Steth IO Spot®

User Guide

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Revision I

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Version: 1 for iOS and Android Operating Systems

www.stethio.com

Steth IO Spot

1.Legal Disclaimers

Steth IO Spot collects data to be used in healthcare for the physical examination of individuals. This device does NOT provide a clinical diagnosis and can only assist the healthcare provider in arriving at a clinical diagnosis. When necessary, it is recommended that clinical expertise should supersede any examination findings suggested by the device.

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2.Contents

3.Introduction

Thank you for choosing Steth IO Spot, which can help you arrive at a clinical diagnosis during auscultation. Steth IO Spot is a device that can provide auscultation as a digital stethoscope in conjunction with a smartphone. The most outstanding care was taken in designing and manufacturing your Steth IO Spot. Steth IO Spot can be utilized by patients with instructions to auscultate and provide the healthcare provider with findings to review during clinical evaluation. Please read these instructions before using this device and save them for future reference.

4.Product Description

Steth IO Spot is an acoustic device used with a smartphone to collect biological sounds. Steth IO Spot attaches to the lightning port/USB TypeC (Universal Serial Bus Type C) and can be utilized to auscultate patients during physical examination. Steth IO Spot, the smartphone application software app or Steth IO powered third party app with Steth IO Spot functionality, performs real-time processing of the audio signals to hear the sounds using headphones. The device can record sound, allowing patients or an assistant to capture biological sounds for providers to review during a telemedicine visit synchronously or asynchronously later. Steth IO Spot is intended as a diagnostic aid, enabling the healthcare provider to identify abnormalities in the collected sounds.

4.1. Components of the Steth IO Spot System

	Steth IO Spot Device: The Steth IO Spot device can transmit your heart, lung, or other biological sounds to the mobile device. This device needs to be connected to your mobile phone's lightning port/USB-Type C port.
	Steth IO Spot Software: The software application is available for download from a designated software repository. A special link to download the software will be provided with the purchase of the system or an alternate software application will be provided by the authorized user of the Steth IO Spot's functionality.

5.General Device Product Specifications

1. Performance Characteristics

The device is designed to guide audio from the skin surface to the transducer. This device does not have a limited shelf-life because of the low likelihood of time-dependent product degradation.

2. Environmental Specifications

When in conflict with the Environmental Specifications of the intended smartphone, adhere to the stricter Environmental Specifications.

Operational Temperature: 0˚C to +35˚C

Operational Humidity: 5% to 95% (Relative, Non-Condensing)

Storage Temperature: 0˚C to +35˚C

Storage Humidity: 5% to 95% (Relative, Non-Condensing)

Operational Pressure: 700 to 1060 hPa

3. User Interface

The device attaches to the smartphone device through the lightning port/USB-Type C port. The user interface is the stethoscope attachment, which is placed on regions of interest on the subject. All software and device interactions are performed via a software interface operating on the handheld or desktop computer.

6. Intended Use

1. Indications for Use

The Steth IO Spot is an electronic stethoscope that enables amplification, filtering, and transmission of auscultation sound data, whereby a clinician at one location on the network can listen to the auscultation sounds of a patient on-site or at a different location on the network. Steth IO Spot is intended for use on individuals undergoing physical examination. The Steth IO Spot is intended to be used by professional users in a clinical environment or by lay users in a non-clinical environment. The device is not intended for self-diagnosis.

2. Intended User

Steth IO Spot is intended to be used by individuals undergoing physical examination under the guidance of healthcare providers. There are no additional training requirements for the use of the Steth IO Spot device.

3. Intended Use Environment and Targeted Patient Population

Steth IO Spot is intended to be used in patients' homes (with guidance from a medical provider) and by healthcare providers in Medical Facilities, Hospitals, Outpatient Clinics, and Physician Offices. Steth IO Spot can be used on any person undergoing a physical assessment. The targeted patient population consists of all types, for which the healthcare provider traditionally utilizes a stethoscope.

4. Limitations of Use

Steth IO Spot may be ineffective in hearing or visualizing biological sounds over thick garments or individuals with a biological mass index (BMI) greater than 45.

Steth IO Spot may not be effective in environments with excessive ambient noise.

5. Contraindications

Steth IO Spot should not be used over open skin lesions if present at the site of examination.

