stemoscope

Smart Wireless Stethoscope

(Model: STEMO310)

Instruction Manual
(DRAFT)

SAFETY WARNINGS AND PRECAUTIONS

⚠ Consult your physician before using the device if you are not a medical professional.

⚠ Keep the device at least 1 meter away from all radio frequency (RF) emitters, including WIFI routers and radios. DO NOT use the device near strong RF signals or portable and/or mobile RF devices. If sudden or unexpected sounds are heard, move away from any radio transmitting antennas.

⚠ Bluetooth Class 2 is used for data transmission. Its maximum radio frequency field strength is considered safe to use with other medical devices. However, audio, video, and other similar equipment may cause electromagnetic interference. If such devices are encountered, and cause interference, immediately move the Stemoscope device away from that device and/or switch OFF the Stemoscope device.

⚠ Store the device and components in a clean and safe place out of the reach of infants and children.

⚠ DO NOT move, slide or push the switch

button when the device is wet. If you do so, liquid droplets may go into the device and damage the internal electrical circuitry.

⚠ Recharge the battery using only the provided charging cable with a UL-certified charger (not provided).

⚠ DO NOT use the device when it is being charged.

⚠ DO NOT subject the device to extreme temperatures, humidity, or direct sunlight.

⚠ DO NOT subject the device to strong shocks, such as dropping the unit on the floor.

⚠ The working distance will be reduced when objects (walls, furniture, people, etc.) are between the device and the connected phone. To improve Bluetooth connection, reduce the distance and/or allow a line of sight between the device and the connected phone.

⚠ No modification of this equipment is allowed.

⚠ Switch off the device to save the battery power when not in use.

⚠ The battery in the device will self-discharge slowly even if it is not used. To avoid self-

discharge induced battery failure and maintain the health state of the battery, please fully charge the device every three months even if you don't use it.

⚠ The audio transmission between the stethoscope and the DrStemo app uses Bluetooth Low Energy (BLE) protocol. If your phone or tablet has other apps running in the background that connect to other BLE devices, please quit these apps to provide the DrStemo app full audio receiving bandwidth.

CONTENT

1. Introduction

Stemoscope 3 (Model: STEMO310) is a smart wireless stethoscope. It transmits audio to the “DrStemo” app installed on a smartphone. The “DrStemo” app provides rich functions such as amplification, visualization, filtering, recording, sharing, etc. The app also allows a user to access premium cloud services, including video call service and cloud data storage.
Before your first use, please read the manual carefully and follow all the instructions. Please contact us if you encountered any problems.

1.1. Essential performance

The stethoscope can detect the sounds produced by the body including heart, lungs, abdomen, arteries, veins and other organ sounds, and transmit the sounds to a smartphone or tablet running the “DrStemo” app for further process.

1.2. Indications for use

The smart wireless stethoscope is designed for medical professionals or lay users to auscultate,

record, and transmit sounds from the heart, lungs, abdomen, arteries, veins, and other internal organs. The device is intended for medical diagnostics purposes but not for self-diagnosis.

1.3. Specifications and technical data

Item	Description
Supported phones	iOS: 10.0 or above Android: 7.0 or above
Frequency range	20 – 2000 Hz
Working distance	< 2 meters typically
Transportation And storage	-10 °C to +60 °C / 15 %RH to 85 %RH / 800 hPa to 1060 hPa
Operating conditions	+10 °C to +40 °C / 15 %RH to 85 %RH / 800 hPa to 1060 hPa
The time required for Stemoscope to warm from the minimum storage temperature (-25°C) between uses until it is ready for intended use when the ambient temperature is 20°C: 1 hour.	

The time required for Stemoscope to cool from the maximum storage temperature (70°C) between uses until it is ready for intended use when the ambient temperature is 20°C: 1 hour.

