

HD-Steth App User Manual

Revision 04

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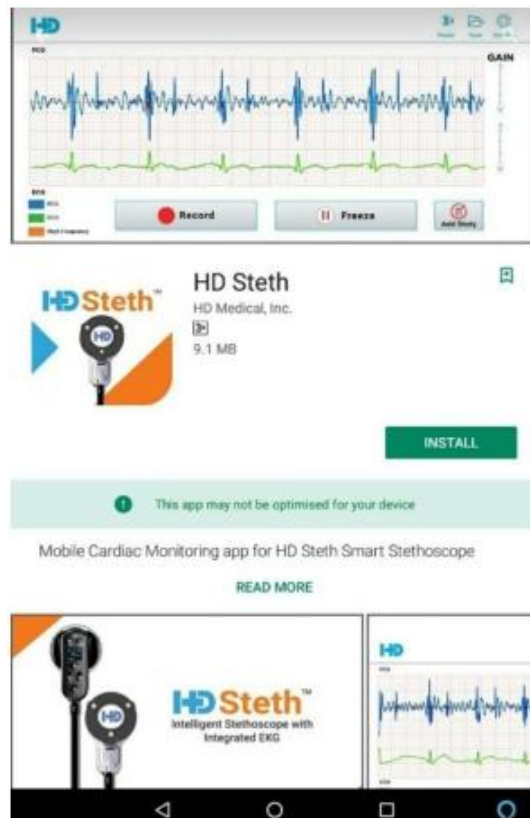
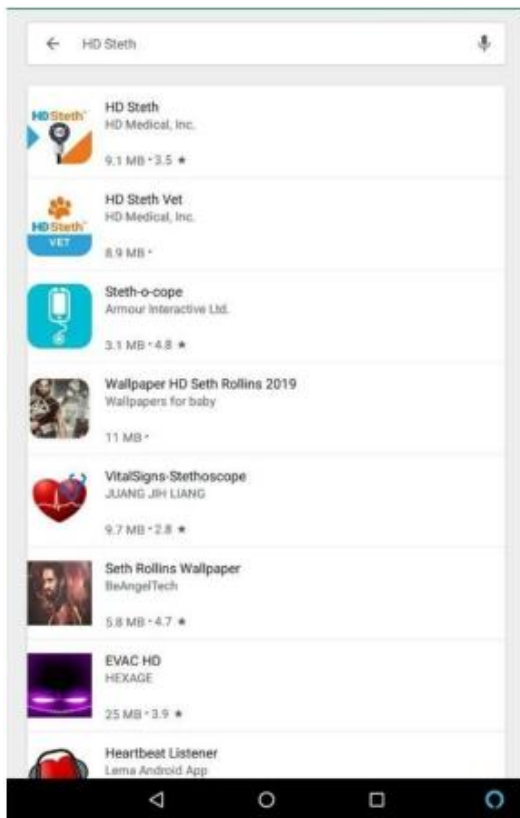
Introduction to Guide

The purpose of this guide is to provide a step-by-step walkthrough of HD Steth Android Application and how it interfaces with HD intelligent Stethoscope with integrated EKG.

1. Getting started with the HD Steth Android App for the first time

The HD Steth pairs with an android application available for download on the Google Play Store.

As shown in below screen, search for the 'HD Steth' App and initiate the download.



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2. HD Steth Minimum Requirements

Please find below the minimum specifications for the HD-Steth app to run on Android OS:

- **Snapdragon 425 processor**
- **2 GB RAM**
- **8 GB Storage**
- **Screen size - 8”**
- **Screen Resolution - 1280X800 - 190dpi**
- **Android 5.0(Lollipop) or above**
- **Bluetooth 4.0**
- **BLE(Bluetooth Low Energy)**
- **GPS**
- **Wi-Fi(For installing from Play Store)**
- **3.5mm jack(to listen to heartbeat from external audio)**

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3. HD Steth User Registration (New Customers Only)

If you are a new HD Steth customer, you have to register customer details for first time to launch the App. In the registration screen, enter customer Name, Email, Device Serial Number, Mobile Number and Address.

The image displays two side-by-side screenshots of the HD Steth App Registration form. The left screenshot shows the form with empty input fields. The right screenshot shows the form with sample data entered: Name: ABC, Email: hdmtestusage@gmail.com, Device Serial Number: SE18120xxxx, Mobile Number: +123456789, and Address: XYZ. Both forms have a blue SUBMIT button at the bottom.

While submitting the user registration form ensure internet connection is active. If internet connection is not enabled then App will not be allowed for user registration.

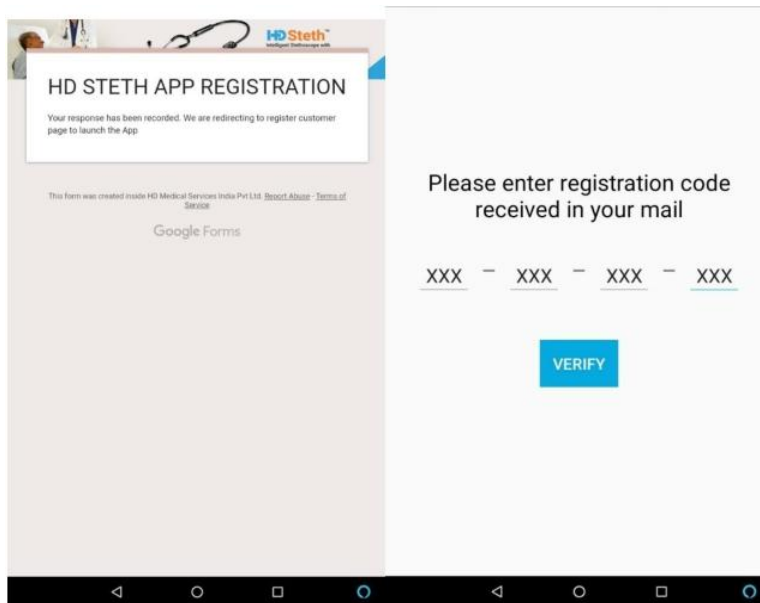
Web page not available

The web page at
<https://docs.google.com/forms/d/e/1FAIpQLSdlgCVbFYoxLLVdVaCOP-q2WH-yfHt5OPY2buGjsno--886Q/formResponse> could not be loaded because:
net:ERR_INTERNET_DISCONNECTED



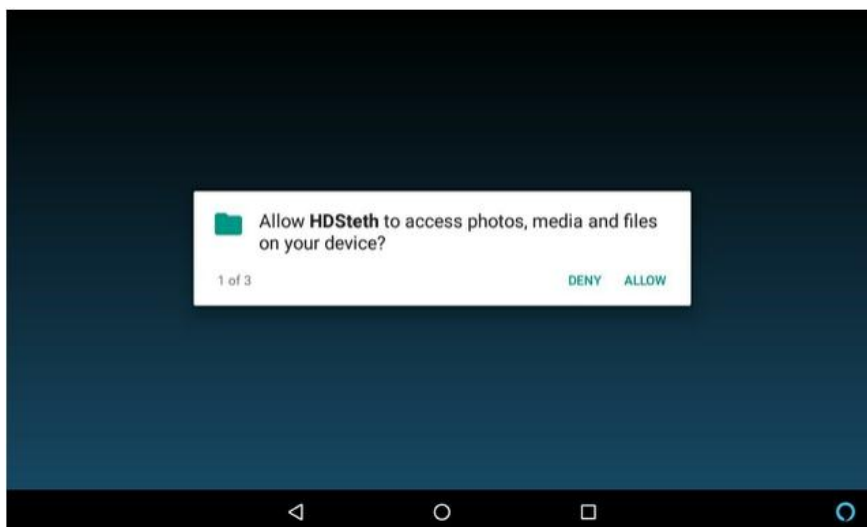
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On successful submission of user registration 12 digit auto registration code is sent to subscribed email from support@hdmedicalgroup.com. If the registration code is valid then App will be launched.

