



QOCA pulse oximeter

Model : o2a

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## CAUTION AND SAFETY 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.
- 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, so as not to affect the measurement ◦
- The following conditions will affect the accuracy of interpretation of result. Examples : contrast media 、 nail polish 、 artificial nails 、 anemia 、 weak pulse signal 、 circulatory

embarrassment 、 carboxyhemoglobin 、 oxyhemoglobin 、  
abnormal environment light 、 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 (eg, 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.
- Please use this product probe correctly to avoid injuring the fingers.
- A function tester cannot be used to assess the accuracy of a pulse oximeter device.
- Please check with doctor if you have any question about the measured SpO2 and pulse rate value data.



## PRODUCT OVERVIEW

### Indication for Use

QOCA pulse oximeter (wireless) is a fingertip and portable device intended for measuring functional oxygen saturation (SpO<sub>2</sub>) and pulse rate for adults. QOCA pulse oximeter device is a non-invasive measurement for continuous and spot check in homecare and professional caring environment. It is designed for during no-motion condition. The device should be worn on the index finger, middle finger or ring finger.

## PACKAGE CONTENT

QOCA pulse oximeter product package:

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List

QOCA pulse oximeter (Model: o2a)	1pcs
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Adaptor (Model: WB-10Q05FU)	1pcs
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User manual	1pcs
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Lanyard	1pcs
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QOCA power bank* (Model: o2a-c1)	
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QOCA power bank Type C cable*	
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QOCA SpO2 app*	
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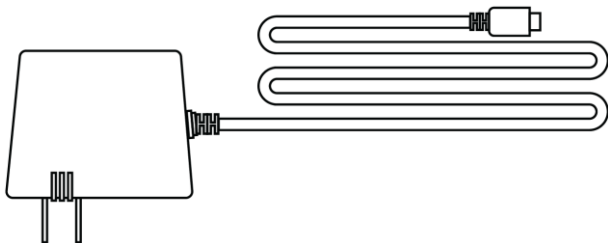
\* Indicates as an optional product

## Product components

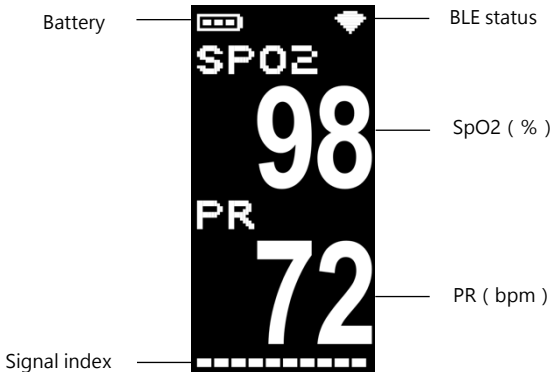
QOCA pulse oximeter (Model: o2a)



## Adaptor



## LCD display



## Product requirement

The following items are required before using :

- QOCA pulse oximeter
- Smart phone with Bluetooth function\*  
(Android version 9 or above; A display resolution of 1920x1080 or above)
- QOCA SpO2 APP\*

Notice:

Items not included in the product package

QOCA pulse oximeter could be operated without QOCA SpO2 APP

## PREPARATION

Please follow up item steps :

1. Charging pulse oximeter battery first
2. QOCA SpO2 APP installation on smartphone
3. Enable bluetooth function

Pulse oximeter charging notes :

Please use adaptor for device battery charging. The LED indicator will run orange color flashing. The LED indicator will run green color with full battery.

QOCA SpO2 APP :

Please turn on the bluetooth function of smart phone.

## Measurement Start

### Step1

Press power key button and turn on the device · The display will turn on when the device is ready. It will automatically shut down after 10 seconds without finger detecting.

### Step2

Put your finger into device rubber. Do not move during measurement.

### Step3

The measurement result will be displayed on the screen. According to the detected signal strength, the measured data will change accordingly. When the measurement of SpO<sub>2</sub> and PR is lower than warning setting, the LCD display will show highlight screen and trigger vibrator function until the condition is removed.



