



Eko DUO

User Manual, Model E5

The Eko Model E5 System is designed to support healthcare professionals in analyzing cardiac and other internal organ sounds. The Eko Model E5 System includes a device capturing heart sounds and ECG readings (herein referred to as DUO), a smartphone application (App), and a web application (Dashboard).

DUO features audio and ECG data transmission via Bluetooth that allows the user to open and playback sounds and visualize phonocardiograms (PCG) and electrocardiograms (ECG) in a mobile application on compatible iOS smartphones and tablets. The App provides the ability to save audio recordings and waveforms (PCG and ECG) within Electronic Health Record (EHR) systems, share patient recordings with other practitioners, and annotate notes on recorded audio. Eko is intended for use on pediatric and adult patients. The device is not intended for infants weighing less than 10 kg.

CAUTION: Federal (USA) law restricts this device to sale to or on the order of a clinician.

For general and product related comments, questions, or concerns, please contact Eko Devices, Inc. directly

Please report any injury or adverse event to Eko using any of the contact methods below.

Eko Devices, Inc.
2600 10th St. Suite 260
Berkeley, CA 94710
USA

General Assistance and FAQs
ekodevices.com/getstarted

Direct Contact
support@ekodevices.com

Phone Support
1.844.356.3384

Product Reference and Information
www.ekodevices.com



Consult instructions for use.



This product contains electrical and electronic components and must not be disposed of using standard refuse collection. Please consult local directives for disposal of electrical and electronic equipment.



This product and packaging does not contain natural rubber latex.



This product contains an intentional RF radiator certified by the FCC.



Catalog Number



Lot Number



Serial Number



Humidity Limit (Operational)



Temperature Limit (Operational)



This product is provided non-sterile. Do not attempt to re-sterilize the device.



This product uses wireless Bluetooth communication



BF Applied Part



Contents (Quantity)



Protection against dust and water jets when earpieces are attached. The earpieces are not IP protected.



MR Unsafe



- To reduce the risk of device interference, keep DUO at least 2 meters away from all RF emitters including Wifi routers and radios when operating or charging.
- To reduce the risks associated with infection follow all cleaning and disinfecting instructions included in this manual. Establish and follow a cleaning and disinfecting schedule after each use.
- To reduce the risks associated with inaccurate data acquisition store and operate this device only as instructed in this manual. It is recommended that the battery be recharged within thirty minutes of the LED indicator turning red. Recharge the battery using only the wireless charging pad provided with the device.
- DO NOT immerse the device in a liquid or subject it to any sterilization processes other than those described in this manual. The device is non-sterile.
- To reduce the risks associated with very strong electromagnetic fields avoid using the device near strong radio frequency (RF) signals or portable and/or mobile RF devices. If sudden or unexpected sounds are heard, move away from any radio transmitting antennas. Using accessories, transducers, and cables not produced by Eko may result in increased RF emissions or decreased immunity of DUO.
- Please read, understand, and follow all safety information contained in these instructions prior to using DUO. It is recommended that these instructions be retained for future reference.
- DUO contains a Bluetooth Class 2 wireless data link. The maximum radio frequency field strength generated by the device is below three volts per meter, a level that 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 DUO away from that device and/or turn the Bluetooth feature OFF.
- To reduce the risks associated with environmental contamination follow applicable regulations when disposing of this device. DUO contains a rechargeable battery; please properly dispose of the device as mandated by local directives.
- No modification of this equipment is allowed. There are no repairable parts inside DUO.
- Disperse any static electricity before using the unit.
- **Warning: MR-unsafe!** Do not expose the device to a magnetic resonance (MR) environment. The device may present a risk of projectile injury due to the presence of ferromagnetic materials that can be attracted by the MR magnet core. Thermal injury and burns may occur due to the metal components of the device that can heat during MR scanning. The device may generate artifacts in the MR image. The device may not function properly due to the strong magnetic and radio frequency fields generated by the MR scanner.
- This device does not detect or measure all heart rate, heart rhythm and heart waveform changes.
- The device has not been tested for use on infants weighing less than 10kgs.
- Conductive parts of electrodes and associated connectors for Type BF Applied Parts, including the neutral electrode, should not contact other conductive parts including earth.
- Do not use DUO while it is charging.
- Do not use on patients with cardiac pacemakers or other electronic implanted devices.
- Do not use the DUO on a portion of the body with too much body fat, body hair or very dry skin, a successful recording may not be possible.
- Do not use DUO while charging your mobile device, this will cause electrical interference with the ECG signal.
- Do not store the DUO in extremely hot, cold, humid, or wet conditions.
- Do not expose to strong electromagnetic fields.
- Do not use as sole basis for medication or treatment decisions.
- Do not take a recording if the electrodes are dirty. Clean them first.
- Do not use the DUO over broken skin or wound areas.

Excessive hair, dirty skin, dry skin, or oily skin can impact the quality of the ECG tracing. Clean the patient's skin with water and soap and remove excess hair as needed to achieve the highest quality tracing. Do not use the DUO over wound areas or areas of broken skin. Do not use an alcohol based skin cleaner as this dries out the patient's skin and increases resistance. Dry the skin vigorously to increase capillary blood flow to the tissues.

