POLYSOMNOGRAPHY COHORT

The Pittsburgh clinic will be performing polysomnography on 500 participants. For these participants there will be some additional measures that need to be completed both at the clinic visit and in the participant's home the day of the sleep study. Detailed procedures are outlined below.

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IN THE CLINIC

BLOOD PRESSURE

1. Background and Rationale

Recent studies have linked hypertension and cardiovascular disease with various sleep conditions such as obstructive sleep apnea. To determine if hypertension is related to sleep disorders in older women, blood pressure measurements will be recorded for participants in the polysomnography cohort during the clinic visit portion of the examination. We will collect blood pressure while the participant is lying down and while they are standing.

2. Equipment and Supplies

- conventional mercury sphygmomanometer.
- blood pressure cuffs (small, regular, large and thigh cuffs).
- Standard stethoscope and ear pieces with bell, tubing to be max of 14 inches long
- double-headed stethoscope (for training only)
- tape measure
- eyebrow pencil
- chair with back support
- digital stop-watch

3. Maintenance of Blood Pressure Equipment

With Each Use:

1) Check the sphygmomanometer for correct zero. Place the instrument flat on the table and disconnect the inflation system. With eyes level with the zero line, assure the top of the meniscus is on the zero line.

2) Check the shape of the meniscus--it should be a smooth, well-defined curve.

Monthly:

1) Check that the mercury rises easily in the tubing and that the mercury column does not bounce noticeably when the valve is closed.

2) Check for cracks in the glass tube.

3) Check the cap at the top of the calibrated glass tube to make sure it is securely in place.

4) Check for spilled mercury in the manometer case.

5) Check the cuffs, pressure bulb, and manometer and stethoscope tubing for cracks or tears.

6) Check the pressure control valve for sticks or leaks.

7) Check the stethoscope diaphragm for cracks.

8) Make sure when you close the manometer case that:

- the manometer tubing is connected and the thumb valve is closed
- the manometer case is stored on its right side so that the mercury will flow back into the reservoir

9) Never attempt to repair the equipment yourself. Send the instrument for repair if any of the above checks reveal a problem.

10) Check the sphygmomanometer for air leaks. Roll the cuff around a plastic bottle or tin can and secure in place. Close the valve on the Air-Flo system and inflate the instrument until the mercury rises to 240 mm Hg. Close the valve. The mercury column should remain stable. If the column continues to fall, there is an air leak and the system should be re-inflated until the column rises to 200 mmHg. Pinch the tubing at various locations to localize the area of the leak, then replace the leaking tubing, cuff, or valve.

General:

With time, the mercury will become dirty and an oxide layer will be deposited on the inside of the glass tube. Do not attempt to clean the glass column with a pipe cleaner, as hazardous levels of mercury aerosol will be produced. You will need to have the instrument sent to your local supplier for repair.

Since mercury is a hazardous, toxic substance, all maintenance and proper disposal procedures must be performed carefully (consult your local institution for guidelines). Do not perform any maintenance procedures that will expose mercury to air. A manometer specialist with expertise in handling toxic substances should be contacted to add or withdraw mercury from the instrument.

Check the blood pressure cuffs on a monthly basis to assure all sizes of cuffs are available. Document the monthly checks of the sphygmomanometer in a calibration log.

Inspect the tape used to measure arm circumference for damage or wear twice a year and record these checks on the "Sphygmomanometer Equipment Maintenance Log."

4. Participant and Exam Room Preparation

Caffeine (from coffee, tea, or soda), eating, heavy physical activity, smoking and alcohol should be proscribed for 30 minutes prior to recording the blood pressure.

Arm circumference

If possible, use the right arm. If the participant's right arm is injured or missing use the left arm for the arm circumference and blood pressure measurement. Measure the participant's arm to determine the appropriate cuff size before allowing the participant to rest.

Use the following procedures to measure the participant's arm and determine the appropriate cuff size:

- Proper measurement requires that the participant's arm is bare to the shoulder.
- Request the participant to stand, bend the elbow, and put the forearm straight across the chest. The upper arm should be at a 90 degree angle to the lower arm.
- Measure arm length from the bony prominence of the shoulder girdle (acromion) to the tip of the elbow using a tape measure.
- Mark the midpoint on the dorsal (back) surface of the arm.
- Ask the participant to relax their arm along the side of the body.
- Draw the tape measure horizontally around the arm at the midpoint mark, but do not indent the skin.
- Use the measurement to determine the correct cuff size.

Do not use the markings on the blood pressure cuff for reference. Instead, use the following criteria for determining the appropriate cuff size for the participant:

Arm Circumference (cm/in.)	Cuff's Bladder Size (cm)*
16.0 - 22.5 cm (6.4 - 9.0 in)	small cuff (9.0 cm)
22.6 - 30.0 cm (9.1 - 12.0 in)	regular cuff (12.0 cm)
30.1 - 37.5 cm (12.1 - 15.0 in)	large cuff (15.0 cm)
37.6 - 43.7 cm (15.1 - 17.5 in)	thigh cuff (17.5 cm)

Keep the above chart of arm circumference measurements and corresponding cuff sizes readily available for easy reference.

