

**SHHS**

**Sleep Heart Health Study**

**SHHS  
Follow-up 2  
Field Site Procedures  
Volume 4**

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## 1. Follow-up Visit 2

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### 1.1. Population

The target population for the second follow-up examination will include all surviving members of the cohort. In general, participants will be sent a letter, announcing the continuation of the study and indicating that a staff member will call them to inquire about their interest in undergoing a second PSG. At some field sites, recruitment contacts will take place at a study clinic, if the SHHS schedule coincides with a parent study examination; at other Field Sites, participants will be recruited by phone. At field sites where participants are often without telephones, other means of contact will be used. Data collection will follow a priority list, described in section 1.10:

### 1.2. Screening

Regardless of the participant's interest in undergoing another PSG or having another home visit, the interviewer should try to administer the Screening Form (SC). The questionnaire has a dual purpose: 1) to determine PSG-eligibility status; 2) to obtain limited, self-reported outcome data.

### 1.3. Eligibility for PSG:

Exclusion criteria for the second PSG are similar to the criteria used at the baseline exam, namely, conditions that pose technical difficulties for PSG:

- Treatment of sleep apnea with continuous positive airway pressure or an oral device in the past 3 months,
- Usual use of oxygen treatment at home delivered by mask or cannula in the past 3 months
- Open tracheostomy

### 1.4. Recruitment cycles

Ideally, the home visit will take place about five years after the date of the first PSG (baseline), but no sooner than 4 years and 9 months (and preferably no later than 5 years and 3 months) after baseline. Field Sites will receive a list of dates of the baseline PSG visits in order to compute the desirable time-window for each cohort member and identify groups of participants that will be contacted each month. The expected starting date is December 2000. If a home visit cannot be scheduled within the desirable time window, it is permissible to schedule the visit for any date after the time window, although the sooner the better. Care must be taken to exclude, from the recruitment database, cohort members who have died and those who have indicated that they do not want to be contacted again. The following table shows the visit window times.



**Visit Window for Follow-up 2**

Start of window	+ 4 yrs	9 months	(1,735 days)
Target time	+ 5 yrs	0 months	(1,826 days)
Close of optimum window	+ 5yrs	3 months	(1,918 days)

**1.5. Recruitment Contact**

At the discretion of the field site, cohort members may be sent an introductory letter before a telephone contact is attempted, or may be contacted by telephone, or at a study clinic, without sending a letter. The Tracking Information form (TI) is provided as a local aid, and may be used to track the progress of recruitment for each individual. The recruiter will use a script to explain the nature of the SHHS follow-up study and determine the person’s level of interest. If a husband and wife are both cohort members who underwent the baseline exam on the same night, or at different times that would still allow a combined home visit to occur within the visit window for both, an attempt should be made to contact both at the same time and schedule a home visit for both on the same night. The recruitment script is as follows:

**Recruitment Script for SHHS 2 (use Form SC)**

*“Hello, I’m -----, from the Sleep Heart Health Study— in which you had an overnight sleep-study in your home a few years ago. Because you were a volunteer in this study, I am calling today to see if you would be willing to help again. Thanks to the efforts of all the volunteers in the study, we were able to do over 6000 sleep studies, and are now starting the second phase of this research”.*

**I. “Before I tell you about that, I would like to first ask you a few questions, mostly about your health history.”:** If no comment from the participant at this point assume yes, and proceed to (a).

(a) **YES:** participant complies, ask questions 1-10 on screening form, then go to II

(b) Participant says; “I do NOT want to have another one of those studies!!”

*“OK, we will not ask you to have another sleep study, but may I ask you a few questions to complete our records?”*

If YES, proceed to questions 1-10 on screening form. When complete, go to part II of this recruitment script.

1.5. Recruitment Contact

If NO, *“Thank you so much, I will not take up any more of your time on the phone, but wonder if I could send you a questionnaire, similar to the one you completed a few years ago, for you to fill out and send back to us?”* (YES,NO) IF NO, this ends the call.

II. If YES to 7,8,9,or 10 (**ineligible** for sleep study portion of home visit) **OR is unwilling** to have another sleep study, go to part II (a). If eligible for sleep study go to part II (b).

(a) *“Thank you, those are all the questions I needed to ask. Now, I would like to ask you if you would agree to have another home visit, but this time, we would not ask you to have another overnight sleep study. The new home visit should only take an hour or so, and would include an EKG, blood pressure measurements, measures of height and weight, and a health interview.”* ?more?

IF YES proceed with site-specific instructions, and tell participant that there will be a questionnaire mailed to them, to complete before the home visit and be picked up at that time.

If NO, *“Thank you so much, I will not take up any more of your time on the phone, but wonder if I could send you a questionnaire, similar to the one you completed a few years ago, for you to fill out and send back to us?”* (YES,NO) IF NO, this ends the call.

(b) If NO to 7,8,9 and 10: (eligible for Sleep Study)

*“Thank you, those are all the questions I need to ask. Now, I would like to invite you/ask you if you would agree to having another home visit and overnight sleep study. The home visit on the evening of the sleep study should take about two hours or so, and would include an EKG, blood pressure measurements, measures of height and weight, and a health interview.”*

IF YES proceed with site-specific instructions, and tell participant that there will be a questionnaire mailed to them, to complete before the home visit and to be picked up at that time.

IF NO *Now, I would like to ask you if you would agree to have another home visit, but WITHOUT another overnight sleep study. The visit should only take an hour or so, and would include an EKG, blood pressure measurements, measures of height and weight, and a health interview?”* more?

IF YES proceed with site-specific instructions, and tell participant that there will be a questionnaire mailed to them, to complete before the home visit and be picked up at that time.

*If NO, “Thank you so much, I will not take up any more of your time on the phone, but wonder if I could send you a questionnaire, similar to the one you completed a few years ago, for you to fill out and send back to us?” (YES,NO)*  
IF NO, this ends the call.

### 1.6. Scheduling home visits

The goal of the recruitment effort is to schedule a home visit even if the participant does not agree, or is ineligible, to undergo a second PSG. Home visits will be scheduled within the participant’s time window, as explained above, and according to the participant’s preference and local logistics. Scheduled visits will be recorded on the Contact form (CF). Cancellations and rescheduling should be tracked locally. A tracking information (TI) form has been provided as an optional Field Site aid.

If during recruitment or scheduling a participant makes inappropriate, strange, rude, threatening, or offensive comments, the scheduler should use his/her discretion to decide whether or not a home visit should be scheduled. The data collection personnel should be fully informed of any concerns prior to the data collection visit. If the scheduler decides not to schedule a participant for this reason, it should be noted on the *CF Form (Contact Form)* in Section B, Question 3 as “Other (specify)” and any comments included in Section D, Question 5. (See also *Section 4.1.*)

### 1.7. Sleep Habits and Lifestyle Questionnaire

The Sleep Habits and Lifestyle questionnaire (SH) is a self-administered questionnaire and an important component of the cohort follow-up. If a home visit is scheduled, the questionnaire will be mailed (if approved by local IRB) 1-2 weeks prior to the appointment along with an appointment reminder and instructions for the night of the study. The participant will be asked to fill it out before the home visit and to keep it at home until the home visit. At the time of the home visit, the technicians will verify completeness of the questionnaire. If not completed, or if misplaced, the technician will ask the participant to fill out the questionnaire as part of the visit. For participants having a home visit without PSG, the participant should be asked to complete the questionnaire during recording of medications (MD), but if the home visit includes a PSG, the questionnaire may be left for pick-up the next morning.

If the participant refused a home visit but agreed to fill out a mailed questionnaire the Sleep Habits and Lifestyle questionnaire (SH) will be mailed shortly after the telephone call along with a cover letter and a postage-paid return envelope.

### **1.8. Final Recruitment Status**

A final recruitment status should be filled out on the Contact Form (CF) for every original member of the cohort, including those who have died or requested no further contact. The Contact Form also serves to record the level of data collection that is acceptable to the participant (e.g., complete visit, home visit without PSG, mailed Sleep Habits and Lifestyle questionnaire (SH) only, Screening Form (SC) only, or no data collection; and PSG-eligibility status (PSG-eligibility status will be unknown in cases where the Screening interview is refused). The CF form also documents which data components are expected to appear in the database, so that data that will not be collected is not considered to be missing. The interviewer should determine PSG-eligibility status according to the Screening Form (SC) guidelines and record the status on the Contact form (CF). If a participant is PSG-ineligible, the interviewer should explain to the participant why s/he cannot undergo a second PSG and should try to schedule a home visit to administer questionnaires and take all other measurements.

### **1.9. Mailed Instructions/Reminder Phone Call**

A reminder/instruction letter will be sent one to two weeks before the home visit. At the discretion of each field site, a reminder phone call may be initiated 1-2 days before the home visit to obtain directions, if needed, and to confirm the appointment.

### **1.10. Types of Follow-up 2 data collection**

Data collection will follow a priority list, as described below:

- Priorities of data collection
  - First priority: Conduct a home visit and obtain complete data from PSG-eligible cohort members including unattended PSG, other physical measurements, and questionnaire data.
  - Second priority: Conduct a home visit and obtain physical measurements (other than PSG) and questionnaire data from: 1) cohort members who refuse to undergo a second PSG; 2) PSG-ineligible cohort members.
  - Third priority: Obtain self-reported data via the Screening form (SC) by telephone and a mailed Sleep Habits and Lifestyle questionnaire (SH) from cohort members who refuse a home visit.
  - Fourth priority: Obtain self-reported data via the Screening form (SC), from cohort members who refuse any other component of data collection.

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**1.10. Types of Follow-up 2 data collection**

This will lead to several types of data collection visits; with or without a sleep study; each with different data collection forms expected to be completed. The following table gives a summary of data collection forms by visit type.

1.10. Types of Follow-up 2 data collection

Home Visit					No Home Visit		
Forms	PSG	Repeat PSG within 3 months‡	Repeat PSG after 3 months‡	No PSG	Sleep Habits questionnaire and Screening form	Screening form alone	No data collection
AA†	✓	✓	✓	✓			
AE	✓	✓	✓	✓			
CF	✓			✓		✓	✓
DG	✓	✓	✓	✓	✓	✓	✓
EC	✓			✓			
EM*†	✓	✓	✓	✓			
EP*	✓			✓			
ET	✓			✓			
HI	✓	✓	✓	✓			
MD	✓	✓	✓	✓			
MS	✓	✓	✓				
NM**	✓	✓	✓				
PM	✓		✓	✓			
QL	✓			✓			
SC	✓		✓	✓	✓	✓	
SE	✓	✓	✓				
SH	✓			✓	✓		
SS	✓	✓	✓				
SV	✓	✓	✓				
TI*	✓			✓	✓	✓	✓

\*Not keyed to data system

\*\*Transfer information to MD and key MD form

†Complete when appropriate

‡Forms collected during a repeat PSG visit that have previously been collected during the initial (failed) PSG visit (i.e., AE, DG, HI, MD, MS, NM, PM, SC, SE, and SV) are recorded as **sequence 2** for the first repeated PSG. If an additional repeat PSG visit is conducted, the associated forms are recorded as sequence 3, etc. Some forms (i.e., AA, EM, SS) may not have been collected during the initial PSG visit and if collected during the repeat PSG visit would be sequence 1 even though they are associated with the second visit.

### 1.11. Consent Procedures

Prior to any data collection at the home, a SHHS technician certified to obtain consent will review the study procedures with the participant, and obtain a consent form signed in duplicate. After concluding the examination of PSG-eligible participants who declined a PSG at the time of scheduling, the technician should gently probe the participant again about his/her interest in having a PSG. A monitor with initialized flashcards ready for recording should always be available in the technician's car, should a participant change his/her mind. If so, the technician should review the PSG-inclusive consent form with the participant and obtain another consent signed in duplicate before connecting the monitor. One of the duplicate originals of the consent form signed by the participant must be given to the participant.

### 1.12. Home Data Collection

Physical measurement data questionnaires will be administered and will be collected during the home visit, before connecting the sleep monitor. Physical measurements will consist of:

- Anthropometry: weight; height; neck circumference
- Blood pressure: seated BP; ankle-arm BP
- 12- lead ECG

The physical measurements are intended to be collected at the time of the home visit; however local practice at certain Field Sites may require the collection of these measurements at a different time. Allowable tolerances for the collection or recording of measurements taken at different times have been established as allowable data collection windows. If a parent cohort value falls within the window, that value may be entered on the PM form.

1.12. Home Data Collection

A summary of windows for physical measurements are as follows:

Physical Measurement Windows	
Weight	-3 months (91 days)
Height	- 1 year (365 days)
Neck Circumference	- 3 months
BP (seated)	- 3 months
AAI	- 5 years (1,826 days)
ECG	- 3 months (91 days) to +2 months (61 days)

**Note:** A minus (-) sign refers to times prior to the reference date. A plus (+) sign refers to times after the reference data. The reference date is the date of PSG-2. If the participant does not have a PSG, the reference date is the date of the Health Interview (HI). A calculator for physical measurements windows is provided in the Field Site data system.

1.13. Home Visit Sequence of Procedures:

- Consent
- Health Interview (HI)
- Quality of Life questionnaire (QL) (at all but Strong Heart Study Field Sites)
- Medications (MD)
- Retrieve Sleep Habits and Lifestyle Questionnaire (SH) or ask participant to fill one out while recording medications (may be left for pick up in morning if PSG to be done)
- Anthropometry (PM)
- Seated BP (PM)
- Ankle-Arm BP (PM) (in bed, on sofa, or in reclining chair)
- ECG (PM) (in bed - may be done prior to Ankle-Arm BP)
- PSG monitor hookup (SV) (if PSG to be done)
- Document and take appropriate action regarding any medical alerts or adverse events.
- If a PSG is conducted, explain how to disconnect the monitor and schedule a time for equipment pick up.
- Give the participant the Morning Survey (MS) and Night Medications (NM) forms to be filled out on the following morning.



**1.14. Activities on morning following a home visit:**

For home visits where PSG study performed:

- Retrieve monitor, MS, NM forms, and QL forms (and SH form, if not already picked up)
- Download and review PSG. Copy to Zip cartridge A for weekly sending to Sleep Reading Center with copies of study forms SE and SV
- Make Field Site backup of PSG on Zip cartridge B
- Prepare the equipment for the next study (troubleshoot any signal/recording problems identified at download before using again.)

For all home visits:

- Transmit ECG data, and fill out ET form; forward hard copy of ECG tracing and EP form for Local Physician Reviewer's reading
- Key data to data system (questionnaires; forms)
- File paper forms

**1.15. Activities at a later date:**

Within 4 days:

- Enter ECG Results into data system (EC), and take appropriate action on ECG alerts/abnormalities according to Field Site local protocol
- Complete Alerts & Adverse Events Action (AA) form for actions that do not occur immediately following the home visit, and send referral letters when indicated

If and when PSG report noting Sleep Alert is received from Sleep Reading Center

- Complete and key Sleep Study Status form (SS), and take appropriate action for Sleep Alert(s)

Within 2 months if ECG done within 2 months after date of home visit:

- Revise and key ECG section of Physical Measurements (PM)
- Complete EC, EP, and ET forms, and key EC and ET forms

Within 10-12 weeks

- Complete and key Sleep Study Tracking form (SS)
- Send report to participant, and if requested by participant, to participant's physician

**1.16. Medical Alerts and Adverse events/Referrals**

Adverse events were uncommon during the baseline visit. Two non-PSG components might trigger medical alerts requiring referral: Blood pressure and ECG findings. Referral procedures will follow the guidelines as laid out in the Medical Alerts and Participant Feedback chapter.

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**1.16. Medical Alerts and Adverse events/Referrals**

The ECG machine reading will not be printed when the tracing is obtained for two reasons:

- It would not be feasible to have immediate clinician over-reading (of many false positive or insignificant findings).
- The ECG tracing will be compared to previously available ECGs from the parent cohort in order to avoid false or unnecessary alerts.

(Field Sites of the Strong Heart Study will use machine readings for referrals. These procedures have been followed previously in the Strong Heart Study and deemed acceptable for that cohort.)

Other Field Sites have developed local protocols for over-reading the tracings within two days following a home visit, and for responding to Field Site determined alert values for ECG.

Medical alerts may be generated at the PSG hook up procedure and Sleep Alerts may be generated when the Sleep Reading Center scores the PSG. Refer to Chapter 8 for Complete information on Alerts and Adverse Events.

**1.17. Failed PSG**

It is expected that some PSGs will fail (less than 5%), due to poor quality; disconnected channels, etc. In those cases, participants should be contacted as soon as possible and asked to undergo a repeated PSG. The repeated PSG should be scheduled for a time as close to the failed PSG as possible. If a repeated PSG is done, the following data collection items should be repeated at the home:

Alerts & Adverse Events Action (AA) - when an alert or adverse event is noted  
Alerts & Adverse Events (AE)  
Health Interview (HI)  
Medications Inventory (MD)  
Morning Survey (MS)  
Physical Measurements (PM)\*  
Night Medications (NM)  
Screening Form (SC)\*  
Sleep Study Status (SS)  
Sleep Study Evaluation (SE)  
Signal Verifications (SV)

- \* If PSG repeated within 3 months (91 days), additional Physical Measurements (PM) and Screening (SC) Forms need not be completed

Note that if the repeat PSG is after 3 months, the ECG need not be repeated.

### 1.18. Participant Feedback

In addition to a Participant Report on the PSG results, participants may be provided with a summary of the following measurements: blood pressure, ankle-arm index, and ECG. Reports may be produced within 10-12 weeks following the home visit. (see Section 8.2.6, 8.3)

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## 2. Equipment and supply list for home visit

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### 2.1. Home Polysomnography - Compumedics Equipment

Sleep Monitoring will be performed using a single lightweight portable device as used in SHHS I. This device (Compumedics Portable Sleep Unit) is composed of:

1) **A Main Unit.** This is the unit that is brought to the participant's home. It receives all of the signals traveling from the sensors attached to the subject, and stores them in a tiny memory card (a PCMCIA flash card). It also contains a power supply (a 15 hour rechargeable battery), a screen display for visualizing signals (after hook-up), and an impedance meter for checking the adequacy of the electrical contacts for recording EEG, EOG, and EMG.

2) **A Participant Interface Box (PIB)** (sometimes referred to as a “headbox”). This device is worn in a pocket of a special vest that also is brought to the participant's home. It is the device that contains amplifiers and filters for proper processing of the physiological signals. All electrodes and probes, other than the oximeter, are connected to this device. The processed signals from this box are sent to the Main Unit by an Analogue cable.

3) **A special vest and sensors.** The vest is a specially designed garment that is worn during sleep monitoring, holds the headbox, secures the chest and abdomen belts, and secures electrode wires and cables. It is designed to improve the comfort of overnight monitoring, minimize the number of visible wires, and improve mobility.

4) **A computer and software** for preparing the PCMCIA card, and for reviewing and transferring data. This computer is based in the area in your office, clinic or hospital where you prepare and process the sleep records. It is not brought to the home.

5) **A battery charger** (for the clinic).

6) **A calibration unit** (for the clinic).

### 2.2. Supplies for PSG

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 pair of scissors

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## 2.2. Supplies for PSG

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

## 2.3. Equipment and Supplies for non-PSG procedures

Information related to equipment use may be found in the Home Visit Procedures chapter of this document. Care, maintenance, and troubleshooting instructions are included in this chapter.

### Equipment\* and Supplies list for non-PSG procedures (by procedure):

General: Table covering to protect furniture from study equipment, gels, pastes, and solutions (hint: fabric stores sell, by the yard, clear plastic wide enough to cover a dining room table)

Weight:

- Scale - SECA Integra 815 digital (manufacturer discontinued product) OR
- Scale - Tanita BWB 800S
- Plexiglass sheet ~18 inch square (on which to place scale)
- Spare batteries - 9 volt - 4 or more, to use with SECA scale (or Doppler probe)
- Spare batteries - AA - 6 or more, to use with Tanita scale in lieu of A/C adapter
- Known weight of approximately 50 lbs, to check scale

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### 2.3. Equipment and Supplies for non-PSG procedures

#### Height:

- Set square, wooden - Handistat
- Tape measure - metal, to >210 cm
- White tape - hypoallergenic paper or cloth, so as not to stick to wall
- Sharp pencils - 2 or more
- Paper bag for disposable items
- Metric conversion chart - from the MoP
- Folding foot stool, so that technician can be at eye level for height measurement

#### Neck Circumference:

- Tape measure - cloth (cm) OR
- Circumference tape measure (available from Perspective Enterprises)

#### Blood Pressure:

- Sphygmomanometer - portable, standard mercury
- Chart of arm circumference and cuff size - from Home Visit Procedures chapter of this document
- Tape measure - cloth (to > 50 cm)
- Stethoscope - suggest Litmann
- BP cuffs in four sizes
  - 3 Regular adult
  - 2 Large adult
  - 1 Pediatric
  - 1 Thigh
- Hand towel
- Black eyeliner pencil OR green felt tip Flair marker (avoid red)

#### Ankle-Arm Index:

- Doppler probe, hand-held 8 megahertz, with built-in speaker - Parks Medical 841-A pencil probe
- Doppler conducting jelly - Aquasonic
- Tissues
- 6/32" screwdriver for battery replacement

#### ECG:

- Marquette Electronics, Inc. MAC<sup>®</sup> 1200 personal cardiograph
- 10 lead ECG Acquisition Module, Power Module & Telephone wall plug connection
- ECG paper
- Adult disposable electrodes (10 per participant)
- Isopropyl alcohol
- Gauze pads 4x4
- Paper tape with dispenser

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**2.3. Equipment and Supplies for non-PSG procedures**

- Felt -tip markers (preferably green - avoid red) and wax cosmetics pencils
  - Three-way adapter
  - Extension cord
-

## 3. Equipment Care, Maintenance and Configuration

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### 3.1. PSG Equipment Care and Maintenance

#### 3.1.1. Understanding the Electrode

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

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

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

##### 3.1.1.1. 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 which increases impedance and distorts the signal. Additionally, an electrode with visible crusted paste cannot be properly disinfected.

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



### 3.1.1.2. Disinfect Gold Disks Between Participants:

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

### 3.1.1.3. 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 at the point it interfaces with the gold cup or the PIB. If the connection is loose at either of these places, the electrode cup may receive an adequate signal but it will never reach the recording unit successfully. Since this wire is very thin and hidden by an opaque covering a broken, or bad, electrode may look perfectly fine yet yield distorted, inaccurate information. The wires should be kept clean and free of crusty paste or sticky tape. If tape is used for the participant hook-up, or a gob of paste ends up on the wires, it should be removed and the wires wiped to remove any stickiness. Never pull excessively on the electrode wire or bend the wire near the point of connection to the gold cup or PIB. Do not wind the wire around any small objects that may cause the wire to kink. After use, any knots that may have formed in the wire should be removed, and the wires straightened. To keep the wires from kinking during storage, after disinfecting electrodes the wires may be wrapped and secured around a larger object, such as an empty plastic water or soft drink bottle. *Wires that are knotted or kinky can increase impedance.*

### 3.1.1.4. Condition new electrodes before the first use:

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

**3.1.2. Conditioning new gold disk electrodes:**

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

**3.1.3. Cleaning and Disinfection of Equipment:**

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

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

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### 3.1.3. Cleaning and Disinfection of Equipment

#### Methods for Cleaning/ Disinfection:

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

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

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

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

#### Gold disk electrodes:

(General cleaning followed by high-level disinfection)

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

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**3.1.3. Cleaning and Disinfection of Equipment**

**Thermistor:**

(General cleaning followed by high-level disinfection)

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

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

(General cleaning that also provides low-level disinfection)

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

**Respiratory Band Covers:**

(General cleaning)

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

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### 3.1.3. Cleaning and Disinfection of Equipment

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.

### 3.1.4. Quick Reference: Measurement Chart

<i>Total Measurement Value (cm.)</i>	<i>50% Value (cm.)</i>	<i>20% Value (cm.)</i>
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 whole number.

