Sleep Apnea Testing Manual for Dentist

Contents

Overview Sleep Disordered Breathing

Sleep-disordered breathing (SDB) refers to a range of conditions where breathing abnormalities occur during sleep. The most prevalent form is obstructive sleep apnea (OSA), caused by the partial or complete blockage of the upper airway during sleep. As the muscles controlling the airway relax during sleep, it can lead to its narrowing or closure, resulting in pauses in breathing known as apneas. These interruptions cause oxygen levels to drop and carbon dioxide levels to rise, prompting brief awakenings to restore normal breathing. Symptoms include chronic snoring, gasping, labored breathing, daytime sleepiness, headaches, difficulty concentrating, irritability, and restless sleep. Sleep-disordered breathing can also increase the risk of cardiovascular problems. Risk factors include obesity, anatomical abnormalities, asthma, smoking, alcohol use, certain medications, and family history. Diagnosis involves a sleep study called polysomnography, which monitors various parameters. Treatment options include lifestyle modifications, weight loss, avoiding alcohol and sedatives, and continuous positive airway pressure (CPAP) therapy, which uses a mask to keep the airway open. In children, adenotonsillectomy is still considered the first line of therapy. Early recognition and appropriate treatment are essential for managing SDB and improving overall well-being.

Sleep Testing

Home Sleep Apnea Testing (History and Overview)

Home sleep apnea testing (HSAT) is a convenient, user-friendly form of diagnostic tool for detecting sleep disorders, particularly OSA. This type of testing uses a using multiple signals in a portable device that you take home to use at night while you sleep, and it is considered a simplified version of a polysomnography, which is the formal, in-laboratory sleep study. HSAT typically monitors several biological parameters such as airflow, breathing effort, blood oxygen levels, and sometimes heart rhythm.

The primary purpose of HSAT is to identify the presence and severity of sleep apnea, a disorder characterized by repeated episodes of partial or complete cessation of breathing during sleep. It's particularly useful for individuals who have a high pretest probability of moderate to severe sleep apnea, are unable to travel to a sleep center, or who prefer the comfort of their own home for testing. For children, very few HSAT have been validated.

HSATs are not suitable for everyone and have limitations in the detection of other sleep disorders. Further, they may not be appropriate for individuals with certain medical conditions like heart failure or respiratory disorders. Despite these limitations, these tests provide a valuable, cost-effective, and accessible tool for many individuals suspected of having sleep apnea.

The history of home sleep apnea testing in North America began in the late 20th century. Prior to that, sleep apnea diagnosis required an overnight stay at a sleep clinic for polysomnography, which was not only inconvenient for patients but also had high costs. This began to change in the 1980s and 1990s when research highlighted the potential of home-based diagnostic tools.

The development of portable sleep monitors started in the 1990s, but adoption was slow due to concerns about accuracy and reliability. However, technology improved over time, and by the early 2000s, the use of HSATs had become more common.

In 2007, the American Academy of Sleep Medicine (AASM) issued guidelines supporting the use of HSATs for the diagnosis of OSA in certain populations. This was a crucial turning point, marking a shift toward the mainstream acceptance of these devices in the healthcare community.

Since then, HSATs have become an increasingly popular option, especially given the convenience, lower cost, and accessibility they offer compared to traditional sleep studies. Today, they represent a key component of the sleep medicine landscape in North America, transforming the way sleep apnea is diagnosed and managed. See indication and contraindication to Home Sleep Apnea Testing – Appendix A

Polysomnogram

A polysomnogram is a comprehensive test conducted while you sleep, primarily used to diagnose sleep disorders. It records the brain waves, oxygen level in the blood, heart rate and breathing, as well as eye and leg movements during the study. These variables are measured through non-invasive sensors attached to your skin. EEG (Electroencephalogram), EOG (Electrooculogram), EMG (Electromyogram), EKG (Electrocardiogram), nasal airflow sensor, chest/abdomen belts, and pulse oximeter are the key components of the test setup. Data gathered is later analyzed by a sleep specialist to determine whether or not you have a sleep disorder, such as sleep apnea, parasomnias, bruxism, or restless legs syndrome among others. A polysomnogram usually involves an overnight stay at a sleep center or hospital, though home-based options have become more prevalent.

Therapy for Sleep Disordered Breathing

CPAP - Primary Therapy for Sleep Disordered Breathing

CPAP (Continuous Positive Airway Pressure) therapy is a common treatment forSDB , particularly OSA. It involves the use of a CPAP machine, which delivers a constant flow of pressurized air through a mask

worn over the nose or both the nose and mouth during sleep. The purpose of CPAP therapy is to maintain an open and unobstructed airway, preventing interruptions in breathing and improving the quality of sleep.

When the CPAP machine is turned on, it generates a prescribed level of air pressure, which is determined based on an individual's specific needs. This pressurized air acts as a pneumatic splint, effectively holding the airway open and preventing collapses or obstructions that can lead to sleep apnea events.

CPAP therapy is typically prescribed by a primary care physician or specialist after a diagnosis of sleep apnea is confirmed through a sleep study. The initial setup involves selecting the appropriate mask size and adjusting the machine's pressure settings to ensure optimal comfort and efficacy. Adherence to CPAP therapy is crucial for its effectiveness, and individuals may require some time to adapt to wearing the mask and sleeping with the airflow.

Regular use of CPAP therapy can lead to significant improvements in sleep quality, daytime alertness, and overall well-being. It helps reduce the frequency and severity of sleep apnea events, which in turn reduces the associated health risks, such as cardiovascular problems and excessive daytime sleepiness.

CPAP machines often have additional features like humidifiers to improve comfort and reduce dryness or congestion in the airway. CPAP therapy is considered a long-term treatment and requires ongoing maintenance, including cleaning and replacing components of the equipment as recommended by the manufacturer. Regular follow-up appointments with the sleep specialist are essential to monitor progress, adjust settings if necessary, and address any issues or concerns.

