PROSOMNUS®
SLEEP TECHNOLOGIES

ProSomnus® RPMO$_2$ OSA Device

USER MANUAL

SMART
SLEEP MEDICINE™

Treat Your Sleep Apnea. Capture Insights. Sleep Better.

The ProSomnus® RPMO$_2$ OSA Device delivers clinical-grade insights that empower you to understand your therapy, optimize recovery, manage Obstructive Sleep Apnea, and achieve your sleep goals.

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SYMBOLS

Consult instructions for use
https://prosomnus.com/instructions

Manufacturer

Non-sterile

Keep dry

Storage temperature limit

Warning / Caution

Prescription Only

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 12.5mm 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

CE Conforms with the 2014/53/EU on the radio equipment directive.

Conforms to the Medical Device standards for home use, IEC 60601-1:2012 for electrical safety, and IEC 60601-1-2:2014 for EMC.

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

INTRODUCTION

This manual provides instructions for the safe and effective use of the ProSomnus® $RPMO_2$ OSA Device.

The device is worn during sleep as part of a treatment plan prescribed by your healthcare provider. Advancement settings for the device will be determined by your dentist or physician as part of your treatment plan.

The device is comfortable to wear, easy to clean, and simple to use as part of your nightly routine.

This manual includes:

- Instructions for setup, daily use and care of the device
- Information on device light indicators and their meaning
- Troubleshooting guidance
- When to contact your healthcare provider

Please read all sections of this manual carefully, and review the ProSomnus® Oxymetryx™ App User Manual prior to use.

INDICATIONS FOR USE

The ProSomnus® $RPMO_2$ OSA Device is intended to reduce nighttime snoring and mild to moderate obstructive sleep apnea (OSA) in adults.

Additionally, the fully embedded $RPMO_2$ oximeter sensor measures, displays, stores, and transmits functional oxygen saturation of the arterial hemoglobin (SpO_2) and pulse rate. It is intended for continuous data collection during sleep. It can be used in home settings, sleep laboratories, long-term care facilities, and hospitals.

When used in combination with the ProSomnus® Oxymetrx™ App and ProSomnus® Oxymetrx™ Provider Portal, the device enables remote collection of patients' physiological data.

The device is intended to be applied in the oral cavity.
The device is intended for use under non-motion conditions in well-perfused areas.
The device is single-patient, reusable.

INTENDED USE

The device is intended for:

- Single-patient (patient-specific), reusable use
- Use in patients 18 years of age and older
- Continuous data collection
- Application within the oral cavity
- Use under non-motion conditions in well-perfused areas
- Use with the patient as the intended operator

CONTRAINDICATIONS

The device is contraindicated for use in patients who:

- Have Central Sleep Apnea
- Have severe respiratory disorders
- Have loose teeth or advanced periodontal disease
- Are under 18 years of age

⚠ WARNINGS

1. Use of the device may cause:
   - Tooth movement or changes in dental occlusion
   - Gingival or dental soreness
   - Pain or soreness to the temporomandibular joints
   - Obstruction of oral breathing
   - Excessive salivation
2. This device does not provide physiological alarms during use.
3. Do not eat, swallow, drop, strike, misuse, open, incinerate, burn or short circuit the sensor, its accessories, or components.
4. Stop using the device and contact your healthcare provider if the device appears damaged or if you experience an allergic reaction.
5. The charging station cable may pose a strangulation hazard.
6. The device may cause significant interference during certain medical procedures, such as magnetic resonance imaging (MRI) or computed tomography (CT) scans.
7. Do not short-circuit the battery.
8. Do not dispose of the device in fire.

⚠ CAUTIONS

1. Do not expose the sensor and accessories to temperatures above 131° F (55° C), as this may damage them.
2. Device maintenance must be performed only by qualified service personnel authorized by the manufacturer. Users must not repair or modify this device.
3. Do not perform maintenance or cleaning while the device is in use.
4. The device cannot be used while charging.
5. Use this device only with accessories and components specified in this manual.
6. Do not use functional testers to verify the SpO_2 accuracy of ProSomnus® $RPMO_2$ oximeter sensors.
7. Electrosurgical equipment may interfere with measurement accuracy.
8. Keep this device away from equipment that generates strong electric or magnetic fields. Such environments may cause interference with nearby radio devices or affect device operation.
9. Do not expose the device to direct sunlight, high temperatures, cotton fibers, dusty environments, or high-humidity environments outside the oral cavity, as this may impair performance.
10. Allow at least 4 hours for the device to acclimate from extreme storage temperature to room temperature before use.
11. Dispose of this device at a designated recycling facility for electronic equipment. Do not dispose of the device with household waste.
12. Do not eat or drink while using the device.
13. Recharge the battery at least every 3 months when not in use.

