Wellue®

Pulse Oximeter

Model: S10

User Manual

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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.
It's not a medical device. This device is for Sports and Aviation use only and not intended for medical use.

Note:
The data and results provided by this device are for pre-check screening purpose only and cannot be directly used for diagnostic or treatment.

The data provided by the APP and PC software (optional) is not intended for diagnosis or treatment purpose, always consult your doctor for any health condition.

⚠ Warnings and Cautionary Advices

- DO NOT squeeze the sensor or apply excessive force on the sensor & cable.

- Do not use this device during MRI examination.
- Never submerge the device in water or other liquids. Do not clean the device with acetone or other volatile solutions.
- Do not place this device in pressure vessels or gas sterilization 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 oxygen level recording may increase the risk of undesirable changes in skin characteristics, such as irritation, reddening, blistering or burns.
- Check the oxygen level sensor application site every 6-8 hours to determine the positioning of the sensor and the circulation and skin sensitivity of the patient. Patient sensitivity varies depending on medical status or skin condition. For patients with poor peripheral blood circulation or sensitive skin, inspect the sensor site more frequently.
- Functional tester cannot be used to assess the accuracy of a oxygen level sensor or a device.
- This device is designed to determine the arterial oxygen saturation percentage of functional hemoglobin. Factors that may degrade pulse oximeter performance or affect the accuracy of the measurement include the following:
  - excess ambient light
  - excessive motion
  - electrosurgical interference
  - blood flow restrictors (arterial catheters, blood pressure cuffs, infusion lines, etc.)
  - moisture in the sensor
  - improperly applied sensor

- incorrect sensor type
- poor pulse quality
- venous pulsations
- anemia or low hemoglobin -concentrations
- cardiogreen and other -intravascular dyes
- carboxyhemoglobin
- methemoglobin
- dysfunctional hemoglobin

1.2 Guide to Symbols

Symbol	Description
	Manufacturer
	Date of manufacture
SN	Serial number
	MR unsafe
	Indicates that the product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling
IP22	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°

	Refer to instruction manual
	Type BF-Applied Part
	No alarm system.
	Indicates that the product complies with the applicable FCC requirements
	Non-ionizing radiation
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	Indicates that the marked item or its material is part of a recovery or recycling process

1.3 Unpacking

Main Unit × 1
Ring Sensor × 1
Cable × 1
User Manual × 1

2 Using the Monitor

2.1 Overview

1. Pulse oximeter
2. Wristband
3. Sensor interface / charging interface
4. Power button
5. Oxygen level sensor

Screen display item description:

SpO2	Oxygen level
	Pulse rate
	Wear the sensor
19:30	Time
	Remaining battery capacity
	Reminder is on
	Reminder is off

	Bluetooth is connecting

2.2 Charging

Charge the battery before using.
Use the charge cable to charge the battery of device in the USB Port of the computer or with USB charging adapter.
After being fully charged, the device will power off automatically.

2.3 POWER ON/OFF

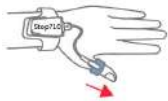
POWER ON:
Press the button for 1 second to turn on the device.

POWER OFF:
Automatically power off: The device will turn off automatically in 2 minutes if no measurement, no operation or without App connection.
Manually power off: You can press the button for about 2 seconds to turn off.

2.4 TAKE THE FIRST RECORDING

START. Wear the device and the Ring Sensor, press the button to power on. And keep yourself in the *quiet environment.*
(For the sake of clarity, recommended the user wear the monitor watch on their left wrist and put the ring sensor on the thumb. **If it is too tight, try another finger. Avoid being loose.**)

STOP. After the record, take off the Ring Sensor (and the device), the recording will be save after the countdown. (If the working time is less than 1 minute, the data will not be saved.)



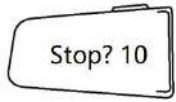
Note:

- Please avoid excessive motion for the sensed finger during recording and avoid any strong ambient light condition.

2.5 Stop monitoring & sync data

Take off the sensor, the countdown will begin.

