Eko

Electronic Stethoscope System

For Eko CORE Digital Attachment
and Eko BUNDLE Electronic Stethoscope

Model E4

Contents

1.1 Introduction, Warnings, and Safety

The Eko Electronic Stethoscope System (herein referred to as *Eko*) is designed to support healthcare professionals in analyzing cardiac and other internal organ sounds. Eko includes a device that is attached to a stethoscope (*CORE*), a smartphone application (*App*), and a web application (*Dashboard*).

CORE features sound amplification and audio transmission to a smartphone via Bluetooth that allows the user to open and playback sounds in a mobile application on compatible iOS smartphones and tablets. The App provides the ability to save sounds within select 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.

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

1.2 For Help and Assistance

Please report any injury or adverse event to Eko Devices using any of the contact methods below. For general and product related comments, questions, or concerns, please contact Eko Devices, Inc. directly

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

1.3 Safety Related Labels & Symbols

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.

REF

Catalog Number

LOT

Batch Number

SN

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.

Manufacturer (Abbreviation Mfg.)

BF Applied Part

Contents (Quantity)

1.4 Signal Word Consequences

Indicates a hazardous situation, which if not avoided, could result in injury and/or property damage and/or damage to the device.

⚠ CAUTION:

• **To reduce the risk of device interference,** keep CORE at least 1 meter away from all RF emitters including Wifi routers and radios.

• **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.

• **To reduce the risks associated with inaccurate data acquisition** store and operate this stethoscope only as instructed in this manual. Though there is an acoustic (non-amplified) mode available with this stethoscope, it is highly recommended that the battery be recharged within thirty minutes of the LED indicator turning red. Recharge the battery using only the USB power cord and charger provided with the device.

• **DO NOT immerse the stethoscope in a liquid** or subject it to any sterilization processes other than those described in this manual.

• **To reduce the risks associated with very strong electromagnetic fields** avoid using the stethoscope 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 Devices may result in increased RF emissions or decreased immunity of the Eko Electronic Stethoscope System.

• **Please read, understand, and follow all safety information** contained in these instructions prior to using the Eko Electronic Stethoscope System. It is recommended that these instructions be retained for future reference.

• **To reduce the risk associated with an electrical shock** do not use the stethoscope on patients without the analog stethoscope's chest piece in place.

• **CORE contains a Bluetooth Class 2 wireless data link.** The maximum radio frequency field strength generated by the stethoscope 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

NOTICE:

and cause interference, immediately move CORE 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 stethoscope. CORE contains a lithium-ion polymer 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 CORE.

1.5 EMC Compliance

FCC Intentional Radiator Certification

Contains FCC ID: QOQBLE113
Contains IC: 5123A-BGTBLE113

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.

1.6 Indications for Use

Eko is intended to be used as a part of a physical assessment of a patient by healthcare professionals for diagnostic decision support in clinical settings. Eko is intended for use on pediatric and adult patients. It can electronically amplify, filter, and transfer sounds to the accompanying mobile application for storage and sharing. 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.

There are no known contraindications for Eko, although care should be taken when considering using the device according to the warnings and precautions below.

Eko is not life-supporting or life sustaining.

1.7 Precautions

The device is intended to be prescribed by licensed medical professionals for use on patients during a physical assessment in a clinical setting. 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.

Eko should be used only by qualified clinicians. Eko is intended for use on patients that can be auscultated on normally with an acoustic stethoscope.

This manual provides instructions for the use of CORE and Eko web and mobile applications. It is assumed that the user is familiar with basic website navigation and mobile application use.

This device is only indicated for use in a hospital, physician's office, or other clinical setting. Standard procedures for auscultation should be followed including background noise reduction and optimal patient positioning.

In order to transmit sounds to the Eko App, the stethoscope and device must be connected via Bluetooth, and in order to fully use certain functions, the mobile device must be connected to the internet via cellular data connection or Wi-Fi.

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

It is highly recommended that users of the Eko Dashboard and Eko App 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. Please consult your institution's technical services to implement appropriate security measures.

1.8 Patient Privacy

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 #. By entering this information, the user assumes any and all risks of and liabilities incurred with using or transmitting such information.

1.9 Contents and Operation

CORE includes (1) CORE, (2) stethoscope tubing adapters, (1) micro USB cable, and (1) USB charger. This device is non-assembled and must be installed by the user. For full functionality, the system requires an acoustic stethoscope and smart mobile device with wireless Internet capabilities (*not included*). The compatible hardware and software platforms are listed below.

The Bundle package includes (1) CORE fully assembled with an acoustic stethoscope, (1) micro USB cable, and (1) USB charger. The digital electronic stethoscope attachment is referred to as CORE, while the Eko BUNDLE is an electronic stethoscope consisting of CORE fully assembled to an acoustic stethoscope.

