Checkme™ O2

Sleep Monitor

Model: Oxiband

User's Manual

Contents

1. Introduction

1.1 Intended Use

This product is intended to be used for measuring, displaying and storing of pulse oxygen saturation (SpO_2) 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.

⚠ Warnings and Cautionary Advices

- Do not use this device during MRI examination.
- Never submerge the device in water or other liquids. Do not clean the device with acetone or other volatile solutions.
- Do not place this device in pressure vessels or gas sterilization device.
- Vital signs measurements, such as those taken with this device, cannot identify all diseases. Regardless of the measurement taken

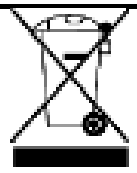
using this device, you should consult your doctor immediately if you experience symptoms that could indicate acute disease.

- 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.
- Use only cables, sensors and other accessories specified in this manual.
- Prolonged continuous SpO_2 monitoring may increase the risk of undesirable changes in skin characteristics, such as irritation, reddening, blistering or burns.
- 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.
- Functional tester cannot be used to assess the accuracy of a SpO_2 sensor or a device.

- This device is designed to determine the arterial oxygen saturation percentage of functional hemoglobin. Factors that may degrade pulse oximeter performance or affect the accuracy of the measurement include the following:

  - excess ambient light
  - excessive motion
  - electrosurgical interference
  - blood flow restrictors (arterial catheters, blood pressure cuffs, infusion lines, etc.)
  - moisture in the sensor
  - improperly applied sensor
  - incorrect sensor type
  - poor pulse quality
  - venous pulsations
  - anemia or low hemoglobin -concentrations
  - cardiogreen and other - intravascular dyes
  - carboxyhemoglobin
  - methemoglobin
  - dysfunctional hemoglobin
  - articial nails or fingermail polish

1.2 Guide to Symbols

Symbol	Description
	Type BF-Applied Part
	Manufacturer
	European authorized representative
CE0197	CE Marking indicating conformance to EC directive No. 93/42/EEC concerning medical devices.
	MRI unsafe. Presents hazards in all MR environments as device contains strongly ferromagnetic materials.
	Indicate separate collection for electrical and electronic equipment (WEEE).
IP22	Protected against spraying water and

	against access to hazardous parts with a tool, per IEC 60529.
	Follow Instructions for Use.
	Warning and Caution!
SN	Serial number
	No alarm system.

1.3 Unpacking

The package includes the following items:

- Main Unit × 1
- SpO_2 Sensor × 1
- Charging Cable × 1
- User's Manual × 1

If any item on this list is missing or damaged, contact the seller.

3. Using the Monitor

2.1 Charging

Connect the device to a standard USB charging port with the provided charging cable. **Charge the battery fully before using to get an overnight recording**.

2.2 Power On/Off

Press the button to power on the device.

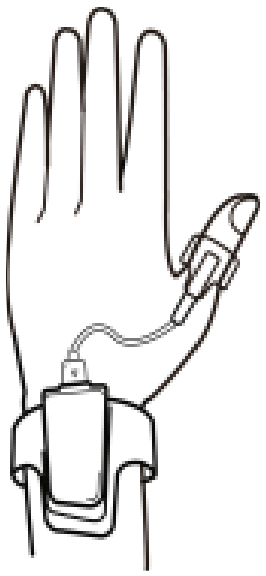
Press the button for three seconds to power off the device normally.

Press the button for five seconds to power off the device forcedly if necessary.

2.3 Wearing the Monitor

1. Wear the monitor on the left wrist.
2. Connect the sensor cable to the device.

3. Slide the ring sensor into the thumb as pictured.
4. Power on the device and choose the proper operation mode per your application. After a few seconds, the device will run the mode you set and your readings will begin appearing on the device screen.



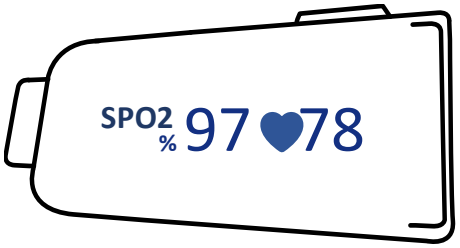
5. Press the button can change different screens.

