SleepHQ Ring User Manual

Email - support@sleephq.com

IOS App - SleepO2 Android App - ViHealth Web App - SleepHQ.com

1. Introduction

1.1 Intended use

Measuring, displaying and storing pulse oxygen saturation (SpO2) and pulse rate data for adults in-home or healthcare facilities. For sleep or daily use

1.2 Warnings and Cautions

- Do not squeeze the sensor part or apply excessive force.
- Do not use this device during MRI examination.
- Do not store this device in the following locations: direct sunlight, high temperatures, high humidity and strong magnetic fields.
- Never submerge the device in water or other liquids.
- Do not clean the device with acetone or other volatile solutions.
- Do not drop the device or subject it to a strong impact.
- The device is provided non-sterile.
- Do not place this device in pressure vessels or gas sterilisation devices.
- Do not dismantle the device. It could cause damage.
- Use only the cables provided.
- Prolonged, continuous monitoring may increase the risk of skin irritation.

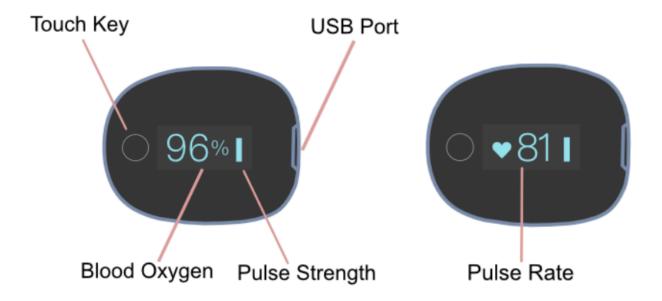
1.3 Guide To Symbols

| Symbol | Description | |
|------------|--|--|
| * | Type BF-Applied Part | |
| *** | Manufacturer | |
| M | Date of manufacture | |
| (3) | Follow Instructions for Use. | |
| MR | MRI unsafe. Presents hazards in all MR environments as device contains strongly ferromagnetic materials. | |
| IP24 | Against ingress of solid foreign objects ≥ 12.5mm diameter, splashing. | |
| SN | Serial number | |
| X | Temperature limitation | |
| Æ | Humidity limitation | |
| € | Atmospheric pressure limitation | |
| <u> </u> | Indicate separate collection for electrical and electronic equipment (WEEE). | |

1.4 Unpacking

- Device
- User Manual
- Data/Charging Cable

2. Overview



3. Device Use

3.1 Charging

Charge the battery before use with the supplied USB cable. Once fully charged, the device will power off automatically.

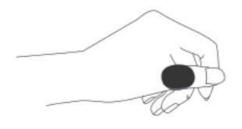
3.2 Power On / Off

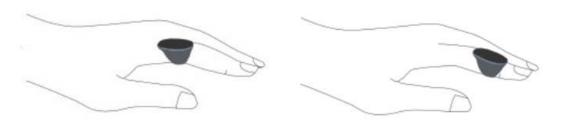
Power On: The device will turn on automatically when placed on the finger. Power Off: The device will turn off automatically shortly after finger removal.

3.3 Steps

- 1. Start Charge the battery & wear the device to power on
- 2. Stop Take off the device; the session is complete after countdown
- 3. Data Sync After the countdown, open the App to sync data

3.4 Operation





- 1. For best results, use the ring on the thumb or index finger. Try moving the device along the forefinger to find the best fit. Loose fitting may cause inaccurate results.
- 2. The device will turn on automatically.

Important

- For best results, DO NOT wear it on the middle finger.
- Sessions less than 2 minutes will not be recorded.
- Avoid excessive motion.
- Avoid strong ambient light.

3.5 Stop Session & Sync Data

Remove the device & wait for countdown completion.

Important: If reapplied during the countdown, the original session will continue.

Sync Data

- When the countdown has finished, open the App to sync data.
- OR during the next session, open the App to sync data.

3.6 Screen Wake Up

The screen will automatically turn off to save power in standard mode. Turn it on by touching the key on the top of the device.

3.7 Battery

Touch the key to switch between display readings and battery level.

3.8 Unavailable Symbol



Displayed when the readings are unavailable.

- Excessive movement
- Poor signal

3.9 Download App

IOS - SleepO2

Android - ViHealth

Desktop - www.sleephq.com

3.10 Bluetooth Connection

Device Bluetooth is enabled automatically when in use. To establish a connection

- 1. Wear the device.
- 2. Turn on the phone Bluetooth.
- 3. Run the app.

Important: Pair the ring IN THE APP and NOT in the phone settings.

5. Maintenance

5.1 Time & Date

Time & Date will sync via phone

5.2 Cleaning

Use a soft cloth or alcohol wipe to clean the device gently.

6. Troubleshooting

| Problem | Possible Cause | Possible Solution |
|-------------------------------------|--|---|
| Device does not turn on / any power | Low batteryDevice damageSoftware problem | Charge the battery and try again Whilst charging, touch and hold the key for 8 seconds |
| App can not find the device | Bluetooth settings off For Android, Bluetooth requires location permission. | Turn on BluetoothAllow location access. |
| Only one light emitter on the ring. | This is normal | |

