

Wearable Oxygen Monitor

User Manual

1. Introduction

1.1.Intended use

This product is intended to be used for measuring, displaying and storing of pulse oxygen saturation (SpO₂), pulse rate of adults in home or healthcare facilities environment for sleep or daily use.

Notice: This product is intended for sports or aviation use only. It should not be used to directly diagnose or treat any medical condition.

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 use this device with a defibrillator.
- 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 cables, sensors and other 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.

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 |
| | MRI unsafe. Presents hazards in all MR environments as device contains strongly ferromagnetic materials. |

| | |
|-------------|---|
| IP22 | Resistant to liquid ingress |
| | This product complies with the rules and regulations of the Federal Communication Commission. |
| | Non-ionizing radiation |
| | This product complies with verpackG. |
| | Temperature limitation |
| | Humidity limitation |
| | Atmospheric pressure limitation |

1.4.Unpacking

- Device
- User Manual
- Data/Charging Cable

2. Overview



3. Using the Device

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.

3.4.Start working



- 1) Wear the device on thumb finger, index finger as option in case of too tight for thumb. Try to move the device along the forefinger to find out a best fit. Avoid being loose. Loose wearing causes inaccurate measure.
- 2) Device will turn on automatically. After a few seconds, the device will begin to monitor.

- Notice:**
- **Keep snug enough, loose wearing may cause inaccurate readings.**
 - **DO NOT use middle finger; if too tight for thumb or forefinger, try little finger.**
 - If the working time is less than 2 minute, 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 minute, 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 in Standard Mode; you can touch the key on top to wake up the screen.

3.7.How to Check Battery

Touch the key on top, you can switch display between readings and battery.

3.8.Unavailable Symbol

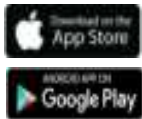
When this symbol displays on device screen, it indicates the readings is unavailable right now. It may caused by:

- Excessive movement;
 - Poor signal, finger is too cold;
- Usually, the readings will recover in a few seconds when at rest.



3.9.Download App

App name: **ViHealth**
iOS: **App Store**
Android: **Google Play**



Compatibility

The device is compatible with iOS versions 9.0+ and Android versions 5.0+. Please Refer the ViHealth app manual for more details.

3.10.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 smart device.

4. PC software

PC Software: **O2 Insight Pro**
Download from:
<https://getwellue.com/pages/pc-software>
Install the software on Windows(win 7/8/10) or MacOS(10.15 or above).

- Install the software on PC:
- 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 |
| Only one Light Emitter on the ring turns red. | This is normal, the O2Ring only has one light emitter. | No need to worry about it. |

For more information about O2Ring, please visit:
<https://getwellue.com/pages/faqs>

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 | 15 g | |
| Size | 38×30×38 mm | |
| Battery | 3.7Vdc, Rechargeable Lithium-polymer | |
| Charge time | 2-3 hours | |
| Battery life | 12-16 hours for typical use | |
| Wireless | Bluetooth 4.0 BLE | |
| Oxygen level range | 70% to 99% | |
| SpO2 Accuracy (Arms) | 80-99%:±2%, 70-79%:±3% | |
| Pulse Rate range | 30 to 250 bpm | |
| Pulse Rate accuracy | ±2 bpm or ±2%, whichever is greater | |
| Vibration source | low oxygen level; high/low pulse rate | |
| Recorded parameters | Oxygen level, Pulse Rate, motion | |
| Data storage | 4 sessions, up to 10 hours for each | |
| 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 <i>Bluetooth</i> 4.0 BLE | |

8. Appendix EMC

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

| 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 | |

| 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. | | | |

| 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 RF IEC61000-4-3 | 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 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 | 80MHz to 800MHz | 80MHz to 2,5GHz |
| | $d=1.2 \sqrt{P}$ | $d=1.2 \sqrt{P}$ | $d=2.3 \sqrt{P}$ |
| 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. | | | |

9. FCC Statement

FCC Warning:
FCC ID: 2AD XK-S9
Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:
(1) This device may not cause harmful interference, and
(2) this device must accept any interference received, including interference that may cause undesired operation.
Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
-Reorient or relocate the receiving antenna.
-Increase the separation between the equipment and receiver.
-Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
-Consult the dealer or an experienced radio/TV technician for help.
The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

Manufacturer: Shenzhen Viatom Technology Co., Ltd.
Address: 4E,Building 3, Tingwei Industrial Park No. 6 Liufang Road, Block 67 Xin’an Street, Baoan District Shenzhen 518101 Guangdong China

Contact us: support@getwellue.com
Website: www.getwellue.com



Product name: Pulse Oximeter
Version: A Date: Mar.22, 2024 Model: S9 PN: 255-07509-00