UNIVERSITY OF CALIFORNIA, SAN DIEGO

Mobile Health Tracking of Sleep Bruxism for Clinical, Research, and Personal Reflection

A thesis submitted in partial satisfaction of the
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by

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The thesis of Julia Y. Lin is approved, and it is acceptable in quality and form for publication on microfilm and electronically:

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Chair

University of California, San Diego

2013

DEDICATION

This work is dedicated to my sister with love.

Now if only she could stop grinding her teeth...

EPIGRAPH

Unless someone like you cares a whole awful lot,
Nothing is going to get better. It's not.
—Dr. Seuss, The Lorax

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ABSTRACT OF THE THESIS

Mobile Health Tracking of Sleep Bruxism for Clinical, Research, and Personal Reflection

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Nadir Weibel, Chair

Sleep bruxism is an oromotor parafunction characterized by clenching or grinding the teeth during sleep time that can lead to severe dental attrition, muscle hypertrophy, headaches and migraines,and even dental destruction. Research has estimated a common prevalence rate of bruxism at 8% to 10% among adults and 10% to 50% among children. While researchers have several ways of diagnosing and monitoring bruxism, accurate methods such as polysomnography are either too expensive or invasive for long term studies, while other methods of assessment such as surveys and clinical examinations can sometimes lead to inaccurate assessments. Carra et al noted that the future direction for sleep bruxism assessment would be to develop a handy tool that can directly, reliably, and rapidly measure ongoing

bruxism activity and that can be used in both clinical (for diagnosis, treatment outcome evaluation, and follow-up) and research settings [10]. Having a device that enables patients and researchers to track duration and frequency of sleep bruxism on a wider scale will be helpful both in gathering a greater population of data for research and for individuals who want to monitor their own condition. While recent developments of devices such as the Grindcare® and BiteStrip® have made it more affordable for individuals to diagnose and monitor bruxism, their sole reliance on EMG for diagnosis reduces the accuracy of assessment.

In this thesis, we examine the possibility of developing an application for mobile phones to help diagnose and monitor sleep bruxism using three channels: audio, video, and electromyography (EMG). Through the use of the channels, we were able to capture sleep bruxism activity throughout the night. In addition, we found evidence that EMG and audio activity follow similar consistent patterns which may indicate that audio signals may potentially be used in lieu of EMG, reducing invasiveness. Our application has the potential to become easily accessible and affordable, allowing individual consumers and researchers to accurately measure bruxism activity.

Chapter 1

Sleep Bruxism Overview

1.1 Definition of Sleep Bruxism

Sleep bruxism is an oromotor parafunction that occurs during sleep time. Bruxism is defined as a repetitive jaw-muscle activity characterized by clenching or grinding of the teeth and/or by bracing or thrusting of the mandible [55]. Bruxism has two different types of manifestations, *awake bruxism* and *sleep bruxism*, which must be distinguished as different nosologic entity, as they likely have different etiology and pathophysiology [55]. Awake bruxism is a semi-voluntary clenching during the daytime and has been proven to be linked with psychosocial factors such as stress and anxiety. Sleep bruxism is characterized by clenching or grinding which strictly occurs while the individual is asleep, whether during the day or at night. The pathology sleep bruxism continues to be the grounds of scientific debate. Although sleep bruxism is not a life-threatening condition, it can affect quality of life. Sleep bruxism has been shown to directly cause morning headaches, jaw aches, pre-mature loss of teeth, excessive attrition, and temporomandibular joint discomfort [9]. Ohayon et al. reported that 23% of the 13,057 participants in their sleep bruxism prevalence study reported the need for dental work due to grinding, 8.1% reported jaw discomfort upon awakening, and 23.3% claimed to grind their teeth loud enough for bedside partners to hear [69]. Not only is the individual with sleep bruxism affected, bedside partner could also experience sleep disruption due to the grinding noises that occur at night.

1.1.1 Relation to Sleep

Rhythmic masticatory movement activity (RMMA) has been associated with sleep bruxism activity. RMMA is a chewing automatism during sleep, typically occurring during sleep arousals. 60% of normal sleepers engage in RMMA, during sleep arousals in NREM sleep stage 1 and 2 [52]. The presence of RMMA and absence of sleep bruxism episode has been observed in patients, and though not all RMMA episodes represent sleep bruxism activity, all sleep bruxism activity is defined by a characteristic electromyographic RMMA [52]. Several studies have also shown that sleep bruxism is a part of a sleep arousal response, modulated centrally by various neurotransmitters [41, 48, 54, 60, 9]. Sleep arousals are defined as a brief awakening, characterized by increased electroencephalographic, muscle, and heart activity without return to consciousness. The occurrences of sleep arousals is a response of the sleeping brain to environmental and internal stimuli. Normal sleepers typically experience sleep arousals 6-14 times per hour of sleep. Patients with sleep bruxism have both lower arousal thresholds and experience RMMA activity up to 2-12 times per hour, 3 times more than normal sleepers [9].

Several studies indicate that subjects with sleep bruxism may have a higher responsiveness to sleep arousal. A previous study has shown that experimentally induced sleep arousals in subjects with sleep bruxism are frequently followed by RMMA and sleep bruxism activity when compared to contro [47]. Any stimulants that might trigger sleep arousals are also likely to increase the frequency of sleep bruxism activities, and thus must be exercised with caution.

1.2 Clinical Diagnosis

There are many techniques available for assessing sleep bruxism. These techniques vary in cost and accuracy, and are typically used for different sizes and

kinds of sleep bruxism studies.

Questionnaires/Patient History Questionnaires are practical tools for assessing sleep bruxism in a large population. They can be used to derive insight into the effects of sleep bruxism on the quality of life by evaluating sleepiness, headaches, and pain a patient perceives. Other sleep bruxism assessment questionnaires target family members of the patient to obtain the noise reports of observed night-time grindings. Though these noises reported are a sign of sleep bruxism, we must keep in mind that not all rhythmic masticatory muscle activity episodes are accompanied by tooth grinding, thus family members may be underreporting. Furthermore, the frequency of sleep bruxism episodes per night, and the frequency of night-time grindings per day is difficult for family members to ascertain. Therefore, the use of questionnaires should be used in conjunction with other assessment tools.

Clinical Assessment Clinical examination of the oral cavity can help identify signs and symptoms that are characteristic of teeth grinding and clenching habits. Some of the signs include tooth wear, jaw muscle tenderness, reports of headaches, and masseter muscle hypertrophy. However, these signs could be the result of other factors, and do not directly indicate sleep bruxism by itself. Furthermore, these signs are incapable of differentiating between awake bruxism and sleep bruxism [9]. Carra et al. cautioned against using tooth wear as an absolute criterion for assessing sleep bruxism severity, since no significance difference in tooth wear between low and high frequency bruxers were found [9]. However, because it is inexpensive and practical, clinical assessment is suitable for larger studies when used in conjunction with a separate assessment method.

Ambulatory EMG monitoring Electromyography (EMG) is a technique of recording or monitoring the electrical activity produced by skeletal muscles. An electromyograph is a device which detects the electric potential of the muscle contraction, where the data produced from a recording is referred to as an electromyogram. Several portable EMG monitoring devices have been developed to assess

Figure 1.1: GrindCare® device

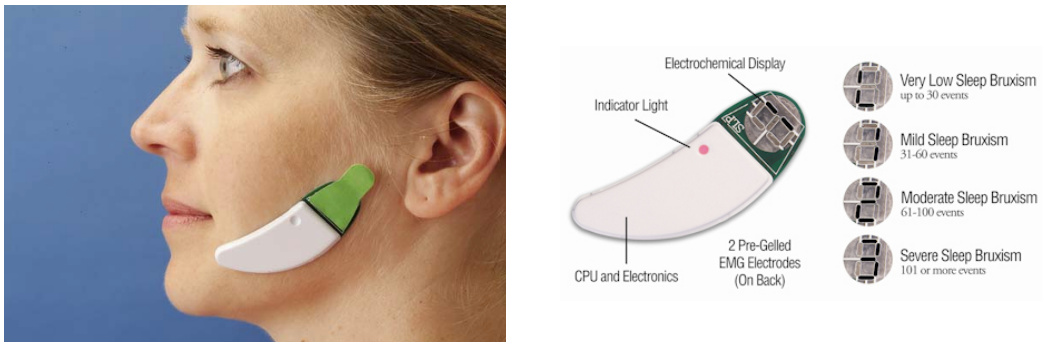


Figure 1.2: Disposable BiteStrip® device

sleep bruxism. Some commercial EMG monitoring devices such as GrindCare® (http://www.grindcare.com) and disposable BiteStrip® (http://www.bitestrip.com), monitor only the EMG activity of temporalis muscle and masseter muscle, respectively. These devices, which can be seen in Figure 1.1 and Figure 1.2, typically allow multiple nights of recording at the patient's home and are useful in producing objective results of muscle activity during the night.

However, because these monitoring devices use a unique algorithms for RMMA scoring, EMG monitoring devices should be used mainly in research and clinical settings until the standardized scoring criteria of these devices is validated [9]. Furthermore, because of the lack of video and audio recording, an overestimation of RMMA episodes may result due to non-specific sleep bruxism motor activities that happen during sleep [9]. However, these tools are moderately priced and useful in medium-sized studies.

Full Audio-Video Polysomnography Recording The gold standard for sleep bruxism assessment is certainly full audio-video polysomnography (PSG) recording. This PSG recording monitors several physiologic parameters including EEG, electrooculogram, electromyogram, electrocardiogram, airflow, respiratory effort, oxygen-saturation, audio, and video recording. Audio recording allows the documentation of teeth grinding noises to be distinguished between purely RMMA and non-specific sleep bruxism motor activities during the night. However, PSG is very costly, and time consuming for data evaluation. To obtain accurate measurements, individuals need to be acclimated to the novel sleeping environment, known as 'first night effect', and needs to be taken into account. Thus, full audio-video polysomnography recording is typically used for small or short-term studies.

1.3 Prevalence

Prevalence of Sleep Bruxism in Adults According to studies which examine its prevalence, sleep bruxism appears to be a common disorder, representing the third most frequent parasomnia [69]. A survey study in Canada analyzed results of 2,019 respondents over 18 years of age, and discovered that 8% of the adult population reported having sleep bruxism [51]. Ohayon et al. conducted a large scale study assessing a total of 13,057 participants over 15 years of age from United Kingdom, Germany, and Italy in 2001 using surveys and questionnaires discovered that 8.2% of the participants reported grinding at least once per week [69]. Since these studies were conducted using surveys and questionnaires, the actual number of participants with sleep bruxism and the severity of their condition is uncertain. Maluly et al. undertook a large-scale single-night polysomnography study of 1,042 randomly selected individuals and discovered that while 12.5% of the participants reported SB on questionnaires, only 7.6% was confirmed with polysomnography [64].

Prevalence of Sleep Bruxism in Children However, consistent with most studies, prevalence of sleep bruxism in children is found to be higher than in adults [51]. Studies on the pervasiveness of sleep bruxism in children has varying results, ranging from 10.2% to 49.6%. A cross-sectional telephone survey in Hong Kong of 3,047 6-12 year old participants reported 20.5% sleep bruxism rate. Cheifetz et al. conducted another survey at the Childrens Hospital Boston Dental Clinic, with 854 participants under the age of 17, and reported an overall bruxism rate of 38%. They further noted that children with psychological disorders had 3.6 higher chances of sleep bruxism [14]. Another cross-sectional study investigated the prevalence of sleep bruxism in Brazilian school-children; 652 randomly selected children aged 7-10 years of age reported a prevalence rate of 35.3% [85]. Insana et al. published the prevalence of parent reported sleep bruxism that occurred at least once per week for 249 pre-school and 2,888 first grade students of 36.8% and 49.6% respectively [42]. They concluded heightened sleep bruxism frequency may be used as an indicator for current or possibly future behavioral problem and requires need for further investigations [42]. Finally, a community survey examining sleep problems of Finnish pre-school aged children in Helsinki discovered a 10.2% rate of sleep bruxism [86].

In summary, studies on prevalence of sleep bruxism indicate a high prevalence rate amongst children which declines with age. However, because sleep bruxism is a sleep-time disorder, and is difficult for patients themselves to monitor their own condition, most of the estimates were from questionnaires and parental reports. Though such methods of assessing sleep bruxism gives a good general idea, they are imprecise, and not useful for gathering long-term data. Only one estimate from a large scale study by Maluly et al. was extracted from single-night polysomnography recordings, but because study did not account for 'first night effect' and that sleep bruxism simply does not necessarily occur every night, Maluly et al. suggested the need for further investigation. To support long-term studies on a large population, a cheap and precise validated diagnostic tool is needed.

1.4 Etiology

Surprisingly little about the etiology of sleep bruxism is understood by researchers. In the past, morphological factors, such as occlusal disharmony and the anatomy of the bone structures of the orofacial region, have been considered the main causative factors for sleep bruxism. However, recent findings in literature show strong evidence supporting bruxism as being regulated centrally (i.e. pathophysiological and psychological) – not due to structural (morphological) features [56, 58].

1.4.1 Morphological Factors

In a controlled study by Kardachi et al., elimination of interferences in occlusal discrepancies was shown to have no influence on bruxism activities [46]. More recently, Lobezzoo et al, compared 26 occlusal variables and 25 cephalometric variables (i.e skeletodental structural variables), between bruxers and non-bruxers and found no differences between the groups, suggesting that morphological factors do not play role in causation of sleep bruxism [57]. Instead, current literature suggests that sleep bruxism etiology is of a multifactorial nature and is possibly contributed by psychosocial factors such as stress and anxiety, smoking, alcohol consumption, sleep apnea, and medicinal use [56].

1.4.2 Psychosocial Factors

Sleep bruxism and stress sensitivity Stress and anxiety are frequently mentioned along-side of sleep bruxism. Urinary levels of patients in both children and adults with and without sleep bruxism were compared; those with sleep bruxism were found to have higher levels of catecholamines, a chemical typically associated with stress [17, 90, 84]. Sleep bruxism is also frequently associated with higher stress sensitivity. Abekura et al. examined the association between sleep bruxism and stress sensitivity by measuring 76 subjects' salivary chromogranin A (CgA)

levels, another stress indicator, before and after a stress task. They found that mean salivary CgA levels of the bruxism group were significantly increased after a stress task in comparison with the non-bruxism group [1].
Giraki et al. assessed the stress parameters of 69 subjects, of which 48 had sleep bruxism, and found that of the parameters investigated ('general strain', 'emotional strain', 'social strain', 'unresolved problems', 'fatigue', 'lack of energy', 'physical problems', 'success', 'social recreation', 'physical relaxation', 'general content', and 'sleep'), those with sleep bruxism were significantly correlated with reporting 'daily problems', 'trouble at work', 'fatigue', and 'physical problems' [32].

SB and stress coping strategies Other survey-based studies also suggest that subjects with sleep bruxism are more likely to have maladaptive stress-coping strategies that lead to a more anxious, stress-oriented, type-A personality [32, 63, 74, 82, 94]. Pingitore G. et al., suggests that stress itself is not significantly associated with sleep bruxism, but rather the combination of a type-A personality and stress that together act as a trigger [74].

The role of psychosocial factors on sleep bruxism patients have not been entirely conclusive [73]. Though psychological factors is clearly considered a risk factor, unlike awake bruxism, which has been evidently shown to be a nervous reactions to stress, effects of psychological factors on sleep bruxism remains still unsettled. A study published in 2012 evaluated the psychopathological profile of patients with awake bruxism, sleep bruxism, and no bruxism, and found that sleep and awake bruxers have higher mean psychopathological scores than non-bruxers, with awake bruxers taking the lead. This suggests that though awake bruxism is more strongly correlated with psychosocial factors than sleep bruxism, sleep bruxism is still correlated, but perhaps to a lesser degree [5]. While there are indications that individuals with sleep bruxism is likely to have higher stress sensitivity, it would be interesting to know if sleep bruxism frequency are affected by the stress levels of the individual during the day.

1.4.3 Exogenous Factors

Several exogenous factors are associated with sleep bruxism. A study examining Finnish twins, controlling for genetic and environmental factors, found that individuals with nicotine dependence are significantly more likely to self-report having bruxism [79]. The relation between tobacco use and bruxism were also supported by Lavigne [53] and Madrid et al. [61]. Other exogenous factors associated include: caffeine intake, medication use, and ecstasy use [3, 21, 24, 31, 80, 81, 95, 93].

1.5 Treatment

There are three main approaches for managing sleep bruxism: use of occlusal appliances, biofeedback approaches, and pharmacotherapy. We reviewed the literature examining efficacy of occlusal appliances and biofeedback approaches, as pharmacotherapy is irrelevant to the nature of our study.

1.5.1 Occlusal Appliances

True Occlusal Interventions True irreversible occlusal interventions that modifies occlusal stress (occlusal equilibration) and corrects irregularities of teeth (orthodontic treatment) are not supported by high-quality evidence in literature [59]. Only one randomized clinical trial examined the effectiveness of an orthodontic technique using buccal separators observed no improvements, reported subjectively and objectively, between the active treatment and control conditions. The remaining majority of reports on the efficacy of true occlusal interventions are of case reports [2].

Splints Occlusal appliances such as soft and hard splints are statistically the most frequently prescribed appliances for managing sleep bruxism [72, 59]. There are several case reports and comparative studies assessing the efficacy of occlusal splints, however, the conclusions drawn are contradictory. An early study by Clark et al., showed that occlusal splint treatment decreased the EMG activity of 50% of

the subjects, no change in 25%, and an increase in EMG activity in the remaining 25% [16]. Another study by Okeson found that hard splints reduced sleep bruxism activity of 8 out of 10 patients, whereas soft splint yielded an increase in sleep bruxism activity in 5 of the 10 patients and a decrease in activity in only 1 subject [70]. Due to the contradictory results on the efficacy of occlusal appliances, Lobbezoo et al. cautioned that oral splints should be used to limit dental damage, but requires further investigation [59].

1.5.2 Behavioral Approaches

A wide variety of behavioral strategies has been investigated in the management of sleep bruxism. The most widely investigated approach is the use of biofeedback devices.

Biofeedback

In past biofeedback approaches have been used to manage sleep bruxism using aversive conditioning, where bruxers 'unlearn' their behavior when a consistent aversive contingent stimulus is applied at the onset of each bruxism episode. Several aversive stimulants have been studied, these include: mechanical [19], auditory [12, 26], vibratory [91], electric [45, 43, 44], and taste stimulus [68]. More recent studies found that certain biofeedback approaches could successfully trigger the jaw-opening reflex (JOR), also mentioned elsewhere as the masseter-inhibitory reflex (MIR), which, when administered, successfully halts each onset of sleep bruxism activity.

Aversive Conditioning The popular aversive stimulant of choice is auditory stimulation designed as a EMG activated nocturnal alarm clock. On the basis of case reports, many authors claimed long-term success in decreasing frequency or duration of sleep bruxism [26, 36, 66, 92, 28, 59]. Other studies took the alarm

clock paradigm one step further, requiring patients to fully wake up and perform simple tasks in order to turn off the sound stimulus. These frequent full awakenings throughout the night is a major disadvantage because of possible serious side effects such as excessive daytime sleepiness [87]. Taste stimulus was also examined by Nissani and, on the basis of a case study, found that aversive taste stimulus was able to inhibit grinding activity [68].

Masseter Inhibitory Reflex Techniques that elicit masseter-inhibitory reflex allow for more subtle feedback system to be used, as they do not fully awake individuals, thereby reducing sleep disturbances of the intervention. This reflex could be elicited by nociceptive stimulants in the mouth or on the facial skin of the maxillary and mandibular trigeminal divisions [44]. Studies have shown that mechanical, electrical, auditory, magnetic, and tactile stimulation all are successful in evoking this inhibitory reflex [30, 40]. Moreover, findings suggest that masseter inhibitory reflex is not affected by conditioning and are potentially useful for longer trials [62]. Watanabe et al. developed a vibratory mouth guard in 2001, which on the basis of a clinical trial, claimed success [91].

Temporal Success of Electrical Stimulation The promising results of a study executed by Nishigawa et al., using contingent electrical lip stimulation to trigger the masseter inhibitor reflex, was followed by a flurry of excitement for exploring electrical stimulation in sleep bruxism management [67]. Commercial products such as GrindCare® were developed adopting the same technique on the tempromandibular region. The advantage of contingent electrical stimulation is that it does not cause major sleep arousal response and has the potential to reduce the duration of bruxism episodes [45]. However, the efficacy of contingent electrical stimulation is on the grounds of debate. The results and efficacy of units like Grindcare® has been supported by some in literature, but has also been found having a lack of evidence by others. Furthermore, because long term studies on these techniques have not been carried out, long-term efficacy remains undeter-

mined [43]. Raphael et al. studied the results of contingent electrical stimulation on 14 women with polysomnographic evidence on sleep bruxism and found that EMG events decline during treatment periods, but return to baseline levels whens stimulus is taken away [75]. Another concern is on initiating contingent electrical stimulation using devices that measures only one channel, EMG, for sleep bruxism detection and, is that it would not be able to accurately distinguish sleep bruxism events from other oromotor functions at night.