5. Detailed Measurement Procedures

In measuring the participant's blood pressure, the participant should rest for approximately five minutes with their feet flat on the floor and legs and ankles uncrossed. The maximum inflation level should be determined and two blood pressure readings obtained.

a) Application of the Cuff

- Ensure that the participant is seated comfortably in a chair with back supported and both feet are flat on the floor.
- Make sure that the participant's arm is resting on the table at a 90 degree angle with the palm facing up.
- Palpate the brachial artery.
- Mark the brachial artery with an eyebrow pencil.
- Place the appropriate-sized cuff around the upper right arm, approximately at heart level, with the participant's palm facing upward (the participant may rest their forearm and elbow on a table or arm of the chair). Place the lower edge of the cuff with its tubing connections about one inch above the natural crease across the inner aspect of the elbow.
- Wrap the cuff snugly about the arm, with the inflatable inner bladder centered over the area of the brachial artery. The brachial artery is usually found at the crease of the arm, slightly toward the body. Secure the wrapped cuff firmly by applying pressure to the locking fabric fastener over the area that it overlaps the cuff. You should be able to insert two fingers under the cuff.
- If it is not feasible to measure blood pressure using the right arm, the left arm may be used.

b) Rest Period

Ask the participant to sit with both feet flat on the floor and to rest without talking for five minutes before measuring their blood pressure. Instruct the participant on the correct posture with the back supported and both feet flat on the floor. The work station should be free of excessive noise and the participant should not be interviewed nor asked to read anything at this time.

c) Ausculatory Gap

An ausculatory gap is the fading or disappearance of sound after the first Korotkoff sounds are heard. The sound then reappears at a level well above the diastolic pressure. The radial pulse can still be felt during the silent phase and the gap usually occurs between Phase I and II. This phenomenon is seen more frequently in older persons.

This means that in an adult with an ausculatory gap, the real systolic pressure may be missed and read as a much lower BP. For example:

Real systolic is 172 but sounds fade at:
168 and reappear at
152 and disappear at 98.

If the correct procedure (inflating to MIL) for BP measurement is not used, this participant's BP may be read as 152/98 instead of 172/98. The only way to avoid this error is to obtain the MIL before BP measurement.

Determine the pressure to which to inflate the cuff for the measurement of the systolic blood pressure. This assures that the cuff pressure at the start of the reading exceeds the systolic blood pressure and allows you to hear the first Korotkoff sound. The procedures for determining maximal inflation level are as follows:

- Attach the cuff tubing to the conventional mercury sphygmomanometer.
- Palpate the radial pulse (if the radial pulse is difficult to palpate, the brachial pulse may be used).
- Inflate the cuff to 70 mmHg. Then increase by 10 mmHg increments until the radial pulse is no longer felt (palpated systolic).
- Deflate the cuff quickly and completely.
- Inflate the cuff to 30 mmHg above the palpated systolic pressure for all subsequent readings.
- Repeat the MIL if the first attempt was unsatisfactory or you have had to readjust the cuff after measuring the MIL. Wait 30 seconds before making a second attempt if the first is unsatisfactory. If the second attempt is unsatisfactory, terminate the procedure and note the problem on the form.
- If the radial pulse is still felt at a level of 270 mm Hg or higher (which means that the MIL is 30 mm Hg higher) repeat the MIL. If the MIL is still 300 mm Hg, terminate the blood pressure measurements and write in "300/MIL" on the form.

6. Performing the Blood Pressure Measurement

a) Place the ear pieces of the stethoscope, with the tips turned forward, into your ears.

b) Apply the bell of the stethoscope over the brachial artery with light pressure, ensuring skin contact at all points. Effective use of the bell requires careful palpation of the brachial artery to know exactly where to place the bell. Place the bell just below, but not touching, the cuff or tubing.

c) Close the thumb valve and squeeze the bulb, inflating the cuff at a rapid but smooth and continuous rate to the maximal inflation level. *Note:* Your eyes should be level with the mid-range of the manometer scale and focused on the level to which you will raise the pressure.

d) Open the thumb valve very slightly and maintain a constant rate of deflation at no more than 2-3 mm per second, allowing the cuff to deflate. Listen throughout the entire range of deflation, from the maximum pressure past the systolic reading (the pressure where the first regular sound is heard) until 10 mmHg below the level of the diastolic reading (i.e., 10 mmHg below the level where you hear the last regular sound).

NOTE: The systolic value (Phase I) is the pressure at which you hear the first of two or more knocking sounds in appropriate rhythm. The diastolic sound (Phase V) is the pressure at which you hear the last muffled sound.

e) Deflate the cuff fully by separating the tubing and remove the stethoscope ear pieces.

f) Record the systolic and diastolic values from the first reading in the spaces provided on the form.

g) Hold the participant's arm vertically above their head for a full five seconds to relieve blood pooling.

h) Have the participant sit quietly for 5-10 minutes, then repeat the blood pressure measurement while the patient is standing and record the systolic and diastolic values from the standing blood pressure measurement on the form.