Note:

- *The monitor can also work as a clock and pedometer without ring sensor, and the steps will restart counting after the ring sensor plugged in.*
- *Please avoid excessive motion for the sensed finger during recording and avoid any strong ambient light condition.*

2.4 Displays

Press the button can switch different displays during recording.



18:45	Time, Remaining battery capacity
MODE	Sleep Mode
MODE M	Monitor Mode
SPO2	Blood oxygen saturation
	Pulse rate in Sleep Mode
	Pulse rate in Monitor Mode
	Slide your finger into the sensor
	Steps
ID ×××× V ×.×	Device ID number, Software version
O2 7.5 13	O2 Score, SpO_2 drop times

2.5 Operation Mode Navigation

The monitor has two operation modes: **Sleep Mode** and **Monitor Mode**. Press the button during the icon flashing to switch between two modes.

	Sleep Mode	Monitor Mode
Parameters	SpO_2, PR, Motion	SpO_2, PR, Motion, Steps
Real-time Wireless (Dashboard)	No	Yes
Recording Length	Max 10 hours	Max 5 hours
Drops Detection	Yes	No
Screen	Activated by button	Always on
The Sensor Vibrates	When SpO_2 is lower than threshold set	When SpO_2 is lower than threshold set Or when step goal is met
Bluetooth	On when the screen lights up	Always on

2.6 Tracking and Recording the Vital Signs

After the mode has been chosen, the SpO_2 and pulse rate will be displayed on the screen. The SpO_2, pulse rate and motion data will be automatically stored in the monitor with 2s interval.

The device can store maximum 4 records. The oldest record will be overwritten when the 5^{th} record is coming in.

2.7 Smart Vibration

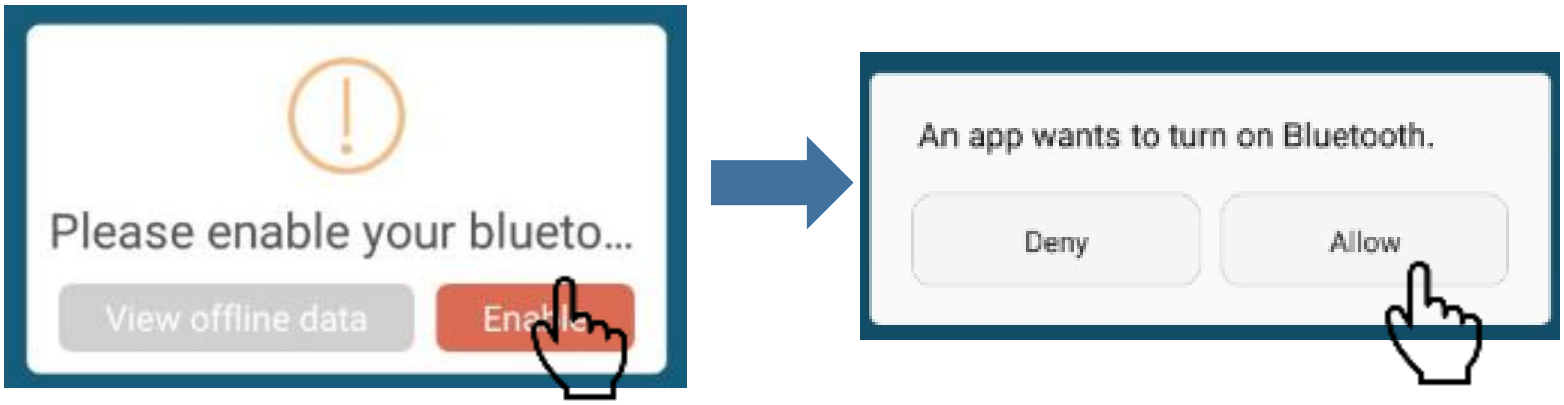
The monitor will monitor the SpO_2 level and steps during the recording. If the vibration is ON, the vibrator in the sensor will be activated when the SpO_2 fall below the pre-set value (Threshold) or meet steps goal. The vibration will stop when the SpO_2 reading go back to normal range, or you can press the button to stop it.

