Instructions for Use

CORE 500™
Digital Stethoscope

eko

Contents

1. General Information

This manual provides information to guide trained medical professionals in the safe and effective operation and proper maintenance of the CORE 500™ Digital Stethoscope. It's important that you read and understand all instructions in this manual before operating the device, and pay careful attention to the warnings and cautions throughout the manual.

Operate and maintain this product according to the safety and operating procedures in this manual, and only for its intended purpose. Always use the information in this document with sound clinical judgment and best clinical procedures.

The device is intended to be used in a professional healthcare facility by a healthcare professional, and for home use when prescribed by a healthcare professional, or used by a lay user.

Note: Depending on your platform, hardware, and country, certain features may not be available.

1.1 Indications and Intended Purpose
The CORE 500™ Digital Stethoscope is intended to be used by clinicians or lay users to electronically amplify, filter, and transfer body sounds and three lead electrocardiogram (ECG) waveforms. The CORE 500™ Digital Stethoscope also displays ECG waveforms and heart rate on the display and accompanying mobile application (when prescribed or used under the care of a clinician or by lay users).

A lay user is not intended to interpret or take clinical action based on the device output without consulting with a qualified healthcare professional.

1.2 Device Description
CORE 500™ Digital Stethoscope (CORE 500™) is an electronic stethoscope with integrated electrodes for electrocardiogram (ECG). The device consists of a chestpiece, detachable earpieces (Eko Earpiece) and a mobile application (Eko App) and is intended as a digital auscultation tool on patients requiring physical assessment by the health care providers, or by lay users. CORE 500™ provides the ability to amplify, filter, and transfer body sounds with the chestpiece diaphragm, and three lead ECG through electrodes integrated around the chestpiece.

CORE 500™ features three auscultation modes for better auscultation experience by filtering acoustic data and enhancing the primary frequency range of particular body sounds: Cardiac Mode for heart sounds, Pulmonary Mode for lung sounds, and Wide Band Mode for general auscultation. CORE 500™ also detects and computes the heart rate in real-time based on the phonocardiogram (PCG) data. The computed heart rate and the ECG waveforms can be displayed on the screen mounted on top of the chestpiece, as well as the accompanying mobile application.

1.3 Clinical Benefit
The CORE 500™ Digital Stethoscope is a digital auscultation tool that improves the physical assessment of patients by clinicians in real-time, via telehealth, and asynchronous review.

As an integral part of a physical assessment, clinicians' interpretations of body sounds via the CORE 500™ Digital Stethoscope can help them rule in or out different pathological conditions in a patient. The integrated ECG lets the clinician quickly evaluate the ECG of adult and pediatric patients.

By helping clinicians accurately detect the presence of conditions that warrant more investigation (or allowing patients to send body sounds and

ECG data to their clinicians for this purpose), further workup and testing can be better focused and more likely to result in the clinical benefit of an accurate diagnosis for the patient.

Moreover, a lay user can use the CORE 500 Digital Stethoscope to collect or send additional information to their clinicians when used Over-the-Counter.

1.4 Continuous Operating Conditions

The operating range of the CORE 500™ is:

- A temperature range of + 5°C to + 45 °C.
- A relative humidity range of 15% to 90%, non-condensing, but not requiring a water vapor partial pressure greater than 50hPa.

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

NOTE: If the device is used for a prolonged time at maximum ambient temperature it can get hot.

*(*CORE 500™ had an increase in temperature up to 47°C when tested at 45°C ambient temperature)*

1.5 Environmental Conditions of Transport and Storage Between Uses

The device is expected to be stored in a room with the following parameters:

- A temperature range of – 20 °C to + 5 °C.
- A temperature range of + 5 °C to + 35 °C at a relative humidity up to 90%, non-condensing.
- A temperature range of > 35 °C to 60 °C at a water vapor pressure up to 50 hPa.

1.6 System Requirements

For full functionality, the system requires users to connect their CORE 500™ with an internet-enabled smart mobile device using the Eko App. The app supports Apple® mobile devices. Make sure your system and mobile device meets or exceeds the minimum performance specifications (refer to Section 2.7 Technical Specification). Additional information on the most up-to-date system requirements can be found at support.ekohealth.com.

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. A minimum of 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.

CORE 500™ uses Bluetooth® LE. Mobile devices used must be compatible with Bluetooth® LE.

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

1.7 Help and Assistance

For general and product-related comments, questions, or concerns, please contact Eko Health, Inc., directly. If you have any questions or concerns about results found with the device, please consult a physician.

Serious Incident Reporting
If a serious incident has occurred in relation to the device, it should be reported to the manufacturer and the local competent authority 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 patient's, user's, fetus's, or other person's state of health, or a serious public health threat.

Manufacturer Information
Eko Health, Inc.
2100 Powell Street, Suite 300
Emeryville, CA 94608 USA

General Assistance and FAQs
support.ekohealth.com
Phone Support
(USA) 1.844.356.3384

Warranty Information
Eko provides a limited warranty for CORE 500™. Please visit ekohealth.com/warranty for a full description of the warranty.

