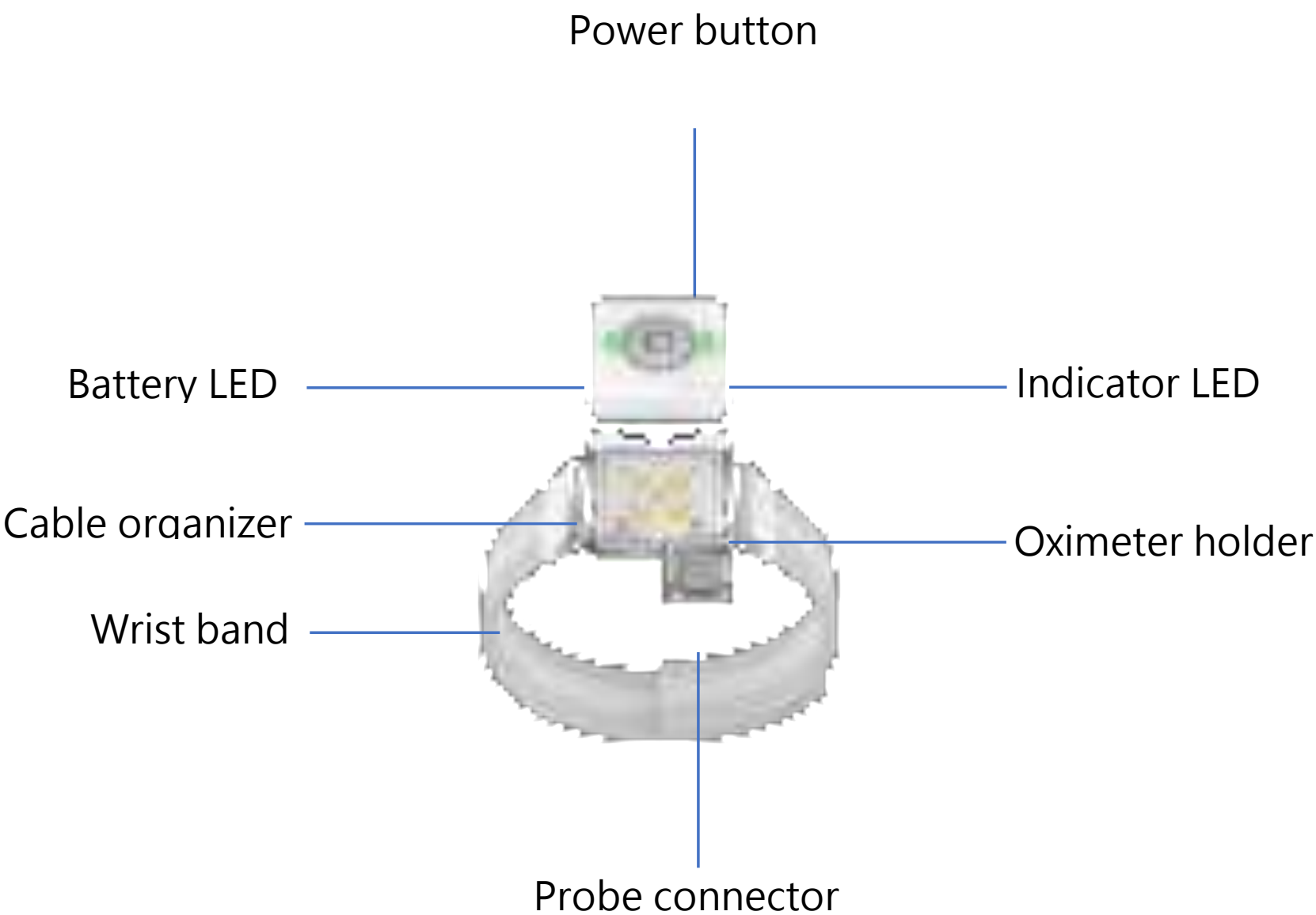
The device is intended for use on adult patients who are not in critical condition.

