DUO

User Manual

Eko

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1.1 Indications for Use

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

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

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

1.2 Introduction, Warnings, and Safety

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

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

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

1.3 For Help and Assistance

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

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

Eko Devices, Inc.
1212 Broadway, Suite 100
Oakland, CA 94612
USA

General Assistance and FAQs
ekohealth.com/getstarted

Direct Contact
support@ekohealth.com

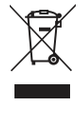
Phone Support
1.844.356.3384

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

Product Reference and Information
www.ekohealth.com

1.4 Safety Related Labels & Symbols


Instructions for use.


Do not dispose with household waste

This product and packaging does not contain natural rubber latex.

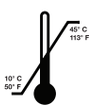

Emits Radio Frequency signal

Catalog Number

Lot Number

Serial Number

Humidity range



Temperature range

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

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


Wireless Bluetooth communication


To identify a type CF applied part complying with IEC 60601-1

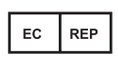
Quantity

MR Unsafe

Requires prescription in the United States.

European technical conformity


Manufacturer



European Authorized Representative


Manufacturing date

1.5 Caution

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

1.6 Skin Preparation

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

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

1.7 EMC Compliance

FCC Intentional Radiator Certification

FCC ID: 2ANB3-DUO
IC: 23063-DUO
MIC ID: 020-210076

This equipment is approved by the FCC under the FCC ID numbers shown above. This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesirable operation.

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

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

1.8 FCC and Industry Canada Compliance Statement

This device complies with FCC Rules Part 15 and with Industry Canada license-exempt RSS standard(s). Operation is subject to two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference that may be received or that may cause undesired operation.

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.

1.9 Cleaning

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

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

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

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

1.10 Precautions

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

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

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

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

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

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

In addition to security features embedded in the system, it is highly recommended that users of the mobile app and web 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.

DUO is not intended to be used in conjunction with OXYGEN RICH ENVIRONMENTS.

DUO is not intended for use with flammable anaesthetic.

DUO is not intended for use with flammable agents.

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

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

1.11 Patient Privacy

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

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

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

1.12 Contents and Operation

This package includes:

- 1 Eko DUO
- 1 Wireless Touch Charging Pad
- 1 5W / 2A USB Power Adapter
- 1 Micro USB to USB Cable
- 1 Eko EARPIECE
- 6 Silicone Rubber Ear Tips
- 1 Getting Started Instruction Card

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

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

System Requirements

The mobile app software can be used with iPhone® 5S and newer models, iPad Mini™ 2, 3, iPad Air®/Air 2, and iPad® 3rd/4th generations with iOS 11.0+.

The mobile app software can be used with Android OS 8 & greater.

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

2.1 Setup

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

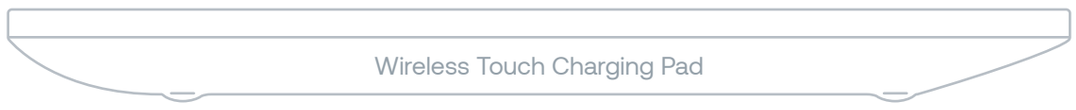
2.2 Charging

To charge DUO, place the device on the Wireless Touch Charging Pad. Connect the charging pad to a power source using the included USB charging cable and power adapter. The lights circling the center button will turn on, indicating that the device is charging and properly placed. An orange light will also appear on the changing pad. The lights on DUO will turn off once fully charged. DUO should be periodically recharged even when in storage. Lithium ion batteries slowly lose charge when in storage and may fall to an unacceptably low level, damaging the battery.