7. List of Cautions and Warnings

1. General Safety Precautions

- Read this instruction manual carefully before using the device
- The device is not operable except for use in conjunction with the Steth IO Spot software application.
- Do not immerse the device in cleaning agents or other liquids.
- Avoid using or placing the device near the source of liquid.
- Do not attempt to sterilize the device in an autoclave or glass sterilizer.
- Do not use the device if physical damage to the case, diaphragm, or other smartphones is visible. Return the device to StratoScientific Inc. if the device has been damaged (cracked, bent, or broken).
- Clean the device between uses as described in 11 Storage, Cleaning, and Maintenance.
- Do not perform any maintenance of the device while the Steth IO Spot is in use.
- Do not use the device for any purposes other than described in the indications for use.
- Do not modify the device except where described in this manual, as in replacing the diaphragm.
- Consult your smartphone or handheld computer manufacturer's electrical and radio-frequency interference instructions.
- Do not use any accessories or methods that are not described in this document with the device.
- Do not continue to use the Steth IO Spot if the skin becomes irritated or inflamed. Continued use may result in worsening the condition.
- Do not share the device with other users without cleaning it with IPA.

2. Warnings

- The device should not be used for patients with pacemakers
- The device can only assist in formulating a clinical diagnosis. When the findings suggested by the device are uninterpretable or not in accordance with your clinical results, we recommend using a traditional stethoscope for confirmation.
- Supplied software is optimized for use with the accompanying hardware, and hence the software should never be used without the accompanying hardware.
- Device cannot identify and hence should not be used to detect ischemic heart conditions
- Do not use the device near magnetic resonance imaging devices.
- Keep out of reach of individuals who are incapable of properly using the device.

- Do not attempt to use Steth IO Spot with software or hardware components/accessories not mentioned in this manual.
- Allergic reactions: Do not use the Steth IO Spot device if you develop any skin irritation or rash at the site of the application of Steth IO Spot. The occurrence of allergic reactions related to the use of the Steth IO Spot is rare, however, do not use the device if you have any known allergy to the polyurethane material used in the construction of the Steth IO Spot
- Do not attempt to use the device while charging. The software will be disabled, and a warning will pop up on the screen.
- The device's connection cord can be a choking hazard, and the device is not a toy
- Keep it away from children under three years of age, and adult supervision is required
- The Steth IO Spot device is NOT MRI-compatible. The device is MR Unsafe because it contains electronically conductive components and should not be worn near an MR environment.

3. Hazards

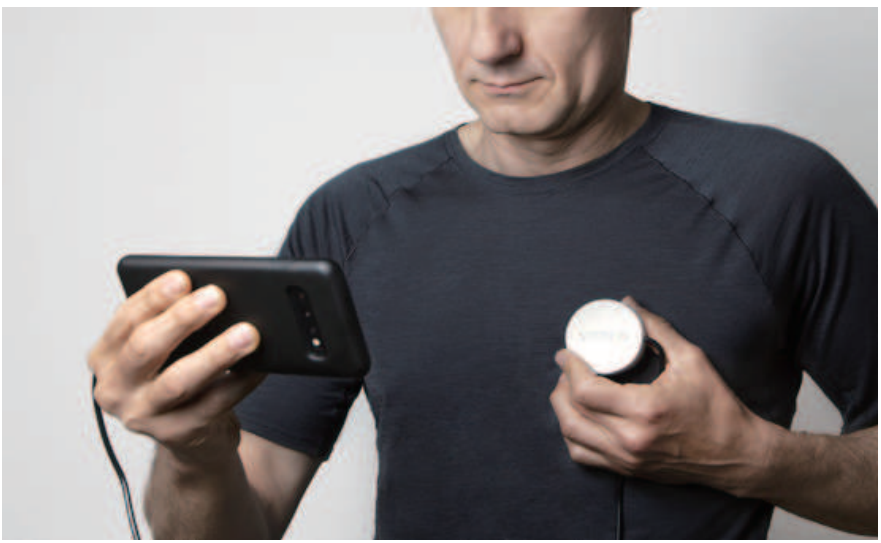
If the safety precautions and warnings mentioned above are not followed, the following hazards could occur:

Hazards	**Harm**	**Risk Control Measures**
Allergic reactions	Potential allergic reactions include dermatitis and tissue injury.	- Diaphragm component in direct contact with skin is made of biocompatible fiberglass epoxy material commonly used in other electronic stethoscopes. - The device should be cleaned with IPA between uses. - Do not share the device with other users without cleaning with IPA.
Infections	Exposure to pathogens transferred through touch contact could lead to infection.	- The device should be cleaned with IPA between uses. - Do not share the device with other users without cleaning with IPA.
Using accessories or components not instructed in User Manual	Device malfunction; Device misuse; delay of examination; incorrect diagnosis	- Steth IO Spot hardware is only operable with Steth IO Spot software.
Attempting to connect the device to other equipment not described in this manual	Device malfunction; Device misuse; delay of examination; incorrect diagnosis	- Steth IO Spot is compatible with smartphone models with iOS and Android operating platforms. - Steth IO Spot hardware can only be connected to smartphones with a USB-C/lightning port.

