Eko

CORE

Model 2nd Generation

1. Indications for Use

The Eko CORE is an electronic stethoscope that enables amplification, filtering, and transmission of auscultation sound data (heart, lungs, bowel, arteries, and veins), whereby a clinician at one location on network can listen to the auscultation sounds of a patient on site or at a different location on the network. Eko CORE is intended for use on pediatric and adult patients. The Eko CORE is intended to be used by professional users in a clinical environment or by lay users in a nonclinical environment. The device is not intended for self-diagnosis.

Figure 1 Eko CORE with CORE attachment and mobile app

2. Introduction

The Eko CORE (also known as Eko Electronic Stethoscope System) is designed to support healthcare professionals in listening to sounds produced by the body, primarily lung, heart, and bowel sounds. Eko device also enables regular users to record, store and share their body sounds with their physician. Eko CORE includes a device that is attached to a stethoscope (CORE attachment) and an application, the Eko App.

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 and Android smartphones and tablets. The App provides the ability for clinicians to save sounds within select Electronic Health Record (EHR) systems, share recordings with other clinicians, and annotate notes on recorded audio.

3. For Help and Assistance

Please contact Eko Devices if you need assistance or any product related concerns. For more information please visit: https://www.ekohealth.com/getstarted

Direct Contact	support@ekohealth.com
Phone Support	1.844.356.3384

4. Equipment Symbols


Instructions for use

European technical conformity

European Authorized Representative


Do not dispose with household waste


Emits Radio Frequency signal

Model number


Humidity range


Temperature range

Non-sterile device. Do not attempt to re-sterilize


Wireless Bluetooth communication


Manufacturer


Manufacturing date

Quantity

IP22 — IP22 indicates protection against access to hazardous parts with a finger, solid objects ≥ 12.5 mm diameter, and vertically falling water drops when enclosure tilted up to 15 degrees.

MR Unsafe

5. Cautions

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

• **Follow all cleaning and disinfecting** 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. It is highly recommended that the battery be recharged within thirty minutes of the LED indicator turning orange. Recharge the battery using only the provided USB power cord with a UL-certified USB wall charger (not provided).

• **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 (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 and/or specific RF emitters that are known sources of electromagnetic disturbance such as diathermy, electrocautery, RFID, security systems (e.g., electromagnetic anti-theft systems, and metal detectors). Interference from hidden RF emitters like RFID might cause packet loss and this will be visible as a "Poor Bluetooth Signal" message on the mobile application. Move away from the hidden RF emitter if this happens.

If sudden or unexpected sounds are heard, move away from any radio transmitting antennas. Using accessories, transducers, and cables not produced by Eko Devices, Inc. may result in increased RF emissions or decreased immunity of the Eko CORE.

• **Please read, understand, and follow all safety information** contained in these instructions prior to using the Eko CORE. 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 without the analog stethoscope's chest piece in place.

• **CORE contains a Bluetooth 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 and cause interference, immediately move CORE away from that device and/or turn the Bluetooth feature OFF.
• **Consult with your physicians** when using the Eko device.
• **To ensure high quality sounds** location and position of CORE placement should be taken into consideration when auscultating.
• **To improve Bluetooth connection**, reduce the distance and/or allow a line of sight between Eko device and mobile device. The Bluetooth range will be reduced when objects (walls, furniture, people, etc) are between the Eko device and a paired mobile device.
• **To reduce risk of asphyxiation and strangulation**, ensure that all components are properly attached and stored. Keep away from children.

6. EMC Compliance

FCC Intentional Radiator Certification

Contains FCC ID: 2ANB3-E6
Contains IC: 23063-E6

47 CFR Part 15.105 required statement for Class B:

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

* Reorient or relocate the receiving antenna.
* Increase the separation between the equipment and receiver.
* Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
* Consult the dealer or an experienced radio/TV technician for help.

Canada regulatory statement(s):
This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) This device may not cause interference; and (2) This device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

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.

7. Contents and Operation

Eko CORE device includes (1) CORE attachment, (2) tubing adapters, and (1) micro USB cable and the Eko App. The compatible hardware and software platforms are listed below.

Compatible Stethoscopes
Eko CORE is designed and tested to be compatible with the 3M Littmann* Cardiology II/III/IV, WelchAllyn Harvey Elite, Medline and ADC analog stethoscopes. Eko CORE is compatible with many other stethoscope brands and models, but there are no performance guarantees when using other stethoscope brands or models.

