



Protocol for the Management of Oral Appliance Therapy by Sleep Medicine Professionals



Additional information available at:
www.advancedbrainmonitoring.com/apneaguard/

ABOUT THE AUTHORS



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He served as President of the American Academy of Sleep Medicine and member of the Board of Directors and Standards of Practice Committee and was acknowledged with a Distinguished Service Award in 1992. He also helped found the National Sleep Foundation and was honored with a Lifetime Achievement Award in 2009. He is a Clinical Professor of Medicine at UCLA, was a clinical fellow and Associate Professor of Medicine at Mayo Medical School in Rochester, MN and founding Director of the Sleep Disorder Centers at the Mayo Clinic from 1980 through 1989 and at Cedars-Sinai Medical Center, Los Angeles, CA from 1989 through 1995. He is an inventor of the Apnea Risk Evaluation System (ARES™) and collaborated in the development of the Apnea Guard®.



Daniel J. Levendowski, M.B.A.

He served as principal investigator in 17 National Institute of Health research grants providing over \$8 million in funding to improve the methods available to diagnose, measure symptoms and treat patients with Obstructive Sleep Apnea. He has co-authored more than 20 journal articles and 15 papers with study results based on home sleep testing or oral appliance therapy. These research efforts have resulted in 16 patents or patents-pending, including the Apnea Risk Evaluation System (ARES™) and Apnea Guard®. He was the principal investigator for a \$1.2 mm, 2.5 year NIH funded research effort to understand and improve outcomes with OAT, which contributed to the design of the Apnea Guard®. He received his MBA from the Anderson School of Management at UCLA.

The Apnea Guard protocol is the evidence-based approach to oral appliance therapy for the treatment of Obstructive Sleep Apnea which evolved from a \$1.1 mm U.S. National Institute of Dental and Craniofacial Research grant to develop novel sleep medicine practices that improve outcomes.

Table of Contents

Section I: Introduction to the Apnea Guard [®] Protocol	2
Section II: Frequently Asked Questions	4
Section III: Dental and Other Considerations	7
A. Patient Limitations and Consent	7
B. Minimum Number of Good Teeth	8
C. Temporary Tooth, Filling or Crown	8
D. Jaw Pain	9
E. OSA Severity and Variability in Outcomes	9
F. Influence of Vertical Dimension of Occlusion	10
G. Lateral Freedom of Movement	10
H. Appliance Retention	10
Section IV: Fitting the Apnea Guard and Assessing Efficacy	11
A. Apnea Guard Fitting	11
B. Outcome Assessment	12
Section V: Transferring Settings to the Custom Appliance	13
Section VI: Apnea Guard Troubleshooting	14
A. Improper Initial Fitting	14
B. Retention material falls out of tray(s)	15
C. Apnea Guard falls out during sleep - retention	15
D. Nocturnal drooling	15
E. Sore selected teeth	15
F. Generalized loosening of teeth	16
G. Lingering afternoon jaw pain	16
H. Lingering afternoon bite discrepancy	16
Appendix 1 –Comfort Surveys for Seven Nights	17

Section I: Introduction to the Apnea Guard® Protocol

The Apnea Guard appliance is fitted in less than 15 minutes and can be worn for up to 30 nights. It incorporates a built-in sliding ruler to determine optimal positioning of the mandible that can be transferred directly to the custom appliance.



Advances at 1mm increments
across full range of protrusion
settings



Apnea Guard® Work Table - 70% Maximum										
MAX	1	2	3	4	5	6	7	8	9	10
Setting	1	2	3	4	5	6	7	8	9	10
5	4									
6	4	5								
7	5	5	6							
8	6	6	6							
9	6	7	7							
10	7	7	8	8	8	9				
11	8	8	8	9	9	9	10			
12	9	9	9	9	10	10	10	11		
13	9	10	10	10	10	11	11	11	12	
14	10	10	11	11	11	11	12	12	12	13
15	11	11	11	12	12	12	12	13	13	13
16	11	12	12	12	13	13	13	13	14	14

The Apnea Guard protocol allows sleep medicine professionals to:

- Inexpensively identify patients who respond favorably to OAT prior to recommending fabrication of a custom appliance.
- Identify patients who should be fitted with an Apnea Guard by a dentist.
- Define the vertical, protrusive, and bite settings to be used by the dentist when ordering the fabrication of the custom oral appliance from the dental lab.
- Provide immediate therapeutic benefit while the patient is waiting for the fabrication of the custom appliance.

Apnea Guard Protocol for Sleep Centers:

1. Explain to the patient that the Apnea Guard is trial appliance that can be used for up to 30 nights to identify responders to oral appliance therapy. Manage expectations by comparing its size and shape to a custom appliance.
2. Follow in instructions for fitting the Apnea Guard using the Technical Manual and the video - <http://advancedbrainmonitoring.com/apnea-guard-instructional-video>
3. Have the patient use the Apnea Guard Dental History and Patient Consent to self-select for fitting with the assistance of a non-dentist. The Apnea Guard is cleared for fitting by any trained healthcare professional.
4. Select the Apnea Guard Low, Medium or High size based on gender and tongue size.
5. Fit with retention material and set the appliance 1 mm (or 1.5 mm) less than 70% of maximum protrusion.
6. Provide Comfort Surveys to assist the patient in managing the first week of side effects. Use the troubleshooting guide to manage expected adaption issues and determine when to refer to a dentist.
7. Direct the patient to the instructions and training video for how to advance the appliance 1mm at: <http://advancedbrainmonitoring.com/apnea-guard-advancement-video>
8. Just prior to the titration sleep study, confirm the appliance is accurately set to 70% protrusion. When the 70% setting is at a one-half mm increment, evaluate efficacy at 0.5 mm below and 0.5 mm above the 70% protrusion setting.
9. Refer the patient to a dentist with the Apnea Guard at the optimal setting with a prescription defined by the Apnea Guard size and optimal protrusion setting - similar to ordering CPAP with a fixed pressure setting (e.g., Apnea Guard medium size, protrusion setting 12).

Section II: Frequently Asked Questions

Q. What is the goal of the titration study?

A. To establish a jaw-forward position that optimizes therapeutic benefit across sleep stages and sleep positions without over-advancement (over-advancement may increase side effects).

Q. Is there a benefit in conducting a titration study on the very first night of mandibular advancement?

A. Yes, a split-night or titration study during the first night of jaw-forward protrusion could potentially immediately identify a patient who will respond to oral appliance therapy.

