KidsO2™
Wearable Oxygen Monitor
User Manual

Download App

Download the ViHealth App from iOS App Store or Google Play Store, or scan the QR code.

Notice: If you have installed the App before, please update it to the latest version.

1 Introduction

1.1 Intended use

This product is intended to be used for measuring, displaying and storing of pulse oxygen saturation (SpO_2), pulse rate of users in home or healthcare facilities environment.

1.2 Warnings and Cautions

• DO NOT squeeze the sensor part or apply excessive force on it.

• Do not use this device during MRI examination.
• Do not store the device in the following locations: locations in which the device is exposed to direct sunlight, high temperatures or levels of moisture, or heavy contamination; locations near to sources of water or fire; or locations that are subject to strong electromagnetic influences.
• Do not use the device in a combustible environment.
• Never submerge the device in water or other liquids.
• Do not clean the device with acetone or other volatile solutions.
• Do not drop this device or subject it to strong impact.
• The device and accessories are provided non-sterile.
• Do not place this device in pressure vessels or gas sterilization device.
• Do not dismantle the device, as this could cause damage or malfunctions or impede the operation of the device.
• Consult your doctor immediately if you experience symptoms that could indicate acute disease.
• Do not self-diagnose or self-medicate on the basis of this device without consulting your doctor. In particular, do not start taking any new medication or change the type and/or dosage of any existing medication without prior approval.
• Use only accessories specified in this manual.
• Prolonged continuous monitoring may increase the risk of undesirable changes in skin characteristics, such as irritation, reddening, blistering or burns.
• Do not open the device cover without authorization. The cover should only be opened by a qualified service personnel.
• The device shall only be maintained by qualified professionals.
• The manufacturer shall provide the service personnel with circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist service personnel to repair the device.

1.3 Guide to Symbols

Symbol	Description
	Manufacturer
	Date of manufacture
SN	Serial number
	Indicates a medical device that is not to be disposed of as unsorted municipal waste.
	Follow Instructions for Use.
	Type BF Applied Part
	No alarm system
MR	MRI unsafe. Presents hazards in all MR environments as device contains strongly ferromagnetic materials.
IP22	Resistant to liquid ingress
CE 0197	CE marking
EC REP	Authorized representative in the European community
UKCA	UKCA marking
UK REP	Authorized Representative in the United Kingdom
(((·)))	Non-ionizing radiation
	This product complies with verpackG.
	Our products and packaging can be recycled, don't throw them away! Find where to drop them off on the www.quefairedemesdechets.fr site (Only applicable for French market).

1.4 Unpacking

• Device
• User Manual
• Data/Charging Cable

2 Overview

Touch Key — USB Port
Blood Oxygen — Pulse Strength
Pulse Rate

3 Using the Device and App

3.1 Charging

Charge the battery before using.
Connect the device to computer USB or USB charging adapter with USB cable.
After fully charged, the device will power off automatically.

3.2 POWER ON/OFF

POWER ON:
Wear the device, it will turn on automatically.

POWER OFF:
The device turns off automatically in a moment after you take it off.

3.3 Typical steps

1) START. Charge the battery. Wear the device to power on.
2) STOP. Take off the device, the recording will be over after the countdown.
3) DATA SYNC. After the countdown, run App to sync data. OR next time after you turn on the device, run App to sync.

Notice: In App Dashboard, you can monitor the real-time oxygen levels, heart rate and PI.

3.4 Start working

1) Wear the device on finger.
2) Device will turn on automatically. After a few seconds, the device will begin to work.

To choose the wearing finger: all fingers can be used for wearing, from thumb to little finger. To get an accurate reading, the wearing should not be loose. For proper wearing, there should be no gap between the inner side of the ring and finger skin.

Notice:
• Tight wearing is helpful for measurement, but may increase the risk of adverse effect to the skin. Always take close care of the skin condition during long-time wearing
• If the working time is less than 2 minutes, the data will not be saved.
• Please avoid excessive motion.
• Please avoid strong ambient light condition.

3.5 Stop working & sync data

Take off the device, the countdown will begin.
(If the working time is less than 2 minutes, there will be no countdown)
During the countdown, if you wear the device again, the record will be resumed.
After the countdown, the data will have been saved in device and ready to sync.