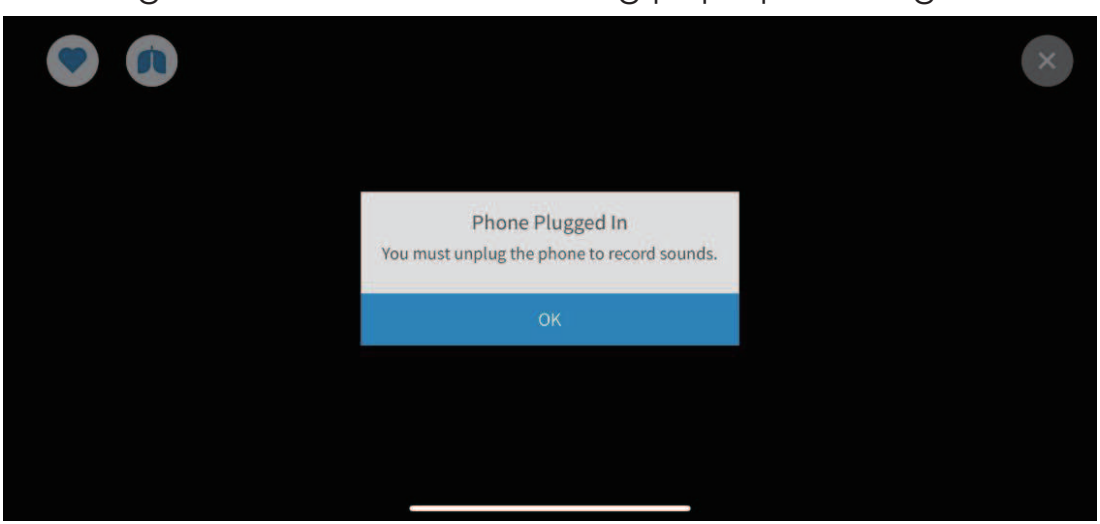
8. Steth IO Spot Device and Software Installation

1. Device Installation

Insert your Spot device into your mobile phone's lightning port/USB-Type C port. The below image will provide a clear image of how the device plugs into a smartphone.



The Steth IO Spot is intended to receive its power from other electrical equipment (i.e., Smartphones). Please note that the device cannot be used while the smartphone is charging, and the attempt of its use while charging would lead to the software being disabled and the following pop-up warning:



2. Downloading and unlocking the Software

Obtain access to the software repository using the App Store on your iPhone or Google Play Store for Android, or the Steth IO powered software provided by the authorized provider. Download the Steth IO Spot software or another Steth IO powered third party application from an authorized provider that works in conjunction with your device to visualize and hear biological sounds during auscultation. If you have difficulties accessing the software repository to download, contact us at support@stethio.com

Installing Steth IO Spot software on the smartphone will place the app's icon on the smartphone's home screen. Access the app via the icon.

3. Software Registration and Unlocking

A healthcare organization will register your mobile number in the Steth IO Spot portal. Alternatively you will be provided the registration page to register your information into your designated clinical organization. You will receive a text message with an app store link to download the Steth IO App or you will be directed to download another authorized third party App powered by Steth IO Spot.

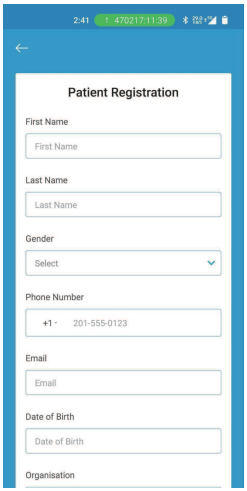
4. Software Registration and Login

NOTE: If you are using another authorized third party app, please follow the instructions provided in the Quick Start Guide and the on-screen instructions in the app to set up your device and create your account. The following instructions and screenshots apply only to the Steth IO Spot software application.

After installation, the app will display the login page with options such as Patient and Clincian.
Choose the appropriate option depending on your role. On clicking the 'Patient' button, the new page will open with two options Login or Register.

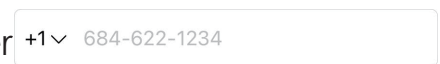
4a. Registering into the Application

On clicking Register the button, a new screen will open with a QR scanner. Continue registering by scanning the QR code provided with the Steth IO device. Or select the appropriate 'Organization' manually if you don't have any QR code.

