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 Pulse Oximeter is intended to be used for measuring, displaying and storing of pulse oxygen saturation (SpO_2), pulse rate of adults in home or healthcare facilities environment.
Intended users: adults.

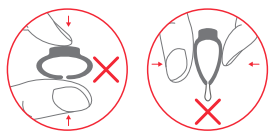
1.2.Name and Model

Name: Pulse Oximeter
Model:PO2, PO2A, PO2S
Model difference description:

Model	Appearance color	Charging	Finger sleeve size
PO2	Blue	Micro USB	M
PO2A	Orange	Micro USB	M
PO2S	Silver	Micro USB	M

1.3.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 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.
- Check the SpO_2 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.
- Continuous use for a long time may cause allergies, redness, blistering or burns. Check the wearing position every 6-8 hours.
- Please keep the cable away from children. It can cause strangulation.
- Keep the device out of reach of pets, pests and children.
- Do not disassemble or modify the product without authorization.
- Laptops should meet the IEC60950 and IEC 62368-1 standards.
- Power adapters should be 5V, 1A or higher and meet the EN/IEC 60601-1 requirements.
- When the signal is incomplete (e.g., excessive signal noise, poor signal quality, or signal loss), the blood oxygen and pulse rate display values will become invalid, i.e., the values will disappear and the display will show '--'.
- The device must be left to stabilize at 20°C for 1 hour after being removed from minimum or maximum storage temperature conditions before normal use.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

1.4.Clinical Benefit

Clinical Benefits: Providing the measurement of both the pulse oxygen saturation (SpO_2) and pulse rate data for adult patients in homes and medical clinics.

1.5. Contraindications

No contraindications.

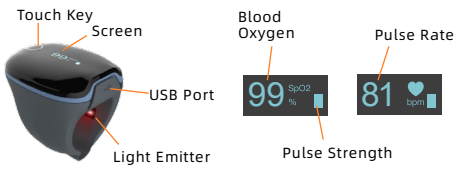
1.6. Guide to Symbols

Symbol	Description
	Manufacturer
	Date of manufacture
SN	Serial number
UDI	Unique device identification
	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	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°.
	Caution
	General warning sign
CE 0197	Indicates that the product complies with the EU Medical Device Regulations(Regulation (EU) 2017/745)
MD	Medical device
EU REP	Authorized representative in the European community
UK CA	UKCA marking
UK REP	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

1.7.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 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 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 be caused by:

- Excessive movement;
- Poor signal, finger is too cold;

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



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 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.



3.10 Cybersecurity

1) The device can transmit clinical data (SpO_2 data) from the subject device to a wireless receiver for storage and display. The common receiver is APP software. So it is needed to install international mainstream anti-virus software such as AVG, Avast, McAfee, etc. In the running environment, even update the virus upgrade package in time and scan for viruses. For IOS system, the APP can run without antivirus software and firewalls because the closed system and access control of the system. The end user needs to select the device ID before they want to conduct Bluetooth connection.
2) In order to support the cybersecurity of this device, we provide information about the risk management with regards to cybersecurity which includes the assets, vulnerabilities, threats and controls. If you have any problems, please contact us.

Identification	Risk Description	Impact
Threats	CR1: Malicious attack such as Counterfeit command	Maybe the device failed to use and the treatment is delayed.
	CR2: Malicious attack such as Violent login attempt / password guessing attack	Maybe the treatment is delayed.
	CR3: Sensitive information including health data and the user information leakage	Maybe Tampering and Embezzlement of the user' information.
	CR4: Wrong operation of critical and/or sensitive information by authorized users	Maybe Tampering and Embezzlement of the user' information.
	CR5: Improper Authority Setting	Maybe the device failed to use.
Vulnerabilities	CR6: Access without authentication	Maybe the device failed to use.
	CR7: Sensitive information with encryption	Maybe the user' data is lost or stolen.
	CR8: Sensitive information with integrity	Maybe the user' data is lost or stolen.
Assets	CR9: Information Assets: Patient data; Device settings; Health data; Connection ID	Maybe the health data is revised or lost.
	CR10: Physical Assets :User interface; Network interface; Device assets (Operating system, Software etc.)	Maybe the device failed to use.

3) The device only includes the embedded software. The firmware is directly coded into the integrated system with on circuit unchangeable package. There is no software transferring during production or distribution. The manufacturer does the burning and upgrading of the subject device software and there is no case of being attacked by malware. Then installing antivirus software and firewalls in the device is unnecessary.
4) The manufacturer regularly checks whether the released app software is the latest version, whether it can be downloaded and installed, and whether the software is attacked (MD5 hash value verification) to ensure software integrity and authenticity.
5) All updates and patches will be released to customer through distributors or by Viatom. A release note or letter will be issued and the version number will be changed accordingly.
6) Device software upgrade can be done remotely through our APP. When the device is connected to the APP, the APP will check the software version of the device, and when a new available version is found, an upgrade button will pop up and the user will authorise the upgrade operation.
APP software, when there is a new available update, When the user opens the APP the APP will send an update alert to the user, if there is no update, the APP will not work.
7) Before discarding the device, it needs to be ensured that all health measurements and user account data stored in the device and the app are secure and confidential (e.g. deleted).
8) The user manual describes the function of the Bluetooth output interface of the device, the function of the Bluetooth input interface of the APP, and the user registration function of the APP.