ECG gels or saline solutions can be used on the electrodes to improve signal quality.

FCC Intentional Radiator Certification

Contains FCC ID: XXXXXXXXXXXX

Contains IC: XXXXXXXXXXXXXXXX

This equipment contains an intentional radiator approved by the FCC under the FCC ID numbers shown above. 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 undesirable operation.

NO MODIFICATION: Modifications to this device shall not be made without the written consent of Eko Devices, Inc. Unauthorized modifications may void the authority granted under Federal Communications Commission rules permitting the operation of this device.

EMC Compliance Europe

This equipment complies with the EMC requirements of the IEC 60601-1-2.

To ensure a proper ECG and PCG recording, clean the electrodes with an alcohol-based cleaning solution prior to use.

Cleaning and Disinfecting Procedure

The device and earpieces should be cleaned between each patient use. All cleaning instructions pertaining to stethoscopes and ECG units in general apply.

Under normal conditions it is unnecessary to separate the device from the earpieces for cleaning. All external parts of the hardware can be cleaned with 70% isopropyl alcohol wipes.

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

The device is intended to be prescribed by licensed medical professionals. The device may be used on patients during a physical assessment in a clinical setting or by patients with a prescription and under the supervision of a clinician. The system provides one source of data that is significant only when used in conjunction with clinician oversight and consideration of other relevant patient information.

DUO should be used only by qualified clinicians or prescribed to patients with an adequate understanding of the device. DUO is intended for use on patients that can be auscultated on normally with an acoustic stethoscope.

This manual provides instructions for the use of DUO and the Eko App. It is assumed that the user is familiar with basic mobile application use on iOS™ and Android™ devices.

Standard procedures for auscultation should be followed including background noise reduction and optimal patient positioning. The quality of the ECG is dependent on proper preparation practices including, but not limited to, patient body temperature and clean contact area.

The device uses a Bluetooth Class 2 wireless data link. The Bluetooth range will be reduced when objects (walls, furniture, people, etc) are between DUO and a paired mobile device. To improve Bluetooth connection, reduce the distance and/or allow a line of sight between DUO and the mobile device.

In order to transmit sounds and record electrical activity to the Eko App, DUO and the mobile device must be connected via Bluetooth, and in order to fully use certain functions, the mobile device must be connected to the internet.

It is highly recommended that users of the mobile App and web Dashboard use device and networking security features to protect patient data created and stored using this software, in addition to security features embedded in the system.

NOTICE: Some of the features of the Eko App require a minimum internet connection speed. The minimum recommended upload speed for the mobile app is 4000 Kbps. 4G cellular data service or similar is recommended for the App.

The app can be used to visualize waveforms and tracings without an internet connection, however an internet connection is necessary to save the data.

The Eko Model E5 System is intended to be used by healthcare professionals to electronically amplify, filter, and transfer body sounds and single-channel electrocardiogram (ECG) waveforms. The Eko Model E5 System also displays ECG waveforms and phonocardiogram waveforms on the accompanying mobile application for storage and sharing (when prescribed or used under the care of a physician). It can be used to record heart sounds and cardiac murmurs, bruits, respiratory sounds, and abdominal sounds during physical examination in normal patients or those with suspected diseases of the cardiac, vascular, pulmonary, or abdominal organ systems. The device can be used on adults and pediatrics.

The data offered by the device is only significant when used in conjunction with physician over read as well as consideration of other relevant patient data.

The device should not be used on infants weighing less than 10kg.

The privacy of patient health information may be protected by state, federal, or international/foreign laws that regulate how such information can be used, stored, transmitted, and disclosed. The Eko system employs security features that are compliant with HIPAA policies. Third party access may be prohibited to such information without obtaining written authorization from the patient.

The user is fully responsible for understanding and following all laws that regulate storage, transmission, and disclosure of any electronic patient data through the use of software. If the user becomes unable to comply with a law or restriction that applies to use and disclosure of such data, the user should not proceed to collect or save such information.

This application may require entry of individually identifiable health information in order to function. Records are stored and recalled through the use of patient name, date of birth, and/or patient ID number. By entering this information, the user assumes any and all risks of and liabilities incurred with using or transmitting such information.

This package includes
(1) Eko DUO
(1) Wireless Touch Charging Pad
(1) 5W / 2A USB Power Adapter
(1) Micro USB to USB Cable
(1) Eko EARPIECE
(6) Silicone Rubber Eartips
(1) Getting Started Instruction Card

For full functionality, the system requires users to connect their DUO with an internet-enabled smart mobile device using the Eko App (not included). The App supports many Apple® and Android™ mobile devices.

NOTE: DUO can be used with other audio equipment or headphones through the 3.5mm audio jack. However, no performance guarantees are claimed using other audio products.

System Requirements

The mobile app software can be used with iPhone® 4S, 5, 5C, 5S, 6, 6 Plus, 6s, 6SE, 6S Plus, iPad Mini™ 2, 3, iPad Air®/Air 2, and iPad® 3rd/4th generations with iOS 7.0+ and at least 25MB of free memory.

DUO uses Bluetooth® Smart; mobile devices used must be compatible with Bluetooth® Smart.