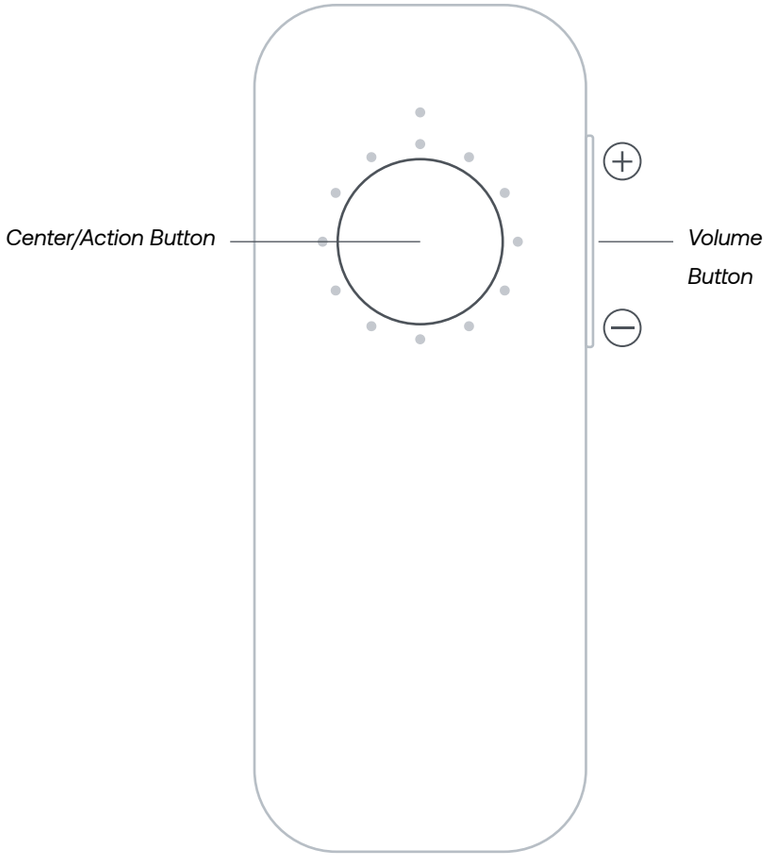
NOTE: DUO will not operate or connect to Eko App while charging.

Insert Eko Earpiece into the audio jack and twist to secure.

Place DUO on the wireless charging pad. The lights circling the center button will turn on, indicating that the device is charging and properly placed. An orange light will also appear on the changing pad. The lights on DUO will turn off once fully charged.



Plug the charging pad into an outlet using the included mirco USB and wall adapter.



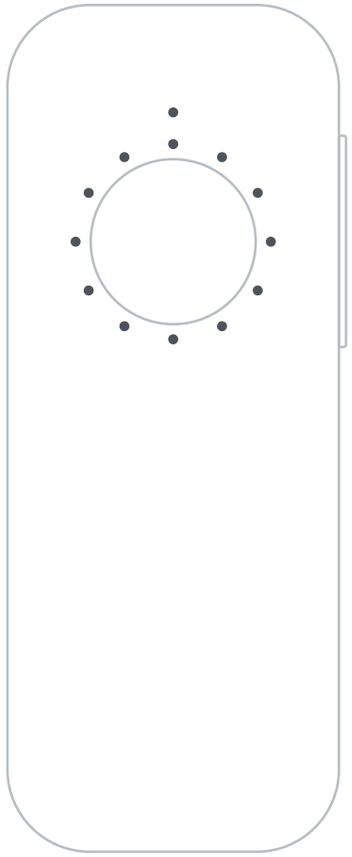
3.1 Turning On and Off, Changing Filters, and Taking a Recording

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

Button Pushes	To	Do This	LED Ring Response
● 1 sec	Power On	To turn on, press and hold the center/action button for one second, then release.	The active LED turns on/off
● 2 sec	Power Off	To turn off, press and hold the center/action button for two seconds, then release.	
● ● ●	Change audio filters	Press the center/action button three times quickly.	The active LED rotates to a new position corresponding to the filter type.
● ●	Take a recording	Double clicking the center/ action button starts a recording and stops a recording in progress Recordings can also be initiated in Eko App.	The active LED remains on.