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

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

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

### 3.1.5. Battery Care

In addition to the fully charged battery placed in the monitor, a spare fully charged battery should be taken to the visit.

- When you first plug the battery charger in, both lights will flash simultaneously as the charger performs a self-test.
- Insert the battery into the charger gently, with the label facing the LEDs on the charger.
- The yellow light will come on, indicating the battery is charging. About three hours is the normal charging time, less can be expected for an already charged/partially charged battery.
- When the battery is fully charged, the green light will come on. The battery may be left in the charger until it is needed. Be sure battery has a minimum 7.8V.

If both LEDs remain lit upon powering up the charger, disconnect power and reconnect. If both LEDs continue to remain lit, the charger may be defective and should be returned/replaced. If the battery charger indicates fully charged after 10 or 15 minutes this may indicate the battery needs to be replaced or discharged and recharged. Refer to Compumedics Manual or contact the Compumedics USA Support office if you are unable to determine the problem.

- The battery can leak or explode if exposed to flames or extremely high temperatures. The battery should *never* be left in direct sunlight in a car or other vehicle.
- A battery loses its charge at colder temperatures (<40°F). Always store or transport at temperatures above 40°F.
- Do not drop, crush, or pierce the battery. Never try to open or otherwise tamper with the battery casing.

### 3.1.6. Portable Monitor Unit - Quick Calibration Procedure

**This is to be used to assist in identifying if a faulty Portable unit is responsible for problem data. This procedure can also be used in the home during hook-up if a problem is noted with any given channel. Consider doing this if you have extra PIBs or monitors that can be swapped during a problematic hook-up.**

Equipment:                    Compumedics Portable Recorder with battery, calibration box, and large test lead (PIB cable with red/black leads).

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**3.1.6. Portable Monitor Unit -Quick Calibration Procedure**

Procedure:

1. Set Calibration box as follows:  
Bank.....B            Switch.....7  
Scale..... $\mu$ V            Impedance.....OFF  
Speaker.....OFF        Power.....ON
2. Connect the test cable between the Portable and the Calibration box (RED=Output, BLACK=Reference).
3. Turn on the Portable.
4. Select CHANNEL, [Next], [Next], then VIEW CHANNEL.
5. Observe sine wave for the following:  
EEG(sec)  
ECG  
EMG  
EOG(L)  
EOG®  
EEG  
SOUND  
AIRFLOW(Channel 17)
6. Change the Scale on the Calibration box to mV.
7. View sine wave for the THOR and ABDO channels.

**If you are able to successfully view appropriate waveforms, the problem is unlikely due to a faulty monitor; proceed with PIB check.**

**3.1.7. PIB Quick Calibration Procedure**

**This is to be used to assist in identifying if a faulty PIB is responsible for problem data. This procedure can also be used in the home during hook-up if a problem is noted with any given channel. Consider doing this if you have extra PIBs or monitors that can be swapped during a problematic hook-up.**

Equipment:            Compumedics Portable Recorder with battery, PIB w/cable, calibration box, and PIB test lead (electrode plug connector and red/black leads).

---

3.1.7. PIB Quick Calibration Procedure

Procedure:

1. Set Calibration box as follows:  
Bank.....B            Switch.....7  
Scale..... $\mu$ V            Impedance.....OFF  
Speaker.....OFF        Power.....ON
2. Connect the test cable between EEG(sec) on the PIB and the Calibration box (RED=Output, BLACK=Reference).
3. Turn on the Portable.
4. Select CHANNEL, [Next], [Next], then VIEW CHANNEL.
5. Observe sine wave for EEG(sec).
6. Move the electrode plug to the next channel (ECG).
7. Select [Next] on the portable.
8. Observe sine wave for new channel (ECG).
9. Repeat 6 - 8 for the following:  
EMG  
EOG(L)  
EOG®  
EEG  
AIRFLOW (Channel 17)

**If you are able to successfully view appropriate waveforms, the problem is unlikely due to a faulty PIB. Consider problems with cables.**

**3.1.8. SHHS Monthly Calibration Verification Procedure (60 minutes)**

The following procedure should be completed on at least one unit each month (minimally) to ensure that the amplitude of signals are correctly recorded and filtered by each portable unit. This will be accomplished by recording test voltages, generated by your Calibration Box, on a flash card used for creating a **TEST STUDY**. The adequacy of signal processing and recording will be tested by:

- a. Viewing each signal on the portable recorder (LED display).
- b. Recording the impedance values of each channel (other than oximetry, bands, light, position).



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**3.1.8. SHHS Monthly Calibration Verification Procedures (60 minutes)**

- c. Producing a paper record of your test study (screen dumps), measuring by hand the excursions of each signal.

You will need to copy Table 1 and maintain copies of these tables in a log book at your clinic site. In this log, also keep all screen dumps used to record the excursions of each channel.

Equipment:

- Compumedics Calibration Box
- Main Calibration cable (connects PIB main interface to Calibration box)
- PIB Calibration cable (connects one electrode socket to the Calibration box)
- Portable monitor w/battery and flashcard
- PIB w/cable
- Computer w/Portable Mgr. and Windows Replay
- Portable Unit Manual, Appendix D (dip switch diagrams)
- Calibration form to be faxed to RC.

Procedure:

Obtain calibration form and complete as steps are accomplished.

1. Connect the Main Calibration Cable between the Calibration Box and PIB:
  - a. insert the **red** plug into the **0.5xOUTPUT** socket of the Calibration box
  - b. insert the **black** plug into the **REFERENCE** socket of the Calibration box
  - c. insert the **grey** electrode plug into **EEG(sec)** on the PIB
2. Connect the PIB and Portable w/the PIB cable
3. Turn on the Portable and the Calibration box
4. Verify noise level by selecting CHANNEL,[next], [next] then VIEW CHANNEL.  
The channel should be free of noise.
5. Start Recording by selecting[**BACK**], **RECORDING**, and **START RECORDING NOW**.

---

**3.1.8. SHHS Monthly Calibration Verification Procedures (60 minutes)**

6. Verify the signal amplitude and impedance (see Diagram):
  - a. go to **CHANNEL** and then **VIEW CHANNEL** on the monitor
  - b. using the arrow keys and the [SCALE] and [SPEED] options, adjust the speed and gain appropriately (refer to the Portable Settings column of the diagram for the correct settings for each given channel). (e.g. EEG(sec) should be at 250 uV, with a speed of 20mm/s)
  - c. verify that the height of each signal (amplitude) matches the description on the below diagram (e.g., EEG(sec) just touches top and bottom of screen).
  - d. turn **IMPEDANCE ON** on the Calibration box (found above signal output) and also select **IMPEDANCE** on the Portable monitor (by selecting [BACK], IMPEDANCE)
  - e. verify the **RED** pin is in **0.5xOUTPUT**. Ascertain that the screen on the Portable monitor reads **5k**. Record this value in column 5 (Impedance 5k) on Calibration Form. If impedance <4 or >6 contact the RC.
  - f. return the **RED** pin to **1.0xOUTPUT**. Ascertain that the screen on the Portable monitor reads **10k**. Record this value in column 6 (Impedance 10k) on Calibration Form. If impedance <9 or >11 contact the RC.
  - g. turn the **IMPEDANCE OFF** on the Calibration Box
7. Move the grey pin connector to the next channel (**ECG**).
8. Verify the signal amplitude and impedance (see Diagram):
  - a. go to **CHANNEL** and then **VIEW CHANNEL** on the monitor
  - b. using the arrow keys and the [SCALE] and [SPEED] options, adjust the speed and gain appropriately (refer to the Portable Settings column of the diagram for the correct settings for each given channel).
  - c. verify that the height of each signal (amplitude) matches the description on the below diagram.
  - d. turn **IMPEDANCE ON** on the Calibration box (found above signal output) and also select **IMPEDANCE** on the Portable monitor (by selecting [BACK], IMPEDANCE)
  - e. move the **RED** pin into **0.5xOUTPUT**. Ascertain that the screen on the Portable monitor reads **5k**. Record this value in column 5 (Impedance 5k) on Calibration Form. If impedance <4 or >6 contact the RC.

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**3.1.8. SHHS Monthly Calibration Verification Procedures (60 minutes)**

- f. return the **RED** pin to **1.0xOUTPUT**. Ascertain that the screen on the Portable monitor reads **10k**. Record this value in column 6 (Impedance 10k) on Calibration Form. If impedance <9 or >11 contact the RC.
- g. turn the **IMPEDANCE OFF** on the Calibration Box
9. Move the grey pin connector to the next channel (**EMG**).
10. Verify the signal amplitude and impedance (see Diagram):
  - a. go to **CHANNEL** and then **VIEW CHANNEL** on the monitor
  - b. using the arrow keys and the [SCALE] and [SPEED] options, adjust the speed and gain appropriately (refer to the Portable Settings column of the diagram for the correct settings for each given channel).
  - c. verify that the height of each signal (amplitude) matches the description on the below diagram.
  - d. turn **IMPEDANCE ON** on the Calibration box (found above signal output) and also select **IMPEDANCE** on the Portable monitor (by selecting [BACK], IMPEDANCE)
  - e. move the **RED** pin into **0.5xOUTPUT**. Ascertain that the screen on the Portable monitor reads **5k**. Record this value in column 5 (Impedance 5k) on Calibration Form. If impedance <4 or >6 contact the RC.
  - f. return the **RED** pin to **1.0xOUTPUT**. Ascertain that the screen on the Portable monitor reads **10k**. Record this value in column 6 (Impedance 10k) on calibration Form. If impedance <9 or >11 contact the RC.
  - g. turn the **IMPEDANCE OFF** on the Calibration Box
11. Move the grey pin connector to the next channel (**EOG(L)**).
12. Verify the signal amplitude and impedance (see Diagram):
  - a. go to **CHANNEL** and then **VIEW CHANNEL** on the monitor
  - b. using the arrow keys and the [SCALE] and [SPEED] options, adjust the speed and gain appropriately (refer to the Portable Settings column of the diagram for the correct settings for each given channel).

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**3.1.8. SHHS Monthly Calibration Verification Procedures (60 minutes)**

- c. verify that the height of each signal (amplitude) matches the description on the below diagram.
  - d. turn **IMPEDANCE ON** on the Calibration box (found above signal output) and also select **IMPEDANCE** on the Portable monitor (by selecting [BACK], IMPEDANCE)
  - e. move the **RED** pin into **0.5xOUTPUT**. Ascertain that the screen on the Portable monitor reads **5k**. Record this value in column 5 (Impedance 5k) on Calibration Form. If impedance <4 or >6 contact the RC.
  - f. return the **RED** pin to **1.0xOUTPUT**. Ascertain that the screen on the Portable monitor reads **10k**. Record this value in column 6 (Impedance 10k) on Calibration Form. If impedance <9 or >11 contact the RC.
  - g. turn the **IMPEDANCE OFF** on the Calibration Box
13. Move the grey pin connector to the next channel (**EOG®**).
14. Verify the signal amplitude and impedance (see Diagram):
- a. go to **CHANNEL** and then **VIEW CHANNEL** on the monitor
  - b. using the arrow keys and the [SCALE] and [SPEED] options, adjust the speed and gain appropriately (refer to the Portable Settings column of the diagram for the correct settings for each given channel).
  - c. verify that the height of each signal (amplitude) matches the description on the below diagram.
  - d. turn **IMPEDANCE ON** on the Calibration box (found above signal output) and also select **IMPEDANCE** on the Portable monitor (by selecting [BACK], IMPEDANCE)
  - e. move the **RED** pin into **0.5xOUTPUT**. Ascertain that the screen on the Portable monitor reads **5k**. Record this value in column 5 (Impedance 5k) on Calibration Form. If impedance <4 or >6 contact the RC.
  - f. return the **RED** pin to **1.0xOUTPUT**. Ascertain that the screen on the Portable monitor reads **10k**. Record this value in column 6 (Impedance 10k) on Calibration Form. If impedance <9 or >11 contact the RC.
  - g. turn the **IMPEDANCE OFF** on the Calibration Box

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**3.1.8. SHHS Monthly Calibration Verification Procedures (60 minutes)**

15. Move the grey pin connector to the next channel (**EEG**).
16. Verify the signal amplitude and impedance (see Diagram):
  - a. go to **CHANNEL** and then **VIEW CHANNEL** on the monitor
  - b. using the arrow keys and the [SCALE] and [SPEED] options, adjust the speed and gain appropriately (refer to the Portable Settings column of the diagram for the correct settings for each given channel).
  - c. verify that the height of each signal (amplitude) matches the description on the below diagram.
  - d. turn **IMPEDANCE ON** on the Calibration box (found above signal output) and also select **IMPEDANCE** on the Portable monitor (by selecting [BACK], IMPEDANCE)
  - e. move the **RED** pin into **0.5xOUTPUT**. Ascertain that the screen on the Portable monitor reads **5k**. Record this value in column 5 (Impedance 5k) on Calibration Form. If impedance <4 or >6 contact the RC.
  - f. return the **RED** pin to **1.0xOUTPUT**. Ascertain that the screen on the Portable monitor reads **10k**. Record this value in column 6 (Impedance 10k) on Calibration Form. If impedance <9 or >11 contact the RC.
  - g. turn the **IMPEDANCE OFF** on the Calibration Box
17. Move the grey pin connector to the next channel (**AUX**).
18. Verify the signal amplitude and impedance (see Diagram):
  - a. go to **CHANNEL** and then **VIEW CHANNEL** on the monitor
  - b. using the arrow keys and the [SCALE] and [SPEED] options, adjust the speed and gain appropriately (refer to the Portable Settings column of the diagram for the correct settings for each given channel).
  - c. verify that the height of each signal (amplitude) matches the description on the below diagram.
  - d. turn **IMPEDANCE ON** on the Calibration box (found above signal output) and also select **IMPEDANCE** on the Portable monitor (by selecting [BACK], IMPEDANCE)

**3.1.8. SHHS Monthly Calibration Verification Procedures (60 minutes)**

- e. move the **RED** pin into **0.5xOUTPUT**. Ascertain that the screen on the Portable monitor reads **5k**. Record this value in column 5 (Impedance 5k) on Calibration Form. If impedance <4 or >6 contact the RC.
  - f. return the **RED** pin to **1.0xOUTPUT**. Ascertain that the screen on the Portable monitor reads **10k**. Record this value in column 6 (Impedance 10k) on Calibration Form. If impedance <9 or >11 contact the RC.
  - g. turn the **IMPEDANCE OFF** on the Calibration Box
19. Remove the grey pin connector.
  20. Connect the oximeter, resp bands, and light sensor to the main unit. Follow instructions in Table 2-B (Calibration of Effort, Position, and Light) and complete log (description of channels).
  21. Verify signals on all remaining channels using Table 2-B
  22. End recording by selecting **[BACK]**, **RECORDING**, and **STOP RECORDING NOW**.
  23. Download file from flash card to computer using Portable Mgr.
  24. Using Windows Replay, view the calibration signals:
    - a. In Replay, Select Options|Config Polygraph from the File menu.
    - b. Set the polygraph as follows, using Add and Delete:

<u>Channel</u>	<u>Size</u>	<u>Color</u>	<u>Grid</u>	<u>Zoom</u>	<u>Channel</u>	<u>Size</u>	<u>Color</u>	<u>Grid</u>	<u>Zoom</u>
EEG(SEC)	6	Black	ON	x1	ECG	6	Black	ON	x1
EMG	6	Black	ON	x1	EOG(L)	6	Black	ON	x1
EOG®	6	Black	ON	x1	EEG	6	Black	ON	x1
AUX/AIR	6	Black	ON	x1	THOR	6	Black	ON	x1
ABDO	6	Black	ON	x1					

- c. Save the montage and assign a name (such as “calibration”) by pressing the button under the Save column on the far left.
- d. Press OK.

**Note:** *Setting the calibration polygraph needs to be done only once. Once configured and saved, this may simply be called up to review calibration signals.*

- e. Page through the study to the recorded channel.

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**3.1.8. SHHS Monthly Calibration Verification Procedures (60 minutes)**

- f. If a problem signal is seen print the screen and fax to RC with the calibration form.

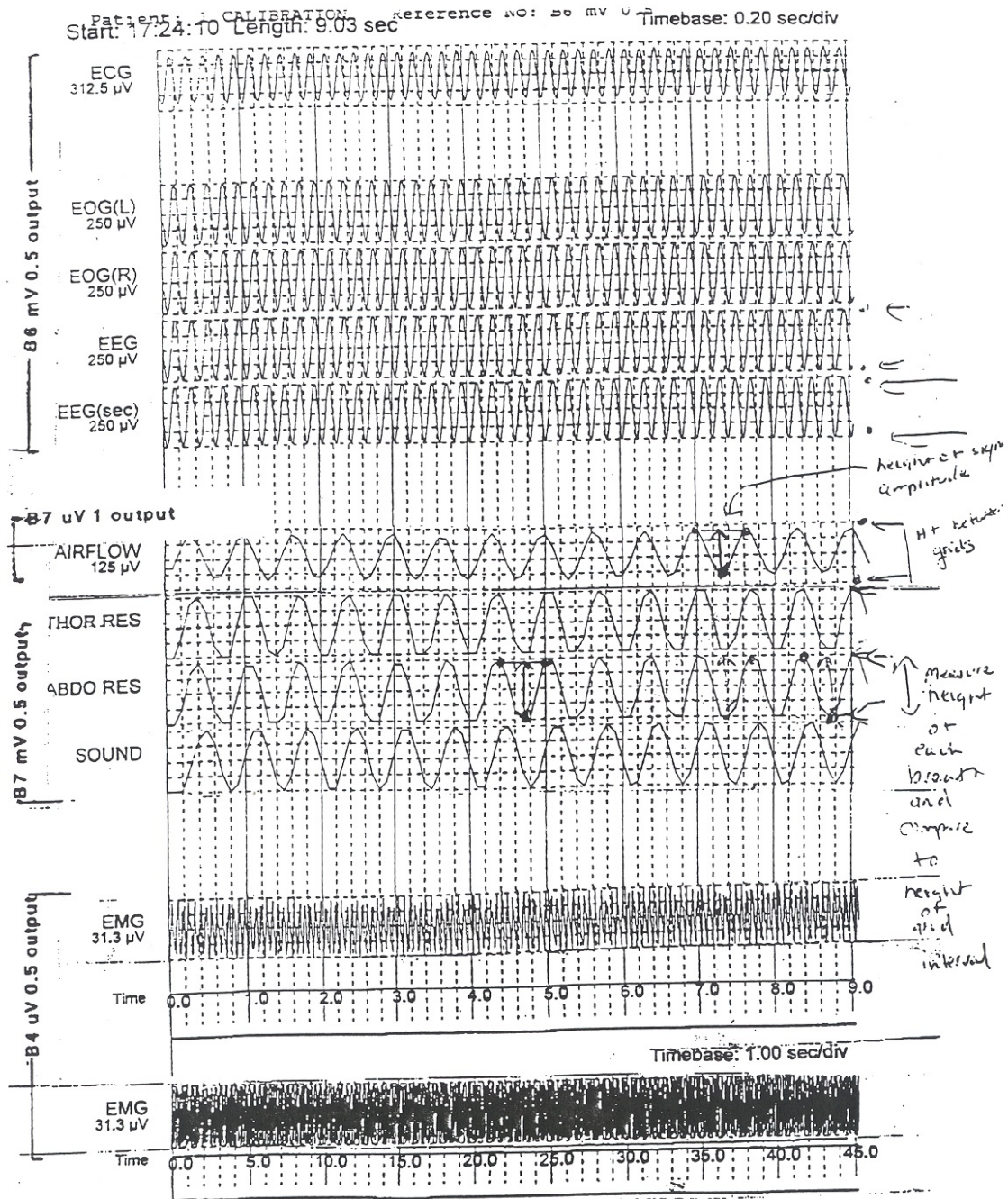
Select File|Print and press OK.

*Note: Be sure that you are printing in landscape mode. Do this by selecting Print Setup from the File menu, and set Paper Size to Landscape.*

**\*\*\*Warning: Be sure to change your polygraph setting back to normal when you are finished.**

25. Compare the printed copies to the figures below.
26. Measure the height of 10 wave forms per channel. Do this with a clear ruler, measuring the VERTICAL height, assessed from nadir to peak. Keep the ruler perpendicular to a horizontal line drawn between peaks and nadir points (see example below). Measure the vertical height between respective grid lines (see example). Average the heights of the 10 waves that you have measured and record this in the appropriate column in Table 1. Divide by the distance between grid marks and record this value next to the preceding value. Ascertain that this ratio is 0.95-1.05. Notify the RC if signal morphology does not match the described wave form (e.g., ECG looks like a QRS complex), and if the average height of the signals differ by > 5% of the maximum deflection (between grid lines; ratio <0.5, >1.05).
27. Fax calibration sheet (and printout of problem signal, if applicable) to RC.

3.1.8. SHHS Monthly Calibration Verification Procedures (60 minutes)





3.1.8. SHHS Every Other Month Calibration Verification Procedures (60 minutes)

\* Please include serial numbers of monitor and PIB tested

Table 1

Calibration Procedure Checklist								
Portable # _____				PIB # _____				
Channel #	Channel Label	Noise levels low? (Y/N)	Signal viewed on LED matches description? (Y/N)	Impedance values displayed (write the actual value)		Signal viewed in Replay matches description? (Y/N)	Average amplitude displacement (from printouts)/ Ratio amplitude/grid line distance	Comments (eg describe differences, excessive noise)
				5k	10k			
1	SaO <sub>2</sub>	---		---	---			
3	EEG(sec)							
4	ECG							
7	EMG							
8	EOG(L)							
9	EOG(R)							
10	EEG							
11	Sound/Mic			---	---			
13	THOR			---	---			
14	ABDO			---	---			
15	Position	---		---	---			
16	Light	---		---	---			
17	Aux/Air							

Conclusion: This portable unit, PIB, and PIB cable passed/did NOT pass the Calibration Check.

Tech: \_\_\_\_\_ Site: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

3.1.8. SHHS Every Other Month Calibration Verification Procedures (60 minutes)

Table 2 - A Calibration Box Settings

For PIB channel:	Set Calibration Box to:				Set the Portable to:		Signal just touches the top and bottom of the screen?
	Bank	Number	Scale	Output	Scale (uV)	Speed (mm/s)	
3 - EEG (sec)	B	6	mV	0.5	250	20	Yes
4 - ECG					625		No*
8 - EOG (L)					250		Yes
9 - EOG (R)					250		
10 - EEG					250		
7 - EMG	B	4	uV		31.3	5	No*
13 - THOR	B	7	mV		x 8	20	
14 - ABDO					x 8		
11 - SOUND					x 1		Yes
17 - AUX/AIR	B	7	uV		62.5	5	No*

\*there should be approximately 2mm gap on the top and bottom

Table 2 - B Calibrations for Effort, Position, and Light

Sensor:	Procedure:	Output: (View channel)
Oximeter (ch. 1)	apply probe to finger with no respiratory disorder (observe normal application procedure)	>95%
Resp. Bands (ch.15 & 16)	Stretch bands approximately 1mm and then back 10 times, 2 seconds each time.	0.5 Hz sine wave taking up full screen (+/- 10%) Peaks may go off screen.
Position (ch. 18)	Place headbox in four positions, simulating patient: back, front, left, and right	Observe the words BACK, FRONT, LEFT, and RIGHT, corresponding to the headbox position
Light (ch. 19)	Expose sensor to light, then cover	observe the words LIGHTS ON and LIGHTS OFF

### 3.2. Scales: Power sources

Check the scale prior to the visit to verify that the batteries are operational.

#### IF USING THE SECA digital scale:

To change the battery in the SECA scale, remove the digital display head from the base to open the battery compartment underneath, and replace with a new standard 9 volt alkaline battery. After connecting the battery terminals, insert the battery and close the cover. Replace the head on the base of the scale.