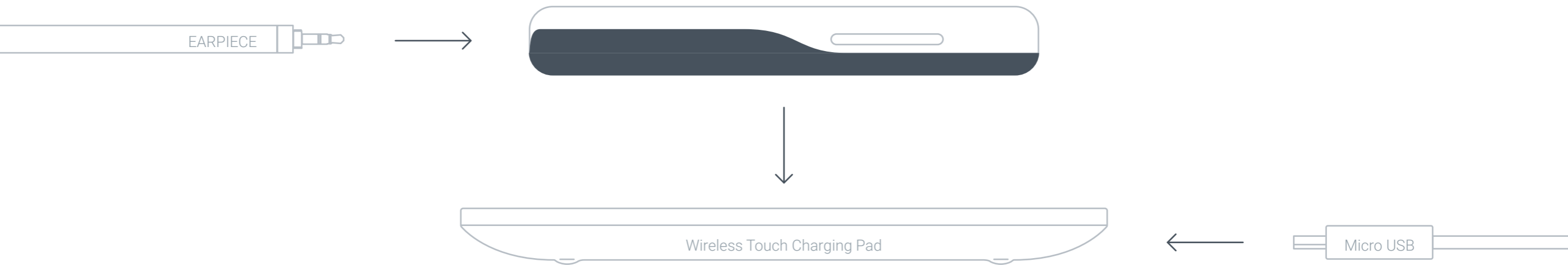
Apple®, iPhone®, iPad®, iPad Air®, and iPad Mini™ are registered trademarks of Apple, Inc.

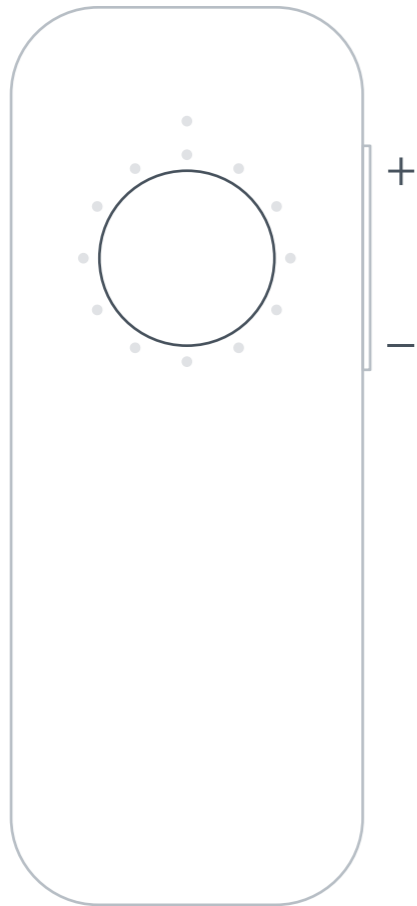
Bluetooth® is a registered trademark of Bluetooth SIG, Inc.

Install included EARPIECE by plugging the audio jack into the 3.5mm audio port at the base of DUO and tightening the threads.

To charge DUO, place the device on the Wireless Touch Charging Pad. Connect the charging pad to a power source using the included USB charging cable and power adapter. The LED light ring on DUO will begin to flash to signal the charging status. All of the LEDs in the ring will light up when the device is fully charged. DUO should be periodically recharged even when in storage. Lithium ion batteries slowly lose charge when in storage and may fall to an unacceptably low level, damaging the battery.

NOTE: DUO will not operate or connect to the Eko App while charging.





DUO is controlled using the action button located on the top face. An LED ring illuminates when the device is powered on.

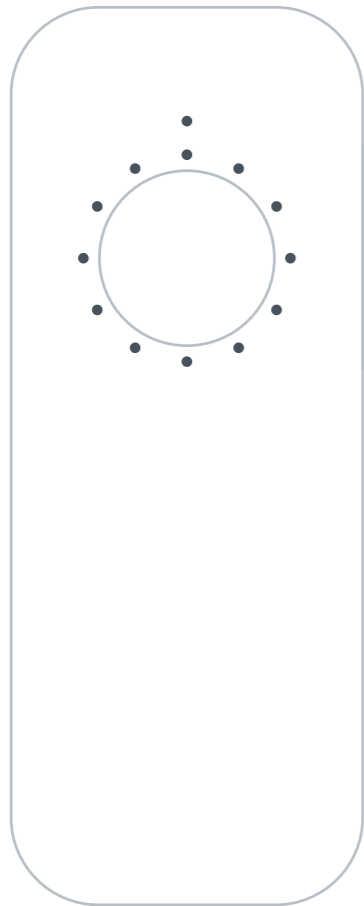
To	Do This	LED Ring Response
● — 2s Power On / Off	Press and hold the action button for two seconds.	The active LED turns on/off
● Change audio filters	Press the action button once.	The active LED rotates to a new position corresponding to the filter type.
● ●		

Power Save Mode

DUO will automatically power off after 5 minutes of continuous inactivity. To resume DUO, press and hold the action button for two seconds.

Volume Control

The device's sound level can be amplified in 12 increments. Change the volume level by pressing the top (+) and bottom (-) of the volume button on the side of the device. Increasing the volume by one level can be confirmed by the increasing number of LEDs lit in the LED ring.