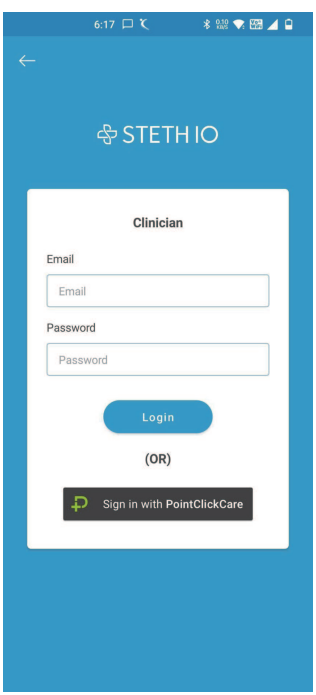


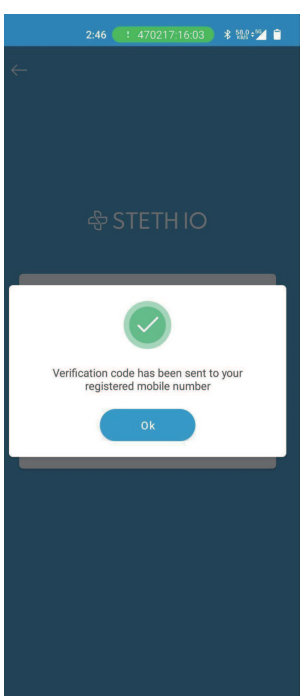
On completing the registration form by inputting all the necessary fields, click on the 'Register' button and get a pop-up 'Patient Registered Successfully' for successful registration.

4b. Login to the Application

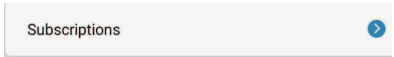
Login to the device directly by entering your mobile number 

to proceed. For enhanced security, we necessitate verification using OTP (one-time-password), which will be received as a text message. You will receive an OTP as a text message when you log back in after logging out of the software application. On entering the OTP, you will be logged in to the application.





5. Software Subscription

Patients will be redirected to the new screen when clicking the' Settings' button. Then, by clicking the 

button, patients will be provided with information about the monthly subscription offered by the Steth IO option.

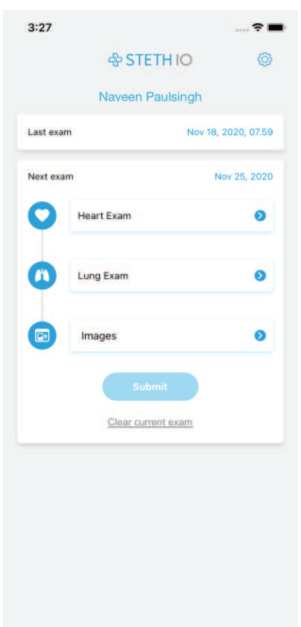
Note: After enrolling into the application, a welcome subscription plan will be activated. Patients can see the details by following the steps mentioned above. Users who are not subscribed are required to pay the amount while submitting the exam or need to renew their subscription plan.

9. Using the Steth IO Spot

NOTE: If you are using another authorized third-party app, please follow the instructions provided in the Quick Start Guide and the on-screen instructions in the app to perform your examination. The following instructions and screenshots apply only to the Steth IO Spot software application.

1. Device Placement

With the app installed on the smartphone, the user logged in, and the Steth IO Spot plugged in or paired, the device is ready for use.



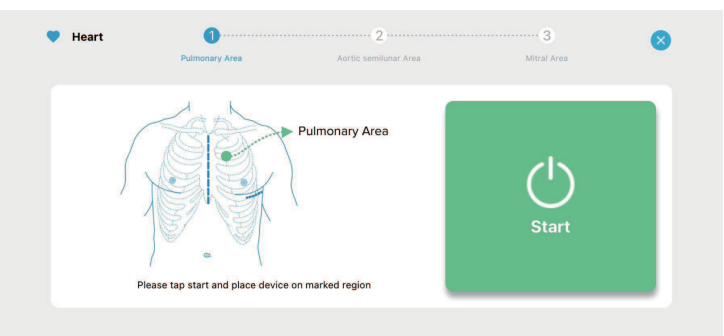
2. Heart Sounds

Please ensure that you are in a quiet environment to perform the examination.