QOCA PULSE OXIMETER COMPONENTS

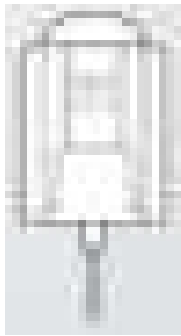
Component	Quantity
QOCA Pulse Oximeter (model: o2c)	1
QOCA Pulse Oximeter Holder (model: o2c-H1)	1
QOCA CHARGER (model: CR1)	1
USB charging cable	1
Glove probe Model: o2c-R1	1

Note: Components are sold and shipped seperately. Please contact the manufacture for purchase quantity.

QOCA Pulse Oximeter (model: o2c) and Holder (model: o2c-H1)



Glove probe (o2c-R1)



Charger (model: CR1)

USB Charging Cable

Product Requirement

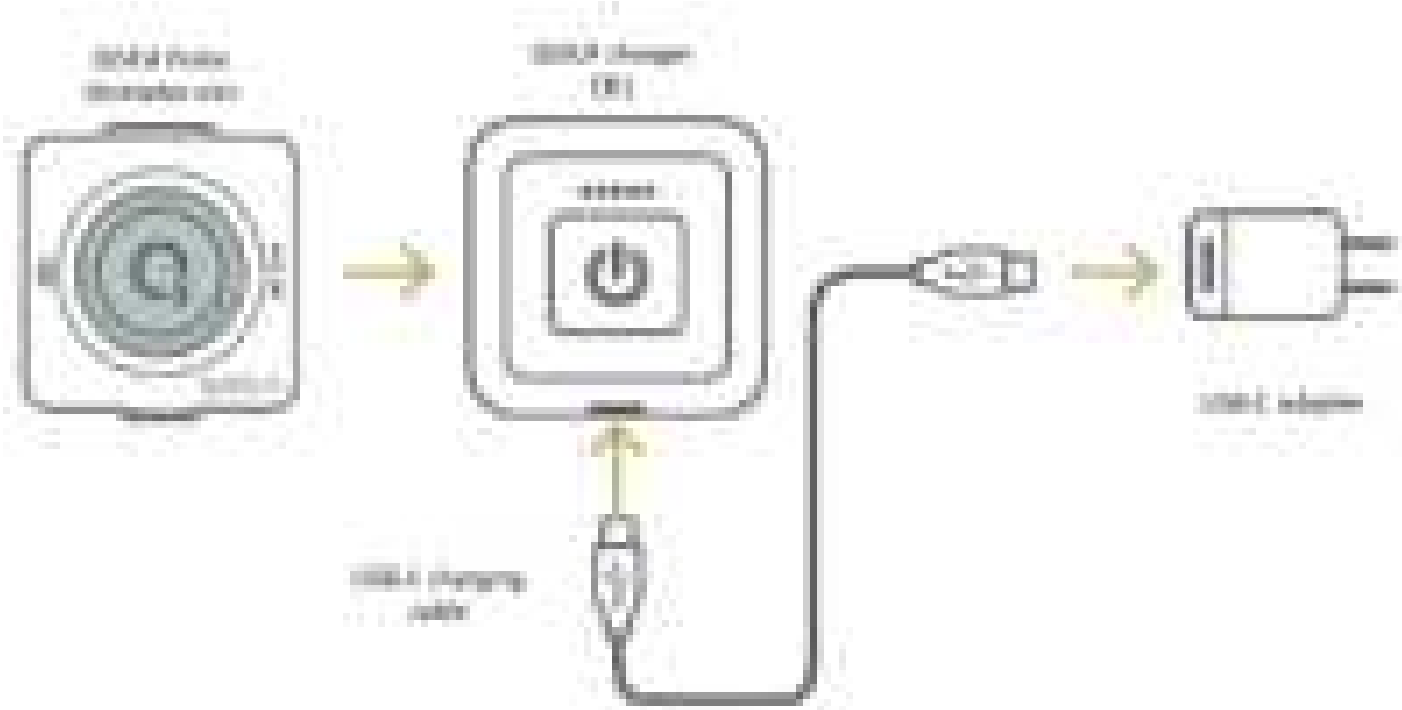
To use QOCA Pulse Oximeter, the following items should be prepared.

