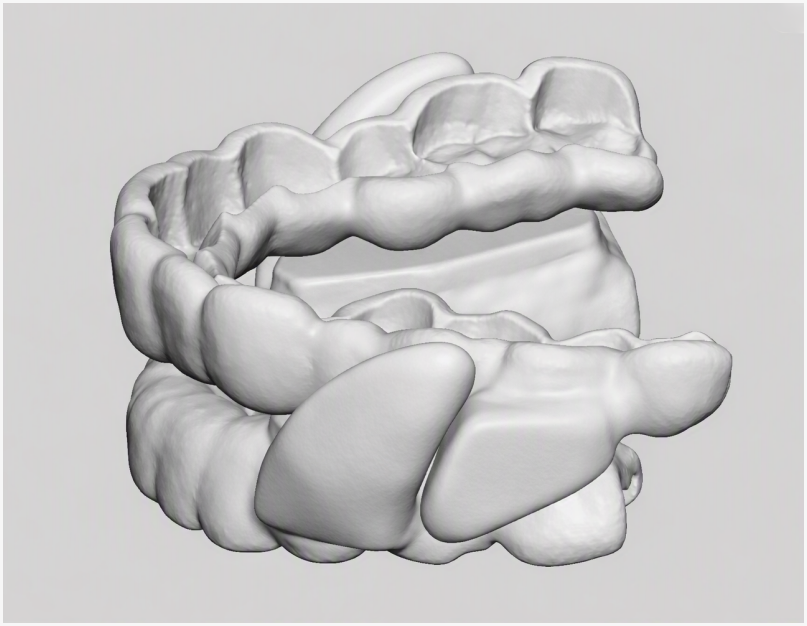
AIOMEGA® Introduces Pediatric Prescribing Precision and AIO Breathe Academy™ for Clinicians Treating Children Ages 6–17

Pediatric OSA clinicians document posterior leaning flange angles within the FDA cleared AIO Breathe design, supported by AIOMEGA's clinician training Academy™.



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



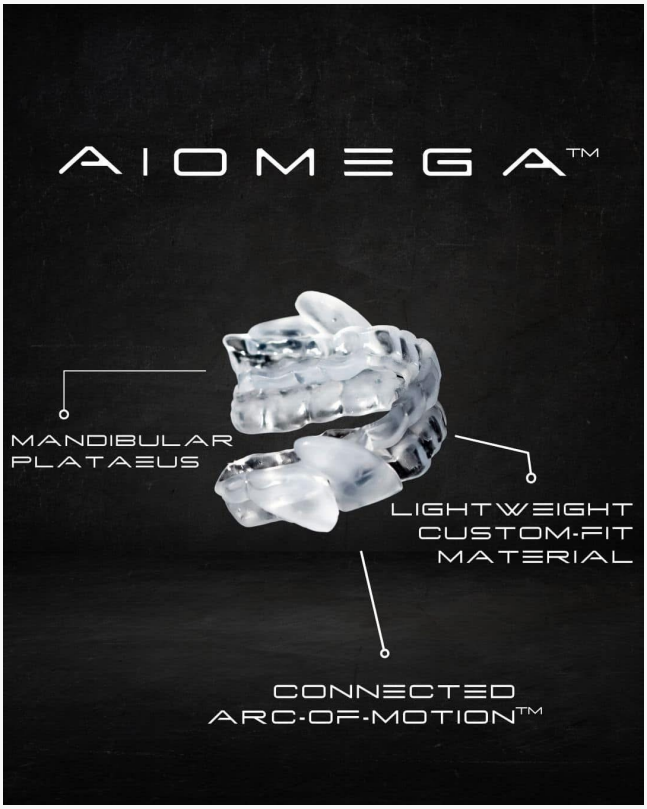
AIO Breathe oral appliance for Obstructive Sleep Apnea in children, teenagers and adults

TYLER, TX, UNITED STATES, September 21, 2026 /EINPresswire.com/ -- AIOMEGA®, a Texas biomedical company, announced that clinicians prescribing AIO Breathe®, an FDA cleared mandibular repositioning device for children ages 6–17 with snoring or mild to moderate obstructive sleep apnea (OSA), may document a posterior leaning flange angle greater than 90 degrees in AIOMEGA's SMART Rx™, AIO Rx™ documentation tools. 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 oral appliance for treatment of adult and pediatric Obstructive Sleep Apnea

AIO Breathe® Pediatric Device Description
AIO Breathe consists of separate custom fabricated upper and lower intraoral trays that fit over the teeth and require adequate dentition for retention. 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

> 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.”
>
> *Raghavendra V Ghuge, MD, MBA, DABSM, FAASM*

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.

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.
FDA Cleared Indications for Use (Pediatric)
Intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in children ages 6–17.

Additional IFU Clarifications

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

AIO Breathe is for children ages 6–17.

The device is prescription only, to be used under the supervision of a qualified clinician.

The FDA cleared pediatric Instructions for Use specify that AIO Breathe may not be modified as the child grows; the device must be replaced to accommodate craniofacial growth and development.

AIO Breathe does not include or require a morning repositioner, consistent with the device's Instructions for Use.

AIO Breathe Academy™ and Growth Conscious Replacement System™ (GCRS™)

The AIO Breathe Academy™ provides clinicians with structured education on the FDA cleared posterior leaning flange design (PLL™), including prescriptive precision options such as documenting a posterior leaning flange angle greater than 90 degrees. The Academy's Growth Conscious Replacement System™ (GCRS™) offers dentists additional training tools to custom order AIO Breathe devices that accommodate craniofacial growth and development in children ages 6–17. Growth and development present unique challenges in pediatric OSA, and AIOMEGA is committed to supporting clinicians with education, training, and precision guided workflows.

Clinical Context: Pediatric OSA and Its Impact

Pediatric obstructive sleep apnea involves repeated upper airway obstruction. It may contribute to oxygen desaturation, increased respiratory effort, sleep fragmentation, behavioral disturbance, impaired learning, and cardiometabolic stress. Maintaining airway patency during sleep is essential for promoting healthy neurocognitive and physiological development in children. Diagnosis and management of childhood obstructive sleep apnea syndrome - PubMed

Pediatric obstructive sleep apnea has been associated with neurocognitive, behavioral, and cardiometabolic consequences, as described in multiple published studies and clinical guidelines, including the American Academy of Pediatrics Clinical Practice Guideline (Marcus et al.), reviews by Lumeng and Chervin, and research by Gozal and Kheirandish Gozal. Craniofacial growth during childhood and adolescence is well documented in orthodontic literature (Enlow & Hans; Proffit et al.), supporting the FDA cleared requirement that AIO Breathe be replaced as children grow. Mandibular advancement has been shown to improve upper airway patency through anterior displacement of the mandible and tongue (Isono et al.; Schwab et al.).

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.

Media Contact
Advait Ghuge AIOMEGA LLC Phone: +1 (903) 787 7533 Email: contact@aiomd.com Website: https://aiomd.com

Raghavendra V Ghuge
AIOMEGA LLC
+1 903-316-1269
email us here
Visit us on social media:
LinkedIn
Instagram
Facebook

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