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		User's manual- Pulse Oximeter	
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Pulse Oximeter



User Manual

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1. The Basics

This manual contains the instructions necessary to operate the product safely and in accordance with its function and intended use. Observance of this manual is a prerequisite for proper product performance and correct operation and ensures patient and operator safety.

1.1 Safety



Warnings and Cautionary Advices

- 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, 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.
- This device is not intended for use by people (including children) with restricted physical, sensory or mental skills or a lack of experience

and/or a lack of knowledge, unless they are supervised by a person who has responsibility for their safety or they receive instructions from this person on how to use the device.

- 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.
- Vital signs measurements, such as those taken with this device, cannot identify all diseases. Regardless of the measurement taken using this device, you should 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.
- Replacing batteries without proper training can be dangerous (e.g., overheating, fire, or explosion).
- The built-in rechargeable lithium-ion battery cannot be replaced. Non-professionals should not open the casing, modify or replace the battery.
- Maintenance personnel or prospective operators can replace the charging cable themselves.
- Instrument repair is limited to qualified repair personnel designated by the manufacturer. Users are not permitted to repair the instrument themselves. The manufacturer may provide repair personnel with a repair manual containing circuit diagrams, component lists, illustrations, calibration details, and other relevant information required for repair.
- 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 '--'.
- Do not disassemble or modify the product without authorization.

1.2 Contraindications

No contraindications.

2. Introduction

2.1 Name and Model

Name: Pulse Oximeter

Model: Oxiband01, Oxiduck, Oxiband, Oxiduckm, Oxiultra, Oxiultra01, Oxiducku, Oxiduckp

Model difference description:

Model	Charging	Wristband Color	Probe
Oxiband	Micro D	Black	Ring
Oxiband01	Micro D	Blue	Ring
Oxiultra	Magnetic	Black	Ring
Oxiultra01	Magnetic	Blue	Ring
Oxiduck	Micro D	Blue	Duckbill
Oxiduckm	Micro D	Black	Duckbill
Oxiducku	Magnetic	Black	Duckbill
Oxiduckp	Magnetic	Blue	Duckbill

[Oxiband, Oxiduckm: FCC ID:2AD XK-1680](#)

[Oxiband01, Oxiduck: FCC ID:2AD XK-1681](#)

[Oxiultra, Oxiultra01, Oxiducku, Oxiduckp: FCC ID:2AD XK-1682](#)

2.2 Intended Use

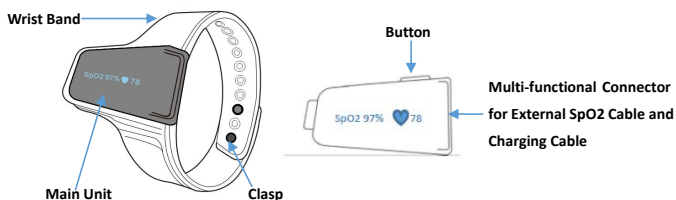
The Pulse Oximeter is intended to be used for measuring, displaying and storing of pulse oxygen saturation (SpO2) and pulse rate in home or healthcare facilities environment.

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

Intended users: adult and pediatric patients.

2.3 How the Oxiband Wrist Pulse Oximeter Works

The Pulse Oximeter measures the oxygen saturation and pulse rate. The Oxiband works by shining two beams into the small blood vessels or capillaries of finger, reflecting the amount of oxygen in the blood and displaying the measurement.



2.4 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°.
	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences
	Indicates that the product complies with the EU Medical Device Regulations(Regulation (EU) 2017/745)
	Medical device
	Authorized representative in the European community
	UKCA marking
	UK Responsible Person
	Authorized Representative in Switzerland
	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

3. Using the Monitor

3.1 Prior to Use

Before using Oximeter, pay attention to the following points in order to obtain precise measurements.

- The finger inserted in SpO2 sensor must be clean to ensure proper reading.
- 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.
- Do not use this device during low perfusion.
 - The Oximeter may not work if you have poor circulation. Rub your finger to increase circulation, or place the SpO₂ sensor on another finger.
 - The Oximeter measures oxygen saturation of functional hemoglobin. High levels of dysfunctional hemoglobin (caused by sickle cell anemia, carbon monoxide, etc.) could affect the accuracy of the measurements.
 - 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 towers, and TV broadcast towers may affect accuracy.



