QOCA Wearable Wireless Digital Stethoscope

User Manual

Brand: Quanta
Model：steth03

Please read this user manual before use.

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Indication for Use:

QOCA Wearable 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 person undergoing a physical assessment. And the data also can be transmitted to a dedicated APP for display, storage, and recording.

QOCA Wearable Wireless Digital Stethoscope is intended for trained healthcare personnel use.

Product Introduction:

QOCA Wearable Wireless Digital Stethoscope brings you the very latest in advanced auscultation and wireless electronics technology in an easy-to-use format. The QOCA Wearable Wireless Digital Stethoscope combination of 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 QOCA Wearable Wireless Digital 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.
- This equipment is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments.
- 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 Wearable Wireless Digital Stethoscope near open flames or in excessive heat.
- Do not use QOCA wearable wireless digital stethoscope on a wounded area.

Package Content:

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

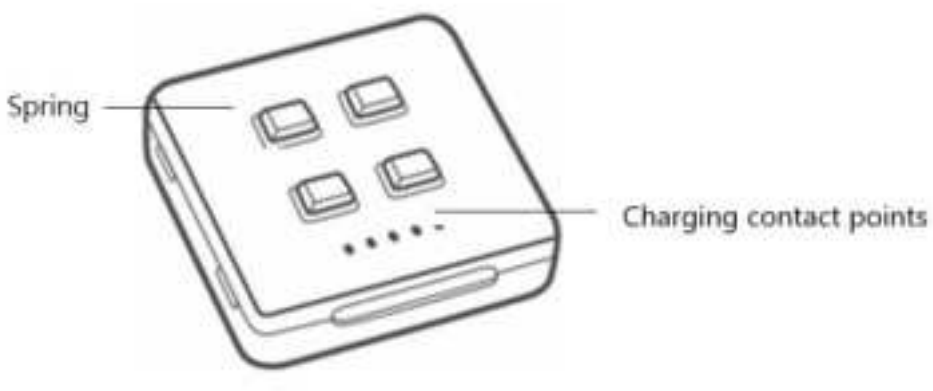
Items	Quantity
QOCA Wearable Wireless Digital Stethoscope (Model: steth03)	1
Charger (Model: CR1)	1
USB Cable	1
The Dedicated Holder (Model: steth03-H1) *	1

*For purchasing the consumable part – the dedicated holder (steth03-H1), please contact the manufacturer.

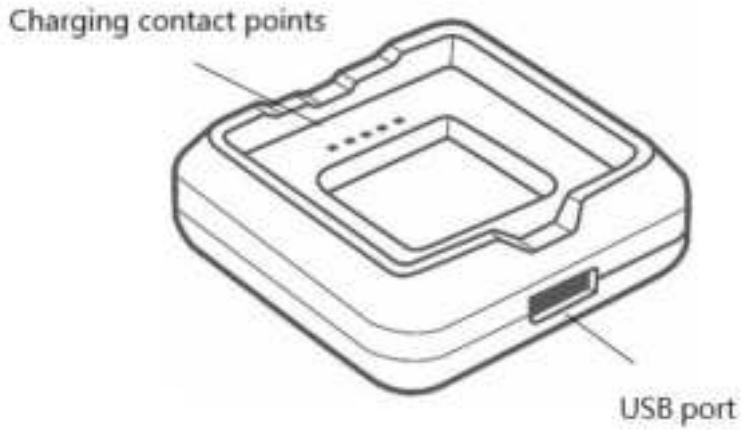
QOCA Wearable Wireless Digital Stethoscope:

Top View:

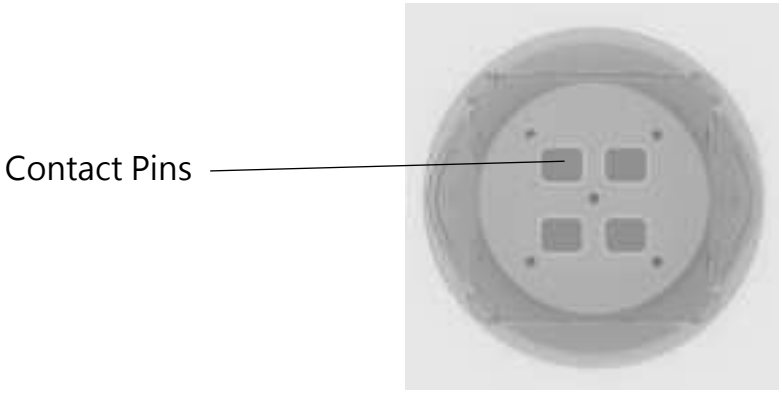
Bottom View:



The Charger (CR1):



The dedicated Holder (Model: steth03-H1)



Product Requirement:

In order to properly use the QOCA Wearable Wireless Digital Stethoscope the following items are required:

The QOCA Wearable Wireless Digital Stethoscope (steth03)

The dedicated holder (steth03-H1)

A Bluetooth-enabled Smartphone* (For Android phone: with Android version 10.x or above and a display resolution of 1920x1080 or 2560x1440. For iPhone: with iOS version14 or above)

The QOCA steth APP *

* Items are not included in the product package.

Before You Start:

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

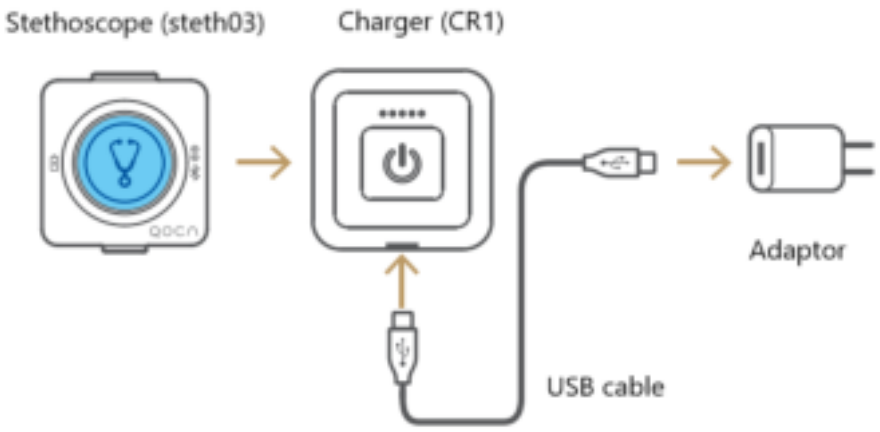
Charge the stethoscope to full capacity.

Install the QOCA steth APP on your smartphone.

Enable the Bluetooth function on your phone.

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

User should charge the stethoscope device by placing the device on the dedicated charger connecting to an AC adapter (complied with IEC 60601-1 / IEC62368-1 Class II). When the battery is fully charged, the battery light on stethoscope device should turn solid green.



2. Install the QOCA steth APP on your smartphone.
User should install QOCA steth APP on their smart phone.

3. Enable the Bluetooth function on your smart phone

Getting Started (With QOCA steth APP):

1.Power on the stethoscope:
Press the power button till the status indicator flash in orange light.

2.Launch QOCA steth APP:
Press the following Icon on your smart phone to launch the QOCA steth APP。

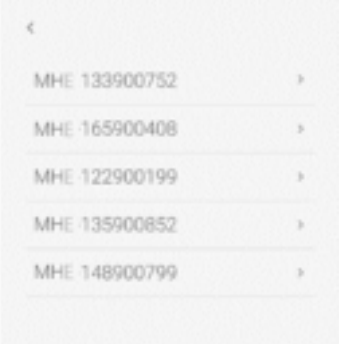
Fig4、The icon of QOCA steth APP

3.Connecting to QOCA steth APP via Bluetooth:
User should enable the Bluetooth on the phone and do the following steps

3-1. Ensure that the stethoscope has completed booting up (after booting up, the " " indicator light will continue flashing orange).

3-2. After booting up, press and hold the power button until the stethoscope enters Bluetooth pairing mode, at which point the " " indicator light will flash blue.

3-3. On the application page, click to enter the pairing connection page. Once the product serial number appears, select the desired product device serial number for automatic pairing connection. Refer to the product's barcode serial number on the back for the product serial number (MHEX********).



3-4. After the connection is established, the phone screen will enter the main interface.