Compatible Stethoscopes
Eko is designed and tested to work with the 3M Littmann* Cardiology II/III, WelchAllyn Harvey Elite, and ADC 601 lines of analog stethoscopes. Eko will work with many other stethoscope brands and models, but no performance guarantees are claimed using other models or brands.

NOTE: CORE is not compatible with any digital stethoscopes.

System Requirements
The mobile app software can be used on iPhone* 4S, iPhone 5/5C/5S, iPhone 6/6 plus, iPhone 6s/6s plus, iPad* Mini 2/3, iPad Air/Air 2, iPod Touch 5G, and iPad 3rd and 4th generations with iOS 7.0 and higher. The mobile app software can also be used with Android devices with BLE support (Bluetooth 4.0) and Android 5.0 and above.

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

*Littmann, 3M , and Cardiology III are registered trademarks of the 3M Corporation.
*iPhone, iPad, iTunes, and iOS are registered trademarks of Apple, Inc.
*Bluetooth is a registered trademark of Bluetooth SIG, Inc.

2.1 Installation to Existing Stethoscopes

Not applicable to Eko Bundle

Detach Chest Piece

Remove chest piece of the analog stethoscope manually. Grip the chest piece with one hand and the tubing in the other, then twist and pull them apart. **This may require some force**. *See Fig. 1 & 2*

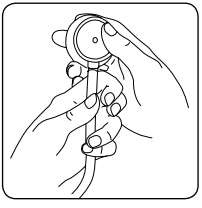

Fig. 1 Detach the Chest Piece

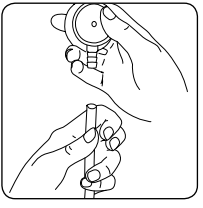

Fig. 2 Detached Chest Piece

Install CORE

Insert the narrow end of CORE into the tubing of the stethoscope. The metal stem fits into the hollow opening of the tube.

NOTE: Ensure the smaller end of CORE is connected to the stethoscope tubing. *See Fig. 3 & 4*

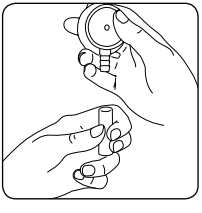

Fig. 3 Tubing Adapter and Chest Piece

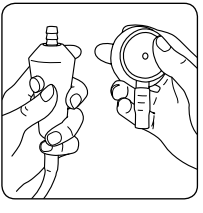

Fig. 4, Left: CORE on Stethoscope Tubing
Right: Connector on Chest Piece

For more information, click here.

Reattach Tubing and Chest Piece
Attach the additional tubing connector onto the end of CORE as shown below. Then attach the chest piece into the tubing connector as it was on the analog stethoscope.

To get the best sound, we recommend you test all Eko-supplied tubing adapters & select the one that provides the tightest fit with your analog stethoscope.

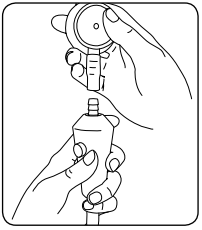

Fig. 5 CORE with Attached Tubing

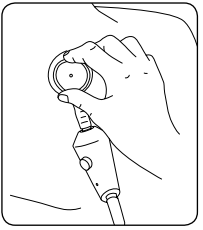

Fig. 6 Completed Installation

2.2 CORE Use

Charge Battery
The battery in CORE will need to be charged; insert the included micro USB cable into the USB port on the device and plug the other end into the included USB charger. The LED will begin to flash yellow, signifying that it is charging. The LED will change to solid yellow when the device is fully charged.

NOTE: CORE will not turn on while it is plugged in and charging.

Power Off
When CORE is turned Off, sounds will be heard as through the analog stethoscope. "OFF" will be displayed on the toggle when the device is powered off.

Power On
Depress the power slider to move the switch from the OFF to the ON position. "ON" will be displayed on toggle when the device is powered on.

Test the Volume Level
CORE's sound level can be amplified in 7 increments up to 40X amplification of an acoustic stethoscope. Change the volume level by clicking the plus (+) and minus (-) volume buttons on the side of CORE.

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

Then, navigate to the Menu screen by clicking on the top left tab in the App. Navigate to Hardware > Bluetooth > Select Device and pair with the device.

The mobile device is now ready to record sounds from CORE. If Bluetooth pairing is unsuccessful, an error message will appear in the App and no sounds will be recorded. If the Bluetooth connection is successful the LED will turn from flashing blue to green See Section 2.3 for the LED states of the device.

Setting up a PIN
Create a secure 4-digit PIN by logging in to the mobile application. Navigate to the Menu screen by selecting the icon on the top left of the Moblie App home screen.

