Checkme O2 Max

Smart Wrist Pulse Oximeter

User Manual

Viatom™

www.viatomtech.com

Contents

1 Introduction

1.1 Intended Use

The Oxiband Pulse Oximeter is a wrist pulse oximeter indicated for use in measuring, displaying, storing and transmitting functional oxygen saturation of arterial hemoglobin (Sp02) and pulse rate for adult patients. It is intended for spot-check and/or continuous data collection, and not continuous monitoring. It can be used in sleep labs, long-term care, hospitals and home use.

⚠ **Warnings and Cautions**

- **Federal law restricts this device to sale by or on the order of a physician.**
- DO NOT squeeze the sensor or apply excessive force on the sensor & cable.

- Do not use this device during MRI examination.
- Do not use this device with a defibrillator.
- 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. Children should be supervised around the device to ensure they

do not play with it.

- Sources of electromagnetic disturbance may affect this device (e.g. microwave cookers, diathermy, lithotripsy, electrocautery, RFID, electromagnetic anti-theft systems, and metal detectors), please try to stay away from them when using.
- This equipment complies with International IEC 60601-1-2:2014 for electromagnetic compatibility for medical electrical equipment and/or systems. This standard is designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare and other environments, it is possible that high levels of such interference due to close proximity or strength of a source might disrupt the performance of this device. Medical electrical equipment needs special precautions regarding EMC, and all equipment must be installed and put into service according to the EMC information specified in this manual.
- Do not use this device in a Magnetic Resonance (MR) environment.
- Radios and cell phones or similar devices might affect the equipment and should be kept at least 2 meters (6.5 feet) away from equipment.
- 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 (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.
- 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.
- Do not open the device cover without authorization. The cover should only be opened by a qualified service personnel.
- The biocompatibility testing has been performed on the materials in contact with the person in accordance with ISO10993.
- The SpO2 sensor can be repeatedly used. Please clean

before reuse.

- Do not place the SpO2 probe on a finger with edema or fragile tissue.
- Check the SpO2 sensor and cable before use. Do not use a damaged SpO2 sensor.
- Prolonged continuous SpO2 measuring 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 functional tester cannot be used to assess the accuracy of the SpO2 sensor or a device.
- The device has no alarm system.
- 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

1.2 Guide to Symbols

Symbol	Description
	Type BF-Applied Part
	Manufacturer
	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.
R_x **Only**	Prescription use

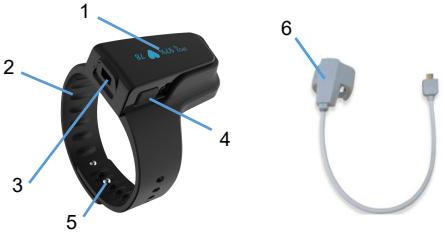
2 Using the Device

2.1 Product information

Name: Pulse Oximeter

Model: Oxiband

2.2 Overview



1. Main unit

2. Wristband

3. Multi-function Connector for External SpO2 Cable and Charging Cable

4. Power button

5. Clasp

6. SpO2 sensor

Screen display item description:

SpO2	SpO2
	Pulse rate
	Wear the sensor
19:30	Time

	Remaining battery capacity
	Bluetooth is connecting

2.3 Charging

Battery must be charged before using.

To charge the device battery, connect one end of the charging cable to sensor/charging interface on the device, and the other end to either a USB charging adapter for a wall outlet or the USB port of a computer.

After the battery is fully charged, the device will power off automatically.

2.4 POWER ON/OFF

POWER ON:

Press and hold the power button for 1 second to turn on the device.

POWER OFF:

Automatically power off: The device will turn off automatically in 2 minutes if there is not a measurement detected, no activity on the device, without Bluetooth connection.

Manually power off: Press and hold the power button for 2 seconds.

2.5 Bluetooth connection

SMARTPHONE REQUIRED

This device requires you to have an Apple or Android smart phone or tablet and connection to the internet.

INSTALL APP

Download the ViHealth app from the Apple App store or Google Play.

AppName: ViHealth

IMPORTANT: Enable Bluetooth on your smartphone and grant Bluetooth access to the ViHealth App.

Follow the steps in the ViHealth App

1) Agree to the Terms & Conditions

2) Enter personal profile information.

3) Ensure the device screen is on to keep the device Bluetooth enabled.

4) Make sure the phone Bluetooth is enabled.