The device is OFF. All functions of the device are disabled.



The device is ON but not paired. Active LED blinks every 1.5 seconds. The device is discoverable and ready to connect via Bluetooth.



The device is ON and paired with a phone/tablet. Active LED is lit and solid. The device is streaming live audio and ECG to the paired device.



The device is ON and playing back sounds and waveforms from a paired phone/tablet. LEDs in LED ring light up based on volume level.



The device is ON. The filter change is indicated by the active LED in the LED ring rotating to a new position.



The device is ON and has low battery. The red warning LED turns on. Device functions normally.



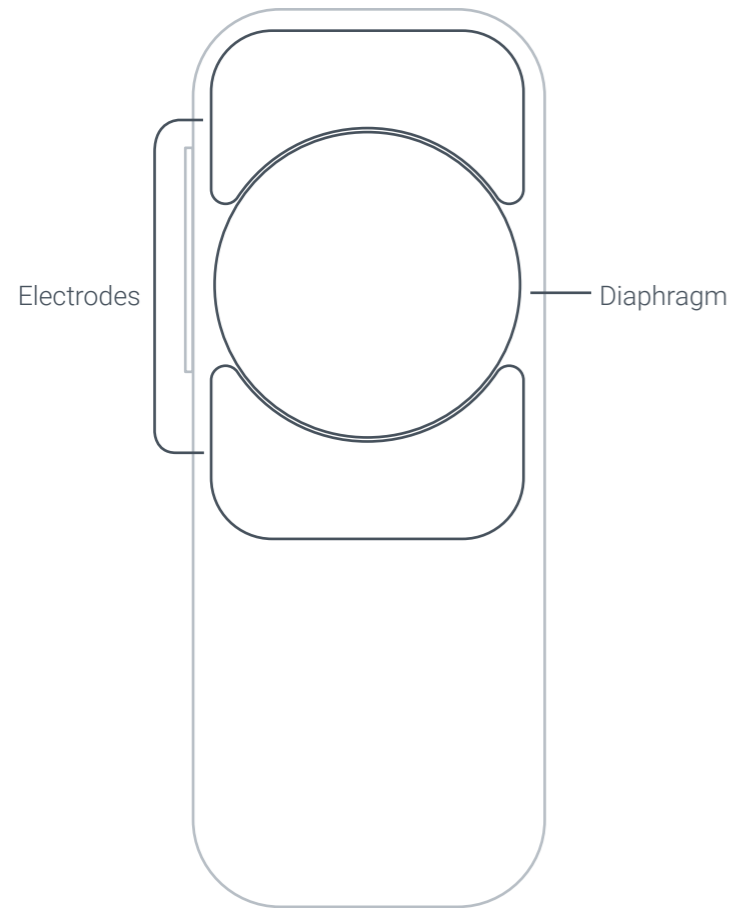
The device is ON and its battery level is below 10%. The LED flashes rapidly for 4 seconds, then turns off. The device will no longer stream or playback audio or ECG.



The device is OFF and is charging. The percent of charge completed is indicated by the fullness of the LED ring.



The device is OFF and fully charged. This is indicated by an LED ring with all 12 of the LEDs lit and solid.



DUO can be used on various locations and orientations of the chest. Each position will produce a unique heart sound and ECG tracing.

PCG

Capture sounds by placing DUO anywhere on the body. For best audio, press the device firmly against the skin to ensure good contact.

ECG

Capture ECG by placing and orienting DUO on the chest. The optimal position to capture ECG data is at an inward-facing 45° angle at the upper left pectoral below the clavicle. If the patient has particularly dry skin, body fat or hair, conductive gel used with other ECG systems may be used to improve the quality of the data.



Environmental

The operating range of the Core is 10° to 40°C (50 to 113°F), and 10% to 95% relative humidity. The storage and transport range is -10° to 60° and 10% to 95% relative humidity. Acceptable pressure is 1 atm.

It is recommended to avoid exposure to extreme heat, cold, solvents and oils. Extreme heats and colds will negatively affect the lithium ion battery in the device, and may affect battery life.

Operating Warnings

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

Eko provides a limited warranty for DUO. Please visit ekodevices.com/warranty for a full description of the warranty.

Installation for iPhone®

Open the App Store® using a supported mobile device. Ensure that the device is connected to the internet and search for the Eko Stethoscope App. Follow the instructions to download the App and wait until it has finished installing.

Installation for iPad®

Open the App Store® using a supported iPad model. Ensure that the device is connected to the internet. When searching the app store for the Eko Stethoscope App, make sure to select “iPhone Only” from the search options. Follow the instructions to download the App and wait until it has finished installing.

For more information, visit <http://ekodevices.desk.com/customer/en/portal/articles/1992653-how-do-i-download-the-eko-app->

Log In with Username and Password

Open the Eko App on the mobile device. When prompted, create a new account, or enter your existing username and password.

Log in with PIN

New users are encouraged to set up a 4-digit login PIN to simplify the login process on the Eko mobile app.

To create or edit a login PIN manually, select the Menu icon on the top left of the home screen. Select Account Settings > PIN and follow the onscreen instructions. To modify your PIN, you need to enter the number twice for verification purposes.