- QOCA Pulse Oximeter o2c
- QOCA Pulse Oximeter Holer o2c-H1
- Glove probe o2b-R1
- A Bluetooth-enabled Android Smartphone* (with Android version 10 or above, BT5.1 or above, and a display resolution of 1920x1080) or an iPhone* with iOS 13.0 (or above)
- The QOCA vital+ App*

** Items not included in the product package.*

HOW TO USE QOCA PULSE OXIMETER

BEFORE YOU START



1. Use an AC adapter conforming to standard IEC 60601-1 與 IEC 62368-1 class II) with a USB-C interface to connect the charger or connect the charger to PC by the provided USB-C cable. ***AC***

adaptor part is not included in the package. Please must use compatible AC adaptor.

2. Place the oximeter into the charger so that the oximeter snaps into the charger and the charging contacts on both the oximeter and charger make contact.
3. Allow the oximeter to charge for 3 hours until the charging indicator light shows solid green. This indicates that the battery is fully charged.
4. Download the QOCA vital+ App from Apple App Store or Google Play.
5. Enable the Bluetooth from you iPhone or Android phone Settings.
6. Bluetooth pairing procedure:

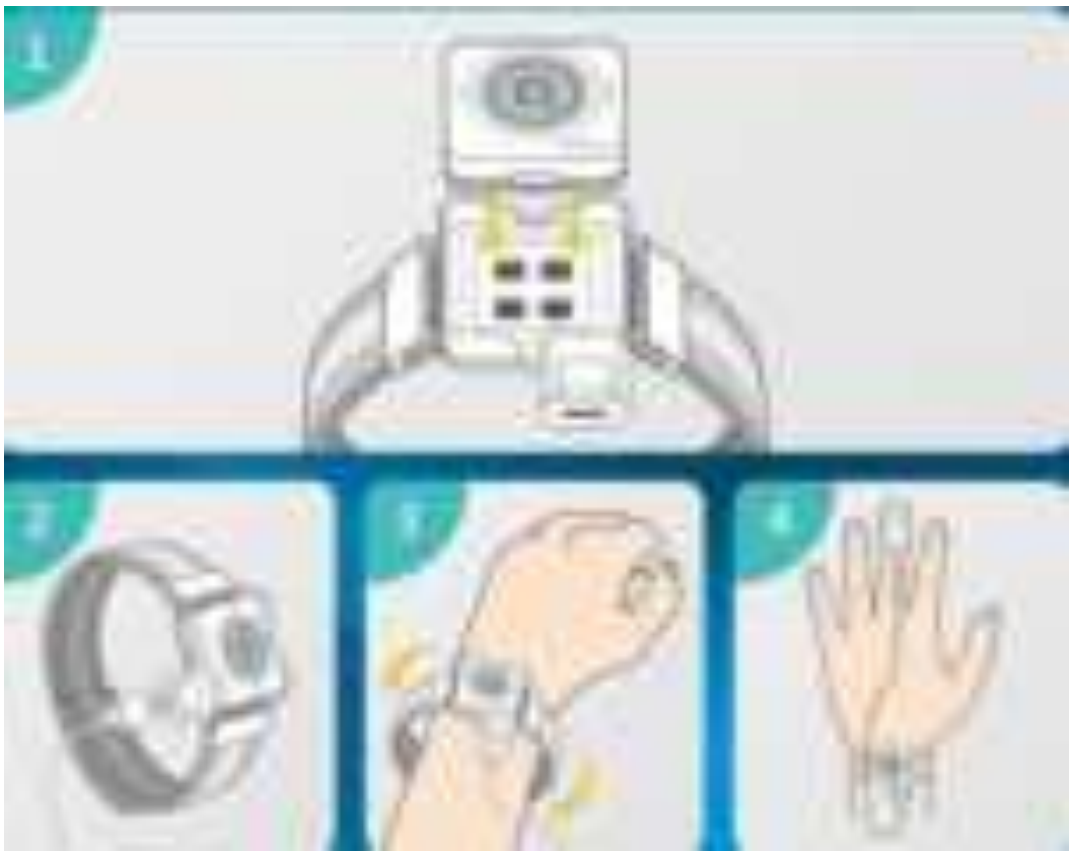
Step 1. Open the QOCA vital+ App and click “add new device”.

