Eko Low Ejection Fraction Tool (ELEFT)

User Manual

Software Version: 7.2.0

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1.0 Overview

This manual is intended to provide information to guide trained operators in the safe and effective operation of the Eko Low Ejection Fraction Tool. 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
Eko Low Ejection Fraction Tool is for prescription use only (Rx). Federal (USA) law restricts this software to sale to or on the order of a clinician.

Eko Health, Inc., 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 Health, Inc., 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.

The lifetime of the device (ELEFT) is 2 years.

1.1 Notices

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

Serious Incident Reporting for the EU Market:

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:	Eko Health, Inc. 2100 Powell St., Suite 300 Emeryville, CA 94608, USA
General Assistance and FAQs:	ekohealth.com/getstarted
Direct Contact:	support@ekohealth.com
Phone Support:	+1.844.356.3384 (US)
Product Reference and Information:	ekohealth.com/ifu
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.
Copyright:	

1.2 Safety and Symbols

 http://www.ekohealth.com/ifu	Consult electronic instructions for use
	Catalogue Number
	Manufacturer
	Caution
	Medical Device
	Unique Device Identifier
	Authorized Representative in the European Union
	CE Marking

1.3 Cautions

- This is NOT a diagnosis. Findings from the Eko Low Ejection Fraction Tool 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 Low Ejection Fraction Tool (ELEFT) 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 interpretations depends heavily upon the quality of the inputted data.
- Final judgement on the diagnosis still lies with the qualified medical personnel.
- The medical history and physical examination results must be taken into consideration during the decision-making process.
- The software should not be used on patients where the physician has difficulty using an electronic stethoscope.
- ELEFT has only been evaluated for the detection of a left ventricular ejection fraction (EF) of less than or equal to 40%. It cannot detect heart attacks. It is not intended for life supporting or life saving functionality.
- 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 Low Ejection Fraction Tool may be unable to return a result if the FDA cleared Eko devices are unable to connect to the mobile device over Bluetooth or if the mobile device is unable to connect to the internet.
- The ELEFT algorithm may generate false positives and many of these false positives can be due to cardiovascular comorbidities (e.g. Left bundle branch block or Permanent Atrial Fibrillation) that are known to cause marked variations in ECG appearance.

1.4 Indications for Use

Eko Low Ejection Fraction Tool (ELEFT) is a software intended to provide decision support to clinicians to identify individuals with Left Ventricular Ejection Fraction (LVEF) less than or equal to 40%. ELEFT takes as input ECG and heart sounds from patients at risk for heart failure.

The interpretations of heart sounds and ECG offered by the software are meant only to provide decision support to the clinician, who may use the result in conjunction with their own evaluation and clinical judgment. It is not intended as a sole means of diagnosis or for the monitoring of patients diagnosed with heart failure. This software is for use on adults (18 years and older).

1.5 Clinical Benefits

Eko Low Ejection Fraction Tool (ELEFT) is a non-invasive heart failure screening tool that is able to identify low ejection fraction with the same or better sensitivity and specificity than any other currently available screening method. Visualizing ELEFT outputs greatly increases the probability of a clinician diagnosing heart failure in patients at risk for heart failure, with the intention of improving patient outcomes.

1.6 Notices

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

Standard procedures for ECG data capture should be followed including background noise reduction and optimal patient positioning when capturing data for the Eko Low Ejection Fraction Tool. The quality of the

ECG is dependent on proper preparation practices including body hair, skin dryness, and clean contact area.

It is highly recommended that users of the mobile app 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 Low Ejection Fraction Tool 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.

