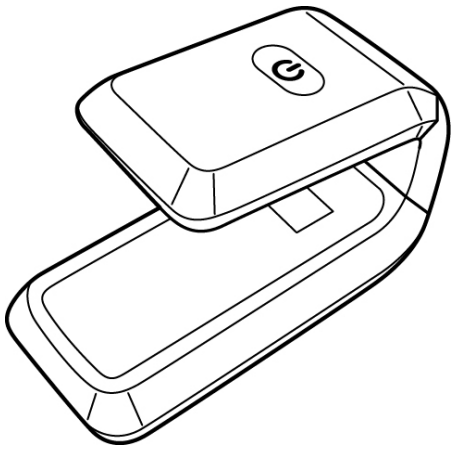
Quanta Pulse Oximeter

User Manual

Model: Q-spo-wu1



Contents

Safety Instructions

Read the *Safety Instructions* thoroughly before using this device. Failure to follow these instructions can cause measuring abnormality or device malfunction.

- The Quanta Pulse Oximeter is to be used for sleep assessment and personal reference only. The Quanta Pulse Oximeter is not intended for diagnostic use.
- The Quanta Pulse Oximeter consists entirely of sophisticated medical electrical parts so maintenance can only be carried out by professional technicians. Unauthorized disassembly of the device by the user is not allowed.
- Do not allow the metal connectors to come into contact with any kind of power source during use.
- When the Quanta Pulse Oximeter is low on power, it will automatically stop taking measurements and the corresponding indicator lights will blink. Please charge the sensor as soon as it shows a low battery state.
- When the Quanta Pulse Oximeter is taking measurements, please try and avoid using any instruments or devices that may affect the accuracy of the readings (e.g. the use of a blood pressure meter will affect the measurement of the pulse).
- The light (the infrared light is invisible) emitted from the device is harmful to the eyes, so service technician or user should not stare at the light.
- Do not clip Quanta Pulse Oximeter on edema or tender tissue.
- Do not use the Quanta Pulse Oximeter in a flammable environment.
- Quanta Pulse Oximeter is not a treatment device.
- Pay attention to ensure that the Quanta Pulse Oximeter is not swallowed by pets or children.
- Please read through this user manual carefully before using the Quanta Pulse Oximeter.
- If the Quanta Pulse Oximeter must be used to take measurements over an extended period of time, please inspect the contact point of the emitter and receiver that they are in the right position.
- When the Quanta Pulse Oximeter is taking measurements and a stable reading cannot be taken then stop taking measurements right away as not everyone is suitable to sensor using the Quanta Pulse Oximeter.
- The Quanta Pulse Oximeter can only take measurements when the subject is stationary (e.g. while sitting or lying down). Any activities not permitted by the attending physician may affect the accuracy of the measurements.
- Do not use the Quanta Pulse Oximeter in an excessively humid environment and never submerge it directly under water.
- Do not clean or wipe the Quanta Pulse Oximeter with corrosive and abrasive cleaning agents.
- The Quanta Pulse Oximeter has been tested and certified to international electro-magnetic compatibility (EMC) standards for medical equipment (EN 60601-1 and EN 60601-1-2).

- The Quanta Pulse Oximeter and its accessories should be disposed of properly.
- **Battery Caution:** There is a risk of explosion if the battery for the Quanta Pulse Oximeter is replaced by an incorrect type.
- The Quanta Pulse Oximeter is intended for adult use.
- Quanta Pulse Oximeter does not provide with a low SpO2 alarm condition or pulse rate physiological alarm condition.
- Quanta Pulse Oximeter does not support low perfusion detection.
- Clean the skin of Quanta Pulse Oximeter sensor and charger with 75% alcohol; and clean the finger sleeve in wash machine.
- If you wear Quanta Pulse Oximeter too long, it may cause uncomfortable by long time pressure. Please check if you have any on the finger every eight hours.
- Quanta Pulse Oximeter Sensor is a compact all-in-one design with Emitter / Receiver embedded inside. So that it doesn't have to verify the compliance of monitor, probe extenders and cable before use.
- Quanta Pulse Oximeter has been validated and tested for compliance with international standard ISO 80601-2-61.
- The self life of Quanta Pulse Oximeter is 2 years.
- Quanta Pulse Oximeter is calibrated to display functional oxygen saturation.
- The pulse rate accuracy is verified by the root-mean-square(rms) method which is the difference between pulse rate data recorded by Quanta Pulse Oximeter and with pulse rate data set by the SpO2 simulator.
- Do not use any unauthorized oximeter simulator to assess the accuracy of Quanta Pulse Oximeter. And if there has any question please contact Quanta Customer Support.
- The SpO2 accuracy validation, Quanta Pulse oximeter clinical trial was performed in accordance with ISO 80601-2-61 and FDA guidance. The study population is healthy volunteers who consent to induced hypoxia and arterial blood sampling more than 200 data points. Participated subjects is including Asian, Caucasian, African, Male, and Female. Their ages are from 21 to 50 years old. The statistically study result indicated that the SpO2 accuracy (±Arms) of Quanta Pulse Oximeter was less than ±3 % in the SpO2 range 70% ~100% complied with the accuracy requirement.
- When the finger sleeve is not viscous, or it is recommended to use finger sleeve for a month if it's used every day.

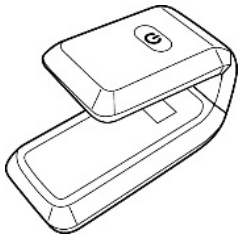
Introduction

Indication for Use

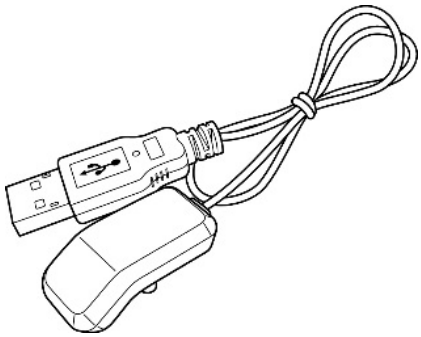
The Quanta Pulse oximeter is intended for use in the non-invasive measurement of patient blood oxygen (SpO2) and pulse rate in healthcare institute, and home environments. The Quanta Pulse oximeter will process SpO2 signals and calculate pulse rate. SpO2 value and pulse rate data will be transferred to a display device via Bluetooth, and further displayed on the display device screen with a dedicated App called Q-SPO2 APP. The device should be worn on the index finger, middle finger and ring finger along with a finger sleeve and it's for adult use only. The Quanta Pulse oximeter is sold to professional organizations such as home care givers, clinics, or trained patient rather than to the general public. Unauthorized installation by users is not allowed.

