

*STUDY OF  
OSTEOPOROTIC  
FRACTURES*

**Procedure Manual  
for  
Polysomnography**

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January 7-9, 2002 (Rev. 8/20/02)

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# *STUDY OF OSTEOPOROTIC FRACTURES*

## **1.1 Definition of Sleep Apnea**

**Sleep Apnea** (also referred to as obstructive sleep apnea syndrome, sleep apnea-hypopnea, sleep disordered breathing) is a condition or syndrome characterized by loud disruptive snoring, snorting/gasping (during sleep), and daytime sleepiness. These symptoms result from abnormal breathing during sleep occurring as a result of intermittent (<1 minute) and repetitive (>5 hour) collapse or partial collapse of the throat (upper airway tissues). When the throat totally collapses (obstructs), ***breathing completely stops (momentarily)***, and an ***apnea*** occurs. When the throat partially collapses, a ***hypopnea*** (or partial obstruction) occurs (***breathing continues but is diminished***). In order to resume breathing after a complete or partial throat obstruction, the body sends signals to the lungs and chest to breathe harder. Eventually (usually only seconds), enough force is developed to open the throat muscles, allowing normal breathing to resume. As the throat tissues are pulled open, a ***loud snort*** or ***gasp*** may result. ***Snoring*** may be heard as the throat tissues vibrate during breathing through a partially blocked throat.

Why does this occur? Normal breathing depends on many factors, including airway (bronchial) size and function, lung tissue factors, the lung's blood supply, and breathing muscles (chest, diaphragm, and throat). The brain controls many of the lung's activities. While we are awake, the brain usually sends the appropriate signals to the muscles of the chest and the throat, maintaining normal breathing. However, during sleep, many of the throat muscles relax too much. When this happens, especially in people with a small throat opening (from big tonsils, a big tongue, fat, or a small jaw), a partial or complete throat collapse (hypopnea or apnea) may occur.

In whom does this occur? Not too long ago, sleep apnea was thought to be a rare condition. Now that doctors know more about it, and have access to sleep laboratories (where sophisticated monitoring equipment aids in making this diagnosis), many people are being diagnosed. What is more, epidemiologists (scientists who study diseases and risk factors in communities) have begun measuring sleep and breathing in large numbers of people in the community. Because of this, we now know that sleep apnea is quite common (perhaps as common as high blood pressure). It is estimated that between 2 and 10% of adults have sleep apnea. Sleep apnea does occur in people of all ages. It may be most common, however, in the elderly, occurring in >25% of some surveys of the elderly. It also occurs in both men and women, although, at least during middle age, men are more likely to be affected than women. Although one of the biggest risk factors for sleep apnea is obesity, thin people may also have sleep apnea.

What does sleep apnea do to a person? Most of the consequences of sleep apnea are due to three phenomena: snoring, sleep disruption, and irregular breathing. One of the most troubling consequences of sleep apnea is the snoring and loud breathing noises that can disturb the sleep of the affected person as well as his/her bed-partner. This may cause embarrassment and marital discord. The intermittent disruptions to sleep also interfere with the brain's normal sleep pattern-causing "arousals," and reducing the amount of sleep time spent in deep sleep and REM (Rapid Eye Movement, or "dream") sleep. This may prevent "restorative" sleep, causing the person to feel sleepy and irritable during the day, and, possibly, "slowing" the person (physically and mentally).

The breathing irregularities often cause the body's oxygen levels to drop. The drops in oxygen levels are thought to cause stress on the heart, and possibly contribute to high blood pressure, to other heart ailments (heart attacks, angina, irregular heart rhythms) or stroke. However, very few studies have carefully examined these issues. **A major purpose of the Sleep Heart Health Study, in fact, to determine the effect of sleep apnea on heart function and overall health and function.**

**How is sleep apnea diagnosed?** Sleep apnea is diagnosed in people who have symptoms of snoring, snorting, and sleepiness, and by an overnight sleep study (with measurement of breathing and brain activities; polysomnography) that shows repetitive periods of obstructed breathing. During sleep, every apnea and hypopnea that lasts at least 10 seconds (and usually also is associated with some drop in oxygen or change in brain waves [arousals]) is counted. If the total number of apneas and hypopneas per hour of sleep is greater than a given threshold (5 to 20, according to local physician practices), a diagnosis of sleep apnea is made.

How is sleep apnea treated? Several fairly simple things are usually recommended to improve breathing during sleep: weight loss (if overweight), sleep posture (side rather than back), nasal decongestants, avoidance of alcohol, and good sleep habits (regular bed/awake times, sufficient sleep time, etc). People who are quite symptomatic often are prescribed a breathing aid, nasal CPAP (continuous positive airway pressure), a bedside device that blows air, under pressure, through the nose into the mouth, acting as a pneumatic stent, keeping the throat open. People who are prescribed this wear a small plastic mask over their nose (to permit the passage of this air). It is recommended that this machine be used nightly. Other therapies include surgery (tonsillectomy or "UPP"- uvulopalatopharyngoscopy- a procedure where excess throat tissue is removed) and dental devices that bring the jaw forward. There is a great deal of controversy, however, concerning the role of specific treatments in people who do not complain of excessive daytime sleepiness. The information proposed for collection in the SHHS, will better define the role of sleep apnea in heart disease, and, thus, provide data useful for deciding which patients should be treated for sleep apnea.

## 1.2 Polysomnography

Evaluation of sleep apnea in clinical settings usually requires **polysomnography**, a procedure in which an individual is monitored, usually for an entire night in a sleep laboratory, with a **polygraph**. This is an instrument designed to record many physiological processes simultaneously. Tiny electrical signals are transmitted to this recording instrument from the body by using specialized sensors, or electrodes, that are applied to different body parts (e.g., the head, chest, face. etc.) The recording instrument contains specialized amplifiers, filters, and computer chips that translate these signals into records that can be looked at and analyzed.

**1.2.1 Signal Types.** There are three types of signals that are collected:

- 1) **Bioelectrical** Potentials. These are produced by the body's own tissues.

Examples:

- *electroencephalogram* (EEG) (brain waves)
- *electrooculogram* (EOG) (eye movements)
- *electromyogram* (EMG) (muscle activity)
- *electrocardiogram* (ECG) (heart rate)

Bioelectrical potentials are recorded by placing sensors (usually in pairs) over the tissues that generate these impulses (e.g., over the scalp for EEG, chest for ECG, next to the eyes for EOG). The application of these sensors requires very special care to ensure that the electrical signals are transmitted clearly without artifact.

- 2) Waveforms received from **Transducers**. These are devices that translate non-electrical physiological activity (e.g., temperature, movement) into electrical signals.

Examples:

- *thermistors / thermocouples* measure airflow in response to temperature changes.
- *inductance respiratory bands* measures chest/abdomen effort in response to movement.
- *position sensors* document physical positioning of the subject during the study.

- 3) Information from **Auxiliary Devices**. These are specialized devices that are used with the polygraph to translate other signals into physiologic data.

Example:

- *oximetry* measures hemoglobin oxygen saturation, which may drop during an apnea.

***Signals that are monitored are those thought important for sleep physiology.***

***An understanding of this process requires some understanding of sleep itself.***

## 1.2.2 Sleep Stages

Although we all know the value of a good night's sleep, most people do not realize that sleep is a complex process. At the onset of sleep, the brain's electrical impulses slow down. As sleep progresses, the brain's electrical activity fluctuates in certain very specific patterns and locations. These patterns define specific sleep stages. During normal sleep, four such patterns can be identified:

<b>Stage 1</b>	"Light Sleep"
<b>Stage 2</b>	"Presence of Sleep Spindles and K-Complexes"
<b>Stage 3/Stage 4</b>	"Slow Wave or Delta Sleep"
<b>REM</b>	"Rapid Eye Movement Sleep" or "Dream" Sleep

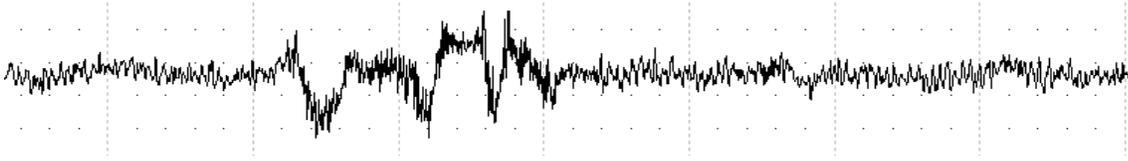
*Stages 1, 2, 3 and 4 are often referred to as non-REM sleep*

Each pattern is characterized by brain waves of specific frequencies and/or amplitudes. Stages may also be associated with certain types of eye movements and muscle activities. **Thus, accurate recording of sleep requires measurement of brain activity (EEG), eye movement (EOG) and muscle activity (EMG).**

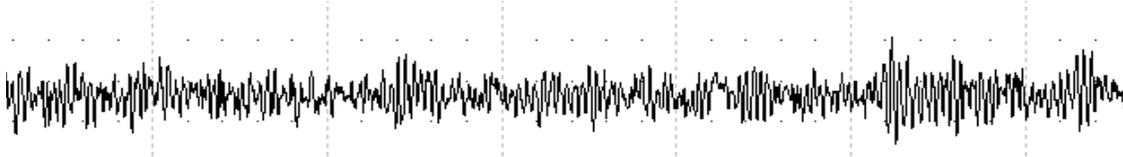
On the following page are examples of how the following stages appear on a polygraph record of EEG:

- Wakefulness - (Awake and Drowsy patterns)  
Note how irregular the pattern looks.
- Stage 1 - Slowing of activity as compared to wakefulness.
- Stage 2 - Scattered very large waves (K-complexes) and very fast waves (spindles).
- Stage 3, 4  
Deep Sleep - Waves are slower and higher in amplitude.
- REM - Waves are irregular, almost resembling wakefulness. However, in this stage, there are rapid eye movements (on EOG) and reduced activity on the muscle (EMG) channels.

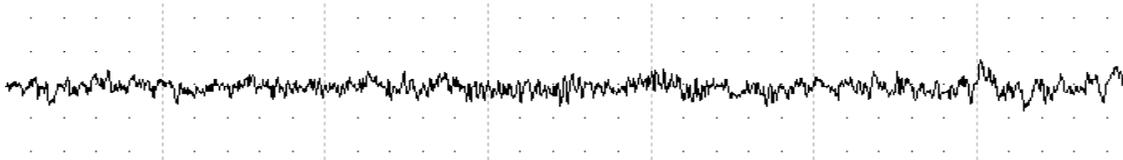
AWAKE - Low voltage - random, fast



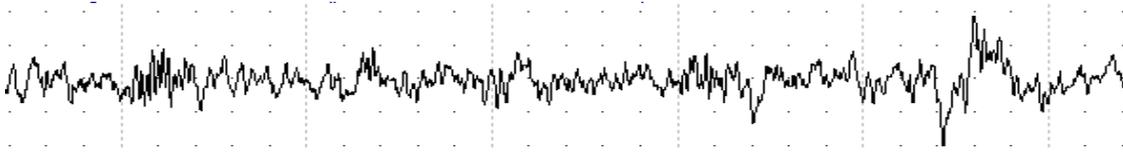
DROWSY - 8-12 Hz alpha waves



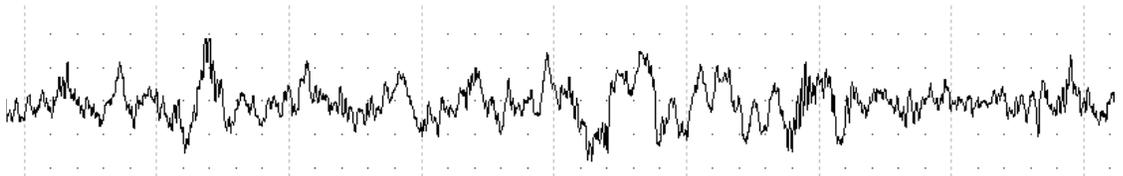
STAGE 1 - theta waves. Note the slowing of activity as compared to wakefulness



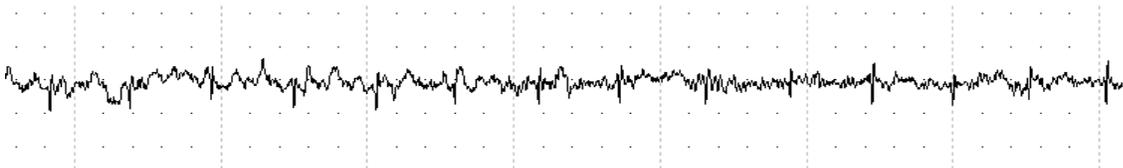
STAGE 2 Note the scattered very large waves (K complexes) and very fast waves (sleep spindles)



DEEP SLEEP (Stage3/Stage 4) - delta waves. Waves are slower and higher in amplitude



REM Sleep - low voltage - random, fast with sawtooth waves. Waves are irregular, almost like wakefulness.



During a normal sleep period, there is a regular progression of sleep stages. A **sleep cycle** is a period of non-REM sleep followed by a period of REM sleep. Generally, there are 4-6 sleep cycles per sleep period.

With disorders such as sleep apnea, **sleep architecture** (the progression and distribution of sleep stages) may be disrupted. The stresses associated with breathing through a blocked or partially blocked throat cause abrupt changes in brain activity (arousals), sometimes waking up the person, and other times, moving him/her to a lighter sleep stage (e.g., Stage 1). This often results in shorter total sleep time and reduced slow wave, Stage 3-4 and REM sleep. Often, this *sleep deprivation and fragmentation* results in daytime sleepiness and poor daytime functioning

### 1.2.3. Respiratory Monitoring – Measurement Tools

The respiratory irregularities which are the focus of the study are **apneas** and **hypopneas**.

An **apnea** is a complete or almost complete cessation of airflow, lasting  $\geq 10$  seconds, and usually associated with desaturation or an arousal.

A **hypopnea** is a reduction in airflow ( $< 70\%$  of a "baseline" level), associated with desaturation or arousal.

Events (apneas or hypopneas) are also classified on the basis of the extent of the associated respiratory effort. "**Obstructive**" events (the most common form in sleep apnea) are associated with chest and/or abdominal respiratory effort (occurring in face of an obstructed throat (upper airway)). "**Central**" events are associated with insufficient or highly irregular breathing efforts; an obstructed upper airway may or may not be a feature. This breathing pattern may be seen in heart failure and after strokes.

Thus, accurate recording of these events requires measurement of airflow, oxygen saturation, respiratory effort, and EEG, EOG, and EMG, as summarized:

**EEG, EOG, EMG.** Provides the information necessary to determine whether the breathing irregularity occurred in wakefulness or sleep. EEG (and EMG) provide information for identifying **arousals** (which may be the physiological response that identifies the event as abnormal).

**Airflow.** Qualitative assessment of breathing amplitude. Often measured with changes in temperature that occur with breathing as measured by a thermistor or thermocouple placed in the pathway of airflow (nose and mouth).

**Respiratory Effort.** Qualitative assessment of effort associated with breathing (allows distinction of central from obstructive events). May be recorded with bands that measure changes in distention/movement with breathing (inductance bands, piezoelectric).

**Oximetry.** Measures oxygen saturation levels in the blood by passing light through the finger and measuring absorption patterns (made by the oxygen carrying pigment-hemoglobin in the blood).

**Leg Movement Sensors.** Provide additional information for identifying arousals during sleep (Periodic Limb Movements of Sleep) as well as disorders which may cause insomnia (Restless Leg Syndrome).

