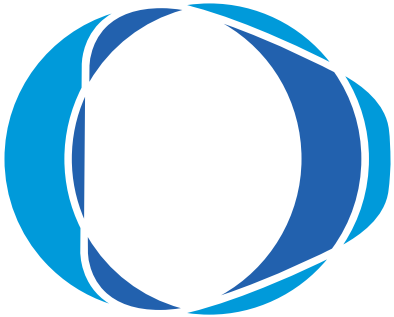

PROSOMNUS®
SLEEP TECHNOLOGIES

ProSomnus® RPMO_2 Oximeter Device

USER MANUAL

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Table of Contents

Caution: Federal (U.S.) law restricts this device to sale by, or on the order of a licensed healthcare practitioner.

Introduction

The ProSomnus® Remote Patient Monitoring ($RPMO_2$) Oximeter Device contains a pulse oximeter sensor intended for measuring arterial blood oxygen saturation (SpO_2) and pulse rate. ProSomnus $RPMO_2$ Oximeter Devices are for single patient use, and are patient specific, simple to use, comfortable and easy to clean.

Indications

The ProSomnus $RPMO_2$ Oximeter Device is an intraoral pulse oximeter indicated for use in measuring, displaying, storing, and transmitting functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate in adult patients. It is intended for continuous data collection. It can be used in sleep labs, long-term care, hospitals and home use.

When used in combination with the ProSomnus Oxymetrx™ Patient App and ProSomnus Oxymetrx Provider Portal, the device allows for remote collection of patient's physiological data.

Intended Use

The device is intended for:

- Patient-specific use
- Patients who are over 18 years of age
- Continuous data collection
- Use inside the oral cavity
- Use in non-motion conditions
- Use in well perfused area
- Use at home, sleep labs, long-term care, and hospitals
- Patient is an intended operator

Contraindications

The device is contraindicated for patients who:

- Have loose teeth or advance periodontal disease
- Are under 18 years of age

⚠ Warnings

Use of the device may cause:

- Tooth movement
- Gingival or dental soreness
- Obstruction of oral breathing
- Excessive salivation

- Does not provide physiological alarms during use
- Do not expose the sensor and accessories to temperatures over 131° Fahrenheit (55° Celsius) as this may damage the sensor
- Do not eat, swallow, drop, hit, abuse, open, incinerate, burn or short circuit the sensor, its accessories, or its components
- Discontinue use and contact your prescriber if the device appears damaged
- Discontinue use if an allergic reaction occurs
- The maintenance of this product is limited to qualified maintenance personnel designated by the manufacturer. Users should not repair this device by themselves and are not allowed to modify this device
- Do not perform maintenance and upkeep during use
- Product cannot be used while charging
- Possible strangulation by charging station cable
- This product is not suitable for use with products other than those specified in this manual
- This device is calibrated to measure blood oxygen saturation
- Functional testers cannot be used to evaluate the SpO_2 accuracy of ProSomnus $RPMO_2$ oximeters
- Data averaging and signal processing cause delays in the transmission of SpO_2 data values, and the measurement data update cycle is less than 30 seconds.
- The recommended maximum usage time for the device is 10 hours daily
- Interference from electrosurgical equipment can affect measurement accuracy
- Device poses a significant risk of interference during certain investigations or treatments such as magnetic resonance imaging (MRI) and computed tomography (CT) scans
- When using this product, avoid proximity to equipment generating strong electric and magnetic fields. Inappropriate usage environments may cause interference with nearby radio devices or impact the product's operation
- Do not place the device in direct sunlight, high temperature, humidity, cotton wool, and dusty areas to avoid affecting the performance of the device
- Excessive ambient light, frequent movement (active or passive) or vigorous activity of the user can affect measurement accuracy
- Expected time for transition from storage temperature extremes to room temperature is 4 hours
- Do not dispose the device with other domestic waste; instead, bring it to a recycling center for electric and electronic equipment
- Do not eat or drink while using the device
- Do not short-circuit the battery
- Do not dispose in fire
- Battery needs to be recharged every 3 months when not in use
- Connecting to the Bluetooth network including other devices may bring unknown risks. If there are any related risks or questions, please contact ProSomnus Sleep Technologies for assistance to solve the related issues

Do's

- Read user manual before use
- Follow the instructions in the ProSomnus Oxymetrx Patient App before use
- Battery service life is one year. Return to the prescriber at least one month before the one-year mark, or when needed, for re-evaluation.
- Fully charge the oximeter before use

Troubleshooting

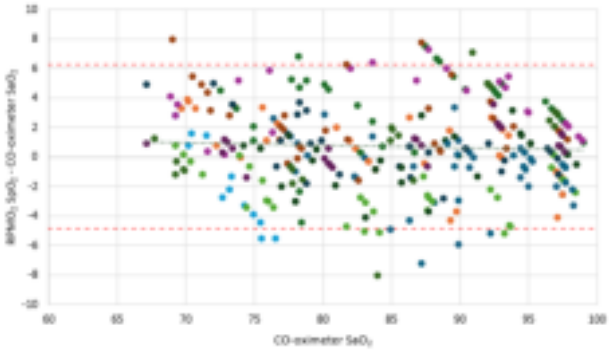
Device does not charge:

1. Ensure the ProSomnus $RMPO_2$ Oximeter Device is centered on the ProSomnus $RMPO_2$ Charging Station. Slightly adjust the device's position on the stand until the LED indicator on the charger turns on.

