



PSG Procedure Manual

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1.0 Sleep Apnea and Polysomnography

1.1 Sleep Disorders - Definitions

1.1.1 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 10% of adults have sleep apnea. Sleep apnea does occur in people of all ages. It may be most common, however, in the elderly, occurring in >25% of some surveys of the elderly. It also occurs in both men and women, although, at least during middle age, men are more likely to be affected than women. Although one of the biggest risk factors for sleep apnea is obesity, thin people may also have sleep apnea.

What does sleep apnea do to a person? Most of the consequences of sleep apnea are due to three phenomena: snoring, sleep disruption, and irregular breathing. One of the most troubling consequences of sleep apnea is the snoring and loud breathing noises that can disturb the sleep of the affected person

as well as his/her bed-partner. This may cause embarrassment and marital discord. The intermittent disruptions to sleep also interfere with the brain's normal sleep pattern- causing "arousals," and reducing the amount of sleep time spent in deep sleep and REM (Rapid Eye Movement, or "dream") sleep. This may prevent "restorative" sleep, causing the person to feel sleepy and irritable during the day, and, possibly, "slowing" the person (physically and mentally). The breathing irregularities often cause the body's oxygen levels to drop. The drops in oxygen levels are thought to cause stress on the heart, and possibly contribute to high blood pressure, to other heart ailments (heart attacks, angina, irregular heart rhythms) or stroke. However, very few studies have carefully examined these issues. **A major purpose of the MrOS 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 MrOS 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.

1.1.2 Insomnia

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), low sleep efficiency (low percentage of time asleep compared to time in bed; e.g., < 65%), and long period of REM sleep (> 30% of sleep time). 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.

1.1.3 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. With movements, there are often “arousals” –or lightening of sleep or even awakening. PLMD is fairly rare 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 MrOS is to better identify what the health impact of PLMD is. Identification of PLMD will be accomplished by measuring leg movements during sleep. MrOS will be the largest study where such measurements will be made.

1.2 Polysomnography

Polysomnography (PSG) is a procedure in which an individual is monitored overnight in a sleep laboratory with a **polygraph**. This is an instrument designed to record many physiological processes simultaneously. Tiny electrical signals are transmitted to this recording instrument from the body by using specialized sensors, or electrodes that are applied to different body parts (e.g., the head, chest, face, etc.) The recording instrument contains specialized amplifiers, filters, and computer chips that translate these signals into records that can be viewed and analyzed.

1.2.1 Signal Types

There are three types of signals that are collected:

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

Examples:

- | | |
|-------------------------------|-------------------------|
| • <i>electroencephalogram</i> | (EEG) (brain waves) |
| • <i>electrooculogram</i> | (EOG) (eye movements) |
| • <i>electromyogram</i> | (EMG) (muscle activity) |
| • <i>electrocardiogram</i> | (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.

1.2.2 Sleep Stages

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

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

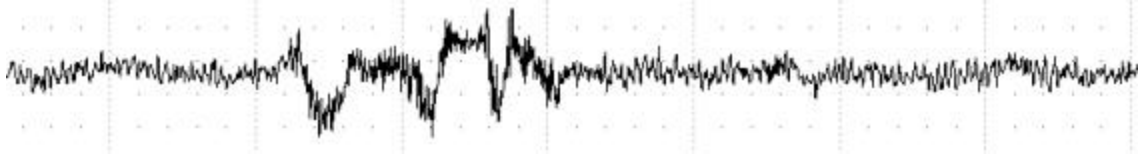
Stages 1, 2, 3 and 4 are often referred to as non-REM sleep

Each pattern is characterized by brain waves of specific frequencies and/or amplitudes. Stages may also be associated with certain types of eye movements and muscle activities. 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.**

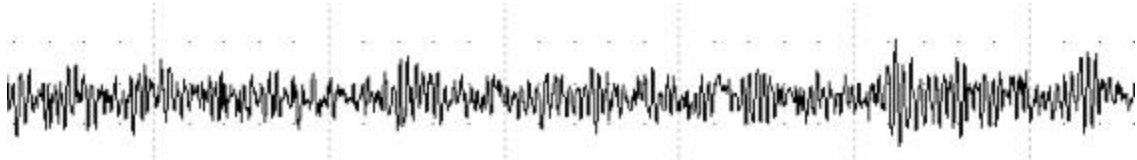
On the following page are examples of how the following stages appear on a polygraph record of EEG:

- 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, 4
Deep Sleep - Waves are slower and higher in amplitude.
- REM - Waves are irregular, almost resembling wakefulness.
However, in this stage, there are rapid eye movements (on EOG) and reduced activity on the muscle (EMG) channels.

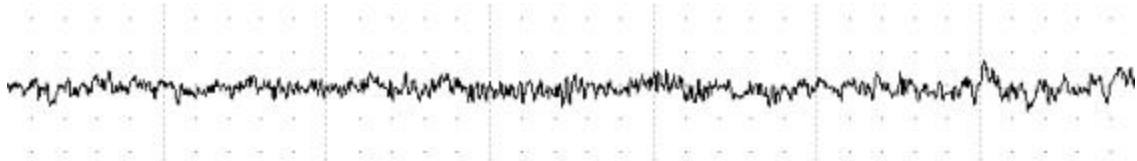
AWAKE - Low voltage - random, fast



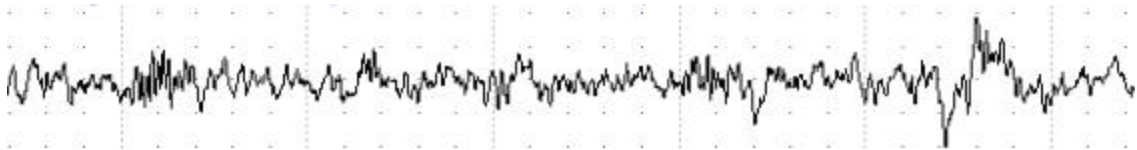
DROWSY - 8-12 Hz alpha waves



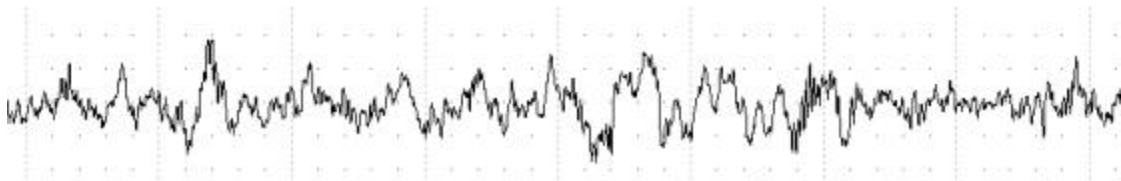
STAGE 1 - theta waves. Note the slowing of activity as compared to wakefulness



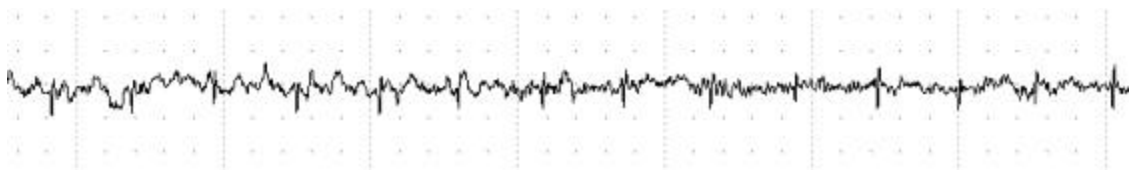
STAGE 2 Note the scattered very large waves (K complexes) and very fast waves (sleep spindles)



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



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



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

With disorders such as 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.)

1.2.3 Respiratory Monitoring – Measurement Tools

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

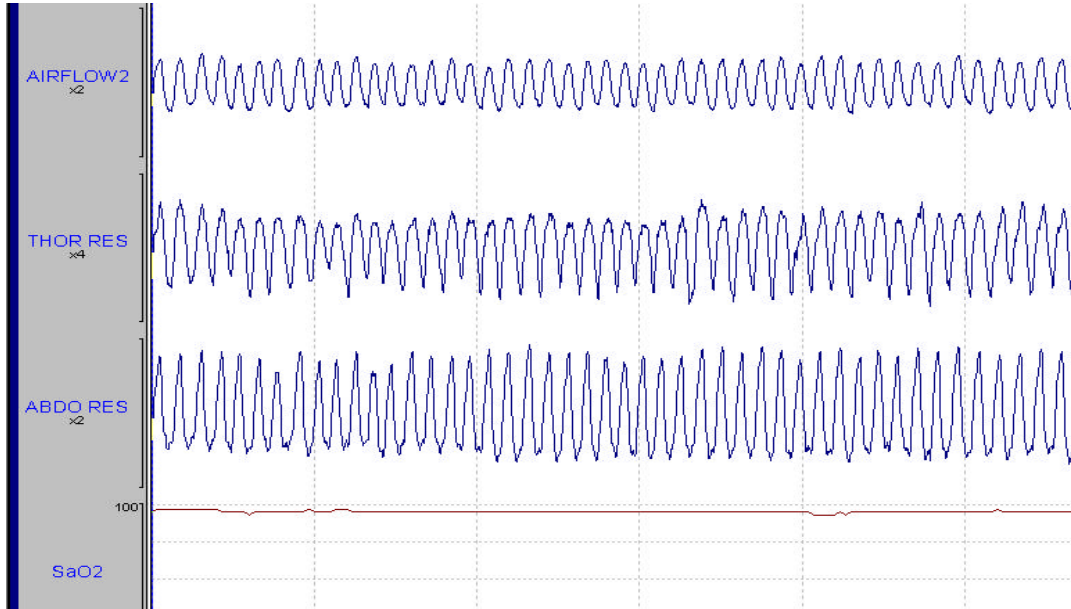
An **apnea** is a complete or almost complete cessation of airflow, lasting ≥ 10 seconds, and usually associated with desaturation or an arousal.

A **hypopnea** is a reduction in airflow (< 70% 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.

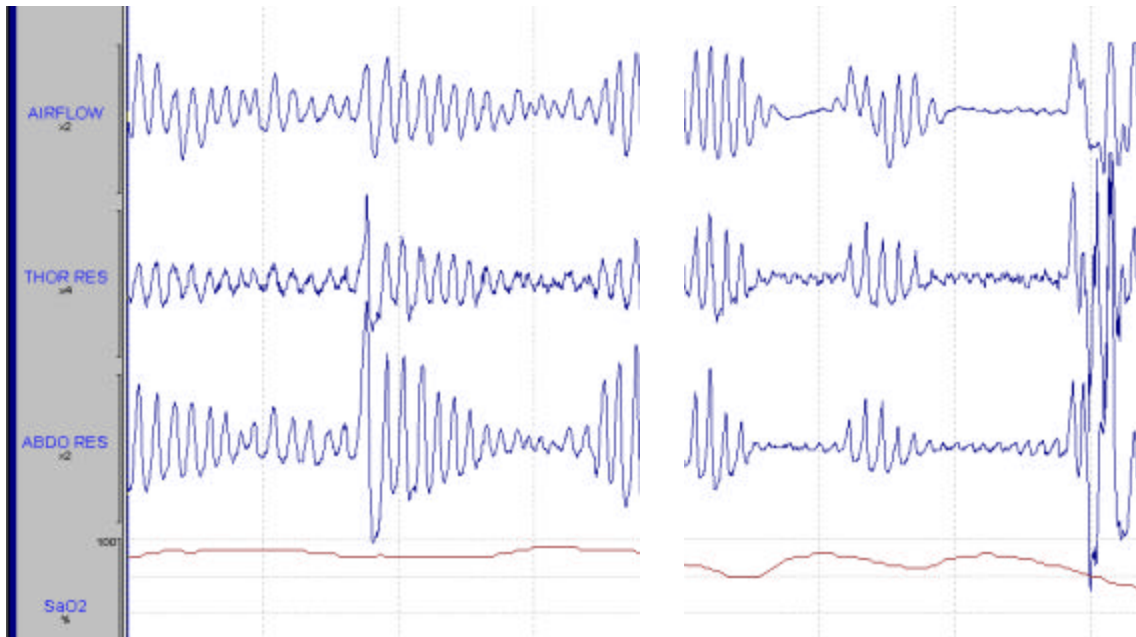
NORMAL BREATHING



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 Safiro Sleep Monitoring System) that permits recording this information in an unattended setting.

Compumedics Safiro Unit



- Small and Lightweight - 300 grams (9.6 ounces) w/battery
- Variable montage - Records up to 32 channels – 1 GB flashcard storage
- True digital filtering during collection and review
- Battery Power

1.3 The MrOS Protocol and Polysomnography Procedures

This flow chart provides an overview of where each of the procedures outlined in this manual fit in the MrOS protocol. The detailed schedule of procedures includes references to sections of this manual in which detailed instructions for each procedure are found.

Procedure	Pre-visit Period	In-Clinic Visit	At-home Actigraphy	In-home PSG
Day	-14 to 0	1	2-6	1-30
Study Enrollment	Administer, determine eligibility	Consent		
Actigraph & sleep diary		Initialize and distribute	Continue for 5 days (minimum of 3 nights of data collection)	
PSG		Perform		Perform
Urine Collection				Collect in AM after PSG Study

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

- Administer Study Enrollment form to determine eligibility and interest in participating.
- Distribute PSG study brochure, SAQ, and other instructions for MrOS Sleep Study.

In-clinic visit

- Describe in-home PSG and obtain informed consent
- Schedule in-home PSG (maximum of 30 days following in-clinic visit)
- Perform all in-clinic measures
- Initialize and distribute Actigraph and instruct participant on use
- Remind participant about use of Sleep Diary; answer questions
- Fax/Scan all completed Data Collection Forms to UCSF CC.

Post in-clinic visit (minimum 5 days/120 hours following in-clinic visit)

- Collect Actigraph and Sleep Diary
- Download and save Actigraphy data.
- Verify Sleep Diary is complete and accurate, phone participant if necessary to complete.
- *Actigraphy files will be e-mailed to the UCSF CC daily (one e-mail sent for each participant.*
- *Sleep Diaries will be sent to the UCSF CC in batches every 2 weeks, via Federal express/mail.*

In-home PSG visit (0-30 days after in-clinic visit)

- Prior to in-home PSG visit (in clinic):
 - Set up equipment and supplies for in-home PSG visit
- Evening of in-home PSG visit (in participant's home):
 - Hook up participant for PSG
 - Perform signal verification & check for any medical alerts

- Update the Medication Inventory Forms that were completed at the Clinic Visit, include any medications that have been taken within 24 hours of the overnight sleep study.
- Provide instructions for completion of morning survey, in-home urine collection
- Begin PSG recording
- Morning after in-home PSG visit (in participant's home):
 - End PSG recording and remove PSG from participant
 - Collect PSG morning survey and urine specimen, return to clinic
- Post-PSG (in-clinic):
 - Clean Electrodes and Sensors
 - Review PSG study
 - Fax/Scan PSG Morning Survey, specimen collection, and updated Medication Inventory Forms to CC data system
 - Copy PSG data to CD and immediately send to Reading Center

1.4 Glossary of Sleep Terms

Alpha rhythm:	EEG rhythm, usually with frequency of 8-12 Hz. in adults; most prominent in the posterior areas; present most markedly when the eyes are closed; attenuated during attention, especially visual. (Characteristic of relaxed wakefulness with the eyes closed.)
Alpha wave:	Individual component of an alpha rhythm.
Amplifier:	An electronic instrument used to increase the strength of an incoming signal.
Apnea:	Period (≥ 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 2 sleep.)
Lead:	Term used to denote a single electrode
Light sleep:	Sometimes used as a synonym for stage 2 sleep.
Location:	Physical site, or area
Low-voltage EEG:	EEG consisting of cerebral activity of 20 μV 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 stages 3 and 4 sleep.
Stage 1 sleep:	Relative low-voltage, mixed-frequency EEG without rapid eye movements; slow rolling eye movements are often present; vertex sharp waves may be seen; EMG activity is not suppressed.
Stage 2 sleep:	12-14 Hz. sleep spindles and K complexes on a background of relatively low-voltage, mixed-frequency EEG activity.
Stage 3 sleep:	Moderate amounts (20%-50%) of high amplitude (75 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.
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 1 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 1 sleep).
Wave:	Any transient change of potential difference in the EEG.

2.0 Polysomnography

2.1 PSG Equipment Care & Maintenance

2.1.1 Understanding the Electrode

The gold disk electrodes supplied by Compumedics 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 in maintaining your gold disk electrodes is 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**

2.1.2 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.

2.1.3 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.*

2.1.4 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	•			•
Thermistor (Airflow sensor)	•			•
Nasal Cannula	No, disposable			
Snap Electrodes (gel filled patch)	No, disposable			
Respiratory Band	Surface clean only	•		
Respiratory Band Covers	Hand or Machine Wash	•		
Re-Useable Oximeter Probe	Surface clean only (unless disposables used)	•		
Position Sensor	Surface clean only	•		
Leg Movement Sensors	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 household bleach. Disinfection procedures with dilute bleach for gold disk electrodes is well established. Thermistors 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, create a dilute solution of household bleach and water using 24 oz. water to ½ oz. bleach. (This is approximately a 1:50 bleach/water ratio).
- 5) Allow electrodes to soak in bleach solution for 20 minutes. Float any brush used in the same bowl, bristle-side down.
- 6) After 20 minutes, remove brush and electrodes from solution. Rinse electrodes under running water. Dry and place into storage for next use.
- 7) Discard bleach solution from bowl and dry the bowl.
- 8) Place cleaning brush into bowl and store for next use.

Thermistor:

(General cleaning followed by high- level disinfection)

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

Oximeter Probe, Position Sensor,**Leg Movement Sensors, ECG Electrode wires (white + red):**

(General cleaning that also provides low-level disinfection)

- 1) Provide initial cleaning by wiping these objects with a soft cloth that has been saturated with isopropyl alcohol (70-90%). Pay particular attention to remove any debris, which may be on the object.
- 2) Allow items to air dry.
- 3) Remove sticky tape residue with adhesive remover (such as Detachol).
- 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 and SUM box with a soft cloth that has been saturated with isopropyl alcohol (70-90%). If the white 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.
- 3) In order to preserve battery life, after each study ensure that both belts are unplugged from SUM box.