#### Step4

The pulse oximeter will automatically shut down after removing your finger for more than 10 seconds.

QOCA pulse oximeter LCD display



Screen after boot



Measuring screen

SpO2 Lo	Lower than SpO2 measurable value
PR Hi	Higher than PR measurable value
PR Lo	Lower than PR measurable value
SpO2 Highlight	Over the warning value setting
PR Highlight	Over the warning value setting
Er	Error measuring data
- -	No signal detection
Vibration	Function trigger when over warning value setting

## QOCA SpO2 APP

Bonding mode:

### Step1

Open the application details page and click "Pair pulse oximeter"

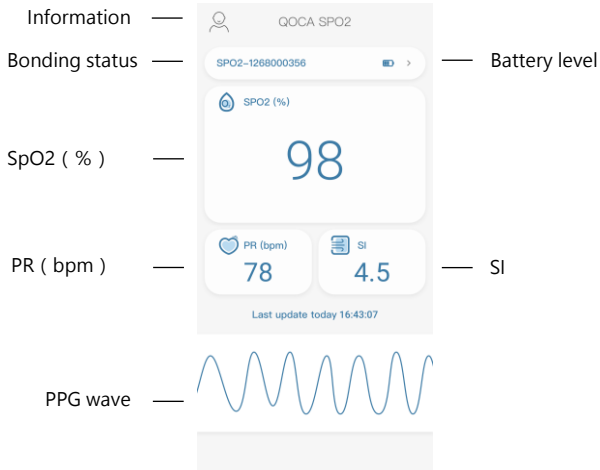
### Step2

Turn on the pulse oximeter first, then press and hold the power button for 3 seconds to enter pairing mode.

### Step3

On the "Connectable pulse oximeter" page of the app, click the serial number to pair, and confirm the pairing process after the app's instructions appearing.

QOCA SpO2 APP main page:



## Main page description:

Information	Setting
Bonding status	Paired pulse oximeter serial number
Battery level	Show battery level
SpO2 (Functional oxygen saturation)	Show range 70-100%
PR (Pulse rate)	Show range 30-240 bpm
SI (Signal index)	Show measuring signal strength
PPG wave	Show PPG wave

Information:

Device information	Pair and Repair device
Serial number	Paired serial number Cancel paired serial number
Battery level	Show battery level
Screen lightness	Adjust device screen lightness Low/Midium/High
SpO2 warning setting	Warning range 80-94%
High PR warning setting	Warning range 100-200 bpm
Low PR warning setting	Warning range 30-90 bpm
Measurement interval	Continous/1 minute/3 minutes/5 minutes
Device version	Device software version
App version	App software version

Notice: The device will enter power saving mode when measurement interval setting change to 1 minute/3 minutes/5 minutes

### **Data transmission**

1. The mobile phone needs to install the QOCA SpO2 app and activate bluetooth connection. The measurement results on pulse oximeter will be transmitted to mobile phone via Bluetooth transmission.

Attention: please make sure the connection between device and phone. The device must be connected with phone at bonding mode. (The outdoor wireless transmission distance is within 10 meters)

## Indicator

Event	Action	Light Indicator
Pulse oximeter power on	Press and hold the power button for 1 second	Flashing green light until power on is completed
Pulse oximeter power off	Automatic power off	No finger is detected for more than 10 seconds
Pulse oximeter low battery	none	Flashing orange light
Pulse oximeter charging	Adaptor or power bank plug in	Flashing orange light



pulse oximeter full battery	Adaptor or power bank plug in	Steady green light
Bonding mode	Press and hold the power button for 3 seconds after booting	Flashing blue light

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## INFORMATION

### Clean and Preservation

Clean :

- Turn off the device before cleaning.
- Clean the device and finger rubber with a water dampened cloth or neutral detergent in moderation. You could also use alcohol to clean. Please clean the device after use.
- Do not immerse the device in any liquid or water for cleaning.

