

	Airway Management	Advanced Brain Monitoring Inc	Glidewell Laboratories
<b>Appliance</b>	 myTAP	 Apnea Guard	 Silent Nite sl
<b>Website</b>	<a href="http://www.tapintosleep.com">www.tapintosleep.com</a>	<a href="http://www.advancedbrainmonitoring.com/apnea-guard">www.advancedbrainmonitoring.com/apnea-guard</a>	<a href="http://glidewell dental.com/services/dental-sleep-medicine/silent-nite-sl">glidewell dental.com/services/dental-sleep-medicine/silent-nite-sl</a>
<b>FDA Status</b>	FDA cleared (Class II Device)	FDA cleared in 2011 (Class II Device)	FDA cleared June 25, 1997
<b>How It Works</b>	Mandibular advancement device.	The Apnea Guard combines a full range of mandibular advancement with one of three vertical dimension settings to define the optimal jaw forward position for the treatment of obstructive sleep apnea. The Apnea Guard can serve as a titration appliance with the optimized settings transferred to a custom appliance or used as a trial/temporary appliance for up to 30 days.	Mandibular advancement appliance. Connectors on right and left buccal side will pull the mandible in protrusion to open up the airway. 6 adjustable settings.
<b>Time to Fit</b>	10-15 minutes (with an AM Aligner)	6-12 minutes (depending on experience)	Varies but shouldn't exceed 15 minutes
<b>Fitting Description</b>	One at a time, the trays are submerged in hot water for 1 minute until the trays turn from white to clear. Once the trays are clear, place the tray over the teeth. The tray cools on the patient's teeth for 2-4 minutes (depending on retention needed).	The Apnea Guard is cleared by the FDA to be fitted by any trained healthcare professional. The retention material is mixed and fitted to the lower teeth into the bottom tray, followed by fitting of the upper teeth into the top tray. The fast-setting retention material enables these two steps to be completed in approximately 6 minutes with no specialized materials (ie, boiling water, etc). The retention material can be removed and the fitting repeated if necessary.	Needs to be snug. Both upper and lower trays will be tugging on each other to get adequate mandibular advancement, so it needs to be snug and not too passive.
<b>Adjustment Description</b>	Use the adjustment dial located on the post. The myTAP can be advanced in 1/3 mm increments and has a 21 mm range of adjustment.	The settings on the Apnea Guard when inserted in the mouth at the natural/neutral jaw position and maximum advancement are used to define the optimal protrusion. The optimal advancement is estimated at 70% of the distance between the neutral and maximum jaw positions, obtained using a look-up table.	May need to switch out the 6 different connectors to get ample advancement of the mandible to open the airway.
<b>Materials</b>	The inner tray material is a patented ThermAcryl material that can be reformed and remolded if necessary.	5.5 grams of catalyst and base retention material are required to fit the top or bottom trays of the low, medium, or high Apnea Guard.	Upper and lower trays and comes with 6 different connectors to advance the mandible. Trays are standard soft inner liner and hard outer layer. May also come in hard/hard based on undercuts.
<b>Efficacy Data</b>	The myTAP design is based on the custom TAP. TAP custom devices have over 38 independent peer-reviewed studies. The myTAP is currently being studied on its own as well.	The trial OA provided superior efficacy as compared to the Custom OA during supine sleep (see research row for citation).	Not provided
<b>Predictive Value Data</b>	Since the myTAP uses the same advancement design as all the custom TAP devices with single point, midline advancement, it is great to use to predict whether oral appliance therapy will work for a patient.	Identifying responders to custom oral appliance: Odds 3.4 p<0.02. Identifying those who achieve a custom OA AHI < 10: Odds 4.0 p<0.002. (Data presented at AADSM 2019)	Not provided
<b>Warranty (days)</b>	30	30	180
<b>Estimated Useful Life</b>	3 months	30 days	Varies based on factors such as clenching, bruxing, and maintenance
<b>Payer Reimbursement Status</b>	Not provided	Providers have been consistently reimbursed using E0485.	Not provided
<b>Research Supporting the Appliance</b>	Not provided	Levendowski DJ, et al. Initial evaluation of a titration appliance for temporary treatment of obstructive sleep apnea. <i>J Sleep Disord Ther.</i> 2012 Jan;1(1). Morgan T, et al. Comparison of efficacy from a custom and trial oral appliance. 2019 Clinical Research Award Recipient from the American Academy of Dental Sleep Medicine.	Borrie F, Keightley A, Blacker S, Serrant P. Mandibular advancement appliances for treating sleep apnoea/hypopnoea syndrome. <i>Evid Based Dent.</i> 2013 Mar;14(1):27-8. doi: 10.1038/sj.ebd.6400921.