7. Criteria for Systolic and Diastolic Blood Pressure

To identify correctly systolic (Phase I) and diastolic (Phase V) Korotkoff values, listen carefully via the stethoscope while reading and interpreting the mercury column.

- The systolic value is the pressure level at which you hear the first of two or more knocking sounds in the appropriate rhythm. *Note:* A single sound heard in isolation (i.e., not in rhythmic sequence) before the first of the rhythmic sounds (systolic) does not alter the interpretation of blood pressure).

- The diastolic value can be identified as the pressure level at which you hear the last of these rhythmic sounds (usually muffled).

- Make the mercury column drop at 2 to 3 mmHg per second, from the maximum inflation pressure until 10 mmHg below that of the last regular sound heard. The control of the deflation rate at 2 to 3 mmHg per second is essential for accurate readings and depends on the handling of the bulb and its control valve.

8. Guidelines for Blood Pressure Readings

- Record all readings to the nearest even digit, rounding up (i.e., read any value that appears to fall exactly between the markings on the mercury column to the next higher even marking).

- Make readings at the top of the meniscus, or rounded surface of the mercury columns.

- When the pressure is released too quickly from a high level, a vacuum is formed above the mercury and the meniscus is distorted. Allow a few moments for it to reappear before reading the manometer or doing a repeat measurement.

- Repeat the MIL whenever a systolic blood pressure reading is less than 10 mm mercury from the MIL, or if sounds are heard immediately.

- If a measurement was interrupted, use the following guidelines:

    1. Repeat the MIL only if the cuff was removed or more than five minutes has lapsed between the MIL and the first blood pressure reading or between any two blood pressure readings.

    2. If the blood pressure sounds are not heard during the first measurement, review your technique, check stethoscope position for loose connections or tubing kinks, and maintain a quiet environment. Relocate the brachial pulse and apply the bell headpiece directly over the pulse point. Take care to wait at least 30 seconds between measurements. Use the procedure to enhance the sounds (see below) and measure the blood pressure a second time, placing the stethoscope in the same position.

9. Procedures to Enhance the Korotkoff Sounds

If you are having difficulty hearing the blood pressure sounds, there are three methods that can be used to increase the intensity and loudness of the sounds.

1. Reduce room noise.

2. Instruct the participant to open and close their fist 8 to 10 times. Inflate the cuff and measure the BP immediately.

3. Have the participant raise their arm and forearm over their head and make a fist several times for at least 60 seconds. Inflate the cuff while the arm is still overhead, but the hand relaxed, to a level 50 mm Hg above the expected systolic level. Then lower the arm rapidly and measure the blood pressure in the usual manner.

10. Quality Assurance

Training Requirements

Clinical experience with blood pressure measurement is required. In addition, training should include:

- Read and study manual
- Observe administration by experienced examiner.
- Practice on volunteers
- Compare measurements with those made by experienced colleagues (Goal: obtain measurements within ± 2 mm Hg of that observed by a trainer listening with a double-headed stethoscope.)
- Discuss problems and questions with local expert

CERTIFICATION REQUIREMENTS

- Complete training requirements
- Explain and demonstrate daily and monthly checks of sphygmomanometer
- Explain procedure if measurement is interrupted
- Explain procedure to enhance Korotkoff sounds
- Recite alert values
- Conduct exam on two volunteers while being observed by QC officer listening with double-headed stethoscope
- Performs exam according to protocol as demonstrated on completed QC checklist
- Three simultaneous readings of systolic and diastolic measurements recorded by the staff member agree with those of the QC officer within 4 mm Hg, with the average of the three readings within 3 mm Hg.

11. QUALITY ASSURANCE CHECKLIST

Blood Pressure

- ❑ Explains procedure
- ❑ Measures for cuff size
- ❑ Wraps cuff snugly, centering bladder over brachial artery
- ❑ Five minute rest period before measurements
- ❑ Palpates brachial artery
- ❑ Determines maximal inflation level
- ❑ Inflates rapidly to maximal inflation level
- ❑ Places bell on brachial pulse

- ❑ Deflates cuff 2-3 mm Hg per second
- ❑ First and fifth phase correctly identified (verified with double stethoscope)
- ❑ Standing blood pressure measurement measured after one minute standing rest period
- ❑ Records reading and disconnects tubes
- ❑ Reviews forms for completeness
- ❑ Correctly completes forms
- ❑ Tells participant BP reading
- ❑ Maintenance log up to date

11. Acknowledgments

Women's Health Initiative Operations Manual. Volume 2, Section 9.2: Blood Pressure. 8/30/95.

WHAS Operations Manual. Section 3.5 Blood Pressure Measurements. 6/18/93.

SERUM

See Serum Protocol.