4. Installation the App

4.1 Download the App

App name: ViHealth Mobile
App Version: V2
iOS: App Store
Android: Google Play
Notice:

- Please download and obtain the APP from the official application shop.
- The mobile phone device prohibits the installation of any APP from illegal sources, and all Apps are recommended to be downloaded from official shops.
- Upgrade the operating system in time according to the official recommendations.
- List of compatible devices:

For iOS devices:
The operating system must be iOS 13.0 or above.
For Android devices:
The operating system must be Android 5.0 or above.

4.2 Install the App

Install the app on an Apple product or Android-powered device, including smart phones and tablets.

5. Using the App

5.1 Preparing to Start

1.Make sure that Bluetooth is enabled on your smart device and run ViHealth.
2.Turn on the Pulse Oximeter and make sure the screen light is on during the connection.

5.2 Connecting to the device

1.Click the device icon when ViHealth finds your Pulse Oximeter.



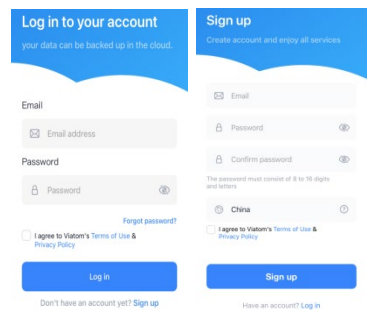
2.Follow the screen guide to start pairing.



3.Once paired, you can log onto ViHealth. The next time you use it, you can select your Pulse Oximeter from the connected devices list.

5.3 Sign up or log in the APP

1. In order to enter the main screen, you could select "an offline mode" when adding a new device, or after you have added a new device.
Then, you could select the "Settings". Follow the screen guide to start signing up.



2. When you have signed up, could select the "Settings". Follow the screen guide to start signing in.

5.4 Transfer Data

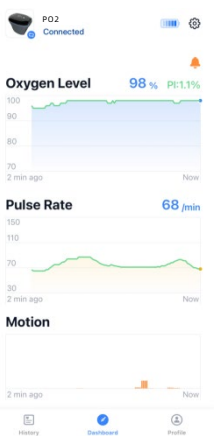
The Pulse Oximeter will automatically transfer the latest data to ViHealth every time it connects.

5.5 Screen Symbol & Label

Item	Description
O_2	O2 Score: The O2 score for analyzed recording data.
	Lowest SpO2: The lowest SpO2 value during the recordings.
Start time	The time to start recording the oxygen level
Recording Time	Duration of the record.
<90% Time	Duration for when oxygen level values drop below 90%.
Oxygen level range	The Oxygen level range during the recordings
Pulse rate range	The Pulse rate range during the recordings
Oxygen level Distribution	The Oxygen level Distribution during the recordings
Pulse rate Distribution	The Pulse rate Distribution during the recordings
Lowest SpO_2	The lowest SpO_2 value during the recording.

5.6 Real-time Monitoring

The ViHealth app supports monitoring SpO2 and P real-time on the Dashboard screen.



5.7 Review Measured Values

To review the measured values from a certain moment during the recording :

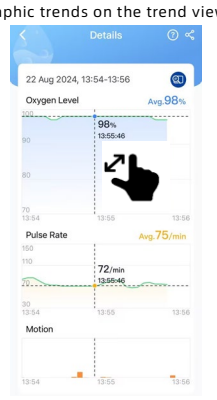
1.Click the icon on the bottom-right corner of the screen.



2.Move the cursor, and the measured value the cursor hovers over will be displayed.

5.8 Zoom Graphic Trends

You can use pinch or spread your fingers to zoom in and out from the graphic trends on the trend view area.

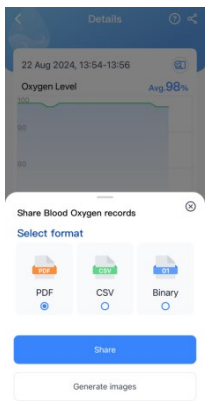


5.9 Share Recordings

To share the current recording and information to your doctor or friends:

1.Click the icon on upper-right corner of the screen.

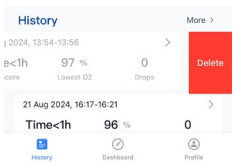
2.Choose the option as you desired.