#### IF USING the Tanita digital scale:

To change batteries, turn the knob on the section which holds the digital readout, slide it out, and insert 6 AA batteries in the direction shown in the battery box. Return the battery box to its original position and tighten the knob. When "Lo" is displayed and → is turned on in the battery replacement warning mark area, replace all 6 AA batteries.

To use the AC adapter in the Tanita, insert the jack into the jack holder on the left side of the display box. Plug the AC adapter into an AC wall outlet.

### 3.3. Doppler

#### Doppler Probe

KEY POINT: Use only ultrasound gel

The probe consists of two crystals; one for transmitting the ultrasound waves and the other for receiving the reflected waves. If either crystal is damaged, the probe will not work properly or will not work at all. The crystals are covered by epoxy resin. This resin is attacked by any gel or liquid containing the chloride ion. Therefore, NEVER use ECG paste or cream as the contact medium between the skin and the crystals. Use AQUASONIC or any gel made for ultrasonic physical therapy equipment. In an emergency use any surgical jelly or lubricant, even Vaseline or mineral oil. After use, remove the gel with a soft tissue. If the probe has dried gel on it, wash it off under running water. Do NOT scrape off the gel because this may damage the epoxy coating. Do NOT autoclave the probe. Gas sterilization is acceptable.

#### Doppler Battery

KEY POINT: To preserve battery, turn off unit immediately after measurements

It takes less than a minute to make a blood pressure measurement. Turn the unit off immediately after removing it from the skin. The signal will weaken as the battery runs down. Use an alkaline-type replacement 9-volt transistor radio battery. Three screws hold the battery in the case. After loosening or removing the screws, gently lift up the back to replace the battery. The battery can be checked before leaving the clinic by listening to your own artery. Take an extra 9 volt battery to home.

Strange noises from the Doppler:

On occasion there are unusual noises from the Doppler that do not indicate a problem with the Doppler. The normal sound will become obvious with experience in performing this test. Following are some common unusual noises and their causes:

- Popping noises when the probe is first placed on the skin. Scratchy sound at first.
  - Cause: Bubbles in the gel that are moving and/or popping. Also hair movement can cause noise.
  - Remedy: Use a new glob of gel that looks clear, push down enough so hair is immobilized, and just wait a few seconds for things to settle down. If the noise isn't there when the probe is clean (no gel) and suspended in the air, the Doppler and/or probe are probably not at fault.
- Severe static when the dry probe is moved in the air
  - Cause: A loose connector where the probe connects to the instrument, a broken shield wire in the cable either at the connector or as it comes out of the probe. This can be diagnosed by wiggling the wire or connectors gently. There is normally a small amount of static generated when the cable is flexed.
  - Remedy: Arrange to replace probe or get connectors fixed.
- High-pitched tone
  - Cause: Radio interference from a mobile service, police station nearby, even another Doppler working nearby. Usually occurs near large open windows, rarely in the center of a building.
  - Remedy: Move to another room.
- Howling noise when the probe with gel on it is held or laid on a table
  - Cause: Acoustic feedback through the probe acting as a microphone
  - Remedy: None needed.

### 3.4. ECG: MAC<sup>®</sup> 1200

#### 3.4.1. Configuring the MAC<sup>®</sup> 1200 for SHHS data fields

The following set of instructions for the setup of the MAC 1200 ECG machines allows necessary information to be entered for the SHHS Participant ID, SHHS alpha-code, and the SHHS Technician ID number. The word “Sleep Heart Health Study” and the site ID number will be set in the default memory. The following setup recommendations will print one paper copy, automatically save the ECG in memory after printing the paper copy, and will not delete the saved electrocardiograms until they are either manually deleted or the machine runs out of memory. The computer interpretation of the ECG findings is suppressed. Site-specific technician ID numbers can be set in the default memory and will appear as a pull down menu for the technician to choose his/her ID number.

##### 3.4.1.1. Initial Setup of MAC<sup>®</sup> 1200

- Press the On/Standby button to turn machine ON
- Wait a few seconds. The self-test screen will appear, then a copyright screen. Finally the 12 lead-tracing screen will appear

##### 3.4.1.2. Configuring the 12 Lead-Tracing Menu

- Press the Setup button. The Setup menu will appear. Using the arrow keys, move the cursor down to “12 Lead” and press return ( ).
- Using the arrow keys, move the cursor down to the “Detailed Results” line and highlight “No”. Press return ( ).
- Using the arrow keys, move the cursor down to the “No. of Copies” line and type in 1. Press return ( )
- Move the cursor down to the “Delete ECG after Transm.” line and highlight “No”. Press return ( )
- Move the cursor down to the “Autosave ECG” line and highlight “yes”. Press return ( ).
- Move the cursor down to the “Override function” and highlight “yes”. Press return ( ).
- Press the Start/Stop key to return to the Setup menu.

##### 3.4.1.3. System Setup

- In the Setup menu, using the arrow keys, move the cursor down to “System Setup” and press return ( ).
- Move the cursor down to “Order. Physician” line and highlight “no” and press return ( ).
- Move the cursor down to “Refer. Physician” line and highlight “no” and press return ( ).

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3.4.1.3. System Setup

- Move the cursor down to “Technician” line and highlight “no” and press return ( ).
- Move the cursor down to “Institution Name” line and type in SLEEPHEARTHEALTHSTUDYSITE(your site number), and press return ( ).
- Move the cursor down to “Site#” line and type in the number 7, and press return ( ).
- Move the cursor down to “Date” line and verify that the date is correct.
- Move the cursor down to “Time” line and verify that the time is correct.
- Move the cursor down to the second “Date” line and highlight “mm/dd/yyyy” and press return ( ).
- Move the cursor down to the second “Time” line and highlight “12” and press return ( ).
- Press Start/Stop key to return to the Setup menu.

3.4.1.4. Patient Data Setup

- In the Setup menu, using the arrow keys, move the cursor to the “Patient Data Setup” line and press return ( ).
- Move the cursor down to “New Patient” line and highlight “yes” and press return ( ).
- Move the cursor down to “Pacemaker” line and highlight “no” and press return ( ).
- Move the cursor down to “Gender” line and highlight “yes” and press return ( ).
- Move the cursor down to “Height” line and highlight “no” and press return ( ).
- Move the cursor down to “Weight” line and highlight “no” and press return ( ).
- Move the cursor down to “Race” line and highlight “yes” and press return ( ).
- Move the cursor down to “Systolic BP” line and highlight “no” and press return ( ).
- Move the cursor down to “Diastolic BP” line and highlight “no” and press return ( ).
- Move the cursor down to “Order. Physician” line and highlight “no” and press return ( ).
- Move the cursor down to “Refer. Physician” line and highlight “no” and press return ( ).
- Move the cursor down to “Technician” line and highlight “yes” and press return ( ).
- Move the cursor down to “Phone No.” line and highlight “no” and press return ( ).
- Move the cursor down to “Medication” line and highlight “no” and press return ( ).
- Move the cursor down to “Comments” line and highlight “no” and press return ( ).
- Move the cursor down to “ID required” line and highlight “yes” and press return ( ).
- Move the cursor down to “Secondary ID” line and highlight “no” and press return ( ).
- Move the cursor down to “Secondary ID required” line and highlight “no” and press return ( ).
- Move the cursor down into the second page of options to “Extra Questions – Prompt 1” and type in ALPHA and press return ( ). An additional line should come up that says: Numbers/letters and others. Highlight “Numbers/letters” and press return ( ).
- Press the Start/stop key to return to the Setup menu.

#### 3.4.1.5. Setup for SHHS Technician ID numbers

- In the Setup menu, using the arrow keys, move the cursor down to the “System Setup” line and press return ( ).
- Move the cursor down to “Technician” line and highlight “others” and press return ( ).

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- The “Technician Menu” appears. Using the arrow keys, move the cursor until it is under the “Last name” column, in the #10 row. Type in a technician ID number for your site (i.e., B01). Press return ( ). Move the cursor under the “Last name” column, in the #11 row. Type in another technician ID number for your site. Press return ( ). Continue to enter technician ID numbers for your site until all are entered.
- Press Start/stop to return to the System setup menu.
- Press Start/stop to return to the Setup menu.
- From the Setup menu, press Start/stop to return to the 12 lead-tracing screen.

#### 3.4.1.6. Configuring the Communication Menu

- In the Setup menu, using the arrow keys, move the cursor down to “Communication” and press return ( ).
  - Using the arrow keys, move the cursor down to the “Modem” line and highlight “Other”. Press return ( ).
  - The Modem menu appears. Using the arrow keys, highlight “MultiTech 19.32”. Press return ( ).
  - Move the cursor down to “Phone No.” and type in 12127467447. Press return ( ).
  - Press the Start/Stop key to return to the Setup menu.
-

## 4. Home visit implementation and conduct

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### 4.1. General implementation of the home visit

Listed are some features that will assure a successful visit:

All home visits:

- Show identification on arrival
- Explain the purpose of the visit
- Help the participant feel at ease and comfortable
- Explain all procedures before and as you do them
- Be courteous and professional
- Be sensitive to participant's needs.
- Be patient
- Be interested
- Keep a positive attitude
- Ask participant what location would be best to “set up” equipment (usually kitchen)
- The participant’s comfort always comes before study needs
- Be respectful of the participant’s home, pets, and belongings
- Make sure s/he understands all relevant aspects of the procedures

Home visits with PSGs:

- Provide overview of the Sleep Study
- Have participant demonstrate or repeat critical areas (e.g., detaching oximeter if needed)
- Provide participant with telephone number to call for “help”
- Schedule morning pick-up according to participant's needs
- Arrive for morning pick-up in a timely fashion

Safety of SHHS staff:

The safety of SHHS staff conducting home visits is of primary importance. As stated in *Section 1.6.*, inappropriate, strange, rude, threatening, or offensive comments made by participants during a recruitment/scheduling call are grounds for refusing to schedule a participant and should be noted on the CF form (Section B, Question 3 and Section D., Question 5).

During the home visit, if a staff member feels his/her security is threatened, he/she should end the home visit immediately. General safety rules should be observed by SHHS staff including: (1) If one technician arrives at a participant’s home before his/ her partner, he/she should not approach and enter the participant’s home until the partner arrives; (2) While inside the participant’s home, technicians should always be in the same room; (3) Study personnel should abort a home visit if at any time a participant makes inappropriate comments or attempts inappropriate physical contact of any kind (touching or striking with the hand or other object). Any such incidents should be recorded on an Incident Report Form (IR). The completed IR form should be sent by overnight courier to the



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4.1. General implementation of the home visit

Coordinating Center and a copy should be filed in the participant's folder. Coordinating Center staff will disseminate the IR form to the Operations Subcommittee and the NHLBI.

Additionally, the IR form may be used to report any type of injury sustained by a staff member during the home visit (e.g., injury from falling on icy steps, dog bite).

4.2. Preparation for Home Visit

4.2.1. General

Home Visits with and without PSG: Note that preparation of the PSG monitor and PSG related data collection and consent forms should be ready for a home visit with PSG even when the participant is a PSG- eligible participant who has refused the second PSG. The participant may change his/her mind, and technicians should be prepared to conduct a PSG should this occur. Special instructions as to dress and showering should be observed also, and may be justified by the ECG procedure. The PSG refuser may be told that if s/he changes his/her mind prior to the arrival of the technicians, that shampooing, and removal of nail polish or shaving, when indicated, will facilitate the PSG.

4.2.2. Scheduling and Logistics

- Approximately 2 weeks to one month before the study, schedule a visit with the participant and provide him/her with specific instructions for the home visit and for a sleep study, if one is to be conducted
- One to two days before the visit, confirm the visit, remind participant about specific instructions, check traveling directions
- Ascertain usual bedtime
- Remind him/her to "pull" all his/her medications for review on the visit

4.2.3. Preparing the Equipment and Data Collection forms

- Check batteries in equipment. Charge sleep monitor battery and change any other batteries as indicated.
- Within one day of the home visit:
  - Check equipment and supplies.
  - Initialize (prepare) the PCMCIA flash card (memory card)
- Prepare PSG equipment for home visit as per instructions in Section 6.2

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**4.2.3. Preparing the Equipment and Data Collection forms**

- Before going to the home:
  - Prepare data collection forms with Participant IDs and Alpha Codes
  - Fill in forms for data items to be found in the participant's study records
  - Use data system calculator to determine which Physical Measurements are necessary according to study windows for data collection

**4.2.4. Preparing the Participant - Before going to the participant's house:**

- Call the participant.
- Describe the personnel who will be going on the visit, and describe what the procedures will consist of (including approximate times).
- Remind the participant to have showered within the last 24 hours, and to have shampooed and refrained from using hair sprays, gels, mousse, and/or oils in the hair.
- Men should be asked to shave before the visit. (Explain that this is not an issue of cleanliness, but that the special procedures require the skin to be as free from oils as possible.)
- Ask the participant to be dressed in a t-shirt, tank top, or 2-piece bed clothes. Encourage the participant to avoid wearing a long nightgown, nightshirt, or other one-piece garment.
- Tell the participant to make 2-3 hours available to facilitate an unrushed and complete visit.

**4.3. At the Home Visit**

**4.3.1. All Home Visits**

- Explain the purpose of the study
- Obtain consent (PSG consent form/No PSG consent form) with second copy to participant
- Conduct the Health Interview (HI)
- If not coming back in morning, give Quality of Life questionnaire (QL) - according to local protocol
- Conduct the Medications Survey (MD)
- Retrieve Sleep Habits and Lifestyle Questionnaire (SH) or ask participant to fill one out while recording medications (may be left for pick up in morning if PSG to be done)
- Anthropometry (PM): weight, height, neck circumference
- Seated BP (PM)
- Ankle-Arm BP (PM) (in bed, on sofa, or in reclining chair)
- ECG (PM) (in bed)
- Document and take appropriate action regarding any medical alerts or adverse events
- Provide Study Information/Feedback Card

#### 4.3.2. Home Visits with PSG

- Attach sensors and vest
- Check signal quality
- Confirm that the participant knows how to make any needed connections/disconnections and move about with the recording unit
  - Review written materials (containing these instructions)
  - Walk around the participant's living area
  - Be sure that he/she feels comfortable moving about with the equipment
- Ask if the participant uses an electric blanket. Electric blankets should not be turned on or even plugged in during the sleep study
- Discuss any potential problems with any interested family members who can be enlisted to help with any sensor adjustments that may be needed
- Record impedances, calibration information, and environmental conditions on Signal Verifications (SV) Form
- Explain how to disconnect the monitor and schedule a time for equipment pick up
- Give the participant the Morning Survey (MS), Night Medications (NM), and Quality of Life (QL) forms to be filled out on the following morning
- Ascertain the participant's preference for removal of electrodes and sensors: self-removal or by a study technician. If the former is chosen, be sure to clearly instruct the participant on all aspects of sensor removal. Stress that all sensors should held by their ends and not their wires. Ask the participant not to discard anything, but to pack all equipment and accessories in the carrying case
- Provide the participant with the telephone number of an on-call technician who could answer any questions should they arise
- Confirm the time of the morning pick-up
- If you will not personally be picking up equipment in the morning, provide the participant with the name(s) and description(s) of the personnel assigned to this task
- Clean up, leaving the area as neat as it was before your visit. Take any rubbish with you.

*Tip: If a male participant reports the need to make frequent trips to the bathroom, consider providing a hand held urinal for bedside use.*

#### 4.3.3. Common Questions and Appropriate Response

1. What if you find that I have sleep apnea?

The results of your sleep study will be known within several weeks of the sleep study. In writing, you will be informed of the number of breathing pauses that were observed during your sleep. If a very high number of pauses are observed, we will contact you sooner and you can discuss the findings with your physician. Choice of proceeding with additional testing or therapy are decisions that should be made by you and your doctor.

2. Will I get electrocuted?

NO! The unit is completely battery operated, using low voltage.

3. Can I go to the bathroom and move around?

YES! You can use the carrying pouch to carry the monitor. Just be careful that all wires and cables are draped away from your feet so you do not trip. You do not need to turn on and off any switches when you are walking around.

4. Are you qualified to diagnose me?

NO, I am a           (fill in title)          . I am trained to collect good quality data, but not to diagnose medical conditions -- diagnosis should be done by a nurse or doctor who does a physical exam and reviews your history and findings from studies.

5. What are the symptoms of sleep apnea?

The most common symptoms are loud disruptive snoring and daytime sleepiness. However, not everyone with these symptoms has sleep apnea. Also, some people with these symptoms do not have sleep apnea.

6. I don't snore (I'm not tired) -- why should I bother?

Your participation will result in information that will allow the SHHS investigators to understand more about the causes of heart and other diseases. Information from people without symptoms is just as important as information collected on individuals with these symptoms. Besides, frequent participation in these studies by people without such symptoms results in information that proves to be interesting or valuable to them (or useful to their doctor in the care of such people).

7. I have insomnia (or I can't sleep) -- will this help? -- or this won't help.

Many people underestimate how much sleep they actually get, and this study may help identify if that is the case. It is likely that you will sleep enough to enable us to collect enough useful information for SHHS and possibly reveal problems that may help explain problems with your sleep.

8. Won't I lose the wires if I twist and turn?

We have secured the wires with special tape and paste that will make it unlikely that they will be lost. Please try not to worry about this -- sleep in your usual fashion. If something does fall off, just gather the wire so it does not pull (demonstrate). (Airflow and oximetry is the exception -- show how to replace.)

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4.3.3 Common Questions and Appropriate Response

9. What about taking my medicines?

Take everything as usual. You can use a straw (or take off airflow sensor) while swallowing.

10. Will my spouse be able to sleep next to me?

Sure! The machine does not make any noise and should not interfere with his/her sleep. It will only record your brain waves and breathing patterns.

11. Will the paste affect my hair color?

No. The paste is water soluble.

**4.4. Morning following the Home Visit:**

**4.4.1. If PSG conducted:**

At the Home:

- Retrieve monitor
- Inquire about any problems or questions that might have arisen. If the participant expresses concern that a sensor fell off, reassure him/her that there is still a good likelihood that the study will be interpretable.
- To remove electrodes, use a wet gauze pad and soap, lightly rubbing until the electrode is released. Work quickly. Do not use the participant's time to disconnect electrodes or sensors from wires or cables – that is better done in the clinic.
- Check to see that all equipment and accessories (the Main Unit, vest with headbox, cables, and sensors) are all present and packed
- Check that all paperwork has been completed. Retrieve, and assist with any problems in filling out self-administered forms (MS, NM, and QL forms - and SH form, if not already retrieved the previous evening).
- Provide the participant with a letter that will detail when results should be sent out
- Clean up
- Thank the participant for his/her time and participation
- Indicate to participant that the study coordinator will make a follow up telephone call inquiring about the visit, or else leave a feedback postcard

At the Field Site:

- Download study from PCMCIA card to hard drive using Compumedics Portable Manager
- View the study using Compumedics Replay Program
- Complete Sleep Study Evaluation Form (SE)

4.4.1. If PSG conducted

- Copy from hard drive and Zip cartridge A for RC Zip cartridge B to be kept as backup at site
- Photocopy the SE and SV forms for transmission to the Sleep Reading Center
- Prepare the PSG equipment and supplies for the next study
  - Clean and disinfect reusable surface electrodes (gold disks)
  - Replace disposable sensors
  - Recharge battery

**For all home visits, regardless of whether or not PSG conducted:**

At the Field Site:

- Transmit ECG data to ECG Reading Center, and fill out ET form (if ECG conducted during home visit)
- Forward hard copy of ECG and EP form for Local Physician's Reviewer (if ECG conducted during home visit)
- Prepare non-PSG equipment and supplies for next visit
- Key data (questionnaires; forms)
- File paper forms

**4.5. Activities at a later date, following the home visit:**

Within 4 days:

- Enter ECG Results into data system (EC), and take appropriate action on ECG alerts/abnormalities according to Field Site local protocol
- Complete Alerts & Adverse Events Action (AA) form for actions that do not occur immediately following the home visit, and send referral letters when indicated
- Send one Zip disk copy of the PSG study to the Sleep Reading Center in Cleveland, with paper copies of the SV and SE forms for that study

If and when early PSG report with Sleep Alert is received from Sleep Reading Center

- Complete and key Sleep Study Status form (SS), and take appropriate action of Sleep Alert(s)

Within 2 months:

- IF ECG done within 2 months after home visit:
  - Revise Physical Measurements (PM) form
  - Key ECG part of PM form
  - Complete and key ECG related forms

4.5. Activities at a later date, following the home visit

Within 10-12 weeks

- Complete and key Sleep Study Status form (SS)
  - Prepare and send a participant feedback letter, and if requested by participant, send a study report to participant's physician
-

## 5. Home Visit Procedures: non-PSG

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### 5.1. General

Step-by-step instructions for each procedure is described in this chapter. These instructions should be adhered to rigorously.

### 5.2. Weight Measurement

#### 5.2.1. Background and Purpose

Obesity is the strongest known risk factor for obstructive sleep apnea (OSA). In clinic samples, approximately two-thirds of patients with OSA have a BMI  $> 28 \text{ kg/m}^2$ <sup>1</sup>. In more general samples, obesity increases the risk of OSA 8-10 fold<sup>2</sup>. Obesity is also a strong risk factor for hypertension. In fact, much of the controversy concerning a potential causal relationship between OSA and hypertension relates to concerns about confounding with obesity. Thus, measurement of weight and determination of body mass index (BMI) will be important for providing data on a key confounder in the relationship between cardiovascular disease (CVD) and OSA.

#### 5.2.2. Methods

- Record weight measurement on the “Physical Measurements” form (PM). In the home, place the scale on a hard floor surface rather than on a carpet. If a hard surface is not available, use the plexiglass sheet under the scale.
- The participant should be wearing lightweight sleeping attire. Remove shoes, slippers, robe, or other heavy clothing prior to the weighing. (If in street clothing, remove belt and items from pockets.)
- Weigh the participant before any of the sleep or blood pressure equipment has been connected to him/her.
- TIPS for working with elderly participants:
  - Do not move quickly
  - Be right there in case participant slips off of scale



IF USING THE SECA digital scale:

To weigh the participant:

- Select kgs measurement using the switch on the display. Switch on the scale by pressing the ON button. The number 888.8 will appear on the digital display.
- The participant may step onto the scale as soon as the number 0.0 appears on the display.
- Wait about four seconds for the numbers to stabilize. Record the weight viewed on the digital display onto the “Physical Measurements” (PM) form. The SECA scale is accurate to 0.5 kilograms over the entire weighing range. [If two values are displayed alternately in the 0.5 kilogram range, then the exact weight is between these values. Round to the nearest whole number. For example, if the scale alternatively shows 143.5 and 144.0 round up to 144.0.] If it shows 144.0 and 144.5 alternately, round up to 144.5.

The scale switches off automatically after 30 seconds.

Problems:

- If no weight display appears under the load: Remove the person from the scale, press the ON button, and wait for the display to read 0.0.
- If ---- appears in the display: Press the ON button and wait for the display to read 0.0.
- If ERR appears on the display: Remove the person from the scale, press the ON button, and wait for the display to read 0.0.
- If BAT appears on the display: Change the battery.

IF USING the Tanita digital scale:

To use the AC adapter in the Tanita, insert the jack into the jack holder on the left side of the display box. Plug the AC adapter into an AC wall outlet.

To weigh the participant:

- Select kgs measurement using the switch on the display box. Switch on the scale by pressing the ON button. The number 8.8.8.8.8 will flash on the digital display.
- The participant may step onto the scale as soon as the number 0.0 appears on the display.

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5.2. Weight Measurement

5.2.2 Methods

- Wait about four seconds for the numbers to stabilize. The arrow will point to the “weight lock” on the display box. Record the weight onto the “Physical Measurements” (PM) form. Then turn off the scale by pressing “OFF”. When using batteries, the scale switches off automatically only after 20 minutes, which may significantly drain the batteries.

