






# ORAL APPLIANCE TITRATION DEVICES/GAUGES

Company	Advanced Brain Monitoring Inc	Airway Management Inc	Apnea Sciences	Kosmo Technologies Inc	Zephyr Sleep Technologies Inc
<b>Product</b>	 Apnea Guard	 myTAP	 ApneaRx	 Andra Gauge	 MATRx
<b>Website</b>	www.advancedbrainmonitoring.com/apnea-guard	www.mytapappliance.com	www.apnearx.com	www.andragauge.com	www.zephyrsleep.com
<b>FDA 510(k) Clearance</b>	Yes	Yes	Yes	Yes	Yes
<b>CAN TITRATE FOR</b>	<b>Mild to Moderate OSA</b>	X	X	X	X
	<b>Severe OSA</b>		X	X	X
	<b>Snoring</b>	X	X	X	X
	<b>Bruxism</b>				X
<b>Titration Done By</b>	Sleep tech, dentist, patient, or clinician	Patient or sleep tech; dentist provides patient with titration schedule	Patient	Dentist	Healthcare professionals working in a sleep lab (eg, sleep techs, sleep physicians)
<b>Titration Location</b>	In sleep lab or at patient's home	In sleep lab or at patient's home	At patient's home	At dental office	In sleep lab
<b>Predictive Value Explanation</b>	Predicts optimal jaw position for custom appliance based on protrusion and vertical dimension of occlusion (VDO).	The myTAP can be used to predict the optimal treatment position by titrating at home or in a sleep lab while maintaining the comfort needed for compliance.	100% positive predictive value to custom oral appliance performance.	The Andra Gauge can move both vertically as well as anteriorly/posteriorly at the same time in fractions of millimeters. The Andra Gauge provides the ability to identify if a mandibular position is comfortable and beneficial before a device is made.	MATRx prospectively determines, in a single night, whether or not a patient will experience therapeutic success* with an MRA before a custom-fitted MRA is made (PPV=94%**; NPV=83%; P < 0.05). MATRx will also determine the efficacious mandibular protrusive position in patients predicted to be therapeutically successful with an MRA (PPV=93%; P < 0.05). *AHI < 10 & 50% baseline AHI reduction. **PPV=100% when therapeutic success defined as AHI < 10.
<b>Adjustment Protocol</b>	Sleep centers: Fit titration appliance to ~60% protrusion; wear for 1 week to resolve muscular adaptation. Advance to 70% and conduct PSG or HST titration study. Refer to dentist to fabricate custom appliance based on titration settings; Dentists: Use titration appliance VDO and 70% protrusion settings for custom appliance delivery. Dispense the titration appliance at 60% protrusion for patient to wear while custom appliance is being fabricated. Conduct titration study to confirm predicted settings.	The adjustment protocol is determined by the dentist. The instructions suggest titrating the device 1/2 turn (1/4 mm) every 2 to 3 nights until the optimum treatment position is reached.	Simple patented adjustment mechanism is unaided by external accessories (screws, bands, etc). Provides 1 mm adjustment and locking capability with a 10 mm range.	"The Step Back Technique" starts with setting the Andra Gauge to an edge-to-edge position and the patient in a supine position. The patient creates a snoring sound. A/P and vertical adjustments are made in a stair-step fashion until the patient can no longer snore, the snore sound is significantly reduced, and/or the practitioner can hear that the airway had nonlabored breathing that accompanies an increase in airway opening.	The mandible is remotely titrated within the patient's pre-determined range of motion using small, consecutive advancement steps (eg, 0.2 mm) so as not to disturb sleep. Titration is continued until apneas/hypopneas are eliminated or the upper limit of allowed advancement is reached. Therapeutic success is predicted when 1 or less apneas/hypopneas are observed in 5 minutes of REM sleep supine. REM lateral can be used for confirmed side sleepers.
<b>Peer-reviewed Study</b>	Levendowski D, Morgan T, Westbrook P. Initial evaluation of a titration appliance for the temporary treatment of obstructive sleep apnea. <i>J Sleep Disord Ther.</i> 2011;1:101.	No (in progress)	No (in progress)	Van Leeuwen M, et al. A two-dimensional gauge and protocol for fitting oral appliances used in treating sleep breathing disorders. <i>Compend Contin Educ Dent.</i> 2015 Feb;36(2):140-2, 144-5.	Remmers J et al. <i>SLEEP</i> 2013;36(10): 1517-1525. Kastoer C et al. <i>J Clin Sleep Med</i> 2016;12(10): 1411-1421. Sutherland K et al. <i>J Clin Sleep Med</i> 2016 (in press).
<b>Additional Information</b>	The dental lab uses the bite registration and titration settings to fabricate the custom appliance to the exact same jaw forward position as the titration appliance.	See entry in the "Oral Appliances" matrix.	Poster presented by Dennis Hwang, MD, demonstrated a 56% responder rate (AHI: 50% reduction and ≤15) with 117 screened sleep apnea patients. That study showed 100% positive predictive value and similar performance to custom OAT.	Watch a detailed video of the entire Step Back Technique protocol at <a href="http://www.andragauge.com/videos">www.andragauge.com/videos</a> .	MATRx is a validated diagnostic device cleared by the FDA to predict therapeutic outcome with a custom-fitted MRA [mandibular repositioning appliance] after a single-night of study in a polysomnographic lab.