

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:

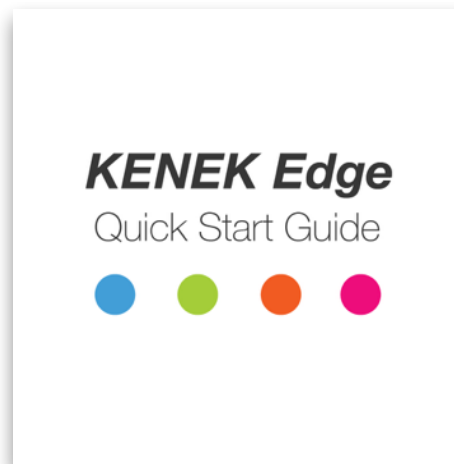
- **Finger Clip Sensor** with cable to connect to the audio port on the Apple device
- ***Kenek Edge*** App downloaded from the **Apple App Store**
- **Quick Start Guide** with **Activation Code**

Included

Kenek Edge
Finger Clip Sensor



Kenek Edge
Quick Start Guide



Kenek Edge
Activation Code



Compatibility

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

- iOS version 7 and 8
- iPod touch 5
- iPhone 4, 4S, 5, 5C, 5S, 6, 6 Plus
- iPad 2, 3, 4, Air, Mini, Mini Retina

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 power source, wall charger, laptop, or computer when using the ***Kenek Edge*** pulse oximeter.



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



Warning: Not for use on children.



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.



Refining Results

Indicates the results are refining. Results may take up to 10 seconds to appear.



Increase Volume

Indicates the volume is low. Increase device volume to maximum.



Unplug Power Cord

Indicates a power source is connected. Remove the power connection.



Unplug Headphones

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



Signal Interference

Indicates poor signal strength. Use a different finger. See the Troubleshooting section for additional information.

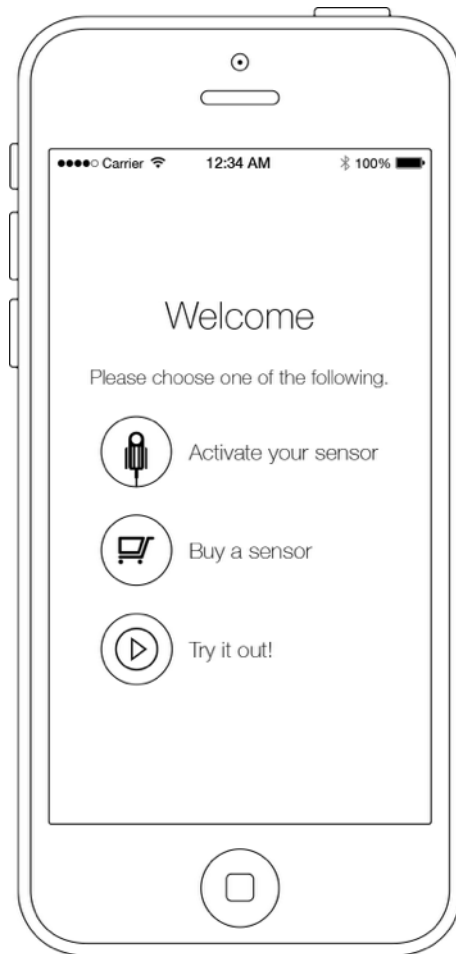
GETTING STARTED

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.

Try it Out



Before activating the sensor, a demo mode is available from the Welcome screen of the ***Kenek Edge*** app. Demo mode uses simulated data to demonstrate app the capabilities and features. This mode allows users to explore the app before purchasing a sensor. The simulated data in demo mode shows typical Heart Rate and SpO₂ values.

