TRACKING PULSE OXIMETER FINDINGS BEFORE, DURING AND AFTER TITRATION OF MANDIBULAR ADVANCEMENT DEVICES FOR PATIENTS WITH MILD AND MODERATE OBSTRUCTIVE SLEEP APNEA

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CERTIFICATE OF APPROVAL

MASTERS THESIS

This is to certify that the Masters Thesis for

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ABSTRACT

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Introduction:
Sleep disorders, to include obstructive sleep apnea (OSA), are prevalent in military personnel and can be risk factors for many medical and pain conditions as well as impact quality of life and operational readiness. Military veterans are four times more likely to have an OSA diagnosis compared to the general population. The management of OSA includes devices that provide positive airway pressure (PAP) to displace oral tissues to affect upper airway patency during sleep. PAP devices have multiple issues regarding their adherence. Another option for OSA management is oral appliance therapy that advances the mandible forward increasing upper airway opening. Patients diagnosed with moderate or severe OSA by providers from the Walter Reed National Military Medical Center (WRNMMC) Sleep Disorders Center will be invited to participate in this study until 20 patients meet study criteria and consent for participation; they will have had their initial sleep study performed by this service.

Methods:
The recruited subjects will be evaluated by Navy Medicine Professional Development Center (NMPDC) Orofacial Pain Center providers for utilization of an oral appliance to help manage OSA symptoms. A mandibular advancement device (MAD), an oral appliance used for the management of OSA, will be fabricated by the NMPDC Maxillofacial Prosthodontic Department and delivered by NMPDC Orofacial Pain Center providers to study participants for use while sleeping at home. Subjective measures will be used to assess daily jaw comfort, stress, oral appliance adherence levels and sleep quality during the six to eight week MAD titration period. MAD titration involves a standardized incremental mandibular advancement each night to facilitate upper airway

opening while sleeping. The VirtuOx portable pulse oximeter will obtain continuous, nightly oxygenation levels during home MAD titration. The objective data captured by the VirtuOx pulse oximeter will be electronically transmitted to a VirtuOx Inc. owned cloud for investigator accessibility. When the mandible has been maximally and comfortably protruded by the MAD, the patients will have a follow up sleep study at WRNMMC to assess MAD efficacy as it relates to the apnea hypopnea index (AHI), a standard measure of the severity of desaturation during sleep.

Results:
The VirtuOx pulse oximeter is successfully transmitting oxygenation data in real time during patient home MAD titration. Other results are pending due to the one participant currently completing the study protocol.

Discussion:
No previous study has tracked real time, nightly pulse oximetry and explored associations with AHI, subjective measures of sleep quality, stress, oral appliance adherence and jaw discomfort levels during MAD titration. Currently, there is no objective data set that captures continuous oxygenation during home MAD titration. Sleep medicine center laboratory technicians may adjust the MAD during the follow up sleep study if oxygenation levels are not optimum; currently only patient subjective measures are used for adequate home MAD titration. This sleep center MAD adjustment causes sleep fragmentation, waking the patient during the sleep study, and potentially advances the mandible too quickly, potentially causing MAD tolerability and/or adherence issues due to jaw pain.

Conclusions:
The VirtuOx pulse oximeter provides an easy, non-invasive capture of quantifiable oxygenation data that can be utilized in combination with subjective information to more accurately improve home MAD titration for OSA patients. The results of this study are important because they serve as a basis for future studies to evaluate how both subjective and objective information during MAD home titration can be used to positively affect AHI and thus improve sleep quality. Maintaining good sleep quality plays a significant role in patient wellbeing and has a tremendous impact on military healthcare and mission readiness.

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LIST OF ABBREVIATIONS

AASM	American Academy of Sleep Medicine
AHI	Apnea-hypopnea index
APAP	Automatically self-adjusted positive airway pressure
ArTH	Arousal threshold
BiPAP	Bi-level positive airway pressure
CNS	Central Nervous System
CO2	Carbon dioxide
CPAP	Continuous positive airway pressure
ESS	Epworth Sleepiness Scale
FOSQ	Functional Outcomes of Sleep Questionnaire
ICSD	International Classification of Sleep Disorders
IRB	Institutional Review Board
MAD	Mandibular advancement device
MRI	Magnetic resonance imagery
NPDS	Naval Postgraduate Dental School
OA	Oral appliance
OCST	Out of center sleep test
ODI	Oxygen desaturation index
OSA	Obstructive sleep apnea
OSAHS	Obstructive sleep apnea-hypopnea syndrome
PAP	Positive airway pressure

POB	Posterior open bite
PSG	Polysomnography
PSQI	Pittsburgh Sleep Quality Index
PSS	Perceived Stress Scale
PTSD	Post traumatic stress disorder
RERA	Respiratory effort-related arousals
RDI	Respiratory Disturbance Index
SaO2	Arterial oxygen saturation
SAHS	Sleep apnea-hypopnea syndrome
SDB	Sleep disordered breathing
SNS	Sympathetic Nervous System
SpO2	Peripheral oxygen in the blood
TMD	Temporomandibular Disorder
TMJ	Temporomandibular joint
TRD	Tongue retained device
UPPP	Uvulopalatopharyngoplasty
VAS	Visual analogue scale
WRNMMC	Walter Reed National Military Medical Center

CHAPTER I: REVIEW OF THE LITERATURE

Types of Sleep Apnea

Sleep-disordered breathing (SDB) refers to a spectrum of disorders characterized by abnormal respiratory patterns, and specifically, pauses in breathing. These disorders can span the range from intermittent snoring to sleep apnea-hypopnea syndrome (SAHS) (Dieltjens et al., 2012). While snoring may not always have adverse physiological effects, SAHS is associated with daytime sleepiness and cognitive issues and increases the risk of developing health problems such as hypertension, arrhythmias, diabetes, stroke and premature death from cardiovascular disease (Ross et al., 1998; Young et al., 2009).

The American Academy of Sleep Medicine (AASM) classifies sleep apnea as central, mixed or obstructive sleep apnea (OSA). OSA represents 85% of all sleep apnea cases, 80% of which are often undiagnosed (Kapur et al., 1999). It has been reported that 15% of the U. S. population has untreated sleep apnea (Young et al., 2009). OSA induced effects are of concern to military service members. Veterans are 4 times more likely to suffer from OSA than the general population (Teng & Won, 2012). Mysliwiec et al. reported 62.7% of the military personnel studied met diagnostic criteria for OSA. Veterans with OSA have significantly more anxiety, post-traumatic stress disorder (PTSD) and mental disorder symptoms compared to veterans without OSA (Sharafkhaneh et al., 2005). Military personnel are at a high risk to sustain blunt evoked traumatic brain injury; these head injuries have been reported to be associated with sleep issues to include OSA (Collen et al., 2011). Central and mixed sleep apnea involve central nervous system (CNS) respiratory center dysfunction that results in inadequate or complete cessation of breathing effort during sleep. OSA, on the other hand, is due to recurrent episodes of complete or partial blockage of the upper airway despite respiratory effort. These apneic and or hypopneic episodes reduce oxygen saturation (hypoxemia), increase carbon dioxide levels (hypercapnia), induce arousals from sleep and cause abnormal pauses in breathing that can last longer than 10 seconds (AASM Task Force, 1999; Malhotra & White, 2002; ICSD-3, 2014).

Apnea is a cessation of breathing attributed to complete airway obstruction during sleep. Hypopnea involves episodes of shallow breathing or a low respiratory rate that does not meet metabolic needs and is attributed to partial airway blockage (Dempsey et al., 2010). An obstructive apnea or hypopnea event can lead to reductions in blood saturation and lasts at least 10 seconds (ICSD-3, 2014). Apneas and hypopneas share similar pathophysiology and are categorized as part of obstructive sleep apnea-hypopnea syndrome (OSAHS) when daytime interference occurs due to this SDB (AASM Task Force, 1999). Although OSAHS is the most accurate acronym, many authors simply use OSA, which will be implemented in this document.

OSA Risk Factors

Like SAHS, OSA has been implicated as a risk factor for a variety of medical conditions, to include cardiovascular disease and diabetes (AASM Task Force, 1999; ICSD-3, 2014). Common consequences of undiagnosed OSA include excessive daytime sleepiness, impaired cognitive performance and reduced quality of life. These symptoms may result in neuropsychological changes, such as decreased concentration, memory loss and an elevated risk for motor vehicle accidents (Teng & Won, 2012). Daytime sleepiness and fatigue can cause periods of inattention, decreased productivity and safety related hazards in the work place.

Snoring, a possible precursor of OSA, afflicts 40% to 60% of all adults and is considered the most prevalent sleep breathing disorder (Ohayon et al., 1997). Loud snoring, sleep arousal due to gasping for breath, and poor sleep quality are hallmark signs of OSA. The pathophysiology for OSA is considered to be due to a mechanical issue by the often enlarged pharyngeal tissues and tongue obstructing the upper airway specifically when sleeping in the supine position. Furthermore, it has been proposed that a low respiratory arousal threshold (ArTH) is a physiologic trait involved in mild and moderate OSA pathogenesis. A decrease in the apnea hypopnea index (AHI), a measure of OSA severity, and oxygen saturation as well as a greater number of hypopneas compared to apneas were found to be significant independent predictors of a low ArTH. These findings by Edwards et al may help characterize why healthy, non-obese and or non-cardiac compromised patients, which comprise the majority of active duty military personnel, may be diagnosed with mild to moderate OSA (Edwards et al., 2014).

Risk factors for OSA include increased age, male gender and obesity (Eckert & Malhotra, 2008). Particular risk factors that increase the probability for the onset of OSA include: (1) a neck circumference greater than 17 inches for men and greater than 16 inches for women, (2) a body mass index greater than 35, (3) a Modified Mallampati score of 3 or 4, (4) craniofacial variation, 5) nasal obstruction, (6) pharyngeal crowding, (7) daytime tiredness (8) snoring history (9) hypertension, and (10) sedative medication use (Epstein et al., 2009; Chung et al., 2008; Culpepper & Roth, 2009). The Modified Mallampati score (1-4) is determined by assessing the visibility of structures in the oral cavity (Nuckton et al., 2006).

- Class 1: Full visibility of tonsils, uvula and soft palate
- Class 2: Visibility of hard and soft palate, upper portion of tonsils and uvula
- Class 3: Only the soft and hard palate and base of the uvula are visible
- Class 4: Only hard palate visible

Individuals with scores of 3 or 4 who have accompanying daytime symptoms should be evaluated for OSA.

Upper airway anatomy, depressed upper airway muscle activity and genetic predisposition are reported as being major factors for upper airway collapse in OSA patients (Deegan & McNicholas,

1995). OSA patient upper airway size is reduced compared to age and weight matched controls during wakefulness using computed tomography and magnetic resonance imaging. OSA patients have smaller retropalatal areas with fat deposits around the upper airway (Horner et al., 1989; Schwab et al., 1993). A 1997 study that compared 17 healthy patients to 40 OSA patients found smaller pharyngeal airways and increased airway collapsibility in OSA patients (Isono et al., 1997).

Adequate upper airway patency for breathing, speech or swallowing involves coordination of peripheral respiratory and oral musculature and the CNS that controls this motor activity. More than 20 pharyngeal skeletal dilatory muscles help maintain upper airway patency. These muscles help reduce upper airway collapse due to negative intraluminal pressure caused by the diaphragm, pressure from surrounding extraluminal tissues and potential nasal obstruction (Malhotra & White, 2002).

In OSA patients, upper airway dilatory muscle activity is greater during daytime inspiration compared to healthy individuals (Mezzanotte et al., 1992). Fogel et al reported that during wakefulness, OSA patients compensated for greater negative intraluminal pressure by increased pharyngeal dilatory muscle activity. This increased effort enabled OSA patients to achieve the same air flow rate (filling the lungs with the same amount of air) as healthy subjects (Fogel et al., 2001); this increased activity is diminished while sleeping. Individuals, who have compromised airway anatomy due to facial skeletal abnormality or the severely obese, are more vulnerable to upper airway collapse during sleep (Malhotra & White, 2002). In OSA patients, reduced reflexive dilatory muscle activity during sleep results in greater reduction of airway patency than occurs in healthy individuals (Dempsey et al., 2010). Sleep-induced restriction of air flow initiates a weak reflexive response to increase dilatory muscle activity, and in OSA patients, this weak increase is generally insufficient to re-establish upper airway patency (Berry & Gleeson, 1997; Gleeson et al., 1990).

Apneas and hypopneas are associated with increased arterial carbon dioxide (CO2) levels sympathetic nervous system (SNS), brain, muscle and heart activity. This sleep arousal (Berry & Gleeson, 1997; Dempsey et al., 2010) induces pharyngeal dilatory muscle activity which improves airflow and decreases arterial CO2 levels. Persistent SNS activity occurs with ongoing apneic events; this may lead to hypocapnia, decreased central respiratory drive and less effective pharyngeal dilatory muscle activity which may compromise upper airway patency (Deegan & McNicholas, 1995). OSA patients are aroused from sleep repeatedly throughout the night to resolve the apnea/hypopnea-induced hypoxemia. If the apneas occur with sufficient frequency, the patient does not progress through a full sleep cycle during the night (AASM Task Force, 1999). It is this sleep fragmentation coupled by surges in SNS activity that can cause daytime drowsiness, negative health outcomes and decreased quality of life (Vanden Brook, 2010).