Other important information that is measured:

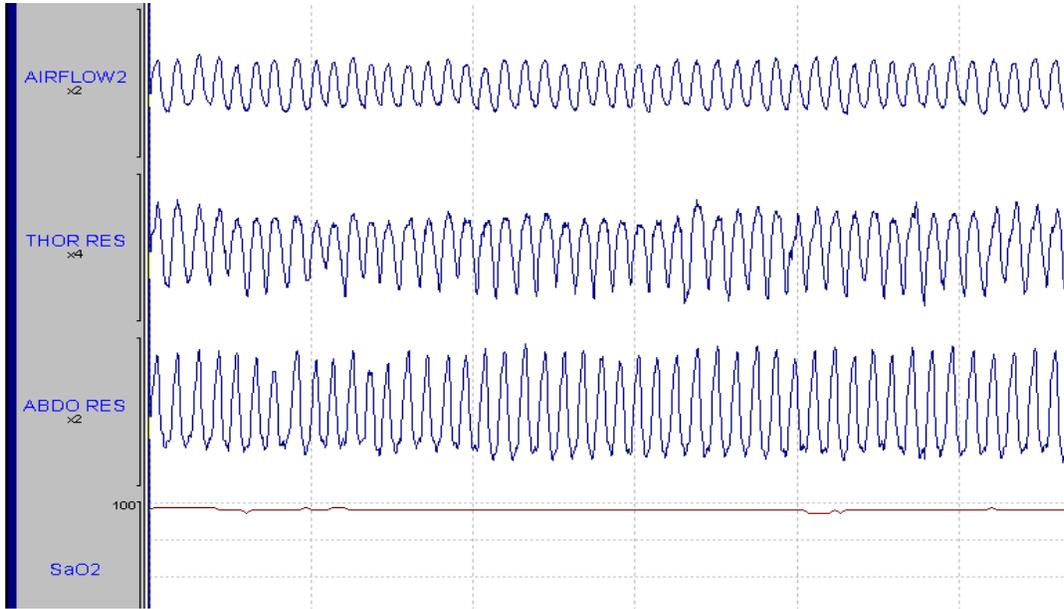
**Body Position.** To distinguish supine, upright, and side positions. This permits identification of the extent to which sleep apnea is positional.

**Heart Rate.** Allows assessment of heart rate responses to breathing-related stresses, and arrhythmia detection.

Thus, it should be apparent that accurate assessment of sleep apnea requires recording of EEG, EOG, EMG, heart rate, airflow, respiratory effort, oximetry, and body position. In the SOF study, we will use very advanced technology (Compumedics Siesta Sleep Monitoring System) that permits recording this information in an unattended setting (the participant's home) with instruments only a little bigger than a paperback book.

Below are examples of breathing as measured by polysomnography:

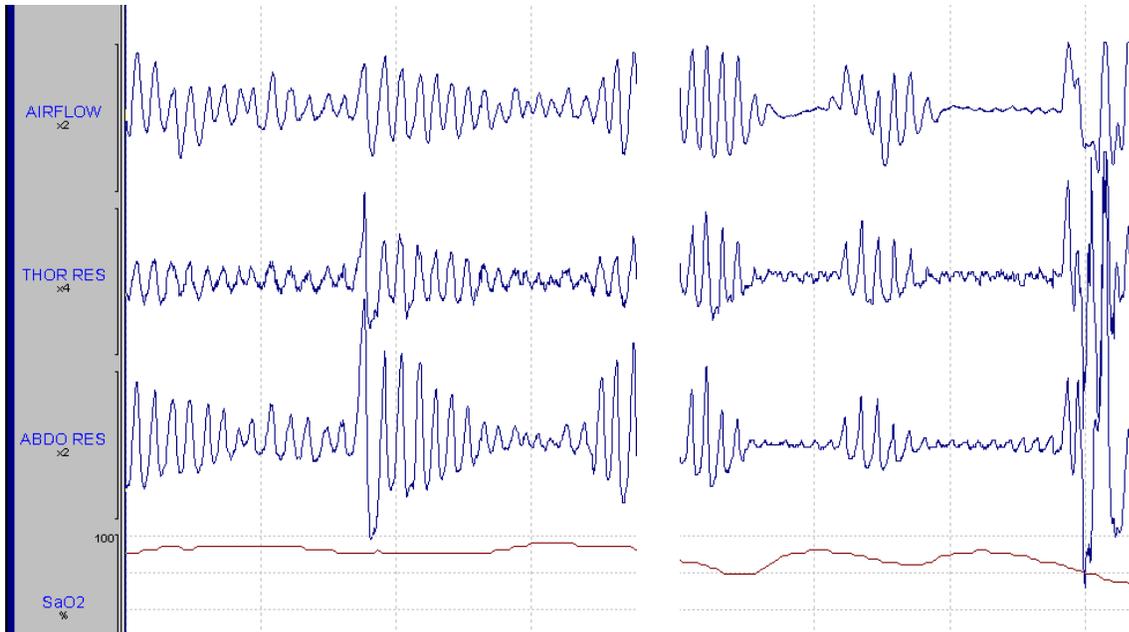
**NORMAL BREATHING**



**OBSTRUCTED BREATHING.** Note changes in oxygen saturation corresponding to changes in respiration.

**Hypopnea**

**Apnea**



### 1.3 Home Polysomnography - Compumedics Siesta Unit



Small and Lightweight - 300 grams (9.6 ounces) w/battery  
Variable montage - Records up to 32 channels - 144 MB flashcard storage  
True digital filtering during collection and review  
Remote monitoring all channels with desktop or laptop computer via Radio LAN  
Battery Power

## 1.4 GLOSSARY OF SLEEP TERMS

Alpha rhythm:	EEG rhythm, usually with frequency of 8-12 Hz. in adults; most prominent in the posterior areas; present most markedly when the eyes are closed; attenuated during attention, especially visual. (Characteristic of relaxed wakefulness with the eyes closed.)
Alpha wave:	Individual component of an alpha rhythm.
Amplifier:	An electronic instrument used to increase the strength of an incoming signal.
Apnea:	Period (>10sec) with no airflow.
Apnea/Hypopnea Index (AHI):	Number of apneas + hypopneas per hour of sleep.
Artifact:	A non-biological signal that appears in an EEG or sleep recording; or a signal that interferes with the derivations being recorded.
Beta rhythm:	EEG rhythm with a frequency higher than 12 cps.
Bioelectric potentials:	Electrical changes originating from living tissue.
Bipolar derivation:	Signals obtained by comparing voltages from 2 electrodes.
Body movement:	Scored during any sleep stage when a phasic increase in the amplitude of the EMG lead of 1 sec or longer is accompanied by muscle artifact in an EEG or EOG trace.
Canthus:	Corner of the eye (plural: Canthi)
C3:	A symbol of the International 10-20 electrode system, identifying left central electrode placement site.
C4:	A symbol of the International 10-20 electrode system, identifying left central electrode placement site.
Central Apnea (Hypopnea):	Cessation (or reduction) of respiratory effort $\geq$ 10 secs
Channel:	The linear (signal) output of an amplifier
Collodion:	An ether-based substance used for gluing electrodes to the scalp.
Delta Rhythm:	EEG rhythm with frequency of 4 Hz. or less.
Delta Sleep:	Sometimes used as a synonym for stages 3 and 4 sleep. (Note that the frequency criterion for scoring slow EEG waves in stages 3 and 4 sleep is 2 Hz. or slower.)
Delta Wave:	EEG wave with duration of more than .25 sec.
Derivation:	Recording from a pair of leads.
Drowsy sleep:	Sometimes used as a synonym for stage 1 sleep.
Duration of a wave:	Time interval from beginning to end of a waveform.
Electrical silence:	Absence of electrical activity.
Electroencephalogram (EEG):	A record of the electrical activity of the brain.
Electromyogram (EMG):	A record of the electrical activity of muscles.
Electrooculogram (EOG):	A record of the electrical activity of eye movements.
Frequency:	The number of complete cycles of a waveform within 1 second.
Gain:	Voltage ratio of amplifier input to output
Ground electrode:	Electrode (or pair of electrodes) connected directly to the polysomnograph and to earth grounds to provide for electrical safety
Hertz:	Cycles per second; a measure of frequency
Hypopnea:	Decrease in airflow or thoracic effort for $\geq$ 10 sec. (usually <50% of baseline); partial airflow obstruction.

Impedance:	Opposition to the passage of alternating current (AC)
Inductive Plethysmography:	Method for measuring changes in circumference.
Inion:	A bony protuberance at the base of the skull
K complex:	An EEG waveform having a well-delineated negative sharp wave immediately followed by a positive component; duration exceeds 0.5 seconds; waves of 12-14 Hz. (sleep spindles) may or may not constitute a part of the complex; generally maximal over vertex regions; occurring during sleep either spontaneously or in response to sudden (usually auditory) stimuli. (Characteristic of stage 2 sleep.)
Lead:	Term used to denote a single electrode
Light sleep:	Sometimes used as a synonym for stage 2 sleep.
Location:	Physical site, or area
Low-voltage EEG:	EEG consisting of cerebral activity of 20 uV or less
Montage:	Combination of multiple derivations.
Morphology:	The shape (form) of a wave
REM sleep:	Rapid Eye Movement. The dream-stage of sleep. A relatively low-voltage, mixed-frequency EEG in conjunction with episodic rapid eye movements and a low-amplitude EMG.
Obstructive apnea (hypopnea):	Absence (reduction) in air exchange despite respiratory effort lasting $\geq 10$ sec.
Ohm:	Unit of electrical resistance.
Ohmeter:	A device used to measure impedance in a circuit.
Oximeter:	Sensor that emits infrared light band transmitted across tissue (e.g., nail, earlobe), to detect hemoglobin oxygen saturation.
Mastoid:	Bony process behind the ear.
Nasion:	Indentation above the bridge of the nose.
Piezoelectric bands:	Bands containing a crystal which generates electrical current when subjected to stress.
Polysomnograph:	Multichannel instrument used to record physiologic parameters during sleep.
Preauricular point:	Small indentation in front of, slightly above, cartilage flap of ear canal.
Quiet sleep:	Sometimes used as a synonym for stages 3 and 4 sleep.
Random:	Occurring at inconstant time intervals.
Respiratory Disturbance Index (RDI):	Number of respiratory disturbances (apneas plus hypopneas per hour of sleep). Synonym for AHI.
Rhythm:	Periodicity
Saw-tooth waves:	Notched wave forms in vertex and frontal regions that sometimes occur in REM sleep.
Sleep spindle:	A waxing and waning wave form with a frequency of 12-14 Hz., most prominent in stage 2 sleep.
Slow-wave sleep:	Sometimes used as a synonym for stages 3 and 4 sleep.
Stage 1 sleep:	Relative low-voltage, mixed-frequency EEG without rapid eye movements; slow rolling eye movements are often present; vertex sharp waves may be seen; EMG activity is not suppressed.
Stage 2 sleep:	12-14 Hz. sleep spindles and K complexes on a background of relatively low-voltage, mixed-frequency EEG activity.
Stage 3 sleep:	Moderate amounts (20%-50%) of high amplitude (75 uV or greater), slow-wave (2 Hz. or slower) EEG activity.
Stage 4 sleep:	Predominance (greater than 50%) of high-amplitude (75 uV or greater), slow-wave (2 Hz. or slower) EEG activity.
Strain gauge:	Device used to detect movement or changes in body (body part) circumference.

Thermistor:	Sensor measuring changes in temperature with inspiration and expiration, used to assess airflow.
Theta activity:	Series of waveforms with durations of .14 to .25 sec. (May be seen in stage 1 or REM sleep).
Theta rhythm:	EEG rhythm with a frequency of 4 cps to less than 8 cps.
Theta wave:	EEG wave with duration of .14 to .25 sec.
Topography:	Distribution of activity with respect to anatomic landmarks. (Synonym: spatial distribution).
Transducer:	Device used to convert non-electrical physiological variables into electrical signals.
Unilateral:	Occurring on one side of the head.
Vertex sharp wave:	Sharp wave, maximal at the vertex and negative in relation to other areas (often occurring during later portions of stage 1 sleep).
Wave:	Any transient change of potential difference in the EEG.

## 2.0 Home Polysomnography (PSG)

### 2.1 Preparing Supplies

Below is a list of supplies for single person use (however, make sure you pack extras):

- 1 tube EC-2 paste
- 4 X 4 gauze pads
- 1 bottle Pre-Tac adhesive synergist
- 1 tape measure
- precut 1 x 1 gauze squares
- 1 scissors
- Alcohol swabs or Electrode Prep pads
- 1 small bottle acetone or acetone prep pads
- 2 cotton tip applicators
- 1 roll Transpore tape
- 1 roll Hypafix or Medipore tape (cut into 1x1" squares) or Cover All Gauze
- 1 roll Scanpor Surgical Tape
- Surgitube tube gauze (cotton wire cover)
- 2 hair pins
- 1 bottle Lemon Prep or NuPrep
- 2 disposable snap ECG pads (Medtronic Cleartrace)
- 1 wax pencil (do not use red, if possible)
- 1 oximeter (attached to cable connected to recorder)
- 1 thermistor
- (2) towels          soap solution          non-latex gloves
- 1 tray              small cup          disposable underpads (Chux)
- drinking straws          face mirror                  plastic trash bags

#### 2.1.1. Understanding the Electrode

The gold disk electrodes supplied by Compumedics are reusable and should last through many cycles of use. The electrode is made of metal (which conduct electrical signals from the patient into the recorder via a wire cable). Certain metals are more stable conductors than others. The gold disk electrodes used by the Compumedics equipment are made of a layer of gold over a silver core. The gold overlayer provides for ease in cleaning and a wider variety of disinfection procedures than would an electrode consisting of pure silver. The weakest part of the electrode is the thin wire cable at the end of the gold disk. Since this wire is very thin and hidden by an opaque covering a broken, or bad, electrode may look perfectly fine yet yield distorted, inaccurate information. The best way to determine if the electrode is working correctly is through the impedance test after the electrodes are placed on the participant. If the electrode yields unsatisfactory impedance levels after proper troubleshooting it is most likely time to replace the electrode.

Since gold disk electrodes are expensive, certain things should be understood about how to obtain the longest life from them. The key points in maintaining your gold disk electrodes is to:

- Keep them clean
- Disinfect between participants
- Treat the wire and connection points with respect
- Condition new electrodes before the first use

### **2.1.1.1 Gold Disks Electrodes – General Care**

Between uses, the surface of the gold disk electrode must be kept free of dried electrolyte paste. An electrode with dried paste does not come into proper contact with the skin and creates an air pocket which increases impedance and distorts the signal. Additionally, an electrode with visible crusted paste cannot be properly disinfected.

*Insure the gold cup and the connection leading to the wire is free of crusted paste.*

#### **Disinfect Gold Disks Between Participants:**

Intact skin is naturally a protective barrier. The participant's skin is prepared with an abrasive material before attaching the electrode. With abrasion the skin loses its integrity as the topmost layer is scratched or rubbed away; the skin is no longer intact. *Any time the skin is abraded there is risk of bloodborne pathogens even if blood, itself, is not visible.* This is called occult blood. Reusable equipment that comes in contact with non-intact skin must be disinfected after use. Disinfection is the best measure to prevent transmission of disease from one participant to another. It is important to understand that there are different levels of disinfection: low, intermediate and high. The step above high-level disinfection is sterilization. Gold disk electrodes do not require sterilization.

*Gold disk electrodes require high-level disinfection between participant's to eliminate the risk of transmitting bloodborne pathogens from occult blood.*

#### **Treat Electrode Wires With Respect:**

The weakest part of the electrode is the thin wire cable at the end of the gold disk. The most vulnerable place for injury to the wire is the point it interfaces with the gold cup or the PIB. If the connection is loose at either of these places, the electrode cup may receive an adequate signal but it will never reach the recording unit successfully. Since this wire is very thin and hidden by an opaque covering a broken, or bad, electrode may look perfectly fine yet yield distorted, inaccurate information. The wires should be kept clean and free of crusty paste or sticky tape. If tape is used for the participant hook-up, or a gob of paste ends up on the wires, it should be removed and the wires wiped to remove any stickiness. Never pull excessively on the electrode wire or bend the wire near the point of connection to the gold cup or PIB. Do not wind the wire around any small objects that may cause the wire to kink. After use, any knots that may have formed in the wire should be removed, and the wires straightened. To keep the wires from kinking during storage, after

disinfecting electrodes the wires may be wrapped and secured around a larger object, such as an empty plastic water or soft drink bottle.