References:

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

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

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

2.2 Preparation for PSG Hookup

2.2.1 Confirmation of 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 subject has any sensitivity to adhesives or latex products.**

The subject should dress for sleep in loose, comfortable clothing. Encourage the subject to avoid wearing one-piece garment. If the subject indicates he does not wear clothing to bed advise him he must wear clothing below the waist during the PSG hook-up and inform the team he intends to disrobe before bed.

2.2.2 Readyng for the Home Set-Up

Preparation of Supplies:

Computer Supplies

- Laptop computer
- Dongle Key
- A/C power plug
- IR Interface Serial Cable

Safiro Equipment

- Safiro Recording Instrument
- 1 GB Flashcard
- Rechargeable battery
- Spare rechargeable battery or 4 AA alkaline batteries

Safiro Hookup Supplies

- 1 tube EC-2 paste
- 4 X 4 gauze pads
- 1 bottle Pre-Tac adhesive synergist
- tape measure – metric!
- precut 1 x 1 gauze squares, one for each EEG electrode plus extras
- scissors
- cotton tip applicators
- Skin tape: Scanpor is preferred; Transpore or Micropore are options
- Hair clips
- NuPrep or Lemon Prep abrasive
- 2 Blue Sensor snap electrodes
- 1 wax pencil (do not use red)
- 1 reusable oximeter sensor (attached to cable connected to recorder)
- 1 thermistor
- 1 nasal cannula
- non-latex gloves
- disposable underpads (Chux)
- drinking straws
- face mirror
- plastic bags (for contaminated electrodes)
- All necessary forms

Preparation for Home Hookup:

Electrode hook-up can be done with the participant in a comfortable chair or on the bed. 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.

The AC adapter should be used to power the laptop during the hook-up. The internal battery only lasts about 4 hours, so if there are problems during the hook-up or more than 1 home visit is scheduled for the night there may not be insufficient power to perform the second study.

2.3 Procedures for PSG Hookup

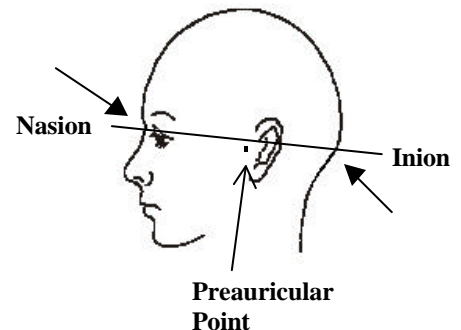
2.3.1 Electrode Placement Measurement

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 pre-auricular points (see glossary for definitions).

Identify your landmarks:

1) 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 pre-auricular 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.



2) 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.

3) 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 theinion 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.

Measure for electrode sites:

- Distance measurements are done with a *metric* tape measure, and taken in centimeters (cm.) and millimeters (mm.). When computing percentages to find the electrode site a quick measurement guide can be found below, as well as in the Equipment Maintenance Section. The guide can be photocopied and kept with your prep materials for handy reference.
- All marks on skin must be done with a non-toxic, non-permanent implement, such as a wax-based china marker. Bright blue is most easily seen against dark hair. Red can be misidentified as blood by the subject or family members, therefore is discouraged.
- When working with subjects having long or thick hair, create a part in the hair by means of a comb or the unpadded 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.)
25	12.5	5.0
26	13.0	5.2
27	13.5	5.4
28	14.0	5.6
29	14.5	5.8
30	15.0	6.0
31	15.5	6.2
32	16.0	6.4
33	16.5	6.6
34	17.0	6.8
35	17.5	7.0
36	18.0	7.2
37	18.5	7.4
38	19.0	7.6
39	19.5	7.8
40	20.0	8.0

Note: If the *total* value measurement contains a fraction, continue to use the percentage values as the whole number.

Example: Total measurement = 35.2, 35.5, 35.7 continue to use the percentage values for 35.

Remember: The 50% values are used to determine Cz.

The 20% values are used to determine C₃ and C₄.

To determine Cz:

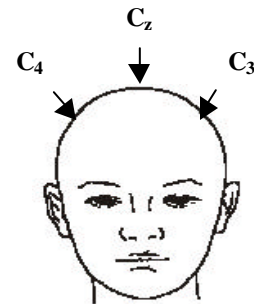
Have the subject sit in a chair. Standing at the side of the subject, place the zero line (0) of the tape measure on the marked inion. Holding the tape measure in place with your non-dominant hand, stretch the tape measure upwards, over the crown of the head, until it reaches the marked nasion. Determine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

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

3) Remove the tape measure and stand behind the 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.

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 measure make another line, following the edge of the tape measure, to intersect the 20% mark. After removing the tape measure, extend both lines so they intersect. The point at which the lines intersect is the site for the C4 electrode placement.

**To determine C3:**

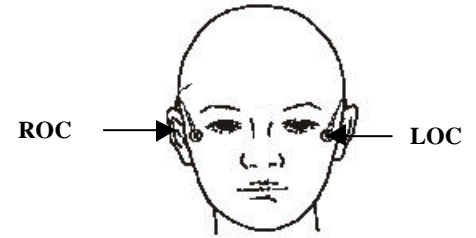
Stand in front of the subject. Place the zero line of the tape measure on the site for the Cz electrode placement. While firmly holding the tape measure in place, allow it to drape over the left side of the subject's head until it reaches the left pre-auricular mark. Compute 20% of the total pre-auricular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

To determine A1 and A2:

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

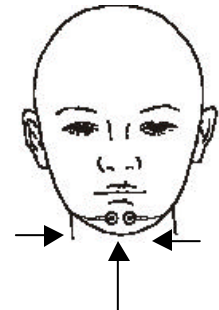
To determine EOG placements:

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

**To determine chin EMG placement:**

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

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



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

Reference:

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

2.3.2 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 $\leq 5 \text{ k}\Omega$ 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 while 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."

Preparing the Electrode Site

1. Place a small amount of skin prep abrasive onto a clean disposable surface (i.e.: 4x4 gauze square or small plastic med. cup).
2. If working in a hairy area, separate the hair in order to see the skin. You may find a comb or hairclips useful to create a part and hold the hair back.
3. Use a cotton-tipped applicator to transfer a small amount of skin prep directly onto the electrode site. Before lifting the applicator, apply a moderate pressure and make small circular motions repeatedly on the skin. Take care that you include the center of the site, not just make circles around it leaving the center un-prepped. You may prefer to use a combination of back and forth strokes along with some circular motions.

4. Continuing with moderate pressure, slowly count to 5 while you scrub the site (1 one-thousand, 2 one-thousand, 3 one-thousand, 4 one-thousand, 5 one-thousand). You are done when the skin “pinks up”. Expect some 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.

2.3.3 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. All sensors should be labeled to simplify their identification and connections.

[Note: When connecting the sensors, be sure to hold the electrode at the neck, **not** by the wires. Also, 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:

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

You will use 12 electrodes:

10 Gold disk Electrodes:

GND (Cz)
 REF (mid-forehead)
 C3
 C4
 LOC
 ROC
 A1
 A2
 L Chin
 R Chin

2 Snap Electrodes:

left ECG
 right ECG

Other Sensors:

- abdomen and chest belts
- 2 leg sensors
- oximeter
- nasal cannula
- nasal/oral thermistor
- body position sensor

Suggested Order of PSG Hook-up

Leg Sensor (2)	Below the knee on the outside of the upper shin (lateral aspect) on the belly of the tibialis anterior muscle, one sensor on each leg <i>Drop electrode wires underneath clothing (underwear, if worn) before attaching electrode to the leg and thread wire upwards</i>
ECG (2 snap electrodes)	White (–) below right clavicle. Red (+) below the left clavicle.
Respiratory belts (2)	Thoracic belt below left armpit Abdominal belt at the “belly button”. <i>When placing respiratory bands observe the participant’s breathing normally to determine proper positioning.</i> Attach power box to thoracic belt via Velcro.
Gold Disk Electrodes (10)	Head: REF (mid-forehead), GND (Cz), C3, C4, A1, A2, LOC, ROC, L Chin R Chin
Snap Electrodes (2)	L ECG, R ECG
Thermistor + Nasal Cannula	Between nose and upper lip. Tape sensors together prior to placement (thermistor sits on top of cannula). To place, cannula should rest inside of nostrils; heat sensors of thermistor should be near, but not touching, nares and upper lip. Tape well to maintain placement.
Oximeter	On a finger (preferably not index) of non-dominant hand, light diode on the nail
Position Sensor	Velcro square at middle and top of thoracic respiratory band. <i>Check function of sensor before placing.</i>

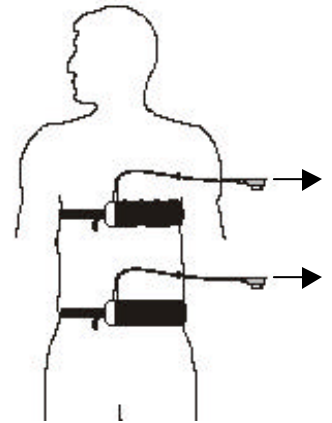
1. LEG SENSORS:

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.



2. RESPIRATORY BELTS:

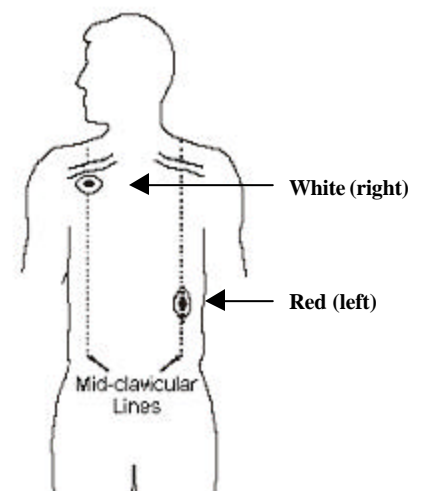
1. Place the black cover sheaths over the respiratory belts before applying to the participant.
 2. The **abdominal band** (blue wire) should be placed on the left side of the body around the lead wire facing upwards. Adjust the black extender belt so the belt is secure, but not tight.
 3. Place the **thoracic band** (yellow wire) under the left armpit, with the lead wire facing upwards. Adjust the black extender belt so the belt is secure, but not tight.
 4. After placing the thoracic belt wrap the wide Velcro holder around the extender at the chest and attach the Summit power box to the Velcro holder so the blue and yellow pin receptacles face the wires. The red and orange connectors will be to the subject's right.
 5. 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.
 6. The power light indicator on the Summit power box will begin to flash as soon as the first belt is plugged in. Make sure the low battery indicator is not flashing.
 7. After attaching the blue and yellow wires, pull any excess cover sheath over the power box. This will keep the box secure and clean.
- Incorrect application of respiratory bands can cause very poor signals.
 - Do not restrict the subject's comfort or breathing.
 - Summit IP belts are battery operated. They will not work if there is not sufficient battery power.
 - After study both belts must be unplugged from the SUM box to turn off battery.



3. ECG ELECTRODES:

White (-) electrode 3-5 cm.(2 finger breadths) below midpoint of right clavicle. Red (+) electrode is below the left ribcage

1. 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.
2. Snap electrode to lead wire **before** applying to subject's skin, unless you have offset snaps.
3. Form a small "stress" loop with the wire immediately feeding the electrode, secure with a small amount of tape.



4. EEG SCALP ELECTRODES (Gold Disk):

Attaching Gold Disk Electrodes

The gold disk electrodes are applied to the prepared sites (see 2.3.2) 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 EC2 electrolyte paste onto a clean disposable surface (i.e.: 4x4 gauze square, small plastic med. cup, or the back of your gloved non-dominant hand).
- If working in a hairy area, separate the hair in order to see the skin. Your site should still be visible from the prep phase.
- If the participant is expected to sweat, there are additional skin preparations that reduce the moisture of the skin (such as PRE-TAC) and help improve the holding power of the adhesive. Try experimenting with such preparations. Generally, these liquids are applied very sparingly to prepped skin and allowed to dry before continuing with electrode application.
- Before using tape, ask the subject about sensitivity to tape, latex or adhesives. **Scanpor is a hypoallergenic tape and is recommended for use in this study.** Micropor (paper) tape is another option, but is not preferred.
- If using EC2 cream on the gauze square to anchor the electrode, it must also be the electrolyte used within the electrode cup.
- When applying disk electrodes, work in a fashion so that the wires on the forehead and top of the head all point to the back of the head and down toward the neck, and the wires on the face and chin point upwards over the ears and then down toward the back of the neck. Use a small piece of tape or coban to hold the wires together at the back of the head, but allow enough slack so there is no pull when the subject moves.
- 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 tape (Scanpor is preferred for facial skin).

2.3

3. Press lightly on the top of the electrode as well as firmly around the rim of the cup to insure a good seal. Hold in place until electrolyte begins to set and feels secure.
4. A larger second piece of tape may be placed over the electrode, if desired.

Scalp with hair:

1. Separate hairs to make sure skin is visible.
2. Using the above technique, fill the electrode cup with EC2 cream and attach to prepped site.
3. Cover the electrode with cut gauze pressing firmly on electrode and hold in place until EC2 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 beard back over the electrode. Apply a small dab of EC2 to the gauze before applying over the electrode.

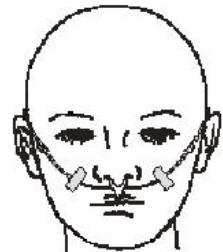
Provide additional security for the head electrodes by using Head Net, which can be placed either like a stocking cap or in an “over the head and under the chin” fashion. Not all subjects will be tolerant of Head Net .

5. ECG SNAP ELECTRODES:

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

6. THERMISTOR AND NASAL CANNULA:

Prior to placing these sensors, check the nasal beads of the thermistor and adjust their position by bending them forward at a 180° angle. This prevents them from riding up into the nostrils while keeping them exposed to exhaled air. Tape the bodies of the thermistor and cannula together, with the thermistor resting on top of the cannula. These 2 sensors will be then placed as a single unit between the nose and upper lip. The nasal prongs of the cannula must be resting within the nostrils but the beads of the thermistor must be outside of the nostrils but in the path of airflow. Secure in place by looping the wires around ear and loosely cinching the slides near the back of the neck. Additional tape should be placed to hold the wires at the cheeks.



Note: The thermistor is sensitive to displacement or moisture, so keep the upper lip dry. Nighttime beverages should be consumed through a drinking straw.

2.3

There is a disposable thermistor that can be a back-up should the reusable sensor not be working properly. It only comes in “adult” size and requires an extender cable. Size is not a problem with

this sensor since the beads can be positioned near the nostrils of even a small child. It is worth having this available as a back up.

If the subject is intolerant of the nasal cannula, the PSG may be performed without. A note of explanation must be provided on the SV form.

7. OXIMETER:

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

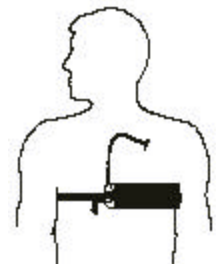
Directions for non-disposable probe: Place probe onto the Flexi-wrap sensor holder following the guide holes and illustration. Place the finger into the sensor nail-side up with the tip of the centerline mark in the curved area. Wrap the tape firmly around the finger. The fingernail should not be covered with tape during this step. Fold the sensor's top over the top of the finger and make sure the two sides are vertically aligned. Do not stretch the tape while applying the sensor. This may cause inaccurate readings or skin blister. Be sure that the emitting and receiving diodes directly “face” each other.

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

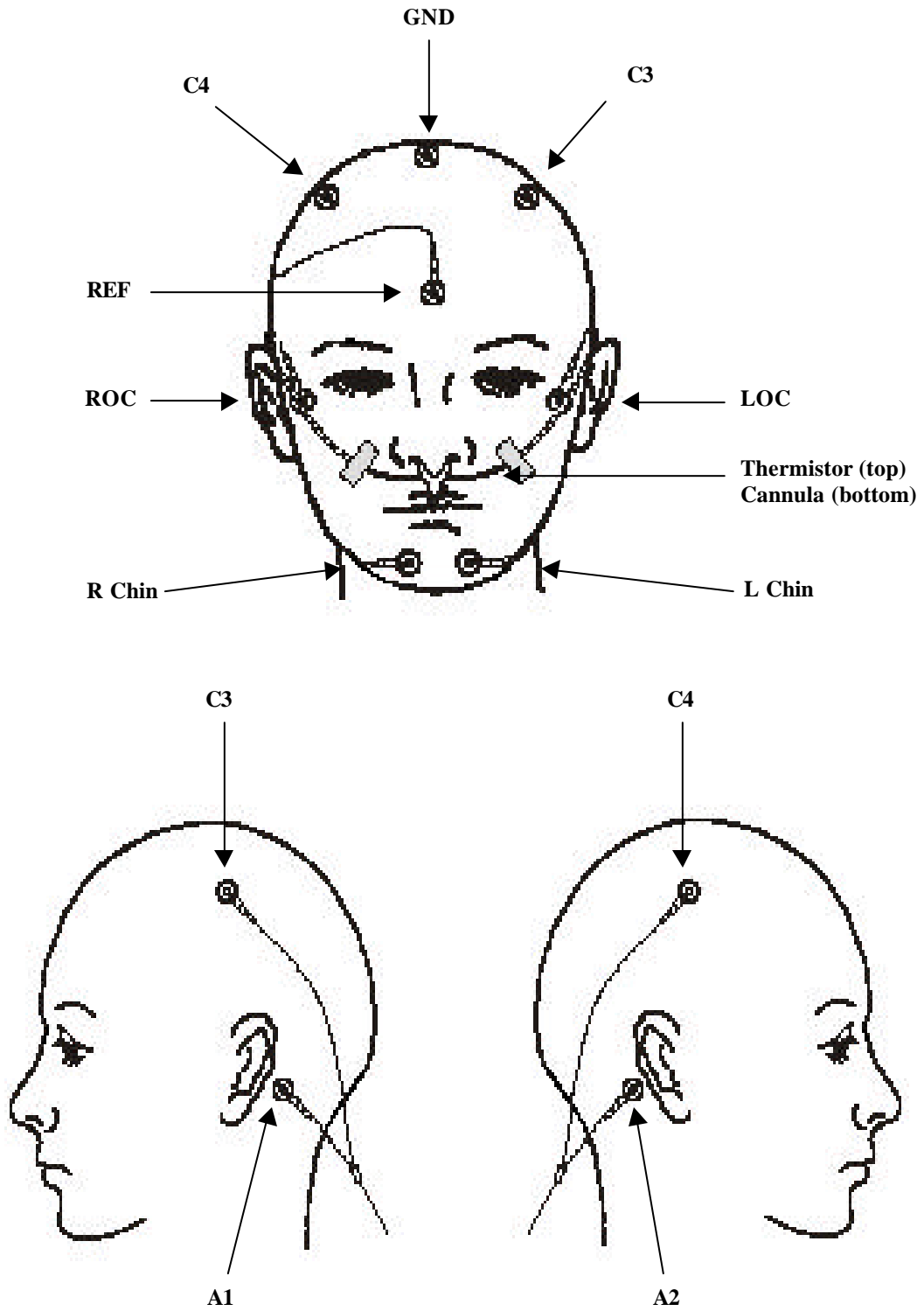
After securing oximeter sensor, ask the participant if any throbbing is felt. If so, reapply, loosening tape. Pass the oximeter cable over the surface of the hand, creating a circular “stress” loop, also securing with tape. Use several additional pieces of tape along the hand and arm, running the oximeter cable up the entire length of the arm to the shoulder, taping the connector to the shoulder. Check that the subject has free movement of the hand and arm.