Product Reference and Information
ekohealth.com

To view the CORE 500 Instructions for Use, or to visit Eko Help Center, go to ekohealth.com/ifu.

1.8 EMC Compliance

FCC Intentional Radiator Certification
CORE 500™ Digital Stethoscope
FCC ID: 2ANB3-E8

US FCC Statements
47 CFR Part 15.105 FCC Interference Statement 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.

FCC Part 15 Clause 15.21

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

FCC Part 15.19(a)

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 undesired operation.

RF Exposure Guidance Statement

In order to comply with FCC RF Exposure requirements, this device must be installed to provide adequate separation from the human body at all times. Refer to section 2.6 Guidance and Manufacturer's Declaration – Electromagnetic Emission.

Canada regulatory statement(s):
ISED Canada RSS-Gen Notice

IC: 23063-E8

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.

RF Exposure Guidance Statement

In order to comply with ISED RF Exposure requirements, this device must be installed to provide adequate separation from the human body at all times. Refer to section 2.6 Guidance and Manufacturer's Declaration – Electromagnetic Emission.

Afin de se conformer aux exigences d'exposition RF ISED, cet appareil doit être installé de manière à fournir une séparation adéquate du corps humain à tout moment. Reportez-vous à la section 2.6 Guidance and Manufacturer's Declaration – Electromagnetic Emission.

Japan MIC ID: PENDING CERTIFICATION

EU RED and United Kingdom EMC Compliance Europe
This equipment complies with the EMC requirements of the IEC 60601-1-2. See section 2.6 Guidance and Manufacturer's Declaration – Electromagnetic Emission.

2. Safety and Security

2.1 Symbols


Consult Instructions For Use


Consult Accompanying Documents


Manufacturer


Date of Manufacture and Country of Manufacture


Caution

Medical Device

Unique Device Identifier

IEC 60529 IP Rating 44
IP44 is protection Against ingress of solid foreign objects ≥ 1.0 mm diameter and splashing water


Type BF Applied Part (Not defibrillation proof)

MR Unsafe


Disposal per WEEE Directive 2012/19/EU


Bluetooth Connectivity

Catalogue Number

Serial Number


Importer

Environmental conditions of transport and storage between uses: – 20 °C to + 60 °C.

Environmental conditions of transport and storage between uses: relative humidity up to 90 %, non-condensing

2.2 Precautions

- The device may be used on patients during a physical assessment in a clinical setting or by patients under the supervision of a clinician or by lay users. 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. The ECG displayed on the device screen is a tool to assist clinical decisions and is not a diagnosis.
- CORE 500™ should be used by qualified clinicians or by patients with an adequate understanding of the device. CORE 500™ is intended for use on patients that can be auscultated normally with an acoustic stethoscope.
- This manual provides instructions for the use of CORE 500™ and the Eko App. It's 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. Use the provided earpiece with the CORE 500™ for best audio quality. The quality of organ sounds is dependent on proper use, including holding the device still and increasing volume as needed.
- The quality of the ECG is dependent on proper preparation practices including, but not limited to, cleaning the contact area, electrodes and using ECG gel. If used on a portion of the body with significant body fat, body hair, or very dry skin, a successful recording may not be possible.
- The device is not intended for diagnostic purposes. The device uses dry electrodes and is not recommended to determine the absolute amplitude of the ECG signal. Eko recommends that the device display and the mobile app be primarily used for ensuring good ECG signal quality and rhythm analysis.
- The device can be used with any wired headphones or wired headsets. No performance guarantees are claimed using other audio products. If using other headphones, insertable earbuds provide the best sound quality. The device can also be used with wireless listening devices, such as hearing aids, connected through the mobile app. For optimal audio quality while using the mobile app, it's not recommended to listen through the mobile device's in-built speaker.
- Please read, understand, and follow all safety information contained in these instructions prior to using the CORE 500™. It's recommended that these instructions be retained for future reference.
- No modification of this equipment is allowed. There are no repairable parts inside the CORE 500™.
- This device does not detect or measure all heart rate, heart rhythm, and heart waveform changes. The heart rate algorithm has not been validated for patients under the age of 1.
- Electromagnetic disturbance may affect the heart rate accuracy of the CORE 500™ Digital Stethoscope.
- DO NOT use the device while it is charging.
- To reduce the risks associated with infection, follow all cleaning instructions included in this manual. Establish and follow a cleaning schedule after each use.
- DO NOT use the device over broken skin or wound areas.