Q. Is there a benefit in having the patient sleep in the jaw-forward position prior to their titration study?

A. Yes, muscle adaptation occurs during the first four to seven days of mandibular advancement. The optimal setting based on Night One in the jaw-forward position may be different from the optimal setting after the muscles adapt.

Q. How far is the jaw advanced in order to obtain the optimal oral appliance setting?

A. Patients will usually receive optimal treatment when the jaw is advanced to approximately 70% of maximum voluntary protrusion.

Q. What other settings are available on an oral appliance?

A. One other factor to consider is the amount of separation between the upper and lower teeth that the appliance provides or “vertical dimension.” Vertical dimension is distinctly different from protrusion, although both improve airway size. Increasing the vertical space in men and women with big tongues improves comfort, reduces TMJ side effects, and improves outcomes.

Q. Does the Apnea Guard need to be fitted by a dentist?

A. The Apnea Guard is cleared to be fitted by the patient with the assistance of any trained healthcare professional. The steps involved in fitting the Apnea Guard are similar to selecting and fitting a CPAP mask.

Q. How can I determine if a patient has dental conditions that could cause a problem should the Apnea Guard is fitted by a non-dentist?

A. This protocol includes dental information which will assist your staff to be prepared with appropriate responses to patient questions regarding Apnea Guard Dental History and Patient Consent form. Appropriate disclosure will allow the patient to make an informed decision as to whether they wish to have the Apnea Guard fitted by a dental professional or, for their convenience, fitted with the assistance of your non-dental staff.

Q. Do patients experience side effects during the first few days of use of an oral appliance?

A. Yes, muscle soreness for the first week is common, and usually subsides in the first few hours after removal. Long-term side effects are uncommon.

Q. What can I do to help minimize the side effects from wearing the Apnea Guard?

A. Because the Apnea Guard is limited to 29 nights, the side effects will be minimal. To minimize side effects, it is important to fit the retention material, accurately measure the neutral and maximum advancement so therapy is initiated 1 mm less than 70%, and use the Comfort Surveys (to guide the patient through the first week).

Q. Where can I learn how to fit an Apnea Guard?

A. The Apnea Guard training videos will assist you and your staff with prepared responses, as well as training on how to select and fit the Apnea Guard.

Q. What is the recommended protocol for determining the optimal jaw-forward setting with a titration appliance?

A. Initiate therapy with the Apnea Guard at a 1 mm less than 70% of maximum advancement for three to four nights; have the patient advance 1 mm after side effects diminish so they are at 70% advancement on the night of their titration study.

Q. What if the patient doesn't advance their appliance the 1 mm to 70% prior to their titration study?

A. Once the titration appliance has been worn for several nights in the jaw forward position, further titration of 1 or 2 mm on the night of the study should not affect the outcome or contribute to side effects.

Q. How do sleep stage and sleep position influence oral appliance therapy outcomes?

A. In general, oral appliance therapy benefits will have the greatest impact on AHI when the patient is sleeping supine and/or in non-REM sleep. Advancement beyond optimal setting applies additional force to teeth and jaw and may increase the likelihood of long-term side effects. Titration goal for oral appliances should target best result in the patient's preferred sleeping position, rather than in the worst case scenario (REM and supine) as is a common practice with CPAP titration.

Q. What should the technician do during an Apnea Guard laboratory titration study?

A. First confirm that the neutral, maximum, and 70% protrusion settings recorded on the device were accurately measured at the initial fitting. Then, begin the titration study at 70% protrusion. For patients who have a protrusion range (i.e., maximum minus neutral setting) of **6 or greater** and when the ideal protrusion (70%) recommended by the Work Table is a number setting (i.e., 12.0 or 13.0), consider recording at least a portion of the study with the appliance 1 mm further advanced (i.e., to 80%). This additional evaluation is not recommended for patients with a limited protrusive range (i.e., less than 6 mm).

Q. How are the settings derived during the titration study transferred to the custom oral appliance?

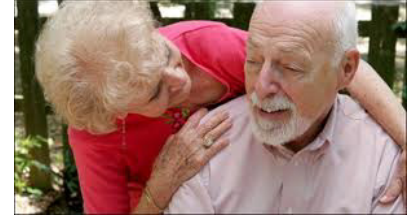
A. The titration study determines the vertical size and protrusive distance with the Apnea Guard that can be directly prescribed for a custom appliance similar to the pressure setting being prescribed for a fixed CPAP device.

- Q. Are the settings established with a temporary appliance really optimal?**
- A. Upon delivery of the custom appliance, the dentist will explain to the patient how to make sub-millimeter adjustments when required. Assuming the Apnea Guard was properly fitted when the optimal settings were confirmed, and the transfer of the settings was performed by an Apnea Guard certified dental lab, the sub-millimeter adjustment should have minimal impact on therapeutic outcomes.
- Q. If the patient is fitted with a titration appliance and they notice immediate benefit, what will keep them from cancelling their sleep study?**
- A. The Apnea Guard is only cleared for 29 night of use. Explain that the appliance will wear out and has potential side effects (i.e., tooth damage) if used beyond the recommended time.
- Q. Will the settings that are identified as “optimal” retain their efficacy over time?**
- A. The effectiveness of the custom appliance at a prescribed advancement setting may diminish over time as patients age, gain weight, etc. Minor movement of the advancement screws over time or improper maintenance on the part of the patient (i.e., reduces instead of increases or asymmetrically advances) can also impact efficacy. Thus the effectiveness of the custom appliance should be monitored at least annually.

Section III: Dental and Other Considerations

A. Patient Limitations and Consent

The Apnea Guard is designed to be fitted by the patient with the assistance of a properly trained healthcare professional. The Apnea Guard Dental History and Patient Consent form is used to assist the patient in determining if he/she is an appropriate candidate for self-fitting.



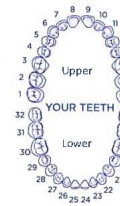
Patients should be provided the option to be fitted by a dentist even if that delays the initiation of therapy. The information below will assist the non-dental healthcare professional with responding to patient questions such that a thoughtful and thorough informed consent is provided.

LONG APNEA GUARD DENTAL HISTORY AND PATIENT CONSENT

Patient name: _____

If you answer YES to any of the Questions below, you should have the Apnea Guard fitted by a dentist.