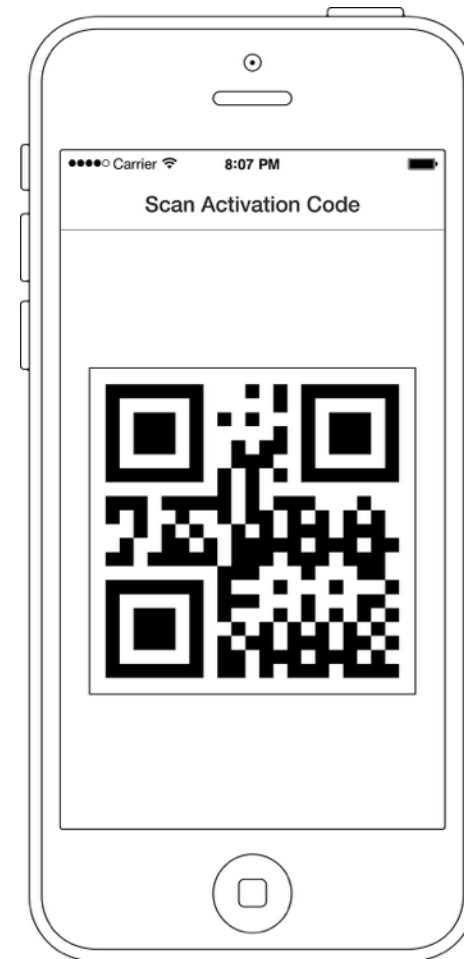
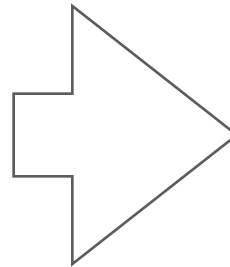
Activate Sensor

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.

The **Activation Code** is a barcode matrix included with your ***Kenek Edge*** sensor package, commonly known as a QR code. Touch **Scan** to launch the device camera. Use the camera to find the **Activation Code**; it will be captured automatically, which will complete the activation process. The **Activation Code** is found in the **Quick Start Guide** included in the sensor package. Up to five devices can be activated using the **Activation Code**.

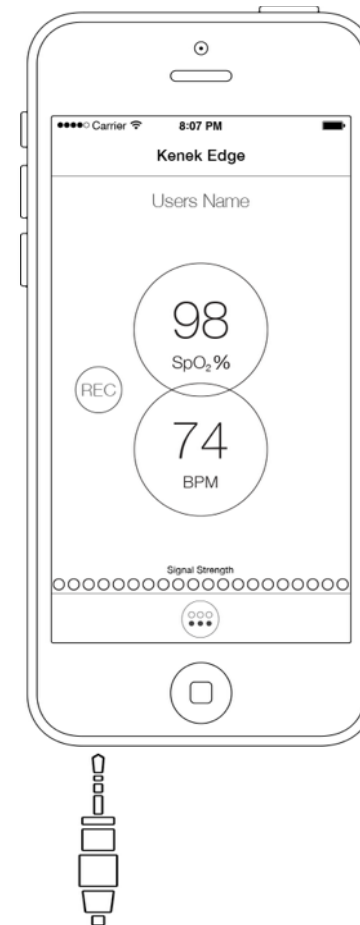
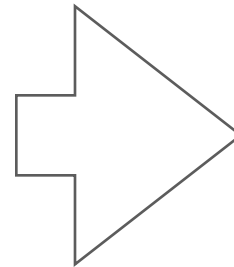
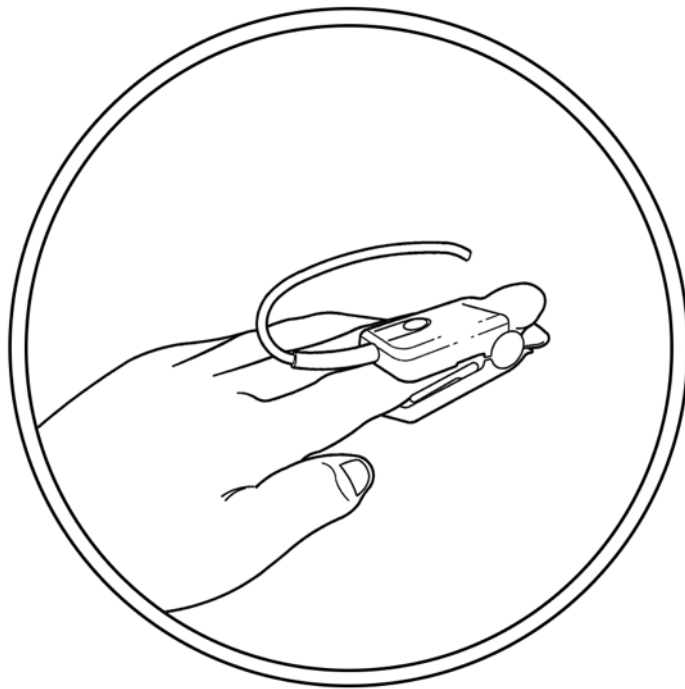