Start recording heart sounds by selecting the 

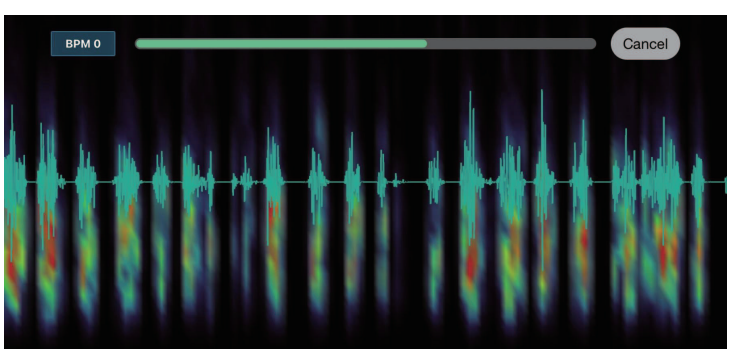
on the patient's dashboard screen. On choosing the heart exam, you will see examination routines assigned to you by your clinician. Place the device on our chest, as shown in the picture on the screen. Hold it gently against the area, and it is not necessary to apply excessive pressure. Pressing the 

will start the selected exam. The start button will invoke digital filters to highlight heart sound frequencies, making them audible and visible on the screen. During the heart exam, the software will analyze the presence of heart sounds to determine the heart rate and the calculated heart rate displayed on the screen.



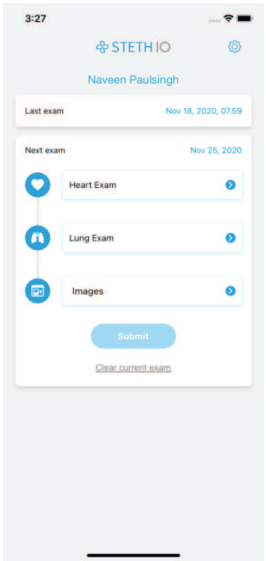
*Note: Clinical determination of the heart rate is recommended.

In the heart exam mode, the cardiac sounds will be processed for evaluation by the clinician.

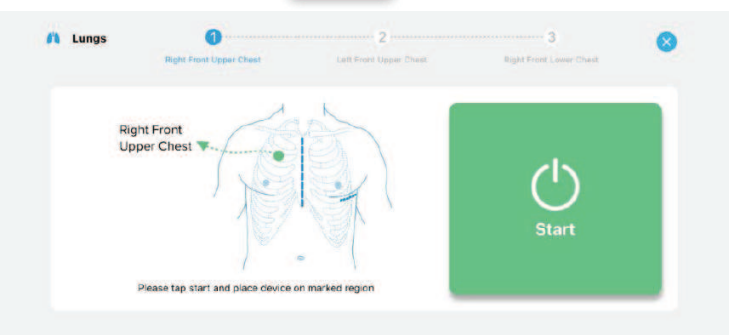


3. Lung Sounds

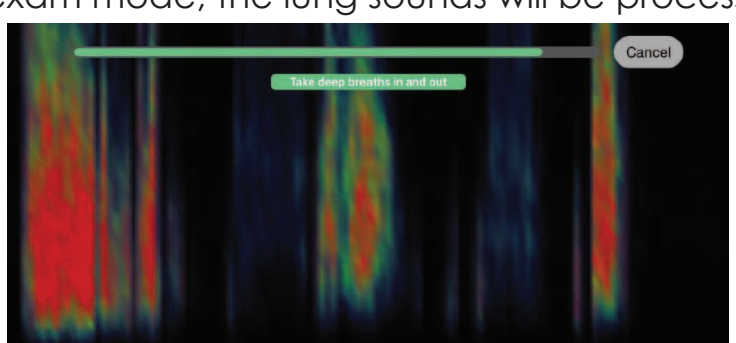
Please ensure that you are in a quiet environment to perform the examination.



Start recording lung sounds by selecting the Lung Exam routine in the patient's dashboard screen. On choosing the lung exam, you will see the clinician's set of lung examination routines. Place the device on our chest as shown in the picture on the screen. Hold it gently against the area, and it is not necessary to apply excessive pressure. Pressing the Start will start the selected exam.

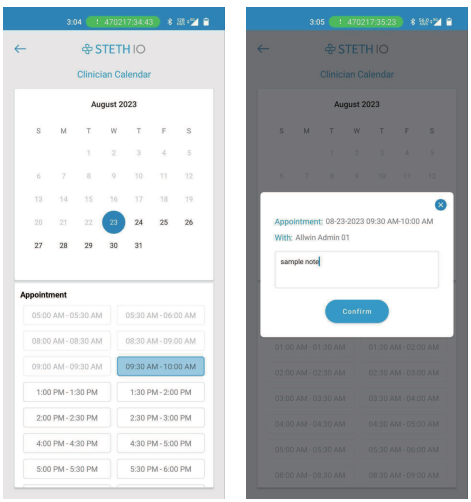


Start will invoke digital filters to highlight lung sound frequencies, making them audible. In the lung exam mode, the lung sounds will be processed for evaluation by the clinician.

