LionsGate Technologies, Inc.

Kenek O2 Pulse Oximeter System
User Manual

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 SpO_2.

Kenek O2

The ***Kenek O2*** pulse oximeter is an easy-to-use system for sampling, or spot-checking, a person's SpO_2 and heart rate. It consists of the portable finger clip sensor and the ***Kenek O2*** app. The finger clip sensor connects to the audio port of any compatible Apple iPod, iPhone or iPad. It is powered by the Apple device, so it does not require batteries. (For the complete list of supported Apple devices, see the *Compatibility* section.) The ***Kenek O2*** app must be downloaded from the Apple App Store.

Intended Use

The ***Kenek O2*** pulse oximeter is indicated for use in a home health care environment to spot-check adults age 21 years and over who are under the care of a physician. It may also be used by a physician or qualified clinician in a professional healthcare office or clinic for spot-check purposes. The portable finger clip sensor is intended for patients with fingers 0.8 cm to 2.0 cm in diameter.

Contraindications

The ***Kenek O2*** pulse oximeter is not intended for:

- long-term, continuous monitoring of patients such as in acute or critical care.
- professional healthcare patient transport such as in ambulances.
- magnetic resonance environments.

The *Kenek O2* pulse oximeter does not have physiological alarms.

SYMBOLS

Follow Instructions for Use

Indicates separate collection for electrical and electronic equipment (WEEE).

Non Sterile

No SpO_2 alarms.

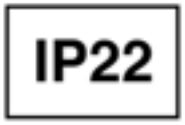
CE Marking: conformance to EC Directive No. 93/42/EEC for medical devices

Avoid exposure to sunlight

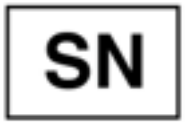
Keep Dry

Type BF-Applied Part (Patient isolation from electrical shock)

Operating temperature range 5 °C to 35 °C



Protected from touch by fingers and objects greater than 12 mm.
Protected from water spray less than 15 degrees from vertical.



Serial Number

Lot Number

Model Numbers

Manufacturer

Date of Manufacture

SYSTEM COMPONENTS

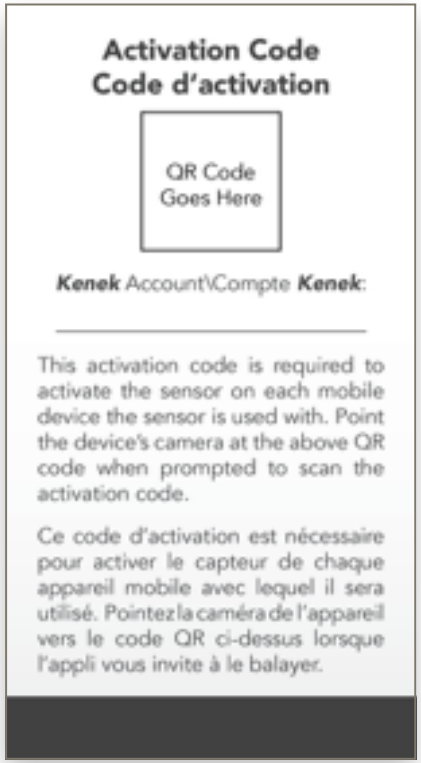
The ***Kenek O2*** pulse oximeter system includes:

- **Finger Clip Sensor** with cable to connect to the audio port on the Apple device
- ***Kenek O2* app** downloaded from the **Apple App Store**
- **Quick Start Guide** and included **Activation Code**

Kenek O2
Finger Clip Sensor

Kenek O2
Quick Start Guide

Kenek O2
Activation Code



Compatibility

The ***Kenek O2*** pulse oximeter is compatible with the following Apple operating systems (iOS) and devices:

- iOS version 7, 8
- iPod Touch 5
- iPhone 5, 5C, 5S, 6, 6 plus
- iPad 2, 3, 4, Air, Air 2, Mini, Mini 2, Mini 3

SAFETY INFORMATION AND WARNINGS

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

Always use the ***Kenek O2*** pulse oximeter in accordance with the directions in this manual.

Warning: The ***Kenek O2*** pulse oximeter does not have physiological alarms.

Warning: Consult your physician for normal ranges for SpO_2 and heart rate for a patient with your history and characteristics.

Warning: Do not connect the portable finger sensor to any device not listed in the *Compatibility* section.

