

QOCA Wireless Digital Stethoscope

User Manual

Model: steth02 for stethoscope
steth02-E1 for earpiece

Quanta Computer Inc.

Please read this user manual before use.
Version: 3A

Indication for Use:

QOCA Wireless Digital Stethoscope may be used for the detection and amplification of sounds from the heart, lungs, anterior/posterior chest, abdomen, arteries, veins, and other internal organs with the use of a selective frequency. It can be used on any person undergoing a physical assessment. The healthcare personnel can assess the sound with a dedicated wireless earpiece. And the data can be transmitted to a dedicated app for display, storage, and recording.

QOCA wireless digital stethoscope is intended for examine, not for diagnosis. And it is intended to be used by trained-adult or healthcare professional.

Product Introduction:

QOCA Wireless Digital Stethoscope brings the wireless electronics technology in an easy-to-use format. The QOCA Wireless Digital Stethoscope combination of Ambient Noise Reduction technology, electronic amplification (conventional bell / diaphragm modes plus an extended range mode), Bluetooth® data transfer, and an all-new user interface takes you to the next level of performance.

Precautions:

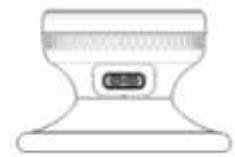
- In order to reduce the risks related to charging, please follow the charging conditions in this manual, set up and comply with the requirements of the charging mode.
- In order to reduce the risk of incorrect results, personal injury and equipment damage, please follow the recommended instructions 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.
- That 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 and at least 1 meter for sensitive equipment.
- Please do not use any other cables or accessories not approved by the manufacturer in this manual to avoid negative influence on electromagnetic compatibility.
- This device should not be used adjacent to or stacked with other equipment.
- If abnormal behavior is observed due to EM disturbances, please relocate the device accordingly.
- Medical electrical equipment needs special precautions regarding EMC and needs to be installed according to the EMC information provided.
- Do not use QOCA Wireless Digital Stethoscope on a wounded area.
- Do not use the QOCA Wireless Digital Stethoscope near open flames, excessive heat,

or in an explosive environment.

- Do not disassemble the device or replace the battery. Contact the manufacturer or distributor for device problems.
- When using QOCA Wireless Digital Stethoscope, please keep away from lint, dust, light (including sunlight).
- When in use, please keep away from pets, pests, or children.

Package Content:

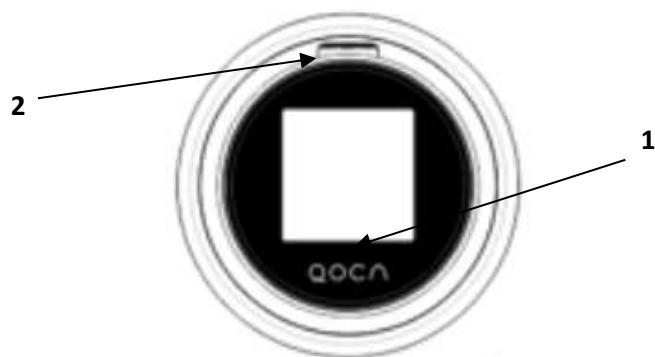
After purchasing the QOCA Wireless Digital Stethoscope, please check the product package to ensure that the following items are included:

			
QOCA Wireless Digital Stethoscope x 1	Wireless Earpiece x 1	USB Type-C Cable x 1	User Manual x 1

Note: The service life of QOCA Wireless Digital Stethoscope and Earpiece is 1 year.

