



PROSOMNUS®
SLEEP TECHNOLOGIES

ProSomnus® Sleep and Snore Devices
USER MANUAL

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ProSomnus Sleep and Snore Devices include the ProSomnus® MicroO₂® Sleep and Snore Device, the ProSomnus® [IA] Sleep and Snore Device with Monogram™ Customization Options, the ProSomnus® EVO® Sleep and Snore Device, the ProSomnus® EVO® [PH] Sleep and Snore Device, the ProSomnus® [CA] Sleep and Snore Device and the ProSomnus® [PH] Sleep and Snore Device. These devices will also be referred to as the ProSomnus Sleep and Snore Devices.

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

INTRODUCTION

ProSomnus Sleep and Snore Devices are intended to reduce snoring and mild to moderate Obstructive Sleep Apnea (OSA) by holding your lower jaw forward during sleep. Your device may have a compliance sensor. The compliance sensor logs the time the device is worn.

Your dentist or physician prescribes the amount of advancement increments according to your treatment plan. ProSomnus Sleep and Snore Devices are single patient use, patient specific, simple to use, comfortable and easy to clean.

INDICATIONS

The ProSomnus Sleep and Snore Devices are intended to reduce night time snoring and mild to moderate Obstructive Sleep Apnea (OSA) in adults.

Optionally, if the DentiTrac micro-recorder is completely embedded in the ProSomnus Sleep and Snore Device, the micro-recorder is intended to measure patient compliance to oral device/appliance therapy in combination with the DentiTrac System.

CONTRAINDICATIONS

The device is contraindicated for patients who:

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



WARNINGS

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

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.

EACH PROSOMNUS SLEEP AND SNORE DEVICE PACKAGE CONTAINS:

- 1 or more lower arches
- 1 or more upper arches
- Instructions for use
- Storage case(s)

Additionally, ProSomnus [CA] Sleep and Snore Device packages contain an adjustment key. ProSomnus EVO [PH] and ProSomnus [PH] Sleep and Snore Device packages contain an adjustment key and/or wrench.

Material Content: Polymethylmethacrylate (PMMA).

Material Content for ProSomnus EVO and ProSomnus EVO [PH] Sleep and Snore Device: Medical Grade Polymer.

Ball Clasps: Medical grade stainless steel.*

ProSomnus EVO [PH] and ProSomnus [PH] Sleep and Snore Device Herbst Arms & ProSomnus [CA] Sleep and Snore Device Jackscrew: Medical grade stainless steel.*
Gold Colored Screw: Titanium nitride coated medical grade stainless steel.*
*Stainless steel contains nickel and chromium. Meets National Institute for Occupational Safety and Health standards.

DIRECTIONS FOR DAILY USE OF THE PROSOMNUS SLEEP AND SNORE DEVICES

1. Insert prior to sleep.
2. Inspect the device prior to use. Contact your prescriber if you observe any abnormalities.
3. Rinse with water before use.
4. Select the prescribed arches, sandwich together.
5. Open wide, secure the arches onto your teeth.
6. Gently relax your jaw and settle down for a restful night.
7. To remove the device:
 - a. First remove the lower arch. Gently open your mouth and place your thumbs into your cheek area below the post on both side edges of the device. Adjust thumbs along the edges if necessary.
 - b. Apply even, upward pressure to lift out and remove.
 - c. Repeat the same process for the upper arch by applying downward pressure, using your index fingers. Adjust index fingers along the edges if necessary.
8. To remove the ProSomnus EVO Sleep and Snore Device:
 - a. First remove the lower arch. Gently open your mouth and place your thumbs into your front areas near the corner of your mouth, near the post on both side edges of the device.
 - b. Apply even, upward pressure to lift out and remove.
 - c. Repeat the same process for the upper arch by applying downward pressure into the front area using your index fingers.

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

 **WARNING:** Always wear both upper and lower arches together. Never wear individual arches only.

HOME CARE INSTRUCTIONS

Note: Sterilization is not required.

Daily:

- After use, thoroughly clean your ProSomnus Sleep and Snore Device using a regular soft toothbrush, cool or warm water and mild detergent, such as orthodontic device cleansers or antibacterial liquid soaps.

- Rinse thoroughly. Store in the container with airholes to ensure that your devices dry.
 - Daily soaking of your devices is not recommended.
- Note:** Mouthwash, bleach solutions, denture cleaners or abrasive toothpaste may harm the device.

STORAGE

Keep out of reach of small children and pets.