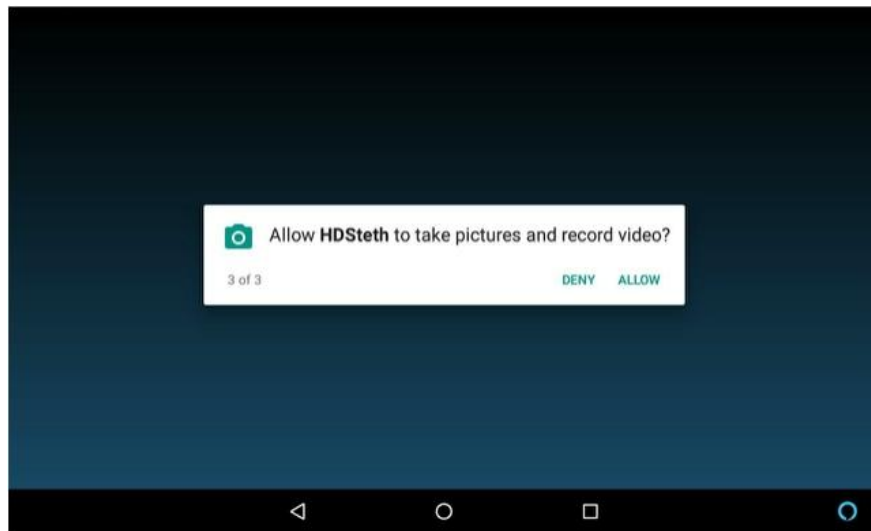
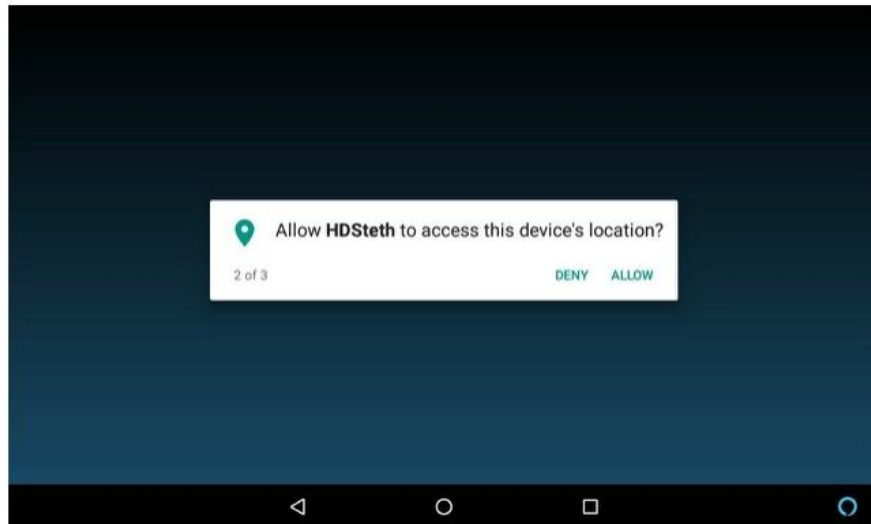


4. App Launch

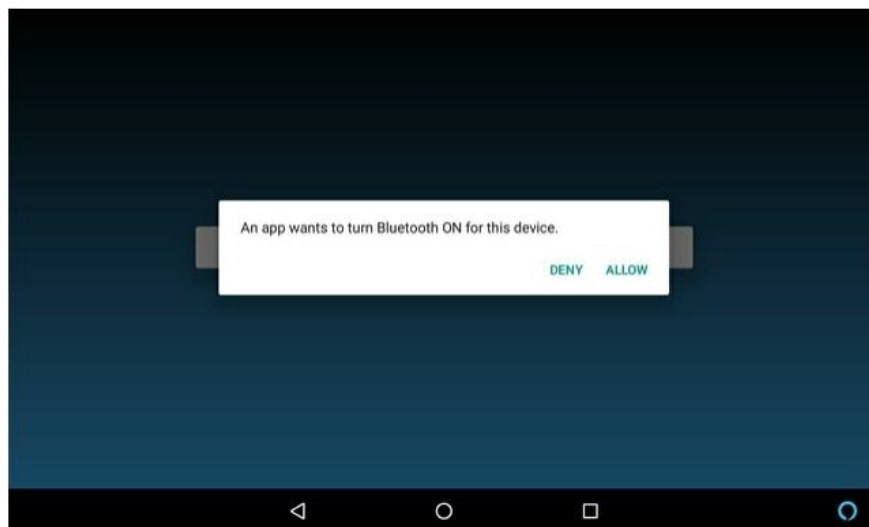
4.1 By clicking the HD Steth icon for first time the App request to access photos, media, files, device location, pictures and record video of the device. If the user allows these settings then App could resume further. These permissions are to access device file system and Bluetooth.



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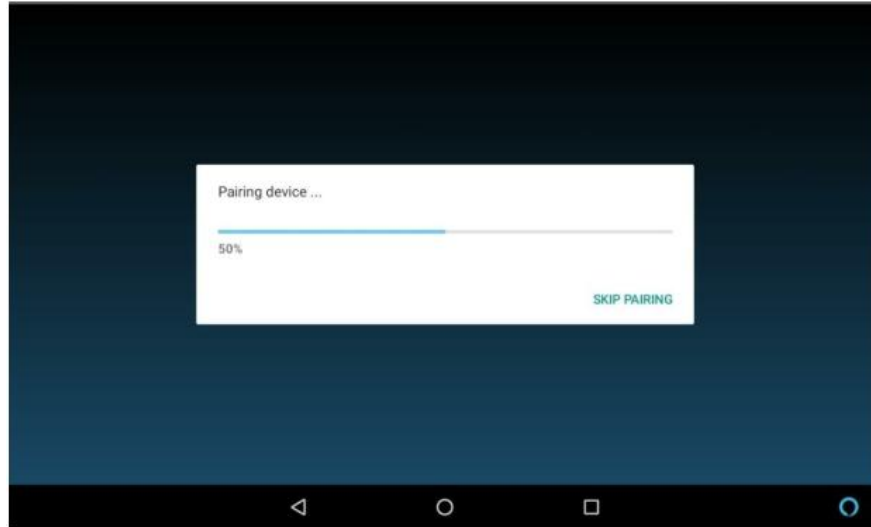
If Bluetooth is OFF in tablet then App will request to turn Bluetooth ON to communicate with HDSteth device.



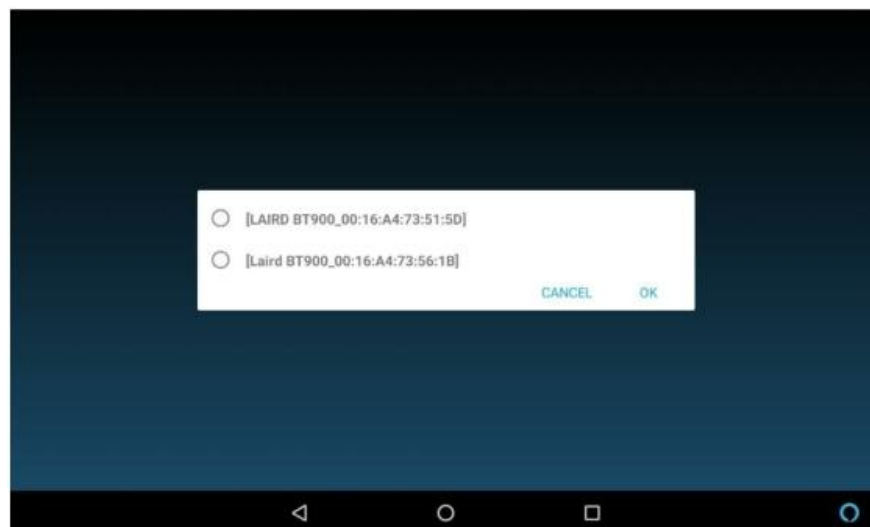
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5. HD Steth Device Discovery

5.1 As soon as the App is launched it proceeds to scan for HDSteth devices in the vicinity. If only one device is available then it proceeds to pair with that device.

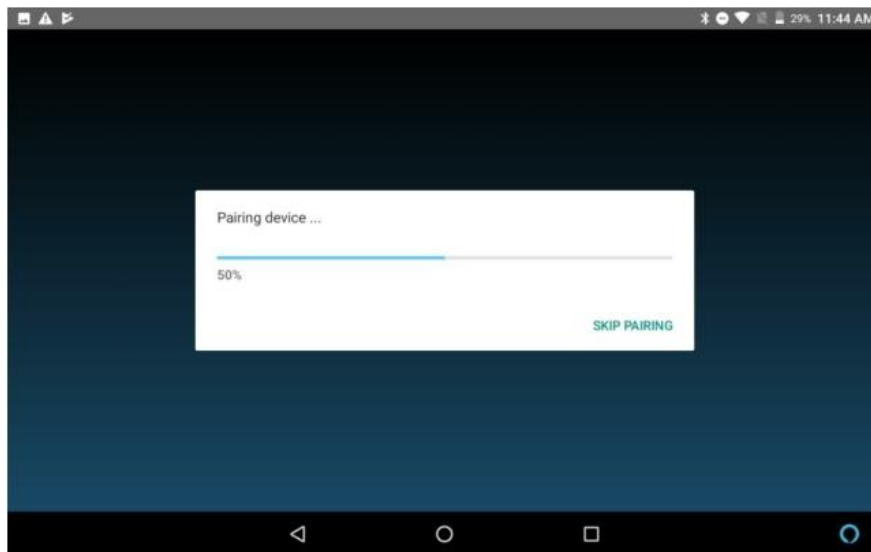
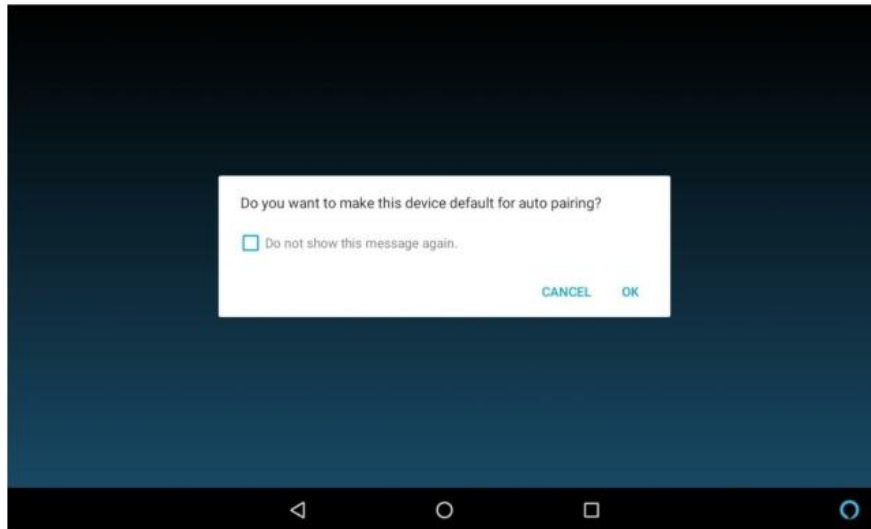


5.2 If multiple devices are available then they will be listed so that the user can select one of the devices for pairing. Even if there are multiple devices available if the lastly paired device is there then the App will proceed to connect with that lastly paired HDSteth device. If it is unavailable then it will go for a full Bluetooth scan and repeat the subsequent steps as described above.