- DO NOT continue to use if you have an allergic reaction to the device materials or if your skin appears irritated or inflamed after use. Check with a healthcare professional before restarting use.
- To reduce the risks associated with inaccurate data acquisition, store and operate this device only as instructed in this manual.
- It's recommended that the battery be recharged within 30 minutes of the low battery indicator warning. Recharge the battery using only the appropriate USB-C cable.
- 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 risk of device interference, keep the device at least two meters away from all RF emitters, including Wi-Fi routers and radios when operating or charging.
- 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.
- The device 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 the device away from that device and/or turn the Bluetooth feature of the interfering device OFF.
- The device uses a Bluetooth Class 2 wireless data link. The Bluetooth range will be reduced when objects (walls, furniture, people, etc.) are between the device and a paired mobile device. To improve Bluetooth connection, reduce the distance and/or allow a line of sight between the device and the mobile device.
- To reduce the risks associated with environmental contamination, follow applicable regulations when disposing of this device. The device contains a rechargeable battery. Please properly dispose of the device as mandated by local directives.
- Do not operate or store the CORE 500™ in extremely hot, cold, humid, or wet conditions.
- The ECG and body sounds should be used in conjunction with a clinical evaluation. Do not use as the sole basis for medication or treatment decisions.
- Never use the stethoscope without eartips firmly locked in place.
- CORE 500™ is not intended for use with flammable anesthetics or flammable agents.
- DO NOT use portable RF communications equipment (including peripherals such as antenna cables and external antennas) closer than 30 cm (12 inches) to any part of the CORE 500™. Otherwise, degradation of the performance of the CORE 500 could result.
- CORE 500™ is not capable of recording ECG activity of an implanted pacemaker.
- CORE 500™ does not perform automated analyses or semi-automated analyses on the ECG or cardiac sounds.
- To reduce the risk of damage to the device by excessive voltage, always use a CSA/UL/CE marked USBIF charger from a trusted manufacturer to charge CORE 500™.

2.3 Warnings

Failure to follow caution and warning 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.

- WARNING: Stethoscope tubing can be a strangulation hazard. Keep away from unsupervised children.
- WARNING: Eartips can be swallowed and cause a choking hazard. Ensure all parts are properly attached and stored.
- 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.
- WARNING: The CORE 500™ is not intended to be used in an oxygen-rich environment.
- WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- WARNING: DO NOT use unapproved accessories. Use of non-Eko approved accessories or transducers and cables could result in electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation.
- WARNING: Only connect to a power supply to mains voltage marked appropriately in it. During charging, the power supply needs to be easily accessible , in case there is a need for disconnection from mains in an unexpected incident.
- WARNING: CORE 500™ is not defibrillation proof and is not guaranteed to work during external defibrillation.
- WARNING: When the network/Eko Cloud connection is unavailable or unresponsive, the users can perform the auscultation, but will not be able to create/retrieve recordings.

2.4 Network Security

When connecting your smart device, use a network that supports Wi-Fi 802.11n. It is recommended to secure this network using WPA (Wi-Fi Protected Access) or WPA2 (Wi-Fi Protected Access II) as your security protocol. For information on setting up your wireless network security, refer to your network equipment's documentation.

All data transmitted from the Eko App is encrypted in transit using TLS 1.2 or greater, and all data is encrypted at rest using AES 256.

In addition to security features embedded in the system, it's highly recommended that users of the Eko App and Eko Dashboard use networking security features to protect patient data created and stored using this software. Common examples include strong passwords, biometric authorization, two-factor authentication, and VPN encryption when available.

For customers who whitelist IP addresses, we recommend whitelisting domains as the IP addresses might change. For a full list of recommended whitelist domains, reference the Eko Support whitelisting overview support page.

CORE 500™ supports the use of Bluetooth as the primary communication protocol to the mobile device during operation. Bluetooth is a short-range wireless technology standard using UHF radio waves in the ISM bands, from 2.402 to 2.48 GHz.

Eko is committed to safeguarding device cybersecurity by establishing an active cybersecurity monitoring program. The CORE 500 device does not perform cybersecurity event detection nor event logging for cybersecurity-related events.

Eko has established instructions for users or user facilities regarding network and connection requirements. Refer to https://support.ekohealth.com

Users are encouraged to review the Instructions for any security actions that the user or user facility are expected to implement to ensure secure use of the CORE 500 device. Refer to information available on https://support.ekohealth.com regarding Eko Administration and IT Support.

If a cybersecurity event has been detected or suspected, please report to security@ekohealth.com and privacy@ekohealth.com.

2.5 Firmware Updates

Firmware updates to the CORE 500 will be made available as over-the-air (OTA) updates through your Eko App on mobile devices. Eko provides regular updates for your Eko App, available through the mobile device app store.

2.6 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, 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.

If a suspected cybersecurity event has occurred, please report to security@ekohealth.com and privacy@ekohealth.com.

2.7 Guidance and Manufacturer's Declaration – Electromagnetic Emission

The CORE 500™ is intended for use in the electromagnetic environment specified below. The user of the CORE 500™ should ensure that it is used in such an environment.

Applicable Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	CORE 500™ uses RF energy only for its internal functions. 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	CORE 500™ 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 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not Applicable	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The CORE 500™ Digital Stethoscope is intended for use in the electromagnetic environment specified below. The user of the CORE 500™ Digital Stethoscope should ensure that it is used in such an environment.