8. POSITION SENSOR:

Before attaching the sensor to the subject its function must be verified. Check the sensor function by holding it in your hand and simulating movement to each direction. Wait long enough to see that the changes in the position channel on the computer are correct for the position. Then attach the position sensor to the Velcro chest extender or top of sleepwear making sure that the figure on the sensor matches that of the subject (head near the head, L to the left, R to the right). Apply tape as needed to further secure the position sensor.



Electrode Placement Quick Reference



2.4 Procedures for Safiro Setup

2.4.1 Power up Laptop

Be sure dongle is attached to laptop before powering on. Attach IR Device to serial port on back of laptop.

2.4.2 Prepare and Power up Safiro

1. **Be sure a formatted flashcard is in the Safiro ready for recording.** This is inserted arrow side up when the Safiro is powered off. You must format the flash card sometime *after* data has been confirmed received at the data center. We recommend that you do this formatting as part of your setup for the next PSG. See Section [5.3](#) for formatting instructions.
2. Insert **completely charged** Compumedics rechargeable battery (or 4 AA alkaline batteries), close Safiro back plate, and secure with retaining screw.
3. Align the IR Device with the Safiro IR Port
4. Turn the Safiro on by holding down the small power button until the amber light comes on.

2.4.3 Open and Configure Safiro Recording Software

1. Open Recording Software

Open Online IRDA (Safiro communication program) by double-clicking the icon.



This will open PSG Online, which will access the Safiro via the IR port and will display the Safiro ID at the top of the back screen. If you do not see the Safiro ID displayed, make sure the Safiro is turned on.



Once the Safiro is recognized, PSG Online will begin to upload the configuration.



2. Configure Device for a New Study

From the Safiro Command bar click on “New.”



On the New Study screen complete the information as follows:

Surname: Enter Participant ID

Given Name: Leave this blank

Reference: Enter Safiro ID-Tech ID

Date of birth will default to the current date – do not change this.

Sex: do not identify the sex.

Configuration: Select **MrOS** from the list.

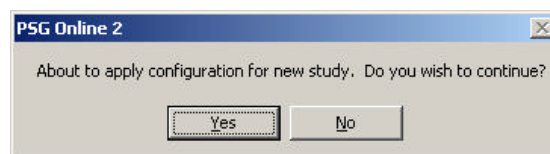
Check “Record to Siesta’s Flash Disk” (If this option is not available it is because the Safiro does not have a formatted flash card or it is not properly inserted. Power off the Safiro and insert a freshly formatted card, arrow side up. Power the Safiro back on and continue from step one of this section.)

“Record to Local Drive” should be grayed out. This is not an option for the Safiro.

“Perform summary analysis during data capture” should be grayed out.

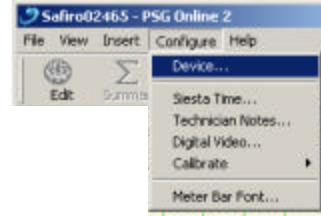
Click **OK**.

Select “Yes” to apply configuration



3. Verify Device Settings

Select the menu item **Configure → Device...**



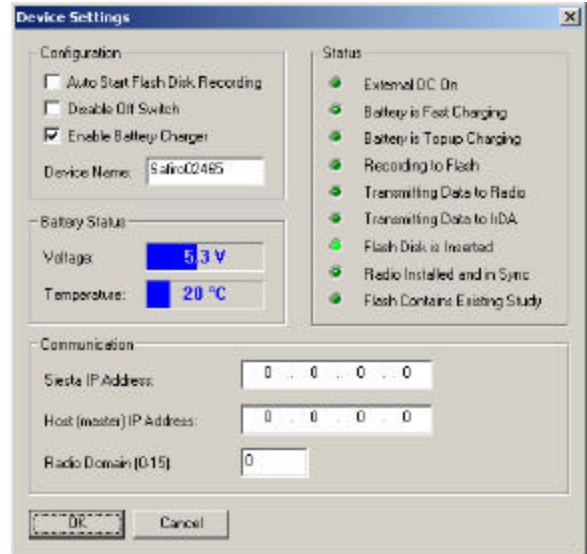
Verify Device Settings as follows:

Auto Start Flash Disk Recording: not selected

Disable Off Switch: not selected

Enable Battery Charger: selected.

Battery Status:
Voltage should be above 4.7 V



Click **OK**.

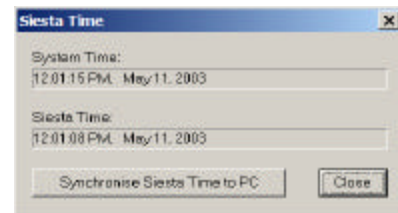
4. Verify Device Time

Select the menu item **Configure → Siesta Time**.

Click **“Synchronize Siesta Time to PC”**

NOTE: This will set the Safiro's time in sync with the laptop's time. Verify that the laptop time is set correctly, and change if necessary before synchronizing Safiro time. If unable to correct laptop time note on SV form.

Click **Close**.



5. View Signals

Click **View** on the toolbar.



The Safiro is now set up to preview signals after the hookup is complete.

6. Begin Recording

When the hookup is complete, begin recording by clicking the “Record” button on the toolbar. It will toggle on and the status window will show red “REC.”



2.4.4 Check Impedances and Signal Quality

Impedance Checking

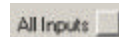
Impedance defeats the passage of signals into the electrode and, in turn, the recorder. For PSG studies, impedance value is measured in Kilohms, or thousandths of an ohm. Later the manual abbreviation k will be used for Kilohms.

1. Open Impedance View

Click on Impedance button on the toolbar and a display to the right will list channels.



- The impedance level of the channel will be displayed in Kilohms ([value] k).
- Slide the bar to select **5k** for the Threshold
- Select “**All Inputs**” by clicking on that box.
- Impedance readings above 5k will display in red.



2. Annotate Signal Verification Form

Enter impedance values on the **Signal Verification Form**.

- For ECG impedance of < 30 k are acceptable.
- For EEG, EOG, and EMG, you want to achieve impedance of < 5k. Most important is the balance (difference) between two sets of paired EEG electrodes. For accurate recording the difference in impedance levels between pairs of EEG electrodes should be less than 3k.

If all electrodes register high:

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

Impedances (Record Value in kohms):

	First Check	# Times re-prepped (*0* if none)	Final Value (if re-prepped)
C3			
C4			
A1			
A2			
ROC			
LOC			
ECG1			
ECG2			
Chin 1			
Chin 2			

If only certain electrodes register high:

If impedance of any electrode (other than ECG) is > 10 k, or the difference between any pair of electrodes is > 3 k remove the electrode that registers high, re-prep the site and replace the electrode.

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

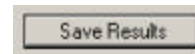
- a) the area of the skin identified for sensor placement has an unusually high impedance; or
- b) the lead wire or sensor is damaged.

Therefore, attempt to address both potential problems by choosing an alternative electrode site (e.g., immediately adjacent to previous site), and change lead wires.

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

3. Save Impedance Check Results

Click on the **Save Results** button.



4. Return to Signal View

When finished, disable impedance testing by clicking on the Impedance button on the toolbar.



Assessment of Signals

Look at each signal on the upper and lower screens. Make sure that all signals look clean and each respiratory channel shows visible deflection (movement). The upper screen will scroll faster than the lower screen. The upper screen is set to a 30 sec timebase and shows gold disk and ECG signals. The lower screen is set to a 2 min timebase and shows leg movement, all respiratory and oxygenation signals as well as position of the participant.

Complete the Assessment of Signals section of the Signal Verification Form, being sure to include the value or reading for SaO₂, HR and STAT.

2.4.5 Document Physiologic Events

As part of the set-up, each channel of the recording should be checked to see that the electrodes are collecting accurately. When instructing the participant to provide signal verification remember that changes on the screen will not be immediate. Complete the Physiological Events section of the Signal Verification Form.

To add a technician note in PSG Online click on the "Note" button on the toolbar.



Select the appropriate note from the drop-down list and click **Close**.

1. Ask the participant to blink several times. Expect to see upward deflections on the eye channels (LOC and ROC). Ask participant to look to the left, then to the right. Expect to see out of phase movement on eye channels.
2. Ask the participant to close their eyes and relax. Expect to see nice signals on the EEG channels (C3-A2 and C4-A1).
3. When settled, ask the participant to swallow or grit his teeth or stick out his tongue. Expect to see a large change in the chin channel.
4. Make sure that the ECG channel displays a reasonable QRS waveform.
5. Look at the signals on the lower screen. Ask the participant to move the left leg, then the right leg. Expect to see a change on the leg channels.
6. Ask the participant to hold his (her) breath and count to 10 slowly, if possible. Expect to see flattening of the respiratory channels and possibly a change in the oxygen saturation. Adjust respiratory sensors, if needed.

2.4.6 Exit PSG Online

If no further adjustments are needed, close the PSG Online window by clicking on the X in the upper right corner of the screen. Do not end the recording, the red REC light should still be flashing when the IR screen is closed.



Shut down and put away the laptop.

2.5 Provide Final Instructions and Exit the Home

Zip the pouch and provide any final instructions as necessary while cleaning the prep area and packing the laptop. The subject should not be expected to operate the instrument but should know how to move about comfortably while wearing the Safiro. Provide a drinking straw for beverages to keep the cannula and thermistor dry and in place. Make final instructions on writing down bedtime and any other important information and discuss how to remove the equipment in the morning and how to isolate the dirty electrodes (provide a plastic bag). Discuss the morning pick-up of the Safiro. Exit the home taking the laptop and set-up supplies.

THE SAFIRO WILL RUN ON BATTERIES FOR 24+ HOURS PROVIDED THE BATTERY HAS BEEN FRESHLY CHARGED*.

*Potential to Cause Data Collection Failure If Protocol Is Not Followed

2.6 Troubleshooting Equipment and Signal Quality

2.6.1 General Approach to 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, RSO (returned for service order), 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.
- Call Compumedics Support Line with problems with Safiro. You will be assigned a Site Customer ID. Be sure to give this ID number when you call for support.

Site Customer ID _____

Compumedics USA Technical Support Hotline:

1-877-294-1346

New Numbers Not Yet In Service:

1 800-814-2965 or 1-800-474-7875

2.6.2 Troubleshooting Guide

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

PROBLEM	LIKELY SOURCE	ACTION TO CORRECT
Low amplitude of respiratory	<p>Incorrect placement or application of sensors.</p> <p>Belts not plugged into power box.</p>	<p>Check positioning and tension of respiratory belts. Observe which muscles move during respiration to determine where to place belts for optimum recording (notate on signal verification form).</p> <p>Plug belts into power box, check readings on light indicators on power box. Replace battery to power box, if necessary.</p>
Low (<95) oximetry values.	<p>Incorrect placement or application of sensor (nail polish or acrylic nail?).</p> <p>History of lung or heart disease.</p>	<p>Change site of oximetry sensor, have participant remove polish/acrylic nail. Check integrity of sensor by removing it from participant and placing it on yourself.</p> <p>Confirm with participant, annotate on SV form.</p>
No data on card upon download.	<p>Safiro not set to record to flash card.</p> <p>Compact Flash was not placed in Safiro or was placed incorrectly.</p> <p>Battery failure.</p>	<p>Confirm that Safiro is set to record to flash card.</p> <p>Remember to place Compact Flash before hook up. Place in Safiro arrow side up.</p> <p>Use freshly charged battery or use 4 AA batteries. Check voltage of battery at time of hook-up.</p> <p>Recondition rechargeable battery monthly.</p>
Absent airflow signals	<p>Mouth breathing and/or improper position of the oral portion of the sensor.</p> <p>Broken sensor beads.</p> <p>Thermistor not plugged in.</p>	<p>Reposition sensor to better pick up warm airflow from the mouth.</p> <p>Check position of thermistor beads and adjust, if necessary.</p> <p>Go to back-up disposable sensor.</p> <p>Check connections and plug in.</p>

PROBLEM	LIKELY SOURCE	ACTION TO CORRECT
Respiratory bands malfunction	Electrodes may be broken. Belts not plugged into power box. Low battery level.	Contact Compumedics for assistance. Plug in belts; or unplug and re-plug. Replace battery in power box. Check for low light indicator. Always good to have one back-up band.
Position sensor gives incorrect reading.	Sensor was not calibrated prior to recording. Mercury in the sensor may be malfunctioning.	Calibrate sensor at time of hook-up (see below). Contact Compumedics for assistance.
Safiro will not power up.	Battery is missing or poor connection.	Open the unit, check for presence of battery. Remove and re-seat battery correctly.
IR (Laptop) does not acknowledge Safiro.	Safiro is powered off.	Power up Safiro, look for flashing orange light.
PSG Online (through IR) sees the Safiro but will not upload configuration.	The Safiro has already been accessed once and PSG Online closed. Once the IR screen is closed you will not be able to access it again without powering off the Safiro Recorder (which will end the study).	Power off the Safiro, ending the study. Realign the IR device, re-power the Safiro and reestablish the IR connection. Once back on, the Safiro must be reconfigured through "New". If recording has been started, the old data written to the card will be lost when reconfiguring the card.
Channel values do not display correctly: HR shows ???, SaO2 and STAT show a voltage.	Safiro may lose its calibration if the unit is powered on without the oximeter, nasal pressure module or position sensor plugged in at the time of power-up.	See the next section and follow the steps to recalibrate the channels, as needed.

2.6.3 Channel Calibration

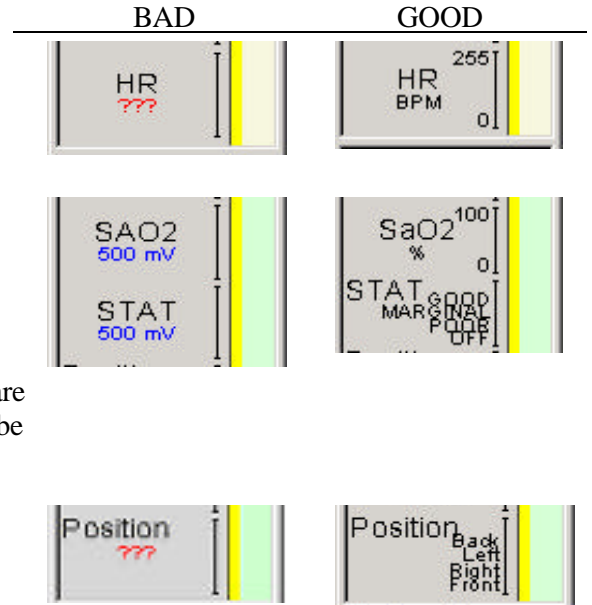
Certain channels may require calibration if they are not giving the proper signal. The initial calibration is set in the montage, but you may need to reset it manually if you experience problems.

Channels that may require calibration:

- Oximeter
 - If HR reads “???” instead of BPM
 - If SaO2 reads a voltage instead of %
 - If STAT reads a voltage instead of a value

Note: since all three of these channels are derived from the oximeter, if one needs to be recalibrated, all three will need to be.

- Position Sensor
 - If Position reads “???” or is reading incorrectly



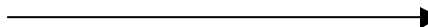
To Calibrate Channels

1. Power up Safiro and laptop and access PSG Online as for a study subject (see Section 3.3.2)
2. Once in PSG Online, choose the MrOS configuration by going to File → Open Study Configuration.

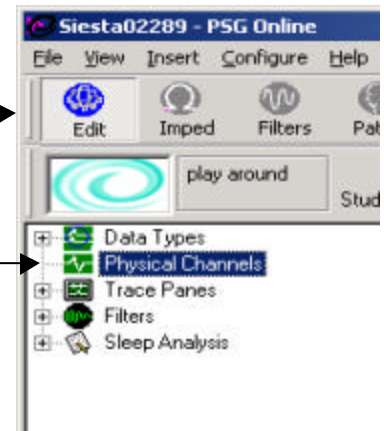
3. Make sure the icon for VIEW is toggled off.



4. Select the EDIT toolbar icon.



5. From the drop-down menu at the left, choose Physical Channels.



6. A graph will appear to the right. In the “Channel” column, find the name of the channel you wish to calibrate (Position, STAT, or SaO2). In the “Data Type” column, right click on the cell next to the channel you wish to calibrate (in the picture below, if calibrating Position, right click the first cell in the data type column with “DC”). Left click on ADD CALIBRATION or MODIFY CALIBRATION.