NOTE: Eko CORE is not compatible with sprague stethoscopes or other digital stethoscopes.

Bluetooth and Data Connection
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. Please keep Eko CORE and Eko App within 15 feet for optimum Bluetooth connection. In the highly unlikely condition that the device is rebooted, revert to using the analog mode. The digital mode should restart in less than ten seconds.

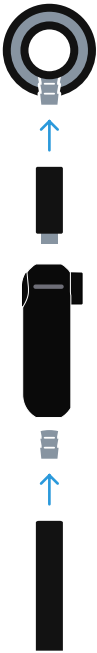
System Requirements
The mobile app software can be used on iPhone 5S, iPhone 6/6 Plus, iPhone 6s/6s Plus, iPhone 7/ 7 Plus, iPhone 8/8 Plus, iPhone X, iPad* Mini 2/3/4, iPad Air/Air 2, iPad Pro, iPod Touch 6G, and iPad 5th and 6th generations with iOS 11.0 and higher. The mobile app software can also be used with Android devices with BLE support (Bluetooth 4.0) and Android 7.0 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.

8. Installation to Existing Stethoscopes

Not applicable to fully assembled digital stethoscope



Step One
Grip chest piece with one hand and pull the tubing with force using the other hand to detach the chest piece from the tubing of the existing stethoscope. Insert the chest piece into the Eko-compatible adapter tubing provided

Step Two
Attach the CORE Digital Attachment to the other end of the Eko-compatible adapter tubing provided

Step Three
Attach the tubing of the existing digital stethoscope to the other end of the CORE Attachment and assembly of the CORE digital stethoscope is now complete

Figure 2

9. 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 a UL-certified USB wall charger. The LED will turn solid yellow, signifying that it is charging. The LED will change to solid green when the device is fully charged. The fully charged battery should last for at least 9 hours in continuous transmission mode (ON, Bluetooth paired with Eko App).

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

Power Off
When CORE is turned Off, analog rather than digital sounds will be transmitted and heard from the stethoscope. "OFF" is when the toggle is protruding from the surface of the volume buttons.

Power On
Depress the power slider to move the switch from the OFF to the ON position. "ON" is when the toggle is flushed with the surface of the volume buttons.

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.

The mobile device is now ready to record sounds from Eko 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 white to solid white (See Section 6.1 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 Mobile 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 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.

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 check mark to save.

Operating CORE
When using the Eko CORE to assess and record heart sounds, it is best to place the CORE stethoscope at the standard auscultation points on the anterior chest wall as shown below with BLACK dots (refer to Figure 4).

When using the Eko CORE to assess and record lung sounds, it is best to place the CORE stethoscope at the standard auscultation points on the anterior chest wall as shown below with BOTH black and blue dots (refer to Figure 4).

The diaphragm side of the stethoscope should be placed on user's chest wall to assess for both heart and lung sounds. Only use the bell (or closed bell) of the stethoscope when assessing low frequency sounds as recommended by a clinician (refer to Figure 2).

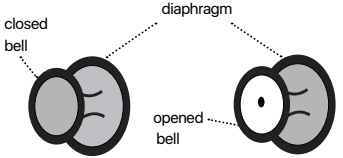


Figure 3

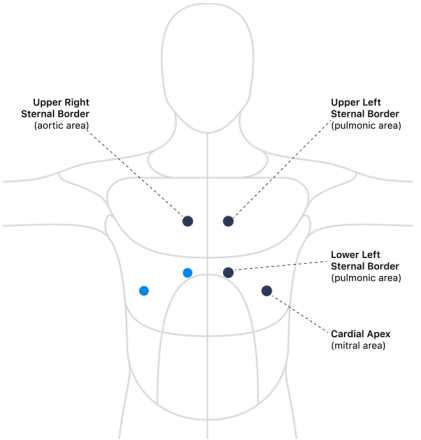


Figure 4

Headset Alignment
Before placing the eartips in your ears, hold the headset in front of you with the eartubes pointing away. Once the eartips are in your ears, they should point forward.

Open the diaphragm
When using a double-sided stethoscope (refer to Figure 3), you need to open (or index) the bell or diaphragm by rotating the chestpiece. If the diaphragm is open, the bell will be closed, preventing sound from coming through the bell, and vice versa.