Immunity Test	IEC 60601-1-2 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 100 kHz repetition frequency	± 2 kV 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 1kV line(s) to line(s) +/- 2 kV line(s) to earth	±1kV (0°, 90°, 180°, 270°) for AC Power Ports	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	Dips: 0 % of U_T for 0,5 cycles And phase angles of 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % of U_T for 1 cycle And phase angle of 0° 70 % of U_T for 25/30 cycles and phase angle of 0° Interruptions: 0 % of U_T for 250/300 cycles	Dips: 0 % of U_T for 0,5 cycles And phase angles of 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % of U_T for 1 cycle And phase angle of 0° 70 % of U_T for 25/30 cycles and phase angle of 0° Interruptions: 0 % of U_T for 250/300 cycles	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 at 50Hz	30 A/m at 50Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial magnetic field or hospital environment.
NOTE 1: U_T is the a.c. mains voltage prior to application of the test level.		NOTE 2: The device is nonfunctional during mains charging.	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The CORE 500™ Digital Stethoscope is intended for use in the electromagnetic environment specified below. The user of the CORE 500™ Digital Stethoscope should ensure that it is used in such an environment.

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Radiated RF IEC 61000-4-3:2010	80 MHz – 2.7 GHz 80 % AM at 1 kHz	10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = [3.5/E1]√P 80MHz to 800MHz d = [7/E1]√P 800MHz to 2.7GHz 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. 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 reflection from structures, objects and people.

a. Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radios, AM and FM radio broadcasts and TV broadcasts cannot be predicted theoretically with accuracy. To assess 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 product is used exceeds the applicable RF compliance level above, the product should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the product.

NOTE 3: If there is any lost or degraded essential performance of the device due to electromagnetic (EM) disturbances, performance of the device can be recovered by switching OFF the device and switching it back ON.

Recommended separation distances between portable and mobile RF communications equipment and CORE 500 Digital Stethoscope

The CORE 500 Digital Stethoscope is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The user of the CORE 500 Digital Stethoscope can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CORE 500 Digital Stethoscope 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 √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	3.7	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.

2.8 Technical Specifications

General Performance	
Audio Frequency Response	Bandwidth of 20 Hz - 2000 Hz
Audio Playback Volume	Output level from 85 to 100 dB SPL A-weighted with user selectable volume levels
User Volume Protection	Max Sound Pressure Level (SPL) output of 100 dB, SPL A weighted
ECG Performance (ECG Frequency Response Range)	2 channel ECG in real-time in the 0.1 - 250 Hz frequency range*
Range of accuracy for heart rate measurement	30 bpm - 200 bpm**, mean absolute error +/- 5bpm
Expected Device Service Life	2 years for CORE 500™ system and battery
Applied Parts	Type BF Applied Part (not defibrillation proof). The 3 electrodes and a right leg electrode on the bottom face of the device are Type BF Applied Part
Mode of Operation	Continuous
Essential Performance	
The CORE 500™ Digital Stethoscope is intended for auscultation. The device also provides the ability to capture, and transmit, heart sounds and ECG readings on the accompanying mobile application. The device displays a heart rate.	
Bluetooth Characteristics	
General	• Support communication with supported Bluetooth Low Energy (BLE) 4.2 and BLE 5.0 clients. • BLE works in the 2.4 GHz frequency band, which is known as the Industrial, Scientific and Medical (ISM) band. • Bluetooth supports data transfer up to 33 feet (10 meters).
Data Transfer Encryption	Data transferred via Bluetooth is encrypted
Power	
Battery Type	Internally powered using rechargeable 3.7 V Lithium-ion polymer cell
Battery Life	<80% of battery capacity self drains in 6 months Minimum 5 hours continuous use
Physical Characteristics	
Dimensions	27 inches (685mm) long
Weight	6.6 ounces (186g) with earpiece

Environmental Specifications	
Environmental Conditions of Transport and Storage Between Uses	– 20 °C to + 5 °C + 5 °C to + 35 °C, relative humidity up to 90 %, non-condensing > 35 °C to 60 °C at a water vapor pressure up to 50 hPa (conforming to IEC 60601-1-11 and IEC 60601-2-47)
Continuous Operating Conditions	5 °C to + 45 °C; relative humidity range of 15 % to 90 %, non-condensing (conforming to IEC 60601-1-11 and IEC 60601-2-47)
Ingress Protection	IP Rating 44 IP44 is protection Against ingress of solid foreign objects ≥ 1.0 mm diameter and splashing water
User Interface	
Chestpiece	Hand-held device with capacitive touch, mode button, volume button, and USB-C port (charging only). CORE 500 can be safely charged using a Certified USB-IF, Class II Double insulated USB charging port with output voltage rated at 4.75V-5.25V and charging current at 500mA - 2A. *(CORE 500 was tested with an Apple Model:A1385 USB Power Adapter.)*
Mobile Device	iPhone with iOS 6.1 and above
Earpiece	Standard 3.5 mm female TRS jack

* The device is capable of recording ECG on infants weighing less than 10 kg.
** The heart rate algorithm has not been validated for patients under the age of 1.