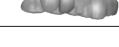
The ProSomnus Sleep and Snore Device should be stored in a cool, dry place. Ensure the device is not exposed to extreme temperature in excess of 60°C/140°F.

ADVANCEMENT INSTRUCTIONS

ProSomnus Micro₂, [IA], [IA] SELECT, EVO SELECT, and EVO Guided Sleep and Snore Devices:

4 DEVICES U0, U2, L0, L1	COMBINATION	ADVANCEMENTS
	Upper 0 + Lower 0	0mm
	Upper 0 + Lower 1	1.0mm
	Upper 2 + Lower 0	2.0mm
	Upper 2 + Lower 1	3.0mm

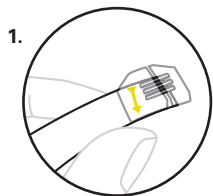
ProSomnus EVO Sleep and Snore Device:

5 DEVICES U0, U2, U4, L0, L1	COMBINATION	ADVANCEMENTS
	Upper 0 + Lower 0	0mm
	Upper 0 + Lower 1	1.0mm
	Upper 2 + Lower 0	2.0mm
	Upper 2 + Lower 1	3.0mm
	Upper 4 + Lower 0	4.0mm
	Upper 4 + Lower 1	5.0mm

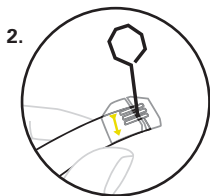
ProSomnus [CA] Sleep and Snore Devices:

Jaw advancements are achieved by adjusting the expansion screw, using the tool provided, per your doctor's prescription. **Note:** The arrows on the side of the expansion screw. These indicate the direction to turn the screw to advance the post. Each 90° turn is 0.1mm.

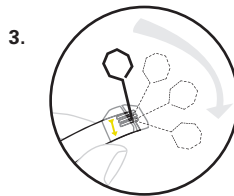
ProSomnus [CA] Sleep and Snore Device Forward Adjustment:



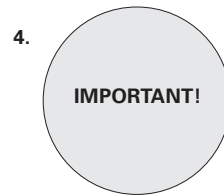
Hold upper tray with expansion screw facing you. Locate yellow reference arrow on device.



Fit the expansion tool into the adjustment keyhole.

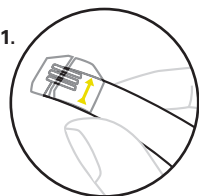


Rotate the expansion tool 90° in the direction of the arrow to advance forward.

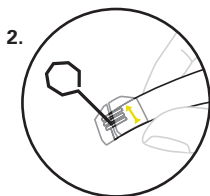


Count your turns and repeat adjustments on both sides.

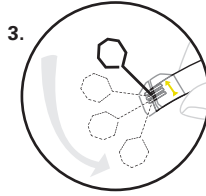
ProSomnus [CA] Sleep and Snore Device Backward Adjustment:



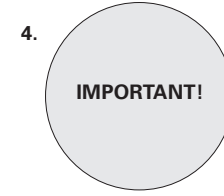
Hold upper tray with expansion screw facing you.



Fit the expansion tool into the adjustment keyhole.

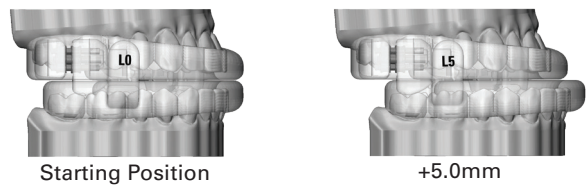


Rotate the expansion tool 90° in the direction opposite of the arrow.



Count your turns and repeat adjustments on both sides.

ProSomnus [CA] Sleep and Snore Device Advancement Tables:



Note: Your ProSomnus [CA] Sleep and Snore Device can be adjusted within a 12.0mm total titration range. Your prescriber will instruct you on the number of 90° screw turns to make based on comfort and symptom reduction. Your prescriber may provide you with an additional lower arch to achieve additional advancement.

Resetting Upper Post: Turn screw on Upper [CA] Arch 90° in the opposite direction to move post to the back of the arch.

*Do not exceed maximum number of turns.

