



MESA Exam 5 – Sleep

PSG Procedure Manual

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Table of Contents

Section	Page #
1. Sleep Disorders and Polysomnography	1
2. MESA Sleep Visit Overview	9
3. Polysomnography	13
PSG Equipment	15
Preparation for PSG	21
Procedures for PSG Hook-up	22
4. Certification Requirements	43
5. Transmission of Data to Sleep Reading Center	
Download of Recorded Study	44
Using SFTP to Transfer Study	49
6. Data Management and Quality Control	
Field PSG Technicians/PSG System Maintenance	58
PSG Data Quality Management	60

Appendix

Home Visit Scripts and Forms

- Sample Phone Script for MESA Sleep Recruitment
- MESA Sleep Questionnaires Guidance on Question by Question Responses
- MESA Sleep Questionnaire
- MESA Sleep Diary (Journal)

PSG

- PSG Signal Verification Form (SV Form)
- PSG Sleep Study Evaluation Form (SE Form)
- PSG Quality Form (QS Form)
- PSG Sample Sleep Report

- Signal and Equipment Troubleshooting Examples
- PSG Equipment Care and Maintenance
- Compumedics Quick_Notes
(Set Up Flashcard/Set Up Somte/Download)
- On Site PSG Tech Training Forms
(Check Off List for Site PSG Tech Training; Practical Exam-Observation; Written Exam)
- ElectraMed MESA Study Pricing Supply Order Sheet

1. Sleep Disorders and Polysomnography

Sleep Apnea

Sleep Apnea (also referred to as obstructive sleep apnea syndrome (OSA), sleep apnea-hypopnea (SAHS), sleep disordered breathing (SDB)) is a condition 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 20% 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 MESA Sleep Study, in fact, is to determine the effect of sleep apnea on heart function and overall health and function, including neurocognitive 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 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"- uvulopalatopharyngoplasty - 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 MESA Sleep Study, 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.

Insomnia and Sleep Duration Variation

Insomnia refers to problems initiating (getting to) or maintaining sleep, including early morning awakenings. Chronic insomnia (lasting \geq one month) affects about 10% of people; however, 30 to 50% of people have suffered from insomnia from time to time. Insomnia may be found in 40% of elderly (>65% years). Insomnia rarely presents as an isolated condition ("primary insomnia") and more commonly is associated with underlying medical (e.g., arthritis, chronic lung problems, renal failure, etc.) or psychologic conditions, including anxiety, depression, and responses to life stress. In the elderly, pain from physical problems is a common cause of insomnia. Those with insomnia often complain of daytime sleepiness and poor waking function. People who regularly sleep < 6 hours also may be an increased risk for death compared to people who get 7 to 8 hours of sleep per night. Diagnosis of insomnia usually requires a careful medical history. Sometimes a 7 day sleep diary along with actigraphy (to measure movement and estimate sleep-wake time) is useful. Sometimes an overnight sleep study is needed to rule out other conditions that may disrupt sleep, including sleep apnea and periodic limb movement disorder (PLMD). If an overnight sleep study (PSG) is done, some typical findings in patients with insomnia are: a long sleep latency (long period of awake before sleep onset; e.g., > 30 minutes) and low sleep efficiency (low percentage of time asleep compared to time in bed; e.g., < 65%). Treatments for insomnia vary according to its cause, including treatment of any underlying medical and psychological conditions and efforts at improving sleep hygiene (following regular and healthy sleep habits). Sometimes behavioral-cognitive therapy or medications are needed.

Periodic Leg Movements Disorder (PLMD)

PLMD is a disorder characterized by repetitive stereotypical movements, usually of the legs, but sometimes of the arms, that occur during sleep. Most of the movements individually last 0.5 to 5 seconds and recur every 20 to 40 seconds in clusters that can last minutes or hours. Often the big toe extends and ankle dorsi-flexes (points upwards). With movements, there are often "arousals" –or lightening of sleep or even awakening. PLMD is not too common in younger people, but may occur in > 40% of the elderly. Many people with PLMD also have restless leg syndrome (RLS) –a syndrome where the subject reports feeling "creeping or crawling" sensations in the legs-especially while resting. PLMD may be a cause of insomnia and/or daytime sleepiness. Much, however, is not known about PLMD. One goal of MESA is to better identify what the health impact of PLMD is. Identification of PLMD will be accomplished by measuring leg movements during sleep. MESA will be the largest study where such measurements will be made.

Polysomnography

Polysomnography (PSG) is a procedure in which an individual is monitored overnight in a sleep laboratory with a polysomnograph. 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 viewed and analyzed.

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, under the chin for the EMG). 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 chest movement.
- *piezo leg sensors* measure leg kicks and jerks
- *position sensor* documents physical positioning of the participant 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 oxyhemoglobin saturation, which may drop during an apnea.
- *Nasal pressure (or cannula flow)* records pressure changes during inhalation and exhalation.

***Signals that are monitored are those thought important for sleep physiology.
An understanding of this process requires some understanding of sleep itself.***

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:

- | | |
|----------------|--|
| Stage 1 | "Light Sleep" |
| Stage 2 | "Presence of Sleep Spindles and K-Complexes" |
| Stage 3 | "Slow Wave or Delta Sleep" |

REM "Rapid Eye Movement Sleep" or "Dream" Sleep

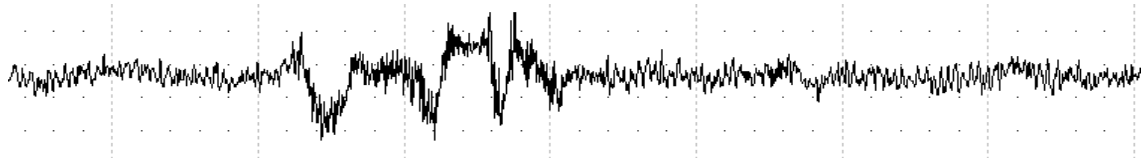
Stages 1, 2, and 3 are often referred to as non-REM sleep

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. Sleep stages may be altered in insomnia or may be affected by different medications. **Sleep recordings require measurement of brain activity (EEG), eye movement (EOG) and muscle activity (EMG) to accurately identify specific sleep stages.**

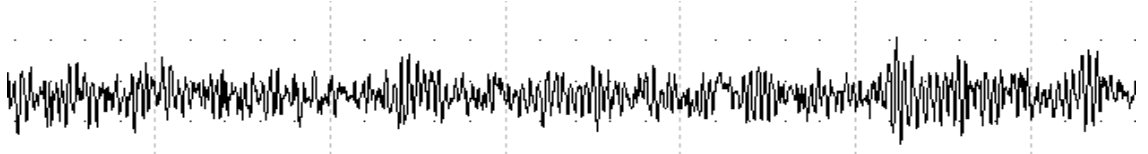
On the following page are examples of how the following stages appear on a polygraph record of EEG:

- 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
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.

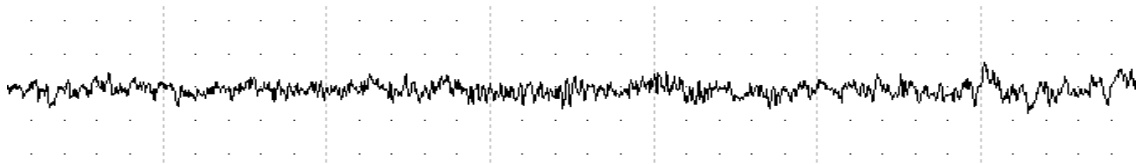
AWAKE - Low voltage - random, fast



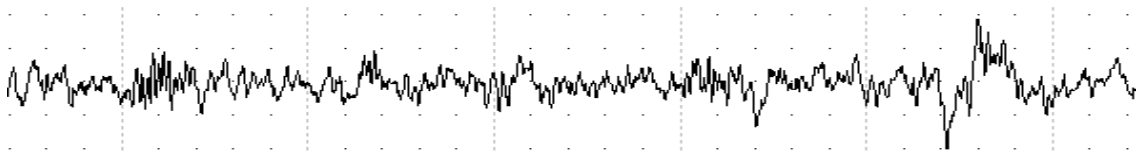
DROWSY - 8-12 Hz alpha waves



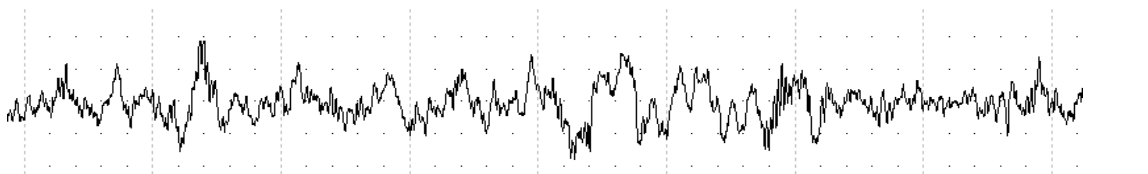
STAGE 1 - theta waves. Note the slowing of activity as compared to wakefulness



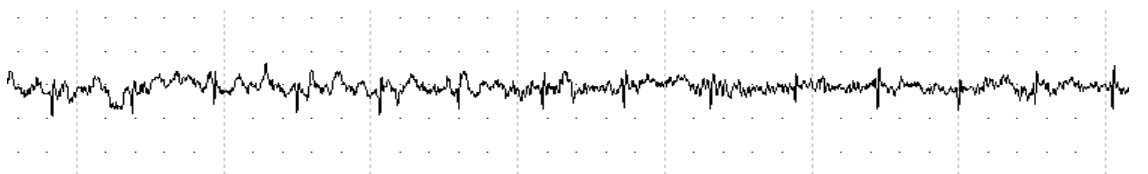
STAGE 2 Note the scattered very large waves (K complexes) and very fast waves (sleep spindles)



DEEP SLEEP (Stage3) - 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 insomnia, sleep apnea, or “restless legs” syndrome with periodic limb movements, **sleep architecture** (the progression and distribution of sleep stages) may be disrupted. These disorders can be associated with 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). Frequent arousals may be associated with shorter total sleep time and reduced slow wave, Stage 3-4 and REM sleep. Excessive numbers of arousals and/or movements can lead to *poor quality sleep*, *sleep fragmentation*, and *sleep deprivation* resulting in daytime sleepiness, mood disturbance and poor daytime functioning.

In addition to information on sleep quality (i.e., sleep stage distributions), there is also interest in **sleep time**. “Normal” sleep time in adults is thought to be 7 to 8 hours. People who sleep much less or much more often have poorer health and may even be at greater mortality risk. **Sleep efficiency** refers to the percentage of time in bed in which the subject actually sleep. Sleep efficiency > 95% often is found in people who are very sleepy or sleep deprived. People with a sleep efficiency of < 65% often have poorer sleep (35% of the sleep time was actually spent awake.) Sleep patterns may be measured with PSG or with actigraphy. Both tools will be used in MESA.

Respiratory Monitoring – Measurement Tools

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

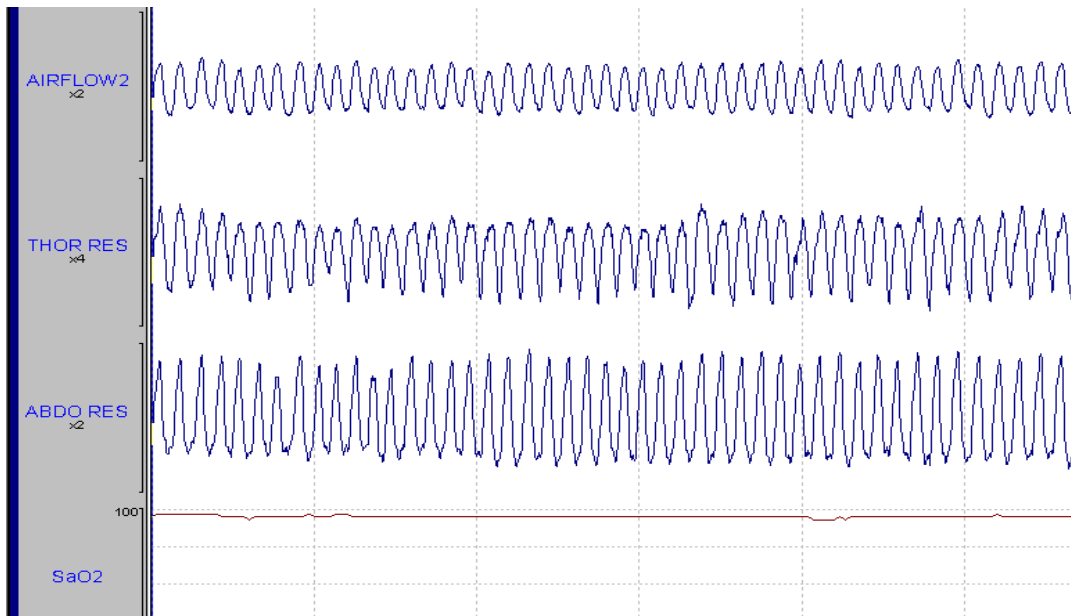
An **apnea** is a complete or almost complete cessation of airflow, lasting ≥ 10 seconds, and usually associated with desaturation or an arousal.

A **hypopnea** is a reduction in airflow (< 50% of a "baseline" level), associated with desaturation or arousal.

On the following page are examples of breathing as measured by polysomnography.

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; and may or may not include an obstructed upper airway. This pattern may be seen in heart failure or after strokes.

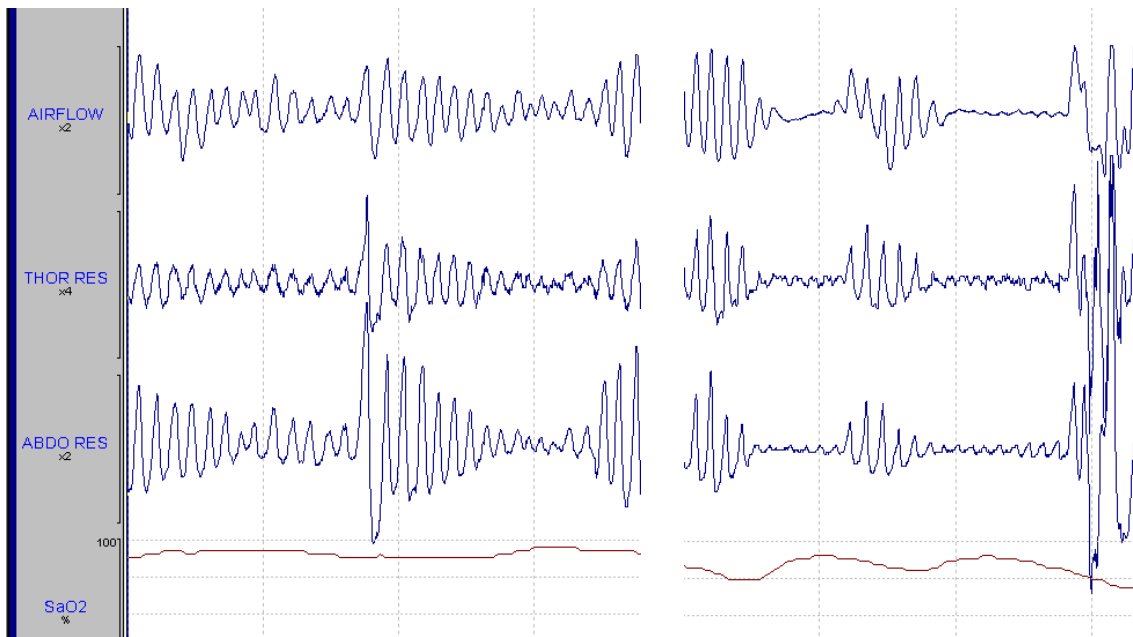
NORMAL BREATHING



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

Hypopnea

Apnea



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

EEG, EOG, chin EMG, leg movement sensors. Provides the information about sleep quality and quantity

Airflow. Qualitative assessment of breathing amplitude. Often measured with changes in temperature which occur with breathing as measured by a sensor placed in the pathway of airflow (nose and mouth).

Cannula Flow. Produces a signal from pressure changes to a nasal cannula during inspiration (pressure drop) and expiration (pressure increase). Some sleep specialists feel this signal may be more sensitive than airflow.

Respiratory Effort. Qualitative assessment of effort associated with breathing (allows distinction of central from obstructive events). Recorded with bands that measure changes in distention/movement with breathing (inductance).

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 the source 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 (on back), prone (on front), and side positions. This permits identification of the extent to which any sleep-related breathing problems are positional.

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

In this study, we will use very advanced technology (Compumedics Somte Monitoring System) that permits recording this information in an unattended setting. It also has special features to measure the ECG overnight to detect arrhythmias.

2. The MESA Sleep Visit Overview

Pre-visit period (2 weeks or more prior to in-clinic visit)

- Distribute study brochure at the end of the MESA Core Exam, as able.
- Mail participant an invitation letter, perform follow-up phone call (follow phone script) and determine eligibility and interest in participating.
- Within 2 days of the home visit, confirm visit and ascertain that no acute medical illnesses occurred. Obtain directions.

In-home Sleep visit (1-180 days after Exam 5)

- Prior to in-home Sleep visit (in clinic):
 - Set up equipment and supplies for in-home sleep visit
 - Actigraph
 - Somte PSG
- Evening of in-home visit (in participant's home):
 - Describe sleep procedures and obtain informed consent
 - Review use of diaries and review Sleep Questionnaire
 - Demonstrate actigraph and record first entry of sleep diary
 - Hook up participant for PSG/Complete signal verification form
 - Perform signal verification & check for any medical alerts
 - Provide instructions for equipment use and retrieval of equipment
- Morning after in-home sleep visit (in participant's home):
 - Retrieve Sleep Questionnaire and PSG equipment/Inquire regarding problems/Remind to continue to wear actigraph and complete diary
- **Post-PSG (in-clinic):**
 - Clean Electrodes and Sensors
 - Review PSG study and save on the computer
 - Complete Signal Review form and transmit data to the Reading Center
 - Verify Sleep Questionnaire is complete and accurate, phone participant if necessary to complete
- **6 days Post Sleep Visit**
 - Call participant and remind them to return actigraphy and sleep diary
- **7 to 10 days Post Sleep Visit**
 - Review retrieved Actigraph and Sleep Diary
 - Transmit actigraphy data to Reading Center - Complete equipment log
 - Clean actigraph

Glossary of Sleep Terms Related to PSG

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 (≥ 10 sec) 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. Can be increased by certain medications
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 right central electrode placement site.
CZ	A symbol of the International 10-20 electrode system, identifying a central electrode placement site.
Central Apnea (Hypopnea):	Cessation (or reduction) of respiratory effort ≥ 10 secs
Channel:	The linear (signal) output of an amplifier
Collodion:	An ether-based substance used for gluing electrodes to the scalp. Not used in this protocol
Delta Rhythm:	EEG rhythm with frequency of 4 Hz. or less.
Delta Sleep:	Sometimes used as a synonym for stages 3 and 4 sleep.
Delta Wave:	EEG wave with duration of .25 sec. or more
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. Defined in Hz.

Gain:	Voltage ratio of amplifier input to output
Ground electrode:	Electrode (or pair of electrodes) connected directly to the polysomnograph to provide for electrical safety or artifact reduction.
Hertz (Hz):	Cycles per second; a measure of frequency
Hypopnea:	Decrease in airflow or thoracic effort for ≥ 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 N2 sleep.)
Lead:	Term used to denote a single electrode
Light sleep:	Sometimes used as a synonym for stage N2 sleep.
Location:	Physical site, or area
Low-voltage EEG:	EEG consisting of cerebral activity of $20 \mu\text{V}$ 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 ≥ 10 sec.
Ohm:	Unit of electrical resistance or impedance.
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	A crystal that generates electrical current when subjected to movement. Used in some respiratory bands and leg movement sensors.
Polysomnograph:	Multichannel instrument used to record physiologic parameters during sleep.
Preauricular point:	Small indentation in front of, slightly above, cartilage flap (tragus) 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

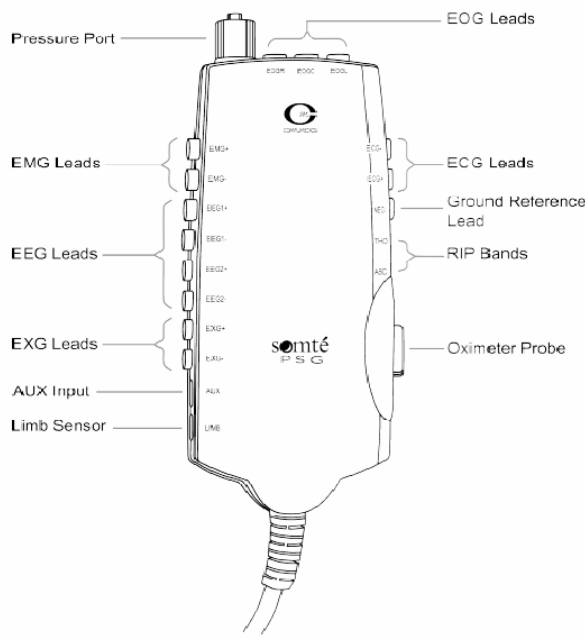
	prominent in stage 2 sleep.
Slow-wave sleep:	Sometimes used as a synonym for stage N3.
Stage N1 sleep:	Relative low-voltage, mixed-frequency EEG without rapid eye movements; slow rolling eye movements are often present; vertex sharp waves may be seen; EMG activity is not suppressed.
Stage N2 sleep:	12-14 Hz. sleep spindles and K complexes on a background of relatively low-voltage, mixed-frequency EEG activity.
Stage N3 sleep:	Moderate amounts (20%-50%) of high amplitude (75 μ V or greater), slow-wave (2 Hz. or slower) EEG activity.
Stage 4 sleep:	Predominance (greater than 50%) of high-amplitude (75 μ V or greater), slow-wave (2 Hz. or slower) EEG activity. Now stage 3 and 4 are combined into a single stage: N3
Thermocouple:	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 N1 or REM sleep).
Theta rhythm:	EEG rhythm with a frequency of more than 4 Hz to less than 8 Hz.
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 or body.
Vertex sharp wave:	Sharp wave, maximal at the vertex and negative in relation to other areas (often occurring during later portions of stage N1 sleep).
Wave:	Any transient change of potential difference in the EEG.

3. Polysomnography

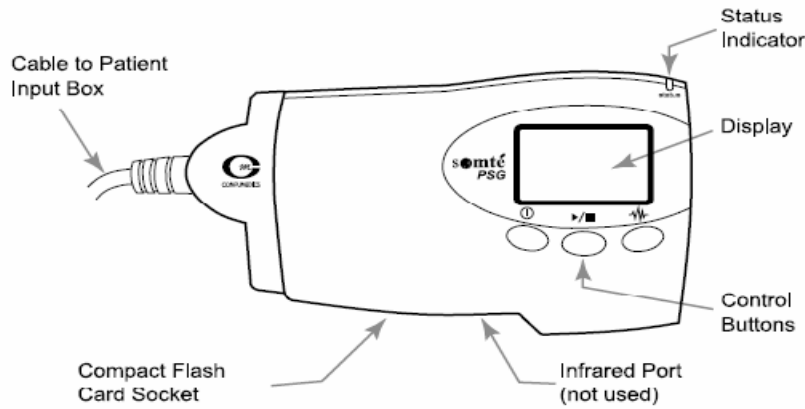


PSG Equipment

MESA will use the Somte unit, a light weight, battery run unit designed to collect overnight multi-channel sleep data in participant’s homes without the need for a computer at the bedside. The Somte PSG consists of 2 devices joined by a cable. The Patient Input Box (PIB) receives the terminals of every sensor and is worn on the chest. The recorder is worn below the PIB and receives and records the information from the PIB. The recorder also configures how the signals from the PIB should be collected. The PIB and recorder are permanently joined by a cable. The signals from the PIB are recorded onto a compact flash card.



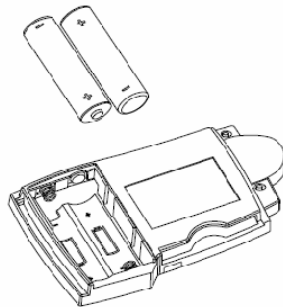
Patient Input Box



Somté PSG recorder main features

Loading Batteries

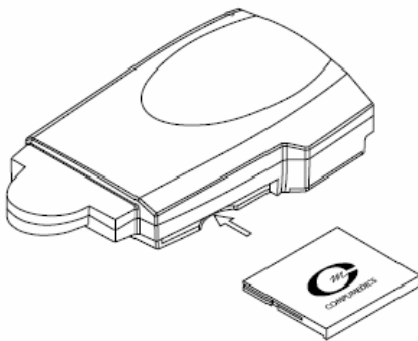
The system is powered by two AA alkaline batteries. To access the battery compartment turn the recorder over and flip open the black back plate. A small screwdriver must be placed deeply into the slot and pulled forward. Replace the battery compartment cover by inserting the tabs at the foot of the compartment and snapping the cover in place. Fresh batteries will be inserted for each recording at the time of the flash card set-up, and followed with synchronizing the Somte clock to the actigraph watch.



Battery orientation

Recording Data: Use of a Compact Flashcard.