3. Installing the Eko App

3.1 Downloading and Installing

The Eko App helps you to easily connect to CORE 500™ for secure transmission and analysis of your recordings.

Downloading the Eko App allows you to:

- Pair the CORE 500™ to your mobile device.
- Listen wirelessly through a headset.
- View PCG and three lead ECG visualizations.
- Start, save, and share recordings.
- Take advantage of additional usage guides.

After you install the Eko App, complete the CORE 500™ device setup on the app. The app walks you through setting up and using your CORE 500™.

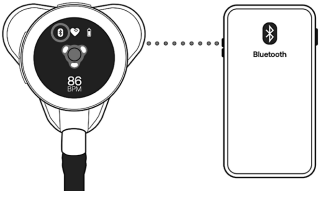
Download the Eko App below: **Or, scan the QR code below to download Eko App:**

Download on the App Store

GET IT ON Google Play

3.2 Connecting CORE 500™ with App

1. Turn on your phone's Bluetooth®.
2. Turn on your CORE 500™.
3. Open the Eko App and sign in.
4. Follow the onscreen instructions for pairing your device.
5. The Bluetooth icon appears on the CORE 500™ screen when connected.



3.3 Onboarding with the Eko App

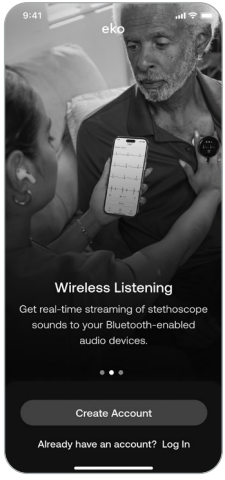
3.3.1 Account Creation

User onboarding to the mobile application (Eko App) begins with creation of an account, and selecting the account type.

Marketing Onboarding

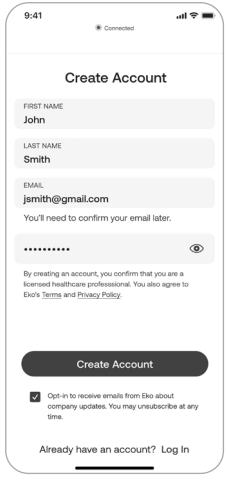
Splash

Marketing Screen

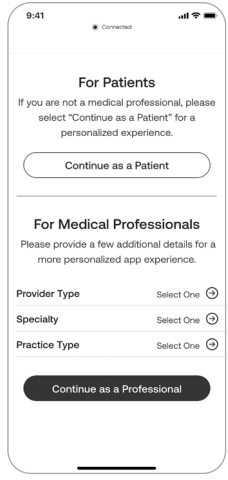


Account Creation

Create Account



Account Balance



3.3.2 Account and Patient Data Security

To ensure account security, Eko requires the use of a unique username (email address) and strong password. Users can further secure access to patient data by enabling the optional 4-digit pincode. Once enabled, this pincode must be entered prior to accessing the patient screen. To enable the pin code navigate to the Enhanced Security option located in the Account Profile section.

3.3.3 Device Onboarding

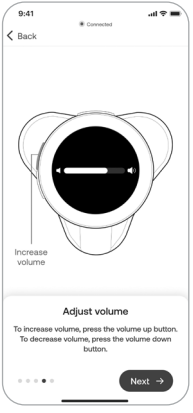
Following the account creation, instructions for getting started are provided which involves understanding the user interface, the graphical interface, proper placement of device, brief description of ECG, and heart rates (BPM), and lastly important things to remember.

User Interface

Turn ON to connect

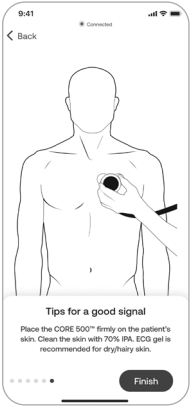
Change Audio Filters

Adjust volume



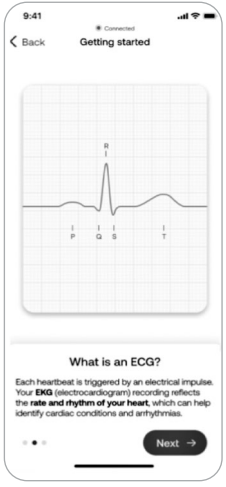
Start a recording

Tips for good signal

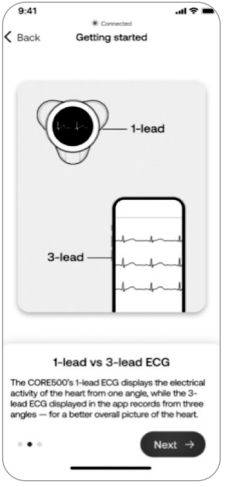


Getting Started

ECG Description



1-lead vs 3-lead ECG



BPM description

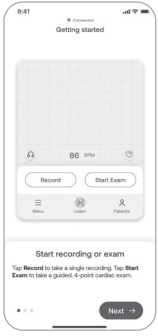
Things to remember

3.3.4 App onboarding

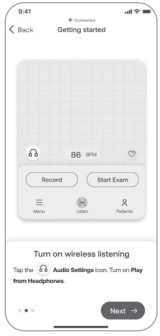
After the user completes the getting started instructions, an app onboarding instructions is provided explaining the features. Once the app onboarding process is complete the user is directed to the landing screen to connect, and start using the application.