2.8 Establishing *Bluetooth* Connection

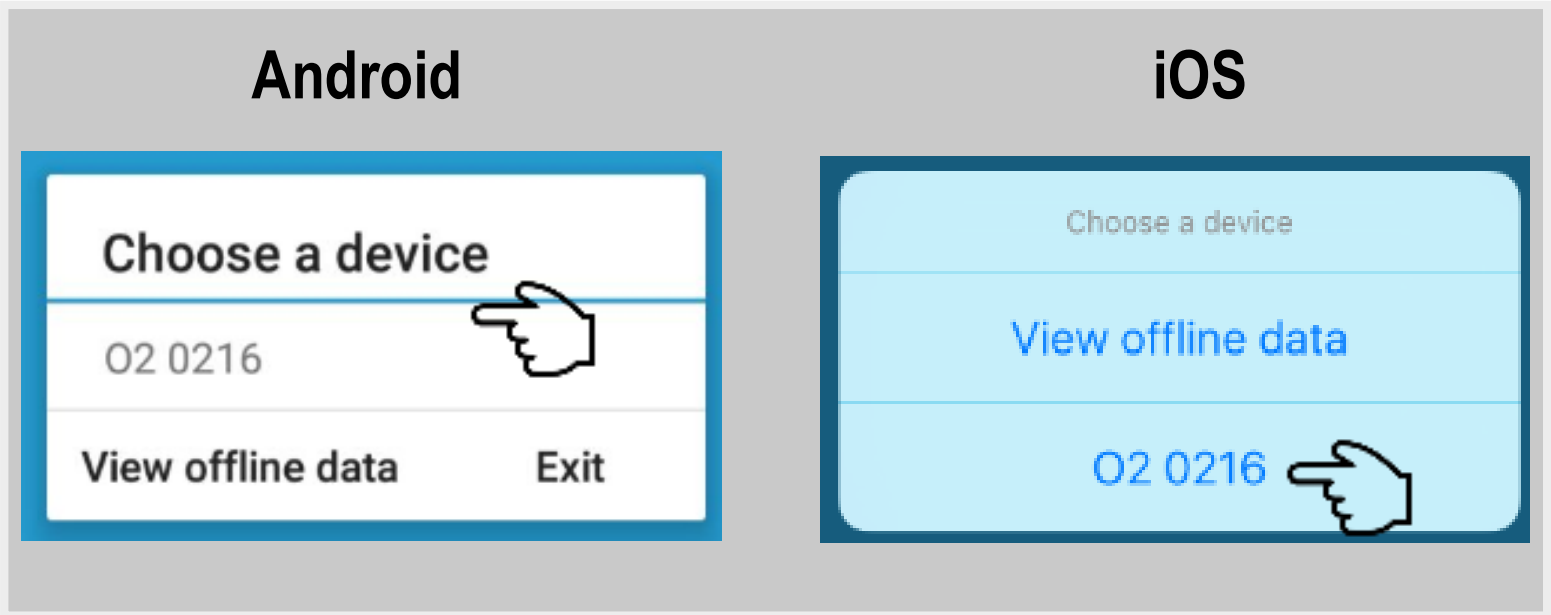
The device *Bluetooth* will open automatically only when the screen lights up.

To establish *Bluetooth* connection,

1. Ensure the monitor screen is on to keep the *Bluetooth* enabled.
2. Run the *Check O2* app and enable the phone *Bluetooth* as below.



3. Choose the right Device ID from the device.



2.9 Using Real-time Wireless Dashboard

After Bluetooth connection established in Monitor Mode, touch the **Dashboard icon** in the app, then your phone / tablet will show real-time SpO_2, PR and Steps.

2.10 Completing the Recording

There are two ways to complete the recording:

- Take off the sensor and it will power off later

automatically, or

- Press the button for 3s to power off the monitor.

2.11 View Results and Settings on Mobile App

Download the Check O2 app from the Apple APP Store or Google Play Store and then install it.