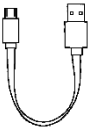
1.4. Signs and symbols

	Follow operating instructions
	Indicates the manufacturer of the unit, including manufacturer's name and address
	The device must be disposed of properly when it will no longer be used. Dispose medical waste based on local regulations and comply with applicable laws.
	Indicates the Batch Code
	Attention, see instructions for use
	MR Unsafe
	Bluetooth

1.5. Package contents

Stemoscope

x1



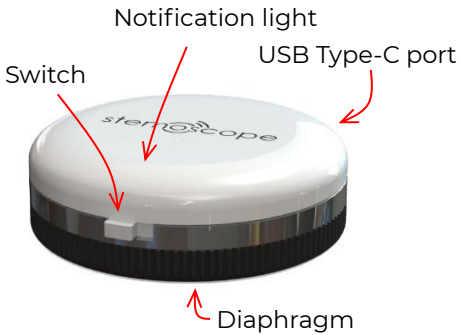
Charging cable

x1

Quick start guide

x1

2. Hardware identification



The switch in the left position is the OFF state. Slide the switch to the right to start Stemoscope.

The diaphragm makes contact with the human body to pick up body sounds.

To charge Stemoscope, plug one end of the charging cable into the USB Type-C port and another end to a UL-certified USB charger (not provided in the package).

The device can output **analog** audio through the USB Type-C port. Earphones support USB "Audio Accessory Mode" can be plugged to listen. **Digital USB earphones with a DAC are NOT supported.**

The device status can be identified by the notification light.

Notification light	Device status
Pulsing (smoothly fading in and out)	Waiting for Bluetooth connection.
Blinking	Connected but not transmitting sound.
Consistently on	Connected and transmitting sounds.
Off	The battery is fully charged if the device is turned off and being charged.
	Out of battery power if the

	device is turned on.

3. Basic steps to listen to the sounds

Here are the basic steps for you to use Stemoscope.

Step 1. Open the "DrStemo" app. If you haven't installed the "DrStemo" app, please search and install it from Apple's App Store or Google's Play Store.

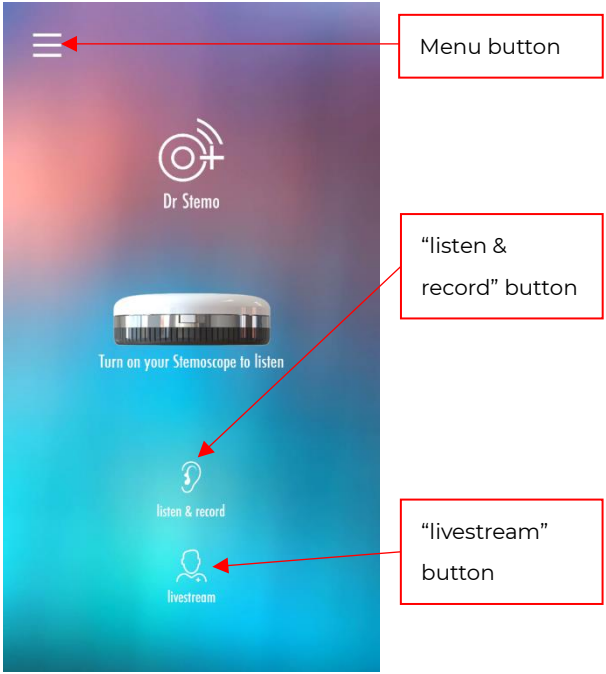
The "DrStemo" App

The app user interface is customized for medical professionals and lay users. The first time you use the app, you will be asked to set your role. Please choose the right one, because a wrong choice can prevent you from using the device correctly. If you want to change later, you need to re-install the app.

The app needs to read the QR code on the diaphragm of your Stemoscope as shown in the picture below. Just follow the simple steps to register.

Find the QR code on your Stemoscope

After registration, you will see the home user interface as shown below. This user interface shows that there is no Stemoscope connected yet. Before Stemoscope is connected, the “listen” button is not active.



