

Company		Advanced Brain Monitoring Inc	Airway Management Inc	Apnea Sciences	BlueSom
Product		 Apnea Guard	 dreamTAP	 ApneaRx	 BluePro
Website		www.advancedbrainmonitoring.com/apnea-guard	www.tapintosleep.com	www.apnearx.com	www.bluepro.pro
Warranty (days)		30	365 (for parts), 60-day satisfaction guarantee	30 (guarantee with full refund); 90 (replacement)	30
INDICATIONS	Mild to Moderate OSA	X	X	X	Pending
	Snoring	X	X	X	Pending
	Bruxism				
TYPE	Custom		X		
	Noncustom	X			X
	Boil and Bite			X	X
How Does the Oral Appliance Work?		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.	The dreamTAP advances and stabilizes the jaw, preventing the tissues of the throat and tongue from collapsing into the airway.	Advances the mandible in precisely marked 1 mm increments.	BluePro is a first-step trial device fitted chair-side by trained dental professionals. High performance thermoplastic provides strong and long-lasting retention while a discrete titration mechanism allows for simple self-adjustment and fine-tuning.
Fitting Description		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.	All TAP custom products empower patients to fine-tune treatment at home, as well as work with the clinician to achieve the best results. With a single point of midline adjustment, the dreamTAP prevents uneven bilateral adjustment that may create an irregular bite and jaw discomfort. Initial protrusion is set during the fitting process and is easily modified. Three different hook sizes allow for the greatest range of adjustment (15 mm) with minimal hardware. Posterior stops may be added for comfort. All TAP custom devices meet Medicare (E0486) requirements to treat OSA.	Fitting takes less than 10 minutes. Submerge in boiled water for 90 seconds. Dip into cup of tap water for 3 seconds to cool off. Place in patient's mouth to custom mold for 30 seconds.	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.
Adjustment Description		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.	Adjustment may be made by the patient with the appliance in the mouth in 1/3 mm increments. An anterior dial with one point of adjustment prevents unequal torque. The clinician teaches a home titration schedule, which engages the patient in the therapy process. The dreamTAP may also be easily adjusted in a sleep lab by the sleep tech during a study.	Simple patented adjustment mechanism is unaided by external accessories (screws, bands, etc). Provides 1 mm adjustment and locking capability with a 10 mm range.	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.
Materials		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.	Cobalt chromium hardware, the trays are made of a durable polymer and the inner lining is one of two types designated by the clinician. Triple Laminare is the most popular, using DuraSoft, which enables retention by comfortably gripping the teeth. ThermAcryl is the other option, which softens when heated to allow reshaping for patients who are having dental work.	Soft thermal plastic and hard acrylic.	Rilsan plastic splints (no latex or BPA) with thermoplastic lining
Recommended Cleaning		Rinse with cold water and air dry.	Clean thoroughly after each use with a regular soft toothbrush, mild soap, and cool water. Always rinse thoroughly and allow to air dry before storing in the container.	Clean daily with soft toothbrush and toothpaste.	Daily cleaning with cold water and soft toothbrush. Regular soaking in a sterilizing solution.
Peer-reviewed Study		Not provided	Hoekema A, Stegenga B, et al. Obstructive sleep apnea. <i>Journal of Dental Research</i> . 2008;87(9):882-887.	Not provided	Braem M. In vitro retention of a new thermoplastic titratable mandibular advancement device. <i>F1000Res</i> . 2015 Feb 26;4:56. doi: 10.12688/f1000research.6061.1. eCollection 2015.

Information for this guide based on data submitted by product manufacturers. Sleep Review strives for accuracy in all data but cannot be held responsible for claims made by manufacturers. Manufacturers were specifically asked to provide FDA-cleared indications only.