Sync data:
• After the countdown, run App to sync data;
• Or next time after you turn on the device, run App to sync.

Notice: The built-in memory can store 4 sessions. The oldest will be overwritten by the 5th. Please sync data to your phone in time.

3.6 Screen Wake up

The screen will go off automatically for saving power; you can touch the key on top to wake up the screen.

3.7 Unavailable Symbol

When this symbol displays on device screen, it indicates the readings is unavailable right now.
It may be caused by:
• Excessive movement;
• Poor signal, finger is too cold, PI is low;
Usually, the readings will recover in a few seconds when at rest.

3.8 How to Check Device Battery and Time

Touch the key on top, you can switch display between readings, battery and time.
In App Dashboard, you can also check battery level.

3.9 Bluetooth Connection

The device Bluetooth will be enabled automatically after it's turned on.
To establish a Bluetooth connection,
1) Keep the device Bluetooth enabled.
2) Make sure the phone Bluetooth is enabled.
3) Run the App.
Notice:
• DO NOT PAIR in the settings of your phone.

3.10 Add a New Device

For the initial use, you need to add a new device.
1) Turn on device, run App, select <KidsO2>;
2) Touch the key on top of device.

3.11 Audio Reminder in Device and App

There are two independent Audio Reminders in device and App.
The Reminder will be activated when the SpO_2 fall below the pre-set value (Threshold).

3.12 Audio Reminder in Device

You can configure it in App's [Profile]->[My device] when your device is connected.
• You can switch on or off the reminder.
• You can adjust the volume of the reminder.
• You can adjust the Threshold.
The reminder will stop when SpO_2 recover, or you can press the key to stop it.

3.13 Audio Reminder in App Dashboard

You can configure it in App's [Profile]->[My device] .
• You can switch on or off the reminder.
• You can adjust the Threshold.
The volume is same as your phone's volume.
The Reminder works only when your phone stayed in Dashboard and not locked.
The Reminder in Dashboard will be activated when SpO_2 fall below the pre-set value (Threshold).
The Reminder will stop when the SpO_2 recover. You can press the Mute icon on Dashboard to mute.

3.14 View Report

In App->[History],
• Tap an item in the list, you can check the report, which includes analysis results and diagrams.
• Slide an item to left, you can delete it.

3.15 O2 Score

O2 Score is overall assessment of oxygen condition, which synthesizes the frequency, depth and duration of oxygen shortage overnight. The range is 0-10 (10 is best). It is provided for each record in App.
Example:

O2 Score 7.5   0   10   (in the APP)

3.16 Data of Multiple Devices

In App's [Profile]->[Select Device], you can select device if you have multiple devices to check data of another device .

4 PC software

PC Software: O2 Insight Pro
Download from:
https://getwellue.com/pages/pc-software
Install the software on Windows PC (win 7/8/10) or MacOS (10.15 or above).
1) Turn on device, connect the device to PC USB port with the supplied Data Cable (it's different from universal USB cable)
2) Run the PC software, click the Download button to download data from the device

With the PC software, you can view and print sleep report, which can also be exported as PDF or CSV files.
Note: while the device is being connected to app, it can't connect to PC software.

5 Maintenance

5.1 Time & Date

After connection with App, device time will sync from your phone time automatically.

5.2 Cleaning

Use a soft cloth moistened with water or alcohol to clean the device surface.

6 Troubleshooting

Problem	Possible Cause	Possible Solution
Device does not turn on or no response	Battery may be low.	Charge battery and try again.
	Device might be damaged.	Please contact your local distributor.
	Software exception	Keep device in charging, touch the key for 8 seconds.
The app cannot find the device	The Bluetooth of your phone is off.	Turn on the Bluetooth in the phone.
	The device Bluetooth is off.	Turn on device
	For **Android**, Bluetooth cannot work without location permission	Allow location access