4.Wearing the QOCA Wearable Wireless Digital Stethoscope

Wearing the QOCA Wearable Wireless Digital Stethoscope:

Important: (Applicable to the dedicated holder model: steth03-H1)

1. The dedicated holder is a disposable product. After one-time attachment, the product becomes ineffective. Do not reuse it, as doing so may result in inaccurate or non-measurable sound signals.
2. A trained healthcare professional should assist in attaching the dedicated holder for better adhesion. The attachment period is 1 to 3 days. Improper attachment methods or individual skin types and daily activities may cause premature detachment. It is recommended to stay in a cool and comfortable environment to prolong wearing time.
3. The skin area contacted by the dedicated holder must be cleaned and dried according to the following instructions before wearing the stethoscope.
4. Ensure that the dedicated holder adheres tightly to the skin.
5. Do not bathe or swim, and do not directly rinse the stethoscope with warm water during showering.
6. Do not apply any lotion or skincare products to the skin area contacted by the dedicated holder.
7. If you experience unbearable itching, rash, redness, or discomfort on the skin area contacted by the dedicated holder, please consult a healthcare professional promptly.

Step 1: Installing the QOCA Wearable Wireless Digital Stethoscope and Powering On

1. Please pay attention to the direction of the contact points of the stethoscope and the dedicated base patch, and attach the stethoscope (steth03) to the dedicated base patch bracket.

2. If the stethoscope is in the power-off state, press and hold the stethoscope power button until the green light comes on to complete the power-on process, then release the button (after powering on, the " " indicator light will continue flashing orange, and the light will go out only when all dedicated base patches are fully attached to the skin).

Step 2: Cleaning the Skin Surface

1. If there is chest hair in the adhesive area, remove it first. If there is no chest hair, this step can be skipped.
2. Exfoliate the area and wipe the skin inside the square area with alcohol swabs and saline solution, wait for the skin to dry completely before using the dedicated base patch.

Step 3: Applying the Dedicated Base Patch

1. Please remove the backing paper from the back and avoid touching the adhesive surface.

Step 4: Pressing the Dedicated Base Patch Firmly

1. Finally, press the entire dedicated base patch area continuously for 30 seconds to ensure that the dedicated base patch is firmly attached to the skin.

Note on removing the QOCA Wearable Wireless Digital Stethoscope from the dedicated holder:

When removing, hold both sides of the dedicated base patch with both hands, and press the center with your thumbs until the QOCA wearable wireless digital stethoscope detaches from the dedicated holder.

QOCA steth APP:

Main Page

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

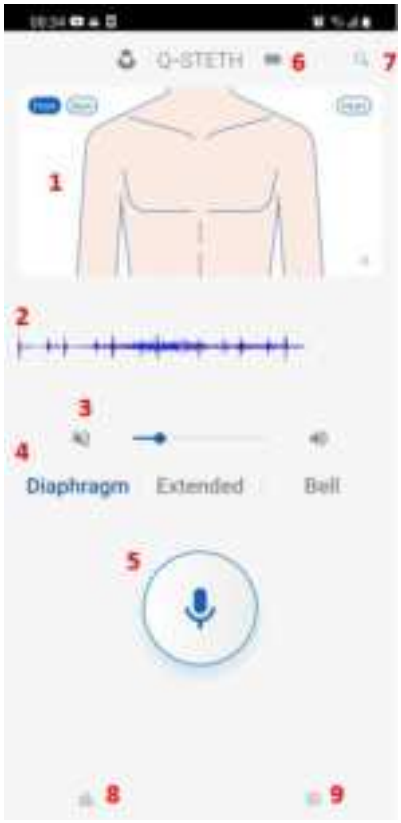


Fig20、The main screen of APP

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

Product Specification:

Item	Specification
Model	steth03
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	5 levels
Recording time	Up to 90 seconds
Battery	3.85V/350mAh
Indicator	One for battery indication, one for status indication
Button	One power button
IP rating	IP34 for stethoscope IP21 for charger
Working Temperature / Humidity	5 ~ 40°C /10~95%RH (non-condensing)
Storage Temperature / Humidity	-20 ~ 60°C /10~95%RH (non-condensing)
Size	30.7 x 30.7 x 9.4 ±0.5 (mm)
Weight	12.6 ±0.5 g

Cleaning:

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

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

- Before cleaning, please turn off the product power.
- Gently wipe the product with a damp cloth or neutral detergent, or you may also use alcohol for cleaning. Please clean after each use.
- Do not immerse the stethoscope directly in water or any other liquid for cleaning purposes.