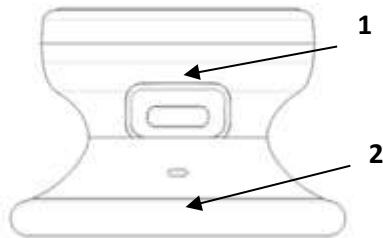
QOCA Wireless Digital Stethoscope:

Top View:



1	0.96" OLED
2	Joystick

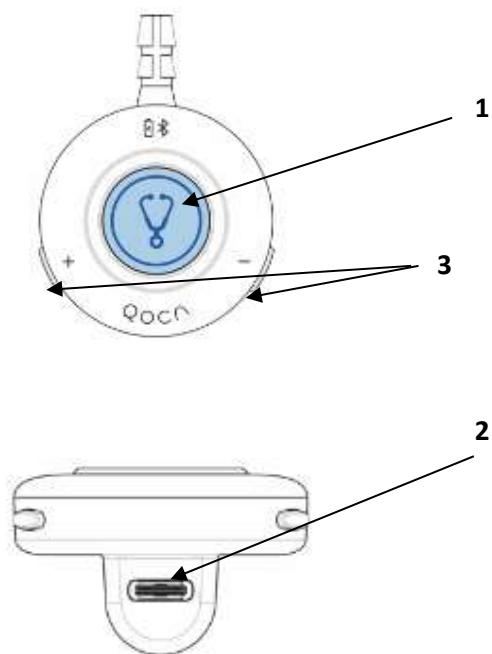
Side View:



1	USB type-C hole (Model No.: steth02)
2	Rubber ring*

Caution*: The rubber ring cannot be removed by bare hands. It' could be removed by a tool, such as flat blade screwdriver. And the disposal of rubber ring should be in accordance with local laws and regulations.

The Head of Wireless Earpiece:



1	Power Button
2	USB type-C hole (Model No.: steth02-E1)
3	Volume up and Volume down

Before You Start:

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

1. Plug the QOCA Wireless Digital Stethoscope with type-C USB cable for charging.

The following icon shown on screen while charging



Fig1 、 Charging



Fig2 、 Charging full

Note1: "The battery should be fully charged in 3.5 hours.

Note2: Full charge provides up to 6 hours of usage. (This is based on recording 60 times, each for 30 seconds. Actual usage time may vary depending on the frequency of recordings. Please refer to the prospectus for detailed information on fund subscription.)

Note3: After 500 charging cycles, the battery capacity remains around 80% of the initial capacity.

2. Install the QOCA steth APP on your Android smartphone.

3. Enable Bluetooth on your smartphone.

Getting Started (With QOCA steth APP):

1. Power on:

Press the joystick in the middle till the screen is light up.



Fig3 、 Press the joystick to power on QOCA Wireless Digital Stethoscope

2.Launch QOCA steth APP:

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

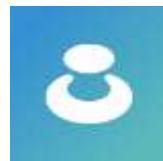


Fig4 、 The icon of QOCA steth APP

3.Connecting to QOCA steth APP via Bluetooth:

3-1. Long press joystick in the middle for 3 seconds till QOCA Wireless Digital Stethoscope enter the Bluetooth pairing mode.



Fig5 、 The operation of joystick to enter pairing mode

3-2. Select the Bluetooth name starts with “MHA” on the list.

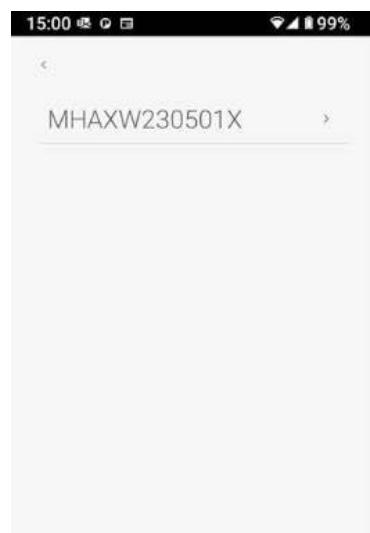


Fig6 、 The Bluetooth Pairing Page of QOCA steth APP

3-3.After pairing successfully, the following icon will show on screen.



Fig7 、 The screen of pairing successfully

Getting Started (With Wireless Earpiece):

1.Power on QOCA Wireless Digital Stethoscope:

Press the joystick in the middle till the screen is light up.



