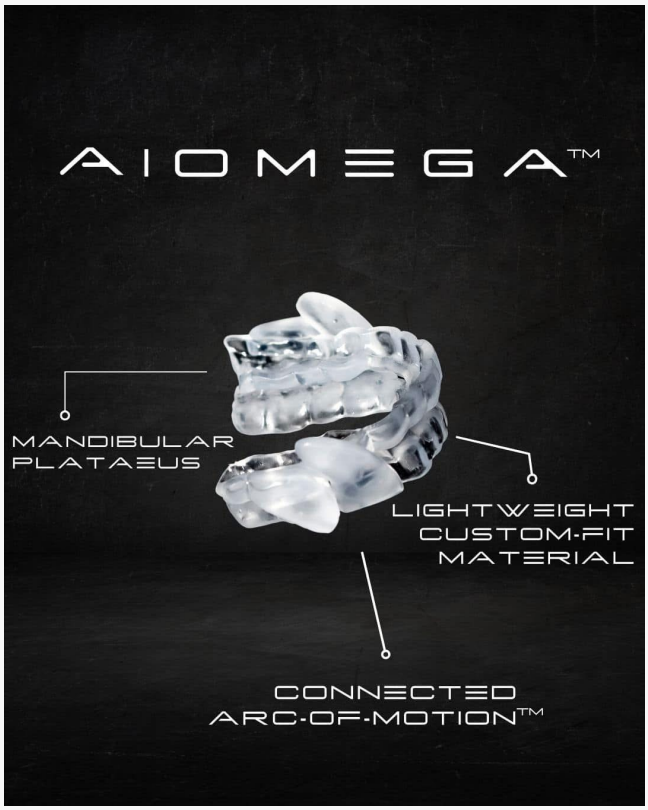
AIOMEGA® Expands Prescribing Precision for the AIO Breathe® Posterior-Leaning Flange Angle

Clinicians may document an angle greater than 90 degrees within the device's existing FDA-cleared posterior-leaning flange design.



AIO Breathe oral appliance for treatment of adult and pediatric Obstructive Sleep Apnea

TYLER, TX, UNITED STATES, September 18, 2026 /EINPresswire.com/ -- AIOMEGA®, a Texas biomedical company, announced that clinicians prescribing AIO Breathe®, an FDA-cleared mandibular repositioning device for adults with snoring or mild to moderate obstructive sleep apnea (OSA), may document a posterior-leaning flange angle greater than 90 degrees. The option is within the device's cleared posterior-leaning flange design and does not change its geometry, features, or indications.

The update gives clinicians a more precise way to document the posterior-leaning flange angle without introducing new geometry, features, or indications beyond the device's existing FDA-cleared design.

"This update reflects our commitment to precision in the way clinicians prescribe and describe mandibular repositioning therapy," said Raghavendra V. Ghuge, MD, MBA, DABSM, FAASM, founder and CEO of AIOMEGA®. "The ability to specify the posterior-leaning flange angle provides a clearer way to document and communicate a configuration already encompassed by the cleared AIO Breathe design."