Long Term Efficacy As described in 'Principles in the Management of Sleep Bruxism', longer term comparative studies were conducted by Clarke et al. and Hudzinski and Walters, showing that the efficacy of biofeedback on sleep bruxism provided positive effects up to 3 months [59]. However, Pierce and Gale found that the positive effects of biofeedback devices that uses contingent aversive tone diminishes after a period of 6 months. As Lobbezoo et al. cautioned, "there are serious doubts whether this is actually an effective treatment for bruxism, especially in the long-term" [59].

Other methods of inhibiting sleep bruxism is the use of relaxation techniques. Restrepo et al. found positive effects of relaxation in 3-6 year old children who have sleep bruxism [78]. One interesting 12 week study conducted in 2007, compared the results of occlusal splints, and cognitive behavioral therapy sessions in patients with sleep bruxism, and found that both groups demonstrated a significant reduction in sleep bruxism [71]. Cognitive behavioral therapy consisted of 12, 1.5 h weekly sessions, with the program consisting of 4 different modules. The first module, consisting of problem solving, and systematic introspection of stress-causing situations, was practiced at the beginning of each session. Participants were instructed in progressive muscle relaxation in the second module and were told to practice everyday from week 3 to 7. During the third module, participants were instructed to use biofeedback devices which emitted an aversive tone contingent upon bruxism events during sleep time from week 8 and 9. The last module, lasting from week 8 to week 12, focused on training of recreation and

enjoyment – participants learned to integrate enjoyable activities into everyday life. During the treatment, both revealed significant reduction in sleep bruxism activity, with cognitive behavioral therapy sessions taking the lead (as measured by Bruxcore®, a 6-month follow up revealed that the cognitive behavioral therapy group tended to return to baseline levels as opposed to the occlusal splint group. What had occurred during the months in between post-treatment and 6-month followup was not mentioned. Did the participants purchase occlusal splints afterwards? Did participants subscribe to other studies? In fact, upon discussing the results of this study, Ommerborn concluded that there is a need for further controlled evaluations, and a more precise method of measuring sleep bruxism [71].

1.6 Motivation of work

As evident from the previous discussion, sleep bruxism is still a topic of much debate. The high prevalence rate, which has been demonstrated at 8%-10% in adults and 10%-50% in children, displays sleep bruxism as a common parafunction. Despite the estimated high prevalence, there is lack of definitive evidence regarding the management of sleep bruxism. Though occlusal splints are the most common treatment prescribed by dentists, they are only effective in preventing further dental attrition, and effects on sleep bruxism are inconclusive. Biofeedback approaches are certainly promising, but need investigation in a larger-scale and longer-term setting. Because much of the published research used surveys, questionnaires, parental reports, or very short lived polysomnography, the results are subject to a certain degree of ambiguity. We believe that by providing reliable, accessible, and cheap methods of quantifying sleep bruxism would help longer-term research take flight. Carra et al. declared that the "future direction for sleep bruxism assessment would be to develop a handy tool that can directly, reliably, and rapidly measure ongoing bruxism activity and that can be used in both clinical (for diagnosis, treatment outcome evaluation, and follow-up) and research settings" [10].

We propose to tackle this problem by developing a mobile phone application for monitoring and tracking sleep bruxism. We chose to use a mobile phone as the platform because these are easily accessible and relatively cheap to obtain. This mobile phone application will monitor 3 channels consisting of audio, video, and EMG, in order to accurately determine sleep bruxism events. We hope that such a mobile phone application which reliably detects sleep bruxism could be adopted as a useful tool in supporting a) clinical, b)research, and c) personal uses.

1.6.1 Supporting Clinical Settings

Currently, clinical assessment of sleep bruxism is most commonly based on reports of tooth-grinding sounds by family members and presence of attrition matching the patterns of repetitive grinding or clenching. However, as explained in Section 1.2, reports of tooth-grinding is not a very precise measurement on its own. For example, the frequency of sleep bruxism events per night and nightly occurrences per week is difficult to ascertain. A mobile phone application, even one which purely monitors tooth-grinding sounds at night, would be beneficial by providing evidence of such sleep bruxism events. Furthermore, such an application enables longer-term monitoring which would help doctors to determine the severity of sleep bruxism more accurately.

1.6.2 Supporting Research Settings

A device that can accurately determine the presence of sleep bruxism cheaply would be beneficial for helping researchers monitor presence of sleep bruxism in their participants. We reviewed many studies that assessed sleep bruxism using questionnaires, parental reports, single night polysomnography, and Bruxcore®, but these methods of sleep bruxism assessment is not definitive, and are criticized by some in literature [59]. Furthermore, studies that utilized polysomnography for

measuring sleep bruxism are often either short-lived or small in scale. As such, there has been a consistent trend in literature reviews that question the conclusions drawn by research studies on the following grounds:

- Lack of long-term sleep bruxism management studies
- Limitations of sample size, as seen in case studies and small comparative studies.
- Questionable methods of measuring sleep bruxism events in large studies such as use of Bruxcore or Surveys/Questionnaires

Though sophisticated polysomnography is the gold standard monitoring method for sleep bruxism research, it is highly costly and time consuming, and also requires participants to sleep in a foreign environment outside the comfort of their beds. Though more accessible alternative diagnostic tools such as one that measures solely EMG activity of the temporalis or masseter muscle have been developed, their reliability has yet to be undoubtedly validated. They do give a good indication of the presence of sleep bruxism, but because the measurement is based on only one channel, the distinction between non sleep-bruxism related RMMA episodes and sleep bruxism episodes are difficult to determine. A mobile application which measures EMG, audio, and video data, would be more capable of discerning different masseter activities during nocturnal sleep-time. In addition, because we are designing this application to be easily extensible, interested researchers could add new monitoring channels to meet their requirements. As such, we believe that a modular and easily extendible real-time bruxism detection mobile device can enable the research community use it as a platform for novel ways of studying sleep bruxism.

1.6.3 Supporting Personal Use

To the extent of our knowledge, no device has been developed to support patients with sleep bruxism on monitoring their own conditions. These ambulatory

EMG monitoring devices mentioned are mostly for clinical and research settings. Thus, sleep bruxism is often a condition that, if a patient is aware of, could be only controlled by using mouth-guards. Most patients, however, are incapable of doing much more otherwise. Especially because sleep bruxism affects patients during sleep-time, they have little control over their own condition. Of course, ambulatory EMG monitoring devices could be purchased, but these devices are both difficult to attain and very expensive. We hope that with a sleep bruxism monitoring application, patients with a smartphone would be able to monitor their own condition cost-effectively.

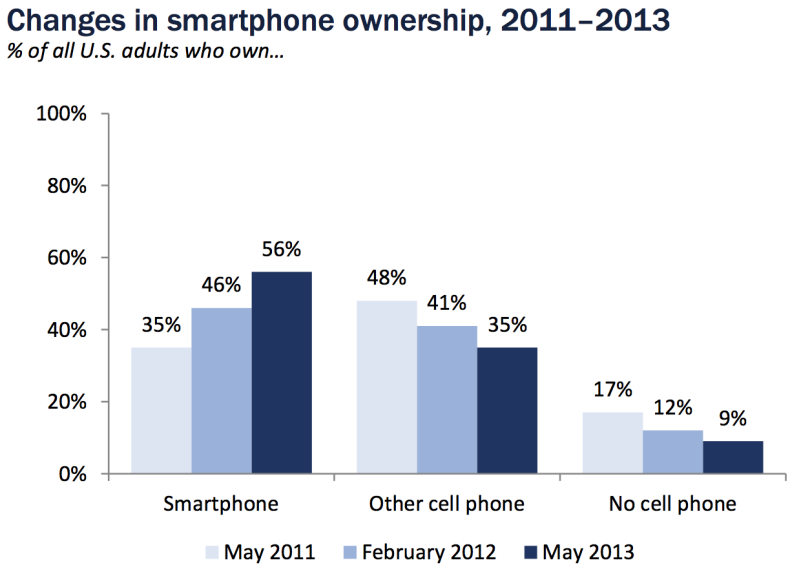


Figure 1.3: Pew Report of Smart Phone Ownership

There are many advantages for using a mobile phone, especially since they have become increasingly ubiquitous. Pew Research Center reported that 56% of adults in 2013 own a smartphone device, with the percentage of ownership rapidly reaching the totality of the pollution (see Figure 1.3). Furthermore, there has been a growing interest in mHealth devices. mHealth devices are often based on a combination of mobile phones, smart phones, PDA (Personal Digital Assistants) and tablets (e.g. the Apple iPad) on the one side, and a variety of wearable sensors or specific systems tracking physiological and psychological signals on the

other side. Currently mHealth devices are used for interventions across a variety of disorders such as diabetes, hypertension, obesity, cancer, asthma, eating disorders, HIV treatment [7, 18, 37, 50], to name just a few. In 2011, 26% of the US adult population used their mobile devices for health information and tools. This represents an increase of up to 12% since 2010 [76]. In the same year mobile health applications generated about $718 million in revenue, about seven times more than the estimated $100 million generated in 2010 [77]. Currently more than 97,000 mHealth apps are listed in dedicated online catalogues to be used by a range of mobile devices such as Apple iPhones and Android smart phones [77]. Thus, because of the growing popularity using mobile devices for health management and because of a rapidly increasing amount of population with a mobile phone, a mobile phone application for monitoring sleep bruxism would potentially empower a larger number people with sleep bruxism to understand and quantify their own condition.

Chapter 2

Portable Biofeedback Device for Sleep Bruxism

2.1 Purpose of Research

The purpose of our research is to collect EMG, audio, and video information on sleep bruxism episodes and design a mHealth system that is able to find the most minimal number of channels needed to determine the occurrence of sleep bruxism. This is an exploratory study, and our intention is to gather initial this data for future evaluation. Furthermore, we hope to examine the accuracy of sleep bruxism events of individuals throughout the night.

We consulted with Dr. Sonia Ancoli-Israel, a Professor of Psychiatry at the University of California San Diego School of Medicine, Director of the Gillin Sleep and Chronobiology Research Center, Co-Director of the Laboratory for Sleep and Chronobiology at the UCSD GCRC, and Director of Education at the UCSD Sleep Medicine Center, for advice on the relationship of such a device and sleep quality. We also maintained correspondence with Dr. Gilles Lavigne, a Professor at the Faculty of Dentistry, Université de Montréal, the foremost expert on sleep bruxism, and author of many sleep-bruxism related publications, who provided insight on our approach of addressing sleep bruxism.

Our study, Project #130259, has been reviewed and approved by UCSD's Institutional Review Boards in accordance with the requirements of the Code of Federal Regulations on the Protection of Human Subjects (45 CFR 46 and 21 CFR 50 and 56). For full copy of IRB, refer to appendix A.

2.2 Participant Selection Criteria

We recruited participants on the UCSD campus that are self-aware of their sleep bruxism condition, who are either informed by a dentist about their sleep disorder, or by friends/family members who report hearing grinding noises at night. Before being admitted into our study, all participants underwent 3-4 nights of evaluation period using the FDA Exempt 510(k) device Grindcare® (see Figure 1.1), a portable bruxism measurement device that monitors the activity of the temporalis muscle. We required at least 3 nights in order to take into account of the first night effect of sleeping with an EMG device attached to the face. Furthermore, severe sleep bruxism is diagnosed as one that occurs at least 3 times per week, and having 3 nights of data will allow us to more accurately determine the existence of sleep bruxism in our participants. Participants exhibiting at least one night of active rhythmic masticatory muscle activity shown by having more than 25 episodes per night as measured by GrindCare® met our criteria and were invited to participate in the study.

2.3 Research Structure

The duration of the study was 7 nights of full recording, including a one-to-one semi-structured interview at at the beginning and another at the end of the study. Recordings did not have to happen during consecutive nights, thus our participants recorded data when it was more convenient for them. We maintained contact with our participants throughout the week via email. During the

initial interview, we asked how the participants knew of their sleep bruxism, their current knowledge of sleep bruxism condition, and what current treatment/intervention they were taking action in. Then we explained the study, and instructed the participants on how to use the devices. A total of three channels were used for gathering data on the participants: audio, EMG, and video. All three channels recorded information contingent upon detecting action in the perspective channels. For example, video channel would only record images upon movement detection. We also informed our participants that if, for any reason, they would like to discard the data collected for particular night, they simply had to contact us the next day before 10AM, and the data will be removed without looking at it.

The compensation for our participants was not lucrative. Participants received $10 for each initial and final interview and $5 for each night of full recording. The maximum amount any participant received was $60 for the full study. No compensation was given for the evaluation period while using the GrindCare® unit. Data collected during this phase was shared with the participants.

2.4 Experimental Procedure and Instruments

Participants were given equipment containing an instruction manual (see Figure 2.1), a Pantech Android mobile phone, a bluetooth EMG recording unit, an infrared light, and a stabilizers/holders.

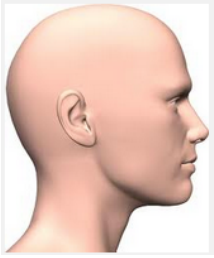
The first night the participant returned home with the equipment, they were instructed to setup the stabilizers and holders, IR light, and phone as shown during the interviewing session. Participants needed 2 available outlets near their bed for the IR light and the mobile phone. We recommended participants to keep both devices connected at all time. This procedure only needed to be done the first night. Then, participants were instructed to place the EMG electrodes on their masseter muscle during sleep time (see Figure 2.1), turn on the EMG unit, and

Sleep Bruxism Research Manual

Equipment list:

1. Cpap holder
2. Clip on extension
3. IR light and adapter
4. Mobile phone and charger
5. 2x sendy batteries and cables
6. EMG device
7. Electrodes
8. 21x Electrode gel pads (6 extra)

Setting up the device

1. Place the base of (1) underneath the mattress directly above sleeping pillow
2. Clip (2) onto the pole of (1) and put it through through the stretchable loop at the top of (1) to secure it's placement.
3. Connect the 12v adapter to the IR light and adjust the IR light fixture so it points directly at the pillow you sleep on. (IR light will turn on when it senses the absence of light)
4. Place phone in the clip below the IR light and connect the micro usb cable for charging the phone. NOTE: phone must be charging throughout the entire night.
5. Connect the EMG device to its batteries, plug in the electrodes into the EMG device, and turn on the device when ready to use. (If batteries have fewer than 2 lights on, please charge them during the day when bit in use. Do not charge them while the EMG device is being used)
6. Place new gel pads on the electrodes each night.
7. Electrodes come in 3 colors, with a specific placement for each
    1. BLACK: place on bony area directly below the temple
    2. RED: place above on protruded masseter muscle when jaws are clenched
    3. BLUE: placed one inch away from the RED electrode along the masseter muscle towards the front of the face.
    4. 
8. Setting up mobile application
    1. Ensure WiFi is available and connected
    2. Start up the application
    3. Check settings to make sure all recording channels are toggled (EMG, AUDIO, VIDEO)
    4. Check to make sure the EMG module under (setup EMG device) matches the name of device as indicated on the box.
    5. Begin recording
    6. Calibration countdown will begin to measure ambient noise level of your room. Please make sure the surrounding is, as similar to sleep time noise level as possible. Clack your teeth loudly 3 times while calibration is ongoing.
    7. Once you see "CALIBRATED", screen should change to the front facing camera on the phone. Three boxes should appear indicating connection status of all the channels. Wait until the boxes disappear, indicating proper connection, before turning off the screen to go to bed.

Repeat steps 5-8 every night.

Figure 2.1: Instruction Manual

start up the monitoring software on the given Android mobile device. This was repeated for seven nights. Because the placement of the electrodes were not precise, this resulted in varying EMG data collected across patients. However, since EMG data is used only as ground truth for comparing the collected audio and video data, not directly for analysis across the board by itself, the small impreciseness of the placement was tolerable. At this point, the mobile device is placed in the phone clamp, positioned next to the infrared light, with the front camera and IR light framing the pillow. Once the application is turned on, it calibrates to the

ambient noise of the surrounding for 20 seconds, then pair and connect with the EMG device. Now the screen of the phone could be turned off, the participant may go to sleep. Upon awakening the next morning, the subject turns on the monitor and stops the software.

2.5 Hardware Design

We had to build the hardware to support our research study. Audio recording required the least additional external hardware, as it could be done with only a mobile phone. Because video recordings must be taken while participants are asleep, we had to use an infrared light, and were limited to using mobile devices with cameras without an infrared filter. Collecting EMG data was the most challenging, since it required us to build a standalone EMG device.

Overall, hardware components that were required were 1) an infrared light that enables us to capture images in the dark, 2) a mobile phone capable of running the application and collecting participants' data, 3) a stabilizing structure to hold the mobile phone and infrared light in place, and 4) a device capable of monitoring EMG activity and communicating with the mobile phone during a recording session.

2.5.1 Night Vision

We wanted to capture image recordings of the actual bruxism events during the night with the phone's camera. Because Dr. Ancoli-Israel informed us of visible light being a sensitive stimulant which could disrupt sleep easily, we were especially weary of this issue. In order to preserve the sleep quality of our participants, we needed to minimize the lights kept on during sleep time, and was unable to rely on visible light sources to capture image frames. Since most Android cameras we've tested have been able to detect infrared light, we went ahead with the technology and integrated infrared LED lights.

We discovered that most commercially available infrared lights emit a dim red glow when turned on. Though the dim light is visible, this is still a far better alternative than bright visible light. In general, we found it to be a little distracting, but participants reported to be okay after adjusting to it the first night. In order to combat this problem, we purchased IR light filters which successfully filtered out most the visible IR light. Though our participants could not use the IR filter in time, this would be very beneficial for future development.

2.5.2 Mobile Device

The mobile device we used for our study was Pantech Burst, model number PantechP9070, running Android version 2.3.5. (see Figure 2.2 for full specification). We had originally intended to recruit only users with Android mobile phones since our software was designed to support versions 2.2+, which covers 90% of the market, but later found that Android mobile phones have varying IR light sensitivity. For example, Samsung Galaxy S3® and HTC One® both had very low IR light sensitivity, and produced dark images of objects only 1ft away from the camera and IR light.

2.5.3 Stabilizer/Structure

Putting together a holder for the phone and IR light to record facial movements during night time required use to adapt to all sorts of bed setup. The holder had to be adjustable by the users themselves since the phone's camera and IR light need to be directly placed above their head, capturing movements above shoulders during sleep-time.The stabilization tools we used were a clip-on phone arm which can be clamped onto a CPAP holder stabilized by the bed.

Physical Characteristics & Battery Info	
Dimensions	4.98 x 2.46 x 0.45 inches
Weight	4.32 ounces
Talk Time	Up to 4.5 hours
Standby Time	Up to 10 days
SIM Type	Micro-SIM (3FF)

Hardware	
System Chip	Qualcomm
Processor	Dual core, 1500Mhz, Scorpion
Graphics processor	yes
Built-in storage	16GB
Maximum User Storage	12.3GB
Storage expansion	microSD, microSDHC up to 32 GB

Camera	
Camera	5 meapixels
Flash	LED
Camcorder	1280x720 (720p HD) (19fps)
Front-facing camera	0.3 megapixels VGA

Connectivity	
Bluetooth	Yes
Data Cable	Micro USB 2.0 High Speed
Headset Jack/Type	Yes / 3.5mm
Near Field Communication (NFC)	No
Wi-Fi	Yes
Wi-Fi Protocols	802.11 a/b/g/n
Wi-Fi Security	WEP, WPA, WPA2

Figure 2.2: Pantech Burst (P9070) specification

Our original design of the stabilizing equipment did not consist of the CPAP holder. The extension arm was designed to clamp onto the headboard of the bed, as shown in Figure 2.3. However, to our surprise, none of our participants' bed had headboards; most of them had a mattress and spring-box. We quickly adjusted our design using CPAP holders that are stabilized by the weight of the mattress for the clip-on extension arm clamp onto. This was not an ideal setup since the CPAP holder is not designed to hold so much weight, and since the rod is rather thin, the clip-on extension arm was not as stable. However, this solution worked for the limited time we wanted to record data from our participants.

Figure 2.3: Equipment setup for beds with headboards. As currently shown, a CPAP holder is not required

2.5.4 EMG Unit

To support our research study, we designed and built six EMG units that communicate with our mobile devices via bluetooth. Electromyography is the measuring of electrical signal produced during both voluntary and involuntary muscle

contraction. The electrical signal produced is an algebraic summation of the motor unit muscle action potential around the electrode. Because muscle fibers are of different motors are frequently intermingled throughout the entire muscle, the action potential is not comprised entirely of one motor. However, since the masseter muscle has a large surface for its superficial layer, it was not difficult to capture the action potential.

Design Requirement

The EMG sensor design requirement was that it had to be wireless, be able to record a full night of data, provide real-time updates to the phone, and be relatively small in size. We wanted it to be a wireless since being attached to a unit is restrictive enough, we did not want the users to also be attached to the wall sockets as well. The second design requirement goes hand in hand with with the first one; since we're relying on batteries, each charge must allow us to record for at least 8 hours. We had envisioned the possibility of immediate interventions upon sleep bruxism event detection, thus real-time communication with the phone is a feature we wanted. Finally, size of the device needed to be small enough to fit on the bed next to the user comfortably. The case of the unit needs to be able to withstand body weight in case the user rolls over it during sleep.

We designed and 3D printed the enclosing case, and integrated a muscle sensor, a bluetooth module, and a micro-controller in each unit. The parts we used are listed in Figure 2.5 and the enclosure design is displayed in Figure 2.6. Our final prototype is shown in Figure 2.7.