	Channel	Data Type
Special DC 1	Position	DC
Special DC 2	Left Leg	Leg Movement
Special DC 3	Right Leg	Leg Movement
Special DC 4	Snore MIC	Sound
Internal AC 5	C3	EEG
Internal AC 6	C4	EEG
Internal AC 7	L occipital	EEG
Internal AC 8	R occipital	EEG
Internal AC 9	A1	EEG
Internal AC 10	A2	EEG
Internal AC 11	ROC	EEG
Internal AC 12	LOC	EEG
Internal AC 13	ECG 1	ECG
Internal AC 14	ECG 2	ECG
Internal AC 15	Chin 1	Chin EMG
Internal AC 16	Chin 2	Chin EMG
Internal AC 17	CH17	Off
Internal AC 18	CH18	Off
Internal AC 19	CH19	Off
Internal AC 20	CH20	Off
Internal AC 21	CH21	Off
Internal AC 22	CH22	Off
Internal AC 23	CH23	Off
Internal AC 24	CH24	Off
Internal AC 25	CH25	Off
Internal AC 26	CH26	Off
Internal AC 27	CH27	Off
Internal AC 28	CH28	Off
Special HP 29	Airflow	HP air flow
Special HP 30	CH30	Off
Special HP 31	Thoracic	HP belts
Special HP 32	Abdominal	HP belts
Oximeter Status	STAT	Oximeter
Oximeter Heart	HR	Oximeter
Oximeter SaO2	SaO2	Oximeter

Position Front STAT GOOD HR 0.00 BPM SaO2 0.00 %

7. This will open the Calibrate Channel window. The channel you selected in step 6 will be selected. You can change channels by clicking the **Next** button. The Name of the current channel will appear in the **Label** box.

8a. Calibrating the Position Sensor

Settings:

Calibration Type: **Step Calibration**

There should be four Labels:

Back
Left
Right
Front

(If there are not 4 positions, add them by clicking on the Append Point button, then rename the Label to Back, Left, Right and Front)

Calibration:

With the position sensor attached to the Siesta, hold the sensor in your hand and simulate one position, and then click the **Acquire** button for that position label. Acquire readings for the other positions in like manner.

When all four positions have been acquired, click **Set Calibration**.

A box will show "Calibration updated successfully." Click **OK**.

Click **Close** (or **Next** if you have other channels to calibrate).

Channel: 1 Label: Position Next ->

Calibration Type:
 Step Calibration
 Linear Calibration

Unit:
 Upper Limit:
 Lower Limit:

	Label	Reading
1	Back	12446
2	Left	15971
3	Right	21907
4	Front	5792

Acquire
Acquire
Acquire
Acquire

Current Reading: 5784

Append Point Delete Point Set Calibration Close

8b. Calibrating SaO2

Check the following settings:

Calibration Type: **Linear Calibration**

Unit: %
 Upper Limit: **100.00**
 Lower Limit: **0.00**

Click **Close** (or **Next** if you have other channels to calibrate).

Channel: 35 Label: SaO2 Next ->

Calibration Type:
 Step Calibration
 Linear Calibration

Unit: %
 Upper Limit: 100.00
 Lower Limit: 0.00

	Value	Reading
1	0	0
2	100	100

Acquire
Acquire

Current Reading: 127

Append Point Delete Point Set Calibration Close

8c. Calibrating HR

Check the following settings:

Calibration Type: **Linear Calibration**

Unit: **BPM**

Upper Limit: **255.00**

Lower Limit: **0.00**

Click **Close** (or **Next** if you have other channels to calibrate).

Channel: 34 Label: HR Next ->

Calibration Type

Step Calibration Unit: BPM

Linear Calibration Upper Limit: 255.00

Lower Limit: 0.00

	Value	Reading
1	0	0
2	100	100

Acquire
Acquire

Current Reading: 511

Append Point Delete Point Set Calibration Close

8d. Calibrating STAT

Settings:

Calibration Type: **Step Calibration**

There should be four Labels:

Good
Marginal
Poor
Off

Click **Set Calibration**.

A box will show “Calibration updated successfully.” Click **OK**.

Click **Close** (or **Next** if you have other channels to calibrate).

Channel: 33 Label: STAT Next ->

Calibration Type

Step Calibration Unit:

Linear Calibration Upper Limit: 0.00

Lower Limit: 0.00

	Label	Reading
1	GOOD	128
2	MARGINAL	132
3	POOR	160
4	OFF	192

Acquire
Acquire
Acquire
Acquire

Current Reading: 511

Append Point Delete Point Set Calibration Close

9. Save the refreshed calibration(s) by selecting **File → Save Study Configuration**.

Choose the configuration “**MrOS**” and click **Save**. You will get a message that says “The configuration file name entered already exists. Do you want to continue anyway?” Click **Yes**.

10. Restart the study by clicking on the **NEW** icon on the toolbar, and apply the updated MrOS configuration.

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3.0 PSG Data Retrieval and Study Review

3.1 Converting Study – Data Card Manager

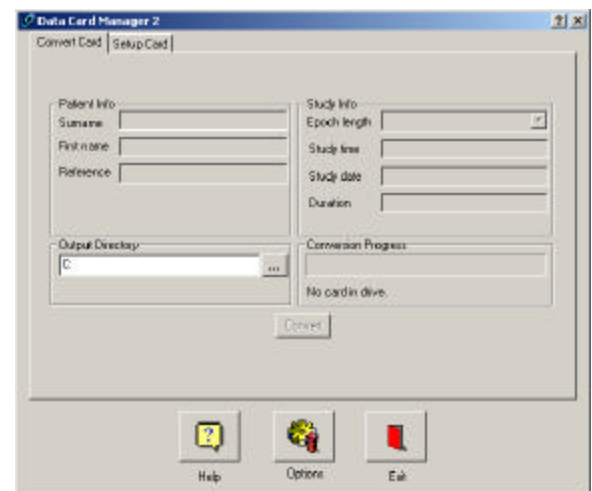
- Make sure the Safiro is powered off before attempting to remove the flashcard.

1. On the laptop, double-click on the Data Card manager icon.

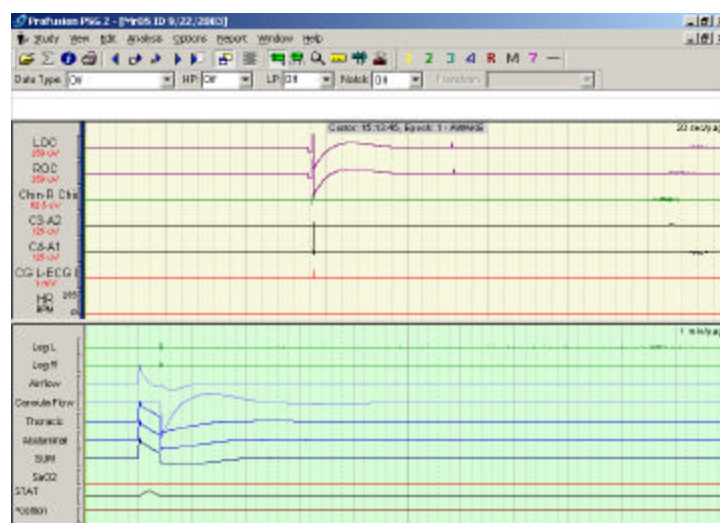


2. Choose the Convert Card page.

3. Insert the flashcard, Compumedics side up, into the lower slot of the flashcard reader. When the reader recognizes the flashcard the conversion will begin automatically. Allow at least 5 minutes for the card to convert. Do not interrupt the conversion process.



Once conversion is complete the card manager will automatically open the Profusion PSG 2 review screen.



3.2 Reviewing Study - ProFusion PSG 2

- ProFusion PSG 2 software is used to view and score studies after collection. On the morning following the sleep study, the study should be viewed in Profusion and the Sleep Study Evaluation form filled out. **ONLY VIEW THE STUDY – DON'T ATTEMPT TO PERFORM ANY SCORING OR EDITING OF THE COMPLETED STUDY WITH THE PROGRAM. PER PROTOCOL, THIS MUST BE DONE BLINDED WITHOUT CLINICAL CORRELATES AT THE READING CENTER BY READING CENTER STAFF.**
- The review of the study gives the technician an opportunity to review the signal quality and determine if the equipment needs to be checked or a hookup technique needs to be reviewed and modified. Loss of oximetry signal, for example, may be the result of a damaged cable that needs to be replaced or an application issue that needs to be addressed. Poor signal quality (“No” answers to questions 1 through 6) must be investigated and resolved prior to the Safiro Sleep System being used for another sleep study. If the Study Coordinator is the designated person to review the study, any signal quality problems must be reported to the PSG Technician(s) and a procedure established for following up with the Technician that the appropriate action was taken to correct the signal problem.
- The Reading Center will provide detailed feedback on any signal quality issue it identifies after receipt of the study, but the review of the study by the technician immediately after collection will help to establish expertise in troubleshooting equipment and sensor problems.

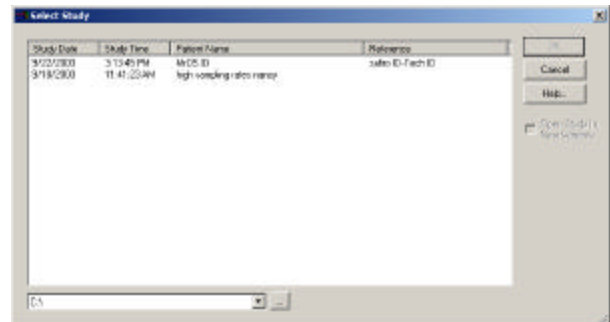
1. Open Study

Upon conversion from flashcard, studies will automatically open in Profusion PSG 2.

If the study was converted at an earlier time you must open the Profusion 2 PSG review software from the desktop by double-clicking the ProFusion PSG 2 icon.

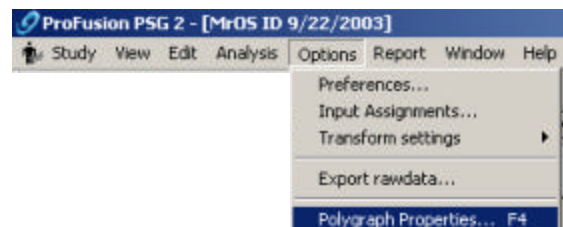


Then select the study you wish to open and click OK.

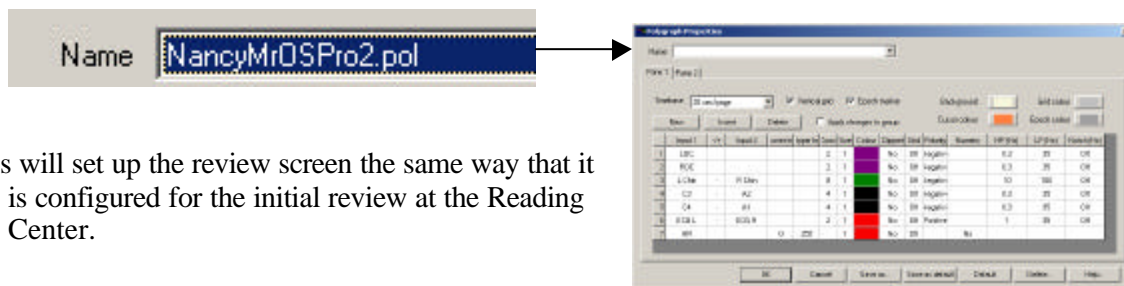


2. Configure Review Screen Properties

Choose the menu item **Options → Polygraph Properties**.

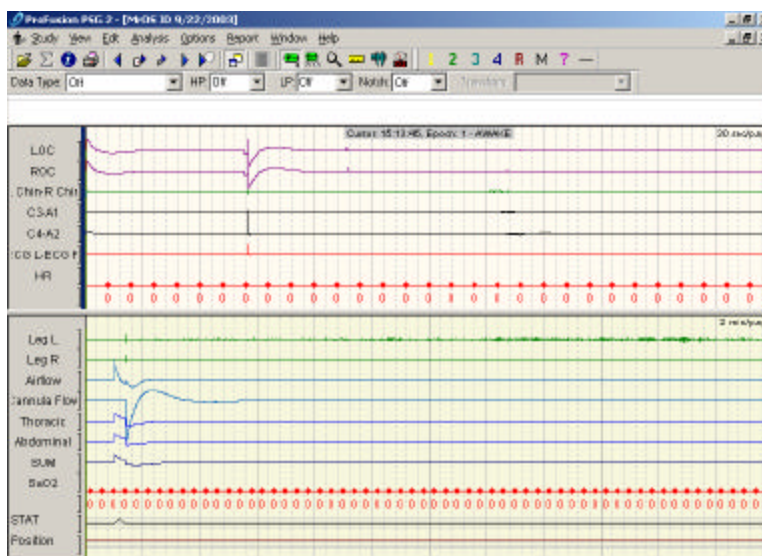


In the Polygraph Properties window, under **Name**, click the down arrow and select **NancyMrOSPro2.pol**



This will set up the review screen the same way that it is configured for the initial review at the Reading Center.

Click **OK** to return to the signal review screen.

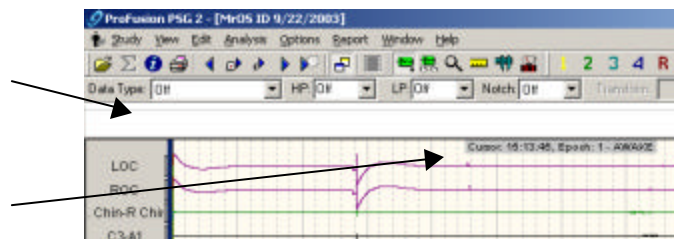


3. Review Study – Sleep Study Evaluation Form

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. When you have completed your review of the study, exit ProFusion PSG 2, and complete the **Sleep Study Evaluation Form**. Include any notes or comments regarding your review and any troubleshooting procedures done.

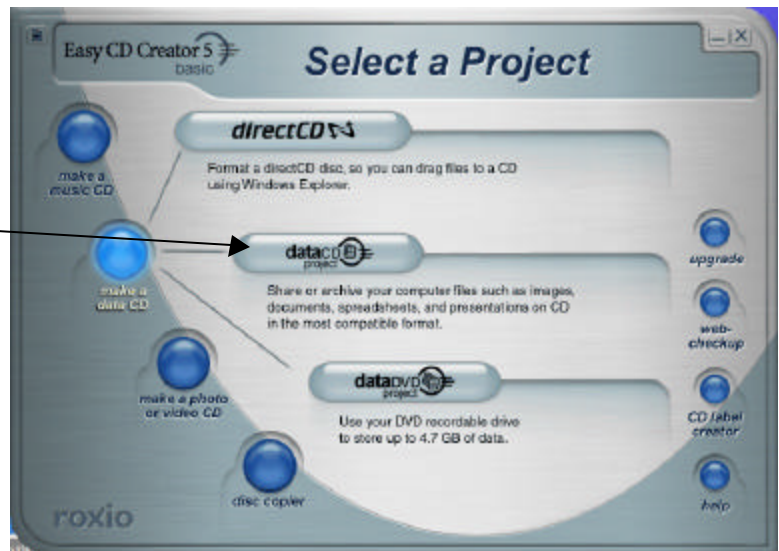
3.3 Copying Data to CDs – Roxio Easy CD Creator

Two CDs will be made of each sleep study after downloading to the computer. One CD will be sent to the Reading Center by overnight mail every week on Monday or Wednesday. The second CD will be kept at the site as a backup. Sending by overnight mail is important to allow the Reading Center an opportunity to review the studies and quickly identify any issues that may need to be addressed at your site or for the entire project. Depending on the size of the sleep study file (based on how many hours were recorded at the home), two to three sleep studies will fit on one CD.

1. Place a new, empty CD into the CD drive.
2. Wait a few moments and the CD creator screen will appear:

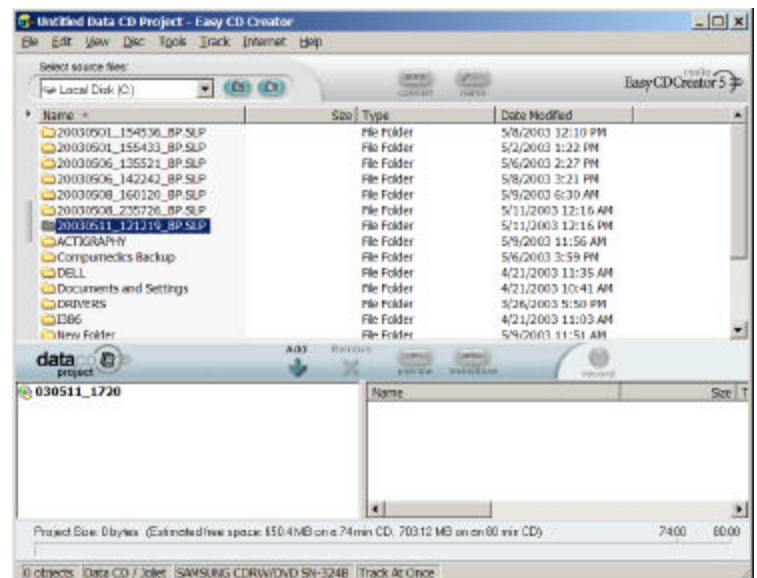
Select 'make a data CD' and click on the 'dataCD project' icon.

(The selection screen can also be accessed by selecting the 'Start Menu' → Programs → Roxio Easy CD Creator 5 → Applications → Easy CD Creator.)



3. The next screen will allow you to select the files you want placed on the CD:

Highlight the name of the file you want to place on the CD by clicking on it once and then click on the Add button. You will see the file name appear on the bottom section, listing files to be placed on the cd. If you have more than one study to place on the CD, you can select and add individually, or hold down the "Ctrl" key and click and highlight all the studies you want, then click on the Add button.



At the bottom of the screen a shaded "bar" will indicate how much room is available on the CD. If you "select" and "add" the studies individually, you will be able to determine if there is room for the third study based on the estimated space available displayed on this bar.

4. Finding files to put on the CD

Sleep Study - The Compumedics Program creates a folder for each study and places all the sleep files within it. These files include the raw data file, configuration files, respiratory and staging formats, etc. The folder naming convention is as follows:

20030511_121219_BP.SLP

[year][month][date]_[time recording started (24-hr format)]_BP.SLP

(e.g., this study was recorded on May 11, 2003; recording began at 12:12 pm 19 seconds.)

Copy this entire folder onto the CD.

