QOCA Wireless Digital Stethoscope

User Manual

Model：Q-steth-w1

Please read this user manual before use.

Version: 3A

Indication for Use:

QOCA Wireless Digital Stethoscope picks up the sounds from the heart, lungs, anterior/posterior chest, abdomen from a patient's body. And when user puts QOCA Wireless Digital Stethoscope on the patient's heart, it could detect ECG signal at the same time. ECG、HR、Sound data will be transferred to a smartphone via Bluetooth and displayed on the smartphone screen.

QOCA Wireless Digital Stethoscope is intended for trained medical personal use.

Function Introduction:

Stethoscope:

With embedded microphone, it could pick up the sound of adult's heart、lung、Blood vessel. With sound signal amplifying and filtering, user can hear the sound through earphones or on smartphone via Bluetooth transmission.

Single lead ECG:

Through two metal electrodes on the button of QOCA Wireless Digital Stethoscope, it could detect the ECG signal and heart rate of adult. And those data will be transferred to a smartphone via Bluetooth for further display and storage.

Product Introduction:

QOCA Wireless Digital Stethoscope is simple use, which can be used as a stand-alone device with headphones. The heart rate and measurement results will be displayed on the screen.

In addition, you can install a software-specific APP on your mobile device to receive auscultation sounds, ECG signals, and heartbeats through Bluetooth, display, store, record, and play, and manage data (auscultation sounds, ECG, and heartbeats). Built-in lithium battery, it can be used continuously for 3 hours when fully charged.

It is intended for trained medical personal use with patient not in critical conditions.

Precautions:

- In order to reduce the risks related to charging, please follow the charging conditions in this manual, set up and comply with the requirements of the charging mode.
- In order to reduce the risk of incorrect results, personal injury and equipment damage, please follow the recommended instructions in this manual to store and operate this product.
- In order to reduce the risk of damaging the auscultation head, please do not place the auscultation head close to a strong sound source.
- To reduce the risk of infection, please follow the cleaning and disinfection instructions in the manual.
- In order to reduce the risk of ear canal damage, please hold the instrument firmly to avoid sudden fall.
- In order to reduce the risk of extremely strong magnetic fields, when using this product, please avoid close to strong radio frequency signals or portable and/or mobile radio frequency equipment. If you hear sudden or unexpected sounds, move away from any radio transmitting antennas.
- In order to reduce the risk of damage to the stethoscope, please put the stethoscope body in the pocket of the doctor's suit to avoid sudden fall.
- Please use the accessories provided or recommended by Quanta to avoid danger.
- Do not immerse the stethoscope in liquid, or immerse it in any disinfectant, which may cause damage to the equipment.
- The battery must be charged continuously for at least 8 hours before using it for the first time. Otherwise, the service life of the battery may be shortened.
- To store and transport this product, please follow the product storage specifications in the manual.
- Do not replace the lithium battery arbitrarily.
- Do not modify or fix this product arbitrarily.
- Do not use it the environment of cotton lint, dust, and sunlight.
- It is use for people who is over 20 years old. And do not use it on critical condition patient.
- The measured ECG data is for reference only, do not use for diagnosis.
- Do not apply on one specific location over 30 seconds.

Package Contents

After purchasing the QOCA Wireless Digital Stethoscope, please check the product package to ensure that the following items are included:

Product Package

			
Q-steth-w1 Sensor x 1	Q-steth-w1-C1 Charger x 1	USB type-C cable x 1 (Material TPE; Length 100cm)	User Manual x 1

Before You Start:

Before you start using the QOCA Wireless Digital Stethoscope you must:

1. Place the QOCA digital stethoscope on charger & contact the five pogo pins for charging.

(As below figure)

The following icon shown on screen while charging

2. Install the QOCA steth APP on your Android smartphone
3. Enable Bluetooth on your smartphone

Getting Started:

1.Power on:

Long Press the power touch key  for 3 seconds till the screen is light up.

