

Kenek Edge Pulse Oximeter System

LionsGate Technologies, Inc.

Kenek Edge Pulse Oximeter System
User Manual

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INTRODUCTION

Pulse oximetry is a non-invasive method of measuring the level of oxygen in a person's hemoglobin, the part of blood that carries oxygen through the body and gives blood its red color. This measurement is known as blood oxygen saturation or SpO₂.

Kenek Edge

The ***Kenek Edge*** pulse oximeter is an easy-to-use, accurate, spot-check pulse oximeter. It is designed to work with specific Apple iPods, iPhones and iPads (see Compatibility Section). It requires no batteries as it is powered by the Apple device. The ***Kenek Edge*** App must be downloaded from the Apple App Stores (see Setup Section). The ***Kenek Edge*** finger clip sensor is purchased separately.

Intended Use

The ***Kenek Edge*** pulse oximeter is for short-term use by consumers, fitness enthusiasts, athletes, and pilots interested in spot-checking their blood oxygenation level (SpO₂) and heart rate. The ***Kenek Edge*** pulse oximeter is not intended for medical use and does not require a prescription from a health care professional. The pulse oximeter can be used in a wide range of settings and environments except for extreme conditions including: noisy or humid environments or excessive ambient light. This product is not intended for self-diagnosis. A user should seek medical attention if feeling unwell.

SYSTEM COMPONENTS

The ***Kenek Edge*** pulse oximeter system includes:

- **Finger Clip Sensor** with cable to connect to the audio port on the Apple device
- ***Kenek Edge*** App downloaded from the **Apple App Store**
- **Quick Start Guide**

Included

Kenek Edge
Finger Clip Sensor



Kenek Edge
Quick Start Guide



Compatibility

The ***Kenek Edge*** pulse oximeter is compatible (may be installed) with the following Apple operating systems (iOS) and devices:

- iOS version 9, 10 and 11
- Apple Health Kit
- iPod touch 5, 6
- iPhone 5, 5C, 5S, 6, 6+, 6S, 6S+, 7, 7+ and 8, 8+
- iPad 3, 4, Air and Air 2, Mini, Mini 2, Mini 3 and Mini 4, Pro

SAFETY INFORMATION AND WARNINGS

This manual, including all precautionary information and specifications, should be read before use.

Always use the ***Kenek Edge*** pulse oximeter in accordance with the directions in this manual.



Warning: Do not plug anything other than a ***Kenek Edge*** sensor into any port of the Apple device, including the audio port and docking port, when using the ***Kenek Edge*** pulse oximeter.



Warning: Use the Apple device in accordance with the safety information provided with the device. Improper use of the Apple device may result in injury or damage to the device. Do not use any charger other than the one provided with the Apple product.



Warning: Do not repair, open, disassemble, submerge in any form of liquid or modify the ***Kenek Edge*** sensor. Injury or equipment damage could occur.



Warning: The finger clip is designed for fingers that are 0.8 to 2.0 cm (0.3 to 0.8 inches) in diameter. Smaller fingers will not fit the sensor correctly, which may impact the accuracy of the measurement.



Warning: The sensor should not be used in high-humidity or high-pressure environments (do not exceed 15% to 93% non-condensing and 700 hPa/mbar to 1,060 hPa/mbar).



Warning: Do not apply the sensor with excessive pressure or for prolonged periods of time. This can lead to possible pressure injury. Not intended for continuous use.



Warning: Do not use a ***Kenek Edge*** sensor with exposed electrical components. Do not use a damaged sensor.



Warning: Do not use in oxygen-rich environments or in the presence of flammable materials.



Warning: Avoid direct sunlight as it can affect the accuracy of the measurements.



Warning: Do not connect the Apple device to any wall charger, laptop, or computer when using the ***Kenek Edge*** pulse oximeter.



Warning: Not for use on children.



Warning: Use only with a ***Kenek Edge*** sensor. Do not use sensors from other models.



Warning: The ***Kenek Edge*** pulse oximeter does not have physiological alarms.



Warning: The accuracy of the ***Kenek Edge*** pulse oximeter may be impacted by the following conditions:

- Intravascular dyes such as indocyanine green or methylene blue
- Externally applied coloring and texture such as nail polish, acrylic nails, glitter, etc.
- Elevated levels of bilirubin
- Severe anemia
- Low arterial perfusion
- Anatomically incorrect finger
- Removal of finger from the sensor
- Removal of sensor from the audio port of the device
- Motion during measurement
- Operation outside of the ambient temperature range of 5 °C to 35 °C (41 °F to 95 °F)

DEFINITIONS

Smart Circles



Blue Circle

The Blue Circle displays the SpO₂ or blood oxygen saturation level.