*Wires that are knotted or kinky can increase impedance.*

### 2.1.1.2 Conditioning New Gold Disk Electrodes

Electrodes are a durable object with a long shelf life. They may have been manufactured long before they are shipped to the user. If spare electrodes are ordered, they may be kept in storage for a long time before they are needed as a replacement. *In order to keep a new electrode looking fresh until the first use, it is treated with a coating before being packaged.* If you have ever used a brand new electrode without conditioning it you may have been puzzled as to why your impedances were just as high as with the broken electrode. Sometimes the patient, PIB or recording unit gets blamed.

*Condition new gold disk electrodes prior to the first use.*

Electrodes carried as spares in the equipment case should also be conditioned for ready use. To condition a gold disk electrode for the first use, lightly brush both sides (top and bottom of the cup) with a stiff nylon brush or haircomb. Brush a new electrode well. The gold disk can then be washed with a soapy solution and rinsed with warm water. Lastly the gold disk is placed in some electrolyte (or smear some conducting paste on both sides). Allow the electrolyte to remain on the gold disk for several hours (or overnight). After the electrolyte soak, rinse to clean with warm water and dry. The electrode is now ready for the first use.

### 2.1.2. Cleaning and Disinfection of Equipment:

**Table of level of cleaning/disinfection required:**

Type of Electrode	Cleaning	Disinfection Level		
		Low	Intermediate	High
Gold disk Electrode	•			•
Thermistor (airflow sensor)	•			•
Respiratory Band	Black cover only			
ECG Electrode (gel filled patch)	No, disposable			
Oximeter Probe	•	•		
Position Sensor	•			

### **Methods for Cleaning/ Disinfection:**

- It is recommended that gloves be worn when handling contaminated electrodes requiring disinfection.
- Disinfection in areas of food preparation such as the kitchen sink is discouraged. Use a utility sink, laundry area or toilet for disposal of any liquids used for soaking.

The method for providing high level disinfection (gold disks and thermistor) has been changed from procedures described in the Compumedics manual. This change shows a departure from Gluteraldehyde in favor of household bleach. Decontamination procedures with dilute bleach for gold disk electrodes is well established. This procedure for the nondisposable Compumedics thermistor has not been adequately bench tested to study for incidence of corruption through repeated cycles.

Compumedics has requested all field techs to tag each thermistor and mark each time the electrode has completed a cycle of use and disinfection. This information will be used as an adjunct to laboratory bench testing performed by Compumedics. Thermistors with evidence of poor signal quality after cyclic use should be brought to the direct attention of Steve Johnson at Compumedics, USA.

High-level disinfection is appropriate to inactivate the human immunodeficiency virus (HIV), hepatitis B virus (HBV), and mycobacterium tuberculosis (*M. tuberculosis*). High level disinfection destroys all microorganisms except bacterial spores, to which intact mucous membranes are resistant.

### **Gold disk electrodes:**

(General cleaning followed by high- level disinfection)

- 1) In a specially reserved bowl, soak gold cups in warm water to help soften dried electrolyte paste.
- 2) Use a soft bristle nylon brush (i.e.: electrode brush, nail brush or toothbrush) to remove all traces of paste.
- 3) Empty bowl and rinse gold disks under running water. Return electrodes to the bowl.
- 4) In the bowl holding the electrodes, create a dilute solution of household bleach and water using 24 oz. water to ½ oz. bleach. (This is approximately a 1:50 bleach/water ratio).
- 5) Allow electrodes to soak in bleach solution for 20 minutes. Float any brush used in the same bowl, bristle-side down.
- 6) After 20 minutes, remove brush and electrodes from solution. Rinse electrodes under running water. Dry and place into storage for next use.
- 7) Discard bleach solution from bowl and dry the bowl.
- 8) Place cleaning brush into bowl and store for next use.

### **Thermistor:**

(General cleaning followed by high- level disinfection)

- 1) Clean the thermistor by wiping with gauze saturated with isopropyl alcohol (70-90%). Pay particular attention to remove any debris which may be on the object.
- 2) Allow the thermistor to dry.
- 3) Soak thermistor electrode with gold disks in a dilute solution of household bleach and water consisting of 24 oz. water to ½ oz. bleach. (This is approximately a 1:50 bleach/water ratio).
- 4) Allow thermistor to soak in bleach solution for 20 minutes.
- 5) After 20 minutes remove thermistor from solution. Rinse under running water. Dry and place into storage for next use.

### **Oximeter Probe, Position Sensor and ECG Electrode wires (white + red):**

(General cleaning that also provides low-level disinfection)

- 1) Provide initial cleaning by wiping these objects with a soft cloth which has been saturated with isopropyl alcohol (70-90%). Pay particular attention to remove any debris which may be on the object.
- 2) Allow items to air dry.
- 3) Discard alcohol-saturated cloth and place sensors into storage for next use.

### **Respiratory Band Covers:**

(General cleaning)

- 1) After each use, wash the black covers in a solution of warm water and mild soap.
- 2) Rinse and allow to dry.
- 3) Place dry covers into storage for next use.
- 4) Do not attempt to clean the white inductance band electrodes. The use of the black covers eliminate the need to clean these sensitive electrodes. If desired, the black electrode wires may be wiped with alcohol however, this is not necessary since they do not come into contact with the participant's skin.

References:

**Report of the Committee on Infectious Diseases**, *Journal of Clinical Neurophysiology* 11(1):128-132, 1994, American Electroencephalographic Society, Raven Press, Ltd., New York.

**Detection of Occult Blood on EEG Surface Electrodes**, *American Journal of Electroneurodiagnostic Technology* 37:251-257, 1997, ASET, Iowa.

**Infection Control: 2000 Review and Update for Electroneurodiagnostic Technologists**, *American Journal of Electroneurodiagnostic Technology* 40: 73-97, 2000, ASET, Iowa.

## 2.2 Preparation Pre-Visit

One to two days before the visit when you confirm the visit, remind the participant to have showered within the last 24 hours, and to have shampooed and refrained from using hairsprays, gels, mousse, and/or oils in the hair. (Explain that this is not an issue of cleanliness, but that the special procedures require the skin to be as free from oils as possible.) Ask if participant has any sensitivity to adhesives or latex products.

Request the participant to be bathed and dressed for bed at your arrival. Discourage silky bedclothes; they cause static electricity and the respiratory belts may slip. Ask the participant to be dressed in a t-shirt, tank top, or 2-piece bed clothes. Encourage the participant to avoid wearing long nightgown, nightshirt or one-piece garment. Ascertain the usual bedtime.

Within one day of the home visit: Charge the battery  
Check equipment and supplies.  
Initialize (prepare) the Flashcard.

## 2.3 Detailed Hook-up Procedures

Upon arrival, identify yourself and show identification. Explain the purpose of the visit. Explain/obtain informed consent (if not already obtained). Be professional and courteous to your participant at all times. Help the participant feel at ease and comfortable. Explain all procedures before and as you do them.

Listed are some features that will assure a successful visit:

- 1) Be courteous, professional, have ID.
- 2) Be sensitive to participant's needs
- 3) Provide overview of the Sleep Study
- 4) Be patient/Be interested
- 5) Make sure participant understands all aspects of study/Have subject demonstrate or repeat critical areas (e.g., detaching oximeter if needed)
- 6) Provide participant with telephone number to call for "help"
- 7) Schedule morning pick-up of the Siesta according to participant's needs
- 8) Keep a Positive Attitude
- 9) The participant's comfort always comes before study needs

### 2.3.1 Setting Up in the Home

Set up can be done in any comfortable chair. Clear a flat surface area to set up supplies. Set all materials on a tray or disposable pad (Chux) and position for easy access. Have the subject sit close to your supply tray during hookup. Make sure you have easy access to subject's head, chest, etc.

If the participant has not taken a shower (24 hrs) prior to your arrival, ask him/her to wash his/her face and chest with soap and water before applying electrodes. Explain that the electrodes will adhere better and a better study will be produced if the skin is cleansed in this manner.

*TIP: If the setting is poorly lighted, you may consider using a camping style headlamp to help illuminate the scalp, the neck and other areas in which placement is critical.*

## 2.3.2 Sensor Placement

Proper sensor placement is very important for effectively recording sleep patterns. Because you will be connecting the sensors to the patient, you should become familiar with each sensor and learn how to correctly place and connect them. All sensors should be labeled to simplify their identification and connections.

[Note: When connecting the sensors be sure to hold the electrode at the neck, **not** by the wires. Also, for cleanliness, use non-sterile patient-care gloves when applying electrodes.]

Below are general rules for good sensor placement:

- 1) Prep only areas of skin that electrodes cover
- 2) Use only small pieces of tape but enough to secure the sensor and wires
- 3) Provide for "stress" in wire/cables
- 4) Secure loose wires/cables with tape
- 5) For elements that require participant's hook-up, have subject demonstrate ability to place/replace/remove sensors (use a mirror if necessary)
- 6) Use non-dominant hand for oximeter placement
- 7) Ask participant about sensitivity to adhesives or latex products or choose to use all latex-free products

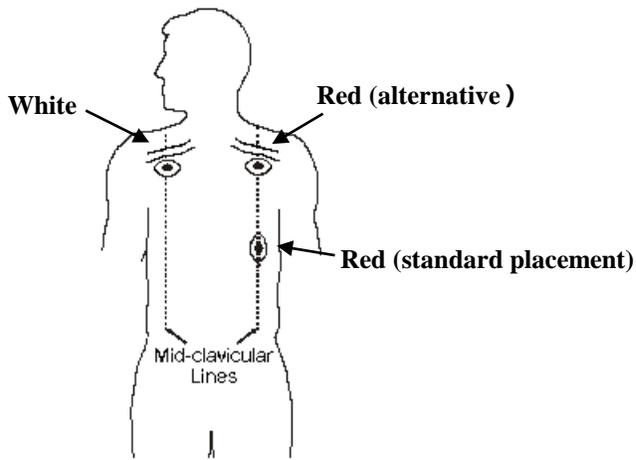
You will use 12 electrodes: Cz (reference) Forehead (GND), C3, C4, A1, A2, left EOG, right EOG, 2 chin EMG, and 2 ECG (snaps). You also will be using abdomen and chest belts, an oximeter, nasal/oral thermistor, nasal pressure cannula, 2 leg sensors and a body position sensor.

## **Suggested Order of PSG Hook-up**

<b>ECG (2 snap electrodes)</b>	White (-) below right clavicle. Red (+) below the left breast, in a line extending from the midpoint of the left clavicle. <i>Drop electrode wire underneath clothing before attaching electrode to the body and thread wire upwards (over the shoulders).</i>
<b>Respiratory belts (2)</b>	Thoracic below left armpit Abdominal below the lower edge of the left ribcage <i>When placing respiratory bands observe the participant breathing normally to determine proper positioning.</i>
<b>Gold Disk Electrodes (10)</b>	Head, eyes and chin
<b>Position Sensor</b>	Velcro square at middle and top of thoracic respiratory band
<b>Oximeter</b>	On a finger of non-dominant hand, light diode on the nail
<b>Thermistor</b>	Between nose and upper lip, atop nasal cannula. <i>Heat sensors should be near, but not touching, nares and upper lip. Tape well to maintain placement.</i>
<b>Nasal Cannula</b>	Beneath nose and upper lip, beneath the body of the thermistor. Tubing should be inside the nares
<b>Leg Sensor (2)</b>	Below the knee on the outside of the upper shin (lateral aspect) on the belly of the Tibialis Anterior muscle, one sensor on each leg <i>Drop electrode wires underneath clothing (underwear, if worn) before attaching electrode to the leg and thread wire upwards</i>

## **Step 1: ATTACHMENT OF ECG ELECTRODES**

White (-) electrode 3-5 cm. (2 finger breadths) below midpoint of right clavicle.  
Red (+) electrode below the left breast crease, in line with the midpoint of the left clavicle.  
When determining this site, please be sensitive to patient modesty issues; lift only as much of the upper garment as necessary to determine placement and afford secure attachment of this electrode.

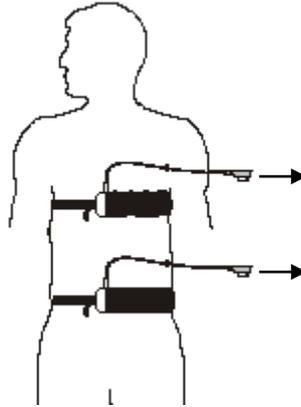


If modesty issues are of concern use alternative placement described below:

Below midpoint of left clavical, for the red (+) electrode can be used if the participant is uncomfortable with the standard placement, or if site cannot be determined due to body mass. This alternate placement is called subclavicular.

1. Feed electrode end of the wire down under the clothing.
2. Remove electrode from sealed package (e.g., Cleartrace or Red Dot Snap). Snap electrode to lead wire **before** applying to subject's skin.
3. Prepare the marked sites by lightly abrading with prep gel. Remove excess prep gel before placing the electrode. Remove backing from electrode and place gel electrode on cleansed sites, with gel side down.
4. Form a small "stress" loop with the wire immediately feeding the electrode, secure with a small amount of tape.
5. Indicate the ECG placement used on the **Signal Verification Form**.

## **Step 2: PLACEMENT OF RESPIRATORY BANDS**



1. Place the **chest band** under the left armpit, with the lead wire facing upwards. Adjust the black extender belt so the belt is secure, but not tight. Run wires upwards and tape to the shoulder.
2. The **abdominal band** should be around the umbilicus (belly button) or, if this position is not possible, *below* the lower edge of the left rib cage with the lead wire facing upwards. Run wires upwards and tape to the shoulder.
  - Incorrect application of respiratory bands can cause very poor signals.
  - Do not restrict the participant's comfort or breathing.

### **Step 3: APPLY EEG SCALP ELECTRODES (Gold Disk):**

The process for placing EEG sensors on the adult participant will follow the 10-20 system for electrode placement. This standard was developed to provide consistent application of EEG electrodes for the collection of brain waves. This system is based on measurements from 4 standard points (landmarks): the nasion, inion, and left and right pre-auricular points (see glossary for definitions).

- Electrodes must be placed in the correct locations to yield valid data.
- Electrode sites must be properly prepared prior to electrode placement to insure tight bonding and low impedance values.
- Secure attachment of gold disk electrodes is crucial to successful recording of data.

#### **Identify your landmarks:**

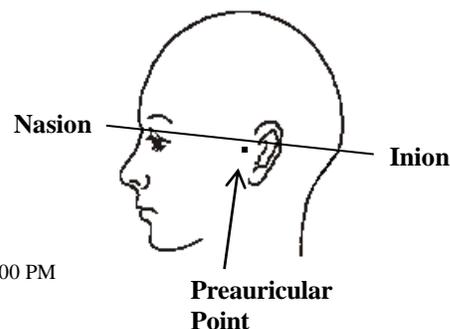
1) Pre-auricular points: Standing at the side of the participant, look at the ear. In front of the ear canal is a small flap of cartilage called the tragus. Just above the tragus is the point at which the top of ear lobe begins to form. The small dimple-like indentation between the tragus and the formation of the top of the ear lobe is the pre-auricular point. If in doubt, ask the participant to open and close his jaw. Look and feel for movement at the indentation above the tragus. Using blue china marker, lightly mark these landmarks on both the right and left sides of the participant.