NECK CIRCUMFERENCE

1. Background and Purpose

Recent data suggest neck circumference, as a measure of central obesity, is better correlated with obstructive sleep apnea (OSA) than is BMI[1]. In particular, among subjects with a BMI <28kg/m^2, an increased neck size may identify those with OSA[2]. Increased neck size, as a marker for upper airway compromise, may be a direct risk factor for OSA.

2. Definitions

Frankfort Horizontal Plan - head parallel to the floor looking straight ahead
Laryngeal prominence - also known as the Adams apple, located in the throat

3. Method

The method described by Callaway et al in Lohman, Rocke, and Martorell[3] will be used to measure the circumference of the neck.

- Perform and record this measurement in triplicate
- Participant sits upright with the head in the Frankfort Horizontal Plane
- An inelastic tape is applied around the neck just below the laryngeal prominence
- Measurement is made perpendicular to the long axis of the neck (which is not necessarily in the horizontal plane)
- Tape should be placed in such a way as to minimize the measurement
- Pressure on the tape should be minimum required to maintain skin contact
- Measurement should be completed in less than 5 seconds, to avoid participant discomfort
- Circumference of the neck is measured to the nearest 0.1 in (round up).

4. References

1. Stradling JR, Crosby JH. Predictors and prevalence of obstructive sleep apnea and snoring in 1001 middle-aged men. Thorax 1991; 46:85-90.

2. Carlson JT, Hedner JA, Ejnell H, Peterson LE. High prevalence of hypertension in sleep apnea patients independently of obesity. Am J Respir Crit Care Med 1994; 150:72-77.

3. Callaway CW, Chumlea WC, Buchard C et al. Circumferences. In Lohman TG, Roche AF Martorell R, eds, Anthropometric Standardization Reference Manual, Human Kinetic Books, Champaign, IL, 1988, pp 41-45.

HIP CIRCUMFERENCE

The subject should wear only nonrestrictive briefs or underwear, or a light smock over underwear. The subject stands erect with arms at the sides and feet together. The measurer squats at the side of the subject so that the level of maximum extension of the buttocks can be seen. An inelastic tape is placed around the buttocks in a horizontal plane at this level without compressing the skin. An assistant is needed to help position the tape on the opposite side of the subject's body. The zero end of the tape should be below the measurement value. The tape is in contact with the skin but does not indent the soft tissue. The measurement is done to the nearest 0.1in and should be done three times.

WAIST CIRCUMFERENCE

The subject should wear little clothing so that the tape may be correctly positioned. The measurement should not be made over clothing. If clothing must be worn, subjects should undress to light underwear and wear only a cloth or paper smock during the measurement. The subject stands erect with the abdomen relaxed, the arms at the sides and feet together. The measurer faces the subject and places an inelastic tape around the subject, at the level of the natural waist, which is the narrowest part of the torso. An assistant is needed to help position the tape in a horizontal plane. In some obese subjects, it may be difficult to identify a waist narrowing. In such cases, the smallest horizontal circumference should be measured in the area between the ribs and iliac crest. The measurement should be taken at the end of a normal expiration, without the tape compressing the skin. It is recorded to the nearest 0.1in and should be done three times.

IN THE HOME

MEDICATION INVENTORY

1. Background and Signficance

The Medication Inventory will be completed according to the Medication Inventory protocol at the clinic visit. Additional medication information will be collected on the day of the polysomnography hook-up in the home. The additional medication information may be used in analysis of the sleep study.

2. Method

The technician performing the hook-up should take the Medication Inventory that has been completed at the clinic visit with them to the home of the participant. In the box entitled 'PITTSBURGH ONLY: In PSG Cohort', 'yes' should be filled in. The technician will ask the participant what medications they have taken that day and what they will take before bedtime. The technician should go through the list of the medications already provided by the participant at the clinic visit and mark "yes/no" in the field 'PSG 24 hr'. The participant should also be asked if they have taken any medication that were not on the original list.

Inform the participant of this additional data collection when they are at their clinic visit so that they may have any additional medications readily available.

3. Transferring Data to the Coordinating Center

After the PSG medication information has been collected the form can be sent to the Coordinating Center. DO NOT fax the medication inventory form in until the PSG has been performed.

NOTE: The medication inventory form needs to be sent in one day before the morning sleep survey. This will ensure that the data system will recognize the sleep survey and additional edits will not be created.

POLYSOMNOGRAPHY HOOK-UP

Supplies

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

1 tube EC-2 paste
4 X 4 gauze pads
1 bottle Pre-Tac adhesive synergist
1 tape measure
precut 1 x 1 gauze squares
1 scissors
Alcohol swabs or Electrode Prep pads
1 small bottle acetone or acetone prep pads
2 cotton tip applicators
1 roll Transpore tape
1 roll Hypafix or Medipore tape (cut into 1x1"squares) or Cover All Gauze
1 roll Scanpor Surgical Tape
Surgitube tube gauze (cotton wire cover)
2 hair pins
1 bottle Lemon Prep or NuPrep
2 disposable snap ECG pads (Medtronics Cleartrace)
1 wax pencil (do not use red, if possible)
1 oximeter (attached to cable connected to recorder)
1 thermistor