Warning: When using the ***Kenek O2*** pulse oximeter, do not connect anything other than a ***Kenek O2*** finger clip sensor into any connector of the Apple device, including the audio port and docking port. It is unsafe to connect or use any accessories, detachable parts or materials not described in this manual.

Warning: The finger clip sensor is not defibrillator proof.

Warning: Not for use on children. This product is not a toy.

Warning: Do not connect the Apple device to any power source, wall charger, laptop or computer when using the ***Kenek O2*** pulse oximeter.

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

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

Warning: Do not run or switch to other apps on your Apple device while recording test data.

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 apply excessive or prolonged pressure to the sensor. This can lead to possible pressure injury. Not intended for continuous use. Do not use continuously for more than 60 minutes.

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: The sensor should be kept away from areas where lint and/or dust are present. Keep the sensor away from pets and children.

Warning: A functional test cannot be used to access the accuracy of the sensor.

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

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

Warning: Do not use the ***Kenek O2*** app if the Apple device has less than 5% battery capacity remaining.

Warning: Use only with ***Kenek O2*** sensors. Do not use sensors from other devices or models.

Warning: Do not use a ***Kenek O2*** sensor that has exposed electrical components. Do not use a damaged sensor.

Warning: The accuracy of the ***Kenek O2*** pulse oximeter may be affected 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
- excessive movement of the finger during the test
- ambient temperatures outside the temperature range of 5 °C to 35 °C.

DEFINITIONS

Smart Circles

Blue Circle

The **blue circle** displays the SpO_2 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.

Insert Sensor

No sensor is attached to the mobile device. Ensure the sensor is inserted completely in the audio port of the mobile device. Do not use splitters or cable extenders between the mobile device and sensor. See the ***Support*** section for additional information.

Insert Finger

There is no finger detected in the sensor clip. Ensure the finger is fully inserted into the clip and resting against the stop. Open the clip and re-insert the finger if the problem persists.

Remove Power

An external power source was detected. Disconnect the mobile device from all data and power sources (computer, charging device, wall outlet).

Refining Signal

The app is collecting and processing the information from the sensor and will display the results in a few seconds.

Remove Headset

Disconnect the headsets or headphones from the audio port. See the ***Support*** section if this message persists.

Low Signal

Signal interference prevents operation of pulse oximeter. See the ***Support*** section to confirm the device is configured correctly. Ensure there are no audio extension cables or splitters between the sensor and the mobile device.

GETTING STARTED

For assistance setting up, using or maintaining the ***Kenek O2*** pulse oximeter or to report unexpected operation or events, please contact LGTmedical Support. See the Support section in this manual for contact information.

The ***Kenek O2*** pulse oximeter should be installed and configured in accordance with the information provided in this manual.

Download the *Kenek O2* App

Download and install the ***Kenek O2*** iOS app from the Apple App Store. The app will ask for permission to access needed features of your device. The Privacy Policy, Volume Control, Microphone, and Camera permissions are required to operate the ***Kenek O2*** pulse oximeter.

Try it Out

You can enable demo mode if you want to try the ***Kenek O2*** app before purchasing a sensor. In demo mode, the app uses simulated data (typical heart rate and SpO_2 values) to demonstrate capabilities and features.

Activate Sensor

Before using the ***Kenek O2*** pulse oximeter, you must activate the sensor. To activate it, you must use the mobile device's camera to scan the Activation Code. The **Activation Code** is a barcode matrix (also known as a QR code). It can be found in the **Quick Start Guide** included in the ***Kenek O2*** sensor package.