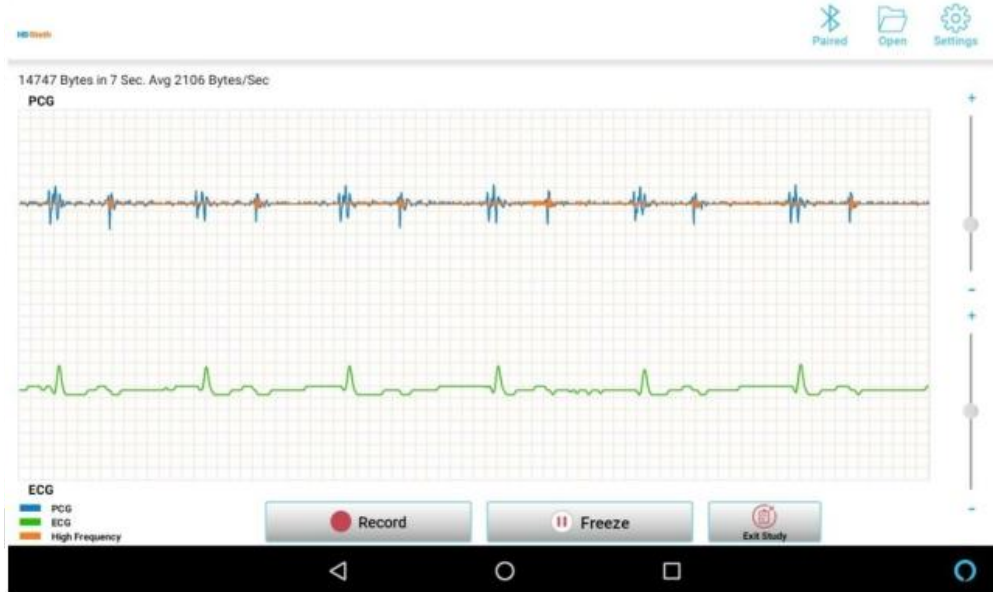


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5.3 On pairing with a device for the first time it asks the user whether that device can be made the default Steth device so that the App can try for direct connection with that device instead of scanning for Bluetooth devices, thereby saving time.



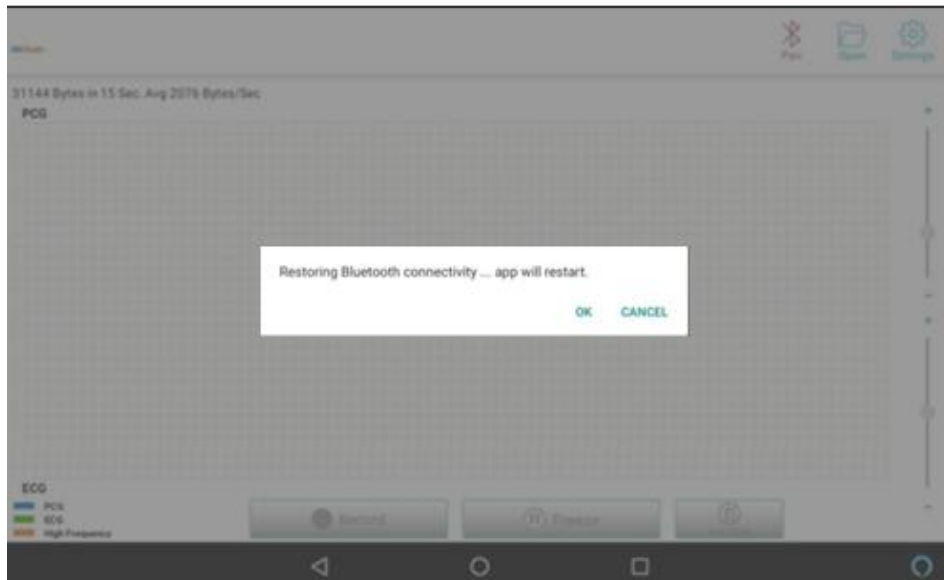
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5.4 While pairing with a device if the user press “SKIP PAIRING” the App will not pair with respective HD Steth device it will navigate to blank auscultation screen with red indication of Bluetooth icon. By pressing the red indicated Bluetooth icon the App will restart to restore Bluetooth connection.

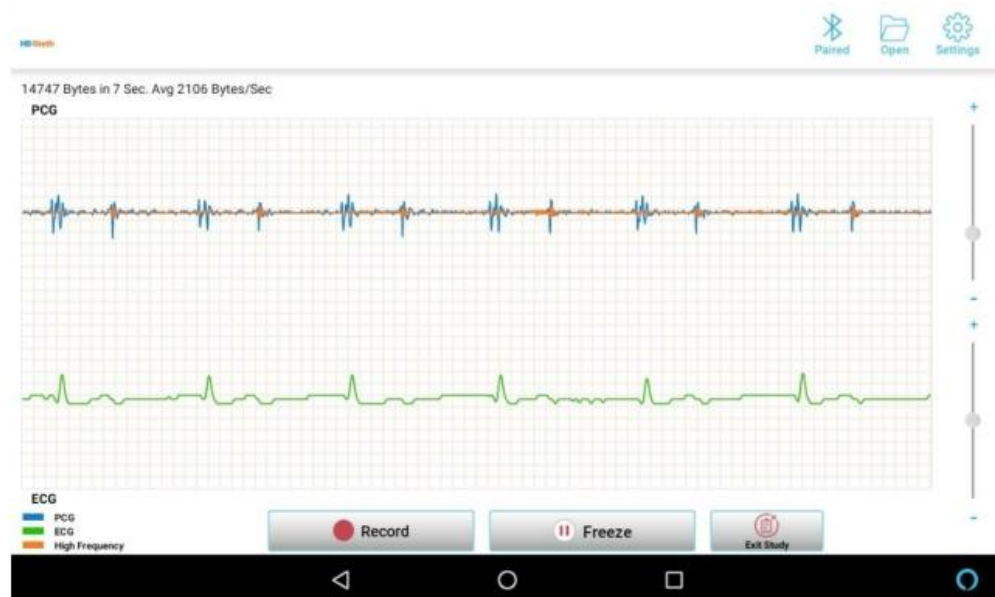


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6. Main Screen/Live Auscultation Screen:

On successful connection with the device the main screen appears depicting the live auscultation waveforms received from the device.



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6.1 Settings button: When user taps, it leads to the Settings screen that contains set of configuration options.

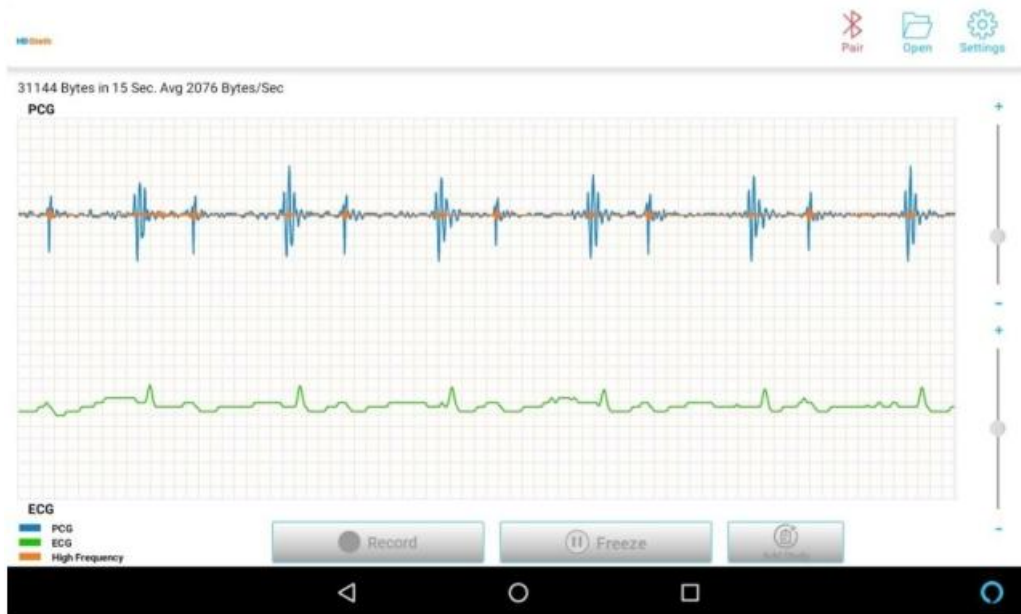
6.2 The Heart Sound a.k.a the PCG data appears as blue (default color) waveform and the High frequency murmur detection (HF MD) will be depicted with orange (default color) waveform interposed with the Heart Sound.