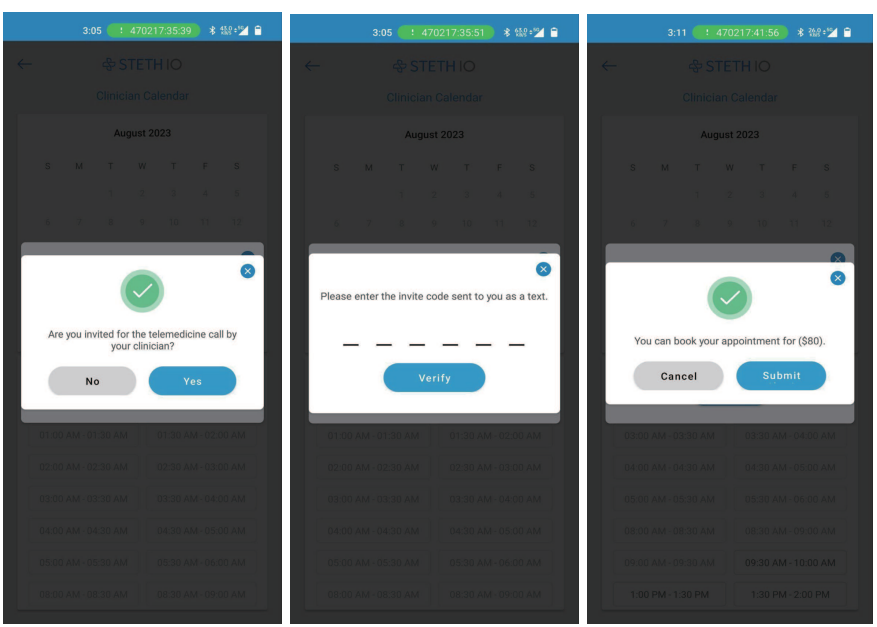


4. Schedule a Telemedicine Call

Steth IO allows the users to schedule the telemedicine call with clinicians. Patients can book an appointment by checking the ‘Clinicians’ availability on their calendar. After blocking the clinician's time, patients can provide notes as appropriate.



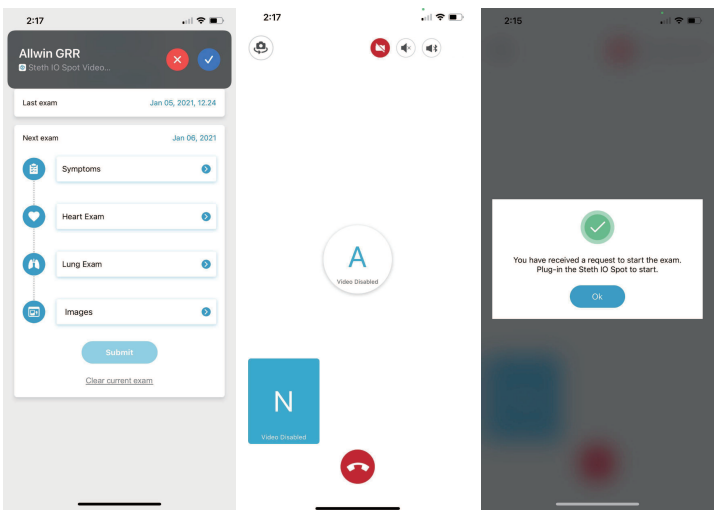
On clicking the Confirm button, the patient will receive a pop-up stating ‘Are You Invited for the telemedicine call by your clinician？ ’. If the patient has an invite code, then needs to enter the given invite code by clicking on the 'Yes' button. If the patient doesn't have an invite code, then click on the ‘No’ button. Now the patient needs to pay the displayed amount to book the appointment.



5. Live exam in a video call

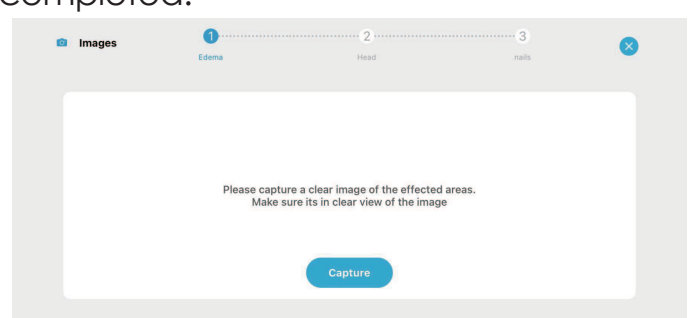
Please ensure that you are in a quiet environment to perform the examination.