(2) towels	soap solution	non-latex gloves
1 tray	small cup	disposable underpads (Chux)
drinking straws	face mirror	plastic trash bags

The In-Lab Visit

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

Listed are some features that will assure a successful visit:

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

9) Keep a Positive Attitude
10) The participant's comfort always comes before study needs

The Setting

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

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

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

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

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

Below are general rules for good sensor placement:

1. Request the participant to be bathed and dressed for bed at your arrival. Discourage silky bedclothes; they cause static electricity and the respiratoy belts may slip.
2. Prep only areas of skin that electrodes cover
3. Use only small pieces of tape but enough to secure the sensor and wires
4. Provide for "stress" in wire/cables
5. Secure loose wires/cables with tape
6. For elements that require participant's hook-up, have subject demonstrate ability to place/replace/remove sensors (use a mirror if necessary)
7. Use non-dominant hand for oximeter placement
8. Ask participant about sensitivity to adhesives or latex products or choose to use all latex-free products.

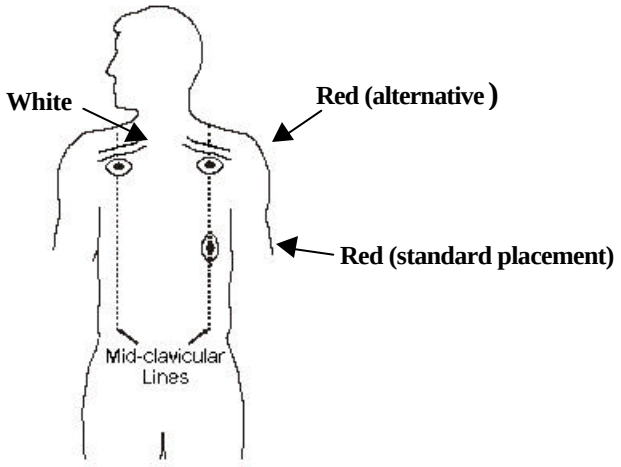
You will use 12 electrodes: Cz (reference) Forehead (GND), C3, C4, A1, A2, left EOG, right EOG, 2 chin EMG, and 2 ECG (snaps). You also will be using abdomen and chest belts, an oximeter, nasal/oral thermistor, nasal pressure cannula, 2 leg sensors and a body position sensor.

Suggested Order of PSG Hook-up:

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

Step 1: ATTACHMENT OF ECG ELECTRODES

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



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

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

1. Feed electrode end of the wire down under the clothing.

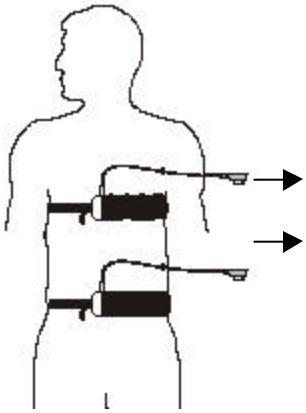
2. Remove electrode from sealed package (e.g., Cleartrace or Red Dot Snap). Snap electrode to lead wire **before** applying to subject's skin.

3. Prepare the marked sites by lightly abrading with prep gel. Remove excess prep gel before placing the electrode. Remove backing from electrode and place gel electrode on cleansed sites, with gel side down.

4. Form a small "stress" loop with the wire immediately feeding the electrode, secure with a small amount of tape.

5. Indicate the ECG placement used on the **Signal Verification Form**.

Step 2: PLACEMENT OF RESPIRATORY BANDS



1. Place the **chest band** under the left armpit, with the lead wire facing upwards. Adjust the black extender belt so the belt is secure, but not tight. Run wires upwards and tape to the shoulder.

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

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

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

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

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

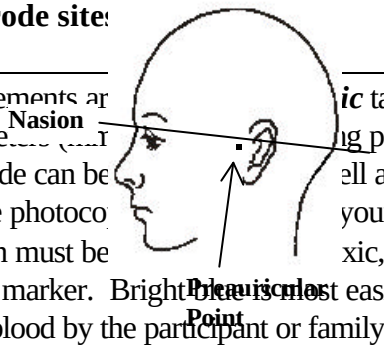
2) Nasion: Facing the participant, look into his/her eyes. Find the small dip at the bridge of the nose between the eyes. This point at which the forehead meets the nose is the nasion. Lightly mark the nasion.

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

When the inion cannot be determined use the following method:

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

Measure for electrode site



- Distance measurements ar ***ic*** tape measure, and taken in centimeters (cm.) and millime ng percentages to find the electrode site a quick measurement guide can be ell a e Equipment Maintenance Section. The guide can be photoco your prep materials for handy reference.
- All marks on skin must be xic, non-permanent implement, such as a wax-based china marker. Bright blue is most easily seen against dark hair. Red can be misidentified as blood by the participant or family members.
- When working with participants having long or thick hair, create a part in the hair by means of a comb or the 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.)**
30	15.0	6.0
31	15.5	6.2
32	16.0	6.4
33	16.5	6.6
34	17.0	6.8
35	17.5	7.0
36	18.0	7.2
37	18.5	7.4
38	19.0	7.6
39	19.5	7.8
40	20.0	8.0

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

Remember: The 50% values are used to determine Cz. The 20% values are used to determine C_3 and C_4.