Package Contents

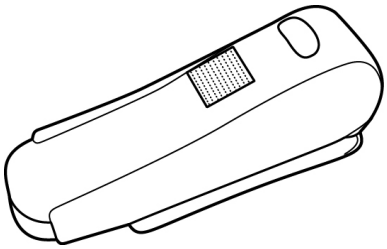
The following items come with your package. If any of the items is missing, please contact your dealer.



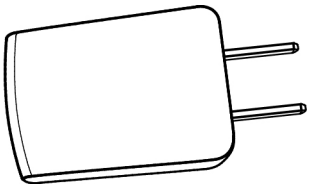
Pulse Oximeter



Charger



Finger Sleeve



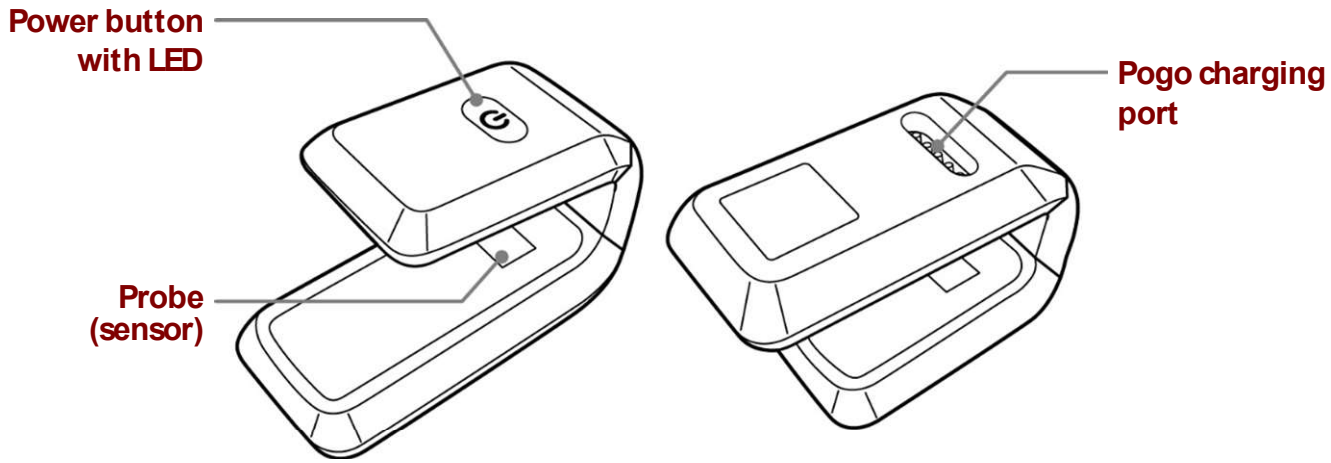
Adapter

User Manual

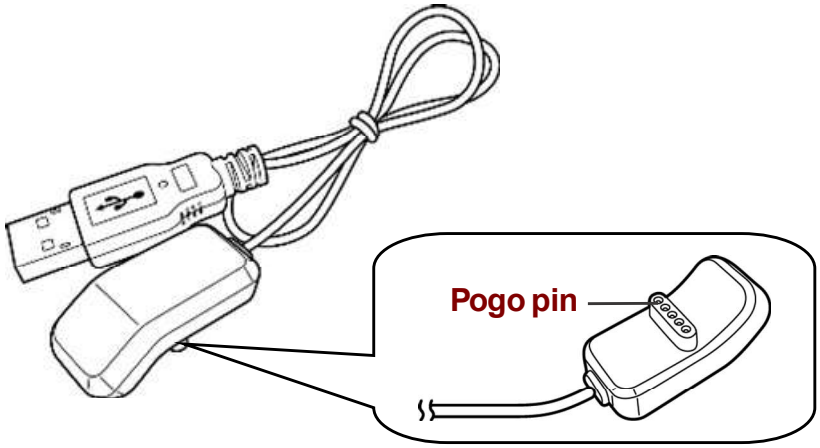
Adaptor: Manufacture by ASIAN POWER DEVICES INC.
Model No: WB-10G05FG
Input: 90-264V,47~63Hz
Output: 5V/2A

Product Overview

Pulse Oximeter



Charger



Product Requirements

In order to properly use the Quanta Pulse Oximeter the following items are required:

- The Qunata Pulse Oximeter Sensor
- Finger Sleeve
- A Bluetooth-enabled Android Smartphone* (with Android version 5.0 or above and a display resolution of 1920x1080 or 2560x1440)
- The Quanta Pulse Oximeter App Q-SPO2*.

* Items not included in the product package.

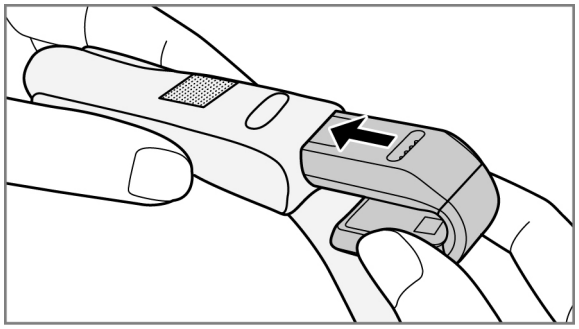
Getting Started

Fitting the Finger Sleeve

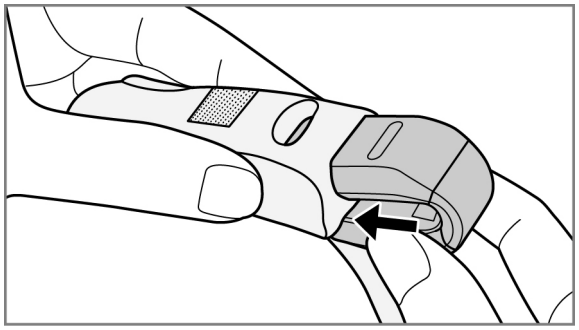
Before inserting the device into the finger sleeve, observe the openings on the finger sleeve.