5) Tap [Add Device]. The App scans for and displays nearby devices.

6) Tap the picture of the device. App shows that it is connecting to the device.

2.6 Start recording

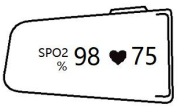
1. Connect the sensor cable to the device.

2. Wear the device on your wrist and the ring sensor on your thumb or index finger.

3. Press and hold the power button for 1 second to power on the device. After a few seconds, the device will begin to record.

Note:

- If the working time is less than 1 minute, the data will not be saved.
- For optimal placement of the device, it is recommended the user wear the device on their left wrist and put the ring sensor on the index finger. If the sensor is too tight, try another finger, with the goal of the sensor being snug but comfortable.
- During recording, please avoid excessive motion for the hand that has the sensor on it. Also, avoid any strong ambient lighting.



2.7 Stop recording

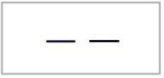
Take off the sensor, the countdown will begin.

During the countdown, if you wear the sensor again, the record will be resumed.

After the countdown, the **data will be ready for uploading**.

Note: The device can store maximum 4 records. The oldest record will be overwritten when the 5th record is coming in. Please upload data in time.

2.8 Unavailable symbol



When this symbol displays on device screen, it indicates the readings is unavailable right now.

It may caused by:

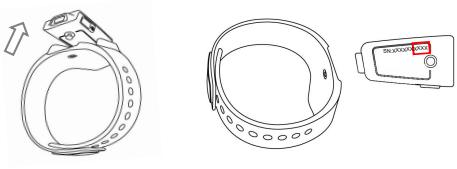
- Excessive movement;
- Poor signal, finger is too cold;
- Low perfusion

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

2.9 LOCATING THE DEVICE ID

1) Detach the main unit from wristband.

2） Flip the main unit over, the device ID is printed on the label of the product.



Note: The device ID is on the back of the device.

2.10 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 Maintenance

3.1 Cleaning

To clean the display panel, use a cotton swab moistened with 70% isopropyl alcohol and gently wipe the panel. To clean the outer surface of the device, use a soft cloth dampened with mild water. Do not allow liquids to enter the interior of the device, then let the main unit and accessories air dry.

Note:

The device is a non-sterile medical device and does not

contain any sterile components. Shelf life is 3 years based on our testing reports and battery specification documentations

3.2 Battery

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

4 Troubleshooting

Problem	Possible Cause	Possible Solution
No SpO2/ PR value	Wear the device incorrectly	Adjust the SpO2 sensor, please reading the chapter 2.6 carefully.
	Excessive ambient light	Replace the measurement environment.
	Other causes	Please reading the chapter 1.1 carefully, or press the button for about 10 seconds to reset. If the problem persists after reboot, please contact your local distributor.
Device does not turn on or there is no	Battery may be low.	Charge battery and try again.
	Unexpected software	Press the button for about 10 seconds to

response.	condition	reset
	Device might be damaged.	Please contact your local distributor.
The app does not detect the device.	The Bluetooth on your smart device is off.	Turn on the Bluetooth in your smart device settings.

5 Specifications

Classifications		
Protection against electric shock	Internally powered equipment	
Degree protection against electrical shock	Type BF	
Electro-magnetic compatibility	Group I, Class B	
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	700 to 1060 hPa

	hPa	
Degree of dust & water resistance	IP22	
Physical		
Weight	12 g (main unit)	
Display	OLED	
Wireless	*Bluetooth 4.0* BLE	
Power Supply		
Charge input:	DC 5V ±10%	
Battery type	Rechargeable lithium-polymer battery (3.7Vdc, 130mAh)	
Battery run time	72 hours	
Charge time	2 hours	
SpO_2		
Standards	Meet standards of ISO 80601-2-61	
Measurement accuracy verification: The 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	0% to 100%	