App Onboarding **Landing Screen**

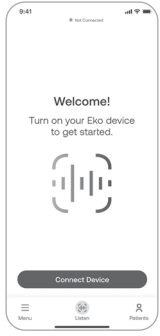
Record



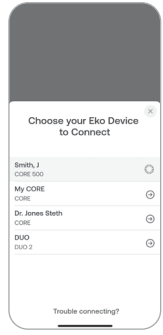
Wireless listening



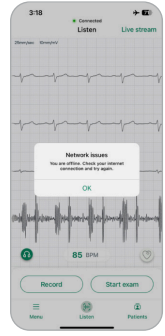
Landing screen
Device not connected



Landing screen
Connect device



Network error/warning message



3.3.5 Network/Eko Cloud availability

The WIFI or Cellular network connection is required to perform recordings, retrieve recordings from the Eko Cloud.

When there is a Network outage/Eko cloud unavailable or unresponsive, the users can perform the auscultation, but will not be able to create/retrieve recordings.

When a user is experiencing a network/Eko Cloud outage, the Eko App shall display the following Network error/warning message, Please check for the WIFI connection or the Cellular Network connection. If the issue persists, please reach out to Eko Customer help center at https://support.ekohealth.com.

4. Using the CORE 500™

4.1 Removing from Packaging
Carefully remove the device from the packaging. Before use, inspect the device for any damage. Do not use a damaged device.

There is no requirement to warm up the device prior to use.

4.2 Skin Preparation
Excessive hair, dirty skin, dry skin, or oily skin can impact the quality of the ECG tracing. Wetting the patient's skin with 70% isopropyl alcohol wipes can improve ECG electrode contact. Do not use the CORE 500™ over wound areas or areas of broken skin. Rub the skin vigorously to increase capillary blood flow to the tissues. ECG gels or saline solutions can also be used on the electrodes to improve signal quality.

4.3 Contents
This package includes:

- 1 CORE 500™ Digital Stethoscope chestpiece
- 1 USB-C cable
- 1 Eko earpiece
- 4 silicone rubber ear tips (2 large, 2 small)
- Alcohol wipes
- 1 Quick Start Guide

4.4 Earpiece Setup
Attach Earpiece

1. Plug the earpiece into the CORE 500™.
2. Twist the earpiece clockwise with a quarter turn until it locks.

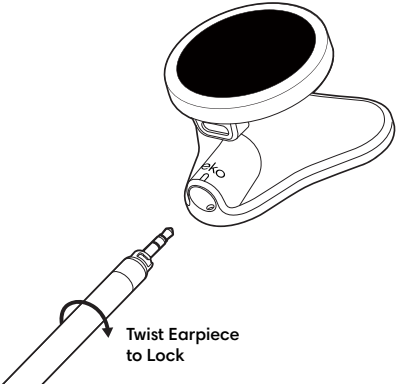
Warning: Do not use excessive force when twisting the earpiece.

Detach Earpiece

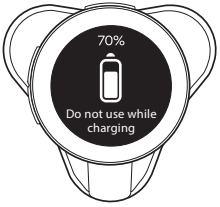
1. Twist the earpiece counterclockwise with a quarter turn until it unlocks.
2. Remove the earpiece from the CORE 500™.

Warning: Do not use excessive force when twisting the earpiece.

Fit Earpiece
Use the right ear tip size. Try out the small or large ear tips for the best fit.



4.5 Charging



1. Connect the CORE 500™ to a power source using the included USB-C cable and a power adapter (not included).
2. The battery indicator shows the charge percentage.

The battery life is subject to use and is expected to last for five hours of continuous use. It takes approximately three hours to fully charge the device from 0%.

The CORE 500™ 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.

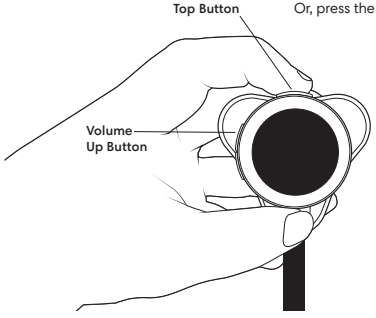
NOTE: The CORE 500™ will not operate or connect to the Eko App while charging.

4.6 Turning On and Off

Turn On

Pick up the device by placing your fingers around the space between the device face and electrodes. The CORE 500™ will turn on automatically.

Or, press the top button to turn on the CORE 500™.