In some cases, alternative treatment options like dental appliances or surgery may be considered if CPAP therapy is not suitable or tolerated well. Overall, CPAP therapy is an effective and widely used treatment for sleep disordered breathing, particularly for obstructive sleep apnea. It provides a constant flow of pressurized air to maintain an open airway during sleep, helping individuals breathe more easily and improving their sleep quality and overall health.

Dental Appliance Therapy in Sleep Disordered Breathing

Dental appliances play a significant role in the treatment of OSA, a sleep disorder characterized by the repeated partial or complete blockage of the upper airway during sleep. These appliances, also known as oral appliances or mandibular advancement devices (MADs), are custom-made devices that are fitted in the mouth to help alleviate OSA symptoms and improve sleep quality.

Dental appliances work by repositioning the jaw and tongue to maintain an open and unobstructed airway during sleep. They are primarily designed to advance the lower jaw slightly forward, which helps to increase the space at the back of the throat and reduce the collapse of soft tissues that contribute to breathing disruptions.

These devices are typically fabricated by dental professionals using various materials such as acrylics, metals, or thermoplastic polymers. They are custom-fit to ensure comfort and effectiveness for individual patients. The fitting process involves taking impressions of the patient's teeth and jaw, which are then used to create a personalized appliance.

Dental appliances are often recommended for patients with mild to moderate OSA or those who cannot tolerate CPAP therapy, the standard treatment for OSA. They can also be used in combination with CPAP to enhance its effectiveness or as an alternative treatment option for specific cases.

The advantages of dental appliances include their non-invasive nature, ease of use, portability, and relatively high patient compliance compared to other treatments. They are also suitable for individuals who may have anatomical variations, such as small jaws or large tongues, which contribute to airway obstruction.

Regular follow-ups with dental professionals are crucial to monitor the progress of treatment and make any necessary adjustments to the appliance. These devices may have some side effects, such as temporomandibular joint (TMJ) discomfort, excessive salivation, or bite changes, which should be addressed promptly.

In conclusion, dental appliances are custom-made devices that help alleviate symptoms of OSA by repositioning the jaw and tongue to maintain an open airway during sleep. They are a valuable treatment option for patients with mild to moderate OSA or those who cannot tolerate CPAP therapy, providing a non-invasive and comfortable alternative to enhance sleep quality and overall well-being.

Alternative Therapy for Sleep Disordered Breathing

There are several alternative therapies available for managing OSA outside of machine-assisted and dental device therapies. Weight loss, particularly for overweight patients, can significantly reduce OSA symptoms. Positional therapy, which encourages sleeping in certain positions like on one's side, can also help alleviate symptoms. Lifestyle modifications such as avoiding alcohol and sedatives, quitting smoking, and regular exercise can contribute to symptom reduction. Surgical options, including uvulopalatopharyngoplasty (UPPP), maxillomandibular advancement (MMA), or hypoglossal nerve stimulation, can be considered in certain cases. Incorporating yoga into one's routine, particularly specific breathing exercises, may help improve respiratory strength and oxygen saturation levels. Finally, acupuncture has shown some promise as a treatment due to its potential to alter the neurochemical balance. Muscle stimulation devices and alternative devices such as the Bongo RX has proven helpful in reducing obstructive apnea events.

Stakeholders

Patient

The patient is an individual who exhibits symptoms or has risk factors associated with sleep apnea and seeks diagnosis and treatment for their condition. They may be experiencing symptoms such as loud snoring, frequent waking during the night, daytime fatigue, morning headaches, nocturia or gasping for air during sleep. When it comes to home sleep apnea testing, the patient actively participates in the diagnostic process. They may visit a healthcare professional or sleep specialist to discuss their symptoms and undergo an initial assessment. Based on their evaluation, the healthcare provider may recommend a HSAT as an initial screening tool or as a follow-up to an in-lab sleep study. The patient's role in the testing process involves following the instructions provided by the healthcare provider or sleep clinic to set up and use the HSAT-device correctly. They may need to wear a portable device that monitors various parameters during their sleep, such as airflow, oxygen levels, heart rate, and body movement. The patient is responsible for ensuring the device is properly worn and used according to the provided

guidelines. Throughout the testing period, which typically spans one or more nights, the patient needs to maintain a sleep routine as close to their usual pattern as possible. This involves going to bed at their regular time and wearing the monitoring device throughout the night to collect accurate data. After the testing period, the patient returns the HSAT-device to the sleep clinic or healthcare provider for data analysis and interpretation. They may schedule a follow-up appointment to discuss the results, receive a diagnosis, and explore potential treatment options. As a stakeholder, the patient's experience, feedback, and adherence to the testing process are essential in ensuring accurate diagnosis and effective treatment planning. Their active involvement and cooperation significantly contribute to the overall success of home sleep apnea testing and subsequent management of their condition.

Dentist

A dentist plays a crucial role as a stakeholder in sleep apnea testing and treatment, although they may not be the first professional that comes to mind when thinking about sleep disorders. Their role involves identification, treatment, and ongoing management of sleep apnea, specifically OSA, which can significantly improve a patient's quality of life, reduce health risks, and even potentially save lives.

Here are a few key roles a dentist serves as a stakeholder in sleep apnea testing and treatment:

1. Screening and Identification: Dentists can play a key role in the early detection of sleep apnea. During regular dental visits, dentists have the opportunity to screen patients for signs of sleep apnea, such as dry mouth (which can be an indication of mouth breathing during sleep), teeth grinding (also known as bruxism, which can be a symptom of sleep apnea), and changes in oral or dental health that could suggest a sleep disorder.

2. Referral for Diagnosis: If a dentist suspects a patient has sleep apnea based on symptoms, they can refer the patient to a sleep specialist or a sleep study for formal diagnosis. While dentists cannot diagnose sleep apnea themselves, they are often one of the first healthcare professionals to spot the potential signs.