2.0 Analysis Results

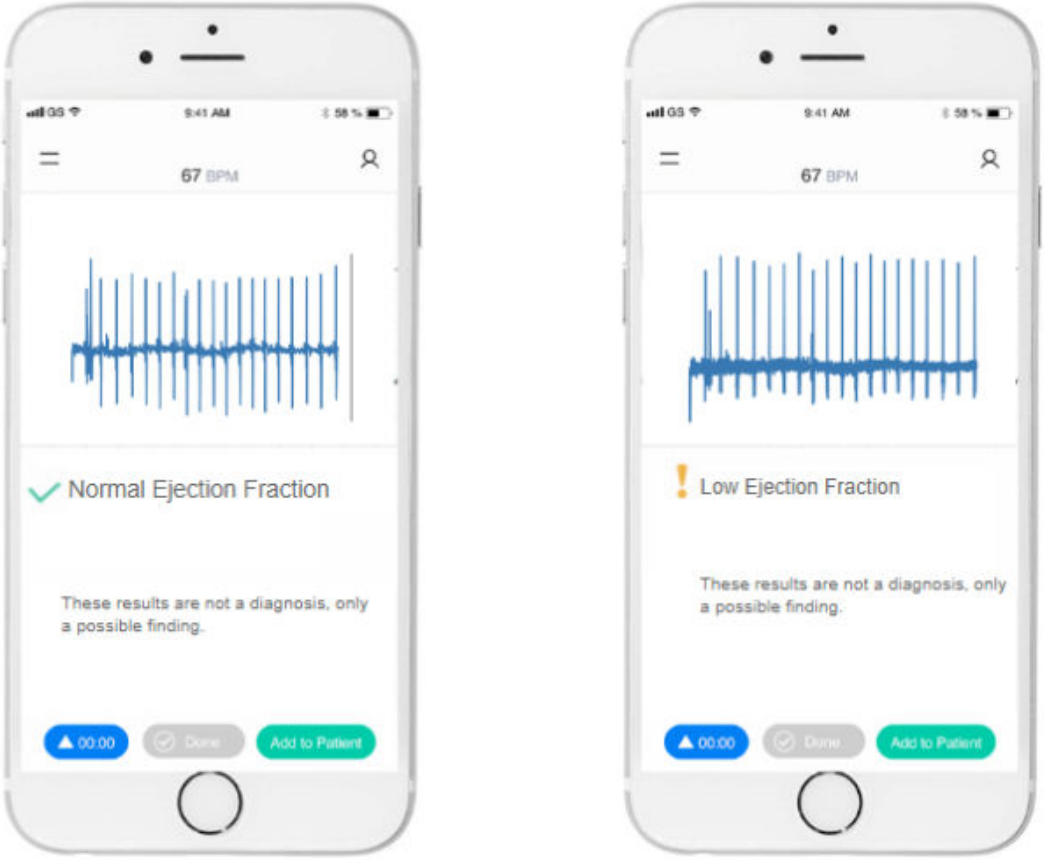
2.1 Low EF Detection

The Low EF detection analysis identifies possible depressed left ventricular EF. It is not a diagnosis; it is only a potential finding. You should conduct further evaluation if a low EF is detected. It will not detect cardiac conditions that do not cause low EF. A low EF finding is often a recommendation for echocardiography or specialist referral.

Proper handling of the stethoscope to minimize external background noises and hand rub/clicks should be practiced. This software cannot analyze lung sounds.

The possible results are:

- Poor ECG Signal
- Normal Ejection Fraction
- Low Ejection Fraction

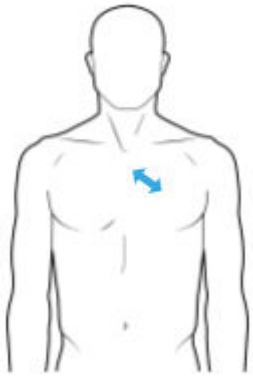


Example user interface design for displaying analysis results in a mobile application

2.2 Analysis Usage

Note that the Eko Low Ejection Fraction Tool has been tested on ECGs captured from modified Lead II. Not every ECG vector will produce high accuracy. A high-quality ECG signal must be present.

The diagram below indicates the optimal placement and orientation of electrodes to capture the necessary ECG vector (modified Lead II). The electrodes are placed over the left pectoral muscle, centered below the clavicle and angled at 45°.



Placement

The arrow above indicates the accepted orientation and positioning of the electrodes.

Each arrowhead represents the position of an electrode.

2.3 Signal Quality Analysis

If a recording has poor ECG, the interpretation will return with a result of “poor quality ECG” and will not analyze the recording.

3.0 Performance Data - Clinical Testing

ELEFT performance has been validated on a proprietary database. The database contains paired ECG and heart sound recordings and echocardiograms from 3,456 unique subjects. The paired ECG and heart sound recordings were captured with the Eko DUO digital stethoscope placed in a modified Lead II orientation. The subject population was comprised of adults over 18 who were 44.3% female and who were 58.2% white. No complications or adverse events were experienced during the use of the ELEFT device.

Ground truth for classification was obtained from gold standard echocardiogram. All subjects underwent echocardiography within a maximum of 7 days of the corresponding ECG and heart sound recordings. The subject’s true ejection fraction was measured by the echocardiogram machine’s integrated cardiac quantification software at the time of the echocardiogram and then overread by a board-certified cardiologist. Ejection fraction status was then assigned by categorizing the subject’s measured ejection fraction into Low EF (≤40%) or Normal EF (> 40%).

Based on these two categories, 9.9% of recordings came from subjects with confirmed Low EF and 90.1% of recordings came from subjects with confirmed Normal EF.

The following table demonstrate the results of the primary performance analysis (Low EF Detection):

Eko Low Ejection Fraction Tool (ELEFT)

	Sensitivity (%)	Specificity (%)
Low EF Detection	74.7 (95% CI: 69.4-79.6)	77.5 (95% CI: 75.9-79.0)

Table 1: Clinical Performance of ELEFT

4.0 Technical Specification

Technical Specification	
Feature	**Value**
PCG Input Characteristics	
Recording length	15s
PCG sensor technology	Digital MEMS microphone
Audio sampling rate	4000 Hz
Audio resolution	16 bit
Audio lossy signal compression	None
Audio frequency range	20 - 2000 Hz (Nyquist frequency)
Diaphragm placement	Upper left sternal border
ECG Input Characteristics	
ECG sampling rate	500 Hz
ECG resolution	16 bit
ECG lossy signal compression	None
ECG frequency range	0.1 - 250 Hz (Nyquistfrequency)
ECG electrode material	Stainless steel
ECG electrode spacing	45 - 55 mm

Electrode placement	AN orientation: Upper left sternal border - modified Lead II orientation

Table 2 : Technical Specification of ELEFT

5.0 System Requirements

Below is a summary of the required system requirements and specifications we provide for third-party integrator software which display results provided by the ELEFT algorithm.

Platform	Platform Compatibility
Android	Android 11 (API level 30) and above Android SDK version 30 BLE 4.2 and above
iOS	iOS version 15 and above Xcode version 14.3.1 and above BLE 4.2 and above

Eko maintains a public-facing website that details all necessary system requirements for enterprise customers. These support pages are reviewed and updated as part of the quarterly cybersecurity review. These pages outline the following:

- Eko Security Overview
- Port and Protocol whitelist requirements
- Customer Network Administration requirements
- Single Sign On configuration

Additionally, Eko Health has a dedicated customer support web page that provides third-party integrators with up-to-date details related to requirements for system compatibility, port and protocol whitelist, and Eko security overview. Eko also has a dedicated Web page for customer support: support.ekohealth.com

To report security and privacy issues or concerns, Customers can contact: security@ekohealth.com or privacy@ekohealth.com.

Compatibility with other devices:

- Approved Eko stethoscopes that can produce ECG/PCG signals
- Third Party API and user interfaces

6.0 Manufacturing and Regulatory Information

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