In our exploratory study, the EMG unit was given to the user with two external 2500mah 5 volt batteries, see Figure 2.7. Originally we had intended to use two 9-volt batteries for each night's recording, however, we discovered that immediate updates to the phone was more expensive than we had previously thought. 9-volt batteries containing 600mah would last at most 6 hours per night. Recharge-

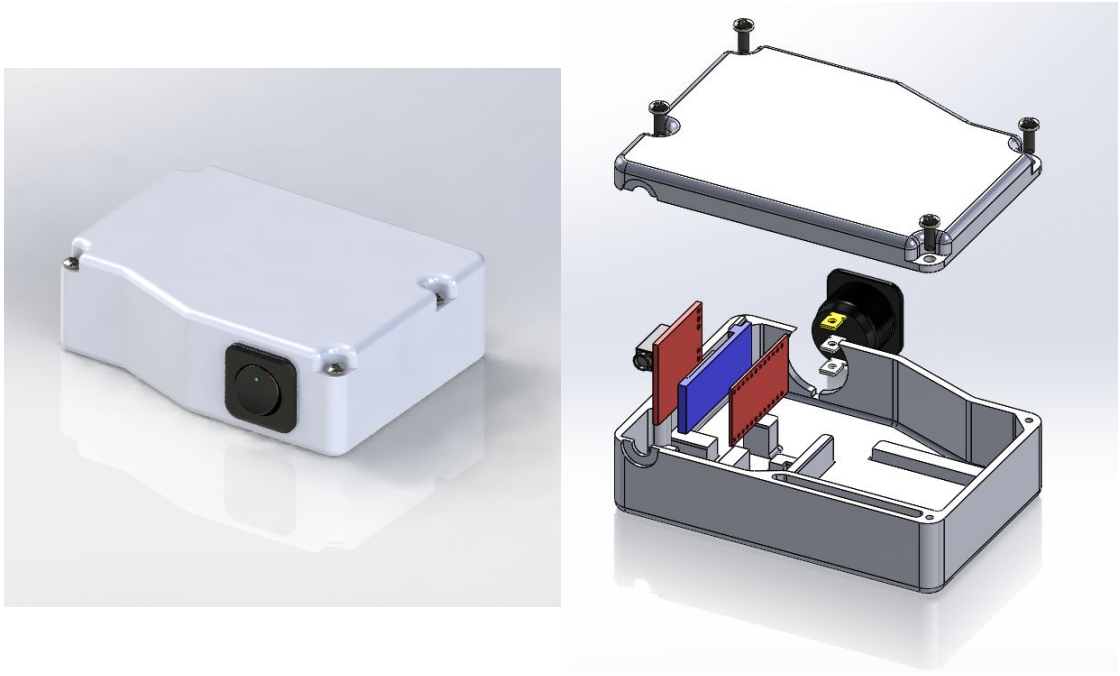


Figure 2.4: EMG device prototype

4	8	MS51957-14		MS51957	Screw, Pan Head, .112-40X .31			
1	7				Muscle Sensor			Funspark.com
1	6				Pro Micro Board			FunSpark.com
1	5				Stwitch, DPDT			
1	4				Bluetooth chip			
2	3				Battery, 5V			
1	2	BSC20005-3			Case, Lid			
1	1	BSC20005-2			Case, bottom half			
QTY.	ITEM NO.	PART NO.	VENDOR CAGE	SPECIFICATION	DESCRIPTION	REFERENCE DESIGNATION	PRICE	Manufacturer

Figure 2.5: Parts list

able 9-volt batteries were further out of the question since they contain even fewer milliamp hours, capping off around 400mah.

To use the external Sendy batteries we purchased, we had to include a 68 ohm resistor, as shown in 2.8. This is only necessary since the Sendy batteries require a load of at least 70mA to stay on. Variations in voltage of the two power supplies will cause inaccurate muscle sensor data readings. We recommend two 9-volt power supplies be used in conjunction with 5-volt regulators to ensure accurate and consistent muscle sensor data as shown in Figure 2.9.

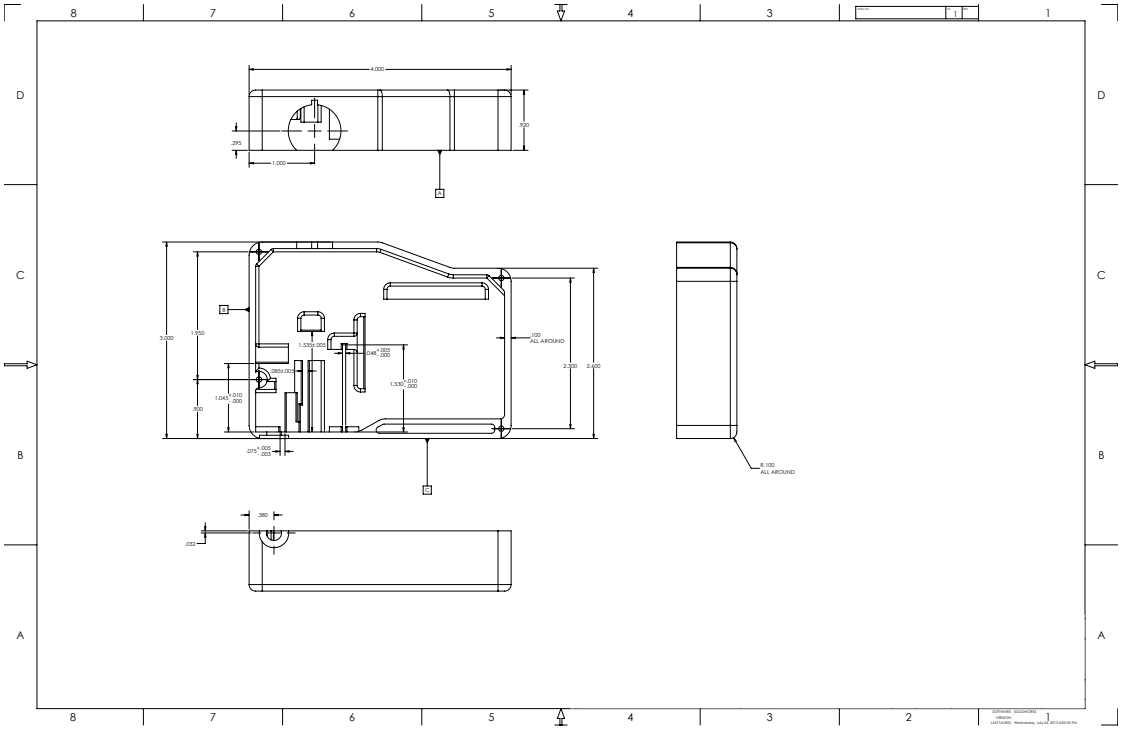


Figure 2.6: Enclosure design

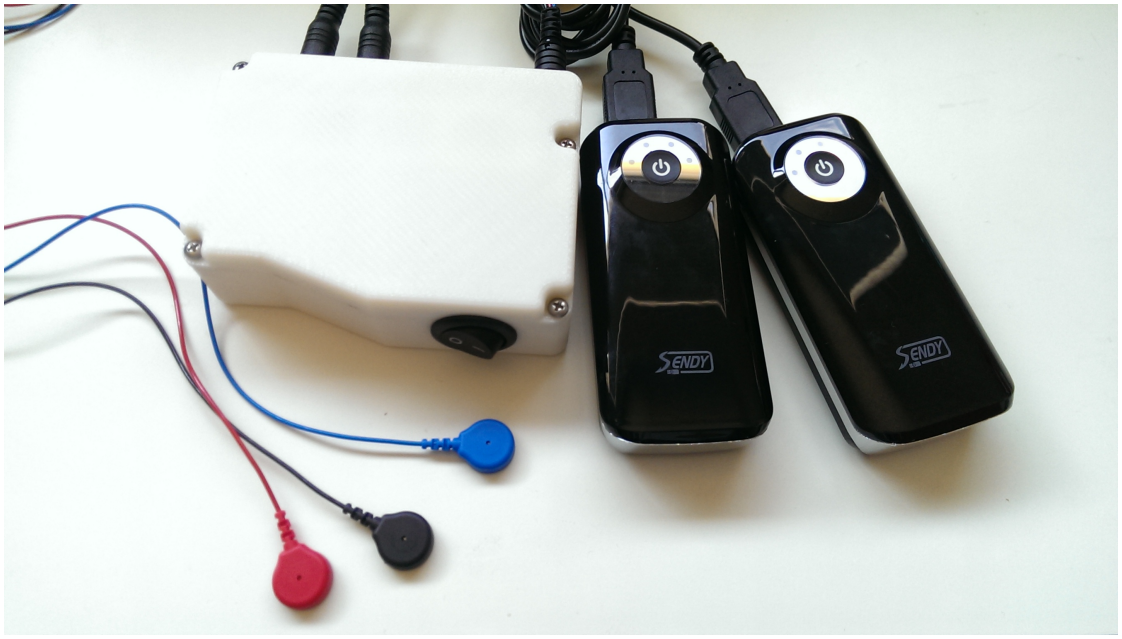


Figure 2.7: EMG unit with two external Sendy 2500mah batteries.

2.6 Software Design

We had two main goals in mind while developing the software to support this study. The first goal of the mobile application is to collect audio, image, and

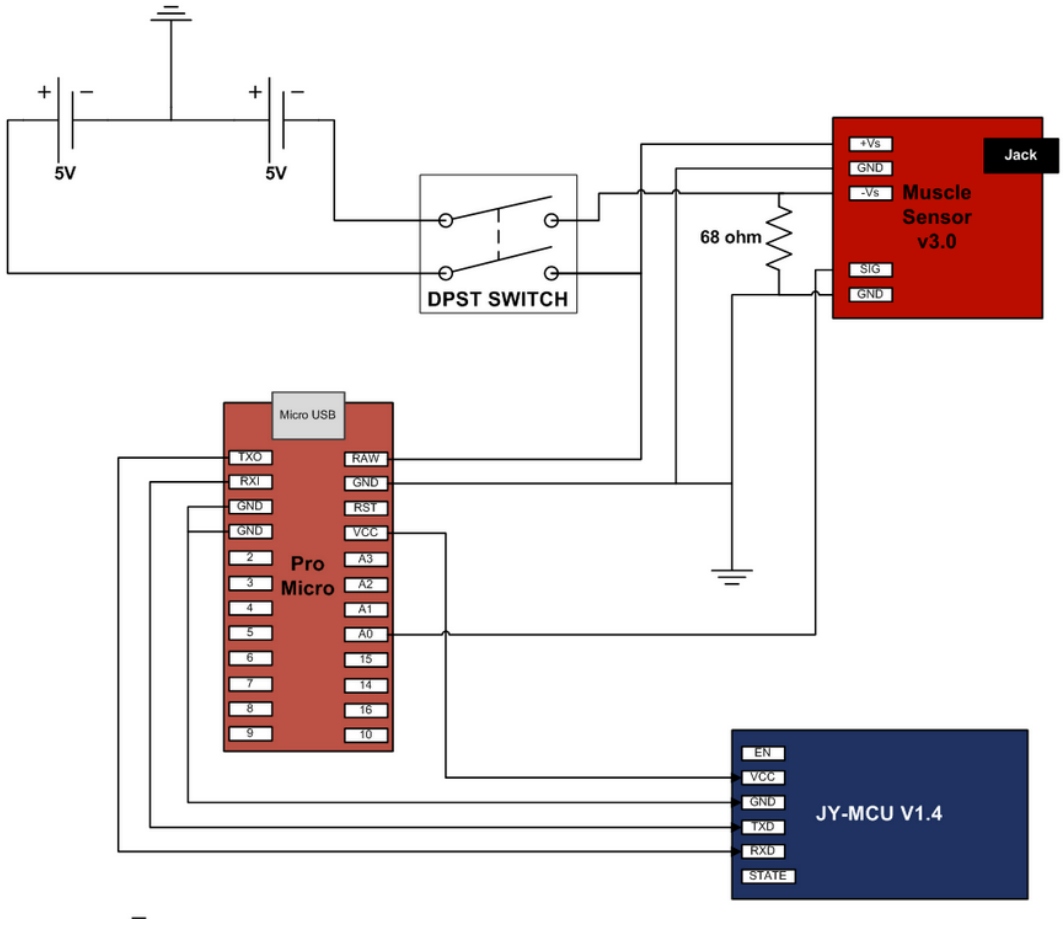


Figure 2.8: EMG schematic

EMG recording, filter out unimportant data with as little delay as possible and transfer them to the server for storage for further analysis. The second goal is to create a very intuitive application for users which promotes ease of use.

The requirements for the Android application were based on the following functions: 1a) recording audio, 1b) posting audio, 2a) recording EMG, 2b) posting EMG, 3a) recording images, and 3b) posting images. The original design consisted of 3 main modules, EMG, audio, and images. Posting and recording functionalites have been developed as submodules of the three, but because recording modules could not be implemented as a service, we restructured the general architecture so that the two top modules are recording and posting. Each recording and posting module contain submodules for handling audio, video, and EMG.

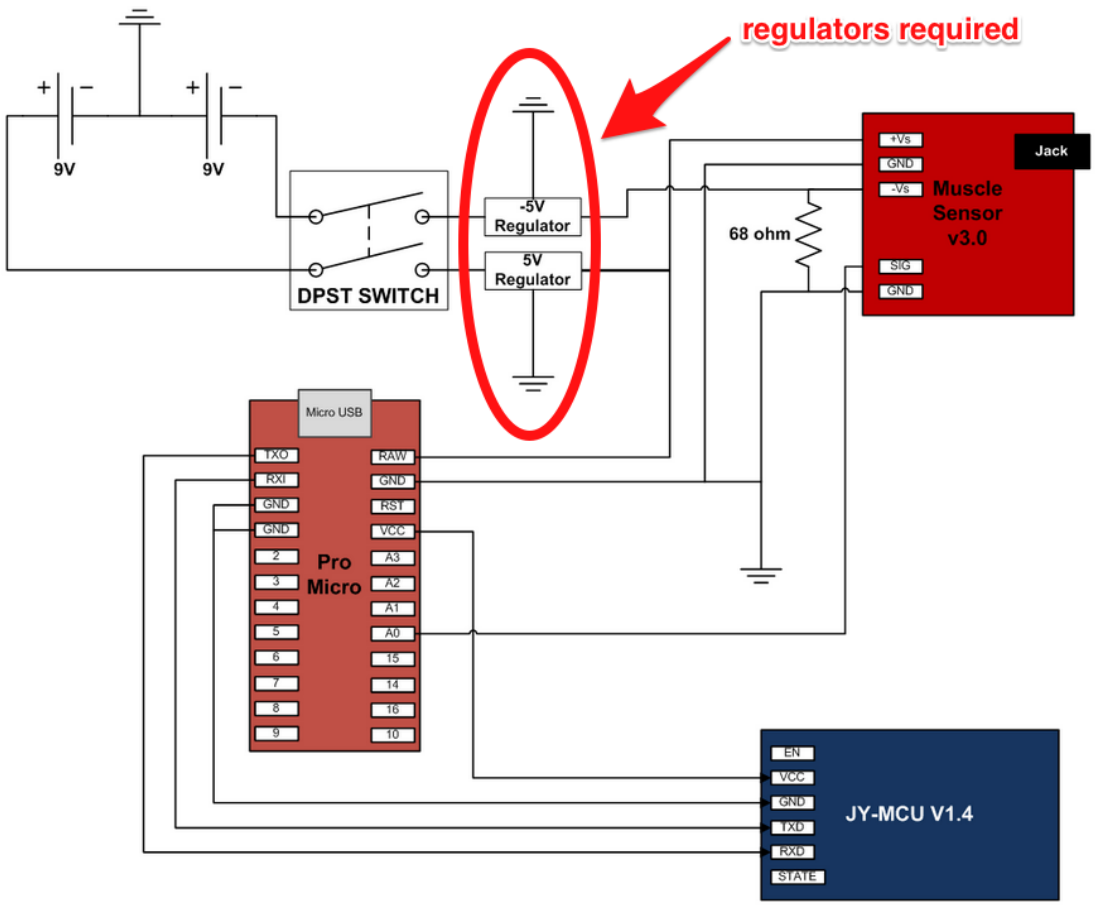


Figure 2.9: EMG schematic with regulator

2.6.1 User Interaction

We wanted to preserve, to the best of our ability, our participants' natural sleeping quality. To achieve this goal, we strove to develop a simple and intuitive interface that minimally increases the stress level of our participants during sleep time. Because our participants use this application every night in bed immediately before falling asleep, minimizing the time the participant spends on the application allows them to start sleep as quickly as possible.

When the user starts the application, the screen will consists of only one

button to begin the recording for the night (see Figure 2.10). Once the user selects "Press to begin sleeping", a screen for ambient audio noise calibration pops up, as seen in Figure 2.11. This screen instructs the user to clack teeth audibly 3 times during a 20 second countdown. The purpose of the audio calibration is to reduce frequency of recording unwanted noise, thereby wasting processing power and storage space.

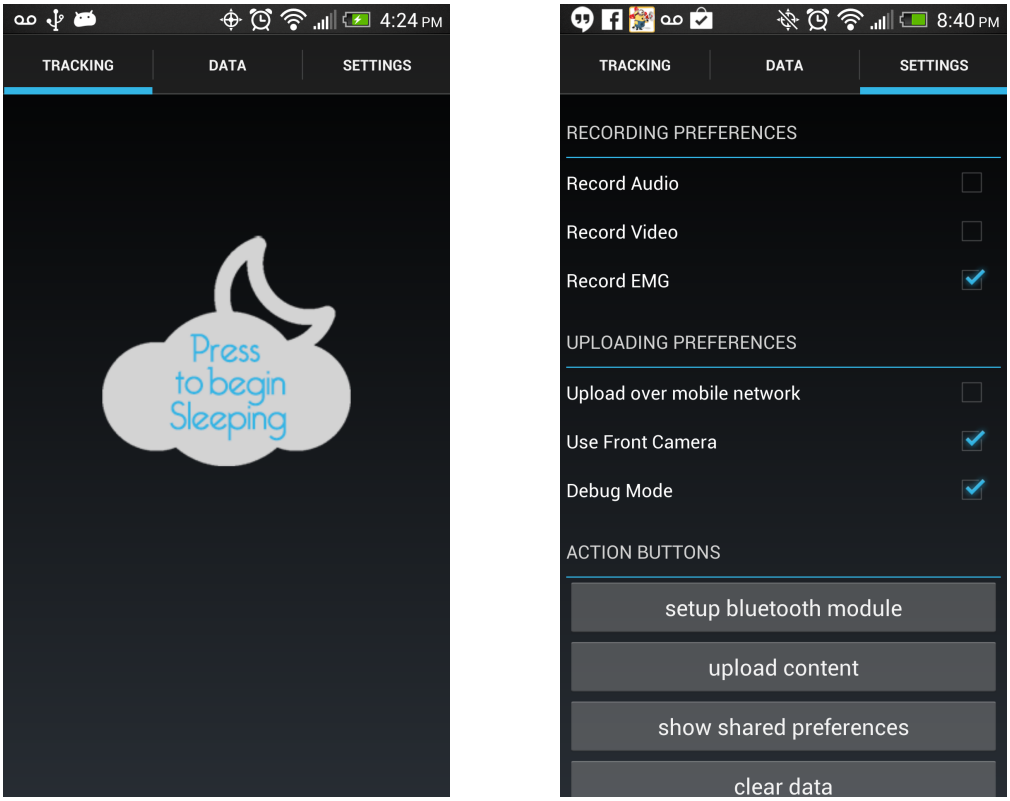


Figure 2.10: Left image: Main activity the user lands on upon turning on application. Right Image: Configuration settings shown when user toggles `SETTINGS` tab

Once calibration ends, the recording activity is displayed. Recording activity is in charge of managing audio, video, EMG recording components, and ensuring that important messages are being communicated with the user. Since bluetooth connection to devices usually take a few seconds, we attempted to reduce the confusion of the user by displaying connection status on the screen. For exam-

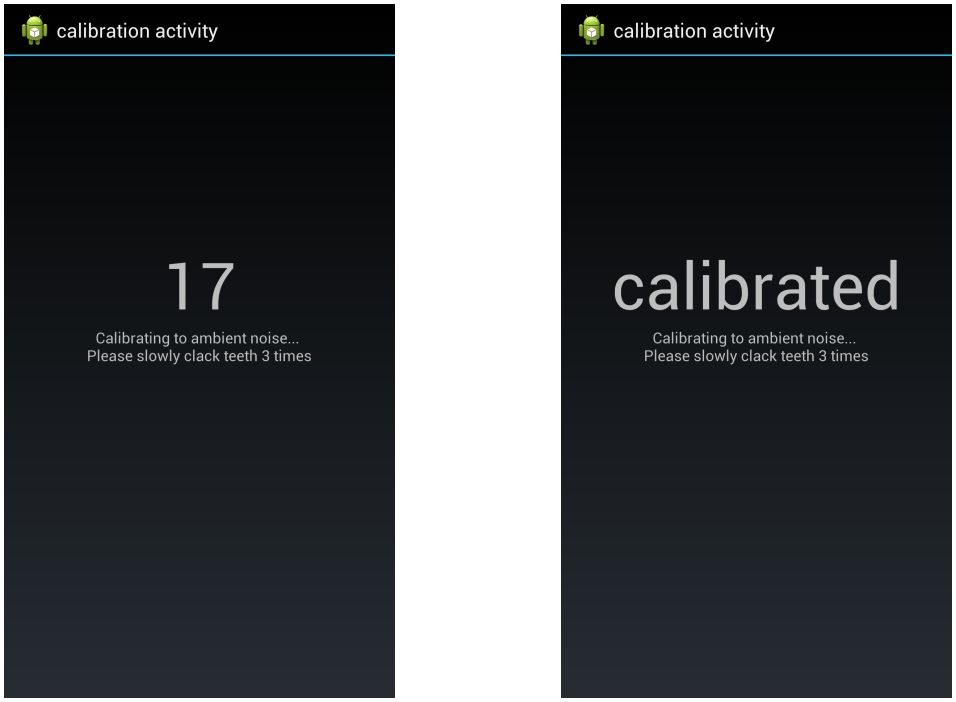


Figure 2.11: Calibration activity

ple, Figure 2.12 shows the interface indicating to the user that the EMG recording is toggled on and device is not connected. Once all components are connected, the gray boxes will disappear. At this point, the user may then turn off the screen by pressing the power button and go to sleep.