7. Specifications

| Environmental | Operating | Storage | | |
|---|--|------------------------------|--|--|
| Temperature | 5 to 40°C | -25 to 70°C | | |
| Relative humidity | 100/ to 050/ | 100/ to 050/ | | |
| (noncondensing) | 10% to 95% | 10% to 95% | | |
| Barometric | 700 to 1060hPa | 700 to 1060hPa | | |
| Protection against | Internally nowered ea | uinment | | |
| electric shock | Internally powered eq | Internally powered equipment | | |
| Degree protection | | | | |
| against electrical | Type BF | | | |
| shock | | | | |
| Electro-magnetic | Oracia I Olaca D | | | |
| compatibility | Group I, Class B | | | |
| Degree of dust & | IP24 | | | |
| water resistance | | | | |
| Weight | 15 g | | | |
| Size | 38×30×38 mm | | | |
| Battery | 3.7Vdc, Rechargeable Lithium- polymer | | | |
| Charge time | 2-3 hours | | | |
| Battery life | 12-16 hours for typical use | | | |
| Wireless | Bluetooth 4.0 BLE | | | |
| Oxygen level range | 70% to 99% | | | |
| SpO2 Accuracy (Arms) | 80-99%: ±2%, 70-79%: ±3% | | | |
| Pulse Rate range | 30 to 250 bpm | | | |
| Pulse Rate accuracy ±2 bpm or ±2%, whiche | | hever is greater | | |
| Vibration source | low oxygen level. | | | |
| vibration source | high/low pulse rate | | | |
| Recorded | Oxygen level, Pulse Rate, motion | | | |
| parameters | | | | |
| Data storage | 4 sessions, up to 10 hours for each | | | |
| Mobile App for iOS | iOS 9.0 or above, | | | |
| mobile App for 103 | iPhone 4s/ iPad 3 or above | | | |
| Mobile App for | ile App for Android 5.0 or above, | | | |
| android | with Bluetooth 4.0 BLE | | | |

• Electromagnetic Compatibility

The device meets the requirements of IEC 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).
- 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.

Guidance and manufacturer's declaration 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 | Group 1 | The device uses RF energy only | |
| CISPR 11 | | 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 | Class B | The device is suitable for use in all | |
| CISPR 11 | | establishments, including domestic | |
| Harmonic | N/A | establishments and those directly | |
| emissions IEC | | connected to the public low-voltage | |
| 61000-3-2 | | power supply network that supplies | |
| Voltage | N/A | buildings used for domestic | |
| fluctuations/ flicker | | purposes. | |
| emissions | | | |
| IEC 61000-3-3 | | | |

Guidance and manufacturer's declaration – electromagnetic immunity

The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Pulse Oximeter should assure that it is used in such an environment.

| Immunity test | IEC 60601 test | Compliance | Electromagnetic |
|------------------|---|---------------------|---------------------------|
| | level | level | environment – |
| | | | guidance |
| | | | Floors should be wood, |
| | | | concrete or ceramic tile. |
| | | | If floors are covered |
| | | | with synthetic material, |
| Electrostatic | | | the relative humidity |
| | ± 8 kV contact | ± 8 kV contact | should be at least 30%. |
| discharge (ESD) | ± 15 kV air | ± 15 kV air | If ESD interfere with the |
| TEC 01000-4-2 | | | operation of equipment, |
| | | | counter measurements |
| | | | such as wrist strap, |
| | | | grounding shall be |
| | | | considered. |
| | ± 2 kV for | | The quality of the |
| Electrical fast | power supply lines ± 1 kV for input/ output lines | ± 2 kV for power | power supply should |
| transient/ burst | | supply lines | meet the requirements |
| IEC 61000-4-4 | | ± 1 kV for input/ | of a typical commercial |
| 1120 0 1000-4-4 | | output lines | (initial power supply) or |
| | | | medical environment. |
| Surge | ± 1 kV line to | ± 1 kV line to line | The quality of the |
| IEC 61000-4-5 | | ±2 kV line to | power supply should |
| 120 01000-4-5 | | earth | meet the requirements |

| Voltage dips, short interruptions and voltage variations on power supply | | ±2 kV line to earth 0% U _T | | of a typical commercial or medical environment. |
|---|--|---|--|---|
| IEC 61000-4-11 for 25/30 cycles for 25/30 cycles 0% UT interruption, it is 0% UT $(100\%$ dip in $U_T)$ for 250/300 uninterruptible power | interruptions and voltage variations on power supply input lines | (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 | (100% dip in UT) for 0.5 cycle 0% UT (100% dip in UT) for 1 cycle 70% UT (30% dip in UT) for 25/30 cycles 0% UT (100% dip in UT) for 250/300 | power supply should meet the requirements of a typical commercial or medical environment. If the user of this product needs to continue poerating during power interruption, it is recommended to use |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 Town and the 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. | (50/60 Hz) magnetic field IEC 61000-4-8 | 30 A/m | | magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |

| Essential Performance | |] |
|---------------------------|-----------|--------------------------------------|
| Essential Performance | | The description of what the operator |
| | | of the device can expect if the |
| | | Esssential Performance is lost or |
| | | degraded due to electromagnetic |
| | | disturbances |
| Oxygen level | 0% to | Please stop using the device |
| range | 100% | immediately and contact the |
| SpO ₂ Accuracy | 70%-100%: | device manufacturer or |
| | ±2% | distributor for service an soon as |
| | (Arms:1 | possible |
| | .77%) | |
| | 70%-80%: | |
| | ±3% | |
| | 80%-90%: | |
| | ±2% | |
| | 90%-100%: | |
| | ±2% | |
| | 0%-69%: | |
| | not | |
| | defined | |
| Pulse Rate range | 30 to 250 | |
| | bpm | |
| Pulse Rate | ±2 bpm or | |
| accuracy | ±2%, | |
| | whiche | |
| | ver is | |
| | greater | |

Manufacturer: Shenzhen Viatom Technology Co., Ltd

Address: 4E, Building 3, Tingwei Industrial Park, No.6 Liufang Road, Block 67, Xin'an Street, Baoan District, Shenzhen, 518101, Guangdong, P.R.China.

MedNet GmbH

Borkstrasse 10 · 48163 Muenster · Germany TEL: +49 251 32266-0 FAX: +49 251 32266-22



Model: PO2、 Version: A

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