eClinic Stethopod User Guide

HomeDiagnostic LLC

1. Indication for use

eClinic Stethopod is an electronic stethoscope intended for any patient or customer who would like the clinicians to listen to their chest or abdomen virtually, such as during telephone communication or video appointments. This device assists clinicians to perform routine health checkups and diagnose patients with heart and lung conditions remotely. This product is not intended for self-diagnoses.

2. Features

eClinic stethoscope allows a real-time sound transmission on most devices including smartphones, tablets, and computers. Clinicians can use them to perform remote heart and lungs auscultations as part of routine health checkups and diagnose patients with heart and lung conditions.

This product also enables the users to record the sounds of their heart or lungs on their mobile devices, then share it with clinicians for virtual medical visits or online communications. When a user has symptoms, such as palpitations, coughing or wheezing, they can listen to their heart or lung sounds and record them right at the moment. The recording can then be sent to the clinician.

This device can also be used in hospitals and clinics for patients who are in isolation units such as patients with infectious diseases to prevent spreading of the diseases. Physicians can easily perform the remote auscultations without being present bedside.

This product is intended for use on both pediatric and adult patients.

The eClinic stethopod is FDA approved. It enables amplification, filtering and transmission of heart, lung and bowel sounds to assist clinicians' virtual diagnosis.

3. Service support and assistance

Please contact HomeDiagnostic LLC if you need assistance or have any product related concerns.

For more information please visit: <u>https://www.eclinicdx.com/getstarted</u> Direct Contact: info@eclinicdx.com

4. Equipment Symbols



5. General Operation

For Patients:

Find a quiet environment and prepare to join the virtual visit with your clinician. Another individual is recommended to assist you in positioning the stethopod stably.

- 1. Attach earphones (see Figure 1) or headset to the eClinic stethopod.
- 2. Join the virtual visit if you have not done so yet. Do not turn on the speaker function of your mobile device, and if it is on, turn it off.
- Listen to the doctor's instructions. When asked to, connect the eClinic stethopod to your mobile device, then put on the earphones or a headset.

For most iPhone users attach an adaptor (see Figure 1) to allow proper attachment of the stethopod on your mobile device.

- 4. As instructed by the clinician, turn up the volume of the mobile device, then hold the stethopod and place the chest piece (stethoscope diaphragm) on the area demonstrated in Figure 2 with firm pressure. The stethoscope diaphragm needs to contact your skin directly in order to achieve the best result.
- Once the chest piece is placed in the right position, keep your hand still. Hold the chest piece in each site for 10 to 20 seconds or as directed by your clinician.
 - a. Your clinician may ask you to take some deep breaths in order to hear your lung sounds.
 - b. It is preferred that someone else holds the stethopod on the back to ensure stable positioning for the clinician to hear the lung sound better.

Note:

-- You may not hear your heart and lung sound when your clinician is listening remotely.

-- If you wish to ask the clinician a question, remove the device from the skin, turn down the volume, and communicate with the clinician.

For Clinicians:

Find a quiet environment for the virtual visit.

- 1. When it is the time for the chest auscultation connect a headset or earphones to your device to hear the sound clearer.
- Notify the patient to follow the steps in user guide:
 i. Connect an earphone or headphone to eClinic stethopod
 ii. Connect the stethopod to his/her mobile device
- 3. Guide your patient where to place the stethoscope chest piece firmly and steadily. Refer to the auscultation areas in Figure 2.
 - -- Patients need to turn off speaker mode of mobile device (if it is on);

-- Tune up the sound volume as needed on both ends (patient's and clinician's).

- 4. Once auscultation is done, remind your patient to detach the eClinc stethopod from their mobile device.
- 5. Now you are back to the routine phone/ video conversation. Adjust the sound volume as needed.

Note:

-- Heart and lung sounds are similar to the sound heard with regular stethoscopes. Due to digital amplification effects, you may hear subtle splits on S1 or S2 sounds, which are normal. However if there is any clinical suspicion of being pathological, please consider calling in the patients to your clinic for further evaluation.

-- Your patients can hear your instructions clearly via their earphones or headset attached to the stethopod. They usually do not hear their heart/lung sounds when you are listening to theirs.

-- If your patient talks to you during the auscultation the sound of the voice may be muffled when the steothopod is attached to their mobile device.

Figure 1 : eClinic stethopod and attachments





Figure 2: Chest piece (diaphragm) placement front and back views

Additional Features and Functions:

1. Patient home recording

When you are having symptoms such as palpitations, coughing, or wheezing, you may want to record your heart or lung sounds using the

following mobile Apps, and then send them to your clinicians along with your symptom descriptions.

eClinic stethoscope is compatible with the following mobile Apps:

i) Voice Record Pro App

Download the App from the App Store. Find a quiet environment, connect your smartphone to the stethopod. Place the chest piece (diaphragm) on your chest (see Figure 2, for heart use front view number 3, and for lungs use back view number 2 and 6). Open the App and press REC to record the heart or lung sounds. Once done you can replay it, rename it, and save it in your photo library, iCloud, dropbox, or email. You can then share this file with your provider via emails. You can also play it to your clinicians at clinic visits.

ii) Microphone Live App

Download the App. Connect your smartphone to the stethopod. Place the chest piece on your chest in the proper position. Open the App and hit the center Play button. Use the Screen Recording function of your mobile device to record the screen. When you are done with the recording it will be saved as a picture file. It can then be replayed or sent via email attachment to your clinicians. If you attach an earphone to the stethopod you will be able to hear the sound from the earphone.

2. Infectious Disease Control (for clinicians):

Clinicians will need to provide eClinic stethopods to patients. Then follow the instructions as above. After each use please follow the following Cleaning and Disinfecting Procedure with standard stethoscope hygiene practice.

6. Cleaning and Disinfecting Procedure

All external parts of the hardware should be disinfected with Clorox or 70% isopropyl alcohol wipes. The device can be cleaned with a disposable wipe using soap and water on its surface, stethoscope tubing, tubing connector, and chest piece.

Note: DO NOT immerse the device in any liquid or subject it to any high-pressure/autoclave sterilization processes.

7. System requirement

Compatible phones:

iPhone 6 and above, XS, XS Max, iPad Mini 4 and above, with iOS 12.0 and higher. Android 8.0 and above.

Compatible softwares:

Zoom 5.4.3 and above; Wechat 7.0.5 and above

8. Operating Conditions

Environmental - The operating temperature range is -20° to 60°C and 10% to 95% relative humidity.

The storage and transport range is -20° to 60°C, and 10% to 95% relative humidity. Acceptable pressure is 1 ATM.

Avoid exposure to extreme heat, cold, solvents and oils.

Note: Failure to follow care and maintenance recommendations could result in damage to the internal components. Internal damage to the product could cause malfunction of the product, which may lead to complete loss of function. If problems are encountered, do not attempt to repair it. Please notify our support team for assistance.

9. Disposal

If the device is damaged, please dispose of it properly.