The default camera is usually the back camera, as this comes built into most Android devices, but we found that the front camera has three distinct advantages. First, it is a lot easier to operate on while lying in bed. Users could leave the mobile phone in the phone holder with the screen facing the them so that they could start up the device, launch application, and turn off screen without having to remove the phone from the holder. Second, the users could see themselves on the screen live while using the front camera. This enabled them to adjust the screen as needed. Finally, most microphones are located in the front of the Android device, so a front-facing camera allowed the device to capture user-generated noise very clearly.

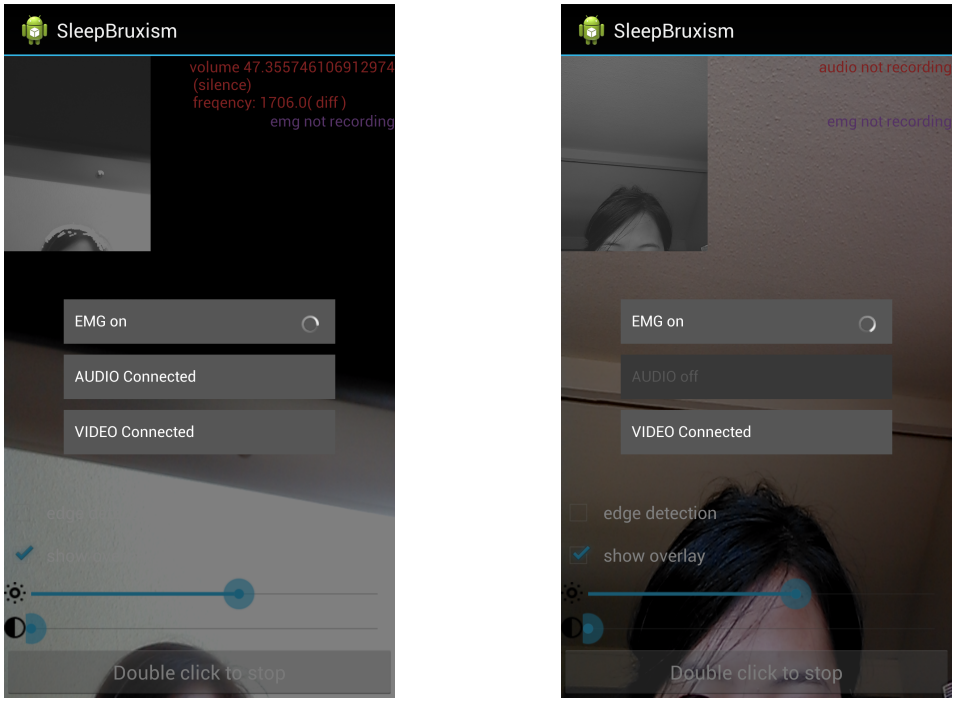


Figure 2.12: Left Image: Application is ready to record audio and video, and is waiting for EMG to connect. Right image: Application is ready to record video and is waiting for EMG to connect. Audio recording has been toggled off.

Configuration

There are a few configuration parameters a user could set with our application. Configuration settings allowed users to toggle a combination of recurring channels consisting of audio, video, and EMG (see Figure 2.10). Furthermore, because certain phones have data plans that were available, the user could specify whether they would like the application to use 4G data if wifi is not available. For example, if `upload over mobile network` is not toggled, and wifi is not available, recording captivity will notify the user to discontinue (see Figure 2.13). Other features include the ability to specify which EMG device to pair with, clearing all application generated data, and uploading any data that have not been sent. Though these configuration settings were not used by our participants very much, these were useful in the development phase for zoning out features for debugging. The configuration page is seen in the left image on Figure 2.10.

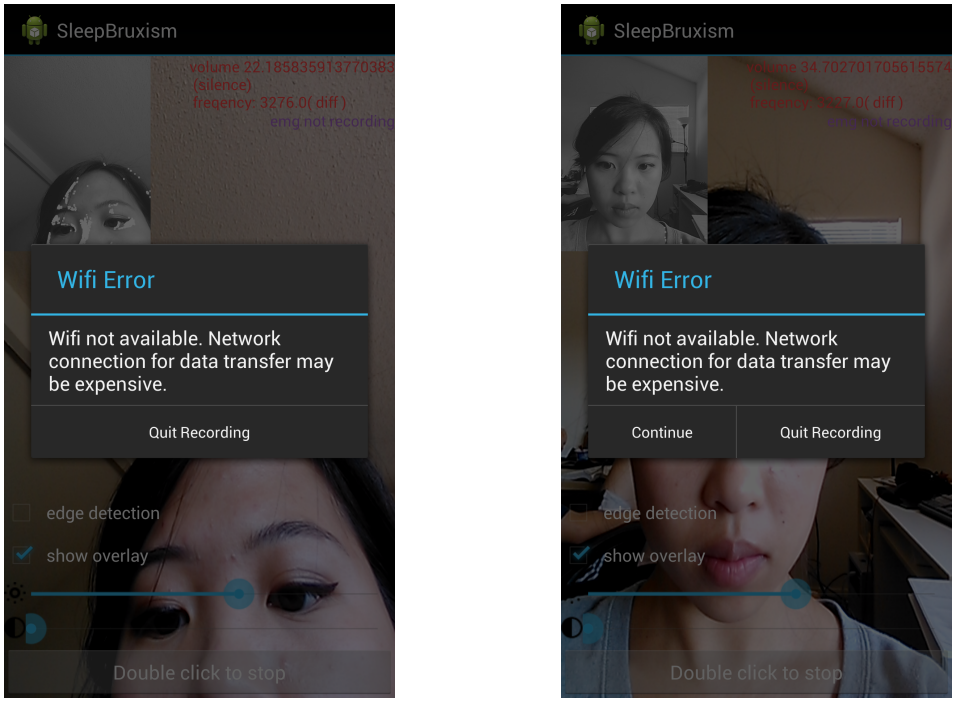


Figure 2.13: Messages above are displayed when WIFI is not available during application launch. `Upload over mobile network` is untoggled in left image, and toggled in right image

The implementation of configuration is through the use of Android API's `SharedPreferences`. `SharedPreferences` is a persistent key/value storage that could be shared across threads in one process. But because `SharedPreferences` is prone to errors, we encapsulated it in our own class called `SynchronizedSharedPreferences`. We will describe in detail in the section below.

SynchronizedSharedPreferences At the main activity level, we first define a class which encapsulates `SharedPreferences` class provided by Android. `SharedPreferences` is an interface for accessing and modifying preferences that is shared across the application. Adding a new key/value pair to `SharedPreferences` without the use of an encapsulating class, requires direct knowledge of the key string, which could result in potential consistency errors in call functions and limit the changeability of the variables. For example, adding a new key/value pair specify-

```
1 SharedPreferences prefs =
      this.getSharedPreferences("com.sleepbruxism.app",
      Context.MODE_PRIVATE);
2 SharedPreferences.editor editor = prefs.edit();
3 editor.putBoolean(``record_audio_toggled'', true);
4 editor.commit();
```

Figure 2.14: `SharedPreferences` set key/value

```
1 SharedPreferences prefs =
      this.getSharedPreferences("com.sleepbruxism.app",
      Context.MODE_PRIVATE);
2 prefs.getBoolean(``record_audio_toggled'', false);
```

Figure 2.15: SharedPreferences retrieve key/value

ing that the user has toggled audio recording for the night to `SharedPreferences`, requires this call in the configuration activity:

As shown in Figure 2.14 and 2.15, there are a few strings that must be shared throughout such as "com.sleepbruxism.app" and "record_audio_toggled". Since our app requires over 10 key/value pairs in the configuration file, it is not only a nuisance to keep the key naming consistent, maintaining the changeability is an issue as well. To overcome this problem, we created `SynchronizedSharedPreferences` to encapsulate `SharedPreferences` and to provide a consistent interface to callers.

As shown in Figure 2.16, `SynchronizedSharedPreferences` is able to control access of `SharedPreferences` – both preventing accidental and unwanted key/value pairs from being generated, and also allowing key names to be changed in a consistent manner. Inclusion criteria for variables to be added to `SynchronizedSharedPreferences` are that it must be used by more than one module, must be editable by either the user or the application (indicated in configuration file), and must be a variable requiring persistent storage. The current key/value pairs managed by `SynchronizedSharedPreferences` are the following:

```
1  public class SynchronizedSharedPreferences {
2
3    public static final String PREFERENCE_FILE_NAME = "globalSettings";
4    public static final String UID = "participant_id";
5    public static final String VIDEO_RECORDING = "video_recording";
6    public static final String AUDIO_RECORDING = "audio_recording";
7    public static final String EMG_RECORDING = "EMG_recording";
8    ...
9
10   public static synchronized SharedPreferences
         getPreferences(Context context) {
11     return context.getSharedPreferences(PREFERENCE_FILE_NAME,
12         Context.MODE_PRIVATE);
13   }
14
15   // VIDEORECORDING//
16   public static boolean getVideoRecording(Context context,
17       boolean defaultValue) {
18     SharedPreferences pref = getPreferences(context);
19     return pref.getBoolean(VIDEO_RECORDING, defaultValue);
20   }
21
22   public synchronized static void setVideoRecording(Context context,
23       boolean bool) {
24     SharedPreferences.Editor editor = getPreferences(context).edit();
25     editor.putBoolean(VIDEO_RECORDING, bool);
26     editor.commit();
27   }
28   ...
29 }
```

Figure 2.16: `SynchronizedSharedPreferences`

- UID
- VIDEO_RECORDING
- AUDIO_RECORDING
- EMG_RECORDING
- UPLOAD_OVER_MOBILE_NETWORK
- USE_FRONT_CAMERA
- ONLY_RECORD_OVER_WIFI
- DEBUG_MODE
- AUDIO_CALIBRATION
- EMG_MODULE_NAME

Overall, this proved to be a very good strategy since it is used frequently in recording module, uploading module, and configuration activity and was kept organized and free of any bugs throughout the development process.

2.6.2 Recording Modules

The recording manager consists of 3 different submodules: audio, video, and EMG. Audio channel records upon noise detection above a certain threshold which is set by the calibration activity. The design goals of these submodules were to achieve acceptable performance and extensibility. Because we had in mind other possible future detection extensions for sleep apnea, night terrors, and other sleep-time disorders, we were cautious in ensuring the separation of data processing and data collecting.

Recording Manager as Activity The recording module was originally implemented as a `Service`, with the intention of allowing the user to use other applications during an ongoing recording. This was fully implemented in Android version 2.2, but we found that Android developers restricted the camera access of an activity that is not currently in the foreground for security reasons. Thus, rendering implementation of recording manager as a service useless. We will go into more detail of this in "Video Module" section.

Audio Module

The design requirements of the audio module are the following:

1. Distinguish meaningful data instead of recording the entire night
2. Ability to apply immediate real-time processing
3. Display audio recording feedback to the user
4. Organize audio recordings that are relevant into one episode
5. Collect accurately timestamped data

Recording in chunks We did not want to maintain an audio file recording of the entire night for a few reasons. First of all, because we had envisioned the possibility of detecting grinding events based on audio recording, we wanted only to store the audio files of each episode for simpler post-processing. Second, we wanted to store uncompressed PCM as WAV files for highest quality recording. Because of the first two restrictions, storing an 8 hour audio WAV file on mobile phone, and later uploading it to the server is expensive in time and space. This is especially relevant to us since we adhered to specified audio recording settings that are guaranteed to work on all devices: 44100 sample rate, `CHANNEL_IN_MONO`, and 16 bit sample sizes. With these settings, each hour of recording is 302MB/hour; a full 8-hour night of recording would create a 2.3GB file. To prevent accumulating such a large quantity of data, we recorded only upon noise detection.

Defining an Episode Carra et al defines a phasic RMMA episode as one that contains at least 3 EMG bursts lasting greater than 0.25 seconds and less that 2 seconds [9]. We translated this definition of EMG episode to an audio episode. Assuming that each EMG burst is accompanied with audible teeth grinding noises, we could apply the definition that an audio sequence contains no more than 2 seconds of silence in between.

Real-time Processing In order to apply immediate real-time processing, we used the `AudioRecord` class provided by the Android API to process the collected audio data in real-time. `MediaRecorder` would have been a simpler option, but since it wrote the data directly to file, it would have prevented us from analyzing the data as quickly as we wanted. We created an `AudioRecorder` class to encapsulate `AudioRecord`, which constantly reads in the next short array of audio data and passes it to listeners. This listener pattern was chosen because it enabled us extend the application to accommodate new listeners for different audio pattern detection. Currently, there are three listeners implemented: one for displaying audio variables on screen, another `SleepBruxismListener` for detecting key audio data and writing to file, and a final one for calibration.

The listener displaying audio variables to the screen is straight-forward. It detects the loudness of each piece of audio sample, performs zero-crossing rate calculation for frequency estimation, and displays this data to the user.

The `SleepBruxismListener` examines each byte array, and upon detection of a byte array with volume above a certain threshold, it writes to file. The audio files we generated were in the waveform audio format (WAV), and were at minimum 3 seconds long. Each file would always be at least 2-3 seconds long according to our definition of an episode. We achieve this by keeping a 1 second window of data collected at all time, with the oldest data constantly being discarded as new ones come in, and 2 seconds of buffer audio at the end. When a noise level exceeding the threshold was discovered, the `SleepBruxismListeners` spawns off a new thread, writes the 1 seconds of pre-recorded data, plus any consecutive byte array

```
1  if (volume > DEFAULT_LOUDNESS_THRESHOLD) {
2    ms_left_to_record = SECONDS_TO_RECORD * 1000;
3    if (!recording) {
4      recording = true;
5      ...
6      writeAudioFile = new WriteAudioFile(this.getAudioVariables(),
           heardTime- tempRecording.getMillisecondsRecorded());
7      pool.submit(writeAudioFile);
8      tempRecording.writeAllToAudioFile(writeAudioFile);
9      ...
10   }
11 }
12 if (recording) {
13   if (ms_left_to_record > 0) {
14     writeAudioFile.put(audioData);
15     ms_left_to_record -= this.getAudioVariables().msPerAudioFrame;
16     ...
17   } else
18     this.stopAudioWrite();
19 }
```

Figure 2.17: `SharedPreferences` retrieve key/value

that has a noise level above the agreed threshold (see Figure 2.17). At this point, a countdown of 2 seconds begins which would continue to write the next incoming byte array regardless whether the threshold has been exceeded. The moment a byte array is detected to be below the threshold after 2 seconds of silence, the WAV file is closed and `SleepBruxismListener` resumes its purely observational function. It is important to note that, this countdown resets every time a byte array exceeds the threshold. With this method, we succeeded in capturing one full episode of phasic bruxism in a single audio WAV file (see Figure 2.18).

WAV File Since Android does not support automatic generation of waveform audio format (WAV) files from `AudioRecord`, we had to implement our own `WavWriter`. WAV files have formatting standards that must be adhered to. The format of the

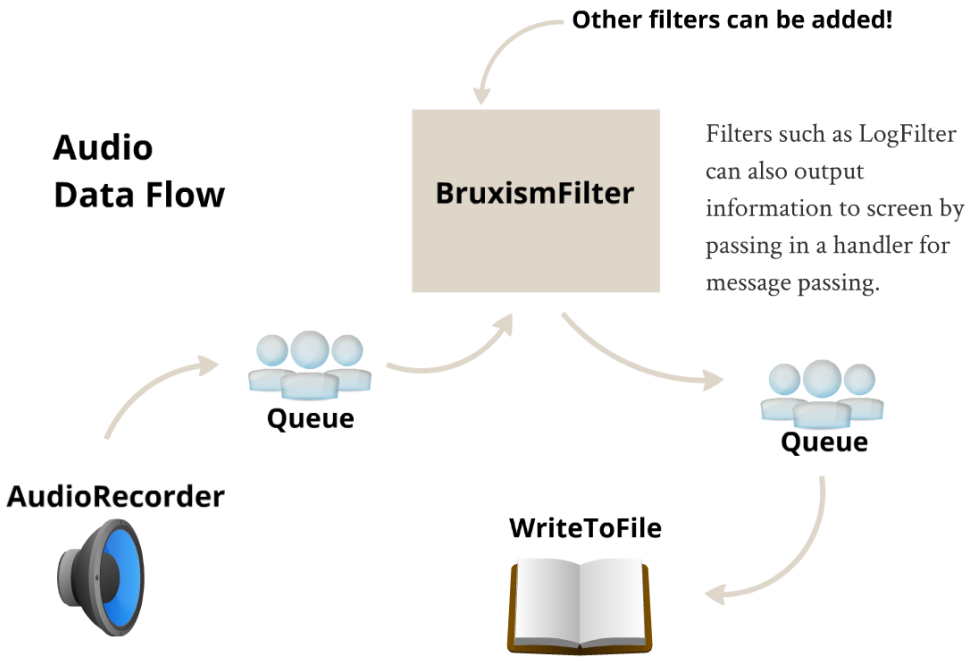


Figure 2.18: Data flow diagram for audio module

data represented in shorts within the WAV file is in little endian, which we accommodated by overriding the `write()` method so that each byte array written is converted to the proper format (see Figure 2.19).

Furthermore, every WAV file requires a header at the very beginning, specifying file attributes such as data length, sample frequency, and number of channels. The total variables required is listed in Figure 2.20. Since certain attributes were unknown until the file closed, our wav file writer allocates a header space at the constructor and fills in the required data when the file is written to disk (see Figure 2.21).

The WAV files are written into a specific folder location with names specifying the epoch time of when the first detection of data exceeding loudness threshold is detected. This proved to be very useful during post-processing when the exact time of data detection is crucial.

```
1  public void writeShortArray(short[] audioData) throws IOException {
2    short reversedData = 0;
3    byte[] buffer = new byte[audioData.length * 2];
4    for (int i = 0; i < audioData.length; i++) {
5      reversedData = Short.reverseBytes(audioData[i]);
6      buffer[i * 2] = (byte)((reversedData >> 8) & 0xff);
7      buffer[i * 2 + 1] = (byte) (reversedData & 0xff);
8    }
9    bufferedOutputStream.write(buffer);
10 }
```

Figure 2.19: `SharedPreferences` retrieve key/value

Endian	File offset Bytes	Field Name	Field Size (bytes)
big	0	ChunkID	4
little	4	ChunkSize	4
big	8	Format	4
big	12	Subchunk1ID	4
little	16	Subchunk1Size	4
little	20	AudioFormat	2
little	22	NumChannels	2
little	24	SampleRate	4
little	28	ByteRate	4
little	32	BlockAlign	2
little	34	BitsPerSample	2
big	36	Subchunk2ID	4
little	40	Subchunk2Size	4
little	44	Data	n

Figure 2.20: WAV Format

Setting Thresholds Because our audio recordings are captured only when a sound is detected, the loudness threshold for setting recording in motion needs to be determined. Ideally, the threshold should be set to pick up the most minimal noise generated by the user. We worried setting a threshold too aggressively would cause us to miss the collection of key audio data. Because of this fear, we consistently leaned towards a lower estimate for our threshold; it was better to have to post-process out unwanted noisy data than to not have the correct data at all. Since the mobile phone is placed a 1-3 feet away from the participant's face, most noise generated by the user is louder than the hum of the room. However, despite the placement of the phone, certain peak noise – such as an ambulance siren in the middle, of the night or the unrelenting alarm clock in the morning – would certainly be collected as well. The threshold we are setting is not same for all our

```
1  public static final int HEADER_SIZE = 44;
2  public WavFile(File file, AudioVariables av) throws IOException {
3    ...
4    try {
5      byte[] header_padding = new byte[HEADER_SIZE];
6      bufferedOutputStream.write(header_padding);
7    } catch (IOException e) {
8      Log.e(TAG, "cannot write header");
9    }
10 }
11 ...
12 public void close() throws IOException {
13     bufferedOutputStream.flush();
14     bufferedOutputStream.close();
15     writeWavHeader();
16 }
```

Figure 2.21: `SharedPreferences` retrieve key/value

users because the placement of the mobile phone will play a role in determining the loudness of user grinding activity. The loudness of grinding will also differ for participants wearing different types of splints.