2) Nasion: Facing the participant, look into his/her eyes. Find the small dip at the bridge of the nose between the eyes. This point at which the forehead meets the nose is the nasion. Lightly mark the nasion.

3) Inion: Using a comb, unpadded cotton swab end or hair clip part the participant's hair down the center, in the back of the head. Starting at the nape of the neck, run a finger up the back of the participant's head until a bony ridge, or bump, can be felt. Having the participant move his/her head up and down may help you to identify this bony ridge. The slight hollow just beneath this bony ridge is the inion. Lightly mark the inion. This landmark may be difficult to feel on some individuals.

When the inion cannot be determined use the following method:

- Re-identify the nasion, which has been lightly marked.
- Re-identify both pre-auricular landmarks, which have been lightly marked.
- Standing on the side of the participant, visualize an imaginary line forming a band around the head using the nasion and preauricular sites that have been marked. The back of this imaginary band should identify the inion. Mark the inion lightly.



## Measure for electrode sites:

- Distance measurements are done with a *metric* tape measure, and taken in centimeters (cm.) and millimeters (mm.). When computing percentages to find the electrode site a quick measurement guide can be found below, as well as in the Equipment Maintenance Section. The guide can be photocopied and kept with your prep materials for handy reference.
- All marks on skin must be done with a non-toxic, non-permanent implement, such as a wax-based china marker. Bright blue is most easily seen against dark hair. Red can be misidentified as blood by the participant or family members.
- When working with participants having long or thick hair, create a part in the hair by means of a comb or the unpadding end of a cotton-tipped swab; then hold the hair in place with hair clips while you work. The skin must be visible at the electrode sites because the electrode must rest on the skin, not on hair.
- All scalp electrode sites are determined by creating 2 lines that intersect. The electrode is placed over the point at which the 2 lines cross.

### Quick Reference: Measurement Chart

<b>Total Measurement Value (cm.)</b>	<b>50% Value (cm.)</b>	<b>20% Value (cm.)</b>
30	15.0	6.0
31	15.5	6.2
32	16.0	6.4
33	16.5	6.6
34	17.0	6.8
35	17.5	7.0
36	18.0	7.2
37	18.5	7.4
38	19.0	7.6
39	19.5	7.8
40	20.0	8.0

Note: If the *total* value measurement contains a fraction, continue to use the percentage values as the whole number.  
*Example:* Total measurement = 35.2, 35.5, 35.7 continue to use the percentage values for 35.

Remember: The 50% values are used to determine Cz.  
The 20% values are used to determine C<sub>3</sub> and C<sub>4</sub>.

### To determine Cz:

1) Have the participant sit in a chair. Standing at the side of the participant, place the zero line (0) of the tape measure on the marked inion. Holding the tape measure in place with your non-dominant hand, stretch the tape measure upwards, over the crown of the head, until it reaches the marked nasion. Determine the total distance between the inion to nasion, in centimeters. Remember this number (it may help to write it down). Compute 50% of this total measurement (or use your measurement guide).

2) Remove the tape measure, and re-position with the zero line on the marked nasion. Stretching the tape measure upwards, over the crown of the head, mark the value for 50% of the nasion to inion total. When marking these sites, make a large enough line so it can be easily found.

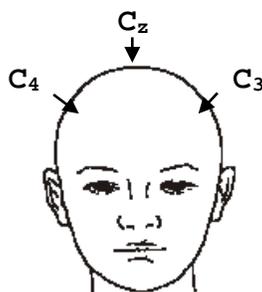
3) Remove the tape measure and stand behind the participant. Place the zero line of the tape measure on the left pre-auricular mark. Stretch the tape measure over the top of the head, and along the mark that has just been made, until it reaches the right pre-auricular mark. Determine the total distance from pre-auricular to pre-auricular in centimeters. Remember this number (it may help to write it down). Compute 50% of this total measurement (or use your measurement guide). While firmly holding the tape measure at the left preauricular mark allow the tape measure to drape over the crown of the head while marking the value for 50% of the total measurement. This mark should intersect the previously made line. The point at which the lines intersect is the site for the Cz electrode placement.

#### To determine C4:

1) Continue to stand behind the participant. Place the zero line of the tape measure on the site for the Cz electrode placement. While firmly holding the tape measure in place, allow it to drape over the right side of the participant's head until it reaches the right pre-auricular mark. Compute 20% of the total pre-auricular to pre-auricular measurement (or use your measurement guide). Continue to hold the tape measure in place as you make a mark at the 20% location. Without moving the tape measure make another line, following the edge of the tape measure, to intersect the 20% mark. After removing the tape measure, extend both lines so they intersect. The point at which the lines intersect is the site for the C4 electrode placement.

#### To determine C3:

1) Stand in front of the participant. Place the zero line of the tape measure on the site for the Cz electrode placement. While firmly holding the tape measure in place, allow it to drape over the left side of the participant's head until it reaches the left pre-auricular mark. Compute 20% of the total pre-auricular to pre-auricular measurement (or use your measurement guide). Continue to hold the tape measure in place as you make a mark at the 20% location. Without moving the tape measure make another line, following the edge of the tape measure, to intersect the 20% mark. After removing the tape measure, extend both lines so they intersect. The point at which the lines intersect is the site for the C3 electrode placement.

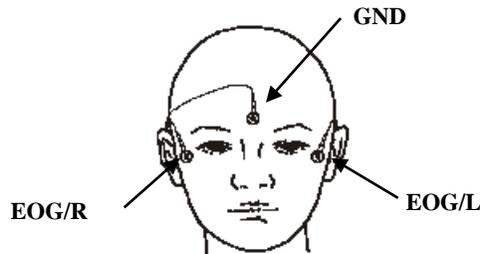


#### To determine A1 and A2:

These placement sites are on the mastoid process (bone behind the earlobe). The electrode should be placed on the skin between the crease of the earlobe and where the hairline begins. Lightly mark these sites. A1 is placed on the left mastoid, A2 on the right.

To determine EOG placements:

The EOG recording electrodes are placed about 1 cm. (one finger breadth) lateral to and 1 cm. below the outer canthus of the eye, (on the ridge of the orbital bone). Lightly mark these sites, and then stand in front of the participant to make certain that they are symmetric. Asymmetric placement of the EOG electrodes can create uncertainties in the data interpretation.

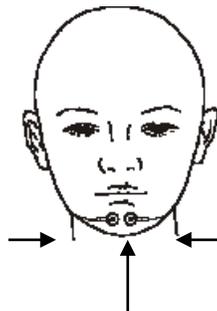


To determine EMG placement:

- The EEG waveforms in REM sleep resemble the waveforms of wakefulness. The facial muscles however, relax in REM sleep; therefore these EMG electrodes are crucial in correctly identifying REM sleep. These electrodes must be attached firmly to prevent displacement and to yield quality data through the recording period.

Place one chin EMG electrode on the face below the lower lip, on the ledge of the chin, this provides a stable area for attachment. For proper pickup of muscle activity, a distance of at least 3 cm must separate the electrodes.

The other two EMG electrodes are placed on each side of the submental, which is a large muscle located underneath the chin. Having the participant activate this muscle may be helpful for determining the placement of the EMG electrodes. To activate the muscle, place your hand under the participant's chin, between the tip of the chin and the neck. Ask the participant to swallow. You will feel the submental muscle move. The electrodes are placed on each side of this muscle but at least 3 cm. apart from each other. Placing one electrode on the ledge of the chin (below the lower lip) and the other on the belly of the submental muscle is also acceptable.



**Two electrodes under the chin  
or  
1 under the chin and the other on the  
ledge of the chin**

Reference:

**A Review of the International Ten-Twenty System of Electrode Placement**, 1974, The Grass Instrument Co., Quincy, Mass.

### **Prepare the Electrode Sites:**

Before the attachment of gold disk electrodes the skin at the marked sites must be properly cleansed and lightly abraded. This insures low impedance values. Excessive impedance defeats the passage of signals into the electrode and, in turn, to the recorder. For optimal recording the impedance readings of the electrodes should be  $< 10 \text{ k}\Omega$  and should be balanced (values should be approximately the same). One exception is ECG, which can tolerate impedance values up to  $30 \text{ k}\Omega$ .

- Successful skin preparation prior to electrode placement helps to reduce the level of impedance thereby improving the quality of signal.
  - Skin preparation requires abrasion to the top layer of the participant's skin at the electrode site. Although blood is not evident, the field technician must understand that these areas are now non-intact skin and pose a risk for blood borne pathogens. SHHS recommends wearing latex or non-latex gloves as personal protective equipment (PPE) at all times when working with non-intact skin and equipment, which has been in direct contact with non-intact skin (i.e.: used electrodes).
  - Use an abrasive preparation. Preparations such as Nu-Prep and Skin Pure contain relatively less pumice and may be preferred for participants with sensitive or fragile skin. Preparations with higher pumice concentration (such as Lemon Prep) may be useful for participants with tough or oily skin (and for bald participants).
  - Abrade only the area at the marked site. Gold disk electrodes have a diameter of 1 centimeter, therefore the abrasion should be limited to an area the size of or just slightly larger than the electrode. On marked sites, remember that the electrode should be placed where the 2 lines intersect.
  - The participant should know what to expect! Please communicate. You may choose to use the following script: "Before I attach the electrodes, I have to get your skin ready. I will be using a special cleaner that sets the skin up for a good contact. You may feel a little bit of scratching on your skin, it may feel a little like sandpaper, but it should not hurt, and it will not harm your skin."
1. Place a small amount of skin prep abrasive onto a clean disposable surface (i.e.: 4x4 gauze square or small plastic med. cup).
  2. If working in a hairy area, separate the hair in order to see the skin. You may find a comb or hairclips useful to create a part and hold the hair back.
  3. Use a cotton tipped applicator to transfer a small amount of skin prep directly onto the electrode site. Before lifting the applicator, apply a moderate pressure and make small circular motions repeatedly on the skin. Take care that you include the center of the site, not just make circles around it leaving the

center un-prepped. You may prefer to use a combination of back and forth strokes along with some circular motions.

4. Continuing with moderate pressure, slowly count to 5 while you scrub the site (1 one-thousand, 2 one-thousand, 3 one-thousand, 4 one-thousand, 5 one-thousand). You are done when the skin “pinks up”. Expect some participants to have more fragile skin than others; keep an eye on what you do. You may have to adjust the pressure or the count time.
5. Prep abrasives are not designed as conductors; remove any excessive prep abrasive from the skin prior to electrode placement.
6. Repeat the above steps for each electrode site. It is much easier to prep 2 or 3 sites, and then to apply those electrodes, provided you do not lose your prepped sites.
7. Discard the applicator and prep abrasive when finished. Never contaminate your original tube or bottle.

## Attach Gold Disk Electrodes:

The gold disk electrodes are applied to the prepared sites with an electrolyte paste. This paste serves a dual purpose: providing both a conductive pathway for the signal to enter the electrode cup, as well as holding the electrode in place on the skin. There are different electrolyte pastes available, as well as different application techniques.

Although different pastes may be used for different electrodes sites (EEG, EOG or EMG sites) both SOF and manufacturers recommend never mixing pastes for the same electrode.

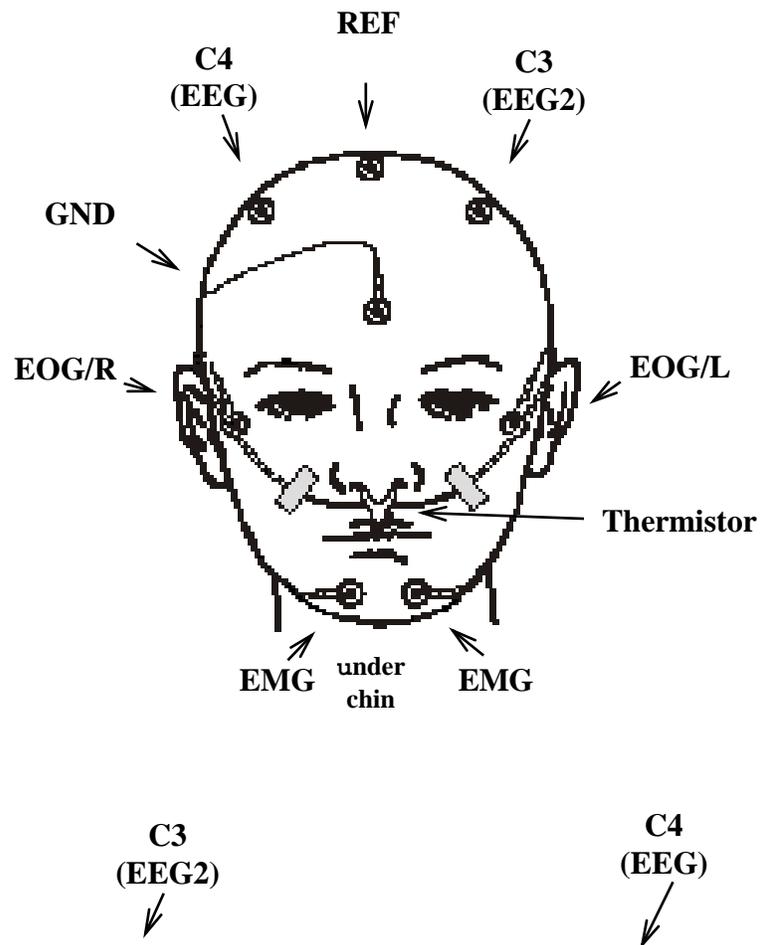
*Adverse reactions to mixing 2 electrolytes together cannot be predicted.*

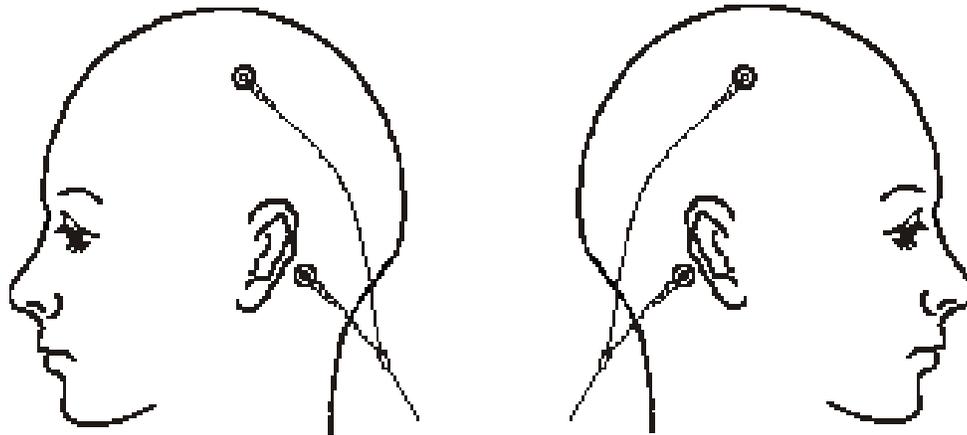
- Assemble your supplies in advance. Have several pieces of cut gauze or pieces of tape ready to place on top of the electrode once it is placed on the skin. Gravity can move the electrode from its proper site while you fumble with equipment.
- Prior to attaching gold disk electrodes, cut a sufficient length (approximately 2 arm's length) of Surgitube 1" tube gauze. Run the gold disk electrodes through the length of the tube gauze to create a cotton sheath encasing all of the wires. Secure the Surgitube sheath with a twisty or another appropriate fastener approximately 12-18" from the gold disks. This will allow for the electrodes to be placed according to the color codes and for range of motion at the neck, yet will still provide for bundling of the 10 electrode wires.
- Place a small amount of EC2 electrolyte paste onto a clean disposable surface (i.e.: 4x4 gauze square, small plastic med. cup, or the back of your gloved non-dominant hand).
- If working in a hairy area, separate the hair in order to see the skin. Your site should still be visible from the prep phase.
- If the participant is expected to sweat, there are additional skin preparations that reduce the moisture of the skin (such as PRE-TAC) and help improve the holding power of the adhesive. Try experimenting with such preparations. Generally, these liquids are applied very sparingly to prepped skin and allowed to dry before continuing with electrode application.
- If using tape, ask the participant about sensitivity to tape, latex or adhesives. For participants with sensitivity use Micropore (paper) or Scanpor tape.
- If using EC2 cream on the gauze square to anchor the electrode, it must also be the electrolyte used within the electrode cup.