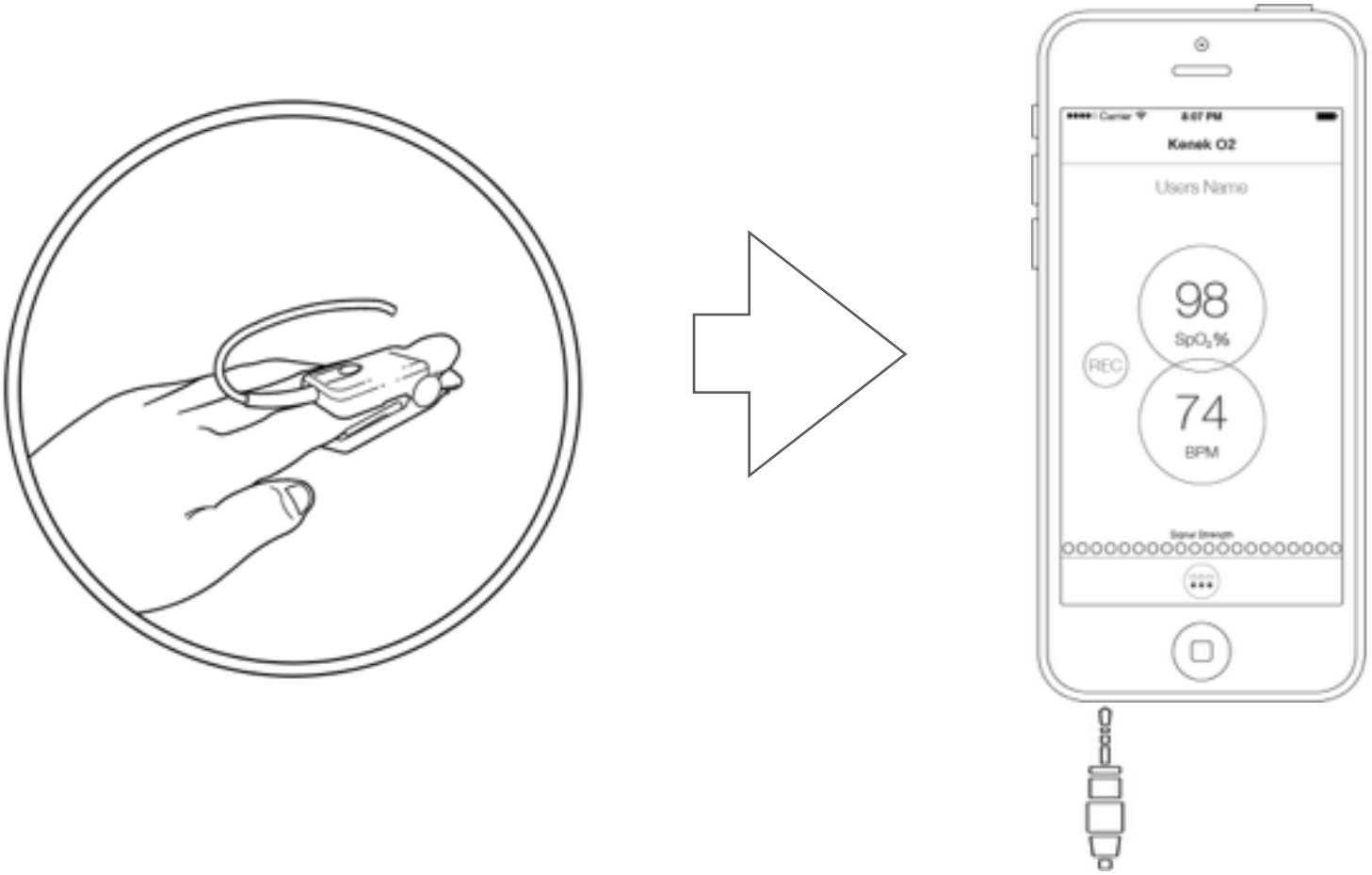
To begin, tap **Activate Sensor** in the **Welcome** screen. If you are a first-time ***Kenek*** user, you will need to create a ***Kenek*** account before activating the ***Kenek O2*** sensor. Follow the on-screen instructions to create an account.

After you have created an account, tap **Scan**. Use the camera to capture the **Activation Code** in the **Quick Start Guide**; it will be captured automatically, which will complete the activation process. (Up to five devices can be activated with one **Activation Code**.)


Activation Code
Kenek Account: _____
This activation code is required to activate the sensor on each mobile device the sensor is used with. Point the device's camera at the above QR code when prompted to scan the activation code.
Carrier
8:07 PM
Scan Activation Code

The Sensor

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



- Select a testing finger. (The index finger is preferred.) It should have good blood flow (not restricted by a blood pressure cuff or other instruments), limited bruising, and no obstructions such as nail polish or artificial nails. Rub cold fingers to improve blood flow.

- Before inserting the finger in the sensor, ensure the finger is dry and clear of all debris.

- Insert the finger completely into the sensor. The finger should be aligned with the finger outline shown on the top of the sensor. The tip of the finger should be touching the stop inside the sensor.