PRECAUTIONS

Patients should consider their medical history, including history of asthma, breathing, or respiratory disorders, or other relevant health problems, and contact the appropriate healthcare provider before using the device.

DEVICE OVERVIEW

The ProSomnus® $RPMO_2$ OSA Device is an oral appliance worn on the upper and lower teeth during sleep. The device is designed to reduce snoring and mild to moderate obstructive sleep apnea (OSA) while monitoring physiological parameters.

The device tracks sleep and breathing by recording oxygen levels and pulse rate. Data is transmitted via the ProSomnus® Oxymetrx™ App to the secure ProSomnus® Oxymetrx™ Provider Portal, where the prescribing physician can review results and generate reports.

Within the app, patients may view information such as:

- **Lower Arch** – The lower arch (titration setting) you are currently using, as prescribed by your healthcare provider.
- **Device Usage** – Shows how often and how long you have worn your device during sleep.
- **Pulse Rate** – The number of times your heart beats per minute. This value may change during sleep depending on your breathing and activity.
- **Blood Oxygen** – The percentage of oxygen in your blood, known as oxygen saturation or SpO_2.
- **Oxygen Desaturation Index (ODI)** – The number of times per hour your blood oxygen level drops below your usual (baseline) level.
- **Sleep Score** – A summary number that reflects your overall sleep quality based on factors such as oxygen levels, breathing patterns and time asleep.

IMPORTANT! These values are for tracking and spotting patterns over time. If you notice repeated low blood oxygen levels, high ODI values, unusual pulse rate changes, or consistently low sleep scores, share your results with your healthcare provider so they can help you understand the information.

The device includes:

- 1 maxillary (upper) arch with sensor
- 3 mandibular (lower) arches
- ProSomnus® Charging Station
- USB Charging Block
- Storage case
- Instructions for use

Note: *The device contains medical grade polymer, medical grade adhesive and a fully embedded printed circuit board assembly (PCBA).*

IMPORTANT! This device is calibrated to measure blood oxygen saturation (i.e., Functional SpO_2).

Figure 1

SIGNAL QUALITY

The ProSomnus® $RPMO_2$ OSA Device records and reports SpO_2 and pulse rate.

Segments with insufficient signal quality are highlighted in gray in the ProSomnus® Oxymetrx™ Provider Portal.

Excessive movement during sleep may temporarily reduce signal quality, which may result in insufficient signal quality. Your healthcare provider may contact you if a significant amount of data is of insufficient quality.

IMPORTANT! Insufficient signal quality data:

- Does not indicate a device malfunction.
- Does not represent apneic events.
- Does not require action unless instructed by your healthcare provider.

USING YOUR DEVICE

Before you begin

Read the ProSomnus® Oxymetrx™ App User Manual and follow the app prompts.

- Scan this QR code with your smartphone or tablet to view the complete user manual.
- Fully charge the device before use.

Note: *Your ProSomnus® RPMO$_2$ OSA Device comes with a 3-year warranty.*

CAUTION: Allow at least 4 hours for the device to acclimate from extreme storage temperature to room temperature before use.

Daily Use Instructions

1. Charge and check

- Make sure the device is fully charged.
- Confirm it is registered with the app.

2. Inspect the device

- Check for any damage or abnormalities.

WARNING: Stop using the device and contact your healthcare provider if the device appears damaged or if you experience an allergic reaction.

3. Rinse and insert the device

- Identify and select the prescribed lower arch (e.g., L0, L1 or L2).
- Rinse both arches thoroughly with water.
- Sandwich the upper and lower arches together.
- Open your mouth wide.
- Position the arches over your teeth and press gently to secure in place.