6.3 ECG waveform is depicted in green (default) color.

6.4 Each page of the screen, waveforms corresponding to 5 sec will be plotted in the graph.

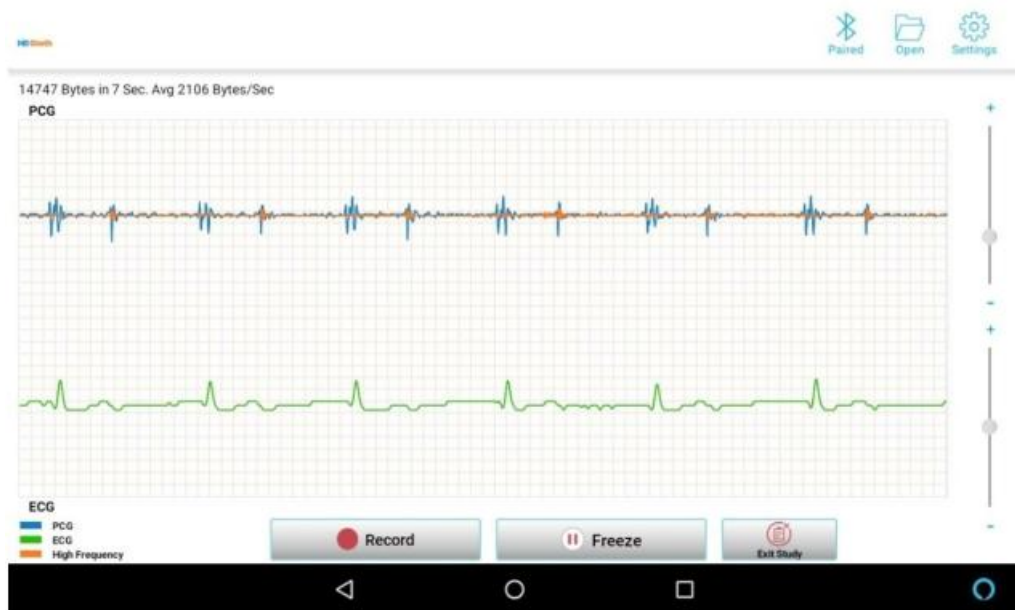
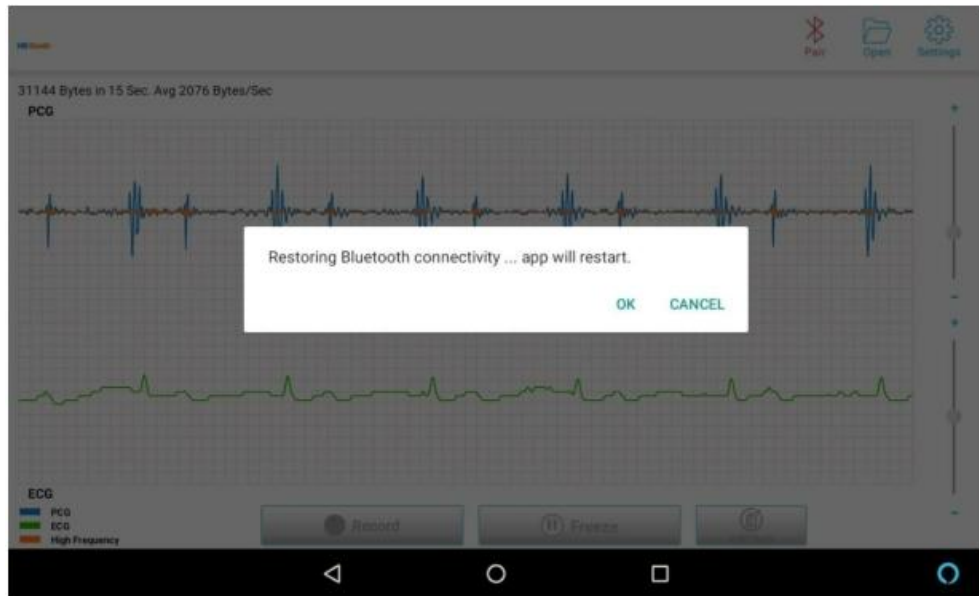
6.5 The Heart Sound & ECG Amplitude Slider Controls appearing on the extreme right side of the waveform windows can be used to modify the amplitudes of these waveforms.

6.6 The Bluetooth button turns Red when the Bluetooth connection gets broken.



6.7 The user can attempt reconnection by tapping it. The App proceeds to restart and attempts to connect with the device.

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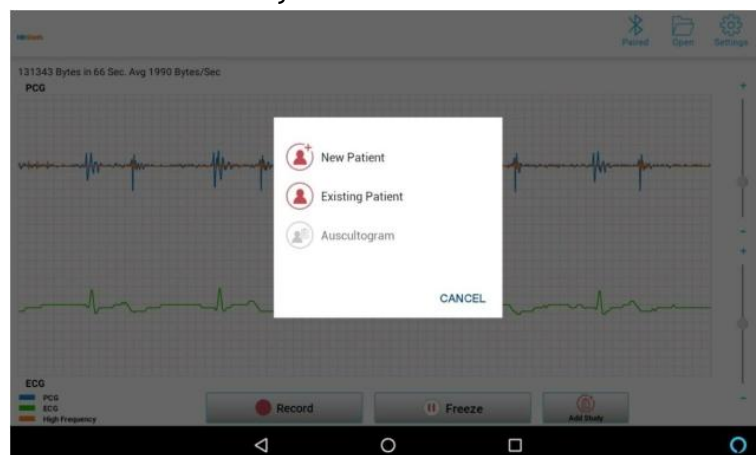
6.8 Record button: On tapping anywhere on the Record button, recording starts and the progress is indicated.

6.8.1 While recording is in progress, rest of the buttons in the screen turn inactive.

6.8.2 After 10 secs of recording, select position and posture screen appears to choose appropriate position and posture done during recording.

6.8.3 Followed by position and posture screen, a preview screen appears where the user can decide whether to save or discard that recording.

6.8.4 Add Study: On tapping Add Study button, the Save Recording pop up window is launched either user have option to create new patient record, or user can add more patient records with existing patient record. Auscultogram feature is currently disabled. It is for future functionality.



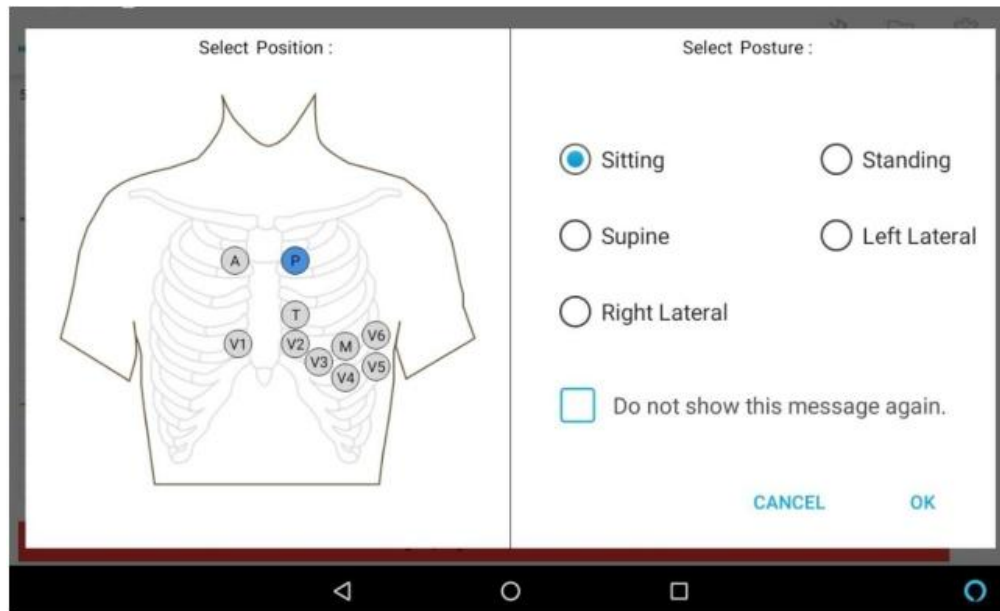
7. Actions after Recording

7.1 Edit: If the selected position is unsatisfactory it can be discarded by tapping Edit button, the App will route to position and posture screen to choose the right indications again.