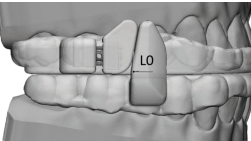
ProSomnus [CA] Sleep and Snore Device, (Upper [CA] Arch + Lower 0 Arch):

	Reverse (90° Screw Turns)		Bite Starting Position	Forward (90° Screw Turns)									
90° Screw Turns	-10	-5	0	5	10	15	20	25	30	35	40	45	*50
Expansion Screw Adj. (mm)	-1.0 mm	-0.5 mm	0.0 mm	0.5 mm	1.0 mm	1.5 mm	2.0 mm	2.5 mm	3.0 mm	3.5 mm	4.0 mm	4.5 mm	5.0 mm

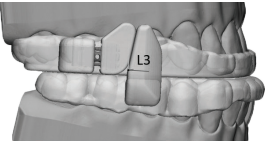
ProSomnus [CA] Sleep and Snore Device with Additional Lower Advancement Arch, (Upper [CA] Arch + Lower +5.0mm Arch):

	Expansion screw reset position	Forward (90° Screw Turns)											
90° Screw Turns	0	5	10	15	20	25	30	35	40	45	50	55	*60
Expansion Screw Adj. (mm)	5.0 mm	5.5 mm	6.0 mm	6.5 mm	7.0 mm	7.5 mm	8.0 mm	8.5 mm	9.0 mm	9.5 mm	10.0 mm	10.5 mm	11.0 mm

ProSomnus [CA] LP Sleep and Snore Device Advancement Tables:



Starting Position



+3.0mm

Note: Your ProSomnus [CA] LP Sleep and Snore Device can be adjusted within a 12.0mm total titration range. Your prescriber will instruct you on the number of 90° screw turns to make based on comfort and symptom reduction. Your prescriber may provide you with an additional lower arch to achieve additional advancement.

Resetting Upper Post: Turn screw on Upper [CA] LP Arch 90° in the opposite direction to move post to the back of the arch.

*Do not exceed maximum number of turns.

ProSomnus [CA] LP Sleep and Snore Device, (Upper LP [CA] Arch + Lower 0 Arch):

	Starting Position	Forward Advancement						
Screw Turns (Forward 90°)	0	5	10	15	20	25	30	*34
Bite Position (mm)	0.0 mm	0.4 mm	0.9 mm	1.3 mm	1.8 mm	2.2 mm	2.6 mm	3.0 mm

ProSomnus [CA] LP Sleep and Snore Device with Additional Lower Advancement Arch, (Upper [CA] LP Arch + Lower +3.0mm Arch):

	Starting Position	Forward Advancement						
Screw Turns (Forward 90°)	0	5	10	15	20	25	30	*34
Bite Position (mm)	3.0 mm	3.4 mm	3.9 mm	4.3 mm	4.8 mm	5.2 mm	5.6 mm	6.0 mm

ADVANCEMENT INSTRUCTIONS

ProSomnus EVO [PH] Sleep and Snore Devices:

Jaw advancements are achieved by adjusting either the Herbst nut screw or pinhole by using the tool provided, per your doctor’s prescription. Advancements up to 12.0mm may be achieved with additional arches as prescribed by your doctor. The “up” arrows on the side of the Herbst arm indicate advancing the Herbst arm “up” by turning the screw or pinhole in an upward direction. Each 90° turn is 0.1mm and each full turn is 0.4mm.

Advancing ProSomnus EVO [PH] with Hex Nut

- 1. Hold the upper arch perpendicular to the lower arch, such that the Herbst arm is straight up and down.
- 2. To advance 0.1mm, position the adjustment tool on the square head advancer screw as shown in Fig. 1a. Rotate 90° upwards, the direction of the etched “up” arrow on the Herbst arm as shown in Fig. 1b. Repeat on the other side.
- 3. To reduce advancement, rotate downwards in the opposite direction of the etched arrow.
- 4. Visual indicator marks in 1.0mm increments are laser etched on the Herbst arm and splint to show advancement location as shown in Fig. 2 and Fig. 2a. A ruler is laser etched on the wrench handle and splint to check the advancement throughout treatment as shown in Fig. 2 and Fig. 2a.



Fig. 3

Advancing ProSomnus EVO [PH] with Pinhole

- 1. Follow steps 1-3 inserting the provided tool into the pinhole as shown in Fig. 3.



Fig. 1a



Fig. 1b

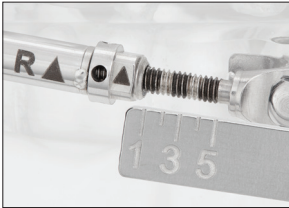


Fig. 2

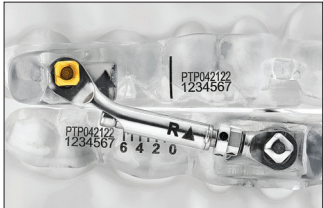


Fig. 2a

*Do not exceed maximum number of turns. Herbst arms should never be extended more than 6.0mm on the “7.0mm standard arm” or more than 4.0mm on the “4.0mm short arm” to avoid breakages and void the warranty.