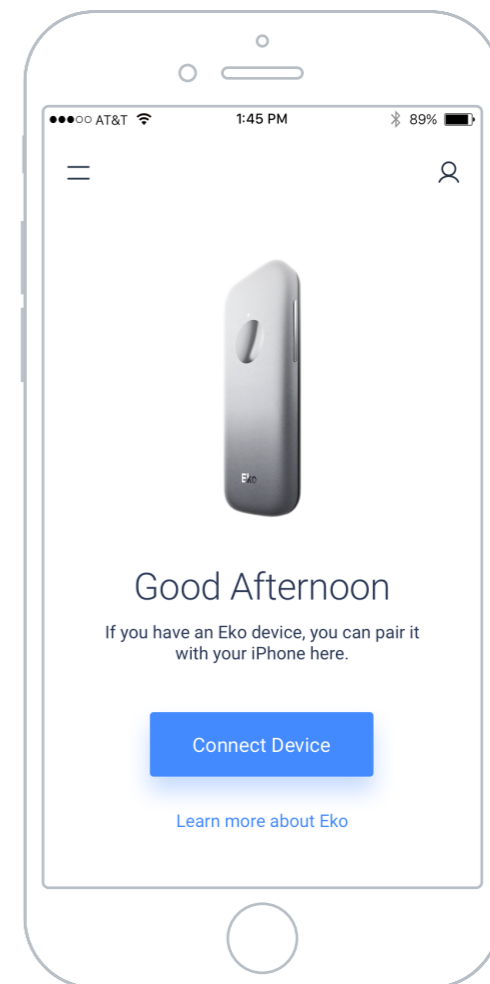
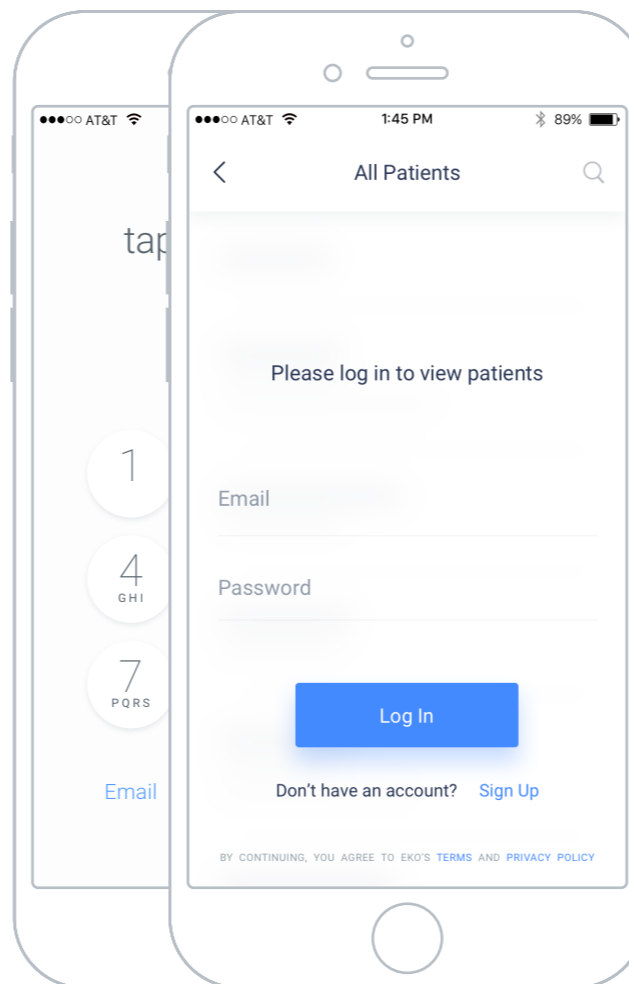
Bluetooth Pairing

Bluetooth must be enabled in the smartphone or tablet’s Bluetooth settings in order to use the device with the Eko App.

First, enable Bluetooth on the selected mobile device. On the iOS device go to Settings > Bluetooth > and tap the slider to turn Bluetooth ON.

Open the Eko App and login to your account. Press “Connect Device” and follow the onscreen instructions to pair with your DUO.

The mobile device is now ready to record sounds and display waveforms from DUO. If Bluetooth pairing is unsuccessful, an error message will appear in the App and no sounds will be recorded. If Bluetooth pairing is successful a waveform will be displayed on the app.



Capture & Save Recordings using the Mobile App

Open the Eko Mobile App and log in. Ensure that DUO is paired to the mobile device (See Bluetooth Pairing).

To associate the recording with a body position, select the target icon on the top center of the screen. Use the figure and icons to select the most appropriate position.

Press the circular button to begin recording. Press the square button (in the same location as start button) to stop and save the recording.

Adding Notes to Recordings on Mobile App

To create notes on any patient recordings, log into the mobile application. Access the list of patients by selecting the patients tab on the top right of the home screen. Select the desired patient and select a recording to add notes to.

Scroll to the bottom of the recording screen. Select "Add Comment" and begin typing your note. Select the check mark to save.