During the countdown, if you wear the sensor again, the record will be resumed.



After the countdown, the **data will be ready for sync**.

Note:

The duration of the recording is 1mins~10 hours. And the device can collect and store maximum 4 recording, when the 5th recording coming, the first recording will be will covered.

Sync data to the ViHealth App

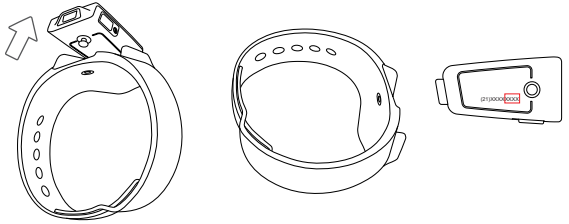
You can Sync the data to your app after the countdown or next time after you turn on the device.

Note: Refer the ViHealth app manual for more details.

2.5.1 How to find the Serial Number？

1）Detach the main unit from wristband.

2）Flip the main unit over, the series number is printed on the label of product.



Note:

The serial number is on the back of the device.

2.6 How to synchronize the time of the device

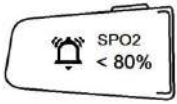
The time of the **monitor** will be automatically synchronized with the network time on your smart device after connected with the app.

Note: Refer the ViHealth app manual for more details.

2.7 Reminder

When the monitor detects low blood oxygen or abnormal pulse rate, it supports triggering vibration reminders or sound reminders.

You can customize the vibration reminder after the monitor power on, or use the App to configure the vibration intensity. The sound reminder only can be configured on the App.



2.8 Download App

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

Compatibility

The device is compatible with iOS versions 11.0+ and Android versions 7.0+. Refer the ViHealth app manual for more details.

2.9 Bluetooth Connection

The device Bluetooth will be enabled automatically when the device is on.

***Note: DO NOT PAIR** in the settings of your smart device.*

3 PC software

3.1 Download the PC Software

PC Software: **O2 Insight Pro**
Download from: getwellue.com/pages/pc-software
Install the software on Windows PC or Mac.

3.2 How to connect the monitor to PC

1. Turn on device, connect the device to PC USB port with the supplied Cable of data.

2. Open the PC software, download data from the device.
3. With the optional PC software,You can view and print report, which can also be exported as PDF or CSV files.

3.3 How to connect the monitor to Mac

1. Turn on device, and turn on the Bluetooth of the Mac.
2. Open the "**O2 Insight Pro"** software and click the "Connect" on the screen. Choose your device to connect.
3. Then click the "download" on the screen. Then the data will sync with your Mac.
4. You can view and print report, which can also be exported as PDF or CSV files.

4 Maintenance

4.1 Cleaning

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

4.2 Battery

To keep the battery in good condition, charge the battery every 6 months when the device is not in use.

5 Troubleshooting

Problem	Possible Cause	Possible Solution
Device does not turn on or no response.	Battery may be low.	Charge battery and try again.
	Unexpected software condition	Press the button for about 10 seconds to reset
	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.

6 Specifications

Classifications		
Degree protection against electrical shock	Type BF	
Environmental		
Item	**Operating**	**Storage**
Temperature	5 to 40°C	-25 to 70°C
Relative humidity (noncondensing)	10% to 95%	10% to 95%
Barometric	700 to 1060 hPa	700 to 1060 hPa
Degree of dust & water resistance	IP22	

Physical	
Weight	18 g (main unit)
Display	OLED
Wireless	*Bluetooth 4.0* BLE
Vibrator	Built in
Power Supply	
Charge input:	DC 5V ±10%
Battery type	3.8V d.c., Li-ion rechargeable
Battery run time	72 hours
Charge time	2.5 hours
Oxygen level	
Standards	Meet standards of ISO 80601-2-61
Measurement accuracy verification: The oxygen level accuracy has been verified in human experiments by comparing with arterial blood sample reference measured with a CO-oximeter. The pulse rate accuracy has been verified by Emulator. Pulse oximeter measurement are statistically distributed and about two-thirds of the measurements are expected to come within the specified accuracy range compared to CO-oximeter measurements.	
Oxygen level range	70% to 100%
Oxygen level Accuracy (Arms)	80-100%:±2%, 70-79%:±3%
PR range	30 to 250 bpm
PR accuracy	±2 bpm or ±2%，whichever is greater
Wave length	660-940nm
Output power	Red/Infrared: 3mW max. avg.
Storage	