Diagnosis and Assessment of OSA;

The diagnosis of OSA is made by a sleep physician. The full night sleep study or polysomnography (PSG) is considered the gold standard for OSA diagnosis as it provides objective measures of neurological, chemical and physical parameters directly related to SDB (Dieltjens et al., 2012). A diagnosis of OSA is confirmed if a PSG, or similar data recording instrumentation, shows an AHI of 5 or more apnea/hypopnea events per hour of sleep and there is no neurological evidence of CNS dysfunction. Patients diagnosed with OSA who fail positive airway pressure (PAP) therapy can consider an oral appliance (OA) as an alternative treatment modality. The OA functions to position the mandible and tongue position forward, thus increasing upper airway patency. If OSA is confirmed, the patient may be referred to a dentist by their sleep physician for OA evaluation.

Four types of instrumentation assess physiological aspects of sleep apnea.

- Type 1: The full night PSG conducted by a sleep lab attendant in a formal sleep lab uses 8 or more channels (7-12 leads) to record data. This PSG includes the following: electroencephalogram, electrocardiogram, electro-oculogram, electromyogram, nasal/oral airflow, chest/abdominal respiratory effort, AHI, blood oxygen saturation, oxygen desaturation index (ODI), respiratory disturbance index (RDI) and respiratory event related arousal (RERA) experienced per hour of sleep (AASM Task Force, 1999; Epstein et al., 2009).
- Type 2: Instrumentation gathers the same parameters as a Type 1 PSG but does not use a sleep lab attendant.
- Type 3: These monitoring devices record at least 4 parameters, including 2 pulmonary functions, heart rate and blood oxygen saturation via pulse oximetry. While not as definitive as Type 1 or Type 2 instrumentation, Type 3 monitoring can be used in an out of center or home sleep environment and still provide the sleep physician sufficient data to make a OSA diagnosis (Collop et al., 2012; ICSD-3, 2014).
- Type 4: These devices typically measure less than 4 parameters, but always include a pulse oximeter. Type 4 devices are inexpensive and easy to use by patients at home. These devices measure pulse rate and blood O2 saturation levels (Dawson et al., 2015). However, they may not provide sufficient objective data to positively diagnose OSA (Collop et al., 2012).

The severity of OSA is measured by the AHI, which the International Classification of Sleep Disorders 3rd Edition (ICSD-3) in 2014, defined as the number of obstructive apnea and or hypopnea events per hour of sleep. A PSG measures multiple physiological parameters and is viewed as the ideal method for determining AHI. The AHI parameters described in the ICSD-3 are listed below.

1. Mild 5 to 15 events per hour
2. Moderate > 15 to 30 events per hour
3. Severe > 30 events per hour

RDI is also used in sleep medicine to categorize the severity of OSA but has a varied definition (Epstein et al., 2009). Like AHI, RDI uses the same numeric range as AHI to define mild, moderate and severe OSA. However, in addition to measuring apnea and hypopnea events per hour, RDI also includes less severe respiratory effort-related arousal (RERA)s as part of its scoring. These events involve reduced airflow that does not meet oxygen desaturation criteria for hypopnea. AHI and RDI can be derived from PSG data and can also be assessed by an out of center sleep test (OCST) using portable/home monitor devices. These home monitors cannot differentiate when the patient is sleeping. Since portable monitors collect data at night when the patient is not always asleep, AHI or RDI can underestimate OSA severity (Park et al., 2011). RDI measured from oximetry during PSG may slightly overestimate AHI, but it may correlate closely with AHI for OSA patients (Vasquez et al., 2000).

OSA Treatment Options:

Patient education is often the first treatment option for all forms of OSA. This information may include lifestyle changes such as weight loss and or smoke cessation, maintenance of nasal patency, avoidance of respiratory depressants such as alcohol intake close to bedtime and adjustments to sleep habits. For some patients with positional OSA, defined as an AHI 2 times more in the supine position vice sleeping with a lateral head position, avoiding the supine position while sleeping can be effective (Malhotra & White, 2002). PAP has long been considered the gold standard medical therapy for OSA (Young et al., 1993; Qaseem et al., 2013) and is recommended for severe OSA. OA therapy should be considered when PAP is not effective or tolerated by patients diagnosed with severe OSA (Ramar et al., 2015). PAP can improve the patency of an obstructed upper airway; PAP is usually delivered through a face mask device (both nose and mouth or nasal only) to prevent upper airway collapse and maintain airway patency during sleep (Sullivan et al, 1981; AASM Task Force, 1999; Qaseem et al., 2013). PAP therapy improves sleep quality because the positive pressure it delivers can be adjusted to reduce the frequency of apneas, hypopneas, snoring as well as improve oxygen saturation. Successful PAP therapy can enhance patient quality of life, decreases excessive daytime sleepiness and depressive symptoms while improving cognitive function and blood pressure (Bazzano et al., 2007; Qaseem et al., 2013). Unfortunately, many patients do not tolerate PAP. In many cases, the intolerable effects are a result of incorrect pressure settings or inadequate device fit or inconvenience and the claustrophobic feeling of the mask on the face. Due to these issues, only 60 to 80% of patients will use PAP (Hsu & Lo, 2003). Low adherence to PAP therapy may warrant the referral from the sleep physician to a dentist for an OA to help

manage OSA symptoms. Other PAP therapies include bi-level positive airway pressure (BiPAP) and automatically self-adjusting positive airway pressure (APAP) devices. BiPAP mimics normal breathing more closely than continuous positive airway pressure (CPAP). APAP devices detect the variability of airway resistance on a breath to breath basis, and vary the air pressure to provide the lowest and most comfortable positive pressure needed to keep the upper airway patent. These alternative PAP devices may be better tolerated than CPAP (Culpepper & Roth, 2009).

For severe OSA cases or for patients who cannot tolerate PAP or OAs, surgical intervention may be a viable treatment option. The various surgery options can reduce upper airway obstruction by increasing the size of the upper airway by tissue removal, advancing the tongue and or mandibular position or stabilizing the pharyngeal tissues by implants. Tonsillectomy and/or uvulopalatopharyngoplasty (UPPP) remove excess tissue to facilitate a more patent upper airway. However, positive results from these irreversible procedures have been inconsistent, ranging from 16% to 83% (Khan et al., 2009). A review by Sutherland et al reported a comparison study of OA treatment to UPPP surgery; it noted greater AHI reduction in the OA group after 12 months and at 4 years (Sutherland et al., 2014).

Since PAP adherence may be challenging for patients, OA therapy has emerged as a viable option (George, 2001; Hoekema et al., 2004; Hoffstein, 2007). A mandibular advancement device (MAD) is often custom fitted to the maxillary and mandibular dentition, worn at night and can be titrated to move the mandible forward thus advancing the base of the tongue. Such forward positioning increases pharyngeal airway space and reduces airway instability (Chan et al., 2007; Culpepper & Roth, 2009; Dieltjens et al., 2012). Greater mandibular protrusion using a MAD is associated with AHI reduction (Kato et al., 2000). The amount of mandibular protrusion is limited by patient anatomy and tolerance/comfort. A more forward MAD induced mandibular position does not always correspond with more favorable AHI reduction, even if subjective findings continue to improve with this protruded mandibular position (Dieltjens et al 2012). This may be due to the fact that in OSA patients, the cross sectional area of the upper airway may be more eliptic shaped than round (Leiter, 1996, Ogawa et al., 2007). An over advanced mandibular position during MAD titration, may actually make this less rounded upper airway morphology less patent thus increasing AHI.

Currently, the AASM indicates OA use as a first-line therapy in patients with mild-to-moderate OSA and for patients with more severe OSA who cannot tolerate PAP or prefer OA therapy as an option (Sutherland et al., 2014). In a 2013 crossover study of 108 OSA patients, MAD therapy was shown not to be inferior to CPAP in the treatment of moderate to severe OSA because the OA adherence was better than that from CPAP (Phillips et al., 2013). Although CPAP continues to be superior to OA therapy in reducing AHI, arousal index and ODI scores for OSA, evidence suggests

that OA adherence is greater than that observed with CPAP (Ramar et al., 2015).

MAD Therapy

A variety of MAD designs that advance the mandible to increase the upper airway space are commercially available for OSA treatment (Aherns et al., 2011). MAD design has evolved from the non-adjustable mono-bloc device where the maxillary and mandibular parts are rigidly fixed together to the current duo-bloc MAD which enables titration (adjustment) of the mandibular protrusive position.

Before initiating MAD titration, the OA is set at a specific degree of mandibular protrusion. When initiating MAD therapy, it has been recommended to set the mandible at approximately 50% of the patient's maximum protrusion. (Doff et al., 2011). An advancement mechanism enables the patient to adjust the MAD before going to sleep. This allows a patient to gradually protrude or retrude the mandible, based on symptoms, until positive subjective OSA effect is achieved to include reduced snoring or daytime tiredness prior to a follow up sleep physician assessment which may include a second PSG (Aarab et al., 2011).

Ideal treatment for MAD OSA management is provided by a multidisciplinary team that includes a sleep physician and a dentist with training in the management of sleep disorders. The specific roles of physicians and dentists in the treatment of snoring and OSA with MADs have been defined by the AASM Task Force as well as the American Academy of Dental Sleep Medicine. A sleep physician completes subjective and objective assessments and based on these evaluations a diagnosis of OSA is made. If the patient is a candidate for a MAD, the sleep physician will make a referral to a dentist for MAD evaluation (Kushida et al., 2005). The referral to the dentist should include a copy of the PSG findings, the Epworth Sleepiness Scale (ESS) score and pertinent medical information (Ferguson et al., 2006).

Upon referral, the dentist assesses the suitability of the patient's dentition for customized MAD treatment (Chan et al., 2007). This assessment includes a complete dental/medical history and examination of extra- and intra-oral tissues. Soft tissue anatomy, periodontal status, dental caries, the temporomandibular joint (TMJ), muscles of mastication and nocturnal bruxism are assessed. Restorative dental treatment must be completed before the fabrication of the MAD to avoid OA fit issues. Patients must have a minimum of six healthy, non-mobile teeth per arch and at least one posterior tooth per quadrant. They must also be able to protrude the mandible at least 6 millimeters (Ferguson et al., 2006; Campbell et al., 2009).

If the patient is a suitable dental candidate for the MAD, it is fabricated in accordance with the manufacturer's instructions. The patient is given written and oral instructions on OA care, use and how to titrate or adjust the MAD. A suggested titration starting point for the MAD is 50-75% of the

patient's maximum mandibular protrusion, which may be reduced if initially not tolerated (Ferguson et al., 2006). The patient may be allowed to accommodate to the 50-75% of maximum mandibular protrusion (Doff et al., 2011) starting mandibular position for one week before active MAD advancement is begun. Clinicians should select FDA approved MADs which may be found at: http://www.ihatecpap.com/oral_appliance.html.

There are both titratable and non-titratable OAs. With titratable OAs, the mandible can be moved in an anterior or posterior direction. Non-titratable OAs keep the protruded mandible in a fixed position (Lettieri et al., 2011). Another type of OA to help manage OSA is a tongue retained device (TRD) that acts like a suction cup on the tongue and pulls it forward to help open the upper airway. The TRD is the best option in an individual who is edentulous or lacks the dental support for a MAD. Mild and transient side effects are common with the use of a MAD and generally decrease with continued use and MAD adjustment (Doff et al., 2011; Perez et al., 2012; Bailey, 2005; Ferguson et al., 1997). Adverse effects may include excessive or reduced salivation, odontogenic pain, gingival irritation, headache and TMJ area discomfort. Other common side effects include the development of a posterior open bite, masticatory myalgia and TMJ sounds. These symptoms usually last several days to months, but may persist even if the MAD is discontinued (Sutherland et al., 2014). Transient signs and symptoms of temporomandibular disorder (TMD) may occur in patients who were pain-free before starting MAD treatment for OSA, however these symptoms usually decrease over time. In a 13 month study by Perez et al, MAD use did not significantly increase pre-existing TMD signs and symptoms in OSA patients (Perez et al., 2012).

Long term use of a MAD can cause occlusal changes (Almeida et al., 2006). One of the most prevalent long term side effects with MAD use is a dental posterior open bite (POB). An average incidence of POB occurred in 17.9 % of patients who used a MAD for 13 months. However, many patients were unaware of these dental changes and the majority concurred that the positive effects of their OSA symptoms when using the MAD outweighed any adverse effects related to dental changes (Perez et al., 2012). Another study reported that after an average of 11 years of treatment using MAD therapy, there was a noted decrease in overbite and overjet. Additionally, these changes in occlusion were progressive and the decrease in overbite and overjet continued for as long as the OA was used (Pliska et al., 2014). Morning jaw exercises may be offered to patients who use OAs; these function to relax the muscles of mastication and help reduce the risk for potential occlusal changes (Perez et al, 2012).

