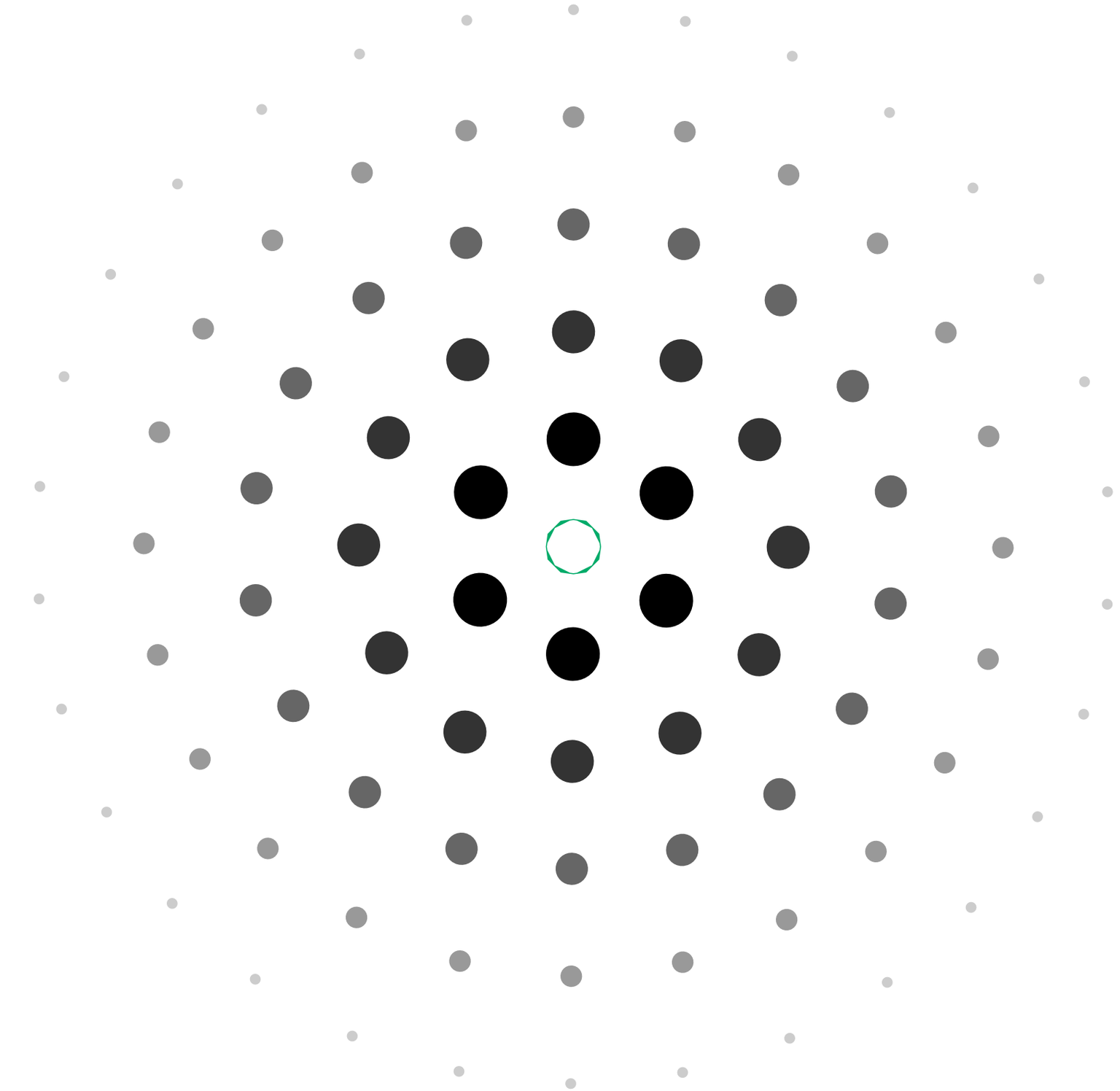

Eko
Analysis Software

User Manual

Software Version - V6.4
English

1.1 Introduction

This manual is intended to provide information to guide trained operators in the safe and effective operation of the Eko Analysis Software. It is 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.