Capacity	4 records,10 hours for each
Mobile APP	
iOS	iOS 9.0 or above, iPhone 4s/iPad 3 or above
Android	Android 5.0 or above, with *Bluetooth* 4.0 BLE

7 FCC Statement

FCC Warning:
FCC ID: 2ADXK-1600
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 Electromagnetic Compatibility

The device meets the requirements of EN 60601-1-2.

⚠**Warnings and Cautions**

- Using accessories other than those specified in this manual may result in increased electromagnetic emission or decreased electromagnetic immunity of the equipment.
- The device or its components should not be used adjacent to or stacked with other equipment.
- The device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.
- Other devices may interfere with this device even though they meet the requirements of CISPR.
- When the inputted signal is below the minimum amplitude provided in technical specifications, erroneous measurements could result.
- Portable and mobile communication equipment may affect the performance of this device.

- Other devices that have RF transmitter or source may affect this device (e.g. cell phones, PDAs, and PCs with wireless function).

Table 1

Guidance and manufacturer's declaration-electromagnetic emissions		
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 device 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 device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply 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 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 environment.			
Immunity test	**IEC60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Floors should be wood, concrete or ceramic tile. If floors are covered

Electrostatic discharge(ESD) **IEC61000-4-2**	±8 kV contact ±15kV air	±8 kV contact ±15kV air	with synthetic material, the relative humidity should be at least 30%. If ESD interfere with the operation of equipment, counter measurements such as wrist strap, grounding shall be considered.
Electrical fast transient/ burst **IEC61000-4-4**	±2kV for power supply lines ±1 kV for input/output lines	±2kV for power supply lines ±1 kV for input/output lines	The quality of the power supply should meet the requirements of a typical commercial (initial power supply) or medical environment.
Surge **IEC 61000-4-5**	±1kV line to line ±2kV line to earth	±1kV line to line ±2kV line to earth	The quality of the power supply should meet the requirements of a typical commercial or medical environment.
Voltage dips, short interruptions and voltage variations on power supply input lines **IEC 61000-4-11**	0% U_T (100% dip in U_T) for 0.5 cycle 0% U_T (100% dip in U_T) for 1 cycle 70% U_T (30% dip in U_T) for 25/30 cycles	0% U_T (100% dip in U_T) for 0.5 cycle 0% U_T (100% dip in U_T) for 1 cycle 70% U_T (30% dip in U_T) for 25/30 cycles 0% U_T	The quality of the power supply should meet the requirements of a typical commercial or medical environment.If the user of this product needs to continue poerating during power interruption,it is recommended to

	0% U_T (100% dip in U_T) for 250/300 cycles	(100% dip in U_T) for 250/300 cycles	use uninterruptible power supply or battery power.
Power frequency (50/60Hz) magnetic field **IEC61000-4-8**	30 A/m	30 A/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 AC 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 environment.			
Immunity test	**IEC60601 test level**	**Compliance level**	**Electromagnetic environment -guidance**
Conducted RF IEC61000-4-6	3 Vrms 150 kHz to 80 MHz(6V in ISM and amateur radio bands between	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the device, 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

Radiated RF IEC61000-4-3	0.15MHz and 80MHz) 3 V/m 80 MHz to 2.5 GHz	10 V/m	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. 

Table 4

Recommended separation distances between portable and mobile RF communications equipment and the Pulse Oximeter

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 $d=1.16\sqrt{P}$	80MHz to 800MHz $d=1.16\sqrt{P}$	80MHz to 2,5GHz $d=2.33\sqrt{P}$
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 meters (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.

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