The power touch key is on the button of screen.

2.Launch QOCA steth APP:

Press the following Icon on your smart phone to launch the QOCA steth APP。

The icon of QOCA steth APP

3.Connecting via Bluetooth:

Select the name of “MH9XSXXXXXXX” on the list for Bluetooth connection.

The launch screen of QOCA steth APP

QOCA Wireless Digital Stethoscope:

1. The touch keys:

There are Six touch keys on the top of device which are volume up、volume down、record、next user、mode select、power key. The location of each touch key is showed as below figure.

Figure 2. The top view of QOCA digital stethoscope showing the location of six touch keys

Table 1. The function of six touch keys

Icon	Touch Key Function
⏻	Power
Fn	Mode select
+	volume up
-	volume down
REC	Recording ECG data、heart or lung sound
NEXT	To the next patient (Disable in current version)

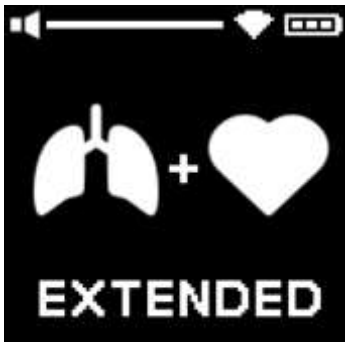
1-1. Power on / Power off:

Long Press the power touch key ⏻ for 3 seconds till the screen is light up.

In the power on state, Long Press the power touch key ⏻ for 3 seconds till the screen is light off.

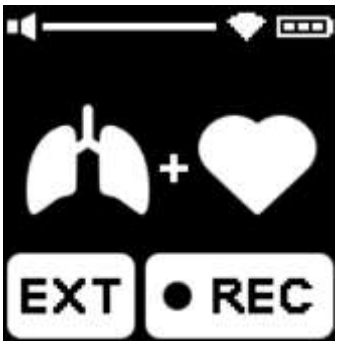
1-2. Mode:

QOCA Wireless Digital Stethoscope has three modes. There are Bell mode, Diaphragm mode and extended mode. User can switch mode by press the following touch key Fn (The mode icon as below figures)



1-3. Record Data:

While connecting to QOCA steth APP，Press the REC key. It would take a 30 seconds data recording and the following icon would be shown on screen.

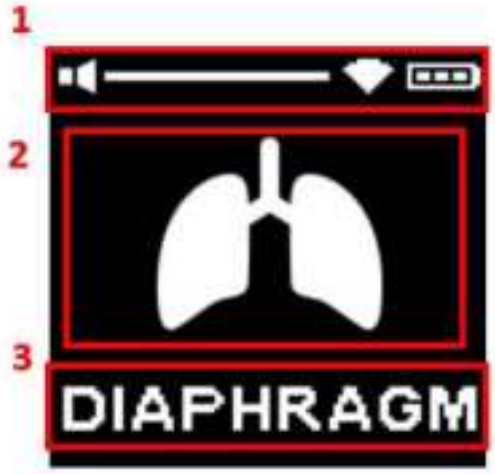


2. Display:

The display shows the following information on screen: volume status、Bluetooth connection status、battery status、recording status、mode status. The detail is described as below figure and table.

Table 2. Indication on screen

Area	The indication on screen
1	Show the volume、Bluetooth connection、battery status
2	Show current mode in figures
3	Show current mode in wordings and status (recording)



The layout of QOCA Wireless Digital Stethoscope's screen

QOCA steth APP on Smart Phone:

1. Main Page

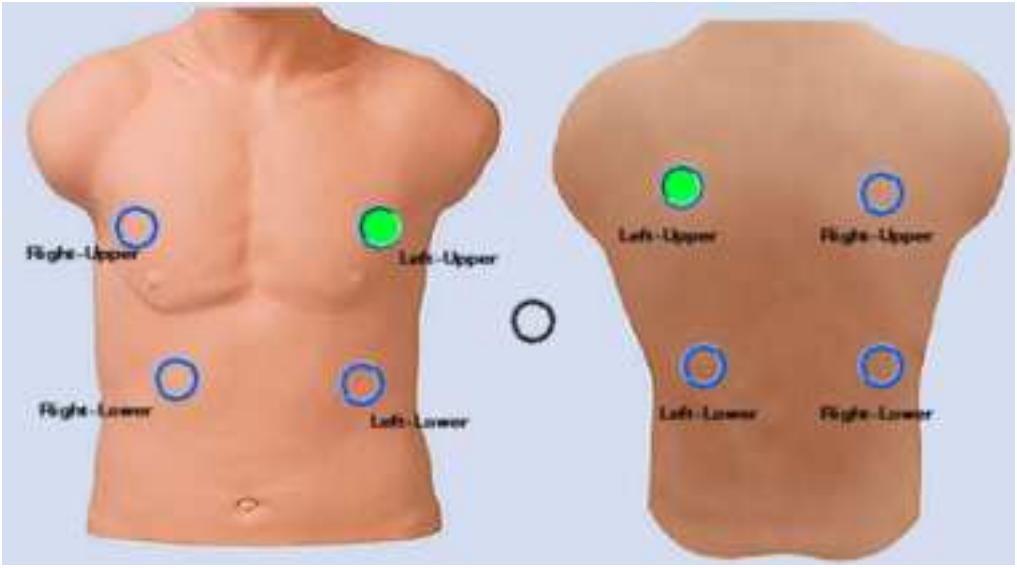
QOCA steth APP is able to display the mode、ECG waveform、audio waveform. Check below figure.

Area	The indication on screen
1	Show ECG waveform
2	Show sound waveform in time domain
3	For volume up/down
4	To select the mode
5	To enable recording
6	Show the connected device's serial number

Take Measurement:

1. Sounds:

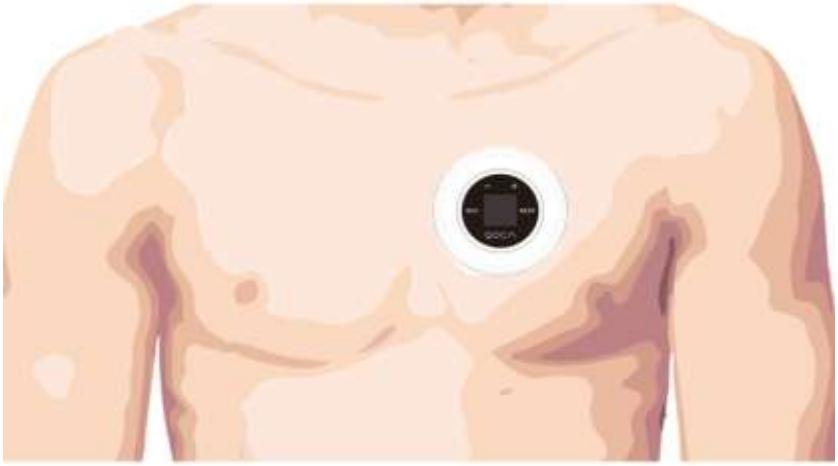
Place QOCA Wireless Digital Stethoscope at the position to be sound measured. Below figure is the suggestive location for sound measurement.