Home user interface before Stemoscope is connected

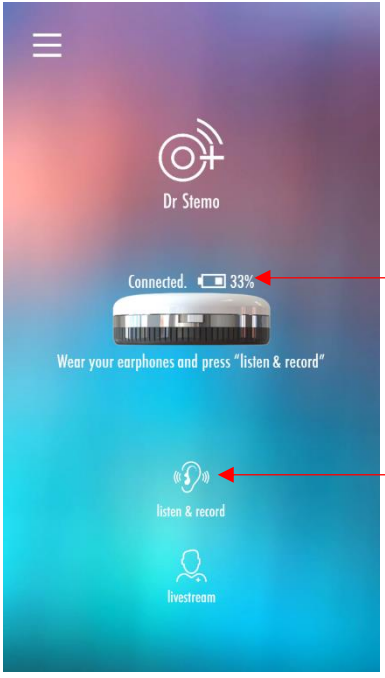
Step 2. Slide the switch button of Stemoscope to the right. The notification light will start to smoothly fade in and out and the app will start to search for and connect to the Stemoscope. When

the Stemoscope is connected, the notification light of the Stemoscope will blink. Bluetooth pairing in the phone settings is NOT needed.

The home user interface will be updated once connected. The “listen” button will start to animate. The battery power level of the Stemoscope is displayed. When the power is low, please charge it timely. You can press the doctor/patient button to make a video call to your doctor/patient if you have access to the cloud service.

Step 3. Press the “listen” button in the app to start listening. The “listen” user interface is customized for non-medical professionals and medical professionals respectively. The “listen” user interface has three themes: “video,” “heart,” and “lung”. You can listen to the sounds in any of these three themes. Internal phone speakers are not good at playing body sounds that have many low-pitched components. Therefore, please use high quality earphones (either wired or Bluetooth) to listen. Even if you just want to record the sounds, you may use earphones to monitor the sounds (for

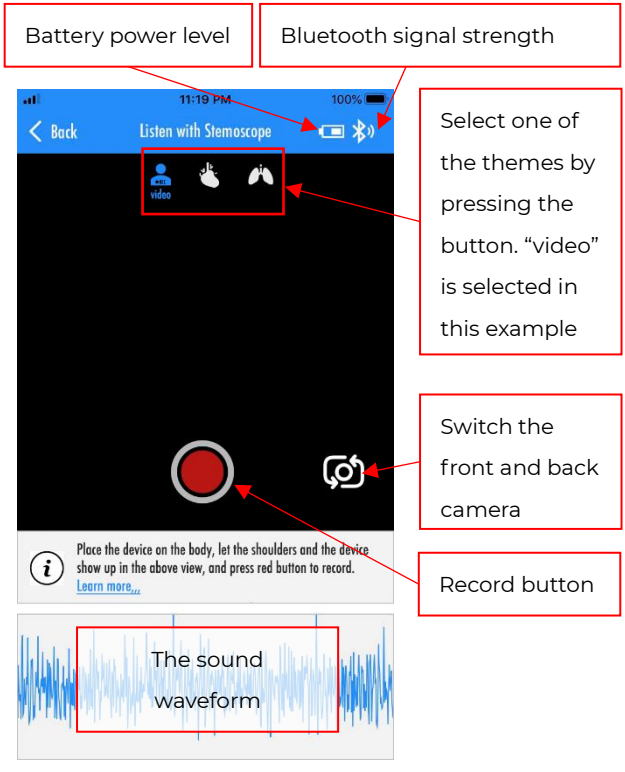
example, holding Stemoscope stable can give better quality). Please consult your doctor on where to listen and record.



The battery level of the connected stethoscope

Animated "listen" button after connection. Press it to listen.