Kenek Edge Activation Code



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 removed during testing.
- Phone activity on the Apple device will stop 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.

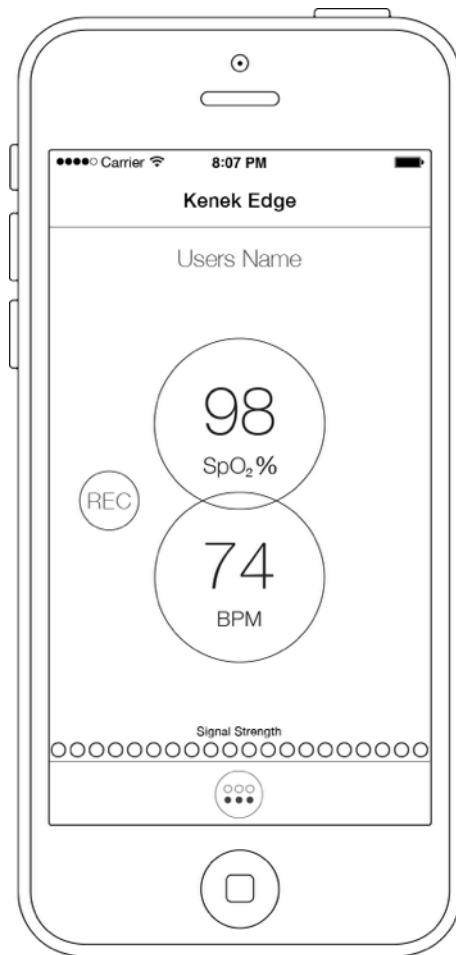
GENERAL USE



Opening Screen

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

Oximeter Screen

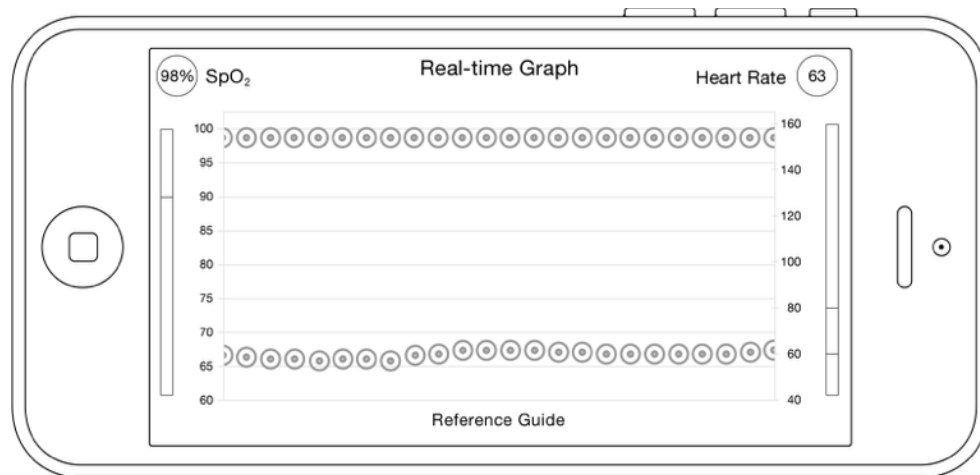


The **Oximeter** screen displays various colored Smart circles. The **Blue** and **Green** circles display values acquired from the sensor, an **Orange** circle displays user instructions and feedback, and a **Purple** circle indicates the app is processing information. These circles appear and disappear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

Signal Strength indicates the strength of the sensor measurement. It 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.