Dream Systems LLC	Glidewell Laboratories		Great Lakes Orthodontics Ltd	Keller Laboratories	Luco Hybrid OSA Appliance Inc
 OASYS with Nasal Dilators (Optional Tongue Repositioners)	 aveoTSD	 Silent Nite sl	 Herbst Appliance	 ClearDream	 The Luco Hybrid OSA Appliance
www.dreamsystemsdentallab.com	www.glidewell dental.com	www.glidewell dental.com	www.greatlakesortho.com	www.kellerlab.com	www.lucohybridosa.com
365	180 (replacement if device defective)	182 (if failure due to defects in materials or craftsmanship)	90 (metal component); 365 (body material)	365	1,695
X	X		X	X	X
X	X	X	X	X	X
X			X		
X		X	X	X	X
	X				
The device repositions the mandible, the nasal dilators improve nasal breathing, and the tongue buttons improve tongue position, plus a removable bracket can be added for combination therapy with CPAP.	Unlike traditional mandibular advancement devices that indirectly move the tongue forward by moving the mandible, the aveoTSD gently suctions onto the tongue, preventing it from falling back into the throat and obstructing the airway.	Silent Nite sl works by positioning the lower jaw forward using special S-shaped connectors that are attached to upper and lower trays, which increases the volumetric capacity of the airway.	It works by repositioning and holding the mandible in a more protrusive position, thereby holding the tongue forward and airway open.	The ClearDream maintains an open airway using titratable posterior hardware on the upper arch, which determines the amount the mandible and pharyngeal tissue are held forward.	Mandibular advancement moves the tongue and jaw forward opening and maintaining the airway. Vertical wing design prevents retraction when sleeping.
The Oasys upper splint is placed. The lower splint with anterior shield is seated. If combination therapy is required, the appliance is retrofitted to include a removable bracket.	The aveoTSD is available in three sizes: small, medium, and large. The medium size fits 90% of individuals, though health professionals can purchase a patient sizing kit to properly choose a device for each patient.	It is custom thermoformed in the laboratory from the patient's models. A bite registration taken with the Slide-Link protrusion gauge is used to determine protrusive position and align the device.	Very few adjustments are required. The hard acrylic snaps into place. When requested, retention clasps can be added.	The ClearDream is custom fabricated from full arch upper and lower casts, scans, impressions. Immerse in warm tap water for 10 seconds to moisten before seating. Insert upper and lower arch separately, ensuring a gentle, but snug fit. Next, reinsert the appliance, starting with the upper, and have the patient protrude until they can engage the mandibular "fins" against the maxillary buccal pads. Inspect the bite relationship.	Very simple to insert, no lingual acrylic. Retained by four small ball clasps per appliance.
The anterior shield is on a sliding/locking system, with mm guides. Pushing on the shield increases protrusion/pulling reduces. Finger adjustment is used for the nasal and lingual buttons.	The aveoTSD is not adjustable.	Slide-Link connectors attach to the upper and lower trays. These connectors come in six lengths (21-26 mm) and are easily interchangeable by the patient if the lower jaw needs repositioning.	Small increments using advancement shims, or up to 5 mm with a 1 mm retrusion using telescopic hardware.	Titrate with provided adjustment key, which fits into screws on each side of the ClearDream's maxillary arch. To advance mandible forward, move key either up or down as guided by the arrow to turn the expansion screw, allowing for titration in as small as 0.1 mm increments with a total range of 5.5 mm. To move mandible backwards, move key in the opposite direction to the arrow.	Titration is by two orthodontic screws that are turned with a key (wire). Adjustable in 0.25 mm adjustments up to 6 mm.
Upper: 1.5 mm/2 mm Vacuform splint; lower: ThermoFlex hard splint, with hard acrylic shield, onlays, and buttons; stainless steel wire, ball clasps, locks; Duraloy wire for the nasal dilators and tongue buttons, plastic bracket and medical-grade nasal CPAP mask.	Medical-grade silicone.	Upper tray: soft polyurethane inner layer and a hard copolyester outer layer, which are BPA-free. Lower tray: this same dual-layered material or all hard copolyester (depending on retention).	Standard hard acrylic and soft version, but can be made of Variflex, a thermo-active option.	Keller's clinically unbreakable Clear 450 Acrylic. Available with a thermo-adaptive lining for ease of insertion and increased patient comfort.	Chrome cobalt, methyl methacrylate, stainless steel.
Brush gently with soft toothbrush and anti-bacterial soap. Use non-alcohol denture cleaner for 15 minutes. Air dry.	Rinse daily in hot water. Once a week, the aveoTSD should be given a thorough wash.	Rinse well with water before and after use and store dry. Clean appliance with soap and warm water only.	Use of DentaSOAK is recommended along with toothbrush and toothpaste daily. Must be stored dry.	Clean after each use with mild soap and water. Store dry. Do not use toothpaste, alcohol, or alcohol-based products.	Clean with liquid soap and a soft toothbrush.
Not provided	Not provided	Not provided	Journal of Sleep 2006	Not provided	Not provided