The threshold is generated by collecting a 20 second sample of the participant's ambient noise room, consisting of 3 teeth clacking noises during the sample time. We then take the amplitudes generated by the 20 seconds of calibration, and set the threshold to one positive standard deviation away from the mean. The three teeth clacking noises is required because we are standard deviations. Without the amplitude spikes from teeth clacking, our threshold will be too low, thus will result in the application recording unnecessary ambient noise.This threshold is then written into a `SharedPreferences` file to be referred to by subsequent activity launches.

Video Module

The design goals of the video module is the following:

1. Maintain acceptable frames per second without too much visible lag.
2. Display processed and unprocessed images to users
3. Capture image frames when movement occurs.
4. Organize collected image sequences into movement episodes, where each episode is defined by movements with less than 2 seconds of stillness between them.
5. Collect accurately timestamped data

The data flow structure employed is very similar to the one used for audio module, where the video module consists of 3 submodules: one for retrieving camera raw data, displaying camera capture onto screen, and another with listeners that process the raw data for each of their own purposes. A movement listener is the only one implemented for this video module, required by the extent of this study. We only needed to capture images when movement is detected. An overview data flow diagram is shown in figure 2.22.

Performance During the design phase of this module, we were concerned about the frame rate. Processing images is fairly CPU intensive and requires a lot of memory, not to mention that this has to be done for every single incoming frame. We wanted to display the processed images and raw camera captures to the user for feedback. To achieve the fps we desired, we had to use multithreaded model. Without it, frame rate would be inevitably slow, with a visible lag. For instance, if we tried to display every processed image on the same thread, the screen would hang as it waits for the image to be processed. Furthermore writing images to disk immediately upon detection of movement would certainly be a bottle neck – especially during an outstanding duration of movement.

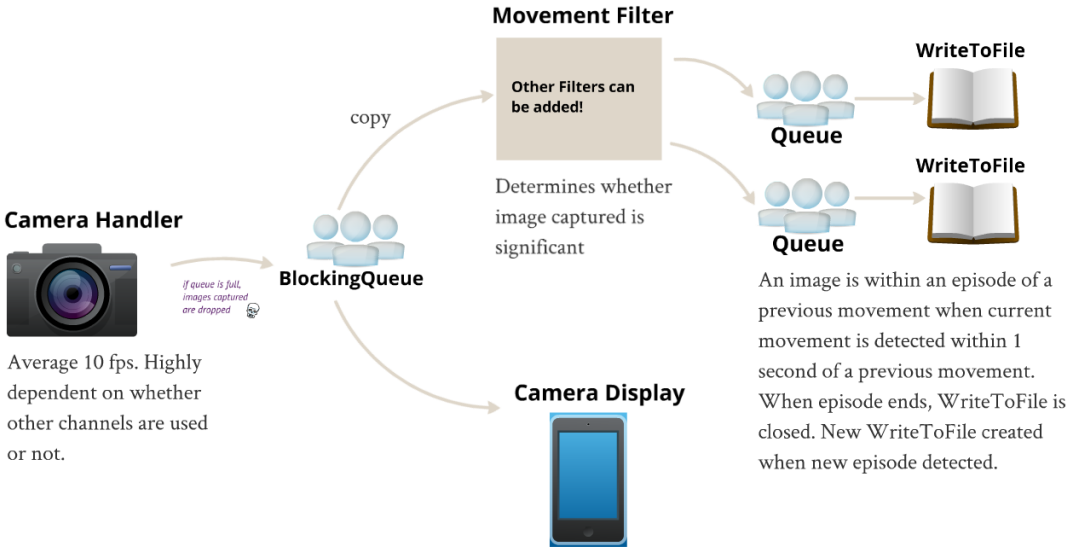


Figure 2.22: Data flow diagram for video module

In order to achieve an acceptable 10 fps with no lag on the images displayed, we created an `EfficientQueue` which enabled sharing of images between many listener threads. Originally, our design consisted of one queue which would notify the listeners if it is not empty, and listeners could then copy out images from this queue. If listeners could not retrieve data in time, and the queue is filled up with another incoming image, the image at the top of the queue is pushed out, and discarded. To mitigate this issue, we separated this queuing such that each listener manages its own queue and determines its own queue size and attributes. Here, the camera handler places images in each of the listener's queue. The downside of this is memory management expense, images are replicated across queues, wasting resources. In the future, if memory management becomes an issue, we should consider reverting back to the original design, and enforce the listeners that requires the full set of data to implement a retrieval system which temporarily stores images for later processing.

We also separately implemented the display of raw camera data and the display of processed images. Raw camera data are displayed in real-time, whereas processed images are inserted into the user's view as they are ready.

```
1  if (edgeCheck) {
2    Imgproc.Canny(current, currentEdges, 80, 90);
3    Core.subtract(currentEdges, previousEdges, edgesMask);
4    Imgproc.threshold(edgesMask, edgesMask, 5, 255,
         Imgproc.THRESH_BINARY);
5    Imgproc.erode(edgesMask, edgesMask, dilate_kernel);
6  }
7  Core.subtract(current, previous, mask);
8  Imgproc.threshold(mask, mask, 5, 255, Imgproc.THRESH_BINARY);
9  Imgproc.erode(mask, mask, dilate_kernel);
10 Imgproc.dilate(mask, mask, dilate_kernel);
11 if (displayOverlay || storeOverlay) {
12   if (edgeCheck)
13     mask = mask.setTo(new Scalar(255, 0, 0), edgesMask);
14   currentProcessed.setTo(new Scalar(255, 0, 0), mask);
15   int count = Core.countNonZero(mask);
16   if (count > MAXIMUM_STILLNESS_THRESHOLD)
17     //movement detected
18 }
```

Figure 2.23: Movement detection

Movement Detection Images are recorded upon detection of movement. Movement is determined by the following steps: First a mask is created by taking the difference of two consecutive image matrices, in order application of thresholding [22], erosion [35], and dilation algorithms [35]. Finally the nonzero pixels of the mask, where zero pixels indicate no movement detection, is counted (see Figure 2.23). If pixels are greater than a certain threshold, then we can deduce a movement has taken place. A more precise method might be to use adaptive thresholding [13] instead, additionally performing canny edge detection and compare the current edges with edges detected from the previous image. However, canny edge detection [8] was not applied in our participants for the study because it detected too much noise, and an abundance of images were collected. Further analysis of the preciseness of these measurements is required.

Defining an Episode Similar to audio recording, once movement has been detected, images will continuously be written to the same episode for up to one second even if no movement is detected. Once a full second has passed, and no movement has been detected during this second, will the episode be closed. This allows us to easily chain a full sequence of movement together. Disk writing is a separate thread that is started for each new episode of movement and closed when the episode ends. The writing thread that has been started will continuously grab files in the queue and write to disk. If there is nothing in the image queue left to be written to disk, it will resume waiting state. Once the episode has completed – 1 full second of no movement detection has passed – the write thread will be closed.

Inability to use `Service` With the later models of Android devices, camera detection is no longer available when the application is not visible. This proved to be a large hurdle to overcome, since we had originally designed all the recording modules to be a `Service` which allow users to interact with their phone during an on-going recording. `Service` is an application component that allows longer-running operations to occur without needing user-interaction. Without the use of `Service`, users are no longer able to use other applications in conjunction with a on-going recording session. More importantly, with a `Service`, the screen for the application could be turned off while the application is running, which helps reduce sleep quality interference. However, by removing the record modules from a `Service`, we had to rethink the initial design requirement, and disallow simultaneous use of our application and another. To allow the screen to be turned off without the application shutting down, we used a `PARTIAL_WAKE_LOCK` to ensure the activity stays active independent of the screen status. `PARTIAL_WAKE_LOCK` ensures that the CPU will run despite the screen or keyboard being turned off. In addition, we also implemented a double click on the back button, at which point a the user will be notified that the activity will be shutting down, so that the inability for our application to be used in conjunction with another is clear.

EMG Module

The EMG module is responsible for collecting essential EMG information from the user and for communicating with the EMG bluetooth device. For this module, we had the following design requirements:

1. Collect accurately timestamped data
2. Clear communication with user regarding status of EMG device

Structure The most challenging aspect of the EMG module is maintaining and communicating the bluetooth states to the user. Data flow structure is straightforward due to small data exchanges of positive integers representing collected muscle activation. Our EMG recording module first tries to discover bluetooth connections that are available int its proximity. Then upon finding the particular EMG unit that it is instructed to pair with, it spawns a thread to connect, and another to communicate data once the connection is successful.

Communication Communication between a user and the Android application on the status of the connection is critical for enhancing user experience. Because the Android application takes a noticeable amount of time to enable bluetooth, discovery and then connect to the external device, the application must provide visible status feedback to the user. We achieved this by implementing an overlay screen which is displayed with appropriate messages while the application is waiting for the EMG to connect (see Figure **??**). Once a connection is properly established, the overlay is removed to provide a cue to the user that app is ready to continue.

Furthermore, since the EMG unit is an external component, the connection is dependent on user's interaction with both devices, which could lead to many potential user errors. Error and status messages must therefore be communicated clearly. For example, if the user starts the application without turning on the

EMG unit, then our application notifies the user that EMG device is not found, suggesting user to check if the EMG unit is turned on. If the EMG unit is turned off while the application is on and connected, a message of unexpected termination is be presented to the user. To provide these visual cues to the user, we relied on the `LocalBroadcastClass` provided by the Android API. Because all interaction with views must be on the designated view thread, LocalBroadcast allows us to communicate to the view thread from our EMG connection thread. The state diagram is presented in Figure 2.24. Strings in red are each assigned a specific message to display to the user.

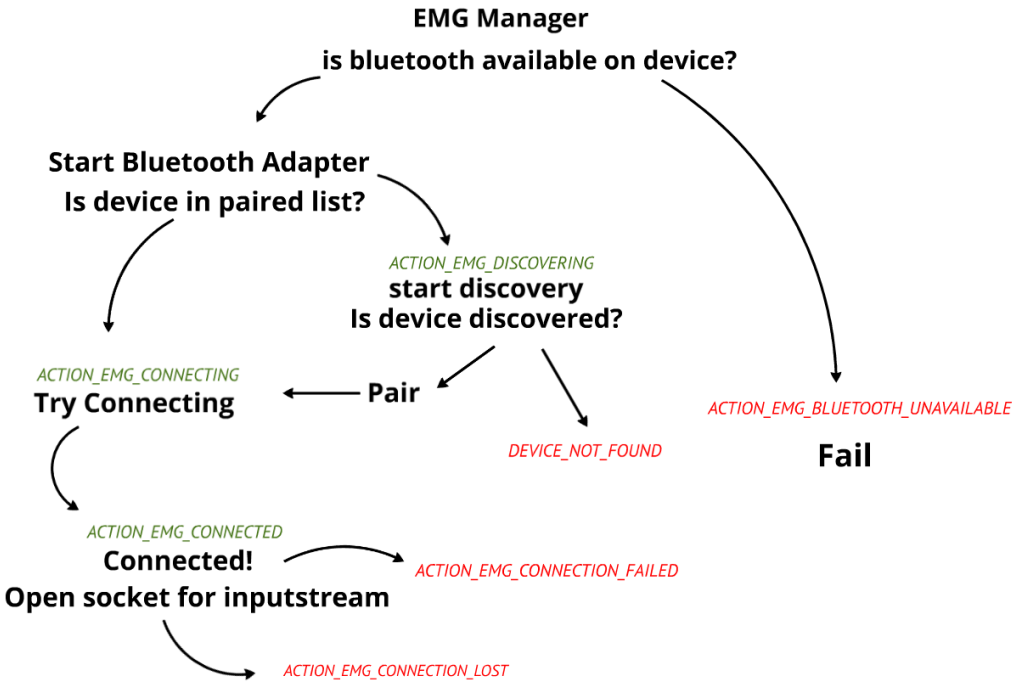


Figure 2.24: State diagram for EMG module

2.6.3 Uploading Modules

The uploading module is responsible for uploading the collected audio, video, and EMG data to the server. This module runs independently of the recording module. The requirements of the uploading module is the following:

1. Run throughout the day, independent of whether the recording activity is on.

2. Upload EMG, Audio, and Video files to the server

3. Communicate clearly the availability of uploads to user

Upload as a Service We found it imperative that the uploading module must be able to run despite the status of the activity because if wireless connection disconnects, or if the large amount of data could not be uploaded in time, the user should be able to upload the remaining data during the day at a more convenient time. To support his feature, uploads of all channels (audio/video/EMG) are implemented within a single `Service`, which constantly runs in the background. There are two modes for the upload, one which terminates when all files have been uploaded, and another which terminates only when commanded. While recording is on-going, the former mode is used. When the recording terminates, the mode is then switched to the latter. There is also an `upload_content` command in the configuration activity, allowing the user to upload all remaining content in the folder, by hand, when desired.

The posting of data is currently uploaded via the HTTP protocol POST request method. The protocol takes up to 2MB of file attachment and a unique user id (see Figure 2.27). Once uploaded, the server returns a success message in JSON. Because the communication with server is synchronous, a pool of threads uploading to the server is required for performance reasons.

```
1  <h1>upload images</h1>
2  <form action="/SleepBruxismApp/upload_images/" method="post"
       enctype="multipart/form-data">
3  <p>
4  <label for="id_participantID">Participant ID:</label>
5  <input id="id_participantID" name="participantID" type="text" />
6  </p>
7  <p>
8  <label for="id_file">File:</label>
9  <input id="id_file" multiple="true" name="file" type="file" />
10 </p>
11 <input type="submit" value="Submit" />
12 </form>
```

Figure 2.25: Image post form

Interface As mentioned, posting and recording modules do not communicate with each other, but they do require to agree on same protocols. A set of interfaces define where the recording module stores the data, where the posting module retrieves the data to be sent, and whether a file in the path is complete and ready to be sent to server. This interface is defined by the "main activity" program which initiates both the recording and posting module. The posting module can be called on any device with full functionality as long as the paths required are configured properly.

The posting module must define methods to upload audio, EMG, and video data. Specifically, this module must define:

1. Where to locate files.
2. The status of the file ready to be sent to the server.
3. The number of files to send to the server.

`AudioPost`, `EMGPost`, and `ImagePost` has are created specifically to address the first two issues. When these modules are instantiated, the parameters required

include the file path to respective folder. Thus, these modules know the location of the files. Because each channel (audio/video/EMG) storage uses different formats, the posting modules need to be aware. For example, image files are organized in a way such that all images that fall within the same episode are listed under an episode directory, where the directory name is the epoch timestamp of when that episode was first detected. On the other hand, because each audio file is already one single episode, they are all simply stored directly under one directory. To address the second issue, all the of the recording modules are required to a static function called `isFileCompleted()`. These functions are called by their respective posting modules to ensure that files are ready to be uploaded. As currently implemented, any file with ".txt" extension is not ready to be uploaded. The number of files to send to the server must be determined dependent on the type of files to upload. For example, image files could be posted 30 at time, whereas the number of audio file that can be posted is dependent on the size of the audio files combined.

Overall, for each posting module, the steps for uploading are the following:

1. Traverse through path given and look for files to upload.
2. When a file is found, check if `isFileCompleted(file)` is true. If It is false, it could be one of two things: either file is not ready to be uploaded, or file is not in the right format and possibly generated by the operating system.
3. If file is ready to be sent out, put them into a pending list, ready to be uploaded when the size of the list is full.
4. Once upload is successful, remove the files uploaded from the mobile phone.
5. If `stopPosting()` has been called, upload all remaining files in the pending list.

To support step 3, we designed an uploading manager called `BatchPost` (see Figure 2.27). This uploading manager takes in any number of files, and uploads the files whenever is necessary. To use this manager, the uploading module

```
1  public boolean flush() {
2    me = new MultipartEntity(HttpMultipartMode.BROWSER_COMPATIBLE);
3    boolean success = false;
4    if (postedFiles.size() > 0) {
5      for (File f : postedFiles)
6        me.addPart("file", new FileBody(f));
7      me = postManager.addAdditionalPostVariables(me);
8      if (postData.post(me) == PostData.MESSAGE_SUCCESS) {
9        bytes_posted = deleteFiles(postedFiles);
10       for (PostChunkyFileListener p : listeners)
11         p.onPostCompletedDataSize(bytes_posted);
12       ...
13       postedFiles.clear();
14       success = true;
15       }
16     ...
17   } else {
18     success = false;
19   }
20   ...
21 }
```

Figure 2.26: BatchPost calls flush to upload files contained in a list to the server

will call `submitFile(file)` when it discovers a file that is ready to be uploaded. `BatchPost` will keep track of the size of submitted files, and once they hit the maximum size, it will flush the submitted files by uploading them to the server. If files are uploaded successfully, `submitFile(file)` will return true. In order for uploading modules to call this manager, they must implement a required interface which allows the uploading modules to append additional information to the upload. For example, an additional variable required in all posts is the user's identification number. The function required by this interface, `addAdditionalPostVariables(MultipartEntity me)`, is called by `BatchPost` right before any uploads occur.

```
1  public boolean submitFile(File file) {
2    boolean flushed = false;
3    totalFileSize += file.length();
4    if (totalFileSize >= MAX_SIZE) {
5      flushed = flush();
6      postedFileSize = file.length();
7    }
8    postedFiles.add(file);
9    return flushed;
10 }
```

Figure 2.27: Once files in list near 2MB BatchPost calls flush to upload files to server (see Figure 2.26)

2.6.4 Server Design

We serve our files using the standard Apache HTTP Server, running a Django web application (https://www.djangoproject.com/) with uploaded file paths stored in a MySQL Database. The files are actually stored in a static folder on the server, while the path to those files are contained in the database. The EER diagram of the database is depicted in Figure 2.28.

Audio and EMG data are uploaded without much need for organization: each audio episode is presented in one single WAV file, while EMG data for the entire night is captured in one single file. Image files are not uploaded grouped by episodes, thus these episodes need to be reconstructed by the server. Because the naming scheme of the uploaded files for images are meaningful, the server would only need to parse the timestamp of the episode and the timestamp of the particular image from the title. By using these two variables, the images can be grouped into correct episodes.

Once grouped into episodes, with paths stored in the database for quick access, data for each of user can be displayed in a way which facilitates readability in the browser. For example, in Figure 2.29, a researcher could easily filter for

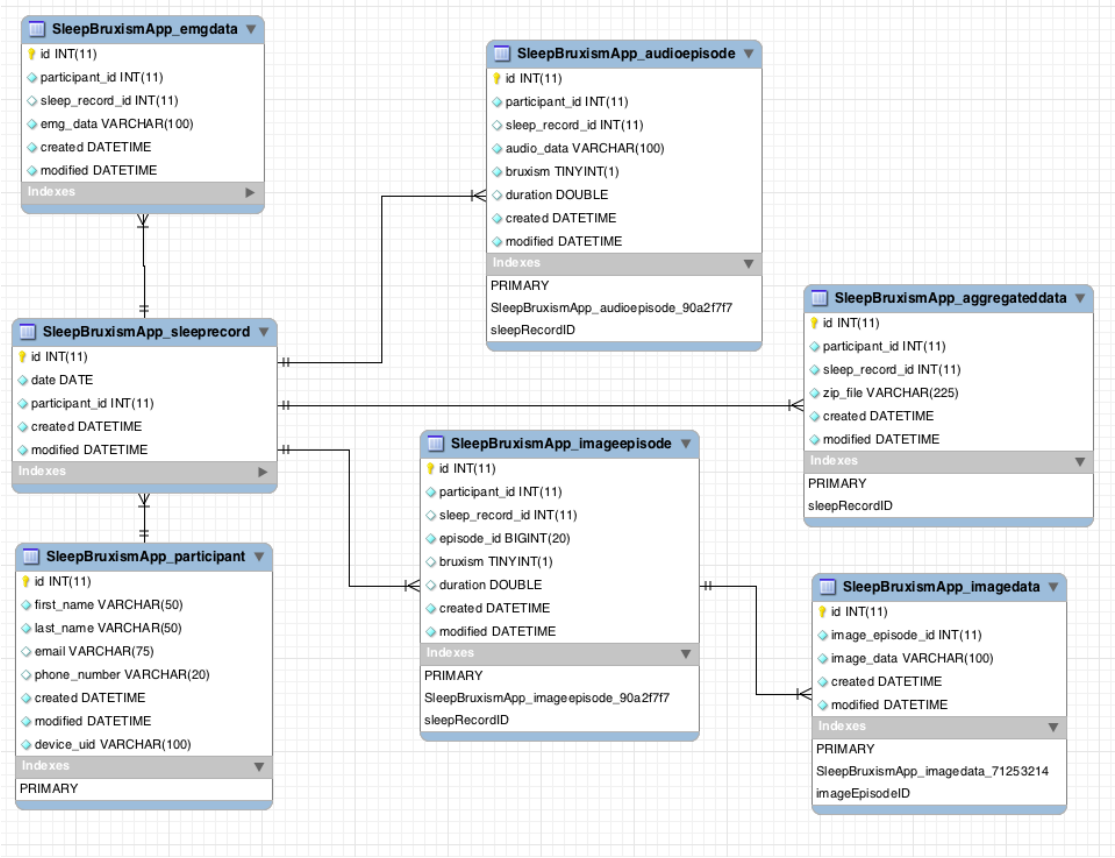


Figure 2.28: EER Diagram

audio data of a particular subject, on a particular night's recordings, and listen to episodes that are toggled as containing sleep bruxism patterns. Other types of filters to capture interesting data could be implemented on this framework.