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

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

3) Remove the tape measure and stand behind the participant. Place the zero line of the tape measure on the left pre-auricular mark. Stretch the tape measure over the top of the head, and along the mark that has just been made, until it reaches the right pre-auricular mark. Determine the total distance from pre-auricular to pre-auricular in centimeters. Remember this number (it may help to write it down). Compute 50% of this total measurement (or use your measurement

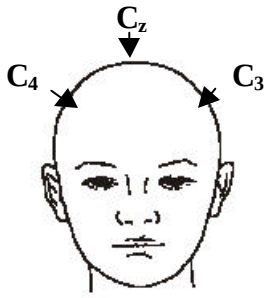
guide). While firmly holding the tape measure at the left preauricular mark allow the tape measure to drape over the crown of the head while marking the value for 50% of the total measurement. This mark should intersect the previously made line. The point at which the lines intersect is the site for the Cz electrode placement.

To determine C4:

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

To determine C3:

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

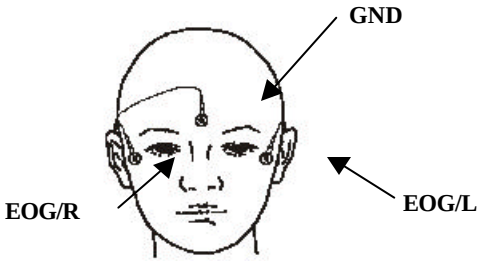


To determine A1 and A2:
These placement sites are on the mastoid process (bone behind the earlobe). The electrode should be placed on the skin between the crease of the earlobe and where the hairline begins. Lightly mark these sites. A1 is placed on the left mastiod, A2 on the right.

To determine EOG placements:

The EOG recording electrodes are placed about 1 cm. (one finger breadth) lateral to and 1 cm. below the outer canthus of the eye, (on the ridge of the orbital bone). Lightly mark these sites,

and then stand in front of the participant to make certain that they are symmetric. Asymmetric placement of the EOG electrodes can create uncertainties in the data interpretation.

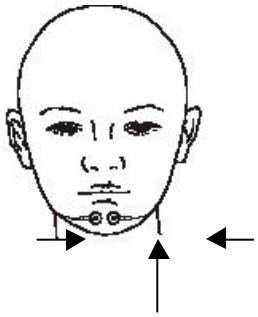


To determine EMG placement:

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

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

The other two EMG electrodes are placed on each side of the submentalis, which is a large muscle located underneath the chin. Having the participant activate this muscle may be helpful for determining the placement of the EMG electrodes. To activate the muscle, place your hand under the participant's chin, between the tip if the chin and the neck. Ask the participant to swallow. You will feel the submentalis 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 submentalis muscle is also acceptable.



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

Reference:

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

Prepare the Electrode Sites:

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

- Successful skin preparation prior to electrode placement helps to reduce the level of impedance thereby improving the quality of signal.

- Skin preparation requires abrasion to the top layer of the participant's skin at the electrode site. Although blood is not evident, the field technician must understand that these areas are now non-intact skin and pose a risk for blood borne pathogens. SHHS recommends wearing latex or non-latex gloves as personal protective equipment (PPE) at all times when working with non-intact skin and equipment, which has been in direct contact with non-intact skin (i.e.: used electrodes).

- Use an abrasive preparation. Preparations such as Nu-Prep and Skin Pure contain relatively less pumice and may be preferred for participants with sensitive or fragile skin. Preparations with higher pumice concentration (such as Lemon Prep) may be useful for participants with tough or oily skin (and for bald participants).

- Abrade only the area at the marked site. Gold disk electrodes have a diameter of 1 centimeter, therefore the abrasion should be limited to an area the size of or just slightly larger than the electrode. On marked sites, remember that the electrode should be placed where the 2 lines intersect.
- The participant should know what to expect! Please communicate. You may choose to use the following script: "Before I attach the electrodes, I have to get your skin ready. I will be using a special cleaner that sets the skin up for a good contact. You may feel a little bit of scratching on your skin, it may feel a little like sandpaper, but it should not hurt, and it will not harm your skin."

1. Place a small amount of skin prep abrasive onto a clean disposable surface (i.e.: 4x4 gauze square or small plastic med. cup).

2. If working in a hairy area, separate the hair in order to see the skin. You may find a comb or hairclips useful to create a part and hold the hair back.

3. Use a cotton tipped applicator to transfer a small amount of skin prep directly onto the electrode site. Before lifting the applicator, apply a moderate pressure and make small circular motions repeatedly on the skin. Take care that you include the center of the site,

not just make circles around it leaving the center un-prepped. You may prefer to use a combination of back and forth strokes along with some circular motions.