Company	MicroDental Laboratories	MPowrx Health and Wellness Products 2012 Inc	Myerson	OravanOSA
Product	 MicrO ₂ Sleep Device	 iSleepSound	 Myerson EMA	 Oravan Herbst
Website	www.micro2sleepdevice.com	www.isleepsound.com	www.myersontooth.com	www.oravansa.com
Warranty (days)	1,095	30	N/A	730
INDICATIONS	Mild to Moderate OSA	X	X	X
	Snoring	X	X	X
	Bruxism		X	
TYPE	Custom	X	X	X
	Noncustom		X	
	Boil and Bite			
How Does the Oral Appliance Work?	MicrO ₂ utilizes vertically mated buccal posts to advance and hold the mandible forward to open the airway.	iSleepSound uses tongue displacement technology to gently and comfortably solve snoring problems. By pulling the tongue gently forward, the device clears blocked airways, resulting in a quieter, more comfortable sleep.	EMA uses interchangeable elastic straps and posterior bite pads attached to thermoformed custom trays to allow gradual advancement of the mandible and increased vertical opening until treatment is successful.	The device opens the patient's airway through advancement of the mandible using an adjustable telescopic Herbst mechanism. Like the Oravan device, Oravan Herbst has a truly open anterior design, encouraging natural protrusion of the tongue and maximum patient comfort.
Fitting Description	The MicrO ₂ consists of a series of incrementally advanced full arches that are uniquely lingual-less and metal free. Dentists must provide MicroDental Lab with patient impressions or digital scans along with a repositioning or neuromuscular bite registration and prescribed advancements. Dentists and patients alike experience easy and fast insertion due to the accuracy of the digital design and milling process.	iSleepSound has been designed as "one size fits all" and requires no special fitting by a sleep specialist. The device fits comfortably between the lips and teeth and has an aperture with a bulb for holding the tongue. Once the bulb is squeezed to reduce the air volume, a vacuum is formed that keeps the tongue comfortably retained within the bulb.	Fit the upper and lower appliances without the elastic straps to check for comfort and to make sure there is no gingival impingement. Check the posterior bite pads for even occlusion.	The Oravan Herbst is custom fitted to each patient by a dentist who takes impressions and bite registration. As a result of the no anterior coverage, less clinical chair time is required, and the Oravan Herbst will not interfere with any anterior dental cosmetic work.
Adjustment Description	Adjustments are accomplished by simply removing an arch and inserting the next arch in the series of advancement arches. Combinations of different arches add up to a new titration increment. No screws, mechanisms, or elastics required.	Some find the device suction too strongly and makes their tongue sore; suggest they leave a pocket of air at end of bulb to ease suction. Others say it does not suction enough and dislodges their tongue; suggest a dab of olive oil inside the bulb to help increase suction. The third group finds it just right; no adjustment suggestions are needed.	The EMA appliance uses 4 different strengths of elastic straps in 9 different lengths to gradually titrate the mandible. The shorter or stronger the strap, the further the mandible is advanced.	The Oravan Herbst can be adjusted by inserting the key into the adjustment mechanism that is located on the anterior mandibular component of the device. Can be advanced in very small increments, up to 5 mm.
Materials	Pre-polymerized, milled polymethyl-methacrylate (PMMA).	Soft, thin, flexible medical grade plastic resin. BPA free.	Completely metal free; the custom trays are made from a proprietary thermoplastic and the straps from a latex-free polymer.	Acrylic.
Recommended Cleaning	Clean daily using a soft toothbrush with mild toothpaste or mild detergent. Do not soak. Store in dry container.	Clean regularly with any denture/orthodontic appliance cleaning solution or tablets. A mix of toothpaste and water can also be used. Let it soak for 10 minutes with the cleaning solution and cold water, swishing it before taking it out to air dry.	Clean appliance in tepid water with a toothbrush and toothpaste or soak it in a denture cleaning solution; no mouthwash.	Clean with cold water and a soft toothbrush every morning. If one wishes to use toothpaste to clean the Oravan Herbst, brush lightly and thoroughly rinse. Shake dry and store the device in its container until the next use.
Peer-reviewed Study	Hu J, Kuhns D, Kim S, Liptak L, Sheppard L. Case Report: The MicrO ₂ Sleep Device. <i>Dental Sleep Practice</i> . Summer 2015;24-7.	Brant R, Dort L. A randomized, controlled, crossover study of a noncustomized tongue retaining device for sleep disordered breathing. <i>Journal of Sleep and Breathing</i> . 2008 Nov;12(4):369-73.	Sutherland K, et al; on behalf of the ORANGE-Registry. Oral appliance treatment for obstructive sleep apnea: an update. <i>J Clin Sleep Med</i> . 2014;10(2):215-227.	Sutherland K, et al; on behalf of the ORANGE-Registry. Oral appliance treatment for obstructive sleep apnea: an update. <i>J Clin Sleep Med</i> . 2014;10(2):215-227.