The overnight physiological signals collected on your participants using the Somte will be temporarily stored on a compact flashcard. Prior to each study, the flashcard needs to be configured for each participant. These data will be transferred to your clinic study computer for download after the recording has completed and the unit returned to the clinic. After download the flash card must be re-formatted before it is set up for another participant. If a replacement flash card is needed a San Disk brand may be purchased but can be no larger than 2GB in recording capacity. The formatting procedure (FAT) used by the software does not work correctly on flash cards with a capacity larger than 2 GB.



Compact flash card insertion

To Configure the Recorder

- Configuration programs the Somte to work to specifications as well as to display current time and date. After a time change to or from Daylight Savings Time the time configuration must be changed before the next use.
- The recorder must be configured before the first use.
- Configuration does not have to be performed for each recording; it is stored in the Somte's memory. The time, however, must be synchronized to the actigraph watch before each use.
- If the recorder does not appear to collect signals properly, or the time or date is incorrect, the configuration should be checked and re-set, if necessary.
- The configuration mode can only be entered for a very brief time during the power-up sequence. If the mode is missed the unit must be powered off and back on.

To Access the Configuration Mode

1. Power on the Somte recorder.
2. Watch the display screen as it changes to the Somte welcome.
3. If a flashcard has been inserted the card set up will be checked and the pre-set start and stop time will be displayed. If there is not a flash card in the recorder this display will be skipped.
4. The display will show the configuration screen.
5. Press the center (start/stop) button.
6. The programming mode begins with a Main Menu.
7. Once the configuration mode is entered the programmer (technician) has control of the recorder. The display changes at the pace of the programmer.

Setting or Changing the Configuration

- In the configuration mode the function of the push buttons changes and is represented by icons.
- The icons may change depending on the level of the programming. You must be alert to the icons.
- The picture below shows the configuration mode main menu. This will be customized for the MESA PSG recording.

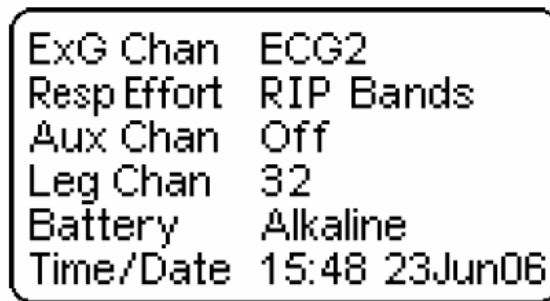







Figure 3-2: Configuration screen, v1.10 firmware

Icon	Function
↑	This button selects the menu choice above the currently selected choice (scrolling the screen if necessary). The selected menu choice is shown in bold type and has a small arrow to its left (for example ExG in Figure 2-6). If at the top choice then do nothing. If held down this button “auto repeats” approximately every half second.

Icon	Function
	This button selects the menu choice below the currently selected choice (scrolling the screen if necessary). If at the bottom choice then do nothing. If held down this button "auto repeats" approximately every half second.
	This button selects the next value (or setting) for the currently selected (shown in bold type) menu choice. For example if the ExG menu choice is selected pushing the button will select the next possible setting for this channel. If this button is pressed repeatedly the settings will cycle through all available settings for that menu choice returning to the original setting. If held down this button "auto repeats" approximately every half second. This button functions slightly differently for setting the date or time. If either of these choices is highlighted this button will select the first (or next) digit. The icon for the other buttons then changes to "+" or "-" allowing the digit to be increased or decreased.
	This button selects the configuration screen corresponding to the currently highlighted menu choice. For example if the "Cal Pos" choice is highlighted this button would move to the "Calibrate Position" screen.
	This button is only used for numeric choices (such as date or time). It increases the currently selected digit by 1. If held down this button "auto repeats" approximately every half second.
	This button is only used for numeric choices (such as date or time). It decreases the currently selected digit by 1. If held down this button "auto repeats" approximately every half second.

Correct Configuration Settings for MESA PSG

The Somte will display its configuration programming when powered on. The following settings should be displayed. If the recorder displays a setting other than what is listed below it must be corrected. *See setting or changing the configuration*

ExG channel	EEG3
Resp Effort	RIP Bands
AUX channel	THERM
Impedance	5KΩ
Date	(correct date)
Time	(correct time)
System	
Format	
Bluetooth	
Contrast	
Battery	Alkaline
Language	English US
Exit	

Synchronize the time on the Somte Recorder

To align the data from the PSG with the actiwatch, it is important to make sure each instrument is synchronized to the same clock. This can be done if you initialize both the Somte and the actigraph using the same computer with a valid time clock or use different computers that each have been synchronized to a common clock. This should be done before the home visit during the time of the flash card set up.

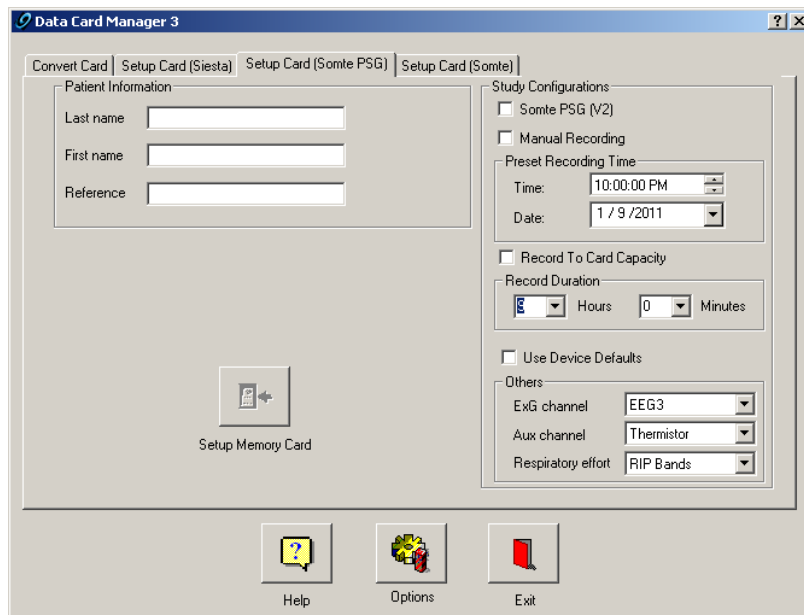
- The recorder has an internal battery that keeps time on the recorder even if the AA batteries are removed, however fresh AA alkaline batteries will be inserted before synchronizing the Somte clock.
 - Press the orange button to the far left in order to power on the Somte recorder. The unit will display a welcome page followed by the configuration screen.
1. Enter the configuration screen by pressing the center orange button. The screen will display the Main Menu.
 2. Use the center button to scroll down the menu until the time is highlighted (5 presses).
 3. Enter the time set option by pressing the right orange button. The flashing cursor will advance to the first digit for the hour setting of the 24 hour clock and each following digit.
 4. Use the center and left keys to execute the - + commands in order to change the clock time.
 5. The cursor must be moved over each digit in order to leave the time setting option. Use the right key to move the cursor. When the cursor is no longer flashing under a digit the time set option is exited by pressing the center button.
 6. Continue pressing the center button to move through the menu options until the option to Exit is highlighted.
 7. Accept the option to exit the program by pressing the right button. After exiting the configuration mode power the unit off.

Prepare the Compact Flash Card

1. Connect the flash card reader to the computer for MESA PSG. If the computer will be stationary there is no need to remove this drive between uses.
2. Place the compact flash card into the reader, face side up.
3. From your desktop double click on the shortcut icon for Data Card Manager3. The card manager screen will open.
4. Click on the tab for Setup Card (Somte PSG)
5. In the patient information box:
 - Insert the 7 digit participant ID followed by the acrostic in the line for Last Name.
 - Leave the First name blank.
 - In the Reference line enter the Tech ID- unit (Somte) ID.
6. In the Study Configurations box:
 - Make sure Somte PSG (V2) is not checked
 - Make sure Manual Recording is not checked
 - Pre-set the Recording time to begin 1 hour before the participant's usual bedtime and make sure the date is set correctly.
 - Make sure the Record to card capacity is not checked.

7. In the Record Duration box:
 - Enter the length for the recording (i.e. number of hours between usual bedtime and wake time plus 2 (1 hour before usual bedtime and 1 hour after reported normal wake time – but no less than 9 hours).
 - Make sure Use Device Defaults is not checked.
8. In the Others box:
 - Set ExG channel to EEG3.
 - Set Aux channel to THERM.
 - Set Respiratory effort to RIP bands.
9. Check the Option Settings.
 - Select the computer drive that the flash card reader has been assigned.
 - For the Notch frequency select 60
10. In the Auto conversion options:
 - Automatically convert unread studies should not be checked.
 - Open Profusion PSG/EEG after convert should not be checked.
 - After conversion remove study should not be checked
 - Minimize to tray when card not inserted should not be checked
11. Click OK.
12. Click on Setup Memory Card. When the set up is complete a pop-up dialog box will appear stating Save successful.
13. Click OK
14. Exit the Card Manager program.
15. Remove the compact flash card.

It is now formatted for the participant indicated in the set-up. It is recommended that the flash card is loaded directly into the Somte recorder at this point. Place the Actigraph and participant hook-up kit with the Somte and label them for the participant they are set for.



Rev Jan 2011

Preparation for PSG

Confirm Appointment and Instructions

When the appointment for the PSG is confirmed, remind the subject to have clean skin and hair for the study. This will help the electrodes stay in place throughout the night. Hair or scalp products such as hairspray, gels, mousse, and/or oils should not be applied. This is not an issue of hygiene, but because the special procedures for the study require the skin to be as free from oils as possible. Ask if the participant has any sensitivity to adhesives or metals. If severe sensitivity is reported, contact the BWH Sleep Reading Center for guidance on approaches.

Ask the participant about his usual bed time and wake time and note this as this information will be needed when setting up the compact flash card before the home visit.

The participant should dress for sleep in loose, comfortable clothing and avoid wearing a one-piece garment for sleep. If the participant indicates (s)he does not wear clothing to bed inform him that clothing above the waist must be worn for the hook-up and sleep and clothing below the waist must be worn during the PSG hook-up but later removed for sleep.

Check that Supplies are Organized for the for Home PSG Set-Up

Organize a supply bag that contains the following and check contents before every visit:

Recorder Equipment

Pre-configured compact flashcard
Somte Recorder with electrodes attached
1 set respiratory belts with covers
1 oximetry sensor
Somte carry case with spares
Somte Hookup Supplies
1 bottle Pre-Tac or other anti-diaphoretic solution
1 container prep gel
1 container electrolyte paste
tape measure –metric!
scissors
Non-latex Skin tape
Hair clips
1 wax pencil (do not use red)
drinking straws
face mirror
1 participant hook-up kit
All necessary forms

Removal Supplies

2 baggies/ rubber bands to isolate gold disks and cannula/ thermistor after removal
carry bag for all sensors and recorder

Setting up the PSG Study

After obtaining informed consent and explaining the study visit, ask the participant where s/he would prefer to be set up. Most participants will prefer the hook up to occur on a kitchen table. Ideally, the light should be good and there should be sufficient room for two staff members to work. If using a kitchen or

dining room table be sensitive to the fact that your equipment carry case and instruments are less sanitary than that surface. Protect the cleanliness of eating surfaces with some sort of barrier (chux, paper or other covering). 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.

Explain that the PSG will provide information on quality and characteristics of:

- Sleep (measured by sensors measuring brain waves over the scalp). To distinguish dream (rapid eye movement) sleep from non-dream sleep also requires measuring eye movements and muscle tone near the chin.
- Breathing and levels of oxygen in the body (by sensors placed under the nose and around the torso and on the finger tip)
- Leg movements (by sensors on the legs)
- Heart rate (by an ECG measured overnight)

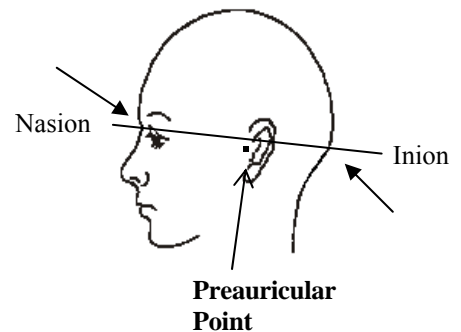
Procedures for PSG Hook-up

1. Identify landmarks

Proper sensor placement is very important for effectively recording sleep patterns and for consistency of data between sites. The PSG technician may prefer to measure and mark the head before beginning to apply the electrodes or during application. Head measurement is required; estimated placement of scalp electrodes is not acceptable.

The process for placing EEG sensors on the subject 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 preauricular points (see glossary for definitions).

- **Pre-auricular points:** Standing at the side of the subject, 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 preauricular point. If in doubt, ask the subject 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.
- **Nasion:** Facing the subject, 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.
- **Inion:** Using a comb, unpadded cotton swab end or hair clip part the subject'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 subject 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 subject, 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.

2. Measure for electrode sites:

Distance measurements are done with a metric tape measure, and taken in centimeters (cm.) and millimeters (mm.). A quick measurement guide can be found below, as well as in the Equipment Maintenance Section, to help in computing percentage measurements. 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 subject or family members, therefore is discouraged. (If you use red, warn them it is only a marker.) When working with subjects having long or thick hair, create a part in the hair by means of a comb or the un-padded 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.

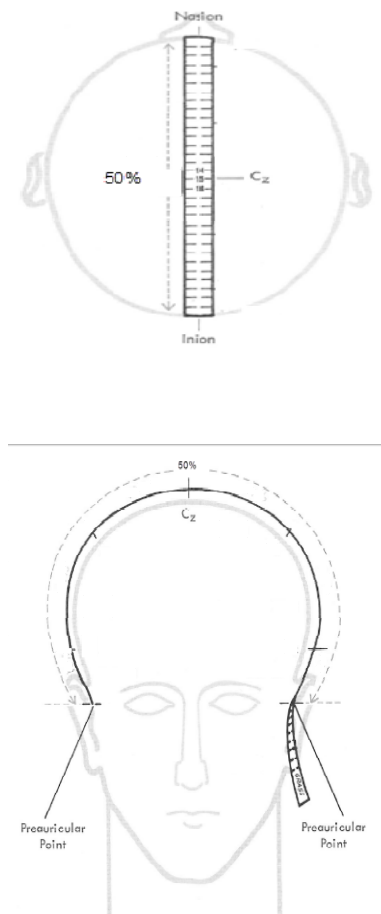
Quick Reference: Measurement Chart

Total Measurement Value (cm.)	50% Value (cm.)	20% Value (cm.)	10% Value (cm.)	5% Value (cm.)
25	12.5	5.0	2.5	1.25
26	13.0	5.2	2.6	1.3
27	13.5	5.4	2.7	1.35
28	14.0	5.6	2.8	1.4
29	14.5	5.8	2.9	1.45
30	15.0	6.0	3.0	1.5
31	15.5	6.2	3.1	1.55
32	16.0	6.4	3.2	1.6
33	16.5	6.6	3.3	1.65
34	17.0	6.8	3.4	1.7
35	17.5	7.0	3.5	1.75
36	18.0	7.2	3.6	1.8
37	18.5	7.4	3.7	1.85
38	19.0	7.6	3.8	1.9
39	19.5	7.8	3.9	1.95
40	20.0	8.0	4.0	2.0

2a. To determine Cz:

Have the subject sit in a chair. Standing at the side of the subject, place the zero line (0) of the tape measure on the marked inion. Hold 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) and mark the scalp at 50% of the total inion to nasion distance. When marking these sites, make a large enough line so it can be easily found.

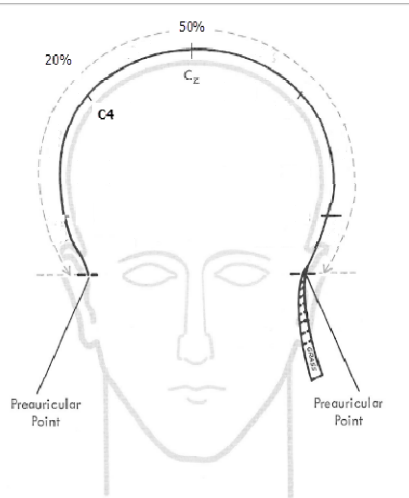
Remove the tape measure and stand behind the subject. Place the zero line of the tape measure on the left pre-auricular mark. Stretch the tape measure over the top of the head, and along the mark that has just been made, until it reaches the right pre-auricular mark. Determine the total distance from 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.



After Cz is located the rest of the measurements can be done in any order.

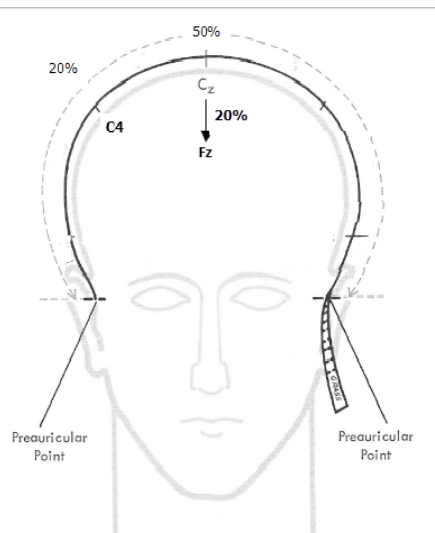
2b. To determine C4:

Continue to stand behind the subject. 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 subject'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 and following its edge, mark a line across the one just made. Remove the tape measure and extend both lines so they intersect. The point at which the lines intersect is the site for the C4 electrode placement.



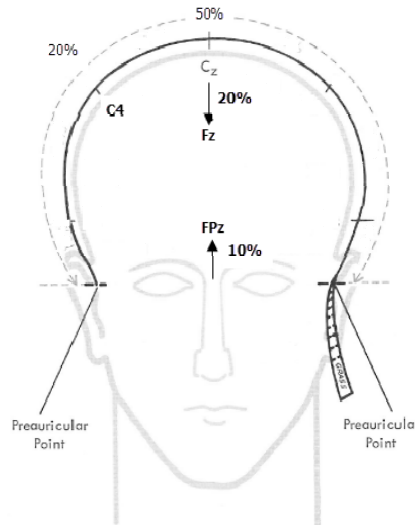
2c. To determine Fz:

Stand in front of the subject. Place the zero line of the tape measure on the site for the Cz electrode placement. While firmly holding the tape measure in place, drape it down the participant's forehead to the nasion. Remembering the total distance from inion to nasion, make a mark at 20%. This mark should be near the hairline in the center line of the upper forehead. Keeping the tape measure in place and using it as a straight edge, make a line to intersect the 20% mark. Remove the tape measure and intersect the lines, if necessary. This is the mark for the Fz electrode placement.



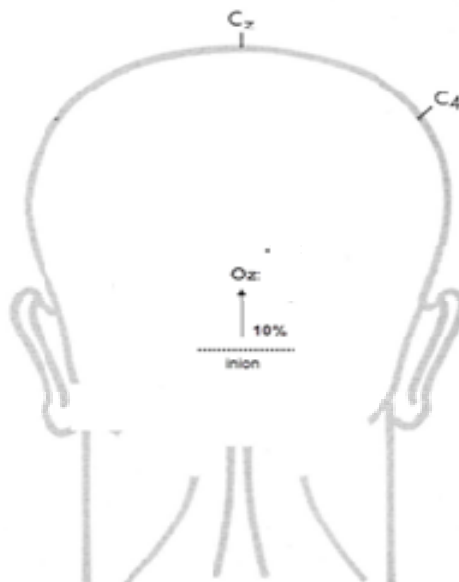
2d. To determine FPz:

FPz is located 10% of the total inion to nasion measurement, above the nasion in the midline of the forehead. The electrode placed at FPz will be used for the EOG channels and will be placed in EOG C.



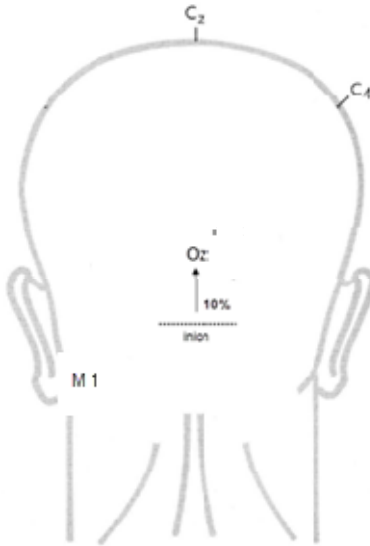
2e. To determine Oz:

Stand behind the participant. Make a part down the back of the head, from the Cz location to the inion, if necessary, so the scalp is visible. Compute 10% of the total measurement from inion to nasion. Place the zero line of the tape measure on the inion and measure upward (toward CZ) to the 10% mark and mark the scalp. This mark should be low but in the center of the back of the head. This mark will be used for the Oz electrode placement.



2f. To determine M1:

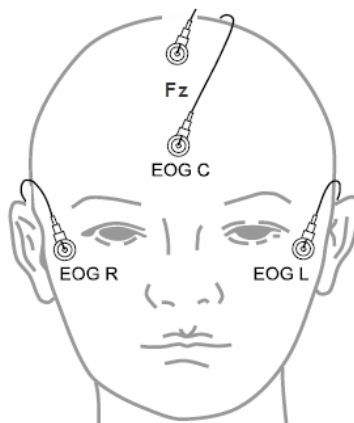
This placement site is on the mastoid process (bone behind the earlobe). The electrode should be placed on the skin between the crease of the earlobe and where the hairline begins. Lightly mark this site. M1 is placed on the left mastoid.



2g. To determine EOG placements:

The EOG recording electrodes are placed 1 cm. (about one finger breadth) lateral to and 1 cm. below the outer canthus of each 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 correct.

The reference for the EOG electrodes is at FPz. This electrode is plugged into EOG C in the PIB.

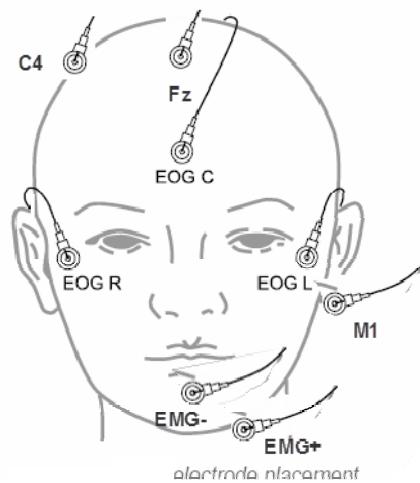


EOG electrode placement

2h. To determine chin EMG placement:

The EEG waveforms in non-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.

One EMG electrode is placed on the side of the geniohyoid muscle, which is a large muscle located underneath the chin that controls the tongue. Having the subject activate this muscle may help identify where to place this electrode. In order to activate the muscle, place your fingers under the participant's chin between the tip of the chin and the neck and ask the participant to swallow. You will feel the geniohyoid muscle move. The electrode is placed on the belly of this muscle (the area of the greatest movement when activated). Another electrode is placed on the ledge of the chin (below the lower lip).



Reference:

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

Test the Internal Position Sensor

The PIB contains a built in position sensor which must be hand tested prior to each recording to verify accuracy. This is done before placing the PIB in the vest and onto the participant. Power on the unit and wait for the idle screen.

1. Press the waveform button 9 times, waiting for each screen to display before advancing to the next.
2. On the 9th button press the screen should display the position of the PIB in words.
3. Move the PIB by hand in all 4 positions (left, right, back, front), waiting for the display to change between each movement.
4. After all positions are verified accurate with hand testing power off the unit and mark the SV form.
5. Power on the unit and wait for the idle screen.

Attach the Vest

The vest delivered with the Somte was specially designed for comfort and freedom of movement during the hook-up and sleep recording process. The vest is worn on the upper chest. The Somte PIB must be placed in the vest correctly. The PIB contains a built-in position sensor so the positioning in the vest is very important for collecting accurate information on body position during sleep.

Because the vest sits near the head the length of the electrodes and other sensors is short. Due to the short length the vest and PIB can be placed on the participant before or after measuring and preparing the skin for electrode placement but must be worn for attaching the electrodes.

Because the vest sits over the area where the chest effort belt should be worn this belt should be placed before the vest is put on.

Electrodes may remain plugged into the PIB during the participant preparation or, if desired remain loose for the PIB and plugged in after they have been attached.

Electrode Site Preparation

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.

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 $< 5 \text{ k}\Omega$ 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 subject's skin at the electrode site. Although blood is not evident, the technician must understand that these areas are now non-intact skin and pose a risk for blood borne pathogens. The Reading Center 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 those with sensitive or fragile skin; Lemon Prep has the highest volume of abrasive and is suitable for weathered scalp or if low impedance cannot be otherwise obtained. 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 but it should not hurt, and it will not harm your skin."

Clean the 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 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 subjects 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.

Sensor Placement

Because you will be connecting the sensors to the subject, you should become familiar with each sensor and learn how to correctly place and connect them. [Note: When connecting the sensors, be sure to hold the electrode at the neck, not by the wires. Also, because abrasion during prep creates non-intact skin, wear non-sterile patient-care gloves when applying electrodes.]