3. Treatment: Dentists can provide treatment for certain types of sleep apnea. For mild to moderate obstructive sleep apnea, dentists may recommend oral appliance therapy. They can custom-fit these appliances for patients to wear when they sleep. The devices work by repositioning the lower jaw and tongue, helping to keep the airway open.

4. Collaboration with Other Professionals: Dentists work in collaboration with other healthcare professionals in the management of sleep apnea. This can include sleep medicine specialists, general practitioners, ear, nose, and throat (ENT) specialists, and others as needed, to provide comprehensive care for sleep apnea patients.

5. Follow-up and Maintenance: For patients who are using oral appliances, regular dental check-ups are critical for ensuring the device is still fitting correctly and working as it should. Dentists monitor the effectiveness of the appliance, make necessary adjustments, and can check for any potential side effects, such as changes in bite or jaw discomfort.

6. Education and Advocacy: Dentists also play an important role in educating patients about the dangers of untreated sleep apnea and promoting good sleep hygiene. They may also advocate

for more research and better insurance coverage for oral appliances, which can be a barrier to care for some patients.

7. In summary, dentists play a critical role in the management of sleep apnea, starting with identification and referral, to treatment and follow-up care. Their involvement can lead to earlier detection, intervention, and better outcomes for patients with this common sleep disorder.

Primary Care Provider (PCP)

The referring primary care provider (PCP) plays an integral role in sleep testing. Firstly, they identify potential sleep disorders based on patient symptoms, health history, and physical examinations. The PCP then refers the patient for sleep testing, which could be in-lab polysomnography, home sleep apnea testing, or other specialized tests, depending on the suspected condition. During the testing phase, the PCP liaises with the sleep specialist to ensure pertinent information is communicated. This collaboration helps in formulating an appropriate diagnosis and treatment plan. Once the results are in, the PCP interprets them in the context of the patient's overall health, communicating the findings to the patient, and working out a comprehensive care plan. This could involve lifestyle changes, medication, CPAP therapy, or surgical interventions.

In the follow-up phase, the PCP tracks the patient's progress, adjusting the treatment as needed. They also coordinate care with other specialists, as sleep disorders often intersect with other medical conditions. This ongoing monitoring ensures optimal management of the patient's health and sleep disorder.

Interpreting Physician

The interpreting physician plays a crucial role in the overall process. The interpreting physician is typically a board-certified sleep specialist or pulmonologist who reviews and analyzes the data collected during a HSAT and provides a diagnostic interpretation.

Here are some key responsibilities and contributions of the interpreting physician:

- Data Analysis: The interpreting physician carefully reviews the recorded physiological data captured during the HSAT. This may include information such as respiratory effort, airflow, blood oxygen levels, heart rate, and body position. They analyze the data to identify any indications of sleep apnea, assess its severity, and identify associated factors.
- Diagnosis and Treatment Recommendations: Based on the analysis of the HSAT data, the interpreting physician makes a diagnosis of sleep apnea or other sleep-related disorders. They determine the type and severity of sleep apnea, considering factors like the frequency of apnea events and the degree of oxygen desaturation. The interpreting physician may also recommend appropriate treatment options, such as CPAP therapy, lifestyle changes, or further diagnostic testing in a sleep laboratory.
- Communication with Stakeholders: The interpreting physician may communicate the diagnosis and treatment recommendations to various stakeholders involved in the HSAT

process. This includes the referring healthcare provider who ordered the test and any other relevant healthcare professionals involved in the patient's care. Clear and concise communication helps ensure that all stakeholders have a comprehensive understanding of the results and the subsequent steps required for managing the patient's condition.

- Overall, the interpreting physician's role in home sleep apnea testing is to analyze the HSAT data, make an accurate diagnosis, provide treatment recommendations, and maintain effective communication. Their expertise is essential in ensuring that patients receive appropriate diagnosis and treatment for sleep apnea, ultimately improving their sleep quality and overall well-being.
  ** See Appendix A for Understanding the Role of the Interpreting Physician

Allied Health Professionals

Allied health professionals play a crucial role in sleep testing. They assist in the diagnosis and management of sleep disorders alongside sleep medicine physicians. Their responsibilities include conducting sleep studies, preparing patients for testing, and ensuring accurate data collection during the procedure. They may perform various tasks such as applying electrodes, monitoring patients' vital signs, and observing sleep patterns. Allied health professionals are trained in the operation of sleep monitoring equipment and are skilled in recognizing abnormal sleep patterns and events. They play a vital role in identifying sleep-related breathing disorders, such as sleep apnea, and other conditions like insomnia or narcolepsy. Additionally, they collaborate with the sleep medicine team to analyze sleep study results, interpret data, and provide valuable insights for diagnosis and treatment planning. They may also educate patients on sleep hygiene practices and offer guidance on lifestyle modifications to improve sleep quality.

In summary, allied health professionals are integral members of the sleep testing team, contributing to the accurate diagnosis and management of sleep disorders through their expertise in conducting sleep studies, data collection, analysis, and patient education.

Medical Directors

The Medical Director for sleep labs and home sleep apnea testing plays a vital role in ensuring the highest standard of care and accurate diagnosis for patients with sleep disorders. They oversee the operations of sleep labs and home testing programs, developing and implementing protocols and policies to ensure compliance with regulatory standards and accreditation requirements. Working closely with sleep technologists, they interpret sleep study results and provide clinical guidance and expertise to healthcare providers and staff. They review and approve sleep study referrals, participate in quality assurance activities, and stay updated on the latest advancements in sleep medicine.