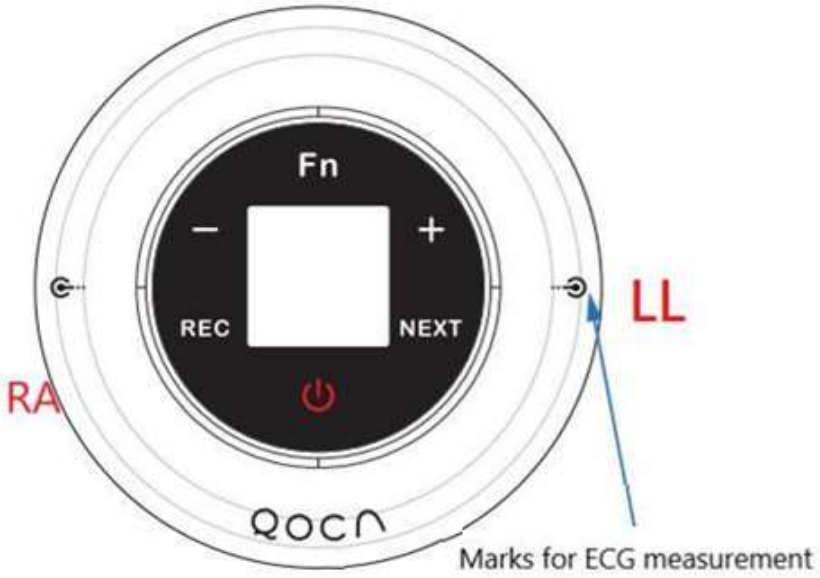
2. ECG measurement:

QOCA Wireless Digital Stethoscope is able to measure single lead ECG. And the two dry electrodes in on the bottom side of device.

Place QOCA Wireless Digital Stethoscope on the heart with QOCA wording in level, and it should not be inclined.



From the top view of QOCA Wireless Digital Stethoscope, the ECG leads RA and LL are introduced as below.



Important: Be sure to perform the measurement according to the specific position, the other ECG measurement position is not be referenced.

Important: Wipe the measuring area with a wet tissue or saline before taking an ECG measurement.

Important: ECG signal and heart rate are only for reference. Do not use it for diagnosis.

Product Specification:

Item	Specification
ECG monitor	Single lead
	Continuous ECG data acquisition and calculation
	Frequency Response: Monitor 0.5 to 40 Hz (-3db)
	Differential Input Impedance: > 10MΩ
	Common Mode Rejection Ratio: > 70 dB
	Sampling rate: default at 256Hz
	Heart rate measurement range*: 30 – 240 bpm *Heart rate is calculated based on the R-R interval of the ECG.
	Heart rate accuracy: ± 3 bpm or ±3% whichever is greater
Lead-off detection	Detect when the target gets loosened from patch
BT connectivity	BT 5.1~~0~~ (10m at open space)
Audio	Diaphragm (100~500Hz) / Bell mode (20~200Hz) / Extended (20~1000Hz)
Audio frequency range	20 Hz ~ 2000 Hz
Volume level degree	10 levels
Record time	20 sec, 30 sec, 40 sec
Battery	3.85V/220mAh
Battery life	Continuous use for 2 hours
Battery indication	100%, 70%, 30%, 10%(low battery)
Screen	0.96” OLED
Key	Six touch keys (Power, Mode, volume up, volume down, record, next)
Working temp	Temperature: 5 ~ 45^{o}C, Humidity: 10% ~ 95% (non-condensing)
Storage temp	Temperature: -20 ~ 60^{o}C humidity: 10% ~ 95% (non-condensing)

Name	Charger
Model Number	Q-steth-w1-c1
Adapter input	5V/0.5A
Working Temperature	5 – 35°C, 10% ~ 95% (non-condensing)
Storage Temperature	-20 – 60°C, 10% ~ 95% (non-condensing)

Cleaning and Maintance:

The table below describes the appropriate cleaning methods for each item：

Parts	Method
QOCA Wireless Digital Stethoscope	Carefully wipe with a cloth with 75% alcohol.
Charger	wipe with a dry cloth

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.
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	Keep both devices within 5 meters.

	Bluetooth transmission range.	
Sound measurement	Cannot hear the measured sound	Retry power on/off the device. Or please contact Quanta customer support.
ECG measurement	No ECG waveform	Wipe the measuring area with a wet tissue or saline
		Place on the heart and keep QOCA wording in level.

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: MedicalService@quantatw.com

EU Representative:

EC REP

EU Representative: MedNet EC-REP GmbH

Address: Borkstrasse 10, 48163 Münster, Germany

Federal Communications Commission (FCC) Statement

The FCC ID is HFSMH9

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.