- When applying disk electrodes, work in a fashion so that the wires on the forehead and top of the head all point to the back of the head and down toward the neck, and the wires on the face and chin point upwards over the ears and then down toward the back of the neck. Use small pieces of tape to hold the wires in place as they course toward the back of the head, but allow enough slack so there is no pull when the participant moves.
- Discard the unused electrolyte paste when finished. Never contaminate your original tube or bottle.

**Attachment sites for gold disk electrodes:**

GND	Middle of the forehead, between the nasion and the start of the hairline.
REF	Cz top of head
EEG	<b>C4</b> right Central <b>A1</b> left mastoid
EEG 2	<b>C3</b> left Central <b>A2</b> right mastoid
LOC	left eye, below outer canthus
ROC	right eye, below outer canthus
EMG (chin)	either side of submental muscle underneath the chin spaced at least 3 cm. apart . or 1 on the belly of the submental muscle (under chin) and 1 on ledge of chin





### **Techniques for disk electrode application:**

#### Bare skin (Face, mastoids):

- 1) Using the gold disk as a scoop, fill the electrode cup with electrolyte paste so it is slightly rounded (there must be no “air pockets” which act to increase impedance).
- 2) Place the electrode onto the prepped site, paste side down and cover with a square of gauze or piece of tape (depending on your preference).
- 3) Press lightly on the top of the electrode as well as firmly around the rim of the cup to insure a good seal. Hold in place until electrolyte begins to set and feels secure.
- 4) A larger second piece of tape may be placed over the electrode, if desired.

#### Scalp with hair:

- 1) Separate hairs to make sure skin is visible.
- 2) Using the above technique, fill the electrode cup with EC2 cream and attach to prepped site.
- 3) Place a small amount of EC2 cream on the gauze or tape used to cover the electrode.
- 4) Press firmly on electrode and hold in place until EC2 begins to set and feels secure.

#### Bearded chins:

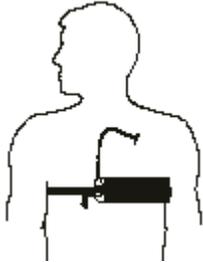
- 1) Separate hairs of beard to make sure skin is visible.
- 2) Fill the electrode cup with EC2 cream and attach to prepped site.
- 3) After attaching electrode to skin, use cotton applicator to place small amount of EC2 cream on top of electrode.
- 4) Crisscross small amounts of beard hair over the electrode, as an anchor
- 5) Place a small amount of EC2 cream on the gauze or tape used to cover the electrode.
- 6) Press firmly on electrode and hold in place until EC2 begins to set and feels secure.

#### **After electrodes are applied:**

1. Plug in each electrode to its Siesta connector.
  2. Gather gold disk electrode wires together just above nape of neck.
- Bundle and secure as desired. If using tape, fold the ends for easier removal.

#### **Step 4 : ATTACH THE POSITION SENSOR:**

Attach the position sensor to the Velcro square on the chest band. Ensure that picture on top of position sensor, indicating correct orientation of patient's left and right, is observed (wire should be going toward participant's head). Apply tape as needed to further secure the position sensor.



#### **Step 5 : ATTACH OXIMETER:**

- The finger oximeter records pulse and oxygen saturation using a small light that shines through the finger. Oximeter should be placed on the ring finger of the non-dominant hand. (If large rings are worn, may use the middle or index fingers.) Colored nail polish defeats the function of the oximeter. Colored nail polish must be removed from the finger prior to sensor attachment.

*Directions for disposable probe:* Grip the tabs on the sensor's bottom adhesive cover and peel the adhesive cover off. Place the finger into the sensor nail-side up with the tip of the centerline mark in the curved area. Wrap the tape firmly around the finger. The fingernail should not be covered with tape during this step. Fold the sensor's top over the top of the finger and make sure the two sides are vertically aligned. Do not stretch the tape while applying the sensor. This may cause inaccurate readings or skin blister. Be sure that the emitting and receiving diodes directly "face" each other.

*Directions for non-disposable probe:* Place probe, white side against adhesive, on the surface of a piece of gauze tape cut so that its width extends approximately .5 cm. on either side of the probe (placed in the middle of the tape), and, its length is approximately 1 cm. longer than each top and bottom edge of the probe. Place the probe (covered with this tape) over the top of finger with light sensor nail side up. Be sure that the receiving circle directly "faces" the light-emitting circle. Place a second piece of gauze tape around the probe (perpendicular to the first tape), spiraling the tape so the beginning and end are displaced approximately .5-1.0 cm. (This prevents perfusion problems to the finger). To further secure, place Posey wrap around sensor/finger, so that the sensor is securely in place but not tight.

After securing oximeter sensor, ask the participant if any throbbing is felt. If so, reapply, loosening tape. Pass the oximeter cable over the surface of the hand, creating a circular "stress" loop, also securing with tape. Use several additional pieces of tape along the hand and lower arm, securing loose areas of cable (to prevent the cable from getting tugged.) Check that the participant can move/bend his hand in all directions; if not, reapply, with more "slack" in the cabling.

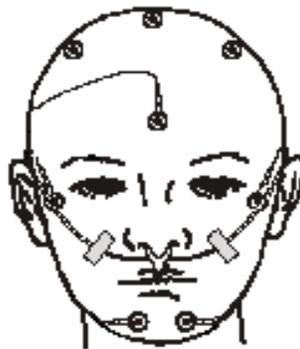
## **Step 6 : ATTACH NASAL CANNULA:**

This is clear tubing, which is positioned directly in the flow of air just under the thermistor. The nasal cannula should be placed under nasal area on participant's upper lip so that the two tubular prongs are resting within the nares. Secure in place by looping wire around ear and taping wires over cheek. The thermistor will be placed on top of the nasal cannula.

## **Step 7 : ATTACH THERMISTOR:**

These are made of temperature sensitive wires, which are positioned directly in the flow of air. Thermistor should be placed between the nose and upper lip, atop the body of the cannula. *The nasal beads of the thermistor should not be within the nares.* Secure in place by looping wire around ear and taping wires over cheek.

Note: The thermistor is sensitive to displacement or moisture. Before leaving, show the participant (in a mirror) and/or a family member how the thermistor should be positioned. Show the participant how to readjust this, if needed. Warn him to try and keep his upper lip dry. Nighttime beverages should be consumed through a drinking straw.



## **Step 8 : ATTACH LEG SENSORS:**

Using adhesive patient tape attach leg sensor over the bulk of the left (right) Tibialis Anterior muscle, where the greatest movement occurs. Ensure sensors are taped at both ends.

## 2.4 Check Impedances and Signal Quality

### 2.4.1 Verify Connections and Auto Start

Interface all electrodes to Siesta. Power up laptop and be sure Siesta is turned on. Access Net Beacon. Access Configure (top task bar). From the drop down menu, select Device. Verify Auto Start Flash Disk Recording is enabled. Check that battery status reads at least 5.7V. Close Device Settings.

### 2.4.2 Checking Impedances and Signal Quality

Click on the IMPEDANCE  $\Omega$  icon on the task bar. When enabled the button will become light grey and a screen will pop-up on the right. Slide the threshold to 10k. Click on All Channels. Impedance values will be displayed to the right. Annotate the Signal Verification form with the impedance values. When finished, disable impedance testing by clicking on the IMPEDANCE icon on the task bar

- Impedance defeats the passage of signals into the electrode and, in turn, the recorder. For PSG studies, impedance value is measured in Kilohms, or thousandths of an ohm. Later the manual abbreviation k will be used for Kilohms.
- For EEG, EOG, and EMG, you want to achieve impedance of < 10 k. Most important is the balance (difference) between two sets of paired EEG electrodes. For accurate recording the difference in impedance levels between pairs of EEG electrodes should be less than 5 k.

*If all electrodes register high:*

During the impedance check, if all electrodes register high (>10 k) remove the ground electrodes (at Cz and the forehead), re-prep the sites and replace the electrodes.

*If only certain electrodes register high:*

If impedance of any pair of electrodes (other than ECG) is > 10 k, or the difference between any pair of electrodes is > 5k remove the electrode, re-prep the electrode site and replace the electrode.

If, on a second placement, impedance is still high there are two possible problems:

- a) the area of the skin identified for sensor placement has an unusually high impedance; or
- b) the lead wire or sensor is damaged.

Therefore, attempt to address both potential problems by choosing an alternative electrode site (e.g., immediately adjacent to previous site, or use of one of the alternative sites indicated above), and change lead wires.

If impedance is still high on a third attempt do not attempt to re-prep area. Document your activities on the **Signal Verification** form.

For ECG impedance of < 30 k are acceptable.

### **2.4.3 View Signal and Final Wrap of Wires**

Enable View on top task bar. The button will turn light grey. Soon you will see live signals scroll across the screen. The upper screen will scroll faster than the lower screen. The upper screen is set to a 30 sec timebase and shows gold disk and ECG signals. The lower screen is set to a 5 min timebase and shows leg movement, all respiratory and oxygenation signals as well as position of the participant. Look at each signal on the upper and lower screens. Make sure that all signals look clean and each respiratory channel shows visible deflection (movement). Adjust respiratory sensors, if needed. When satisfied with signal quality, power off the Siesta. Wrap or bundle wires as desired. Close PSG Online. Power off the laptop.

### **2.4.3 FINAL INSTRUCTIONS TO PARTICIPANT AND MORNING AFTER PROCEDURES**

With the Siesta off, review instructions on how to turn the unit on. Have the participant demonstrate the power up. After successful demonstration, turn the Siesta off and place the Flash Disk into the Siesta, arrow side up. Prior to leaving the home, repeat instructions to power up at bedtime, but do not demonstrate (*once powered on with the card in the Siesta will begin to record!*). Provide instructions for electrode removal the following morning and for details of equipment retrieval.

Before leaving the home, clean up, leaving the area as neat as it was before your visit.

#### **The following morning:**

- Pick up equipment and questionnaires.
- Clean and disinfect reusable surface electrodes (gold disks).

Within 2 days after the sleep study (preferably the next morning):

- View the data collected on the card on the clinic computer.
- Complete form "Sleep Study Evaluation Form" .
- Copy the data from the card to 2 zip cartridges (or other media).
- Clean equipment/replace disposable sensors/recharge battery.

Within 4 days after the sleep study:

- Send one copy of the study to Cleveland, with a list of participant IDs being sent.

Within 60-90 days after the sleep study:

- Prepare and send a participant feedback letter.

## **2.6 Troubleshooting Equipment and Signal Quality**

### **General Approach to Troubleshooting**

- Carry backup equipment whenever possible (especially items which are most likely to be problematic, such as sensors).
- Label each interchangeable component in order to easily track problems and “swap out” with back-ups.
- When “swapping out” start with the most likely item first (such as individual sensors).
- Keep a bound log of all QA procedures, fault reports, troubleshooting efforts, and tracking data for each unit/cable. Include information on dates and recording # of initial use, returned for repair, replacement and number of studies performed before end of service.
- Label problem units as soon as possible to avoid returning to the field with an inoperable recording system.
- Do not send a problem unit on a home visit until the problem has been identified and corrected. Review every study before reusing the unit.

**Compumedics USA Technical Support Hotline: (877) 294-1346**

## Troubleshooting Guide

PROBLEM	LIKELY SOURCE	ACTION TO CORRECT
Flat lines on recorder	Cables or sensors disconnected from unit or participant.	Check integrity of cables/sensors at connections.  Check integrity of sensors on participant.
Black, fuzzy signal on recorder.	Poor connection from participant to Siesta. Participant may be lying on sensors or cables.	Check integrity of sensors on participant. Free cables from beneath participant. Bind together excess wires from gold disk electrodes.
Unstable signals on recorder.	Poor connection from participant to recorder.	Check integrity of cables at connections.
60 Hz artifact	High impedance levels at electrode sites.	Remove electrode, re-prep site, replace electrode.
	Poor or incorrect placement of sensor (electrode)	Remove sensor, re-evaluate placement site, replace sensor.
	Broken sensor (electrode)	Replace the sensor (electrode) with a back-up.
	Electrical interference from environment. Look for presence or use of: nearby electrical equipment (microwave ovens, cell phone, electric blankets or heaters, air conditioner, fans, hearing aids, florescent lights, TV, radio.	Turn off and unplug excessive equipment if agreeable to participant. (Do not compromise comfort or needs of participant). Turn off florescent lighting. Sometimes this is difficult to correct when environmental.
Signals show no improvement after replacing electrodes	Replacement electrodes (gold disk only) have not been conditioned before first use.  If replacements have been conditioned and problem persists, the electrode is not the likely source.	Condition new gold disk electrodes prior to first use. See Care and Maintenance Section.  Consider another source. Call Compumedics for assistance.
Strong ECG signal on other channels	Horizontally displaced heart (physiologically altered electrical field).  Participant with indwelling pacemaker.  Strength of signal ratio (cardiac vs. cerebral)	This is physiologic artifact and usually not correctable by the field tech.  Please confirm and notate on signal verification form.
Slow, rolling		

baseline on monitor (“baseline sway”)	Participant is sweating or febrile, or room is too warm.	Attempt to cool room. Use additional diaphoretic prep. (PRE-TAC) for patients expected to sweat.
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PROBLEM	LIKELY SOURCE	ACTION TO CORRECT
Low amplitude of respiratory signals on recorder or low oximetry signal.	Incorrect placement or application of sensors.	Change site of oximetry sensor.  Check positioning and tension of resp. belts. Observe which muscles move during respiration to determine where to place belts for optimum recording (notate on signal verification form).
No data on card upon download.	Participant failed to power on Siesta.  Compact Flash was not placed in Siesta.  Battery failure. Battery reads below 5.7V.	Explain importance of the task, instruct clearly as to the task, demonstrate the task, have the participant re-demo the task.  Remember to place Compact Flash before departure.  Check battery level at time of hook-up. Replace with 4 disposable AA batteries.
Respiratory bands malfunction	Electrodes may be broken.	Contact Compumedics for assistance.
Position sensor gives incorrect reading.	Sensor was not calibrated prior to recording.  Mercury in the sensor may be malfunctioning.	Calibrate sensor at time of hook-up.  Contact Compumedics for assistance.
Siesta will not power up.	Battery is missing or poor connection.	Open the unit, check for presence of battery. Remove and re-seat battery correctly.
NetBeacon (Laptop) does not acknowledge Siesta.	Siesta is powered off.	Power up Siesta, look for flashing orange light.

## 3.0 PSG Data Collection Procedures

All Compumedics software is copy protected by the use of a "dongle" key. The dongle key is attached to the computer at the printer parallel port at the back of the computer. The software will not operate without this key. You may piggyback another parallel device such as a printer on the back of the dongle with no side effects. The dongle is in effect your software license. Compumedics does not issue replacement dongles. Should you lose it for any reason, you will be required to purchase another software license.

There are four Compumedics Software programs that are used for PSG recording and file management with the Siesta: ***Data Card Manager, NetBeacon connecting to PSG On-Line, Study Manager, and ProFusion PSG.*** All programs contain detailed on-line help screens which can be accessed by selecting "Help" in whatever program you are using. The on-line help provides more detailed information than the manual and can be accessed in any screen while using the software.

