Pulse Oximeter

Model:Night O2

User Manual

Content

Revision History

This manual has a revision number. This revision number changes whenever the manual is updated due to software or technical specification change. Contents of this manual are subject to change without prior notice.

- Version: A0
- Release time: 2026/08/07

Contact Information

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1 Introduction

1.1 Intended Use

The device is intended to be used for measuring, displaying and storing of oxygen level (SpO2), pulse rate(PR) 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 is not intended for diagnosis or treatment purpose, always consult your doctor for any health condition.

1.2 Warnings and Cautions

(1) DO NOT squeeze the sensor or apply excessive force on the sensor & cable.
(2) Do not use this device during MRI examination.
(3) Do not use the device together with a defibrillator.
(4) Do not operate the device in flammable and combustible environments.
(5) Do not drop the device or subject it to strong impact or collision.
(6) The device and its supplied accessories are non-sterile upon delivery.
(7) Never submerge the device in water or other liquids. Do not clean the device with acetone or other volatile solutions.
(8) Do not place this device in pressure vessels or gas sterilization device.
(9) The device cannot function as an apnea monitor and must not be used for arrhythmia analysis.
(10) The device has no visual alert or audible alarm functions and does not support continuous monitoring.
(11) Consult your doctor immediately if you experience symptoms that could indicate acute disease.
(12) 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.
(13) Use only cables, sensors and other accessories specified in this manual.
(14) Prolonged continuous oxygen level recording may increase the risk of undesirable changes in skin characteristics, such as irritation, reddening, blistering or burns.
(15) Check the oxygen level(SpO2) sensor application site every 6-8 hours to determine the positioning of the sensor and the circulation and skin sensitivity of the user. User sensitivity varies depending on medical status or skin condition. For users with poor peripheral blood circulation or sensitive skin, inspect the sensor site more frequently.
(16) Functional tester cannot be used to assess the accuracy of a SpO2 sensor or a device.
(17) Do not disassemble the device without permission; unauthorized disassembly will lead to device damage, malfunction and abnormal operation.
(18) 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

1.3 Symbols

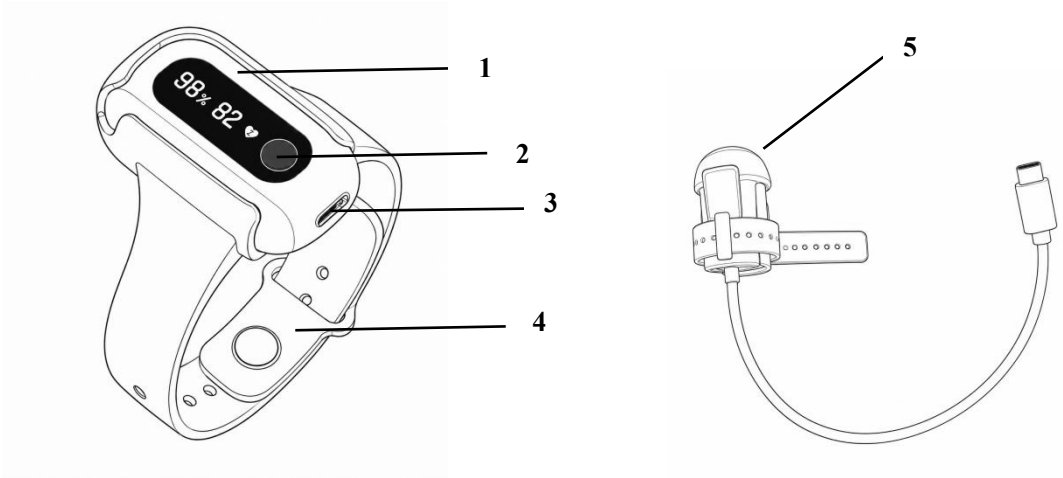
Symbol	Description	Symbol	Description
	Manufacturer		No alarm system
	Date of Manufacture		Indicates that the product complies with the applicable FCC requirements
	Batch code		Non-ionizing radiation
	Serial Number		Humidity Limitation
	Type BF-Applied Part		Temperature Limitation
IP22	Indicates that 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°		Atmospheric Pressure Limitation
	Refer to User Manual		Indicates that the marked item or its material is part of a recovery or recycling process
	Indicates that the product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling		MR unsafe

1.4 Unpacking

Main Unit(with band) × 1, SpO2 Sensor × 1 , Type-C Charging Cable × 1 , User Manual × 1

2 Product operation

2.1 Overview



1.Main unit
2. Power button
3. Type C:Sensor interface / charging interface
4. Wristband
5. SpO2 sensor (Multiple sensor models are available; please refer to the supplied physical sensor.)