5. Rename the CD Project

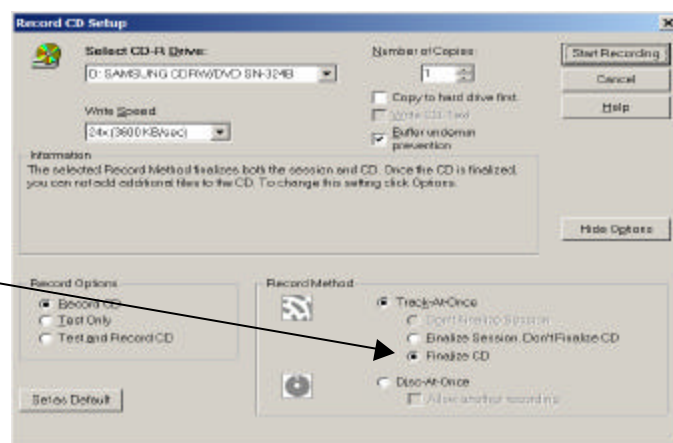
Click on the CD name (030511_1720 in this example) directly under the dataCD project icon on the bottom half of the screen. Rename it as your siteID_CD# (MN_001). Keep a log of CDs sent to RC and number CDs consecutively (i.e. MN_001, MN_002, etc.). Note in log studies that were on the CD and the date sent to RC.



6. Burn the CD

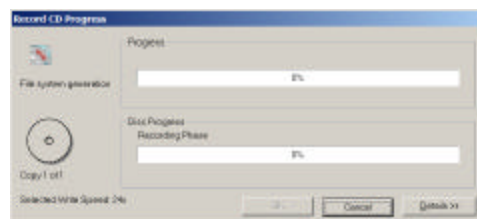
Once all of the files you want on the CD are in the 'Name' Column, click on the RED record button. The first time this screen comes up the 'Finalize Session' under Record Method will be checked - **DO NOT USE THIS SELECTION.**

Click on the button to finalize CD (this allows the CD to be read by any computer). If you do not finalize the CD it will not be readable in a non-RW CD drive and may be incompatible with other computers. Once selected, click Save as Default to have this setting come up each time the Setup screen is displayed. **ALWAYS** verify this is the selected recording method when making CDs.



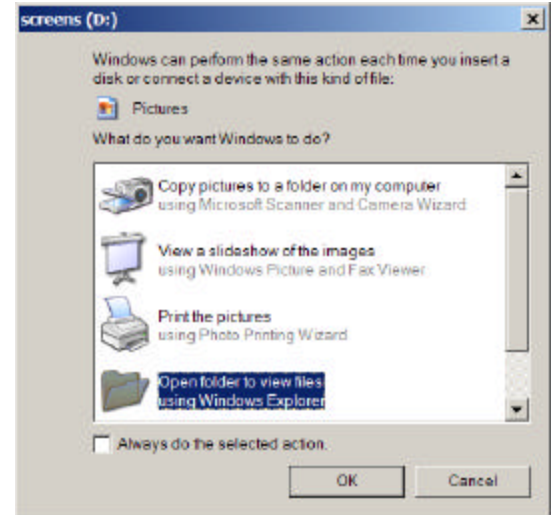
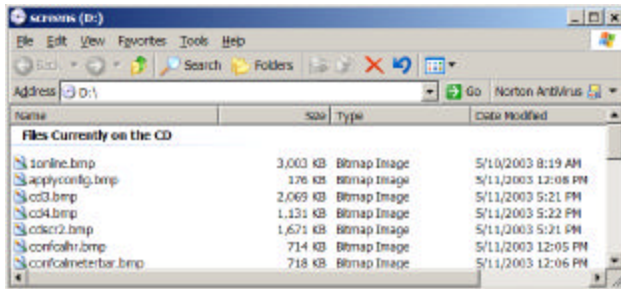
All other settings should match those as displayed, except for number of copies select '2'. When you have verified the selections are completed correctly, click on the Start Recording.

As it records the progress will be displayed and will display 'Done' when complete.

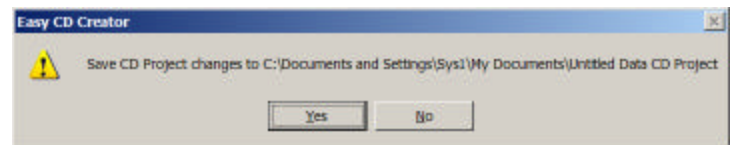


Once done recording, select **open folder** to confirm all files copied correctly.

Display of files on CD. Check in each folder that the "Rawdata.slp" file is approximately 200,000 kb and not 0. This is your actual sleep study file and if there is problem copying it due to some corruption during processing it will display as "0". If this happens, check the file on your hard drive and if that is complete - create a new CD.



After recording is completed, the program will ask you to save the layout that you used to create the CD. Select **No**.



7. Label and Ship the CD

Remove the CD and label it with the SiteID and date created. **YOU MUST** also write **ON THE CD** - the SubjectID and date of study for each study.

Prepare the overnight package. **Be sure to include a copy of the Signal Verification Form and Sleep Study Evaluation Form for each study.** Package should be sent to:

Susan Surovec
Case Western Reserve University
UH-Division of Clinical Epidemiology
11400 Euclid Avenue – Suite 260 (must include Suite #)
Cleveland, Ohio 44106-

Do not delete the sleep studies on the hard drive until you have received a Sleep Study Scored Report from the Reading Center. Occasionally there are problems with the copy on the CD that only show up at the time of scoring. If this occurs you will be asked to resend another copy made from the original on the hard drive.

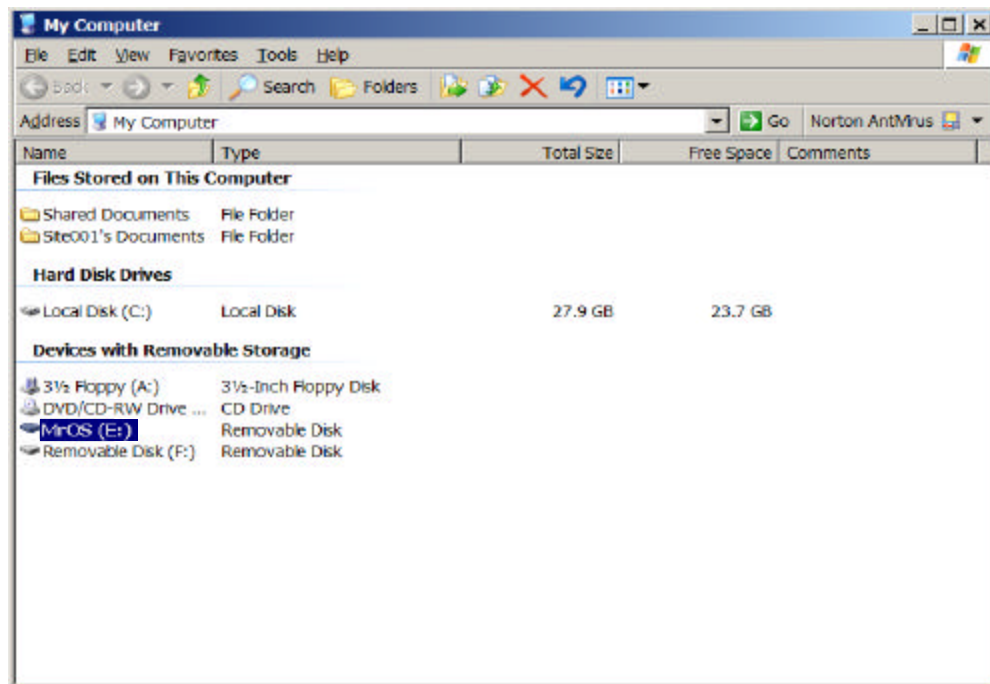
3.4 Reformatting the Flashcard

After the sleep study has been copied to the CD, you must reformat the flashcard before the next study is recorded. The Safiro will not record any data to a card unless it has been reformatted before each use.

1. Plug the SanDisk card reader into one of two USB ports on the back of the computer. The flashcard is inserted into the card reader with the arrow on the bottom side as you insert (Compumedics side up). **This is opposite how it is inserted into the Safiro.**

2. Click on the 'My Computer' icon.

The first time the card is reformatted it will display under Devices with Removable Storage as Removable Disk E. To avoid any possibility of reformatting the wrong drive you will need to name the flashcard **MrOS** in the appropriate box displayed below. (Note: Once the flashcard has been named with a reformat you will not need to do this again and it will appear as "MrOS (E:)" for all future formatting.



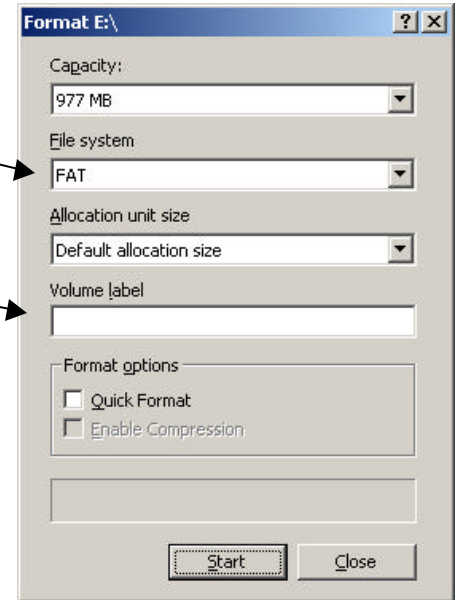
3. Right click on the MrOS drive (E:) and select 'Format.'

Under File System, you must select **FAT** and NOT FAT 32.

The first time you format a new flashcard there will be no name under Volume Label. **Type in MrOS**. After that it should read **MrOS** each time you format that card.

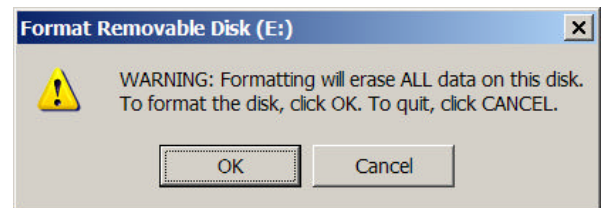
Do not check Quick Format

Click **Start**.

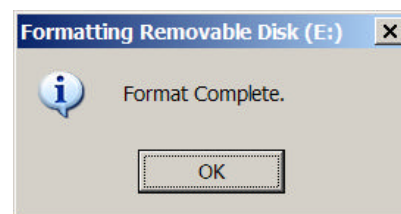


4. Confirm Format

You will be asked to confirm the format – make sure you are formatting E:, and click OK.



5. When formatting is complete, click OK.



The flash card is now ready to record another study.

4.0 Data Management at the Reading Center

4.1 Study Receipt

Upon receipt of studies at the Reading Center (RC) the Study Receipt\Quality form will be completed. The Receipt information includes: Subject ID, Study Date, CD number, date received, Safiro Number, and Technician ID. If there is a discrepancy between the data contained on the Signal Verification Form and the Compumedics Safiro Sleep Study recorded file or any missing data on the forms (i.e. Safiro number, Technician ID), an e-mail will be sent to the Site Coordinator requesting clarification. The data from the study receipt form will be entered into the Receipts table database.

A copy of the Signal Verification form and Sleep Study Evaluation form will be sent to the Reading Center regardless of the quality or length of the recording. If at the time of download of the flashcard there is no data, both of these forms must still be sent weekly. 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" for scoring at preliminary review, should still be sent to RC with any notes as to what troubleshooting was done, and if the reason for the short study can be determine. The Reading Center tracks all problems relating to lost sleep studies and must receive this paperwork on a regular basis. The problem studies are monitored and if any pattern is observed study wide we will contact Compumedics to assist in resolving

4.2 Preliminary Review

The Compumedics Profusion2 Offline Analysis program will be run at the Reading Center prior to review of studies by the Chief Polysomnologist (CP) and final scoring to allow generation of reports and visualization of signals and graphic screens. After offline analysis of the record, the CP, or trained Project Coordinator will then review each study to determine the overall quality. In addition, the CP will note any signal quality issues, possible monitor malfunctions, and recommendations for electrode replacements on the Receipt form.

The record must contain at least 4 hours of scorable EEG, oximetry, and respiratory data (either airflow, thoracic, or abdomen) to be classified as reliable sleep data. Studies containing less than the minimal requirements will not be processed for scoring and the site will be notified to request a repeat study from the participant.

4.3 Preliminary Feedback of Sleep Data

After preliminary review by CP is completed, the overall status of the record is entered into the Receipts table database (Status = 1 study passed, will be scored, and a full sleep study report will be generated; Status = 2 study signal quality insufficient to generate reliable sleep study data). Comments and feedback notes regarding quality of the study and equipment troubleshooting will also be entered into the Receipts table database.

A Preliminary Study Quality Report will be e-mailed to the Study Coordinator designated at each site which will contain: Subject ID, Study Date, Tech ID, Safiro Number, Overall status, and comments from the CP regarding study quality. These will be sent to the sites on Tuesday and will include all studies received the prior week.

Upon receipt via e-mail the site coordinator is to verify all information on the Record of Receipts is accurate and notify the RC of any changes or corrections to be made. This Preliminary Study Quality Report should be made available to the site technician(s) to insure quality issues are reviewed and recommendations from the CP regarding equipment and/or hookup procedures are addressed.

4.4 Assignment of Studies to Scorers

Studies identified as potential medical alerts will be triaged for immediate full scoring (within 48 hours of assignment to the scorer). Once fully scored and determined to meet criteria for Medical Alerts, a physician investigator will be asked to review the study. If the medical alert is ascertained, it will be logged into a Medical Alert Log and the site will receive the full report and quality grades (QS form) within a week after final scoring is completed.

4.5 Quality Grades (QS Form)

The quality of each signal and overall study quality will be assessed at the time of scoring of the record. The Scorer will code each channel of information according to the duration of i) scorable signals; ii) duration of artifact free signals during sleep, and iii) an overall QA grade to each study. The total duration of the study (from Time to Bed to the lights on) and the total duration of sleep will also be indicated. Scoring notes regarding staging, event identification, outliers, and specific 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.

4.6 Scored Sleep Data

After full scoring, the scorer will generate:

Sleep Data Summary Report, output using WORD (rtf format) that contains summary data. Data in the report will include the RDI (the number of apneas and hypopneas per hour of the sleep associated with a desaturation), a summary of the desaturation profile, time in REM/Non-REM sleep, stage distributions and the arousal index. (See sample Sleep Report in the Forms Section 6.0)

SAS report containing >760 variables.

Completed QS form containing all quality grades and scoring notes.

The Sleep Data Summary Report and QS Report are e-mailed to each site (generally within 4-6 weeks of receipt of the sleep study at the RC, except for studies that are triaged as possible Medical Alerts, which will be returned within one week after scoring completion.

4.7 Archival of Data

After QS data has been entered and reports are sent to sites, the complete study folder containing the raw data sleep file, scored files, sleep study report, and the SAS report is placed in a site directory for the creation of data backup CDs. These complete scored sleep study folders will be archived onto CDs (in triplicate). Copy A will be retained at the RC, Copy B will be maintained at an off site location, and Copy C will be sent to the Coordinating Center on a quarterly basis along with a SAS file containing the data collected to date.

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

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5.0 Field Tech Certification Pack

5.1 Certification of the PSG Technician

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-one training from someone in attendance at Central Training. If trained at site, Training Check off List (see 5.2) must be completed by the instructor and submitted to the Reading Center.
2. Submission of the practical exam (pp. 15-16). The evaluator must be a member of the training staff or a certified tech that attended Central Training.
3. Submission of the written exam (pp. 5-11).
4. Submission of 5* 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 MrOS PSG protocol and procedure and must include:
 - Impedance check
 - Documentation of physiological events (“biocals”)
 - Completed Signal Verification (SV) and Signal Evaluation (SE) forms.

* PSG field techs that have been certified for SOF, and remain in good standing, need to submit a total of 2 passable practice studies.

Maintaining Certification

Once certification is obtained the PSG technician must maintain certification to remain in good standing. Certification is maintained by submitting 4 actual (study subject) PSGs per month. If recruitment fails to afford 4 studies/month the technician must provide enough *practice hook-ups*, that when combined with actual studies the total is 4 submissions/month. Practice hook-ups must be a complete hook-up on a non-subject volunteer with impedance check and recording of physiological events on all channels as well as complete paperwork (SV and SE forms). Such practice hook-ups should be clearly marked as: “Hook-up only for certification maintenance.”

All requirements must be submitted to the Reading Center: Items 2-3 sent to Nancy Scott;
All studies and practice hook-ups sent to Susan Surovec.

Make copies of this section of the manual as needed for certifying additional techs.