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

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



3.2 LED Indicator Lights

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

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

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

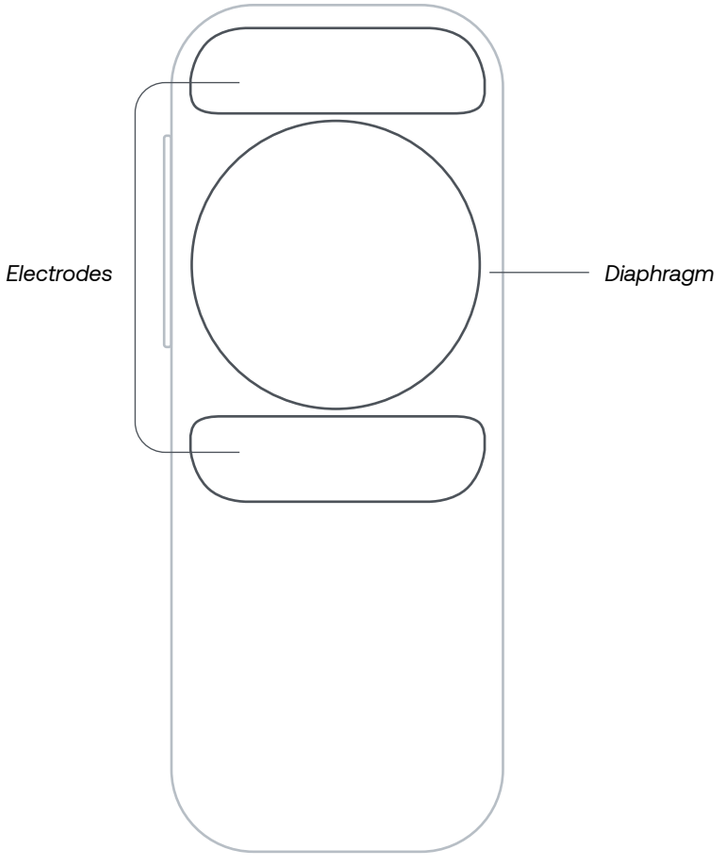
The device is ON. The filter change is indicated by the active LED in the LED ring rotating to a new position.

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

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

The device is OFF and is charging. The lights flash in the LED ring in a circular pattern.

The device is OFF and fully charged.



3.3 Capturing Sounds and ECGs

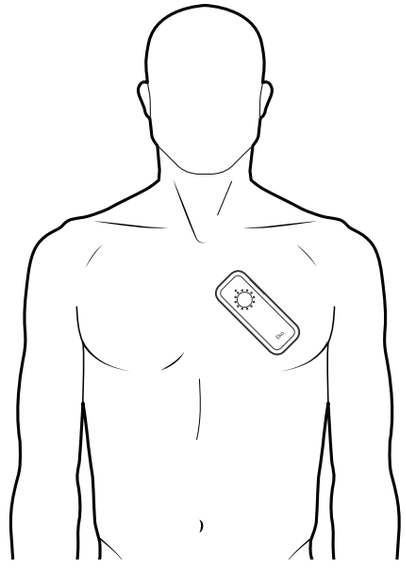
To capture sounds and ECGs, DUO can be used on various locations and orientations of the chest. Each position will produce a unique heart sound and ECG tracing.

Audio

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

ECG

Capture the ECG signal by placing DUO on the chest. One position that works well is over the left pectoral muscle, centered below the clavicle and angled at 45°, as shown in the illustration below. If the patient has particularly dry skin, significant body fat or chest hair, then the conductive gel used with other ECG systems may be applied to DUO electrodes to improve the quality of the ECG signal.



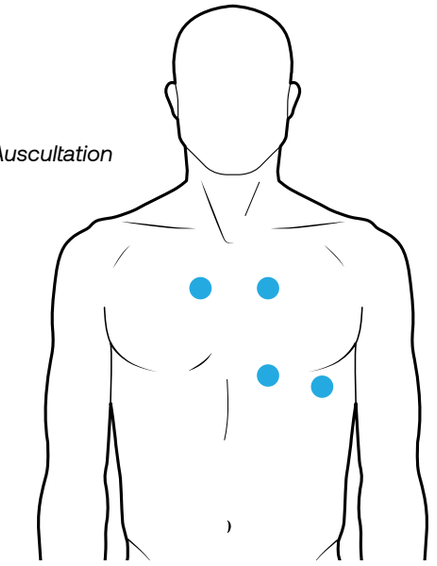
Placement

DUO streams a single lead ECG. Best placement can vary.