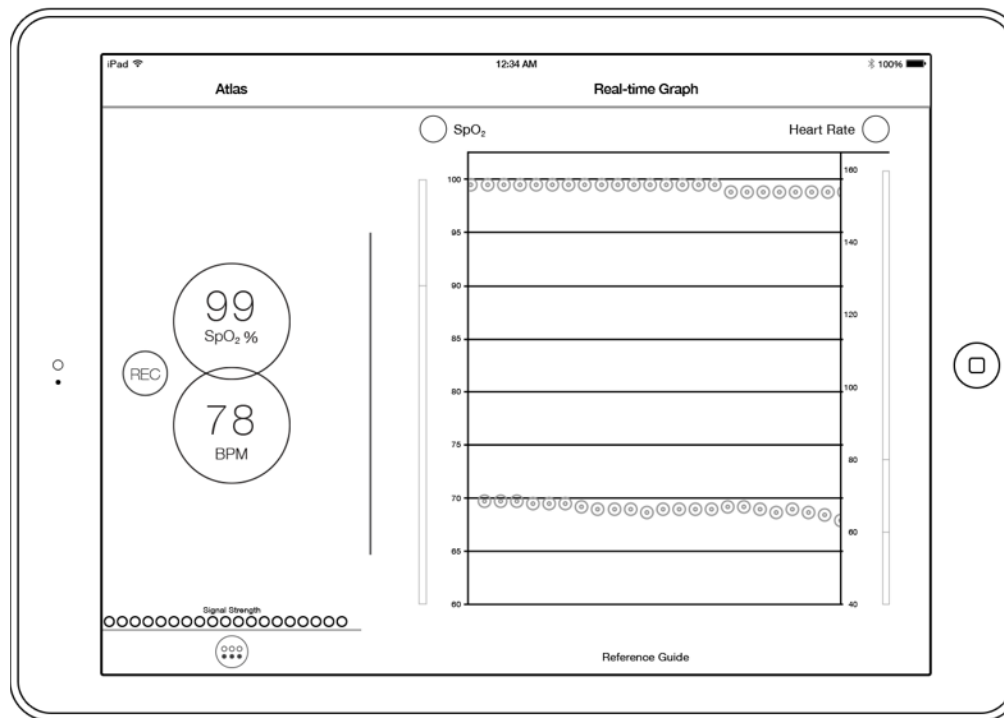
Graph

The Graph displays all the points for the data capture. On an iPad, the Graph is displayed on the right panel of the screen. On iPods and iPhones, the Graph is displayed by rotating the device. Touching any point displays information about the captured data. Swiping left and right moves the Graph forward and backwards in time. Pinching in and out on the Graph zooms in and out. Touching the link “Reference Guide” displays the SpO₂ scale relative to altitude and the Heart Rate relative to physical activity.



iPad Only

The ***Kenek Edge*** pulse oximeter supports iPad's larger screen. The iPad display shows the pulse oximeter and graph view without rotating the device.



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.



Profiles Icon

Goes to the **Profile** section where a new profiles can be created or an existing profiles can be edited.