With the APP, you can:

- Review all measurement and analysis results with detailed data plots,
- Change the settings of the monitor,
- Update the monitor,
- Manage the data in the cloud.

2.12 Using the Cloud

1. Touch the **Cloud icon**  in the up right corner of the app, and then create a cloud account.
2. Sign in your account in the APP.

3. Data will be updated to the cloud automatically or manually based on your setting.

3. Maintenance

3.1 Care and Cleaning

Clean the device by carefully swabbing the device surface with a soft cloth swab with water or alcohol.

3.2 Firmware Update

1. Connect the monitor with the APP.
2. Enter the APP, visit **Device**  **→Device update→Update.** check the version and start an update if you want.

3.3 Battery

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

4. Troubleshooting

Problem	Possible Cause	Possible Solution
Device does not turn on.	Battery may be low.	Charge battery and try again.
	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* is off in Sleep Mode.	Press the button, the *Bluetooth* will be turned on when the screen lights up.

5. Specifications

Classifications		
EC Directive	MDD, 93/42/EEC	
	R&TTE, 1999/5/EC	
	ROHS 2.0, 2011/65/EU	
Degree protection against electrical shock	Type BF	
Environmental		
Item	**Operating**	**Storage**
Temperature	5 to 40°C	-25 to 70°C
Relative humidity (noncondensing)	10% to 95%	10% to 95%
Barometric	700 to 1060 hPa	700 to 1060 hPa
Degree of dust & water resistance	IP22	

Physical	
Weight	35 g (main unit)
Display	OLED
Wireless	*Bluetooth 4.0* BLE
Vibrator	Built in
Power Supply	
Charge input:	DC 5V ±10%
Battery type	Rechargeable lithium-polymer battery
Battery run time	Sleep Mode: > 10 hours Monitor Mode: > 5 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. 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.	
SpO_2 range	70% to 100%
SpO_2 Accuracy (Arms)	80-100%:±2%, 70-79%:±3%
PR range	30 to 250 bpm
PR accuracy	±2 bpm or ±2%， whichever is greater
Wave length	660-940nm
Output power	Red/Infrared: 3mW max. avg.
Pedometer	
Range	0 to 99999 steps
Sleep analysis	

Record parameters	SpO_2, pulse rate, motion
Record length	Max 10 hours
Record interval	2s
Drop analysis	Yes
Mobile APP	
iOS	iOS 9.0 or above, iPhone 4s/iPad 3 or above
Android	Android 4.4 or above, with *Bluetooth* 4.0 BLE

6. Electromagnetic Compatibility

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

⚠ Warnings and Cautions

- Using accessories other than those specified in this manual may result in increased electromagnetic emission or decreased electromagnetic immunity of the equipment.
- The device or its components should not be used adjacent to or stacked with

other equipment.

- The device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.
- Other devices may interfere with this device even though they meet the requirements of CISPR.
- When the inputted signal is below the minimum amplitude provided in technical specifications, erroneous measurements could result.
- Portable and mobile communication equipment may affect the performance of this device.
- Other devices that have RF transmitter or source may affect this device (e.g. cell phones, PDAs, and PCs with wireless function).

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

Harmonic emissions IEC61000-3-2	Class A	establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
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	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 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
Surge	± 1 kV line(s) to	± 1 kV line(s) to	

IEC 61000-4-5	line(s) ± 2 kV line(s) to earth	line(s) ± 2 kV line(s) to earth	environment.
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**
Conduced RF IEC61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands	3 Vrms 150 kHz to 80 MHz outside ISM bands	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 2.5 GHz	3 V/m 80 MHz to 2.5 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.

Shenzhen Viatom Technology Co., Ltd
4E,Building 3, Tingwei industrial Park,
Honglang North 2nd Road, Baoan, 518100
Shenzhen, P.R.China
www.viatomtech.com
info@viatomtech.com

EC REP **MedNet GmbH**

Borkstrasse 10, 48163 Muenster, Germany

Tel:+49 251 32266-0 Fax:+49 251 32266-22

PN：255-00917-00 Version: A

Contents of this manual are subject to changes without prior notice.