- Avoid movement while operating the ***Kenek O2*** pulse oximeter. Movement can interfere with the sensor's operation.

- The finger must remain inside the sensor until testing is complete.

- Phone activity on the device will stop the pulse oximeter.

GENERAL USE

Welcome Screen

When the ***Kenek O2*** app is launched, the **Welcome** screen is displayed. From the **Welcome** screen, you can access the **Oximeter**, **History**, **Profiles**, or **Help and About** screen by tapping on the appropriate icon or word.

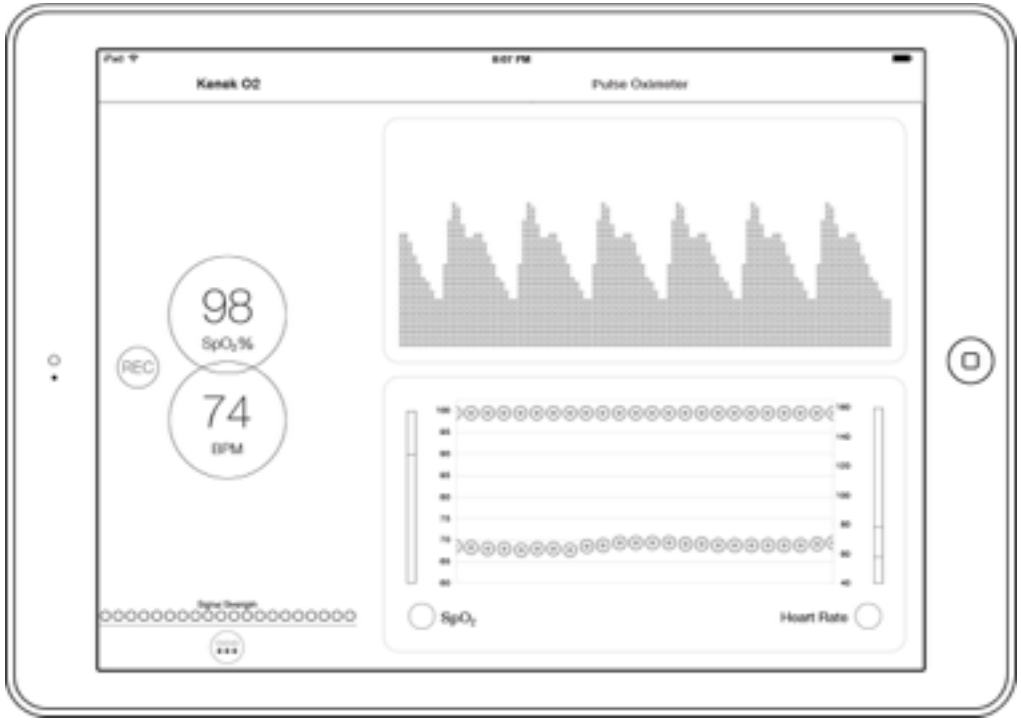
Oximeter Screen

The **Oximeter** screen uses colored *Smart circles* to display important information. These circles may appear at different times based on user interaction with the app and the sensor. The **blue** and **green** circles display values acquired from the sensor, **orange** circles are used to show user instructions and feedback and **purple** circles are used to indicate the app is processing information.

Signal Strength indicates the strength of the sensor measurement. It is affected by the position of the finger in the sensor, movement, how much blood is flowing in the finger (perfusion) and the presence of any discoloration such as nail polish or bruising under the fingernail.