Help & About Icon

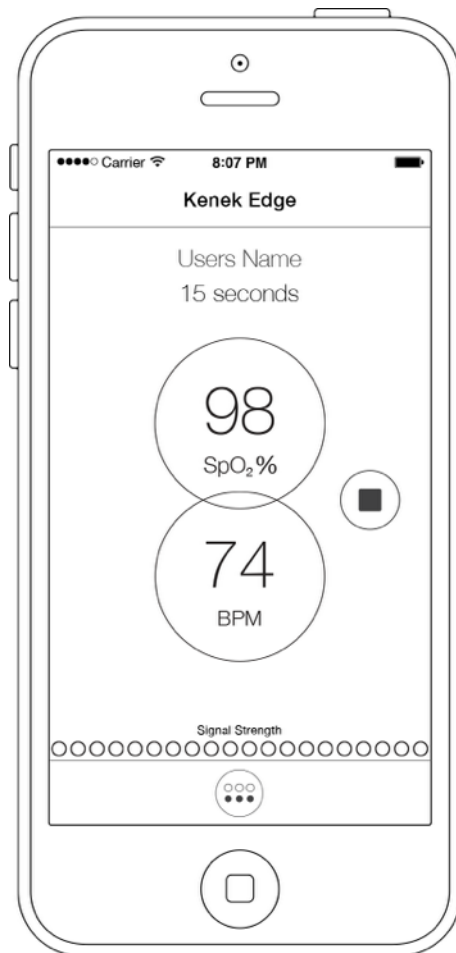
Goes to the **Help and About** section where addition ***Kenek Edge*** app information is available.



Duration

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

Data Recording



Touching the **REC** icon starts data or test 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.

When the recording is complete, the **Test Complete** message will appear. The options are to **View the Test** just recorded or **No**, and return to the main **Oximeter** screen.

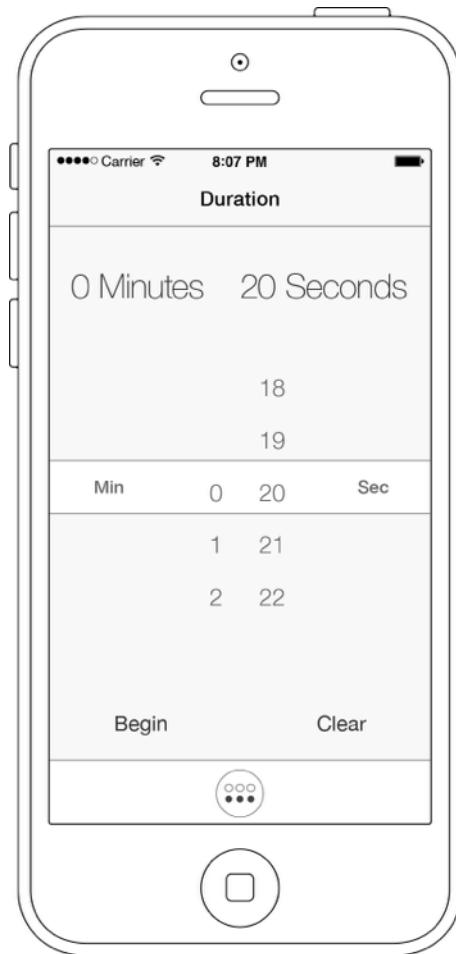
Duration

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

Swiping up and down on the minute and second sliders adjusts the capture time.

Touching **Clear** returns the previously saved value.

Touching **Begin** starts a data capture. If the Begin selection does not appear, a **Save** option will present in its place.