	BlueSom	HealthyStart/Ortho-Tain	SomnoMed Inc
<b>Appliance</b>	 BluePro	 Snore-Cure	 SomnoDent ALPHA
<b>Website</b>	www.bluepro.pro	www.orthotain.com	somnomed.com/en/dentists/somnodent/alpha
<b>FDA Status</b>	FDA registered for snoring and mild to moderate sleep apnea in 2016	FDA cleared for snoring	FDA 510(k) cleared for snoring and mild to moderate obstructive sleep apnea in 2016
<b>How It Works</b>	BluePro is a first-step trial device fitted chair-side by trained dental professionals. Thermoplastic provides strong and long-lasting retention while a discrete titration mechanism allows for simple self-adjustment and fine-tuning.	4 mm (SC1) or 7 mm (SC2) of mandibular protrusion.	The SomnoDent ALPHA appliance consists of two generic splints, which fit over the upper and lower teeth, and the lower splint is held in a protrusive position by an advancement mechanism. The device advances the mandible in the sagittal plane to increase the patient's pharyngeal space during sleep and reduce the apneic symptoms.
<b>Time to Fit</b>	10 minutes	Deliver as is or customize chair-side by adding Snore-Cure's lining material to lower portion for more retention	10 minutes
<b>Fitting Description</b>	Upper and lower splints are immersed in boiling water for 1-2 minutes until the thermoplastic material becomes soft and clear. Each splint is removed from the water to cool for 1 minute before fitting separately to upper and lower arches. After cooling and setting on the teeth for 4 minutes, the splints are removed and finished by trimming any excess thermoplastic material with a sharp knife. Upper and lower splints are connected to form the finished appliance before re-inserting in the mouth to find the optimal level of mandibular protrusion to begin therapy.	Deliver as is.	There are 4 simple steps to achieve a great fit with SomnoDent Alpha. To ensure the fit is accurate, SomnoMed recommends fitting by a health care professional.
<b>Adjustment Description</b>	A comfortable starting position can be found under the supervision of a trained dentist by inserting the device unlocked into the mouth and moving the lower jaw. When the optimal level of protrusion is found, the device is removed and locked in position before wearing during sleep. A titration protocol is recommended whereby the lower jaw is advanced 1 mm per week if required until symptoms are relieved.	No adjustments needed unless customized.	The appliance has an adjustable coupling mechanism enabling the amount of mandibular advancement to be titrated. The SomnoDent Alpha utilizes the interaction of a wing and a lug, both affixed to rails on the sides of the respective splints. The coupling of the wing/lug to the rail uses a clip-lock technology to prevent retrusion motion and allows the user to adjust the advancement with protrusion motion. The wings and lugs are adjustable in 1.0 mm steps. The wing or lug is pushed along the rail in direction of the arrow and operator will hear a distinct "click" as it moves each 1.0 mm.
<b>Materials</b>	Rilsan plastic splints (no latex or BPA) with thermoplastic lining	Medical-grade elastomer	Not provided
<b>Efficacy Data</b>	See research row for citations (Gagnadoux, Ibrahimi, and Braem studies).	Not provided	Not provided
<b>Predictive Value Data</b>	See research row for citations (Gagnadoux and Ibrahimi studies).	Not provided	Not provided
<b>Warranty (days)</b>	30	90	30
<b>Estimated Useful Life</b>	1 year	2 years	SomnoDent Alpha is a transitional device designed to be used for no longer than 3 months, after which the patient should be fitted for a custom-made SomnoDent oral device
<b>Payer Reimbursement Status</b>	Pending in the United States. In France, reimbursed by social security as a test appliance.	Not provided	Reimbursable by medical insurance
<b>Research Supporting the Appliance</b>	Gagnadoux et al. Comparison of titrable thermoplastic versus custom-made mandibular advancement device for the treatment of obstructive sleep apnoea. <i>Respir Med.</i> 2017 Oct;131:35-42. El Ibrahimi M, et al. Pilot study of a new adjustable thermoplastic mandibular advancement device for the management of obstructive sleep apnoea-hypopnoea syndrome: a brief research letter. <i>Open Respir Med J.</i> 2016 Jul 15;10:46-50. Braem M. In vitro retention of a new thermoplastic titratable mandibular advancement device. <i>F1000Res.</i> 2015 Feb 26;4:56.	Not provided	Not provided