4. Continuing with moderate pressure, slowly count to 5 while you scrub the site (1one-thousand, 2 one-thousand, 3 one-thousand, 4 one-thousand, 5 one-thousand). You are done when the skin "pinks up". Expect some participants to have more fragile skin than others; keep an eye on what you do. You may have to adjust the pressure or the count time.

5. Prep abrasives are not designed as conductors; remove any excessive prep abrasive from the skin prior to electrode placement.

6. Repeat the above steps for each electrode site. It is much easier to prep 2 or 3 sites, and then to apply those electrodes, provided you do not lose your prepped sites.

7. Discard the applicator and prep abrasive when finished. Never contaminate your original tube or bottle.

Attach Gold Disk Electrodes:

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

Although different pastes may be used for different electrodes sites (EEG, EOG or EMG sites) both SOF and manufacturers recommend never mixing pastes for the same electrode.
Adverse reactions to mixing 2 electrolytes together cannot be predicted.

- Assemble your supplies in advance. Have several pieces of cut gauze or pieces of tape ready to place on top of the electrode once it is placed on the skin. Gravity can move the electrode from its proper site while you fumble with equipment.

- Prior to attaching gold disk electrodes, cut a sufficient length (approximately 2 arm's length) of Surgitube 1" tube gauze. Run the gold disk electrodes through the length of the tube gauze to create a cotton sheath encasing all of the wires. Secure the Surgitube sheath with a twisty or another appropriate fastener approximately 12-18" from the gold disks. This will allow for the electrodes to be placed according to the color codes and for range of motion at the neck, yet will still provide for bundling of the 10 electrode wires.

- Place a small amount of EC2 electrolyte paste onto a clean disposable surface (i.e.: 4x4 gauze square, small plastic med. cup, or the back of your gloved non-dominant hand).

- If working in a hairy area, separate the hair in order to see the skin. Your site should still be visible from the prep phase.

- If the participant is expected to sweat, there are additional skin preparations that reduce the moisture of the skin (such as PRE-TAC) and help improve the holding power of the adhesive. Try experimenting with such preparations. Generally, these liquids are applied very sparingly to prepped skin and allowed to dry before continuing with electrode application.

- If using tape, ask the participant about sensitivity to tape, latex or adhesives. For participants with sensitivity use Micropore (paper) or Scanpor tape.

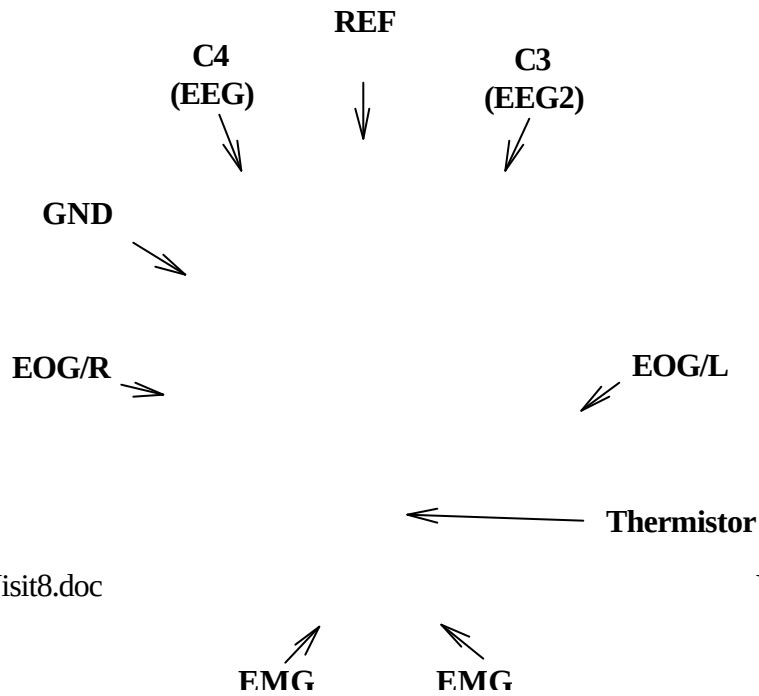
- If using EC2 cream on the gauze square to anchor the electrode, it must also be the electrolyte used within the electrode cup.

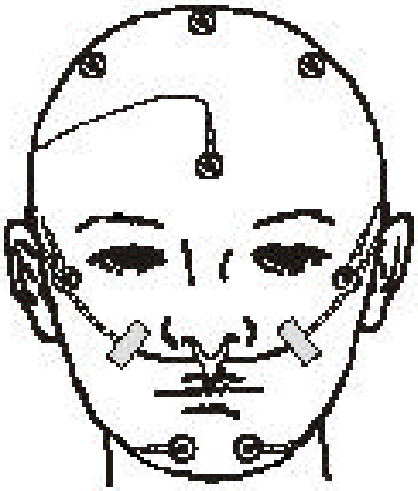
- When applying disk electrodes, work in a fashion so that the wires on the forehead and top of the head all point to the back of the head and down toward the neck, and the wires on the face and chin point upwards over the ears and then down toward the back of the neck. Use small pieces of tape to hold the wires in place as they course toward the back of the head, but allow enough slack so there is no pull when the participant moves.