As a Medical Director, they also have the responsibility of training and educating staff on sleep disorders and diagnostic procedures. They collaborate with other healthcare professionals to develop comprehensive treatment plans for patients and assess and manage those with complex sleep-related

medical conditions. Additionally, they conduct research, participate in clinical trials, and communicate with patients and their families regarding diagnosis and treatment options.

Ensuring patient safety during sleep studies and home testing is a crucial aspect of their role, and they review and update sleep lab equipment and technology as needed. They actively participate in professional organizations and conferences, supervise and mentor sleep medicine fellows and residents, and collaborate with insurance providers to obtain authorization for sleep studies. Additionally, they participate in multidisciplinary meetings, conduct regular audits to ensure data accuracy, and provide expert testimony in legal cases related to sleep disorders.

The Medical Director also assists in the development of sleep disorder screening programs, conducts performance evaluations for sleep lab staff, and promotes public awareness and education about sleep disorders. They advocate for improved access to sleep medicine services and resources, aiming to make a positive impact in the field of sleep medicine and improve the overall well-being of individuals affected by sleep disorders.

Homecare Service Providers

The homecare service provider plays a vital role in home sleep apnea testing. They are responsible for providing the necessary equipment and support to individuals undergoing sleep apnea testing in the comfort of their own homes.

The role of the homecare service provider begins with educating the patient about the testing process and ensuring they understand how to use the equipment correctly. They deliver the sleep apnea testing equipment to the patient's home and provide instructions on how to set it up. The homecare service provider ensures that the equipment is properly calibrated and functioning accurately. They may assist the patient in applying the necessary sensors and electrodes to monitor their breathing patterns, oxygen levels, and other relevant parameters during sleep. Throughout the testing period, the homecare service provider remains available to address any concerns or technical difficulties the patient may have. They may provide troubleshooting assistance and offer guidance to ensure the smooth progress of the sleep apnea test. Once the testing period is complete, the homecare service provider retrieves the equipment from the patient's home. They ensure that the data collected is securely transmitted to the sleep physician or a designated healthcare professional for analysis and interpretation.

In summary, the homecare service provider is responsible for delivering, setting up, and retrieving the sleep apnea testing equipment in a home environment. They play a critical role in ensuring proper equipment usage, troubleshooting, and facilitating the transfer of data for accurate analysis and diagnosis by healthcare professionals.

Provincial Regulations (Canada)

In Canada, the regulatory bodies play a crucial role in overseeing sleep testing to ensure quality, safety, and adherence to standards. The primary regulatory bodies involved in sleep testing in Canada are:

Health Canada: Health Canada is responsible for regulating medical devices used in sleep testing, such as sleep monitoring equipment and devices. They establish guidelines and standards for the safety, efficacy, and quality of these devices.

Canadian Sleep Society (CSS): The CSS is a professional organization that represents sleep researchers, clinicians, and educators in Canada. They work to promote and advance the field of sleep medicine, including establishing guidelines for sleep testing procedures and protocols.

Provincial Regulatory Colleges: Each province in Canada has its own regulatory college for healthcare professionals. These colleges, such as the College of Physicians and Surgeons, College of Respiratory Therapists, or College of Polysomnographic Technologists (U.S), govern the practice of healthcare professionals involved in sleep testing. They set standards of practice, issue licenses, and enforce ethical guidelines.

Accreditation Canada: Accreditation Canada is an independent organization that assesses and accredits healthcare facilities, including sleep clinics and laboratories. They ensure that these facilities meet specific quality and safety standards in conducting sleep testing.

These regulatory bodies collaborate to establish and enforce guidelines, protocols, and regulations pertaining to sleep testing. Their aim is to ensure the provision of accurate diagnostic information, appropriate patient care, and the safety and well-being of individuals undergoing sleep testing in Canada.

Equipment Specific Information

Sleep Image

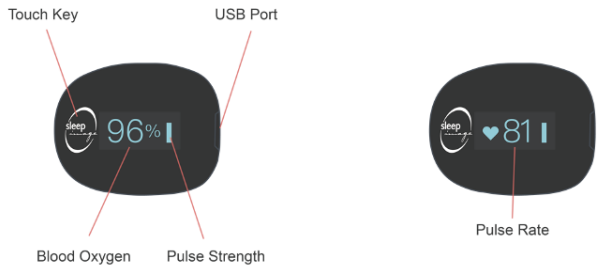
1. Indications for Use

The SleepImage System® is FDA Cleared for use to diagnosed sleep apnea in children and adults. The SleepImage system comprises of a ring-based device that collects data during the sleep period and software that analyses collected data for sleep quality and sleep apnea. The output is intended only for use by or on the order of a Healthcare Professional to aid in the evaluation of sleep disorders, where it may inform or drive clinical management for children, adolescents and adults. The SleepImage Apnea Hypopnea Index (sAHI), is intended to aid healthcare professionals in diagnosis and management of sleep disordered breathing disorders. The SleepImage System output is not intended to be interpreted or clinical action taken without consultation of a qualified healthcare professional. When used by dentist, report reading by a sleep physician is mandatory.

2. Intended Use & Patient Interface

2.1 The SleepImage-Ring

The data-collection device (SleepImage Ring) is intended to be used for measuring, displaying and storing pulse oxygen saturation (SpO_2) information, plethysmography-data (PLETH) and actigraphy data that is transferred via Bluetooth to the SleepImage App SleepImage App during the recording session. No data is stored on the SleepImage-ring.



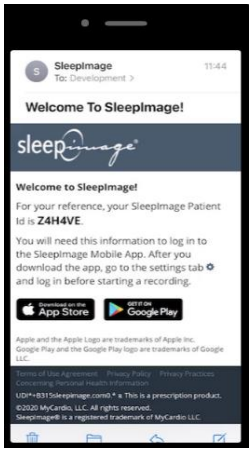
SleepImage offers the convenience of a consumer wearable, using commonly understood functionality of mobile apps to make sleep testing easy for patients, without sacrificing the accuracy of the output for clinicians to diagnose & manage sleep apnea for their patients.