Steth IO Spot allows for live auscultation examination of patients who have the Spot. Live exams can only be requested by the clinician. Patients can log in with their mobile number. Once patients log in, clinicians can make video calls to patients. Patients will receive a call from the clinician in their notification bar. Accept the call, and you will be redirected to the video call screen. Patients can disable video by pressing the button. The camera can be switched between front and back by pressing the button. When the clinician performs the exam, you will receive a popup like below. Make sure you connect your Steth IO Spot device and press Ok .



6. Images Exam

During the image exam, multiple images can be sequentially captured. Pressing the Images button on the dashboard screen will open the image examination screen. The images that should be acquired will be seen as a linear list at the top of the screen. Pressing the Capture button will bring up the camera screen. Press the camera icon to capture the required image. Repeat this action until all the images needed in the examination routine are completed.



7. Ending and Saving an Exam

Once all the assigned exams have been completed, you can press the Submit to send the data securely for the healthcare provider to review.

8. Transmitting Exam Report

A saved examination on the smartphone can be sent to another person responsible for care via email or another method. Open an exam and tap on the Share button in the upper right-hand corner. Choose to Email or Export. In case of Email, a HIPAA warning alert indicates you should only send the record to individuals responsible for care. The transmitted email report will contain:

- Time and Date of the Exam
- Patient Name
- Segment Number
- Duration of the recording
- Type of digital filter utilized
- .wav file of the exam
- Visual of the recorded sound
- A stethio file that can be opened on another device with the Steth IO Spot app.

10. Storage, Cleaning, and Maintenance

1. Storage

Do not store the unit in:

- Locations exposed to direct sunlight
- Locations subject to high temperatures and high humidity
- Wet or damp locations where water may get on the unit
- Dusty locations
- Near fires or open flames
- Locations exposed to strong vibration
- Locations exposed to strong electromagnetic fields.
- Extreme temperatures.
- Do not drop the device.

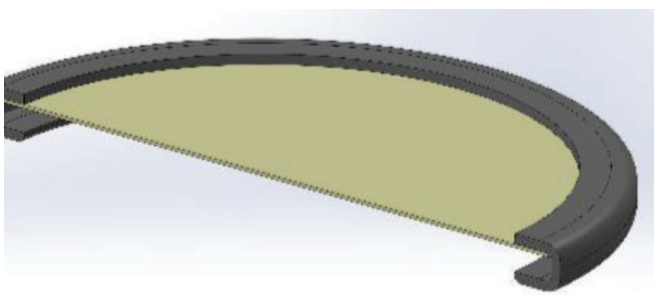
2. Cleaning

- **Use Lysol® Disinfecting Wipes, Caviwipes®, Super Sani-Cloth®, OxivirTM disinfectant cleaner, or other EPA List N recommended disinfectant to clean the exterior surfaces of the device, following EPA guided dwell time**
- The device should be cleaned before and after using it on each patient to reduce the risk of infection transmission.
- Do not submerge the device in any liquid.
- Notice: Do not subject the device to any sterilization.

3. Maintenance

Steth IO Spot hardware is not expected to require periodic service or maintenance. Depending on usage, the diaphragm and the retainer ring may require periodic replacement. The diaphragm and the retainer ring can be replaced without special tools. To replace the diaphragm, situate the diaphragm in the groove of the retainer ring. With the diaphragm in place, align the lip of the retainer ring with the groove along the rim of the bell of Steth IO. Apply firm pressure with your fingers along the retainer ring to snap the retainer ring along with the diaphragm into place. Your Steth IO Spot is ready for use as before.

The diaphragm is assembled into the retainer ring. Illustration to show the lip of the retainer ring to be aligned with the groove along the rim of the Steth IO Spot bell.



Experiencing difficulties or have questions on use? Please contact us at support@stethio.com.
WARNING: DO NOT replace the diaphragm while Steth IO Spot is in use.
The replaced diaphragm should be disposed of per local regulations.

11. Expected Service Life and Disposal

1. Expected Service Life

The typical operating time of the device is 60 seconds per session. The anticipated number of procedures is 250 per year for an anticipated total duration of two years, equivalent to a smartphone's expected battery life of two years.
The Steth IO Spot has been designed to have an expected service life of 2 years.