Sleep

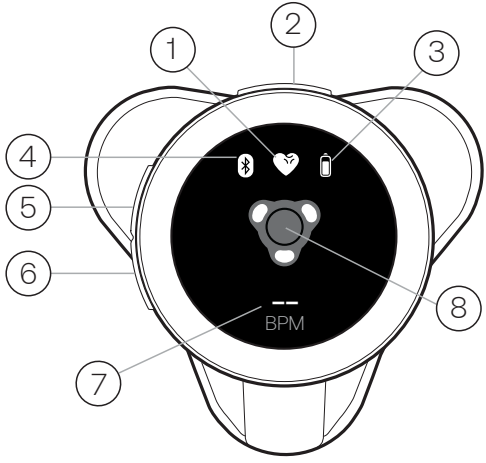
The 500™ automatically sleeps when not touched for 15 seconds.
Pick it up by the neck of the chestpiece to turn it on. You can turn off this setting in the Eko App.

Turn off

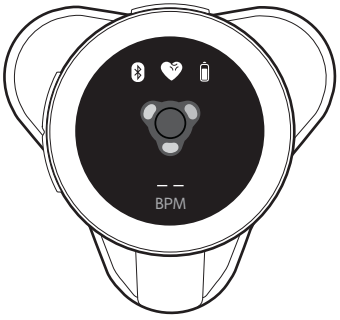
Hold the top button while pressing the volume-up button once to turn it off.

Once you see the confirmation screen, press the volume-up button again to confirm.

Resting State



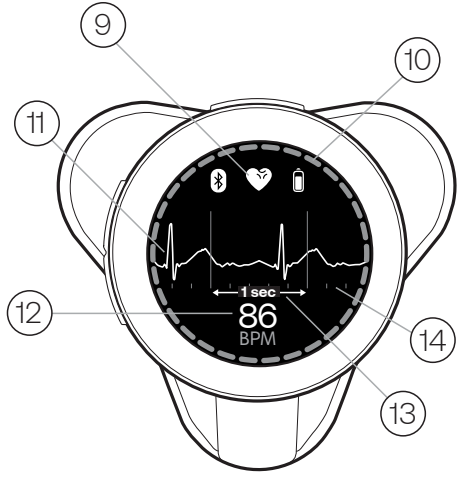
1. Current audio filter:
   - Wide (for all use cases)
   - Cardiac (with ECG)
   - Pulmonary (with lung sounds)
2. Top button:
   a. Change filter:
      = press for <1 second
   b. Start Recording:
      = press for 2 seconds
3. Battery level
4. Bluetooth connected
5. Volume up button
6. Volume down button
7. Real-time heart rate in beats per minute
8. Leads indicator:
   a. O = No skin contact detected
   b. ✓= Skin contact detected



If the electrodes do not make contact with skin, the lead indicator will be gray.

If the electrodes make contact with skin, the lead indicators will turn green. The mock ECG trace between the top two electrodes illustrates that the real-time waveform will show the ECG on the screen when active.

Active State

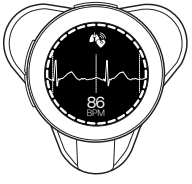


9. Current audio filter
10. Recording in progress
11. ECG waveform (shown in cardiac and wide filter)
12. Real-time heart rate in beats per minute
13. 1-second intervals
14. 0.2-second intervals

Each filter mode described below accentuates particular body sounds while auscultating: The cardiac mode is weighted toward heart sounds, pulmonary toward lung sounds, and wide band provides coverage for both.

Cardiac audio filter
In the cardiac audio filter mode, the CORE 500™ screen shows a heart icon at the top, the ECG waveform for a two-second interval, and the real-time heart rate in beats per minute. If a recording is in progress, green bars light up around the screen as the recording progresses.

Pulmonary audio filter
In the pulmonary audio filter mode, the CORE 500™ screen shows a lung icon at the top and the real-time heart rate in beats per minute. If a recording is in progress, green bars light up around the screen as the recording progresses.



Wide audio filter
In the wide audio filter mode, the CORE 500 screen shows an icon with a heart and lungs and the real-time heart rate in beats per minute. If a recording is in progress, green bars light up around the screen as the recording progresses.

4.8 Changing the Volume

The device's sound level can be amplified in seven increments. Change the volume level by pressing the top (+) and bottom (-) of the volume button on the side of the device. The volume change is confirmed on the screen of the device.

4.9 Changing the Audio Filters

Press the top button for less than one second to switch to a different audio filter. You must press for less than one second between each audio filter. The available filters are cardiac (with ECG), pulmonary (with lung sounds), and wide (for all use cases) .

Example

The device is in cardiac mode. You press the top button for less than one second. The audio mode changes to pulmonary mode. You press the top button for less than one second. The audio mode changes to wide mode.

4.10 Capturing Sounds and ECGs

To capture sounds and ECGs, the CORE 500™ can be used on various locations and orientations of the chest. Each position will produce a unique body sound and ECG tracing. For ECG, place the device directly onto the patient's skin. Do not perform an ECG over the patient's clothing.