5.10 Delete Recordings

To delete a recording:

1. Use gestures to swipe left on the record.
2. Choose “Delete” to delete the current recording.



Note: To check the ViHealth app version, tap **Settings > About ViHealth**. To check the device firmware version, tap **My device**.

6. 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.

7. Maintenance

7.1.Time & Date

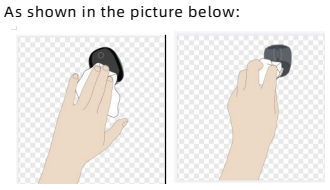
After connection with App, device time will sync from your phone time automatically.

7.2.Cleaning

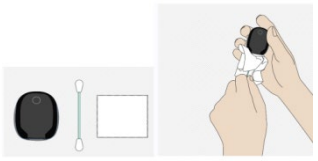
Use a soft cloth moistened with water or alcohol to clean the device surface.

7.3.Disinfection

Use 75% alcohol wipes to clean the screen of the device and the crevices and around the edges of the device, and then let it air dry. As shown in the picture below:



Use 75% alcohol wipes to clean the SpO2 sensor carefully, and then let it air dry. As shown in the picture below:



CAUTION: To avoid permanent damage to the device, do not use petrol, thinners or similar solvent.

CAUTION: After cleaning, check the surface and, the interiors of the Finger Nail Position and especially the Lighting Position under using a magnifying glass or sufficient light.

CAUTION: If dirt is found, please repeat the above steps using a fresh wipe.

CAUTION: If you find that the surface or inside of the finger cover is cracked or the product cannot be turned on, please contact us immediately.

The device is a non-sterile medical device and does not contain any sterile or degradable component thus the device is not subject to the shelf life requirements.

In order to ensure its long service life, please pay attention to the maintenance.

7.4.Battery

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

8. 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.
The device screen displays “Error 1”.	Errors occur during data analysis.	Connect the power supply and plug in the charging cable, press and hold the touch key for 3s to reset the hardware.

For more information about O2RIng, please visit:
https://getwellue.com/pages/faqs

9. Specifications

Environmental	Operating	Storage
Temperature	5 to 40°C	-25 to 55°C
Relative humidity (non-condensing)	10% to 80%	10% to 93%
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	38mm×30mm×38 mm	
Battery	3.7Vd.c.,Rechargeable Lithium-polymer	
Charge time	2-3 hours	
Charge requirement	DC 5V 1A	
Battery life	12-14 hours for typical use	
Wireless	Bluetooth 4.2 BLE	
Oxygen level range	0% to 100%	
SpO2 Accuracy (Arms)	70-100%:±2%(Arms:1.77); 70-80%: ±3%; 80%-90%:±2%; 90%-100%:±2% 0%-69%: not defined	
Pulse Rate range	25 to 250 bpm	
Pulse Rate accuracy	±2 bpm or ±2%, whichever is greater	
A functional tester or SpO_2 simulator (Model: PRONK TECHNOLOGIES OX-1) can be used to determine the pulse rate accuracy.		
Vibration source	low oxygen level; high/low pulse rate	
Recorded parameters	Oxygen level, Pulse Rate	
Data storage	4 sessions, up to 10 hours for each	
Data update period	< 10s	
Frequency range	2.402-2.480GHz GFSK Modulation Adaptive Frequency Hopping (AFH)	
Wireless Quality of Service (QoS)	Transmission Distance: 1.5m Transmission Time: ≤10s Data integrity: 100%	
Network topology	Point-to-Point	
Band width	1Mbps	
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±5nm/940nm±10nm, 0.8mW/1.2mW	

10. Appendix EMC

The equipment meets the requirements of IEC 60601-1-2:2020.

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.
Radiated RF IEC61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	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 $d=2.3\sqrt{P}$
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.

Shenzhen Viatom Technology Co., Ltd.
901, Building West, Lepu Tower, No.66 Xingke Road, Xili Community, Xili Street, Nanshan District, Shenzhen, 518055, Guangdong, P.R. China
www.viatomtech.com

EU REP
MedNet EC-REP GmbH
Borkstrasse 10, 48163 Muenster, Germany
Tel: +49 251 32266-0
Fax: +49 251 32266-22
Email: contact@mednet-ecrep.com

UK REP
MediMap Ltd
2 The Drift, Thurston, Suffolk IP31 3RT, United Kingdom
Tel: +49 251 32266-0
Fax: +49 251 32266-22
Email: contact@mednet-ecrep.com

CE 0197 UKCA

FR
Vous êtes responsable de remettre tous les appareils électriques et électroniques usagés à des points de collecte correspondants.
Pour en savoir plus:
www. quefairedesmesdechets.fr

Product name: Pulse Oximeter
Version: V1.0 Date: May 2026 PN: 256-000238-00