Sharing from the Eko Mobile App

Patients and recordings can be shared to other clinicians and collaborators within the Eko App. Navigate to the patient list by selecting the top right tab and selecting the patient to be shared. Select the sharing icon on the top right of screen and select the preferred method of sharing. Press the checkmark to complete the process.

NOTE: Only the original creator of a patient account is granted access to share patient profile with a collaborator.



The Main Recording Screen allows users to view audio data captured by the device, begin the recording process, retrieve patient-specific data, or adjust settings. Audio data is represented in real-time as a phonocardiogram and the ECG waveform. The grid behind the waveform denotes 25mm/s and 10mm/mV.

Recording Setup
Select Position

Settings
Modify Bluetooth
Adjust Volume
Change Audio Source
 iPhone speakers or DUO
Earpieces
Adjust Account Details
 Name
 Username
 Password/PIN
 Contact Information



Patient Selection
Create a patient-specific recordings
Review patient records
Import patients from select EHR systems

ECG Waveform
Retrieved from device

Audio Waveform
Retrieved from device

Tap to Record

The Settings icon on the Main Recording Screen allows the user to access Bluetooth pairing to the device, remaining battery charge level of a connected device, playback volume, view mode, grid settings, and audio filter modes. The Settings screen also allows users to change email and password information or set a login PIN. The PIN allows for quicker access to the Eko App. Setting a PIN is recommended so that users do not have to enter full login information each time the App is opened. Finally, users may log out of the App from this screen.

