

CORE

User Manual

1. Indications/Intended Purpose

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
Fully assembled digital stethoscope and mobile app

2. Introduction

The Eko CORE (CORE) is designed to support healthcare professionals in listening to sounds produced by the body, primarily lung, heart, and bowel sounds. CORE also enables regular users to record, store and share their body sounds with their physician. CORE includes a device that is attached to a stethoscope (Eko CORE Digital Attachment/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 selected Electronic Health Record (EHR) systems, share recordings with other clinicians, and annotate notes on recorded audio.

3. For Help and Assistance

Please contact Eko if you need assistance or any product related concerns.

For more information please visit: https://www.ekohealth.com/IFU

Direct Contact: support@ekohealth.com

Phone Support: 1.844.356.3384

This User Manual also applies to: Eko CORE Digital Stethoscope

Eko CORE Digital Attachment

3M™ Littmann® CORE Digital Stethoscope

4. Equipment Symbols



Consult instructions for use



European technical conformity



Authorized Representative in the European Union



WEE Symbol Separate collection facilities for recovery and recycling



Emits Radio Frequency signal



Model number



Humidity limitation



Temperature limit



Wireless Bluetooth communication



Manufacturer

Date of manufacture



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







Medical device



Unique device identifier

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 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. 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 (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 CORE.

Please read, understand, and follow all safety information contained in these instructions prior to using the 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

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

CORE is designed and tested to be compatible with the 3M" Littmann® Cardiology III", 3M" Littmann® Cardiology IV", WelchAllyn Harvey" Elite®, Medline and ADC analog stethoscopes. CORE is compatible with many other stethoscope brands and models, but there are no performance auarantees when using other stethoscope brands or models.

NOTE: 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 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, XS, XS Max, iPad* Mini 2/3/4, iPad Air/Air 2, iPad Pro, iPad Touch 6G, and iPad 5th and 6th generations with iOS 12.0 and higher. The mobile app software can also be used with Android devices with BLE support (Bluetooth 4.0) and Android 8.0 and above.

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

*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

This section is not required for pre-assembled digital stethoscopes



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

9. CORE Use

Charge Battery

The battery in ĆORE will need to be charged; insert the included micro USB cotale 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 8 hours in continuous transmission mode (ON. Bluetooth paired with Eko Apo).

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 flush 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 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 the CORE

When using the 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 4a).

When using the 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).

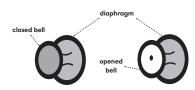
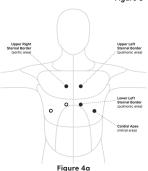
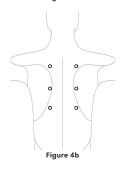


Figure 3





Headset alianment

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 stethoscope 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 conditions of transport and storage between uses -40° to +55°C, relative humidity range of 15% to 93% at an atmospheric pressure range of 700 hPA to 1060 hPa (conforming to IEC 60601-1-11).

Continuous operating conditions

-30° to 40°C; relative humidity range of 15% to 93%, at an atmospheric pressure range of 700 hPa to 1060 hPa (conforming to IEC 60601-1-11)

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.

Additional processing between uses

Eko CORE Attachment should be sufficiently charged and disinfected between uses following instructions provided in this manual."

"Eko CORE Attachment should not be reused if

- 1. The device enclosure or attachment has visible damage,
- The device does not power ON/OFF,
- The device cannot be sufficiently charged,
- 4. The device exhibits acoustic issues.
- 5. The device exhibits other operational anomalies."

Contact Eko customer support for further assistance.

Serious Incident Reporting

If a serious incident has occurred in relation to the device, it should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established. A serious incident means any incident that directly or indirectly led, might have led or, in case of recurrence, could lead to any of the following: the death of a patient, user or other person, the temporary or permanent serious deterioration of a patent's, user's, fetus or other person's state of health, or a serious public health threat.

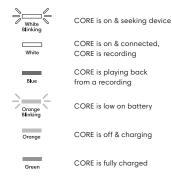
Disposal

The device should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling according to applicable local or national laws.

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.



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.

14a. Eko App – Provider Workflow







Sign up: Create your Eko account by entering in name and email address

Login: Enter in your login credentials

Turn on CORE







Start Recording: Place CORE on the patient's chest; Press the blue button to start recording.