2. Disposal

At the end of the Steth IO Spot's expected service life, dispose of device components per local regulations.

12. Customer Service

1. Warranty

We are confident that you will be happy with purchasing your Steth IO Spot. Our hardware has a warranty against the manufacturer's defects for one year from the original purchase date. This warranty does not cover regular wear and tear. Periodic updates for
The Steth IO Spot software will be provided to the original purchaser as long as they own the Steth IO Spot device. This warranty is not transferable.

Questions or Comments? Please contact support@stethio.com.

13. Troubleshooting

App-related Issues	
Problem	**Solution**
I cannot activate the heart or the lung auscultation.	Verify the Spot's connectors are entirely plugged into the smartphone's lightning port/USB-Type C port. Verify that the correct examination modality is selected (heart or lung).
I cannot hear the sound of interest, or there is a lot of noise in the auscultation.	You will see phonocardiographic activity on the screen As a patient, you are not expected to hear the sounds If you do not see any phonocardiographic activity on the screen, verify if the device is installed correctly and plugged securely into the smartphone. Verify if the correct examination modality is selected (heart or lung). Ensure that the device is resting flush on the area being examined.
I cannot submit the examination.	Contact your healthcare provider's office with whom the device is connected.

Home-Use Related Issues		
Problem	**Potential Cause(s)**	**Solution**
Sound data is not captured appropriately during a remote or live examination.	Excessive lint or dust in a diaphragm or USB-C/lightning port connector.	Carefully dust off diaphragm component or USB-C/lightning port connector using a soft cloth.
Sound data is not captured appropriately during remote or live examination.	Degraded diaphragm component.	Replace diaphragm component following instructions in Section 10 of this manual.
Sound data is not captured appropriately during remote or live examination.	Excessive noise due to pets, children or other surrounding noise.	Perform examinations in quiet environment. If a quiet environment is not available at time of examination, perform examination at later time.
Smartphone's display is dark or not visible.	Excessive sunlight	Perform examination indoors to avoid excessive sunlight.

14. Appendix

1. Equipment Classification

a) The Steth IO Spot is a Type BF-applied part, according to IEC 60601-1.

b) This device has a rating of IP22 in accordance with IEC 60601-1-11, which means it is protected against:

a. Solid particle protection: greater than 12.5mm (e.g., fingers or similar objects)

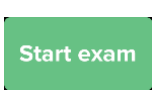
b. Liquid ingress protection: vertically dripping water shall have no harmful effect when the enclosure is tilted an angle up to 15 degrees from its normal position.

2. Symbols used for system or package labeling

Symbol	Title of Symbol	Description and Meaning of Symbol	Designation Number
	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/ EEC, 93/42/EEC and 98/79/EC.	ISO 15223-1: 2016, Ref # 5.1.1 21 CFR 801.1 (a)(d)
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified	ISO 15223-1: 2016, Ref # 5.1.5 21 CFR 801.3 (2)(i)
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	ISO 15223-1: 2016, Ref # 5.1.6
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.	ISO 15223-1: 2016, Ref # 5.3.7
	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.	ISO 15223-1: 2016, Ref # 5.3.8
	Atmospheric pressure limitation	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.	ISO 15223-1: 2016, Ref # 5.3.9

	Type BF Applied Part	Indicates applied parts that have conductive contact with the patient, or have medium or long term contact with the patient.	IEC 60417-5333
IP22	Ingress Protection	Indicates the device has protection against solids >12.5 mm (e.g., fingers or similar objects) and against dripping water when tilted up to 15°	IEC 60529
	MR Unsafe	Indicates the medical device is MR Unsafe and should remain outside the MRI scanner room.	ASTM F2503
	Read instructions for use	Indicates the need for the user to consult the instructions for use	ISO 7010-M002
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	ISO 15223-1: 2016, Ref # 5.4.4

3. Explanation of Symbols

	Icon for Steth IO Spot mobile application
	Heart filter
	Lung filter
	Close
	Back
	Setting icon
	Stop video during call
	Mute
	Connect to bluetooth speakers
	Start Exam
	Okay

3. Explanation of Symbols

	Hold & talk
	Successful button
	Camera swap
	Call decline icon
	Heart
	Lung
	Images

4. Performance Testing Information

The following mobile platforms were utilized for performance testing of the Steth IO Spot.

- iPhone 7 Plus (iOS ver 13.3.1)
- Poco F1 (Android 10, 6GB RAM)

 Questions or Comments? Contact us at support@stethio.com