Screen display item description:

%	Oxygen Level(SpO2)
	Pulse Rate(PR)
19:30	Time
	Remaining battery capacity
	Please insert the SpO2 sensor
	SpO2 Sensor is connected
	Bluetooth is connecting
LOW BAT CHARGE	Low-battery indicator

2.2 Download APP

App name: YiMi Health

iOS: App Store

Android: Google Play

- **Compatibility**

The device is compatible with iOS versions 16.0+ and Android versions 9.0+. Refer to the YiMi Health App manual for more details.

2.3 Bluetooth Connection

The device Bluetooth will be enabled automatically when the device is on.
To establish a Bluetooth connection:

1) Keep the device Bluetooth enabled.
2) Make sure the phone Bluetooth enabled.
3) Run the App.

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

2.4 Charging

1) Charge the battery before using.
2) Use the charge cable to charge the battery of device in the USB Port of the computer or with USB charging adapter.
3) After being fully charged, the device will display the full-battery icon.

2.5 Power ON/OFF

1) POWER ON:

Press the button for 3 seconds to turn on the device.

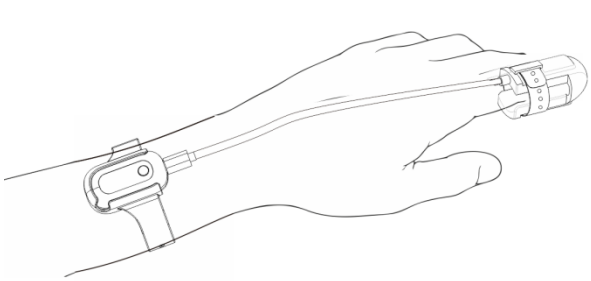
2) POWER OFF:

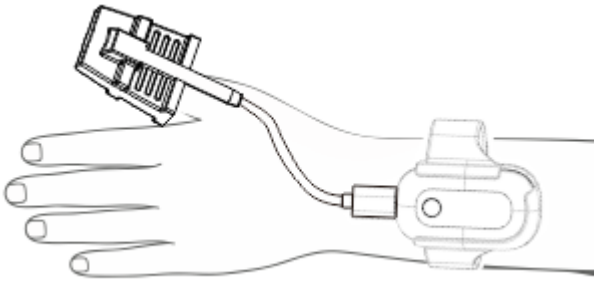
- Automatically power off: The device will turn off automatically in 1 minute if no measurement, no operation or without App connection.
- Manually power off: You can press the button for about 3 seconds to turn off.

2.6 Take the first recording

1) **START:**Wear the device and the SpO2 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 SpO2 sensor on the finger.(**If it is too tight, try another finger. Avoid being loose.**)





2) **STOP:**After the record, take off the SpO2 Sensor (and the device), the recording will be saved after the countdown.

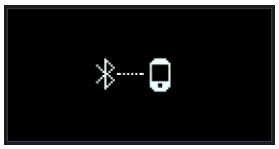
Note:

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

2.7 Stop monitoring & sync data

1) Take off the sensor, the countdown will begin.
2) During the countdown, if you wear the sensor again, the record will be resumed.
3) After the countdown, the data will be ready for sync.