Below are general rules for good sensor placement:

- Prep only areas of skin that electrodes cover
- Use only small pieces of tape but enough to secure the sensor and wires
- Provide for "stress" in wire/cables
- Secure loose wires/cables with tape
- Use non-dominant hand for oximeter placement
- Ask subject about sensitivity to adhesives or latex products or choose to use all latex-free products

You will use 13 electrodes:

** 10 Gold disk Electrodes:*

- FPz (EOG C)
- E1 (EOG L)
- E2 (EOG R)
- L Chin (EMG+)
- C Chin (EMG-)
- Fz (EEG1+)
- Cz (EEG1- jumpered to EEG2+)
- Oz (EEG2-)
- C4 (ExG+)
- M1 (EXG-)

** 3 Snap Electrodes:*

- left ECG (ECG-)
- right ECG (ECG+)
- Ground (NEG)

Other Sensors:

- Chest belt (THO)
 - Abdominal belt (ABD)
 - Leg movement sensor (LIMB)
 - ThermiSense Nasal/oral thermistor (AUX)
 - ThermiSense Nasal Cannula
 - Finger pulse oximeter sensor
-
- If a site prefers to use snap electrodes for some of the gold disk placements (only permitted in non-hairy areas) this will be allowed only after written request by the site and approval of the Reading Center. Cost of additional snap lead wires and patch electrodes cannot be included in the participant kits and must be the responsibility of the requesting site.

Suggested Order of PSG Hook-up when using the Somte Vest

ECG electrodes and NEG ECG (2 snap electrodes)	1 (-) below right clavicle. 1 (+) lower left rib
NEG (1 snap electrode) Somte Vest	1 below left clavicle Around neck with front bib high and all flaps open.
Thoracic RIP band (yellow)	Thoracic belt below left armpit but over the vest. When placing respiratory bands observe the participant's normal breathing to determine proper positioning
PIB	Secure the PIB onto the loop on the top of the bib of the opened vest. Connect the electrodes that have been placed on the participant. The rest of the electrodes can also be connected to the PIB at this point, if desired.
Gold Disk Electrodes (10)	FPZ (EOG C), Fz, Cz, C4, Oz, M1, E1 (EOG L), E2, (EOG R) L Chin, C Chin. Feed wires to the head along either shoulder flap.
Thermistor + Nasal Cannula	Attach the thermistor to the cannula prior to placing on participant. Place between nose and upper lip. Cannula should rest inside of nostrils.
Abdominal RIP band (Blue)	Abdominal belt at the "belly button". When placing respiratory bands observe the participant's normal breathing to determine proper positioning. After activating the sensors the recorder will be secured to the abdominal RIP band.
LIMB (1 piezo electrode)	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 Attaching electrodes with wires facing downwards (towards feet) and tape to the outside of pajama legs near the ankles will allow for bathroom needs. For bare leg, tape wire to outside of each thigh
Close the vest	Check all connections to the PIB, tidy the wires and secure into the side flaps. Close the vest by bringing up the bottom of the vest and snapping it to the vest bib. The pocket on the front of the closed vest can be used to secure additional length of cables or wires.
Oximeter sensor	On a finger (preferably not index) of non-dominant hand, light diode on the nail

Rev Jan 2011

Map for plugging electrodes into the PIB

PIB must have 1 jumper lead plugged into EEG1- and EEG2+

<i>Correct electrode name</i>	<i>Plug into PIB receptacle</i>	<i>Type of sensor</i>	<i>Anatomical placement</i>
LIMB	Limb	Piezo (dual end)	L on left leg tibialis anterior muscle R on right leg tibialis anterior muscle
R ECG	ECG-	Patch	Below R clavicle
L ECG	ECG+	Patch	Left lower rib
Ground	NEG	Patch	Below L clavicle
Abdominal	ABD	Inductance band	Upper to mid abdomen, near umbilicus. Look for movement
Chest	THO	Inductance band	Upper chest between armpit and nipple. Look for movement
Ground	NEG	Patch	Below left clavicle
Fz	EEG1+	Gold disk	Mid-line front of head near hairline
Cz	EEG1- and EEG2+ (jumpered)	Gold disk	Midline, center of head (this is the 1st placement you will mark)
Oz	EEG2-	Gold disk	Midline, back of head , 10% frominion
C4	ExG+	Gold disk	Right side of head, 20% to the right of Cz
M1	EXG-	Gold disk	Behind left ear on mastoid process
FPz	EOG C (at top)	Gold disk	Mid-line of forehead above eyebrows, 10% above nasion
E1	EOG L (at top)	Gold disk	Outer canthus left eye, 1 cm lateral and 1 cm below crease, on orbital bone
E2	EOG R (at top)	Gold disk	Outer canthus right eye, 1 cm lateral and 1 cm below crease, on orbital bone
L Chin C Chin	EMG+ EMG-	Gold disk	Under the chin, just to the left of the muscle Front ledge of the chin
Airflow	AUX	ThermiSense nasal sensor	Attached to ThermiSense nasal cannula, resting below nostrils
Nasal Cannula	PIB next to EOG R	Nasal Cannula	Cannula tips on the floor of and within the nostrils
Pulse Oximeter	Connector below ABD	Nonin 8000J or Soft-tip finger oximeter sensor	Non-index finger of non-dominant hand

ECG Electrodes:

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.

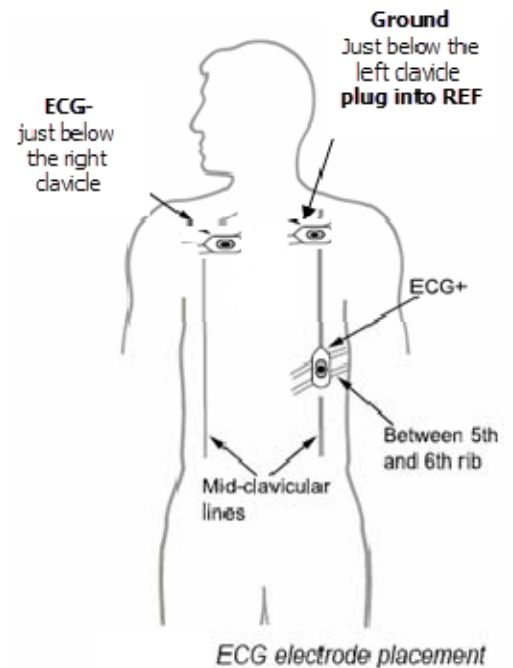
Negative (-) electrode 3-5 cm.(2 finger breadths) below midpoint of right clavicle.

Positive (+) electrode placed on left side between the 5th and 6th rib.

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.

Snap electrode to lead wire before applying to subject's skin.

Placement for the Ground/reference electrode.
Plug into NEG in PIB



Attach the Somte vest:

After the ECG electrodes have been securely attached to the participant the Somte vest should be placed around the participants neck, with all of the flaps opened and the bib of the vest high over the upper chest. The thoracic RIP belt is then placed on the participant over the vest.

Respiratory belts:

Place the black cover sheaths over the respiratory belts before applying to the participant.

The abdominal band (blue wire) should be placed on the left side of the body around the lead wire facing upwards. Adjust the black extender belt so the belt is secure, but not tight.

Place the chest band (yellow wire) on the left side between the left armpit and nipple, with the lead wire facing upwards. Adjust the black extender belt so the belt is secure, but not tight.

Plug the belt wires into the correct (by color code) receptacle. The pins go in one way only; one side of the pin connector is rounded and the other side of the connector is squared.

When placing respiratory belts, watch the participant breathe normally. Place belts where greatest amount of movement is seen.

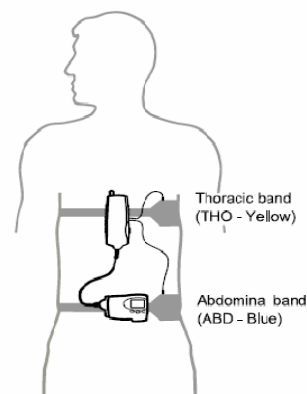
Incorrect application of respiratory bands can cause very poor signals..

Do not restrict the subject's comfort or breathing.

The Somte vest should be placed on the participant before applying the RIP belts; after the vest is placed, the Thoracic belt should be placed over the vest. This helps to secure the vest to the participant if he rolls to a side while in bed.

The Abdominal RIP belt can be placed under the open flap of the vest bib at any time before closing the flap. The restraining strap at the bottom be looped around the Abdominal belt to prevent the belt from slipping during sleep.

Colour	Designation	PIB Label
Yellow	Thoracic band	THO
Blue	Abdominal band	ABD



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. Provide stress loops at the side of the knee. Sensor wire may be taped again at the lateral thigh.



EEG Scalp Electrodes (Gold Disk):

Attaching 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.

The Reading Center and manufacturers recommend never mixing pastes to create a new product.
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.
- Place a small amount of electrolyte paste onto a clean disposable surface (i.e.: 4 x 4 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.
- Before using tape, ask the subject about sensitivity to tape, latex or adhesives.
- Discard the unused electrolyte paste when finished. Never contaminate your original tube or bottle.

Techniques for Disk Electrode Application

Bare skin (Forehead):

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 piece of non-latex skin tape.
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 electrode cream and attach to prepped site.
3. Cover the electrode with cut gauze pressing firmly on electrode and hold in place until electrode cream begins to set and feels secure.

Additional step for beards:

1. After applying the electrode but before covering it with cut gauze, work a few strands of the beard back over the electrode.
2. Apply a small dab of electrode cream to the gauze before applying over the electrode.

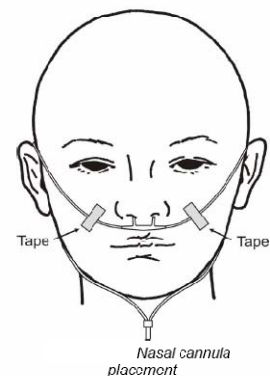
ECG Snap Electrodes:

1. Prepare the skin as for gold disk electrodes.
2. Snap the electrode onto the lead wire before attaching to its site, unless you have offset snaps.

Thermistor and Nasal Cannula

1. Hold the cannula toward you, with the nasal prongs curved downward.
2. Insert the tip of the oral sensor into the holding tube behind the nasal prongs.
3. Gently slide the thermistor through the holding tube until it fits into the notch at the base of the thermistor. Make sure the sensor is fitting snugly in the notch; this will ensure it stays in the correct position during the recording.
4. These 2 sensors will be then placed as a single unit between the nose and upper lip.
5. Place the thermistor/ cannula on the participant so the nasal prongs fit into the nostrils.
6. Secure in place by looping the wires around ear and loosely cinching the slides near the back of the neck. Additional tape may be placed to hold the wires at the cheeks.
7. Adjust the oral sensor so it hangs in front of the mouth but not touching the lips or skin.

Note: The thermistor is sensitive to displacement or moisture, so keep the upper lip dry. Nighttime beverages should be consumed through a drinking straw. Participants should be encouraged, when possible to drink or take medications before the final placement of this sensor, if able.



Oximeter

- The finger oximeter records pulse and oxygen saturation using a small light that shines through the finger. Colored nail polish defeats the function of the oximeter, and must be removed from the finger prior to sensor attachment.
- Oximeter should be placed on the ring finger of the non-dominant hand (preferably the 4th or 5th digit).

There are 2 types of oximeter sensors for use, depending on preference and participant comfort:

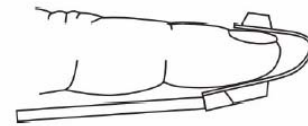
Flexi-Fit (8000J):

1. Place probe onto the Flexi-wrap sensor holder following the guide holes and illustration.
2. Place the finger into the sensor nail-side up with the tip of the centerline mark in the curved area.

3. 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.
4. Be sure that the emitting and receiving diodes directly “face” each other.

Soft Tip: There is an optional soft sensor that is placed over the fingertip. This sensor is manufactured by Nonin to be used with the XPOD oximeter and work the same as the standard 8000J Flex sensor.

- After securing either type of oximeter sensor, ask the participant if any throbbing is felt. If so, reapply, loosening tape. Tape the oximeter cable over the surface of the hand to minimize stress. Check that the subject has free movement of the hand and arm.



*Flex-wrap oximeter
probe placement*

Close the Vest

After the electrodes and sensors have been securely attached to the participant the wires should be straightened and closed into the side flaps. If there is any slack on the electrodes they may be bundled together at the back of the head and secured with a posey wrap. The bib of the vest should be closed and snapped but the recorder must remain unattached to the participant and freely available to the technician at this point. The recorder will be attached to the abdominal respiratory belt after the sensor activations have been performed.

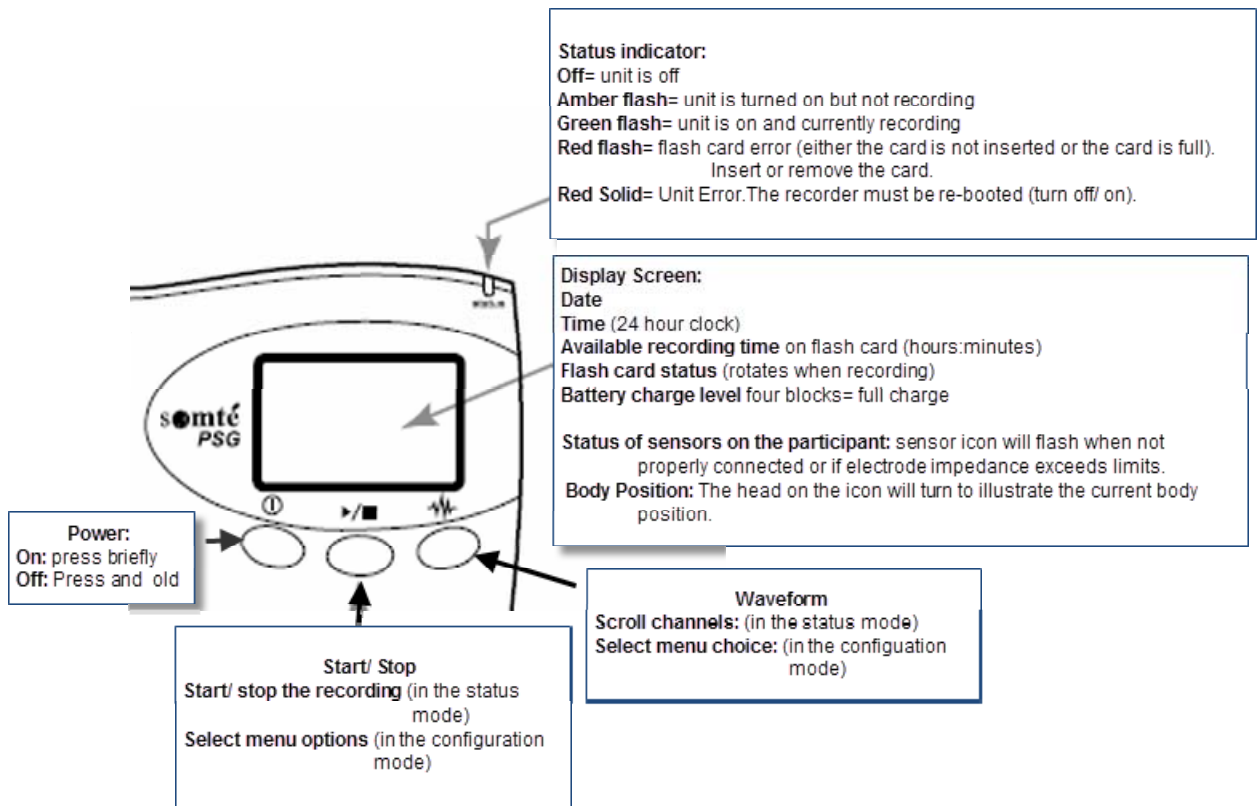
Procedure for Beginning the PSG Recording

You are now ready to begin to test the connections and begin recording!

Power up the Recorder

1. Be sure a formatted flashcard is in the Somte and ready for recording. If not, open the back cover of the recorder. Insert the flash card into the slot with the top side of the flashcard faces the front of the recorder. If not already done, pry open the back plate of the recorder and insert 2 AA alkaline batteries into the compartment. Replace the back plate which will snap securely.
2. Turn the Somte on by holding down the small orange power button (left) until the amber status light begins to flash.
3. The recorder will perform an internal test.
 - If the internal testing fails the unit will display an error message and the status indicator will turn solid red. To clear the error message and restart the internal testing power the unit off, and then back on.
4. The display will proceed to the Somte welcome screen.
5. The card set up will be displayed. Make sure the configuration is correct as follows:
7. Next the display will show the configuration for the recording. Make sure the unit displays the following:
 - EEG3
 - RIP

- AUX THERM
 - Alkaline, English US
 - Time and Date
 - The display will then rest at an idle status screen.
8. Check Impedances
- Once on the idle status screen if any of the head sensors have impedance greater than 5 k Ω they will be displayed. These must be fixed before the recording begins:
 - Begin by making sure the electrode end is properly placed into the PIB, then check the attachment on the head for security.
 - If secure and the display is still flashing the sensor must be removed and the placement re-prepped before replacing.
 - For errors with the respiratory signals the sensor with a problem will flash. These must be fixed before the recording begins.
 - Begin with making sure the sensor is attached securely (i.e.: belts not too tight or too loose, thermistor placed properly within cannula body, and cannula in place within the nostrils).
 - For error with oximetry make sure the finger sensor is properly placed.
 - If placement seems OK, remove and place on another finger.
 - If error continues remove from the participant and test sensor on yourself.
 - If error continues replace the finger sensor.
9. Complete the SV form to indicate if there were any problems with the signals
10. Check Signal Quality
- From the idle status screen press the waveform button. Here each signal will be displayed in groups of 2.
 - Make sure that all signals look clean and each respiratory channel shows visible deflection (movement).
 - If any of the signals look thick and fuzzy refer to the troubleshooting guide in the appendix.
 - As you move through the display ask the participant to activate each signal and check that the sensors are working properly.
 - Following the SV form, check the assessment of each signal.
 - Annotate the SV form with the values for SpO₂ and Pulse.
11. Attach the recorder to the abdominal belt by undoing the belt and passing it through the slot on the back of the recorder. Re-tighten the belt on the participant.



Activation for each signal

EEG1 EEG2	Have the participant relax and close his eyes. The signals should not waver from baseline.
EEG3	Have the participant relax and close his eyes. The signals should not waver from baseline.
EOG L EOG R	Ask the participant to look straight ahead and blink, the signals should both go ↑ Have the participant look left and right, signals should move out of phase
EMG	Ask the participant to bite down; signal will get big and fuzzy.
ECG Pleth	Look for clean waveforms. Pleth should match pulse rate.
Press Flow	For CPAP/ not used For CPAP/ not used
THERM	Clean thermistor signal should move with breathing, flatten with breath holding
Flow Snore	This is the cannula. Clean signal should move with breathing This is from the cannula. Have participant mimic snoring. Signal moves above baseline
Thor ABDO	These both should move with breathing
Leg POS	Have the participant move his legs, change in signal should appear. Current position, in words, should be displayed on screen. Have the participant lean to the right and left and check the reading. If possible, have the participant lie down and check the reading for “back.”
SPO2 Pulse	Oxygen saturation % will be displayed. Note this on SV form Pulse rate bpm will be displayed. Note this on SV form

- You may continue scrolling the channels as long as necessary but you cannot leave the scroll .
- When scrolling has been completed the display will return to the configuration settings.
- The display will then rest at idle.

11. If satisfied and the SV form has been completed the recorder should be left powered on and placed on the abdominal belt.
 - If the recorder begins recording during the home study it may be left on but the SV form must be annotated.

Instruct the Participant

Instructions should be given regarding how to move with the equipment in place and what to do if a sensor comes loose. The cannula and thermistor and finger oximeter are important sensors so if the participant removes any of these in order to eat, blow the nose or wash the hands they should be instructed how to replace the sensor with a return demonstration. A complete list of instructions should be reviewed with and then left with the participant.

1. Explain that the recorder is set to start and stop automatically. Instruct the participant that the recorder will begin recording automatically before his usual bedtime and the flashing amber light will change to flashing green. The steady red light from the oximeter sensor will remain steady red. No action is needed unless the cannula needs to be removed before eating or drinking.
2. Also instruct the participant on how to remove the sensors, equipment and vest in the morning, unless there is a plan to have clinic staff assist with the removal. Review the participant instruction sheet.
 - After removing the gold disk electrodes the dirty ends should be placed in the baggie from the hook-up kit to isolate these from other items. These require high level disinfection upon return to the clinic.
 - The cannula/thermistor should also be isolated in the same way in a different baggie. The cannula is disposable but the thermistor requires high level disinfection upon return to the clinic.
3. Instruct the participant to wrap all sensors, recorder and PIB into the vest and place into the return bag and complete any necessary paperwork.

Departure

All items used for the hook-up should be wrapped in the protective under pad and disposed in the trash can. The home should be left in the same condition, or better, as on arrival.

The Next Morning

Accepting the Equipment

At return of the sleep equipment the flash card should be removed for downloading. Paperwork should be placed with the card to keep items together.

Cleaning and Disinfection

1. Gloves should be worn when handling the recorder and its components while preparing to clean and throughout the cleaning process. Gloves must be removed before the tech leaves the cleaning area for any reason.
2. The gold disk electrodes and thermistor must undergo high level disinfection after each use, and all other items must be sanitized.

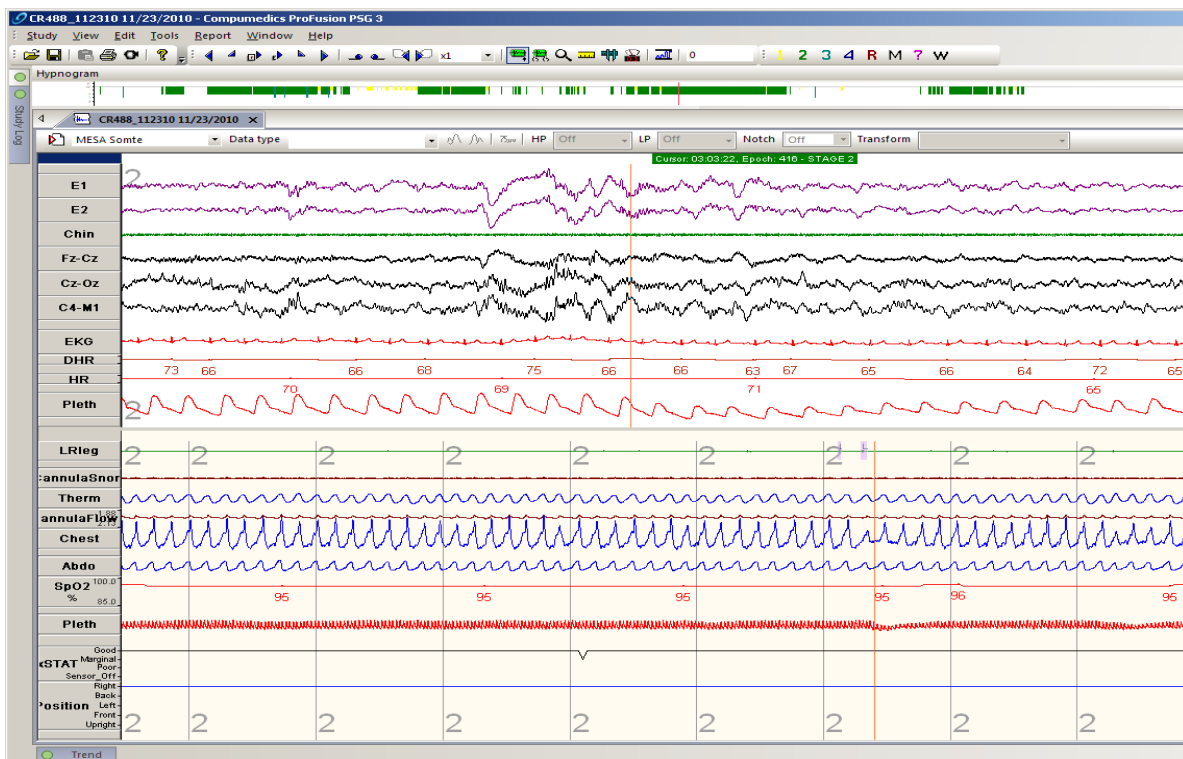
See Appendix for detailed instructions on cleaning and disinfection.

Downloading the Flash Card

1. On your computer desktop open the icon for Data Card Manager.
2. Insert the flash card face up into the card reader.
3. Click on the command to Convert the card. After this process is completed you can close Data Card Manager and Click on the Profusion 3 icon on your computer desktop and open the study.
4. The study is now ready for you to review quickly before sending to the Reading Center. Complete the Study Evaluation (SE) form at the time of review.

Reviewing the study

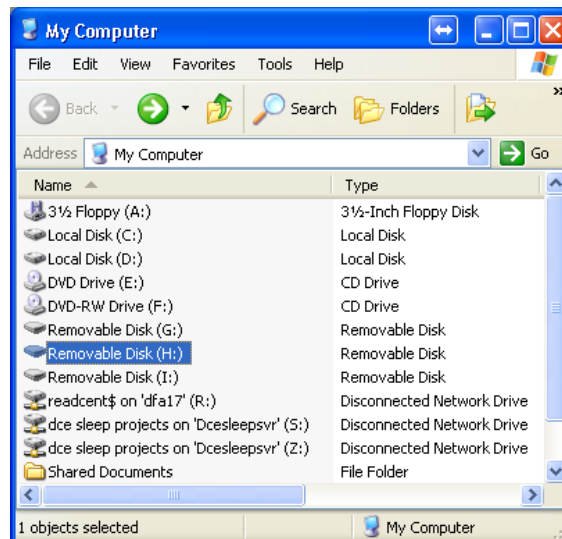
1. The study must be manually opened in review software (Profusion3) after download is completed.
2. Press the F4 key when the study displays to apply the MESA Somte display layout.
3. Make sure the ID and date in the top bar of the computer screen are correct and match the paperwork.
4. Scroll through the study:
5. Make sure signals quality is good throughout the recording.
6. Look at SpO2 and Heart rate values for signs of abnormal readings.
7. Complete the SE form.
 - If any cause for immediate processing is anticipated (i.e.: low SaO2 values, excessive respiratory events, possible unit problems) email the RC identifying the study ID and request an expedited review.