Oventus	Panthera Dental	ResMed	SML-Space Maintainers Laboratories	SomnoMed
				
O ₂ Vent	Panthera D-SAD (Digital – Sleep Apnea Device)	Narval CC	Lamberg–Sleep Well Appliance	SomnoDent Herbst Advance with Compliance Recorder
www.ventus.com.au	www.pantherasleep.com	www.resmed.com/narval	www.smlglobal.com	www.somnomed.com
1,825 (for titanium mouth guard) 365 (for polymer inserts)	1,825	1,095	1,095	365 (non-Medicare); 1,095 (Medicare)
X	X	X	X	X
X	X	X	X	
	X		X	
X	X	X	X	X
The Oventus O ₂ Vent is a new, custom-made, comfortable oral device that is successfully treating snoring and sleep apnea. It can also treat people with nasal obstruction equally well as those with patent nasal airways. The device includes a patented airway that is designed to direct the flow of air through to the back of the throat and bypass nasal, soft palate, and tongue obstructions.	The appliance uses the posterior teeth to maintain the lower jaw in a protruded position. The D-SAD is a CAD/CAM appliance that offers the option of Braebon Dentitrac (in some countries), thus enabling compliance monitoring.	Narval CC uses an optimized articulation method that maintains the mandible in an advanced position, opening the upper airway to enable effective treatment.	It advances the mandible by holding it in a protrusive position.	The first oral device with compliance recording (only can be offered by SomnoMed in its oral devices), it advances the mandible to open the airway and hold the jaw in position.
The clinician takes impressions and bite registration for the patient, which are sent to Oventus for manufacturing the appliance. Scans of the dental models are loaded into proprietary software to design the appliance. The bespoke designs are then 3D printed using titanium. Following polishing and forming the polymer inserts on the top and bottom, the appliance is packaged and sent to the clinician for delivery to the patient.	Compatible with intra-oral scanning technology or regular dental impressions. Each case is designed on proprietary software so that retention can be adjusted individually. Panthera Dental can work with any bite and can design the case according to any dentists' requirements.	Narval is a computer-aided design and computer-aided manufacturing (CAD/CAM) MRD device, and each device is fitted specifically to the patient by their dentist. The dentist will take an impression—just like they would for any dental procedure—and will define the initial amount of protrusion required. The lateral flexibility allows patients to talk and drink while wearing the device.	The dentist seats the upper and lower appliance separately to determine: a snug and secure fit, patient comfort, and the ability of the patient to easily insert and remove the appliance. Adams clasps adjust to achieve optimal comfort and retention.	The patient will be fitted for the device by a qualified dental sleep professional. The dentist will make a model of the patient's teeth and take a protrusive bite registration.