Step 2. Power on QOCA Pulse Oximeter and press the power button for 8 seconds to enter pairing mode.

Step 3. On the device list showed on the screen, click the serial number that matches the serial number on the

back of QOCA Pulse Oximeter (starts with MHRXS) and follow the instructions to complete pairing.

GETTING STARTED

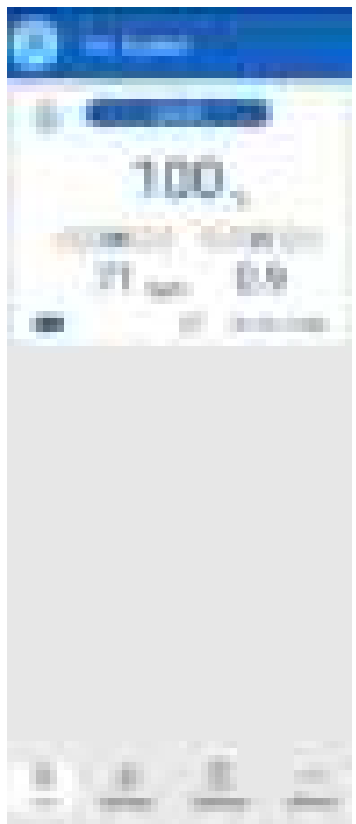


Step 1: Snap OQCA Pulse Oximeter onto the Holder.
Step 2: Connect glove probe to the Holder.
Step 3: Wear the Oximeter on the wrist.
Step 4: Place the finger into the glove probe with the QOCA logo on the top of the finger. The suggested fingers for wearing the probe are index finger, middle finger, and ring finger.

Step 5: Press the power button for 1 second to power on the QOCA Pule Oximeter to start the measurement. Keep the hand steady during the measurement. If the finger is not in the probe in 10 seconds after power on, the device will be turned off the save battery power.

QOCA VITA+

Main page



The main page shows the SpO2, pulse rate, and signal intensity.

Record

The record page shows all the measurement records in the past 30 days.

Device information

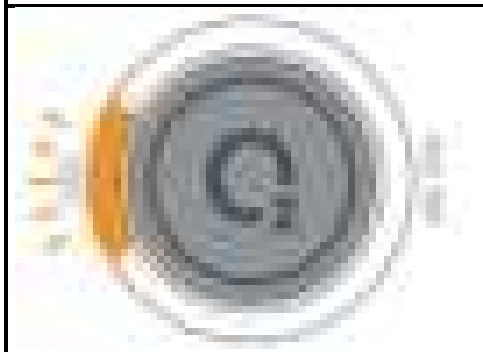
In the device information page, users can change the measurement interval and check firmware version.

Others

In this page users can set the warning threshold of SpO2 and pulse rate and also check the App version.

OTHER INFORMATION

LED Indicators

LED	Status
	Power on
	Low battery/charging Battery LED flashes orange

	Probe off Probe is disconnected or finger is not in the probe

Cleaning the oximeter and glove probe

- Power off QOCA Pulse Oximeter before cleaning
- Clean with wet cloth or alcohol pad.
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Storage condition

- Do not expose QOCA Pulse Oximeter to extreme temperatures, extremely moist environments,
- The storage condition for the QOCA pulse oximeter and the glove probe is -20degC to 60degC with relative humidity below 95% non-condensing.

Product Spec

Model o2c

Pulse Oximeter

Pulse rate range：30~240 bpm

Pulse rate accuracy：±3 or ±3 %

Functional Oxygen Saturation Range : 70~100%

Functional Oxygen Saturation Accuracy : ±3 %

Sampling Rate (Hz)：100Hz

Optical sensor

Red light (wavelength is 660nm), Infrared (wavelength is 905nm); Typical mV : 7mV

Connectivity

BLE 5.0

Bluetooth transmit distance：10 meters (Open space)

Battery

3.85V/350 mAh

Battery life

1.5 days with continuous measurement

Charging

Input：5V/0.5A

Operating temp / humidity

5 – 40℃, 10% – 95%

(non-condensing)

Storage temp / humidity

-20 – 60℃, 10% – 95%

(non-condensing)

Atmospheric pressure range

800 hPa to 1013 hPa

Altitude: 2,000 m

Ingress protection (for oximeter only) IP22, protection from ingression of particulates > 12.5mm and ingression from dripping water.