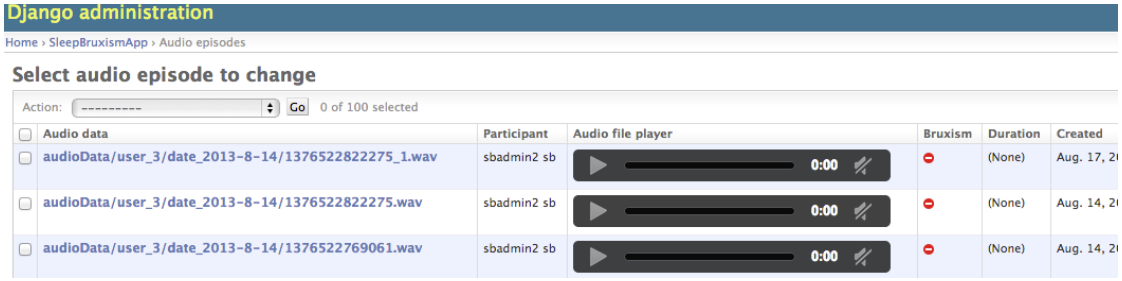


Figure 2.29: Web view

Chapter 3

Sleep Bruxism Data

In this section, we will discuss our initial results, and our methods for analyzing the collected data.

3.1 Participants

A total of 6 participants, 4 male and 2 females, were evaluated using GrindCare®. Two of the participants, 1 male and 1 female, did not meet our participant selection criteria (see Section 2.2) because the GrindCare® measurements reported less than 25 EMG episodes on all three nights. We must emphasize that this is not necessarily a clear indication of the absence of sleep bruxism. A patient with sleep bruxism does not necessarily exhibit teeth grinding every single night. In addition, none of our participants were able to record 3 full nights of measurements using GrindCare® because the gel pads did not adhere to their temporal region correctly. However, we admitted participants as long as there was one night of full recording indicating 25+ episodes. In total we had 4 participants in our study, 3 male and 1 female. We collected full audio, video, and EMG data for a total of 7 nights from each participant, a total of 224 hours.

3.2 ChronoViz Data Visualization

In order to replay all the channels of collected data from a particular subject on any given night, we used a visualization tool for time-coded data called ChronoViz developed at UCSD by Adam Fouse et al. [29]. ChronoViz allows us to import different types of data, align data by timestamps, and re-play the events in synchronously (see Figure 3.1). To import the data we collected, we generated an XML `ChronoVizTemplate`. This XML is specified by ChronoViz and allows researchers to open just one file and create a new ChronoViz session displaying the synchronized recorded files.

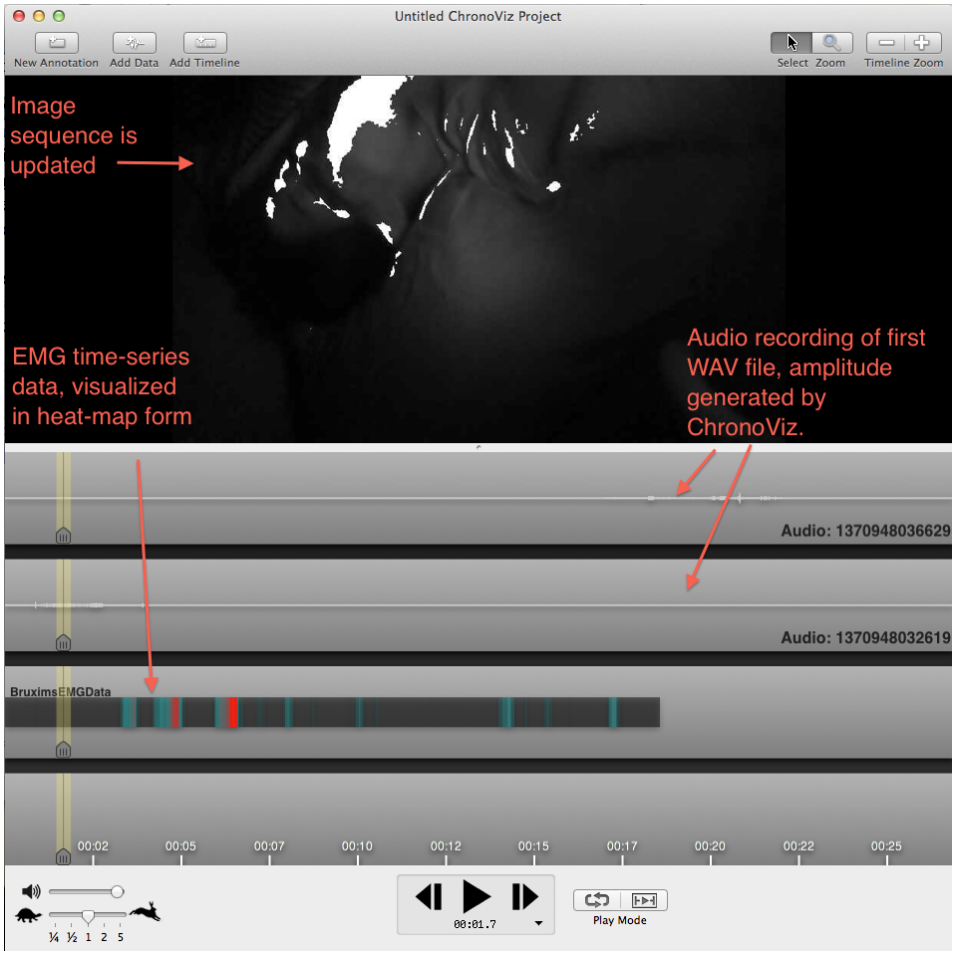


Figure 3.1: ChronoViz visualization showing synchronized audio, video, and emg data

In our case, the types of data we needed to visualize were EMG, audio, and video recordings. The EMG data was described in a separate CSV document, with columns timestamp and data. Video data was described in a CSV file as well, with columns timestamp and image file path. The two external CSV files were then linked into the `ChronoVizTemplate`, with description of the kinds of data they represented. Because Chronoviz required audio files to be linked directly in `ChronoVizTemplate`, we did not need to create a separate CSV file for audio timestamp and path. The details of this process will be described in sections below.

3.2.1 Video

The specification of ChronoViz required that `ImageSequence` data types are defined at the beginning of the playback. Because our application does not ensure that all 3 channels begin at the same time, we needed to adjust the timestamp of each data-set so image sequence defines the beginning. In order to achieve this, we performed a search over the collected data to determine the earliest start-time. If the earliest start time is not generated by a video image, we insert a blank video image at the discovered earliest start time.

To achieve accurate image synchronization, we adjusted all the absolute timestamp of data collected to a relative timestamp offset by the earliest start time. For example, if the earliest start time is 8:12:11, an image timestamped at 8:22:13 would have a relative timestamp of 0:10:02.

In order to adjust our data to display a sequence of images in ChronoViz, we provided a CSV file specifying each image path and timestamp of image detection. Our server stores the images in paths such as this `imageData/user_11-/date_2013-8-20/1377020551363/1377020551382.jpeg`. In this example, `1377-020551363` specifies the start of an episode of movement, and `1377020551382` specifies the timestamp of this particular image. To generate the relative time for each image, the latter timestamp is transformed by offsetting the earliest start time.

```
<dataSource>
  <filePath>image/chronoviz_image.csv</filePath>
  <type>CSVDataSource</type>
  <timeCoding>Relative</timeCoding>
  <startTime>00:00:00.000</startTime>
  <timeColumn>timestamp</timeColumn>
  <dataSets>
    <dataSet>
      <variableName>data_path</variableName>
      <dataLabel>InfraredBruxismImages</dataLabel>
      <dataType>DataTypeImageSequence</dataType>
    </dataSet>
  </dataSets>
</dataSource>
```

Figure 3.2: Image sequence inclusion for ChronoVizTemplate

This relative time is then written into a CSV file called `chronoviz_image.csv` along with the path to the file. Once `chronoviz_image.csv` has been generated (see in Figure 3.3), we included its path and datatype in `ChronoVizTemplate`. Figure 3.2 shows the final XML snippet included in the `ChronoVizTemplate`.

3.2.2 Audio

Our application produces hundreds of audio files per night, with each file containing potential grinding episode. In order to adjust the audio files to fit the visualization tool, we reduced the number of audio files included by concatenating audio files that were less than 20 minutes apart. The time difference between two audio files was filled in with a silent buffer. Furthermore, we ensured that each concatenated file were at most 30 minutes in length to allow us to quicker access to the files.

In order to support concatenation of the audio files, we first generated a CSV file specifying relative start time, duration, and length of silent audio needed

timestamp	data_path
00:00:00.000	1374644646056.jpeg
00:00:00.415	1374644646471.jpeg
00:00:00.719	1374644646775.jpeg
00:00:00.978	1374644647034.jpeg
00:00:01.289	1374644647345.jpeg
00:00:01.561	1374644647617.jpeg
00:00:01.807	1374644647863.jpeg
00:00:02.095	1374644648151.jpeg
00:00:02.394	1374644648450.jpeg
00:00:02.672	1374644648728.jpeg
00:00:02.967	1374644649023.jpeg
00:00:03.235	1374644649291.jpeg

Figure 3.3: ImageSequence specification for Chronoviz. Note that the earliest start time is always 00:00:00.000.

for each audio file. This CSV file generated is called `audio_record.csv` and is shown in Figure 3.4.

index	actual_epoch	relative_timestamp	relative_chrono_epoch	relative_chrono_ts	ms_of_file	filename
0	0	00:00:00.000	1137	00:00:01.137	22000.0	/home/sbadmin/sleepbruxism/uploaded_me
blank	22000.0	00:00:22.0000	23137.0	00:00:23.1370	5023.0	blank
1	27023	00:00:27.023	28160	00:00:28.160	3000.0	/home/sbadmin/sleepbruxism/uploaded_me
blank	30023.0	00:00:30.0230	31160.0	00:00:31.1600	3973.0	blank
2	33996	00:00:33.996	35133	00:00:35.133	3000.0	/home/sbadmin/sleepbruxism/uploaded_me
blank	36996.0	00:00:36.9960	38133.0	00:00:38.1330	6066.0	blank

Figure 3.4: CSV file specifying relationship of audio files

Then, we concatenated audio files by iterating through the `audio_record.csv`, collecting the frames from recording into a concatenated audio file, buffered by silence. The visualization tool automatically generates amplitude files for each of the audio samples included. However, because of the silence buffer we included, the concatenated audio file became too large and unwieldy. To work around this issue, we generated our own timestamped audio amplitude from the audio files,

```
#emg.csv
...
1374645268670,   1,3,1,4,1,
1374645268677,   1,8,4,4,3,7,8,8,5,7,7,10,10,8,
1374645268678,   8,11,9,12,
1374645268679,   10,9,11,
1374645268707,   10,9,9,11,9,12,9,10,8,8,8,7,7,6,5,4,4,8,7,9,10,13,15,
...
```

Figure 3.5: EMG output from Application. Note that the number of columns vary due to selective streaming and communication speed

and included those as type data series in the `ChronovizTemplate` instead of the audio WAV files themselves.

3.2.3 EMG

The EMG file produced by our application is a CSV file with timestamp and EMG data columns (see Figure 3.5). The timestamps provided in the EMG data is recorded in POSIX time, in millisecond units. To control the size of the generated EMG output file, we designed the EMG device to communicate with the mobile phone only when positive muscle activity is detected. Therefore, the size of the data columns vary partially due the EMG device streaming selective data, and partially because detection speed varies in the hardware.

Formatting Output To better visualize our data, we expanded the timestamps to accommodate data that falls beyond column two. Our choice was to display only the data collected in the first data column, but we realized that the remaining data is valuable in describing an ascending or descending trend. In order to expand the data, we could spread the data evenly across the difference between the current timestamp and the next timestamp, but because zero values are not transmitted, there could be minutes of zero values between the current timestamp and the next one causing our data to be severely altered. Instead, we noticed that during high

```
#chronoviz_emg.csv
...
00:10:22.614000,   1
00:10:22.614166,   3
00:10:22.614332,   1
00:10:22.614498,   4
00:10:22.614664,   1
00:10:22.614830,   0
00:10:22.621000,   1
00:10:22.621066,   8
00:10:22.621132,   4
00:10:22.621198,   4
...
```

Figure 3.6: Sample `chronoviz_emg.csv` offset by start time of video images and values expanded

concentration of muscle activity, timestamps are frequently one millisecond apart from each other. Therefore, we decided to spread the recorded that across one millisecond. If there were 10 values in a row, then we would pair each value with a timestamp offset by 10/1000 milliseconds multiplied by the position of the data (see Figure 3.6).

3.2.4 Discussion

We collected 28 nights of recorded data, totaling up to 224 hours. In total, we have gathered over a million EMG data points, 170,000 images of movement, and 12,000 snippets of audio recording form our participants over the course of 7 nights. In order to characterize sleep bruxism in terms of the three data channels we recorded (EMG, video, and audio), we would need to analyze all of this data and look for correlations between the signals.

An initial analysis of the collected data shows that audio and EMG follow similar patterns. Specifically, we discovered consistent pattern by comparing EMG and audio amplitude (see Figure 3.7). As shown in the Figure 3.7, spikes in EMG

activity frequently occur in conjunction with increased audio amplitude. Although still based on preliminary data analysis, and a subset of data, this finding demonstrates that it is potentially feasible to detect instances of grinding events using audio and images.

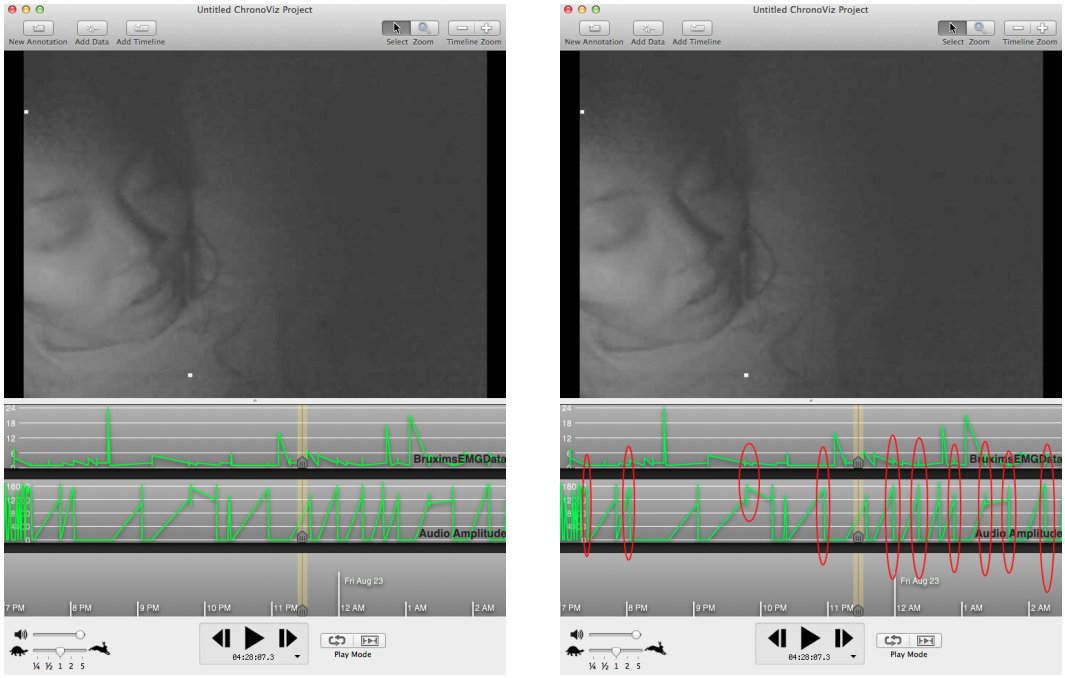


Figure 3.7: EMG and audio data follow similar patterns which is highlighted in red

When we take a closer look at some of the spikes in EMG and audio, we can visually see a bruxism event taking place. Figure 3.8 and Figure 3.9 shows series of images captured during a bruxism episode in one of our participants. The white mask over the images are areas of movement.

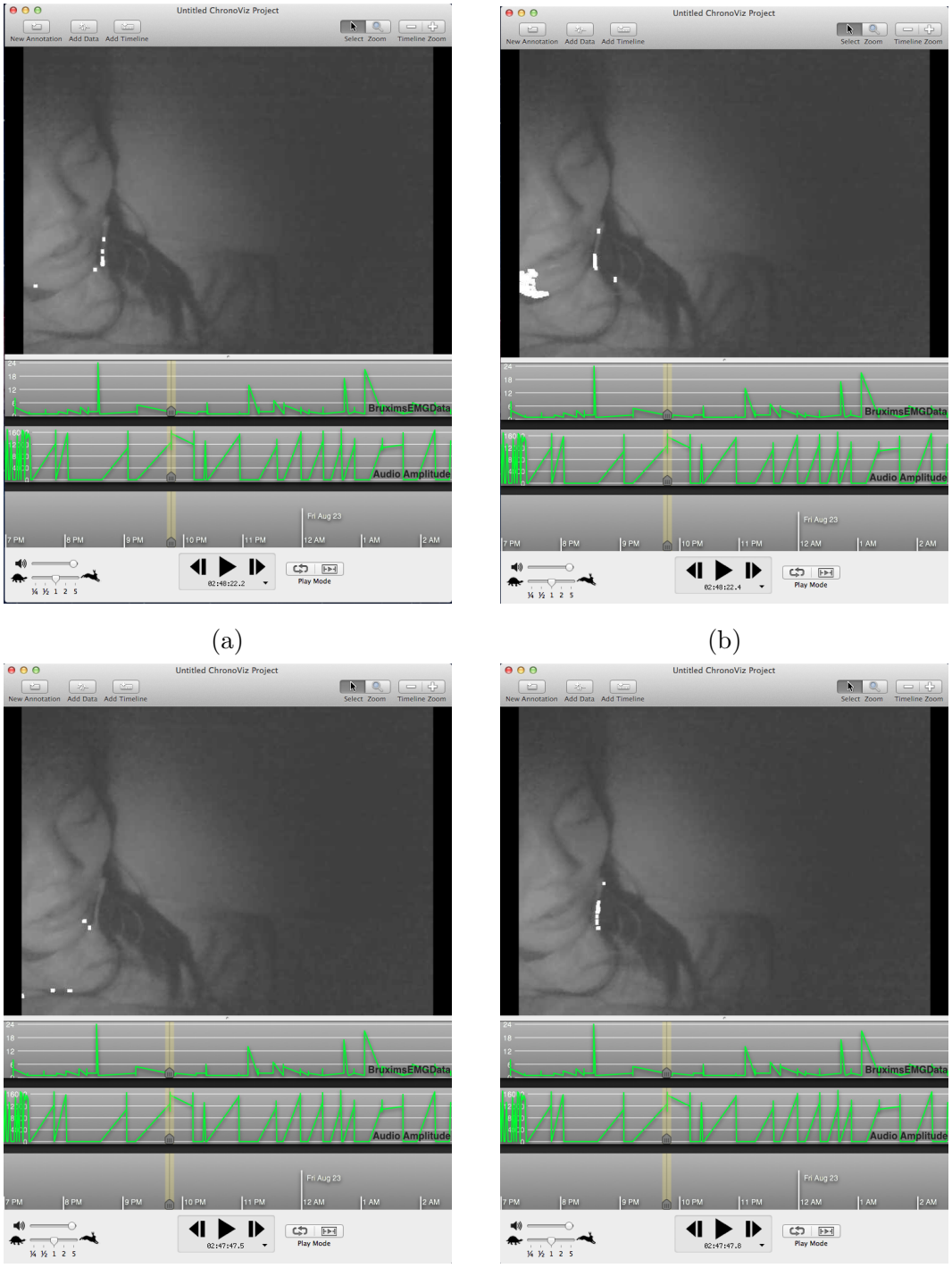
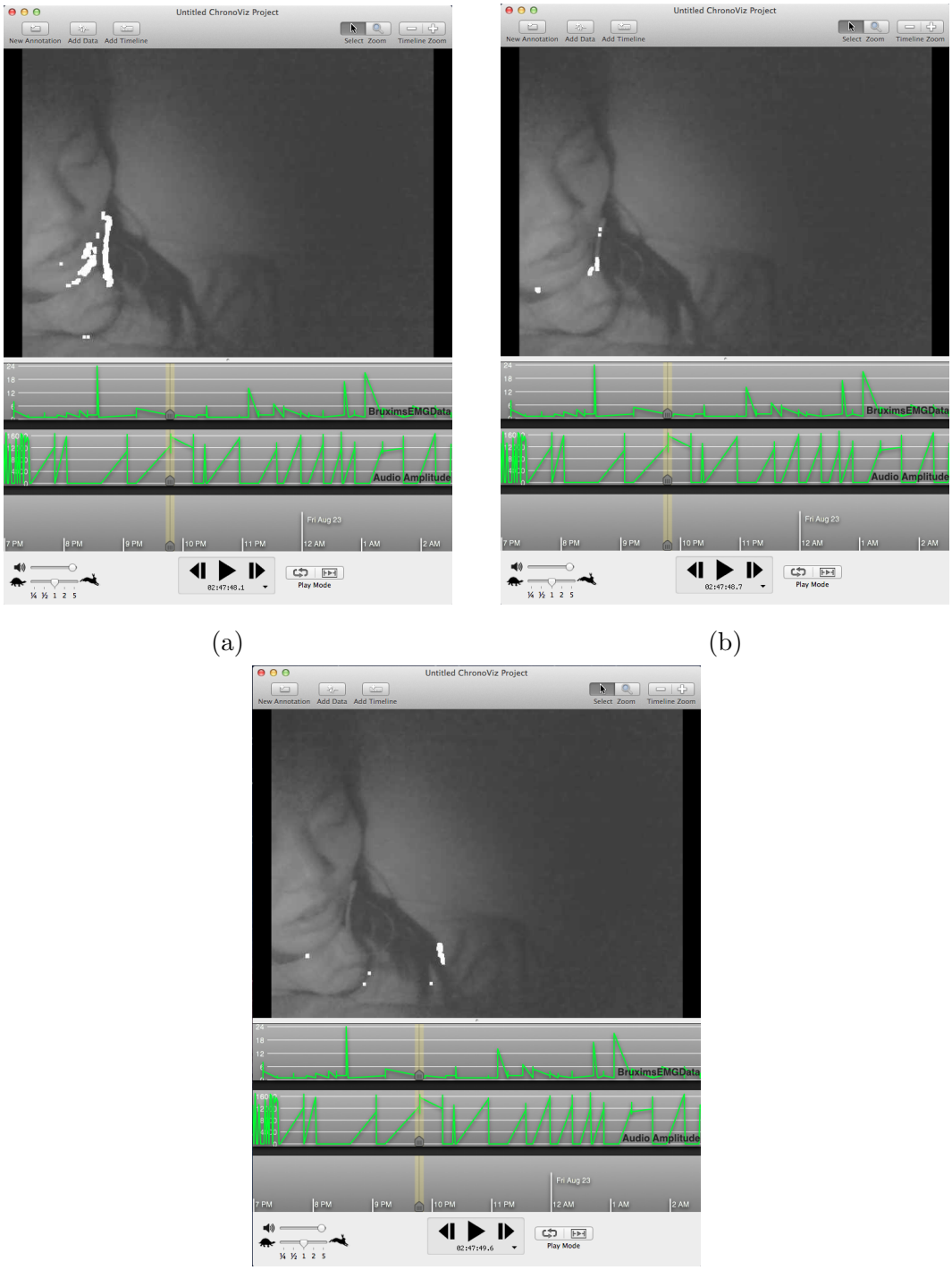


Figure 3.8: Images in an episode visible sleep bruxism. White pixels represent area of movement. Note the similar patterns in amplitude and EMG data spikes.