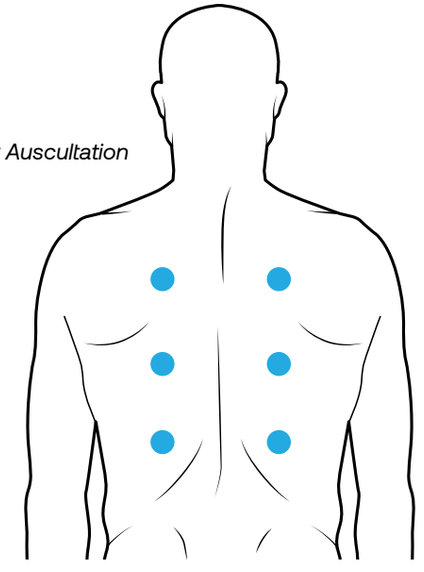
ECG electrodes must be placed on the skin.

DUO can also be used to auscultate at all anatomical positions.

Front:
Cardiac Auscultation Positions



Back:
Pulmonary Auscultation Positions



Placement

The dots above indicate generally accepted DUO placement positions for listening to the heart (front) and lungs (back). DUO is sensitive to vibration and hand noise. Remember to apply firm and constant pressure against the body to ensure good contact.

4.1 Operating Conditions

Environmental
The operating range of DUO is 10° to 45°C (50 to 113°F), and 10% to 95% relative humidity. The storage and transport range is -10° to 60° C and 10% to 95% relative humidity. Acceptable pressure is 1 atm.

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

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

5.1 Eko App Use

Eko App helps you easily connect to DUO for secure transmission and analysis of your recordings.

Downloading Eko App allows you to:

- Pair DUO to your phone
- Listen wirelessly
- View PCG and ECG visualizations
- Save and share recordings
- Enable AI analysis*
- Take advantage of additional usage guides

Download Eko App at one of the app stores below:

Download on the App Store

GET IT ON Google Play

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

*available with Pro Plan

6.1 Electrical Safety

Guidance and Manufacturer's Declaration - Electromagnetic Emission

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

Applicable Emissions Test	Compliance	Electromagnetic Environment- Guidance
RF emissions CISPR 11	Group 1	DUO uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	DUO 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 DUO.

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

6.1 Electrical Safety

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

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

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment-Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/- 15 kV air	+/- 8 kV contact +/- 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical Fast Transient/ Burst IEC 61000-4-4	+/- 2 kV for supply lines +/- 1kV for input/output lines	+/- 2 kV for supply lines +/- 1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	+/- 1 kV line to line +/- 2 kV line to earth	+/- 1 kV line to line +/- 2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	5% U_T (95% dip in U_T) for 0.5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycle <5% U_T (>95% dip in U_T) for 5 sec	5% U_T (95% dip in U_T) for 0.5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycle <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial magnetic field or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 150kHz - 80 Mhz	3 Vrms 150kHz - 80 Mhz	Portable and mobile RF communications equipment should be used no closer to any part of DUO, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = [3.5 / V_1] \sqrt{P}$ $d = [3.5 / E_1] \sqrt{P}$ 90 MHz to 800 MHz $d = [7 / E_1] \sqrt{P}$ 800 Mhz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: ((;)) Δ
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 Mhz to 2.5 Ghz	

NOTE 1 - At 80 MHz and 800 MHz, the higher frequency range applies

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

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

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

6.1 Electrical Safety

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

DUO is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The user of DUO can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and DUO as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter (W)	**Separation Distance According to Frequency of Transmitter (m)**		
	150 kHz to 80 MHz d = 1.2 √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.

7.1 Manufacturing and Regulatory Information

Manufactured by:
Eko Devices, Inc.
1212 Broadway, Suite 100
Oakland, CA 94612 USA
www.ekohealth.com

CE 0537
Notified Body:
Eurofins Expert Services Oy
Notified Body No. 0537

EC REP
EC Authorized Representative:
Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands

Eko

ekohealth.com

LBL 215 Rev A — August, 2021