Warnings and Cautionary Advices

- Use only cables, sensors and other accessories specified in this manual.
- The device has no alarms and will not sound if the measurement reading is too low or too high.
- Limit finger movement as much as possible when using the Oximeter, which might result in incorrect reading or analysis.
- Do not use the Oximeter on the same hand/arm when using a blood pressure cuff or monitor.
- Do not use the Oximeter outside the specified operating and storage temperature ranges.
- Prolonged continuous SpO₂ monitoring or sleep monitoring may increase the risk of undesirable changes in skin characteristics, such as irritation, reddening, blistering or burns.
- 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 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.

3.2 Unpacking

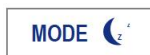
- Main Unit × 1
- SpO2 Sensor × 1
- Charging Cable × 1
- User Manual × 1

3.3 Overview



1. Pulse oximeter
2. Wristband
3. Sensor interface / charging interface
4. Power button
5. SpO2 sensor

Screen display item description for model Oxiband01, Oxiduck:



Sleep Mode



Monitor Mode



Pulse rate in Sleep Mode



Steps



O2 Score, SpO2 drop times

Screen display item description for model Oxiband01, Oxiduck, Oxiband, Oxiduckm, Oxiultra, Oxiultra01, Oxiducku, Oxiduckp:

SpO2	SpO2
	Pulse rate
	Wear the sensor
19:30	Time
	Remaining battery capacity
	Bluetooth is connecting

During measurement, press the button, you can switch different displays.

3.4 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.

3.5 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.

3.6 Initial Settings

After Bluetooth paired, you can follow the instructions in the APP to set your target step numbers, switch on/off the vibration, adjust the vibration intensity and the lowest SpO2 threshold (default is 90%) to set up your Oxiband wrist pulse oximeter.

3.7 Data storage

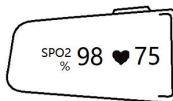
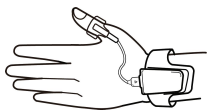
The device can store 4 measurement results, and the result which measured shorter than 2 minutes will not be stored.

3.8 Take the first recording

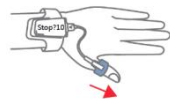
START. Wear the device and the Ring Sensor, press the button to power on. And keep yourself in the quiet environment.

(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.

3.9 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.

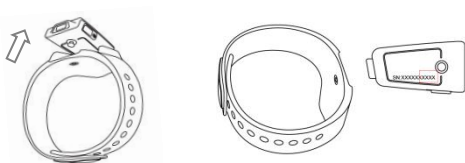


Note: Refer the ViHealth app manual for more

details.

3.10 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.

3.11 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.

3.12 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+. Refer the ViHealth app manual for more details.

3.13 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.

3.14 PC software

3.13.1 Download the PC Software

PC Software: **O2 Insight Pro**

Download from: getwellue.com/pages/pc-software

Install the software on Windows PC or Mac.

3.13.2 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.

3.13.3 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.

3.13.4 Cybersecurity

- 1) The device can transmit clinical data (SpO₂ 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 need 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	Maybe the device failed to

	Setting	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.

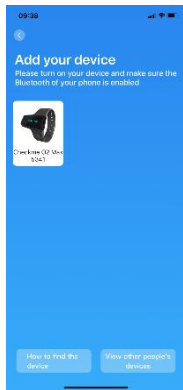
4 Using the App

4.1 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.

4.2 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.

4.3 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.

The image shows two side-by-side screenshots of the Viatom app's login and sign-up screens. The left screen, titled "Log in to your account", has a blue header with the text "your data can be backed up in the cloud." Below this are input fields for "Email" (with an envelope icon) and "Password" (with a lock icon). There is a "Log in" button at the bottom and a "Sign up" link. The right screen, titled "Sign up", has a blue header with the text "Create account and enjoy all services". It includes input fields for "Email", "Password", and "Confirm password", along with a "Country" dropdown menu. There is a "Sign up" button at the bottom and a "Log in" link.

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

4.4 Transfer Data

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

4.5 Screen Symbol & Label

Item	Description
	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 SpO2	The lowest SpO2 value during the recording.

4.6 Real-time Monitoring

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



4.7 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.