Preservation :

- Do not place in direct sunlight or places with high temperature and humidity. The suitable storage environment is -20 degrees Celsius to 60 degrees Celsius, and the relative humidity is 10% to 95%.
- Do not drop the device and avoid collision.
- To avoid damage, do not disassemble the device.
- No need for device regular calibration

## Technical data

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Model

o2a

pulse oximeter

Pulse rate range : 30~240 bpm

Pulse rate accuracy :  $\pm 3$  or  $\pm 3$  %

Functional Oxygen Saturation Range :  
70~100%

Functional Oxygen Saturation Accuracy :  
 $\pm 3$  %

Sampling Rate (Hz) : 100Hz

Value refresh period : 1/ every second

Optical sensor

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

Connectivity	Bluetooth transmit distance : 10 meters (Open space)
Battery	Lithium battery; 3.8V/298 mAh
Battery life	Pulse oximeter continuous measuring 12 hours (BLE off)
Input	5V/0.16A
Working Temperature / Humidity	5 – 40°C, 10% – 95% (non-condensing)
Storage Temperature / Humidity	-20 – 60°C, 10% – 95% (non-condensing)
Atmospheric Pressure Range	800 hPa to 1013 hPa

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Altitude	2,000 m
IP Rating	IP22
Weight	30 ± 5g (Adaptor not included)
Dimension (mm)	60.8 x 26.8 x 24.5 ± 0.5mm
Standard	IEC/EN60601-1; IEC/EN60601-1-2 IEC/EN60601-1-11; ISO80601-2-61
Function tester	Fluke biomedical model : INDEX2LFE

For additional technical information, contact Quanta Customer Support Department.

Quanta Computer Inc. (QCI)

Address:

No. 188, Wenhua 2nd Rd.,  
Guishan Dist., Taoyuan City 333, Taiwan

TEL: +886-3-327-2345

FAX: +886-3-318-4207

Email: [MedicalService@quantatw.com](mailto:MedicalService@quantatw.com)

### Warranty

This instrument is covered by a 1 year guarantee from the date of purchase, batteries and accessories are not included. The guarantee does not cover damage, accidents or non-compliance with the instruction manual.

## Trouble shouting

Problem	Possible cause	Solution
pulse oximeter can't power on	Low power	Please charge battery
BLE or Bonding connectivity fail	Check phone bluetooth setting	Enable bluetooth function
	Device didn't power on	Please make sure the device is at power on status
SpO2 and PR data cannot be displayed	No finger input detected	Put your finger back in place
	Device bluetooth connection off	Please check whether the connection and pairing are working, then power on again

SpO2 and PR cannot be displayed stably	Trembling fingers or body movement	Keep fingers and body steady
	Improper finger placement	Put your finger back in place
No LCD display information	When no signal is detected, it will automatically power off	Please power on the device and then put your finger back in place
	Low battery	Please charge battery
	Enter power saving mode	Normal case. Press the power key button and the screen will light up briefly
	electromagnetic interference	Please stay away from the environment



Abnormal measurement results	Lower finger surface temperature	Please raise your finger temperature
	Foreign Influence on finger surface	Please remove foreign objects
	Hi/Lo/Er on screen	Put your finger back in place
	SpO2 and PR data are highlighted and vibration trigger	The set warning range is activated. Please exclude the situation

If the problems cannot be resolved, please contact the supplier or hospital for further information, and do not disassemble the device.

## **Federal Communications Commission (FCC) Statement**

### **The FCC ID is HFSMH7**

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 PORTABLE ECG MONITORING DEVICE 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 and Symbols

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Type BF applied part

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Caution

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Separate collection for electrical and electronic equipment (WEEE)

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Follow instructions for use

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IP22

Protected against solid foreign objects of 12.5 mm diameter and greater and protection against vertically falling water drops when enclosure is tilted at 15 degrees

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FCC ID

Identifies unit has been registered as a radio device

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No SpO2 Alarms

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Barcode\_ver.2A