To fit the finger sleeve, do the following:

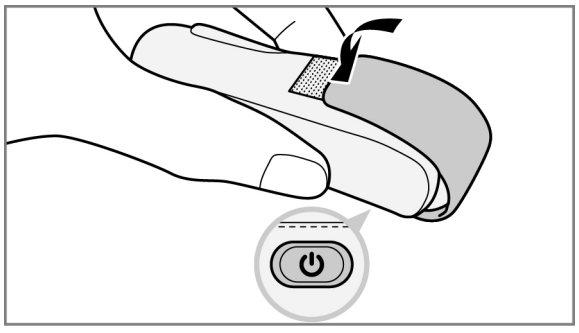
1. With the charging port is facing outwards, insert the bottom side of the device halfway into the bottom opening of the finger sleeve.



2. Insert the upper side of the device into the upper opening of the finger sleeve. Then push the device firmly into the finger sleeve until it fully seated.



3. Use the Velcro strip to fit the device snugly around the finger sleeve.

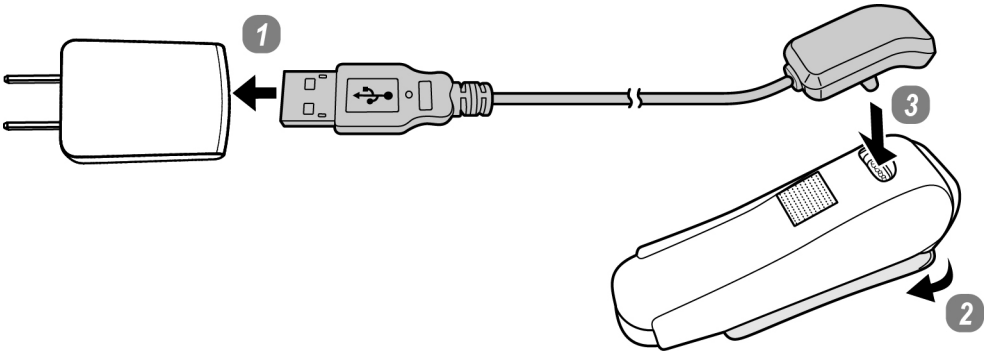


Charging the Device

It is recommended that you charge your device prior to first use. It takes approximately 1.5 hours to fully charge.

To charge the battery, do the following:

1. Connect the other end of the charger to the USB port of the adapter.
2. Detach the Velcro strip and flip it over to another side of the finger sleeve so that you can access the pogo charging port.
3. Align and attach the pogo pin of the charger with the charging port of the device.



4. Plug the adapter to a wall outlet.
   - The Power LED lights orange while the battery is charging.
   - Once the Power LED lights green, this indicates the battery is fully charged.

Note: *You can also directly charge the device before fitting it into the finger sleeve*.

Installing the APP

To obtain the readings from the device, you have to install **Q-SPO2** APP first on your smartphone.

1. Make sure your smartphone is connected to the Internet.
2. Launch ***Google Play Store*** application and search for **Q-SPO2** APP.
3. Follow the on-screen instructions to download and install **Q-SPO2** APP on your smartphone.

Note: *In order to install the Q-SPO2 app your smartphone will need at least 8MB of storage capacity available.*

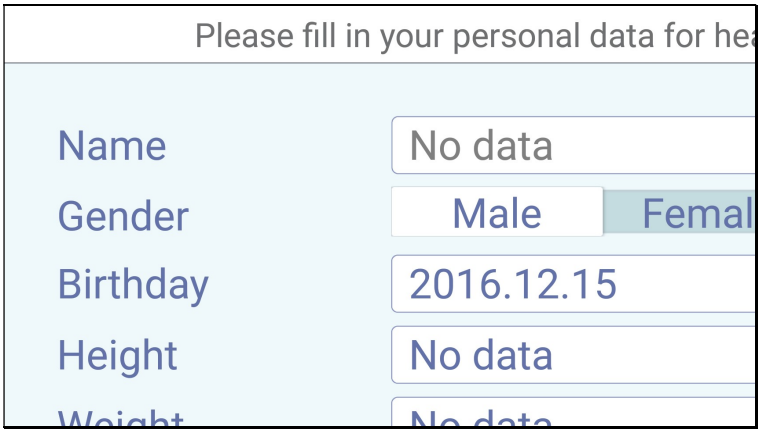
.

Creating User Profile

The first time you launch **Q-SPO2** APP, you will be prompted to create a user profile.

1. Launch **Q-SPO2** APP ( ). The welcome screen appears.

2. Enter your personal data into the required entry fields.

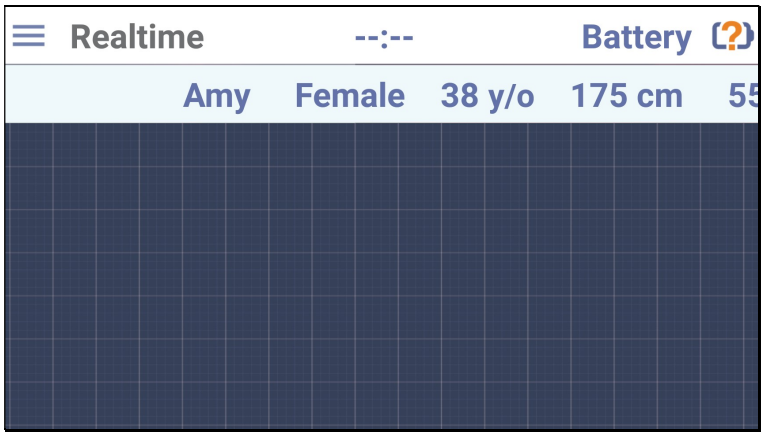


IMPORTANT: *It is important to enter the correct resting heart rate to ensure the reading accuracy.*

To determine your resting heart rate, do one of the following:

- *Measure your heart rate after at least 5 minutes of resting.*
- *Obtain a more accurate heart rate measurement performed by a trained professional.*

3. Tap **Done** to save the data. The main screen appears.

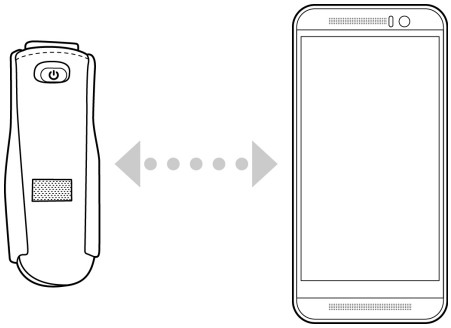


Note: *You can also modify your user profile later via **Profile** setting. Refer to page 16.*

Using the Device

Pairing the Device with Your Smartphone

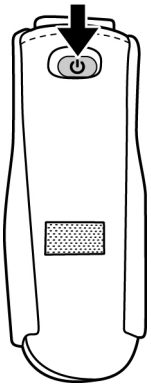
The device connects and transfers data wirelessly to your smartphone via Bluetooth.