Home user interface (after Stemoscope is connected)



The “video” theme of the “listen” user interface

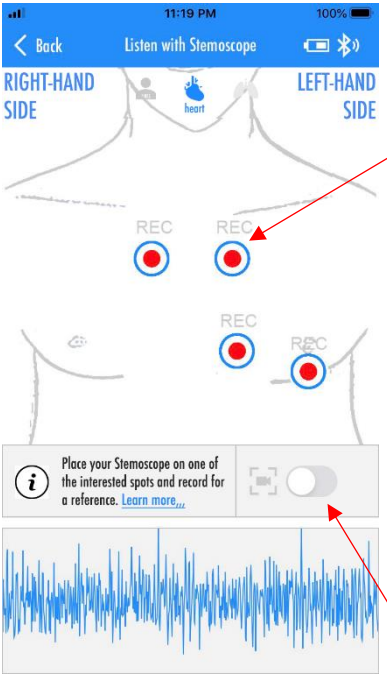
4. **Record a video composed of the auscultatory sounds and the camera view**

You can use the “video” theme of the “listen” user interface to record a video composed of the video showing where Stemoscope is placed and the sounds transmitted from this Stemoscope. Sounds from different body spots may have different characteristics, so it is critical to know what part of the body emitted those sounds. A video can record the sounds and associated location of the Stemoscope. When you do the recording, please make sure the location of the Stemoscope can be determined in the camera view. For example, a doctor may determine the spot based on its relative location to the neck. Using the “video” theme for recording is the preferred recording option if you are not sure about the correct spots for listening.

5. **Record the sounds on a predefined body spot**

Besides the “video” theme in the “listen” user interface, there are another two themes: “heart”

and “lung,” providing some predefined spots to save heart sounds and lung sounds respectively. The following picture shows the “heart” theme. You can place Stemoscope on one of the body spots shown in this user interface and press the corresponding “red dot” recording button to record the corresponding sounds. You may choose to screen record so that the sounds and the waveform displayed on the screen can be composed into a single video file. To do so, toggle on the screen recording option button before you press the “red dot” recording button. When you look at the picture that shows the interested body spots (red dots), pay attention to the orientation of the human body marked with right-hand side and left-hand side. Make sure you do not mix the left and the right of the human body where the Stemoscope is placed**.**



The “heart” theme of the “listen” user interface

6. More features for medical professionals

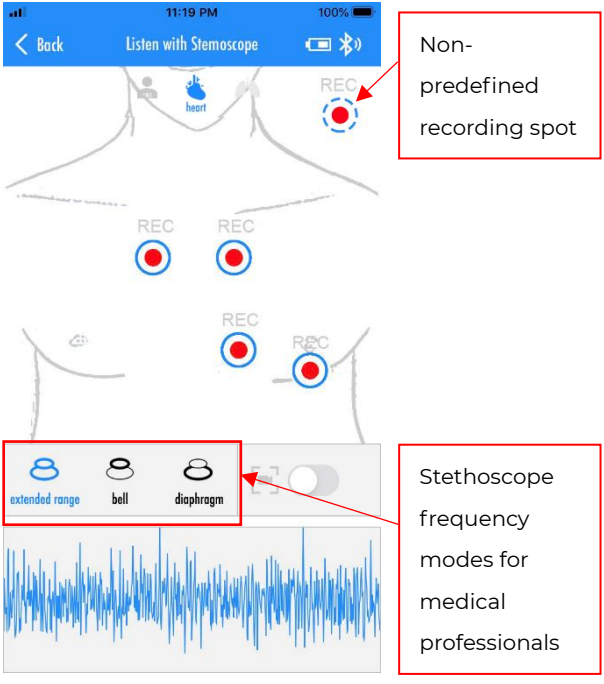
Two extra features were provided in the “listen” user interface for medical professionals. Medical professionals sometimes need to filter the sounds

for better interpretation or record the sounds from some body spots that are not commonly used.

- **Choose Stemoscope frequency modes**

The auscultatory sounds can be filtered in three different frequency modes: bell mode, diaphragm mode, and extended range mode respectively. The following table shows the frequency ranges of these modes.