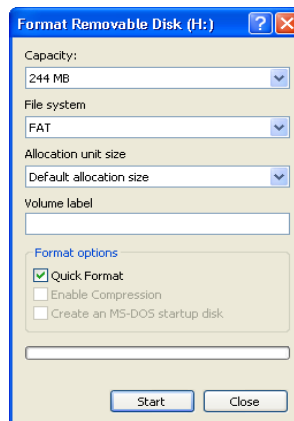
Rev Jan 2011

Re-Format the Flash Card

- The flash card should only be reformatted after the download has been successful and the study has been reviewed.
 - Reformatting the card erases all data and readies it to be configured.
 - To reformat you must know the drive label for the card reader.
1. Insert the flash card in the reader.
 2. Access My Computer from either a desktop shortcut or the Microsoft Start button (lower left corner of computer screen).
 3. A pop up screen will open showing a list of the available drives.
 4. Choose the drive for the card reader. In order to be sure you have the correct drive you may wish to open it and check the files.
 5. When you are satisfied the correct drive has been chosen select the drive to highlight it and right click.



6. Scroll downwards on the drop down list to the Format command.
7. In the pop up window make sure the file system is FAT.
8. Choose Quick Format and click the Start button.





4. Certification Requirements: PSG Field Tech

Obtaining Certification

The Reading Center requires the PSG technician to obtain certification prior to performing actual data collection. PSG certification is awarded upon (1) demonstration that the technician has basic understanding of sleep and its variables, polysomnography, understanding and application of sensors and electrodes used for the PSG, (2) successful operation of the PSG instrument, and (3) demonstrated compliance with the study protocol for data collection.

In order to obtain PSG certification the following items must be met:

1. Attendance at Central Training conducted by the Reading Center or one-to-one training from someone in attendance at Central Training. If trained at site, the On-Site Training Check Sheet must be completed by the instructor and submitted to the Reading Center.
2. Submission of the PSG practical exam. The evaluator must be a member of the training staff or a certified tech that attended Central Training.
3. Submission of the PSG written exam.
4. Submission of 2* acceptable practice (non-subject) PSG recordings. One of these practice recordings can be done during Central Training, and the others should be done in a home setting. This serves both as part of the tech certification and as practical experience in using the equipment in the study environment. Certification studies also allow for verification that all sensors and equipment are functioning properly before being used on a study participant.

*To be considered acceptable the study must:

- a) Be an overnight recording on a non-study volunteer.
- b) Have good quality signal on each channel (i.e.: all electrodes must work) and signals must be relatively free from artifact.
- c) Reflect MESA PSG protocol and procedure and must include completed Signal Verification (SV) and Signal Evaluation (SE) forms.
- d) Be named correctly as a certification study: CR[techID]_date.

Maintaining Certification

Maintenance for PSG certification will be accomplished by performing actual collection. Once certified, a MESA sleep technician must do a minimal of two MESA sleep studies per month to maintain proficiency. If participant scheduling or vacations prevent this, a limited hook up on a volunteer can substitute for a full recording. If maintenance hook-ups are performed an SV form must be submitted to the RC and correctly named as: MR[techID]_date.

The Reading Center will give quality grades for each recording and report the average grade. If an individual technician's quality grade falls below 85% and the low grade cannot be attributed to the participant or an instrument problem that tech must work under the supervision of another certified tech until quality improves.

All requirements for certification must be submitted to the Reading Center via ftp server transmission.

5. Transmission of Data to SRC

The programs used for MESA are Data Card Manager 3, Profusion PSG 3 and Profusion Study Manager.

Data Card Manager 3

- Set Up Card with Participant ID, Tech ID, Unit ID and Study Configuration
- Set Flash Card Reader Drive Letter
- Set Options for Download Conversion from flashcard
- Set Directory Path to Folder where Sleep Studies will be kept on computer

Profusion PSG 3

- View PSG studies after download to determine signal quality and complete Signal Evaluation Form

Profusion Study Manager

- Data management of sleep studies on hard drive (delete unwanted studies, copy to other media for transfer to SRC SFTP, or archive media).

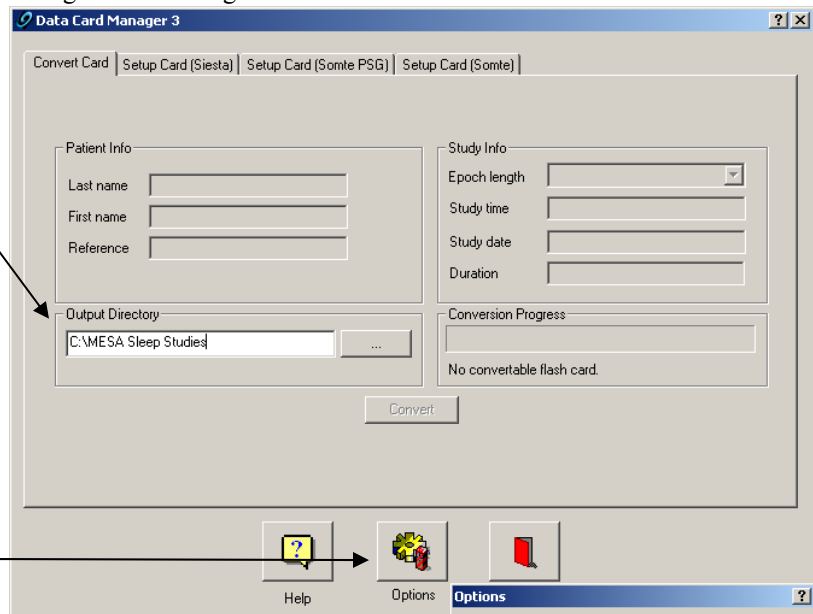
Setting Up Data Card Manager

Several Options need to be set in Data Card Manager before using.

Select the “Convert Card” tab.

In Output Directory type in the path where sleep studies will be downloaded (suggested C:\MESA Sleep Studies).

If you prefer this can be on a D: drive or Desktop but the folder should be named MESA Sleep Studies)

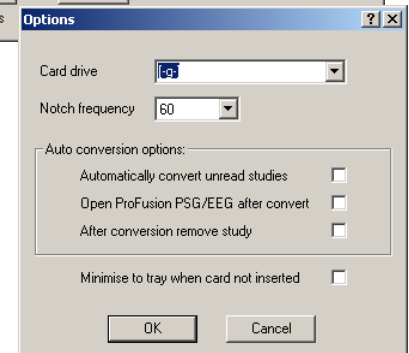


Next Select the Options button

The Card Drive here refers to the drive letter assigned to where the card reader is connected to the computer. It is VERY important this is identified properly and preferred that the flash card reader remain connected to the same computer using the same USB port. This can help avoid problems when trying to identify the correct drive before “formatting” the card.

Notch frequency should be set at 60.

It is recommended none of the Auto Conversion Options be selected. This allows you to see “Study Info” before downloading.



Use the Help Button to access a complete instruction manual for using Study Manager.

Downloading Recorded Study – Data Card Manager 3

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. During download note any problems or error messages on the Signal Evaluation Form (SE Form). If you are unable to download contact the Sleep Reading Center before reformatting the flash card. The SE and SV forms will still need to be send to the Reading Center.

ALWAYS USE THE COMPUMEDICS DATA CARD MANAGER 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. The time it takes to complete the conversion depends upon the length of the study.

Renaming the File Folder containing the Sleep Study

At the time of download the Compumedics program automatically names the folder with a very lengthy key which consists of the date of the recording followed by a large group of random numbers.

(20100824_5A055023-10D1-4464-BF4F-F....)

Locate the folder in the C:\MESA Sleep Studies directory. If you have downloaded several studies and are unsure of which participant is in the directory use Profusion Study Manager to identify the correct study.

The folder should be renamed: ParticipantID_mmddyr_PSG (1234567_010911_PSG)

Profusion PSG 3

If download was successful open Profusion 3 to review the study.

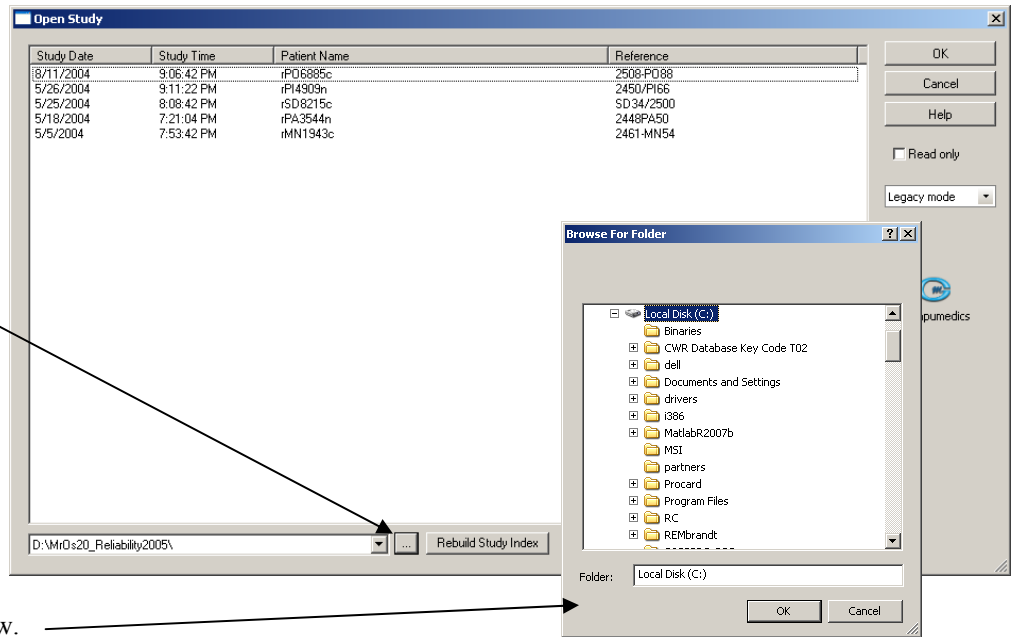
The “Open Study” screen will appear displaying studies on your computer based on the directory used the last time your opened Profusion 3.

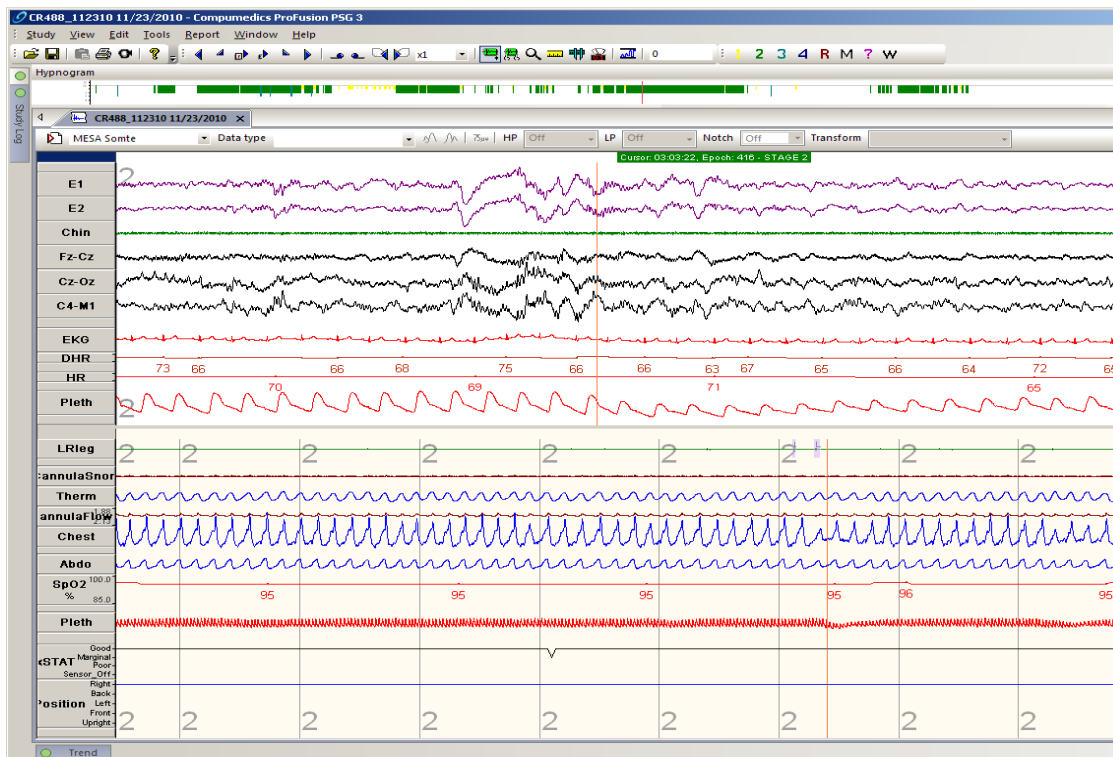
If you need to select another directory where your studies are located, then select the button to access the directory listing on your computer.

The Browse For Folder window will display and allow you to locate the MESA Sleep Studies folder. Always “Rebuild Study Index” to refresh the display for current listings. Highlight and select OK to open the study you wish to review.

The study will open displaying the signals for your review and filling out the SE form.

Rev Jan 2011

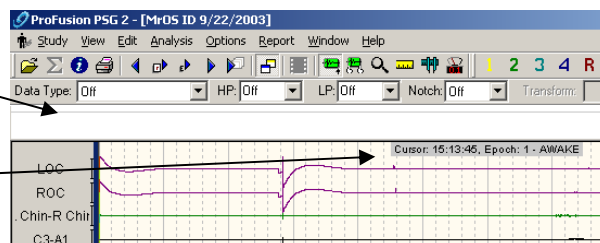




Press F4 and select the MESA Somte display
 Page through the study evaluating the channels on
 both upper and lower screens. Use the Page Up and
 Page Down keys to move through the study page by page.

You can also click on the line bar at the top to move
 to any part of the study.

The epoch number, time of recording, and sleep
 stage (after scoring) are displayed at the top of the
 page in the center.

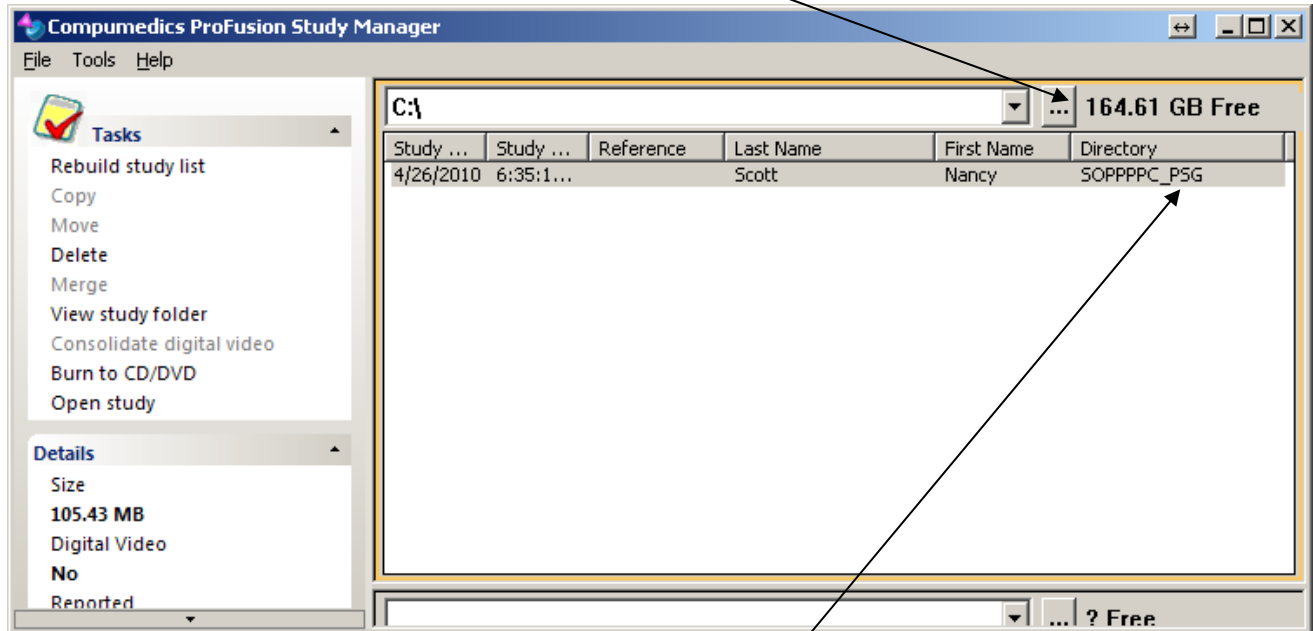


Annotate the **Sleep Study Evaluation Form** as the study is reviewed. Include any notes or comments regarding
 your review and any troubleshooting procedures done.

Profusion Study Manager

Profusion study Manager is another tool that will allow you to open a study for review. You can also use it to view a list of studies on your computer, delete unwanted studies and select studies you may want to burn to a CD/DVD for archiving. Do not delete studies until you have received final reports from the Reading Center.

It is similar to Profusion PSG 3 in that you will use the “...” button to locate the folder where you have downloaded the sleep study, then Rebuild study list, then proceed to use the tools available.



Profusion Study Manager is a useful tool if you have downloaded several studies and not had time to rename the folders properly. It will display the name of the folder and that will help you identify which participant sleep study is in that folder so it can be properly named.

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. All data will be sent using Secure (SSH) File Transfer Protocol (SFPT). Data will be encrypted in a zip file before sending.

After successful download the Sleep Study folder containing the sleep files will need to be named appropriately. All PSG Sleep folders should have been renamed after download using the Participant ID_PSG format. It is important to verify the accuracy of the Participant ID before proceeding with zipping and encrypting the file.

The SE and SV form can be scanned to create a PDF copy which will be sent to the SRC. The SRC also has created a PDF copy of these forms which can be placed on your computer and the data entered before transmitting.

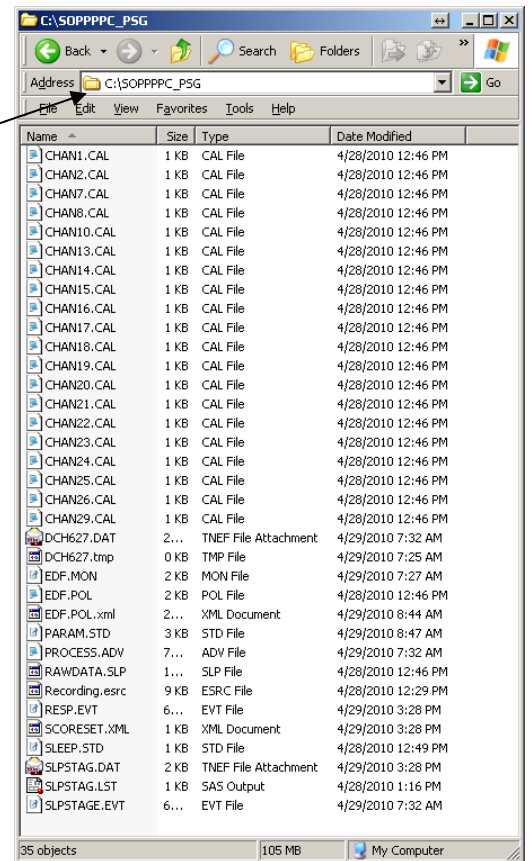
Be sure the folder containing the sleep study has been properly named before creating the encrypted zip file.

The zip file should include:

- Sleep study folder containing the raw data file and other files created by the software.
- The SE Form
- The SV Form

The standardized naming conventions for data being sent are as follows:

- ZIP file – “ParticipantID_mmddyr_PSG.zip”
- PSG Sleep Study Folder to be named “ParticipantID_mmddyr_PSG”
- SE Form: ParticipantID_SE.doc or .pdf
- SV Form: ParticipantID_SV.doc or .pdf



Site Instructions for Uploading Data to BWH Sleep Reading Center

These instructions for connecting to and uploading data to the Sleep Reading Center at Brigham and Women's Hospital (BWH) are for use by authorized users of the MESA Exam 5 – Sleep project

1. Username and Password

- 1.1. Each clinical site will receive a designated username and password that will be used for data upload. This password will be changed periodically to ensure security. Sites will be notified in advance when a change is to occur. The user name and password will be sent to the site Project Coordinator.
- 1.2. Each project will have a separate zip password that will be used for encrypting data files and this will also be sent to the site Project Coordinator.

2. SFTP Software and Connection

Uploading of data to the Sleep Reading Center will be done via Secure (SSH) File Transfer Protocol (SFPT), which provides additional security for research data during transmittal. Sites uploading data will need FTP client software installed on the designated computer and may need to configure their firewall to allow outgoing traffic for SFTP on port 22. The site institution's IT personnel should be able to assist in this configuration.

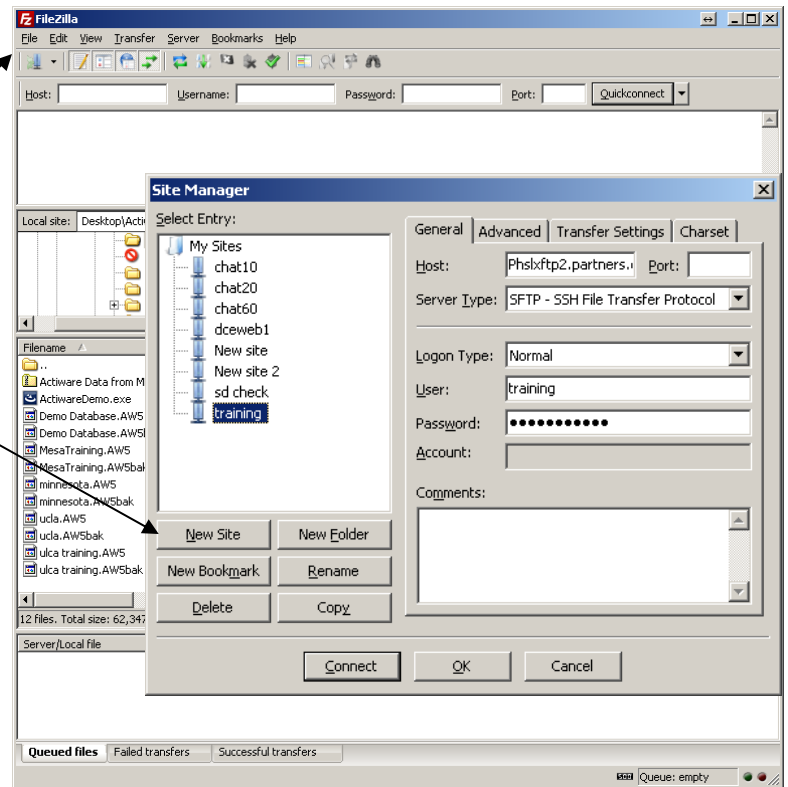
2.1. FTP Client Software

A number of FTP client software packages which support SFTP transfers are available free or for purchase. The Sleep Reading Center recommends [FileZilla](http://filezilla-project.org/download.php), (<http://filezilla-project.org/download.php>) but this is not required.

After installation of FileZilla, click on the FileZilla icon to display the main screen.

Select File -> Site Manager to Display the Site Manager setup screen. Once a new site is set up and appropriate information is filled in it can be used to connect whenever needed.

Select New Site and name BWH



Host: Phsxfp2.partners.org
Port: 22
Server Type: SFTP (SSH File Transfer Protocol)
Logon Type: Select normal to receive options for User and Password
User: *(the site FTP username provided by the Sleep Reading Center to the Coordinator)*
Password: *(the site FTP password provided by the Sleep Reading Center to the Coordinator)*

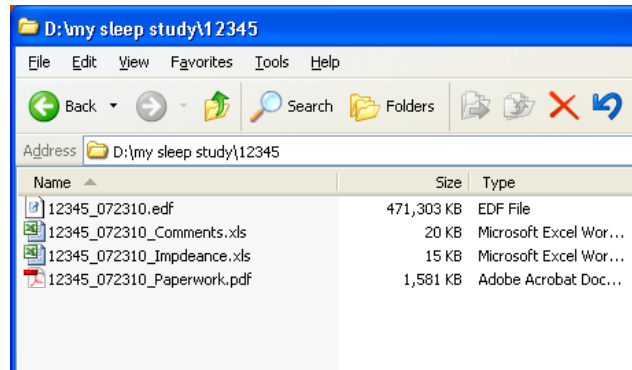
3. Preparation of Data for Upload

In order to both ensure data security and integrity, and to make transfers more efficient, all data that is sent to the Sleep Reading Center must be prepared as follows:

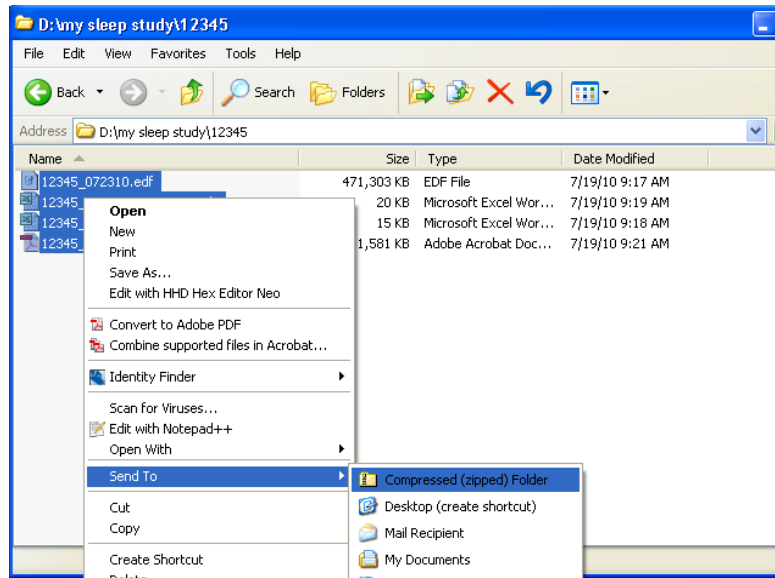
- **Deidentification** all files sent to the reading center must be devoid of all personal health identifiers, including participant names, dates of birth, etc. Each file should only contain the participant id and other study information as indicated in the study manual of procedures.
- **Compression** all files sent to the reading center must be in a compressed (.zip) file. This can be accomplished through [WinZip](#) or through [Windows Compressed Folders](#) (XP or later) as detailed below. A single .zip file can contain multiple files, and sites are encouraged to use zip archives to make their transfers more efficient.
- **Encryption** all file sent to the reading center must be encrypted. This can be accomplished by an additional step when the zip file is created as detailed below.