### 3.1.1 Data Card Manager

- Set Up and Manage Study Configurations (Study Configurations button)
- Set Compact Flash Card Drive Letter (Options button)
- Set Options for Auto Conversion (Options button)
- Copy Patient Information and a Study Configuration to the Compact Flash Card (Setup Memory Card button)
- Transfer study data from the Compact Flash card back to the computer for analysis and archiving

### 3.1.2 Net Beacon (PSG On Line)

- Establishes connection to Siesta Unit
- Enables access to PSG OnLine where signals can be viewed after hookup
- While in PSG OnLine allows for electrode impedance checks and signal and sensor alibrations

### 3.1.3 Profusion Study Manager

- Copy and make backup disks for transmittal to Reading Center
- Data management of sleep studies on hard drive (delete unwanted studies, copy or move studies to archive media or backup network drives)

### 3.1.4 Profusion PSG

- View PSG studies after download to determine signal quality
- Score Studies
- Generate Sleep Reports

### 3.1.1 Data Card Manager - Setup Compact Flash Card

#### Preparing the Compact Flash Card to record PSG Data

Prior to the Home Visit and hookup, the Compact Flash Card must be setup with the Study Configuration and Participant identifying information. This is accomplished using the Data Card Manager.

The Study Configuration defines the recording and default display properties of a study and must be set up prior to setting up the compact flash card with participant information. Study configurations include:

Data Types	Type of physiological signal input for the channels and key input properties. This includes "sampling rate" which is the number of times per second (Hz) that the data from a particular signal is stored. The higher the sampling rate, the higher the accuracy of the signal, but the larger the file, resulting in shorter available recording time.
Physical Channels	Refers to the specific input on the Siesta Recording Unit Labels have been placed on all channel input adaptors to the Siesta to match the physical channels defined in the SOF configuration that has been set up.
Trace Panes	Defines how data is displayed in PSG Online or Profusion PSG according to Trace Display Parameters.
Filters	Allows selection of digital filtering ranges to channels to filter out unwanted noise.

When preparing for a home visit PSG, a flashcard needs to be setup with the participant information and the ***SOF configuration***. The file name for the configuration that has been set up on your laptops as SOF(revision#).smn and this must be selected and displayed as the Study Template at the time of card setup. Updates to the configuration file are numbered consecutively and the "highest" number should be chosen (currently SOF5.smn). Any channel not defined and properly set up in the configuration file will not be recorded to the compact flash card and data will be lost. Based on the sampling rates that have been selected for the SOF configuration, the Compact Flash Card of 128 megabytes being used for the study will hold approximately 10-12 hours of data.

Steps to Prepare the Compact Flash Card for a Sleep Study:

- Insert compact flash card into card reader slot on the computer.
- Open Data Card Manager
- Enter following information in the boxes:

Surname:	Participant ID
First name:	[leave blank]
Reference:	Siesta Serial number* - Technician Number**
Study template:	Select "SOF(current#)"

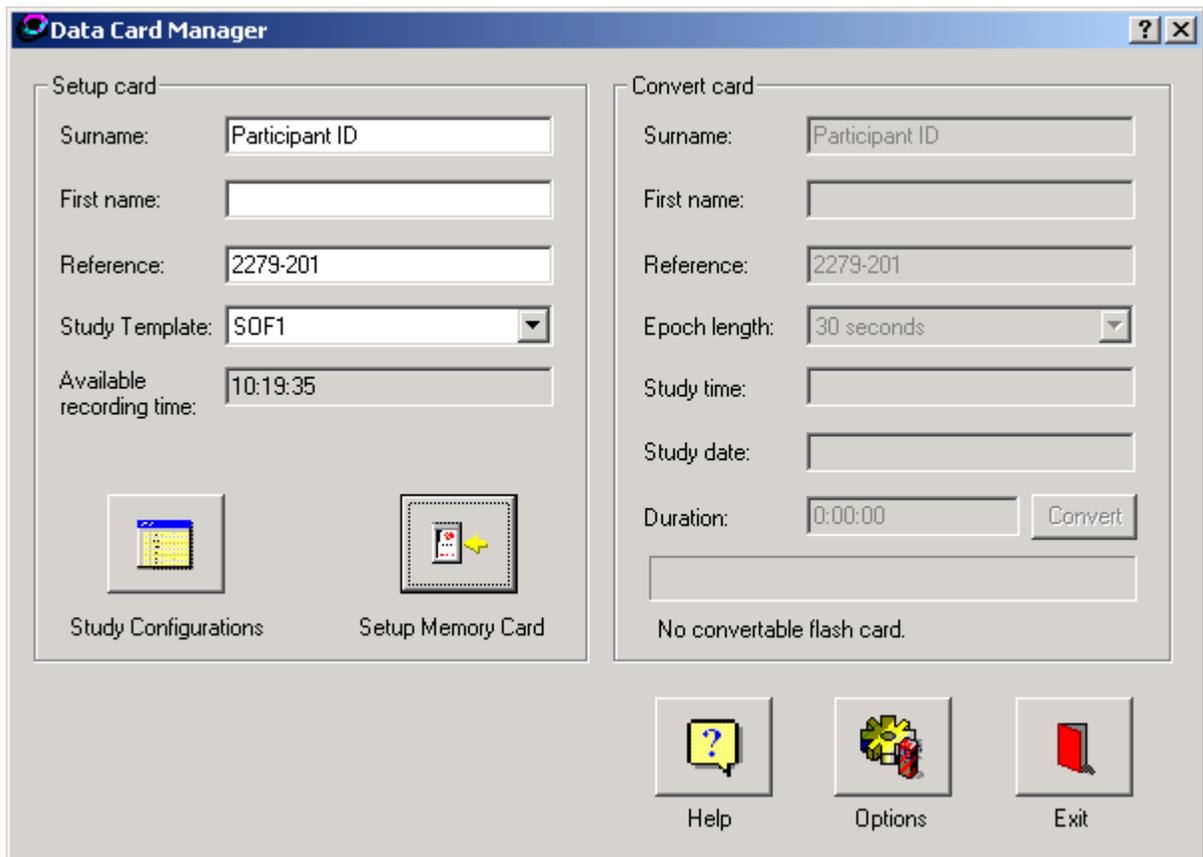
Siesta Serial Numbers are located on the bottom of the Siesta Unit

\*The three SOF Unit serial numbers are: 2273, 2279, 2290

\*\*The technician numbers are: 351, 373  
(same ID as used for SOF)

Example of entry in reference line: 2273-351

- Select Options button - Check the correct Card drive is selected - this is Drive "e" on the laptop computers.



*(The compact flash card can be set up on the clinic office computer or on the laptop when at the home visit. It is recommended that when the flash card reader is installed on the clinic office computer it be assigned the drive letter "e" to match the drive letter on the laptops if possible to avoid any confusion when setting up the cards.)*

- Auto conversion options should be set as follows:
  - Automatically convert unread studies - Checked
  - Open Profusion after convert - leave blank (not checked)
  - After conversion remove study - leave blank (not checked)
  - Minimize to tray when card not inserts - leave blank (not checked)Click OK after confirming all options correctly selected
  
- Click on Setup Memory Card button (this transfers the configuration settings and the participant, siesta ID, and technician ID to the compact flash card and it is now ready).

*(Once the compact flash card has been initialized the Available Recording Time will display the number of hours available for recording on the card. This MUST be a minimum of 9-11 hours. If the time displayed is less than this you should troubleshoot to determine if card needs to be reformatted first and then setup, check if correct drive letter selected, correct study template used, etc. If you are unable to determine the cause please call Compumedics support line before attempting to use card)*

### ***Compact Flash Card Care and Handling Tips***

- *Do not bend or flex the Compact Flash Card*
- *Do not expose the Compact Flash Card to dirt, moisture, water or fluids of any kind*
- *Always carry the Compact Flash card in the adaptor case when not inserted in your computer slot or the Siesta Recording Unit*
- *Never write to the Compact Flash Card when the computer/laptop battery is low*
- *Never eject the Compact Flash Card while the Siesta Recording Unit, Computer or Laptop is writing to it.*
- *Do not force Compact Flash Card into slot if resistance is encountered. This will damage the slot and/or Compact Flash Card*
- *Observe correct orientation when inserting Compact Flash Card into the Recording Unit, Computer or Laptop.*

**( Net Beacon - PSG On-Line covered with PSG Hookup Procedures Handout )**

**Note: You cannot access the PSG On-Line unless you have access to a Siesta Unit that is turned on.**

## 3.2 *PSG Sleep Data Retrieval Procedures*

Download - Backup - View Signals - Send to Reading Center

On the morning following the sleep study (or as soon as possible after pick up of the monitor), the sleep study data stored on the compact flash card should be downloaded to the site computer, copied to two zip cartridges (one cartridge for backup to be kept at the site, and one for transfer to the Sleep Reading Center), and then reviewed for adequate signals (Sleep Study Evaluation Form).

### Downloading Study

Be sure that the Siesta Unit power is turned "OFF" before removing the compact flash card. All studies should be reviewed and determined to be of acceptable quality prior to the Siesta being released to go back into the field to collect additional data.

1. Remove the compact flash card from the Siesta and open Data Card Manager.
2. Insert compact flash card into the card reader connected to the PC. Card reader should beep indicating card has been completely inserted.  
*(Note: If option to automatically download study has been selected, the download process will begin as soon as the compact flash card has been inserted into the PCMCIA slot.)*
3. If study has been downloaded once, you will need to click on "Convert" button to start the download process.

(The time it takes to complete the conversion depends upon the length of the study.)

**ALWAYS USE THE COMPUMEDICS SOFTWARE TO DOWNLOAD STUDIES -- DO NOT** use Windows to copy folders or files from the flashcard. During the download process certain files are created by the Compumedics software that are needed for viewing the study.

*If the ID displayed at the time of download was incorrect, note on the Sleep Study Evaluation form the correction that needs to be made. Make the necessary corrections using the Profusion PSG software before creating the backup copy and the copy being sent to the ReadingCenter. To do this, open the study using the Profusion PSG software, select View Patient Information, type in the corrections and select OK*

## 3.3 *Backup Study to Zip Cartridges*

using Compumedics Study Manager Software

Use the Study Manager software to copy the sleep study folder from the hard drive to the 250 meg zip cartridges. The zip cartridge should hold two studies. In order to prevent accidental data loss, all studies should be copied on two different zip cartridges immediately after downloading to the office computer. (Be sure any corrections that need to be made to the file are done before creating the backup copies.) Each cartridge should be labeled as SOF, followed by a sequential number indicating whether it is the 1st, 2nd, 3rd disk sent to the Sleep Reading Center followed by a code indicating whether it is an A (active) tape to be transferred to the Sleep Reading Center,

or a B (back-up) cartridge for local filing (for example, SOF-001A, SOF-001B). The sequential numbering will assist in identifying missing cartridges that may not have been sent or received. Zip Cartridges sent to the Sleep Reading Center will be returned on a monthly basis for re-use.

Open the *Compumedics Study Manager* software to create zip cartridges A and B.

Insert Cartridge A in the zip drive. Select the drive letter "C" as the Source drive. Select the destination drive letter. Select "Backup" button. The study or studies selected are copied to the zip cartridge. Remove Cartridge A, replace with Cartridge B and repeat procedure.

If you view the directory of the zip cartridge or the C:\ directory where the studies are stored using Windows "Find" or "My Computer," you will notice that the Compumedics software creates a directory for the sleep study based on the date the study was recorded followed by the time the study began:

"20001010\_211527"  
Study done 10/10/2000 Recording began 9:15 P.M. (i.e. 21:15:27)

These file folders contain the multiple files generated by the Compumedic system when it records the sleep study. If you use the Study Manager Software to view studies on the zip cartridge and the hard drive, it will display the Participant IDs in the sleep file and not the folder name.

### ***3.4 Review Downloaded Study - Sleep Study Evaluation Form*** **Using the Profusion PSG software**

Once the study has been downloaded to the hard drive and backup copies made double click on the Profusion PSG icon. Select Study/Open... Select the ID/Name to be reviewed then click OK. (If the study you wish to review is not located on the C: drive you can select another drive to locate the study you wish to view). A polygraph for viewing has already been set up. Use the "Compumedic Quick Start Guide" to become familiar with moving through the study.

The Sleep Study Evaluation Form is used to determine if the quality of the study is sufficient to be sent to the Sleep Reading Center for scoring. It also gives the technician an opportunity to review the signal quality and determine if the equipment needs to be checked or a hookup technique needs to be reviewed and modified. Loss of oximetry signal, for example, may be the result of a damaged cable that needs to be replaced or an application issue that needs to be addressed. Poor signal quality ("No" answers to questions 3 through 6) must be investigated and resolved prior to the Siesta unit being used for another sleep study.

If the answer to question #6 on the Sleep Study Evaluation Form is "No," or if there is no readable data, do not send this study to the Sleep Reading Center. Notify the Coordinator that a repeat study will need to be scheduled. If the study appears to have some scorable data, review this study and any others with problems (as noted for questions #3 thru #5) with your Sleep Study Resource or call the Reading Center for assistance. If the reason for the problem signal was identified at the time of the visit (noted on the Signal Verification form) you can note that under #7 Comments.

If after review it is determined that the data file will not be sent to the Sleep Reading Center it should be removed from the zip cartridges A and B. However, a copy of the Signal Verification paperwork and the sleep study evaluation should be sent to the Reading Center along with your regular studies with a note that study was not sent and reason why indicated on the sleep evaluation form. In order for the Reading Center to assist with troubleshooting efforts it is important we are aware of any studies that have not been sent and will be repeated.

### ***3.5 Transfer of Data to the Sleep Reading Center***

Data should be sent to the Sleep Reading Center on a weekly basis. This will enable the Sleep Reading Center to evaluate the signal quality and equipment functioning in a timely manner.

It is helpful if at the site a log of Sleep Study Review and Transfer for each study downloaded is kept. In addition, all zips sent to the Reading Center must be accompanied by a transmittal sheet of some type that lists the following::

**Zip Cartridge Number, Study ID, Tech ID, Siesta ID,  
PSG Study Date, indicate if sent to Reading Center (Yes/No)**

A copy of the Signal Verification Form and Sleep Evaluation Form for each study downloaded and reviewed should be included for all studies being sent (and for any study that may have failed review). These should be sent via Priority Mail or Federal Express to:

Susan Surovec, Project Manager  
Case Western Reserve University  
The Triangle Building  
11400 Euclid Avenue - Suite 260  
Cleveland, Ohio 44106-6003.

## **4.0 Data Management at the Reading Center**

### **4.1 Study Receipt**

Upon receipt of studies at the Reading Center all zip cartridges will be scanned for viruses. The Study Receipt form will be completed, including the following information: Participant ID, Study Date, Zip cartridge number, date received, Siesta Number, and Technician ID. If there is a discrepancy between the data contained the Signal Verification Form and the Compumedics Siesta Sleep Study recorded file, an e-mail will be sent to the Site Coordinator requesting clarification. The data from the study receipt form will be entered into the Receipts table database.

The Signal Verification Form and Sleep Study Evaluation form for studies that have been evaluated at the site and determined to be Failed will be sent to the RC along with the weekly zip cartridges. This data will also be entered into the Receipts table database when received, indicating study was Not Sent and coded with a reason for the failure.

### **4.2 Preliminary Review**

The Compumedics Profusion Offline Analysis program must be run prior to review of studies by the Chief Polysomnologist and final scoring to allow visualization of signals and graphic screens. After offline analysis of the record, the CP will then review each study to determine the overall quality is sufficient to be scored (passed/failed), and identify any potential medical alerts (defined as preliminary RDI >45). In addition, the CP will note any signal quality issues, possible monitor malfunctions, and recommendations for electrode replacements on the Receipt form.