The Bell mode emphasizes the low frequency sound, which makes the major part of normal heart sounds, while the Diaphragm mode weakens the low frequency sounds, which may reduce the interference of heartbeat when you listen to the lung sounds. The Extended range mode covers the whole frequency range from 20-2000 Hz. You may switch among these modes based on your preference. We don't make recommendations on what frequency mode should be used.



Extra features for medical professionals in the "listen" user interface

- Record on non-predefined auscultation spots

If you want to record the sounds emitted from the body spots other than those predefined red dots, you can use the non-predefined recording spot button. After you record, you can add some notes to describe the spot when you save the audio.

7. Live stream the auscultatory sounds

As a part of premium cloud services, the app lets a patient make a video call with a doctor, and in the video call the patient can livestream the sounds of the Stemoscope to the doctor. During the video call, the doctor can instruct the patient on where and how to place Stemoscope so that the doctor can listen to the desired spots of the patient's body remotely. Here is the process flow.

Step	Doctor	Patient
1	Both the doctor and the patient install the app and the patient has a Stemoscope.	
2	The doctor adds the patient as a contact or vice versa. The one who receives the invitation email needs to accepts the invitation.	
3	The doctor and the patient schedule the call offline.	

4	On the scheduled call time, the doctor opens the app, enters the “call & livestream” user interface, finds the patient’s name in “my patients,” presses the patient’s name, and then the “make video call” button.	Before the scheduled call starts, the patient switches on Stemoscope and connects it to the app. Enter “call & livestream” and then the “waiting room” page in the app to wait for the call.
5	The doctor talks with the patient in the video call. The doctor can press the “start auscultation” to start Stemoscope sound transmission.	The patient talks with the doctor in the video call. The patient follows the doctor’s instructions on the use of Stemoscope.
6	Hang up the call when the session is completed.	

The doctor can ask the patient to register an account for the video call function if the patient has not done that. To add a contact, the doctor

needs to press “call & livestream” in the home user interface, and then on the “my patients” page, press the button on the top left to enter the invitation page. Type the email address that your patient used for the video call account registration and an invitation email will be sent to this email address. Please remind your patient to accept the invitation in the app.

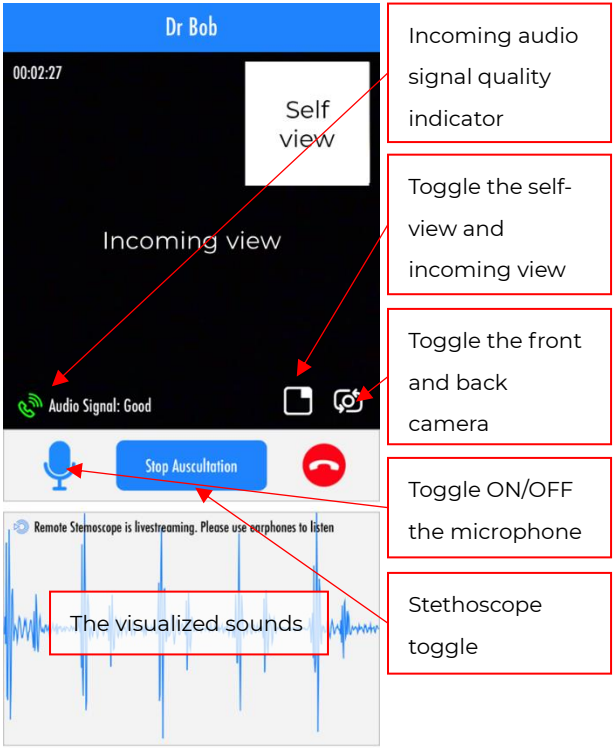
Several minutes before the scheduled time and date, the patient needs to open the app and enter the “wait room” page after pressing the “call & livestream” button in the home user interface as shown below. The patient needs to make sure the status is ONLINE. If it is OFFLINE, a “log on” button will show up and the patient can press it to go ONLINE.

	ONLINE. You can make and receive a call.
	OFFLINE. You might not make or receive a call.