Green Circle

The Green Circle displays the Heart Rate in beats per minute (BPM).



Orange Circle

The Orange Circle displays user instructions and feedback.



Plug In Sensor

Indicates the sensor is not plugged in. Insert the sensor into the device audio port. See the Troubleshooting section for additional information.



Finger Placement

Indicates no finger is detected. Place a finger in the sensor clip to begin measurement.



Unplug Headphones

Indicates a headset is connected. Remove headsets and headphones from the audio port.



Signal Interference

Indicates poor pulse signal. Try a different finger. See the Troubleshooting section for possible causes and remedies.

GETTING STARTED

Download the *Kenek Edge* App

Download and install the ***Kenek Edge*** app from the Apple App Store.

You will be prompted to allow the ***Kenek Edge*** app access to the microphone and camera.

- Select “Allow” for both requests.

You will be prompted to allow the ***Kenek Edge*** app access and update Heart Rate and Oxygen Saturation health data.

- Enable the options to write data.

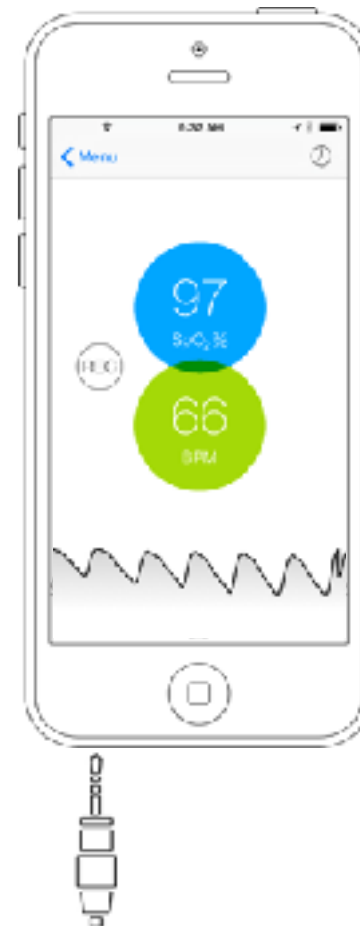
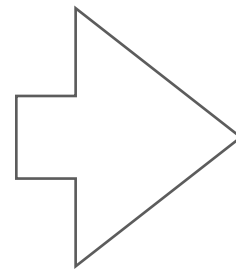
Activate Sensor

Sensor activation is available from the **Welcome** screen and from the **About** option in the menu. Sensor activation is required before using the ***Kenek Edge*** pulse oximeter. Choosing **Activate Sensor** leads you through the activation process where you will create a ***Kenek*** account and activate the ***Kenek Edge*** sensor.

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The Sensor

- Connect the sensor to the audio port of your supported Apple device.



- Select a testing finger. It should have good blood flow, limited bruising, and no obstructions such as nail polish or artificial nails. The index finger is preferred.
- The finger should be cleaned of debris and dry prior to sensor placement. Rub cold fingers to warm them.
- Ensure the finger is aligned with the finger outline on the top of the sensor.
- Ensure the finger is inserted correctly and completely into the sensor. The tip of the finger should be touching the stop inside the sensor.
- Ensure the sensor is placed on a finger with free blood flow, not restricted by a blood pressure cuff or other instruments.

- This sensor is not motion tolerant. Movement should be minimized while operating the pulse oximeter.
- Finger should not be removed during testing.
- Sensor should not be unplugged during testing.
- Phone activity on the Apple device will interfere with the pulse oximeter.

SPECIFICATIONS

The ***Kenek Edge*** pulse oximeter measures SpO₂ and heart rate within these ranges:

Oxygen Saturation Display range:	70% - 99%
Oxygen Saturation Declared Accuracy:	70% - 100% +/- 3%
Heart Rate Display range:	30bpm - 250bpm
Heart Rate Declared Accuracy:	30bpm – 250bpm +/- 2bpm

The sensor is not made with natural latex.

Operating Temperature = 5 °C to 35 °C (41 °F to 95 °F)

Storage Temperature = -20 °C to 35 °C (4 °F to 95 °F)

MAINTENANCE

Cleaning and Storage

The sensor should be stored at room temperature in an environment free of dust and lint. Do not use in high-humidity or high-pressure environments: do not exceed 15% to 93% non-condensing and 700 hPa/mbar to 1,060 hPa/mbar.