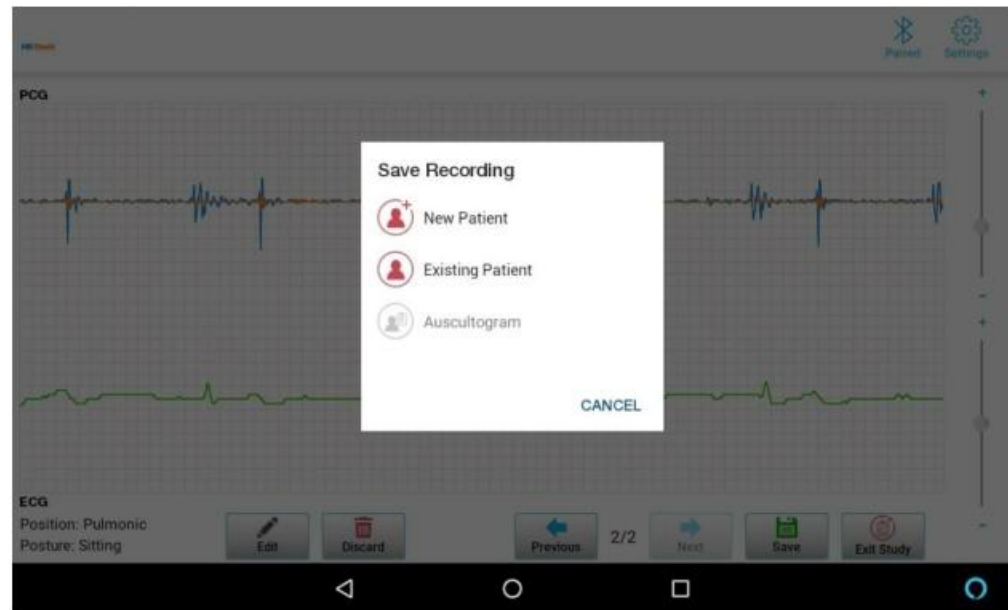
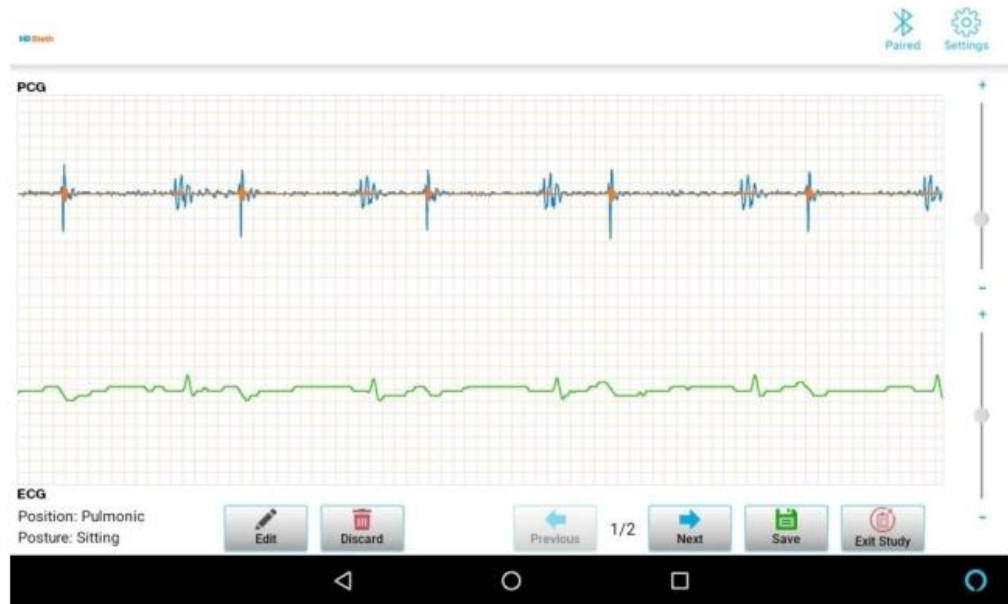
7.2 Discard: If the recording is unsatisfactory it can be discarded by tapping the Discard button, as a result the program leads to the Live Auscultation screen so that user can do a fresh recording.

7.4 Previous & Next: These buttons support scrolling of waveform screens in left & right sides one page a time.

7.5 Save Button: After previewing, the user can proceed to save the recording through this button. It leads to a Save menu with options New, Existing Patient & Auscultogram. Auscultogram feature is currently disabled. It is for future functionality.



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7.5.1 Choosing New Patient leads to a screen for adding new patient profile

← Demo One SAVE

First Name *
John

Last Name:
Smith

Patient ID*:
DEMO_1

Gender *:
Male

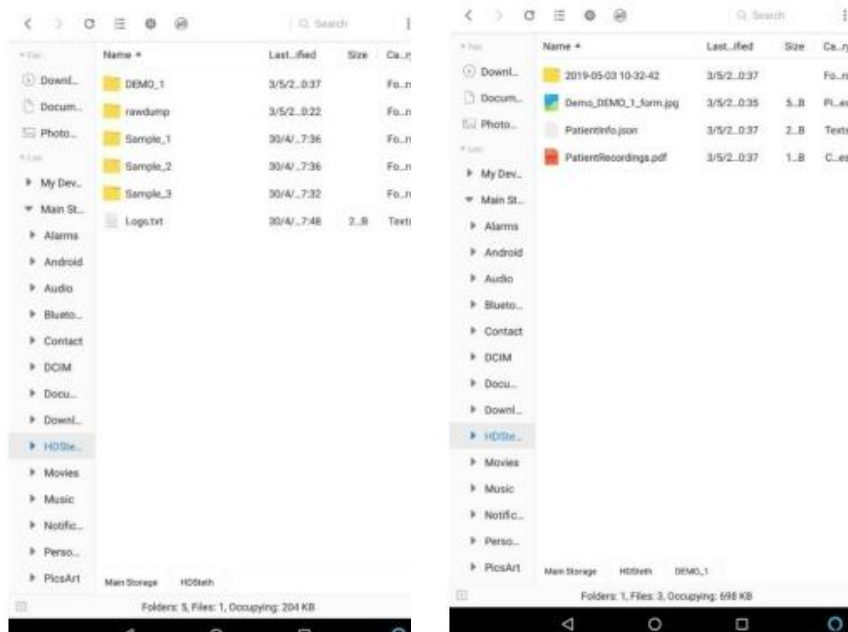
Date of Birth(DD/MM/YYYY)*:
08/01/1993

Age(yrs):
26 Years 4 Months 25 Days

Add more fields below (Optional)

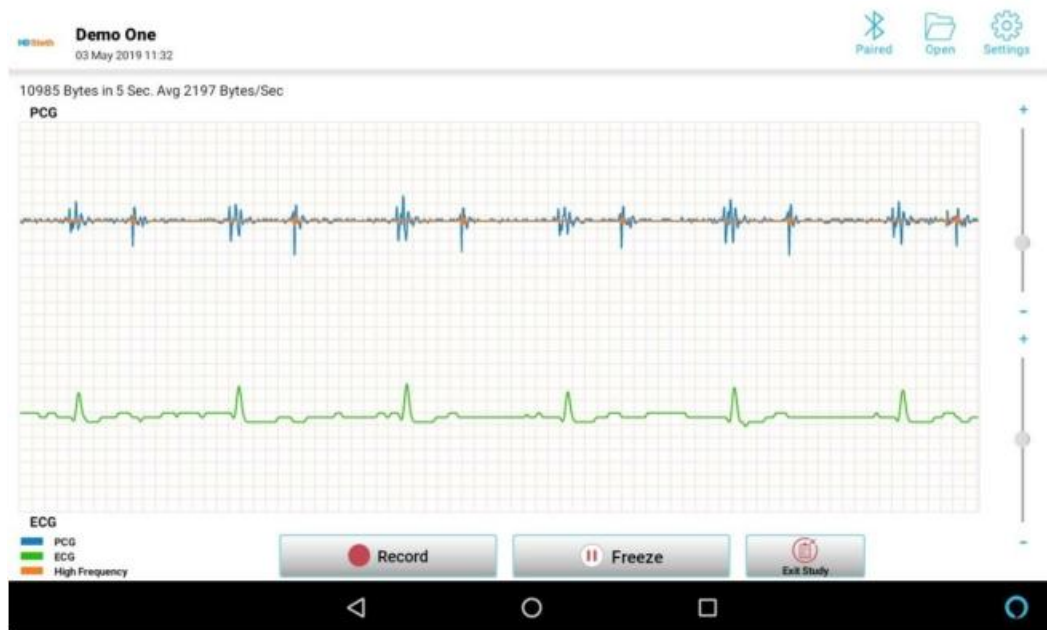
After entering the mandatory fields marked by red star, the user can save by tapping the save button available on the top right corner. On successful save the patient record is stored under Main Storage

- HDSteth
- Patient ID
- Date and Timestamp.

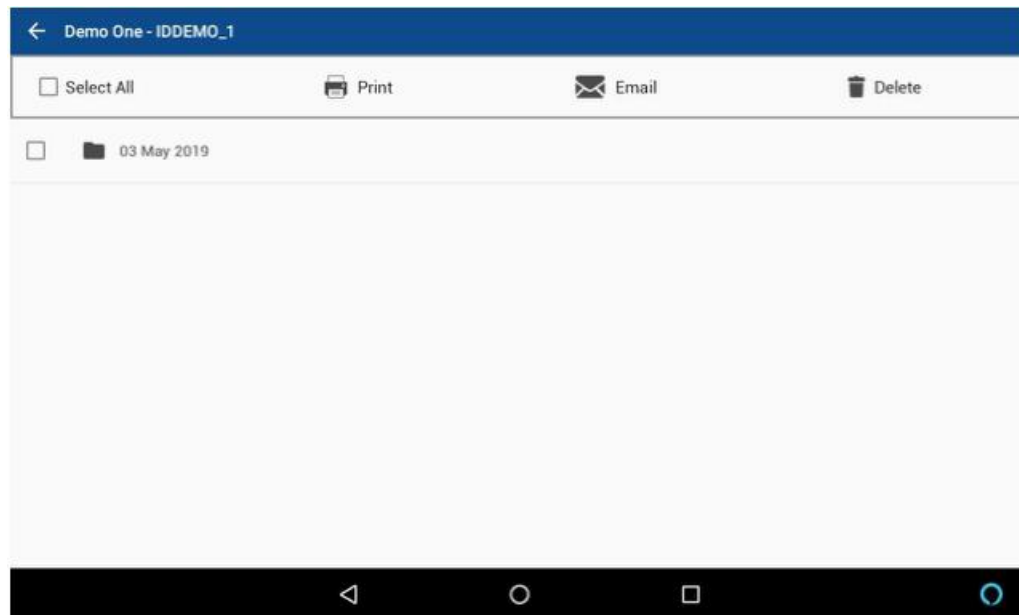


As soon as saving is over the Live Auscultation screen appears with current patient study.