The instructions below are for creating a Zip File using Windows Compressed Folders. If you are using WinZip please follow the instructions provided with that software.

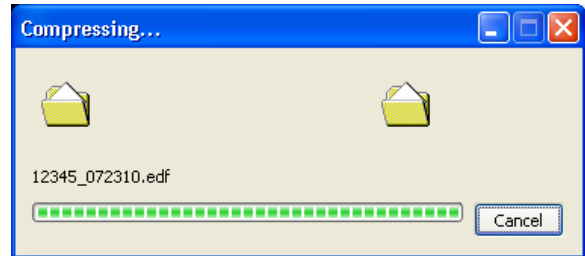
- 3.1. Creating and Encrypting Zip File (using Windows Compressed Folders)
Locate the files that are to be sent to the reading center.



Right-click on the files and select **Send To > Compressed (zipped) Folder**



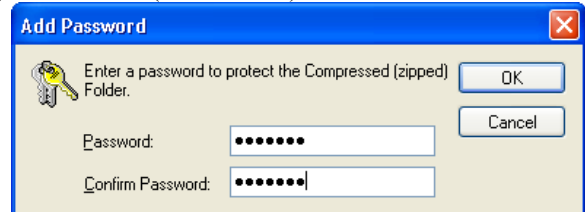
The selected files will be added to the zip file.



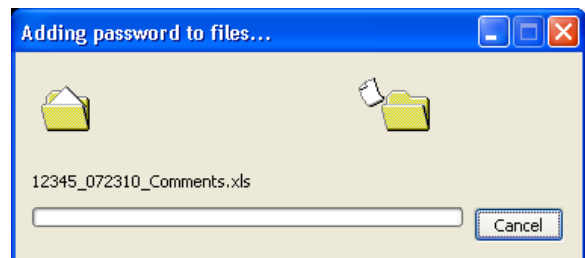
The archive file now appears in the directory. The file can be renamed as necessary before uploading. Open the compressed folder (double-click on the compressed folder, or right-click and select **Open With > Compressed (zipped) Folders**)

Encrypt the files by selecting **File > Add a Password...**

Enter the project encryption zip password provided to Study Coordinator (and confirm). Click OK.



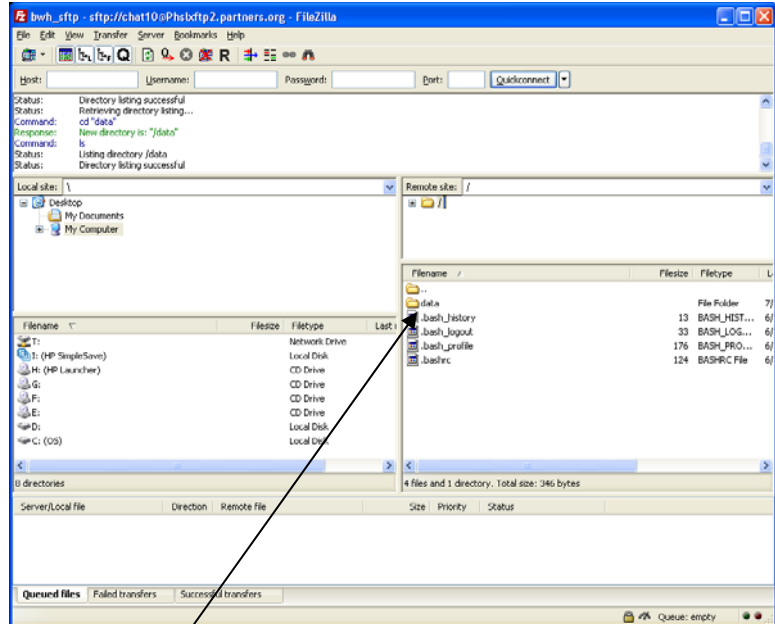
The files will be encrypted.



4. Uploading Data – Connecting and Dropping the Zip File

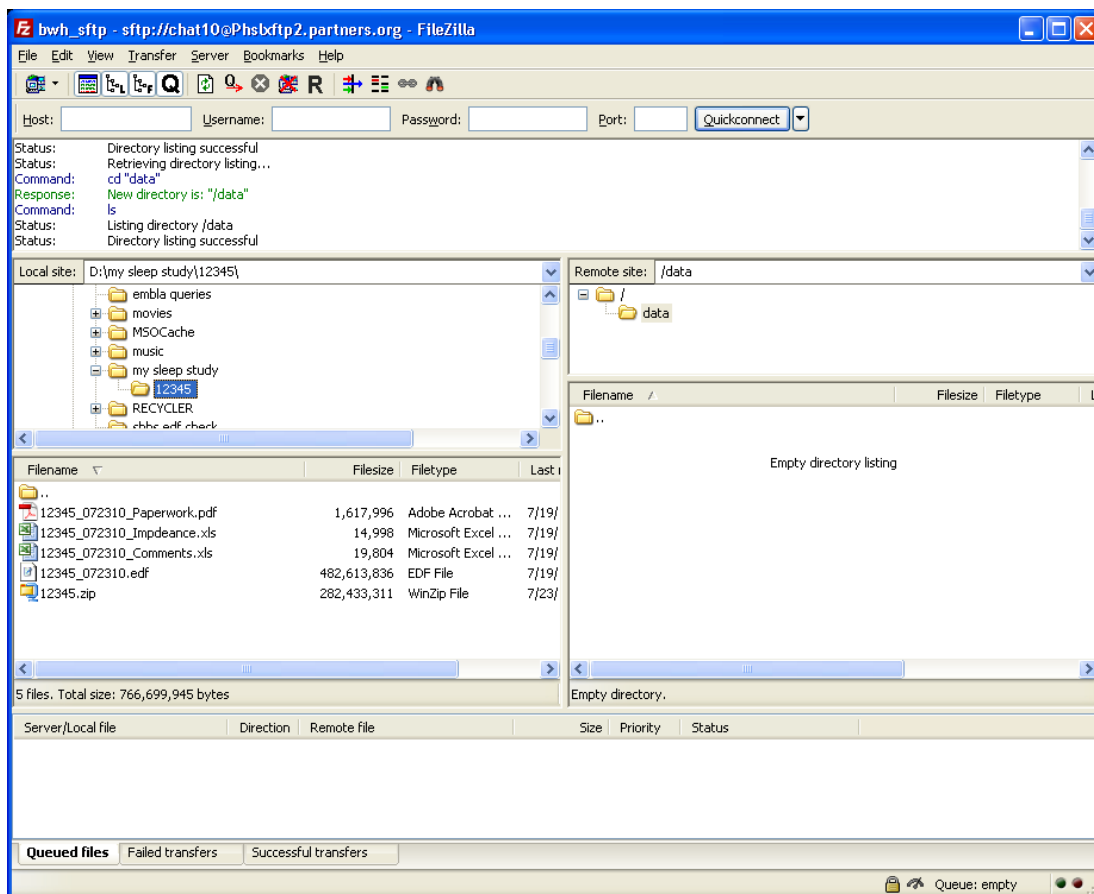
The screenshots below are from FileZilla, yours may differ depending on the FTP version you are using. If you still need to download FileZilla, click here: <http://filezilla-project.org/download.php?type=client> and choose the appropriate Operating System.

- 4.1. Open the FTP Client software, and connect to the BWH SFTP server using the information provided in Section 2 and the user name and password sent to your site coordinator. You will automatically be routed to a root folder specific to your site.



- 4.2. Select/OPEN the “data” folder on the server (Remote Site). **You must in “inside” this folder before attempting the upload. Once inside it will read “Empty Directory listing” or list other files you may have already placed on the server that have not been picked up yet.**

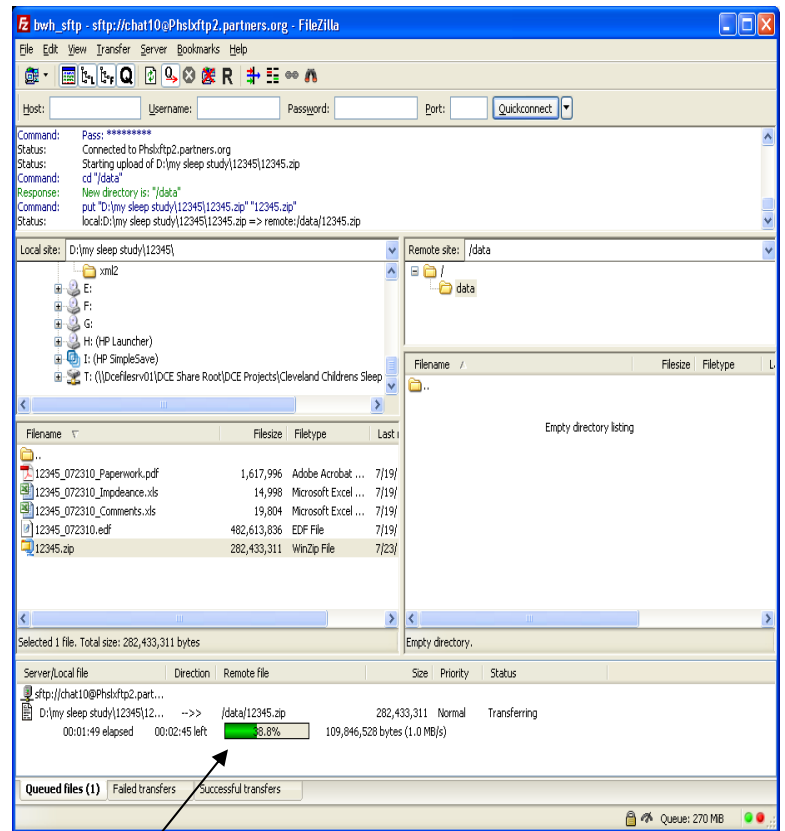
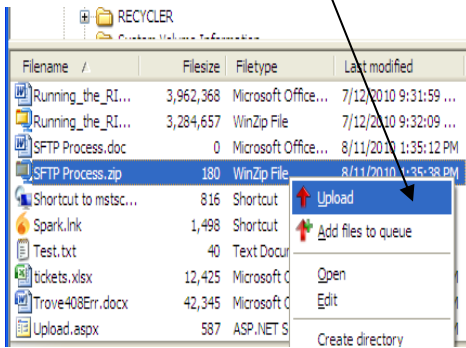
4.3. Locate the encrypted zip file(s) to be uploaded on your local system.



Note: The <Left Panes> represent your <local computer>. The <Top Left> displays <all your drives> and the <Middle Left> displays the <folder you're currently in>. You can navigate anywhere on your computer by using these two panes:

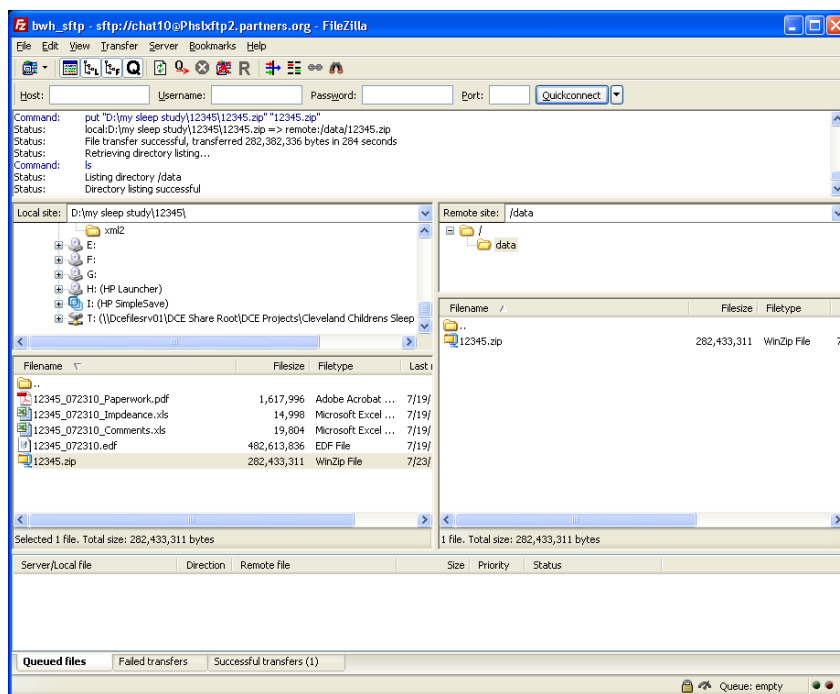
4.4. Double-click on the zip files or drag them to the server or use the right click select “Upload” method shown below to begin uploading (see the software help section for additional details if needed).

1. Right-click <the file> from the <Left Pane>
2. Click <Upload>



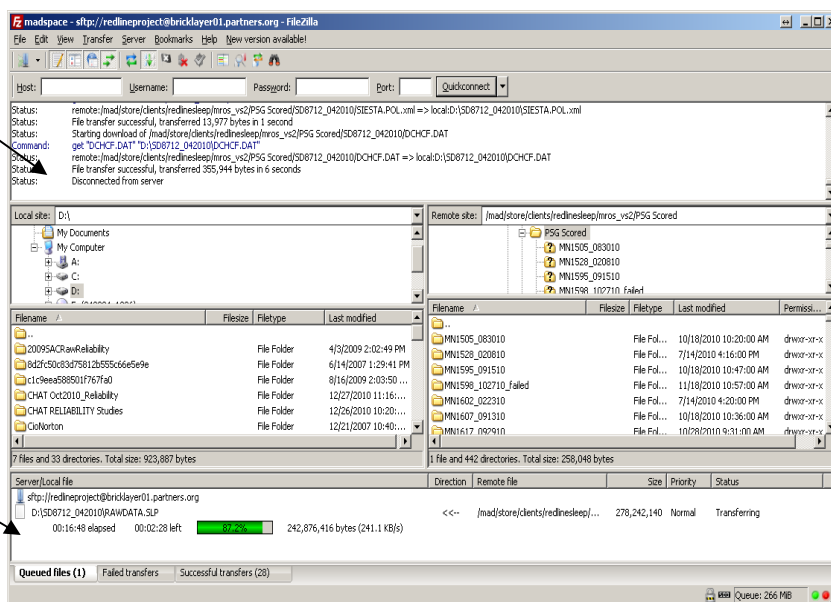
You will see the progress of the transfer in the bottom pane.

4.5. When the upload is complete the file will appear on the server.



If you see a “Disconnected from server” status it should be **ignored** as long as the transfer is continuing at the bottom pane.

DO NOT STOP THE TRANSFER thinking you are disconnected. As long as you see activity continuing in the bottom pane there is no disconnect. Wait until the bottom pane has completed transferring.



5. Contact

If you have questions about uploading files or have difficulty connecting, please contact the Sleep Reading Center Susan Surovec (ssurovec@partners.org) at (216) 702-6050.

If you require your IT person to contact someone at Partners directly they can contact Brad McKenna (bmckenna@partners.org) at (617) 726-0331.

Jan 2011

6. Data Management and Quality Control at SRC

Field PSG Technicians/PSG System Maintenance

Following initial certification PSG technicians will be evaluated continuously to monitor and assure quality control. The Sleep Reading Center requires that one Technician from each site must attend Central Training and complete the initial certification process at Central training. After completion of all required Certification procedures they will be able to observe and certify others at the site.

1.1 It is recommended one PSG Technician at each site be identified as the Lead Technician responsible for maintaining equipment records and tracking any problems identified, including any resulting in returns of the unit to the Manufacturer.

1.2 Because proper maintenance is a key aspect for the quality of the PSGs, the lead technician will be responsible to ensure that all equipment is checked at the time it is returned to the site and before it is scheduled for use on a home visit. PSG technicians are responsible for maintaining the unit in good working order and identifying and replacing any electrodes or other peripherals that were damaged in the home or are no longer functioning properly.

1.3 Maintenance and repair log shall be kept for each instrument including date and description of any software installation or upgrades. All leads and peripherals used should be labeled and kept with the same unit to enable accurate troubleshooting methods. If an oximeter or electrode is “borrowed” from another unit to facilitate a visit, it should be returned to the original unit and a replacement obtained for the original unit. Date of replacement should also be recorded in the maintenance and repair log.

1.4 If a technician or unit is identified in a monthly report as falling below an acceptable performance level of 85% good quality recordings, the Chief Polysomnologist will contact the site to review steps to be taken to improve technician performance and/or work with lead technician to identify unit repairs that need to be made.

A Sample of this Summary Report tracking quality by Site/Tech/Unit is displayed on the next page.



Overall PSG Quality by Site
January - August 2010

Site	Total N	% 3-Fair	% 4-Good	% 5-VGood	% 6-Exc	% 7-Outst	Total % VGood, Exc, Outstanding
3	76	0.0%	6.6%	6.6%	67.1%	19.7%	93.4%
4	86	0.0%	4.5%	4.5%	77.3%	13.6%	95.5%
5	83	1.2%	4.8%	16.9%	65.1%	12.0%	94.0%
6	54	0.0%	5.6%	14.8%	64.8%	13.0%	92.6%
7	20	0.0%	5.0%	10.0%	65.0%	20.0%	95.0%
8	42	2.4%	11.9%	4.8%	73.8%	7.1%	85.7%
Totals	341	0.9%	6.2%	10.0%	68.9%	14.1%	93.0%

Overall PSG Quality by Tech

Tech ID	Total #	% 3-Fair	% 4-Good	% 5-VGood	% 6-Exc	% 7-Outst	Total % VGood, Exc, Outstanding
1062	1	0.0%	0.0%	0.0%	100.0%	0.0%	100.0%
1063	11	0.0%	18.2%	9.1%	54.5%	9.1%	72.7%
1064	8	0.0%	0.0%	12.5%	62.5%	25.0%	100.0%
1067	3	0.0%	0.0%	0.0%	100.0%	0.0%	100.0%
1068	11	0.0%	9.1%	0.0%	63.6%	27.3%	90.9%
2066	6	0.0%	0.0%	0.0%	100.0%	0.0%	100.0%
2068	4	0.0%	0.0%	0.0%	75.0%	25.0%	100.0%
2070	5	0.0%	20.0%	0.0%	80.0%	0.0%	80.0%
2071	9	0.0%	0.0%	0.0%	77.8%	22.2%	100.0%
2072	4	0.0%	0.0%	0.0%	100.0%	0.0%	100.0%
7071	1	0.0%	0.0%	0.0%	100.0%	0.0%	100.0%
7072	6	0.0%	16.7%	16.7%	66.7%	0.0%	83.3%
7073	11	0.0%	18.2%	9.1%	63.6%	0.0%	72.7%

7 = Outstanding. All signals (EEG+MI, M2, both EOGs, chin, airflow, cannula flow, both belts, RCO2 and oximetry) good for at least 6 hours lights off to lights on and almost entire (95%) sleep time.
 6 = Excellent. At least one central EEG (C3 or C4), one EOG channel, chin, airflow, both belts, and oximetry good for 6 hours lights off to lights on and minimum of 75% of the sleep time.
 5 = Very good. At least one central EEG (C3 or C4), one EOG, airflow, one belt (either thoracic or abdominal) or cannula flow and oximetry good for 6 hours lights off to lights on and minimum of 50% of the sleep time.
 4 = Good. At least one central EEG (C3 or C4), one EOG, one respiratory channel (any flow (*) or either band), and oximetry good for 6 hours lights off to lights on and minimum of 50% of the sleep time.
 3 = Fair. At least one central EEG (C3 or C4), one respiratory channel (any flow (*) or either band), oximetry usable for minimum of 4 hours lights off to lights on OR study scored sleep/wake only (because of study-tolerance issues) with usable oximetry for >75% of study duration.

Overall PSG Quality by Unit
January - August 2010

Unit	Total N	% 3-Fair	% 4-Good	% 5-VGood	% 6-Exc	% 7-Outst	Total % VGood, Exc, Outstanding
101	27	0.0%	3.7%	14.8%	59.3%	22.2%	96.3%
102	28	0.0%	7.1%	3.6%	75.0%	14.3%	92.9%
103	18	0.0%	11.1%	0.0%	61.1%	27.8%	88.9%
104	4	0.0%	0.0%	0.0%	75.0%	0.0%	75.0%
201	49	0.0%	4.1%	6.1%	81.8%	8.2%	95.9%
202	5	0.0%	20.0%	0.0%	60.0%	20.0%	80.0%
203	9	0.0%	0.0%	0.0%	55.6%	44.4%	100.0%
204	3	0.0%	0.0%	0.0%	100.0%	0.0%	100.0%
301	1	0.0%	0.0%	0.0%	100.0%	0.0%	100.0%
305	51	2.0%	5.9%	7.8%	68.6%	13.7%	90.2%
308	32	0.0%	3.1%	31.3%	56.3%	9.4%	96.8%



PSG Data Quality Management

Data Preparation and Patient Confidentiality

Procedures to assure confidentiality will be strictly observed. All certification and research data transmitted to the SRC will have identification numbers and no personal identifiers. All documents and the sleep files should be checked to ensure no personal or identifying information is contained in these files before transmitting the files the SRC. If there are problems with transmittal the PSG Reading Center will request the site resend the study. A copy of the PSG should be retained at the site until final reports are received from the Sleep Reading Center indicating the SRC has a final archived copy. Periodically the sites will want to check the available storage on the computers where studies are downloaded and delete copies of older PSGs that have been finalized with reports from SRC if needed.

Transmittal of PSG Data to SRC

The PSG data file and appropriate forms will be electronically transmitted to the SRC via a secure SFTP (SSH File Transfer Protocol) connection. Instructions for configuring FTP client software, connecting to the SRC SFTP server, and encryption are included in Section 5 of this manual. The signal verification form and sleep evaluation form should be included in the encrypted zip file with the PSG study being transmitted. Site Coordinators will be sent individual login and password information.

Data Security and Archival at the SRC

All systems are secured behind the Partners firewall and follow Partners Healthcare Information Security policies for authenticated, minimum access. All systems are patched, monitored and scanned routinely for vulnerabilities and intrusions by the systems administrator and PHS Information Security. Data is encrypted, where applicable, in compliance with state and federal government standards, regulations, and in accordance with Partners Security and Privacy policies. All configuration changes that could affect accessibility or security are approved by management.

The virtual services and databases are backed up nightly via the enterprise backup system, IBM Tivoli Storage Management, and maintained on encrypted storage tapes for tapes that are stored off site

All systems administrative personnel and support staff have completed the NIH training program in Computer Security and have additionally completed their certification in The Collaborative IRB Training Initiative (CITI) program. CITI was developed by experts at PHS, MGH, and BWH and with outside institutions in the "IRB community" and consists of courses in the Protection of Human Research Subjects for Biomedical research.

Study Receipt and Processing

All data placed on the BWH SFTP server by sites are transferred to an Incoming processing folder at 2:00 and 11:00 PM daily. Receipt date will be recorded as the day the study was received in the Incoming folder. Upon receipt of studies at the SRC the study data will be checked for accuracy. The Receipt information includes: Participant ID, Study Date, Date Received, Somte ID, and Technician ID. If there is a discrepancy between the data contained on the Signal Verification Form and the Somte Sleep Study recorded file or any missing data on the forms (i.e. Somte ID, Technician ID), an e-mail will be sent to the Site Coordinator requesting clarification. The receipt data will be entered in a database and summary receipt data will be sent to site coordinators on a weekly basis, or when requested by the site, to verify SRC has received all studies sent by the site. This summary receipt data will also indicate overall study quality grade.