Clean the sensor between each use if it may come in contact with another person to reduce the possibility of communicable illness transmission. The sensor should be cleaned at least every 10 uses even if it does not appear dirty.

How to Clean the Sensor

1. Disconnect the sensor from the Apple device.
2. Wipe the sensor with a soft cloth that has been dampened with warm water or an alcohol-based cleaner. Be careful not to soak or immerse any portion of the sensor in the liquid solution.
3. Do not repair, open, disassemble, or modify the sensor while cleaning.
4. Allow the sensor to dry prior to using.

SUPPORT

Consult the LGThealth website for further and current troubleshooting information. The website is updated regularly.

Web: **lgt.freshdesk.com**

Email: **support@LGThealth.com**

Address:

LionsGate Technologies

Suite 600 - 1090 West Georgia Street

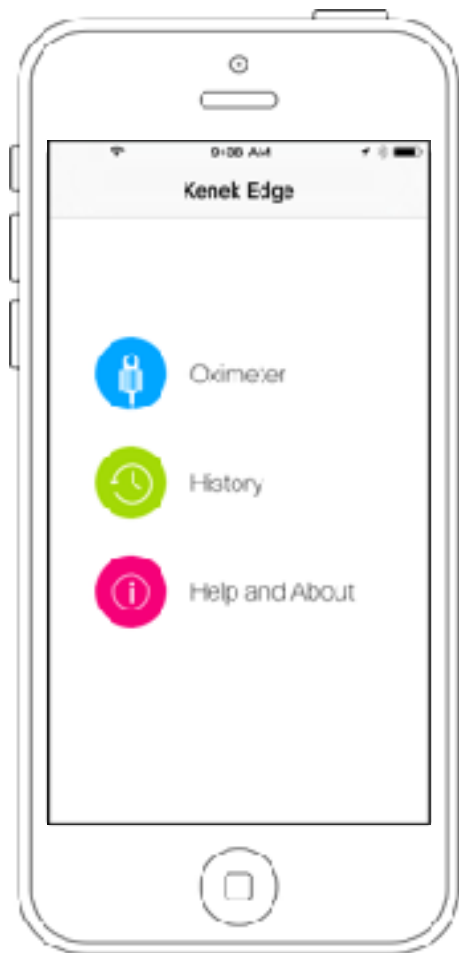
Vancouver, BC V6E 3V7, Canada

Troubleshooting

- The sensor should be completely plugged into the audio port of the Apple device.
- Select a testing finger that has good blood flow, limited bruising, and no obstructions such as nail polish or artificial nails.
- The finger should be cleaned of debris and dry prior to placing in the sensor. If the signal is poor, the finger may be cold. Rub it or warm it, then insert it again into the sensor.
- Ensure the finger is aligned with the finger outline on the top of the sensor.
- Do not remove the finger from the sensor during testing.

- Ensure the finger is inserted correctly and completely into the sensor. The tip of the finger should be touching the stop inside the sensor.
- Ensure the sensor is put on a finger with free blood flow, not restricted by a blood pressure cuff or other instruments.
- The sensor is not motion tolerant. Movement should be minimized while using the ***Kenek Edge*** pulse oximeter.