Fig8 、 Press the joystick to power on QOCA Wireless Digital Stethoscope

2.Power on Wireless Earpiece:

Press the power button till it's flashing green light.

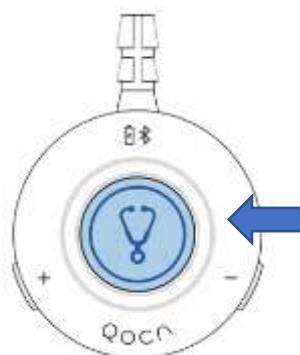


Fig9 、 Press the power button on Wireless Earpiece

3. Enable the Bluetooth pairing mode on QOCA Wireless Digital Stethoscope.

Long press joystick in the middle for 3 seconds till QOCA Wireless Digital Stethoscope enter the Bluetooth pairing mode.

4. Enable the Bluetooth pairing mode on Wireless Earpiece:

Long press the power button for 3 seconds till Wireless Earpiece enter the Bluetooth pairing mode.

5. You have to enable Both devices into Bluetooth pairing mode at the same time.

After pairing successfully, the following icon will show on screen.



Fig10 、 The screen of pairing successfully

QOCA Wireless Digital Stethoscope:

1. Joystick:

The joystick is at the side of QOCA Wireless Digital Stethoscope. The function of power on, power off, mode selection, volume up, volume down, recording can be trigger by joystick.



Fig11、QOCA Wireless Digital Stethoscope with joystick on the side view

1-1. Power on / Power off:

When it's in power off status, press joystick in the middle till the screen is light up. For power off, press joystick in the middle for 1 second till the screen is light off in the operation mode.

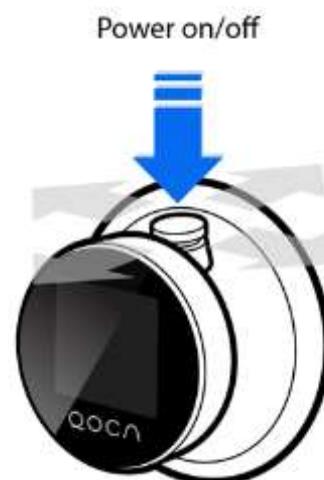


Fig12、The operation of joystick to enable Power on/Power off

1-2.Record:

Press the joystick to the up direction for enable recording function. And then the screen would show a microphone icon. 



Fig13、The operation of joystick to enable record function



Fig14、The icon show on screen while recording



Fig15、The screen shows recording status

1-3. Set Parameters

In the operation mode, press joystick in the middle shortly. It would enter the parameter setting mode

1-3-1. Mode Selection:

There are three modes for QOCA Wireless Digital Stethoscope, which are diaphragm mode, bell mode, extended mode.

When QOCA Wireless Digital Stethoscope is in parameter setting mode. Press right/left of joystick can switch the modes.



Fig16、The operation of joystick to switch mode



Fig17、The screen shows in parameter setting mode

1-3-2. Volume:

When QOCA Wireless Digital Stethoscope is in parameter setting mode. Press up/down of joystick can adjust the volume.

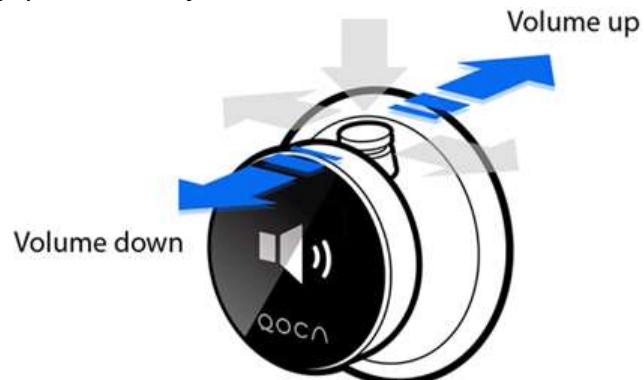


Fig18、The operation of joystick to adjust the volume

2. Display:

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



Fig19 、 The layout of screen

Table1. Indication on screen

Area	Description
1	Show the volume, Bluetooth status, Battery status
2	Show current mode by figure
3	Show current mode by wording and recording status
4	Show storage information, such as record number, record time.