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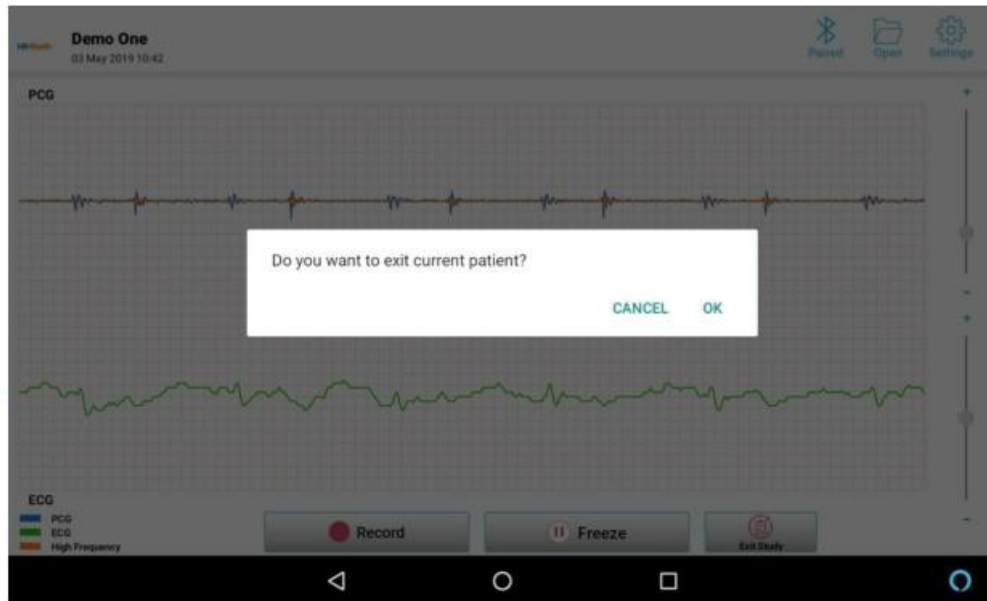
7.5.2 In case the user choose Existing Patient, the list of existing patients will be displayed.



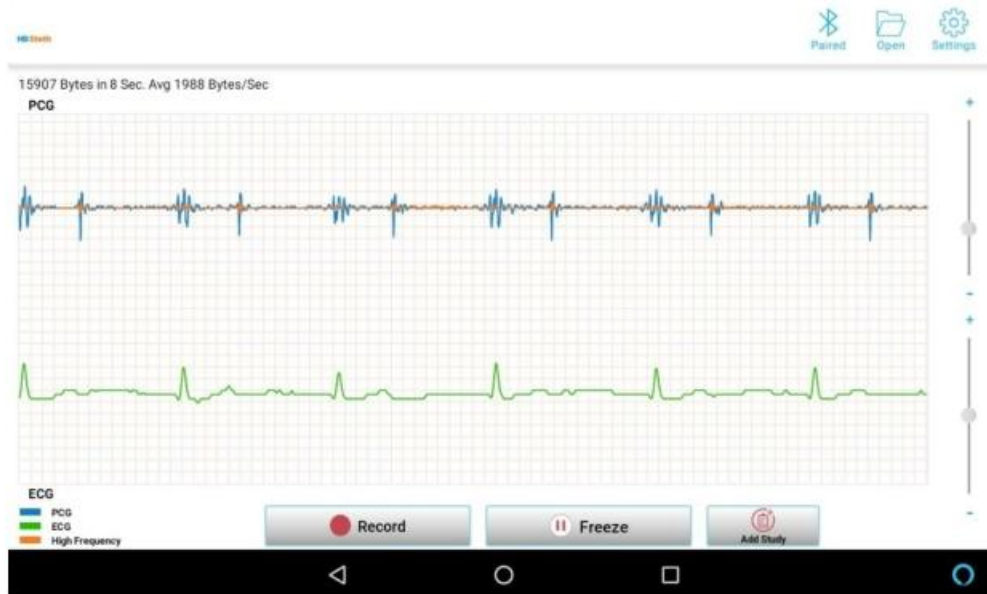
The user can search/select an existing user and save the recording.

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7.5.3 If the user press Exit Study the App will indicate to exit current patient study.

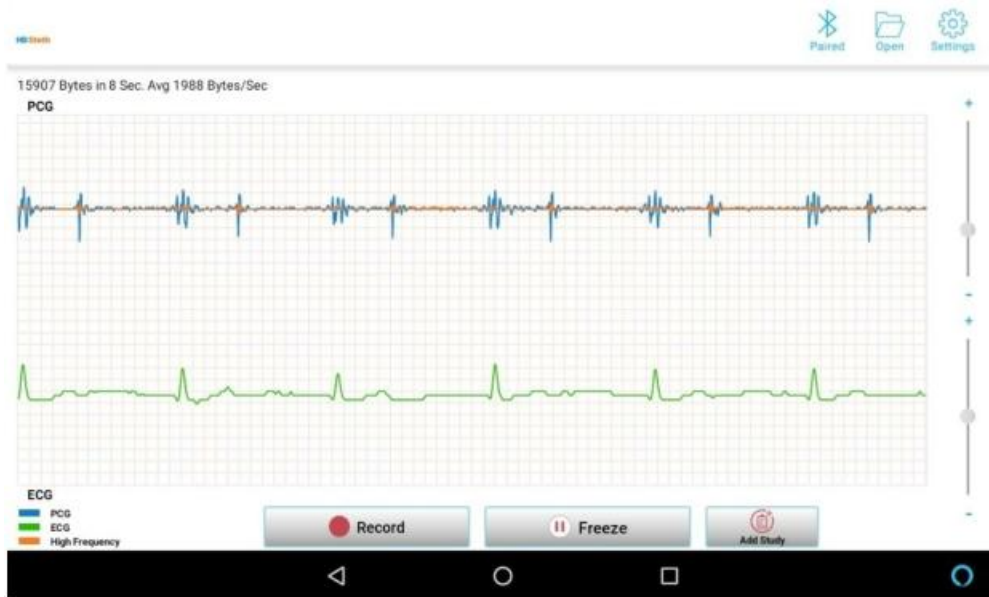


If the user press Ok the App exit current patient record and it will route to new study with Auscultation screen

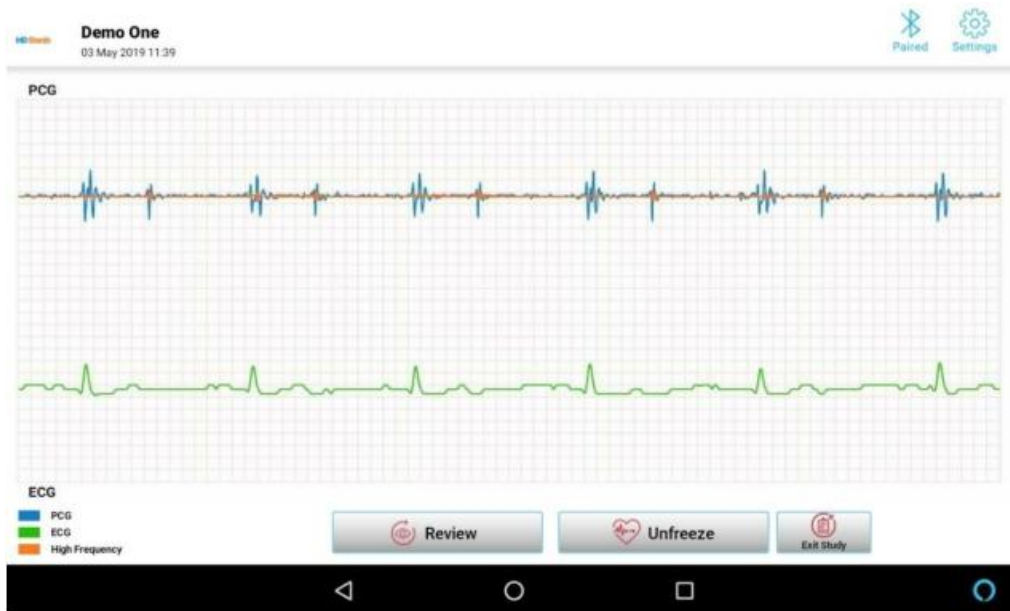


If the user press CANCEL the App will remain in current patient record as it is to continue further recordings.