1. A **broken** tooth/teeth YES | No
Note: A broken tooth may have caused discomfort when exposed to air or hot or cold food.
2. An **infected** tooth/teeth YES | No
Note: An infected tooth will likely cause continuous obvious pain.!
3. A **loose** tooth/teeth YES | No
Note: Have you had a recent accident that loosened a tooth? Are you are currently under a dentist's care for active gum disease or do your gums bleed regularly when you brush your teeth?
4. **Less than eight** (8) good Upper teeth YES | No
Note: Do not count broken, infected and loose teeth, or removable or fixed dentures.
5. **Less than eight** (8) good Lower teeth YES | No
Note: Do not count broken, infected and loose teeth, or removable or fixed dentures.
6. Wearing a **temporary** filling or crown YES | No
Note: Are you waiting for completion of treatment and have been warned by your dentist to avoid chewing hard or sticky foods with the temporarily filling?
7. **Current TMJ** (Temporomandibular Joint) pain YES | No
Note: Have you had active TMJ pain in the last two years?



For Fitting Use Only

Sex: Male | Female

Tongue Size:
Normal | Large

Apnea Guard Size:
L | M | H

Based on my dental history, I choose NOT to have the Apnea Guard fitted by a dentist; I consider myself a candidate for self-fitting with assistance of a non-dentist. I have read the Apnea Guard Patient Instructions. The instructions listed possible side effects and informed me when I should notify my physician of complications, and when to stop wearing the Apnea Guard. I understand the Apnea Guard should only be worn for up to 30-nights, and that use beyond 30-nights may cause complications for which I will be responsible.

Signature: _____ Date: _____

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B. Minimum Number of Good Teeth

Given the forces applied to the teeth by forward advancement of the jaw during oral appliance therapy, patients need to have a good dental status. Most patients undergo routine dental check-ups and will be familiar with their own conditions that may rule out fitting of the Apnea Guard by a non-dental professional.



Oral appliance therapy requires at least eight good upper and eight lower teeth. The Apnea Guard **should not** be used when teeth are *suspected* to be:

- Broken
 - Infected
 - Loose
1. Broken teeth: broken or cracked teeth usually result from biting down on something hard, falling, or having a cavity that weakens the tooth. A broken tooth that is uncomfortable when exposed to air, or hot or cold foods or drinks should be obvious to the patient as an indication that they should be fitted for an Apnea Guard by a dentist.
 2. Infected teeth: an acute abscess is usually caused by a bacterial infection resulting from untreated tooth decay, a cracked tooth, extensive periodontal disease, or a failed root canal. The pain associated with an infected tooth should be obvious to the patient, and must exclude them for fitting of the Apnea Guard by a non-dentist.
 3. Loose tooth/teeth: Uncontrolled periodontal disease can compromise the health of a tooth. Patients likely to have active periodontal disease should respond affirmatively to one of the following questions:
 - Are you currently under the care of a dentist for active gum disease?
 - Do your gums bleed when you brush your teeth?
 - Have you teeth loosened or have you lost teeth due to gum disease?



If any of the above listed problem are suspected the patient should be provided the option of a referral to a dentist for fitting of the Apnea Guard.

C. Temporary Tooth, Filling or Crown

Temporary dental fillings or crowns can loosen during the setting of the Apnea Guard retention material. If this were to occur at a dental office, the dentist would simply reset/re-glue the temporary material after fitting the Apnea Guard.

A temporary tooth, filling or crown usually means that the patient is under the active care of their dentist and waiting for completion of treatment, such as:

- The fabrication of a crown, or;
- Resolution of sensitivity or infection due to a deep cavity or root canal.

When a temporary procedure is performed the dentist will usually warn the patient to avoid chewing hard or sticky foods with the temporarily filled tooth(s).

Avoid or delay inserting the Apnea Guard until dental treatment is completed or refer to the dentist for fitting.

D. Jaw Pain

Jaw pain that immediately begins when the Apnea Guard is inserted and before the device is worn overnight is a contraindication to use. Refer the patient to a dentist for fitting.



Bruxism: If the patient inquires, the Apnea Guard will serve as a replacement to their “night guard” appliance. It will be important to perform the titration study and refer the patient to a dentist as soon as possible as the retention material may wear down more rapidly and not provide the standard 29-nights of use.

Muscular Pain: Upon initiation of therapy, most patients will initially experience some muscular discomfort upon awakening. This common side effect usually resolves by the end of the morning and within three to seven days after initiation of therapy. Discomfort can be managed with nightly use of an over-the-counter anti-inflammatory medication. Alternatively, advancement can be reduced by 1 mm until symptoms improve.

If discomfort is lingering into the afternoon hours, and is persisting 3-4 days, the patient should be referred to a dentist. If pain is significant, increases when biting, or only occurs on one side, the patient should be referred to a knowledgeable dentist.

Temporomandibular joint (TMJ) Pain: Although a *history* of joint point is not necessarily a contraindication to oral appliance therapy, and overall, TMJ complications are rare, caution is advised. To identify patients with active TMJ pain/dysfunction consider their “yes” response to the following questions:

- Have you had *active* TMJ pain *in the last 2 years*?
 - Do you suffer with significant and routine headache pain?
 - Have you been told that your jaw joint(s) display signs of degeneration on X-ray?
 - Have you ever had a significant injury to, or surgery on the TMJ?
- Do you have significant neck pain, cervical spine disease?

E. OSA Severity and Variability in Outcomes

Oral appliance therapy (OAT) is generally recommended for patients with mild to moderate OSA and those with predominantly supine/positional sleep apnea have better outcomes with OAT, independent of OSA severity. In contrast, patients with moderate non-positional OSA seldom exhibit a good treatment response from OAT. The perception of successful outcomes may also be influenced by the amount of sleep in the supine position or nocturnal consumption of alcohol, hypnotic sleeping pills, or narcotic pain medication.

While snoring is a good indicator of patients with OSA, an immediate reduction in snoring is not always an indication of successful outcomes. Snoring duration may actually increase upon initiation of therapy as apnea events are converted to hypopnea events. Snoring should subsequently decrease as the jaw is further advanced to 70% protrusion.

F. Influence of Vertical Dimension of Occlusion

The distance between the upper and lower tray changes the inter-occlusal space (i.e., vertical dimension of occlusion or VDO) and influences outcomes. Patients with large tongues, identified by scallops in the sides, need greater VDO to create room for the tongue to advance forward. Independent of tongue size, oral appliance outcomes improve if VDO is lower in females and greater in males, presumably due to differences in airway length. Increased VDO also improves outcomes in patients who sleep supine. Increasing vertical separation may also improve comfort and reduce the risk of TMJ symptom. Conversely, *excessive* VDO is uncomfortable, may cause mouth breathing and dry mouth. Therefore, it becomes important to select the appropriate size Apnea Guard tray that will best combine the protrusive and vertical components.