Oximeter dimension

30.7 x 30.7 x 9.4 ±0.2mm

(not including the holder and the wrist band)

Trouble shooting

Trouble	Possible cause	Solution
Cannot power on QOCA Pulse Oximeter	Low battery	Charge the battery
Cannot pair with QOCA vital+ App	Bluetooth is not enabled on the smartphone	Enable the Bluetooth on the smartphone.
	Pulse oximeter is not powered on or not in pairing mode.	Make sure the pulse oximeter is power on and enters Bluetooth paring mode (refer to pairing section of this manual)

QOCA vital+ shows “—” on SpO2 and pulse rate window	Finger is not detected(finger off)	Replace the finger in the right position in the probe.
	The ambient light is overly bright.	Avoid the finger to be exposed to direct strong light source.
	Patient is in low perfusion condition.	Heating or rubbing hands may increase blood perfusion.
	Bluetooth is disconnected	Reconnect the oximeter with QOCA vital+ by Bluetooth.
SpO2 and pulse rate reading are	Hands or body is moving.	Keep the hand and body still and stable.

not stable or accurate.	The probe is not properly worn.	Adjust the probe and finger placement.
	Patient is in low perfusion condition.	Heating or rubbing hands may increase blood perfusion.
Abnormal SpO2 and pulse rate reading	Electromagnetic interference	Leave the area with electromagnetic interference immediately.
	The patient’s hand is cold.	Heating or rubbing the hands to augment hand temperature.

	There is a foreign object on the applied finger.	Remove the foreign object.
	Hi/Lo/Er displayed	Adjust the finger in the probe.
	The SpO2 or pulse rate window background turns white and the oximeter vibrates.	The SpO2 or pulse rate exceeds the set limit. Unplug and re-plug the probe to resolve this and keep body and hand stable for measurement. If the problem remains, consult the medical

		personnel for medical advice.

Federal Communications Commission (FCC) Statement

The FCC ID is HFSMHR

15.21

You are cautioned that changes or modifications not expressly approved by the part responsible for compliance could void the user's authority to operate the equipment.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

1) This device may not cause interference and
2) This device must accept any interference, including interference that may cause undesired operation of the device.

15.105(b)

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.

- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

FCC RF Radiation Exposure Statement:

1) This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

For body worn operation, this device has been tested and meets FCC RF exposure guidelines. When used with an accessory that contains metal may not ensure compliance with FCC RF exposure guidelines

Regulatory Marks

The QOCA PULSE OXIMETER conforms to the following regulatory requirements.

Administrative Regulations on Low Power Radio Waves Radiated Devices (930322)

Article 12

Without permission granted by the NCC, any company, enterprise, or user is not allowed to change frequency, enhance transmitting power or alter original characteristic as well as performance to an approved low power radio-frequency devices.

Article 14

The low power radio-frequency devices shall not influence aircraft security and interfere with legal communications. If found, the user shall cease operation immediately until no interference is achieved.

The said legal communications means radio communications is operated in compliance with the Telecommunications Act. The low power radio-frequency devices must be susceptible with the interference from legal communications or ISM radio wave radiated devices.

Signs & Symbols

	Type BF applied part
	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself

	Indicates that the body sensor is classified as electrical or electronic equipment requiring proper disposal (WEEE Directive)
	Indicates the need for the user to consult the instructions for use.
IP22	Protected against solid objects down to 12mm.

	Protection against Dripping water when tilted at 15°

Supplier's Declaration

The QOCA PULSE OXIMETER conforms to the international EN 60601-1 and EN 60601-1-2 standards for electromagnetic compatibility with medical electrical devices and systems.