Titration refers to adjustment of a particular device or therapy and the subsequent evaluation of clinical parameters that assess treatment efficacy. During a PSG, PAP and MAD position can be titrated; some of the objective clinical parameters that can be assessed for optimum therapeutic effect during this titration include AHI (Epstein et al., 2009) oxygen saturation and ODI (Dieltjens

et al., 2012). If the MAD is titrated during a single night PSG by a sleep medicine lab technician, the patient will be awakened multiple times. A protrusive setting that attains a target AHI may be achieved during this PSG, but whether or not this target AHI can be maintained with subsequent MAD use is a potential concern. Additionally, mandibular discomfort could subsequently develop and inhibit future MAD use if the advancement was performed rapidly by the sleep medicine lab technician (Dort et al., 2006; Petelle et al., 2002). A home sleep environment allows patients to comfortably accommodate to slow (daily) MAD mandibular titration, reducing the risk of TMD symptoms.

A full-night PSG or an AASM compliant OCST is required for the diagnosis of OSA (ICSD-3, 2014). Initial OSA OA designs used a mono-bloc construction that did not permit titration; these fixed OAs attempted to maximally reduce AHI without causing adverse symptoms. Currently, adjustable MADs make titration feasible. A review of MAD titration protocols by Dieltjens et al summarized numerous studies in which MADs were titrated to optimal mandibular protrusion positions during a single night PSG study before the patient used the MAD at home. In most cases, the patients had to be woken to adjust the MAD (Dieltjens et al., 2012; Almeida et al., 2009; Kuna et al., 2006). Some studies employed experimental motorized devices which allow sleep medicine lab technicians to remotely titrate the MAD and minimize patient waking (Dort et al., 2006; Tsai et al., 2004; Petelle et al., 2002). Attempting to negotiate optimal mandibular protrusion in a single night's PSG to maximize objective PSG measures, may not allow adequate time for the muscles of mastication and or the TMJ to adapt/accommodate to an increased mandibular protruded position. Single night MAD titration during a PSG, may interfere with the patient's already compromised normal sleep cycle and can alter the ratio of the various sleep stages. Since the severity of OSA may change during the sleep stages throughout the night, the results of MAD titration by a sleep medicine lab technician during a PSG can bias mandibular protrusion settings (Almeida et al., 2009).

Subjective and objective sleep measures to assess sleep quality can be used during home MAD titration. MAD. Subjective measures include daytime sleepiness, snoring and mandibular comfort; these can be used to assess how or when to adjust the MAD. Objective measures may comprise the following: Portable Type 2 instruments are a type of OCST equipment, that collect similar data to that of a PSG, but these devices are expensive. Portable Type 3 instruments are less expensive but are not simple to use. They typically have four channels of recorded data to assess pulse oximetry, air flow from which an AHI is derived, snoring by sound and head movement. The OCST equipment must meet AASM practice parameters and have been shown to be comparable in diagnostic ability to PSG (ICSD-3, 2014). A Type 4 pulse oximeter can be used to derive an ODI which could serve as a monitoring parameter for MAD titration at home (Chung et al., 2012).

Using objective or subjective measures during MAD titration does not always achieve optimal therapeutic endpoints (AHI reduction) (Levendowski et al., 2007; Fleury et al., 2004). Patients may subjectively over-titrate the MAD based on the assumption that more is better. Others may under-titrate the MAD based on perceived improvement in subjective sleepiness outcomes, regardless of the objectively measured ODI levels (Almeida et al., 2009; Fleury et al., 2004). Optimal mandibular titration for a MAD, can be guided by a combination of both subjective symptom improvement and objective monitoring of overnight oximetry to achieve the most effective mandibular protrusion position that normalizes AHI (Sutherland et al., 2014).

Pulse Oximetry

A pulse oximeter uses a non-invasive probe and a microprocessor to continuously measure the saturation level of peripheral oxygen in the blood (SpO2). It assesses the percentage of available hemoglobin saturated with oxygen. Although it is an indirect measurement of arterial oxygen saturation (SaO2), SpO2 closely correlates with actual oxygen saturation (Gries & Brooks, 1996). The probe has two light emitting diodes that emit red and infrared light (respective wavelengths of 660 nm and 940 nm) and photo detectors that receive the light as it passes through a pulsatile tissue bed. The probe is typically worn on the finger, though a toe, ear lobe or the nose can be used. The microprocessor is worn on the wrist or may lay by the patient's side. It receives data from the photo detectors, detects the pulse of arterial flow and analizes the changes in light absorption in the tissue to yield SpO2 (Clark et al., 2006; Valdez-Lowe et al., 2009). Blood that is highly saturated with oxygen allows more red light and less infrared light to pass through tissue to the photo detectors. As saturation decreases, less red light passes through the blood while the amount of infrared light that passes increases. The photo detectors measure the amount of light at each wavelength transmitted through the blood and sends this data to the microprocessor. Awake, healthy individuals typically have SpO2 in the range of 97- 99% when breathing room air (Schutz, 2001). Pulse oximeter readings with a SpO2 of 95% or greater are considered clinically acceptable (Clark et al., 2006). With increased age, oxygen saturation rate tends to decrease. An average SpO2 below 90% indicates hypoxemia, a red flag for clinicians (Schutz, 2001).

Oxygen Desaturation Index

ODI is the average of hourly number of oxygen desaturation events that persist for greater than 10 seconds. An oxygen desaturation event is defined as a decrease in SpO2 by 3-4% below the baseline level during the preceding 2 minutes (Chung et al., 2012). ODI obtained from a pulse oximeter has a strong positive correlation with the AHI obtained from a PSG (Chung et al., 2012). For most OSA patients, ODI diagnostic accuracy is not affected by its night-to-night variability (Fietze et al., 2004). In a study by Chung et al., ODI slightly underestimated AHI by 1.6 events per hour, (plus or minus 10), over the range of 5 to 30 events per hour; this closely

predicted the AHI at 5, 15 or 30 events per hour which characterize mild, moderate and severe OSA.

- An ODI > 5 was 87% accurate in predicting AHI > 5
- An ODI > 15 was 84% accurate in predicting AHI > 15
- An ODI > 30 was 93% accurate in predicting AHI > 30

These authors concluded that ODI from a high-resolution nocturnal oximeter is a sensitive and specific tool to detect undiagnosed SDB. Their findings reinforced conclusions from earlier studies (Tsai et al., 1999; Magalang et al., 2003; Vazquez et al., 2000) indicating that ODI derived from a finger mounted pulse oximeter has excellent correlation with AHI derived from PSG.

Type 3 or 4 PSG instrumentation, with the addition of a pulse oximeter, have high sampling frequency and resolution and require little training. They detect fluctuations in oxygen saturation caused by episodes of apnea and hypopnea that can be analyzed by commercially available computer programs (Chung et al., 2012). In portable multichannel sleep screening devices that lack electroencephalographic or thoracic muscle activity monitoring capability, pulse oximetry is considered the most important parameter for identifying SDB (Netzer et al., 2001). Even though pulse oximetry can be an effective preliminary screening instrument for SDB, it cannot be used to definitively diagnose OSA since oxygen desaturation cannot be discerned if it is due to OSA or some other cause (Niijima et al., 2007; Chung et al., 2012). Further, if a diagnosis of OSA using Type 1, 2 or 3 PSG instrumentation is confirmed by a sleep physician, an increased ODI derived from pulse oximetry data can be attributed to OSA (Collop et al., 2012).

The practice guidelines for pulse oximetry, published in 1992 by the American Association for Respiratory Care, recommend 2 uses for pulse oximetry:

1. As a warning signal for patients at risk for arterial desaturation.
2. For evaluating response to a therapeutic intervention or a diagnostic procedure.

This second recommended use is how the pulse oximeter will be used in this protocol to monitor home MAD titration.

Pulse oximeters are inexpensive and easy to use. They can provide a noninvasive, objective measurement of oxygen saturation levels. This may enhance the clinical ability to determine what mandibular protrusion setting, during MAD titration, offers optimum oxygen saturation while minimizing jaw discomfort. Although high resolution pulse oximetry is a convenient and inexpensive way to screen for SDB, it has limitations. Because pulse oximetry only measures the oxygen saturation change and does not monitor nasal flow and respiratory effort, it is not able to distinguish OSA from central sleep apnea (Chung et al., 2012). Pulse oximetry relies on

pulsatile blood flow for its measurements and is vulnerable to the effects of poor peripheral arterial blood flow. Bodily movements, vasoconstriction and hypotension can cause artifacts through an interruption of the pulse signal. Since pulse oximeters do not always detect movement, artifacts due to motion would overestimate the number of desaturations (Netzer et al., 2001).

This study is a first of its kind that will track nightly, continuous pulse oximetry for correlations with AHI and subjective / objective measures during MAD home titration. Pulse oximetry data may influence and guide MAD titration for optimum jaw protrusion and improved sleep quality. Maintaining good sleep quality plays a significant role in patient wellbeing and has a tremendous impact on military healthcare and mission readiness

CHAPTER II: MATERIALS AND METHODS

This study will evaluate if the nightly use of home pulse oximetry during MAD titration is feasible and acceptable to patients who have been diagnosed with moderate or severe OSA. Additionally, exploring the association of home pulse oximetry, objective data, subjective recall of sleep quality, stress, MAD adherence and pain levels with pre and post treatment AHI measures will also be assessed.

Participants must be diagnosed with moderate to severe OSA by a sleep provider at the Walter Reed National Military Medical Center (WRNMMC) Sleep Disorders Center and be able to meet the inclusion and exclusion criteria for this study.
The study participant must be 18 years of age or older, available for 6 months and have greater than 5 healthy teeth per dental arch. Exclusion criteria include a mouth opening of less than 24 mm, Temporomandibular Disorder (TMD) symptoms that would prevent MAD use, dental disease and any previous treatment for obstructive sleep apnea. Participants who do not meet these criteria will be treated for their OSA by the WRNMMC Sleep Disorders Center. The total number of participants that will complete the project protocol will be 20. Refer to Table 1 for the listing of inclusion and exclusion criteria.

The following inventories will serve as subjective measures:

- Epworth Sleepiness Scale (ESS): this is a subjective measure of the participant's sleepiness level.
- Functional Outcome of Sleep Questionnaire (FOSQ): this determines if participants have difficulty performing activities due to being too sleepy or tired.

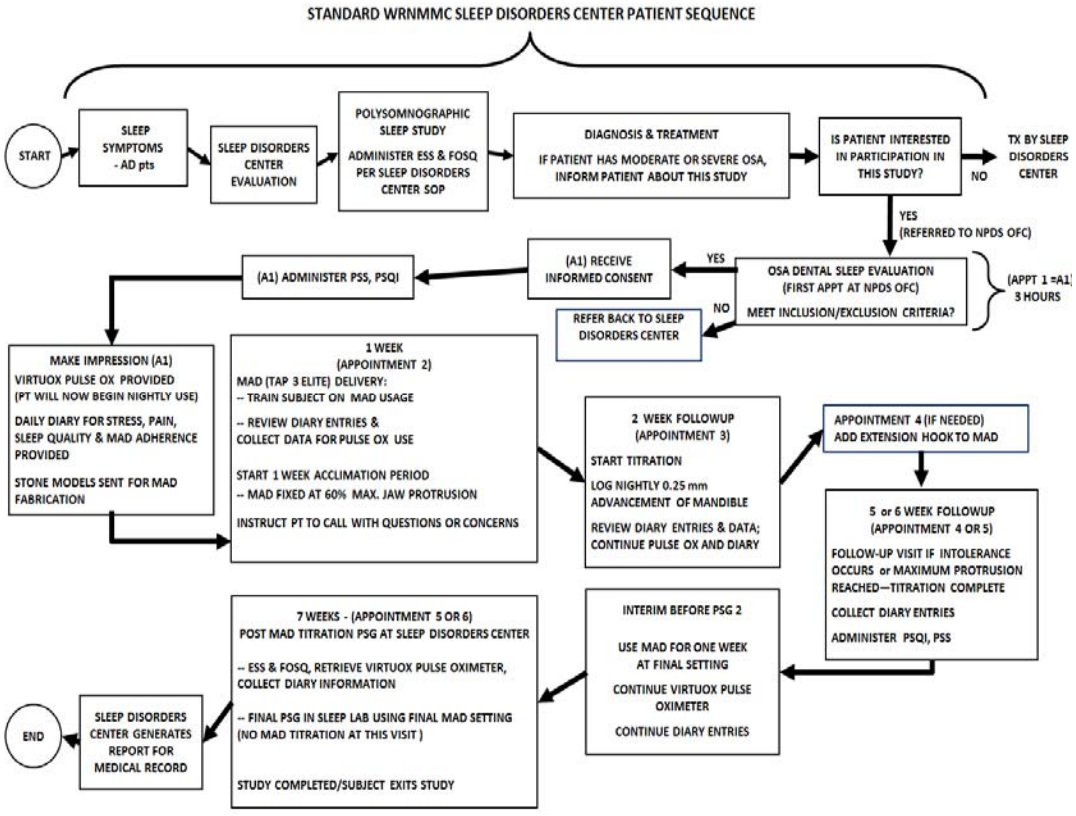
- The Perceived Stress Scale (PSS): this measures a participant's subjective appraisal of the stressfulness of situations within the past 30 days.
- The Pittsburgh Sleep Quality Index (PSQI): this assesses a participant's usual sleep habits during the past month.