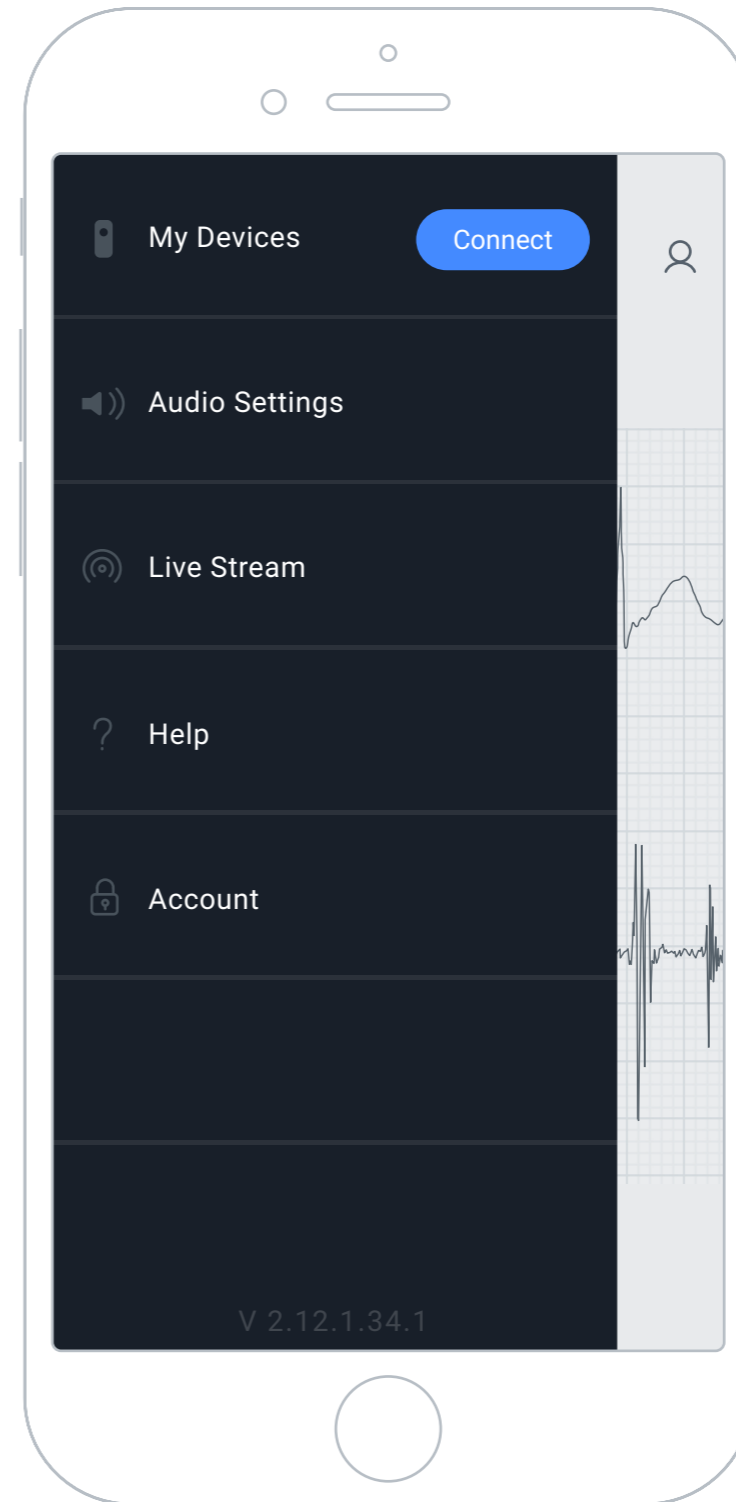
My Devices
Connect to DUO or CORE

Audio Settings
Adjust Volume
Change Audio Source
iPhone speakers or DUO

Live Stream
Turn Livestream ON/OFF
Share Livestream Link

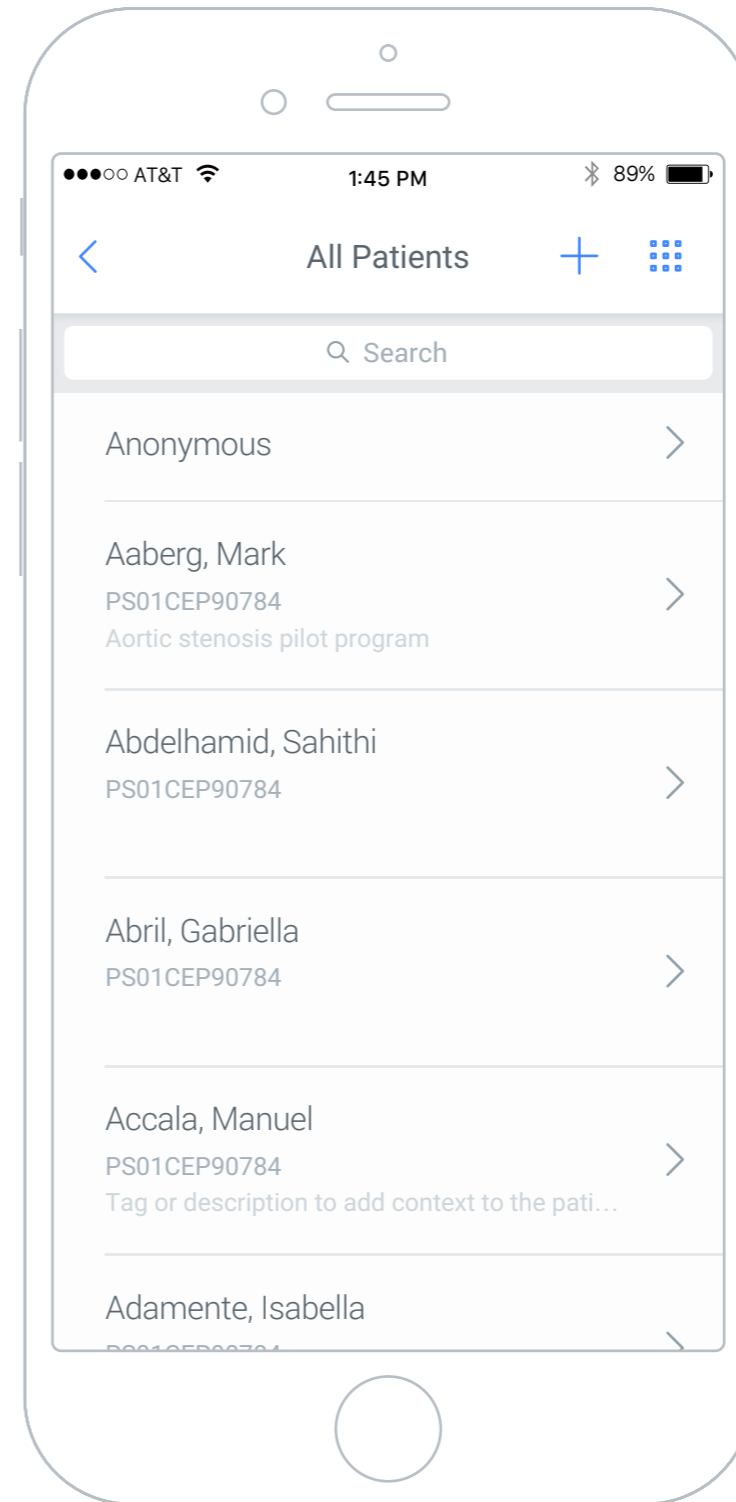
Support
Help (Link to www.ekodevices.com/support)

Account
Modify Name
Modify Username
Modify Password and PIN
Update Contact Information
Log Out



Return to Previous Screen

Selecting the Patient Search icon on the main screen brings up the patient list and search bar. Patients appear in alphabetical order by default. The search bar narrows the list to entries containing the alphanumerical digits entered. Selecting a patient displays a list of all recordings associated with the patient. Patients may be added to the list individually through manual input or syncing with compatible EHR services.