IMPORTANT! Always wear both upper and lower arches together. Never wear individual arches only.

4. Check proper fit

It is normal to notice mild pressure or tightness when first wearing the device. A properly fitted device should:

- Seat fully and securely over both upper and lower teeth.
- Feel snug and stable, without rocking, shifting, or causing pain.
- Remain in place during gentle jaw movement.

IMPORTANT! If the device feels loose, does not seat fully, or causes pain or discomfort, stop using it and contact your healthcare provider.

Do not attempt to adjust the device yourself.

5. Relax and sleep

- Gently relax your jaw and prepare for sleep.
- Keep the device in place for the entire night.

IMPORTANT! Signal quality may be reduced by excessive ambient light, frequent movement, or vigorous activity, which may result in a reduction in the amount of valid data collected.

6. Remove the device in the morning

- Begin with the lower arch. Gently open your mouth and place your thumbs in the cheek area, just below the posts on both side of the arch. Adjust your thumbs along the edges if needed.
- Apply gentle, even upward pressure to lift the lower arch out.
- Next, remove the upper arch. Place your index fingers along the front of the arch and apply gentle, even downward pressure until the arch releases.

Note: *Do not remove the device one-handed, as this can put torque on the arch frame and cause breakage.*

IMPORTANT! A fully charged battery supports up to 8 hours of continuous overnight use.

7. Upload your data

- Open the app.
- Connect to the device to upload your data to the provider portal.
- Upload your data regularly, preferably after each use or at least once daily.

IMPORTANT! The device can store up to 24 hours of cumulative wear data.

If stored data is not uploaded before the device memory is full, the oldest data may be overwritten.

8. Recharge the device

- Place the upper tray on the ProSomnus® Charging Station.
- Check the lights to confirm charging.

CAUTION: Recharge the battery at least every 3 months when not in use.

Figure 2

LED QUICK GUIDE

Device LED	Charger LED	Meaning	Action Required
Flashing green light	Flashing green light	Charging in progress	Leave device on charger until charging completes.
Green light on for 15 seconds	Solid green light	Charging complete	Device is ready for use.
Flashes green twice	—	Connecting to app	Wait until connection is established.
Solid green light	—	Firmware upgrade in progress	Do not remove from charger or interrupt process.
Solid red light	—	Device clock reset	Connect to app to set clock and clear indicator light.
Flashing red light	Flashing red light	Fault detected	Contact your healthcare provider.

TROUBLESHOOTING GUIDE

Issue	Possible Cause	Solution
Device will not power on	Battery is depleted	• Fully charge the device on the charging station. • Make sure the LEDs indicate charging.
Device does not charge	Device not correctly placed on the charging station	• Center the device on the charging station. • Slightly adjust the device's position until the charger's LED indicator turns on.
Device not connecting to the app	Bluetooth turned off	• Turn on Bluetooth and retry.
	Device is not registered	• Register the device in the app before connecting.
	Weak connection	• Move the device to your smartphone/tablet (within 3 meters).
	Another device/app connected	• Turn off or disconnect any devices or applications that may have previously connected to the device. • Attempt to discover the device again using the app.
No data appearing in the app	Data upload not completed	• Open the app and connect to the device after removing it in the morning.
Red light flashing on device or charger	Device fault	• Remove from use and contact your healthcare provider.
Green light does not turn solid when charging is complete	Battery not fully charged	• Keep the device on charging station until solid green LED appears.
Measurement results appear inconsistent	Improper device positioning, intermittent or inconsistent contact with oral tissues, or excessive movement	• Make sure the device is seated fully and securely on your upper teeth during use. • Ensure there is no debris or residue on the device surface. • Avoid excessive motion.

Note: *If there are a significant number of low-signal or incomplete data collections over time, your healthcare provider may contact you with guidance.*

IMPORTANT! Due to data averaging and signal processing, SpO_2 values are transmitted with a delay; the measurement data update cycle is less than 30 seconds.

Connecting to Bluetooth networks or other devices may present unknown risks. For assistance with any related concerns, contact ProSomnus.

ADVANCEMENT INSTRUCTIONS

The ProSomnus® RPMO$_2$ OSA Device consists of one upper arch and three lower arches, each manufactured to the dentist prescriber's specified advancement positions.