10. Cleaning

Cleaning and Disinfecting Procedure
The stethoscope and CORE should be disinfected between each use. Infection control guidelines from the Centers for Disease Control and Prevention (CDC) state that reusable medical equipment, such as stethoscopes, must undergo disinfection between patients. Standard stethoscope hygiene practices apply to the Eko device.

All external parts of the hardware should be disinfected with 70% isopropyl alcohol wipes. Under normal conditions, it is not necessary to remove CORE attachment from the stethoscope tubing during the disinfecting procedure.

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 of the CORE attachment on both ends. Wipe all parts of the stethoscope clean with 70% isopropyl alcohol wipes or disposable wipe with soap and water including CORE's surface, stethoscope tubing, tubing connector, and chest piece. A 2% bleach solution may be used to disinfect your stethoscope tubing, tubing connector, and chest piece; however, the tubing may become discolored after exposure to bleach.

To prevent staining of stethoscope tubing, avoid contact with pens, markers, newsprint, or other printed material. It is good practice to wear your stethscope over a collar whenever possible.

Reassemble the stethoscope by reinserting the metal stems of the Core attachment into the stethoscope tubing as described above in the installation section.

11. 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.

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.

No Modifications
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, which may lead to complete loss of function. If problems are encountered with CORE, do not attempt to repair it. Please notify our support team for assistance.

Disposal
If the enclosure of the Eko device is damaged, please dispose of it appropriately.

12. Warranty

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

13. CORE Modes and Corresponding LED States.

	CORE is on & seeking device
	CORE is on & connected
	CORE is recording
	CORE is low on battery
	CORE is off & charging
	CORE is fully charged

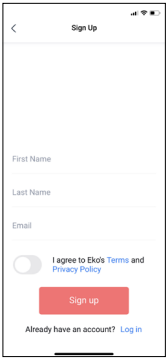
14. Eko App

Download the Eko app, available on the App Store® and Google Play and follow the on-screen instructions to connect to CORE (as shown on the next two pages).

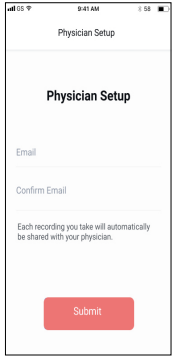
Bluetooth must be enabled in the mobile or desktop's Bluetooth settings in order to use CORE with the Eko App.

When using the Eko Dashboard and Eko App, enable device and networking security features to protect patient data that is created and stored using this software, in addition to security features embedded in the system. Update to the latest version of the Eko App.

14. Eko App (setup and pairing)

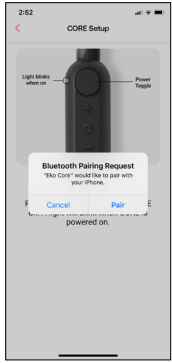


1 Sign up: enter names and email address



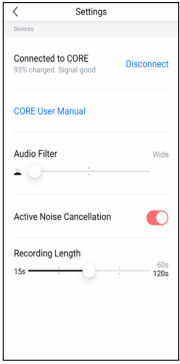
2 Physician setup: enter physician email address

3 Turn on Eko CORE

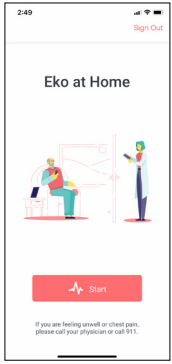


4 Pair Eko CORE

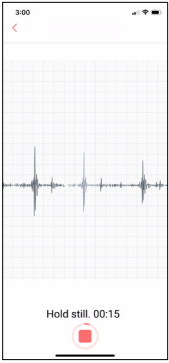
14. Eko App (recording)



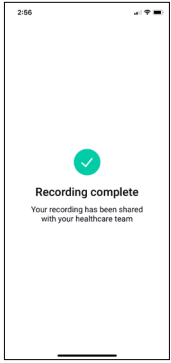
5 Settings



6 Start recording



7 Recording in progress



8 Recording complete

15. 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	+/- 8 kV contact +/- 15 kV	+/- 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 +/- 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	100% drop in UT for 0.5 cycle 0/45/ 90/135/ 180/225/ 270/315 degrees, 100% dip in UT for 1 cycle, 30% dip in UT for 25 cycle, 100% drop in UT 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	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.
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	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 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.

16. Manufacturing and Regulatory Information

Eko

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