Minimal criteria for study acceptability: The record must contain at least 4 hours of scorable EEG, oximetry and respiratory data (either airflow, thoracic or abdomen) between Time indicated on Signal Verification Form that Siesta was turned on and participant went to bed, and (edited) lights off (Total Recording Time). Recorded time after final awakening will not contribute to this time. Two continuous blocks of scorable data, each at least 2 hours long are required to consider study acceptable for scoring.

### **4.3 Preliminary Feedback of Sleep Data**

After preliminary review by CP is completed, the pass/fail status of the record is entered into the Receipts table database along with any comments and feedback notes regarding quality of the study and equipment troubleshooting. On a weekly basis the following reports are e-mailed to the site coordinator:

**Record of Receipts** - Lists Participant ID, Study Date, Date Received at RC, Zip Cartridge Number, Siesta Number, Tech ID, and Pass/Fail Status.

**Preliminary Study Quality Report** - Contains Participant ID, Study Date, Tech ID, Pass/Fail status and Comments from the CP regarding study quality, requests for troubleshooting or replacement of electrodes, and/or reasons for failure.

The site coordinator is to verify all information on the Record of Receipts is accurate and notify the RC of any changes or corrections to be made. The Preliminary Study Quality Report should be made available to the field site technicians and quality issued reviewed and discussed.

Failed studies are removed from the zip cartridges prior to scorer assignment and archived to CDs for troubleshooting exercises and review.

### **4.4 Assignment of Studies - Potential Medical Alerts**

Potential Medical Alerts - Studies identified as potential medical alerts will be triaged for immediate full scoring (within 48 hours of assignment to scorer). Once fully scored and determined to meet criteria for Medical Alerts (final RDI > 50, time in desaturation of <70% for >10% TST, or average heart rate > 150 BPM or <30 BPM for 2 minutes), a physician investigator will be asked to review the study. If the medical alert is ascertained, it will be logged into a Medical Alert Log and the site will receive the full sleep report and quality grades (QS form) with the regular weekly reports sent every Monday to the site.

### **4.5 Quality Grades (QS Form)**

The quality of each signal and overall study quality will be assessed at the time of scoring of the record. The Scorer will code each channel of information according to the duration of :

- i) scorable signals;
- ii) duration of artifact free signals during sleep, and
- iii) an overall QA grade to each study.

The total duration of the study (from Time to Bed to the lights on) and the total duration of sleep will also be indicated. Scoring notes regarding staging, event identification, outliers, and specific physiologic signal issues are also recorded on the QS form

All data contained in the QS form (quality grades and scoring notes) will be entered in the QS table database which contains only passed scored studies.

## 4.6 Scored Sleep Data

After full scoring, the scorer will generate:

- **SHHS Sleep Data Summary Report**, output using WORD (rtf format), that contains summary data. Data will be displayed in two parts (top/bottom of form), including the RDI (the number of apneas and hypopneas per hour of the sleep associated with a desaturation  $\geq 3\%$ ), a summary of the desaturation profile, time in REM/Non-REM sleep, stage distributions and the arousal index. The top half of the report will be used in the Participant Feedback Letters, and the bottom half (containing stage distribution and arousal indices) can be used in communications with local physicians.
- **SAS report** containing >760 variables.
- Completed **QS form** containing all quality grades and scoring notes.

The Sleep Data Summary Report and QS Report are e-mailed to each site on Mondays following the week scored (generally within 12 weeks of receipt of the RC, except for studies which are triaged as possible Medical Alerts, which will be returned within one week of receipt).

## 4.7 Archival of Data

After QS data has been entered and weekly reports are sent to sites, the complete study folder containing the raw data file, scored files, sleep study report, and the SAS report is placed in a site directory for the creation of CDs. When sufficient studies have been scored (15-20 studies), they will be archived onto CDs (in duplicate). Copy A will be retained at the RC, Copy B will be sent to the site along with zip cartridges that can now be reused and the matching back up cartridge at the site.

The summary scored data (>760 SHHS variables) are output as individual .txt files. After outlier checks they are imported on a monthly basis into a SAS file. This file will be sent to appropriate personnel as defined by PI.

## 4.8 PSG Training and Certification Requirements

Personnel charged with the responsibility of participant hook-ups will be required to meet performance standards that indicate an understanding of sleep physiology, polysomnology, the study goals and methods, medical alert levels and responses, equipment use and sensor placements. Only personnel who meet these standards will be “certified” (and approved) to perform sleep studies.

Personnel will be required to attend a central training session, or undergo local training by a centrally-certified technician.

Training will consist of:

- An overview of Sleep Physiology and Sleep Apnea

- An overview of the Study Protocol

- An overview of Polysomnology

  - Detailed training on use of the Compumedics Siesta System, including hands-on activities.

  - Detailed training on all aspects of the SOF protocol specific for performing and processing sleep studies.

Certification:

Demonstration of the requisite knowledge and adequacy of technical performance will be assessed with a written and practical examination (requiring a grade of >75%). After passing these examinations, personnel will be required to perform a minimum of 5 studies of acceptable quality (interpretable) on non-cohort volunteers.

Those personnel trained locally will be required to perform 5 studies under the supervision of a centrally trained technician and perform a minimum of 5 studies of acceptable quality (interpretable) on non-cohort volunteers prior to being authorized to perform a study independently.

Personnel who serve as “back-up” technicians (for illness, scheduling conflicts, etc.) will be required to do a minimum of 4 studies/month to remain certified.

Re-certification will be required of any personnel who fall below the pre-set levels of performance standards, or who obtain <90% acceptable sleep studies in any given month evaluation period (or, for “back-up” personnel, who obtain 2 or more inadequate studies in any given month). The Director of the Reading Center, after consulting with the PI of the investigative center, will determine whether local or central (Reading Center) re-certification is indicated.



# Signal Verification

Participant ID	_____
Date of Study	_____
Siesta ID	_____
Tech ID	_____

Impedances			
	a. First Check Imp	b. Final Check (use 1st check if orig. placement was accurate	c. # Times Electrodes Replaced ("0") if original = final
C3			
C4			
A1			
A2			
LOC			
ROC			
ECG1			
ECG2			
EMG/L			
EMG/R			

Indicate first impedance value; if >10 (except ECG-30) check each individual channel to identify the problem channel. Replace the higher sensor and recheck both.

**CALIBRATION CHECKS (Mark each box after performing specific calibration)**

Data entry: enter 1 if check performed, 0 if check not performed.

Position: a. Back                      b. Front  
                    c. L Side                      d. R Side

	a. Good Deflection		b. Fuzzy Line		Value
	Yes	No	Yes	No	
7. EEG2					
8. ECG					
9. EMG Chin					
10. EOG -L					
11. EOG - R					
12. EEG 1					
13. Chest					
14. Abdomen					
15. Thermistor					
16. Nasal Cannula					
17. Legs					
18. Oximeter*					
19. Pulse					
20. Manual Pulse**					
21. Battery Check					

\* (If <88% re-position, check sensor, consult Med Alerts)  
 \*\* (If >120 or <30, check for 2 minutes; consult Med Alerts for HR >150)

Write in below the reported bed time (time turned off lights) from the Morning After Survey: \_\_\_\_\_

Was the Siesta turned on by:                      Participant \_\_\_\_\_                      Tech before leaving home \_\_\_\_\_

Was hookup completed:     \_\_\_1 Yes           \_\_\_0 No

a. Why not?

1. Participant not home
2. Participant sick/indisposed
3. Participant refused entry in home
4. Participant refused Informed Consent
5. Participant refused hookup
6. Participant could not tolerate hookup
7. Other: \_\_\_\_\_

b. Was study rescheduled?   \_\_\_1 Yes           \_\_\_0 No

Were any environmental conditions present which could cause problems with sleep monitoring?  
                                  \_\_\_1 Yes           \_\_\_0 No

(Check "Yes" if >3 people sleeping in room; extremely cold or hot; or frequent noises in home or outside home, etc.)

Comments: \_\_\_\_\_  
                  \_\_\_\_\_  
                  \_\_\_\_\_

Describe any problems with hook-up or sensor checks?  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Technician ID:           \_\_\_\_\_

Time of arrival:       \_\_\_:\_\_\_ am/pm

Time of departure:   \_\_\_:\_\_\_ am/pm



## *Sleep Study Evaluation Form*

**Participant ID** \_\_\_\_\_

**Siesta ID** \_\_\_\_\_

**Date of Sleep Study** \_\_\_\_\_

**Tech ID** \_\_\_\_\_

- |    |  |                                |                               |
|----|--|--------------------------------|-------------------------------|
| 1. | Are there signals on each of the channels?<br>(i.e., no "flat-lined" signal) | <input type="checkbox"/> 1 Yes | <input type="checkbox"/> 0 No |
| 2. | Is each channel mostly clear of artifact<br>(thick fuzzy lines)?             | <input type="checkbox"/> 1 Yes | <input type="checkbox"/> 0 No |
| 3. | Are there at least 6 hours of recorded data?                                 | <input type="checkbox"/> 1 Yes | <input type="checkbox"/> 0 No |
| 4. | Are there at least 4 hours of oximetry data?                                 | <input type="checkbox"/> 1 Yes | <input type="checkbox"/> 0 No |

- If answer to any question 1 through 4 is "No," review study with Sleep Study Resource.
- If answer to question #4 is "No," record study as "Inadequate" and do not transfer to Sleep Reading Center. Notify Study Coordinator of need to repeat study.

Comments by Sleep Study Resource/Reviewer:

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Tech or Reviewer of Study ID \_\_\_\_\_ Date Reviewed \_\_\_\_\_

Data File Sent to Reading Center?  1 Yes  0 No



*STUDY OF  
OSTEOPOROTIC  
FRACTURES*

**QS form**

**SOF Pittsburgh - Site 88**

**Participant ID#:** \_\_\_\_\_

**Study Date:** \_\_\_\_\_

**1. Scorer ID:** \_\_\_\_\_ **Total Rec. Time** \_\_\_\_\_ **4.Date entered:** \_\_\_\_\_

**2. Date scored:** \_\_\_\_\_ **Total Sleep Time** \_\_\_\_\_ **Siesta Unit ID** \_\_\_\_\_

**31.CD #:** \_\_\_\_\_ **3. RDI** \_\_\_\_\_ **Tech ID** \_\_\_\_\_

Channels	Hours of usable signal (a)	Signals quality (b)
5. EEG - C3		
6. EEG(sec)C4		
7. EOG L		
8. EOG R		
9. Chin EMG		
10. ECG		
11. Airflow		
12. Thoracic		
13. Abdomen		
14. Oximetry		
14a. Cannula		
14b. L Leg		
14c. R Leg		

**Code for signals quality:**

Entire sleep time(> 95 %)	<b>5</b>
75 - 94 % of sleep time	<b>4</b>
50 - 74 % of sleep time	<b>3</b>
25 - 49 % of sleep time	<b>2</b>
< 25 % of sleep time	<b>1</b>

**15. Overall Study Quality:**

- (7) **Outstanding.** All channels good for  $\geq 6$  hours and entire sleep time.
- (6) **Excellent.** At least one EEG channel, one EOG channel, EMG, oximetry, all respiratory channels usable for  $\geq 5$  hours and  $\geq 75\%$  of the sleep time.
- (5) **Very good.** At least one EEG channel, oximetry, airflow and either chest or abdomen usable for  $\geq 5$  hours and  $\geq 50\%$  of the sleep time
- (4) **Good.** At least one respiratory channel (airflow or either band), oximetry and one EEG usable for  $\geq 5$  hours and  $\geq 50\%$  of the sleep time
- (3) **Fair.** At least one respiratory channel, oximetry and one EEG usable for  $\geq 4$  hours or study scored sleep-wake only (because of the EEG artifact).

**16. Participant Reported Time to Bed** \_\_\_\_\_

**18. Was position signal changing during study?**  (1) **Yes**  (0) **No**

**19. Comments:** \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

<b>20. Medical Alert?</b>	<input type="checkbox"/> (0) No	<input type="checkbox"/> (1) Yes	Initials Date
a) Heart rate > 150 bpm for ≥ 2 minutes	<input type="checkbox"/> (8) N/A	<input type="checkbox"/> (1) Yes <input type="checkbox"/> (0) No	
b) Heart rate < 30 bpm for ≥ 2 minutes	<input type="checkbox"/> (8) N/A	<input type="checkbox"/> (1) Yes <input type="checkbox"/> (0) No	
c) Oxygen saturation < 75 % for > 10% TST	<input type="checkbox"/> (8) N/A	<input type="checkbox"/> (1) Yes <input type="checkbox"/> (0) No	
d) RDI > 50	<input type="checkbox"/> (8) N/A	<input type="checkbox"/> (1) Yes <input type="checkbox"/> (0) No	

<b>21. Was any data lost?</b>	<input type="checkbox"/> (0) No	<input type="checkbox"/> (1) Yes
a) Recording started after sleep onset	<input type="checkbox"/> (8) N/A	<input type="checkbox"/> (1) Yes <input type="checkbox"/> (0) No
b) Recording ended before partic. awoke	<input type="checkbox"/> (8) N/A	<input type="checkbox"/> (1) Yes <input type="checkbox"/> (0) No
c) Loss of the data at the beg. of the study	<input type="checkbox"/> (8) N/A	<input type="checkbox"/> (1) Yes <input type="checkbox"/> (0) No
d) Loss of the data at the end of the study	<input type="checkbox"/> (8) N/A	<input type="checkbox"/> (1) Yes <input type="checkbox"/> (0) No
e) Loss of the data during the study	<input type="checkbox"/> (8) N/A	<input type="checkbox"/> (1) Yes <input type="checkbox"/> (0) No

<b>22. Was study scored Sleep/Wake only?</b>	<input type="checkbox"/> (0) No	<input type="checkbox"/> (1) Yes
<b>23. Were there problems with scoring sleep stages?</b>	<input type="checkbox"/> (1) Yes	<input type="checkbox"/> (0) No <input type="checkbox"/> (8) N/A
a) Wake / Sleep unreliable	<input type="checkbox"/> (1) Yes <input type="checkbox"/> (0) No	<input type="checkbox"/> (8) N/A
b) Stage 1/ Stage 2 unreliable	<input type="checkbox"/> (1) Yes <input type="checkbox"/> (0) No	<input type="checkbox"/> (8) N/A
c) Stage 2 / Deep sleep unreliable	<input type="checkbox"/> (1) Yes <input type="checkbox"/> (0) No	<input type="checkbox"/> (8) N/A
d) REM / NonREM unreliable	<input type="checkbox"/> (1) Yes <input type="checkbox"/> (0) No	<input type="checkbox"/> (8) N/A

<b>24. Were arousals ignored due to poor EEG signal?</b>	<input type="checkbox"/> (0) No	<input type="checkbox"/> (1) Yes
<b>25. Were there problems with scoring arousals?</b>	<input type="checkbox"/> (1) Yes	<input type="checkbox"/> (0) No <input type="checkbox"/> (8) N/A
a) Arousals unreliable	<input type="checkbox"/> (1) Yes <input type="checkbox"/> (0) No	<input type="checkbox"/> (8) N/A
b) Arousals in REM (only) unreliable	<input type="checkbox"/> (1) Yes <input type="checkbox"/> (0) No	<input type="checkbox"/> (8) N/A

<b>26. Were there problems scoring resp. events (RDI may be unreliable)?</b>	<input type="checkbox"/> (0) No	<input type="checkbox"/> (1) Yes
<b>27. Was apnea/hypopnea distinction unreliable?</b>	<input type="checkbox"/> (0) No	<input type="checkbox"/> (1) Yes