Receipt Report

Site 3: WFU

As of 08/30/2010

September, 2010

PPTID	Acrostic	Study Date	Received	Unit	Tech	Study Passed	Overall Quality
3466789	ddr	8/24/2010	8/20/2010		*2: Tech2	1: Passed	Not scored

Total Studies Received in September, 2010: 1

Total Studies Received for Site 3: WFU: 1

A copy of the Signal Verification form and Sleep Study Evaluation form will be included with the Sleep Study file when sent via SFTP. If at time of download of the flashcard there is no data, both of these forms must still be sent. A note should be made on the forms that there was no data on the card at time of download. Short studies or problem studies that do not meet the criteria to be "passed" based on the Sleep Study Evaluation form, should still be sent to SRC with any notes as to what troubleshooting was done and if the reason for the short study can be determined. The SRC tracks all problems relating to lost sleep studies and must receive this paperwork. The problem studies are monitored and if any pattern is observed study wide not related to technician technique we will work to resolve the problem with the vendor.

The study will be reviewed by RC Polysomnologist to assess criteria for minimal technical acceptability and Urgent Referral status. The RCP will note any signal quality issues and record recommendations for sensor replacements or adjustment. These review notes will be sent to the designated Coordinator and PSG staff at the site via e-mail. RCP will also notify the site if a study has failed, or if other technical problems occurred due to faulty technique or equipment not identified by the site.

To be classified reliable sleep data the record must contain at least 4 hours of scorable EEG, 3 hours of reliable oximetry accompanied by one scorable respiratory channel (either airflow, thoracic, or abdomen after reported bedtime. Studies containing less than the minimal requirements will not be processed for scoring and the site coordinator will be notified via e-mail to request a repeat study from the participant.

Urgent Referrals

If Urgent Referral Criteria are met, the study is reviewed by the SRC Director and a notice is sent to the site personnel identified to receive Urgent Referral notices. The DCC will also receive a copy of this e-mail. The site is expected to acknowledge receipt of the alert from the SRC and notify the appropriate physicians, site personnel and/or family. Site will provide alternate staff contacts should personnel normally receiving these notices be unavailable.

All Urgent Referral Alerts will be logged into a PSG Alert Log indicating the date reviewed and date site coordinator was notified. A copy of the acknowledged receipt of the Urgent Referral by the site will be kept with the PSG Quality documents. If the urgent alert is ascertained the site will receive the full report and quality grades (QS form) within a week after final scoring is completed. All other studies will be scored based on date received at the Reading Center via the SFTP site.

Urgent Alert criteria include: O2sat <85% for >10% of TST; HR \geq 150 bpm or \leq 30 bpm (no A-fib/flutter); Acute ST segment (suggests ischemia); 2nd or 3rd degree block; Non-sustained v-tach (3 beats duration at rate >120); Other. Potential Urgent Referrals include all cases of atrial fibrillation, regardless of rate, pre-existing diagnosis, or duration or rhythm disturbance. This information will be communicated to CC and field site. Cases will be determined as not meeting Urgent Referral criteria if the condition was known to be pre-existing (and not only paroxysmal) AND the ventricular rate was "controlled" (between 50 to 110). Otherwise, if a new case, if the participant was last in sinus rhythm or ventricular response was <50 or >100, then the event qualifies as an Urgent Referral and FC notifies participant by phone and mail, and with permission, his/her physician, that values are at a level that may require intervention.

PSG Quality Grades (QS Form) and Quality Summary Reports

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 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 physiological signal issues are also recorded on the QS form. All data contained in the QS form (quality grades and scoring notes) will be entered into the QS table database. This QS data is reported to the site for individual reports and used to generate Quality summary reports. (Sample QS Form is included in the Appendix)

The SRC will generate monthly summaries on overall quality of the PSG sleep studies by site, by technician, and by unit using the QS form data. Sites and Technicians are expected to maintain quality of 85% of studies in the Very Good, Excellent, and Outstanding range. If a Technician is noted to fall below the 85% performance level (and it is not due to faulty equipment or identified participant issues in the home), the site will be notified so that the technician can be observed by another on site tech to improve performance and be retrained as needed.

Monthly Summary Reports will also be sent to the QC Committee on a Quarterly or as needed basis. These reports will include monthly and cumulative failure rates by site, urgent referral rates and quality grades by site.

PSG Sleep Data

After full scoring, the scorer will generate:

- Sleep Report containing summary sleep data, including the OAI (all obstructive and mixed apneas regardless of desat per hour of sleep) and AHI (all obstructive and mixed apneas and all hypopneas with 3% desat or arousal per hour of sleep), a summary of the desaturation profile, time in REM/Non-REM sleep, stage distributions, and the arousal index.
- SAS report containing all sleep variables.
- Completed QS form containing all quality grades, scoring notes, and eligibility criteria met.

Before reports are generated, report data from each study is checked for outlying values and data integrity. These outlier and data integrity checks are repeated when PSG data from multiple participants are combined into a single dataset along with the data from the QS form generated by the scoring staff. This full PSG dataset will be cumulatively compiled and electronically transmitted to the DCC on a regular basis

Archival of Data

After QS data has been entered and reports are sent to sites, the complete PSG study folder containing the raw data sleep file, scored files, sleep study report, and the SAS report is placed in a site directory. These files are backed up on a daily basis and a backup copy is kept off-site. Summary PSG sleep data will be sent to the Coordinating Center on a monthly basis.

The Sleep Reading Center for MESA gratefully acknowledges permission from Compumedics, LTD to use copy written text and graphic additions to this manual.



APPENDIX A

HOME VISIT SCRIPTS AND FORMS

Sample Phone Script for MESA Sleep Recruitment
MESA Sleep Questionnaires Guidance on Question by Question Response
MESA Sleep Questionnaire
MESA Sleep Diary (Journal)

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Sample Phone Script for MESA SLEEP RECRUITMENT

Hello, may I speak to Mr/Ms _____?

We appreciate your recent participation in the MESA Exam 5 clinic visit. You may already be aware that MESA is conducting a sub-study called MESA-Sleep. We are now contacting you to invite you to consider participating in this sub-study, which is designed to measure your sleep quality, sleep patterns, and to determine if you have a sleep disorder such as sleep apnea, which is when the throat closes at night, causing snoring and drops in oxygen levels, or periodic leg movement disorder, which is when the legs jerk frequently at night.

If you are eligible and agree to participate in the MESA-Sleep exam, you will be asked to take part in an overnight sleep study performed in your home. Two staff members from MESA will arrange to visit you in your home in the early-evening time on a day that is convenient for you. You will also be asked to wear an actigraph, which is a device that resembles a watch and is worn on your wrist, for a period of 7 days. The actigraph measures movements of your wrist which are used to estimate sleep and wake activities.

If you decide to participate in the MESA-Sleep exam, as a token of our appreciation for your help in the MESA-Sleep exam, we will offer you a stipend of \$50 for completion of study activities. After the studies are scored, you will receive the results of your actigraphy (activity monitor) test and overnight sleep study.

May I ask you a few questions to see if you are eligible to participate in this study?

If no: Thank you for your time. We greatly appreciate your participation in the main MESA study through the years, and hope you will continue to participate in MESA in the future.

If yes:

Do you currently using any of the following at night:

A CPAP or BIPAP machine? ___ Yes ___ NO

Oxygen ? ___ Yes ___ NO

A dental (oral) appliance (device)? ___Yes ___NO

(Example of devices: Somnomed, EMA, Hurbst, PM Positioner, Tongue Retaining Device, TAP).

[Note: If any answer to the following was YES, ask, “ Do you usually use this at night?” If the participant reports only past use—more than one month prior to the call---or only reports using any of these treatments rarely (less than once per week) then the participant is eligible for MESA SLEEP. If the participant reports more recent or more frequent use then thank him/her as follows:

Thank you for your time and ongoing participation in MESA. Because of your use of (CPAP, oxygen, an oral device) the research sleep study cannot be accurately performed and it will be best that we do not schedule this visit. Although you are not eligible to participate in this substudy, we still encourage you to participate in other MESA studies.

Otherwise, ask:

Do you have any questions about the MESA-Sleep exam procedures? Would you like to participate in this MESA sub study?

If interested, proceed to schedule the participant, at a date/time which is convenient for him/her. Thank the participant for their involvement with MESA, and their willingness to participate in the MESA-Sleep sub-study.



MESA SLEEP QUESTIONNAIRES Guidance on Question By Question Responses

Although participants are being asked to self-complete the sleep questionnaires and diaries, they may have questions on how to answer various questions. For the Sleep Diary, the interviewer needs to review each item and provide specific instructions on how to complete these questions as noted below. Also, when reviewing the Sleep Questionnaire with the participant, please review the purpose of key questions below (in bold). If asked about the meaning of other questions, please refer to the guides below.

Sleep Diary (Journal).

Purpose: This instrument is intended to provide the subject's reports of his/her daily sleeping patterns. This information will provide a comparison to what is objectively recorded using the actigraph. It also provides a back-up for characterizing sleep patterns should the actigraph fail. Finally, this information will be reviewed by the Actigrapher Scorer (at BWH Sleep Reading Center) to assist with editing the actigraph record.

Overview: Stress that the journal has a distinct "page" for each day of the week. The recording time should begin- refers to the morning of the initial home Sleep Visit. The diary should be completed every evening for a total of 7 nights during which the actigraph also will be worn. Before handing the journal to the participant, be sure that the date of the Sleep Visit is recorded on the top right corner of the form. The day of the week (M-Tues- etc), beginning on the Sleep Visit day should be recorded in each box marked "DAY".

Help the participant complete the first question about wake up time. Tell him he will complete the question about that day's sleep time when he is ready to turn the lights off. He will continue do this every evening for the next seven days, recording his morning wake up time, periods of napping and watch removal, and lights off time.

1. **Wake up time:** Refers to the time when the participant first woke up and stayed awake after his longest sleep period (usually overnight other than shift workers who may sleep in the day). If the participant wakes up and stays in bed awake, he should record the time of actual waking, not when he gets out of bed. If the participant wakes up and then falls back to sleep before getting out of bed, this time should not be recorded. Rather the time that he wakes up which is followed by getting out of bed should be recorded. Make sure he checks the AM or PM circles. AM refers to midnight to 11:59 AM (one minute before noon) and PM refers to NOON to 11:59 PM (one minute before midnight).
2. **Work or school?** The participant should answer YES if any part of the day involved following a schedule which required him to work or go to school following a schedule. Working in a home office would qualify as work if the home office work was scheduled for specific blocks of time (usually 5 days per week). However, work in the home that could occur daily without a strict schedule (housework, doing the bills) should lead to a NO response. Retired or unemployed participants or homemakers without specific out of home work schedules should answer NO to this question.
3. **Times of watch off:** Each time the watch is taken off for more than 5 minutes, the participant should record the time in hours and minutes and AM and PM when the watch is removed. If there are more than 5 watch removals in a day, he should record the 5 episodes of longest removal. Leave blank if no napping.

4. Naps for 5 minutes or more. Any known periods when the participant deliberately takes a nap or is aware he fell asleep (for example, watching TV) for more than 5 minutes, he should record the time when he first felt he fell asleep. If there are more than 5 naps, he should record the longest ones he recalls. Leave blank if no napping.
5. Planned bedtime. The participant should complete this at the time he is about ready to turn the lights off. Since people often have a hard time estimating exactly what time they actually falls asleep, the participant should record time he plans to turn lights off, shut eyes and attempt to sleep before his longest sleep period.

MESA Sleep Questionnaire

This section of the interview asks about sleep patterns and symptoms of sleep disturbances.

Q1-2. Ask the participant what (clock) times they usually go to bed **in order to sleep**. The participant should provide the times relative to their usual longest period in bed (i.e., not including naps). If they are a shift worker, they should provide the most frequent times they go to sleep for a period that includes their longest sleep period (e.g., if working the night shift, this may be 7 AM to 2 PM). The clock times should reflect times from "lights off" to arising from bed. For example, if they read in bed, or watch TV in bed before sleep, they should report the times they turn off the light and close their eyes in an attempt to sleep. If they lay in bed awake in the morning, they should report the times they actually get out of bed. Part a refers to their schedule on weekdays and part b for weekends. Sleep schedules may vary during vacation times compared to work or school times. If so, they should report usual weekend and weekday times for the times of the year when working or going to school (a) vs other days (b), unless they only work or go to school for a minority of the year. Check to make sure that the times for awakening occur after the times reported for falling asleep. **Use a 12 hour clock time frame, and also check that AM and PM are checked appropriately.** Provide information to the nearest minute.

Q3. Asks how often they nap for 5 or more minutes during a usual week. Include all naps whether they are voluntary (planned) or involuntary (unplanned). It does not matter if they nap in their usual sleep quarters or elsewhere, or fall asleep in a chair or bed.

Q4-10. Asks the participant to estimate how often they have experienced each of the identified symptoms over the **prior 4 weeks**. Note to the participant the time frame of this question. If symptoms have varied over this period, the participant should estimate how often this occurred.

Q 4 refers to trouble getting asleep after turning off the lights for their longest sleep period.

Q5 refers to waking up 2 or more times during their longest sleeping period. These can be very short or long periods, and should be counted regardless of whether or not they got out of bed.

Q6 typically refers to early morning wakenings- waking up earlier than they intended or needed to, or earlier than the alarm clock was set.

Q 7 refers to problems getting back to sleep if waking up too early. If they answered no to Q 6, they should answer no to Q 7. Q8 refers to any use of sleeping pills to help them sleep over the last 4 weeks. These may be prescription (e.g., Ambien) or non-prescription medications, such as anti-histamines, including herbal remedies that come in pill form.

Q9 refers to their assessment of whether sleep problems made them feel grumpy—this could be based on self impression or what others told them.

Q10 refers to their self perception of feeling overly sleepy during the day. They do not need to report actual instances of falling asleep as the only episodes of feeling sleepy. Some people have trouble distinguishing tiredness or fatigue from sleepiness. Here, sleepiness refers to trouble staying awake and alert—not just tired.

Q11. Asks the participant to rate the quality of his usual night's sleep. Average quality refers to something mid way between very sound to very restless—not perceived to be particularly restful or restless, and does not refer to what they think if the “average” person's sleep.

Q12. Asks the participant to rate his change of dozing off (not just feeling tired) in each of the situations a-j. If the person has never or only rarely engages in any given activity (e.g., driving), he should guess how likely he would fall asleep if he actually did that activity. C. refers to activities where the participant may be sitting quietly in a public place, such as a movie theatre or a meeting hall or church, but does not refer to loud active places like a ball stadium. E refers to situations where the participant can lay down and rest, whether it was a planned nap or not. H refers to likelihood of dozing while driving a car and stopped for a few minutes in traffic or at a traffic light. I refers to sitting at the dinner table for a meal. J refers to any likelihood of dozing while driving a car.

Q13-14. Asks the participant to estimate his frequency of snoring (Q 13) (or stop breathing, Q 14) over a typical week (number of nights per week.) If the participant's usual sleep time is in the day (i.e., shift workers), he should estimate his sleeping frequency during his longest period of sleeping in the day. He can report these symptoms based on his own perceptions or based on what others have told him. He does not have to judge how loudly his snoring was to answer this question. If he only knows how often he snored or stopped breathing in the past (because there were people who witnessed his sleep in the past but not the present) he should answer the question based on the most recent information he is aware of. Stop breathing may include breathing pauses followed by snorting sounds.

Q15. Ask the participant whether he ever experiences a need to move his legs because of uncomfortable feelings in his calves or thighs. This should not include feelings that his feet “fell asleep” or were “numb” but refer to more of an irritating, creeping, crawling sensation and also not just restlessness. If answering no, then the participant does not answer parts a-c. If answering yes to Q 15, then the participant is asked if this disagreeable feeling results in a need to move his legs with walking, rubbing his legs, to relieve this sensation? If these leg symptoms are usually worse when resting and feel at least temporarily better by moving the legs. If these leg symptoms are worse in worse later in the day or at night compared to earlier in the day. If participants cannot seem to understand what is referred by feelings of needing to move legs due to discomfort, they can answer Don't Know.

Q16. Participant is asked to choose the time block when he feels he would most naturally wake up (apart from any need to go to work or school or attend to family needs) and feel the most ready to start the day. If he feels that his “best” occurs exactly at a time that overlaps two blocks (for example, exactly at 6:30AM, he should pick the earlier time (e.g., 5:00 to 6:30). If he feels best a time later than 11 AM and earlier than 5AM he should choose the last back (after 11 AM).

Q17. Refers to how tired the participant usually feels on his usual (work) day in the first half hour after getting out of bed.

Q18. Refers to the time block when the participant first feels so sleepy that he would, if able, choose to go to bed.

Q19. Refers to the time slot when the participant feels his most alert on his usual "free" (off work day, when able to adjust his own schedule.)

Q20. He clearly feels best (most alert and ready to be active) in the morning or evening, he should choose the "definitely" category, respectively. If he tends to feel better in the morning, but this is not a strong preference, he should pick "rather a morning person". If he tends to feel better in the evening, he should pick "rather an evening person." If he absolutely cannot decide whether he feels better in the morning or evening, he should "neither."

Q21. Questions refer to whether a health care professional ever diagnosed the participant with sleep apnea, insomnia or restless legs. If the participant believes he has or had the condition, but was never diagnosed with these conditions, he should answer no. He should answer YES regardless of whether the condition was diagnosed in the past or recently. If answering yes to sleep apnea, he should indicate whether he was ever prescribed a PAP machine (CPAP or BIPAP or BiLevel), oxygen for overnight use, or a dental/oral device/appliance. These are devices that typically extend the tongue or jaw. Example of devices: Somnomed, EMA, Hurbst, PM Positioner, Tongue Retaining Device, TAP.

Q22. Those who don't work outside of the home or if working in the home, do not get paid for defined work, should answer "don't work." Participants should indicate their most usual work schedule. Typical times for shifts are: Day 8 to 4 or 5 to 9; Afternoon: 4 to midnight; Night: 11 to 7AM Split: Usually within one day, 2 4 hour periods separated by an unpaid block of time (as in food industry workers working from 10 am to 2 PM and then 5 to 9 PM), Irregular: Following no pattern, erratic and changing as work needs change; Rotating: a schedule of alternating day/afternoon/evening shifts (any combination; period of rotation may be every day(s) or over days.)

Q23. Should indicate average number of hours per month worked outside of the assigned week schedule (or how many hours more than a 40 hour week if a full time employee.)

Multi-Ethnic Study of Atherosclerosis



Sleep Questionnaire

Participant Id#:

Acrostic:

Staff ID:

/ /

Completion Date

INSTRUCTIONS: Enter the response given by the participant for each question. The standard missing value, "=", is allowed for cases where items are permanently missing or the response "don't know/refused" is not listed as an option.

The following **two questions** refer to the times you get in and out of bed in order to sleep (not including naps).

1. What time do you usually go to bed:

- | | | | | | | | | | |
|--|----------------------|----------------------|-----------|----------------------|----------------------|----------------------|----------------------|-----------------------|-----------------------|
| | <u>hr</u> | <u>min</u> | <u>am</u> | <u>pm</u> | | | | | |
| a. On weekdays or work or school days? | <input type="text"/> | <input type="text"/> | : | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="radio"/> | <input type="radio"/> |
| b. On weekends, or days off? | <input type="text"/> | <input type="text"/> | : | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="radio"/> | <input type="radio"/> |

2. What time do you usually wake up:

- | | | | | | | | | | |
|--|----------------------|----------------------|---|----------------------|----------------------|----------------------|----------------------|-----------------------|-----------------------|
| a. On weekdays or work or school days? | <input type="text"/> | <input type="text"/> | : | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="radio"/> | <input type="radio"/> |
| b. On weekends, or days off? | <input type="text"/> | <input type="text"/> | : | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="radio"/> | <input type="radio"/> |

3. During a usual week, how many times do you nap for 5 minutes or more?

- None
- 1 or more times

The next questions ask about your sleep habits. Please choose one of the answers for each of the following questions. Pick the answer that best describes how often you experienced the situation in the **past 4 weeks**.

- | | No,
not in the
<u>past 4 weeks</u> | Yes,
less than
<u>once a week</u> | Yes,
1 or 2
<u>times a week</u> | Yes,
3 or 4
<u>times a week</u> | Yes,
5 or more
<u>times a week</u> |
|--|--|---|---------------------------------------|---------------------------------------|--|
| 4. Did you have trouble falling asleep? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 5. Did you wake up several times a night? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 6. Did you wake up earlier than you planned to? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 7. Did you have trouble getting back to sleep after you woke up too early? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 8. Did you take sleeping pills to help you sleep? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 9. Did you have sleep difficulties that made you very irritable? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 10. Did you feel overly sleepy during the day? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

11. Overall, was your typical night's sleep during the **past 4 weeks**:

- O₀ Very sound or restful
- O₁ Sound and restful
- O₂ Average quality
- O₃ Restless
- O₄ Very restless

12. What is the chance that you would doze off or fall asleep (not just "feel tired") in each of the following situations? If you are never or rarely in the situation, please give your best guess for what would happen. *(Mark only one for each item)*

	<u>No Chance</u>	<u>Slight Chance</u>	<u>Moderate Chance</u>	<u>High Chance</u>
a. Sitting and reading	<input type="radio"/> O ₁	<input type="radio"/> O ₂	<input type="radio"/> O ₃	<input type="radio"/> O ₄
b. Watching TV	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Sitting inactive in public place (such as a theater or a meeting)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. Riding as a passenger in a car for an hour without a break	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
e. Lying down to rest in the afternoon when circumstances permit	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
f. Sitting and talking to someone	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
g. Sitting quietly after a lunch without alcohol	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
h. In a car, while stopped for a few minutes in traffic	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
i. At the dinner table	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
j. While driving	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

13. Over the **past 4 weeks**, how often have you snored? *(Mark only one)*

- O₁ Never
- O₂ Rarely (1-2 nights a week)
- O₃ Sometimes (3-5 nights a week)
- O₄ Always or almost always (6-7 nights a week)
- O₉ Don't know

14. Over the past 4 weeks, how often do you have times when you stop breathing during your sleep?

- O₁ Never
- O₂ Rarely (1-2 nights a week)
- O₃ Sometimes (3-5 nights a week)
- O₄ Always or almost always (6-7 nights a week)
- O₉ Don't know

15. Do you ever experience a desire to move your legs because of discomfort or disagreeable sensations in your legs?

If YES:

- O₀ No
- O₁ Yes →
- O₉ Don't know

a. Do you sometimes feel the need to move to relieve the discomfort, for example by walking, or by rubbing your legs?

- O₀ No
- O₁ Yes
- O₉ Don't know

b. Are these symptoms worse when you are at rest, with at least temporary relief by activity?

- O₀ No
- O₁ Yes
- O₉ Don't know

c. Are these symptoms worse later in the day or at night?

- O₀ No
- O₁ Yes
- O₉ Don't know

16. Considering only your own "feeling best" rhythm, at what time would you get up if you were entirely free to plan your day?

- O₁ 5:00 - 6:30 am
- O₂ 6:30 - 7:45 am
- O₃ 7:45 - 9:45 am
- O₄ 9:45 - 11:00 am
- O₅ After 11:00 am

17. During the first half hour after having woken in the morning, how tired do you feel?

- O₁ Very tired
- O₂ Fairly tired
- O₃ Fairly refreshed
- O₄ Very refreshed

18. At what time in the evening do you feel most tired and, as a result, most in need of sleep?

- O₁ 8:00 - 9:00 pm
- O₂ 9:00 - 10:15 pm
- O₃ 10:15 pm - 12:45 am
- O₄ 12:45 - 2:00 am
- O₅ After 2:00 am

19. At what time of the day do you think that you reach your "feeling best" peak?

- ₁ 5:00 - 8:00 am
- ₂ 8:00 - 10:00 am
- ₃ 10:00 - 4:45 pm
- ₄ 4:45 - 9:45 pm
- ₅ After 9:45 pm

20. One hears about "morning" and "evening" types of people. Which ONE of these types do you consider yourself to be?

- ₁ Definitely a "morning" type
- ₂ Rather more a "morning" than an "evening" type
- ₃ Rather more an "evening" than a "morning" type
- ₄ Definitely an "evening" type
- ₅ NEITHER a "morning" or an "evening" type

21. Have you been told by a doctor that you have any of the following:

a. Sleep Apnea (or obstructive sleep apnea, OSA)?

₀ No

₁ Yes

If YES:

Did you receive treatment for sleep apnea with any of the following?

- CPAP or BIPAP machine
- Dental (oral) device
- Throat/Uvula surgery

b. Insomnia? ₀ No ₁ Yes

c. Restless Legs? ₀ No ₁ Yes

22. Which of the following best describes your usual work schedule? (Mark only one)

- ₁ Day shift
- ₂ Afternoon shift
- ₃ Night shift
- ₄ Split shift
- ₅ Irregular shift/On-call
- ₆ Rotating shifts
- ₇ Don't work

23. How many days per month do you work extra hours beyond your usual schedule?

number of days

Participant Id#:

DATE:

/ /

DAY: Sun Mon Tues Wed Thurs Fri Sat

1. What time did you wake up this morning? : am
 pm

2. Did you go to work or school today? No Yes

3. Were there any times today that you took off the watch for 5 or more minutes?

No
 Yes →

If yes, at what time(s)?

			<u>am</u>	<u>pm</u>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>

4. During the day, did you take any naps or fall asleep for periods of 5 or more minutes?

No
 Yes →

If yes, at what time(s)?

			<u>am</u>	<u>pm</u>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>

5. Tonight, what time are you planning to go bed?
(turn the lights off and try to fall asleep) : am
 pm

* Remember to wear the sleep watch AND press the marker button when going to sleep.