Manufacturer's declaration-electromagnetic emissions
The o2c is intended for use in the electromagnetic environment (for home and professional healthcare) specified below. The customer or the user of the o2c should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment-guidance (for home and professional healthcare environment)
RF emissions CISPR 11	Group 1	The o2c 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 emissions CISPR 11	Class B	The o2c 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	Class A	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Compliance	

Bluetooth Technical Specification:

Technical Specification	Value
Operating Frequencies	2402~2480MHz
Channel Spacing	2MHz
Channel number	40
Operating Voltage	1.8V
Modulation	GFSK

Antenna Gain	FPC Antenna, Peak Gain: -2.51 dBi
Rated Power (EIRP)	4.03dBm

Manufacturer's declaration-electromagnetic immunity

The o2c is intended for use in the electromagnetic environment (for home and professional healthcare) specified below.

The customer or the user of the o2c should assure that it is used in such an environment.

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment-guidance (for home and professional healthcare environment)**
Electrostatic **discharge** (ESD) IEC 61000-4-2	Contact:±8 kV Air±2 kV,±4 kV,±8 kV,±15 kV	Contact:±8 kV Air±2 kV,±4 kV,±8 kV,±15 kV	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	± 2kV for power supply lines ± 1kV for input/ output lines	± 2kV for power supply lines Not applic able	Mains power quality should be that of a typical home healthcare environment.
Surge IEC 61000-4-5	± 0.5kV, ±1kV line(s) to line(s) ± 0.5kV, ±1kV,± 2kV	± 0.5kV, ±1kV line(s) to line(s) Not	Mains power quality should be that of a typical home healthcare environment.

	line(s) to earth	applic able	
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage dips: 0 % *U*T; 0,5 cycle 0 % *U*T; 1 cycle 70 % *U*T; 25/30 cycles Voltage interruptions:	Voltage dips: 0 % *U*T; 0,5 cycle 0 % *U*T; 1 cycle 70 % *U*T; 25 cycles Voltage interruptions:	Mains power quality should be that of a typical home healthcare environment. If the user of the o2c requires continued operation during power mains interruptions, it is recommended that the o2c be powered from

	0 % *U*T; 250/300 cycle	0 % *U*T; 250 cycle	an uninterruptible power supply or a battery.
Power frequency(50, 60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz	The o2c power frequency magnetic fields should be at levels characteristic of a typical location in a

			typical home healthcare environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Manufacturer's declaration-electromagnetic immunity			
The o2c is intended for use in the electromagnetic environment (for home and professional healthcare) specified below. The customer or the user of the o2c should assure that it is used in such and environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment-guidance (for home and professional healthcare environment)**
Conducted RF	3 Vrms:	3 Vrms:	**Portable and mobile RF**

IEC 61000-4-6 Radiated RF	0,15 MHz – 80 MHz 6 Vrms: in ISM and amateur radio bands between 0,15 MHz and 80 MHz	0,15 MHz – 80 MHz 6 Vrms: in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	**communications equipment should be used no closer to any part of the** o2c including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

IEC 61000-4-3	and 80 MHz 80 % AM at 1 kHz 10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	**Recommended separation distance:** $d = 1,2 \sqrt{P}$ $d = 1,2 \sqrt{P}$ 80MHz to 800 MHz $d = 2,3 \sqrt{P}$ 800MHz to 2,7 GHz 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). Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Recommended separation distance between portable and mobile RF communications equipment and the o2c
The o2c is intended for use in an electromagnetic environment (for home and professional healthcare) in which radiated RF disturbances are controlled. The customer or the user of the o2c can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications

equipment (transmitters) and the o2c as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz d $=1,2\sqrt{P}$	**80 MHz to 800 MHz** d $=1,2\sqrt{P}$	**800 MHz to 2,7 GHz** d $=2,3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* 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.

NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Manufacturer's declaration-electromagnetic emissions

The o2c is intended for use in the electromagnetic environment (for home and professional healthcare) specified below. The customer or the user of the o2c should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment-guidance** **(for home and professional healthcare environment)**
RF emissions CISPR 11	Group 1	The o2c 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 emissions CISPR 11	Class B	The o2c 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
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Compliance	

		for domestic purposes.

Customer Supoprt

For additional technical information, contact Quanta Customer Support Department

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