2.2 Sleep Image Software

SleepImage is FDA-cleared Software as a Medical Device. With one point of contact on the finger to capture 6 channels of raw data, data is streamed live to a mobile device during the sleep test. Data is then automatically uploaded to the secure Clinical Portal. Output is automatically created for interpretation and diagnosis. Detailed instructions on how to use the Sleep Image System user interface can be found in at Sleep Image Instructions for Use

The SleepImage System is built with the vision to simplify the home sleep test process.
Supported by wearable and flexible recording devices that are worn on the finger and paired with a mobile app that automatically uploads the recorded data at the end of the sleep test to the cloud-based SleepImage System, the SleepImage System to help physicians and other healthcare providers to evaluate, diagnose and manage their patients' sleep quality and sleep disorders.

SleepImage does not require the use of consumables, wires, belts or cannulas to provide a sleep report that identifies both sleep quality associated with health outcomes, such as blood pressure control and sleep apnea for diagnosis on par with polysomnography (PSG), with automated output and 6-channels of raw data that can be interpreted and manually scored.



**See Appendix C – Sleep Image Report

3. Using the SleepImage-Ring and the SleepImage-App

3.1 Charging

Charge the battery before giving the SleepImage-Ring to a patient by connecting the SleepImage-Ring to computer USB or USB charging adapter with the included USB cable. When fully charged, Ring will power off automatically. If doing multi-night testing, advice your customer how to charge the ring after each sleep recording.

3.2 Display

Touch the SleepImage logo on the display to switch between displaying (1) time & battery level, (2) serial number and (3) Pulse/SpO_2. The screen turns off automatically during recordings; you can touch the SleepImage logo on the display to wake up the screen. Device will turn on automatically by placing a finger in the SleepImage-Ring and turn off automatically be removing a finger from the SleepImage-Ring.

3.3 The SleepImage-App and Ring fit

When patient is created in providers account, it offers the opportunity to send important information to the patient regarding how to use the system for sleep recordings. This includes information on how to download the SleepImage-App and pair with the SleepImage-Ring Instruction for SleepImage App &

Ring, alternatively assist with downloading the App and pairing the SleepImage-Ring for them to be fully ready to do their study.

It is also important that all providers go over with their patients how to wear the SleepImage-Ring. It is recommended to wear the SleepImage-Ring on the thumb or index finger. A proper fit is essential, it should not be too loose which may cause artifacts in the recording or so tight that blood flow is restricted which may cause unreliable data collection. If the SleepImage-Ring is too tight for thumb and index fingers, try an alternate finger but avoid the middle finger. If the SleepImage-Ring is too loose advice your patient too secure with a e.g., "creptape" emphasizing to fasten too tightly.

3.4 Sleep Recordings

Ring will turn on automatically when worn and the patient has then to start the sleep-data recording in the App. When they wake up after the sleep-period, they will need to stop the recording in the App and then remove the SleepImage-Ring that will then automatically turn itself off. After the recording is stopped in the App, the recording will upload to the SleepImage-portal. If study does not upload, check the Troubleshooting in the SleepImage-App instructions on www.sleepimage.com

4. Cautions and Warnings

The SleepImage System is intended to assist qualified healthcare professionals to evaluate sleep disorders. The sAHI is intended to aid in diagnosis and management of sleep disordered breathing. The SleepImage Report is not intended to be interpreted or clinical action taken without consultation of a qualified healthcare professional and only studies with good signal quality should be utilized for diagnostic purposes. Any interpretation of the data to diagnose a medical condition is the sole responsibility of the treating healthcare professional. SleepImage is not responsible for any such use of information reported from the SleepImage System, patient reports or the data therein.

5. Interpreting the SleepImage Report

5.1 The SleepImage Science

The science behind the SleepImage-system is discussed in this short document Introduction to SleepImage. As a provider, please make sure you have familiarized you with the method before utilizing the system to evaluate sleep in your patients. At the end of this document, you will find a list of publications that you may find helpful.

5.2 Important steps when reviewing the SleepImage Report

5.2.1 Signal Quality

Always start by evaluating the quality of the recording by looking at the Signal Quality Line. ONLY reports with predominantly green signal quality should be considered for clinical decision making. Yellow- and

Red-signal needs to be evaluated for signal abnormalities (signal noise) or signal loss. There are three primary reasons why the Signal Quality Line may report segments of yellow, amber or red signal:

(1) Signal Loss- The mobile app was not able to communicate with the recorder and therefore no signal is received for that period. The result will be a gap in the analysis – this is important to include when interpreting the data output.

(2) Artifact – this can be caused by a poor sensor contact or excessive motion during recording, causing noise in the signal that does not produce valid output. The result is a signal that does not have the appearance of a physiological signal and may exceed the upper and lower extremes of the graph.

(3) Physiological abnormalities – in patients with chronic arrhythmia, The SleepImage System may be unable to successfully analyze the signal for quality output. In these cases, the Signal Quality Line will be yellow, amber or red. If a patient is suspected of having arrhythmia, it is a good practice to refer them to the appropriate specialist for further evaluation. The SleepImage System is not intended to rule in or rule out arrhythmia. Examples Arrhythmia