G. Lateral Freedom of Movement

By restricting lateral movement, the Apnea Guard ensures the mandible remains advanced at its fixed distance when patients are sleeping lateral or prone (especially in rapid eye movement sleep, when muscular tone is lost). It has been argued that lateral freedom of movement is preferred by patients and reduces the likelihood of development of TMJ. However, appliances that allow lateral movement may provide reduced therapeutic benefit in the supine or lateral positions and, additionally these patients may be more prone to hyper-extension of the TM joint if the chin gets pushed aside during sleep.

H. Appliance Retention

Poor retention (i.e., appliance does not retain to the teeth) can result from sub-optimal fitting of the oral appliance (as described below) or when a patient has severe gasping and mouth-opening responses to apnea events. The solution for retention problems in patients with severe apnea is to advance the mandible forward as quickly as possible (even if it increases the jaw discomfort).

Section IV: Fitting the Apnea Guard and Assessing Efficacy

A. Apnea Guard Fitting

1. When applicable, review the diagnostic sleep study results. Set the patient's expectations by discussing the predicted likelihood of a successful outcome.
2. Explain the differences between the Apnea Guard and the custom appliance – manage the patient's expectations.
3. Use the technical manual and training video to fit the Apnea Guard:
 - a. Determine and note the "fitting" setting. Make sure:
 - 1) The jaw and lips are relaxed
 - 2) Both trays are against the teeth
 - b. Advance the lower tray fitting setting +4 mm
 - c. Fit the lower tray
 - 1) Mix and be ready to insert in < 1 min 15 Sec
 - 2) Remind patient to:
 - Center, bite down very firmly
 - Smooth edges with tongue
 - 3) Explain contraindications while waiting 3 minutes
 - d. If the front teeth within 2 mm of the anterior or posterior edge of the tray, remove and reset the retention material
 - 1) Advance the lower tray if the teeth are too close to the anterior edge
 - 2) Reduce the advancement if the teeth are too close to the posterior edge
 - e. When finished with the lower tray, reduce the advancement setting -4mm
 - f. Fit upper tray
 - 1) Mix and be ready to insert in < 1 min 15 Sec
 - 2) Remind patient to:
 - Center, bite down very firmly
 - Smooth edges with tongue
 - 3) Explain possible side effects while waiting 3 minutes
 - g. With the Apnea Guard inserted measure neutral and max three times and note the average settings.
 - h. Use the Work Table to determine and note the exact 70% advancement (i.e., retain the x.5 if applicable).
 - i. Write the neutral, maximum and 70% advancement on the handle (include the x.5 if applicable)
 - j. Set the lock 1 mm less than 70%, 1.5 mm less if 70% is x.5 setting
4. Explain the adaption protocol:
 - a. Review what to expect during the first week of jaw-forward positioning:
 - Some minor discomfort for the first 3 to 7 days is part of the accommodation process,
 - Recommend Aleve (or aspirin or ibuprofen) at bed time to daytime reduce symptoms,

- How and when to adjust the Apnea Guard by 1 mm to 70% protrusion in preparation for their treatment efficacy study. Identify symptoms that warrant a phone call or termination of treatment.
- b. Introduce the Comfort Surveys and identify symptoms that warrant calling the Doctor's office
- c. Describe how to care for the Apnea Guard and that it is limited to 29 nights of use.

B. Outcome Assessment

1. Confirm the neutral, maximum and 70% protrusion settings recorded on the device were accurately measured at the initial fitting.
2. Begin the titration study at 70% protrusion. The oral appliance titration goal should be to confirm the optimal setting in the patient's preferred sleeping position across sleep stages.
3. For patients who have a protrusion range (i.e., maximum minus neutral setting) of 6 or greater and when the ideal protrusion (70%) recommended by the Work Table is a number setting (i.e., 12.0 or 13.0), consider recording at least a portion of the study with the appliance 1 mm further advanced (i.e. to 80%).
4. Use caution with patients who have a limited protrusive range (i.e., less than 6) given 1mm of added protrusion becomes a highly significant overall percentage of advancement (15-25%).
5. Find a compromise setting that optimizes efficacy across positions and sleep states. Unlike CPAP titration, avoid focus solely on the setting that resolves the worst case scenario, (i.e., stage REM and in the supine position) given over-advancement applies incremental force to teeth and jaws and increases the likelihood of long term side effects.

Section V: Transferring Settings to the Custom Appliance

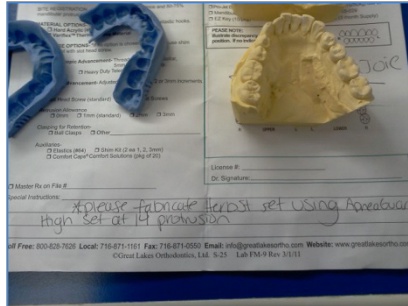
Transferring the Apnea Guard setting to the custom appliance is straight forward when using an Apnea Guard certified dental lab (list available at www.advanced-sleep.com). The Apnea Guard certified dental lab is prepared to combine the Apnea Guard jig and bite registration with pre-fabricated shims to accurately match the Apnea Guard VDO into a high quality control articulation to a range of commonly prescribed custom appliances (e.g., Herbst, Tap, dorsal).

The Sleep Center will:



Fit the retention material, determine the optimal setting, and prescribe with AG size and protrusion setting

The Dentist will:



1. Remove retention material for bite registration, make the impressions and submit the lab order.

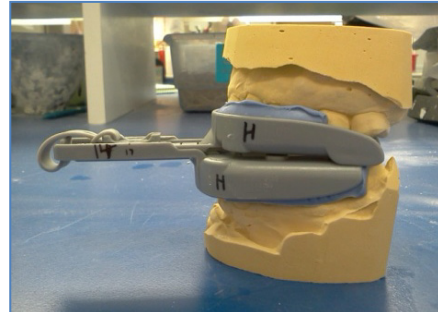


2. Then refit AG with retention material for continued patient use while custom appliance is being fabricated.

The Dental Lab will:



1. Insert the retention material that defines the bite registration into their Apnea Guard jig.



2. Insert the models with the bite registration into the prescribed Apnea Guard jig size (VDO) at the prescribed protrusion.