7 Specifications

Environmental	Operating	Storage
Temperature	5 to 40°C	-25 to 70°C
Relative humidity (non-condensing)	10% to 95%	10% to 95%
Barometric	700 to 1060hPa	700 to 1060hPa
Protection against electric shock	Internally powered equipment	
Degree protection against electrical shock	Type BF	
Electro-magnetic compatibility	Group I, Class B	
Degree of dust & water resistance	IP22	
Weight	12 g	
Size	38mm×30mm×27 mm	
Battery	3.7Vd.c., Rechargeable Lithium-polymer	
Charge time	2-3 hours	
Battery life	14 hours for typical use	
Wireless	Bluetooth 4.0 BLE	
Oxygen level range	70% to 100%	
SpO2 Accuracy (Arms)	80-100%:±2%, 70-79%:±3%	
Pulse Rate range	30 to 250 bpm	
Pulse Rate accuracy	±2 bpm or ±2%, whichever is greater	
Reminder source	low oxygen level; high/low pulse rate	
Recorded parameters	Oxygen level, Pulse Rate	
Data storage	4 sessions, up to 10 hours for each	
Frequency range	2.402-2.480GHz	
Max RF power	-10 dBm	

Expected service life	3 years
Mobile App for iOS	iOS 9.0 or above, iPhone 4s/ iPad 3 or above
Mobile App for android	Android 5.0 or above, with Bluetooth 4.0 BLE
Wavelength/Max emission power	660nm/940nm, 0.8mW/1.2mW

8 Appendix EMC

The equipment meets the requirements of IEC 60601-1-2:2014.

Table 1

Guidance and manufacturer's declaration-electromagnetic emission		
The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Pulse Oximeter should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The Pulse Oximeter uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Pulse Oximeter suitable for use in all establishments, including domestic establishments and those directly network that supplies buildings used for domestic purposes.
Harmonic emissions IEC61000-3-2	N/A	
Voltage fluctuations/flicker emissions IEC61000-3-3	N/A	

Table 2

Guidance and manufacturer's declaration-electromagnetic emission			
The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Pulse Oximeter should assure that it is used in such an environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge(ESD) IEC61000-4-2	±8 kV contact ±15kV air	±8 kV contact ±15kV 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 IEC61000-4-4	±2kV for power Supply lines ±1 kV for input/output lines	N/A	N/A
Surge IEC 61000-4-5	±1kV line (s) to line(s) ±2kV line(s) to earth	N/A	N/A
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle <40% UT (60% dip in UT) for 5 cycles <70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 s	N/A	N/A
Power frequency (50Hz/60Hz) magnetic field IEC61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: UT is the a.c. mains voltage prior to application of the test level.

Table 3

Guidance and manufacturer's declaration – electromagnetic immunity			
The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of The Pulse Oximeter should assure that it is used in such an electromagnetic environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment -guidance
Conducted RF IEC61000-4-6	3 Vrms 150 kHz to 80 MHz	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the Pulse Oximeter, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2\sqrt{P}$
Radiated	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d=1.2\sqrt{P}$ 80MHz to 800MHz $d=2.3\sqrt{P}$ 800MHz to 2.5GHz
RF IEC61000-4-3			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). b 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, and electromagnetic site survey should be considered. If the measured field strength in the location in which The Pulse Oximeter is used exceeds the applicable RF compliance level above, The Pulse Oximeter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating The Pulse Oximeter.
b: Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Table 4

Recommended separation distances between portable and mobile RF communication the equipment			
The Pulse Oximeter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of The Pulse Oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Pulse Oximeter as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W(Watts)	Separation distance according to frequency of transmitter M(Meters)		
	150kHz to 80MHz $d=1.2\sqrt{P}$	80MHz to 800MHz $d=1.2\sqrt{P}$	80MHz to 2,5GHz $d=2.3\sqrt{P}$
0,01	N/A	0.12	0.23
0,1	N/A	0.38	0.73
1	N/A	1.2	2.3
10	N/A	3.8	7.3
100	N/A	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance in metres (m) can be determined 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.

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Illustration

All illustrations provided in this manual are for reference only, and the settings or data in the illustrations may not be exactly the same as the actual display you see on the product.

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Vous êtes responsable de remettre tous les appareils électriques et électroniques usagés à des points de collecte correspondants.

Pour en savoir plus: www.quefairedemesdechets.fr

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