GENERAL USE

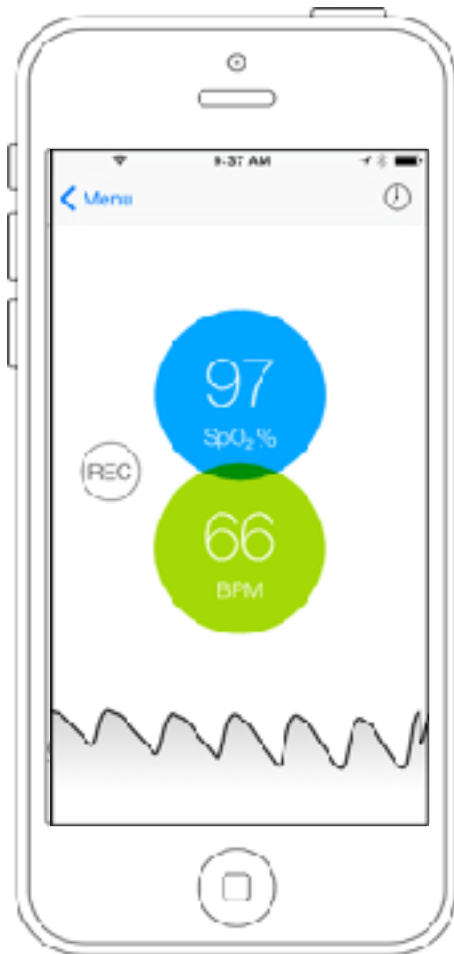


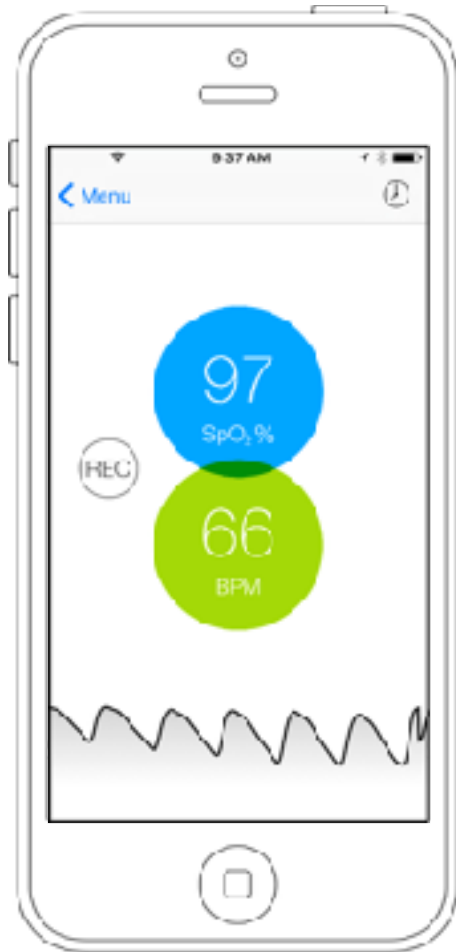
Opening Screen

Every time ***Kenek Edge*** app is started, the opening screen is displayed providing the choice to directly access the **Oximeter**, **History**, or **Help and About** by tapping on the appropriate icon or word.

Oximeter Screen

The **Oximeter** screen displays various colored Smart circles. The **Blue** and **Green** circles display values acquired from the sensor and an **Orange** circle displays user instructions and feedback. These circles appear and disappear based on user interaction with the app and the sensor.





Pulse Signal is below the SpO2 and Heart Rate circles. It shows the pulse waveform from measured from the blood flow of the finger. When the sensors is first placed on a finger, the pulse signal will be irregular. The pulse signal will stabilize in a few second and show a regular saw-tooth trace with equal spacing and height.

A stable pulse signal is required to produce SpO2 and Heart Rate measures. The pulse signal is affected by factors such as the positioning of the finger in the sensor, movement, how much blood is flowing in the finger (perfusion), and the presence of discoloration such as nail polish or a bruised nail bed.

Menu

The Menu can be accessed at any time by selecting the icon at the bottom of the screen. By selecting the **Menu** button, the following menu choices will appear:



Oximeter

Returns to the main **Oximeter** measurement and display screen.



History Icon

Goes to the **History** section presenting previously recorded tests.

Help and About Icon



Goes to the **Help and About** section where additional ***Kenek Edge*** app information is available.



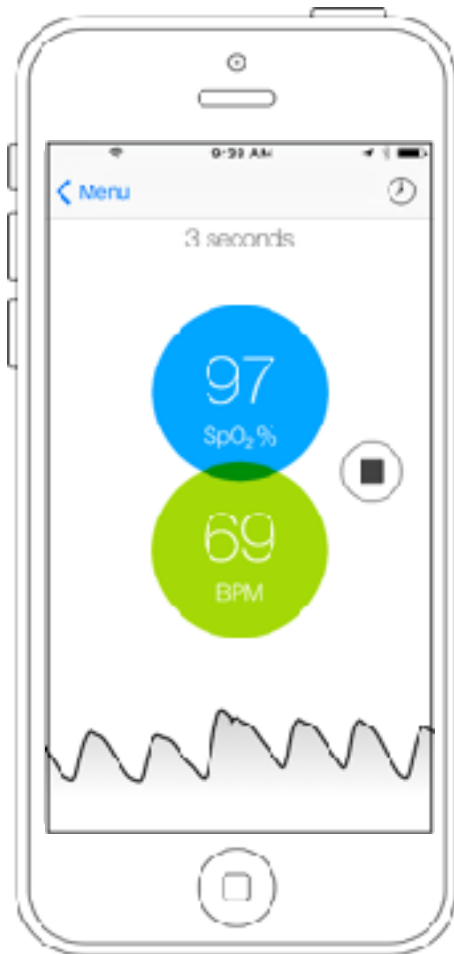
Duration

Goes to the **Duration** screen where a duration is set for the length of time to be recorded.