Mandibular advancement is titratable by sequentially replacing the current lower arch with the next arch in the prescribed advancement series.

When you change your lower arch, as instructed by your healthcare provider, update the value in the app to match your current device configuration. Refer to the ProSomnus® Oxymetrx™ App User Manual for instructions.

ProSomnus® RPMO$_2$ OSA Device Advancement Instructions		
	Combination	**Advancements**
4 Arches: **UO Oximeter Arch, LO, L1, L2** **Note:** Unlimited advancement arches L3, L4 can be prescribed.	Upper 0 Oximeter Arch + Lower 0	0mm
	Upper 0 Oximeter Arch + Lower 1	1.0mm
	Upper 0 Oximeter Arch + Lower 2	2.0mm

CLEANING AND STORAGE INSTRUCTIONS

Note: *Sterilization, calibration and maintenance are not required. Mouthwash, bleach solutions, denture cleaners or abrasive toothpaste may damage your device.*

Cleaning After Use

1. Thoroughly clean your device using:
   - A regular soft toothbrush
   - Cool or warm water
   - Mild detergent (e.g., orthodontic device cleansers or antibacterial liquid soaps)
2. Avoid scuffing or damaging the area near the LED light.
3. Rinse thoroughly.
4. Place the upper arch on the charging station to make sure it is adequately charged for the next use. The upper arch does not need to be dry before charging.
5. Store the lower arch on top of the upper arch (see Figure 1) to allow the device to dry completely.
6. **Do not** soak your device daily—this is not recommended.

Storage

1. Keep your device and its accessories away from small children and pets.
2. Store in a cool, dry place.
   - When not in use, keep your device on the charging station.
   - When traveling, store your device in its storage case.

⚠ **CAUTION:** Do not expose the sensor and accessories to temperatures above 131° F (55° C), as this may damage them.

Do not expose the device to direct sunlight, high temperatures, cotton fibers, dusty environments, or high-humidity environments outside the oral cavity, as this may impair performance.

CYBERSECURITY INFORMATION

This section explains how your ProSomnus® $RPMO_2$ OSA device communicates, stores data, and what you should know to support secure use.

Bluetooth Communications and Data Protection
The device communicates with the authorized mobile application using Bluetooth® Low Energy (BLE). Data transmitted between the device and the mobile application is encrypted to help reduce the risk of unauthorized access or data modification.

Users should only use the device with authorized mobile applications provided or approved by ProSomnus.

Local Data Storage
The device will store 24 hours of measurement data locally. As new data is collected, the oldest stored data is overwritten.

Data is transmitted and permanently stored on the provider portal via the mobile app once a secure connection is restored. To avoid data loss, it is important to connect and upload data daily.

A gap in the data displayed in the app or provider portal may indicate that data was not collected, was not uploaded, or was overwritten prior to upload.

Monitoring Controls
Monitoring may automatically start or stop based on whether the device is being worn.

Monitoring is disabled during charging or under conditions that may compromise data accuracy.

Firmware Updates
The device supports wireless firmware updates through the authorized mobile application. Firmware updates may include improvements to performance, reliability, or cybersecurity protections.

If a firmware update cannot be completed successfully, the device may enter a safe state to prevent unintended operation.

User Responsibilities for Device Cybersecurity
To support secure operation of the device, users should:

- Use only authorized mobile applications.
- Install firmware updates when notified.
- Avoid unauthorized software or attempts to modify the device or firmware.
- Report suspected cybersecurity issues or unusual device behavior to ProSomnus.

Operating Environment and Secure Use Conditions
The device is intended to be used with the authorized mobile application on supported mobile platforms.

Reliable Bluetooth connectivity is required for device communication and data synchronization. Bluetooth permissions must be enabled on the mobile device.

Cybersecurity Limitations and User Awareness
Temporary loss of connectivity may delay data synchronization but does not typically result in data loss.

BIOLOGICAL BIOHAZARDS

The ProSomnus® RPMO$_2$ OSA Device may be exposed to harmful microorganisms, including bacteria, viruses, fungi (molds, yeasts), and parasites. This includes potential exposure to COVID-19.