Additionally, study participants will complete daily diaries for stress, sleep quality and jaw pain utilizing a 0-10 visual analog scale.

Objective measures include the night to night ODI, captured by the VirtuOx pulse oximeter. The VirtuOx Pulse Oximeter Device, or VPOD, is FDA approved to track respiratory data. The wireless VPOD uploads oxygen saturation data to the Virtuox Inc owned internet cloud. This technology allows real time monitoring of ODI during home MAD titration.

The FDA approved MAD utilized in this study is the Thornton Adjustable Positioner (TAP)-3 Elite. It can slowly be titrated to move the mandible forward, incrementally increasing upper airway opening. A 180 degree clockwise turn of the adjustment key for this MAD equates to 0.25 mm anterior mandibular advancement. Refer to Figure 1 for the description of the study protocol.

Figure 1: Study Participant Protocol



Interested and eligible participants will be identified by a WRNMMC Sleep Disorders Center physician after receiving a diagnosis of moderate or severe OSA (Visit 3 at Sleep Disorders Center). If the participant is interested in the study, then an appointment will be scheduled at the Naval Postgraduate Dental School (NPDS) Orofacial Pain Center (OPC) (Visit 4). The participant will be evaluated for inclusion/exclusion criteria and if they meet them and agree to participate, written informed consent will be received. If the participant does not meet study criteria, (Table 1 and 2 below), or is not interested in study participation, follow-up at the WRNMMC Sleep Disorders Center will be arranged for standard OSA treatment options.

Table 1: Inclusion and Exclusion Criteria

Inclusion Criteria

1. Diagnosed in WRNMMC Sleep Center with moderate or severe OSA (AHI < 45) and referred to Orofacial Pain Center
2. Age 18 or older
3. Non smoker
4. Available for 6 months
5. Agrees to participate by informed consent
6. $\geq$ 6 healthy teeth per dental arch
7. $\geq$ 1 posterior tooth per dental quadrant
8. Protrude the jaw $\geq$ 5 mm
9. Restorative dental treatment completed

Exclusion Criteria

1. AHI <15
2. Under 18 years of age
3. Smoker
4. $\leq$ 6 healthy teeth per arch
5. A dental quadrant without posterior teeth
6. Restricted jaw opening $\leq$25 mm
7. TMD symptoms that prevent MAD use
8. Dental caries, periodontal disease, oral pathosis
9. Previous upper airway intervention for OSA: CPAP, MAD, Surgery
10. Periodic limb movement
11. Nighttime supplemental oxygen therapy
12. Cannot tolerate 50% mandibular advancement
13. Maximum mandibular protrusion $\geq$14 mm

Table 2: Reason for the "NO" path in the block diagram

1. **Sleep disorders other than OSA (central or mixed sleep apnea)**
2. **Candidates must have an AHI ≥15 but <45.**
3. **Candidates who cannot adhere with the protocol are returned to the WRNMMC Sleep Disorders Center for conventional treatment.**
4. **Candidates must meet the inclusion / exclusion criteria of the study. Those failing to qualify, who drop out of the study or for whom the MAD was not effective are referred to the appropriate clinic for conventional treatment:**
    - **WRNMMC Readiness Dental Clinic for dental issues not quickly correctable**
    - **Orofacial Pain Center for temporomandibular disorder issues**
    - **WRNMMC Sleep Disorders Center for those who are edentulous, at high risk for dental caries, restricted mouth opening, previously treated for sleep apnea**

● Visit 1 at the Sleep Disorders Center (standard care for all patients): Active duty patients referred with sleep disturbance are evaluated by a sleep medicine physician. If a PSG is recommended, then the patient continues to visit 2.
● Visit 2 at the Sleep Disorders Center (standard care for all patients): The patient completes the following: the ESS, FOSQ and receives an in lab PSG sleep study.
● Visit 3 at the Sleep Disorders Center (standard care for all patients): The sleep medicine physician offers, when appropriate, the patient PAP vs. OA therapy if positive for OSA. They inform all patients that if the first treatment chosen is not effective, the other treatment option is provided. All patients are counseled on their choices regarding PAP and OA therapy for OSA. After this counseling, if the diagnosis of moderate or severe OSA is made, then the patient is informed about the study and invited to participate.

- If the patient is interested in this study, they are referred to the OPC located at the NPDS, Navy Medicine Professional Development Center (NMPDC).
- If the patient is not willing to participate in the study they are provided other treatment options by the WRNMMC Sleep Disorders Center.

● Visit 4 at the OPC (standard care for all patients): This will be the first appointment for the potential study participant at the NPDS OPC. They will be evaluated for MAD use. If they are candidates for a MAD and meet study inclusion/exclusion criteria they will be informed about the study.

- If they do not meet study criteria, they will be referred to the WRNMMC Sleep Disorders Center for standard care.

- If they meet study criteria, the study will be explained and written informed consent will be reviewed and received.
- If the patient is not interested in study participation, they will be referred to the WRNMMC Sleep Disorders Center for standard care.

- If they are interested in study participation, the following will be received.
    - The study participant will complete the PSS and the PSQI.
    - OPC providers will make maxillary and mandibular alginate impressions. Stone dental models will be made from the molds and sent to the NPDS Maxillofacial Prosthodontic Lab for MAD fabrication.
    - The VirtuOx pulse oximeter will be provided to the participant with instructions on nightly device use.
    - Daily diaries will be reviewed and provided regarding stress, pain, sleep quality and MAD adherence measures.

● Visit 5 at the OPC: 1 week after visit 4, the participant will return to the OPC for the following:

- MAD delivery.
    - The participant will be trained on how to use the TAP-3 Elite.
- Review and collect the participant's diary entries for stress, pain, sleep quality and MAD adherence levels.
- Begin the one week MAD acclimation period at the fixed position of 60% of the participant's maximum jaw protrusion.
- Inform the participant to call the OPC if any questions or concerns arise.

● Visit 6 at the OPC: 1 week after visit 5.

- Begin nightly MAD titration (0.25 mm mandibular advancement each night).

Review and collect daily diary entries; continue pulse oximeter use and recording daily diary entries.

● Visit 7 at the OPC:

- This appointment is only needed if an extension hook is necessary to be added to the MAD to continue mandibular advancement.

● Visit 7 or 8 at the OPC:

- This will be a follow-up visit if MAD intolerance occurs.
- If maximum protrusion is achieved, then MAD titration is complete.
- Administer the PSQI and PSS.
- Between visits (7 or 8) and (8 or 9), the participant will continue to use the MAD at the final mandibular protrusion setting with the VirtuOx pulse oximeter and continue to make daily dairy entries.

● Visit 8 or 9 at the WRNMMC Sleep Disorders Center: One week after visit 7 or 8, the participant will return to the Sleep Disorders Center for the following:

- Second PSG using the final MAD setting (no additional titration made).
- Complete ESS & FOSQ, retrieve the VirtuOx pulse oximeter and collect diaries.
- Study completed; the participant will exit the study and continue follow up care by WRNMMC Sleep Disorders Center regarding their OSA condition (standard of care).

This research investigation is a feasibility pilot study for 20 participants. The analysis of the data will be exploratory. AHI will be used to assess the efficacy of the MAD home titration protocol by evaluating pre and post PSG AHI. PSG AHI data will also be utilized to measure the accuracy of pulse oximetry measurements. The association between MAD titration and home pulse oximetry data will be analyzed using a mixed model with subject level random effect. Covariates may include subjective sleep quality, stress, MAD adherence and pain levels as these may influence sleep quality and pulse oximetry.

CHAPTER III: RESULTS

Pending initial study participant enrollment and its completion, the following are anticipated results:

- Continuous pulse oximetry use during home MAD titration is feasible and acceptable by patients. Additionally, study results may establish an objective and subjective data set which may be used to more accurately guide MAD titration for OSA patients.
- Study results may influence future standards of care for home MAD titration protocols for OSA patients by possibly reducing the need for a post-MAD titration PSG. This may maximize MAD adherence, positively influence AHI and minimize jaw pain as a potential MAD side effect.

CHAPTER IV: DISCUSSION

Active duty participants with moderate and severe OSA will incrementally and maximally advance the mandible to a protrusive setting that does not cause discomfort and improves sleep quality based on subjective measures. Participants will wear a portable pulse oximeter to monitor ODI during home MAD titration. During home titration of the MAD, nightly ODI data uploaded to a secure internet cloud, protrusive jaw settings and standardized subjective data will be received and evaluated. At the post titration PSG, the sleep medicine laboratory technician will not adjust the

MAD. Pre and post MAD titration ODI will be correlated to the mandibular protrusive settings, with ESS, FOSQ, PSQI, PSS, visual analogue scale for stress, discomfort and sleep quality as well as the diagnostic and post titration PSG AHIs. These subjective data with nightly measures of protrusion and ODI may help identify how ODI may indicate when optimal MAD titration has been objectively achieved.

No previous study has tracked real time, nightly pulse oximetry and explored associations with AHI, subjective measures of sleep quality, stress and jaw protrusion with MADs. Currently, there is no objective data set to evaluate for the feasibility and adequate oxygenation during home MAD titration prior to the patient's follow up sleep medicine center study. Because of this, sleep medicine center laboratory technicians often adjust the MAD during the follow up sleep center study if oxygenation levels have not been optimally determined by subjective measures during home MAD titration. This sleep center MAD adjustment not only causes sleep fragmentation, waking the patient during the sleep study, but potentially advances the mandible too quickly, leading to future MAD tolerability and/or adherence issues due to jaw pain. The VirtuOx pulse oximeter provides an easy, non-invasive capture of quantifiable oxygenation data that can be utilized in combination with subjective information to more accurately improve home MAD titration for OSA. An objective and subjective data set is lacking that shows how a home mandibular titration protocol could optimize clinical outcomes achieved by MADs. This pilot study may fill this gap in knowledge.

A low respiratory ArTH is a physiologic trait involved in OSA pathogenesis. A significant predictor of low respiratory ArTH includes a decrease in oxygen saturation (Edwards et al., 2014). This may help characterize why healthy, non-obese and/or non-cardiac compromised patients, which comprise the majority of military personnel, may receive OSA as a diagnosis. No study has assessed the subjective recall of stress as a possible variable that may affect night to night variation of oxygenation levels during MAD home titration.

The results of this study are important because they serve as a basis for future studies to evaluate how both subjective and objective information during MAD home titration can be used to positively affect AHI and thus improve sleep quality.

CHAPTER V: CONCLUSION

This will be the first study of its kind that will track nightly, continuous pulse oximetry for correlations with AHI and subjective and objective measures during MAD home titration. The VirtuOx pulse oximeter may provide an easy, non-invasive capture of quantifiable oxygenation data that can be utilized in combination with subjective information to more accurately improve home MAD titration for OSA patients.

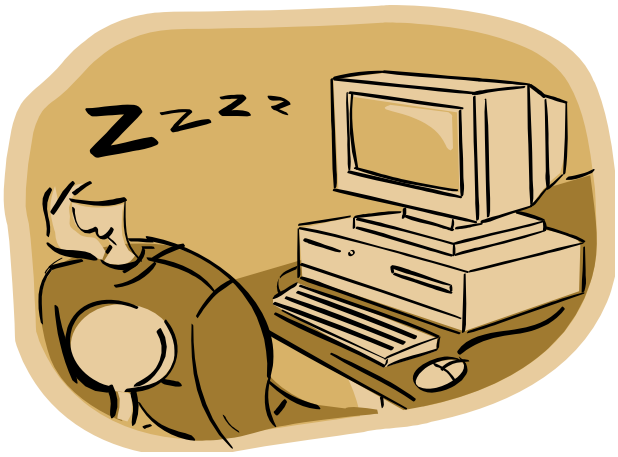
Objective pulse oximetry data may influence MAD titration for optimum jaw protrusion and improved sleep quality.

Maintaining good sleep quality plays a significant role in patient wellbeing and has a tremendous impact on military healthcare and ultimately on mission readiness.

APPENDIX A

DENTAL SLEEP MEDICINE EXAM FORM

Orofacial Pain Center
Naval Postgraduate Dental School
8955 Wood Road
Bethesda, MD 20889
(301) 295-1495
FAX (301) 295-2070



Dental Sleep Medicine Exam Form (MAY 2016)

Please complete pages 1 through 8 & circle choices whenever available.