3. Place the Apnea Guard and models into and adjust the articulator.



4. Use the articulated settings to confirm the custom appliance is set to the Apnea Guard settings and bite registration.

Photos courtesy of Great Lakes Orthodontics/Christine LaJoie

Section VI: Apnea Guard Troubleshooting

The troubleshooting guidance provided below correspond to the recommendation that the patient seeks further instruction when they “agree” to potential issues identified by use of the daily protocol surveys (see Appendix 1).

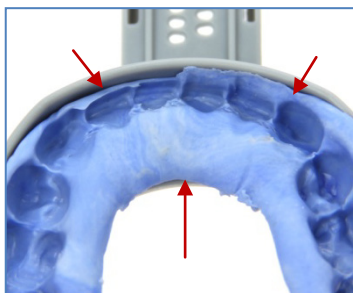
No.	Question as presented in the protocol survey	Sections
1	The Apnea Guard fell out of my mouth during the night?	A, B, C
2	I had muscular or jaw pain in the morning when I woke up after wearing my appliance?	G
3	My bite felt “off” in the morning when I woke up?	H
4	I had a difficult time due to excessive salivation throughout the night?	A, D
5	One or two teeth hurt when I woke up and continued past 2 PM in the afternoon?	A, E, F
6	The muscular or jaw pain continued past 2 PM in the afternoon?	G
7	My bite was off past 2 PM in the afternoon?	H
8	Please log adjustments to your appliance setting?	C, G, H

A. *Improper Initial Fitting*

1. Possible cause:

- The “fitting” setting is too far posterior. This limits the amount of retention material between the teeth and tray and causes the excessive retention material to exude posterior to the tray and limit tongue room.
- “Fitting” setting is too far anterior. When teeth are set too far posterior in the tray, retention material may exude posteriorly and may result in retention issues during sleep. Incorrect setting of the lower tray will likely cause improper setting of the upper tray.
- All teeth do not seem to be impressed fully into the retention material. An uneven bite may cause the unavoidable condition where the front but not rear, the rear but not front, or the left but not right teeth to not reach the bottom of the tray.

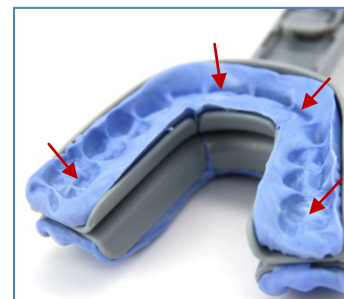
2. Possible solution:



When teeth are too far anterior, advance the “fitting” setting by 2 mm and reset the tray



When teeth are too far posterior, reduce the “fitting” setting by 2 mm and reset the tray



When all teeth do not touch the bottom of the tray, reset the retention material. Take care not to exceed the work time, and instruct the patient to bite fully

B. Retention material falls out of tray(s)

1. Possible cause:
 - Did not use heavy base polyvinyl siloxane (PVS).
 - Did not remove saliva from the Apnea Guard tray prior to applying PVS
2. Possible solution:
 - a. Dry the tray and retention material. Reinsert the retention material and ask the patient to bite into both trays. In many cases the problem will be resolved.
 - b. If the material falls out a second time, replace by following the instructions.

C. Apnea Guard falls out during sleep - retention

1. Possible cause:
 - Insufficient retention material around teeth
 - Severe OSA – oral appliances have a tendency to disengage during apneic events until the protrusion is sufficient to maintain the airway in a sufficiently open position.
2. Possible solution:
 - a. Refit the upper and lower trays and ensure patient bites fully to the tray(s).
 - b. Advance the appliance more aggressively, use Aleve or similar medication to manage pain, or have the patient remove the appliance for a portion of the night until the soreness subsides.
 - c. Wear a CPAP chin strap, see photo



D. Nocturnal drooling

1. Possible cause:
 - Stimulation of tongue or cheeks by foreign object in mouth during sleep
 - Too much retention material was used and has exuded outside the tray
2. Possible solution:
 - a. Prescribe Atropine.
 - b. Trim the retention material exuding beyond the tray, being careful not to create sharp edges for the tongue to rub against.

E. Sore selected teeth

1. Possible cause:
 - Insufficient retention material between the tooth and tray
 - Patient sleeping prone and Apnea Guard handle is pressed against the mattress.
 - Loading on teeth is problematic as a result of periodontal or endodontic status
2. Possible solution:
 - Replace the retention material.
 - Inform patient to avoid prone sleeping or to prop their head with a pillow

F. Generalized loosening of teeth

1. Possible cause:
 - Periodontal pathology
 - Use of the Apnea Guard beyond the recommended 30 days use.
2. Possible solution:
 - a. Discontinue Apnea Guard trial

G. Lingering afternoon jaw pain

1. Possible causes of discomfort:
 - Muscular inflammation due to nocturnal positioning
 - Exacerbation of pre-existing TMJ condition
2. Possible solutions for muscular pain prior to referral to a dentist:
 - a. Temporarily reduce protrusion 1 mm
 - b. Use Aleve or similar medication

Possible solutions for joint pain:

- a. Discontinue Apnea Guard trial and refer to a dentist.

H. Lingering afternoon bite discrepancy

1. Detecting lingering bite discrepancy:
 - The upper and lower teeth do not return to their normal bite relationship by 2 PM each day to due poor muscular adaptation.
2. Possible solution for lingering bit discrepancy:
 - a. Jaw movement exercises and gum chewing
 - b. Reduce protrusion by 1 mm
 - c. If still problematic, suspend therapy and refer to a dentist

Appendix 1 –Comfort Surveys for Seven Nights

**For management of patients during the
first week of an Apnea Guard trial**

AN INTRODUCTION TO YOUR FIRST WEEK OF ORAL APPLIANCE THERAPY FOR SLEEP APNEA

Congratulations on your decision to begin oral appliance therapy! The Apnea Guard was selected for use during the preparation of your custom oral appliance so you could begin therapy immediately.

To treat your sleep apnea, an oral appliance advances your lower jaw to position the tongue forward during sleep. This new jaw position can cause muscular discomfort during the first week of therapy. Don't worry, muscles adapt very quickly and teeth can handle this job. The key to getting through the first week is recognizing when the symptoms are expected and when it might requires discussion with your doctor and his team.