4.8 Zoom Graphic Trends

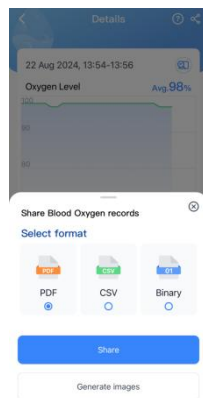
You can use pinch or spread your fingers to zoom in and out from the graphic trends on the trend view area.



4.9 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.



4.10 Delete Recordings

To delete a recording:

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



5 Using

5.1 Take a Measurement

To start a Oximeter measurement,

1. Connect the external SpO₂ sensor to the multi-functional connector.
2. Slide your index finger from either hand into the external SpO₂ sensor as pictured.

5.2 Switch Mode (Applicable only for Oxiband01, Oxiduck)

When turn on the device, screen shows the real time, working mode and battery capacity.

The device have two mode, Sleep Mode and Living Mode:



Sleep Mode



Living Mode

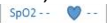
Press the button can change between this two modes, when you turn on the device next time, it will show the mode you set last time. Please note that O2 has only sleep mode.

	Sleep mode	Living mode
Parameters	SpO ₂ , PR, Movement	SpO ₂ , PR, Movement, Steps
Data storing interval	5s/10s self-adaptive	10s fix
Bluetooth	Off	On
Battery working time	>10 hours	>5 hours

5.3 Sleep Mode (Applicable only for Oxiband01, Oxiduck)

There are two statuses under sleep mode, normal state and hibernation. When it is in normal state, the screen shows the result of SpO₂ and pulse rate, while in hibernation, it does not light up.

The device turns on with normal state, 2 minutes later it goes into hibernation automatically. Press the button can change display between measurement result  and sleep mode , and the screen will goes out when there is no operation for 3 seconds.

1. In normal state, when there is no measurement result, the screen will show . When measurement result comes out, the screen will show .
2. In sleep mode, when the sensor slips from your finger, or the plug falls from the device, it shows as below and starts countdown from 10 seconds.
 
3. If you did no operation in 10S, it will stop measurement automatically and show the O2 score and how many times the SpO2 lower than threshold. It will automatically power off after it shows for 2 minutes if you don't put on the sensor or insert the plug.


5.4 Living Mode (Applicable only for Oxiband01, Oxiduck)

The Bluetooth will open continuously in living mode, and mirrors the result to APP in your phone.

Turn on the device, press the button can change display among measurement results , step numbers , and living mode .

1. In living monitor mode, when the sensor slips from your finger, or the plug falls from the device, it shows as below and starts countdown from 30 seconds.
 
2. If you did no operation in 30S, it will stop measurement automatically.

6 Maintenance

Warnings and Cautionary Advices

- Have the device repaired by authorized service centers only, otherwise its warranty is invalid.

6.1 Warranty

The product is warranted to be free from defects in materials and

workmanship within warranty period when used in accordance with the provided instructions.

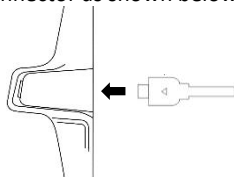
6.2 Battery

On-screen battery symbols indicate the battery status as follow:

-  The battery is fully charged.
-  The solid portion represents the remained battery energy. If the solid portion moves from left to right, then it means that the battery is being charged.
-  Indicates that the battery is almost depleted and need to be charged immediately. Otherwise the device will shut down automatically.

To charge the battery,

1. Connect the smaller end of the USB charging cable to the multi-functional connector as shown below.



2. Connect the other end of the USB charging cable to the USB charging port.



Warnings and Cautionary Advices

- The device cannot be used for any measurement during charging.
- Use charging adapter provided by manufacturer, or USB charging devices which comply with the standard IEC 60950 or IEC60601-1.

6.3 Cleaning and Disinfection

The device can be reused. Please clean and disinfect it before use, or as dirty.

Based on the patient contact, the device is considered a non-critical device and should be cleaned thoroughly and subjected to low-level disinfection depending on the nature and extent of contamination.

WARNING: Before cleaning and disinfection, please close the charging port cover, and be careful to avoid wetting it or letting liquid into it.

CAUTION: Thoroughly clean and low level disinfect the device before applying it to on a new patient.

CAUTION: It is recommended that clean and low level disinfect once before use.