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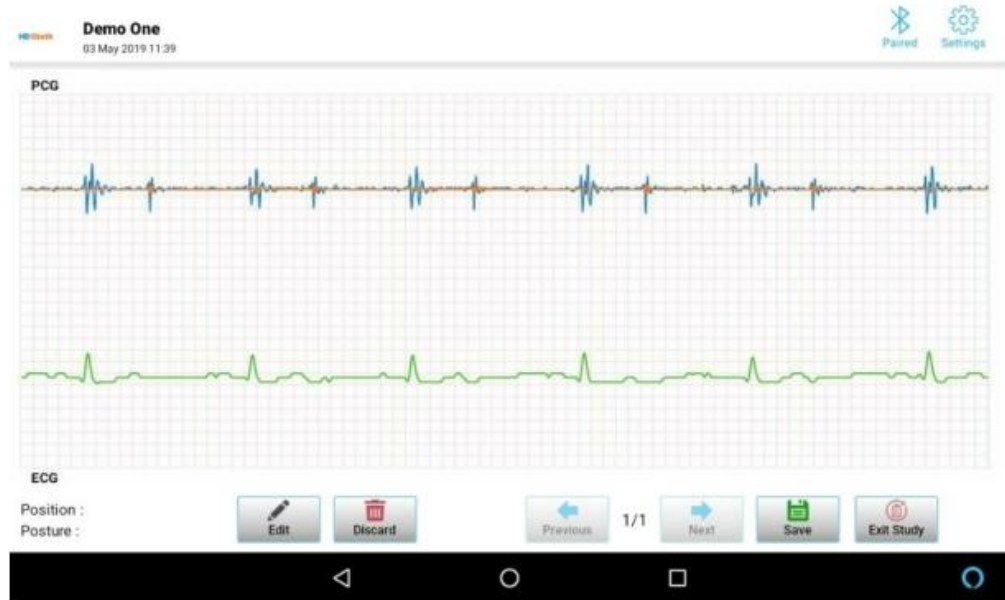


Like saving patient record in a study, user has one more option to freeze 5 secs screen by pressing Freeze button and the screen will be under evaluation by the user.

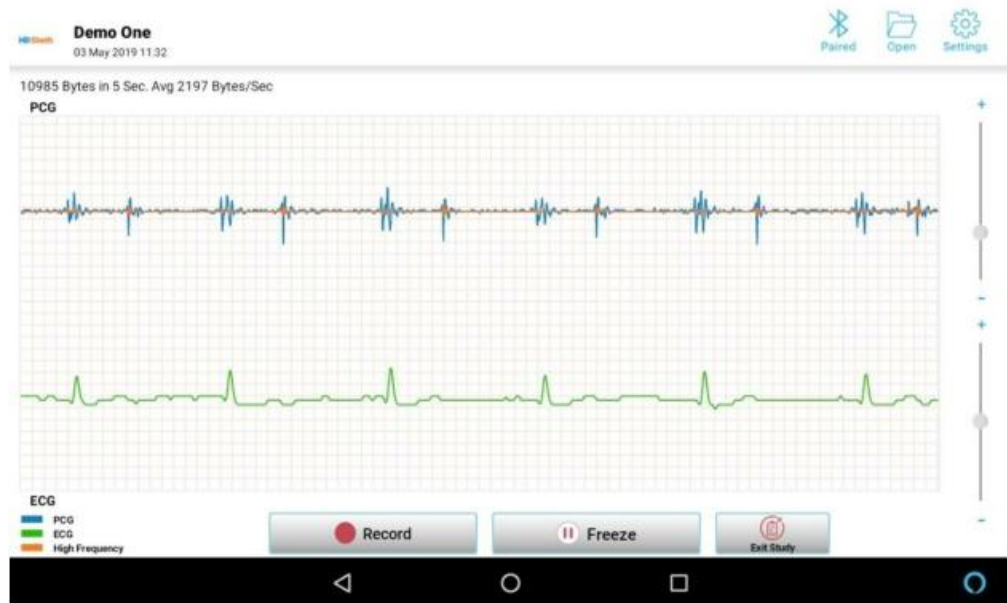


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If user wants to add the current screen then he has to press Review button. By pressing Review button the App will navigate to add or discard the screen to current patient study.



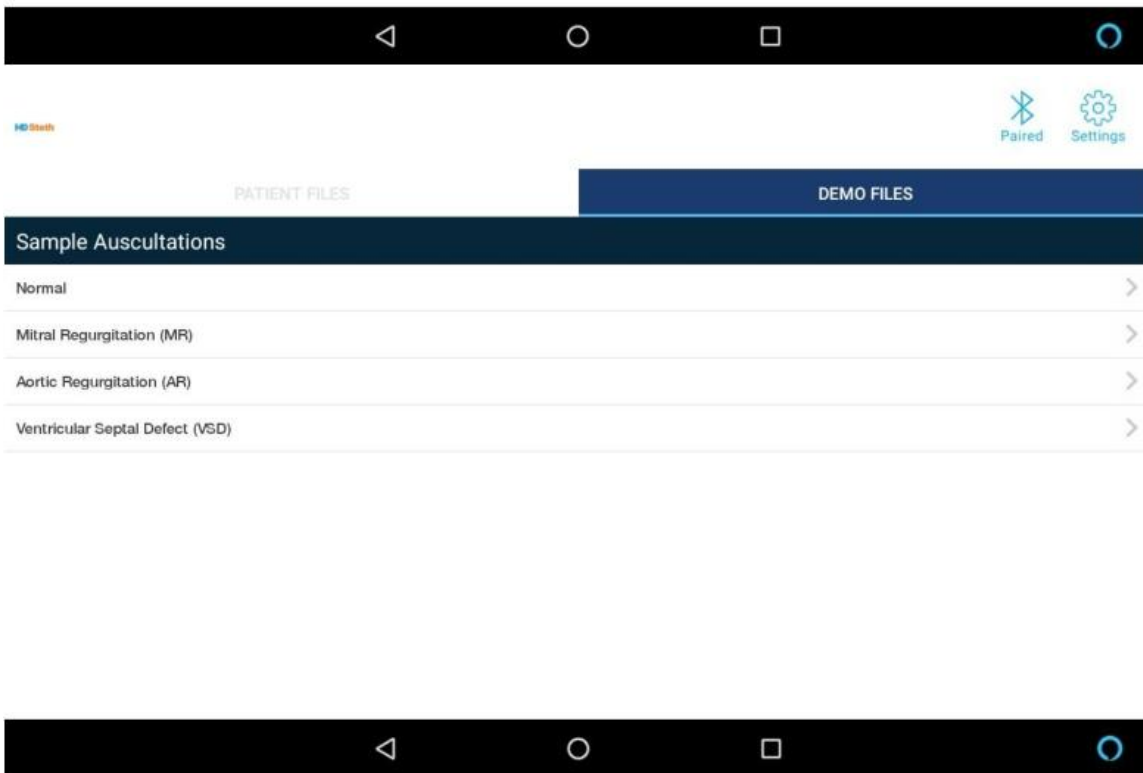
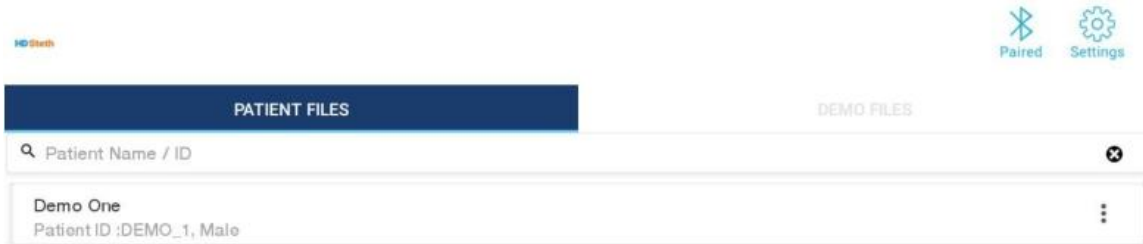
If user doesn't want to add the current screen then he has to press Unfreeze button. By pressing Unfreeze button the App directly discard the screen and it will navigate to auscultation screen with current patient study.



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8. Patient & Demo Files

On tapping the Open button present in the Live Auscultation screen, the following screen appears displaying two tabs **Patient files** (default) and **Demo files tab** (contains a list of demo files which will be available for the user reference).

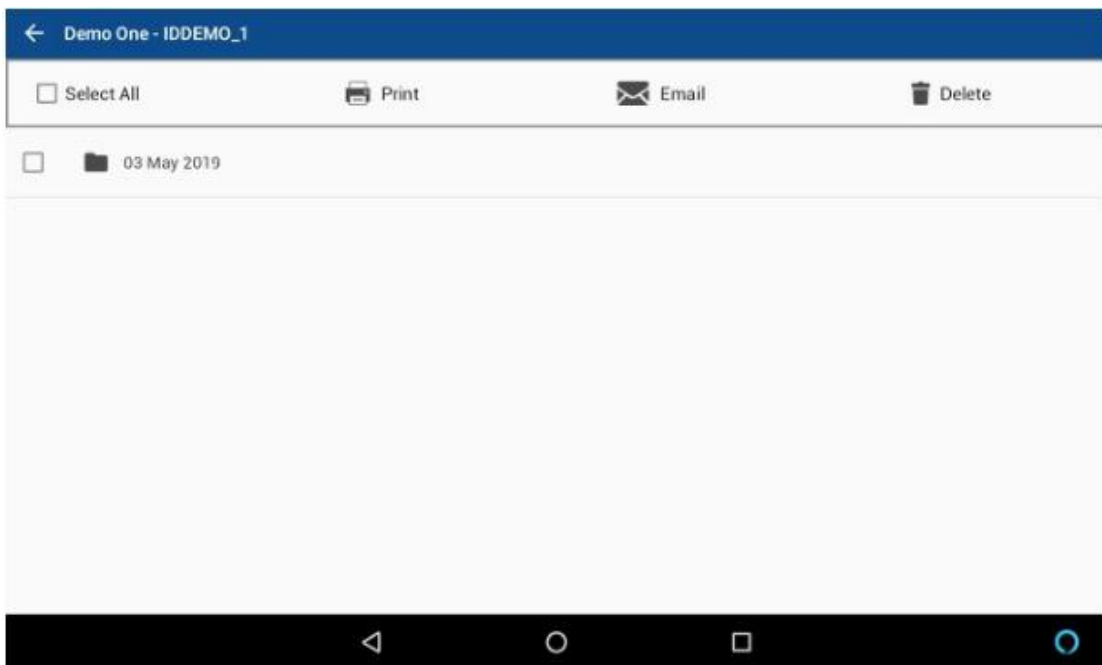


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The user can navigate to a patient record by entering the patient id/ name in the search space.