Graph

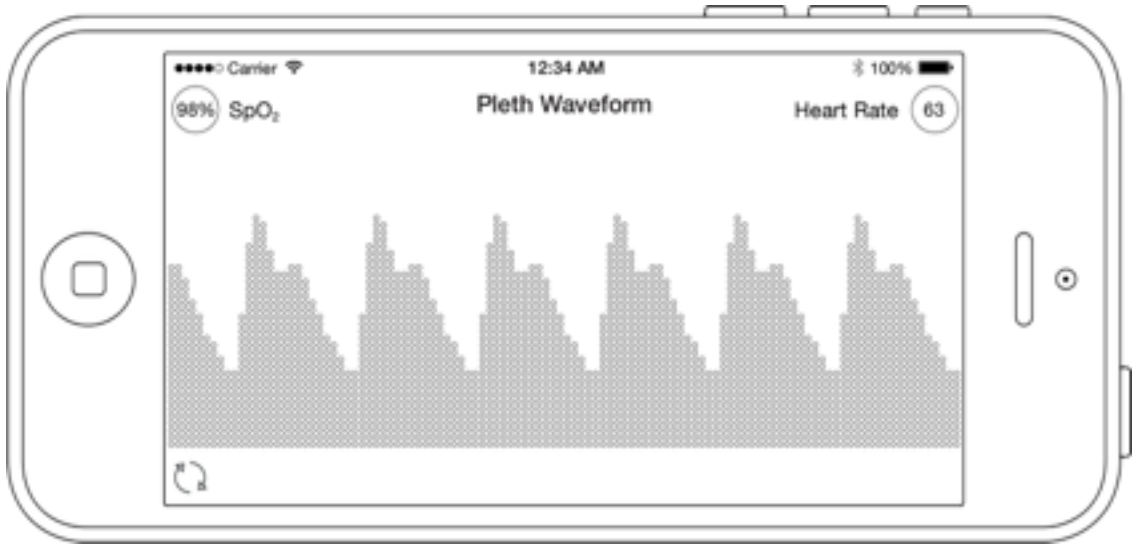
The **Graph** displays all the points for the data capture. On iPods and iPhones, the **Graph** is displayed by rotating the device. On an iPad, the **Graph** is displayed on the right panel of the screen.



Touch any point on the **Graph** to display detailed information about the captured data. Swipe left and right to move forward and backwards in time. Pinch in and out to zoom in and out.

Pleth Waveform

With each heart beat, blood is pumped throughout the body. The **Pleth Waveform** visualizes blood volume changes at the measurement site with each heart beat. The **Pleth Waveform** shape indicates blood volume changes and peak separation indicates heart rate.



A **Pleth Waveform** with consistent shape and regular peak separation indicates good measurement conditions. An irregular **Pleth Waveform** is caused by movement and indicates poor measurement conditions. Remain still while operating the pulse oximeter for best results

The **Pleth Waveform** has no absolute value and varies between patients and with sensor placement. The **Pleth Waveform** signal is scaled to the proportions of the device display. It is normal for the **Pleth Waveform** to be irregular while the signal is refining.

The **Pleth Waveform** can be accessed when the real-time graph is displayed while viewing or recording. Select the **Pleth Waveform** / **Graph** toggle control to switch between those views.

Menu

To access the menu, tap the icon at the bottom of the screen. The menu contains the following choices:

Oximeter Icon

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

History Icon

Shows the **History** section, which contains all previously recorded tests.

Profile Icon

Shows the **Profile** section, where user profiles can be created and edited.

Help & About Icon

Shows the **Help and About** section, which contains additional information.

Duration

Shows the **Duration** screen, where you can set the length of time for capturing data. The **Duration** screen is available from the **Oximeter** screen.

Data Recording

The **REC** icon only appears when the sensor is properly connected, a finger is placed in the sensor and valid SpO_2 and heart rate values are available. (For more information, see the section titled **The Sensor**.)

Tap the **REC** icon to start recording. The **REC** icon disappears and the **Stop** icon is displayed to the right of the main display circles while recording.

To stop recording, tap the **Stop** icon. The **Test Complete** message is displayed. Tap **View Test** to see the results that were just recorded or tap **No** to return to the main **Oximeter** screen.

Duration

The **Duration** screen allows you to adjust the length of time that the sensor will capture data during tests.

Swipe up and down on the minute and second sliders to adjust the capture time.

When you are done making changes, tap **Save** or tap **Clear** to undo changes and revert to the previously saved values.

If the sensor is connected and a finger is inserted in the sensor, you will see a **Begin** icon instead of a **Save** icon. Tap **Begin** to save your changes and start a data capture.

Profile

The **Profile** screen lets you create and edit user profiles. If you need to record results for more than one person, you must create a profile for each one. Before starting a data capture, make sure the correct user profile is selected.

To edit a profile, tap “Name of User” next to the icon. Enter the person's name. Tap **Male** or **Female**. Then enter the **Activity** and **Location**. (Gender, Activity and Location are optional.) When you are done, tap **Save**.

To add another **Profile**, swipe from left to right.

History

The **History** screen displays the list of previous recorded tests.

Tap a row to display additional information for that test. Use the options at the top of the screen to sort the tests by date, name or activity. To search for a specific test, tap the **Menu** icon and tap the **Search** icon at the bottom right of the screen. Tap the **Search** icon again to switch between displaying the **Search** and **Sort** fields.