5.2.2 SleepImage quality and pathology markers

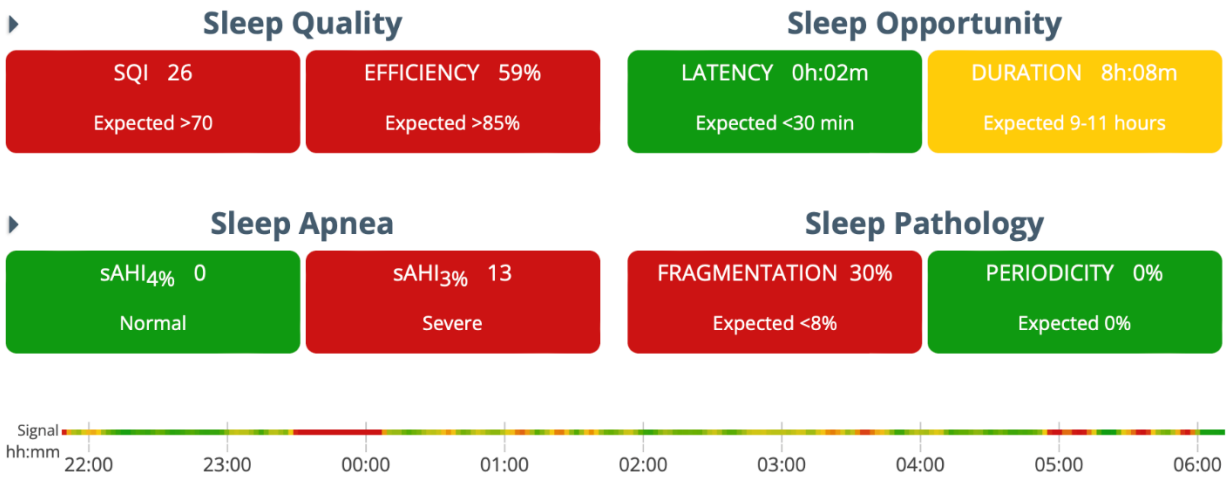
Evaluate the SleepImage quality and pathology markers in relationship with patient complaints. It is highly important to evaluate all the parameters including sleep timing, sleep duration and sleep continuity even though the focus is on sleep apnea.

(1) If there is a suspicion that the patient has sleep apnea, make sure to evaluate all the parameters related to sleep disordered breathing (SDB) presented on the report (sAHI, sRDI, Fragmentation, Periodicity CVHR and oxygen summary information (the duration of SpO_2 below 90%, 88% & 80%) when reviewing the output.

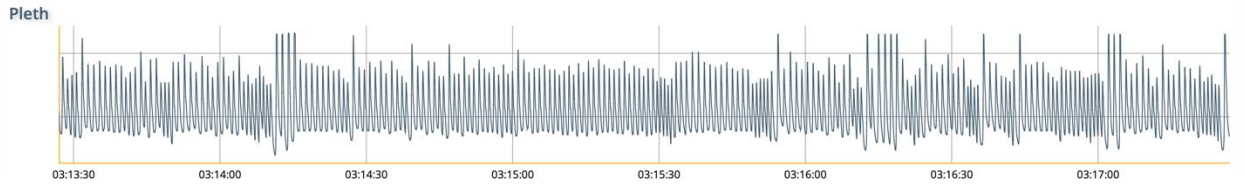
(2) Finally, when all the automatically calculated parameters have been reviewed it is a good clinical practice to review the autoscoring of sAHI before sending the report to the sleep physician you are working with for diagnosis.

5.2.3 Examples of artifacts that may affect autoscoring of the sAHI

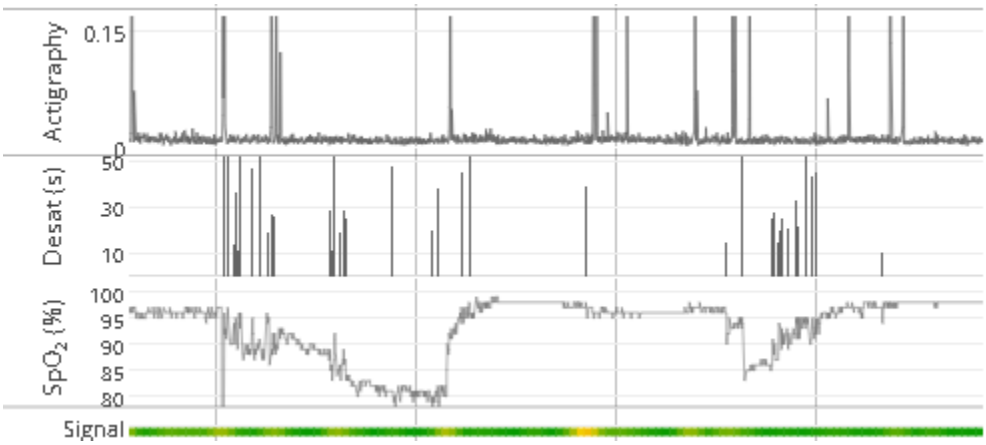
(1) 9-year-old girl, sAHI autoscored is 13. When looking at the Signal Quality Line it is highly yellow and red. Based on the issues with the signal quality this study should not be utilized for diagnostic purposes.



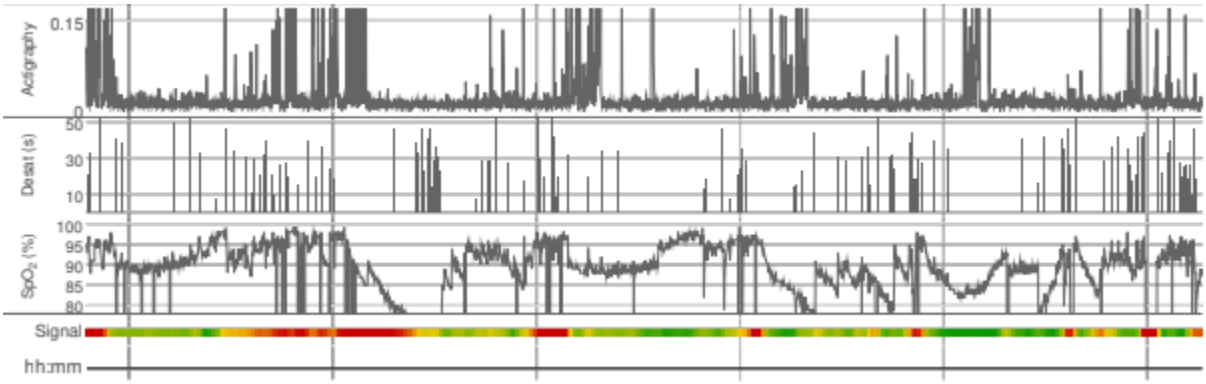
When further looking into the raw signal arrhythmias are detected. Please remember that the SleepImage System if not cleared to detect arrhythmias but based on the persons health as a provider it might be appropriate to suggest further cardiac evaluation.