AIO Breathe® Adult Device Description

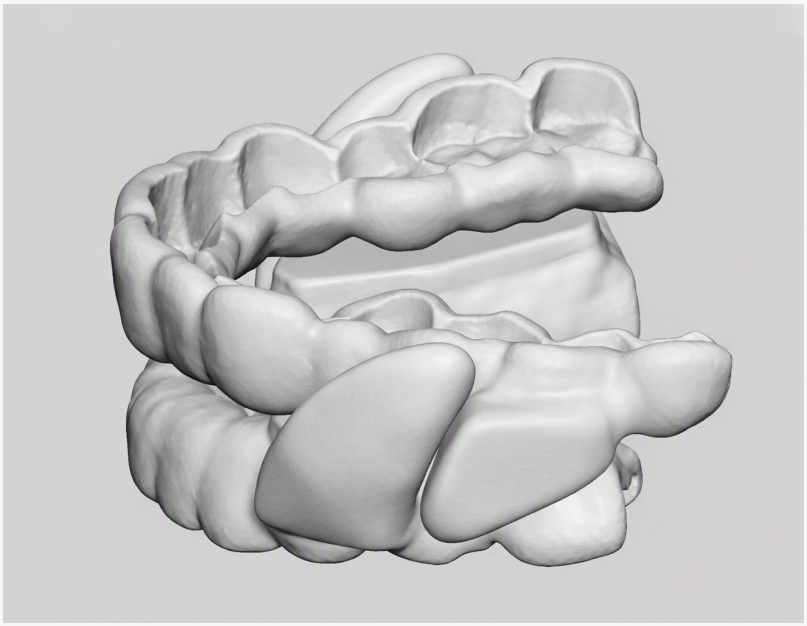
AIO Breathe consists of separate custom-fabricated upper and lower intraoral trays that fit over the teeth and require at least eight maxillary and eight mandibular teeth. The trays are produced with additive manufacturing technology and biocompatible materials suitable for intraoral use, based on intraoral scans and the dentist's prescription.

Right and left protrusive flanges on the buccal sides of the upper tray engage corresponding vertical flanges on the lower tray to reposition the mandible according to the dentist's prescribed

anterior advancement. Mandibular plateaus on the occlusal cranial surfaces of the lower tray guide the mandible downward to create additional anterior airway space. Together, the flanges and plateaus maintain mandibular advancement while allowing natural tongue migration.

Mechanism of Action

As the mouth opens, the Connected Arc of Motion™ mechanism guides the mandible anteriorly to maintain forward positioning during jaw rotation. This function is particularly relevant during supine sleep, when airway patency may be more vulnerable.



AIO Breathe oral appliance for Obstructive Sleep Apnea in children, teenagers and adults

The device permits anterior, vertical, and lateral jaw movement. It is designed to maintain an open airway and increase air exchange by advancing the mandible and tongue during opening, closing, and lateral mandibular movement.

> This update reflects our commitment to precision in the way clinicians prescribe and describe mandibular repositioning therapy"
>
> *Raghavendra V Ghuge, MD, MBA, DABSM, FAASM*

FDA-Cleared Indications for Use (Adult)

Intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) while sleeping in adults.

Additional IFU Clarifications

These clarifications do not modify the FDA cleared Indications for Use:

- AIO Breathe is for adults 18 years of age and older.
- The device is prescription only, to be used under the supervision of a qualified clinician.
- AIO Breathe does not include or require a morning repositioner, consistent with the device's Instructions for Use.

Clinical Context: OSA and Its Impact

Obstructive sleep apnea involves repeated upper-airway obstruction during sleep. It may contribute to oxygen desaturation, increased respiratory effort, sleep fragmentation, sympathetic activation, and cardiometabolic stress. Untreated OSA has been associated with:

- Impaired cognitive performance
- Behavioral dysfunction and mood disturbance
- Daytime sleepiness and reduced vigilance
- Cardiovascular strain and elevated cardiometabolic risk
- Metabolic dysregulation

Mandibular repositioning devices are commonly used to reduce upper-airway collapsibility by advancing the mandible. AIO Breathe's traction-based design is intended to maintain mandibular advancement during mouth opening and help preserve airway space in vulnerable sleep positions, including supine sleep.

About AIOMEGA®

AIOMEGA® is a Texas-based biomedical company developing airway and sleep-health technologies through engineering, clinical innovation, and precision-guided intraoral device design, including the FDA-cleared AIO Breathe® mandibular repositioning device.

Patent Notice

The posterior□leaning flange angle specifications referenced in this release are protected by issued and pending U.S. patents whose inventor is Raghavendra Ghuge and whose assignee is Sleep Solutions of Texas, LLC.

Trademark Notice: The AIOMEGA name and design and AIO Breathe are trademarks of AIOMEGA LLC.



AIO Breathe oral appliance for Obstructive Sleep Apnea in children and teenagers

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