IMPORTANT: *Before pairing, make sure both devices are within Bluetooth range (10m).*

To pair the device with your smartphone, do the following:

1. Press the **Power** button for one second (flash green LED) to turn the device on.

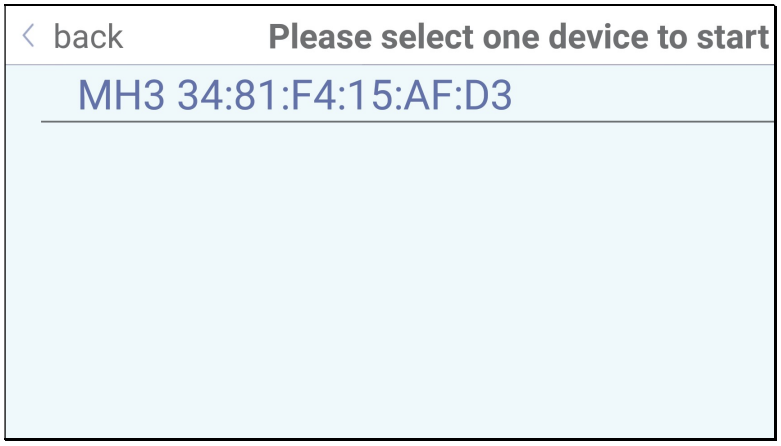


2. On your smartphone, launch **Q-SPO2** APP ( ).

   Note: *By default, the Bluetooth function will automatically turn on. Otherwise, go to **Settings** > **Bluetooth** and set the setting to **ON** to turn on the Bluetooth function.*

3. Tap ☰ > **Pairing**.

4. Tap the device to pair.

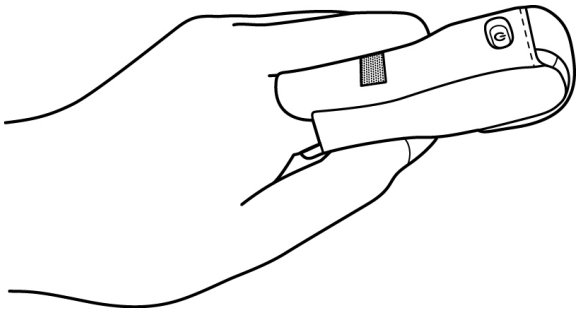


Note: *Not all smartphones can pair with the device directly through* **Q-SPO2** *app. In this case, you will need to perform the pairing process via* **Settings** *app (go to* ***Settings*** *>* ***Bluetooth****, and then select the device to pair).*

Performing Measurement

Before performing the measurement, make sure you have successfully paired your smartphone with the device.

1. Insert your index finger fully into the finger sleeve. Make sure your finger is accurately placed on the probe of the device.



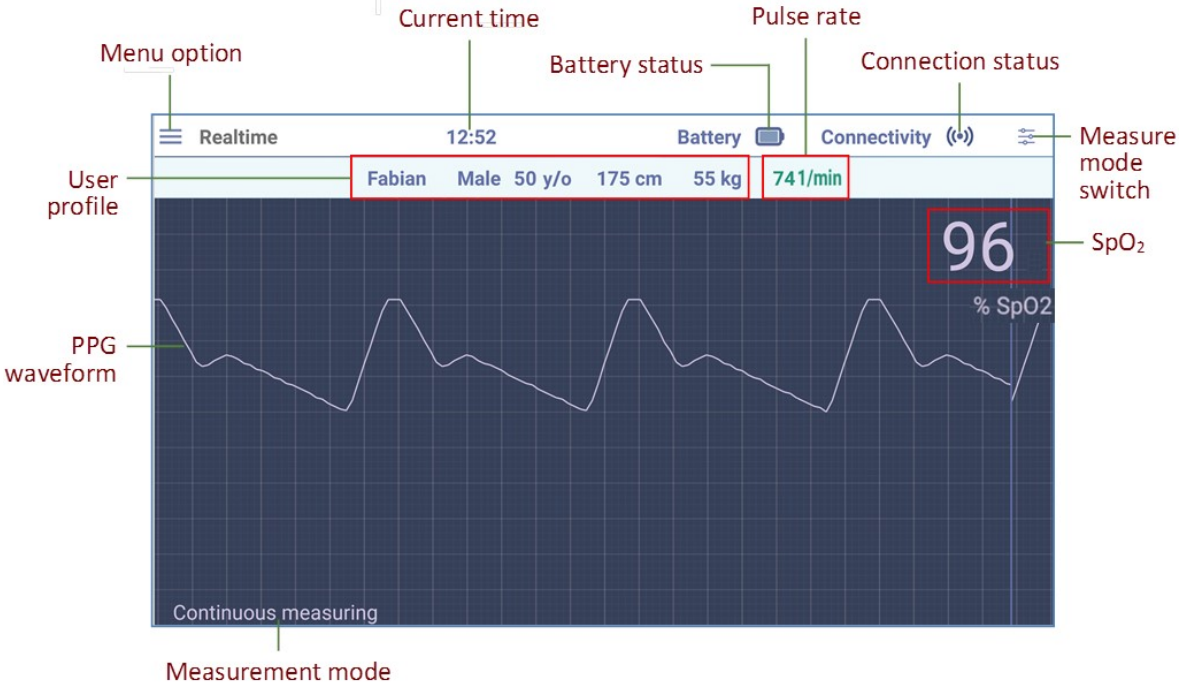
Note: *Keep your finger and hand still during measurement.*

2. On your smartphone, launch **Q-SPO2** APP and the real-time readings will appear on the screen.
3. Press the **Power** button for one second (flash orange LED) to turn the device off.

Note: *when you start to measure SpO2 value, make sure to connect Q-SPO2 APP every time.*

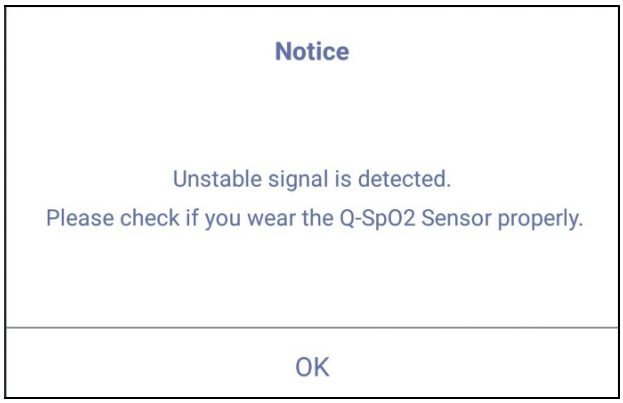
Viewing Real-time Readings

The main screen displays a real-time PPG waveform, SpO_2 value, and pulse rate which you can present to a medical professional for evaluation.