Name _____ Date_____
Sponsor SSN _____ DOB _____

Gender: M _____ F_____

Active Duty / Retired / Family member Age_____

Ethnicity_____

Branch of Service _____ Rank / Rate _____

Phone (H) (_____)_____ (W) (_____)_____

(Cell) (____)_____

Address _____

City _____ State _____ Zip _____

Email _____

Are you enrolled in? TRICARE Prime TRICARE Extra TRICARE Standard Medicare

Do you have other Insurance? Y N Insurance Company _____

Who referred you for this evaluation? _____

Name _____

BP _____/_____

Pulse _____

O_2 Sat _____%

Height _____

SLEEP HISTORY:

Why are you here? Describe your sleep problem(s):

When did your problem(s) start? _____

Who have you seen for this problem? _____

What position do you fall asleep? Back Side Stomach

Do you have a consistent sleep schedule? Y N Are you a shift worker? Y N

How many hours do you sleep? Average night ____ Good night ____ Bad night ____

How long does it take to fall asleep? Average night ____Good night ___Bad night___

Do you have difficulty falling asleep? Y N _____

Do you have difficulty staying asleep? Y N _____

* What may interrupt your sleep? _____

Do you snore? Y N _____

Do you hold your breath or gasp for air while sleeping? Y N_____

Is your sleep? sound light restless _____

Do you have nightmares? Y N How often & are they recurrent? _____

Is your sleep restorative/restful? Y N _____

Have you had a sleep study in the past 12 months? Y N _____

To be completed by staff	
Date of PSG:	
AHI:	RDI:
O_2 Sat:	Sleep Efficiency (%)
Sleep latency:	Time is stage N3:
Other:	

How have you managed your sleep issues in the past? _____

Have you used an air mask to manage your sleep apnea before? Y N N/A

* What was your experience with this/side effects?

_____

Have you used an oral appliance to manage your sleep apnea before? Y N N/A

* What was your experience with this/side effects? _____

_____

Do you use any of the following sleep aids? (Circle all that apply)

Ambien Sonata Lunesta Trazodone Belsomra Benadryl Tylenol PM Melatonin

Alcohol Other _____

* What is the dose?_____ How soon before bed do you take this? _____

* How many days per week do you use this? _____

* How long have you been using this? _____

* How well does this work? Good Fair Poor

What sleep issue(s) has any provider diagnosed you with? (Circle all that apply)

Sleep apnea Insomnia Snoring Restless legs syndrome Tooth grinding

Narcolepsy Sleepwalking Sleep talking Sleep eating Night terrors
Other: _____

Other sleep information: **(**Circle all that apply)

With the lights out, is your bedroom… Too bright Too dark Just right

The temperature of your bedroom is… Too warm Too cold Just right

The environment around your bedroom is… Too noisy Too quiet Just right

How sleepy are you?

How likely are you to doze off or fall asleep in the following situations, in contrast to feeling just tired? This refers to your usual way of life in recent times. Even if you have not done some of these things recently, try to work out how they would have affected you. Use the following scale to choose the most appropriate number for each situation:

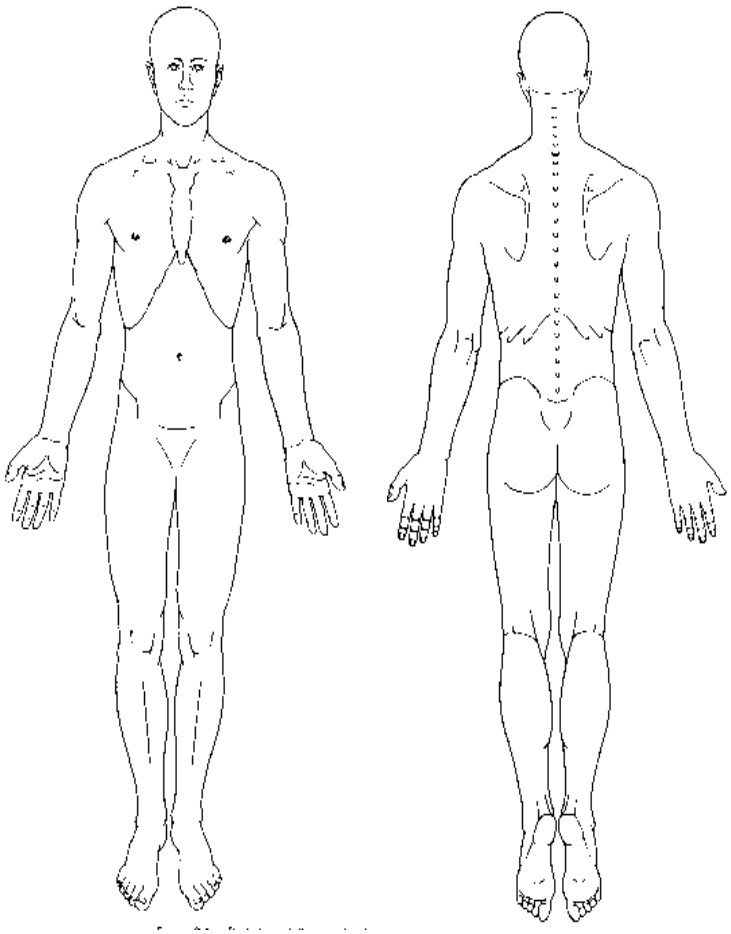
0 = no chance of dozing
1 = slight chance of dozing
2 = moderate chance of dozing
3 = high chance of dozing

SITUATION	CHANCE OF DOZING
Sitting and reading	_____
Watching TV	_____
Sitting inactive in a public place (e.g a theater or a meeting)	_____
As a passenger in a car for an hour without a break	_____
Lying down to rest in the afternoon when circumstances permit	_____
Sitting and talking to someone	_____
Sitting quietly after a lunch without alcohol	_____
In a car, while stopped for a few minutes in traffic	_____

TOTAL SCORE _____

PAIN HISTORY:

Draw the location(s) of **ANY & ALL** pain area that you experience.



List your pain problems.
Prioritize (worst pain first)

1. _____

2. _____

3. _____

4. _____

5. _____

Which pain occurred first?

_____

Does movement initiate or aggravate your pain? Y N

_____

Circle which word(s) characterize your pain(s)?

Sharp Burning Electric-like Aching Throbbing Dull Pulsing Pressing Stabbing

What is the level of your overall body pain/tension? (Mark the levels on the lines below

	No discomfort	Worst pain imaginable
Today	0_____	10
At its Worst	0_____	10
On Average	0_____	10
Pain on Best day	0_____	10

Any pain free days? Y N How many pain free days per month? _____
* When were you last completely pain free? _____

Please rate your overall levels of:

	None	Worst possible
Stress	0_____	10
Anxiety	0_____	10
Depression	0_____	10
Anger	0_____	10

Have you ever thought of harming yourself? Y N _____

Estimate in hours, for any reason, how long your teeth are together or touching in a 24 hour period? _____hours

Circle the feeling(s) that let you know when your teeth are touching?

pain tightness fatigue motion touch

Do you clench or grind your teeth? Y N Don't know

* If yes, how do you know?

self-aware told by dentist told by others

Do you have any of the following habits? Y N
* Circle all habits that apply.

bite nails bite the inner aspect of the cheeks

chew gum hold phone between the head & shoulder

protrude the tongue forward hold the tongue to the roof of the mouth

move the jaw forward or side to side bite the lower or upper lip

Describe any other habit(s): _____

MEDICAL & DENTAL HISTORY:

Medical Conditions:

_____

_____

Allergies: _____

Current prescription medications: _____

_____

Herbal/dietary supplements: _____

Current non-prescription medications: _____

When was your last dental check up? _____

Do you have any dental care required that has not yet been completed? Y N

* If yes, please explain _____

Do you have a history of headaches? Y N

* Location of headache (s): _____

* Do you wake up with headache(s)? Y N

Do you experience any of the following?

Jaw pain/stiffness? Y N
* Is this worse in the morning mid day evening varies

Tooth pain? Y N _____

A changed or different bite? Y N _____
* If yes, location and how is it changed? _____

Altered jaw movement(s)? Y N _____

Jaw (joint) sounds? Y N _____

* When were you first aware of the jaw sound(s)? _____

* Have there been any changes to the jaw sound(s)? _____

* Does the jaw sound/pain affect your ability to eat? Y N _____

Ear symptoms? Y N pain ringing fullness muffled hearing

What is your consumption of the following?

Nicotine: Y N cigarettes _____/day cigars_____ pipe _____ snuff _____

Alcohol: Y N beer ____ /day wine _____ glasses/day liquor ____drinks/day

Caffeine: Y N cups(cans)day _____ coffee tea soda chocolate

Is your diet? balanced high sugar high carbohydrate high fat

Do you skip any meals? Y N Which? Breakfast Lunch Dinner

* Any recent weight gain/loss? _____

Personal/Family History

Occupation: _____

Do you have a history of the following or other similar threatening, stressful or frightening life events? Abuse, at any age (physical, emotional or sexual), childhood neglect, physical or sexual assault, near drowning, panic attacks, post-traumatic stress disorder, deployment to a conflict zone, a significant motor vehicle accident? Y N
Other:_____
_____

Exercise level: None Slight Moderate Active

* Activity limitations: _____

_____

Thank you.

EXAMINATION

CN SCREENING EXAM:

(I-XII): WNL Finding(s): _____
Not assessed

CERVICAL EXAM:

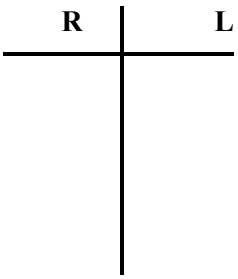
Head/ Neck Position _____ WNL Forward head/body_____
Head tilt _____ R L Head turned _____ R L
Rounded shoulders _____
Neck circumference: _____ inches
Cervical ROM with or without pain: _____
_____
_____

MANDIBULAR RANGE OF MOTION:

Incisal opening: without increasing pain ____ mm Pain level ____
maximum unassisted ____ mm Pain level ____
maximum assisted ____ mm Pain level ____

Location of pain _____

Is there pain on?



Right Lateral Movement ____ No ____ Yes____ R ____ L ___ mm

Left Lateral Movement ____ No ____ Yes ____ R ____ L ___ mm

Protrusive Movement ____ No ____ Yes ____ R ____ L ___ mm

Deflection / Deviation _____No ____ Yes _____R ____ L ____ mm

End Feel (with restriction) Hard Soft

Overbite: _____ mm Overjet: _____ mm

TMJ SOUNDS:

Crepitus: None Right Left Mild Moderate Severe

Click/pop: None Right Opening Reciprocal Intermittent Painful

None Left Opening Reciprocal Intermittent Painful

Is sound eliminated with protrusion? _____ No _____ Yes

CLENCHING TEST:

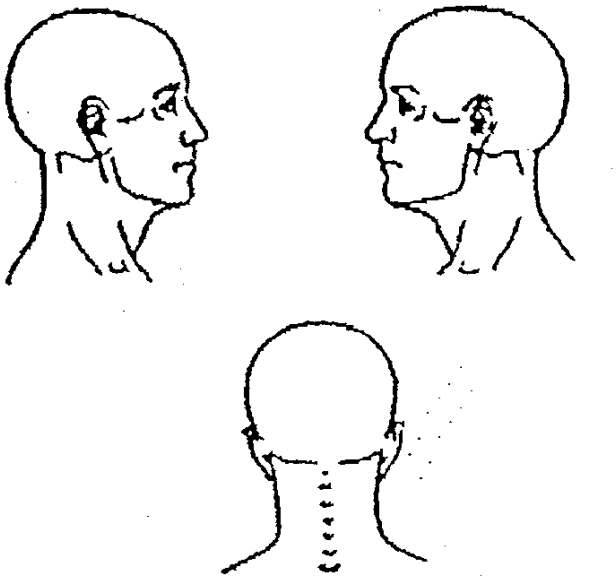
Is there pain when clenching on posterior teeth? ____ No ____ Yes R L
Clenching on tongue blades is?