When viewing the **History** screen, the following options are available through the **Menu** icon:

Trend Icon

View one or more recorded results in a trend graph.

Export Icon

Export one or more recorded results.

Delete Icon

Delete one or more recorded results. Deletion is permanent.

Search and Sort Icon

Sort recorded results or search for recorded results by Profile Name, Activity and/or Location. Tap **Search** again to switch between **Search** and **Sort**.

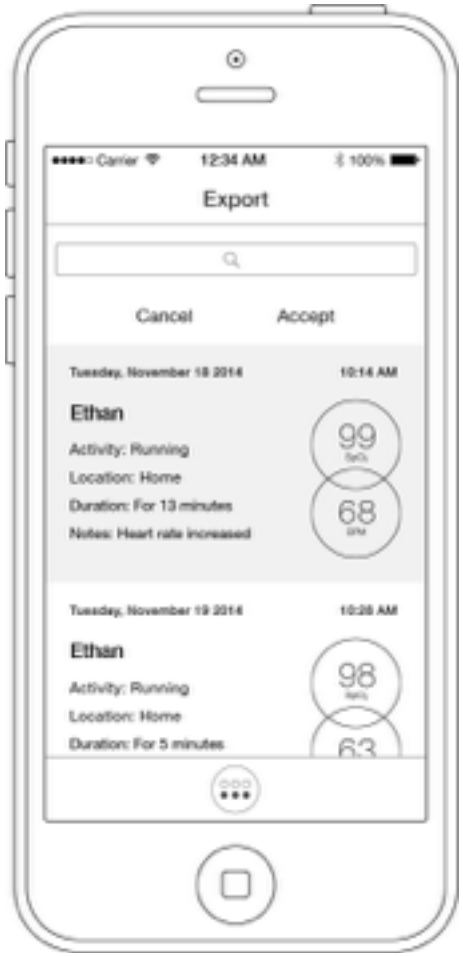
Note Icon

You can add notes to individual recorded results. From the **History** screen, tap a result row to expand it and then tap the **Note** icon. Enter your note text. When you are done, tap the **Note** icon again or tap **Return** on the on-screen keyboard to save the note.

Trend

The **Trend** view is accessed from the **History** screen. Tap the **Menu** icon at the bottom of the screen then tap the **Trend** icon in the lower left of the menu.

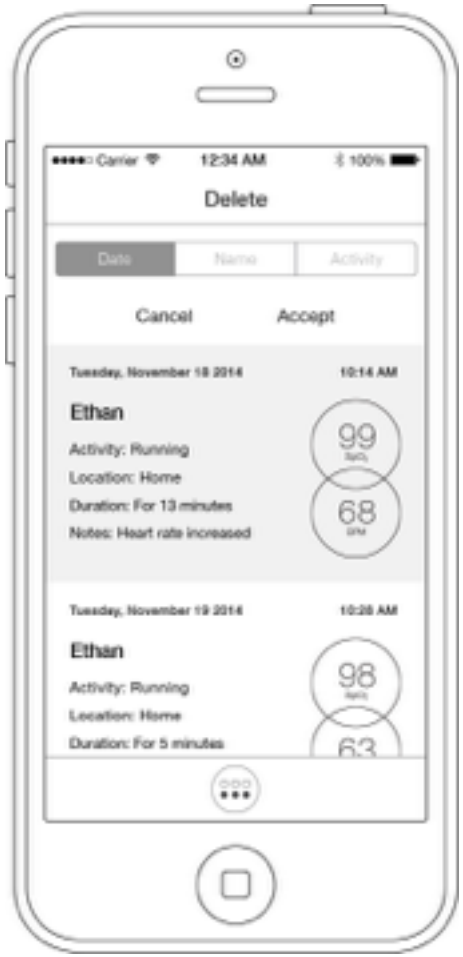
Tap the result row(s) that you want to shown as a **Trend**. On the iPad, the **Trend** view is displayed automatically on the right side of the screen. On the iPhone and iPod touch, rotate the device to display the **Trend** view.



Export Data

The **Export** screen can be accessed from the **History** screen by touching the **Export** icon. (Note that the device must be configured with an email account to use the **Export** feature.)