Next, select Account Settings > Create Pin. Follow the instructions on the screen to create and save a 4 -digit PIN. You will need to enter your PIN twice for verification purposes.

Adding Notes to Recordings on Moblie 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.

On the bottom of the recording screen, select the Notes icon. The Notes icon looks like a post-it with writing on it. Select "Add Note" and begin typing your note. Select the the check mark to save.

3.1 Cleaning

Cleaning and Disinfecting Procedure
The stethoscope and CORE should be cleaned between each patient use. All cleaning instructions pertaining to the original stethoscope apply.

Under normal conditions it is unnecessary to remove CORE from the stethoscope tubing 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.

If it becomes necessary to remove CORE, pull the stethoscope tubing off of the metal stem on both ends of the device. Wipe all parts of the stethoscope clean with 70% isopropyl alcohol wipes including CORE's surface, stethoscope tubing, tubing connector, and chest piece. Reassemble the stethoscope by reinserting the metal stems into the stethoscope tubing as before.

4.1 Warranty

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

5.1 Operating Conditions

Environmental
The operating range of CORE is -30° to 40°C (-22° to 104°F), and 15% to 93% relative humidity. The storage and transport range is -40° to 55°C (-40° to 131° F), and 15% to 93% 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 CORE. Internal damage to the product could cause malfunction of the product, possibly leading to complete loss of function. If problems are encountered with CORE, do not attempt to repair it. Please notify our support team for assistance.

6.1 CORE Modes and Corresponding LED States.

	Off	CORE is OFF. Sounds from the stethoscope pass through unfiltered.
	On *Not Paired*	CORE is ON but not paired. The CORE is discoverable and ready to connect via Bluetooth.
	On *Paired*	CORE is ON and paired with a phone/tablet. The CORE will stream live audio from the stethoscope chest piece to the paired device.
	On (quick blink) *Playback*	CORE is ON and playing back sounds from a paired phone/ tablet.
	On *Volume Change*	CORE is ON and changing playback volume based on commands from the volume buttons or paired phone/tablet. The LED will blink once for each volume interval changed.

	On *Low Battery*	CORE is ON and its battery level is below 25%.
	On *Battery Expired*	CORE is ON and its battery level is below 10%. The CORE will no longer stream or playback audio.
	Off *Charging*	CORE is OFF and connected to a power source. The battery is charging.
	Off *Fully Charged*	CORE is OFF and connected to a power source. The battery is fully charged (100%).

7.1 Eko App

Download the Eko app, available on the App Store® and Google Play and follow the on-screen instructions to connect to CORE.

Bluetooth must be enabled in the mobile or desktop's Bluetooth settings in order to use CORE with the Eko App.

8.1 Electrical Safety

Guidance and Manufacturer's Declaration - Electromagnetic Emission		
The Eko Electronic Stethoscope System is intended for use in the electromagnetic environment specified below. The user of the Eko Electronic Stethoscope System should assure that it is used in such an environment.		
Applicable Emissions Test	**Compliance**	**Electromagnetic Environment- Guidance**
RF emissions CISPR 11	Group 1	The Eko Electronic Stethoscope System 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.
RF emissions CISPR 11	Class B	The Eko Electronic Stethoscope System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 6100-3-2	Not Applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable	

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 the Eko Electronic Stethoscope System.

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

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The Eko Electronic Stethoscope System is intended for use in the electromagnetic environment specified below. The user of the Eko Electronic Stethoscope System 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	+/- 6 kV contact +/- 8 kV	+/- 6 kV contact +/- 8 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 +/- 1 kV for input/ output lines	Not Applicable	
Surge IEC 61000-4-5	+/- 1kV line(s) to line(s) +/- 2 kV line(s) to earth	Not Applicable	
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 cycle 40% U_T (60% dip in U_T) for 5 cycle 70% U_T (30% dip in U_T) for 25 cycle < 5% U_T (>95% dip in U_T) for 5 sec	Not Applicable	

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment-Guidance
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial magnetic field or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The Eko Electronic Stethoscope System is intended for use in the electromagnetic environment specified below. The user of the Eko Electronic Stethoscope System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment-Guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not Applicable	
Radiated RF IEC 61000-4-3	3V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 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 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 the Eko Electronic Stethoscope System is used exceeds the applicable RF compliance level above, the Eko Electronic Stethoscope System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Eko Electronic Stethoscope System.

[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

The Eko Electronic Stethoscope System is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The user of the Eko Electronic Stethoscope System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Eko Electronic Stethoscope System 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.

9.1 Manufacturing & Regulatory Information

Eko

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CE 0537

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(Notified Body No. 0537).

EC REP

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Sydney, NSW 2000 Australia

Brazilian Registration Holder:
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Curitiba - PR, 82820-440, Brazil