

制作说明：

黑白印刷，双面印刷,采用80g书写纸。

纸张大小：（宽）25.5cm*（高）39cm

折叠后的尺寸为（宽）8.5cm *（高）6.5cm。

要求字迹清晰

此页不印刷

Wellue®

Pulse Oximeter

Model: S11

User Manual

Dowload App

App name: ViHealth

iOS: App Store

Android: Google Play

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 oxygen level (SpO₂), pulse rate of adults.

This product is intended for general wellness use. 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
	Serial number
	Unique device identifier
	Indicates that the product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling
	Refer to instruction manual
	Type BF Applied Part
	No alarm system
	MR unsafe
	Indicates that the product is protected against solid foreign objects of 12,5 mm Ø and greater; and protected against vertically falling water drops when enclosure tilted up to 15°
	Indicates that the product complies with the applicable FCC requirements
	Non-ionizing radiation
	Indicates that the marked item or its material is part of a recovery or recycling process.

	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation

1.4 Unpacking

- Device (main unit)
- Ring Sensor
- User Manual
- Data/Charging Cable

1.5 Overview

Wear the device during sleep. It continuously monitors your oxygen level, heart rate and motion. The smart vibration protects you from oxygen shortage.

Next morning, take off the device, **open app to sync data** which will help you get sleep insight.

You can customize Smart Vibration in App to help you sleep better.

2 Using the device

2.1 Charging

Charge the battery before using.

Connect the device to USB of computer or USB charging adapter with the supplied cable.

After fully charged, the device will power off automatically.

2.2 POWER ON/OFF

POWER ON:

Wear the Sensor, the device will turn on automatically.

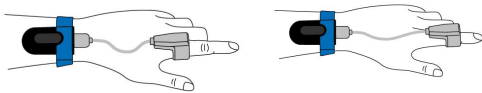
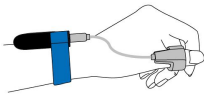
POWER OFF:

The device turns off automatically in a moment after you take off the sensor.

2.3 Typical steps

- START.** Charge the battery. Wear the sensor to power on. Go to sleep.
- STOP.** Next morning, take off the sensor, the recording will be over after the countdown.
- DATA SYNC.** After the countdown, run App to sync data. **OR** next time after you turn on the device, run App to sync.

2.4 Start working



- Wear the sensor on thumb finger, index finger as option in case of too tight for thumb. Try to move the sensor along the forefinger to find out a best fit. Avoid being loose. Loose wearing causes inaccurate measure.
- 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.

2.5 Stop working & sync data

Take off the sensor, 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.

2.6 Display

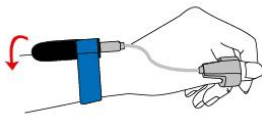
Blood Oxygen Saturation



Pulse Strength

Pulse Rate

2.7 Screen wake up



During measurement, the screen will go off automatically for saving power; you can turn your wrist to wake up the screen.

2.8 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.

2.9 Bluetooth Connection

The device Bluetooth will be enabled automatically after it's turned on.

To establish a Bluetooth connection,

- keep the device Bluetooth enabled.**
- Make sure the phone Bluetooth is enabled.**
- Run the App.**

Notice:

- DO NOT PAIR** in the settings of your smartphone.

2.10 Add a new device

For the initial use, you need to add a new device.

- Turn on device, run App, select <SleepU>;
- Then input the **last 4 digits on the back of your device.**

2.11 How to check battery

- After you turn on device, it will display battery for a few seconds.
- You can also check Battery and real-time SpO₂, Heart Rate in App->Dashboard.

2.12 Smart Vibration

The vibrator in the sensor will be activated when the SpO₂ fall below the pre-set value (Threshold). The vibration will stop when the SpO₂ recover or by turning your wrist.

You can customize the vibration to help you sleep better. Make sure your **device is connected** to App first. Then you can configure it in **App->Profile->My device.**

- You can **switch on or off** the vibration.
- You can adjust the **Intensity** of vibration.
- You can adjust the **Threshold**. If the vibration disturbs you during sleep too much, you can lower the **Threshold**. If you would like to get more protection from oxygen shortage, you can turn up the **Threshold**.

2.13 View Report

In App->History,

- Tap an item in the list, you can check the detailed report, which includes analysis results and diagrams.
- Slide an item to left, you can delete it.

2.14 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:



2.15 App Offline Mode | Multiple Devices

If you enter App Offline Mode, you can view history data, in App Profile->Select device, you can select device if you have multiple devices. In this Mode, device is not connected so you cannot sync data or set device.

3 PC software

PC Software: O2 Insight

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 Windows PC.

- Turn on device, connect the device to PC USB port

with the supplied Cable.

2) Run the PC software, click the **Download** button to download data from the device.

With the optional PC software, you can view and print sleep report, which can also be exported as PDF or CSV files.

4 Maintenance

4.1 Time & Date

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

4.2 Cleaning

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

5 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.
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

6 Specifications

Environmental	Operating	Storage
Temperature	5 to 40°C	-25 to 70°C
Relative humidity (noncondensing)	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	31g (main unit with band and sensor)	
Size	49×27×14 mm (main unit)	
Battery	3.7Vd.c., Li-ion rechargeable	
Charge time	2-3 hours	
Battery life	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	Triggered by low oxygen level	
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	

7 FCC Statement

FCC Warning:
FCC ID: 2AD XK-S11

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.

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 $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 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. 
Radiated RF IEC61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

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.

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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