Troubleshooting

1. The stethoscope cannot complete pairing with the phone: Please refer to the pairing process in the manual and try again.
2. The status indicator light flashes orange: This indicates that the dedicated base patch is not properly attached. Please check if the stethoscope is securely fastened and reconfirm the steps for attaching the dedicated base patch until the status indicator light stops flashing orange. If the issue persists, you may replace the dedicated base patch and repeat the attachment steps.
3. The stethoscope test waveform repeatedly shows a straight line or no waveform: If the issue persists, you may replace the dedicated base patch and repeat the attachment steps.
4. Abnormal connection between the stethoscope and the phone, unable to connect properly: Please check if the phone's Bluetooth function is enabled. If the issue persists even after enabling it, please close and reopen the application or power off and restart the stethoscope before attempting to reconnect.
5. The battery indicator light flashes orange: This indicates that the stethoscope is in a low battery state. It can still be used for auscultation, but should be recharged as soon as possible after use. When not in use, the stethoscope should be powered off to conserve battery power.
6. The battery indicator light does not illuminate during charging: Please ensure that the charging dock connection cable is properly plugged in, and place the stethoscope correctly on the charging dock.

Note: If the issue cannot be resolved, please contact the manufacturer or distributor for device problems. Do not disassemble the device or replace the battery.

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

Symbol:

	**Type applied part**
	Notice
	Indicates that it is classified as electrical or electronic equipment requiring proper disposal (WEEE)
	Indicates the need for the user to consult the instructions for use.
IP	IP rating
	NCC number

Federal Communications Commission (FCC) Statement

The FCC ID is HFSMHE

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

Supplier's Declaration

The QOCA WEARABLE 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		
The steth02 is intended for use in the electromagnetic environment (for Professional healthcare environments) specified below. **The customer or the user of the steth02 should assure that it is used in such an environment.**		
Emission test	**Compliance**	**Electromagnetic environment-guidance (for Professional healthcare environments)**
RF emissions CISPR 11	Group 1	The steth02 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 A	The steth02 is suitable for use in all establishments other than domestic 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	Not applicable	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Not applicable	

Manufacturer's declaration-electromagnetic immunity The steth02 is intended for use in the electromagnetic environment (for Professional healthcare environments) 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	± 2kV for power	Not applicable	Mains power quality should be that of

transient/burst IEC 61000-4-4	supply lines ± 1kV for input/output lines	Not applicable	a typical Professional healthcare environments
Surge IEC 61000-4-5	± 0.5kV, ±1kV line(s) to line(s) ± 0.5kV, ±1kV,± 2kV line(s) to earth	Not applicable Not applicable	Mains power quality should be that of a typical Professional healthcare environments
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage dips: 0 % *UT*; 0,5 cycle 0 % *UT*; 1 cycle 70 % *UT*; 25/30 cycles Voltage interruptions: 0 % *UT*; 250/300 cycle	Voltage dips: Not applicable Not applicable Not applicable Voltage interruptions: Not applicable	Mains power quality should be that of a typical Professional healthcare environments. If the user of the steth02 requires continued operation during power mains interruptions, it is recommended that the steth02 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 steth02 power frequency magnetic fields should be at levels characteristic of a typical location in a typical Professional healthcare environments.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Manufacturer's declaration-electromagnetic immunity			
The steth02 is intended for use in the electromagnetic environment (for Professional healthcare environments) specified below. The customer or the user of the steth02 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 Radiated RF IEC 61000-4-3	3 Vrms: 0,15 MHz – 80 MHz 6 Vrms: in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz 3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	Not applicable Not applicable 3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	**Portable and mobile RF communications equipment should be used no closer to any part of the** steth02 including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ 80MHz to 800 MHz $d = 2,3\sqrt{P}$ 800MHz to 2,7 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Recommended separation distance between portable and mobile RF communications equipment and the steth02			
The steth02 is intended for use in an electromagnetic environment (for Professional healthcare environments) in which radiated RF disturbances are controlled. The customer or the user of the steth02 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the steth02 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	N/A	0,12	0,23
0,1	N/A	0,38	0,73
1	N/A	1,2	2,3
10	N/A	3,8	7,3
100	N/A	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 Professional healthcare environments) 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 Professional healthcare environments)
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 –	LTE Band	Pulse	0,2	0,3	9	9

745	787	13, 17	modulation b) 217 Hz				
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.