Problems:

- If nothing is displayed when the ON/ZERO switch is pressed: check the AC adaptor connection at the display box and at the outlet. If batteries are sued, they may be weak and should be replaced.
- If no weight is displayed under the load: Remove the person from the scale, and check the connection of the connector between the scale and the display box.
- If the measurement is not accurate: check that all legs of the scale are steady. Accurate measurement may not be possible if there is excessive vibration in the area.

5.2.3. References

- 1) Guilleminault C, Dement WC. Sleep apnea syndromes and related disorders. Williams RL, Katacan I, eds. Sleep Disorders: Diagnosis and Treatment. New York: Wiley; 1978.
- 2) Redline S, Kump K, Tishler PV, Browner I, Ferrette V. Gender differences in sleep disordered breathing in a community-based sample. Am J Respir Crit Care Med 1994; 149:722-726.

5.3. Height Measurement

5.3.1. Background and Purpose

Accurate height measurement is important for determination of the body mass index (BMI).

5.3.2. Methods

- Record the height measurement on the “Physical Measurements” form (PM). Indicate whether measurement was obtained the night of the home visit or at the clinic. If measured at the clinic, indicate date of measurement.

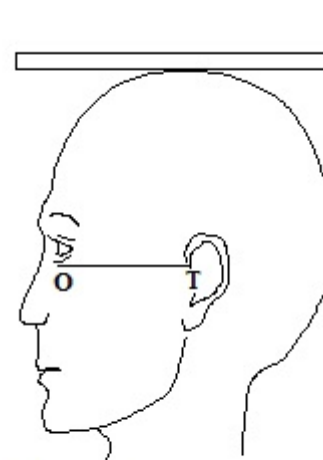
- Insofar as possible, use a hard, flat floor, which is even and without carpet. Measurement may be inside a doorway, against a closed door, or in a hallway. Use an area that does not have a baseboard, threshold, or other protrusion.
- Explain the procedure to the participant. Ask him/her to remove shoes or slippers. Ask him/her to stand with feet flat on the floor, heels together, with heels, hips, shoulders and head directly against the wall.
- Ask the participant to tilt the head forward, so you can place a piece of adhesive tape vertically on the wall in the area where the height will be measured. Place the tape loosely, with one end folded over so that it will be easy to remove without damaging the wall. Now ask the participant to look straight ahead with the head against the wall.
- Rest the wooden base of the Handistat set square against the wall above the participant's head with the right angle toward the floor. Slide it down slowly until it touches the top of the participant's scalp, carefully centered with their nose. Make sure one wooden edge is flat and held steadily against the wall. Mark the tape exactly where the corner of the right angle touches the tape. Be sure to mark the tape from underneath the set square with the pencil angled upward.
- Remove the square and ask the participant to step away from the wall. Open the metal measuring tape and make sure it is straight. Secure it against the wall by pressing it with your foot at the "0" end, or by taping it. Keeping the tape flat against the wall and vertical, read the measurement closest to the mark on the tape and record to the nearest 0.1 cm. If necessary, stand on the folding stool to be at eye level with the mark. It may be necessary to solicit assistance from the second technician or the participant if you use a stool.
- Record the height measurement on the "Physical Measurements" form (PM). After the result has been recorded, use the Metric Conversion Chart (below) to convert the height to feet and inches for the participant.
- Remove the tape carefully from the wall. Discard the tape into the paper bag.

5.3. Height Measurement

5.3.2. Methods

Conversion of Height in cms to height in feet and inches.

Centimeters	Inches	Feet + Inches	Frankfort Plane
122	48	4 ft 0 in	
124.5	49	4 ft 1 in	
127	50	4 ft 2 in	
129.5	51	4 ft 3 in	
132	52	4 ft 4 in	
134.5	53	4 ft 5 in	
137	54	4 ft 6 in	
139.5	55	4 ft 7 in	
142	56	4 ft 8 in	
145	57	4 ft 9 in	
147.5	58	4 ft 10 in	
150	59	4 ft 11 in	
152.5	60	5 ft 0 in	
155	61	5 ft 1 in	
157.5	62	5 ft 2 in	
160	63	5 ft 3 in	
162.5	64	5 ft 4 in	
165	65	5 ft 5 in	
167.5	66	5 ft 6 in	
170	67	5 ft 7 in	
172.5	68	5 ft 8 in	
175	69	5 ft 9 in	
178	70	5 ft 10 in	
180.5	71	5 ft 11 in	
183	72	6 ft 0 in	
185.5	73	6 ft 1 in	
188	74	6 ft 2 in	
190.5	75	6 ft 3 in	
193	76	6 ft 4 in	
195.5	77	6 ft 5 in	
198	78	6 ft 6 in	
200.5	79	6 ft 7 in	
203	80	6 ft 8 in	
205.5	81	6 ft 9 in	



CRESTALE (O) Lower margin of eye socket  
TRAGION (T) Notch above ear at upper margin of zygomatic bone at first point  
FRANKFORT PLANE Orbitale-tragion line horizontal

1 Inch = 2.54 cm; 1 cm = 0.39 in.

#### 5.4. Neck Circumference

##### 5.4.1. 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<sup>1</sup>. In particular, among subjects with a BMI < 28 kg/m<sup>2</sup>, an increased neck size may identify those with OSA<sup>2</sup>. Increased neck size, as a marker for upper airway compromise, may be a direct risk factor for OSA. Increased neck size may also be a marker for altered lipid/glucose metabolism and an indicator for hyperlipidemia, and thus be another confounder in the relationship between OSA and CVD.

##### 5.4.2. Definitions

- Frankfort Horizontal Plane - head parallel to the floor looking straight ahead (see figure above).
- Laryngeal prominence - also known as the Adams apple, located in the throat.

##### 5.4.3. Methods

The method described by Callaway et al in Lohman, Roche, and Martorell<sup>3</sup> will be used to measure the circumference of the neck.

- Record measurement on the “Physical Measurements” (PM) form
- Perform and record this measurement in triplicate
- Participant sits upright with the head in the Frankfort Horizontal Plane
- Use a cloth tape or the plastic circumference measuring tape from Perspective Enterprises, Inc.
- An inelastic tape is applied around the neck just below the laryngeal prominence
  - IF using circumference measuring tape, note that the first 1 inch of the tape is not marked, and this device can not be used in the same way as a cloth tape. There is a demarcation as to where the reading must be taken. The small end of the tape should be threaded through the guide holes at the larger end of the tape, and the reading taken according to the line marked for reading the measurement.
- 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 the 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 ½ cm, rounded up (measurement always ends with .0 or .5)

**5.4.4. 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, Bouchard C et al. Circumferences. In Lohman TG, Roche AF, Martorell R, eds, Anthropometric Standardization Reference Manual, Human Kinetics Books, Champaign, IL, 1988, pp 41-42.

**5.5. Seated Blood Pressure<sup>1-6</sup>**

**5.5.1. Background and Purpose**

The level of blood pressure (BP) is subject to biologic and observer variations, the latter being due to errors in measurement. The purpose of a specific protocol for the measurement of BP and a stringent certification procedure for technicians who measure BP in SHHS is to minimize error in measurement. Three BP readings will be taken. The official SHHS BP will be calculated as the average of the second and third readings.

**5.5.2. Methods**

Blood pressure measurements are taken using a conventional mercury sphygmomanometer. The design and operation of this instrument are based upon the combined principles of compression of the brachial artery under an elastic, inflatable cuff, and direct registration of pressure levels by a mercury manometer. The observer inflates the cuff, listens for the first (systolic) and the last (diastolic) Korotkoff sounds, reads the mercury level in the column, deflates the cuff, and records the readings on the "Physical Measurements" (PM) form.

Blood pressure is usually measured on the right arm. Exceptions are those who have been taking shots, had a mastectomy, or have some other condition that precludes using the right side. Indicate on the PM form if the blood pressure was measured on the left arm instead of the right (and the reason).

If the participant had been engaging in an activity that could affect his/her blood pressure (e.g., smoking, drinking coffee), record this in the Comment field at the end of the form.

5.5. Seated Blood Pressure

5.5.2.1. Arm Measurement to Determine Cuff Size

Proper cuff size must be used to avoid under- or over-estimation of the correct blood pressure. Cuff size is the size of the cuff's bladder, not the cloth. A copy of the chart below should be attached to the sphygmomanometer for easy reference.

- Ask the participant to bare the upper arm, using the right arm, except as discussed above
- Instruct the participant to stand holding the forearm horizontal to the floor (across front of body)
- Measure arm length from the acromion (bony extremity of the shoulder girdle) to the olecranon (tip of the elbow), using a metric tape
- Mark the midpoint on the dorsal surface of the arm with the eye liner pencil or green felt tip marker
- Ask the participant to relax the arm along the side of the body
- Draw the tape snugly around the arm at the midpoint mark. NOTE: Keep the tape horizontal. The tape should not indent the skin.
- Use the criteria below for determining cuff size. Round up to nearest cm. (Do not use the markings on the blood pressure cuff for reference, as these do not match the protocol given below.)
- Record the cuff size used on the "Physical Measurements" (PM) form.

Arm Circumference in cm	Cuff Bladder Size in cm*	Cuff Label
16.0 to 22.5	9.0	Pediatric
22.6 to 30.0	12.0	Regular (adult)
30.1 to 37.5	15.0	Large arm
37.6 to 43.7	17.5	Thigh

\*Bladder widths shown are at least 40% of the largest corresponding arm circumferences.

5.5.2.2. Application of Blood Pressure Cuff

- Place appropriate size cuff around the upper right arm so that:
  - Midpoint of the length of the bladder lies over the brachial artery
  - Mid-height of the cuff is at heart level
- Place lower edge of the cuff, with its tubing connections, about 1 inch above the natural crease across the inner aspect of the elbow.
- Wrap cuff snugly about the arm, with the palm of the participant's hand turned upward
  - Do not wrap cuff too tightly around the arm
  - Observer should be able to insert the first joint of two fingers under the cuff
  - Cuff should be snug but not tight

**5.5. Seated Blood Pressure**

**5.5.2.2. Application of Blood Pressure Cuff**

- Secure the wrapped cuff firmly by applying pressure to the locking fabric fastener over the area where it is applied to the cuff

**5.5.2.3. Rest Period**

The participant should be allowed to rest for a full five minutes prior to measuring his/her blood pressure. Instruct the participant on correct posture, with his/her back supported, both feet flat on the floor and arm resting on the table. The participant should also be instructed not to talk or read or adjust clothing until after the BP measurements are completed. The area should be free of excessive noise. Pets should be out of the area. The technician should not leave the room.

**5.5.2.4. Determining the Maximal Inflation Level (MIL)**

The maximal inflation level is the pressure to which the cuff is to be inflated for the systolic blood pressure measurement. This assures that the cuff pressure at the start of the reading exceeds the systolic blood pressure and thus allows the first Korotkoff sound to be heard. The sphygmomanometer should be at the eye level of the technician.

The procedure for determining Maximal Inflation Level are as follows:

- Attach the cuff tubing to the mercury sphygmomanometer.
- Palpate the radial pulse.
- Inflate the cuff rapidly to 70 mm Hg, and then inflate by 10 mm Hg increments until the radial pulse is no longer felt. This is the palpated systolic BP.
- Do not inflate the cuff over 270 mmHg
- Deflate the cuff quickly and completely.
- Inflate the cuff to 30 mm Hg above the palpated systolic pressure for all subsequent BP readings.

**5.5.2.5. General Procedures for Blood Pressure Measurement**

Once the cuff and device are connected as required for determination of the maximal inflation level, the steps in measurement are as follows:

- If a blood pressure measurement has been taken, wait at least 30 seconds after complete deflation of the cuff. (It is not necessary to wait 30 seconds after determination of the maximal inflation level.)
- Wait at least 25 seconds before proceeding with any additional reading.
- Place the earpieces of the stethoscope into the ears with the tips turned forward.



5.5. Seated Blood Pressure

5.5.2.5. General Procedures for Blood Pressure Measurement

- Apply the bell of the stethoscope over the brachial artery with light pressure, ensuring skin contact at all points. The brachial artery is found at the crease of the arm, slightly toward the body. The bell should be placed just below but not touching the cuff or tubing. If a thigh size cuff is required by the arm measurement, but the participant is short, use that cuff and touch the edge of the cuff with the stethoscope bell during BP readings.
- Close the thumb valve and squeeze the bulb to inflate the cuff at a rapid but smooth, continuous rate to the maximal inflation level. **NOTE:** The eyes of the technician should be level with the mid-range of the manometer scale and focused at the level to which the pressure will be raised.
- Open the thumb valve slightly and maintain a constant rate of deflation at approximately 2 mm Hg per second to allow the cuff to deflate, listening throughout the entire range of deflation from the maximum pressure past the systolic reading (the pressure where the first regular sound is heard) to 10 mm Hg below the level of the diastolic reading (that is, 10 mm Hg below the level where the last regular sound is heard). **NOTE:** Phase V diastolic BP is that point at which the last sound is heard. At least two beats must be heard to record Phase I systolic BP.
- Deflate the cuff fully by opening the thumb valve, and disconnect the tubing from the cuff. Remove stethoscope earpieces from the ears and enter the systolic and diastolic readings in the spaces provided on the form.
- Remove the cuff and store the equipment safely after the last reading.

5.5.2.6. Criteria for Systolic and Diastolic Blood Pressure

To correctly identify the 1st-phase (systolic) and 5th-phase (diastolic) Korotkoff values, listen carefully via the stethoscope while reading and interpreting the mercury column.

- The systolic value is the pressure level where the first of two or more sounds are heard in appropriate rhythm.
- The diastolic value can be identified as the pressure level where the last of these rhythmic sounds is heard.
- The mercury should be made to drop at 2 mm Hg per second, from the maximum pressure until 10 mm Hg below that of the last regular sound heard. The control of the deflation rate is essential for accurate readings and depends on handling of the bulb and its control valve.

**NOTE:** A single sound heard in isolation (i.e., not in rhythmic sequence) before the first of the rhythmic sounds (systolic) or following the last of the rhythmic sounds (diastolic) does not alter the interpretation of the blood pressure.

#### 5.5.2.7. Guidelines for Blood Pressure Readings

- All readings are made to the nearest even digit, rounding up.
- Any reading which appears to fall exactly between markings on the mercury column should be read to the next higher marking i.e., 2, 4, 6, 8 or 0.
- All readings are made at the top of the meniscus, the rounded surface of the mercury column.
- When the pressure is released 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.
- If sounds are heard immediately after the cuff is inflated, start the procedure over, including the 30 second rest period (with 5 seconds vertical.)
- Keep stethoscope in ears during the entire time the three readings are being taken.

#### 5.5.2.8. Blood Pressure Measurement - First Reading

- Ask the participant to hold his/her arm as close to vertical as possible for a full 5 seconds. Examiner may assist if needed. Wait at least 25 seconds before proceeding with reading.
- Perform the BP reading as described above.
- Record this reading on the form, although it will not be included in the official study average blood pressure values.

#### 5.5.2.9. Blood Pressure Measurement - Second and Third Readings

- Ask the participant to hold his/her arm as close to vertical as possible for a full 5 seconds. Examiner may assist if needed. Wait at least 25 seconds before proceeding with second readings.
- For the second reading, repeat the steps shown above for the first readings. Record the systolic and diastolic readings on the paper form.
- Repeat all of the steps again for the third reading. Record the systolic and diastolic readings on the "Physical Measurements" (PM) form.
- Inform the participant of the higher of the second and third readings.

#### 5.5.2.10. References

- 1) 1997 Joint National Committee, The Sixth Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. Arch Intern Med, 157, 1997, pp. 2413-2446.
- 2) Working Group on Hypertension in the Elderly, Statement on Hypertension in the Elderly. JAMA, 1986, 256, No. 1, pp. 70-74.

5.5. Seated Blood Pressure

5.5.2.10. References

- 3) Labarthe DR, Palmer M. Measurement of Blood Pressure: A Manual for Training and Certification. Adapted for the Systolic Hypertension in the Elderly Program (SHEP). June 5, 1985.
- 4) Borhani N, LaBaw F, Dunkle S. Blood pressure measurement in an ambulatory setting. In: Ambulatory Blood Pressure Monitoring. New York: Springer-Verlag, 1984: 75-81.
- 5) Frohlich EC, Grim C, Labarthe DR, et al. Recommendations for human blood pressure determination by sphygmomanometers. Hypertension 1988; 11: pp. 209A-222A.
- 6) Atherosclerosis Risk in Communities Study (ARIC) Protocol, Manual 2: Cohort Component Procedures, Version 2.0 1/88. ARIC Coordinating Center, Suite 203 NCNC Plaza, 137 E. Franklin St, Chapel Hill, NC 27514.

**5.6. Ankle-Arm Index (AAI)**

The AAI section which follows is adapted from the Operations Manual of the Health ABC Study<sup>1</sup>.

**5.6.1. Background and Purpose**

The ankle-arm index (AAI) is the ratio of the ankle to arm systolic blood pressure. It is reduced to less than 1.0 when there is obstruction to blood flow in legs. The AAI is a non-invasive measure of atherosclerotic obstruction in the legs and is a general marker of atherosclerotic burden<sup>2</sup>. The degree of subclinical and clinical atherosclerosis is hypothesized to be related to the decline in lean mass and increase in abdominal adiposity with age. AAI is associated with atherosclerotic disease in other vascular beds and predicts subsequent mortality and cardiovascular mortality. The impact of subclinical cardiovascular disease on loss of bone and muscle mass and subsequent disability is not clear.

**5.6.2. General Methods**

**5.6.2.1. Using the Doppler**

For the Doppler probe to remain in proper condition, NEVER use ECG paste or cream as the contact medium between the skin and the crystals. Use AQUASONIC or any gel made for ultrasonic physical therapy equipment. In an emergency use any surgical jelly or lubricant, even Vaseline or mineral oil. After use, remove the gel with a soft tissue. If the probe has dried gel on it, wash it off under running water. Do NOT scrape off the gel.

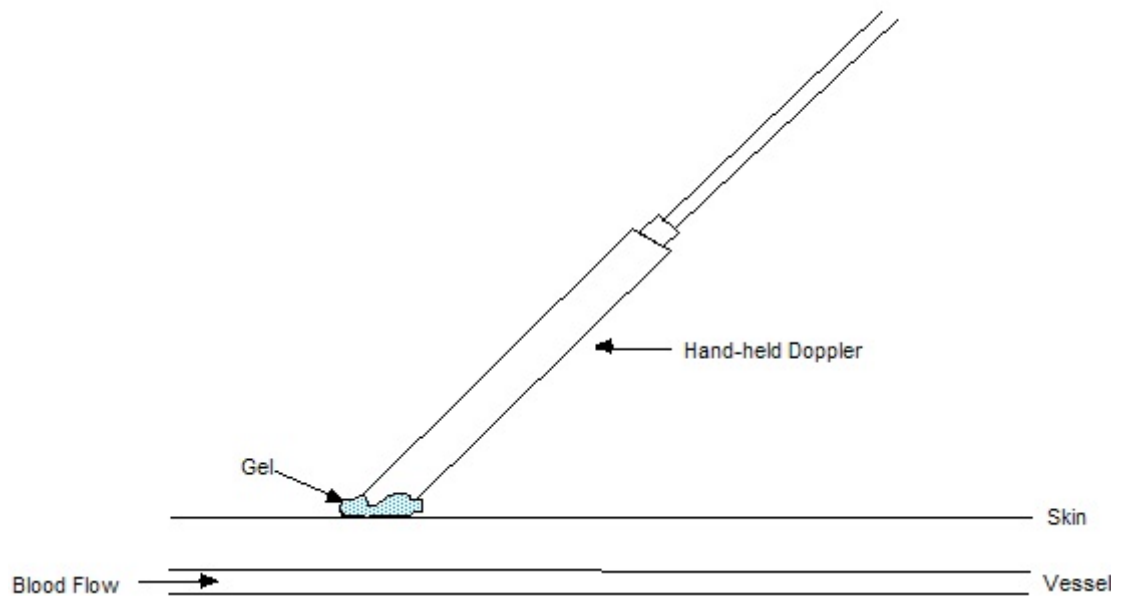
5.6. Ankle-Arm Index (AAI)

5.6.2.1. Using the Doppler

To preserve the battery, turn off the unit immediately after measurements. It takes less than a minute to make a blood pressure measurement. Turn the unit off immediately after removing it from the skin.

The Doppler unit (for maintenance and troubleshooting see chapter on Equipment) is operated on by pushing the button on the unit to turn it on, and gradually turning the volume up. The probe is then placed over the artery (brachial or posterior tibial). The brachial artery is at the crease of the elbow, slightly toward the body. The posterior tibial artery is behind the outside ankle bone.

The frequency is 8 Megahertz (vibrations of 8 million times per second). In order to hear the signal above background noise, the instrument must be pushed in toward the artery. Angling the beam upstream improves the signal. For deeper vessels, the unit will have to be tilted back toward perpendicular, but NOTE: the instrument works poorly or not at all if held fully perpendicular to the flow. It must always be angled into and IN LINE with the flow. See the figure on the next page.



Strange noises from the Doppler. On occasion there are unusual noises from the Doppler that do not indicate a problem with the Doppler. The normal sound will become obvious with experience in performing this test. See the chapter on Equipment for some common unusual noises and their causes.

Please note that the Doppler unit turns itself off after 5 minutes automatically. This may occur in the middle of a measurement.

---

**5.6. Ankle-Arm Index (AAI)**

**5.6.2.1. Using the Doppler**

The purpose of the Doppler is to determine that blood is or is not flowing under the cuff. For correct interpretation, the probe **MUST** be centered directly over the artery and must not be moved while inflating the cuff.

In some places along the posterior tibial artery there is anatomical hiding of the vessel by muscle or tendons. Move up or down the vessel a little to find the best signal above background noise.

**5.6.2.2. Safety Issues and Exclusions**

If an exclusionary criterion exists for one leg, the AAI may still be performed using the other leg. If an exclusionary criterion exists for the participant, the AAI may not be performed.

Exclusionary criteria for a limb include:

- legs with open wounds (including ulcers) or rashes
- legs with amputations
- artery cannot be occluded before the mercury column reaches 300 mm Hg (rigidity of artery)
- sound cannot be heard

Exclusionary criteria for a participant include:

- inability to lie flat or in a semi-recumbent position
  - Flat or semi-recumbent is defined as the trunk being raised no more than 45 degrees from a flat surface parallel to the floor
- bilateral amputation of legs or arms

The presence of exclusionary criteria for limbs and participants is recorded on the “Physical Measurements” (PM) form.

**5.6.2.3. Participant Preparation**

- Ask the participant to remove his/her shoes, socks and stockings so that the ankles are bare to mid-calf, if this has not been done already
- Remove or roll up the sleeve of the arm to be used for the BP
- Lay the participant on a flat surface with the side of the body on which the arm BP will be taken toward the observer
- Keep the participant recumbent or semi-recumbent for at least five minutes before measuring blood pressure.

#### 5.6.2.4. Application of BP Cuffs

- Place three blood pressure cuffs on the participant and attach the sphygmomanometer to the arm cuff for the first reading:
  - Place one cuff on the arm.
    - ▶ Use the same arm and cuff size that were used for the seated blood pressure measurement
    - ▶ If it is not feasible to measure blood pressure using the right arm, the left arm may be used
    - ▶ The change in arm and the reason for the change should be noted on the comments section of the form
  - Place one standard adult size (or appropriate size\*) cuff on each ankle
    - ▶ Apply the ankle cuffs with the midpoint of the bladder over the posterior tibial artery, with the lower end of the bladder approximately 3 cm above the medial malleolus.
    - ▶ Rarely, the velcro will not hold due to the ankles being very thin or large. In these cases use pediatric or large adult cuffs. The size guidelines\* used above in the section on seated blood pressure can be applied here as well. If not enough cuffs of the correct size are available, the appropriate cuff will need to be moved to make measurements.
- Apply ultrasound gel on each limb over the appropriate artery at this time.