Save Recording: Click save once your recording is complete

14a. Eko App – Provider Workflow (cont'd)





Eko Settings Menu
Adjust your settings by clicking on the (=) top left home screen

14b. Eko App – Patient Workflow



Sign up



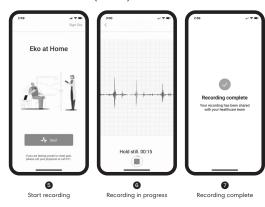




3 Turn on CORE

Pair CORE

14b. Eko App Patient Workflow (cont'd)



15. Specifications & Electrical Safety

| 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 | | |
| Harmonic Emissions IEC 6100-3-2 | Not Applicable | for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies | | |
| Voltage fluctuations / flicker emissions IEC 61000-3-3 | Not Applicable | buildings used for domestic purposes. | | |

Guidance and Manufacturer's

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 | |
| 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: It is the a.c. mains voltage prior to application of the test level | | | • |

 $\mathbf{NOTE:}\ \mathbf{U_{\tau}}$ 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: |
| | | | (<u>^</u>)) |

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.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity Continued

- Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mabile radio, and mater radio, AM and RM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To address the electromagnetic environment due to fixed RF transmitters, an electromagnetic is survey should be considered. If the measured field strength in the location in which the Exo Electronic Stethoscope System is used exceeds the applicable RF compliance level above, the Exo Electronic Stethoscope System should be observed to verify normal operation. If electronic Stethoscope System should be observed to verify normal operation, if redocation the Exo Electronic Stethoscope System should be observed to verify normal operation. If redocation the Exo Electronic Stethoscope System is used as the state of the stat
- ^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 Exo Electronic Stethoscope System is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The user of the Exo Electronic Stethoscope System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Exo Electronic Stethoscope System as recommended below, accordina 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 √P | 80 MHz to 800 MHz d = 1.2 √P | 800 MHz to 2.5 GHz d = 2.3 √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 | | 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 of 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 mountains.

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 CORE Specifications | | | |
|--|---|--|--|
| General Performance | | | |
| Shelf life | 2 Years | | |
| Audio output | .WAV file | | |
| Audio A/D sampling rate | 4000 Hz | | |
| Frequency response | 20Hz-2000Hz | | |
| Max audio playback intensity | 100db | | |
| Bluetooth Characteristics | | | |
| Frequency band | 2400-2482MHz | | |
| Receiver sensitivity level | -95dBm | | |
| Operational distance | Up to 15 ft unobstructed | | |
| Power | | | |
| Battery type | Rechargeable 3.7 V Lithium-ion polymer cell | | |
| Battery life | ~10 hours continuous use, 1 week typical use | | |
| Physical Characteristics | | | |
| Dimensions | 71 mm long. 24 mm in diameter | | |
| Weight | 34 grams (capsule only) | | |
| Environmental Specifications | | | |
| Environmental conditions of transport and storage between uses | -40°C to +55°C, relative humidity range of 15% to 93%, (conforming to IEC 60601-1-11) | | |
| Continuous operating conditions | -30°C to +40°C: relative humidity range of 15% to 93%, (conforming to IEC 60601-1-11) | | |
| Standards Compliance | | | |
| Medical electrical equipment Part 1: General requirements for basic safety and | IEC 60601-1 | | |
| Part 1: General requirements for basic safety and essential performance | IEC 60601-1-2 | | |
| | IEC 60601-1-11 | | |
| User Interface | | | |
| Core device hardware | Hand-held device with LED, buttons, micro USB port (charging only) | | |
| Mobile device | iPhone or iPad with iOS 6.1 and above | | |
| | | | |

Windows OS or Mac OS X with supported web, browsers

PC

16. Clinical Benefits

The Eko CORE is a digital auscultation tool that improves the physical assessment of patients by providing sound amplification, active noise cancellation, and wireless listening.

The Eko CORE also includes a clinical decision support tool for automated murmur detection with the use of Eko Analysis Software (EAS) or Eko Murmur Analysis Software (EMAS) as available.

As an integral part of a physical assessment, clinicians' interpretations of body sounds via the Eko CORE and Eko Al outputs can help them rule in or out different pathological conditions in a patient.

By helping physicians accurately detect murmurs that warrant further investigation, further workup and testing could be better focused and more likely to result in the clinical benefit of an accurate diagnosis for the patient.

Manufacturing and Regulatory Information

Please see the translated Instructions for Use at support.ekohealth.com



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