    - Discard the unused electrolyte paste when finished. Never contaminate your original tube or bottle.

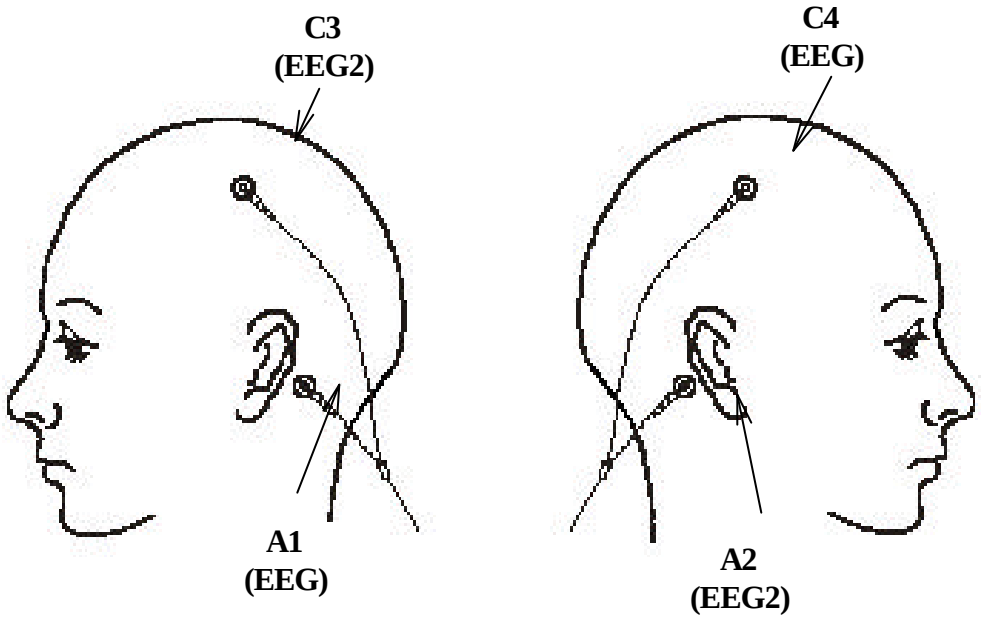
Attachment sites for gold disk electrodes:

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





under chin



Techniques for disk electrode application:

Bare skin (Face, mastoids):

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

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

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

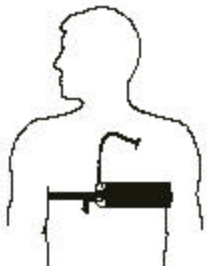
After electrodes are applied:
1. Plug in each electrode to its Siesta connector.
2. Gather gold disk electrode wires together just above nape of neck.

Bundle and secure as desired. If using tape, fold the ends for easier removal.

Step 4 : ATTACH THE POSITION SENSOR:

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

Step 5 : ATTACH OXIMETER:



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

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

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

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

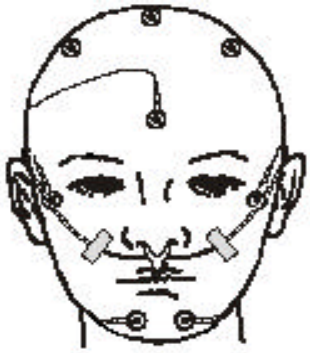
Step 6 : ATTACH NASAL CANNULA:

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

Step 7 : ATTACH THERMISTOR:

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

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



Step 8 : ATTACH LEG SENSORS:

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

Step 9 : INTERFACE SENSORS TO SIESTA, VERIFY AUTO START

1. Interface all electrodes to Siesta.

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

Step 10 : CHECK IMPEDANCE, ANNOTATE SV FORM:

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

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

- For EEG, EOG, and EMG, you want to achieve impedance of < 10 k. Most important is the balance (difference) between two sets of paired EEG electrodes. For accurate recording the difference in impedance levels between pairs of EEG electrodes should be less than 5 k.

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

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

1. If, on a second placement, impedance is still high there are two possible problems:
   a) the area of the skin identified for sensor placement has an unusually high impedance; or
   b) the lead wire or sensor is damaged.

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

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

For ECG impedance of < 30 k are acceptable.

Step 11: CHECK LIVE SIGNALS AND WRAP WIRES:

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

Step 12 : INSTRUCT PARTICIPANT FOR FINAL DETAILS:

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

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

MORNING SURVEY

1. Background and Significance

The Morning Survey is completed by the participant to ascertain how they slept the evening that they were hooked up to the polysomnography equipment and to understand what they may have done the night before to influence their sleep that night.

2. Method

The survey should be completed in the same manner that the SAQ is completed, by the participant. When the technician goes to the home the morning after the sleep study they should review the survey for any missing answers and should clarify any answers that do not make sense.

The morning survey will be sent to the Coordinating Center in the same manner that all forms are sent. The morning survey should not be sent until one day after the medication inventory has been sent to the Coordinating Center.