#### 5.6.3. Detailed Methods

##### 5.6.3.1. Determination of the Maximal Inflation Level (MIL)

Determine the pressure to which to inflate the cuff for the measurement of the systolic blood pressure. Determine the MIL independently of the MIL found at seated BP measurement. (The Doppler is more sensitive, so these values may differ.) 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. Again, the examiner should be at eye level with the manometer. The maximal inflation level should be measured specifically for the ankle-arm index measurement, using the Doppler, independently from its measurement for the regular blood pressure measurement. The procedures for determining maximal inflation level are as follows:

- Attach the cuff tubing on the arm to the conventional mercury sphygmomanometer
- Locate the brachial pulse with the Doppler
- Inflate the cuff until the brachial pulse is no longer heard - this is the Doppler systolic pressure
- Deflate the cuff quickly and completely

**5.6. Ankle-Arm Index (AAI)**

**5.6.3.1. Determination of the Maximal Inflation Level (MIL)**

- Inflate the cuff to 30 mm Hg above the Doppler systolic pressure for all subsequent readings - this is the maximal inflation level (MIL)
- Repeat the maximal inflation level if the first attempt was unsatisfactory or you have had to readjust the cuff after measuring the maximal inflation level. Wait 30 seconds before making a second attempt if the first is unsatisfactory.
- If the brachial pulse is still heard at a level of 270 mm Hg or higher (which means that the maximal inflation level is 300 mm Hg or higher) repeat the maximal inflation level. If the maximal inflation level is still 300 mm Hg, terminate the blood pressure measurements and write in "300" in the place for MIL on the Physical Measurements (PM) form. Indicate the Doppler systolic blood pressure at the level actually heard. Note: The Doppler BP will always be higher than the blood pressure taken with a stethoscope. Medical alerts for BP are related to stethoscope readings.

**5.6.3.1.1. Performing the Measurements**

Wait 30 seconds after determination of the maximal inflation level and follow the steps below for performing the blood pressure measurement:

**5.6.3.1.2. 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.

**5.6.3.1.3. Arm (Brachial) Systolic Blood Pressure Measurement (see above for General Methods for this measurement).**

- Participant should lie flat, straight knee. (Feet will be flexed.)
- Attach the cuff tubing to the manometer.
- Turn the Doppler unit on.
- Sit next to the participant's arm.
- Locate the brachial artery by palpation. If you need to, you can also locate the brachial artery by using the Doppler.
- Apply more ultrasound jelly over brachial artery, if needed

**5.6. Ankle-Arm Index (AAI)**

**5.6.3.1.3. Arm (Brachial) Systolic Blood Pressure Measurement**

- Locate brachial artery using the Doppler
- Measure the systolic blood pressure using the Doppler:
  - Inflate the cuff quickly to the maximal inflation level
  - Deflate at 2 to 3 mm Hg per second to 10 mm Hg below the appearance of systolic pressure
  - Deflate the cuff quickly and completely
- Record systolic blood pressure in space provided for brachial BP on form.

**5.6.3.1.4. Ankle Systolic Blood Pressure Measurement**

Place the manometer between the participant's ankles.

**5.6.3.1.5. Right Ankle Systolic Blood Pressure Measurement**

- Locate the posterior tibial artery by palpation
- Apply more ultrasound jelly over posterior tibial artery if needed
- Measure the systolic blood pressure using the Doppler: Inflate the cuff quickly to the maximal inflation level
- If sounds are still present, continue to inflate 10 mm Hg at a time, until the sound is obliterated
- Deflate at 2 to 3 mm Hg per second to 10 mm Hg below the appearance of systolic pressure
- Deflate cuff quickly and completely
- Record the systolic value from the first reading in the space provided for right posterior tibial BP on the "Physical Measurements" (PM) form

**5.6.3.1.6. Left Ankle Systolic Blood Pressure Measurement**

- Repeat systolic blood pressure measurement as for right leg
- Record the systolic value from the first reading in the space provided for left posterior tibial BP on the form

**5.6.3.2. Repeating the Ankle-Arm Measurements**

- Wait at least 30 seconds
- Repeat the sequence immediately in the following order (reverse order from previous readings):
  - left ankle
  - right ankle



5.6. Ankle-Arm Index (AAI)

5.6.3.2. Repeating the Ankle-Arm Measurements

- right arm
- Review the form for completeness.
- Remove cuffs and conducting jelly.

5.6.3.3. Tips for the Ankle-Arm Measurements

- Mark the location of maximal pulse or Doppler signal on the brachial artery and both posterior and tibial arteries with an eyeliner pencil to improve the speed and accuracy of localizing them the second time and to help maintain position
- Hold the Doppler pen absolutely still while inflating and deflating the cuff; moving a few millimeters will lose the pulse
- Always use enough jelly to ensure good contact
- The systolic value is the pressure level at which you hear the first of two or more swishing 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)

5.6.3.4. Calculations of Ankle-Arm Indexes

The SHHS data system is set up to automatically calculate the Right and Left Ankle-Arm Indexes from the raw data on the PM form. Instructions for printing the Ankle-Arm Index for a participant are found in the SHHS Manual of Procedures, Volume 5, Data System Manual data entry chapter, Section 5.4. The formulas used to calculate the Ankle Arm Indexes are shown below:

$$\text{Right Ankle-Arm Index} = \frac{\left( \frac{\text{RightAnkle}_1}{\text{Arm}_1} + \frac{\text{RightAnkle}_2}{\text{Arm}_2} \right)}{2}$$

$$\text{Left Ankle-Arm Index} = \frac{\left( \frac{\text{LeftAnkle}_1}{\text{Arm}_1} + \frac{\text{LeftAnkle}_2}{\text{Arm}_2} \right)}{2}$$

Notes:

1. The calculated Right and Left Ankle-Arm Indexes are not recorded on any study forms but are included in the reports to participants ( 8.1.11 of this volume).
2. Subscripts 1 and 2 refer to the first and second measurements, respectively.

#### 5.6.3.5. References

1. Health ABC Operations Manual AABP.OM4 11/1/99.
2. Newman AB; Siscovick DS; Manolio TA; Polak J; Fried LP; Borhani NO; Wolfson SK. Ankle-arm index as a marker of atherosclerosis in the Cardiovascular Health Study. Cardiovascular Heart Study (CHS) Collaborative Research Group. *Circulation*, 1993 Sep, 88(3):837-45.

### 5.7. Electrocardiogram (ECG)

#### 5.7.1. Background and Purpose

The Sleep Heart Health Study is a population-based longitudinal study of approximately 6,440 men and women designed to examine the association between sleep disordered breathing and cardiovascular disease. Standard 12-lead ECGs will be acquired on all participants at the time of PSG. The main purpose of this ECG monitoring is to augment the identification of coronary outcome events i.e. myocardial infarction – both symptomatic and silent. This monitoring will also serve to describe the prevalence and incidence of other cardiovascular conditions.

A standard 12-lead ECG will be performed in a supine or semi-recumbent position for all participants that agree to participate in the follow-up visit. The safety and comfort of the participant are the highest priorities. The MAC<sup>®</sup> 1200 electrocardiograph, available at all of the Field Sites will be used to record the ECGs that will be transmitted to the ECG Reading Center in New York for diagnostic classification and data extraction.

#### 5.7.2. Recommended ECG Acquisition Procedures for the SHHS Study

The following information is intended to provide special instructions for the technicians at each of the SHHS Field Sites. These instructions relate to ECG acquisition and transmission. These instructions augment but do not replace the information provided in the MAC<sup>®</sup> 1200 Operator's Manual. Prior to the home visit, technicians that will be performing the ECG should familiarize themselves with the MAC<sup>®</sup> 1200 operations manual. Complete instructions for operating the MAC<sup>®</sup> 1200 are provided for MAC<sup>®</sup> 1200 users by Marquette Electronics.

The key piece of equipment is the MAC<sup>®</sup> 1200 ECG machine. Other equipment and supplies are listed. For the SHHS Study, the function of the MAC<sup>®</sup> 1200 will be to obtain and store data for transmission to the ECG Reading Center. The MAC<sup>®</sup> 1200 can store up to 40 ECGs before transmission. However, it is *advisable* to store only up to 10 ECGs before transmitting data to the ECG Reading Center.

### 5.7.3. Using the MAC<sup>®</sup> 1200

#### Keyboard Description:

The LCD (Liquid Crystal Display) is on the top part of the MAC<sup>®</sup> 1200 keyboard and is used for entering information and displaying messages. The keyboard descriptions listed below correspond to the MAC<sup>®</sup> 1200 keyboard in Figure 1.






**Setup note:** RgainS function must be set to R10S and not RautoS. Failure to set the MAC1200 to R105 may result in misinterpretation by local physician reviewer.

5.7. Electrocardiogram (ECG)

5.7.3. Using the MAC<sup>®</sup> 1200

- 1 Power input
- 2 Paper door, windows allows you to check the paper supply
- 3 Patient cable connector
- 4 Serial interface (see chapter 13 "Technical Specifications")
- 5 Power switch (ON/STANDBY)
- 6 Keys to select a higher or lower HR alarm limit
- 7 Backspace key (to correct entered data)
- 8 Confirms entered data (Enter)
- 9 Displays the setup menu
- 10 Enables/disables the muscle filter (elimination of muscle artifact)
- 11 Selects the writer speed (25, 50, 5 mm/s) in 6 Lead Mode and the report formats in 12 Lead Mode
- 12 Selects the gain (5, 10, 20, 40 mm/mV)
- 13 Press to print the report or additional copies of the ECG, or to send/receive ECGs
- 14 Selects the ECG lead in 6 Lead Mode (in 12 Lead Mode, on the display only)
- 15 Sends ECG to memory/retrieves ECG from memory
- 16 Selects the 12 Lead Mode
- 17 Selects the 6 Lead Mode
- 18 Selects the Arrhythmia Mode
- 19 Starts/stops the selected operating mode, exits the setup menu and patient data entry
- 20 Indicators, green: selected mode started, amber: selected mode stopped
- 21 Enables entry of patient data
- 22 Indicator is illuminated when battery needs to be charged
- 23 Indicator is illuminated when unit is connected to the power line
- 24 Cursor control keys
- 25 Space bar
- 26 Shift key
- 27 Press to access special characters

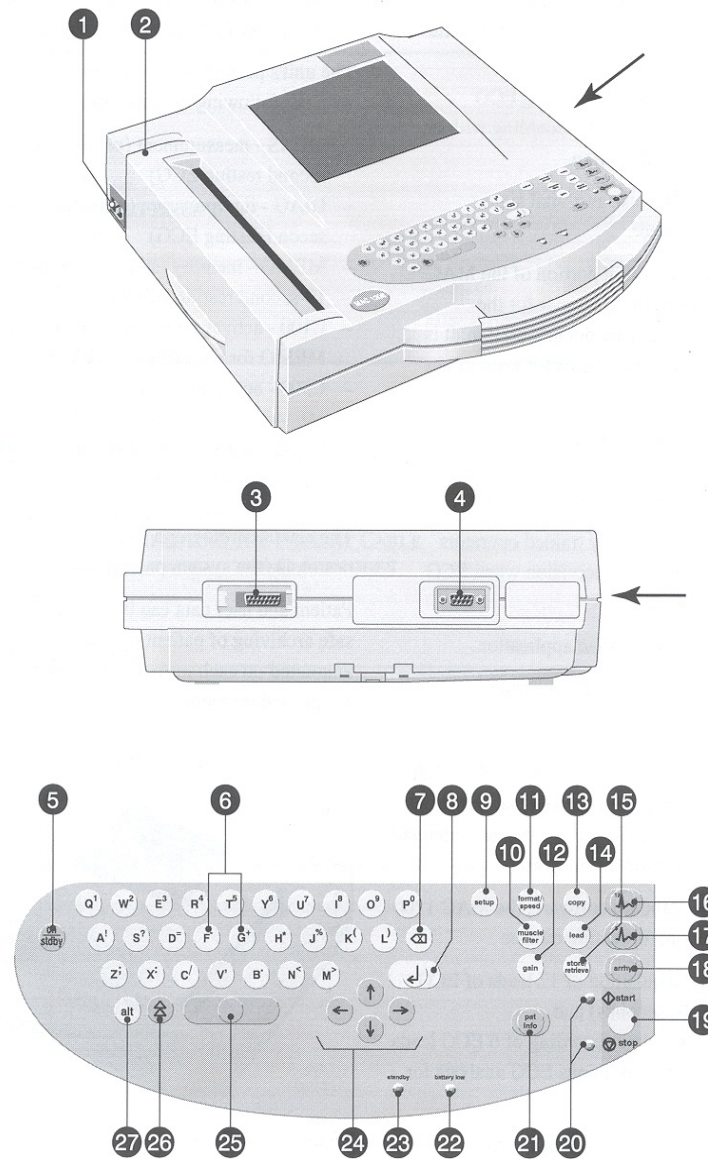
Explanation of symbols used on the device

- |   |  |   |       |
|---|--|---|-------|
|  | Consult accompanying documents                               |  | Start |
|  | Signal input   |  | Stop  |
|  | Type CF signal input, highly insulated, defibrillation-proof |   |       |

5.7. Electrocardiogram (ECG)

5.7.3. Using the MAC<sup>®</sup> 1200

Figure 1



#### 5.7.4. Preparing the Participant

The ECG requires that the participant remove all clothing above the waist. Insofar as gender matching of the technician and the participant is possible, a technician of the same gender should perform the procedure, especially if the participant is a female.

The SHHS ECGs will be taken in a supine or semi-recumbent position (some participants may be too infirm to be comfortable in a supine position). The participant's safety is imperative. The ECG technician needs to be attentive to special disabilities that may cause serious injuries especially for the elderly (hip fractures, etc.)

The location for ECG recording must be stable and properly supported (i.e., bed). A reclining chair (eg., Lazy Boy) can be used for the ECG if necessary.

To assure comparability of data, follow the uniform procedures for electrode placement, skin preparation and quality assurance below:

Explain why we are doing this, especially if participant appears curious. "We are trying to improve our understanding of the relationship between breathing during sleep and heart disease. ECGs will be transmitted for evaluation to our ECG Reading Center in New York, for research purposes."

The participant, with all clothing removed above the waist, is asked to sit or lie in a supine position on the recording bed with shoulders straight and arms related at the sides. Some participants are too infirm to lie flat.

If participant is female, have her remove her arms from her clothing, but keep a piece of clothing or a sheet draped over her chest.

Ask the participant to avoid movements that may cause errors in marking the electrode locations, but encourage participant to talk.

**Check the following:**

- Bed **must** be wide enough to support the elbows
- Participant is comfortable and relaxed

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5.7. Electrocardiogram (ECG)

5.7.5. Enter Participant Data into the MAC<sup>®</sup> 1200

ECGs that are performed in the home will be transferred to the ECG Reading Center with unique participant identifiers. The MAC<sup>®</sup> 1200 has a menu for entering patient data. To preserve participant confidentiality, only the unique identifiers (Participant ID, and Alpha Code) for the participant will be entered into the MAC<sup>®</sup> 1200 patient data menu.

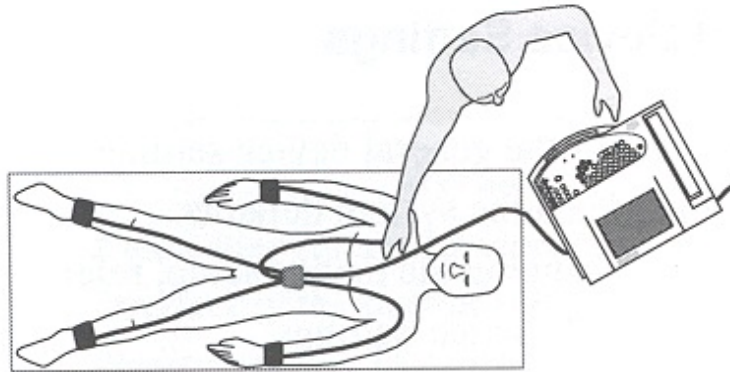
- Press Pat info key. The Enter Patient Data screen appears. Using the arrow keys, move the cursor to the “New Patient” line and highlight “yes”. Press return ( ).
- Move the cursor down to “Date of Birth” line and type in the participant date of birth. Press return ( ).
- Move the cursor down to “Patient ID” line and type in the Participant ID number. Press return ( ).
- Move the cursor down to “Gender” line and highlight either “Female” or “Male”. Press return ( ).
- Move the cursor down to “Race” line and highlight “others”. Press return ( ).
- Highlight a race from the menu in the upper right corner of the screen and press return ( ).
- Move the cursor down to “Technician” line and highlight “others”. Press return ( ).
- Highlight a technician ID number from the menu in the upper right corner of the screen and press return ( ).
- Move the cursor down to “ALPHA” line and type in the Alpha code, replacing the dash with a space. Press return ( ).
- Press Pat info key to return to the 12 Lead tracing screen.

5.7.6. Limb Lead Electrode Placement (Fig 2)

- Begin with the **RIGHT LEG**. This is an important connection as this is the ground connection. A careless skin electrode connection here will influence all ECG leads. On the inner side of the right leg (between the knee and ankle), place a dot with a felt tip pen or a wax cosmetic pencil. Prepare an area about 1-2 inches in diameter. Use firm circular motions with the alcohol gauze. Rub about 10 times or until skin becomes red. For participants with dark skin, rub 10 times. After preparing the skin, re-mark the position with your marker.
- Repeat this procedure for the **LEFT LEG**.
- Proceed to prepare the **RIGHT ARM** inner side (between the wrist and elbow). Mark and prepare the skin and re-mark the location.
- Repeat this procedure for the **LEFT ARM**.
- Place the limb electrodes on the four sites prepared and marked, starting with the right leg.
- Use the newest type disposable silver chloride electrodes. These disposable electrodes do not need electrode paste, yield better ECGs, and offer other advantages. Do not connect electrode cables until you have completed preparations for the chest electrodes.

5.7. Electrocardiogram (ECG)  
5.7.6. Limb Lead Electrode Placement

Figure 2



correct



wrong



### 5.7.7. Locating Chest Electrodes

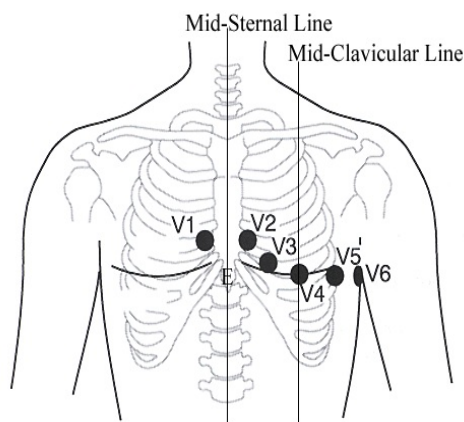
#### 5.7.7.1. Locating Electrodes V1 and V2

Standing on the left side of the participant, locate the sternal angle (where the manubrium joins the sternum) firmly in between the index and middle fingers of your right hand at the mid-sternal line. Move your fingers along the sternal angle laterally to the right sternal border. This is where the second rib joins the sternum. Locate the second rib firmly in between your two fingers. You now have your index finger in the second intercostal space at the right sternal border. Replace your index finger position by your middle finger and move your index finger to the third intercostal space. Make sure that you feel the third rib in between your two fingers. Replace the position of your index finger by your middle finger and move your index finger to the fourth intercostal space at the right sternal border. Your index finger is now at the location of V1. Make an X with your pen.

Now locate V2 at the level of V1 at the left sternal border. Feel the fourth intercostal space and firmly mark the V2 location with your pen (See Figure 3 below).

At this point, mark a dot in the midsternal line in between V1 and V2. This mark will serve as a reference level for V1 and V2 and the fourth intercostal space in case you lose the location marks of V1 and V2 during skin preparation.

Figure 3



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5.7. Electrocardiogram (ECG)

**5.7.7.2. Location of the horizontal reference level for electrodes V4, V5 and V6 (point E).**

Starting from the V2 location, keep the middle finger of your right hand firmly in the fourth intercostal space and move it laterally and slightly diagonally downwards in the fourth intercostal space towards the nipple. Feel the fifth rib with your index finger and move your middle finger to the fifth intercostal space. Move your finger in the fifth intercostal space laterally to where the left midclavicular line intersects the fifth intercostal space. (The midclavicular line starts where you feel a bend in the clavicle. The midclavicular line is a longitude that runs from the bend in the clavicle downwards in the center of the thorax. See Figure 3 above.) Now mark the exact transverse (horizontal) level of the point of intersection of the midclavicular line with the fifth intercostal space at the midsternal line below V1 and V2. It comes close to about one inch below the dot in between V1 and V2. This is your reference level E for the locations of V4, V5 and V6.

**5.7.7.3. Location of electrode V6**

Move the participant's elbow laterally away from his/her body. Note the starting point of the left midaxillary line between the axillary folds formed by the anterior and posterior axillary lines. Follow the midaxillary line in the exact vertical center plane of the thorax down to the intersection of the horizontal plane marked by the location of E. This is the exact location of the V6 electrode. (Note that it is a common mistake to locate the midaxillary line too far anteriorly, towards V5 location.)

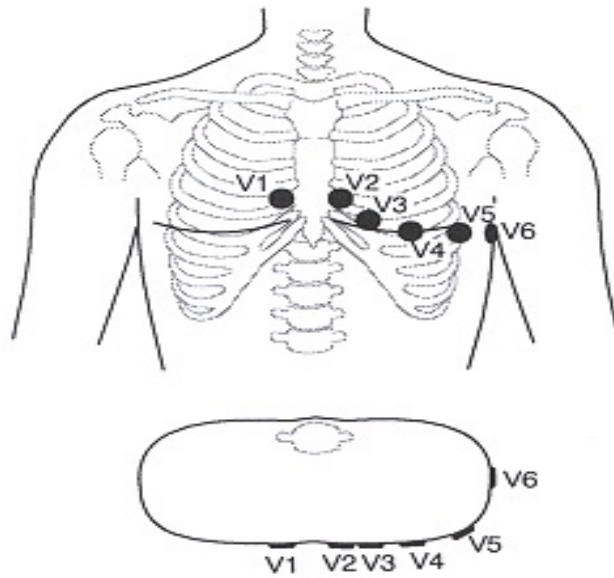
**5.7.7.4. Location of V3, V4 and V5 electrodes (See Figure 4 below)**

- a) Place to mark the location of V4, which is at the intersection of the midclavicular line and the fifth intercostal space
- b) Proceed to mark location V3, which is equidistant between V2 and V4, and V5, which is equidistant between V4 and V6

*Note that chest electrode positions are determined with respect to anatomical landmarks on the thorax. In women with large pendulous breasts, place electrodes on top of the breast in their natural positions when supine. Do not attempt to place the electrodes under the breast or to move the breast upwards or laterally. If the position for V4 is at the nipple, move electrode a bit to the side.*

5.7. Electrocardiogram (ECG)

Figure 4



5.7. Electrocardiogram (ECG)

5.7.8. ECG Strips

5.7.8.1. Suppress interpretive feature on MAC 1200

ECGs are obtained with suppression of the computer reading in the field (see MOP volume 2, Protocol, section 8.3).

5.7.8.2. Providing participant with ECG strip

ECG strips are not routinely given out to participants. However, at the discretion of a site's Principal Investigator, ECG strips without an oral or printed interpretation may be given to the participant during the home visit upon the participant's request.

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## 6. Home Visit Procedures for PSG

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### 6.1. Home Polysomnography - Compumedics Equipment

Sleep Monitoring will be performed using a single lightweight portable device as used in SHHS

1. This device (Compumedics Portable Sleep Unit) is composed of:

1) **A Main Unit.** This is the unit that is brought to the participant's home. It receives all of the signals traveling from the sensors attached to the subject, and stores them in a tiny memory card (a PCMCIA flash card). It also contains a power supply (a 15 hour rechargeable battery), a screen display for visualizing signals (after hook-up), and an impedance meter for checking the adequacy of the electrical contacts for recording EEG, EOG, and EMG.