4993226038

Participant Id#:

DATE:

/ /

DAY: Sun Mon Tues Wed Thurs Fri Sat

1. What time did you wake up this morning? : am
 pm

2. Did you go to work or school today? No Yes

3. Were there any times today that you took off the watch for 5 or more minutes?

No
 Yes →

If yes, at what time(s)?

			<u>am</u>	<u>pm</u>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>

4. During the day, did you take any naps or fall asleep for periods of 5 or more minutes?

No
 Yes →

If yes, at what time(s)?

			<u>am</u>	<u>pm</u>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>

5. Tonight, what time are you planning to go bed?
(turn the lights off and try to fall asleep) : am
 pm

* Remember to wear the sleep watch AND press the marker button when going to sleep.

3219226038

Participant Id#:

DATE:

/ /

DAY: Sun Mon Tues Wed Thurs Fri Sat

1. What time did you wake up this morning? : am
 pm

2. Did you go to work or school today? No Yes

3. Were there any times today that you took off the watch for 5 or more minutes?

No
 Yes →

If yes, at what time(s)?

			<u>am</u>	<u>pm</u>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>

4. During the day, did you take any naps or fall asleep for periods of 5 or more minutes?

No
 Yes →

If yes, at what time(s)?

			<u>am</u>	<u>pm</u>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>

5. Tonight, what time are you planning to go bed?
(turn the lights off and try to fall asleep) : am
 pm

* Remember to wear the sleep watch AND press the marker button when going to sleep.

8828226039

Participant Id#:

DATE:

/ /

DAY: Sun Mon Tues Wed Thurs Fri Sat

1. What time did you wake up this morning? : am
 pm

2. Did you go to work or school today? No Yes

3. Were there any times today that you took off the watch for 5 or more minutes?

No
 Yes →

If yes, at what time(s)?

			<u>am</u>	<u>pm</u>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>

4. During the day, did you take any naps or fall asleep for periods of 5 or more minutes?

No
 Yes →

If yes, at what time(s)?

			<u>am</u>	<u>pm</u>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>

5. Tonight, what time are you planning to go bed?
(turn the lights off and try to fall asleep) : am
 pm

* Remember to wear the sleep watch AND press the marker button when going to sleep.

2288226033

Participant Id#:

DATE: / /

DAY: Sun Mon Tues Wed Thurs Fri Sat

1. What time did you wake up this morning? : am
 pm

2. Did you go to work or school today? No Yes

3. Were there any times today that you took off the watch for 5 or more minutes?

No
 Yes →

If yes, at what time(s)?

			<u>am</u>	<u>pm</u>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>

4. During the day, did you take any naps or fall asleep for periods of 5 or more minutes?

No
 Yes →

If yes, at what time(s)?

			<u>am</u>	<u>pm</u>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>

5. Tonight, what time are you planning to go bed?
(turn the lights off and try to fall asleep) : am
 pm

* Remember to wear the sleep watch AND press the marker button when going to sleep.

5500226033

Participant Id#:

DATE:

/ /

DAY: Sun Mon Tues Wed Thurs Fri Sat

1. What time did you wake up this morning? : am
 pm

2. Did you go to work or school today? No Yes

3. Were there any times today that you took off the watch for 5 or more minutes?

No
 Yes →

If yes, at what time(s)?

			<u>am</u>	<u>pm</u>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>

4. During the day, did you take any naps or fall asleep for periods of 5 or more minutes?

No
 Yes →

If yes, at what time(s)?

			<u>am</u>	<u>pm</u>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>
<input type="text"/> <input type="text"/>	:	<input type="text"/> <input type="text"/>	<input type="radio"/>	<input type="radio"/>

5. Tonight, what time are you planning to go bed?
(turn the lights off and try to fall asleep) : am
 pm

* Remember to wear the sleep watch AND press the marker button when going to sleep.

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APPENDIX B

PSG Forms and Procedures

Signal Verification Form (SV Form)
Sleep Study Evaluation Form (SE Form)
Quality Form (QS Form)
Sample Sleep Report

Signal and Equipment Troubleshooting Examples

PSG Equipment Care and Maintenance

Compumedics Quick Notes
(Set Up/Flashcard/Set Up Somte/Download)

On Site PSG Tech Training Forms
(Check Off List for Site PSG Tech Training; Pratical Exam–Observation; Written Exam)

ElectraMed MESA Study Pricing Supply Order Sheet

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PSG Signal Verification Form

Participant ID _____ Technician ID _____ Somte ID _____ Date of Study _____ Time of Arrival _____

_____ Time of Departure: _____

Position: Was hand testing performed and verified to be accurate? yes no → explain: _____

Problems with hook-up: Were there any problems with the hook-up? no yes → explain: _____

Impedance: Did any sensors flash for value > 5 kΩ? no yes → successfully fixed? no yes

Signal Assessment: Scrolling through the signals was there a problem signal? no → explain: _____

Channel	Activation Instructions	Expected Response to Activation	No	Yes
EEG1 EEG2	Relax and close your eyes.	The signals should not waver from baseline		
EEG3 -----	Relax and close your eyes	The signals should not waver from baseline		
EOG L EOG R	Look straight ahead and blink Look left and right	Both channels go upward with blinks Channels move opposite from each other		
EMG -----	Bite down or swallow, then relax	Becomes thick then returns to baseline		
ECG Pleth	Sit still and relax	Clean, stable ECG waveforms Pleth movement matches ECG rate		
Press Flow			N/A	N/A
THERM	Breathe normally, hold your breath	This is the thermistor. Clean signal should move with breathing, flatten with breath holding		
Flow Snore	Close mouth, breathe through nose Make snoring sounds	Cannula; clean signal should move with breathing signal moves above baseline		
Thor Abdo	Relax, breathe normally	Clean signals, both should move with breathing		
Leg POS	Move your legs Must be tested before hook-up	Becomes thick then returns to baseline Current position is displayed on screen		
SPO2 Pulse	Sit still and relax	Reading is stable and above 92% Reading is greater than 30 but less than 120		

SPO2 reading: _____% *A reliable reading below 85% is an Urgent Alert*

Pulse reading: _____bpm *Reliable rate below 40 or above 150 is an Urgent Alert*



Sleep Study Evaluation Form

Participant ID

Technician ID

Somte ID

Date of Study

Date of Review

Reviewer ID

Participant's Reported Time to Bed: _____

Recording Assessment:

	Yes	No
Is the study ID on the recording correct and match the ID on paperwork? <i>If "No" must explain</i>		
Did the recording begin 1 hr. before the reported usual bedtime? <i>If "No" must explain</i>		
Are there signals on each of the channels? (able to visualize waveforms) <i>If "No" must explain</i>		
Is there at least 3 hours of oximetry after bedtime? <i>If "No" must explain</i>		
Were any electrodes or cables visibly broken upon Somte return and cleaning? <i>If "Yes" must explain</i>		
Were any factors identified on SV form that may have affected study quality? <i>If "Yes" must explain</i>		

Explanation or additional specific comments/complaints from the participant that may have affected this study:



ID: _____
Date of Study: _____

PSG Receipt

Date received:	Somte ID:	Site Number: 3 4 5 6 7 8
Week ending date:	Tech ID:	Code for site number : 3-WFU, 4-COL, 5-JHU, 6-UMN, 7-NWU, 8-UCLA

Study Passed? (1) Yes (2) No - Failed at RC (3) No - Study Not Sent

Failure Reason: _____
Reason Codes for Failure: 1-Oximetry; 2-EEG; 3-Short Recording; 4-No Data on Card; 5-Other; 6-Participant; 7-Multiple; 8-Equipment-Unknown; 9-Disconnect; 10-Respiratory; 11-Corrupted file - no back up

Comments: _____

High Priority Scoring: (1) Yes (0) No

QS Form

Partic. rpt time to bed:	Total time in bed: hrs min	Scorer ID:
Lights out:	Total sleep time: hrs min	Date scored:
Sleep onset:	AHI:	Week End Date:
Lights on:	SPO2 SV Form:	Pulse SV Form:

Channels	Hours of usable signal	Signal quality
E1 (EOGL)		1 2 3 4 5
E2 (EOGR)		1 2 3 4 5
Chin (Lchin-Cchin)		1 2 3 4 5
Fz-Cz		1 2 3 4 5
Cz-Oz		1 2 3 4 5
C4-M1		1 2 3 4 5
ECG (R ECG-L ECG)		1 2 3 4 5
Limb (Lleg- Rleg)		1 2 3 4 5
Airflow		1 2 3 4 5
Cannula Flow		1 2 3 4 5
Chest		1 2 3 4 5
Abdo		1 2 3 4 5
SpO2		1 2 3 4 5
Pleth		1 2 3 4 5
CannulaSnore		1 2 3 4 5

Code for signals quality:	
Entire sleep time (> 95 %)	5
75 - 94 % of sleep time	4
50 - 74 % of sleep time	3
25 - 49 % of sleep time	2
< 25 % of sleep time	1

Overall Study Quality:
 (7) **Outstanding.** All channels good for ≥ 6 hours and entire sleep time.
 (6) **Excellent.** At least one EEG channel, one EOG channel, EMG, oximetry, all respiratory channels usable for ≥ 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 ≥ 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 ≥ 5 hours and $\geq 50\%$ of the sleep time
 (3) **Fair.** At least one respiratory channel, oximetry and one EEG usable for ≥ 4 hours or study scored sleep-wake only (because of the EEG artifact).
Scored Sleep/Wake only: (1) Yes (0) No

M1 Issues.	<input type="checkbox"/> (1) Yes	<input type="checkbox"/> (0) No
FPz (EOG C) issues.	<input type="checkbox"/> (1) Yes	<input type="checkbox"/> (0) No
Gnd/Ref (Lclav) Issues.	<input type="checkbox"/> (1) Yes	<input type="checkbox"/> (0) No
Position Issues.	<input type="checkbox"/> (1) Yes	<input type="checkbox"/> (0) No

	Yes (1)	No (0)	Comments
1. Urgent Referral - RDI > 50			
2. Urgent Referral - O2sat <85% for >10% TST			
3. Urgent Referral - Unusual HR/ECG 0 = no heart rate issues 1 = Abnormalities seen - not clinically significant 2 = A-fib/flutter HR within limits (50-120) and is a known diagnosis 3 = URGENT REFERRAL - A-fib/flutter 4 = URGENT REFERRAL - Heart Rate (no A-fib)	3 4	0 1 2	If 3, check all that apply <input type="checkbox"/> New A fib <input type="checkbox"/> HR >120 or < 50 If 4, check all that apply: <input type="checkbox"/> 2nd or 3rd degree block <input type="checkbox"/> HR above 150 bpm for ≥ 2 min <input type="checkbox"/> Acute ST Segment <input type="checkbox"/> HR < 30 bpm for ≥ 2 min <input type="checkbox"/> NSVT 3-beat run <input type="checkbox"/> Other
4. Data lost - Recording ended before awoke			
5. Data lost at the beginning of the study			
6. Data lost at the end of the study			
7. Data lost – Other			
8. Scoring stage Wake/Sleep unreliable			
9. Scoring Stage 1/ Stage 2 unreliable			
10. Scoring Stage 2/ Deep sleep unreliable			
11. Scoring REM/NREM unreliable			
12. Scoring arousals unreliable			
13. Scoring arousals in REM (only) unreliable			
14. Scoring respiratory events (RDI) unreliable			
15. Scoring Apnea/Hypopnea unreliable			
16. Abnormal awake EEG			
17. Physiologic alpha intrusion			
18. Periodic breathing ≥ 10 min			
19. Periodic large breaths			
20. Flow limitation - >10% of sleep time			
21. Leg movements at least 75% present in 10 minutes minimum wake			
22. Extreme staging distribution			
23. RDI = 0 verified			
24. Arousal Index < 3 verified			
25. Max length respiratory event >150s verified			
26. PLM > 100 verified			
27. Other outlier			
28. DHR data invalid. N/A on Short Report			

Signal Quality Issues - Other Comments



Sleep Report

Participant ID SOPPPC

Study Date 6/13/2010

Sleep latency = 00:34
 Total time in bed = 08:24
 Total sleep period = 05:47
 Sleep efficiency = 68.8 %
 Total time for REM (dreaming) sleep = 01:49

AHI = 7.45
 (Total number of apnea and hypopnea associated with \geq 3% desat per hour of sleep)

	% sleep time	Minutes
Stage 1	2.02	00:07
Stage 2	55.8	03:14
Stage 3	10.8	00:38
Stage REM	31.3	01:49

Arousal Index = 15.4 /hr
 Obstructive Apnea Index (# of obstructive apneas per hr /sleep) = 0.0
 Central Apnea Index (# of central apneas per hr of sleep) = 0.0
 Average Heart Rate for sleep time = 47 bpm

SaO2 %	% Sleep time
< 95	99.2
< 90	9.83
< 85	0
< 80	0
< 75	0
< 70	0

SaO2 %	REM	NREM
Average	91	92
Minimum	90	88
Maximum	97	96

Periodic Limb Movements:

Number of movements during sleep: 94
 PLM Index: 16.3 # per hour of sleep

Signal and Equipment Troubleshooting

- Backup equipment should be available whenever possible. Remember: poor oximetry signal can cause the study to fail.
- 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 problems, troubleshooting efforts and tracking data for each unit and peripheral component. Include information on dates and recording # of initial use, sensor replacement and number of studies performed before end of service.
- Review studies as soon as possible to identify and correct problem units before the follow-up study.
- Notify Nancy Scott (Reading Center) of problems with PSG signals.

The following examples show general principles that apply to all signals captured by the Somte

Signal wanders from baseline

- Is the participant moving or talking? Ask the participant to sit at rest during the signal check.
- Is the patient still but the electrode moving? Secure the electrode wires with tape or bundle in a posey wrap. If this does not improve consider repositioning the electrode wire.
- Is the participant perspiring? Try to cool the participant or the environment.
- Is the electrode impedance excessive? Remove electrode and re-prep the skin.



Figure 3-11: ECG waveform with baseline wander

Excessive noise

- Is the REF securely on the participant? The electrode in NEG (under left clavicle) affects all signals, if it is unapplied, poorly applied or has high impedance all signals will appear thick and fuzzy. Check the connection, re-prep and reapply if necessary.
- Is the NEG electrode good? An electrode fresh from the package can still be bad or dried out. Try replacing the electrode.
- Is the wire for the NEG electrode bad? Swap out the wire.
- Is this an electrically hostile environment? Many electrical appliances or poor grounding in the home may cause interference in the Somte signals. This may be out of the control of the technician.

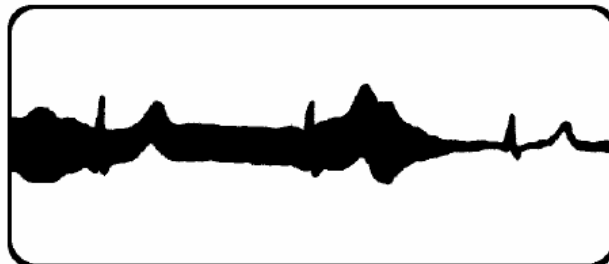


Figure 3-12: ECG waveform with excessive noise

Intermittent Signal

- Is the electrode securely on the participant and in the PIB? Check the connections on both ends.
- Is the electrode good? Even if the electrode is secure on both ends the wire inside may be broken. Try replacing the electrode. Treat the electrode with respect (*see Appendix on Care and Maintenance*).



Figure 3-13: Intermittent ECG waveform

Low Amplitude signal

- Incorrect electrode placement. Re-adjust the electrode placement. The electrode must be near the source generator for the desired signal.
- If the cannula signal is low the participant may be mouth breathing. Ask that he breathe through the nose.
- Is there a physiological cause? An example of this is low amplitude pleth signal caused by poor perfusion to the hand. Try the oximeter sensor on another finger.

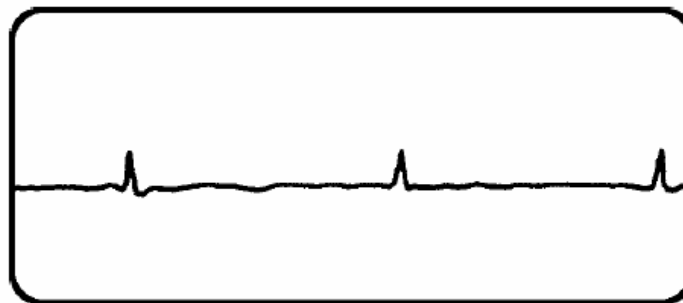


Figure 3-14: ECG waveform with low amplitude

Consistently poor signal

- If poor signals repeat with the same unit and does not improve with troubleshooting techniques it may be a problem with the Somte system. Call Compumedics for help.

What If?

What if the recording starts during the hook-up?

The Somte should be set to begin automatically but if the hook-up is delayed and the unit begins to record just let it continue and write a note on the SV form. The Reading Center can tell if electrodes are being applied or removed.

What if during the physioals the signals are not good?

Make sure electrodes have not pulled off of the participant or out of the PIB.

Make sure the participant is relaxed and not moving, talking or clenching the jaw excessively.

Remove, re-prep and replace the electrode in NEG (under left clavicle). This electrode affects every channel and must have good impedance and a good connection.

Check the lead wire for the NEG electrode, the electrode may be OK but the wire may be broken.

What if the config on the Somte is not correct?

If the recording configuration has an incorrect time or ExG is set to ECG2 instead of EEG3 fix it by entering the configuration screen and programming the recorder. The configuration screen can only be entered once so if you don't enter it in time the recorder must be powered down and back on to be able to get back to the configuration screen.

What if the flash card was set up for a different participant?

This cannot be fixed in the home or after the download at the site. Make a big note on the paperwork that the ID is incorrect and needs to be changed. The correct ID needs to be provided to the RC. Also email the RC to expect a study that contains an error.

What if the oximeter reading is bad?

Replace the oximeter sensor; make sure that the LED light is directly in line with the receptor. Make sure the participant does not have dark fingernail polish or acrylic nails. Make sure there is good blood perfusion to the hand and the finger tip (try another finger). Check if the participant may have anemia or low oxygen levels from a medical condition. Test the oximeter sensor on yourself to prove it is reliable. Make a note on the SV form.

What if you need to communicate to the RC regarding a specific study?

Always identify the study ID in your email. The RC needs to know which study you are referring to in your email.

PSG Equipment Care & Maintenance

Understanding the Electrode

The gold disk electrodes for the Somte are re-useable 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 over-layer 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 to maintain your gold disk electrodes are to:

- **Condition any new electrodes before the first use** (we have already conditioned the sets that you will be using in this training session)
- **Treat the wire and connection points with respect**
- **Keep them clean**
- **Disinfect between participants**

Conditioning New Gold Disk Electrodes

Electrodes are durable objects 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, the connecting cable 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 hair comb. 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.

Gold Disks Electrodes – General Care

Keep Gold Disks Clean:

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 that 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.*

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 where it plugs into the patient cable. 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. 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 patient interface cabling. 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.*

Cleaning and Disinfection of Equipment

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 blood-borne pathogens even if blood itself is not visible.* This is called occult blood. Re-useable 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 participants to eliminate the risk of transmitting blood-borne pathogens from occult blood.*

Table of level of cleaning/disinfection required:

Type of Electrode	Cleaning	Disinfection Level		
		Low	Intermediate	High
Gold disk Electrode	Cleaning and disinfection			•
Thermistor (Airflow sensor)	Cleaning and disinfection			•
Nasal Cannula	No, disposable			
Snap Electrodes (gel filled patch)	No, disposable			
Snap Electrode Wires	Surface clean only	•		
Respiratory Band	Surface clean only	•		
Respiratory Band Covers	Hand or Machine Wash	•		
Re-Useable Oximeter Probe	Surface clean only	•		
Leg Movement Sensor	Surface clean only	•		

Methods for Cleaning/ Disinfection:

- Gloves must 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 commercially prepared non-corrosive high level disinfectant. Full strength Control III Elite, Cavacide or other quaternary ammonium compound that provides high level disinfection should be used according to label instructions with proper contact time ensured. A thermistor with evidence of poor signal quality after cyclic use should be disinfected, tested, and replaced if necessary prior to the next study.

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 special 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 pour enough disinfection solution to completely cover the electrode disks.
- 5) Allow electrodes to soak in the disinfectant for the appropriate contact time to achieve high level disinfection (usually 10 minutes). Float any brush used in the same bowl, bristle-side down. Do not leave the electrodes soaking for longer than the required time.
- 6) After the required contact time, remove brush and electrodes from solution. Rinse electrodes under running water. Dry and place into storage for next use.
- 7) The disinfectant in the soaking container may be re-used for up to 24 hours. After 24 hours it must be discarded. After discarding the solution rinse the container and allow to dry.
- 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%) or a disinfecting wipe. Pay particular attention to remove any debris that may be on the object.
- 2) Allow the thermistor to dry.
- 3) Thoroughly wet (do not immerse) all sides of the thermistor with spray application of Control III Elite (or other quaternary ammonium compound that provides high level disinfection).
- 4) Ensure the required contact time, per label, to achieve high level disinfection (usually 10 minutes). The sensor must remain wet during this period for disinfection.
- 5) After the contact time the sensor may be hand dried with clean gauze or may be air dried. Place the dry sensor into a clean storage bag for next use. Tag storage bag to document that the sensor has been cleaned and disinfected).

Oximeter Probe, Leg Movement Sensors, ECG Electrode wires:

(General cleaning that also provides low-level disinfection)

- 1) Provide initial cleaning by wiping these objects with a soft cloth that has been saturated with a non-corrosive disinfectant. Pay particular attention to remove any debris, which may be on the object.
- 2) Wipe a second time with fresh disinfectant. Allow items to air dry.
- 3) Remove sticky tape residue with adhesive remover (such as Detachol or Goo-Gone).
- 4) Discard alcohol-saturated cloth and place sensors into storage for next use.

Respiratory Bands:

(General surface cleaning)

- 1) After each use, wipe the wires with a disinfectant wipe or soft cloth that has been saturated with a non-corrosive disinfectant. If the body of the belt has been soiled, it may be surface cleaned with a moist cloth (never saturate or immerse the belt body in liquids).
- 2) Velcro straps and the black belt covers may be removed and hand washed in a Woolite-type detergent, or machine-washed in separate “delicates bags” if necessary. Air dry or tumble dry on low setting.

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.

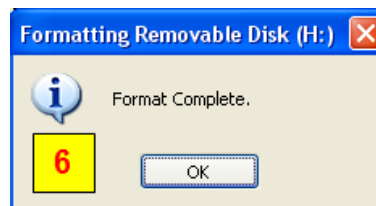
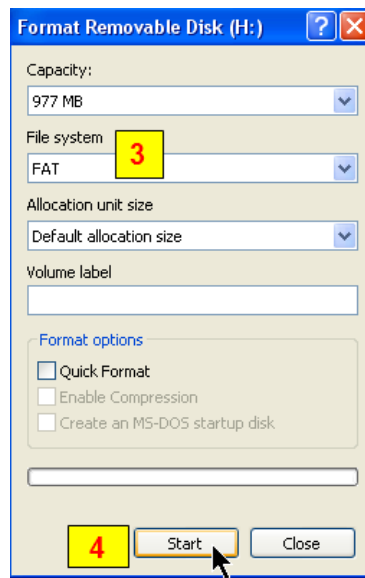
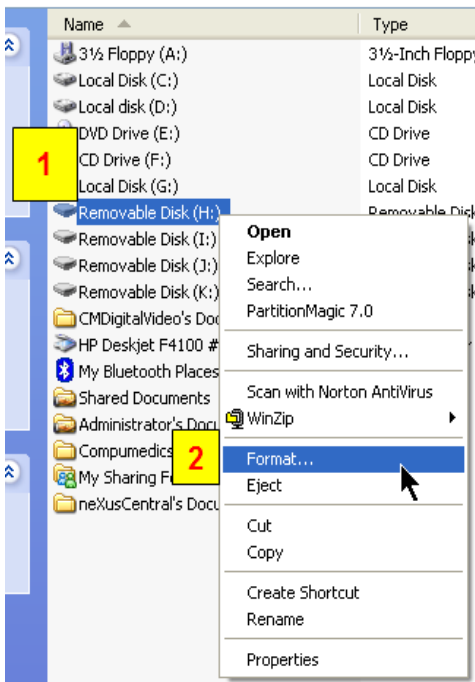
Detection of Occult Blood on EEG Surface Electrodes, *American Journal of Electroneurodiagnostic Technology* 37:251-257, 1997, ASET, Iowa.

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

Somte PSG - Recording an Unattended Study

Recording Unit Set Up

- A. Insert Compact Flash card into disk reader.
- B. to format flash card and double left click on My Computer:
 - 1) Locate correct removable drive
 - 2) Right click and select **Format**
 - 3) Verify the File System type is set to **FAT** (*Do not use FAT32*)
 - 4) Click on **Start**
 - 5) This will erase all of the data on the card, click **yes**
 - 6) Once completed you will get a dialog box that tells you it is completed. Click ok.