To help guide you through this adaptation period, we ask that you complete the Apnea Guard Comfort surveys each morning and evening during the first seven days of therapy. In the morning you will respond to four questions related to your comfort and symptoms that occurred at night, and each evening respond to four questions related to your comfort and symptoms that occurred during the day. Under each question notes are provided to remind you of instructions you were provided or to assist you in determining next steps. Your doctor and his team are always standing by to help if the notes suggest that you seek consultation or when you have an urgent question.

You may be instructed to advance the Apnea Guard (i.e., from 12 to 13) during or upon successful completion of adaption period. Remember, the arrow on the locking mechanism points to the left for odd and right for even numbered settings. You will always need to shift the locking strap to the opposite side of the lock to adjust one setting. If you lose track of your setting, look at the number written on the handle. The setting for "70%" is the target for your custom appliance. To advance the Apnea Guard 1mm, please follow the six steps below, or watch the training video at: <http://advancedbrainmonitoring.com/apnea-guard-advancement-video>



1. Remove the lock with your index finger



2. Rotate the tether to the opposite end of the lock.



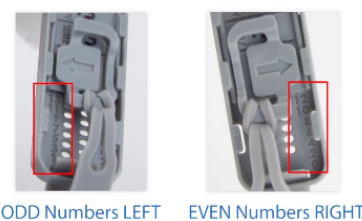
3. Adjust the upper tray so that the 70% (optimal) setting is fully readable.



4. Affix the lock with the arrow pointing left for 70% setting with an even number, or right for odd numbered settings.



5. Affix the lock into the two holes.



6. Confirm the number is correctly set. Slide the cover back over the Apnea Guard.

Apnea Guard Comfort Survey Patient Name: _____**DAY 1: COMPLETE IN THE MORNING:** Date: _____

1. The Apnea Guard fell out of my mouth during the night:

	Strongly Agree	Agree	Neither Agree or disagree	Disagree	Strongly Disagree
Circle one response	----- ----- ----- -----				

Note: If the material fell out, call for instructions. The problem should resolve once you advance the appliance.

2. I had muscular or jaw pain in the morning when I woke up after wearing my appliance:

	Strongly Agree	Agree	Neither Agree or disagree	Disagree	Strongly Disagree
Circle one response	----- ----- ----- -----				

Note: This is normal for the first week; please remember to take Naproxen Sodium (i.e., Aleve) before bedtime.

3. My bite felt "off" in the morning when I woke up:

	Strongly Agree	Agree	Neither Agree or disagree	Disagree	Strongly Disagree
Circle one response	----- ----- ----- -----				

Note: Remember to do jaw movement exercises or chew gum for one-hour to stretch the muscles in the morning.

4. I had a difficult time due to excessive salivation throughout the night:

	Strongly Agree	Agree	Neither Agree or disagree	Disagree	Strongly Disagree
Circle one response	----- ----- ----- -----				

*Note: This is normal and it may take several nights for this symptom to begin to subside.***IN THE EVENING: DAY 1**

5. One or two teeth hurt when I woke up and continued past 2 PM in the afternoon:

	Strongly Agree	Agree	Neither Agree or disagree	Disagree	Strongly Disagree
Circle one response	----- ----- ----- -----				

Note: Avoid having the Apnea Guard handle press against your mattress. Monitor for two more days.

6. The muscular or jaw pain continued past 2 PM in the afternoon:

	Strongly Agree	Agree	Neither Agree or disagree	Disagree	Strongly Disagree
Circle one response	----- ----- ----- -----				

Note: Remember to take Naproxen Sodium (i.e., Aleve) before you go to sleep. Monitor for two more days.

7. My bite was off past 2 PM in the afternoon:

	Strongly Agree	Agree	Neither Agree or disagree	Disagree	Strongly Disagree
Circle one response	----- ----- ----- -----				

Note: It is important to do jaw movement exercises or chew gum for one-hour in the morning to stretch the muscles.

8. Please log adjustments to your appliance setting:

		Backward 1 mm	Did not Adjust	
Circle one response	I adjusted	-----		to setting number: _____

Comments: _____

Apnea Guard Comfort Survey Patient Name: _____**DAY 2: COMPLETE IN THE MORNING:** Date: _____

1. The Apnea Guard fell out of my mouth during the night:

Strongly Agree Agree Neither Agree or disagree Disagree Strongly Disagree

Circle one response |-----|-----|-----|-----|

Note: If the material fell out, call for instructions. The problem should resolve once you advance the appliance.

2. I had muscular or jaw pain in the morning when I woke up after wearing my appliance:

Strongly Agree Agree Neither Agree or disagree Disagree Strongly Disagree

Circle one response |-----|-----|-----|-----|

Note: To reduce daytime symptoms, take Naproxen Sodium (i.e., Aleve) before bedtime.

3. My bite felt "off" in the morning when I woke up:

Strongly Agree Agree Neither Agree or disagree Disagree Strongly Disagree

Circle one response |-----|-----|-----|-----|

Note: Remember to do jaw movement exercises or chew gum for one-hour to stretch the muscles in the morning.

4. I had a difficult time due to excessive salivation throughout the night:

Strongly Agree Agree Neither Agree or disagree Disagree Strongly Disagree

Circle one response |-----|-----|-----|-----|

Note: This is normal and it may take two to three more nights for this symptom to begin to subside.

DAY 2: IN THE EVENING

5. One or two teeth hurt when I woke up and continued past 2 PM in the afternoon:

Strongly Agree Agree Neither Agree or disagree Disagree Strongly Disagree

Circle one response |-----|-----|-----|-----|

Note: Avoid having the Apnea Guard handle press against your mattress. Monitor for one more day.

6. The muscular or jaw pain continued past 2 PM in the afternoon:

Strongly Agree Agree Neither Agree or disagree Disagree Strongly Disagree

Circle one response |-----|-----|-----|-----|

Note: Remember to take Naproxen Sodium (i.e., Aleve) before you go to sleep. Monitor for one more day.

7. My bite was off past 2 PM in the afternoon:

Strongly Agree Agree Neither Agree or disagree Disagree Strongly Disagree

Circle one response |-----|-----|-----|-----|

Note: It is important to do jaw movement exercises or chew gum for one-hour in the morning to stretch the muscles.