(2) Patient laying on the ring causing artifacts



(3) Movement artifacts affecting sAHI autoscoring



General Requirement

Data quality and Patient Information Requirements

It is imperative that the data quality is good so that a proper and accurate interpretation can be generated. Factors that contribute to a good quality study are:

A) Equipment data output

i) Time:
ii) Movement Artifacts
iii) Circulation

B) Patient History Data

IMPORTANT - It is important to ensure that the information critical to formulating a high quality interpretation is present. The following is patient information required to complete an interpretation:

- Age
- Gender
- BMI
- ESS (Epworth Sleepiness Sale)
- Reason for testing
- Relevant Symptoms
- Relevant past medical history
- Medication (Especially opioids or other medications that may impact muscle tone and respiratory drive)
- Smoking/Vaping (Current and/or History)
- Allergies (especially environmental)
- ENT related information (e.g. Tonsil / Adenoids / Reconstruction / Modification / Polyps / Trauma)

General Process Overview

*** Note – the following is a high level review of the process to provide a general idea of the procedure. Each clinic will be required to develop their own workflow***

Assessment Phase

1. Identifies the need for Home Sleep Apnea Test
2. Ensures age appropriate
3. Ensures patient/family have mobile technology available to record and transmit data
4. Ensures patient/family have the technological know how to utilize the equipment
5. Reviews indications and contraindications
6. Establishes length of time patient will have device
7. Records relevant patient history

Adding Patient

1. Enter Patient information to the Sleep image data base
2. Assign a clinician to the patient

Patient Education

1. Review the device functionality with the patient
2. Review the mobile app functionality
3. Review the risks and potential complications
4. Establish a plan to return the device

Receiving and sharing the study data

1. Enter the patient portal
2. Review the study details
3. Accept or Reject each study to generate the pending report
4. Select the study that you wish that the interpreting Physician interpret
5. Add the clinical notes to the selected study
6. Share the data with the interpreting physician. An automatic email will be generated advising the physician that the study is ready for interpretation.

Generation of interpretation (Interpreting Physician)

1. Physician will review the study
2. Physician will review the relevant past medical history, symptoms, indications and additional data in the notes such as AGE, BMI etc.
3. Physician will add their interpretation with recommendations.
4. The study will be signed and an automatic email will be generated advising the dental clinic that the interpretation has been completed.
5. The interpretation will generally be returned to the referring dentist within 14 days.

Patient Follow-up and Care Plan

1. The dentist or PCP will review the interpretation with the patient

2. The dentist will establish a care plan based on, but not limited to, the below:

i. Study Findings
ii. Specialist Interpretation
iii. Physical exam
iv. Patient history
v. Available Healthcare Funding

3. The Dentist may choose to solely provide care to the patient and/or collaborate with other who may be involved. Based on the finding, the dentist must be prepared and willing to refer and collaborate with other entities and healthcare professional to service the patient needs. Note: A provincial Practitioner ID is required to refer to a medical Specialist. A Practitioner ID can be applied for using the following link https://formsmgmt.gov.ab.ca/Public/AHC11234.xdp.

Below is a list of potential collaborators:

Otolaryngologist (ENT)	Polysomnography Laboratories
Pulmonologist	Homecare Service Providers
Board Certified Sleep Specialist	Funding sources / Insurance Companies
Specialty Clinics	etc.

Appendix A –Indications and Contraindication of Home Sleep Apnea Testing

Indications

Home sleep apnea testing (HSAT) is typically used to diagnose or rule out obstructive sleep apnea (OSA), a condition characterized by repeated episodes of partial or complete blockage of the upper airway during sleep. The test can be performed in the comfort of a patient's own home and typically involves the use of a portable monitoring system.

Here are some common indications for home sleep apnea testing:

1. High Pretest Probability of Moderate to Severe OSA: HSAT is best suited for patients with a high pretest probability of having moderate to severe OSA. This might include patients who exhibit common symptoms such as excessive daytime sleepiness, loud snoring, observed episodes of breathing cessation during sleep, and frequent waking up gasping or choking.
2. No Significant Comorbidities: HSAT is generally recommended for individuals who have no significant comorbidities such as severe pulmonary disease, neuromuscular disease, or congestive heart failure. These conditions can complicate the diagnosis of OSA.
3. Inability to Undergo In-Lab Sleep Testing: Some patients might have difficulty going to a sleep lab for testing due to issues such as mobility problems, illness, or lack of local facilities. In such cases, home testing may be a suitable alternative.
4. Patient Preference: Some patients might prefer home testing over in-lab testing for reasons of convenience and comfort.

From a dentist's perspective, there are additional considerations:

1. Bruxism (Teeth Grinding): Dentists often see patients with evidence of teeth grinding, which can be a sign of sleep apnea. If a patient with bruxism reports symptoms such as daytime sleepiness or a bed partner reports snoring or gasping sounds, the dentist might recommend HSAT.
2. Temporomandibular Joint Disorder (TMD): There's a documented relationship between TMD and sleep disorders, including sleep apnea. If a patient with TMD symptoms also presents symptoms suggestive of sleep apnea, a HSAT may be indicated.
3. Dental Appliances: Dentists play a key role in the management of sleep apnea with oral appliances. If a patient is already using an oral appliance for sleep apnea, a dentist might recommend HSAT to assess the effectiveness of the appliance.
4. Dental and Facial Anomalies: Certain dental and facial anomalies, such as retrognathia (a condition where the lower jaw is set further back than the upper jaw), can increase the risk of OSA. Dentists can identify these risk factors and may recommend HSAT.