Audio

Capture sounds by placing the CORE 500™ anywhere on the body. For best audio, press the device firmly against the patient to reduce movement.

ECG

Capture the ECG signal by placing the CORE 500™ on the skin. The audio filter icon should be at the top, facing up. One position that works well is the left upper sternal border (next to the left sternum edge between the second and third rib), as shown in the placement illustration below. If the patient has particularly dry skin, significant body fat or chest hair, then alcohol wipes or conductive gel used with other ECG systems may be applied to CORE 500™ electrodes to improve the quality of the ECG signal.

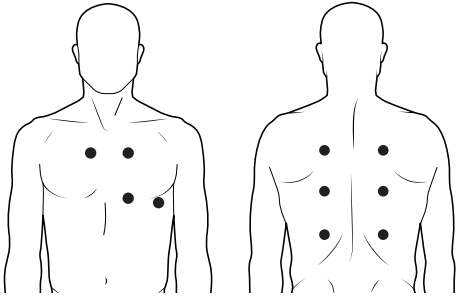
The device will confirm all electrodes have contact with the patient's skin by the lead indicator icon turning green simultaneously as it detects skin contact. If the lead indicator is gray, there is not sufficient skin contact.

Note that device display is not recommended to determine the absolute amplitude of the ECG signal. We recommend that the display be primarily used for ensuring good ECG signal quality. The accompanying mobile app should be used to read and interpret the three lead ECG.

Placement

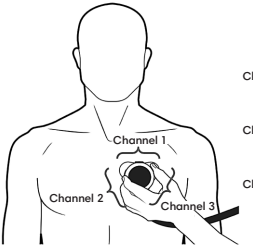
CORE 500™ streams a 3-lead ECG. Best placement can vary. ECG electrodes must be placed on the skin. CORE 500™ can also be used to auscultate at all anatomical positions.

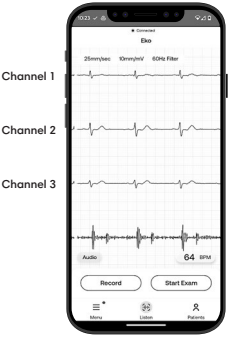
The dots below indicate generally accepted CORE 500™ placement positions. CORE 500™ is sensitive to vibration and hand movement. Remember to apply firm and constant pressure against the body to ensure good contact.



Interpret the ECG

The CORE 500™ displays Channel 1 tracings on the display when in active skin contact. Channels 1, 2, and 3 will be displayed in the sequence shown on the Eko App as shown in the figure below. When the CORE 500 is held vertically, as shown below, the Channels 1, 2, and 3 will correspond to modified Leads I, II and III, respectively.





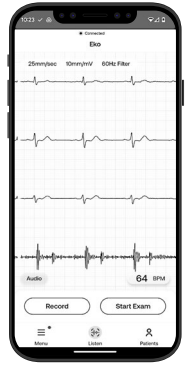
4.11 Starting a Recording

From the CORE 500™
Press the top button for two seconds to start a recording. The bars encircling the device interface light up green to indicate the recording is in progress.

Note: To initiate a recording from the device, the device must be connected to the Eko App via Bluetooth.

From the Eko App
On the **Listen** screen, click the **Record** button.

Note: To initiate a recording from the app, the device must be connected to the Eko App via Bluetooth.



5. Processing, Cleaning, and Disposal

The CORE 500™ is a multiple patient, multiple use device.

Processing between uses
The CORE 500™ should be sufficiently charged and disinfected between uses following instructions provided in this manual. The CORE 500™ does not perform nor require periodic self-check maintenance activity to maintain functionality.

Ensure the CORE 500™ is within the specified Continuous operating conditions (section 2.7) prior to use.

There is no warm-up or cool-down period required between uses.

There are no known adverse effects of lint, dust, or direct sunlight on the functionality of CORE 500™. However, the device should be stored in a clean location.

The device should be stored away from children and pets to prevent unintended tampering.

CORE 500™ should not be reused if:

- The device enclosure or attachment has visible damage.
- The device does not turn ON/OFF.
- The device cannot be sufficiently charged.
- The device exhibits acoustic or ECG issues.
- The device exhibits other operational anomalies.
- The device packaging has visible damage, contamination, unintentional opening or exposure to environment conditions outside of specification.

Cleaning
All external surfaces of the hardware can be cleaned with isopropyl alcohol wipes. Under normal conditions, it is not necessary to remove the chestpiece from the earpiece during the cleaning procedure.

Ensure all external surfaces are dry prior to use.

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

Disposal per WEEE Directive 2012/19/EU
The device should not be discarded as unsorted waste but must be sent to separate collection facilities for electronic recovery and recycling according to applicable local or national laws. The device does not contain any potentially bio-hazardous parts and accessories.

6. Manufacturing and Regulatory Information

Eko Health, Inc.
2100 Powell Street, Suite 300
Emeryville, CA 94608 USA
www.ekohealth.com

Chestpiece Made in Malaysia

Earpiece Made in Vietnam

ekohealth.com

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