Educational Services

Training Documentation

Subject: Quick Notes-Record Somté PSG Unattended

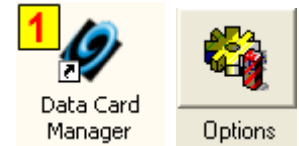
Author: Tina Jukich

Date: 1/18/11



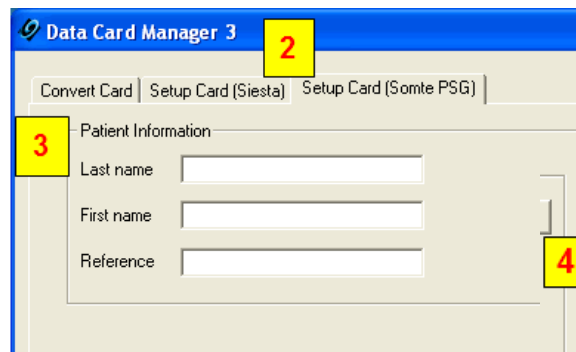
Set-up flash card for recording

1. Double left click on Data Card Manager shortcut icon
 - a. Set/check Options (Card drive, auto conversion options)

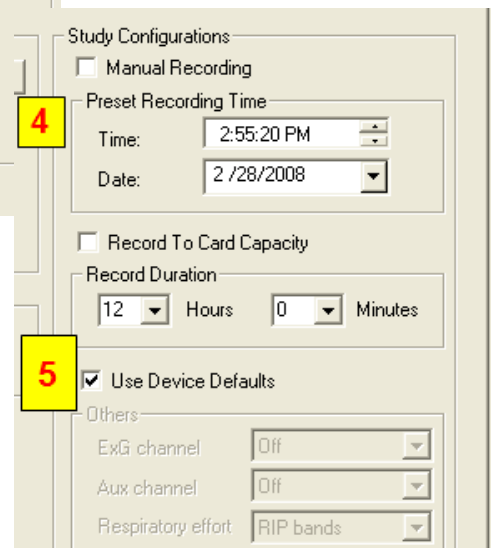


2. Click on Setup Card (Somte PSG) tab

3. Enter participant ID in box for last name. Skip first name. Enter tech ID-unit ID in Reference box.



4. Set Manual or Preset recording time for the time to begin the recording (i.e.: 1 hour before usual bedtime).



5. Set Record Duration

- a. Record to card capacity should be un-checked.
- b. Set length of recording in hours and minutes for usual length of sleep + 2 hours). This means the recorder is set to begin 1 hour before usual bedtime and stop 1 hour after usual wake time. There should be a minimum of 8 hours set to record.

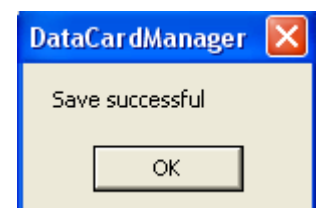
6. Use Device defaults should be un-checked. This will allow you to set channels to:

- a. set ExG to EEG3
- b. set Aux channel to Thermistor
- c. set Respiratory effort to RIP bands

7. Click on Setup Memory card to program card with settings. Message will alert with a successful set up.



8. Remove from card reader

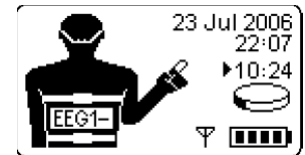


Somte Unit Set up

1. Insert 2 new AA alkaline rechargeable batteries into the Somté PSG
2. Insert formatted and set up flash card into the Somté PSG
3. Prepare the participant and attach the electrodes into the PIB and vest.
4. Turn the Somte PSG unit on. Check that the configuration is correct at power up.
5. Verify the position sensor

6. Verify the Impedances

- A. Indicators found on display. EEG name will display in the center of the patient icon and will cycle through if more than one electrode has impedances higher than the set threshold. Fix electrodes as necessary.



7. Check integrity of waveforms by pushing waveform button

- A. Far right button.
- B. Have participant activate each sensor (physio-cals). Continue to check additional channels by pushing waveform button repeatedly until all waveforms have been checked
- C. At the end of waveforms it will cycle back to main screen

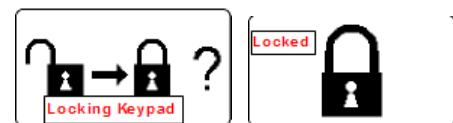


8. Leave the unit on

- A. Unit will begin to record at the programmed start time. Lock engages automatically at start of recording.

9. If the recorder must be unlocked:

- A. Hold the two outer keys down
- B. Push the center key. Status of the lock will be reversed.
- C. Locking will only be allowed during recording. If the recording has not ended automatically, the recording must be stopped in order to unlock the unit.



Educational Services

Training Documentation

Subject: Quick Notes-Record Somté PSG Unattended

Author: Tina Jukich

Date: 1/18/11



Download Recorded Study

1. Turn off Somté PSG
 - A. Unlock key pad if needed. Hold both outer keys down the push center button



2. Open clip and remove the flash card

3. Place flash card into card reader



4. Double left click on Data Card Manager

5. Verify the Patient Name

&

Output Directory

- A. If location to save is not correct browse to the appropriate folder to which you want to download the recording

6. Study Info will appear on the right

- A. Epoch Length
- B. Study Time (begin time)
- C. Study Date (begin date)
- D. Duration (length of recording)

7. Click on Convert

- A. Study can now be opened and reviewed before sending to the Reading Center



Check Off List for at site PSG Tech Training:

Name: _____

Site: _____

Date: _____

Topic	Date	Instructor	Trainee
<p>Introduction to Sleep Science: Disturbances of sleep:</p> <ul style="list-style-type: none"> • sleep disordered breathing (apnea/hypopnea) • Restless Leg Syndrome and Periodic Leg Movements of Sleep <p>Polysomnography as a tool for evaluation of sleep:</p> <ul style="list-style-type: none"> • Sleep Stages (EEG, EMG, EOG changes) • Respiratory Changes (SaO2 changes) • Heart Rate Changes • Positional changes (simple body adjustment; effects on respiration) 			
<p>Types of electrodes, care and maintenance (including cleaning and disinfection used in PSG):</p> <ul style="list-style-type: none"> • gold disk (areas of stress, conditioning, cleaning and disinfection) • Thermistor (areas of stress, cleaning and disinfection) • Nasal pressure (cannula and Somte interface) • ECG patch (interface to lead wires) • Oximeter (areas of stress, interface to Somte, cleaning) • IP respiratory bands (surface cleaning) • Leg movement sensor 			
<p>Unattended Studies: Noting conditions which may affect the hook-up or PSG:</p> <ul style="list-style-type: none"> • Limited ability to cooperate • Intolerance to sensor(s) • Handicaps: head, face or torso abnormalities • Alterations in standard electrode placement • Problem signals (providing notes when troubleshooting efforts have been exhausted) • Any environmental conditions, temperature (extreme heat or cold, pets, electric blankets, etc.) 			
<p>Interaction with the study participant:</p> <ul style="list-style-type: none"> • Safety issues and courtesy (for the participant/ for the field team) • Instruction to subject on how to ambulate safely • Instructions to participant at bedtime (pushing the event button) • Instructing the participant on morning removal of equipment • Confirming pick-up time for equipment 			

Mechanics of Somte PSG Recorder:

- Powering on/off
- Lock and un-lock features
- Battery compartment/ flash card compartment
- Status indicator
 - Off (off)
 - Flashing amber (powered on and idle)
 - Flashing green (recording in progress)
 - Solid red (unrecoverable error, power unit off/on)
- Flash card set-up (through Data Card Manager)
- Main display at power up
- Auto and manual start/ stop recording (automatic lock on record)
- Verifying the configuration, how to re-program if needed
- Impedance check, sensor status (high impedance electrodes will display)
- Control buttons, how to scroll the waveforms
- Performing electrode activations (physio- cal)
- Verifying the internal position sensor
- Main display during recording
 - Time/ date
 - Flash card status
 - Time remaining
 - Battery status
- Performing electrode activations (physio- cal)
- Signal review
- MESA PSG configuration
 - ExG= EEG3 (C4)
 - Resp= RIP bands
 - Aux= Thermistor (ThermiSense thermistor)
 - Impedance= 5k Ω
- Setting display screen
 - Setting time/ date
 - Formatting flash card (all data and study info is erased)
 - Contrast
 - Battery type
 - Language
 - Exit programming
- PIB
 - Interfacing gold disks
 - Jumpering Cz as EEG1- and EEG2+
 - “Keyhole” connectors: correct orientation for plug in: Limb, Belts, Thermistor (Aux)
 - Interfacing oximeter and sensor (2 types of sensors)
 - Pulse display

<p>Formatting flash card</p> <ul style="list-style-type: none"> • Through My Computer (must know drive assignment) • Format as FAT (not FAT 32) • No to Quick Format • Size of replacement flash cards (not to exceed 2 GB) <p>Flash card set-up (Data Card Manager)</p> <p>Programming the Data Card Manager</p> <ul style="list-style-type: none"> • Location to download • Manually convert (do not remove study after conversion) <p>Flash card set-up</p> <ul style="list-style-type: none"> • Participant ID • Tech ID-unit ID • Set recording time (1 hr before bedtime until 1 hour after wake time) • Minimum of 8 hours of recording time <p>Set up Memory Card (saves the set-up)</p> <p>Downloading the study</p> <ul style="list-style-type: none"> • Manual convert and open Profusion 3 • Verify correct participant ID, date, tech and unit ID (note to RC if changes are needed) • Scan the recording for signs urgent scoring will be needed Constant dips in SpO2, issues with heart rate, other issues 			
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Practical Exam for PSG Tech Training

Date: _____

Name: _____

Site: _____

Examiner: _____

Performed Correctly?

Power on/ off	y <input type="checkbox"/> n <input type="checkbox"/> → explain: _____	Flash Card set-up	y <input type="checkbox"/> n <input type="checkbox"/> → explain: _____
Lock/ unlock	y <input type="checkbox"/> n <input type="checkbox"/> → explain: _____	Load card in Somte	y <input type="checkbox"/> n <input type="checkbox"/> → explain: _____
Insert batteries	y <input type="checkbox"/> n <input type="checkbox"/> → explain: _____	Verify card set up	y <input type="checkbox"/> n <input type="checkbox"/> → explain: _____
Data Card Manager	y <input type="checkbox"/> n <input type="checkbox"/> → explain: _____	Verify position sensor	y <input type="checkbox"/> n <input type="checkbox"/> → explain: _____

For each of the following procedures check yes or no to indicate correct performance:

Sensor	Positioning		Skin Prep		Impedance		Additional Comments
	Yes	No	Yes	No	Yes	No	
Fz (EEG1+)							
Cz (EEG1- jumped to EEG2+)							
Oz (EEG2-)							
C4 (ExG+)							
M1 (ExG-)							
Chin (EMG+ and -)							
EOG L							
EOG R							
FPz (EOG C)							
ECG- (R clavicle)							
ECG+ (left lower rib)							
Left Clavicle (NEG)							
Therm. (AUX)							
Cannula (NP port)							
Belts							
Limbs							
Oximeter							

Was SpO2 and Pulse checked? y n → explain: _____

Were signals activated (physio-cals) performed? y n → explain: _____

Additional comments: _____



Written Exam for MESA-Sleep Certification

Name

Site

Date

Score

Circle the best answer for the following questions:

1. MESA- Sleep is designed to assess cardiovascular risk factors in association with:
 - a) Sleep disordered breathing (breathing disturbances, changes in oxygen levels and arousals)
 - b) The amount of slow wave sleep, quality and length of sleep in individuals
 - c) Sleep patterns and the amount of napping over a 1-week period.
 - d) All of the above

2. The following will be collected for MESA Sleep:
 - a) 1 night of PSG
 - b) sleep questionnaires
 - c) 7 days of actigraphy
 - d) Night time ECG embedded in the PSG
 - e) all of the above
 - f) a, b, c but not d

3. The purpose of actigraphy in MESA-Sleep is to:
 - a) Measure energy expenditure
 - b) To find out how much slow wave sleep a participant has
 - c) To measure sleep patterns over a day period
 - d) To quantify average sleep duration
 - e) c and d

4. Which of the following are true concerning the Spectrum Actiwatch actigraphs?
 - a) They detect heat and light
 - b) They detect light and movement
 - c) They cannot be immersed in water due to electrical sensitivity
 - d) They should be removed at bedtime and during contact sports

5. Actigraphs should be cleaned:
 - a. Using alcohol or a high level disinfectant
 - b. Using mild detergent and water
 - c. By sending back to the manufacturer for sterilization
 - d. None of the above

6. The dark blue line on the actigraph auto score output screen indicates:
 - a) A failed study
 - b) A period of “watch off” time
 - c) Exposure to blue wave length light
 - d) A period of increased activity

7. The actigraph should be placed on:
 - a. The dominant wrist
 - b. The non-dominant wrist
 - c. Snugly, with one small finger of room available
 - d. Loosely to enable maximal movement
 - e. b and c
 - f. b and d

8. When an actigraph is returned and no data are available, which are the following steps to take:
 - a. Check with the participant on whether he wore the device
 - b. Try wearing the device and determine if the device is recording
 - c. Contact the Reading Center for advice
 - d. Immediately return to Philips-Respironics
 - e. b and c.

9. The purposes of the sleep diary are to:
 - a. Determine how caffeine intake influences sleep
 - b. To provide a backup record of sleep wake times in case the actigraph fails
 - c. To provide information needed to edit the actigraph files
 - d. b and c.

10. Polysomnography is performed to:
 - a) Quantify the number of apneas/hypopneas
 - b) Quantify the number of arousals
 - c) Assess sleep continuity
 - d) Characterize eye movement disorders
 - e) a, b, c
 - f) a and b
 - g) a, b, c, d

11. Sleep stages are distinguished by:
 - a) The frequency of waveforms on EEG
 - b) The amplitude of waveforms on EEG
 - c) Associated changes on the EMG channel
 - d) Associated changes on the EOG channel
 - e) a and b
 - f) a, b, c
 - g) a, b, c, d

12. “Central” and “obstructive” respiratory events are:
- a) Distinguished by the absence or presence of effort on the respiratory belts (abdominal and thoracic).
 - b) Distinguished by the absence or presence of airflow (thermistor).
 - c) Distinguished by their associated type of brainwave (EEG) signal.
 - d) a and b
 - e) none of the above
13. In polysomnography, thermistors measure “airflow” by recording:
- a) Changes in volume
 - b) Changes in pressure
 - c) Changes in temperature
14. Which of the following can result in low oximetry values?
- a) Oximeter electrode placed too loosely
 - b) Oximeter electrode placed too tightly
 - c) Oximeter light receptor misaligned
 - d) Participant with lung disease
 - e) Oximeter electrode placed over nail polish or acrylic nail.
 - f) a, b
 - g) a, b, c
 - h) a, b, c, e
 - i) a, b, c, d, e
15. If upon placing the oximeter a reading of 75% is obtained, what is the first course of action?
- a) Explain to the subject that you will need to call your supervisor
 - b) Call 911
 - c) Re-position the electrode and re-check the new reading: test the sensor on yourself, if necessary
 - d) Remove the gold disk electrode at M1, re-prep the area and reapply
16. Desired impedance levels for gold disk electrodes should be:
- a) <30k
 - b) ≤5k
 - c) between 5k-25k
 - d) impedance values do not matter
 - e) as high as possible
17. The purpose of the oximeter electrode is to:
- a) Prove the participant is asleep
 - b) Provide a reference for the gold disk electrodes
 - c) Record the amount of oxygen in the bloodstream

18. The software program used to set up and download the compact flash card is:
- Data Card Manager
 - Somte PSG
 - Profusion PSG
19. What setting is not correct when programming the compact flash card?
- AUX= THERM
 - Program for usual sleep duration + 2 hours.
 - Tech ID-unit ID in reference line
 - Program to start at bedtime
 - Participant IDacrostic in Last name line
 - Program to start 1 hr before bedtime
20. Which of the following statements is true regarding about disinfection of gold disk electrodes in between participants?
- Disinfection eliminates high electrode impedances
 - Placement on non-intact skin creates risk of blood borne pathogens
 - Soap and water cleaning is sufficient
 - Soap and water cleaning with an alcohol wipe down is sufficient
 - Disinfection is aimed at reducing risk of blood borne pathogens that could arise by placing used electrodes on non-intact skin
 - b and e
 - all of the above
21. If the thoracic respiratory belt shows minimal deflection with breathing:
- Tighten the belt until the subject complains of discomfort
 - Have the participant lie down and recheck the signal quality
 - Watch the chest to see the area of largest movement with breathing
 - Reposition and insure the belt is not too tight or too loose
 - The channel will flash on the Somte idle screen
 - All of the above except a
22. The optimal position of the abdominal respiratory belt is:
- Around the umbilicus
 - Over the nipples
 - Just above the hips
 - Under the left armpit
23. After use, proper disinfection of the gold disk electrodes is assured by
- Rinsing dried electrolyte paste with water
 - Wiping the electrodes lightly with alcohol
 - Removing dried paste and soaking disks in a high level disinfectant.
 - It doesn't matter, disinfection is not needed if the subject looks healthy and no skin break was visible

24. According to PSG protocol a “ground” electrode will be placed under the left clavicle. Where on the PIB will this electrode be plugged?
- a) ExG-
 - b) EOG C
 - c) AUX
 - d) EMG+
 - e) NEG
25. The left lower rib electrode should be plugged into:
- a) ECG-
 - b) ExG+
 - c) ECG+
26. When placing the nasal cannula, subjects should be told
- a) Not to touch it once it has been placed
 - b) Clean it by dipping in water if it becomes moist or soiled
 - c) To remove it if nose needs to be blown, and then replace
 - d) None of the above
27. The morning following the study the gold disk electrodes should be:
- a) Rinsed off and re-packed for the next study
 - b) Cleaned of all debris, and then soaked in a high level disinfectant.
 - c) Discarded since they are not reusable
 - d) Sterilized at a local hospital
28. Which of the following are exclusion criteria for scheduling a sleep exam:
- a) Discharge from the hospital for a heart attack within the prior one week
 - b) Regular use of CPAP
 - c) Regular use of oxygen at night
 - d) Regular use of an oral appliance at night
 - e) Edentulous (no teeth)
 - f) All of the above
 - g) a-d
29. The best timing for a home MESA-Sleep visit is:
- a) On weekends when participants are well rested
 - b) Before dinner
 - c) Early evening, approximately 2 hours before bedtime
 - d) Immediately before bedtime
30. MESA Sleep Exams should be scheduled:
- a) Before Core EXAM 5
 - b) Immediately after Core EXAM 5
 - c) Within 9 months of Core EXAM 5
 - d) None of the above

31. The following are considered Urgent Medical Referrals, requiring clinic investigator review and participant feedback within 2 weeks, as appropriate:

- a) An oxygen level at time of hook up of 75%
- b) An AHI greater than 30
- c) An AHI greater than 50
- d) Percentage time in oxygen desaturation <85% for > 10% of the sleep period on PSG
- e) New onset atrial fibrillation on the overnight ECG from PSG
- f) a, d and e
- g) All of the above

32. When transmitting data to the Reading Center:

- a) Bundle sleep journals and Signal Verification forms together and zip
- b) Bundle sleep journals with actigraph records and zip and encrypt
- c) Bundle Signal Verification/Study Evaluation forms with the PSG files and zip and encrypt
- d) b and c

33. When prepping the skin for PSG electrode placement:

- a) Wipe all areas clean with alcohol
- b) Gently abrade using Nu-Prep or similar abrasive
- c) Wipe with alcohol, then with an abrasive
- d) Scrub hard with Nu-Prep so there is no oil in the skin

34. What advice should participants **not** be provided before you leave the home visit?

- a) To return the actigraph and PSG the next day together
- b) To carefully remove the PSG sensors in the morning, using the plastic bags you provide to contain the sensors
- c) To return the actigraph in 7 days.
- d) To be careful moving, aware of wires
- e) Not to be afraid if anything falls off
- f) To use a warm wash cloth to help remove sensors

35. If participants are concerned that do not regularly sleep well and thus think they should not participate in MESA Sleep, what information can be provided to them:

- a) Tell them you will refer them to a doctor and after this will arrange for them to participate
- b) Thank them for their interest in MESA and tell them that although they are not eligible to participate in MESA Sleep, they are still welcome to participate in other MESA studies
- c) Tell them that you can do the actigraphy only
- d) Reassure them that sleep studies are routinely performed on people with sleep problems and that the information is often useful in helping to understand the reasons people sleep poorly

ElectraMed Corporation Order Sheet

P.O. #: _____ Name: _____

Date: _____ Phone #: (_____) _____

Phone # (800) 678-4856

Fax # (810) 232-1028

Item Number	Description	Price	Unit	Quantity Ordering
EM-1350-0005	Cleartrace Electrode 5/pk, 10pk/box, 20box/case (600 elect	126.00	pack	
EM-2007-0002	Tape Measure, Round 72"	3.00	each	
EM-5210-0001	Eveready AA Battery 24/box	8.64	box	
EM-6000-0001	Comb 5"	1.00	bag	
EM-6000-3395	Adult Toothbrush 12/bag	1.00	bag	
EM-6310-0001	Sani-Cloth Plus Canister	6.95	each	
EM-6325-0001	Transpore Tape 1" 12/box	14.50	box	
EM-6326-0001	Micropore Tape 1" 12/box	9.10	box	
EM-6326-3552	Generic 1" Paper Tape 12/box	6.95	box	
EM-6328-2034	Cover Roll Stretch Cloth Adhesive Tape 2"x10yds	10.75	box	
EM-6331-00F	Nonin 8000J Flex Wrap 25/pack	21.00	pack	
EM-6331-6554	Posey Pulse Oximeter Probe Wrap - 12/box	8.75	box	
EM-6485-0008	Pill Cups 3/4 oz.(soufflet) 250/sleeve	2.50	sleeve	
EM-6487-0001	Medicine Cup 1oz. - Poly 100/sleeve	1.50	sleeve	
EM-6500-5930	Glove, Trilon Latex Free & PF Small 100/box	6.85	box	
EM-6500-5950	Glove, Trilon Latex Free & PF Medium 100/box	6.85	box	
EM-6500-5970	Glove, Trilon Latex Free & PF Large 100/box	6.85	box	
EM-6620-0001	6" Swabs, Non-Sterile, 1,000/box	6.50	box	
EM-6623-0002	1"x 1" NS Gauze 500/bag	6.25	bag	
EM-6627-0001	4"x 4" NS 12-Ply Gauze, 200/sleeve	4.50	sleeve	
EM-6627-9024	4"x 4" 4 ply Versalon NS Sponge, 200/pack	7.90	pack	
EM-6629-0002	Tongue Depressor Senior 6", NS, 500/box	4.50	box	
EM-6631-2247	4"x 75" Conform NS Stretch Gauze 12/bag	7.75	bag	
EM-6643-0001	Coban 1" 5/bag	37.00	bag	
EM-6643-0002	Coban 2" NS 36/box	67.50	box	
EM-6643-0004	Coban 4" 18/box	55.25	box	

Item Number	Description	Price	Unit	Quantity Ordering
EM-6702-0001	Detachol 4oz.	9.75	each	
EM-6708-0005	Control III Elite-32oz. Spray	8.50	each	
EM-6708-0006	Control III Elite-Gallon	27.50	each	
EM-6871-0301	Scissors 5 1/2" Bandage	3.95	each	
EM-7910-0003	Blue Underpads - Medium 22"x 21" 200/case	39.50	case	
EM-9511-00SM	8000SM Soft Sensor Medium, Nonin	195.00	each	
NR-1020-0005	Ten20 Conductive Adhesive EEG Paste 8oz. jar, 3/pack	32.25	pack	
NR-1021-0004	NuPrep 4oz.3/pack	23.40	pack	
NR-1021-1704	Green Prep 4oz. bottle 3/pack	20.00	pack	
NR-1021-1904	Lemon Prep 4oz. bottle 3/pack	20.00	pack	
NR-1650-0148	EC2 Electrode Cream 3.5oz.	5.50	each	
NR-2015-0524	Jumper Cables 12" 3/pack	22.05	each	
NR-354S-5751	Nasal Airflow Press. Cannula, Adult w/Ther. Hldr-short 25/	61.60	case	
NR-3700-0050	Gold Cup Electrode 60" Multicolor 10/set	67.00	set	
NR-3700-0100	Left Leg Sensor	80.00	each	
NR-3700-0101	Right Leg Sensor	80.00	each	
NR-3701-0020	Oximeter Probe 8000J 1 Meter	102.00	each	
NR-3712-0013	ABD Inductive Respiratory Effort Belt - Summit IP/Somte	225.00	each	
NR-3712-0014	Thoracic Inductive Respiratory Effort Belt - Summit IP/Somt	225.00	each	
NR-5001-BLUE	Marking Pencil 3/pack - Blue	5.25	pack	
NR-5800-0060	Multicolor ECG Leads 60" 10 pack	45.00	pack	
NR-6627-M281	Head Net Large Adult Tube	16.95	box	
NR-9102-570E	ThermiSense Sensor-Embla, Adult 7" w/Keyhole Connector	139.00	each	

ElectraMed Corporation Order Sheet

P.O. #: _____ Name: _____

Date: _____ Phone #: (_____) _____

Phone # (800) 678-4856

Fax # (810) 232-1028

Item Number	Description	Price	Unit	Quantity Ordering
<u>List Additional Items Below</u>				

Item Number	Description	Price	Unit	Quantity Ordering
-------------	-------------	-------	------	----------------------