Tap the test result row(s) that you want to export. Then tap **Accept** near the top of the screen. The selected data is exported to a Comma Separated Values (CSV) file and sent to the provided email address. The CSV file can then be opened using a spreadsheet application such as Microsoft Excel.



Delete

The **Delete** screen can be accessed from the **History** screen. Tap the **Menu** icon. Then tap the **Delete** icon at the bottom of the menu.

Tap the result row(s) that you want to delete. Then tap **Accept** near the top of the screen. The selected data is permanently deleted.

Search and Sort

Search and **Sort** make it easier to locate specific results in the **History** screen. Tap the **Search** icon to switch between **Search** and **Sort** functions.

Search compares the value entered in the search field to each result's **Location**, **Profile** and **Activity** and displays only those results with matching values.

Sort allows you to display the result rows in order of **Date**, **Name** or **Activity**.

SPECIFICATIONS

The ***Kenek O2*** pulse oximeter is calibrated to display functional oxygen saturation. The ***Kenek O2*** pulse oximeter measures a person's SpO_2 and heart rate within these ranges:

Oxygen Saturation Display range: 0% - 99%
Oxygen Saturation Declared Accuracy: 70% - 100% +/- 3%
Heart Rate Display range: 30 bpm - 250 bpm
Heart Rate Declared Accuracy: 30 bpm – 250 bpm +/- 2 bpm

The measurements presented for SpO_2 and heart rate are updated at minimum every 2 seconds. The heart rate is averaged over an 8 second period.

The time delay between a change in reference SaO_2 and a change in the displayed value due to the combined effect of data averaging, data update

period and other signal processing operations has been measured using an SpO_2 simulator and is estimated at 15 seconds or less.

Note all tests using the ***Kenek O2*** *pulse oximeter must be with the subject stationary with no motion.*

SpO2 Accuracy

In a controlled desaturation study of 11 subjects of mixed race, gender and skin pigmentation, the statistics for the pooled data show the RMSD accuracy is 2.35% over the range from 70% to 100% blood oxygen saturation within limits of agreement of -3.7% and +5.1%. The study was conducted by an independent research lab.

The study involved inducing hypoxia to different levels of oxyhemoglobin saturation between 70% to 100%. Oxyhemoglobin saturation was reduced to a series of targets and stabilized at the plateau value for at least 30 seconds. Two arterial blood samples, approximately 30 seconds apart were then obtained for a total of 24 samples per subject. A multi-wavelength oximeter was used to perform reference measurements.

Only about two-thirds of pulse oximeter equipment measurements can be expected to fall within +-2.35% of the value measured by a CO-oximeter

Pulse Rate Accuracy

Pulse rate or rate RMSD accuracy is 0.61 bp for the range of 40-240 bpm under no motion condition. The heart rate accuracy was tested using a SpO_2 simulator.

LED Characteristics

The emitted wavelengths range from 660 nm to 880 nm and the peak optical power at 20 mA is less than or equal to 6 mW.

Temperature Test

In a study of 17 subjects indicated no statistically significant temperature rise beneath the ***Kenek O2*** pulse oximeter LEDs after applying the pulse oximeter to the subject's finger at full power. Subjects in the study had a mean initial temperature of 35.5 °C.

Materials

The ***Kenek O2*** sensor is Latex and BPA free.

Classifications per IEC 60601-1 / CAN/CSA-C22.2 601.1

Degree of Protection
Type BF Applied Part

Enclosure Degree of Ingress Protection Mode of Operation: IP22

This equipment complies with International Standard IEC 60601-1-2:2004 for electromagnetic compatibility for medical electrical equipment and/or systems. This standard is designed to provide reasonable protection against harmful interference in a typical installation. However, because of the proliferation of radio frequency transmitting equipment and other sources of electrical noise in health care, home, and many other environments, it is possible that high levels of such interference due to close proximity or strength of a source might disrupt the performance of this device.

This product complies with ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing.