(a) (b)

(c)

Figure 3.9: Continuation of Figure 3.8. Images in an episode visible sleep bruxism. White pixels represent area of movement. Note the similar patterns in amplitude and EMG data spikes.

Chapter 4

Discussion, Conclusion, and Future Work

The present study was designed to examine if sleep bruxism detection is feasible via mobile devices. We have found that the use of mobile devices for sleep bruxism detection is feasible and is worth examining despite some shortcomings.

4.1 Discussion

As presented in Chapter 3, we believe that sleep bruxism monitoring and detection is feasible with mobile phones. Our system has shown that we are able to capture sleep bruxism events throughout the night using audio, video, and EMG recording. Paired with the visualization generated by ChronoViz, such a system could be beneficial for research and clinical uses.

Our system would provide a relatively cheap and accurate method of monitoring sleep bruxism over prolonged periods of time. Especially as mobile phones are becoming more ubiquitous, our application could potentially be run on any Android mobile phones, thereby lowering cost of purchasing additional hardware. As discussed in Chapter 1, the current tools for sleep bruxism assessment for clinical and research settings are limited. Though polysomnography with full audio

and video recording is the gold standard, it is financially costly and time consuming. This limits the use of polysomonography to smaller clinical trials and studies with a smaller sample set. Ambulatory EMG monitoring devices are good for moderately-sized studies, as they are a little less expensive. However, such devices monitor only one channel, and are unable to accurately distinguish between sleep bruxism activity and non-specific sleep bruxism motor activities such as swallowing and sleep talking. Questionnaires and clinical examination are the most commonly used for large studies, however, these techniques are unable to provide detailed information on sleep bruxism.

Furthermore, the possibility of using audio signal processing to detect the occurrences of sleep bruxism is promising due to the similar patterns with EMG data as recorded by our system. If we could achieve detection of sleep bruxism using only the audio recording channel, this application could provide patients with sleep bruxism a cheap and non-invasive way of tracking their own condition. Currently, there are few tools that a patient with sleep bruxism could use to monitor themselves at night. Such tools are Bruxcore® (http://www.bruxcore.com) and GrindCare® (http://www.grindcare.com), and both require purchasing expensive hardware for sleep bruxism monitoring.

4.1.1 Shortcomings

There are many aspects of our software/hardware design that could be improved for future studies. Our immediate step is to analyze the data that we have gathered more carefully. We could analyze our data by reviewing all 224 hours of recorded EMG, audio, and video in ChronoViz, and annotating the occurrences of sleep bruxism, tossing, and sleep talking. Once these large data sets have been fully annotated, we could purely examine the recordings of sleep bruxism and find the correlation between EMG, audio, and video data sets.

Hardware Development Though the EMG unit we have developed is not sensitive enough to be suited for clinical use, it meets the requirements for our exploratory study. However, because the placement of the electrodes is not precise (our participants estimates their own placement), and different units have slightly different EMG sensitivity, we are unable to perform cross patient EMG data analysis.

The battery supply of our EMG unit is also very limited. Most of our participants commented that the bulkiness of the EMG unit and electrodes prevented them from tossing and turning during their sleep. One participant even brought up her concern on being tangled by the electrode wires while sleeping. Methods of minimizing the EMG unit needs to be examined. One ground-breaking research in the UCSD Neural Interaction lab (http://coleman.ucsd.edu/), directed by Dr. Coleman, is epidermal electronics that is capable of monitoring EMG activity [49]. If this could replace the EMG device that we have developed, not only would it be more comfortable for users to wear, but it would also reduce the additional stress caused by being attached physically to a device.

In the future, in addition to improving the EMG device hardware in general, we should also explore generating microsecond timestamps for each EMG data collection. This would result in more accurately timestamped measurements.

Software Development The software of our system could be improved by focusing even more on user interaction. Especially because there is an additional external device that needs to be used in conjunction with the mobile phone, the system might be unintuitive to the user. For example. one of our participants found that the status updates of the EMG module on mobile device is unclear. Instead of pairing with the EMG module via sleep bruxism application, he tried to pair with the mobile phone's bluetooth settings. This caused our application to miss his EMG data collection for the first few nights as it was unable to pair properly. In the future, we need to improve the status updates of the EMG connection, and perhaps provide a tutorial screen overlay.

Other methods of improvement would be to observe user interactions in focus groups. This would be helpful in discovering users understanding of our software, the time it takes to learn how to operate the application, and also pitfalls in our user interface designs. In our study, each participant was given a detailed instruction manual and an in-person demo of the application, and then sent home with all the equipment. Thus, we were unable to observe the user's initial interaction, and therefore, was not able to improve on creating a user-centric UI design. This is especially important if this tool is to be used primarily by individuals with sleep bruxism.

Visualization Tool There are many limitations on data analysis due to inability of visualizing large quantities of audio data. Though data has been collected, we must find more suitable tools for visualization which supports audio playback of hundreds of short WAV files. Currently, ChronoViz is unable to load the numerous audio data that is required for our purposes. However, an update is currently pending. In addition, we should also explore other audio formats that are more compressed than WAV file with PCM encoding.

4.2 Future Direction

There are many potential benefits for having a cheap and accurate tool for monitoring sleep bruxism events. In this section, we will evaluate both immediate and long-term potential future directions.

4.2.1 Analysis

The most obvious step forward is to perform an in-depth analysis the data that we have collected. A brief examination of an audio file of teeth grinding noises shows that there are potential patterns that could be detected/classified.

An approach to collect the audio files we have on sleep bruxism episodes is to decompose the signal to find what the optimal features would be for extraction and classification. A basic preliminary analysis of sleep bruxism audio sample shows that, for this particular patient, the grinding noises appear to occur in very regular bursts with 3K Hz containing the most energy (see Figure 4.1). This pattern and frequency is most likely only relevant to this particular patient and we need to collect more audio data of grinding occurrences.

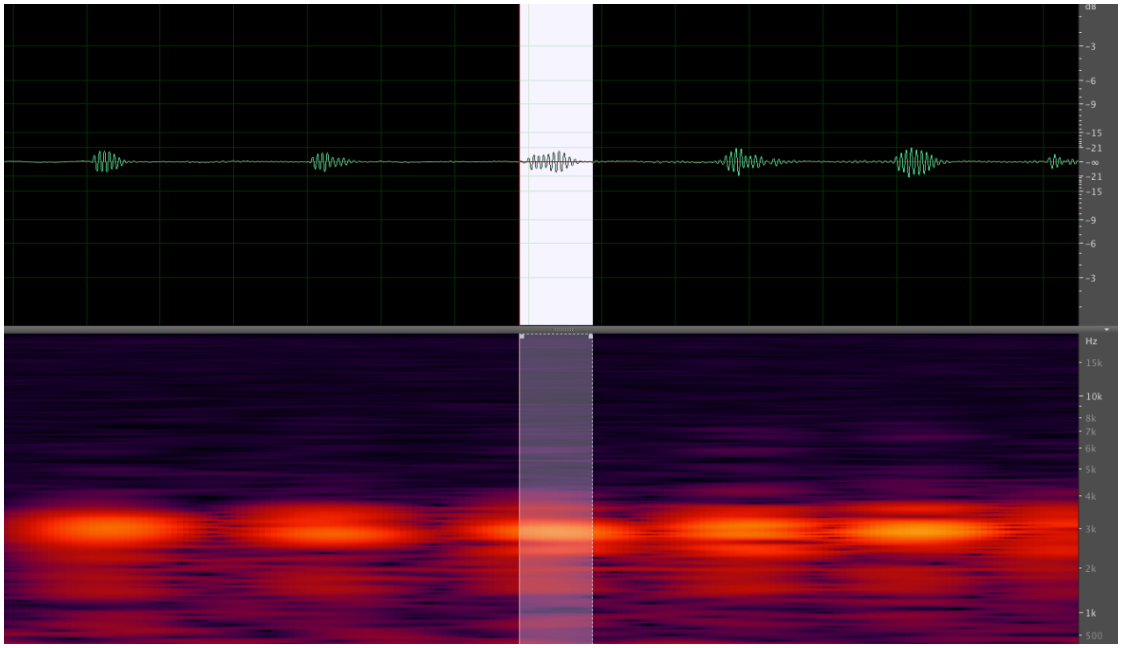


Figure 4.1: Fourier transform of a grinding episode. Notice that the bursts occur with 3K Hz containing the most energy in a very regular pattern. Such patterns could be useful in classification of grinding noises.

4.2.2 Pre/Post-sleep Questionnaire

Questionnaires are simple ways to examine exogenous factors that may affect sleep bruxism over a prolonged period of time. In the future, we could include pre-sleep and post-sleep questionnaires directly into our mobile application during a longer-durational study to examine effects of internals and external factors.

For example, a pre-sleep questionnaire could record the stress level, caffeine intake, alcohol consumption, and medicinal use of participants at bedtime. These data could then be examined in parallel with the measured sleep bruxism data. This could be helpful in locating long term relationships between these exogenous factors and sleep bruxism. Especially since many studies have shown that there is a relationship between sleep bruxism and stress sensitivity, anxiety, and even personality, (see Section 1.4), we could examine the effect increases in stress and anxiety has on sleep bruxism.

Post-sleep questionnaires are especially useful for monitoring the user's sleep quality. Well-known sleep assessment questionnaires such as the Pittsburgh Sleep Quality Index [6], Epiworth Sleepiness Scale, Leeds Sleep Evaluation Questionnaire could be applied as a post-recording pop-up activity. If a treatment for sleep bruxism is being evaluated, the results of these indicators could signal when sleep quality declines. We have outlined a second phase in our research design for sleep bruxism intervention using olfactory stimulation (see appendix A). Post-sleep questionnaires would be useful in providing daily information a patients' sleep quality, helping us monitor and ensure that patients do not experience excessive daytime sleepiness.

Dynamic question generation To support pre- and post- sleep questionnaires, we should be able to update questionnaires dynamically from the server-side, based on the patient themselves. This is especially helpful in long-term studies, which prevent us requiring participants to come in and update their mobile phones. Furthermore, it would be helpful for us to remotely update the questions on the mobile device of a particular participant as the situation requires. For example, if the user has been reporting significant amounts of stress in a particular night, and given our understanding of the situation the participant, say a single college student, we could generate targeted questions asking whether the stress is caused by finances, relationships, school-work, or family. As reported stress level declines again, these additional questions should be removed.

Approach To generate questions from the server and push them to a targeted user's mobile device, we could rely on a questionnaire activity which communicates with the server upon loading. To display the questionnaires properly, the server would send a JSON file specifying the question ID and display format. The question ID would refer to a unique ID of the question in the database. The display format would distinguish between the types of questions (e.g. multiple choice, checkboxes, and sliders).

4.2.3 Long-term studies on Sleep Bruxism Trends Amongst College Students

The relationship between stress, anxiety, and sleep bruxism is still a topic of debate amongst researchers. Many of the studies conducted were criticized for having few subjects, non-evidence based results, and insufficient duration. Though polysomnography provides the highest grade of data, a study with large number of subjects over a prolonged duration using polysomnography would be costly and time-consuming. Furthermore, such a study would require participants to sleep in a lab that does not represent their usual sleeping condition. A system that is designed for mobile phones would lower the cost of these studies significantly, be easily distributable in large group, and with pre and post sleep questionnaires, provide constant feedback of the participant's data with the researchers. Long-term studies could be made feasible with a mobile phone application as the one presented in this project.

We find college students to be of particular interest to examine the relationship between sleep bruxism and stress, mainly because stress levels are typically uniform – high peaks during mid-terms and finals. First year students also typically have higher anxiety levels due lack of belonging and being away from home. In this setting, a comparative study might provide very interesting results. For example, we could analyze sleep bruxism prevalence amongst randomized samples

of students in different sets of GPA. Furthermore, an article published by Hicks et al. observed a four-fold increase of self-reported sleep bruxism amongst college students over a period of 23 years [38]. They suggested that the dramatic increase may be an effect of psychological variables, and should be investigated further. To examine the increase as described by Hicks et al [38], we could evaluate the differences in sleep bruxism frequency of randomized samples of students in different years of college.

4.2.4 Studies of pre-bedtime stress-relieving techniques on sleep bruxism

Our mobile phone application is easily extensible, and could accommodate additional features such as a guided mindfulness meditation in addition to the aforementioned post-sleep questionnaire. This is one of the benefits to a mobile application, such features could be added on without too much trouble. As described earlier, Ommerborn et al. has shown us in a preliminary study that a 12-week cognitive behavioral therapy consisting of problem-solving, progressive muscle relaxation, nocturnal biofeedback, and training of recreation and enjoyment resulted in a significant reduction of sleep bruxism activity [71]. With our device, we could further investigate the effects of cognitive behavioral therapy with the advantage of monitoring EMG, audio, and video instead of the use of Bruxcore® (http://www.bruxcore.com).

4.2.5 Olfactory Stimulant as Biofeedback

Various stimulants used in sleep bruxism biofeedback studies sought to elicit jaw-opening reflex for order halting sleep bruxism episodes. However, no study to our knowledge examined the effects of olfactory stimuli in eliciting jaw-opening reflex. Olfactory stimuli is a particularly attractive option for sleep bruxism prevention because many studies have shown that selective olfactory stimuli does not

lead to significant nocturnal arousals in humans [4, 11, 33, 88]. Carskadon et al. conducted a polysomnography of 6 participant's reaction to positive and aversive olfactory stimulation, peppermint and pyridine, during sleep [11]. They found that peppermint was ineffective in arousing the participant during stages 2,4 and REM sleep. A 3 minute maximal intensity peppermint stimulation elicited only EEG activation and no behavioral response for 15% of stage 2 sleep, 20% of REM sleep, and 3% of stage 4 sleep [11].

Furthermore, Schredl et. al conducted a controlled study in 2009, examining the effect of olfactory stimuli on dream content and emotions [83]. Schredl et al. presented a strong dose of hydrogen sulphide (smell of rotten eggs) and phenyl ethyl alcohol (smell of roses) to different groups of participants during REM sleep and compared with a control condition without stimulation. They found that olfactory stimulation significantly affected the emotional content of dreams upon waking. Aversive olfactory stimuli resulted was followed by reports of negative toned dreams, whereas positive olfactory stimuli was followed by reports of positively toned dreams. We don't know the relationship between olfactory stimuli and sleep bruxism, however, it would be an interesting exploratory study to examine the effects of such a stimuli.

Many studies on the effects of aromatherapy have observed a reduction of anxiety levels and increased sleep quality [15, 33, 39, 34, 25]. Diego et al. demonstrated that a 3 minute dose of lavender olfaction resulted in a significant reduction of anxiety scores [20, 27]. A polysomnography study by Goel et al, found that use of lavender stimulation during nocturnal sleep led to an increase the percentage of slow wave sleep in both men and women and increased alertness upon awakening [33]. A more recent study Hirokawa et al. also supported the findings of improved alertness [39]. These findings suggest a potential for further investigation.

4.3 Conclusion

Currently in the field of bruxism study, there exists a demand for a device that both cheaply and accurately diagnoses and monitors bruxism for wide spread consumption. Our goal in undertaking this thesis was to create such a device. Our device is developed on smartphones enabling extensions beyond EMG sensors, leading to a more detailed analysis and diagnosis. In this thesis we focused our attention on two additional channels: audio and video. The incorporation of easily accessible smartphones as our main device also enables longer duration studies, as well as larger population studies. Our device may prove to not only be a cost effective way for researchers to further their studies, but also for individual consumers to satiate the curiosity they have for their own condition.

Our immediate objective moving forward is two-fold and can be carried out simultaneously. The first objective is to perform an in-depth analysis of the data that we have collected with the purpose of discovering patterns that allow us to create an algorithm that deterministically concludes the presence of a sleep bruxism episode. The second objective is to decrease the size of the EMG device, overcoming the challenge of power consumption, creating a more wearable unit that allows participants to sleep more comfortably. Once we have completed the two immediate objectives, we could integrate the algorithm into the smartphone for real-time sleep bruxism detection and conduct a polysomnography study using the wearable EMG unit to evaluate the accuracy of our real-time sleep bruxism detection device.

We feel that the sleep bruxism monitoring system we have developed and the approaches introduced in this thesis provide an inexpensive and reliable technique for assessing sleep bruxism. We hope that such a technique opens up the possibilities of future extensions to the system for specific clinical, research, and personal use, to further our understanding of sleep bruxism.

Appendix A

IRB document

UCSD Human Research Protections Program
New Biomedical Application
RESEARCH PLAN

1. PROJECT TITLE

Portable Biofeedback Device for Bruxism

2. PRINCIPAL INVESTIGATOR

Dr. Nadir Weibel, Ph.D.
Department of Computer Science and Engineering

3. FACILITIES

The study will be carried out at the Department of Computer Science and Engineering, located in the EBU-3B building. The Principal Investigator has at his disposal a well equipped systems and network research facility with approximately 3000 sq. ft. of space available for students.

The Computer Science and Engineering department provides extensive computing resources for research and education. This includes more than 300 high-performance UNIX/Linux and Windows-based workstations, a large number of laptop systems, and several hundred wireless personal digital assistants. In addition to general-purpose file, e-mail, Web, and compute servers, the department maintains two network-attached terabyte disk arrays and four separate high-performance compute clusters supported by two recent NSF infrastructure grants.

Data collection and testing will be conducted at UCSD and at private residences mostly in the greater San Diego area, after obtaining appropriate permissions from participant consent. Data collection at private residences during phase 1 consists of nighttime measurements of the subject's sleep bruxism using audio, EMG, and visual tracking. Visual tracking will be limited to the region of head and shoulders of the subject. Phase 2 will consist of phase 1 data collection in addition to placing auditory and olfactory stimulation within 3 feet of the bed to ensure proper delivery of stimuli.

4. ESTIMATED DURATION OF THE STUDY

The estimated duration of this study is 5 years, starting in Winter 2013.

5. LAY LANGUAGE SUMMARY OR SYNOPSIS (no more than one paragraph)

Currently, sleep bruxism is difficult to track over prolonged period of time. Though polysomnography is the gold standard for diagnosing bruxism, using polysomnography on large-scale trials is far too costly and uncomfortable for patients for long-term studies. Instead, assessment for determining bruxism in research is frequently based on surveys and reports of tooth-grinding sound during sleep and the presence of clinical symptoms. Having a device that could enable subjects and researchers to track duration and frequency of sleep bruxism could be helpful both for furthering understanding of bruxism and giving immediate feedback to the subject. The goal of our research is to provide a cheap, accessible, and portable device for sleep bruxism patients to monitor their conditions without disrupting sleep. Moreover, we believe that a modular and easily extendible real-time bruxism detection device can enable the research community use it as a platform for novel ways of intervening bruxism.