WASTE DISPOSAL INSTRUCTIONS

⚠ **CAUTION:** Dispose of this device at a designated recycling facility for electronic equipment. Do not dispose of the device with household waste.

For Patient-Users

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

For Organizations

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

COVID-19 Considerations

- Take extra precautions when handling any parts or accessories that may have been exposed to COVID-19.
- Follow all applicable guidelines from health authorities for COVID-19-related waste management.

ESSENTIAL PERFORMANCE

In human subject experiments, SpO_2 accuracy is validated by comparing measurements from arterial blood samples with those obtained from co-oximeters. Pulse rate accuracy is validated through human subject testing compared to ECG.

Functional Oxygen Saturation (SpO_2) Accuracy	
SpO_2 Measurement Range	70-100% (resolution 1%) Below 70% no definition
A_{RMS}*	2.94%
Pulse Rate (PR) Accuracy	
PR Measurement Range	50 -109 bpm
A_{RMS}*	2.08 bpm

The pulse rate accuracy was also tested by a functional pulse rate tester for the range of 45-220 bpm per the recommendation of ISO 80601-2- 61.

Pulse Rate (PR) Accuracy	
PR Measurement Range	45-220 bpm
A_{RMS}*	2.09 bpm

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

FCC COMPLIANCE AND WARNING

ProSomnus® $RPMO_2$ OSA 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.
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.

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

Notes:

- *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. If not installed and used in accordance with the instructions, it may cause harmful interference to radio communications.*
- *There is no guarantee that interference will not occur in a particular installation. If interference to radio or television reception occurs (determined by turning the device off and on), try one or more of the following measures:*
    - *o Reorient or relocate the receiving antenna.*
    - *o Increase the separation between the device and receiver.*
    - *o Connect the device into an outlet on a different circuit from the receiver.*
    - *o Consult the dealer or an experienced radio /TV technician for assistance.*

PROSOMNUS® CHARGING STATION

This device complies with part 18 of the FCC Rules.

Information to the user:

1. This device has potential to cause interference, but the risk is very small and within FCC limits.
2. Maintenance requirements are minimal; refer to the user manual for guidance.
3. Users may reduce interference by:
    - Staying away from interference sources
    - Turning off nearby interference sources

⚠ **WARNING:** The device may cause significant interference during certain medical procedures, such as magnetic resonance imaging (MRI) or computed tomography (CT) scans.

⚠ **CAUTION:** Keep this device away from equipment that generates strong electric or magnetic fields. Such environments may cause interference with nearby radio devices or affect device operation.

ISED COMPLIANCE

The ProSomnus® $RPMO_2$ OSA Device complies with RSS-247 Issue 4 of Innovation, Science and Economic Development Canada (ISED) regulations.

The charging station complies with RSS-216 Issue 3 of ISED regulations.

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions:

1. This device may not cause interference.
2. This device must accept any interference, including interference that may cause undesired operation of the device.

RF Exposure Statement (Charging Station):

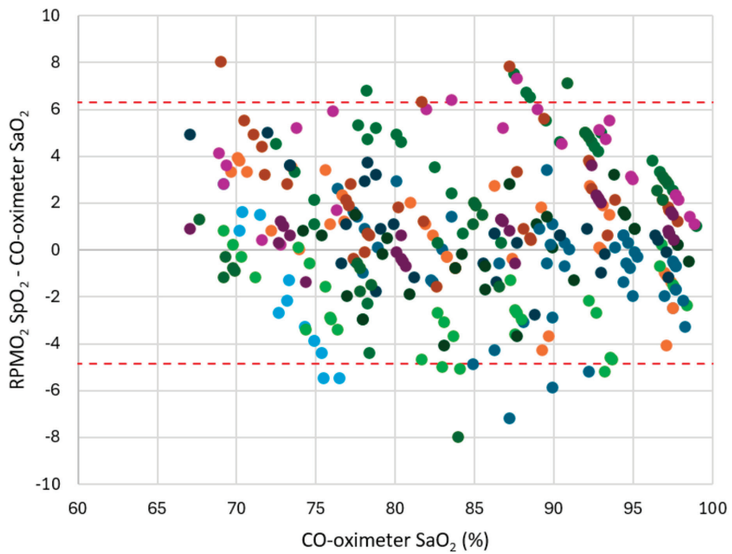
During operation, the charging station must be used at a distance of at least 20 cm from the human body.