The current FDA-cleared device is not adjustable. A new, enhanced adjustable version is pending 510(k) clearance, which is expected later in 2016. Adjustment is by way of a screw in the front section of the device attaching the upper and lower sections with up to 14 mm of advancement achievable in total and lateral movement also possible.	Panthera Dental uses a patented locking mechanism so the rods can be easily replaced for titration. The rods will not disengage during sleep and will not elongate, even in the case of patients with bruxism. Rods come in 0.5 mm increments and lengths vary from 18 mm to 35 mm.	If patients are still experiencing symptoms at first follow-up, the dentist will adjust fit by replacing the flexible, non-metal connecting rods to adjust fit. Narval CC is easy to titrate and highly adjustable with connecting rods that allow for 15 mm of protrusive range at 0.5 mm increments.	Each patient receives his/her own box of inserts, which includes a sequence of numbered protrusive elements that advance the mandible in 0.5 mm increments. The patient simply pops out the insert on the upper member and replaces it with the following insert in the numbered sequence.	Herbst Advance can easily be adjusted in 0.1 mm increments by using provided titration key; gauge protrusive movement by using the proprietary visual indicator, giving total control of their treatment. With an 8 mm range of calibration, even when starting patients with a conservative protrusive registration you can offer patients continuous therapeutic efficacy.
Polished titanium (permanent 3D printed mouth guard); dental polymer laminate (customized plastic molds to fit the teeth).	Type 12 organic polyamide (appliance and rods). This flexible and lightweight nylon is available through a CAD/CAM process.	A flexible, lightweight polymer that is CAD/CAM custom-made for a patient's mouth.	Special SML brand sleep appliance acrylic.	Acrylic.
Wash daily under running water. Twice a week use an ultrasonic cleaner in warm water with an effervescent retainer cleaning tablet.	Prepare the provided solution using tap water. Soak appliance in solution during the day. Rinse under fresh water before use.	Daily cleaning recommended. Rinse in lukewarm water; clean with a soft, clean toothbrush. (Do not use the same toothbrush used to brush teeth, as toothpaste can damage the device.) Rinse in lukewarm water, and dry with a clean paper towel before putting it back in storage box.	Clean once daily with OAP anti-microbial dental appliance cleaner.	Clean the device every morning after removing it from the mouth using a soft toothbrush, but never use toothpaste as it contains abrasives. SomnoMed recommends using SomnTabs for daily cleaning of a SomnoDent device.
Not provided	Not provided	Vecchierini MF, Attali V, Collet JM, et al. A custom-made mandibular repositioning device for obstructive sleep apnoea-hypopnoea syndrome: the ORCADES study. <i>Sleep Med.</i> 2015.	Not provided	Not provided