ProSomnus EVO [PH] Sleep and Snore Device Adjustment Table:

	Reverse (90° Turns)		Bite Starting Position		Forward (90° Turns)										
90° Turns	-10	-5	0	5	10	15	20	25	30	35	40	45	50	55	*60
Herbst Arm Adj. (mm)	-1.0 mm	-0.5 mm	0.0 mm	0.5 mm	1.0 mm	1.5 mm	2.0 mm	2.5 mm	3.0 mm	3.5 mm	4.0 mm	4.5 mm	5.0 mm	5.5 mm	6.0 mm

ProSomnus EVO [PH] S “Short Arm” Sleep and Snore Device Adjustment Table:

	Reverse (90° Turns)		Bite Starting Position		Forward (90° Turns)						
90° Turns	-10	-5	0	5	10	15	20	25	30	35	*40
Herbst Arm Adj. (mm)	-1.0 mm	-0.5 mm	0.0 mm	0.5 mm	1.0 mm	1.5 mm	2.0 mm	2.5 mm	3.0 mm	3.5 mm	4.0 mm

ProSomnus [PH] Sleep and Snore Devices:

Jaw advancements are achieved by adjusting either the Herbst hex nut screw or pinhole by using the tool provided, per your doctor’s prescription. Advancements up to 12.0mm may be achieved with additional arches as prescribed by your doctor. The “up” arrows on the side of the Herbst arm indicate advancing the Herbst arm “up” by turning the screw or pinhole in an upward direction. Each 90° turn is 0.1mm and each full turn is 0.4mm.

Advancing ProSomnus [PH] with Hex Nut

- 1. Hold the upper arch perpendicular to the lower arch, such that the Herbst arm is straight up and down.
- 2. To advance 0.1mm, position the adjustment tool on the square head advancer screw as shown in Fig. 1a. Rotate 90° upwards, the direction of the etched “up” arrow on the Herbst arm as shown in Fig. 1b. Repeat on the other side.
- 3. To reduce advancement, rotate downwards in the opposite direction of the etched arrow.
- 4. Visual indicator marks in 1.0mm increments are laser etched on the Herbst arm to show advancement location as shown in Fig. 2. A ruler is laser etched on the wrench handle to check the advancement throughout treatment as shown in Fig. 2.



Fig. 3

Advancing ProSomnus [PH] with Pinhole

- 1. Follow steps 1-3 inserting the provided tool into the pinhole as shown in Fig. 3.



Fig. 1a



Fig. 1b

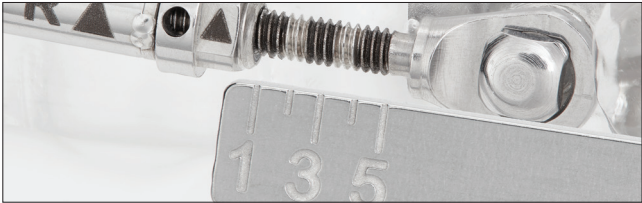


Fig. 2

ProSomnus [PH] Sleep and Snore Device Adjustment Table:

90° Turns	Reverse (90° Turns)		Bite Starting Position		Forward (90° Turns)										
	-10	-5	0	5	10	15	20	25	30	35	40	45	50	55	*60
Herbst Arm Adj. (mm)	-1.0 mm	-0.5 mm	0.0 mm	0.5 mm	1.0 mm	1.5 mm	2.0 mm	2.5 mm	3.0 mm	3.5 mm	4.0 mm	4.5 mm	5.0 mm	5.5 mm	6.0 mm

*Do not exceed maximum number of turns. Herbst arms should never be extended more than 6.0mm to avoid breakages and void the warranty.

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PROSOMNUS®
SLEEP TECHNOLOGIES



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ProSomnus Sleep Technologies
5675 Gibraltar Drive
Pleasanton, CA 94588, USA

Main +1 844 537 5337 | ProSomnus.com
The Leading non-CPAP OSA Therapy®

ProSomnus Sleep Technologies oral devices are manufactured in a facility whose Quality Management System is certified to ISO 13485:2016 by Intertek.



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



Manufacturer



Non-sterile



Keep dry



Upper limit of temperature



Warning



Prescription only



Authorized representative
in the European Community



Authorized representative
in Switzerland



European conformity



Medical Device



Single Patient – multiple use