It's important to remember that while HSAT can be very useful, it does have limitations. In some cases, such as when the test results are inconclusive or when a patient has certain other medical conditions, in-lab polysomnography may still be necessary. Additionally, all recommendations should be made in coordination with other healthcare providers involved in the patient's care.

Contraindication

Contraindications for home sleep apnea testing (HSAT) often relate to the limitations of the equipment, potential for inaccurate results, or the presence of certain health conditions. It's also important to remember that while home testing can be useful, it is not suitable for everyone.

Here are some common contraindications for home sleep apnea testing:

1. Low Pretest Probability of Obstructive Sleep Apnea (OSA): HSAT may not be sensitive enough to accurately identify mild OSA. Therefore, if there is only a low pretest probability of OSA, in-lab polysomnography might be a better choice.
2. Presence of Significant Comorbidities: HSAT is generally not recommended for individuals with significant comorbidities such as severe pulmonary disease, neuromuscular disease, or congestive heart failure. These conditions can affect breathing patterns and thus may complicate the interpretation of HSAT results.
3. Central Sleep Apnea or Other Sleep Disorders: HSAT primarily assesses for OSA and may not be accurate in diagnosing central sleep apnea or other sleep disorders. Therefore, in-lab testing may be preferred for patients with symptoms suggestive of these conditions.
4. Severe Insomnia: For individuals with severe insomnia, the limited number of channels monitored in HSAT might not provide an accurate representation of sleep duration and architecture.

From a dentist's perspective, there are additional considerations:

1. Oral Appliances: If a patient is using a mandibular advancement device (MAD) or any other oral appliance for OSA, and the device interferes with the HSAT equipment, this could be a contraindication.
2. Oral and Maxillofacial Conditions: Certain oral and maxillofacial conditions, such as recent oral surgery or severe periodontal disease, might limit the use of certain HSAT devices, particularly those that require an oral component.

3. Uncooperative Patients or Cognitive Impairment: HSAT requires patient cooperation to correctly use the equipment. If a patient is unable or unwilling to follow instructions, or if they have cognitive impairments that may affect their ability to use the equipment properly, in-lab testing may be a better option.

In all cases, the benefits and limitations of HSAT should be discussed with the patient, and the decision to proceed should be made in conjunction with other healthcare providers involved in the patient's care. Remember, these are general considerations, and individual patient circumstances can significantly influence the decision-making process.

Appendix B - Understanding the Role of the Interpreting Physician

The interpreting physician is a crucial member of the service delivery team in sleep medicine. Their primary role is to understand the data provided and deliver an interpretation of the data based on the information provided. In many cases, the interpreting physician will provide recommendations or suggestions based on the information that they have been provided.

There are, and have been, many misconceptions related to the role of the Interpreting Physician in sleep testing. It is very important to understand that the interpreting physician does not, by way of the associated work conducted, take responsibility for the ongoing care of the patient. Nor does the interpreting physician have the legal authority to write prescriptions for therapy, medication, further testing etc. solely based on the work completed as part of the interpretation. Initial of the reader____.

It is also very important to understand that providing a sleep interpretation **does not**, by way of the associated work, constitute a referral to the interpreting physician. Often the physician is interpreting hundreds of studies per month. It is not feasible to expect the physician to take responsibility for a vast number of patients. Initial of reader _____

In some case the interpreting physician will agree to see the patient in consultation. In these cases, a formal referral **must** to be sent to the interpreting physician. A referral to the interpreting physician must be accompanied by the Practitioner ID of the referring Physician. All Specialists, Family Physician and Nurse Practitioners have a Practitioner ID. Some Dentists also have a Practitioner ID. A Practitioner ID can be applied for using the following link https://formsmgmt.gov.ab.ca/Public/AHC11234.xdp. Only after the consultation, which includes a comprehensive review of the patient history and a physical exam, may the interpreting physician write orders for the patient. Initial of reader _____

I have read and understand the role of the Interpreting Physician:

_____

Print Name

_____

Signature

_____

Clinic Name

Appendix C - The Sleep Image Report

The SleepImage report is auto generated displaying information commonly used for sleep evaluation to aid diagnosis or management of sleep disorders. The quality of the data collected during the sleep study is presented on the signal quality line as green (good signal), yellow and red (compromised signal). For further information on Sleep Quality, Sleep Opportunity, Sleep Apnea and Sleep Pathology, click the triangles located to the left of the headlines above the two rows of the colored boxes to expand the view. Further information on the SleepImage system https://sleepimage.com/

Appendix D - Billing

Dental Clinic Payment Structure

The Dental clinic will determine the patient fee structure and schedule based on the individual needs and goals of the clinic.

Interpreting Physician Payment Terms, Guidelines and Instructions

The interpreting physician will charge the dental facility $75 per interpretation. This will be billed monthly to the dental clinics accounts payable department. Invoices will be sent via email at the beginning of every month. Payment terms are net 30 days. Payments shall be made via PayPal or internet transfer (Interac). Late payment fees shall be charged at a rate of 6% per month. The interpreting service reserves the right to suspend services in the case of overdue accounts. The Interpreting service reserves the right to send overdue account to a collection agency when the accounts is in arrears for greater than 90 days.

Other Billing Considerations

- Dental clinic will only be charged for interpretations that have been completed and not studies that are “pending” or awaiting interpretation.
- Dental clinic will not be charged for studies that are deemed “not interpretable”.

I have read and acknowledge the Interpreting Physician’s payment terms, guidelines and instructions:

_____

Print Name

_____

Signature

_____

Clinic Name