Record

Touching the **REC** icon starts data recording. The **REC** button appears on the screen only when valid SpO₂ and Heart Rate values are available. The **REC** icon will disappear and a **Stop** icon will appear to the right of the main display circles while recording.

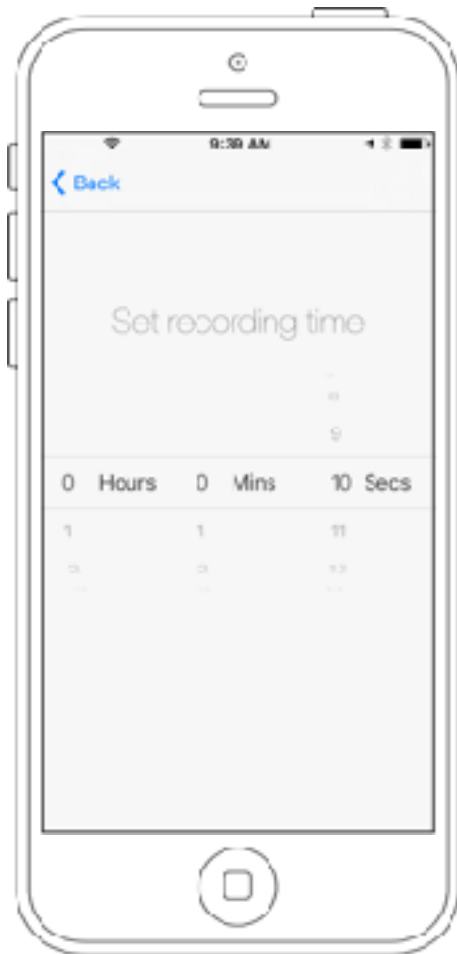
To halt the current data recording tap the **Stop** icon.



Duration

The **Duration** screen allows the editing and saving of the length of the data capture.

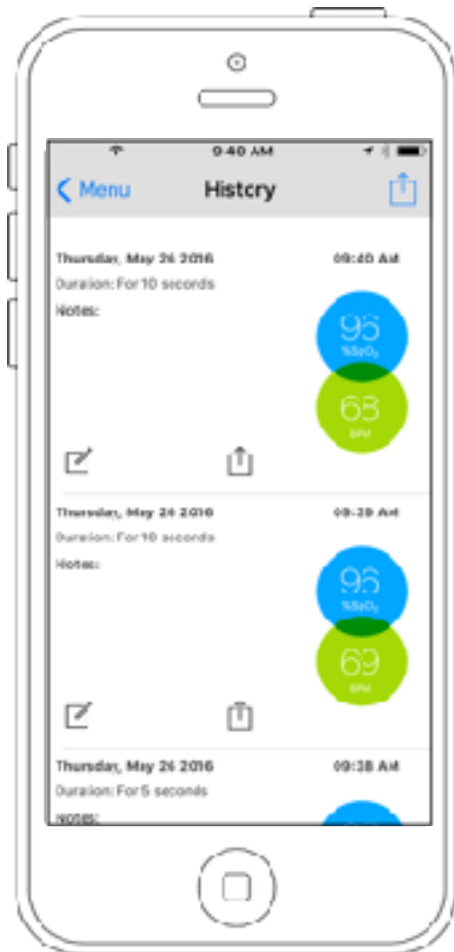
Swiping up and down on the hour, minute and second sliders adjusts the capture time. Select Back when complete.



History

The **History** screen displays a list of previous data captures. The newest data captures are shown at the top of the list.

Notes, **Export** and **Delete** functions are available from the **History** screen.



Notes



You can add or edit personalized notes to individual data recordings by selecting the **Notes** icon from the **History** screen. Select Done to close the note.

Export



From the **History** screen, select the export button of the desired data row. A new email with an attachment containing the exported data will be created. The Apple device must be configured with an email account to use the **Export** feature.

Data is exported in a Comma Separated Values (CSV) file format and opened using spreadsheet applications.

Delete

From the **History** screen, swipe a row left ← to reveal the delete button. Select Delete to complete the deletion. Swipe right → to cancel delete.

Deletion is final. Once data is deleted it cannot be recovered.



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