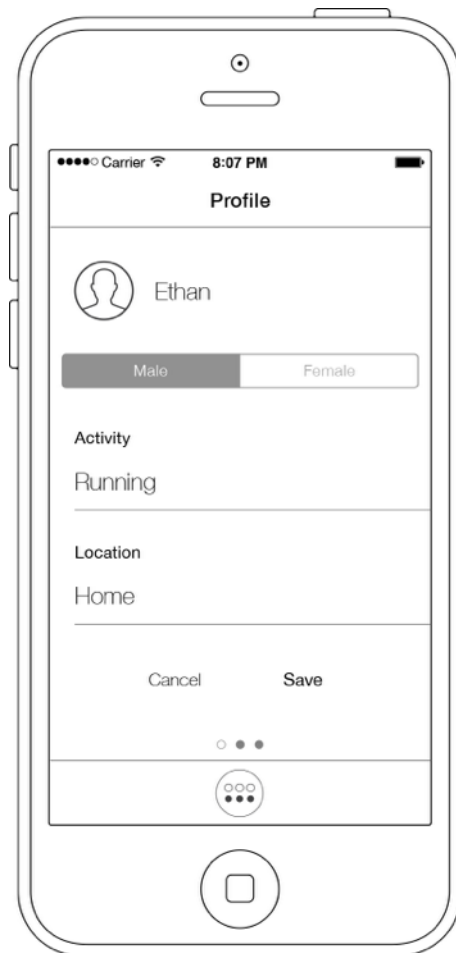


Profile Records

The **Profile** screen allows personalization of the app which is useful if recording results for more than one person.

To edit tap “Name of User” next to the icon. Enter the name, choose **Male** or **Female**, then enter in an **Activity** and/or **Location**. **Gender**, **Activity** and **Location** are not required to be entered.

To add more than one **Profile**, swipe left to right.

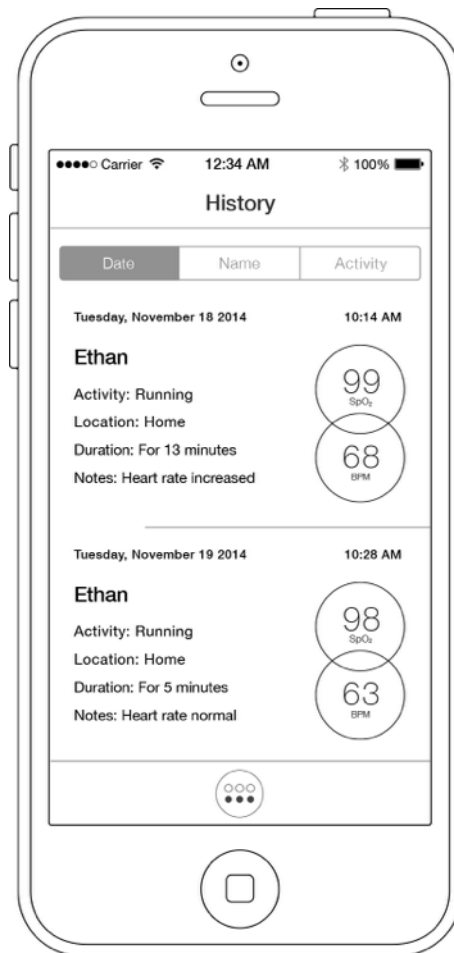


History

The **History** screen displays a list of previous data captures.

Touching a row displays additional information for the test. Rotating the device will display the corresponding graph for the test.

Sort options are available at the top of the screen to sort by **Date**, **Name** or **Activity**. To Search, select the **Menu** icon and choose the **Search** icon located at the bottom right of the screen. This icon toggles between displaying the Search and Sort fields for the **History** screen.



The following options are available through the **Menu** icon when viewing the History screen:



Trends

View one or more recorded results in a trend graph.



Export

Export one or more recorded results.



Delete

Delete one or more recorded results. Deletion is permanent.



Search

Search for recorded results by Profile Name, Activity and Location. Select again to toggle between Search and Sort.