6. SPECIFIC AIMS

The immediate goal of this research is to provide a cheap, accessible, and portable device for sleep bruxism patients to monitor their conditions without disrupting sleep by using binaural microphone, EMG sensors, and video recording via smartphone extensions. We plan to use portable devices to facilitate diagnosis of bruxism for both research and clinical settings. For example, analyzing the long term correlation between emotional and stress triggers on bruxism. We also envision anyone with sleep bruxism to find this approach useful in gaining personal insight to the level severity of his or her condition. This device will be made modular and extendable to easily

Figure A.1: Approved IRB document page 1

allow integration of intervention mechanisms aimed at reducing duration and frequency of bruxism by the research community.

The long-term goal of this research is to look into real-time intervention techniques that will help reduce the frequency of duration of sleep bruxism without diminishing sleep quality. Our contingent biofeedback includes auditory and olfactory stimuli.

7. BACKGROUND AND SIGNIFICANCE

Sleep bruxism is reported to affect 8% of the general population [4,8]. This sleep disorder typically peaks amongst children aged less than 11 years old with 30-40% prevalence and decreases after adulthood [3,11]. Although percentage of population with bruxism declines with age, affecting only 3% of the elderly, effects of bruxism leaves a significant impact during intervening years. High force sleep bruxism causes significant detrimental effects on the teeth and is suspected to cause myofacial pain, temporomandibular disorders (TMD), and arthralgia [2,7,10].

There is a demand in the bruxism research community for a device that can enable researchers to accurately track bruxism over prolonged periods of time. Though polysomnography is the gold standard for diagnosing bruxism, using polysomnography on large-scale trials is far too costly and uncomfortable for patients for long-term studies. Instead, assessment for determining bruxism in research is frequently based on surveys and reports of tooth-grinding sound during sleep and the presence of clinical symptoms [20]. Sleep bruxism is a multifactorial sleep disorder and its exact etiology is still unknown. Previously, the main causation of bruxism was thought to be due to orofacial anatomy [5,6]. However, more recent studies have shown that bruxism may be related to psychosocial factors such as personality character and stress [1,12]. Having a device that could enable subjects and researchers to track duration and frequency of sleep bruxism while engaging in, for example, stress relieving techniques before bed, would be helpful both for data collection and for immediate feedback for the subject.

In addition, because of the difficulty in conducting long-term studies, long-term effects of innovative research in using contingent biofeedback are still in question [6, 13-19]. In a literature review on sleep bruxism, Lobbezoo et al. concluded that within the set of 135 studies on bruxism published between 1966 and 2007, the vast majority of publication types were case reports, reviews, comparative studies, and sundries [6]. Only 13% of the studies were clinical trials [5]. Even after the leaps and bounds the research community has achieved in our understanding of bruxism, occlusal splints for protection of teeth still remain as the most common sleep bruxism management prescribed in dentistry even though the studies have shown decrease, increase, or no effect at all, in muscle activity while wearing occlusal splints [9]. We believe that a modular and easily extendible real-time bruxism detection device can enable the research community use it as a platform for novel ways of intervening bruxism.

8. PROGRESS REPORT

None, this is a new project.

9. RESEARCH DESIGN AND METHODS

Research will be conducted in two phases. The first phase involves a combination screening trials and observational study. Screening trials will involve switching between audio, video, or EMG recording for detecting the presence of bruxism. Phase one study will be purely observational, without any interference during the bruxism episodes of our subjects. Once we establish a device that can accurately measure the presence of sleep bruxism, we will move onto our second phase of treatment trials. These treatment trials involve non-nociceptive olfactory, auditory, and somatosensory stimuli as real-time intervention mechanisms for sleep bruxism. Subjects will be informed of the potential stimuli, and may also decline to be a participant of phase two.

Figure A.2: Approved IRB document page 2

In phase one, subjects will be asked to use the device during nocturnal sleep time. The technologies used may involve audio recording, video recording, and EMG recording to track sleep patterns and bruxism episodes. Data will be collected by logging subjects' sleep and bruxism episodes on a private and secure server. To protect security and confidentiality we will exploit the extensive support made available at UCSD by resources such as iDASH (Integrating data for Analysis Sharing and Anonymization). This approach to research information security and confidentiality is specifically designed to comply with the requirements of relevant federal regulations and guidelines, including: DHHS/NIH Automated Information Systems Security Program Handbook, current HHS standards for security of person identifiable health data transmitted over the Internet, and the HIPAA Privacy and Security Rules. At any point and for any reason if unwanted private data is collected, the subject may delete them from our server using the interface provided on their device.

Phase 1

During the initial phase, we will use dedicated devices to measure bruxism activity at night. We will use the FDA Exempt 510(k) device Grindcare®[1] − a portable bruxism measurement device that monitors the activity of the temporalis muscle − as our guideline for categorizing the severity of sleep bruxism and therefore select our subjects. Grindcare® has agreed to lend us their units for evaluation. Grindcare® also has a comprehensive manual that will direct us in correct usage of their device. The company will not be receiving any data on the subjects. We will also employ wireless EMG sensors on the patient's masseter muscles, as well as binarual microphones placed in the subject's ear to record grinding occurrences. We will also detect sleep movement and visible grinding activity using the cameras available on the phone through our software. Subjects will then begin to track their sleep bruxism with a downloaded application on a smartphone. These measurements will allow us to determine the exact timing of bruxism episodes and establish the accuracy of audio and video detection. Our goal is to develop reliable algorithms for sleep bruxism detection based on audio recording and/or infrared recording, as enabled by most smart phones cameras. Data collected will be buffered on the smartphone and streamed to a secured server at intervals throughout the night. Privacy and confidentiality of the recorded data will be ensured by the extensive measures in place at UCSD (see earlier in this section, points 15 and 16). Subjects will be able to monitor, via the application's interface, frequency and average duration of bruxism episodes. They may also re-watch recording of recorded episodes.

Phase 2

Once we establish a sensor or a combination of sensors that can accurately detect bruxism throughout the night, we will move onto phase two. We will recruit new participants with the same method described in phase 1: we will use the FDA Exempt 510(k) device Grindcare® as a guideline for selecting subjects that do have bruxism. Subjects who participated in phase one is not required to participate in phase two, however, they may choose to also participate in phase two. The first week of phase two will involve familiarizing the participants with our bruxism detection device and getting a baseline measurement. After the first week, we will introduce different non-nociceptive stimuli to randomized groups of participants. Non-nociceptive stimuli include auditory and olfactory stimuli. Auditory stimuli will be delivered during a pre-sleep relaxation phase. The pre-sleep relaxation lasts for 5 minutes and uses a selection of auditory stimuli such as soothing music, white noise, and nature sound. Olfactory stimuli will be delivered during sleep-time, contingent to occurrences of sleep bruxism. Subjects will be asked to choose the type of olfactory stimuli he/she feels most relaxing during the first week of trial. Upon detection of sleep bruxism, we will trigger release of pleasant olfactory stimuli in the subject's surroundings. The trigger device will be similar to an automatic air freshener spray. Instead of being triggered by movement, we will be triggering the device wirelessly via infrared or bluetooth. We will take into consideration that since sleep bruxism frequently occurs during S1 and S2 stages of sleep, with higher occurrences during the ascending phases, our subjects will be easily aroused. We will let our subjects know that

Figure A.3: Approved IRB document page 3

though our goal is to introduce stimuli that will not disrupt their sleep quality, it is likely to happen. Our subjects will need to work closely with us by filling out sleep/tiredness questionnaire on their phone every morning after using the device. The stimuli will be constantly re-evaluated and adjusted according to the reported sleep quality. Auditory stimuli will be delivered through binaural microphones or their smartphone's sound system. Olfactory stimuli will be based on a separate bedside device that is notified every time a bruxism episode begins and triggers release.

During the experiment (phase 1 and phase 2), subjects will be asked to fill out pre-sleep and post-sleep surveys. Each survey will consist of no more than 5 questions. Pre-sleep surveys will help us demonstrate the possibility of tracking external effects in relation to occurrences of sleep bruxism. Questions in the pre-sleep questionnaire include the following:

1. What is your current stress level? (Scroll bar: very relaxed -- very stressed)
2. Do you feel difficulties are piling up so high that you cannot overcome them?
3. Did you consume alcohol today?

Post-sleep surveys will focus on helping us assess whether the device is affecting the subject's sleep quality. This survey will measure sleep quality subjectively. Questions in the post-sleep survey are modifications of the Pittsburgh Sleep Diary [21] and include the following:

1. After falling asleep, how many times did you wake up during the night?
   (How many times was this due to a stimulus?)
2. What is your sleep quality? (scroll bar: very bad - very good)
3. Mood of final awakening? (scroll bar: tense-calm)
4. Alertness on final awakening? (scroll bar: very sleepy - very alert)

If sleep quality appears to be decreased due to our study, the subject will be notified and may leave if they so choose. Not continuing the study will not be considered punitive in any way.

Following their use of the technology, in both phases subjects will be asked to participate in an interview about their experience. Each interview will be conducted with a single participant. Questions for the interviews will be derived from observations of technology use. For example, if we observe that a participant stated that they strongly disliked a feature of the technology, the follow-up interview would ask them specifically what was it they disliked about that feature and how to improve it.

All identifying details (e.g., names, patient or resident ID numbers, phone numbers, etc.) will be concealed in the presentation of data. If our data includes conversation about a condition or treatment, we will ensure that no names or other identifying information is associated with this information. In general we will take care to cater to the needs of subjects such as reminding them when they are being video recorded, placing the camera in a noticeable location, reminding them that they may cease involvement at any time, and responding to issues such as fatigue during their participation. To minimize the risk of loss of confidentiality, participant information will be accessible only by the research staff.

10. HUMAN SUBJECTS

Over the course of this research project we anticipate that 10 to 50 subjects from UCSD and the neighborhood communities will participate. During phase 1, we will need fewer than 10 participants. The goal of this phase is to establish a set of algorithms to accurately determine occurrences of sleep bruxism. Since phase 2 is an exploratory study, we will need more data. We approximated a total of 45 subjects, 15 subjects per group exposed to the following stimuli: auditory, olfactory, auditory & olfactory. Furthermore, this will also fulfill one of our research motivations for developing a device that can support large studies of sleep bruxism

Figure A.4: Approved IRB document page 4

efficiently and cheaply by using smartphones. Will be recruiting mostly from the undergraduate student population, but also via referrals from dental clinics. We will contact dental clinics available to UCSD students as specified by the UCSD Pre-Dental Society (http://fdc-pds.ucsd.edu) and explain the study in person. The dentists from the clinic will then approach potential students and refer them to the research team to further information and eventually to be enrolled in the study. Subjects will be male and female (recruited in equal percentages) and from a variety of ethnic backgrounds. We will recruit only participants based on self-report by means of questionnaires for bruxism. Bruxism questionnaire includes the following questions:

1. Do you have tooth sensitivity?
2. How often do you wake up with jaw pain and tightness in your jaw muscles?
3. How often do you wake up with tired jaw muscles?
4. Do you get earaches?
5. Do you get headaches often?
6. Has others told you about grinding noises you make during your sleep?
7. How often do you think that these episodes occur per week?

All potential subjects will use the Grindcare unit for bruxism assessment. If sleep bruxism is detected within the first week, the subject will be allowed to participate in the rest of the study.

Our inclusion criteria is the following:

1. Participants must exhibit sleep bruxism as indicated by Grindcare(r) at least once per week.
2. Participants must own a current model of an Android smartphone. No smartphone will be lend to participants.

11. RECRUITMENT

Our research team will recruit participants through flyers on UCSD campus and online postings. By working directly with dental clinics, we will have these professionals present the study flyer to potential participants that exhibit bruxism conditions. The potential participants will then contact our research team if interested in the study. Specific letters of cooperation will be solicited from these dental clinics, and copies of these letters will be submitted to the IRB for record-keeping purposes.

During recruitment, subjects will be told that the research project is exploring new ways of tracking sleep bruxism through a portable device. We will also let the subjects know that the study may require videotaping, audio recording, and EMG-recording during their sleep in their homes. Recruitment will be ongoing and a subject may withdraw from the study at anytime.

During the course of the project we will continue to iteratively involve new participants accordingly. We will keep the IRB informed of additional centers and field sites for research, including written approval from center administrators.

12. INFORMED CONSENT

Participants will be consented during the first lab session. This will take place on UCSD campus in the CSE Building room 3224 or 3150. A researcher will first explain the study to each participant. Then the participant will be given sufficient time to review the consent form and sign if they choose to participate. The consent will describe the measures to protect privacy and anonymity of the subjects and, as well as the confidentiality of any information they provide.

13. ALTERNATIVES TO STUDY PARTICIPATION

The alternative to participation is to not participate. All participants will be allowed to discontinue participation

Figure A.5: Approved IRB document page 5

at any time with no penalty.
After the study, the technologies may be made available to the general public where people who decided not to participate in the research study may be able to use them.

14. POTENTIAL RISKS

There are no major health risks associated with this study.

Some participants may find the portable bruxism detection device disruptive during their sleep. We will constantly reassess the sleep conditions reported by the subjects. Shall any disruptions occur; the subject may choose to leave the study.
It is possible that some information observed by a researcher, captured in field notes, or recorded on video will contain private and sensitive information about a person's medical history. Sharing this type of information with a researcher present may become a source of anxiety or embarrassment for the subject.

15. RISK MANAGEMENT PROCEDURES AND ADEQUACY OF RESOURCES

Prior to beginning the use of our device, we will tell participants to inform us immediately shall any sleep disruption occurs. We will also inform our subjects that during the trial, we will be in touch with them once per week to assess their sleep quality and to answer any questions they may have. Subjects will be made aware that they can remove any unwanted audio, video, and EMG data from our server via their device if they are uncomfortable with the data collected.

Despite the relatively low risk of harm should confidentiality be broken, the PI will make every effort to maximize confidentiality. Participants may ask a researcher to destroy all or part of recordings that include sensible information. No images of the subjects will be published or presented at scientific meetings, or use for software development, except where subjects gave explicit written consent for their face images to be published. In case of accidental presence of other subjects in the recorded data (such as while video-taping), the recorded data will be deleted accordingly.

Paper files (consent forms, notes) will be kept in a locked cabinet in a locked room in the PI office, and only the PI and lab administrators will have access to that cabinet. Electronic files will be stored on highly secure computers. These computers run firewall and anti-virus software (updated regularly), and the only persons with knowledge of the computers' passwords are the PI and carefully-selected lab personnel.

Project Termination: The study shall be terminated at any point at the discretion of the subject. Based on our past experience in the project we do not anticipate special conditions or circumstance under which a participant would be terminated from the study.

16. PRIVACY AND CONFIDENTIALITY CONSIDERATIONS INCLUDING DATA ACCESS AND MANAGEMENT

To minimize the risk of loss of confidentiality, participant information and collected data will be anonymized, stored on a private and secure server, and associated with a randomly generated user identification number. Participant information and data will be accessible only by the research staff, who will be required to login to the secure server with personal passwords.

Moreover, to protect security and confidentiality we will exploit the extensive support made available at UCSD by resources such as iDASH (Integrating data for Analysis Sharing and Anonymization). This approach to research information security and confidentiality is specifically designed to comply with the requirements of relevant federal regulations and guidelines, including: DHHS/NIH Automated Information Systems Security Program Handbook, current HHS standards for security of person identifiable health data transmitted over the Internet, and the HIPAA Privacy and Security Rules. At any point and for any reason if unwanted private data is collected, the subject may delete them from our server using the interface provided on their device.

Figure A.6: Approved IRB document page 6

17. POTENTIAL BENEFITS

A potential benefit for participants is that they will be able to track and view their own data of sleep-bruxism frequency and duration via our interface. In addition, if they so choose, they could track their stress level, and other factors to gain a better understanding of the onset of sleep bruxism.

The usage of a portable sleep bruxism detection device enables researchers, therapists, and doctors to track the occurrences of sleep bruxism. For researchers, this could an invaluable tool for non-invasive long term tracking of new methods for managing bruxism. For therapists and doctors, this tool provides them understanding of the well being of their patients and associations with other potential disorders. This research may prove beneficial to society at large by providing tools for understanding the etiology of sleep bruxism.

18. RISK/BENEFIT RATIO

The overall risk for this project is very low, there are no health risks associated with this study and no images of subject's faces will be published without explicit written consent. Prototype versions of technologies explored with subjects in this research study may eventually become available to larger audiences, thus benefiting a broader population. With minimal, managed risks and potentially far-reaching results, the benefits associated with this project outweigh the risks.

19. EXPENSE TO PARTICIPANT

There will not be any kind of monetary expense for participants.

20. COMPENSATION FOR PARTICIPATION

Participants might be compensated based on their level of participation in the study, up to a maximum of $60 per phase, in the form of cash. Compensation is limited to up to $20 for attending lab sessions and up to $40 for using the provided equipment. Lab sessions take place 2 times per phase: 1-hour introductory training session and a 1-hour interview after the study. We will be in constant contact with subjects via questionnaires throughout the study. Information that will be exchanged at lab sessions for phase 1 include:

1. How to use device correctly
2. How difficult is it to use the application?
3. Did using bruxism application affect sleep quality?
4. How could we improve?
5. Address any bugs/technical issues subjects may have.

Information exchanged at lab sessions for phase 2 include:

1. How did the subject feel about pre-sleep option? Was it a nuisance or did it help?
2. Are there adjustments that need to be made about pre-sleep? Adjusting music? Changing duration?
3. Do subjects recall waking up at night due to olfactory sensory stimulation?
4. Did subjects feel increase/decrease in sleep quality?
5. Address any bugs/technical issues subjects may have

If a participant does not complete the study, compensation will be prorated based on the level of participation up to that point. The amount of payment is adequate but not coercive.

Please see the *Incentive Structure* document for both Phase 1 and Phase 2 for more details.

Figure A.7: Approved IRB document page 7

21. PRIVILEGES/CERTIFICATIONS/LICENSES AND RESEARCH TEAM RESPONSIBILITIES

The PI, Dr. Nadir Weibel will lead the main efforts of this project. Dr. Weibel holds a Masters and PhD in Computer Science from ETH Zurich, and has been a postdoctoral researcher in the Distributed Cognition and Human Computer Interaction laboratory at UCSD. He is now a Research Scientist in the Department of Computer Science and Engineering, and a Research Health Science Specialist at the VA San Diego.

Dr. Weibel has extensive experience in introducing cutting edge technology as a support for healthcare. He is currently involved in several projects that assess technology in critical situation both at UCSD, at the VA Hospital, at the Children's Hospital of Washington DC. Finally the PI is associated to the Calit2 Center for Wireless Population Health Systems, which provides support and counseling by senior faculty members (MDs and PhDs).

Although Dr. Weibel is not an MD and does not have experience with bruxism, the design of this study, involving a commercially available device (Grindcare) to evaluate Bruxism, the PI's technical background, training in cognitive science and human-computer interaction, and his experience with healthcare and critical populations will ensure the appropriate handling and leading of the proposed project. Moreover, the PI has access to a series of physicians with experience in deploying interactive technology in healthcare such as Dr. Kevin Patrick, MD, as part of the affiliated Calit2 Center for Wireless Population Health Systems.

Additionally, prior to the start of this project, literature on bruxism, sleep disorders, etiology of sleep, and neurophysiology has been carefully reviewed to understand the challenges of conducting research with the diverse subjects involved in this project. Finally, the research group will continually seek the guidance of healthcare specialist and sleep researchers at UCSD and beyond to ensure that we are culturally sensitive in approaching communities of interest and have an adequate understanding of the issues that might arise when working with these participants. To this extent we are already in contact with Dr. Ancoli-Israel who directs the Gillin Sleep and Chronobiology Research Center, and co-directs the Laboratory for Sleep and Chronobiology at UCSD, and who is advising the research team.

Dr. Weibel will be assisted by graduate and undergraduate students and research assistant to accomplish the outlined project. All involved students and research assistants will be trained in human subjects protections procedures, and be current on their CITI training certificates.

Different assistants will be part of the team throughout the course of the study. We list here the research assistants currently involved in the study. We will inform the HRPP with the name and qualifications of research assistants joining the team in the future.

Research Assistants:

1. Julia Yuhsin Lin is a CSE Masters student at UCSD with concentration in Software Engineering. She has received a B.A. in Economics and minor in Computer Science during her undergraduate study at UCSD.

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Figure A.8: Approved IRB document page 8

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Figure A.9: Approved IRB document page 9

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23. FUNDING SUPPORT FOR THIS STUDY

Request for funding for this project are currently being submitted to the department of Computer Science and Engineering. We are also working on a large NIH-proposal to fund this project

24. BIOLOGICAL MATERIALS TRANSFER AGREEMENT

Not Applicable

25. INVESTIGATIONAL DRUG FACT SHEET AND IND/IDE HOLDER

Not Applicable

26. IMPACT ON STAFF

Not Applicable

27. CONFLICT OF INTEREST

There are no known conflicts of interest.

28. SUPPLEMENTAL INSTRUCTIONS FOR CANCER-RELATED STUDIES

Not Applicable

29. OTHER APPROVALS/REGULATED MATERIALS

Not Applicable

30. PROCEDURES FOR SURROGATE CONSENT AND/OR DECISIONAL CAPACITY ASSESSMENT

Not Applicable

Figure A.10: Approved IRB document page 10

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