15.19

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 WIRELESS DIGITAL STETHOSCOPE 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.

CE 1639	CE Mark: Indicates that the body sensor has been certified and conforms to EC Directive 93/42/EEC on medical devices.
	Type applied part
	Indicates that the body sensor is classified as electrical or electronic equipment requiring proper disposal (WEEE Directive)
	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.
IP22	Protected against solid objects down to 12mm. Protection against low pressure jets of water, limited ingress permitted.

Supplier's Declaration

The QOCA WIRELESS DIGITAL STETHOSCOPE 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 immunity The Q-steth-w1 is intended for use in the electromagnetic environment (for home and professional healthcare) specified below. The customer or the user of the Q-steth-w1 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 applicable	Mains power quality should be that of a typical home and professional healthcare environment.
Surge IEC 61000-4-5	± 0.5kV, ±1kV line(s) to line(s) ± 0.5kV, ±1kV,± 2kV line(s) to earth	± 0.5kV, ±1kV line(s) to line(s) Not applicable	Mains power quality should be that of a typical home and professional healthcare environment.
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: 0 % U_T; 250/300 cycle	Voltage dips: 0 % U_T; 0,5 cycle 0 % U_T; 1 cycle 70 % U_T; 30 cycles Voltage interruptions: 0 % U_T; 300 cycle	Mains power quality should be that of a typical home and professional healthcare environment. If the user of the Q-steth-w1 requires continued operation during power mains interruptions, it is recommended that the Q-steth-w1 be powered from 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 and 60 Hz	The Q-steth-w1 power frequency magnetic fields should be at levels characteristic of a typical location in a typical home and professional healthcare environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Manufacturer's declaration-electromagnetic immunity			
The Q-steth-w1 is intended for use in the electromagnetic environment (for home and professional healthcare) specified below. The customer or the user of the Q-steth-w1 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 IEC 61000-4-6	3 Vrms: 0,15 MHz – 80 MHz 6 Vrms: in ISM bands between 0,15 MHz and 80 MHz 3 Vrms 0,15 MHz – 80 MHz 6 V m) in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 Vrms: 0,15 MHz – 80 MHz 6 Vrms: in ISM bands between 0,15 MHz and 80 MHz 3 Vrms 0,15 MHz – 80 MHz 6 V m) in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	**Portable and mobile RF communications equipment should be used no closer to any part of the** Q-steth-w1 including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	10Vm 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10Vm 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.			

Manufacturer's declaration-electromagnetic immunity

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

The Q-steth-w1 is intended for use in the electromagnetic environment (for home and professional healthcare) specified below.

The customer or the user of the Q-steth-w1 should assure that it is used in such an environment.

Test frequency (MHz)	**Band** [a] (MHz)	**Service** [a]	**Modulation** [b]	**Maximum power** (W)	**Distance** (m)	**IMMUNITY TEST LEVEL** (V/m)	**Compliance LEVEL** (V/m) (for home and professional healthcare)
385	380 –390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27	27
450	430 – 470	GMRS 460, FRS 460	FM c) ±5 kHz deviation 1 kHz sine	2	0,3	28	28
710	704 – 787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0,2	0,3	9	9
745							
780							
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0,3	28	28
870							
930							
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 217 Hz	2	0,3	28	28
1 845							
1 970							
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0,3	28	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9	9
5 500							
5 785							

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Recommended separation distance between portable and mobile RF communications equipment and the Q-steth-w1

The Q-steth-w1 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 Q-steth-w1 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Q-steth-w1 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 Q-steth-w1 is intended for use in the electromagnetic environment (for home and professional healthcare) specified below. The customer or the user of the Q-steth-w1 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 Q-steth-w1 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-steth-w1 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	3.3V
Modulation	GFSK
Antenna Gain	PCB printed antenna, Peak Gain: 0.825 dBi
Rated Power (ERP)	2.59 dBm