Note:

- *If the SpO_2 level falls below 90%, this indicates a need for supplemental oxygen. If this persists, please consult your doctor for proper evaluation.*
- *The SpO_2* level and pulse rate would update every three seconds. And it has no alarm functions.
- *The device will trigger smartphone to vibrate when the battery level is low ( ).*
- *If the current time displays "--:--" and these two icons (/) appear on the screen, this indicates one of the following:*
  - *The device is turned off.*
  - *The distance between the device and your smartphone exceeds the Bluetooth transmission range.*
- *When Quanta Pulse Oximeter is connected to smart phone. And the sensor detects unstable signal or data updating over 30 seconds, it would show below message.*

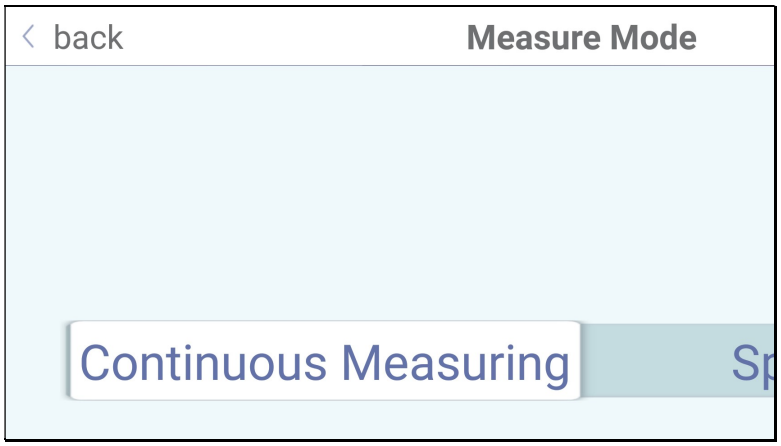


Switching Measurement Mode

This device supports both spot-check and continuous monitoring of SpO_2 and pulse rate. By default, the measurement mode is set to Continuous monitoring.

To switch to spot-check measurement, do the following:

1. Tap .
2. Tap **Spot Check**.

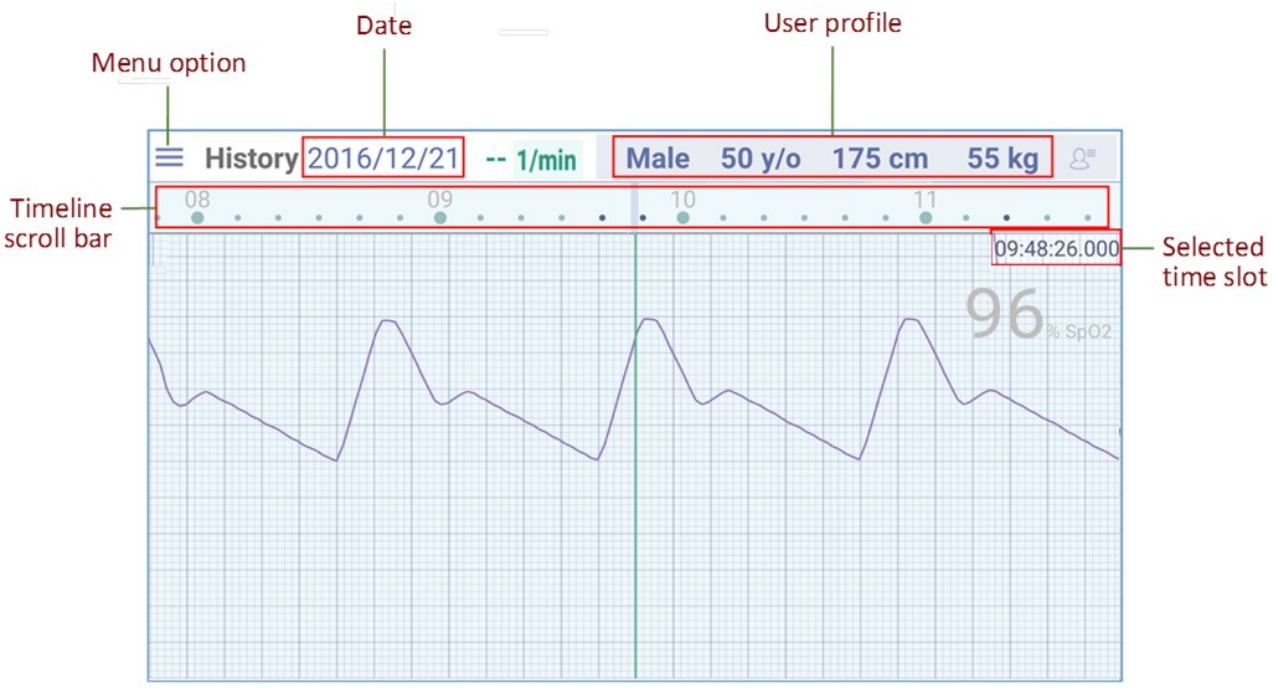


In spot-check mode, the sensor performs measurement every 12~18 seconds and then turns off emitter for a while (12~51 seconds) for power saving.