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

Eko Health, Inc. (Eko) assumes no responsibility for any injury to anyone, or improper use of the product, that may result from failure to use this product in accordance with the instructions, cautions, warnings, or statement of intended use published in this manual.

Eko may have patents, patent applications, trademarks, copyrights, or other intellectual property (IP) rights covering subject matter in this document. The use of this document does not give anyone license to these patents, trademarks, copyrights, or other intellectual property.

1.2 For Help and Assistance

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

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 patient's, user's, fetus or other person's state of health, or a serious public health threat.

Manufacturer's Address:
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General Assistance and FAQs
ekohealth.com/getstarted

Direct Contact
support@ekohealth.com

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Patents
Listing of applicable U.S. Patents in compliance with 35 U.S.C. §287:
ekohealth.com/patents

Disclaimer
The information contained in this document is subject to change without notice.

1.3 Safety Related Labels & Symbols

Consult electronic instructions for use
http://www.ekohealth.com/ifu

Catalogue Number


Manufacturer

Authorized Representative in the European Union


Caution

Medical Device

Unique Device Identifier


CE Marking

1.4
Cautions

- **“This result is not a diagnosis, only a possible finding. Recording and analyzing all auscultation positions is recommended before making a diagnosis”.** Findings from the Eko Analysis Software are only meaningful in conjunction with clinician over-read and interpretation. This software is not intended to be the sole means of diagnosis.
- The Eko Analysis Software can provide automatic computer interpretations. A computer generated interpretation cannot replace sound medical reasoning by a trained professional. Therefore, a physician should always review the interpretation and final analysis should always be obtained by a physician. Proper administration, diagnosis and implementation of the test is the physician’s responsibility.
- The quality of the computer interpretations depends heavily upon the quality of the inputted data. Only analyze high quality recordings of ECG and heart sounds.
- Clinicians should look at all outputs: rhythm classification, heart rate, and QRS interval before making an interpretation based on the ECG.
- The medical history and physical examination results must be taken into consideration during the decision-making process.
- The software is intended for use in a quiet environment on patients with an audible heart sound and a clear, noise free ECG tracing.
- The software should not be used on patients where the physician has difficulty to auscultate with an electronic stethoscope, obese patients and patients with pulmonary noise.
- The ECG classifier has only been evaluated for the detection of AFib or normal sinus rhythm and is not intended to detect any other type of arrhythmia. It cannot detect heart attacks.
- The murmur classifier only informs the clinician about the presence or absence of murmurs in the phonocardiogram. It does not attempt to classify murmurs as innocent or pathologic. The physician should conduct a more complete analysis of the detected murmur to determine whether it is innocent or pathologic.
- The Bradycardia detection indicates that atrial fibrillation is not detected and the heart rate is less than 50 beats per minute, which is slower than normal for most people. Please note, less than 50 beats per minute can be normal for healthy adults, athletes, and during sleep.
- The Eko Analysis Software derives QRS duration from a single-channel ECG tracing and may underestimate the actual QRS duration.
- Notifications made by this feature are potential findings, not a complete diagnosis of cardiac conditions. All notifications should be reviewed by a medical professional for clinical decision-making.
- The Eko Analysis Software may be unable to return a result if the Eko CORE, Eko DUO, CORE 500 device is unable to connect to the mobile device over Bluetooth or if the mobile device is unable to connect to the internet.
- Final judgment on the diagnosis still lies with the qualified medical personnel.

1.5
Indications for Use

The Eko Analysis Software is intended to provide support to the physician in the evaluation of patients’ heart sounds and ECG’s. The software analyzes simultaneous ECG and heart sounds. The software will detect the presence of suspected murmurs in the heart sounds. The software also detects the presence of atrial fibrillation and normal sinus rhythm from the ECG signal. In addition, it calculates certain cardiac time intervals such as heart rate and QRS duration and EMAT. The software does not distinguish between different kinds of murmurs and does not identify other arrhythmias.

It is not intended as a sole means of diagnosis. The interpretations of heart sounds and ECG offered by the software are only significant when used in conjunction with physician over-read and is for use on adults (> 18 years).