Notice: Please power off QOCA Wireless Digital Stethoscope before change the rubber ring and film:

QOCA steth APP on Smart Phone:

1. Main Page

QOCA steth APP is able to show the mode and audio waveform. It also can switch mode, adjust the volume and enable recording. Check below figure.

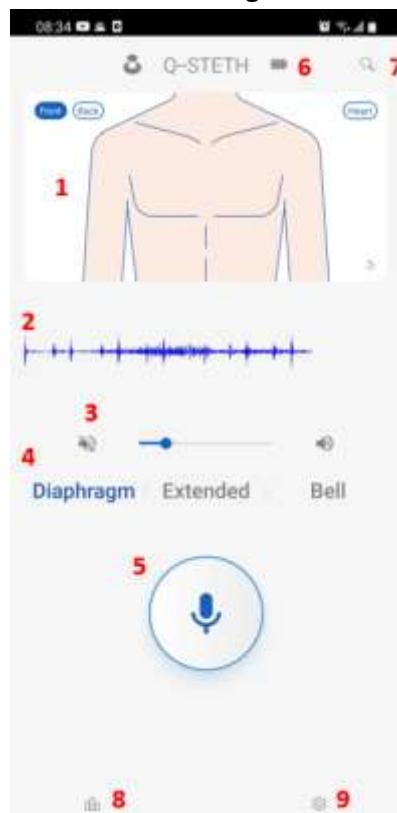


Fig20 、The main screen of APP

Table2 、The function of APP main screen

Area	The indication on screen
1	The measured location
2	The audio waveform
3	Adjust the volume
4	Switch the mode
5	Record
6	Show the connected device ID and battery level
7	Enter the Bluetooth pairing page
8	Enter the history page
9	Enter the basic information page

Wireless Earpiece:

The Wireless Earpiece is an accessory of QOCA Wireless Digital Stethoscope. The buttons function and definition is described as below table.

Table3 、 The button function of Wireless Earpiece

Button	Functions
Power Button	To power on/off To enter the Bluetooth pairing mode
Volume up/Volume down	To adjust the volume

There has one LED on Wireless Earpiece. Please see below table for detail information.

Table4 、 LED behavior of Wireless Earpiece

Behavior	LED definition
Power On / Connecting	Flash green light
In Bluetooth Pairing Mode	Flash blue light
Battery Low	Blinking orange light slow
Battery Charging	Blinking orange light fast
Battery Full	Solid green light



- To purchase the Wireless Earpiece, please contact manufacturer.

Product Specification:

Item	Specification
Model	steth02
Bluetooth	BT 5.1 (10 meters in open space)
Frequency Range	20~1000Hz
Mode	Diaphragm mode (100~500Hz) / Bell mode (20~200Hz) / Extended mode(20~1000Hz)
Volume Level	10 levels
Recording time	Up to 90 seconds
Battery	3.85V/190mAh
Screen	0.96" OLED
Button	Joystick
Working Temperature / Humidity	5 ~ 40°C /10~95%RH (non-condensing)
Storage Temperature / Humidity	-20 ~ 60°C /10~95%RH (non-condensing)

Accessory	Wireless Earpiece
Model	steth02-E1
Bluetooth	BT 5.1 (10 meters in open space)
Button	Three buttons (one for power on/off, one for volume up, one for volume down)
Working Temperature / Humidity	5 – 40°C /10~95%RH (non-condensing)
Storage Temperature / Humidity	-20 – 60°C /10~95%RH (non-condensing)

Troubleshooting:

- Once the low battery icon displays on screen, please charging QOCA wireless digital stethoscope immediately.
- Once there has no Bluetooth connection icon displays on screen, please check the following items.
 1. Enable smart phone Bluetooth.
 2. Launch QOCA steth APP.
 3. Enter the pairing page of QOCA steth APP.
 4. Long press the button of QOCA wireless digital stethoscope for enabling Bluetooth pairing mode.
 5. Select the QOCA wireless digital stethoscope on the paring page.
- For adjusting volume or mode, please check the section 1-3-1 and 1-3-2.