Viewing History

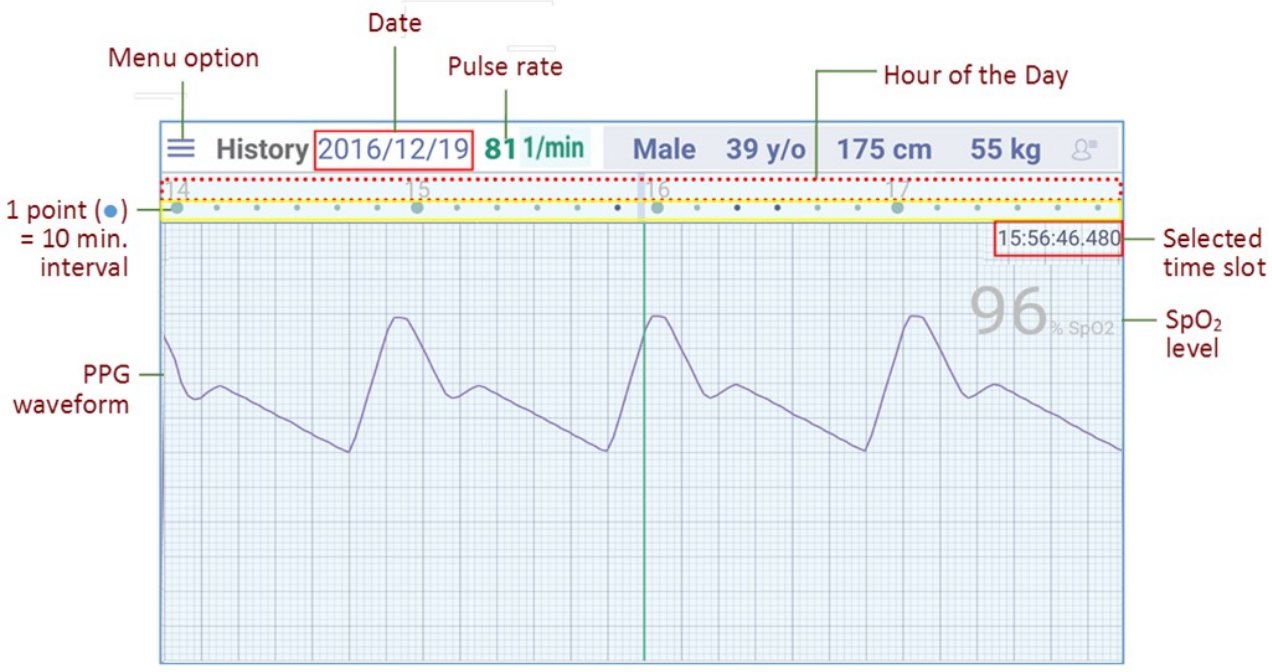
Tap ☰ > **History** to view the recorded data that includes a scrollable and scalable PPG waveform.

The information appears in *History* main screen as following:



Quick Search

Slide the timeline scroll bar to quickly select the desired time. The numbers on the scroll bar represent the hour of the day shown, and each point on the scroll bar represents 10 minutes interval.

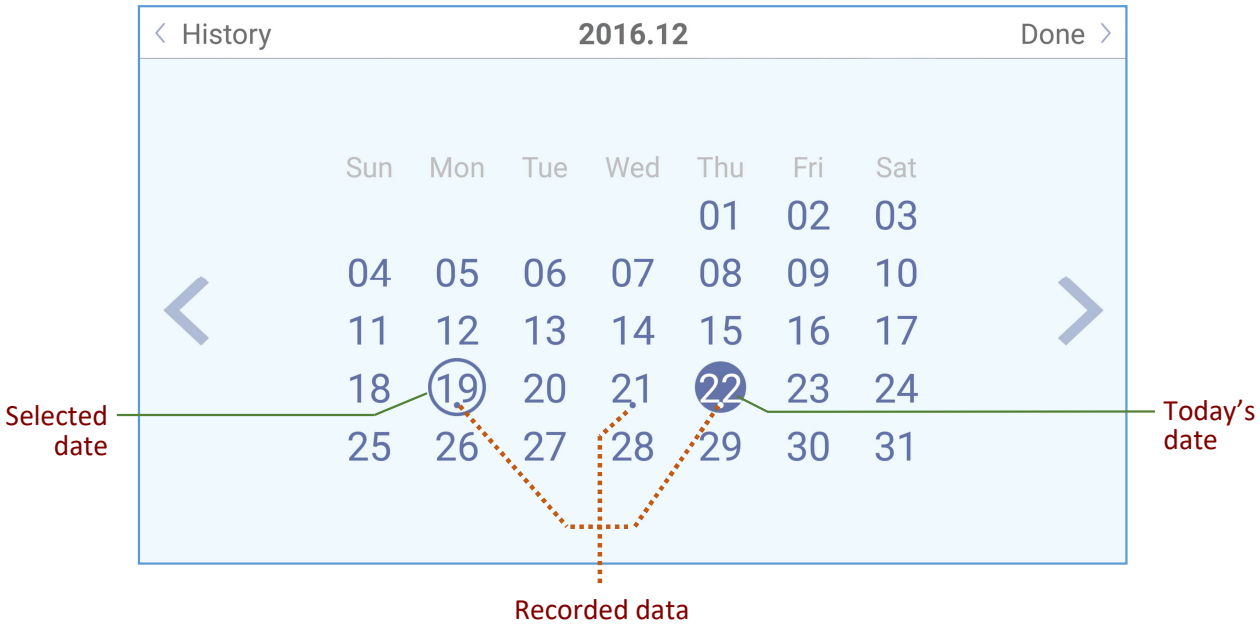


Switching Date

Tap the date to switch to the *Calendar view* screen.

In Calendar view, the date with the recorded data is marked by a dot(•). Tap < or > to go to other months.

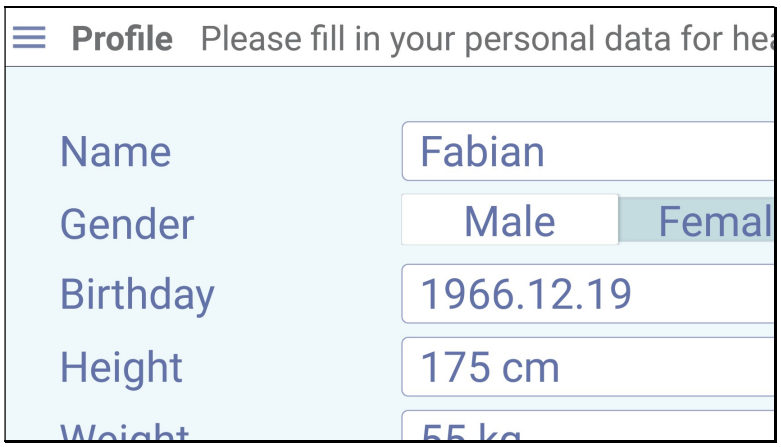
Select the desired date and tap **Done** to view the recorded data on that day.



Note: **Q-SPO2** *app will store the recorded data up to 7 days.*

Editing User Profile

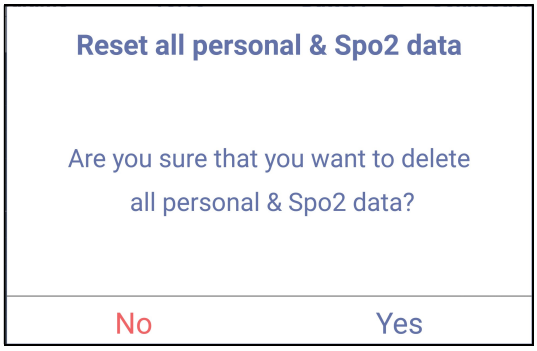
Tap ☰ > **Profile** to edit the profile settings.