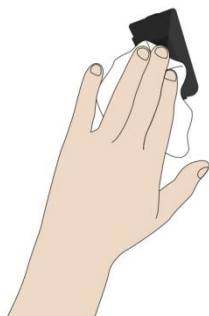
5.3.1 Cleaning

- Visibly wet the outer surfaces using a dampened soft cloth with clean water or soapy water, and dry with a piece of cloth, or until the surfaces are free of any visible residue.

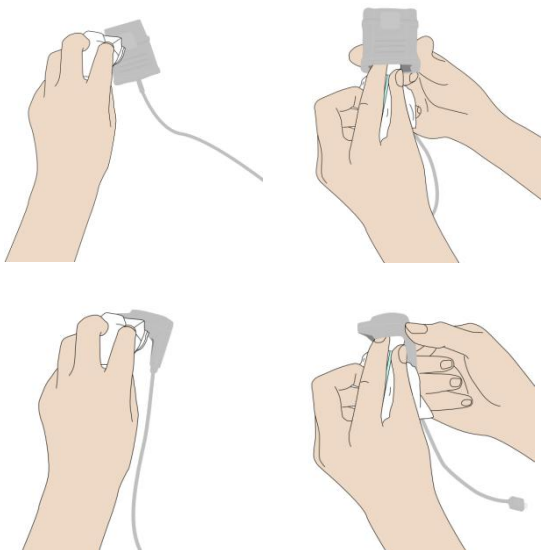
5.3.2 Disinfection

- 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.

6.4 Use Life

The use life of this device is 3 years.

Note:

- Due to the variety of daily use, the use life may vary.
- If a visual inspection reveals cracks on the surface or inside of the finger sleeve or the product fails to turn on, please contact us immediately.

6.5 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	Please contact your local

	damaged.	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 in Sleep Mode.	Press the button, the Bluetooth will be turned on when the screen lights up.
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.
The device screen displays "Error 4".	Sensor error.	Please re-plug the sensor.

7 Specifications

Classifications		
EU Regulation / EC Directive	MDR, EU 2017/745	
	RED, 2014/53/EU	
Degree protection against electrical shock	Type BF	
Environmental		
Item	Operating	Storage
Temperature	5 to 45°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	Oxiband01,Oxiduck:12g Oxiband,Oxiduckm: 18g Oxiultra,Oxiultra01,Oxiducku,Oxiduckp:23g	
Size	Oxiband01,Oxiduck:48×25×15mm Oxiband,Oxiduckm: 51×30×18mm Oxiultra,Oxiultra01,Oxiducku,Oxiduckp:55×30×22mm	
Display	OLED	
Connector	Micro D connector	
Wireless	Oxiband01,Oxiduck:Bluetooth 4.0 BLE Oxiband,Oxiduckm,Oxiultra,Oxiultra01,Oxiducku,Oxiduckp:Bluetooth 5.1BLE	
Power Supply		
Charge input:	DC 5V ±10%	
Battery type	Rechargeable lithium-polymer battery Oxiband01,Oxiduck:3.7Vdc, 130mAh Oxiband,Oxiduckm: 3.8Vdc, 370mAh Oxiultra,Oxiultra01,Oxiducku,Oxiduckp:3.8Vdc, 500mAh	
Battery run time	Oxiband01,Oxiduck: > 16 hours Oxiband,Oxiduckm: > 52 hours Oxiultra,Oxiultra01,Oxiducku,Oxiduckp: > 95 hours	
Charge time	Less than 2 hours to 90%	
SpO ₂		

Standards	Meet standards of ISO 80601-2-61	
Measurement accuracy verification: The SpO ₂ accuracy has been verified in human experiments by comparing with arterial blood sample reference measured with a CO-oximeter. 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.		
SpO2 range	0% to 100%	
SpO2 Accuracy (Arms)	Display Range	Accuracy (Arms)
	70% to 100%	±2% (Arms:1.866)
	90-100%	±2%
	80-90%	±2%
	70-80%	±3%
	0%-69%	not defined
PR range	30 to 250 bpm	
PR accuracy	±2 bpm or ±2%, whichever is greater	
Wavelength / Max emission power	660nm/940nm, 0.8mW/1.2mW	
Bluetooth RF		
Frequency range	2.402-2.480 GHz 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	
Storage		
Capacity	Oxiband01,Oxiduck: 4 records,10 hours for each Oxiband,Oxiduckm: 4 records,10 hours for each Oxiultra,Oxiultra01,Oxiducku,Oxiduckp: 4 records,12	

	hours for each
Record	
Record parameters	SpO ₂ , pulse rate
Record interval	1s
Use life	
Expected use life	3 years
Accessory	
SpO ₂ sensor	Oxiband,Oxiband01,Oxiultra,Oxiultra01:FP-10R Oxiduck,Oxiduckm,Oxiducku,Oxiduckp:FP-10RH
Data update period	Oxiband01,Oxiduck: ≤21s Oxiband,Oxiduckm: ≤18s Oxiultra,Oxiultra01,Oxiducku,Oxiduckp: ≤16s