2) **A Participant Interface Box (PIB)** (sometimes referred to as a "headbox"). This device is worn in a pocket of a special vest that also is brought to the participant's home. It is the device that contains amplifiers and filters for proper processing of the physiological signals. All electrodes and probes, other than the oximeter, are connected to this device. The processed signals from this box are sent to the Main Unit by an Analogue cable.

3) **A special vest and sensors.** The vest is a specially designed garment that is worn during sleep monitoring, holds the headbox, secures the chest and abdomen belts, and secures electrode wires and cables. It is designed to improve the comfort of overnight monitoring, minimize the number of visible wires, and improve mobility.

4) **A computer and software** for preparing the PCMCIA card, and for reviewing and transferring data. This computer is based in the area in your office, clinic or hospital where you prepare and process the sleep records. It is not brought to the home.

5) **A battery charger** (for the clinic).

6) **A calibration unit** (for the clinic).

### 6.2. Supplies for PSG

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

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6.2. Supplies for PSG

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

**6.3. Preparation of PSG Equipment for home visit**

**6.3.1. Preparing the Equipment and Initializing the Flashcard (memory card)**

In the clinic prior to the home visit you will:

- Check all equipment is cleaned and that the PIB is set up properly
- Check to be sure you have spare supplies packed
- Initialize the memory card with the Participant ID
- Insert the memory card and fully charged battery into the Main Unit
- Perform the 15 minute QA check

**6.3.2. Patient Interface Box (PIB)**

The Patient Interface Box (sometimes referred to as a “headbox”) is embedded in a pocket in the vest that is brought to the participant's home. It is the device that contains amplifiers and filters for proper processing of the physiological signals. All electrodes and probes, other than the oximeter, are connected to this device. The processed signals from this box are sent to the Main Unit by an Analogue cable.

Dip switches located within the PIB determine which channels are turned on or off. Improper setting of these switches can result in no data being collected. Correct settings can be found on the

6.3. Preparation of PSG Equipment for home visit  
6.3.2. Patient Interface Box (PIB)

next page and in the Equipment Care and Maintenance section of this manual. If you ever encounter a completely flat line signal, one of the first items to check is the dip switch to make sure it has not accidentally been turned off.

The table below shows the PIB/headbox configuration for SHHS II as it is displayed on the PIB:

PIB Display	NUMBER OF LEAD WIRES WITH WIRE DESCRIPTION
Air	- Compumedics Triple Thermistor
Thor	- Thorax Respiratory Band (yellow)
Abdo	- Abdomen Respiratory Band (blue)
Posn	- Position sensor
Mic	- Light sensor
EEG/2	- Two gold cup electrodes (blue and yellow)
ECG	- Two snap electrodes (red and white)
Leg/L	- N/A
Leg/R	- N/A
EMG	- Two gold cup electrodes (brown and orange)
EOG/L	- Two gold cup electrodes (white and gray - PG1)
EOG/R	- One gold cup electrode (purple)
EEG	- Two gold cup electrodes (beige and red)
Aux	- N/A
PtRef	- One gold cup electrode (green)
EEG/A	- N/A
EEG/B	- N/A
EEG/C	- N/A

It may be helpful to use small pieces of color coded tape, or marker, to label each electrode wire at several points, visible to you during electrode placement. Be sure to use consistent labels to mark electrode wires as “negative” or “positive”.

*TIP: You may want to separately gather all right sided electrodes (C4, A2, EOG/R) and all left sided electrodes (C3, A1, EOG/L) and secure them through a styrofoam cup that has had a hole punched into its bottom. This may prevent tangling, and help with easier identification during placement.*

6.3. Preparation of PSG Equipment for home visit  
6.3.2. Patient Interface Box (PIB)

Dip switches located within the PIB determine which channels are turned on or off. Improper setting of these switches can result in no data being collected or very poor data quality.

Below is a picture of correct dip switches settings as they appear on the open PIB. Pay attention to the ON and OFF directions as they are different for the banks on the left and right (directions are printed inside PIB over banks).

Switchbank 6

Sw	Label	ON↔OFF	
8	EEG- &		OFF
7	EOG/R- &	ON	
6	EOG/L- +R-	ON	
5	INT ⊗		OFF
4	INT ⊕		OFF
3	MIC Δ	3	OFF
2		2	OFF
1		1	OFF

Switchbank 5

Sw	Label	ON↔OFF	
6	INDUCT	A	ON
5		T	ON
4		A	ON
3		T	ON
2	PIEZO	A	OFF
1		T	OFF

Switchbank 1

Sw	Label	OFF↔ON	
8	EEG/2	+	ON
7		-	ON
6	ECG	+	ON
5		-	ON
4	LEG/L		OFF
3	LEG/R		OFF
2	EMG	+	ON
1		-	ON

Switchbank 2

Sw	Label	OFF↔ON	
8	EOG/L	+	ON
7		-	ON
6	EOG/R	+	ON
5		-	ON
4	EEG	+	ON
3		-	ON
2	MIC		ON
1	AIR		ON

Switchbank 3

Sw	Label	OFF↔ON	
8	THOR		ON
7	ABDO		ON
6	POSN		ON
5	LIGHT		ON
4	AUX	OFF	
3	EEG/A	OFF	
2	EEG/B	OFF	
1		OFF	

Switchbank 4

Sw	Label	OFF↔ON	
6	EEG/B	OFF	
5		OFF	
4	EEG/C	OFF	
3		OFF	
2		OFF	
1		OFF	



6.3. Preparation of PSG Equipment for home visit

6.3.3. Preparing (Initializing) the PCMCIA flash (memory) card

Using the *Compumedics Portable Manager Software Program*

- Confirm Montage sampling rates are correct for SHHSV3.MON and SHHSV4.MON
- Verify SHHS Polygraph setup
- Initialize flashcard with Participant ID

6.3.3.1. SHHS Study Template and Polygraph Setup

Before initializing the flashcard for the home visit you must check that the sampling rates are set properly for the SHHS montage file and the polygraph settings. The sampling rate for each channel is the number of samples recorded per second. The maximum sample rate for each channel is 250 samples/sec, or 256 samples/sec for PS2 Rev 4. Note that a higher sample rate implies more memory used on the Memory Card per hour. The storage rate per hour based on the sampling rates selected is displayed in the lower right hand corner. This rate should not exceed 2.5 Mb per hour if an 8-hour recording is required on a 20 Mb Memory Card. In SHHS II we will be using a higher sampling rate of 250 for the ECG which will require more memory and we will be using the 32 Mb or 40 Mb.

The following sampling rates are to be used for all V3 (refurbished) units only - The rates listed below will NOT work with the newer V4 units.

Channels || Polygraph  
Epoch length 30 seconds

Channel	Label	Sampling Rate (Hz)	Display Sensitivity
1	SaO <sub>2</sub>	1	-
2	P.R.	1	-
3	EEG(sec)	125	250uV
4	ECG	250	2.5mV
5	LEG(L)	0	x1
6	LEG(R)	0	x1
7	EMG	125	62.5uV
8	EOG(L)	50	250 uV
9	EOG(R)	50	250 uV
10	EEG	125	250 uV
11	SOUND	0	x1
12	AIRFLOW	10	x1
13	THOR RES	10	x1
14	ABDO RES	10	x1
15	POSITION	1	-
16	LIGHT	1	-
17	AUX	0	250 uV
18	CPAP	0	-
19	Ox status	1	-

(power 5 sample rates)

2.6 MB/hour

---

6.3. Preparation of PSG Equipment for home visit  
6.3.3.1. SHHS Study Template and Polygraph Setup

The *Compumedics Portable Manager Program* is used to:

- Setup the Memory Card
- Download Study from Memory Card
- Set up Study Template
- Define Card Reader Drive Letter Numbers

You will want to verify that the SHHSV3.MON containing the proper sampling rates is present on your system. This must be set up properly BEFORE initializing the memory card. To check the current settings:

Open the *Compumedics Portable Manager Program*.  
Select “Study Template Manager”

*From the Study Template Manager (PS2) window you are able to create a NEW template, Edit an existing template, Copy, Rename, or Delete an existing template*

Open (click on Edit) the SHHSV3.MON file and verify the sampling rates are correct. If this montage file is not available as a selection you need to create the SHHSV3.MON file. To Create a new File:

- Select New
- On the Channels tab for Epoch length: select 30 seconds
- DO NOT select the Power of 2 box (this is for V4 Monitors) - leave box empty
- Enter sampling rates to match above table
- Select OK
- Enter File Name: SHHSV3.MON
- Select OK

### Next Check Polygraph Settings

After saving/reviewing the sampling rate settings, set up the Polygraph with the channels in the order listed below. The signal traces will be displayed in this order when reviewing the study. These setting also remain when the study is received at the Sleep Reading Center and the scorer reviews them. It is important that all studies be uniform in this setup when received at the Sleep Reading Center.

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6.3. Preparation of PSG Equipment for home visit  
6.3.3.1. SHHS Study Template and Polygraph Setup

Select Polygraph tab and enter signals in the following order  
(highlight cell, click on the little arrow and select name for the drop down list)

- 1 EOG(L)
- 2 EOG(R)
- 3 EMG
- 4 EEG
- 5 EEG(sec)
- 6 ECG
- 7 P.R.
- 8 AIRFLOW
- 9 THOR RES
- 10 ABDO RES
- 11 SaO2
- 12 POSITION
- 13 LIGHT

Study Template Settings for new units (Version 4)

The newer units require a different study template set up. Memory cards prepared with a SHHSV3.MON will not record properly if used with a Version 4 monitor. ***All sites need to be aware of the different settings as there is the possibility you might receive a newer version unit as a loaner if your equipment is sent in for repair.*** When setting up this sampling rate you must select the “Power of 2 rate” before modifying any of the channel sampling rates.

**6.3. Preparation of PSG Equipment for home visit**  
**6.3.3.1. SHHS Study Template and Polygraph Setup**

**SHHSV4.MON**

Channel	Label	Sampling Rate (Hz)	Display Sensitivity
1	SaO <sub>2</sub>	1	-
2	P.R.	1	-
3	EEG(sec)	128	250uV
4	ECG	256	2.5mV
5	LEG(L)	0	x1
6	LEG(R)	0	x1
7	EMG	128	62.5uV
8	EOG(L)	64	250 uV
9	EOG(R)	64	250 uV
10	EEG	128	250 uV
11	SOUND	0	x1
12	AIRFLOW	8	x1
13	THOR RES	8	x1
14	ABDO RES	8	x1
15	POSITION	1	-
16	LIGHT	1	-
17	AUX	0	250 uV
18	CPAP	0	-
19	Ox status	1	-

2.8 MB/hour

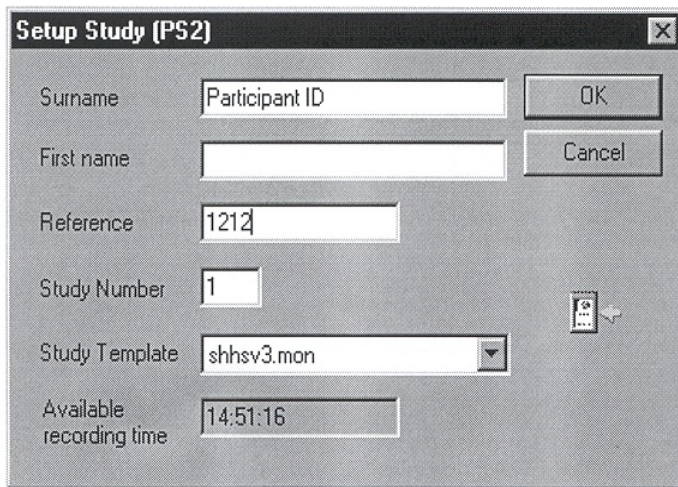
Proceed with setting up the Polygraph in the same way and save as “SHHSV4.MON”.

**IF YOU ARE USING BOTH TYPES OF UNITS (V3 AND V4) IT IS RECOMMENDED THAT YOU MARK YOUR FLASHCARD V3 AND V4 AND ONLY USE THOSE CARDS WITH APPROPRIATE UNITS.**

**6.3.3.2. Initializing flashcard with participant ID**

- Insert memory card into slot on the computer.  
[WARNING: The memory card can only be inserted in one direction. It should slide into the slot easily. Insert carefully; never force in. This may damage the card and the recorder.]
- Open Portable Manager program.
- Select Setup Memory Card button.

6.3. Preparation of PSG Equipment for home visit  
6.3.3.2. Initializing flashcard with participant ID



Type in the Participant ID in the Surname line.

Leave the First Name field blank.

Type in the Monitor/Headbox numbers as shown. The first 2 numbers are the monitor, the second 2 numbers are the headbox. Use "0" for monitor and headbox numbers below 10 (i.e. 0101).

Be sure the correct sampling template is displayed.

Available recording time displayed indicates how many hours of recording are available based on the study template selected and the size of the

**Select OK**

BE SURE THE LIGHT FOR THE PCMCIA CARD READER FLASHES indicating the card in this drive is being initialized. If it does not light up - check the option button on the main menu of Portable Manager to be sure you have the selected the correct drive letter for the PCMCIA card reader.

Wait until computer finishes initialization (window: Initializing... please wait )

- Exit program
- Remove memory card from the computer
- Insert memory card into the monitor that is being prepared for the visit.

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6.3. Preparation of PSG Equipment for home visit  
6.3.3.2. Initializing flashcard with participant ID

*Each main unit (monitor) and PIB/headbox has been assigned an SHHS ID. Be sure all monitors and PIBs are clearly labeled with the correct SHHS ID numbers and that they are visible when the monitor is placed in the leather case.. This will enable you to verify Monitor ID/Headbox ID when completing forms during the home visit.*

6.3.3.3. Final Preparation of PSG Equipment for home visit

Always check your equipment carrying case contains the following before going on a visit:

- 1) Main Unit with **fully charged** battery (>7.8 V)
- 2) Initialized PCMCIA card (memory card) has been inserted in the Unit
- 4) Cable to connect PIB/headbox to Monitor recorder
- 5) Patient sleep vest with PIB/headbox and sensors:
  - (2) Non-disposable electrode leads and snaps
  - (10) gold disk electrodes with attached lead wires
  - (2) thoracic/abdominal belts
  - (1) thermistor
  - (1) light sensor
  - (1) position sensor
- 6) Oximeter cable/disposable or reusable oximeter

Have back-up supplies in the case, including spare electrodes and cables, oximeter and thermistor. Always have an extra battery with you on the visit.

**Perform “15 Minute QA Check”** (see next page). Replace any defective parts with parts supplied by or approved by Compumedics. (SEE *Compumedics manual for supplemental details regarding equipment configuration*) The Compumedics System and its accessories should not be modified.

6.3. Preparation of PSG Equipment for home visit  
6.3.3.3. Final Preparation of PSG Equipment for home visit

**SHHS Technician 15-minute QA Procedure: Pre-study**

(✓)

- 1. Ensure sensors, leads, vest, and leather case are clean, tidy and in good condition.
  - Leads should be free of tape adhesive.
  - Gold cup electrodes should be free of gel/paste/tape, a shiny gold color, and not distorted. Disk electrodes must have been disinfected since last use.
  - Re-usable oximeter probe should be free of dirt and adhesive.
  - Vest and black respiratory band covers have been washed in warm soapy water or dry-cleaned. Foam padding (if used) and extension straps should be included.
  - Leather case should be wiped with a damp cloth.
- 2. Ensure that all electrode wires and connecting cables are securely attached to PIB. Pack an extra set of all leads, thermistor, cable/probes, oximeter.
- 3. Check position of all dipswitches on the PIB.
- 4. Fully charged battery (>7.8V) in monitor and second battery in briefcase as a backup.
- 5. Flashcard card in monitor has been set-up with correct montage (eg SHHSV3.MON), ID.
- 6. Enclose portable main unit within leather case. Check that ID of unit is visible.
- 7. Connect headbox to main unit. Listen for click when connecting cable to headbox and main unit. Pull cable with moderate force to ensure it does not disconnect easily at both ends.
- 8. Connect oximeter probe to main unit. Pull firmly on cable and ensure it is secure.
- 9. Switch main unit ON, listen for "BEEP" and observe the 3 Oks:  
A/D1.....OK A/D2.....OK Realtime Clock.....OK
- 10. Time and Date correct (Time and date are found at the top of the recorder's viewing screen)
- 11. With flashcard inserted, check for the READY message.
- 12. Check for correct information on card  
Participant ID  
MonIDHdbxID
- 13. Automatic START and END times correct (At Main Menu, arrow up to "recording", press OK.
- 14. Battery voltage indicate full charged: >7.8 Volts (Main Menu, OPTIONS...)
- 15. Settings correct (Main Menu, OPTIONS, SETTINGS...):  
EMG NOTCH 60  
OXIMETER ALARM OFF  
REMOTE ON  
AUTO RECORD ON
- 16. Oximeter
  - red light shining brightly from probe, even when cable moved (as a patient would)
  - surface of probe clean
- 17. Before using main unit, check that previous study yielded good quality data on all channels (See Sleep Study Evaluation Form).
- 18. Disconnect Main Cable from PIB to Recorder prior to patient hookup.
- 19. Turn off recorder to save battery life. \_\_\_\_\_(initials/date)

\_\_\_\_\_ (monitor ID)

#### 6.4. The setting for the PSG Study

Ask to see the sleeping quarters to identify any problems (e.g. where will the monitor unit sit?). This will also help you to determine which hand the oximeter should be placed (e.g., closest to a bed table, or the non-dominant hand). At this time, also ascertain the sleeping arrangement involving any bed partners. Notate on Signal Verification Form.

Electric blankets should not be used during a sleep study because the electrical field created can influence the electrodes of the PSG recording system. Participants should be asked about electric blanket use. If a participant uses an electric blanket, he/ she may use the blanket to warm the bed *but the blanket must be turned off and unplugged before the participant gets into bed.* (Note: Some participants may have trouble unplugging their blankets. If this is the case, technicians should offer to unplug the blanket and then plug it back in the morning when they pick up the equipment.) If the participant is unwilling or otherwise unable to do this, the study should be deferred until warmer nighttime temperatures are achieved in the geographical setting.

Set up can be done in any comfortable chair. Many people will be comfortable with having the hook-up performed in the kitchen. Clear a flat surface area to set up supplies (kitchen table, dining room, etc.). Set all materials on a tray or disposable pad and position for easy access. Have the subject sit close to your supply tray during hookup. Place a cover (e.g., a towel) over the back of any finished or upholstered furniture to avoid stains from the various electrode creams. 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.*

#### 6.5. 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 sensors by the ends 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) Have subject shampooed, shaved, showered and in bedclothes
- 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



### 6.5. Sensor Placement

- 6) For elements that require participants hook-up, have subject demonstrate ability to place/replace/remove sensors (use a mirror if necessary)
- 7) Use non-dominant hand for oximeter placement

You will use 10 electrodes (2 ground [PG1 and PG2], C3 , C4 , A1, A2, left EOG, right EOG, 2 chin EMG, and 2 ECG [snaps]). You also will be using a vest, abdomen and chest belts, an oximeter, a thermistor, and a position and light sensor.

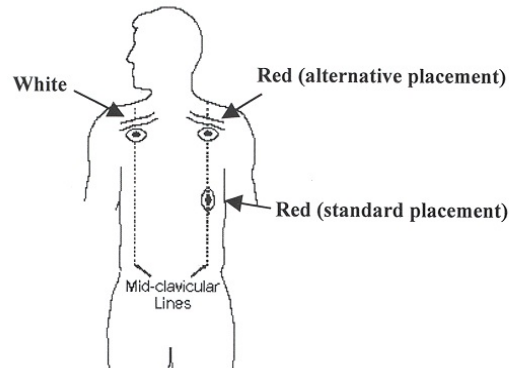
#### 6.5.1. Suggested Order of PSG Hook-up:

- |                                 |  |
|---------------------------------|--|
| (1) ECG (2 electrodes)          | White (-) below right clavicle. Red (+) below the left breast, in a line extending from the midpoint of the left clavicle. <i>Drop electrode wire underneath clothing before attaching electrode to the body and thread wire upwards (over the shoulders).</i> |
| (2) Respiratory belts (2 bands) | Yellow (thoracic) below left armpit<br>Blue (abdominal) below the lower edge of the left ribcage.  |
| (3) Sleep vest                  | Torso of body  |
| (4) Gold Disk Electrodes        | Head, eyes and chin  |
| (5) Light Sensor                | Through buttonhole in vest   |
| (6) Position Sensor             | Velcro square at top of Thoracic respiratory band  |
| (7) Oximeter                    | On the finger of non-dominant hand   |
| (8) Thermistor                  | Under nose, above upper lip  |

##### 6.5.1.1. 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.

6.5. Sensor Placement  
6.5.1.1. Step 1: Attachment of ECG Electrodes



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

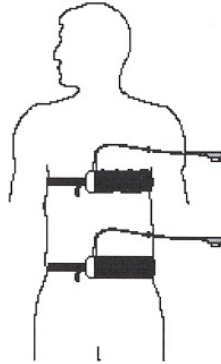
Below midpoint of left clavicle, for the red (+) electrode can be used if the participant is uncomfortable with the standard placement, or if site cannot be determined due to body mass. This alternate placement is called subclavicular.

1. Feed electrode end of the wire down under the clothing.
2. Remove electrode from sealed package (e.g., Medtronic Medclear ECG electrodes). 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 Verifications Form**.

6.5. Sensor Placement

6.5.1.2. Step 2: Placement of Respiratory Bands

Yellow lead = chest band  
Blue lead = abdomen band



1. Place the respiratory bands into the black nylon covers.
2. Place the **chest band** (yellow lead) under the left armpit, with the lead wire facing upwards. The stretchy white material should extend minimally from the mid back to the mid front (around the left). The Velcro patch should be in front of the subject, between the breastbone. Adjust the black extender belt so the belt is secure, but not tight. Run wires upwards and drape over the shoulder.
3. The **abdominal band** (blue lead) 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 blue lead wire facing upwards. Run wires upwards and drape over the shoulder.
  - To ensure that the respiratory bands are attached firmly around the patient the bands should be stretched 6 inches to join clips.
  - Incorrect application of respiratory bands can cause very poor signals.
  - Do not restrict the participant's comfort or breathing.

6.5. Sensor Placement

6.5.1.3. Step 3: Position the Sleep Vest (bib design)

Have the participant sit in a chair while placing the vest. This will allow you to help guide the wires of the sensors that have already been placed.

1. Undo the velcro pouch on the sleep vest. The pouch has 2 levels separated by a velcro strip. Make certain the pouch is completely open so the hole on the inside of the lower level is visible.
2. Ask the participant what position he usually sleeps in (front, back, sides, etc.) to determine whether the PIB headbox should be worn on the front or back. Participants that sleep on the back should wear the PIB on the front, those who sleep on the abdomen should wear the box on their back.
3. Undo the velcro straps on the side of the sleep vest. Turn the vest so the pouch flap is to the chest or back, depending on the sleeping position. Have the participant put the vest on over his head.
4. Thread wires from abdominal and thoracic belt through the hole in the front of the vest into pocket. Attach wires to PIB and close PIB cover. Using a rubber band or twisty, bundle excess belt wires so they don't get tangled in the rest of the equipment. Place the bundled excess in the lower level of the pouch and close the velcro strip separating the levels (leaving the upper level undone).
5. Secure the side velcro straps, using the extenders if necessary for large girth. Adjust the velcro shoulder straps so that the pocket of the vest is at a comfortable level. If a participant has an extremely long torso, the extender straps can be used at the shoulders also. Make sure that the side velcro straps are as tight as comfortably possible, because the weight of the headbox has a tendency to pull the vest pouch down, bringing the opposite side uncomfortably close to the neck. If the bottom straps are secure, this does not happen as easily.
6. Close the velcro strips on the sides of the upper level of the pouch.