Bilateral: Better Same Worse R or L
Right: Better Same Worse R or L
Left: Better Same Worse R or L

PALPATION:

Codes: 0 = Non Painful, 1 = Tenderness, 2 = Painful, 3 = Pain with withdrawal
T = Trigger Point (draw arrow to depict pattern of referral, if present)
A = allodynia, H = hyperalgesia ↑ = hypertrophy ↓ = atrophy

	Right	**Left**
Rhomboids	_____	_____
Lev Scap	_____	_____
Trapezius	_____	_____
SCM	_____	_____
Splenius	_____	_____
Occipital	_____	_____
Paracervical	_____	_____
C Spine	_____	
Masseter	_____	_____
Temporalis	_____	_____
Frontalis	_____	_____
TMJ (static)	_____	_____
TMJ (dynamic)	_____	_____
TMJ (EAC)	_____	_____
Lat Ptery	_____	_____
Joint Loading	_____	_____
Temp Tend	_____	_____
Med Ptery	_____	_____
Digastric	_____	____



ORAL EXAM:

Acute malocclusions? _____ No _____ Yes Location/when? _____

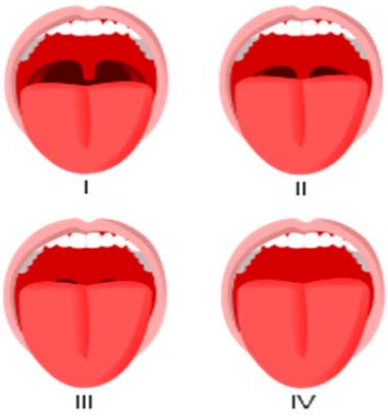
Soft Tissue _____ WNL: _____

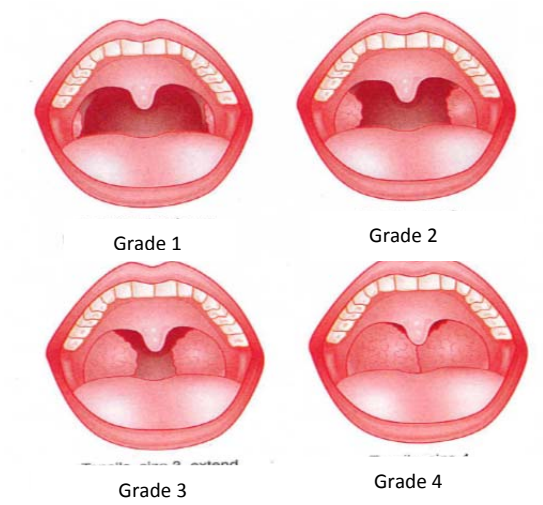
Periodontal Health: _____ WNL: _____

Tooth sensitivity/percussion:_____

General description of the dentition: _____

Tooth Wear: Physiologic ____ Moderate ____ Severe ____





Mallampati Classification: _____ Tonsil size grading: _____

Is the occlusion stable? No Yes _____
Class I ____ Class II ____ Div 1 2 Class III ____

Open Bite? No Yes _____

Guidance/interferences? No Yes _____

Splint History: No Yes _____

Mandibular posturing/tongue thrusting? No Yes _____

Dental criteria for MAD? No Yes

- At least 6 teeth per arch
- One posterior tooth per quadrant
- Able to protrude at least 5 or more mm

IMAGING:

Radiographs/ Imaging: _____ Not Indicated

____ Panoramic _____
____ TMJ Series _____
____ Intraoral _____
____ CT Scan _____
____ MRI _____
____ Other _____

MANAGEMENT PLAN:

___ Sleep hygiene

___ Sleep diary

___ Nutritional counseling/weight mgmt

___ MAD (mandibular advancement device) therapy

Appliance of choice: _____

___ Sleep Medicine referral

___ Rx Hypnotic

___ Other: _____

Procedure	CPT Code	Cost	
New pt, expanded (20)	99202	$184	
New pt, moderate complexity (45)	99204	$400	
New pt, high complexity (60)	99205	$501	
Established pt, expanded (15)	99213	$179	
Established pt, detailed (25)	99214	$265	
Established pt, comprehensive (40)	99215	$355	
Observation/inpt hospital care (25)	99232	$176	
Observation/inpt hospital care (45)	99234	$323	
Prolonged service w/o contact	99358	$258	
Prolonged service w/o contact (ADD)	99359	$124	
Injection, tendon sheath ligament	20550	$138	
Trigger point injection (1 or 2)	20552	$130	
Trigger point injection (3 or 4)	20553	$152	
Muscle testing, extremity or trunk	95831	$65	
Range of motion measurements	95851	$43	
Biofeedback training	90901	$97	
Application of hot or cold packs	97010	$14	
Application of electric stimulation	97032	$39	
Ultrasound one or more areas	97035	$31	
Manual therapy, myofascial release	97140	$73	
Prevent. med ind. counseling (15)	99401	$87	
Exercises, develop range of motion	97110	$78	
Neuromuscular reeducation	97112	$81	
Acupuncture, w/o stim, 15 min	97810	$86	

Procedure	Code	Cost	
Detailed, extensive evaluation	D0160	$95	
Pall (Emerg) tx: dental pain	D9110	$87	
Local anes injection (GON)	64405	$234	
Local anesth not conj w opr/surg	D9210	$33	
Regional block anesthesia	D9211	$36	
Trigeminal div block anesthesia	D9212	$58	
Therapeutic drug injection	D9610	$47	
Pulp vitality tests	D0460	$47	
Behavior management (1/15min)	D9920	$85	
Nutrition counseling	D1310	$39	
Tobacco counseling	D1320	$43	
Individual OHI	D1330	$41	
Other drugs/ meds	D9630	$26	
Occlusal orthotic device	D7880	$592	
Sleep apnea device	A7881	$1,197	
Athletic mouth guard	D9941	$144	
Repair/ reline occlusal guard	D9942	$127	
Occlusal adjustment, limited	D9951	$85	
Diagnostic casts	D0470	$80	
Oral/ facial photography	D0350	$47	
Patient seating	A9999	$0	
Botox injection (per 10 units)	A9875	$91	
Imaging			

Acupuncture, w/o stim, (ADD 15 min)	97811	$65		Panoramic image	D0330	$99	
Acupuncture w stim, 15 min	97813	$93		Intraoral, first image	D0220	$25	
Acupuncture, w stim (ADD 15 min)	97814	$74		Intraoral, each additional image	D0230	$21	
Disability eval by treating doctor	99455	$263		Occlusal Image	D0240	$38	

Patient Name: _____
Last 4 SSN:_____

Provider: _____
Status:_____

Date: _____
Jan 2016

Wounded warrior: Yes No

Co-morbidities:

Combat TBI PTSD IBS GERD Anxiety

Abuse/Assault IC FM CFS OSA Panic Depression

Diagnosis: (Number 1 – 5 as applicable, where 1 is the primary diagnosis)

Atypical facial pain
Burning mouth syndrome
Trigeminal nerve disorder
Disorders of other cranial nerves

Cluster headache
Hemicrania
Chronic daily headache
Migraine with aura
Migraine without aura
Tension type headache

Myalgia (masticatory, cervical)
Cervical MFP
Masticatory MFP
Non-neutral head and neck posture
Protective co-contraction

TMJ arthralgia
Disc displacement with reduction
Disc displacement without reduction
Osteoarthritis
Subluxation

Sleep apnea
Sleep disturbance
Sleep disorder
Insomnia

Bruxism
Fibromyalgia
Otalgia (specify)
Reaction to chronic stress

APPENDIX B

EPWORTH SLEEPINESS SCALE

How sleepy are you? How likely are you to doze off or fall asleep in the following situations, in contrast to feeling just tired? This refers to your usual way of life in recent times. Even if you have not done some of these things recently try to work out how they would have affected you. Use the following scale to choose the most appropriate number for each situation:

0 = no chance of dozing
1 = slight chance of dozing
2 = moderate chance of dozing
3 = high chance of dozing

SITUATION	CHANCE OF DOZING
Sitting and reading	_____
Watching TV	_____
Sitting inactive in a public place (e.g a theater or a meeting)	_____

As a passenger in a car for an hour without a break	_____
Lying down to rest in the afternoon when circumstances permit	_____
Sitting and talking to someone	_____
Sitting quietly after a lunch without alcohol	_____
In a car, while stopped for a few minutes in traffic	_____

TOTAL SCORE _____

APPENDIX C

SCORING INSTRUCTIONS FOR EPWORTH SLEEPINESS SCALE

The Epworth Sleepiness Scale

The Epworth Sleepiness Scale is widely used in the field of sleep medicine as a subjective measure of a patient's sleepiness. The test is a list of eight situations in which you rate your tendency to become sleepy on a scale of 0, no chance of dozing, to 3, high chance of dozing

When you finish the test, add up the values of your responses. Your total score is based on a scale of 0 to 24. The scale estimates whether you are experiencing excessive sleepiness that possibly requires medical attention.

How Sleepy Are You?

How likely are you to doze off or fall asleep in the following situations? You should rate your chances of dozing off, not just feeling tired. Even if you have not done some of these things recently try to determine how they would have affected you. For each situation, decide whether or not you would have:

- No chance of dozing =0
- Slight chance of dozing =1
- Moderate chance of dozing =2
- High chance of dozing =3

Write down the number corresponding to your choice in the right hand column. Total your score below.

Situation Chance of Dozing

Sitting and reading
Watching TV
Sitting inactive in a public place (e.g., a theater or a meeting)
As a passenger in a car for an hour without a break
Lying down to rest in the afternoon when circumstances permit
Sitting and talking to someone
Sitting quietly after a lunch without alcohol
In a car, while stopped for a few minutes in traffic

Total Score = _____

Analyze Your Score

Interpretation:

0-7: It is unlikely that you are abnormally sleepy.

8-9: You have an average amount of daytime sleepiness.

10-15: You may be excessively sleepy depending on the situation. You may want to consider seeking medical attention.

16-24: You are excessively sleepy and should consider seeking medical attention.

Reference: Johns MW. A new method for measuring daytime sleepiness: The Epworth Sleepiness Scale.

Sleep

1991; 14(6):540-5.

This printed version of the Epworth Sleepiness Scale is provided courtesy of Talk About Sleep, Inc.

www.talkaboutsleep.com

APPENDIX D

FUNCTIONAL OUTCOME OF SLEEP QUESTIONNAIRE

Site: _____ ID #: _____
Date of Data Entry: _____ Trial _____
Name: _____ Date: _____

FUNCTIONAL OUTCOMES OF SLEEP QUESTIONNAIRE (FOSQ)

Some people have difficulty performing everyday activities when they feel tired or sleepy. The purpose of this questionnaire is to find out if you generally have difficulty carrying out certain activities because you are too sleepy or tired. In this questionnaire, when the words "sleepy" or "tired" are used, it means the feeling that you can't keep your eyes open, your head is droopy, that you want to "nod off", or that you feel the urge to take a nap. These words do not refer to the tired or fatigued feeling you may have after you have exercised.

DIRECTIONS: Please put a (_) in the box for your answer to each question. Select only **one** answer for each question. Please try to be as accurate as possible. All information will be kept confidential.

	(0) I don't do this activity for other reasons	(4) No difficulty	(3) Yes, a little difficulty	(2) Yes, moderate difficulty	(1) Yes, extreme difficulty
1.Do you have difficulty concentrating on the things you do because you are sleepy or tired?		❒	❒	❒	❒
2.Do you generally have difficulty remembering things, because you are sleepy or tired?		❒	❒	❒	❒
3.Do you have difficulty finishing a meal because you become sleepy or tired?		❒	❒	❒	❒
4.Do you have difficulty working on a hobby (for example, sewing, collecting, gardening) because you are sleepy or tired?	❒	❒	❒	❒	❒

Site: _____ ID #: _____
Date of Data Entry: _____ Trial _____
Name: _____ Date: _____

	(0) I don't do this activity for other reasons	(4) No difficulty	(3) Yes, a little difficulty	(2) Yes, moderate difficulty	(1) Yes, extreme difficulty
5.Do you have difficulty doing work around the house (for example, cleaning house, doing laundry, taking out the trash, repair work) because you are sleepy or tired?	❒	❒	❒	❒	❒
6.Do you have difficulty operating a motor vehicle for short distances (less than 100 miles) because you become sleepy or tired?	❒	❒	❒	❒	❒
7.Do you have difficulty operating a motor vehicle for long distances (greater than 100 miles) because you become sleepy or tired?	❒	❒	❒	❒	❒
8.Do you have difficulty getting things done because you are too sleepy or tired to drive or take public transportation?	❒	❒	❒	❒	❒
9.Do you have difficulty taking care of financial affairs and doing paperwork (for example, writing checks, paying bills, keeping financial records, filling out tax forms, etc.) because you are sleepy or tired?	❒	❒	❒	❒	❒

Site: _____ ID #: _____
Date of Data Entry: _____ Trial _____
Name: _____ **Date:** _____

	(0) I don't do this activity for other reasons	(4) No difficulty	(3) Yes, a little difficulty	(2) Yes, moderate difficulty	(1) Yes, extreme difficulty
10. Do you have difficulty performing employed or volunteer work because you are sleepy or tired?	❒	❒	❒	❒	❒
11. Do you have difficulty maintaining a telephone conversation, because you become sleepy or tired?	❒	❒	❒	❒	❒
12. Do you have difficulty visiting with your family or friends in <u>your</u> home because you become sleepy or tired?	❒	❒	❒	❒	❒
13. Do you have difficulty visiting with your family or friends in <u>their</u> home because you become sleepy or tired?	❒	❒	❒	❒	❒
14. Do you have difficulty doing things for your family or friends because you are too sleepy or tired?	❒	❒	❒	❒	❒

	(4) No	(3) Yes, a little	(2) Yes, moderately	(1) Yes, extremely	
15. Has your relationship with family, friends or work colleagues been affected because you are sleepy or tired?	❒	❒	❒	❒	

In what way has your relationship been affected? _____

_____

_____

Site: _____ ID #: _____
Date of Data Entry: _____ Trial _____
Name: _____ **Date:** _____

	(0) I don't do this activity for other reasons	(4) No difficulty	(3) Yes, a little difficulty	(2) Yes, moderate difficulty	(1) Yes, extreme difficulty
16. Do you have difficulty exercising or participating in a sporting activity because you are too sleepy or tired?	❒	❒	❒	❒	❒
17. Do you have difficulty watching a movie or videotape because you become sleepy or tired?	❒	❒	❒	❒	❒
18. Do you have difficulty enjoying the theater or a lecture because you become sleepy or tired?	❒	❒	❒	❒	❒
19. Do you have difficulty enjoying a concert because you become sleepy or tired?	❒	❒	❒	❒	❒
20. Do you have difficulty watching TV because you are sleepy or tired?	❒	❒	❒	❒	❒
21. Do you have difficulty participating in religious services, meetings or a group or club, because you are sleepy or tired?	❒	❒	❒	❒	❒