<table>
<tr><td rowspan="6">SpO2 Accuracy (Arms)</td><td>Display Range</td><td>Accuracy (Arms)</td></tr>
<tr><td>70% to 100%</td><td>±2% (Arms:1.88)</td></tr>
<tr><td>90-100%</td><td>±2%</td></tr>
<tr><td>80-90%</td><td>±2%</td></tr>
<tr><td>70-80%</td><td>±3%</td></tr>
<tr><td>0%-69%</td><td>not defined</td></tr>
<tr><td>PR range</td><td colspan="2">30 to 250 bpm</td></tr>
<tr><td>PR accuracy</td><td colspan="2">±2 bpm or ±2%，whichever is greater</td></tr>
<tr><td>Wavelength / Max emission power</td><td colspan="2">660nm/940nm, 0.8mW/1.2mW</td></tr>
<tr><td colspan="3">Bluetooth RF</td></tr>
<tr><td>Frequency range</td><td colspan="2">2.402-2.480 GHz
GFSK Modulation
Adaptive Frequency Hopping (AFH)</td></tr>
<tr><td>Wireless Quality of Service (QoS)</td><td colspan="2">Transmission Distance: 1.5m
Transmission Time: ≤10s
Data integrity: 100%</td></tr>
<tr><td>Network topology</td><td colspan="2">Point-to-Point</td></tr>
<tr><td>Band width</td><td colspan="2">1Mbps</td></tr>
</table>

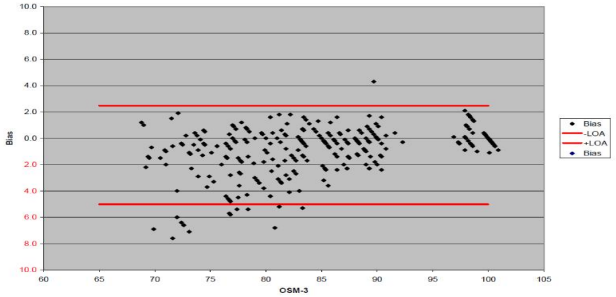
Storage	
Capacity	4 records,10 hours for each
Record	
Record parameters	SpO_2, pulse rate
Record interval	4s
Use life	
Expected use life	3 years
Accessory	
SpO_2 sensor	FP-10R

SpO2 test summary:

This graph shows plots of the error (SpO2-SaO2) by SaO2 using the Checkme Pro health monitor with a linear regression fit and upper 95% and lower 95% limits of agreement. Subject from a clinical study in non-motion conditions identifies each sample data point. Clinical study was performed using healthy adult subjects.

The device is not intended to be used during motion and therefore testing in accordance with Clause 201.12.1.102 of ISO 80601-2-61:2011 was not conducted. Viatom does not make any claims about the accuracy of SpO2 measurements under conditions of low perfusion, and therefore testing in accordance with Clause 201.12.1.103 of ISO 80601-2-61:2011 was not conducted.

The Oxiband device uses the same SpO2 measurement technology provided in the Checkme Pro health monitor. So the graph can also reflect the clinical study condition of the Oxiband pulse oximeter.



6 FCC Statement

FCC ID: 2ADXK-1600

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.

(2) This device must accept any interference received, including interference that may cause undesired operation.

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.

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.

7 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 manufacturer's declaration– electromagnetic emissions		
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 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 IEC 61000-3-2	N/A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A	

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 environment.			
Immunity test	**IEC 60601 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%. If ESD interfere with the operation of equipment, counter measurements such as wrist strap, grounding shall be considered.
Electrical fast transient/ burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	N/A	--
Surge	± 1 kV line to	N/A	--

IEC 61000-4-5	line ±2 kV line to earth		
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T (100% dip in U_T) for 0.5 cycle 0% U_T (100% dip in U_T) for 1 cycle 70% U_T (30% dip in U_T) for 25/30 cycles 0% U_T (100% dip in U_T) for 250/300 cycles	N/A	--
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 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 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 environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**

Conducted RF IEC61000-4-6	$3V_{rms}$ 150kHz to 80MHz (6V in ISM and amateur radio bands between 0.15MHz and 80MHz)	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80MHz to 800MHz $d = 2.3\sqrt{P}$ 800MHz to 2.5GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). 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: 
Radiated RF IEC61000-4-3	3V/m 80MHz to 2.7GHz	10V/m	

Recommended separation distances between portable and mobile RF communications equipment and the Pulse Oximeter
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)	**Separation distance according to frequency of transmitter (m)**		
	150kHz to 80MHz $d = 1.16\sqrt{P}$	80MHz to 800MHz $d = 1.16\sqrt{P}$	800MHz to 2.5GHz $d = 2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (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, No.6 Liufang Road, Block 67, Xin'an Street, Baoan District, Shenzhen, 518101, Guangdong, China
www.viatomtech.com

Model: Oxiband

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