Add New Patient

Groups

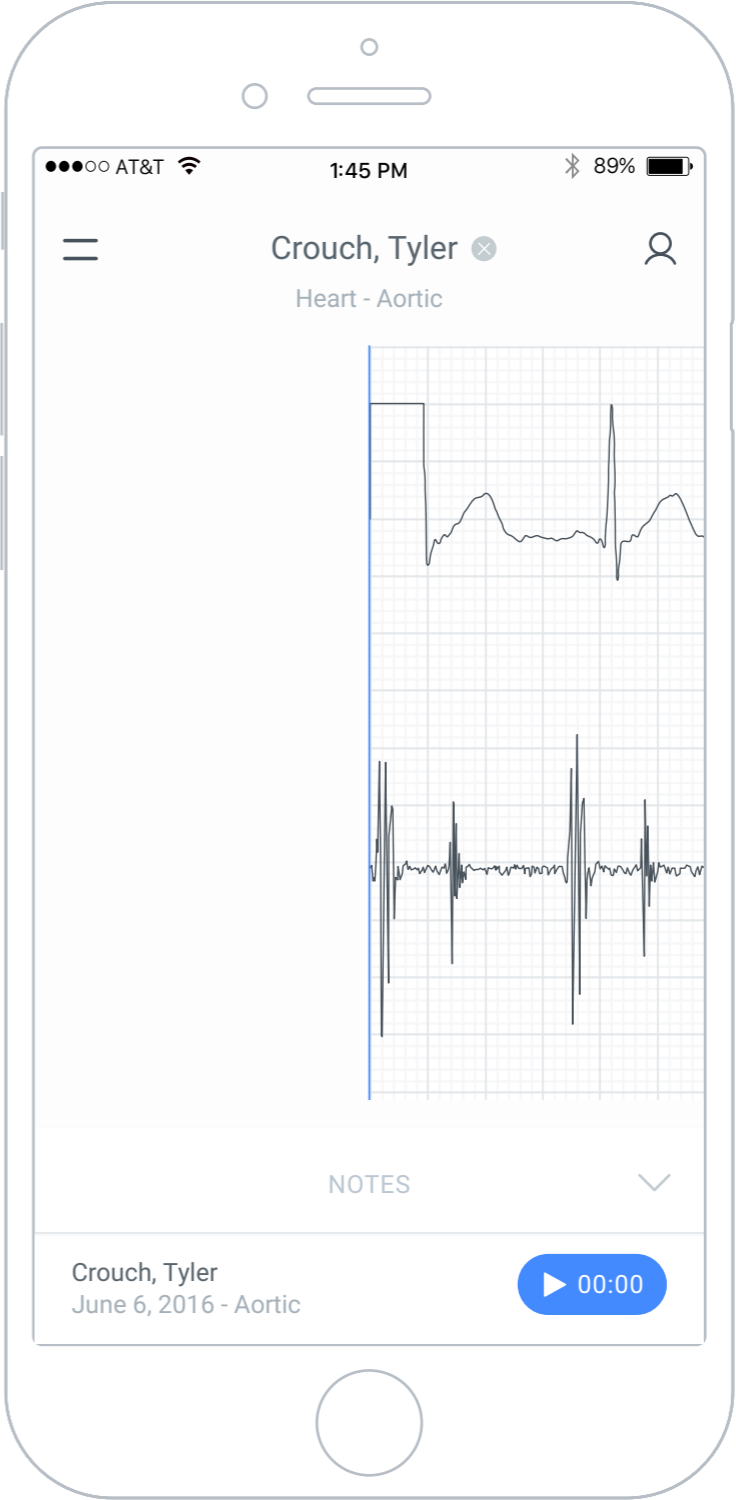
Search Patient List

Patient List

Hospital ID

Description Tag

This screen displays a waveform of each recording, options to playback the sound, or add notes. Notes may be added by any user with access to the patient's profile.



Patient Information

Recording Data

Comments

Guidance and Manufacturer’s Declaration - Electromagnetic Emission

DUO is intended for use in the electromagnetic environment specified below. The user of DUO should assure that it is used in such an environment.


Applicable Emissions Test	Compliance	Electromagnetic Environment- Guidance
RF emissions CISPR 11	Group 1	DUO 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.

Warning: The use of accessories other than those specified, with the exception of accessories sold by Eko as replacement parts, may result in increased emissions or decreased immunity of DUO.

Warning: DUO should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, DUO should be observed to verify normal operation in the configuration in which it will be used.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

DUO is intended for use in the electromagnetic environment specified below. The user of the Eko DUO should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment-Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/- 15 kV air	+/- 8 kV contact +/- 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%
Electrical Fast Transient/Burst IEC 61000-4-4	+/- 2 kV for supply lines +/- 1kV for input/output lines	+/- 2 kV for supply lines +/- 1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	+/- 1 kV line to line +/- 2 kV line to earth	+/- 1 kV line to line +/- 2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	5% U _T (95% dip in U _T) for 0.5 cycles 40% U _T (60% dip in U _T) for 5 cycles 70% U _T (30% dip in U _T) for 25 cycle <5% U _T (>95% dip in U _T) for 5 sec	5% U _T (95% dip in U _T) for 0.5 cycles 40% U _T (60% dip in U _T) for 5 cycles 70% U _T (30% dip in U _T) for 25 cycle <5% U _T (>95% dip in U _T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment.
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 magnetic field or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 150kHz - 80 Mhz	3 Vrms 150kHz - 80 Mhz	Portable and mobile RF communications equipment should be used no closer to any part of DUO, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = [3.5 / V_r] \sqrt{P}$ $d = [3.5 / E_r] \sqrt{P}$ 90 MHz to 800 MHz $d = [7 / E_r] \sqrt{P}$ 800 Mhz to 2.5 GHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 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 meters (m). 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 80 MHz and 800 MHz, the higher frequency range applies

NOTE 2 - These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and is affected by absorption and reflection from structures, objects and people.

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To address the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which DUO is used exceeds the applicable RF compliance level above, DUO should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating DUO.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Eko Electronic Stethoscope System

DUO is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The user of DUO can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and DUO 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 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d is meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Eko

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