28. Were unusual occurrences?	<input type="checkbox"/> <sup>(0)</sup> No	<input type="checkbox"/> <sup>(1)</sup> Yes	Initials Date
a) Abnormal awake EEG	<input type="checkbox"/> <sup>(8)</sup> N/A	<input type="checkbox"/> <sup>(1)</sup> Yes <input type="checkbox"/> <sup>(0)</sup> No	
b) Physiologic alpha intrusion	<input type="checkbox"/> <sup>(8)</sup> N/A	<input type="checkbox"/> <sup>(1)</sup> Yes <input type="checkbox"/> <sup>(0)</sup> No	
c) Abnormal eye movements	<input type="checkbox"/> <sup>(8)</sup> N/A	<input type="checkbox"/> <sup>(1)</sup> Yes <input type="checkbox"/> <sup>(0)</sup> No	
d) Periodic breathing $\geq$ 5 min	<input type="checkbox"/> <sup>(8)</sup> N/A	<input type="checkbox"/> <sup>(1)</sup> Yes <input type="checkbox"/> <sup>(0)</sup> No	
e) Periodic breathing $\geq$ 10 min	<input type="checkbox"/> <sup>(8)</sup> N/A	<input type="checkbox"/> <sup>(1)</sup> Yes <input type="checkbox"/> <sup>(0)</sup> No	
f) Periodic large breaths	<input type="checkbox"/> <sup>(8)</sup> N/A	<input type="checkbox"/> <sup>(1)</sup> Yes <input type="checkbox"/> <sup>(0)</sup> No	

29. Outliers: Were extreme values found?	<input type="checkbox"/> <sup>(0)</sup> No	<input type="checkbox"/> <sup>(1)</sup> Yes	Initials Date
a) Scored Sleep-Wake only	<input type="checkbox"/> <sup>(8)</sup> N/A	<input type="checkbox"/> <sup>(1)</sup> Yes <input type="checkbox"/> <sup>(0)</sup> No	
b) Unusual staging	<input type="checkbox"/> <sup>(8)</sup> N/A	<input type="checkbox"/> <sup>(1)</sup> Yes <input type="checkbox"/> <sup>(0)</sup> No	
c) RDI=0 real	<input type="checkbox"/> <sup>(8)</sup> N/A	<input type="checkbox"/> <sup>(1)</sup> Yes <input type="checkbox"/> <sup>(0)</sup> No	
d) Max length of resp. event > 150s real	<input type="checkbox"/> <sup>(8)</sup> N/A	<input type="checkbox"/> <sup>(1)</sup> Yes <input type="checkbox"/> <sup>(0)</sup> No	
e) Other - see Notes	<input type="checkbox"/> <sup>(8)</sup> N/A	<input type="checkbox"/> <sup>(1)</sup> Yes <input type="checkbox"/> <sup>(0)</sup> No	

30. Notes: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

31. Nasal Pressure - Flow Limitation Observed for at least 10% of total sleep time ?  <sup>(0)</sup> No     <sup>(1)</sup> Yes  
 (Flow Limitation defined as episodic flattening of otherwise rounded sinusoidal nasal pressure signal for a duration of 10 seconds to 10 minutes.)

31a. If Yes, were PLMs associated with flow limitation at least 50% of the time?  <sup>(1)</sup> Yes     <sup>(0)</sup> No

32. Were more than 50% of PLMs deleted due to occurrence at the end of respiratory events?  <sup>(1)</sup> Yes     <sup>(0)</sup> No

SOF5.smn – Reading Center - Current Montage/Configuration Settings and Offline Analysis Settings as of July 26, 2002

**Data Types**

These settings determine the sampling rates and settings for flashcard. The type of signal, filters, and P-P (peak to peak) ranges determine how the “raw data” signal is obtained.

	Name	Type	Rate	Coupling	HP Filter	P-P Range	Impedance
1	Off	Internal AC	0	AC	0.15	500 mV	No
2	EMG	Internal AC	128	AC	0.15	2 mV	Yes
3	Oximeter	Oximeter	1	DC	0.15	Direct	No
4	ECG Group	Internal AC	256	AC	0.15	10 mV	Yes
5	DC	Special DC (Ch 1-4)	4	DC	0.15	500 mV	No
6	HP	Special HP (Ch 29-32)	16	AC	0.05	2 mV	No
7	EEG	Internal AC	128	AC	0.15	2 mV	Yes
8	HP Resp	Special HP (Ch 29-32)	16	AC	0.05	10 mV	No
9	Leg	Internal AC	64	AC	0.15	10 mV	No
10	EOG	Internal AC	128	AC	0.15	2 mV	Yes
11	External DC 10V	External DC	64	DC	0.15	10 V	No
12	External DC 1V	External DC	64	DC	0.15	1 V	No
13	Nasal Pressure	External Pressure	16	Special	Special	Fixed	No
14	External Airflow	External Pressure	32	Special	Special	Fixed	No
15							

**Physical Channels** (see next page)

This defines each channel being used by the Siesta and its location which ultimately determine where each electrode, belt, etc. is plugged into. It also determines, based on the defined type selected, what sampling rate and group it belongs to in the data types.

**SOF5 - Study Configuration Manager** [ \_ ] [ □ ] [ X ]

File Help

New Open Save

- Data Types
- Physical Channels**
- Trace Panes
- Filters
- Sleep Analysis

	Channel	Data Type
Special DC 1	Position	DC
Special DC 2	Leg/L	Leg
Special DC 3	Leg/R	Leg
Special DC 4	CH04	Off
Connector 5 Cha	C3	EEG
Connector 6 Cha	C4	EEG
Connector 7 Cha	O1	Off
Connector 8 Cha	O2	Off
Connector 9 Cha	A1	EEG
Connector 10 Ch	A2	EEG
Connector 11 Ch	ROC	EOG
Connector 12 Ch	LOC	EOG
Connector 13 Ch	ECG1	ECG Group
Connector 14 Ch	ECG2	ECG Group
Connector 15 Ch	EMG/L	EMG
Connector 16 Ch	EMG/R	EMG
Connector 17 Ch	CH17	Off
Connector 18 Ch	CH18	Off
Connector 19 Ch	CH19	Off
Connector 20 Ch	CH20	Off
Connector 21 Ch	CH21	Off
Connector 22 Ch	CH22	Off
Connector 23 Ch	CH23	Off
Connector 24 Ch	CH24	Off
Connector 25 Ch	CH25	Off
Connector 26 Ch	CH26	Off
Connector 27 Ch	CH27	Off
Connector 28 Ch	CH28	Off
Special HP 29	Airflow	HP
Special HP 30	CH30	Off
Special HP 31	Thoracic	HP Resp
Special HP 32	Abdominal	HP Resp
Oximeter status	STAT	Oximeter
Oximeter heart r	HR	Oximeter
Oximeter SaO2	SAO2	Oximeter
Ext Pressure 1	Nasal Pressure	Nasal Pressure
Ext Pressure 2	CH37	Off

For Help, press F1

NUM

**SOF5 - Study Configuration Manager**

File Help

New Open Save

- Data Types
- Physical Channels
- Trace Panes
  - Pane 1 Traces
  - Pane 2 Traces
- Filters
- Sleep Analysis

	Trace Name	Channel 1	Channel 2	Colour	Zoom	Size	Grids	Data Type	Polarity
1	LOC	LOC			8.0	1.0	0	EOG	Positive
2	ROC	ROC			8.0	1.0	0	EOG	Positive
3	EMGL-EMGR	EMGL	EMGR		20.0	1.0	0	EMG	Negative
4	C4-A1	C4	A1		16.0	1.0	0	EEG	Negative
5	C3-A2	C3	A2		16.0	1.0	0	EEG	Negative
6	ECG1-ECG2	ECG1	ECG2		4.0	1.0	0	ECG Group	Positive
7	HR	HR				1.0	0	Oximeter	Positive
8									

For Help, press F1

NUM

**SOF5 - Study Configuration Manager**

File Help

New Open Save

- Data Types
- Physical Channels
- Trace Panes
  - Pane 1 Traces
  - Pane 2 Traces
- Filters
- Sleep Analysis

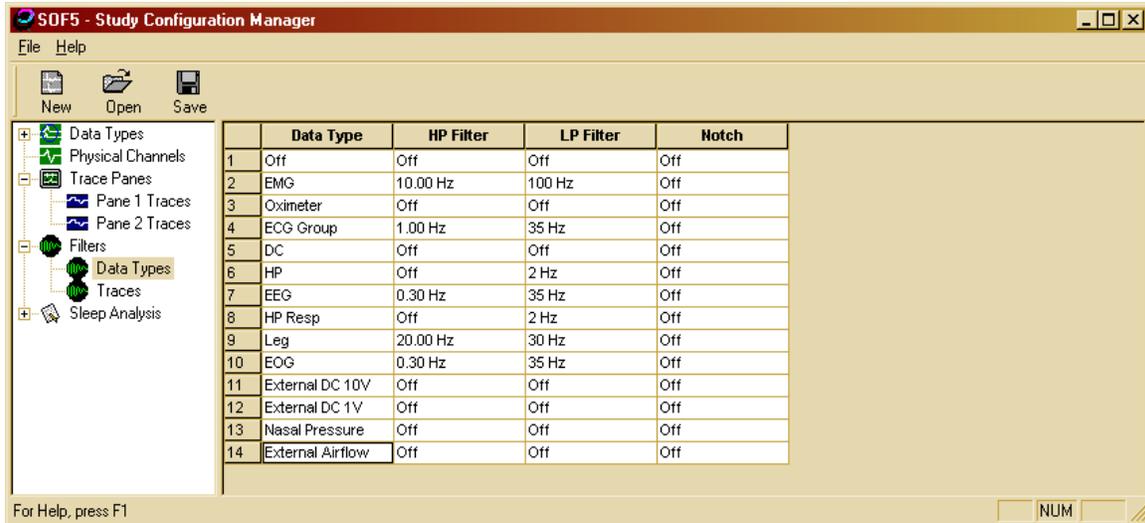
	Trace Name	Channel 1	Channel 2	Colour	Zoom	Size	Grids	Data Type	Polarity
1	LegL	LegL			4.0	1.0	0	Leg	Positive
2	LegR	LegR			4.0	1.0	0	Leg	Positive
3	Airflow	Airflow			4.0	1.0	0	HP	Positive
4	Nasal Pressure	Nasal Pr			100.	1.0	0	Nasal Pressure	Positive
5	Thoracic	Thoracic			4.0	1.0	0	HP Resp	Positive
6	Abdominal	Abdomin			4.0	1.0	0	HP Resp	Positive
7	SAO2	SAO2				1.0	0	Oximeter	Positive
8	STAT	STAT				1.0	0	Oximeter	Positive
9	Position	Position				1.0	0	DC	Positive
10									

For Help, press F1

NUM

## Filters – Data Types

The Filters set here affect the viewing screen display when you are viewing a hookup. The actual raw data is not changed.



SOF5 - Study Configuration Manager

File Help

New Open Save

Data Types  
Physical Channels  
Trace Panes  
  Pane 1 Traces  
  Pane 2 Traces  
Filters  
  Data Types  
  Traces  
Sleep Analysis

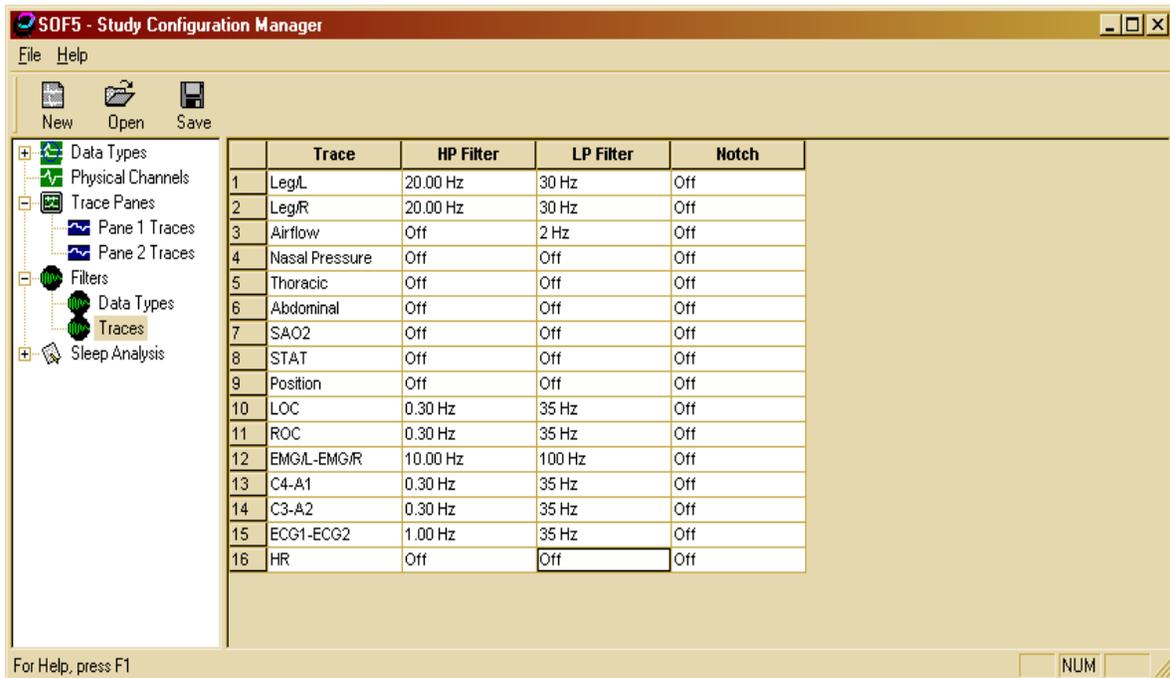
	Data Type	HP Filter	LP Filter	Notch
1	Off	Off	Off	Off
2	EMG	10.00 Hz	100 Hz	Off
3	Oximeter	Off	Off	Off
4	ECG Group	1.00 Hz	35 Hz	Off
5	DC	Off	Off	Off
6	HP	Off	2 Hz	Off
7	EEG	0.30 Hz	35 Hz	Off
8	HP Resp	Off	2 Hz	Off
9	Leg	20.00 Hz	30 Hz	Off
10	EOG	0.30 Hz	35 Hz	Off
11	External DC 10V	Off	Off	Off
12	External DC 1V	Off	Off	Off
13	Nasal Pressure	Off	Off	Off
14	External Airflow	Off	Off	Off

For Help, press F1

NUM

## Filters – Traces

Settings here only affect how the signals are viewed at the time of collection.



SOF5 - Study Configuration Manager

File Help

New Open Save

Data Types  
Physical Channels  
Trace Panes  
  Pane 1 Traces  
  Pane 2 Traces  
Filters  
  Data Types  
  Traces  
Sleep Analysis

	Trace	HP Filter	LP Filter	Notch
1	LegL	20.00 Hz	30 Hz	Off
2	LegR	20.00 Hz	30 Hz	Off
3	Airflow	Off	2 Hz	Off
4	Nasal Pressure	Off	Off	Off
5	Thoracic	Off	Off	Off
6	Abdominal	Off	Off	Off
7	SAO2	Off	Off	Off
8	STAT	Off	Off	Off
9	Position	Off	Off	Off
10	LOC	0.30 Hz	35 Hz	Off
11	ROC	0.30 Hz	35 Hz	Off
12	EMGL-EMGR	10.00 Hz	100 Hz	Off
13	C4-A1	0.30 Hz	35 Hz	Off
14	C3-A2	0.30 Hz	35 Hz	Off
15	ECG1-ECG2	1.00 Hz	35 Hz	Off
16	HR	Off	Off	Off

For Help, press F1

NUM

## Sleep Analysis

These settings are saved with the study and are default settings used by the Reading Center for purposes of running offline analysis and scoring. They do not change how the raw data is collected. The Reading Center may change these settings once the sleep study has been viewed and it is determined that certain channels are difficult to read at the default settings.