5.2 Check Off List for at site PSG Tech Training:

Name: _____

Site: _____

Date: _____

Topic	Date	Instructor	Trainee
<p>Introduction to Sleep Science: Disturbances of sleep: sleep disordered breathing (apnea/hypopnea) Restless Leg Syndrome and Periodic Leg Movements of Sleep</p> <p>Polysomnography as a tool for evaluation of sleep: Sleep Stages (EEG, EMG, EOG changes) Respiratory Changes (SaO2 changes) Heart Rate Changes Positional changes (simple body adjustment; effects on respiration)</p>			
<p>Types of Signals recorded on the PSG: Bioelectric Transducer Auxiliary Devices</p>			
<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 module) ECG patch (interface to lead wires) Position sensor (importance of correct placement) Oximeter (areas of stress, interface to oxi-cable, cleaning) Summit IP respiratory bands (surface cleaning) Leg movement sensors 			
<p>Unattended Studies:</p> <p>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>Electrode Application:</p> <ul style="list-style-type: none"> • Identifying landmarks, head measurement for scalp electrode placement, EOG, chin EMG, mastoid • Identifying placement sites for ECG <ul style="list-style-type: none"> • Skin prep • Application technique • Placement sites and application of leg EMG sensors • Placement sites and application of Summit IP belts (thoracic, abdominal, power box) • Placement sites and application of thermistor/ nasal cannula • Placement sites and application of oximeter sensor <p>Interfacing electrodes into Safiro unit</p>			
<p>Basic mechanics of Safiro:</p> <ul style="list-style-type: none"> • Powering on/off • Battery charging (AA battery alternative) • Establishing the IR connection/ accessing PSG Online • Synchronizing Safiro time to computer • Setting Safiro to record to flash disk • Flash card set-up (through PSG Online) • Preview/ Record buttons • Impedance check and physiological event verification • Signal review 			
<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 (notating time to bed) • Instructing the participant on morning removal of equipment • Confirming pick-up time for equipment 			

<p>Morning removal and treatment of used equipment:</p> <ul style="list-style-type: none"> • Correct removal of electrodes <ul style="list-style-type: none"> Discarding disposables Handling and containing dirty electrodes for disinfection • Cleaning and disinfecting reusables • Packaging after disinfection • Re-packing set-up case 			
<p>Study download and internal logging:</p> <ul style="list-style-type: none"> • Converting the flashcard (troubleshooting problems) • PSG review and paperwork completion • Copying and submitting studies to Reading Center • Formatting the flashcard 			
<p>Performance review:</p> <ul style="list-style-type: none"> • Practical exam • Written exam • Submission of practice studies for certification • Submission of check off list for at site training 			

5. 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

6. 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
 - d) Remove the gold disk electrode at CZ, re-prep the area and reapply

7. 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

8. 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

9. If the first reading of impedance values are excessive on all electrodes on the head and face the PSG tech should:
 - a) Verify the flashcard is properly situated in the Safiro
 - b) Begin troubleshooting by re-prepping and reapplying the electrodes at Cz and forehead
 - c) Annotate the Signal Verification Form and proceed with the study

10. To correct absent airflow deflections from the thermistor channel as the subject breathes:
 - a) Clean the prongs with alcohol (they must be dirty)
 - b) Make sure the beads are touching the mucous membranes inside the nostrils
 - c) Re-prep and replace the gold disk at Cz
 - d) Gently reposition to insure the beads are in the path of nasal/oral airflow

11. Which of the following statements are true regarding about disinfection of gold disk electrodes in between participants?
 - a) Disinfection eliminates high electrode impedances
 - b) Placement on non-intact skin creates risk of blood borne pathogens
 - c) Soap and water cleaning is sufficient
 - d) Soap and water cleaning with an alcohol wipe down is sufficient
 - e) Disinfection is aimed at reducing risk of blood borne pathogens that could arise by placing used electrodes on non-intact skin
 - f) b and d
 - g) all of the above

12. If the thoracic respiratory belt shows minimal deflection with breathing:
 - a) Tighten the belt until the subject complains of discomfort
 - b) Have the participant lie down and recheck the signal quality
 - c) Reposition the belt
 - d) Reposition and insure the belt is not too tight or too loose
 - e) It doesn't matter, just zoom the channel
 - f) b, then d

13. The optimal position of the abdominal respiratory belt is:
 - a) Around the umbilicus
 - b) Over the nipples
 - c) Just above the hips
 - d) Under the left armpit

14. After use, proper disinfection of the gold disk electrodes is assured by
 - a) Rinsing dried electrolyte paste with water
 - b) Wiping the electrodes lightly with alcohol
 - c) Removing dried paste and soaking disks in bleach water
 - d) It doesn't matter, disinfection is not needed if the subject looks healthy and no skin break was visible

15. 60 Hz artifact can be caused by:
- a) Low impedance values
 - b) Long inter-electrode distances
 - c) Stray airborne electrical signals
 - d) Unequal (unbalanced) impedance values
 - e) an electrode in poor contact with the desired site
 - f) a and e
 - g) c, d, e
16. A good way to minimize artifact on the PSG recording is to:
- a) Insure impedance levels are low and balanced.
 - b) Place electrodes and sensors securely.
 - c) Bundle electrode wires together.
 - d) All of the above
17. For high-level disinfection, the potency of bleach remains intact how long after initial uncapping?
- a) 6 months
 - b) 1 week
 - c) 6 weeks
 - d) 1 year
18. When placing the Compact Flash Card into the Safiro the correct orientation is:
- a) Arrow facing up
 - b) The Compumedics name facing up
 - c) It doesn't matter
19. If the subject has nail polish:
- a) The oximeter should be cleaned extra thoroughly and applied over the nailbed
 - b) The nail polish should be removed with acetone
 - c) The oximeter should not be used
20. 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, then soaked in 1:50 bleach/water solution for 20 minutes
 - c) Discarded since they are not reusable
 - d) Sterilized at a local hospital

21. Upon arriving at the home the subject refuses to do the PSG. You should:
- Call your PI or coordinator and ask him/her to speak with the participant over the phone.
 - Insist the study be performed, after all he already agreed.
 - Leave the home immediately
 - Inquire if there are specific concerns that you or other staff members can address.
22. After the hook-up and before leaving the home, which of the following need to be checked:
- All sensors are securely attached
 - The equipment is placed conveniently and securely in a bedroom
 - The participant has a phone number of a staff to call if encountering problems
 - The participant understands how to reposition sensors
 - The participant knows the time the equipment will be retrieved the next day
 - The subject is asleep
 - a and e
 - a, c,d,e
 - All of the above
23. When placing the nasal cannula, subjects should be told
- Not to touch it once it has been placed
 - Clean it by dipping in water if it becomes moist or soiled
 - To remove it if nose needs to be blown, and then replace
 - None of the above
24. Leg sensors are placed to:
- Measure the strength of the legs
 - To record how many times the legs move at night, a finding that could indicate Periodic Limb Movement Disorder
 - To record leg movements associated with breathing disturbances
 - b and c
 - All of the above
25. What statement(s) are true regarding the way sleep changes as people age:
- Sleep time and sleep need goes down as people age
 - Sleep time and sleep stages remain constant during adulthood
 - Sleep depth generally goes down, with reduced slow wave sleep commonly observed after age 60
 - REM (Dream) sleep increases 2-fold as people age
 - c and d

26. “Popping” of electrodes:
- a) Is a real signal indicating abnormal brain activity
 - b) May be due to loosening of the electrode attachments at the skin (poor or intermittent contact with the skin)
 - c) May be due to electrode malfunction, indicating need to replace
 - d) a and b
 - e) a, b, and c
 - f) b and c
27. Participants who complain of poor sleep or insomnia
- a) Should be told that the study will diagnose their disorder
 - b) Should not participate in the protocol, since not enough sleep will be measured to be of any use
 - c) Should be reassured that PSGs are commonly done in people with insomnia, and often those patients sleep better than usual with the equipment
 - d) None of the above
28. Subjects who usually take medicines should be told:
- a) Not to use any medicine for 24 hours prior to the study
 - b) Not to use any medicine once the equipment is hooked up until it is removed the next day
 - c) Make no changes in usual medicines but let the staff know what medicines were used
 - d) None of the above
29. Optimal preparation of the skin for electrode attachment requires that:
- a) Large skin areas are prepped in case electrodes move
 - b) Alcohol should first be used to sterilize the area, then abrasive cream
 - c) A small circular motion should be used until the skin gently “pinks”
 - d) Bald participants need less abrasion than others
30. When using a thermistor and nasal flow cannula:
- a) The thermistor should be taped under the cannula
 - b) The cannula should be taped under the thermistor
 - c) Only use one-not both at the same time
 - d) Do not tape the thermistor and cannula

31. Before leaving the home, to assure that data will be captured on the data card:
- Set the Online Command button to PREVIEW and make sure the pink light is flashing
 - Leave the impedance check running before closing PSG Online
 - Set the Online Command button to RECORD and make sure the red light is flashing before closing PSG Online
32. When placing the Compact Flash Card into the card reader the correct orientation is:
- Arrow facing up
 - The Compumedics name facing up
 - It doesn't matter
33. When placing the Compact Flash Card into the Safiro:
- Make sure the Safiro is powered off
 - Make sure the Safiro is powered on
 - Make sure the card is arrow side up
 - Make sure the card is Compumedics-side up
 - It doesn't matter, the Safiro will always recognize the card
 - a and c
 - b and d
34. To insure the capture and successful recording of PSG signals make sure the oximeter, nasal pressure module and flashcard are:
- In the Safiro before powering the unit on
 - Placed into the Safiro after powering the unit on
 - It doesn't matter, the Safiro will recognize them even if they are unplugged and re-plugged

Written MrOS 092003

6. When checking the signal for the thermistor, only vertical lines can be seen in a chaotic fashion. What do you do to determine whether or not the thermistor needs to be replaced?

7. Upon checking impedance levels you find that all impedances are $> 30k$. What do you do to troubleshoot?

5.5 Practical Exam for PSG Tech Training

Date: _____

Name: _____

Site: _____

Examiner: _____

Did tech operate Safiro correctly to power on/off? _____

Was PSG Online accessed correctly? _____

Was subject information entered correctly (through NEW)? _____

Did tech correctly choose configuration for recording (MrOS)? _____

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	
REF (Forehead)							
GND (Cz)							
C3							
C4							
A1							
A2							
LOC							
ROC							
Chin							
ECG							
Therm.							
Cannula							
Belts							
Legs							
Oximeter							

Were live signals checked? _____

Were physio-events performed? _____

Additional comments: _____

Oral Questions:

1. **Explain what to do if impedance too high.**
(Needs to indicate removal and re-prep of area). (2 points)

2. **Explain possible source of excessive artifact on a channel (1 point)**
(broken lead, poor application, disconnected sensor)

3. **Explain at least two possible problems with oximeter placement.**
(misaligned, too tight, too loose, poor pulse) (2 points)

4. **Explain 3 sources of poor respiratory signals.**
(belts too tight, too loose, poorly positioned) (3 points)

5. **Indicate 3 ways to maximize good signals.**
(good positioning, good electrical contacts, secure leads,
good skin prep) (3 points)

6. **Explain what to do if a poor signal is noted after study download.**

7. **Were any problems noted during hook-up?**
If so, how were they resolved

A-----	B-----	C-----	D
Very			Haphazard
Systematic			

8. **Describe overall quality of interactions with “volunteer.”**

A-----	B-----
C-----	D
Sensitive,	Insensitive,
Gentle,	Abrasive,
Explained	Didn't Explain Procedures
Procedures	



6.0 Forms

The purpose of this section is to provide you with the useful forms and documents you will need for the study. Make additional copies of these forms for your use.

The contents are as follows:

6.1 PSG Forms

Signal Verification Form – completed during PSG hookup and submitted with the downloaded sleep study to the Reading Center.

Sleep Study Evaluation Form – completed upon downloading and review of PSG, and submitted with the downloaded sleep study to the Reading Center

Review Screen for PSG Signals – summary of the Safiro collection configurations and screen layout for our study montage.

Safiro PSG Collection Configuration for MrOs – detailed screen views of the Safiro collection configurations.

6.2 Equipment Forms

Return of Compumedics Equipment for Repair – used when returning any Safiro equipment.

Neuro Supplies Order Form – may be used to reorder PSG sensors and hookup supplies from Integra Neuro Supplies.

6.3 Reports

Preliminary Study Report – generated by the CP at Reading Center to give feedback to sites on study quality and equipment issues.

Sleep Report – PSG Feedback Information – this is a sample of the report that is generated from a scored PSG.

Study Quality Report (QS) – Generated at the Reading Center containing individual signal quality scores, overall quality, and notes from scorer regarding quality of the PSG data.

Monthly Quality Summary Reports – Study Overall, Individual Site Quality, Quality by Technician and Monitor, and Overall Signal Quality.



Signal Verification Form

Participant ID: _____

Technician ID: _____ - _____

Study Date: ____ / ____ / ____

Safiro ID: _____

Time of Arrival: ____ : ____

Impedances (Record Value in kohms):

Electrode	First Check	# Times re-prepped ("0" if none)	Final Value (If re-prepped)
-----------	-------------	----------------------------------	-----------------------------

C3			
A1			
A2			
ROC			

LOC			
ECG L			
ECG R			
Chin L			
Chin R			

Indicate first impedance value; if $\geq 5k$
ECG electrodes may be $> 30K$

Remember: Balanced impedances are critical

Assessment of Signals:

Channel	Good Waveform Visible		Difficulty Visualizing Waveform		Value or Reading	Comments Regarding Signal Assessment
	Yes	No	No	Yes		
LOC						
ROC						
Chin						
C3-A2						
C4-A1						
ECG						
Left Leg						
Right Leg						
Airflow						
Cannula Flow						
Thoracic						
Abdominal						
SUM						
SaO2 value						If $<92\%$: reposition, check sensor, troubleshoot value
HR value						If <30 or >150 , check for 1 minute manually

STAT reading			If not "GOOD" and stable, troubleshoot oximetry
---------------------	--	--	---

Check Function of Position Sensor:

		Performed and Correct	Not Performed
Position Reading	Back		
	OVER →		
	R Side		

Physiological Events: Activation for Each Channel

Activation (expect to see)	Time	Epoch#	Comments:
Open your eyes 1 min , lie quietly and relax (upward blinks on LOC, ROC; alpha blocks)			
Close your eyes 1 min , lie quietly and relax (blinks are absent or minimal, alpha appears)			
Blink 5 times (upward blinks on LOC, ROC)			
Look to the left (LOC goes down, ROC goes up)			
Look to the right (LOC goes up, ROC goes down)			
Look up over your head (LOC, ROC go upwards)			
Look down to your feet (LOC, ROC go downwards)			
Swallow, or stick out your tongue or bite teeth together (increased activity on Chin channel)			
Move left leg (increased activity on left leg channel)			
Move right leg (increased activity on right leg channel)			
Hold your breath for 10 secs (airflow and belt channels flatten, SaO2 may dip)			

Were any environmental conditions present affecting hook-up or to cause potential for affecting the recording:

No **Yes** (if yes, describe below)

Additional Comments regarding hook-up or function of Safiro:

Time of Departure: ____ : ____



Sleep Study Evaluation

Participant ID: _____

Technician ID: _____ - _____

Study Date: ____ / ____ / ____

Safiro ID: _____

Date of Review: ____ / ____ / ____

Reviewer ID: _____ - _____

Participant's Reported Time to Bed: _____ : _____

- | | Yes | No |
|--|--------------------------|--------------------------|
| 1. Are there signals on each of the channels?
(i.e. no flat-lined channels) | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Is each channel mostly clear of artifact?
(able to visualize waveforms) | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Is there at least 4 hours of oximetry? | <input type="checkbox"/> | <input type="checkbox"/> |

If answer to any question 1 to 3 is "No", review study with Reading Center

- | | | |
|---|--------------------------|--------------------------|
| 4. Were any electrodes or cables visibly broken upon morning equipment retrieval and cleaning? | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. Were any factors identified on the SV form that affected this study? (i.e. intolerance to sensor placement, environment, etc.) | <input type="checkbox"/> | <input type="checkbox"/> |

Additional specific comments/complaints from the participant that may have affected this study:

Additional comments from reviewer about this study:

Preliminary Study Report

Site: xx

Studies reviewed between 4/1/2003 and 4/30/2003

<i>ID</i>	<i>Study</i>	<i>Tec</i>	<i>Pass =</i>	<i>Comments</i>
32377	4/16/200	351	1	Lights Airflow Artifact on thermistor for last 2 studies with this unit. Please replace electrode.
32013	4/16/200	362	1	Lights Poor airflow until 23:52. Patchy belts and airflow after 01:00 - Please check and replace if necessary
32012	4/15/200	366	1	Lights EEG Airflow Please replace thermistor on this unit. Popping artifact on C4
39117	4/14/200	351	1	Lights Airflow Where is cannula signal on this study? PPT appears to have removed thermistor before bed; uninterpretable
39101	4/10/200	375	2	 Incorrect PP settings on SOF8 config. Can zoom to visualize EEGs but cannot tell sleep from wake. Not technician related.
3026	4/9/2003	351	2	 Incorrect P-P setting for EEG data type on SOF8 config. Can zoom to visualize EEGs but cannot distinguish wake vs sleep. Not technician related.
3033	4/3/2003	351	1	Lights Erratic position sensor. Pls re-calibrate.
3181	4/2/2003	373	1	Lights Airflow Belts Thanks for notes and diagram of ECG placement! Artifact on C4. Airflow and cannula may have moved at 03:14. May be time to replace this thermistor.
3147	3/27/200	351	1	Lights Position monitor may have loosened during an arousal and was dangling. ABD looks ok with zoom. Cannula signal lost for 15 minutes at 7 am. Good job.
3051	3/25/200	351	1	Lights Belts Variable quality on ABD. Thoracic belt may have broken during this study (around 01:00). Please replace.

Sunday, April 27, 2003

Page 1 of 1

Settings for Review Screen (NancyMrOSPro2)



Pane 1

Polygraph Properties



Name: NancyMrOSPro2.pol









Pane 1 | Pane 2

Timebase: 30 sec/page Vertical grid Epoch marker

Background:  Grid colour: 

New Insert Delete Apply changes to group

Cursor colour:  Epoch colour: 

	Input 1	-/+	Input 2	Lower In	Upper In	Zoon	Size	Colour	Clipped	Grid	Polarity	Numeric	HP (Hz)	LP (Hz)	Notch (Hz)
1	LOC					2	1		No	Off	Negative		0.3	35	Off
2	ROC					2	1		No	Off	Negative		0.3	35	Off
3	L Chin	-	R Chin			8	1		No	Off	Negative		10	63	Off
4	C3	-	A1			4	1		No	Off	Negative		0.3	35	Off
5	C4	-	A2			4	1		No	Off	Negative		0.3	35	Off
6	ECG L	-	ECG R			4	1		No	Off	Positive		1	35	Off
7	HR			30	150		1		Yes	Off		Yes			
8							1								

OK Cancel Save as... Save as default Default Delete... Help...

Settings for Review Screen (NancyMrOSPro2)



Pane 2

Polygraph Properties



Name: NancyMrOSPro2.pol












Pane 1 | **Pane 2**

Timebase: 2 min/page Vertical grid Epoch marker

Background:  Grid colour: 

New Insert Delete Apply changes to group

Cursor colour:  Epoch colour: 

	Input 1	+/+	Input 2	Lower In	Upper In	Zoom	Size	Colour	Clipped	Grid	Polarity	Numeric	HP (Hz)	LP (Hz)	Notch (Hz)
1	Leg L					2	1		No	Off	Positive		20	30	Off
2	Leg R					2	1		No	Off	Positive		20	30	Off
3	Airflow					10	1		No	Off	Positive		0.15	5	Off
4	Cannula Flow					20	1		No	Off	Positive		0.05	5	Off
5	Thoracic					4	1		No	Off	Positive		0.05	5	Off
6	Abdominal					4	1		No	Off	Positive		0.05	5	Off
7	SUM					4	1		No	Off	Positive		0.05	5	Off
8	SaO2			0	100		1		Yes	Off		Yes			
9							1								
10	STAT						1			On					
11	Position						1			On					

OK Cancel Save as... Save as default Default Delete... Help...