8. Please log adjustments to your appliance setting:

Backward 1 mm Did not Adjust

Circle one response I adjusted |-----| to setting number: _____

Comments: _____

Apnea Guard Comfort Survey Patient Name: _____**DAY 3: COMPLETE IN THE MORNING:** Date: _____

1. The Apnea Guard fell out of my mouth during the night:

Strongly Agree Agree Neither Agree or disagree Disagree Strongly Disagree

Circle one response |-----|-----|-----|-----|

Note: If the material fell out, call for instructions. The problem should resolve once you advance the appliance.

2. I had muscular or jaw pain in the morning when I woke up after wearing my appliance:

Strongly Agree Agree Neither Agree or disagree Disagree Strongly Disagree

Circle one response |-----|-----|-----|-----|

Note: This is normal for the first week, to reduce daytime symptoms, remember to take Naproxen Sodium (i.e., Aleve) before bedtime.

3. My bite felt "off" in the morning when I woke up:

Strongly Agree Agree Neither Agree or disagree Disagree Strongly Disagree

Circle one response |-----|-----|-----|-----|

Note: Remember to do jaw movement exercises or chew gum for one-hour to stretch the muscles in the morning.

4. I had a difficult time due to excessive salivation throughout the night:

Strongly Agree Agree Neither Agree or disagree Disagree Strongly Disagree

Circle one response |-----|-----|-----|-----|

Note: This is normal and it may take another night or two for this symptom to begin to subside.

DAY 3: IN THE EVENING

5. One or two teeth hurt when I woke up and continued past 2 PM in the afternoon:

Strongly Agree Agree Neither Agree or disagree Disagree Strongly Disagree

Circle one response |-----|-----|-----|-----|

Note: Avoid having the Apnea Guard handle press against your mattress. If any teeth feel like they are becoming "loose" discontinue use and call for instructions.

6. The muscular or jaw pain continued past 2 PM in the afternoon:

Strongly Agree Agree Neither Agree or disagree Disagree Strongly Disagree

Circle one response |-----|-----|-----|-----|

Note: If you took Naproxen Sodium (i.e., Aleve) and the pain has been constant and getting worse, call for instructions.

7. My bite was off past 2 PM in the afternoon:

Strongly Agree Agree Neither Agree or disagree Disagree Strongly Disagree

Circle one response |-----|-----|-----|-----|

Note: It is important to do jaw movement exercises or chew gum for one-hour in the morning to stretch the muscles.

8. Please log adjustments to your appliance setting:

Backward 1 mm Did not Adjust Forward to 70%

Circle one response I adjusted |-----|-----| to setting number: _____

Comments: _____

Apnea Guard Comfort Survey Patient Name: _____**DAY 4: COMPLETE IN THE MORNING:** Date: _____

1. The Apnea Guard fell out of my mouth during the night:

Strongly Agree	Agree	Neither Agree or disagree	Disagree	Strongly Disagree
Circle one response ----- ----- ----- -----				

Note: If the material fell out, call for instructions. If you DO NOT have afternoon pain, advance to 70% setting.

2. I had muscular or jaw pain in the morning when I woke up after wearing my appliance:

Strongly Agree	Agree	Neither Agree or disagree	Disagree	Strongly Disagree
Circle one response ----- ----- ----- -----				

Note: Remember to take Naproxen Sodium (i.e., Aleve) before bedtime. If you DO NOT have afternoon pain, advance to 70% setting.

3. My bite felt "off" in the morning when I woke up:

Strongly Agree	Agree	Neither Agree or disagree	Disagree	Strongly Disagree
Circle one response ----- ----- ----- -----				

Note: Remember to do jaw movement exercises or chew gum for one-hour to stretch the muscles in the morning.

4. I had a difficult time due to excessive salivation throughout the night:

Strongly Agree	Agree	Neither Agree or disagree	Disagree	Strongly Disagree
Circle one response ----- ----- ----- -----				

Note: Apnea Guard causes more salivation than the custom appliance, if it is getting worse, call for instructions.

DAY 4: IN THE EVENING

5. One or two teeth hurt when I woke up and continued past 2 PM in the afternoon:

Strongly Agree	Agree	Neither Agree or disagree	Disagree	Strongly Disagree
Circle one response ----- ----- ----- -----				

Note: Avoid having the Apnea Guard handle press against your mattress. If any teeth feel like they are becoming "loose" discontinue use and call for instructions.

6. The muscular or jaw pain continued past 2 PM in the afternoon:

Strongly Agree	Agree	Neither Agree or disagree	Disagree	Strongly Disagree
Circle one response ----- ----- ----- -----				

Note: If you took Naproxen Sodium (i.e., Aleve) and the pain has been constant and getting worse, call for instructions.

7. My bite was off past 2 PM in the afternoon:

Strongly Agree	Agree	Neither Agree or disagree	Disagree	Strongly Disagree
Circle one response ----- ----- ----- -----				

Note: It is important to do jaw movement exercises or chew gum for one-hour in the morning to stretch the muscles.

8. Please log adjustments to your appliance setting:

	Backward 1 mm	Did not Adjust	Forward to 70%	
Circle one response	I adjusted ----- -----			to setting number: _____

Comments: _____

Apnea Guard Comfort Survey Patient Name: _____**DAY 5: COMPLETE IN THE MORNING:** Date: _____

1. The Apnea Guard fell out of my mouth during the night:

	Strongly Agree	Agree	Neither Agree or disagree	Disagree	Strongly Disagree
Circle one response	----- ----- ----- -----				

Note: If the material fell out, call for instructions. If you DO NOT have afternoon pain, advance to 70% setting.

2. I had muscular or jaw pain in the morning when I woke up after wearing my appliance:

	Strongly Agree	Agree	Neither Agree or disagree	Disagree	Strongly Disagree
Circle one response	----- ----- ----- -----				

Note: Remember to take Naproxen Sodium before bedtime. If you DO NOT have afternoon pain, advance to 70% setting.

3. My bite felt "off" in the morning when I woke up:

	Strongly Agree	Agree	Neither Agree or disagree	Disagree	Strongly Disagree
Circle one response	----- ----- ----- -----				

Note: Remember to do jaw movement exercises or chew gum for one-hour to stretch the muscles in the morning.

4. I had a difficult time due to excessive salivation throughout the night:

	Strongly Agree	Agree	Neither Agree or disagree	Disagree	Strongly Disagree
Circle one response	----- ----- ----- -----				

Note: Apnea Guard causes more salivation than the custom appliance, if it is getting worse, call for instructions.