Company	Somnowell Inc	Tomed GmbH	Whole You Inc
Product	 Somnowell Chrome	 SomnoGuard AP	 Respire Blue EF
Website	www.somnowell.com/en-us	www.tomed.com	www.wholeyou.com
Warranty (days)	2,555	365 (against manufacturer's defects)	365
INDICATIONS	Mild to Moderate OSA	X	X
	Snoring	X	X
	Bruxism		
TYPE	Custom	X	X
	Noncustom		
	Boil and Bite		X
How Does the Oral Appliance Work?	It holds the jaw forward in a non-laterally displaced position using an adjustable telescopic Herbst mechanism. The chrome cobalt frameworks act as anchorage.	The 2-part SomnoGuard AP repositions the lower jaw forward and thereby prevents the collapse of the upper airway. With the device in place, the upper airway is wider and the patient can breathe more easily without snoring.	The Respire Blue EF maximizes tongue space by using a thin, yet strong chrome material on the lingual and anterior areas.
Fitting Description	The dentist will take accurate records to include dental impressions and a forward positioned non-laterally displaced bite. Additionally, the dentist will take a Facebow registration so the technician can mount the records on a jaw simulator (semi-adjustable articulator), so the Somnowell Chrome should work in harmony with the patient's jaw joints.	Fitting can be done by doctors or their trained staff in approximately 15 minutes. No special accessories needed apart from a boiling water bath, a small pair of scissors, and gripping tongs.	Place the upper piece in first, and then the lower.
Adjustment Description	The telescopic Herbst arms have a fine adjustment/titration facility. This is achieved by turning the adjustment nut. Adjustment of up to 5 mm is possible. The frameworks can have minor adjustments made by the dentist.	The lower jaw can be infinitely repositioned forward (titration) by any degree up to about 10 mm by an adjusting screw inserted into the screw guide of the lower jaw tray. Adjustments are quickly and easily made outside of the mouth. Protrusion changes can be done by doctors or the instructed patients themselves.	The adjustment screw allows advancement up to 6 mm.
Materials	Chrome cobalt and stainless steel.	Rigid tray walls: rigid polycarbonate; lining: soft thermal copolymer; stainless steel adjusting screws.	Acrylic and chrome.
Recommended Cleaning	Scrub under clean water with a toothbrush. Dishwasher safe.	Clean daily with soft toothbrush and mild liquid soap or a liquid denture cleaner. Rinse and let the device dry in the open air.	Upon removal the device should be rinsed and cleaned with soap and water, using a soft brush.
Peer-reviewed Study	Ash SP, Smith AM. Chrome cobalt mandibular advancement appliances for managing snoring and obstructive sleep apnoea. <i>Journal of Orthodontics</i> . 2004;31:295-299.	Banhiran W, Kittiphumwong P, Assanasen P, Chongkolwattana C, Methetrairut C. Adjustable thermoplastic mandibular advancement device for obstructive sleep apnoea: outcomes and practicability. <i>Laryngoscope</i> . 2014 Oct;124(10):2427-32.	Not provided

Dental Sleep Services



Ez Sleep

Ez Sleep is a national provider of home sleep testing diagnostic services for the medical and dental community. It has a large array of HST devices from top-line manufacturers and provides baseline and efficacy testing metrics and 24/7 tech support. Concierge-level service and data-driven product offerings increase patient/provider engagement. Over 1,300 active clients use Ez Sleep Academy online training modules to learn methods to identify patients and other practice growth resources. Ez Sleep also provides innovative products like the Night Shift wearable for positional therapy and the Apnea Guard trial appliance. Through strategic partnerships, Ez Sleep offers an end-to-end solution for practices to screen, test, trial, and treat patients. inquiries@ezsleepstest.com; www.ezsleeptest.com



Rondeau Seminars Ltd

Brock Rondeau, DDS, is a Diplomate of the International Board of Orthodontics, Diplomate American Board of Craniofacial Pain, Diplomate-Academy of Clinical Sleep Disorders Disciplines, Diplomate American Board of Dental Sleep Medicine, Diplomate American Board of Craniofacial Dental Sleep Medicine, Master Senior Certified Instructor for the International Association for Orthodontics, and was awarded the Leon Pinker Award and Duane Stanford Award. His expertise in teaching, combined with his insatiable thirst for knowledge in the orthodontic arena, has pushed Rondeau to the top of the orthodontic/orthopedic lecture circuit. www.rondeauseminars.com

JOIN OUR SLEEP REVIEW LINKEDIN GROUP

Industry Discussions
Article Suggestions
Feedback