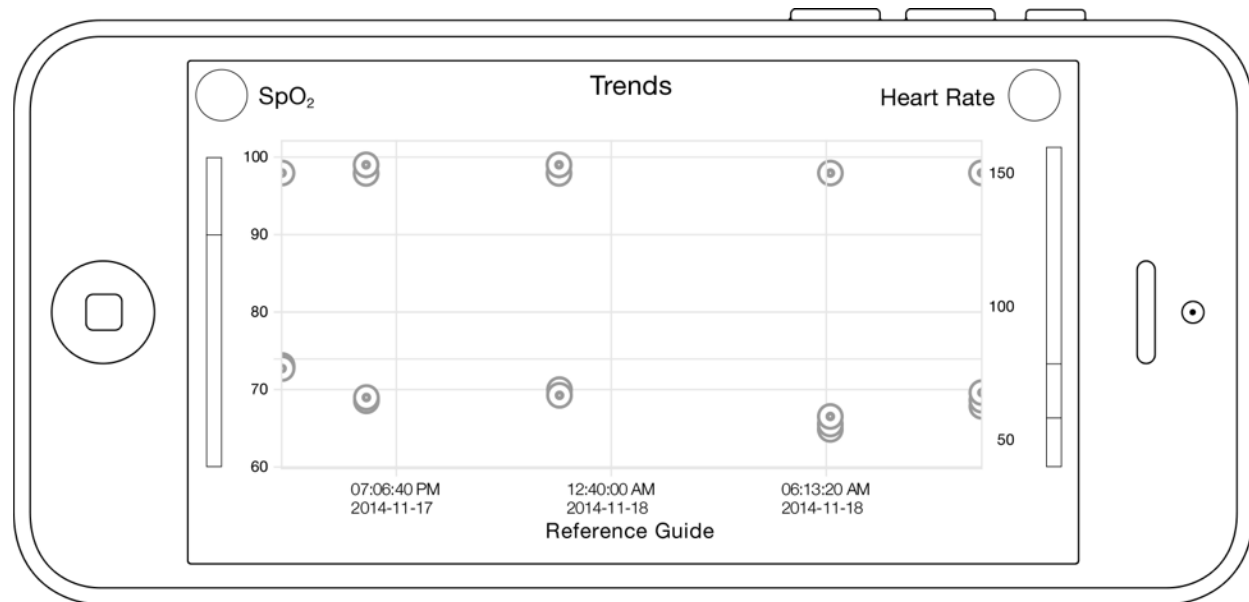
Notes



You can add or edit personalized notes to individual recorded results by selecting the **Notes** icon. The **Notes** entry screen is available from the **History** screen, by expanding a result row and selecting the **Note** icon. Select the **Note** icon again, or tap "Return" on the on-screen keyboard, to save the note.

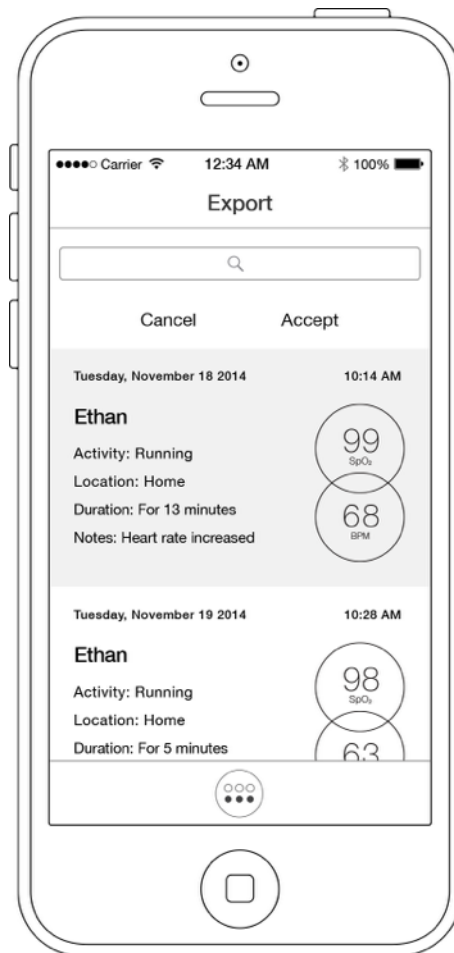
Trends View

The **Trends**, or graph, view options can be accessed on the **History** screen. Touching the **Trends** icon (choose Menu at the bottom of the screen, then select the trend icon in the lower left of the menu) displays options to select one or multiple datasets. On an iPhone or iPod, rotate the device to see the **Trends** view. iPad devices display **Trends** view without rotating.



Export Data

The **Export** screen is accessed on the **History** screen by touching the **Export** icon. The device must be configured with an email account to use the **Export** feature.