8.1 On choosing a patient, all recordings belonging to that person will be listed. Each recording is identified by its timestamp.



8.2 On tapping a recording it commences to play in the playback screen.

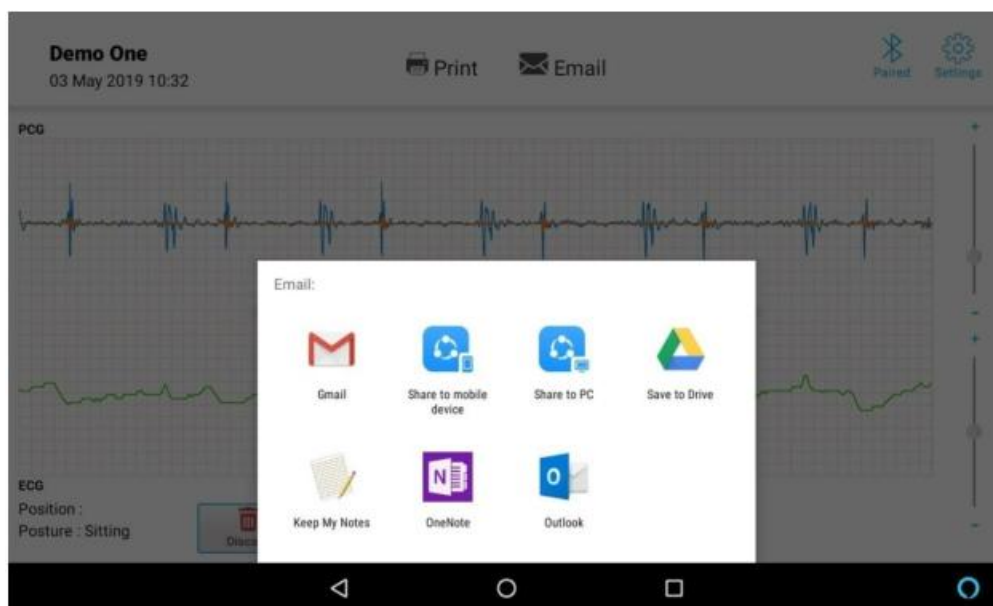
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8.3 Replay button is available to play the recording whereas Previous & Next are there for moving back and forward page wise. For example if this patient study has 10 patient records with various timestamp the nearest timestamp i.e descending order with current date is shown first in preview screen.

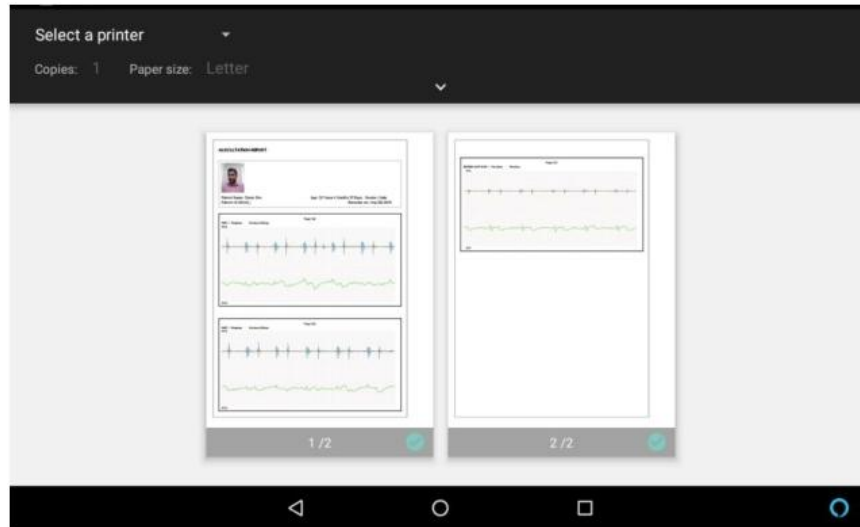
8.4 By pressing Discard button current patient record will be deleted from the study.

8.5 The user has option to email current patient study to multiple recipients.

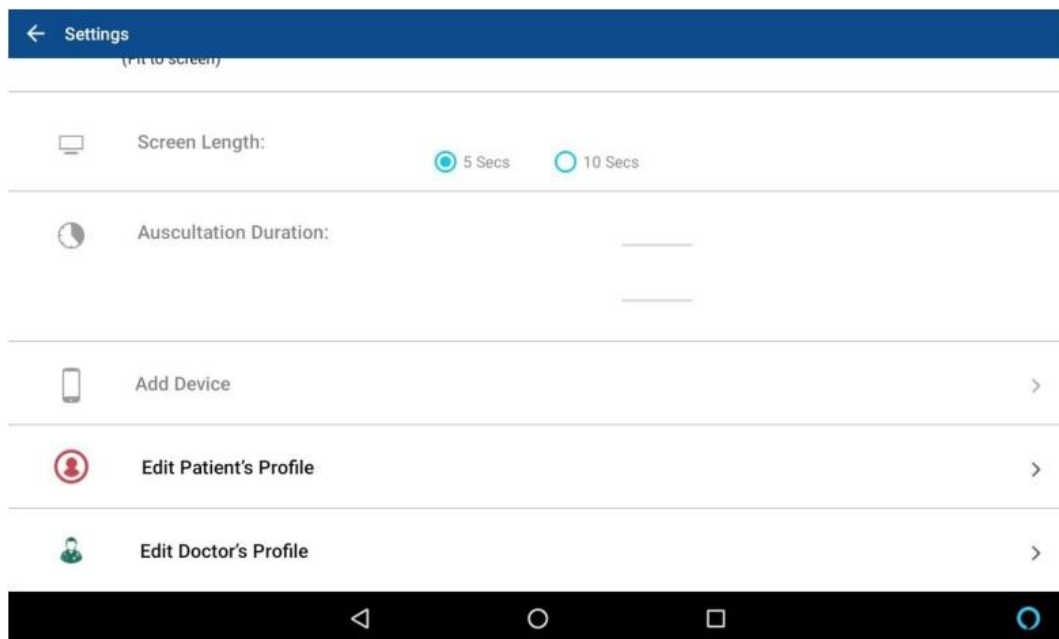


8.6 The user has option to print the patient study by connecting with external printer.

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9. Settings Screen



9.1 The user can select a color from the color palette that appears on tapping the color buttons for Heart Sound, ECG & High frequency Murmur detection Waveforms

9.2 Right now the check box to enable/disable the High Frequency Murmur Detection Waveform has been disabled.

9.3 A check box to enable ECG grid has been provided. It appears **enabled by default**.

9.4 Edit Patient's Profile is available to edit an existing patient's profile.

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9.5 Edit Doctor's Profile is available to edit an existing doctor's profile.

9.6 Rest of the controls are disabled.

10. Cybersecurity Risk Mitigation

HD Steth Mobile app is designed to connect directly with HD Steth devices via Bluetooth without need of any network for transfer of data. Neither the HD Steth nor the app connect to the internet or intranet. So direct Cybersecurity challenges will not be applicable to HD Steth Mobile app. HD Steth Mobile app is hosted on Mobile devices (smart phones/tablets) which can be connected to other networks hence there is a probability of indirect Cybersecurity challenges. All users should ensure the confidentiality, integrity, and availability of all e-PHI (electronic protected health information) they create, receive, maintain or transmit. The cybersecurity controls that were established for the device include

10.1 Cybersecurity controls established for device and App

10.1.1 Direct connection between HD Steth and Mobile App without need of any network.

10.1.2 Clinical data from device is packed (propriety format) in transit to the App.

10.1.3 Smart device controls user access to the App

10.1.4 Bluetooth protocol employed (SPP - Serial Port Protocol) allows only 1-to-1 connection. Data tapping is not possible

10.1.5 App monitors for Bluetooth connection, and alerts user upon sudden event of disconnection

10.1.6 Medical Practitioners are advised not to connect the mobile device which have Steth App to unknown / public networks

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11 Revision History

Date of release	Revision	Change Description
07-Jun-2018	00	Initial release
26-July-2018	01	Device Discovery - Default Auto pairing updated
21-Feb_2019	02	Auscultation Screen - Freeze/Unfreeze added
08-Aug-2019	03	User Registration Form added in Mobile App Print and Email option added for Patient Record
16-Jun-2020	04	Old User Manual download link from website is removed. Cybersecurity Risk Mitigation included