The doctor needs to enter the “virtual clinic” page after pressing the “call & livestream” button in the home user interface. The doctor needs to make

sure the status is ONLINE. If it is OFFLINE, a “log on” button will show up and the patient can press it to go ONLINE. The doctor can see if a patient is online. If the patient to call is OFFLINE, the doctor may fail to call the patient. In case this happens, contact the patient to check if the patient is in the “waiting room” of the app. The doctor needs to call the patient to initiate the video call. The patient does not have the option to call the doctor.

Once the doctor calls the patient and the patient successfully accepts the call, the video call user interface will show up. The doctor and the patient can speak to as well as see each other.



The video call user interface

If the video call is disconnected for some reason, to reconnect, the doctor needs to call the patient because the patient cannot call the doctor.

If you feel the audio quality is not good, please do

not livestream the sounds of the Stemoscope because the sounds of the Stemoscope can be damaged. You can learn the audio signal quality by looking at the audio signal quality indicator and the associated texts. Here is the list of signal quality indicators and their meaning.

	Audio signal receiving quality is good.
	Audio signal receiving quality is bad.
	Audio signal receiving quality is very bad.

When the sound of the Stemoscope is being transmitted, the doctor may ask the patient to mute the microphone. The patient can toggle the microphone button.

	Microphone is toggled on. Press to toggle off.
	Microphone is toggled off. Press to toggle on.

It is recommended that both sides wear earphones for the video call.

8. Share (send) a recording

A recording can be shared or sent in two ways: share the audio or video files or share through the cloud service.

After you record an audio or a video, you can choose to share/send an audio file or a video file or both. To do so, in the “recorded sounds” user interface after the recording was finished, press the “share” button  at the top right corner. All the recordings can also be found: “Home user interface” -> ”menu button on the top left” -> “history”.

If you use the “DrStemo” app as a non-medical professional user and use the premium cloud service, you can save the data online and share the data with your doctors.

9. Care, cleaning, and disinfection

The stethoscope should be wiped clean and disinfected with 70% isopropyl alcohol wipes. DO NOT immerse the device in any liquid or subject it

to any high-pressure/autoclave sterilization processes.

10. Data security

When using the “DrStemo” App, please enable the security features of your smartphone or tablet and the network to protect your data or patient data that is created and stored using this software, in addition to security features embedded in the system. The device security features protecting against malware may include but not be limited to 1. Do not root your phones or tablets that run the App. 2. Do not install any app from none-trusted source. Update to the latest version of the “DrStemo” App.

11. Trouble shooting

Symptom	Possible cause	Solution
The notification light is	Out of battery power.	Charge Stemoscope before use.

consistently OFF when the device is switched ON.	Hardware malfunction.	Contact customer service.
Can't connect to a smartphone.	Permissions are not given to the mobile app.	Open the app → Settings → Search for Stemoscope, check if right permissions have been allowed. If not, please allow and try again.
	Smartphone compatibility issue.	Find another phone or tablet to try again.
	Other issue.	Contact customer service.
The sounds are not sufficiently loud.	Earphones are not used.	Internal speaker is not good at playing body sounds. Please use earphones to listen.
	The phone volume is set low.	Please increase the phone volume. Body sounds are mainly

		composed of low-pitched sounds that are less audible. Higher volume is needed than that for other sounds such as music.
	Earphones compatibility with the smartphone.	Please check if your earphones are loud in listening to other sounds on this phone. Try another set of earphones or another smartphone to confirm.