TECHNICAL SPECIFICATIONS

FCC ID	2BKS2-RPMO2OXIMETER 2BKS2-RPMO2CHARGER
IC	35130-RPMO2DEVICE 35130-O2CHARGER
SN	See outer package for details
Date of Manufacture	See outer package for details
Bluetooth Version	4.1 and above
Bluetooth Effective Range	Within 10 meters
Battery Capacity	24mAh
Battery Runtime (per charge)	4+ hours of continuous recording
Battery Service Life	Approximately 3 years under normal use
Device Service Life	Approximately 3 years under normal use, based on battery performance
Charging Input	USB-A 5V 1A
Waterproof Grade	IP68 for ProSomnus RPMO2 OSA Device IP22 for ProSomnus 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
SpO2 Specification	±3.5%
Pulse Rate Specification	3 bpm or ±3%, whichever is greater
Local Data Storage	24 hours of measurement data

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.

GRAPHICAL PLOT OF ALL SAMPLED DATA POINTS



SpO_2 Accuracy: Validated in human studies by comparing device measurements with arterial blood samples analyzed using a CO-oximeter.

Pulse Rate Accuracy: Validated through human testing and using a simulator.

DEVICE ACCURACY TESTING

Pulse oximeter accuracy was tested in twelve healthy adult subjects under non-motion conditions. Demographic characteristics of the study population are summarized in the table below.

Gender (M/F; n)	8/4
Age (years; mean ± SD; range)	30.7 ± 6.7 (22-39)
Body mass index (kg/m2; mean ± SD; range)	26.0 ± 5.5 (17.5-38.0)
Fitzpatrick skin type (n by category)	I: 2; II: 3; III: 2; IV: 2; V: 1; VI: 2

The following tables present bias and accuracy results stratified by gender and skin pigmentation.

Overall

SaO_2 range (%)	**70-100 (overall)**	**70-80**	**80-90**	**90-100**
# of data pairs	325	108	100	117
Bias [95% LOA]	0.72 [-4.86 – 6.31]	0.94 [-4.42 – 6.30]	0.26 [-6.24 – 6.76]	0.92 [-3.93 – 5.78]
A_{RMS}	2.94	2.88	3.31	2.63

Female Gender

SaO_2 range (%)	**70-100 (overall)**	**70-80**	**80-90**	**90-100**
# of data pairs	109	35	33	41
Bias [95% LOA]	0.65 [-3.78 – 4.88]	0.54 [-3.53 – 2.08]	-0.39 [-4.51 – 3.72]	1.60 [-2.11 – 5.30]
A_{RMS}	2.25	2.11	2.10	2.45

Male Gender

SaO_2 range (%)	**70-100 (overall)**	**70-80**	**80-90**	**90-100**
# of data pairs	216	73	67	76
Bias [95% LOA]	0.76 [-5.41 – 6.92]	1.13 [-4.74 – 6.70]	.57 [-6.77 – 7.91]	0.56 [-4.70 – 5.82]
A_{RMS}	3.23	3.18	3.76	2.72

Fitzpatrick Skin Type I-IV

SaO_2 range (%)	**70-100 (overall)**	**70-80**	**80-90**	**90-100**
# of data pairs	248	86	77	85
Bias [95% LOA]	0.35 [-5.00 – 5.70]	0.46 [-4.7 – 5.7]	-0.21 [-6.01 – 5.60]	0.75 [-4.20 – 5.70]
A_{RMS}	2.75	2.68	2.95	2.62

Fitzpatrick Skin Type V-VI

SaO_2 range (%)	**70-80 (overall)**	**70-80**	**80-90**	**90-100**
# of data pairs	77	22	23	32
Bias [95% LOA]	1.92 [-3.80 -7.64]	2.81 [-1.55 – 7.17]	1.81 [-6.02 – 9.63]	1.38 [-3.15 – 5.92]
A_{RMS}	3.48	3.55	4.30	2.66

PROSOMNUS®
SLEEP TECHNOLOGIES

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