Make the necessary changes and the system will automatically update the user profile.

Clear Data

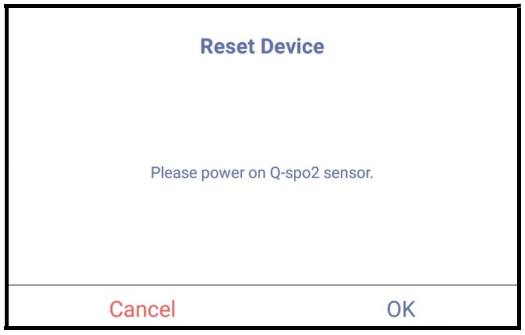
Tap ☰ > **Clear Data** to delete the user profile and all recorded data.



A confirmation message appears on the screen. Tap **Yes** to clear all data.

Reset the Device

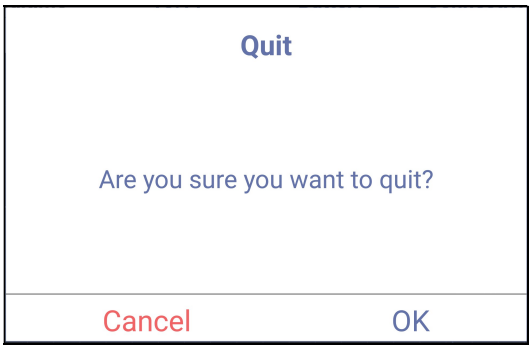
Tap ☰ > **Reset Device** to restore the factory default settings.



A confirmation message appears on the screen. Tap **OK** to reset the device.

Exit APP

Tap ☰ > **Quit** to stop **Q-SPO2** app from running in the background.



A confirmation message appears on the screen. Tap **OK** to exit **Q-SPO2** app.

Note: *Once* **Q-SPO2** *app is launched, it keeps running in the background to ensure the data synchronization will continue when you use the device.*

Specifications

Pulse Oximeter Specifications

Item	Specifications
Sensor	Continuous SPO2 data acquisition and calculation
	Pulse Rate: • <100, ±3 1/min • >=100, ±3% 1/min SpO2 Value: • Declared Accuracy Range, 70%~100% ±3digits
Emitter wave length	Red 660 nanometer @ 1.91 mWwmaximum average IR 905 nanometer @ 0.92 mWwmaximum average
G-sensor	Activity Status detection by G-sensor • G-sensor (3 axis): ±8g • G-sensor sampling rate: 52Hz • G-sensor accuracy: ±0.0156g
Connectivity	Bluetooth 4.0 BLE Transmit distance: 10 meters (open space)
USB	USB2.0
Battery	3.7V/80mAh
Battery Life	• Continuous measuring: > 5 hours • Spot checking: > 7 hours • Charging time: 1.5 hours
Operating Temperature / Humidity	• Operating temperature: 5ºC ~ 40ºC • Operating humidity: 10% ~ 95% (non-condensing)
Storage & transportation Temperature / Humidity	• Temperature: -20ºC ~ 60ºC • Humidity: 10% ~ 95% (non-condensing)
Atmospheric Pressure Range	800 hPa ~ 1013 hPa
IP classification	IP22 (Vertically dripping water shall have no harmful effect)
Altitude	2000m
Weight	11g
Dimensions	14.6 x 22.5 x 4.1 mm

Charger Specifications

Item	Specifications
Input	5V/0.5A
Operating Temperature	5°C ~ 40°C
Storage Temperature	-20°C ~ 60°C
Weight	18g
Dimensions	30.7 x 17 x 20.64 mm

Additional Information

Troubleshooting

If you encounter any problems when using the device, try the following solutions.

Problem	Possible Cause	Solution
The device cannot be turned on.	The battery is low.	Charge the battery and try again.
	Device malfunction.	Please contact Quanta Customer Support.
Q-SPO2 APP cannot detect the device.	The device is turned off.	Press the **Power** button to turn the device on.
	The Bluetooth function on your smartphone is disabled.	Go to **Settings** > **Bluetooth** and set the setting to **ON** to turn on the Bluetooth function.
	Both devices are out of the Bluetooth transmission range.	Keep both devices within 10 meters.
SpO_2 or pulse rate does not display on the main screen.	Finger might not be placed accurately on the probe.	Retry by inserting the finger into the finger sleeve until it touches the probe (sensor) area.
	The probe (sensor) is dirty.	Remove the device from the finger sleeve. Then wipe the probe area using a soft dry cloth.
	Excessive movement during measurement.	Keep your finger, hand, and body still during measurement.

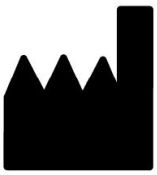
Cleaning

It is important to perform cleaning once devices are grease and dirt.

Item	Cleaning Method
Pulse Oximeter Sensor	Wipe the external surface with a soft dry cloth.
Charger	Wipe the external surface with a soft dry cloth.
Finger Sleeve	• Hand wash. If you are using a washing machine, place the finger sleeve inside a laundry bag. • Do not use bleach. • Line drying. Do not dry the finger sleeve in the dryer.

Customer Support

For additional technical information, contact Quanta Customer Support Department.