## 6.5. Sensor Placement

### 6.5.1.3. Step 3: Position the Sleep Vest (bib design)

7. Place the PIB headbox in the upper pouch so that the wires point up toward the participant's head (keep in mind where the recorder will sit in the bedroom). The cable should exit the pouch on the side where the recorder will be situated.
8. Open the velcro strip on one of the shoulder straps. Unwrap the lead wires from the PIB and lay them over the participant's shoulder, run the wires through and close the velcro securely. Place the position sensor away from the other wires, or allow to dangle from the vest pocket.
9. Leaving a path for the electrode wires from the PIB, close the velcro strip at the top of the pouch.

### 6.5.1.4. Step 4: 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.

#### 6.5.1.4.1. 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.

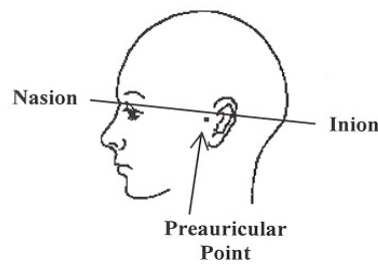
3) Inion: Using a comb, unpadded cotton swab end or hair clip part the participant's hair down the center, in the back of the head. Starting at the nape of the neck, run a finger up the back of the participant's head until a bony ridge, or bump, can be felt. Having the participant move his/her head up 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.

6.5. Sensor Placement  
6.5.1.4.1. Identify your landmarks

*Tip:*

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.



6.5.1.4.2. Measure for electrode sites

- Distance measurements are done with a metric tape measure, and taken in centimeters (cm.) and millimeters (mm.). When computing percentages to find the electrode site a quick measurement guide can be found below, as well as in the Equipment Maintenance Section. The guide can be photocopied and kept with your prep materials for handy reference.
- All marks on skin must be done with a non-toxic, non-permanent implement, such as a wax-based china marker. Bright blue is most easily seen against dark hair. Red can be misidentified as blood by the participant or family members.
- When working with participants having long or thick hair, create a part in the hair by means of a comb or the 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.

Please see page 103 for a diagram of EEC placements.

6.5. Sensor Placement  
6.5.1.4.2. Measure for electrode sites

**Quick Reference: Measurement Chart**

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

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

Remember: The 50% values are used to determine Cz.  
The 20% values are used to determine C3 and C4.

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 markedinion. 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

**6.5. Sensor Placement**  
**6.5.1.4.2. Measure for electrode sites**

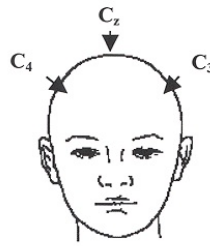
down). Compute 50% of this total measurement (or use your measurement guide). While firmly holding the tape measure at the left preauricular mark allow the tape measure to drape over the crown of the head while marking the value for 50% of the total measurement. This mark should intersect the previously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

To determine C4:

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

To determine C3:

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



To determine A1 and A2:

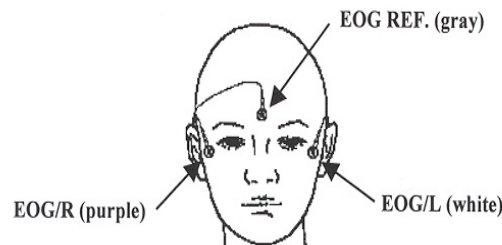
These placement sites are on the mastoid process (bone behind the earlobe). The electrode should be placed on the skin between the crease of the earlobe and where the hairline begins. Lightly mark these sites. A1 is placed on the left mastoid, A2 on the right.



6.5. Sensor Placement  
6.5.1.4.2. Measure for electrode sites

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, 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.

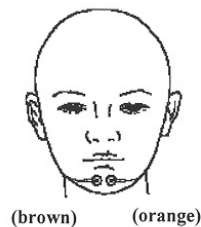


To determine EMG placement:

**Background:** 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.

Placing both chin EMG electrodes on the face below the lower lip, on the ledge of the chin, provides a stable area for attachment. For proper pickup of muscle activity, the electrodes must be separated by a distance of at least 3 cm. Color coding for sides is not necessary.

An alternative placement is on 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 of the chin and the neck. Ask the participant to swallow. You will feel the submentalis muscle move. The electrodes are placed on either 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 electrode on the belly of the submentalis muscle is also acceptable.



6.5. Sensor Placement  
6.5.1.4.2. Measure for electrode sites

Reference:

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

6.5.1.4.3. Prepare the Electrode Sites

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

- Successful skin preparation prior to electrode placement helps to reduce the level of impedance thereby improving the quality of signal.
  - Skin preparation requires abrasion to the top layer of the participant's skin at the electrode site. Although blood is not evident, the field technician must understand that these areas are now non-intact skin and pose a risk for bloodborne 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).

**6.5. Sensor Placement**  
**6.5.1.4.3. Prepare the Electrode Sites**

2. If working in a hairy area, separate the hair in order to see the skin. You may find a comb or hair clips useful to create a part and hold the hair back.
3. Use a cotton tipped applicator to transfer a small amount of skin prep directly onto the electrode site. Before lifting the applicator, apply a moderate pressure and make small circular motions repeatedly on the skin. Take care that you include the center of the site, not just make circles around it leaving the center un-prepped. You may prefer to use a combination of back and forth strokes along with some circular motions.
4. Continuing with moderate pressure, slowly count to 5 while you scrub the site (1 one-thousand, 2 one-thousand, 3 one-thousand, 4 one-thousand, 5 one-thousand). You are done when the skin “pinks up”. Expect some participants to have more fragile skin than others; keep an eye on what you do. You may have to adjust the pressure or the count time.
5. Prep abrasives are not designed as conductors, remove any excessive prep abrasive from the skin prior to electrode placement.
6. Repeat the above steps for each electrode site. It is much easier to prep 2 or 3 sites, and then to apply those electrodes, provided you do not lose your prepped sites.
7. Discard the applicator and prep abrasive when finished. Never contaminate your original tube or bottle.

**6.5.1.4.4. 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 SHHS 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 it's 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

**6.5. Sensor Placement**

**6.5.1.4.4. Attach Gold Disk Electrodes**

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 participant's with sensitivity use Micropore (paper) 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:

PG2 driven ground (Pt. REF)	Cz top of head (Green wire)
EEG	C4 right Central (Beige wire) A1 left mastoid (Red wire)
EEG 2	C3 left central (Blue wire) A2 right mastoid (Yellow wire)
PG1 Ground (REF. for EOG)	middle of the forehead, between the nasion and the start of the hairline. (Grey wire)
EOG Left	left eye, below outer canthus (White wire)

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**6.5. Sensor Placement**

**6.5.1.4.4. Attach Gold Disk Electrodes**

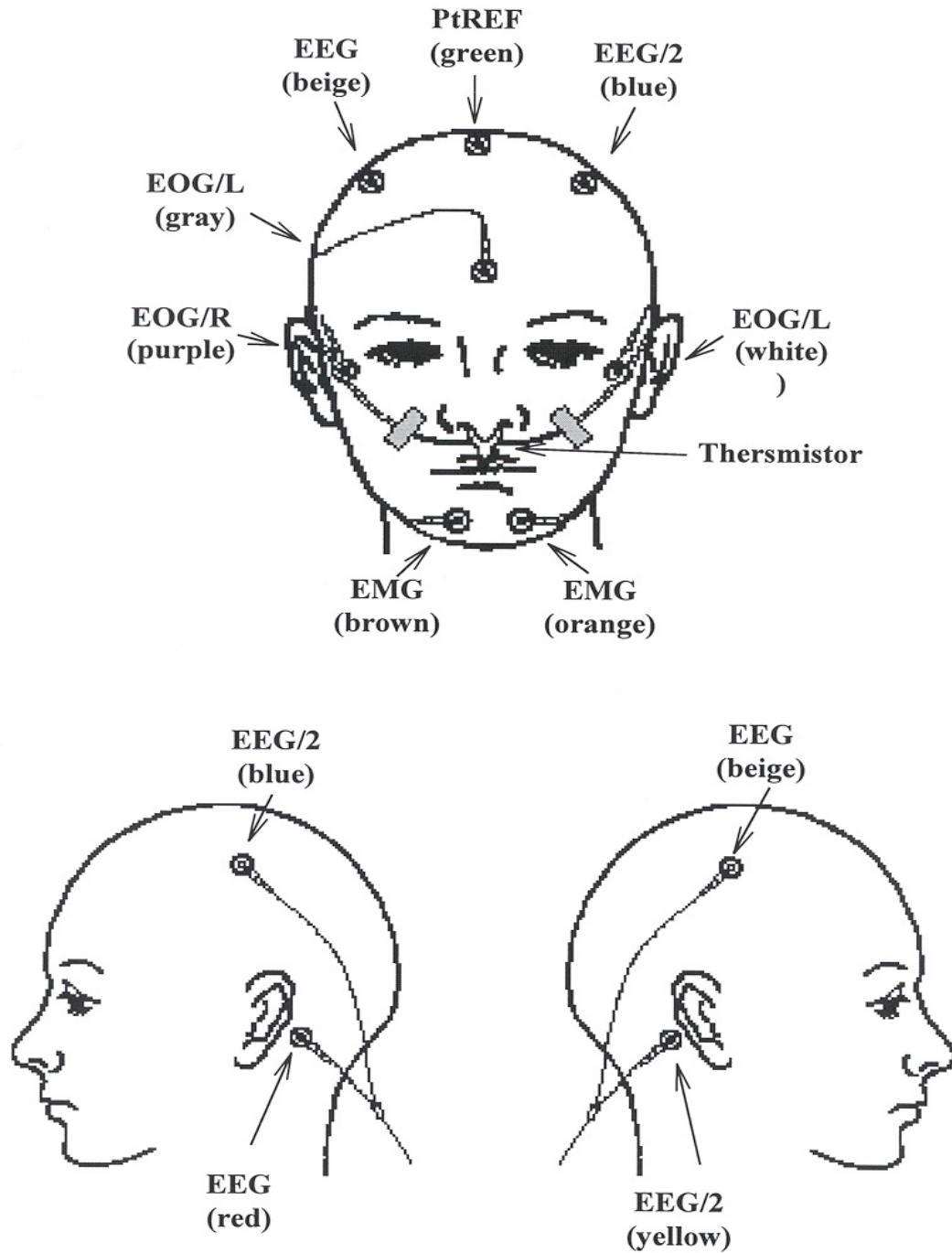
EOG Right

right eye, below outer canthus (Purple wire)

EMG

on the ledge of the chin at least 3 cm. apart, or on either side of submental muscle underneath the chin. (Brown and orange wires) Color coding for sides is not important, more important is spacing (at least 3 cm. between disks), and that the electrodes are securely attached.

6.5. Sensor Placement  
6.5.1.4.4. Attach Gold Disk Electrodes



**6.5. Sensor Placement**  
**6.5.1.4.4. Attach Gold Disk Electrodes**

Techniques for disk electrode application:

Bare skin (Face, mastoids):

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

Scalp with hair:

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

Bearded chins:

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

**6.5.1.4.5. After electrodes are applied**

1. Gather electrode wires together just above nape of neck.
2. Bundle and secure with pieces of tape which have had the ends folded over for easy removal. Bundle the wires approximately every 4-6 inches. This reduces artifact and tangling.
3. Re-open the velcro strip of the shoulder pocket on one side of the vest. Adjust the bundled wires as necessary. Feed enough out of the shoulder pocket to allow plenty of slack at the base of the neck.
4. Re-open the velcro strip at the top of the upper pocket. Working from the inside to outside, pull the light sensor through the buttonhole of the upper level of the pouch (so it's exposed to the light). Loop the excess bundled electrode wire and place into pouch.
5. Close the velcro strip on the on the top of the pouch.

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6.5. Sensor Placement

**6.5.1.5. Step 5: Secure the Light Sensor:**

1. Tape light sensor to the outside of the upper pouch, placing the tape on the inside of the pocket. Never place tape directly over the sensor

**6.5.1.6. Step 6: Calibrate and Attach the Position Sensor:**

1. Connect cable from the PIB to the main unit. The PIB cable connects to the recorder at the side of the display screen. The connector is shaped so it only fits in one way for proper connection.
2. Verify that the memory card is placed correctly.  
Turn on the recorder.  
You should hear a single beep and three OK's will be displayed briefly. The recorder then will display the Main Menu.
3. Following the button guide at the bottom of the Main Menu screen [Down] [Up] [OK] press [Up] until the arrow cursor rests at CALIBRATION. Press [OK] to accept your choice. From the Calibration menu arrow [Up] to POSITION, press [OK].
4. Hold the sensor in your hand with the wire leading toward you (the picture on the sensor will represent positions of the participant).
5. Arrow [Down] to FRONT and turn position sensor in the position that will represent participant lying on his stomach. Press [OK] and an asterisk (\*) will appear next to the FRONT to indicate that the position was calibrated.
6. Arrow [Down] to BACK and turn position sensor to represent the participant lying on his back. When performing this position calibration, consider and duplicate the angle the sensor will sit when the participant is reclined on his/her usual pillows in bed. Press [OK] and an asterisk (\*) will appear next to the BACK.
7. Repeat for LEFT and RIGHT positions. All four positions will now be marked with an asterisk (\*).
8. Press [Cal] button. This accepts and stores the positions as a calibration. The screen will return to the Calibration menu and the word "Done" will appear briefly in the upper right corner.
9. 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.
10. Indicate the completion of position sensor calibration on the **Signal Verifications Form**.



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6.5. Sensor Placement

6.5.1.7. Step 7: Calibrate the Light Sensor

- You will need to do this in the room in which the participant will sleep. Ambient light conditions may differ from room to room. At this point, explain that you need the monitor the amount of light in the room during sleep.
1. Accompany the participant to the bedroom and ask him/her to adjust the lights to reflect the brightness of the room before he/she actually turns off the lights for bed
  2. From the Calibration Menu arrow [Up] to select LIGHT, press [OK].
  3. Press [Down] to move the cursor to ON, press [OK].  
An asterisk (\*) will appear next to ON.
  4. Cover the light sensor with your hand, to block out all light.
  5. Press [Down] to move the cursor to OFF, press [OK]. An asterisk (\*) will appear next to OFF.
  6. Press [Cal] button. This accepts and stores the light amounts as a calibration. The screen will return to the Calibration menu and the word “Done” will appear briefly in the upper right corner. Press [Down] to arrow cursor to BACK. Press [OK]. This returns the recorder to the Main Menu.
  7. Indicate the completion of this calibration on the **Signal Verifications Form**.
  8. If possible, it is during this bedroom check that re-checking for any displacement of the chest or abdominal bands is recommended. Ask the participant to lie on the bed. Check that the respiratory bands still feel secure (have not loosened) while the participant is recumbent. If they have loosened, tighten. Verify that the cable for the recorder is exiting the pouch on the proper side.

6.5.1.8. Step 8: 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 tab 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 center line 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 and that the light sensor diode is on the nail bed.

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**6.5. Sensor Placement**  
**6.5.1.8. Step 8: Attach Oximeter**

*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 resting on nail bed. 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.

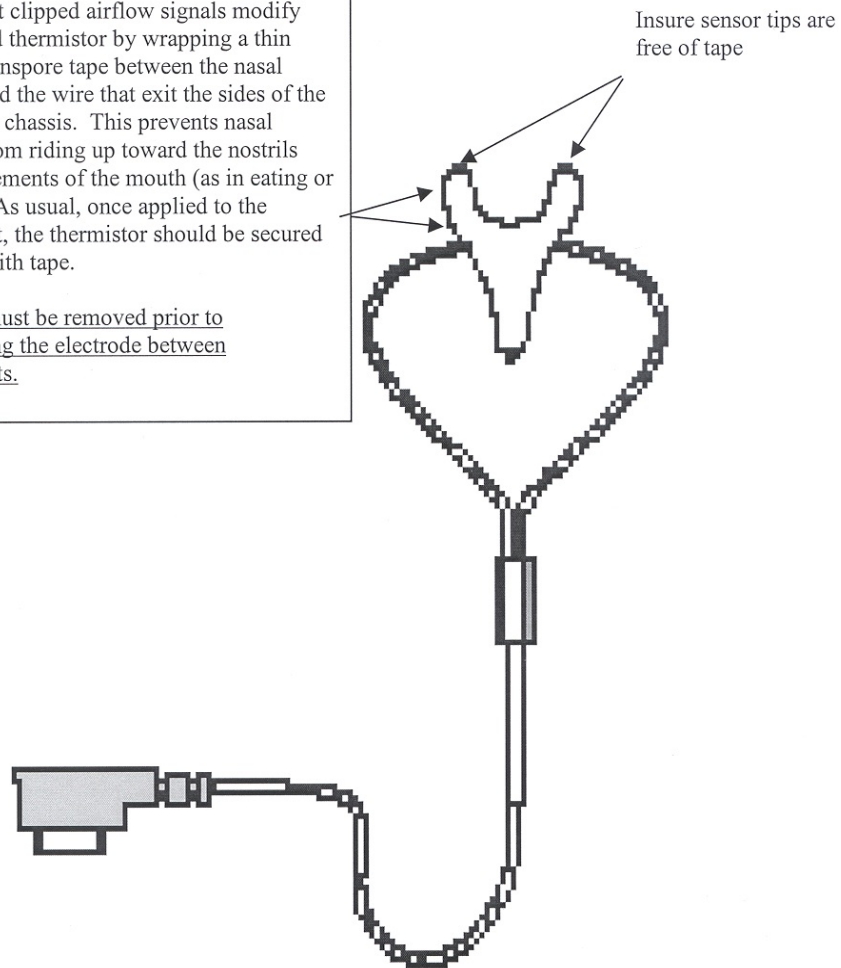
After securing oximeter sensor, ask the participant if any throbbing is felt. If so, reapply, loosening tape. Pass the oximeter cable over the surface of the hand, creating a circular “stress” loop, also securing with tape. Use several additional pieces of tape along the hand and lower arm, securing 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.

6.5. Sensor Placement

6.5.1.9. Step 9: Modify Thermistor:

To prevent clipped airflow signals modify adult sized thermistor by wrapping a thin strip of transpore tape between the nasal sensors and the wire that exit the sides of the thermistor chassis. This prevents nasal sensors from riding up toward the nostrils with movements of the mouth (as in eating or talking). As usual, once applied to the participant, the thermistor should be secured in place with tape.

All tape must be removed prior to disinfecting the electrode between participants.

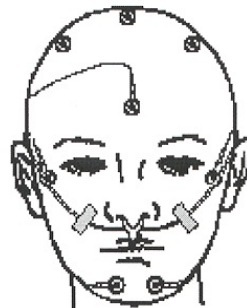


6.5. Sensor Placement

6.5.1.10. Step 10: Attach Thermistor:

These are made of temperature sensitive wires which are positioned directly in the flow of air. Prior to application, place adhesive tape on the electrode of the thermistor. The thermistor should be placed under nasal area on participant's upper lip so that the three thermistor beads are exposed to the patient's nasal and oral airflow. Secure in place by looping wire around ear and taping wires over cheek. The beads should not touch the lips, skin or nasal mucosa membranes.

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



6.6. Signal Verifications - Impedance Checks - Calibration

6.6.1. Documenting Hook-up Procedures - Signal Verifications Form

After hook-up, you will test the quality of each signal from each electrode or sensor. You will check the impedance of each EEG, EOG, ECG, and EMG sensor. You will also be able to check the quality/accuracy of the tracings or values of the signals. You will record the results of your impedance and signal checks on a **Signal Verifications Form** (see Forms). This form is a log of key events related to the in-home procedures. Data from this document will be used to monitor the technical aspects of the study (time requirements, adequacy of hook-ups, etc), will be used to identify and document Immediate and Urgent Referrals, and will provide information that may be useful for “trouble-shooting” bad studies (e.g., impedance checks). This form includes the following:

1. Time of arrival (to home)
2. Time of departure (from home)
3. Notation for presence of living conditions that might influence sleep quality (usual sleeping quarters; number of people in sleeping quarters, presence of unusual noise, extreme temperatures, etc.)
4. The values of oximetry and heart rate noted during hook-up

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**6.6. Signal Verifications - Impedance Checks - Calibration**  
**6.6.1. Documenting Hook-up Procedures - Signal Verifications Form**

5. The values of the impedance for each channel.
6. Confirmation of calibration of light and position sensors.
7. Notes on any problems during hook-up.
8. Note on Monitor if ID is incorrect.

**6.7. Checking the memory card information**

From the MAIN menu, press [Up] button to arrow cursor to PATIENT. Press [Ok]. Ascertain that the following information is correct:

- a) That the Participant ID displayed matches the Participant ID on all paper forms and is correct. If the ID on the monitor and the ID on the front of the Signal Verifications Form differ, the technician must immediately determine which is correct. If the flashcard is correct all the forms from the home visit must be changed; if the paper forms are correct, note the error on the Signal Verifications Form and tape a note to the monitor, so the error can be corrected in the morning. You will need to correct this information during in-clinic data retrieval. (*described under procedure for correcting ID during data retrieval process*). When completed, Press [Ok].
- b) Check the MonIDHbxID corresponds to the monitor and PIB being used, and matches ID written on the Signal Verifications Form.

**6.8. Checking battery charge**

At the MAIN menu select OPTIONS. Press [Ok]. Check that battery voltage is > 7.8 V. If it is less than this, use spare battery. Note battery voltage reading on the Signal Verifications Form.

Move cursor arrow to BACK. Press [Ok].

**6.9. Checking Impedance and Signal Quality**

- 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.

### 6.9. Checking Impedance and Signal Quality

*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  $> 5$  k, remove the electrode, re-prepare the electrode site and replace the electrode.
2. 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.

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

For ECG impedance of  $< 30$  k are acceptable.

When troubleshooting high impedance, first check that the system (all cables) are connected and electrodes are tightly in place. Loose electrodes create excessive impedance.

- While working with the main unit use buttons under display. Functions of the button change for different screens, and are displayed at the bottom of the screen in use:  
**Up** and **Down** buttons will move cursor (arrow)  
**OK** selects an option  
**Back** returns to the previous screen.
- Checking of the signal can be done in any order however is described here in the order of display on the screen.

#### Steps to Check Impedance and Signals on the Recorder Screen:

1. At the Main Menu select CHANNEL. Press [Ok].  
Channel 1 SaO<sub>2</sub> this channel only displays a value of oxygen saturation in %. The adequacy of the oximeter reading will be assessed by:  
Checking that oxygen saturation reads "GOOD". A reading of "POOR" or "MARGINAL" indicates that the pulse reading is poor, probably due to poor placement or an overly tight probe. Sometimes, a poor or marginal reading will occur during movement. If so, wait 10 seconds and recheck. If still poor, replace sensor.  
Checking that the reading appears reasonable ( $>88\%$ ). If  $<88\%$ , re-position, wait 2 minutes, and re-record. If abnormal on a second try, apply to your own finger. If signals is correct on your finger ( $>88\%$  sat and correct heart rate), try again on the participant using a different finger and/or switch probes. If still abnormal, see **Medical Alerts**. Note oximetry reading on the Signal Verifications Form.

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### 6.9. Checking Impedance and Signal Quality

2. Press [Next]. The screen will advance to Channel 2.  
Channel 2 PULSE - this channel displays value of pulse.  
Check that the pulse from the oximeter agrees with a pulse that you will manually check.  
Take subject's pulse at his/her wrist (count the beats per 30 seconds, multiplying X 2 to get the minute pulse). Compare this with the display. If the displayed pulse rate differs by > 5 beats per minute from the pulse recorded at the wrist, reposition sensor.  
On the Signal Verifications Form note the readings from the unit and from the manual check.  
If heart rate >150 or <30, monitor this for 2 minutes. If, over this 2 minute period, the heart rate averages >150 or <30, then follow procedures for **Immediate Medical Alerts**.
- The menu choices will change beginning with Channel 3. You will now be able to choose whether to view the impedance level or the actual live data from each channel. The Signal Verifications Form requires you to do both, but you may choose the order in which they are performed.