Safiro PSG Collection Configuration for MrOs

Data Types

MrOS - Study Configuration Manager

File Help

New Open Save

Data Types

- Diff
- Oximeter
- ECG Group
- DC
- HP
- EEG
- HP Resp
- Leg Movement
- Cannula Flow
- Physical Inputs
- Trace Panes
- Filters
- Sleep Analysis
- User Inputs
- Other Settings

	Name	Type	Rate	Coupling	HP Filter	P-P Range	Impedance
1	Off	Internal AC	0	AC	0.15	500 mV	No
2	Oximeter	Oximeter	1	Special	Special	Direct	No
3	ECG Group	Internal AC	512	AC	0.15	2 mV	Yes
4	DC	Special DC (Ch 1-4)	4	DC	0.15	500 mV	No
5	HP	Special HP (Ch 29-32)	16	AC	0.05	2 mV	No
6	EEG	Internal AC	256	AC	0.15	500 uV	Yes
7	HP Resp	Special HP (Ch 29-32)	16	AC	0.05	10 mV	No
8	Leg Movement	Internal AC	64	AC	0.15	10 mV	No
9	Cannula Flow	External Pressure	64	Special	Special	Fixed	No
10							

For Help, press F1

NUM

Physical Channels

MrOS - Study Configuration Manager

File Help

New Open Save

Data Types

- Off
- Oximeter
- ECG Group
- DC
- HP
- EEG
- HP Resp
- Leg Movement
- Cannula Flow
- Physical Inputs**

Trace Panes

Filters

Sleep Analysis

User Inputs

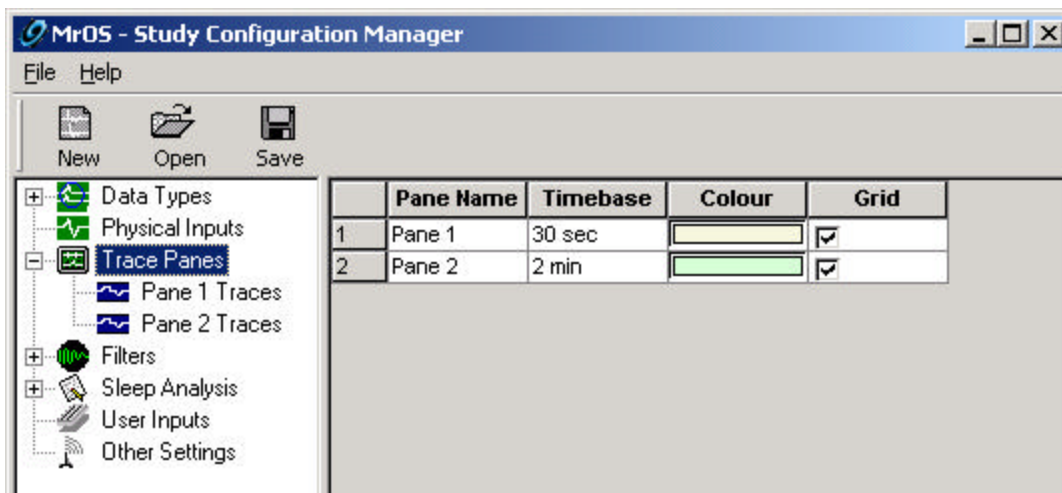
Other Settings

	Input	Data Type
Special DC 1	Position	DC
Special DC 2	Leg L	Leg Movement
Special DC 3	Leg R	Leg Movement
Special DC 4	pin 4 (sound)	Off
Internal AC 5	C3	EEG
Internal AC 6	C4	EEG
Internal AC 7	pin 7=O1	Off
Internal AC 8	pin 8=O2	Off
Internal AC 9	A1	EEG
Internal AC 10	A2	EEG
Internal AC 11	ROC	EEG
Internal AC 12	LOC	EEG
Internal AC 13	ECG L	ECG Group
Internal AC 14	ECG R	ECG Group
Internal AC 15	L Chin	EEG
Internal AC 16	R Chin	EEG
Internal AC 17	CH17	Off
Internal AC 18	CH18	Off
Internal AC 19	CH19	Off
Internal AC 20	CH20	Off
Internal AC 21	CH21	Off
Internal AC 22	CH22	Off
Internal AC 23	CH23	Off
Internal AC 24	CH24	Off
Internal AC 25	CH25	Off
Internal AC 26	CH26	Off
Internal AC 27	CH27	Off
Internal AC 28	CH28	Off
Special HP 29	Airflow	HP
Special HP 30	SUM	HP Resp
Special HP 31	Thoracic	HP Resp
Special HP 32	Abdominal	HP Resp
Oximeter Status	STAT	Oximeter
Oximeter HR	HR	Oximeter
Oximeter SpO2	SaO2	Oximeter
Ext Pressure 1	CH36	Off
Ext Pressure 2	Cannula Flow	Cannula Flow

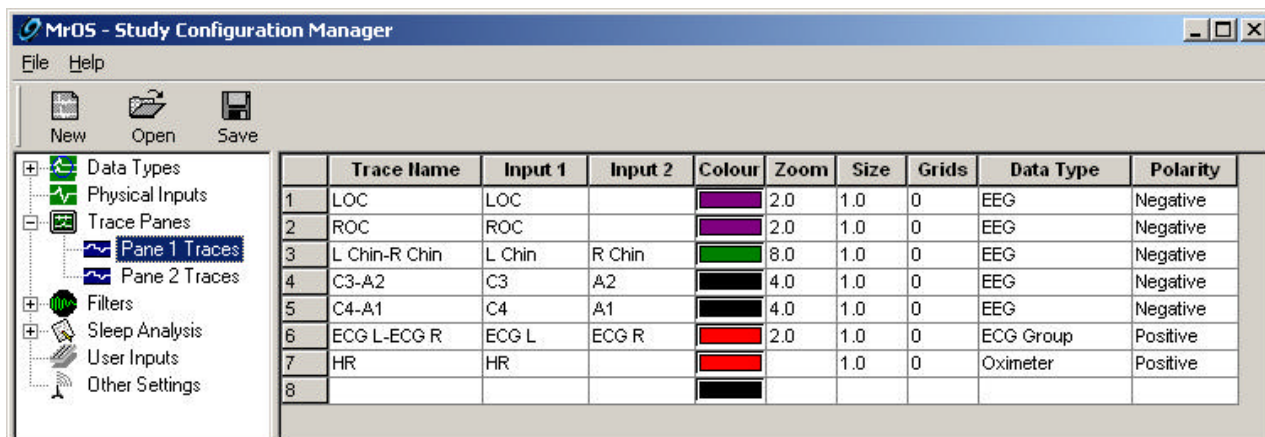
For Help, press F1

NUM

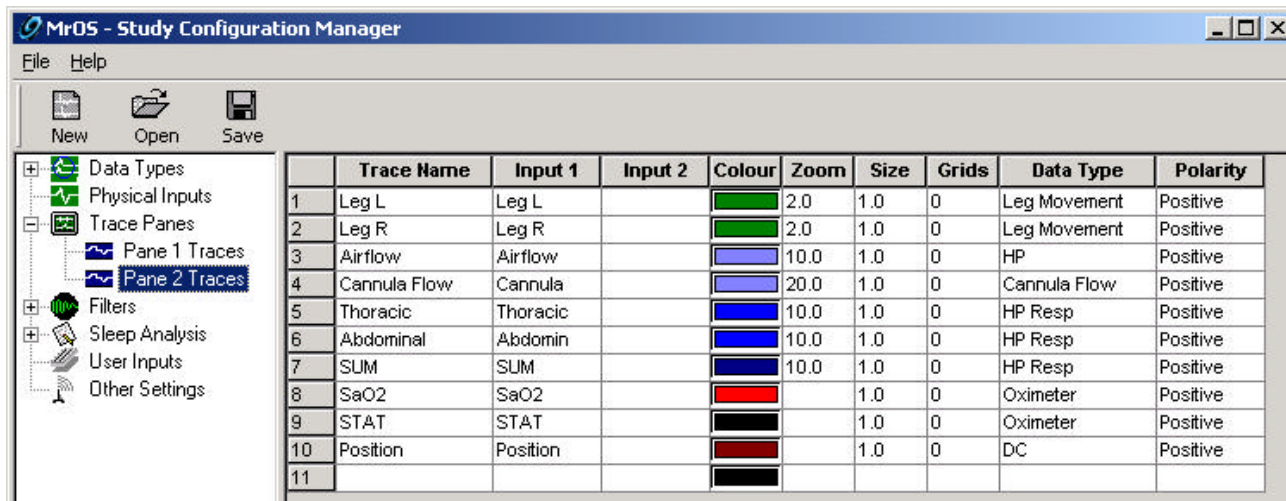
Trace Panes



Trace Panes: Pane 1 Traces



Trace Panes: Pane 2 Traces



Filters: Data Types

MrOS - Study Configuration Manager

File Help

New Open Save

Data Types
 Physical Inputs
 Trace Panes
 Filters
 Data Types
 Traces
 Sleep Analysis
 User Inputs
 Other Settings

	Data Type	HP Filter	LP Filter	Notch
1	Off	Off	Off	Off
2	Oximeter	Off	Off	Off
3	ECG Group	1.00 Hz	252 Hz	Off
4	DC	Off	Off	Off
5	HP	0.05 Hz	8 Hz	Off
6	EEG	0.30 Hz	70 Hz	Off
7	HP Resp	0.05 Hz	8 Hz	Off
8	Leg Movement	20.00 Hz	30 Hz	Off
9	Cannula Flow	0.05 Hz	32 Hz	Off

For Help, press F1

NUM

Filters: Traces

MrOS - Study Configuration Manager

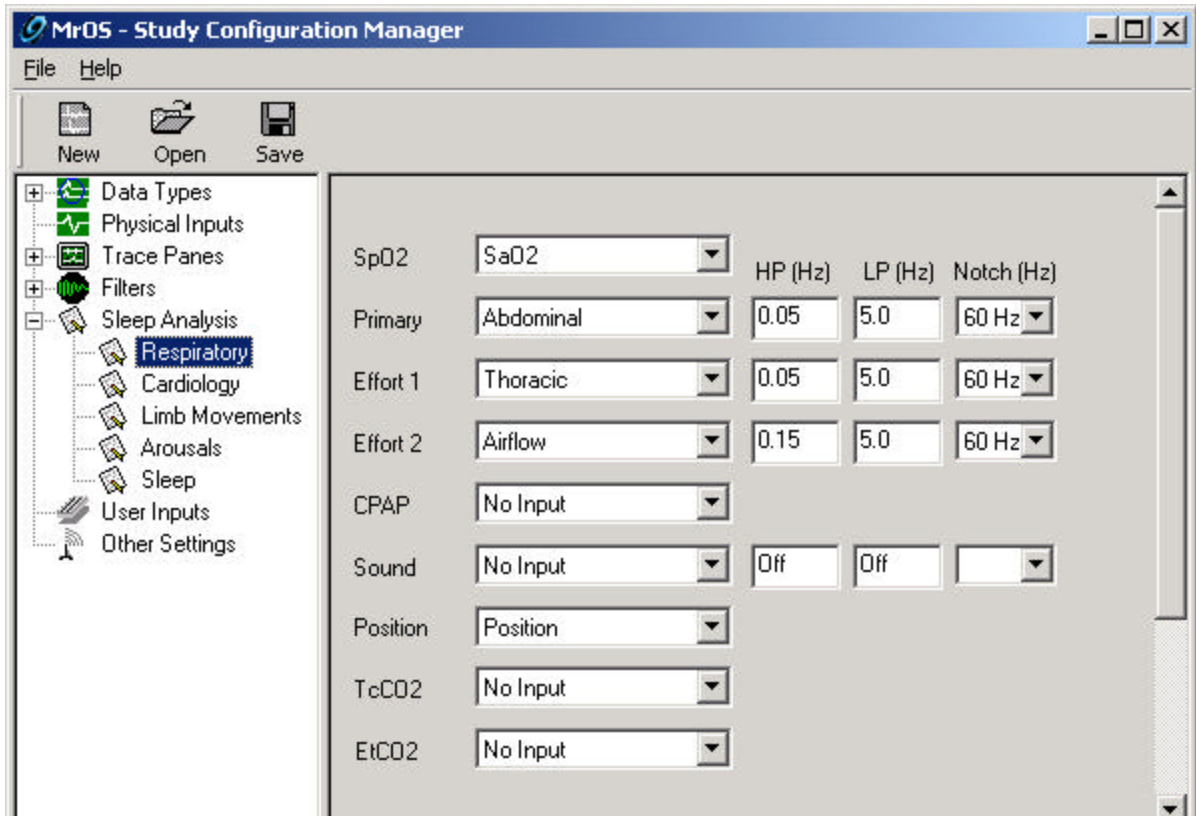
File Help

New Open Save

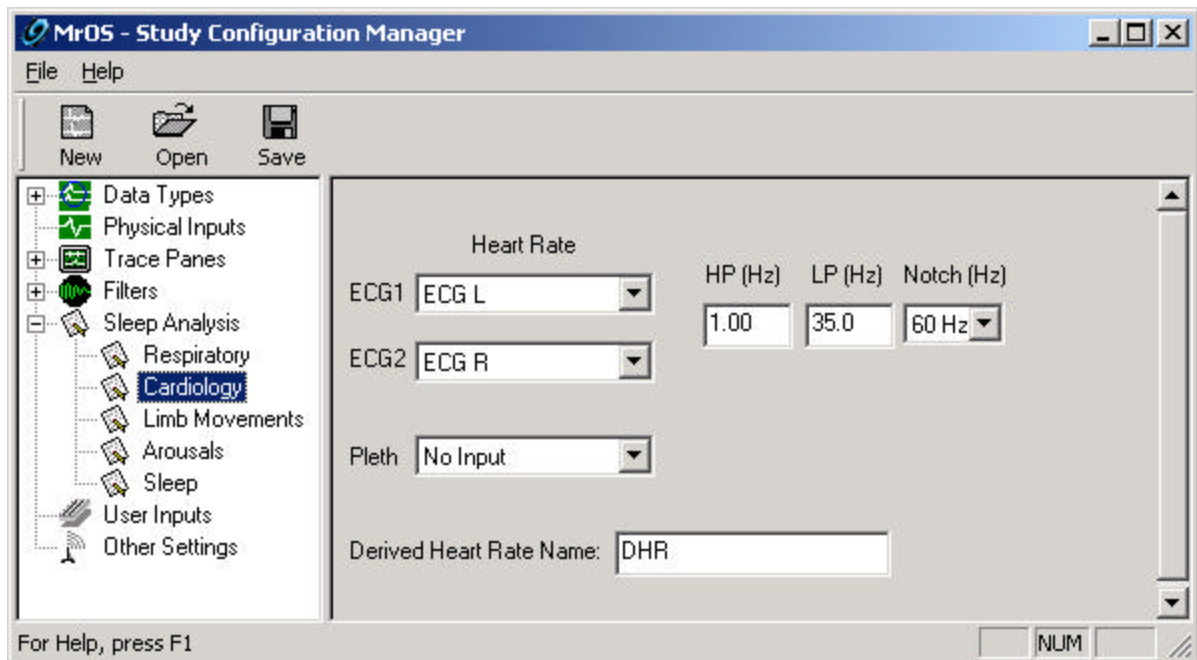
Data Types
 Physical Inputs
 Trace Panes
 Pane 1 Traces
 Pane 2 Traces
 Filters
 Data Types
 Traces
 Sleep Analysis
 User Inputs
 Other Settings

	Trace	HP Filter	LP Filter	Notch
1	Leg L	20.00 Hz	30 Hz	Off
2	Leg R	20.00 Hz	30 Hz	Off
3	Airflow	0.15 Hz	5 Hz	Off
4	Cannula Flow	0.05 Hz	5 Hz	Off
5	Thoracic	0.05 Hz	5 Hz	Off
6	Abdominal	0.05 Hz	5 Hz	Off
7	SUM	0.05 Hz	5 Hz	Off
8	LOC	0.30 Hz	35 Hz	Off
9	ROC	0.30 Hz	35 Hz	Off
10	L Chin-R Chin	10.00 Hz	100 Hz	Off
11	C3-A2	0.30 Hz	35 Hz	Off
12	C4-A1	0.30 Hz	35 Hz	Off
13	ECG L-ECG R	1.00 Hz	35 Hz	Off
14	HR	Off	Off	Off
15	SaO2	Off	Off	Off
16	STAT	Off	Off	Off
17	Position	Off	Off	Off