Device is not discoverable:

1. Place the ProSomnus $RMPO_2$ Oximeter Device on the charger.
2. Ensure the device is within 10 feet of the mobile phone.
3. Disable devices or applications which may have connected with the device in the past.
4. Attempt to discover the device with the ProSomnus Oxymetrx Patient App.

Graphical Plot of All Sampled Data Points



In human experiments, the accuracy of SpO_2 is verified by comparing measurements from arterial blood samples with those from a CO-Oximeter.

Pulse rate accuracy is verified in human experiments and using a simulator.

Each ProSomnus $RPMO_2$ Oximeter Device Package Contains:

- 1 maxillary arch with sensor
- 1 ProSomnus $RPMO_2$ Charging Station
- User Manual
- Storage case(s)

Material Content:

- Medical grade polymer
- Medical grade adhesive
- Fully embedded Printed Circuit Board Assembly (PCBA)

The ProSomnus $RMPO_2$ Oximeter Device sensor captures and stores patient's physiological data. The ProSomnus Oxymetrx Patient App and ProSomnus Oxymetrx Provider Portal are required to view and analyze this data. The data collected and stored in the ProSomnus $RPMO_2$ Oximeter Device is transferred to the ProSomnus Oxymetrx Provider Portal via the ProSomnus Oxymetrx Patient App. The prescribing physician can view and create reports to analyze patient data and results from the ProSomnus Oxymetrx Provider Portal. Patients can view their sleep score, device usage, SpO_2, pulse rate, and Oxygen Desaturation Index (ODI) using the ProSomnus Oxymetrx Patient App.

Directions for Daily Use of the ProSomnus $RPMO_2$ Oximeter Device

1. For physiological data collection, ensure the ProSomnus $RMPO_2$ Oximeter Device sensor is fully charged and registered with the ProSomnus Oxymetrx Patient App.
2. Insert prior to sleep.
3. Inspect the device prior to use. Contact your prescriber if you observe any abnormalities.
4. Rinse with water before use.
5. Open your mouth wide, and secure the device onto your teeth.
6. Gently relax your jaw and settle down for a restful night.
7. To remove the device:
   a. Gently open your mouth and apply downward pressure on the front of the device with your index fingers.
   b. Open the ProSomnus Oxymetrx Patient App, connect with the oximeter device to upload physiological data to ProSomnus Oxymetrx Provider Portal.
   c. Charge the ProSomnus $RMPO_2$ Oximeter Device by placing it on the ProSomnus $RPMO_2$ Charging Station, ensuring both device and station LEDs indicate charging is in progress as shown in Figure. 1.

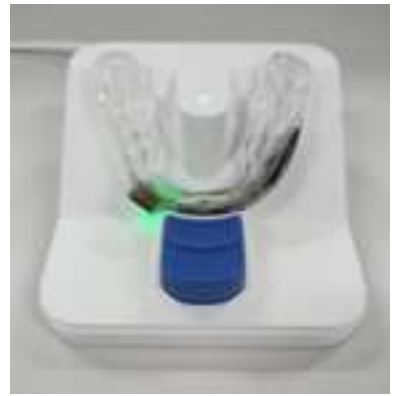


Figure. 1

Note: Do not remove one-handed, this will place unnecessary torque on the arch frame and can cause breakage.

Light Indication

Operation Mode	Sensor	Charger
Charging	Green light flashing	Green light flashing
Charging complete	Green light on for 15s	Green light solid on
Connect to ProSomnus Oxymetrx Patient App	Green light flashes twice	N/A
Device Firmware Upgrade	Green light always on	N/A
Fault	Red light flashing	Red light flashing

Cleaning Instructions for the ProSomnus RPMO$_2$ Oximeter Device

Note: Sterilization, calibration and maintenance are not required.

Daily:

- After use, thoroughly clean your ProSomnus RPMO$_2$ Oximeter Device using a regular soft toothbrush, cool or warm water and mild detergent, such as orthodontic device cleansers or antibacterial liquid soaps.
- Avoid scuffing or damaging the surface location near the LED.
- Rinse thoroughly. Place on the ProSomnus RPMO$_2$ Charging Station to ensure adequate charge. When traveling, store in the travel container.
- Daily soaking of your device is not recommended.

Note: Mouthwash, bleach solutions, denture cleaners or abrasive toothpaste may harm the device.

Storage

Keep the ProSomnus RPMO$_2$ Oximeter Device and its accessories away from small children and pets.