1.6
Intended Users

The Eko Analysis Software is intended to be used by the physician, in the evaluation of adults (>18 years) patients.

1.7
Compatibility

Please refer to Systems Requirements at ekohealth.com for system requirements and compatibility,.

1.8
Other Considerations

This manual provides instructions for the use of the Eko Analysis Software. It is assumed that the user is familiar with basic application use on mobile and desktop devices.

Standard procedures for auscultation should be followed including background noise reduction and optimal patient positioning when capturing data for the Eko Analysis Software. The quality of the ECG is dependent on proper preparation practices including, but not limited to, body hair, skin dryness, and clean contact area.

It is highly recommended that users of the mobile App and web Dashboard use device and networking security features to protect patient data created and stored using this software, in addition to security features embedded in the system.

The Eko Analysis Software requires a minimum internet connection speed. The recommended upload speed for the mobile app is 4000 Kbps. 4G cellular data service or similar is recommended.

MURMUR DETECTION

The murmur detection analysis identifies possible murmurs in a heart sound recording. It is not a diagnosis, it is only a potential finding. You should conduct further evaluation if a murmur is detected. It will not detect cardiac conditions that do not cause heart murmurs. A murmur finding is often a recommendation for echocardiography or specialist referral.

Proper handling of the stethoscope to minimize external background noise and hand rub/clicks should be practiced. All heart sound positions should be analyzed before making a referral decision. This software cannot analyze lung sounds.

This device has not been tested on a pediatric population and is not recommended for use on children. The murmur classifier only informs the clinician about the presence or absence of murmurs in the phonocardiogram of adults. It does not attempt to classify murmurs as innocent or pathologic.

Children commonly have innocent murmurs, e.g. Still's Murmur. Innocent murmurs are common during infancy and childhood and often disappear by adulthood. These are sometimes known as "functional" or "physiologic" murmurs. Please refer to recommended clinical guidelines to determine appropriate actions for innocent and pathologic murmurs.

The possible results are:

- No Murmur Detected
- Murmur Detected in Heart Sounds
- Poor quality heart sounds.

ATRIAL FIBRILLATION AND SINUS RHYTHM

The Atrial Fibrillation (AF) analysis detects atrial fibrillation in an ECG tracing. After you have recorded an ECG, if atrial fibrillation is detected you will be notified within the app. This finding is not a diagnosis, it is only a potential finding. You should conduct further diagnosis if AF is found. The AF analysis detects atrial fibrillation (AF) only. It will not detect other potentially life threatening arrhythmias, and it is possible that other cardiac arrhythmias may be present. The AF detector only detects AF during a recording. If an ECG is neither AF nor sinus rhythm, the analysis will return "unclassified."

The possible results are:

- Normal Sinus ECG Rhythm
- Possible Atrial Fibrillation
- Unclassified ECG
- Poor quality ECG

If poor quality ECG is detected, try to improve the ECG quality (e.g. by adding gel to the electrodes and by ensuring good and stable skin contact).

If poor quality ECG or unclassified ECG is continued to be found, consider an alternative diagnosis method for rhythm diagnosis.

BRADYCARDIA AND TACHYCARDIA

The Bradycardia and Tachycardia analysis provides alerts for low and high heart rates in the ECG or heart sounds.

Bradycardia is defined as a heart rate below 50 BPM.

Tachycardia is defined as a heart rate above 100 BPM.

ANALYSIS USAGE

Note that the analysis software has been trained and tested on a limited number of ECG vectors. Not every ECG vector will produce high accuracy. A high quality ECG and heart sound signal must be present for an analysis to be run successfully.

SIGNAL QUALITY ANALYSIS

If a recording has poor ECG or heart sound signal, the interpretation will return with a result of poor quality ECG or heart sounds and will not analyze the recording.

2.1
Technical Specifications

General Performance Specifications	
QRS Duration	+/- 12 milliseconds
Heart Rate	+/- 5 BPM mean absolute error
EMAT Calculation	5% absolute error

3.0
Eko App

Download the Eko app, available on the App Store® or Google Play Store® and follow the on-screen setup instructions to access the Eko Analysis Software.

4.0
Regulatory Information

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LBL046 Rev 3.0 - Issue Date: June 2023