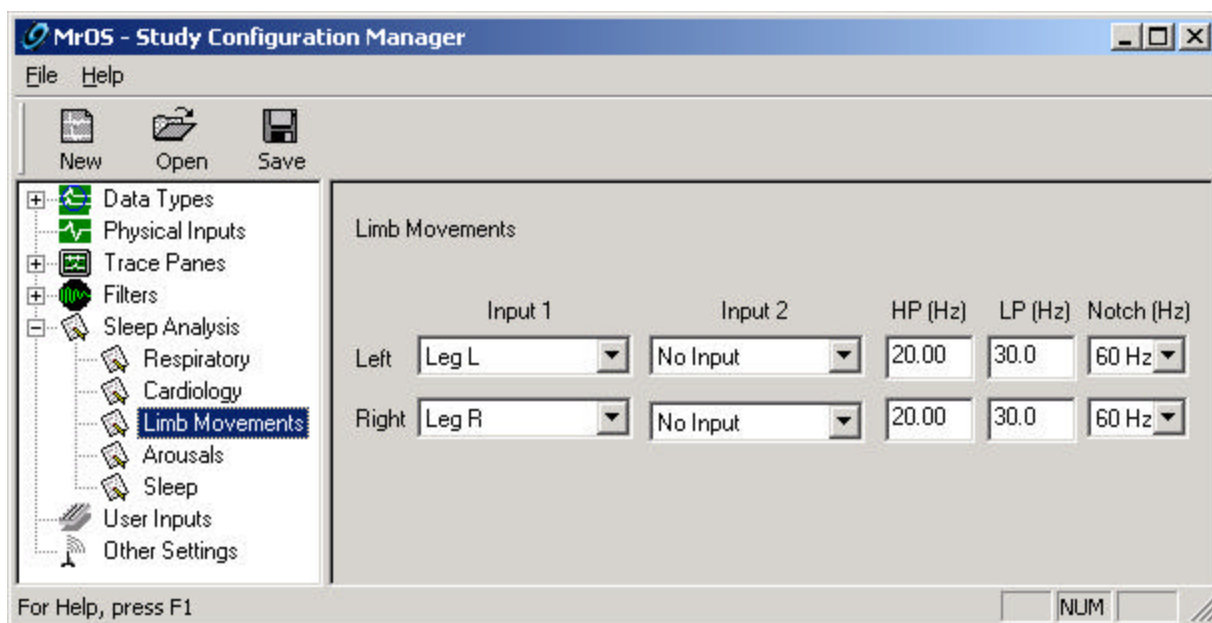
Sleep Analysis: Respiratory



Sleep Analysis: Cardiology



Sleep Analysis: Limb Movements



Sleep Analysis: Arousals

The screenshot shows the 'MrOS - Study Configuration Manager' window. The left sidebar contains a tree view with categories: Data Types, Physical Inputs, Trace Panes, Filters, Sleep Analysis (expanded), User Inputs, and Other Settings. Under 'Sleep Analysis', sub-items include Respiratory, Cardiology, Limb Movements, Arousals (selected), and Sleep. The main panel is titled 'Automatic Settings' and includes a checked 'Use Sleep Settings' option. Below this is a table for filter settings:

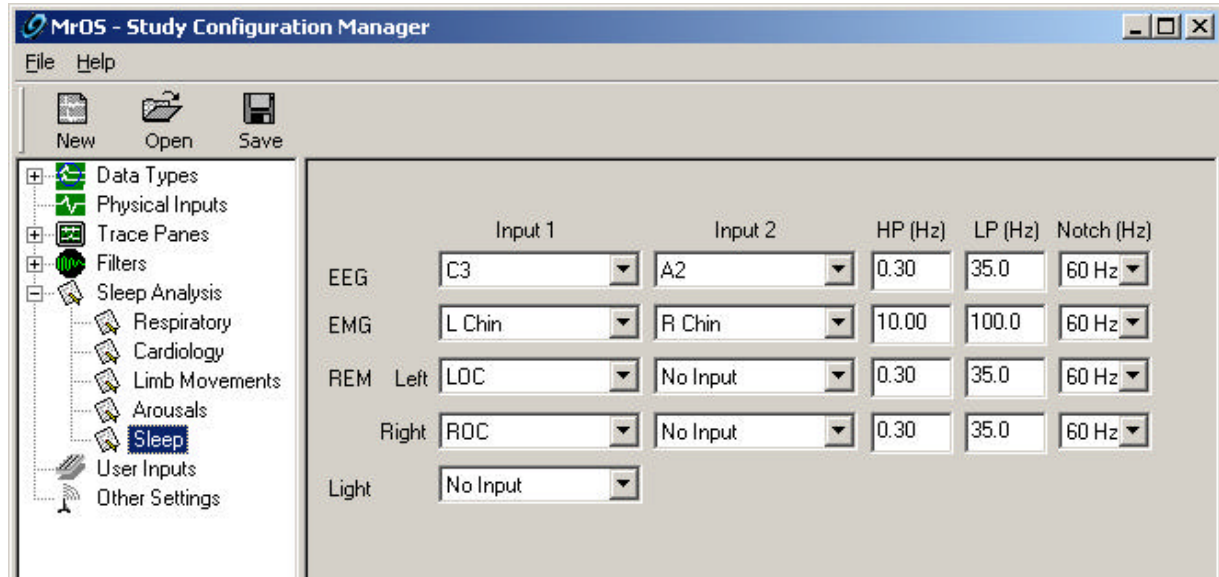
	Input 1	Input 2	HP (Hz)	LP (Hz)	Notch (Hz)
EEG	C3	A2	0.30	35.0	60 Hz
EMG	L Chin	R Chin	10.00	100.0	60 Hz

Below the table are five configuration rows for arousals:

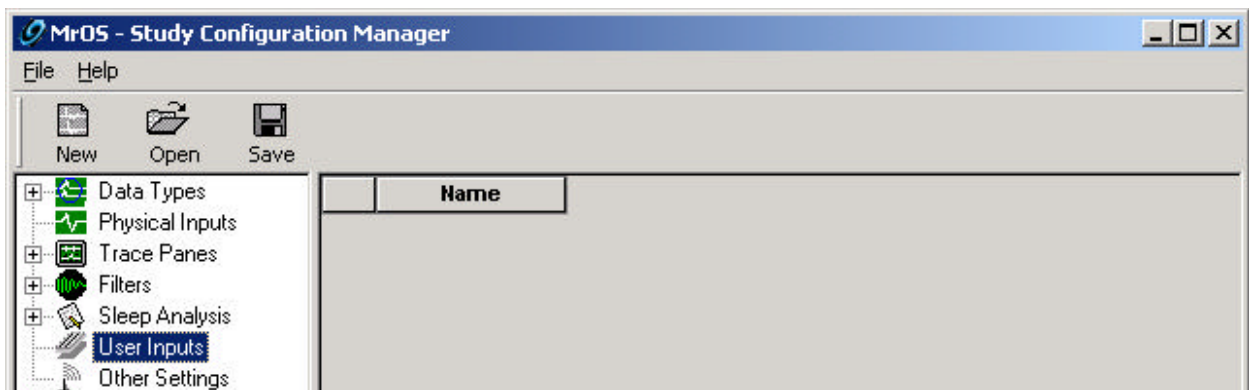
- 1: Type: User Defined, Input: C3, Label: ASDA
- 2: Type: User Defined, Input: C4, Label: ASDA
- 3: Type: Limb Movements, Input: Leg L, Label: (empty)
- 4: Type: Limb Movements, Input: Leg R, Label: (empty)
- 5: Type: User Defined, Input: No Input, Label: (empty)

At the bottom of the window, there is a status bar with the text 'For Help, press F1' and a 'NUM' button.

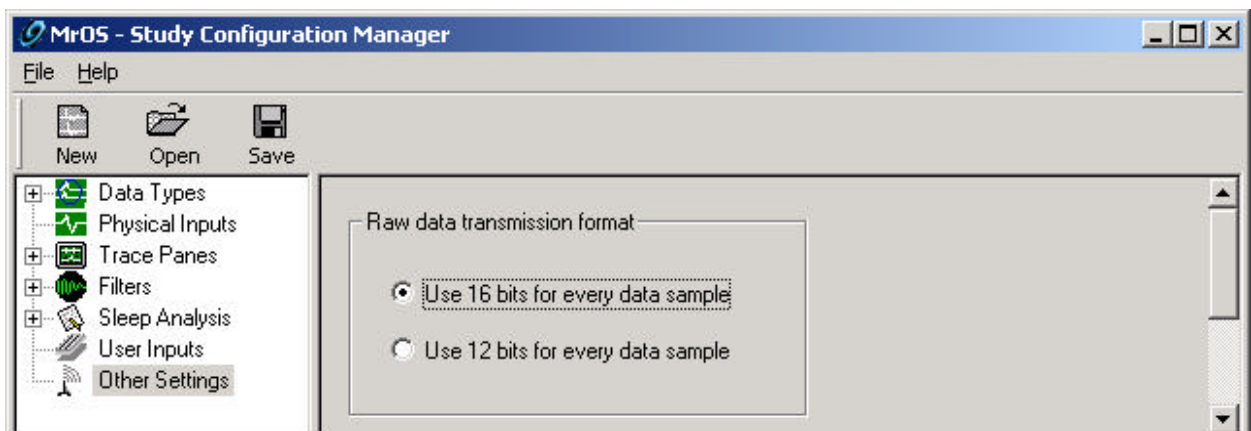
Sleep Analysis: Sleep



User Inputs



Other Settings





RETURN OF COMPUMEDICS EQUIPMENT FOR REPAIR SERVICE ORDER

- Please fax a copy of this form to Nancy at PSG Reading Center: 216 844-2580
- Keep one copy of completed form for your records
- Include this form with all equipment sent to Compumedics for repair

Field Site: _____ **Customer #** _____

Contact Name: _____ **Phone:** _____

Delivery Address: _____

Safiro Unit ID: _____ **RSO Number:** _____

Date: _____ **Loaner ID (if applicable):** _____

Description of Problem: _____

<p>Send Equipment To:</p> <p>Compumedics USA, Inc. 7850 Paseo Del Norte Suite 101 El Paso, TX 79912</p> <p>(1-877-717-3975)</p>	<p>Date equipment sent: _____</p> <p>Date received at Compumedics: _____</p> <p>Date returned to site: _____</p>
---	---

Frequently Used Supplies For MrOS Sleep Studies

Supplies are obtainable from:

Integra Neuro Supplies, Inc.
12 Riverside Dr., Suite #3
Pembroke, MA 02359-1937

Fax: 1-800-303-3748
Ph: 1-800-638-7693

SHIP TO:	BILL TO: CUSTOMER # 44106C

ITEM/ DESCRIPTION	Catalog #	Package Unit	MrOS Pricing	Units Ordered
Grass brand EEG electrodes, gold 60"	E565	Bag/10	91.80	
Electrode, Blue Sensor Large	E065	Pk/25	9.90	
EC-2 Paste / Electrolyte adhesive for gold disk application	M148	ea.	2.93	
EC-2 Paste / Electrolyte adhesive for gold disk application	M119	box/10	27.00	
4X4 Non-sterile gauze/ for set-up and clean-up	M113	bag/200	5.63	
Tape measure/ for head measurement	M007	ea.	4.28	
China Marker- Blue/ for marking head measurement	P012	box/12	12.60	
1X1 gauze squares/ pre-cut gauze for gold disk application	M057	bag/500	6.53	
Scissors (Blunt tip)	M184	ea.	4.05	
Cotton-tip applicators (6")	M003	Pk/1000	7.43	
Transpore Tape 1"/ porous plastic tape	T013	box/12	19.85	
Micropore Tape 1"/ paper like tape	T012	box/12	10.40	
HY-TAPE 1"/ waterproof tape with zinc oxide base	T043	roll	3.56	
Scanpor Tape 1"/ paper like tape (orange core)	T017	box/12	39.33	
Self-Adherent wrap 1"	T038	box/12	12.38	
Nu-Prep Abrasive/ Blue skin prep.	M009	tube	6.80	
Lemon Prep/ Highest abrasive skin prep.	M353	bottle	7.16	
Pre-TAC/ adhesive enhancer for diaphoretic subjects	M081	bottle	5.76	
Anti-Perspirant Lotion	M409	bottle	7.16	
Plastic Med. Cup 1oz./ for electrolyte or abrasive	M369	pk/100	4.05	
Professional towel/ 13.5"x18" plastic backed underpad	M396	cs/500	22.95	
Latex-free non-powdered gloves-SMALL	G004	bx/100	8.78	
Latex-free non-powdered gloves-MEDIUM	G005	bx/100	8.78	
Latex-free non-powdered gloves-LARGE	G006	bx/100	8.78	
Medical Adhesive Remover	M450	bottle	9.68	
Reusable adult oximeter probe w/25 Flexi-wraps	E046	Ea	87.30	
Disposable Flexi-Wrap Sensor Holder	M398	Pk/25	19.35	
Disposable Oximeter Probe, Adult	E043	Pk/10	134.55	
Adult Sensor Cannula	M275	cs/50	162.00	
One Channel, Nasal/Oral Sensor-Adult	M301	Ea	151.20	
Head Net, adult, large	M281	Roll/25 yd	20.16	



Site ID _____

Participant ID#: _____

1. Scorer ID: _____ Total Rec. Time _____ 4. Date entered: _____

2. Date scored: _____ Total Sleep Time _____ Siesta Unit ID _____

31. CD #: _____ 3. RDI _____ Tech ID _____

Channels	Code for signals quality:	
	Entire sleep time (> 95 %)	5
LOC	75 - 94 % of sleep time	4
ROC	50 - 74 % of sleep time	3
Chin	25 - 49 % of sleep time	2
C3-A2	< 25 % of sleep time	1
C4-A1		
ECG		
Left Leg		
Right Leg	Working = 1 Non-Working = 0	
Airflow	A1	
Cannula Flow	A2	
Thoracic	Ref	
Abdomen		
Oximetry		

15. 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).

16. Participant Reported Time to Bed _____ Scorer Sleep Onset Time _____

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

19. Comments: _____

SOF QS Form

Participant ID _____

Date of Study _____

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

21. Was any data lost?	<input type="checkbox"/> ⁽⁰⁾ No	<input type="checkbox"/> ⁽¹⁾ Yes	
a) Recording started after sleep onset	<input type="checkbox"/> ⁽⁸⁾ N/A	<input type="checkbox"/> ⁽¹⁾ Yes <input type="checkbox"/> ⁽⁰⁾ No	
b) Recording ended before partic. awoke	<input type="checkbox"/> ⁽⁸⁾ N/A	<input type="checkbox"/> ⁽¹⁾ Yes <input type="checkbox"/> ⁽⁰⁾ No	
c) Loss of the data at the beg. of the study	<input type="checkbox"/> ⁽⁸⁾ N/A	<input type="checkbox"/> ⁽¹⁾ Yes <input type="checkbox"/> ⁽⁰⁾ No	
d) Loss of the data at the end of the study	<input type="checkbox"/> ⁽⁸⁾ N/A	<input type="checkbox"/> ⁽¹⁾ Yes <input type="checkbox"/> ⁽⁰⁾ No	
e) Loss of the data during the study	<input type="checkbox"/> ⁽⁸⁾ N/A	<input type="checkbox"/> ⁽¹⁾ Yes <input type="checkbox"/> ⁽⁰⁾ No	
22. Was study scored Sleep/Wake only?	<input type="checkbox"/> ⁽⁰⁾ No	<input type="checkbox"/> ⁽¹⁾ Yes	
23. Were there problems with scoring sleep stages?		<input type="checkbox"/> ⁽¹⁾ Yes <input type="checkbox"/> ⁽⁰⁾ No	<input type="checkbox"/> ⁽⁸⁾ N/A
a) Wake / Sleep unreliable		<input type="checkbox"/> ⁽¹⁾ Yes <input type="checkbox"/> ⁽⁰⁾ No	<input type="checkbox"/> ⁽⁸⁾ N/A
b) Stage 1/ Stage 2 unreliable		<input type="checkbox"/> ⁽¹⁾ Yes <input type="checkbox"/> ⁽⁰⁾ No	<input type="checkbox"/> ⁽⁸⁾ N/A
c) Stage 2 / Deep sleep unreliable		<input type="checkbox"/> ⁽¹⁾ Yes <input type="checkbox"/> ⁽⁰⁾ No	<input type="checkbox"/> ⁽⁸⁾ N/A
d) REM / NonREM unreliable		<input type="checkbox"/> ⁽¹⁾ Yes <input type="checkbox"/> ⁽⁰⁾ No	<input type="checkbox"/> ⁽⁸⁾ N/A

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

26. Were there problems scoring resp. events (RDI may be unreliable)?	<input type="checkbox"/> ⁽⁰⁾ No	<input type="checkbox"/> ⁽¹⁾ Yes
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27. Was apnea/hypopnea distinction unreliable?	<input type="checkbox"/> ⁽⁰⁾ No	<input type="checkbox"/> ⁽¹⁾ Yes
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28. Were unusual occurrences?	<input type="checkbox"/> ⁽⁰⁾ No	<input type="checkbox"/> ⁽¹⁾ Yes	Initials Date
a) Abnormal awake EEG	<input type="checkbox"/> ⁽⁸⁾ N/A	<input type="checkbox"/> ⁽¹⁾ Yes <input type="checkbox"/> ⁽⁰⁾ No	
b) Physiologic alpha intrusion	<input type="checkbox"/> ⁽⁸⁾ N/A	<input type="checkbox"/> ⁽¹⁾ Yes <input type="checkbox"/> ⁽⁰⁾ No	
c) Abnormal eye movements	<input type="checkbox"/> ⁽⁸⁾ N/A	<input type="checkbox"/> ⁽¹⁾ Yes <input type="checkbox"/> ⁽⁰⁾ No	
d) Periodic breathing ≥ 5 min	<input type="checkbox"/> ⁽⁸⁾ N/A	<input type="checkbox"/> ⁽¹⁾ Yes <input type="checkbox"/> ⁽⁰⁾ No	
e) Periodic breathing ≥ 10 min	<input type="checkbox"/> ⁽⁸⁾ N/A	<input type="checkbox"/> ⁽¹⁾ Yes <input type="checkbox"/> ⁽⁰⁾ No	
f) Periodic large breaths	<input type="checkbox"/> ⁽⁸⁾ N/A	<input type="checkbox"/> ⁽¹⁾ Yes <input type="checkbox"/> ⁽⁰⁾ No	

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

31. Nasal Pressure - Flow limitation observed for at least 10% of TST?	<input type="checkbox"/> ⁽⁰⁾ No <input type="checkbox"/> ⁽⁸⁾ N/A	<input type="checkbox"/> ⁽¹⁾ Yes
a) were PLMs associated with flow limitation at least 50% of the time?	<input type="checkbox"/> ⁽⁸⁾ N/A	<input type="checkbox"/> ⁽¹⁾ Yes <input type="checkbox"/> ⁽⁰⁾ No

32. Were more than 50% of PLMs deleted due to the occurrence at the end of the respiratory events?	<input type="checkbox"/> ⁽⁰⁾ No	<input type="checkbox"/> ⁽¹⁾ Yes
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30. Notes:	_____