Sync data to the YiMi Health App:



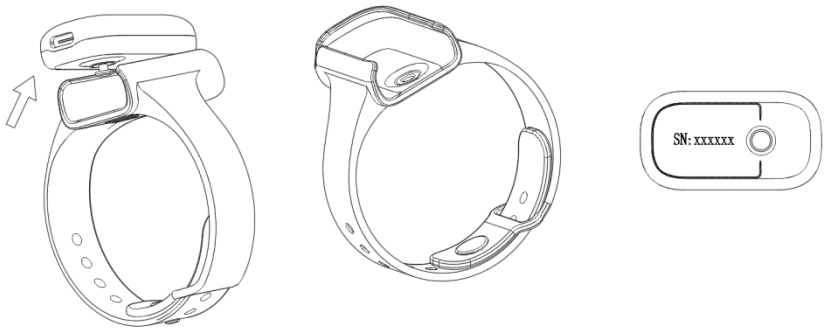
1) After the countdown,run App sync data;
2) OR next time after you turn on the device,run App to sync.

Note:

- The device saves one valid SpO2 record every 4 seconds. The duration of a single SpO2 data recording ranges from 4 seconds to 24 hours.
- The built-in memory of the device can collect and store maximum 4 recordings,24 hours for each. The oldest will be overwritten by the 5th. Please sync data to your phone in time.
- Refer to the YiMi Health App manual for more details.

2.7.1 Locating the device ID

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.

2.8 How to synchronize the time of the device

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

Note:
Refer to the **YiMi Health App** manual for more details.

2.9 Screen wake up

During measurement,the screen will go off automatically for saving power,you can press the button to wake up the screen.

2.10 Reminder

The main unit has a built-in vibrator. The device will vibrate to alert users under the following three conditions:

1) Turn on the device and inserting the sensor into the main unit, the device vibrates to indicate successful connection.
2) During night monitoring (19:00-10:00 next day): vibration reminder for battery level below 25%, preventing incomplete night measurement due to power shortage.
3) If the finger slips out of the SpO2 sensor during measurement, the device will trigger a vibration alert by vibrating 3 consecutive times to remind the user.Users can turn this vibration function ON or OFF in the APP.

3 Maintenance

3.1 Cleaning

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

3.2 Battery

To keep the battery in good condition, charge the battery every 3 months when the device is not in use.

4 Accessories

Warning

- Only use accessories specified in this manual. Use of other accessories may damage the oximeter.
- Stop using any accessory that shows visible signs of damage.
- The SpO2 sensors described in this chapter meet the bio-compatibility requirements and comply with the relevant ISO 10993-1 series standards.
- Reference information for SpO2 sensor selection:

Model	Sensor Type	Intended User
WS-01	Reusable Wrap-Type SpO2 Sensor	Adult
WS-02	Reusable Silicone Finger Sleeve SpO2 Sensor	Adult

5 Troubleshooting

Trouble	Possible Causes	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 3 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.
	The device Bluetooth might be damaged.	Turn on the device and confirm the Bluetooth icon is displayed normally. If the icon does not appear, please contact your local distributor first.

6 Product Specifications

● **Classifications**		
Type of protection against electric shock	Internally powered	
Degree protection against electrical shock	Type BF	
Degree of dust & water resistance	IP22	
● **Physical**		
Weight	16g (main unit); About 60g (main unit with band and sensor)	
Size	52mm×28.5mm×16.8mm (main unit)	
Display	OLED	
Wireless	Bluetooth 5.3 BLE	
Vibrator	Main unit Built-in	
● **Power Supply**		
Battery Type	3.7Vdc,230 mAh ,Rechargeable Li-ion battery	
Charge input	DC 5V,1A	
Battery run time	≥16 hours (with sensor connected,BLE off, display off)	
Charge time	2 ~ 3 hours	
● **Environmental specifications**		
Item	**Operating**	**Transportation and Storage**
Temperature	5℃ to 40 ℃	-20℃ to 60℃
Relative humidity (non-condensing)	15% to 95%	10% to 95%
Atmospheric pressure	70kPa to 106kPa	50kPa to 106kPa
● **Oxygen (SpO2) level**		
Standards	Meet standards of ISO 80601-2-61	
Measurement accuracy verification: The oxygen level(SpO2) 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.		
SpO2 range	35%~100%	
SpO2 Accuracy (Arms)	70%~100%: ±2%; 35%~69%: undefined	
Oxygen (SpO2) Resolution	1%	
PR range	30 to 250 bpm	
PR Accuracy	±2 bpm	
PR Resolution	1bpm	
● **Optical sensor specification**		
Wave length	660-905nm	
Red Led	The wavelength of red light is about 660nm and the optical output power is 9-13mW	
IR Led	The wavelength of infrared light is about 905nm and the optical output power is 3-7 mW	
● **Data Storage**		