The ProSomnus RPMO$_2$ Oximeter Device should be stored in a cool, dry place. Ensure the device is not exposed to extreme temperatures in excess of 55°C/131°F.

Biological Hazards and Waste Disposal

Biological Hazards:

The ProSomnus RPMO$_2$ Oximeter Device may be exposed to harmful bacteria, viruses, fungi (molds, yeasts), and parasites, including COVID-19.

Waste Disposal Instructions:

For Patient-Users:

- Contact local authorities for guidance on disposing of potentially biohazardous parts and accessories.
- Follow healthcare provider or local health department instructions for biohazardous waste disposal.

For Organizations:

- Consult with local authorities to determine proper disposal methods for biohazardous materials.
- Ensure personnel handling biohazardous waste are trained and equipped with protective gear.

COVID-19 Considerations:

- Take additional precautions when handling parts exposed to COVID-19.
- Adhere to guidelines from health authorities regarding COVID-19 . waste management.

Essential Performance

PULSE RATE (PR) ACCURACY	
PR Measurement Range	45-220 bpm
A_{RMS}	1.86 bpm

The pulse rate accuracy was tested by a pulse rate functional tester per the recommendation of ISO 80601-2-61.

FUNCTIONAL OXYGEN SATURATION (SpO_2) ACCURACY	
SpO_2 Measurement Range	70-100% (Resolution: 1%) Below 70% no definition
A_{RMS}	2.94%

*A_{RMS} accuracy is a statistical calculation of the difference between device measurement and reference measurements.

The sensors' accuracy was assessed against co-oximeter samples across the SpO_2 range of 70% to 100%. This accuracy data was determined using the root-mean-square A_{RMS} value for all subjects, in accordance with ISO 80601-2-61: Medical Electrical Equipment—Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.

FCC Warning

ProSomnus RPMO_2 Oximeter Device

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.

Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the device.

Note: This device 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 device 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 device does cause harmful interference to radio or television reception, which can be determined by turning the device 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 device and receiver.
- Connect the device 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.

The device has been evaluated to meet general radio frequency (RF) exposure requirement. The device can be used in portable exposure condition without restriction.

ProSomnus RPMO_2 Charging Station

Note: This device complies with part 18 of the FCC Rules.

Information to the user.

1. The device has potential interference, but the interference is very small and meets the requirements of the FCC rule.
2. Device system maintenance is simple, please refer to the manual.
3. The user can take simple measures to correct the interference. Such as staying away from interference sources, turning off interference sources, etc.

FCC Radiation Exposure Statement:
This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20cm between the radiator & your body.

Technical Specifications

FCC ID	2BKS2-RPMO2OXIMETER 2BKS2-RPMO2CHARGER
SN	See the outer package for details
Date of Manufacture	See the outer package for details
Bluetooth Version	4.1 and above
Bluetooth Effective Range	Within 10 meters
Battery Capacity	24 mAh
Battery Life	Recording continuously for 8 hrs
Charging Input	USB-A 5V 1A
Waterproof Grade	IP68 for ProSomnus RPMO$_2$ Oximeter Device IP22 for ProSomnus RPMO$_2$ Charging Station

Green light	Wavelength about 525nm, maximum optical output power 4.5mW
Red light	Wavelength about 660nm, maximum optical output power 7.3mW
Infrared light	Wavelength about 940nm, maximum optical output power 5.3mW
Operating Condition	5°- 40°C (41°- 104°F). Do not operate when pressure is below 740 mbar.
Storage and Transportation Conditions	-25°- 55°C (-13°- 131°F). Relative humidity ≤85%. No corrosive gas. Good ventilation. Air pressure not less than 740mbar indoor storage and transportation.

ProSomnus Oxymetrx Patient App

Scan for the App User Manual:

	Consult instructions for use: prosomnus.com/instructions
	Manufacturer
	Non-sterile
	Keep dry
55°C -25°C	Storage temperature limit
	Warning
	Prescription only
MD	Medical Device
	Single Patient – multiple use
	Federal Communications Commission (FCC) licensing
	Indicates a radio frequency is transmitted
	Signifies waste from electrical and electronic equipment
	Type BF applied part
	This way up
	Fragile

	Do not crush
	Storage relative humidity
	No SpO_2 & pulse rate alarms during use.
	Keep away from direct sunlight
	Unsafe in magnetic resonance (MR) environment
IP68	Protected against dust ingress and other particles and its internal components, and against continuous immersion in water under depth of 1 meter for 1 hour.
IP22	Protected against solid objects larger than 12mm in diameter, such as fingers, and against vertically falling water droplets when the enclosure is tilted or rotated to 15 degrees.
RoHS	Restriction of (the use of certain) Hazardous Substances
	Recycle battery at specialized battery recyclers
	Read instructions
	Repackaging
	Conforms with the 2014/53/EU on the radio equipment directive
	Device conforms to the Medical Device standards for home use, IEC 60601-1:2012 for electrical safety, and IEC 60601-1-2:2014 for EMC.

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PATENTED

MADE IN USA

prosomnus.com/patents

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