Oxyfit™

Pulse Oximeter

User Manual

Contents

English

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 Pulse Oximeter is intended to be used for measuring, displaying and storing adult' s pulse oxygen saturation (SpO2), pulse rate of adults in home or healthcare facilities environment.

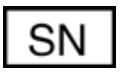
1.2.Warnings and Cautions

- 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, lint, dust, 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 (i.e., oxygen-enriched 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.
- The biocompatibility testing has been performed on the materials in contact with the person in accordance with ISO10993.
- Do not place the SpO2 probe on a finger with edema or fragile tissue.
- Check the SpO2 sensor and cable before use. Do not use a damaged SpO2 sensor.
- Check the SpO2 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.

- The functional tester cannot be used to assess the accuracy of the SpO2 sensor or a device.
- The device has no alarm system.
- Continuous use for a long time may cause allergies, redness, blistering or burns. Check the wearing position every 6-8 hours.
- The local laws and regulations should be followed when disposing of the device and accessories.
- Do not maintain the device while it is charging.
- Please keep the cable away from children. It can cause strangulation.
- Keep the device out of reach of pets, pests and children.
- The PULSE OXIMETER EQUIPMENT is calibrated to display FUNCTIONAL OXYGEN SATURATION.
- Nail polish may affect the measuring accuracy, and too long fingernail may cause failure of measurement or inaccurate results.

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

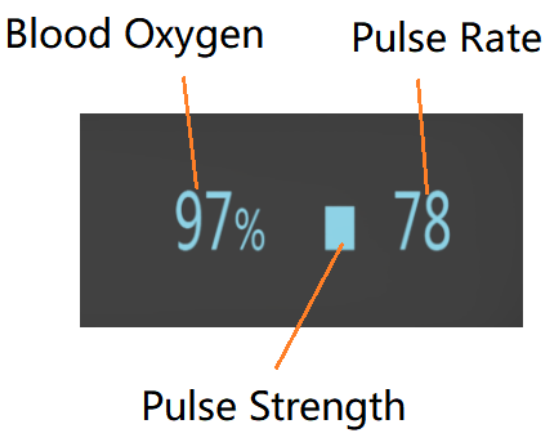
	Type BF Applied Part
	No alarm system
	MR unsafe
IP22	Indicates that the product is protected against solid foreign objects of 12,5 mm Ø and greater; and protected against vertically falling water drops when enclosure tilted up to 15°.
CE 0197	Indicates that the product complies with the EU Medical Device Regulations(Regulation (EU) 2017/745) Article 120, Annex II of 93/42/EEC and Reg ulation (EU) 2023/607.
	Medical device
	Authorized representative in the European community
	UKCA marking
	UK Responsible Person
	Non-ionizing radiation
	Indicates that the marked item or its material is part of a recovery or recycling process.
	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).
	Temperature limit

	Humidity limitation
	Atmospheric pressure limitation

1.4.Unpacking

- Device
- User Manual
- 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 index finger. 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 work.

Notice:

- If the working time is less than 30 seconds, 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 30 seconds, 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 be ready for uploading.

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 up to 4 sessions of record. Each session can store up to 1 hour data, and the oldest session will be overwritten by the new one when the memory is full. Please upload data to your phone in time.

3.6.Screen Display

The screen is always on and displaying the measuring value during monitoring.

You can press the Power button to switch to displaying the time and battery level.

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;

Usually, the readings will recover in a few seconds when at rest.

3.8.Bluetooth Connection

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

To establish a Bluetooth connection,

1) Keep the device on.
2) Make sure the phone Bluetooth is enabled.
3) Run the App and follow the on-screen instructions.

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

3.9.Reminder on Device

The device supports audible reminders triggered by user-defined SpO_2 or Heart rate threshold.

You can setup the reminder threshold on App.

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.
	Software exception	Press and hold 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

For more information about Oxyfit, please visit:

https://getwellue.com/pages/faqs

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	28 g
Size	38×30×38 mm
Battery	3.7Vdc, Rechargeable Lithium-polymer
Charge requirement	DC 5V, 1A
Charge time	2-3 hours
Battery life	12-14 hours for typical use
Wireless	Bluetooth 4.0 BLE
Oxygen level range	0% to100%
SpO_2 accuracy (Arms)	70-100%: ±2% (Arms:1.88); 70-80%: ±3%; 80%-90%:±2%; 90%-100%: ±2%; 0%-69%: not defined.
Pulse Rate range	30 to 250 bpm
Pulse Rate accuracy	±2 bpm or ±2%, whichever is greater
A functional tester or SpO_2 simulator can be used to determine the pulse rate accuracy.	
Wavelength / Max emission power	660nm/940nm, 0.8mW/1.2mW
Beep reminder source	low oxygen level; high/low pulse rate
Recorded parameters	Oxygen level, pulse rate
Record interval	4s
Data storage	4 sessions, up to 1 hours for each

Frequency range	2.402 – 2.480 GHz
Max RF power	-10 dBm
Expected service life	5 years

7. 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	<5% UT (>95% dip in UT) for 0.5 cycle <40% UT	N/A	N/A

voltage variations on power supply input lines IEC61000-4-11	(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		
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
			Portable and mobile RF communications equipment should be used no closer to

Conducted RF IEC61000-4-6 Radiated RF IEC61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	N/A 3 V/m	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.
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 $d=2.3\sqrt{P}$

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