Electromagnetic Compatibility

Kenek O2 pulse oximeter is compliant with the following emissions and immunity regulations:

Emissions Testing as referenced in EN 60601-1-2: 2007

- CISPR 11, Radiated Emission

Immunity testing as referenced in EN 60601-1-2: 2007

- IEC 61000-4-2, Electro-Static Discharge
- IEC 61000-4-3, Radiated Immunity
- IEC 61000-4-6, Conducted Immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The Kenek O2 pulse oximeter is intended for use in the electromagnetic environment specified below. The customers or the user of the Kenek O2 pulse oximeter 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	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 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 power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV 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(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) 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 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the [ME EQUIPMENT or ME SYSTEM] requires continued operation during power mains interruptions, it is recommended that the [ME EQUIPMENT or ME SYSTEM] be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The Kenek O2 pulse oximeter is intended for use in the electromagnetic environment specified below. The customers or the user of the Kenek O2 pulse oximeter should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601 TEST LEVEL	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the [ME EQUIPMENT or ME SYSTEM], including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = [\frac{3,5}{V_1}]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 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 metres (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: 

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 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 assess 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 the Kenek O2 is used exceeds the applicable RF compliance level above, the Kenek O2 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Kenek O2 .

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

Recommended separation distances between portable and mobile RF communications equipment and the Kenek O2 pulse oximeter

The Kenek O2 pulse oximeter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Kenek O2 pulse oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Kenek O2 pulse oximeter 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 $d = [\frac{3,5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3,5}{E_1}]\sqrt{P}$	800 MHz to 2,5 GHz $d = [\frac{7}{E_1}]\sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output 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.

The ***Kenek O2*** pulse oximeter complies with International Standard IEC 60601-1-2:2007 for electromagnetic compatibility for medical electrical equipment and/or systems. Wireless communication devices such as wireless network devices, mobile phones and walkie talkies can affect this equipment and must be kept away from the device. An active cell phone for example should be kept at least a distance of 3.3 m away from the device.

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 isopropyl alcohol with a minimum concentration of 70%. 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.

Storage and Transport

The ***Kenek O2*** finger clip sensor should be stored or transported in temperatures not to exceed those stated by Apple for its mobile devices. The temperature range for storage and transport should be -20 °C to 45 °C 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.

SUPPORT

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

Web: **lgtmedical.com/support**

Email: **support@lgtmedical.com**

Address: **V3-318 CSB, 950 West 28th Ave,**

Vancouver, BC

V5Z 4H4, Canada

Usage Guidelines

- 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 O2*** pulse oximeter.

Functional Testing of the *Kenek O2* Pulse Oximeter

A functional test may be performed by a qualified professional according to the following instructions.

Open the ***Kenek O2*** pulse oximeter app and start with the **Oximeter** screen (main screen) open.

The following tests may be performed:

- With no sensor plugged in, verify the **Insert Sensor** icon appears indicating the sensor needs to be plugged in.

- With the sensor plugged in and the device at full headphone volume, verify that the LED in the finger clip of the sensor is illuminated. The sensor must remain closed during this step. Do not look directly at the LED.

- With no finger in the sensor, verify that the **Insert Finger** symbol appears indicating there is no finger in the sensor.

- Attach the sensor to a finger. Verify that heart rate and SpO_2 values are shown within 20 seconds.

Testing with the Fluke SPOTLight simulator

Specified simulator is the Fluke Biomedical, ProSim SPOT Light SpO_2 Tester pulse oximeter analyzer (US model: 4111101, Firmware v1.07)

- Start the ***Kenek O2*** pulse oximeter app and remain at the main screen showing the SpO_2 and Heart Rate circles. Plug in the ***Kenek O2*** sensor to the Apple device and connect the sensor to the Fluke SPOTLight simulator.
- Set the simulator to the following settings:
  - SpO_2: 97%
  - HR: 80 bpm
  - PA: 2.0%
  - Trans: Med Finger
  - Artif: None
  - Type: Masimo
  - Test: Manual

- Verify that ***Kenek O2*** reads an SpO_2 value of 97% and a heart rate of 80 bpm.
- Change the simulator to the following settings:
    - SpO2: 75%
    - HR: 120 bpm
    - PA: 2.0%
    - Trans: Sm Finger
    - Artif: None
    - Type: Masimo
    - Test: Manual
- Verify that ***Kenek O2*** pulse oximeter reads an SpO_2 value of 75% and a heart rate of 120 bpm.

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Warranty and Service Life

The ***Kenek O2*** pulse oximeter has a one year warranty from the date of purchase. The ***Kenek O2*** sensor has an expected service life of a minimum of one year. If the sensor becomes faulty prior to one year from the date of purchase, it will be replaced under the one year warranty. The ***Kenek O2*** pulse oximeter is not to be serviced or repaired.

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Published February 2015