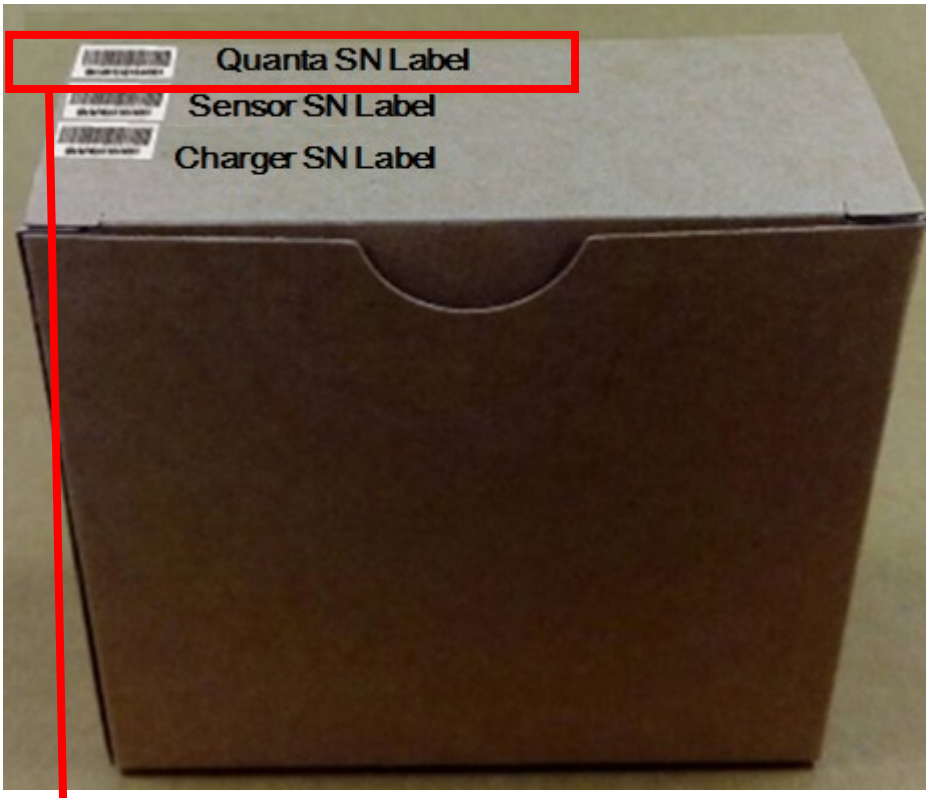
Quanta Computer Inc.(QCI)
Address:
No. 188, Wenhua 2nd Rd., Guishan Dist.,
Taoyuan City 333, Taiwan
TEL: +886-3-327-2345
FAX: +886-3-318-4207
Email: MedicalSales@quantatw.com

EU Representative

EU Representative: MedNet GmbH
Address: Borkstrasse 10, 48163 Münster, Germany

Manufacture Date

The year of manufacture label and format of the wireless home health management system's sensor, charger is shown below:



In the serial number on the product label, the 6th and 7th character starting from the left represents the year of manufacture, while the 8th and 9th character represents the week of manufacture. In the example shown the “17” represents a manufacture year of 2017 and the “10” represents the 10th week of 2017.

Supplier's Declaration

The Quanta Pulse Oximeter conforms to the international EN 60601-1 and EN 60601-1-2 standards for electromagnetic compatibility with medical electrical devices and systems.

Guidance and manufacturer's declaration-electromagnetic emissions		
The Q-spo-wu1 is intended for use in the electromagnetic environment specified below. The customer or the user of the Q-spo-wu1 should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment-guidance**
RF emissions CISPR 11	Group 1	The Q-spo-wu1 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 Q-spo-wu1 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	

Guidance and manufacturer's declaration-electromagnetic immunity			
The Q-spo-wu1 is intended for use in the electromagnetic environment specified below. The customer or the user of the Q-spo-wu1 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	+ 2kV for power supply lines + 1kV for input/output lines	+ 2kV for power supply lines Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+ 1kV line(s) to line(s) + 2kV line(s) to earth	+ 1kV differential mode Not applicable	Mains power quality should be that of a typical commercial or hospital environment.

Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT(>95% dip in UT) for 0,5 cycle 40% UT(60% dip in UT) for 5 cycles 70% UT(30% dip in UT) for 25 cycles <5% UT(>95% dip in UT) for 5 s	<5% UT(>95% dip in UT) for 0,5 cycle 40% UT(60% dip in UT) for 5 cycles 70% UT(30% dip in UT) for 25 cycles <5% UT(>95% dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Q-spo-wu1 requires continued operation during power mains interruptions, it is recommended that the Q-spo-wu1 be powered from an uninterruptible power supply or a battery.
Power frequency(50, 60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	The Q-spo-wu1 power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration-electromagnetic immunity			
The Q-spo-wu1 is intended for use in the electromagnetic environment specified below. The customer or the user of the Q-spo-wu1 should assure that is used in such and environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment-guidance**
Conducted RF IEC 61000-4-6 Radiated RF	3 Vrms 150 KHz to 80 MHz 3 V/m	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Q-spo-wu1 including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1,2 \sqrt{P}$

IEC 61000-4-3	80MHz to 2,5 GHz		d = 1,2 √P 80MHz to 800 MHz d = 2,3 √P 800MHz to 2,5 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). 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 Q-spo-wu1 is used exceeds the applicable RF compliance level above, the Q-spo-wu1 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Q-spo-wu1.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended safety distance

The following table lists the recommended safety distance between the device and mobile RF communications equipment.

Recommended separation distance between portable and mobile RF communications equipment and the Q-spo-wu1			
The Q-spo-wu1 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Q-spo-wu1 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Q-spo-wu1 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√*P*	**80 MHz to 800 MHz** d =1,2√*P*	**800 MHz to 2,5 GHz** d =2,3√*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 metres (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 80 MHz and 800 MHz, 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.			

CE 0120	CE Mark: Indicates that the body sensor has been certified and conforms to EC Directive 93/42/EEC on medical devices.
	Type **BF** applied part
	Indicates that the body sensor is classified as electrical or electronic equipment requiring proper disposal (WEEE Directive).
REF	Indicates the manufacturer's catalogue number. **Attention: Catalogue number may also be referred to as the reference number or reorder number.**
SN	Indicates the manufacture's serial number.
	Indicates the manufacturer's name and address.
	To indicate on the rating plate that the equipment is suitable for alternating current only; to identify relevant terminals.
	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 it is mandatory to refer to the instruction manual before using this device.
	Indicates no alarm function.
IP22	Indicates the international protection marking.

Federal Communications Commission (FCC) Statement

The FCC ID is HFSMH3.

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.

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.

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.

RF Radiation Exposure Statement:

To comply with the FCC RF exposure compliance requirements, this device and its antenna 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 no metal and that positions the device a minimum of 5 mm from the body. Use of other accessories may not ensure compliance with FCC RF exposure guidelines

Regulatory Marks

The Quanta 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.

第十二條　經型式認證合格之低功率射頻電機，非經許可，公司、商號或使用者均不得擅自變更頻率、加大功率或變更原設計之特性及功能。

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.

第十四條　低功率射頻電機之使用不得影響飛航安全及干擾合法通信；經發現有干擾現象時，應立即停用，並改善至無干擾時方得繼續使用。前項合法通信，指依電信法規定作業之無線電通信。低功率射頻電機須忍受合法通信或工業、科學及醫療用電波輻射性電機設備之干擾。