Clearing:

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.
Wireless Earpiece	Carefully wipe with a cloth with 75% alcohol.

Customer Support:

For additional technical information, contact Quanta Customer Support Department.

Quanta Computer Inc.(QCI)

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Email: MedicalService@quantatw.com

Federal Communications Commission (FCC) Statement

The FCC ID is HFSMHA · HFSMHAЕ.

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.

	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.

Bluetooth Technical Specification:

Manufacturer's declaration-electromagnetic emissions		
Electromagnetic environment-guidance (for home and professional healthcare environment)		
Emission test	Compliance	
RF emissions CISPR 11	Group 1	The <u>steth02</u> 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 <u>steth02</u> is suitable for use in all establishments, including domestic
Harmonic emissions IEC 61000-3-2	Class A	establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Compliance	

Manufacturer's declaration-electromagnetic immunity

The steth02 is intended for use in the electromagnetic environment (for home and professional healthcare) specified below.

The customer or the user of the steth02 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	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines	Mains power quality should be that of a typical home and professional healthcare environment.
Surge IEC 61000-4-5	± 0.5 kV, ± 1 kV line(s) to line(s) ± 0.5 kV, ± 1 kV, ± 2 kV line(s) to earth	± 0.5 kV, ± 1 kV line(s) to line(s)	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_f ; 0,5 cycle 0 % U_f ; 1 cycle 70 % U_f ; 25/30 cycles Voltage interruptions: 0 % U_f ; 250/300 cycle	Voltage dips: 0 % U_f ; 0,5 cycle 0 % U_f ; 1 cycle 70 % U_f ; 25/30 cycles Voltage interruptions: 0 % U_f ; 250/300 cycle	Mains power quality should be that of a typical home and professional healthcare environment. If the user of the <u>steth02</u> requires continued operation during power mains interruptions, it is recommended that the <u>steth02</u> 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 <u>steth02</u> 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 <u>steth02</u> is intended for use in the electromagnetic environment (for home and professional healthcare) specified below.			
The customer or the user of the <u>steth02</u> 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)
Conducted RF IEC 61000-4-6	3 Vrms: 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	3 Vrms: 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	Portable and mobile RF communications equipment should be used no closer to any part of the <u>steth02</u> including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	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	<p>Recommended separation distance:</p> <p>$d = 1,2\sqrt{P}$</p> <p>$d = 1,2\sqrt{P}$ 80MHz to 800 MHz</p> <p>$d = 2,3\sqrt{P}$ 800MHz to 2,7 GHz</p> <p>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).</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
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 <u>steth02</u>			
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 immunity

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

The steth02 is intended for use in the electromagnetic environment (for home and professional healthcare) specified below.

The customer or the user of the steth02 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	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.

Manufacturer's declaration-electromagnetic immunity Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields				
The <u>steth02</u> is intended for use in the electromagnetic environment (for home and professional healthcare) specified below.				
The customer or the user of the <u>steth02</u> should assure that it is used in such an environment.				
Frequencies	Test Level [A/m]	Modulation	Dwell time [s]	Compliance LEVEL [A/m] (for home and professional healthcare)
30 kHz (a)	8	CW	3	8
134,2 kHz	65	Pulse modulation (b) 2,1 kHz	3	65 (c)
13,56 MHz	7,5	Pulse modulation (b) 50 kHz	3	7,5 (c)

Note:

(a) This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME AND PROFESSIONAL HEALTHCARE ENVIRONMENT.

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

(c) r.m.s., before modulation is applied.

NCC Warming:

LP0002 低功率射頻器材技術規範_章節 3.8.2

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低功率射頻器材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。

前述合法通信，指依電信管理法規定作業之無線電通信。

低功率射頻器材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。