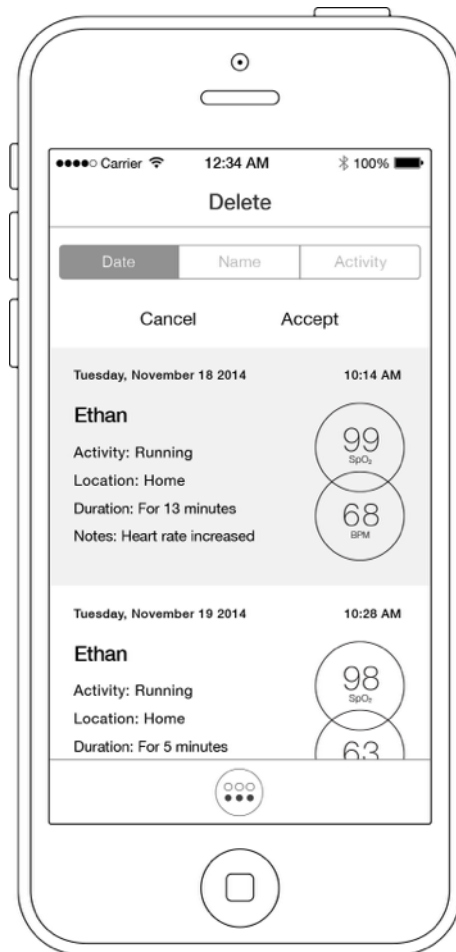


Select datasets to export with a tap and then tap the “Accept” or “Cancel” links near the top of the screen. Data is exported in a Comma Separated Values (CSV) file format and opened using spreadsheet applications.

Delete Data

The **Delete** screen is accessed on the **History** screen by touching the **Delete** icon.

Select datasets to delete with a tap and then tap the “Accept” or “Cancel” links near the top of the screen. The selected data is permanently deleted.

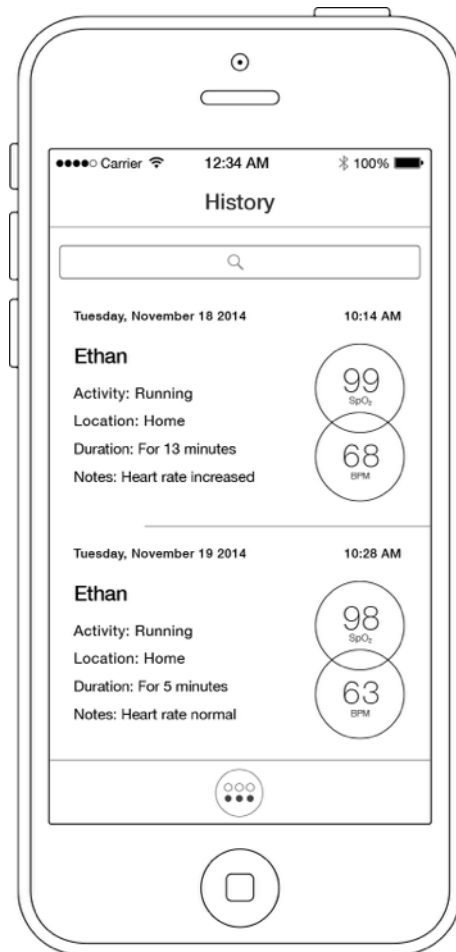


Search and Sort

Search and **Sort** organize the History results. Selecting the **Search** icon toggles between **Search** and **Sort** functions.

Search finds results matching Location, Profile and Activity entered in the search field.

Sort orders results by Date, Name and Activity.



SUPPORT

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

Web: **lgtmedical.com/support**

Email: **support@lgtmedical.com**

Address: **Suite 5, 6063 Iona Drive, Vancouver, BC V6T 0B1, 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.

- Do not plug in the device power adapter while using the ***Kenek Edge*** pulse oximeter.
- 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.

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