8 FCC Statement

FCC WARNING

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.

Note: The Grantee is not responsible for any changes or modifications not expressly approved by the party responsible for compliance. Such modifications could void the user's authority to operate the equipment. The device has been evaluated to meet general RF exposure requirement.

This equipment complies with FCC's RF radiation exposure limits set forth for an uncontrolled environment. This device and its antenna(s) must not be co-located or conjunction with any other antenna or transmitter.

9 Electromagnetic Compatibility

The device meets the requirements of EN/IEC 60601-1-2. All the accessories also meet the requirements of EN/IEC 60601-1-2 when in use with this device.



Warnings and Cautionary Advices

- 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).
- Electromagnetic fields avoid using the product near strong radio frequency (RF) signals or portable and/or mobile RF devices and/or specific RF emitters that are known sources of electromagnetic disturbance such as diathermy, electrocautery, RFID, security systems (e.g., electromagnetic anti-theft systems, and metal detectors). Interference from hidden RF emitters like RFID might cause packet loss and this will be visible as a “Poor Bluetooth Signal” message on the mobile application. Move away from the hidden RF emitter if this happens.

Essential Performance		
Essential Performance		The description of what the operator of the device can expect if the Essential Performance is lost or degraded due to electromagnetic disturbances
Oxygen level range	0% to 100%	Please stop using the device immediately and contact the device manufacturer or distributor for service as soon as possible
SpO ₂ Accuracy	70%-100%: $\pm 2\%$ (Arms:1.866%)	
	70%-80%: $\pm 3\%$	
	80%-90%: $\pm 2\%$	
	90%-100%: $\pm 2\%$	
	0%-69%: not defined	
Pulse Rate range	30 to 250 bpm	
Pulse Rate accuracy	± 2 bpm or $\pm 2\%$, whichever is greater	

Guidance and Declaration - Electromagnetic Emissions		
The Health Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emission tests	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	Class A	
Voltage Fluctuations / Flicker Emissions IEC 61000-3-3	Complies	

Guidance and Declaration - Electromagnetic Immunity			
The Health Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Health Monitor should assure that it is used in such an environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV 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 IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	
Voltage dips, short Interruptions and Voltage variations on power supply input lines IEC 61000-4-11	<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	<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	Mains power quality should be that of a typical commercial or hospital environment. If the user of our product requires continued operation during power mains interruptions, it is recommended that our product be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the AC mains voltage prior to application of the test level.			

Guidance and Declaration - Electromagnetic Immunity			
The Health Monitor is intended for use in the specified electromagnetic environment. The customer or the user of the Health Monitor should assure that it is used in such an environment as described below.			
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 0.15MHz and 80MHz)	3 Vrms 150 kHz to 80 MHz (6V in ISM and amateur radio bands between 0.15MHz and 80MHz)	Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter. Recommended separation distances: $d = 1.2\sqrt{P}$
Radiated RF IEC61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	Recommended separation distances: 80 MHz~800 MHz: $d = 1.2\sqrt{P}$ 800MHz-2.5GHz: $d = 2.3\sqrt{P}$ 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 meters (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: 
Note 1: At 80 MHz to 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.			
^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, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device. ^b Over frequency range 150kHz to 80MHz. For Resp field strength should be less than 1V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the device

The Health Monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Health Monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the monitor as recommended below, according to the maximum output power of the communications equipment.

Rated max. output power of transmitter (W)	Separation distance according to frequency of the transmitter (m)		
	150 kHz - 80 MHz $d = 1.2\sqrt{P}$	80 MHz - 800 MHz $d = 1.2\sqrt{P}$	800 MHz - 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.20	1.20	2.30
10	3.80	3.80	7.30
100	12.00	12.00	23.00

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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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