12. Electrical Safety

Guidelines and manufacturer's declaration - electromagnetic emissions		
This STEMO300 stethoscope is expected to be used in the following electromagnetic environment. The purchaser or user should ensure that it is used in this electromagnetic environment:		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The STEMO300 stethoscope uses RF energy only for its internal function. There for, 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 STEMO300 stethoscope 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	

Guidelines and manufacturer's declaration - electromagnetic immunity

This STEMO300 stethoscope is expected to be used in the following electromagnetic environment. The purchaser or user should ensure that it is used in this electromagnetic environment:

Immunity test	IEC 60601 test level	Coincidence level	Electromagnetic environment - guide
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 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 %.
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines 100 kHz repetition frequency ± 1 kV for input/output lines	Not applicable	
Surge IEC 61000-4-5	± 0.5 kV, ± 1 kV, Line-to-line ± 0.5 kV, ± 1 kV,± 2 kV Line-to-ground	Not applicable	
Voltage dips,	0 % UT; 0,5 cycle	Not applicable	

short interruptions and voltage variations on power supply input lines IEC 61000-4-11	At 0°, 45°, 90°, 135°,180°, 225°, 270° and 315° 0 % UT; 1 cycle And 70 % UT; 25/30 cycles Single phase: at 0°		
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: UT refers to the AC network voltage before the test voltage is applied.			

Guidelines and manufacturer's declaration-electromagnetic immunity			
This STEMO300 stethoscope is expected to be used in the following electromagnetic environment. The purchaser or user should ensure that it is used in this electromagnetic environment:			
Immunity test	**IEC 60601 test level**	**Coincidence level**	**Electromagnetic environment - guide**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 10 V/m 80 MHz to 2.7 GHz	Not applicable 10 V/m 80 MHz to 2.7 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance PVd]5.3 [1 = PEd]5.3 [1 = 80 MHz to 800 MHz PEd]7[1 = 800 MHz 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).b 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 central frequency of 80 MHz and 800 MHz, the formula for higher frequency band shall be used.

Note 2: These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by absorption and reflection from buildings, objects, and humans.

a. Fixed transmitters, such as base stations for wireless (cellular/cordless) phones and terrestrial mobile radios, service radios, AM and FM radio broadcasts, and TV broadcasts, of which the field strength cannot be accurately predicted in theory. In order to assess the electromagnetic environment of fixed radio frequency transmitters, electromagnetic field surveys should be considered. If the measured field strength of the place where this product is located is higher than the above applicable RF compliance level, the product should be observed to verify that it can operate normally. If abnormal performance is observed, supplementary measures may be necessary, for example, reorienting or relocating the product.

b. In the entire frequency range of 150 kHz ~ 80 MHz, the field strength should be lower than [3] V/m.

Recommended isolation distance between portable or mobile RF communication equipment and this product

This STEMO300 stethoscope is expected to be used in an electromagnetic environment where RF radiation disturbances are controlled. According to the maximum output power of the communication equipment, the purchaser or user can prevent electromagnetic interference by maintaining a minimum distance between the portable or mobile RF communication equipment (transmitter) and the product.

Maximum rated output power of transmitter W	Isolation distance corresponding to different transmitter frequencies / m		
	150 kHz~ 80 MHz $d = 1.2\sqrt{P}$	80 MHz~ 800MHz $d = 1.2\sqrt{P}$	800 MHz~ 2.5GHz $d = 2.3\sqrt{P}$

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 the maximum rated output power of the transmitter not listed in the above table, the recommended isolation distance d, in meters (m), can be determined by the formula in the corresponding transmitter frequency column, where P is the maximum rated output power of the transmitter provided by manufacturer, in watts (W).

Note 1: At central frequencies of 80 MHz and 800 MHz, the formula for higher frequency band shall be used.

Note 2: These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by absorption and reflection from buildings, objects, and human bodies.

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment						
Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 –390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430 – 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						
1720	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						
2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500						
5785						

13. FCC Caution

Part 15.21

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Part 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 harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

FCC Part15.105

Note: 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.

2. This equipment complies with RF radiation exposure limits set forth for an uncontrolled environment.

3.This equipment should be installed and operated with minimum distance 0mm between the radiator& your body.

14. Disposal

The device must be disposed properly after they will no longer be used. Dispose medical waste based on local regulations and comply with

applicable laws.

15. Warranty

A limited warranty is provided for Stemoscope. Please visit stemoscope.com/warranty for a full description of the warranty.

16. Contact information

Email: hello@stemoscope.com