Site: _____ ID #: _____
Date of Data Entry: _____ Trial _____
Name: _____ **Date:** _____

	(0) I don't do this activity for other reasons	(4) No difficulty	(3) Yes, a little difficulty	(2) Yes, moderate difficulty	(1) Yes, extreme difficulty
22. Do you have difficulty being as active as you want to be in the <u>evening</u> because you are sleepy or tired?		❒	❒	❒	❒
23. Do you have difficulty being as active as you want to be in the <u>morning</u> because you are sleepy or tired?		❒	❒	❒	❒

	(0) I don't do this for other reasons	(4) No difficulty	(3) Yes, a little difficulty	(2) Yes, moderate difficulty	(1) Yes, extreme difficulty
24. Do you have difficulty being as active as you want to be in the <u>afternoon</u> because you are sleepy or tired?		❒	❒	❒	❒
25. Do you have difficulty keeping pace with others your own age because you are sleepy or tired?		❒	❒	❒	❒

	(1) Very Low	(2) Low	(3) Medium	(4) High
26. How would you rate your general level of activity?	❒	❒	❒	❒

Site: _____ ID #: _____
Date of Data Entry: _____ Trial_____
Name: _____ **Date:** _____

	(0) I don't engage in sexual activity for other reasons	(4) No	(3) Yes, a little	(2) Yes, moderately	(1) Yes, extremely
27. Has your intimate or sexual relationship been affected because you are sleepy or tired?	❒	❒	❒	❒	❒
28. Has your desire for intimacy or sex been affected because you are sleepy or tired?	❒	❒	❒	❒	❒
29. Has your ability to become sexually aroused been affected because you are sleepy or tired?	❒	❒	❒	❒	❒
30. Has your ability to "come" (have an orgasm) been affected because you are sleepy or tired?	❒	❒	❒	❒	❒

Thank you for completing this questionnaire.

APPENDIX E

SCORING INSTRUCTIONS FOR FUNCTIONAL OUTCOMES OF SLEEP QUESTIONNAIRE

FUNCTIONAL OUTCOMES OF SLEEP QUESTIONNAIRE (FOSQ)

Scoring Instructions September 1996 Version
(Revised 7/18/00)

Subscales	# Questions	Item #
General Productivity	8 questions	1 - 4, 8 - 11
Social Outcome	2 questions	12, 13
Activity Level	9 questions	5, 14 - 16, 22 - 26
Vigilance	7 questions	6, 7, 17 - 21
Intimate Relationships and Sexual Activity	4 questions	27 - 30

Subscale Scores: A response score of 0 for an item should be coded as a N/A or missing response. Thus, the potential range of scores for any item is 1 - 4. Calculate the mean of the answered items with responses equal to or greater than 1 for each subscale. This is the weighted mean item total or subscale score. For example, if a subscale has six questions, and one question has a missing response and one with a N/A response, then you would not include those two questions when you added the responses and you would divide by four instead of six when calculating the mean. This prevents a score bias due to missing answers or skipped questions because an individual does not engage in a particular activity do to reasons other than disorders of excessive sleepiness. The potential range of scores for each subscale is 1 - 4.

To obtain a Total Score: Take all of the subscale scores and calculate the mean of these scores and then multiply that mean by five. Multiply by five regardless of the number of subscales scores used in the computation of the mean. For example, if you a subscale score for all subscales, then you multiply the mean of those scores by 5; if you have subscale scores for only 4 of the 5 subscales, then you would also multiply the mean by five. The potential range of scores for the Total Score is 5 - 20.

APPENDIX F

PITTSBURGH SLEEP QUALITY INDEX

For staff use only:
Global PSQI Score: _____

Pittsburgh Sleep Quality Index (PSQI)

Instructions:

The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month. Please answer all questions.

1. During the past month, what time have you usually gone to bed at night?
   BED TIME_____
2. During the past month, how long (in minutes) has it usually taken you to fall asleep each night?
   NUMBER OF MINUTES_____
3. During the past month, what time have you usually gotten up in the morning?
   GETTING UP TIME_____
4. During the past month, how many hours of actual sleep did you get at night? (This may be different than the number of hours you spent in bed.)
   HOURS OF SLEEP PER NIGHT _____

For each of the remaining questions, check the one best response. Please answer all questions.

5. During the past month, how often have you had trouble sleeping because you…

	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
a. …cannot get to sleep within 30 minutes	☐	☐	☐	☐
b. …wake up in the middle of the night or early morning	☐	☐	☐	☐
c. …have to get up to use the bathroom	☐	☐	☐	☐
d. …cannot breathe comfortably	☐	☐	☐	☐
e. …cough or snore loudly	☐	☐	☐	☐
f. …feel too cold	☐	☐	☐	☐
g. …feel too hot	☐	☐	☐	☐
h. …have bad dreams	☐	☐	☐	☐
i. …have pain	☐	☐	☐	☐
j. Other reason(s), please describe: _____				
How often during the past month have you had trouble sleeping because of this?	☐	☐	☐	☐

	Very good	Fairly good	Fairly bad	Very Bad
6. During the past month, how would you rate your sleep quality overall?	☐	☐	☐	☐

	Not during the past month	Less than once a week	Once or twice a week	Three or mor times a week
7. During the past month, how often have you taken medicine to help you sleep (prescribed or "over the counter")?	☐	☐	☐	☐
8. During the past month, how often have you had trouble staying awake while driving, eating meals or engaging in social activity?	☐	☐	☐	☐

	No problem at all	Only a very slight problem	Somewhat of a problem	A very big problem
9. During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done?	☐	☐	☐	☐

	No bed partner or roommate	Partner/room mate in other room	Partner in same room, but not same bed	Partner in same bed
10. Do you have a bed partner or roommate?	☐	☐	☐	☐

If you have a room mate or bed partner, ask him/her how often in the past month you have had:

	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
a. Loud snoring	☐	☐	☐	☐
b. Long pauses between breaths while asleep	☐	☐	☐	☐
c. Legs twitching or jerking while you sleep	☐	☐	☐	☐
d. Episodes of disorientation or confusion during sleep	☐	☐	☐	☐
e. Other restlessness while you sleep	☐	☐	☐	☐

Please describe:_____

NPDS/OPC – PQSI (Reviewed: Sep 2013)

APPENDIX G

SCORING INSTRUCTIONS FOR PITTSBURGH SLEEP QUALITY INDEX

Pittsburgh Sleep Quality Index (PSQI)

Form Administration Instructions, References, and Scoring

Form Administration Instructions

The range of values for questions 5 through 10 are all 0 to 3.

Questions 1 through 9 are not allowed to be missing except as noted below. If these questions are missing then any scores calculated using missing questions are also missing. Thus it is important to make sure that all questions 1 through 9 have been answered.

In the event that a range is given for an answer (for example, '30 to 60' is written as the answer to Q2, minutes to fall asleep), split the difference and enter 45.

Reference

Buysse DJ, Reynolds CF, Monk TH, Berman SR, Kupfer DJ: The Pittsburgh Sleep Quality Index: A new instrument for psychiatric practice and research. *Psychiatry Research* 28:193-213, 1989.

Scores – reportable in publications

On May 20, 2005, on the instruction of Dr. Daniel J. Buysse, the scoring of the PSQI was changed to set the score for Q5J to 0 if either the comment or the value was missing. This may reduce the DISTB score by 1 point and the PSQI Total Score by 1 point.

PSQIDURAT **DURATION OF SLEEP**
IF Q4 $\geq$ 7, THEN set value to 0
IF Q4 < 7 and $\geq$ 6, THEN set value to 1
IF Q4 < 6 and $\geq$ 5, THEN set value to 2
IF Q4 < 5, THEN set value to 3
Minimum Score = 0 (better); Maximum Score = 3 (worse)

PSQIDISTB **SLEEP DISTURBANCE**

IF Q5b + Q5c + Q5d + Q5e + Q5f + Q5g + Q5h + Q5i + Q5j (IF Q5JCOM is null or Q5j is null, set the value of Q5j to 0) = 0, THEN set value to 0

IF Q5b + Q5c + Q5d + Q5e + Q5f + Q5g + Q5h + Q5i + Q5j (IF Q5JCOM is null or Q5j is null, set the value of Q5j to 0) ≥ 1 and ≤ 9, THEN set value to 1
IF Q5b + Q5c + Q5d + Q5e + Q5f + Q5g + Q5h + Q5i + Q5j (IF Q5JCOM is null or Q5j is null, set the value of Q5j to 0) > 9 and ≤ 18, THEN set value to 2

IF Q5b + Q5c + Q5d + Q5e + Q5f + Q5g + Q5h + Q5i + Q5j (IF Q5JCOM is null or Q5j is null, set the value of Q5j to 0) > 18, THEN set value to 3

Minimum Score = 0 (better); Maximum Score = 3 (worse)

PSQILATEN **SLEEP LATENCY**

First, recode Q2 into Q2new thusly:
IF Q2 ≥ 0 and ≤ 15, THEN set value of Q2new to 0
IF Q2 > 15 and ≤ 30, THEN set value of Q2new to 1
IF Q2 > 30 and ≤ 60, THEN set value of Q2new to 2
IF Q2 > 60, THEN set value of Q2new to 3
Next
IF Q5a + Q2new = 0, THEN set value to 0
IF Q5a + Q2new ≥ 1 and ≤ 2, THEN set value to 1
IF Q5a + Q2new ≥ 3 and ≤ 4, THEN set value to 2
IF Q5a + Q2new ≥ 5 and ≤ 6, THEN set value to 3

Minimum Score = 0 (better); Maximum Score = 3 (worse)

PSQIDAYDYS **DAY DYSFUNCTION DUE TO SLEEPINESS**

IF Q8 + Q9 = 0, THEN set value to 0
IF Q8 + Q9 ≥ 1 and ≤ 2, THEN set value to 1
IF Q8 + Q9 ≥ 3 and ≤ 4, THEN set value to 2
IF Q8 + Q9 ≥ 5 and ≤ 6, THEN set value to 3
Minimum Score = 0 (better); Maximum Score = 3 (worse)

PSQIHSE **SLEEP EFFICIENCY**

Diffsec = Difference in seconds between day and time of day Q1 and day Q3

Diffhour = Absolute value of diffsec / 3600

newtib =IF diffhour > 24, then newtib = diffhour – 24

IF diffhour ≤ 24, THEN newtib = diffhour

(NOTE, THE ABOVE JUST CALCULATES THE HOURS BETWEEN GNT (Q1) AND GMT (Q3))

tmphse = (Q4 / newtib) * 100

IF tmphse ≥ 85, THEN set value to 0
IF tmphse < 85 and ≥ 75, THEN set value to 1
IF tmphse < 75 and ≥ 65, THEN set value to 2
IF tmphse < 65, THEN set value to 3
Minimum Score = 0 (better); Maximum Score = 3 (worse)

PSQISLPQUAL **OVERALL SLEEP QUALITY**
Q6
Minimum Score = 0 (better); Maximum Score = 3 (worse)

PSQIMEDS **NEED MEDS TO SLEEP**
Q7
Minimum Score = 0 (better); Maximum Score = 3 (worse)

PSQI **TOTAL**

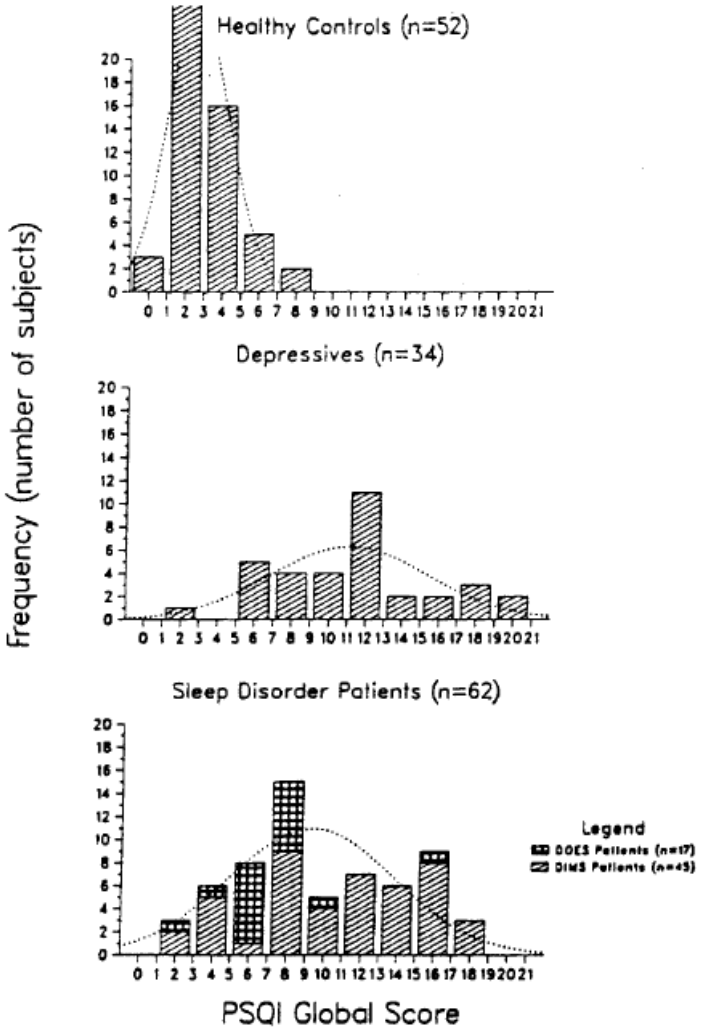
DURAT + DISTB + LATEN + DAYDYS + HSE + SLPQUAL + MEDS