DAY 5: IN THE EVENING

5. One or two teeth hurt when I woke up and continued past 2 PM in the afternoon:

	Strongly Agree	Agree	Neither Agree or disagree	Disagree	Strongly Disagree
Circle one response	----- ----- ----- -----				

Note: Avoid having the Apnea Guard handle press against your mattress. If any teeth feel like they are becoming "loose" discontinue use and call for instructions.

6. The muscular or jaw pain continued past 2 PM in the afternoon:

	Strongly Agree	Agree	Neither Agree or disagree	Disagree	Strongly Disagree
Circle one response	----- ----- ----- -----				

Note: If you took Naproxen Sodium (i.e., Aleve) and the pain has been constant, discontinue use and call for instructions. If the problem started after you advanced to 70%, adjust the setting backward, and then wait two nights before trying the 70% setting again.

7. My bite was off past 2 PM in the afternoon:

	Strongly Agree	Agree	Neither Agree or disagree	Disagree	Strongly Disagree
Circle one response	----- ----- ----- -----				

Note: If the problem has been constant and you've been doing your jaw movement exercises, call for instructions.

8. Please log adjustments to your appliance setting:

	Backward 1 mm	Did not Adjust	Forward to 70%	
Circle one response I adjusted	----- -----			to setting number: _____

Comments: _____

Apnea Guard Comfort Survey Patient Name: _____**DAY 6: COMPLETE IN THE MORNING:** Date: _____

1. The Apnea Guard fell out of my mouth during the night:

	Strongly Agree	Agree	Neither Agree or disagree	Disagree	Strongly Disagree
Circle one response	----- ----- ----- -----				

Note: If the material fell out, call for instructions. If you don't have afternoon pain, advance to 70% setting.

2. I had muscular or jaw pain in the morning when I woke up after wearing my appliance:

	Strongly Agree	Agree	Neither Agree or disagree	Disagree	Strongly Disagree
Circle one response	----- ----- ----- -----				

Note: Remember to take Naproxen Sodium before bedtime. If you DO NOT have afternoon pain, advance to 70% setting.

3. My bite felt "off" in the morning when I woke up:

	Strongly Agree	Agree	Neither Agree or disagree	Disagree	Strongly Disagree
Circle one response	----- ----- ----- -----				

Note: Remember to do jaw movement exercises or chew gum for one-hour to stretch the muscles in the morning.

4. I had a difficult time due to excessive salivation throughout the night:

	Strongly Agree	Agree	Neither Agree or disagree	Disagree	Strongly Disagree
Circle one response	----- ----- ----- -----				

Note: Apnea Guard causes more salivation than the custom appliance, if it is getting worse, call for instructions.

DAY 6: IN THE EVENING

5. One or two teeth hurt when I woke up and continued past 2 PM in the afternoon:

	Strongly Agree	Agree	Neither Agree or disagree	Disagree	Strongly Disagree
Circle one response	----- ----- ----- -----				

Note: Avoid having the Apnea Guard handle press against your mattress. If any teeth feel like they are becoming "loose" discontinue use and call for instructions.

6. The muscular or jaw pain continued past 2 PM in the afternoon:

	Strongly Agree	Agree	Neither Agree or disagree	Disagree	Strongly Disagree
Circle one response	----- ----- ----- -----				

Note: If you took Naproxen Sodium (i.e., Aleve) and the pain has been constant, discontinue use and call for instructions. If the problem started after you advanced to 70%, adjust the setting backward, and then wait two nights before trying the 70% setting again.

7. My bite was off past 2 PM in the afternoon:

	Strongly Agree	Agree	Neither Agree or disagree	Disagree	Strongly Disagree
Circle one response	----- ----- ----- -----				

Note: If the problem has been constant and you've been doing your jaw movement exercises, discontinue use and call for instructions.

8. Please log adjustments to your appliance setting:

	Backward 1 mm	Did not Adjust	Forward to 70%	
Circle one response I adjusted	----- -----			to setting number: _____

Comments: _____

Apnea Guard Comfort Survey Patient Name: _____**DAY 7: COMPLETE IN THE MORNING:** Date: _____

1. The Apnea Guard fell out of my mouth during the night:

Strongly Agree Agree Neither Agree or disagree Disagree Strongly Disagree

Circle one response |-----|-----|-----|-----|

Note: If the material fell out, call for instructions. If you Do NOT have afternoon pain, advance to 70%.

2. I had muscular or jaw pain in the morning when I woke up after wearing my appliance:

Strongly Agree Agree Neither Agree or disagree Disagree Strongly Disagree

Circle one response |-----|-----|-----|-----|

Note: Remember to take Naproxen Sodium (i.e., Aleve) before bedtime. If you DO NOT have afternoon pain, advance the Apnea Guard to the 70% setting

3. My bite felt “off” in the morning when I woke up:

Strongly Agree Agree Neither Agree or disagree Disagree Strongly Disagree

Circle one response |-----|-----|-----|-----|

Note: Remember to do jaw movement exercises or chew gum for one-hour to stretch the muscles in the morning.

4. I had a difficult time due to excessive salivation throughout the night:

Strongly Agree Agree Neither Agree or disagree Disagree Strongly Disagree

Circle one response |-----|-----|-----|-----|

*Note: Apnea Guard causes more salivation than the custom appliance, if it is getting worse, call for instructions.***DAY 7: IN THE EVENING**

5. One or two teeth hurt when I woke up and continued past 2 PM in the afternoon:

Strongly Agree Agree Neither Agree or disagree Disagree Strongly Disagree

Circle one response |-----|-----|-----|-----|

Note: Avoid having the Apnea Guard handle press against your mattress. If any teeth feel like they are becoming “loose” discontinue use and call for instructions.

6. The muscular or jaw pain continued past 2 PM in the afternoon:

Strongly Agree Agree Neither Agree or disagree Disagree Strongly Disagree

Circle one response |-----|-----|-----|-----|

Note: If you took Naproxen Sodium (i.e., Aleve) and the pain has been constant, discontinue use and call for instructions. If the problem started after you advanced to 70%, adjust the setting backward and then wait two nights before trying the 70% setting again.

7. My bite was off past 2 PM in the afternoon:

Strongly Agree Agree Neither Agree or disagree Disagree Strongly Disagree

Circle one response |-----|-----|-----|-----|

Note: If the problem has been constant and you’ve been doing your jaw movement exercises, discontinue use and call for instructions.

8. Please log adjustments to your appliance setting:

Backward 1 mm Did not Adjust Forward to 70%

Circle one response I adjusted |-----|-----| to setting number: _____

Comments: _____