Local storage capacity	4 records, 24 hours for each
● **Mobile APP**	
Android	Android 9.0 or above
iOS	iOS 16.0 or above
● **Bluetooth RF**	
Modulation Type	GFSK
Frequency Range	2402-2480MHz
RF Conducted Power(Max.)	6.2 dBm
Transmission distance(Max.)	10m
● **Durable period**	
Expected service life	3 years

7 FCC statement

FCC ID:2A949YW10

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.

This device meets the government's requirements for exposure to radio waves. The guidelines are based on standards that were developed by independent scientific organizations through periodic and thorough evaluation of scientific studies. The standards include a substantial safety margin designed to assure the safety of all persons regardless of age or health. The SAR limit of USA (FCC) is 1.6 W/kg averaged. Device types: Pulse Oximeter (FCC ID: 2A949YW10) has also been tested against this SAR limit. SAR information can be viewed on - line at http://www.fcc.gov/oet/ea/fccid/. Please use the device FCC ID number for search. This device was tested simulation typical 0mm to face and Wrist. To maintain compliance with FCC RF exposure requirements, use accessories should maintain a separation distance between the user's bodies mentioned above, use accessories should not contain metallic components in its assembly, the use of accessories that do not satisfy these requirements may not comply with FCC RF exposure requirements, and should be avoided.

8 EMC

The device complies with the requirement of standard IEC60601-1-2:2014+AMD1:2020(EN 60601-1-2:2015+A1:2021)"Electromagnetic disturances – Requirements and tests".

Warning：Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

Warning： Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation."

Warning：Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Table 1

Guidance and manufacturer's declaration - electromagnetic emissions	
Emissions test	**Compliance**
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	N/A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A

Table 2

Guidance and manufacturer's declaration - electromagnetic Immunity		
Immunity Test	**IEC 60601-1-2** **Test level**	**Compliance level**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	Power supply lines：±2 kV 100 kHz repetition frequency	N/A
Surge IEC 61000-4-5	line(s) to line(s)：±1 kV.	N/A

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0%U_T; 0.5 cycle At 0º, 45 º, 90 º, 135 º, 180 º, 225 º, 270 º and 315 º 0%U_T;1 cycle And 70%U_T;25/30 cycles Single phase: at 0 0%U_T;300 cycle	N/A
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conduced RF * IEC61000-4-6	150KHz to 80MHz： 3Vrms 6Vrms (in ISM and amateur radio bands) 80% Am at 1kHz	N/A
Radiated RF IEC61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
Proximity magnetic fields IEC 61000-4-39	30 kHz: 8A/m 134,2 kHz: 65A/m 13,56 MHz: 7.5A/m	30 kHz: 8A/m 134,2 kHz: 65A/m 13,56 MHz: 7,5A/m
NOTE: U_T is the a.c. mains voltage prior to application of the test level. Remark: "*" : Only test for User Coupling line.		

Table 3

Guidance and manufacturer's declaration - electromagnetic Immunity								
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	**Test Frequency** (MHz)	**Band** (MHz)	**Service**	**Modulation**	**Maximum Power**(W)	**Distance** (m)	**IEC 60601-1-2 Test level** (V/m)	**Compliance level** (V/m)
	385	380 – 390	TETRA 400	Pulse modulation 18 Hz	1,8	0.3	27	27
	450	430–470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28	28
	710	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0.3	9	9
	745							
	780							
	810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28	28
	870							
	930							

	1720 1845 1970	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28	28
	2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28	28
	5240 5500 5785	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0.3	9	9

Table 4

Guidance and manufacturer's declaration - electromagnetic Immunity		
Test frequency	Modulation	IMMUNITY TEST LEVEL (A/m)
30 kHz	CW	8
134,2 kHz	Pulse modulation [a] 2,1 kHz	65 [b]
13,56 MHz	Pulse modulation [a] 50 kHz	7,5 [b]
a) The carrier shall be modulated using a 50% duty cycle square wave signal. b) r.m.s., before modulation is applied.		