Minimum Score = 0 (better); Maximum Score = 21 (worse)

Interpretation: TOTAL ≤ 5 associated with good sleep quality

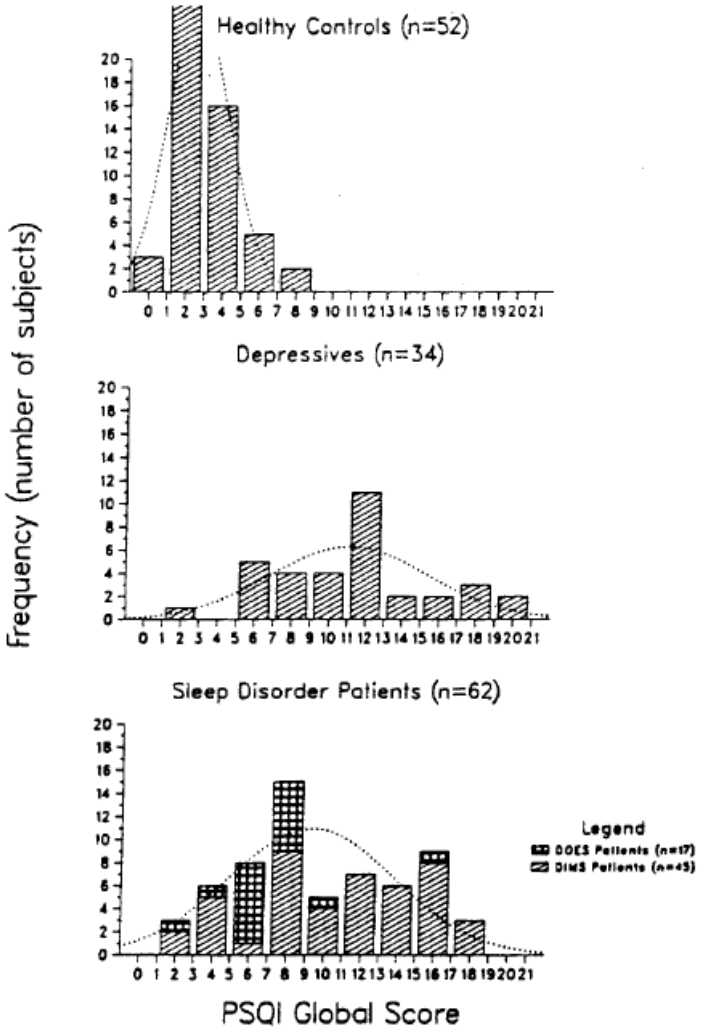
TOTAL > 5 associated with poor sleep quality

Fig. 2. Pittsburgh Sleep Quality Index (PSQI) global scores



PSQI global scores showed different distributions for control subjects, depressed patients, and sleep-disorder patients. A global score cutoff of > 5 correctly identified 88.5% of all controls and patients, yielding a sensitivity of 89.6% and a specificity of 86.5% (Kappa = 0.75, $p < 0.001$).

Fig. 2. Pittsburgh Sleep Quality Index (PSQI) global scores



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Reference:

Buysse DJ, Reynolds CF, Monk TH, Berman SR, Kupfer DJ: The Pittsburgh Sleep Quality Index: A new instrument for psychiatric practice and research. Psychiatry Research 28:193-213, 1989.

APPENDIX H

PERCIEVED STRESS SCALE

For staff use only:

PSS Total Score: _____

Perceived Stress Scale

The questions in this scale ask you about your feelings and thoughts **during the last month**. In each case, you will be asked to indicate by circling *how often* you felt or thought a certain way.

0 = Never 1 = Almost Never 2 = Sometimes 3 = Fairly Often 4 = Very Often

1.	In the last month, how often have you been upset because of something that happened unexpectedly?	0	1	2	3	4
2.	In the last month, how often have you felt that you were unable to control the important things in your life?	0	1	2	3	4
3.	In the last month, how often have you felt nervous and "stressed"?	0	1	2	3	4
4.	In the last month, how often have you felt confident about your ability to handle your personal problems?	0	1	2	3	4
5.	In the last month, how often have you felt that things were going your way?	0	1	2	3	4
6.	In the last month, how often have you found that you could not cope with all the things that you had to do?	0	1	2	3	4
7.	In the last month, how often have you been able to control irritations in your life?	0	1	2	3	4
8.	In the last month, how often have you felt that you were on top of things?	0	1	2	3	4
9.	In the last month, how often have you been angered because of things that were outside of your control?	0	1	2	3	4
10.	In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?	0	1	2	3	4

References:
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NPDS/OPC – PSS (Reviewed: Sep 2013)

APPENDIX I

SCORING INSTRUCTIONS FOR PERCEIVED STRESS SCALE

Perceived Stress Scale Score

The Perceived Stress Scale is a 10-item self report questionnaire that measures a persons' subjective appraisal of the stressfulness of the situations in the past 30 days.

- Each item is rated on a 5-point Likert scale ranging from *never* (0) to *almost always* (4).
- There are two subscales within the ten questions: 6 negatively worded questions and 4 positively worded questions. Question numbers 4, 5, 7, and 8 are the positively stated items. Questions 1, 2, 3, 6, 9 & 10 are the negatively stated items.
- Scores can range from 0 to 40, with higher scores indicating greater stress.

Score Calculation:

1. Reverse the scores on the four positive items (4, 5, 7 & 8): 0 = 4, 1 = 3, 2 = 2 and 1 = 1.
2. Negative item scores do not change (1, 2, 3, 6, 9 & 10): 0 = 0, 1 = 1, 2 = 2, 3 = 3 and 4 = 4
3. The overall PSS-10 score is the sum all 10 items.

Interpretation

The PSS is not a diagnostic instrument, so there are no cut-offs. There are only comparisons between people in a given sample. There are some normative data on the PSS based on a *1983 Harris Poll of a representative U.S. sample.

Higher PSS Scores are associated with:

- Higher levels of stress
- Increased stress interference with daily activity and quality of life
- Increased susceptibility to stress-induced illness
- Increased vulnerability to compromised health, especially if a significant life stressor (loss of a job, end of a relationship, death of a loved one, etc.) occurs in the near future

Question:	Score: (0-4)
1	
2	
3	
4 (reversed)	
5 (reversed)	
6	
7 (reversed)	
8 (reversed)	
9	
10	

Total Score: _____

*Total Score	*Your Perceived Stress Level is:	* Health Concern Level
6	Much Lower than Average	Very Low
7 - 10	Slightly Lower than Average	Low
11 - 18	Average	Average
19 - 22	Slightly Higher than Average	High
22 and over	Much Higher than Average	Very High

APPENDIX J
PERSONAL DATA LOG BOOK

Personal Data Log Book

Titration of Mandibular Advancement Device (MAD)

Visual Analogue Scales

INITIAL 7-DAY ACCLIMATION PERIOD LOG

DAILY TITRATION LOG

Study ID: _____

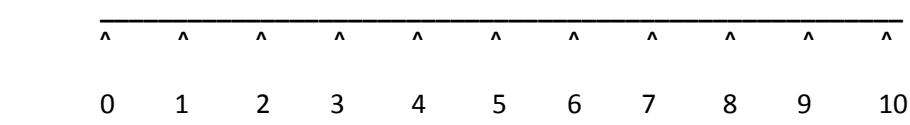
Sleep Study Daily VAS (Visual Analog Scales)

Study ID: _____

Date _____

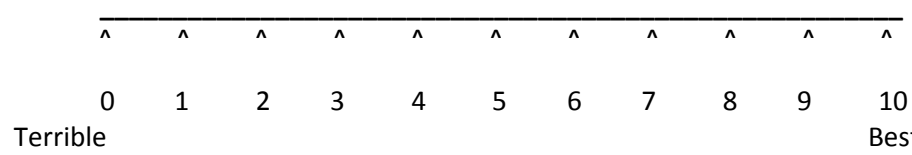
Before Dinner: VAS for Day's Stress

Please rate how stressful your day was by circling a number on the 0 to 10 scale below. 0 represents a completely stress-free day and 10 represents the worst stress imaginable.



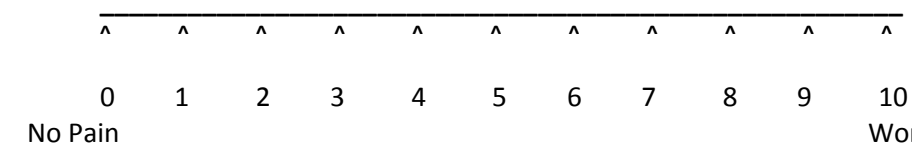
Upon waking: VAS for Sleep Quality

Please rate the quality of each night's sleep by circling a number on the 0 to 10 scale below. 0 represents the worst sleep imaginable and 10 represents the best sleep imaginable.



Upon waking: VAS for any Jaw Pain

Please rate the amount of jaw pain you are experiencing upon awakening by circling a number on the 0 to 10 scale below. 0 represents no pain and 10 represents extreme pain.



DO NOT FORGET TO FILL OUT THE DAILY TITRATION LOG

INITIAL 7-DAY ACCLIMATION PERIOD LOG

STUDY ID: _____

DATE (DD/MM/YY)	**RETIRE TIME** (HH:MM)	**RISE TIME** (HH:MM)	**APPLIANCE WORN?** (Estimate # of Hrs 0-10)	**ADJUSTMENT** 0=none +1= 1/2 turn clockwise (advance) -1=1/2 turn counterclockwise (reverse)	**PULSE OX WORN?** (Estimate # of Hrs 0-10)	**Any Adverse effects** (If yes, Please describe on the notes page)	**Download Data & Charge battery (√)**
				0			**x**
				0			
				0			**x**
				0			
				0			**x**
				0			
				0			**x**

DAILY TITRATION LOG

STUDY ID: _____

DATE (DD/MM/YY)	**RETIRE TIME** (HH:MM)	**RISE TIME** (HH:MM)	**APPLIANCE WORN?** (Estimate # of Hrs 0-10)	**SCHEDULED ADJUSTMENT** (TOTAL ADVANCEMENT)	**SUBJECT ACTION** 0=none +1= 1/2 turn (180^o) clockwise (advance) -1=1/2 turn (180^o) counterclockwise (reverse)	**PULSE OX WORN?** (Estimate # of Hrs 0-10)	**Any Adverse effects** (If yes, Please describe on the notes page)	**Download Data & Charge battery (√)**
				1/2 turn (0.25 mm)				
				1/2 turn (0.5mm)				
				1/2 turn (0.75 mm)				
				1/2 turn (1.0 mm)				
				1/2 turn (1.25 mm)				
				1/2 turn (1.5 mm)				
				1/2 turn (1.75 mm)				
				1/2 turn (2.0 mm)				
				1/2 turn (2.25 mm)				

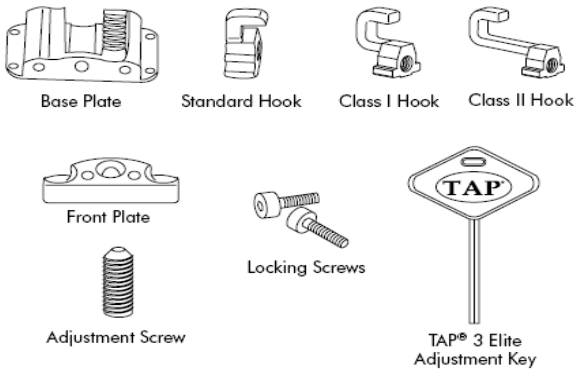
				1/2 turn (2.5 mm)				
				1/2 turn (2.75 mm)				
				1/2 turn=(3.0 mm)				
				1/2 turn (3.25 mm)				
				1/2 turn (3.5mm)				
				1/3 turn (3.75 mm)				
				1/2 turn (4.00 mm)				
				1/2 turn (4.25 mm)				
				1/2 turn (4.5 mm)				
				1/2 turn (4.75 mm)				
				1/2 turn (5.00 mm)				

NOTES & COMMENTS

Study ID No:

DATE (DD/MM/YYYY)	

APPENDIX K
TAP 3-ELITE AND PROGAUGE



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APPENDIX L
VIRTUOX PULSE OXIMETER

Permission to use VirtuOx images kyle.miko@virtuox.net; www.virtuox.net

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