### 6.9. Checking Impedance and Signal Quality

3. Check Impedance of channels 3 through 10. Impedance display will cycle through the following order: Channel 3 -EEG(sec), Channel 4 - ECG, Channel 7 - EMG, Channel 8 - EOG(L), Channel 9 - EOG®, Channel 10 EEG. Further pressing Next will cycle back to Channel 3.

#### To Navigate Within this Menu

To check impedance: Press [Up] until the cursor arrow rests at IMPEDANCE.

Press [Ok]. The impedance level of the channel will be displayed as > (a number) k.

The cursor arrow will be resting at BACK.

- To advance to the next channel press [Next].
- To leave the impedance check option press [Ok].  
The display will return to the Channel Menu.
- To exit the Channel Menu: Press [Up] until the cursor arrow rests at BACK. Press [Ok]. The screen will return to the Main Menu.

To view live recording: Press [Up] until the cursor arrow rests at VIEW CHANNEL.

Press [Ok]. The screen will display the actual live data of the channel.

The name of the channel, the screen sensitivity and time base display will be listed at top of the screen.

- To advance to the next channel press [Next].
- To change the size of the display sensitivity press [Next]. The vertical size of the data will change, becoming larger or smaller with each depression of the button, and the sensitivity will be listed at the top of the screen. Waveforms displayed at uV settings will appear larger than waveforms displayed at mV settings.
- To change the time base display press [→] then press [Speed]. The speed of the display will change with each depression of the button, and the display speed will be listed at the top of the screen. The setting 20/s will give a faster display than 1 mm/s.
- To advance to the next channel press [←] then press [Next].
- To exit this menu option press [→] then press [Back].
- To exit the Channel Menu: Press [Up] until the cursor arrow rests at BACK. Press [Ok]. The screen will return to the Main Menu.

*For further description of menu options see your Compumedics manual.*



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### 6.9. Checking Impedance and Signal Quality

4. Note impedance levels of each channel on the Signal Verifications Form.
5. Check quality of the live data. As each signal is checked, indicate the quality of that channel on the Signal Verifications Form (View Signals area). Signals will be displayed in the following order: EEG(sec), ECG, LEG(L), LEG®, EMG, EOG(L), EOG®, EEG, MIC, Airflow, Thoracic, Abdomen, AUX. SHHS will not use LEG(L), LEG®, MIC, AUX.

When viewing live data, use the following procedure for specific channels:

- Channel 3 - EEG(sec): ask patient to close eyes and relax: trace should be moving about the center, and less than 1 mm thick with trace speed on 20mm/s and scale set to 250uV(default)
- Channel 4 - ECG: centered, less than 2 mm thick on speed 20 mm/s, scale 2.5 mV
- Channel 7 - EMG: centered. Ask the participant to relax. Trace should be about half of full scale (this can be different for different people). Ask participant to smile for a moment. Trace should increase to full scale than recover to previous level as the muscles relaxes.
- Channel 8 - EOG(L): Ask patient to stare at a point on the wall and not blink. Trace should be centered and less than 2mm thick on 5mm/s trace speed. Ask patient to look left and right, and keep head still. Trace should be deflect full scale.
- Channel 9 - EOG®: the same as Channel 8 (EOG(L)).
- Channel 10 - EEG: ask patient to close eyes and relax: trace should be moving about the center, and less than 1 mm thick with trace speed on 20mm/s and scale set to 250uV(default)
- Channel 12 - Airflow: centered line less than 1 mm thick on default settings (timebase 5 mm/s and scale x1), clean sine wave
- Channel 13 - Thor Res: centered, less than 1 mm thick on default settings (timebase 5 mm/s and scale x1), smooth sine wave trace without spikes or noise
- Change bands if signal is noisy.
  - If signal amplitude is too small, unclip band and shorten strap.
  - If signal amplitude is too large, unclip band and lengthen strap.
- Channel 14 - Abdomen Res: The same as Channel 13 (Thoracic Res).
6. Complete Signal Verifications Form.
  7. After Channel 14, press [Ok]. This returns the recorder to the Main Menu.

### 6.10. Final Sensor Equipment Check

Now that you have ascertained that all sensors have been properly applied, you will need to check that everything is secured (both to guarantee that leads won't be lost during the night as well as to maximize the participant's comfort and mobility).

1. Make sure that all lead wires on the face and scalp point down and back towards the back of the neck. Wires from the face and scalp should be pulled away from the face and draped to back of subject's head, with enough lag to prevent them from being pulled out but not so much as to restrict head movement. (Check by having subject move head back and forth and ascertaining that sufficient freedom of movement exists).
2. Secure wires through the loop at the shoulder of the vest and tuck excess wires in the pouch with PIB.
3. The recorder is preset to Auto Record. The start and stop times are listed on the third line of the Main Menu. Check with participant for his bedtime and waketime and adjust preset autorecording time if necessary. To adjust Auto Record press [Down] to arrow cursor to RECORDING. Press [Ok]. From here start and end times can be adjusted. Pressing RESET enters the default times of 10PM-8AM.

**Note:** When performing two or more hookups on the same night in the same home do not set identical start times. Each monitor should have a unique time (different from other monitors).

4. Instruct the participant to activate the light sensor immediately before going to bed. This is done by deliberately exposing the sensor to light, then completely covering the sensor from light.
5. Re-check oximetry signal (see appropriate section) to verify the probe still giving the same reading as during initial hook-up. Check that the respiratory bands and thermistor are still secure and in place.
6. Leave main unit on.

### 6.11. Leaving the Home

If it is early in the evening, or the subject wishes to remove the thermistor before bed, instruct him carefully on its reapplication at bedtime, providing him with a written reminder to reposition it at bedtime. (Try to discourage this, offering him a straw to use for drinking).

Carefully check that the subject understands all aspects of the study, knows how to move about with the recording unit and/or connect/disconnect it for bathroom trips. Review written materials (containing these instructions). Walk around the participant's living area. Be sure that he/she feels comfortable moving about with the equipment.

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### 6.11. Leaving the Home

Discuss any potential problems with any interested family members who can be enlisted to help with any sensor adjustments that may be needed.

Provide the subject with the telephone number of an on-call technician who could answer any questions should they arise.

Confirm the time of the morning pick-up. **Ascertain the participant's preference for removal of electrodes and sensors: self-removal or by a study technician. If the former is chosen, be sure to clearly instruct the participant on all aspects of sensor removal. Stress that all sensors should held by their ends and not their wires. Ask the participant not to discard anything, but to pack all equipment and accessories in the carrying case.**

Clean up, leaving the area as neat as it was before your visit. Take any rubbish with you.

**If you will not be picking up equipment in the morning, provide the participant with the name(s) and description(s) of the personnel assigned to this task.**

*Tip: If a male participant reports the need to make frequent trips to the bathroom, consider providing a hand held urinal for bedside use.*

### 6.12. Morning Pickup

Be prompt and courteous! Many participants have a busy morning schedule and will become distressed if you are delayed. They have the option of removing the equipment prior to the technician's arrival.

At the morning visit:

1. Inquire about any problems or questions that might have arisen. If the participant expresses concern that a sensor fell off, reassure him that there is still a good likelihood that the study will be interpretable.
2. To remove electrodes, use a wet gauze pad and soap, lightly rubbing until the electrode is released. Work quickly. Do not use the participant's time to disconnect electrodes or sensors from their wires or cables - that is better done in the clinic.
3. Check to see that all equipment and accessories (the Main Unit, vest with headbox, cables, and sensors) are all present and packed.
4. Check that all paperwork has been completed.
5. Provide the participant with a letter that will detail when results should be sent out.

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**6.12. Morning Pickup**

6. Clean up.
  7. Thank them for their time and participation.
  8. Indicate to participant, study coordinator will make a follow up telephone call inquiring about the visit or leave feedback postcard.
-

## 7. Field Site Data Management

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### 7.1. General

All electrocardiograms taken during a SHHS data collection visit will be reviewed by a site-specific physician reviewer and by the ECG Reading Center in New York for ascertainment of any alert conditions.

### 7.2. ECG

#### 7.2.1. Transmission of ECG to Central ECG Reading Center

The morning after the home visit, an ECG recorded at home should be electronically transmitted to the ECG Reading Center by modem. See the section 3.4.1.6 on “Configuring the Communication Menu”.

To Transmit ECGs to the Central ECG Reading Center:

- Plug the small end of the modem cable into the MAC<sup>®</sup> 1200 ECG machine on the upper right side. Plug the large end of the modem cable into the MultiTech 19.32 modem on the back side. Plug the round end of the modem power cord into the back of the modem and plug the other end into a wall outlet. Connect the telephone cord into the back of the modem in the slot marked “line” and connect the other end of the telephone cord into the jack of an incoming phone line. Turn the modem switch to “on”.
- Press the double-triangle key and the store/retrieve key. The stored ECGs appear. To transmit all stored ECGs, highlight “send” underneath “All stored ECGs”. Press return ( ). To transmit individual ECGs, highlight “send” underneath the selected ECG. Press return ( ).
- A box appears with the transmission telephone number. Press return ( ) to begin transmission. Transmission will take several minutes for each ECG sent. During transmission, a message appears listing how many ECGs have currently been sent. After transmission, a message appears listing the total amount of ECGs sent. Press Start/Stop to return to the 12 Lead ECG tracing screen. Do **NOT** delete the transmitted ECGs from memory until after receipt of confirmation from the ECG Reading Center that all ECGs were successfully transmitted and archived.

7.2. ECG

7.2.1. Transmission of ECG to Central ECG Reading Center

- After confirmation of receipt, the transmitted ECGs should be deleted from memory. Press the double-triangle key and the store/retrieve key. The stored ECGs appear. To delete all stored ECGs, highlight “delete” underneath “All stored ECGs”. Press return ( ). To delete individual ECGs, highlight “delete” underneath the selected ECG. Press return ( ). Press Start/Stop to return to the 12 Lead ECG tracing screen.

7.2.2. Transmission of ECG to Field Site Physician

The Field Site coordinator should fax or carry the EP form and a hard copy of the ECG to the Local Physician Reviewer the morning after the ECG.

7.2.3. Completion of Electrocardiogram Transmission form (ET)

The Field Site coordinator should complete form ET (Electrocardiogram Transmission) to document the transmission of the ECG to:

- ECG Reading Center
- Local Physician Reviewer

7.2.4. Physician Reviewer completion of Electrocardiogram Physician Review form (EP)

Physician reviewers at each site will complete the EP form to provide the necessary information on alerts and interpretive comments. A completed EP form should be faxed back to the Field Site within 24 hours.

7.2.5. Upon Receipt of completed EC form from Physician Reviewer

After receiving the EP form from the physician reviewer, the Field Site coordinator should complete form EC (Electrocardiogram). Completion of this form requires abstraction of information from both the MAC<sup>®</sup> 1200 paper output and any alert information from the Field Site physician reviewer. If any alerts are noted, follow the local Field Site protocol for notifying participants and their physicians.

Key the EC form to the data system as soon as the EP form from the physician reviewer has been obtained and abstracted to the EC form.

### 7.2.6. After Receipt of the ECG Reading Center Report

Information provided by the central ECG Reading Center should be added to the ECG Reading Center results sections of the EC form when the ECG Reading Center report is received. If any alert conditions are noted by the Reading Center that were not noted by the local physician reviewer, these additional alerts should be referred to the local physician reviewer. Under the advisement of the local physician reviewer, follow local field site protocol for notification of participants and physicians. Document notification actions taken on the EC form.

Key the additional information into the data system by re-opening the EC form and entering those items.

### 7.3. Sleep Data Retrieval

#### 7.3.1. General

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

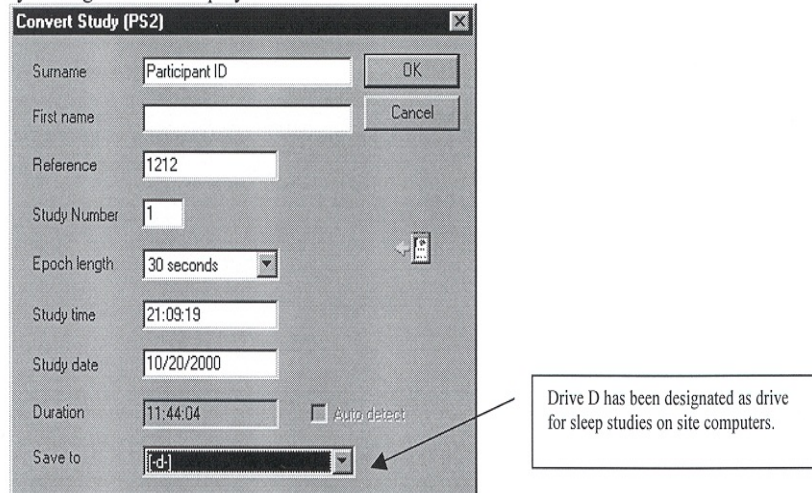
#### 7.3.2. Downloading Study from Memory Card to Hard Drive -- using Compumedics Portable Manager Program

Be sure that the Main Unit power is turned "OFF" before removing the memory card from the Compumedics monitor. All studies should be reviewed and determined to be of acceptable quality prior to a monitor being released to go back into the field to collect additional data.

1. Insert memory card into PCMCIA slot. Card reader should beep and the drive light flash on when the card is inserted.
2. Open Compumedics Portable Manager program
3. Click on "Download Study from Memory Card" button

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

The Convert Study Dialogue Box is displayed:



**Verify that the Participant ID is correct** and that it agrees with the data on the Signal Verifications Form.

***If the SV Form (page 4) had a note indicating that the ID as recorded was incorrect it can be corrected NOW. Click on field containing the incorrect ID and type in the CORRECT ID. This process does NOT CHANGE the ID on the memory card and if you download the study again you will need to change the ID again.***

***IF THE ID WAS INCORRECT AND YOU CHANGED IT AT THE TIME OF DOWNLOADING NOTE THE CHANGE MADE ON THE SLEEP STUDY EVALUATION FORM.***

Verify the “Save to:” field has the correct drive letter designated for sleep studies. Click “OK” Message “Converting in process” displayed.

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

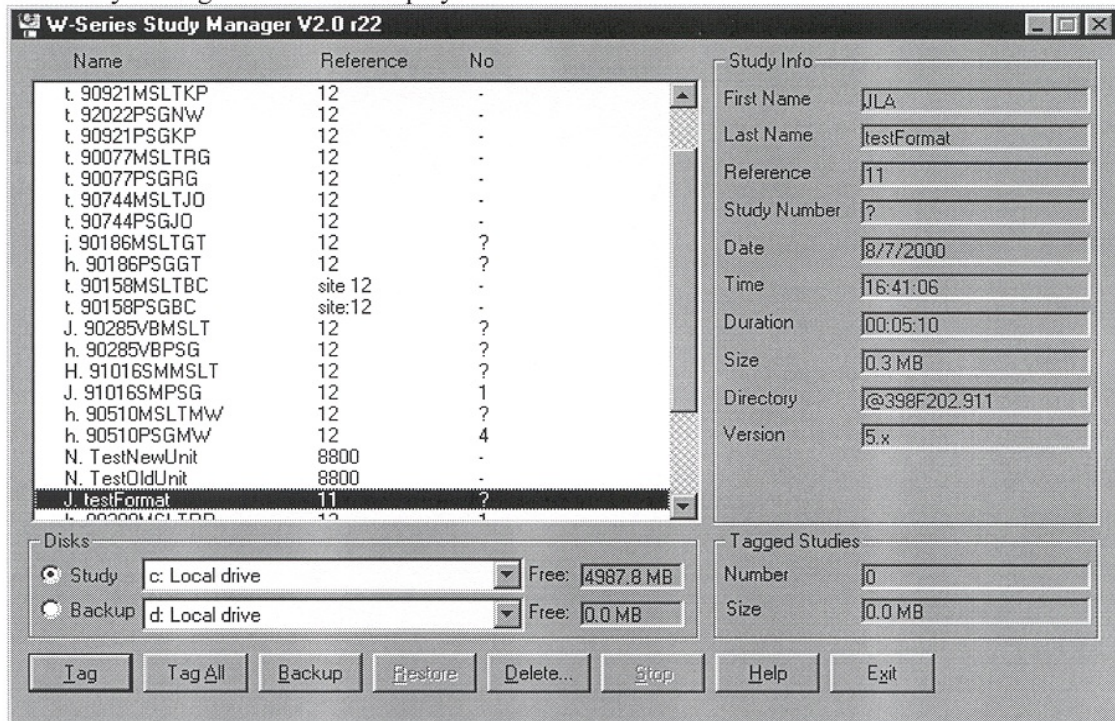


**7.3.3. Backup Study to Zip Cartridges using Compumedics Study Manager Software**

The Zip Cartridge drive on the site computer can use either 100 or 250 megabyte Zip cartridges. The 100 megabyte cartridges can store approximately 3 sleep studies, and the 250 megabyte cartridges can store up to 7 sleep studies. In order to prevent accidental data loss, all studies should be copied on two different magnetic cartridges immediately after the download and review (SE) process is complete. Each cartridge should be labeled with the Site ID, a sequential number indicating whether it is the 1st, 2nd, 3rd disk sent to the Sleep Reading Center, followed by a code indicating whether it is an A (active) disk to be transferred to the Sleep Reading Center, or a B (back-up) cartridge for local filing (for example, 11-001A, 11-001B). The sequential numbering will assist in identifying missing cartridges that may not have been sent or received. Zip Cartridges sent to the Sleep Reading Center will be returned on a monthly basis for re-use.

Open the *Compumedics Study Manager* software to create Zip cartridges A and B. The Study Manager Window is displayed:

The Study Manager Window is displayed:



7.3. Sleep Data Retrieval

7.3.3. Backup Study to Zip Cartridges

Insert Cartridge A in the Zip drive. If a single study is to be backed up, it does not need to be tagged, however the highlight must be over that study. If you are backing up more than one study then use the Tag button to tag several studies. Check the Backup drive letter displayed is the drive letter for your Zip cartridge drive. Select "Backup" button. The study or studies selected are copied to the Zip cartridge. Remove Cartridge A, replace with Cartridge B and repeat procedure.

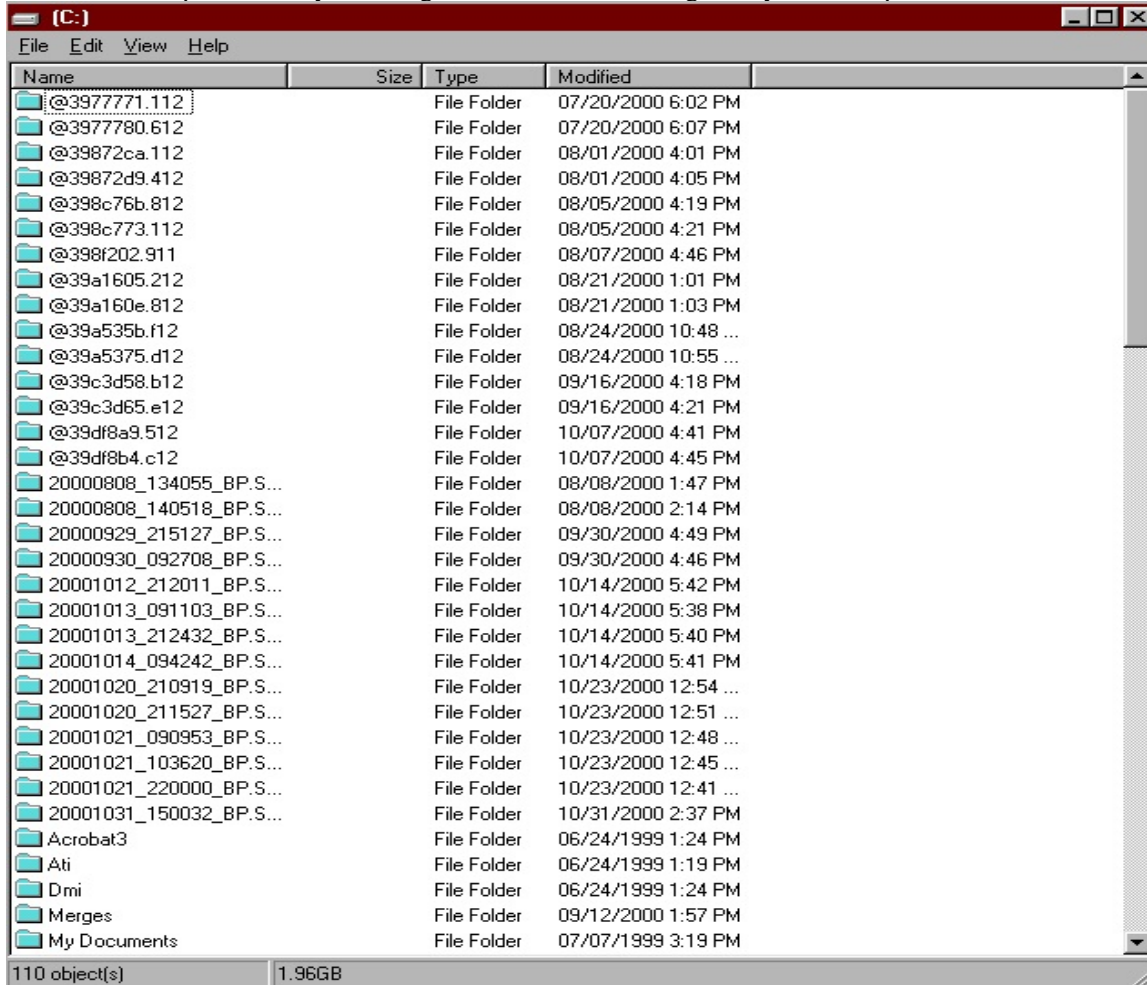
If you view the directory of the Zip cartridge or the D:\ directory where the studies are stored using Windows "Find" or "My Computer," you will notice that the Compumedics software creates a directory for the sleep study based on the date the study was recorded followed by the time the study began:

"20001010\_211527"  
Study done 10/10/2000 Recording began 9:15 P.M.

7.3. Sleep Data Retrieval

7.3.3. Backup Study to Zip Cartridges

Below is a sample directory showing the folder names assigned by the Compumedics software.



These file folders contain the multiple files generated by the Compumedics system when it records the sleep study. If you use the Study Manager Software to view studies on the Zip cartridge and the hard drive, it will display the Participant IDs.

**7.3.4. Review Downloaded Study - Sleep Study Evaluation (SE Form)**

The Sleep Study Evaluation Form is used to determine if the quality of the study is sufficient to be sent to the Sleep Reading Center for scoring. It also gives the technician an opportunity to review the signal quality and determine if equipment needs to be checked or a hookup technique needs to be

**7.3. Sleep Data Retrieval**

**7.3.4. Review Downloaded Study - Sleep Study Evaluation (SE Form)**

reviewed and modified. Loss of oximetry signal, for example, may be the result of a damaged cable that needs to be replaced or an application issue that needs to be addressed. Poor signal quality ("No" answers to questions 3 through 6) must be investigated and resolved prior to the unit being used for another sleep study.

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

If after review it is determined that the data file will not be sent to the Sleep Reading Center it should be removed from the Zip cartridges.

**7.3.5. Using the Compumedics Replay Software to View Signal Quality**

1. Open Compumedics Replay Software
2. Select Study/Open. Make sure that correct drive is selected (D: for studies on hard drive, E: for studies on Zip disks)
3. Double-click on study to open or click on study and "OK" button.

The signals will be displayed in the study template order (i.e. the Polygraph tab used when SHHSV3.MON file was set up). Signals will be displayed with a 30 second timebase.

It is recommended to view signals on a split screen with the top part displayed in 30 second pages for EOG(L), EOG®, EEG, EEG(sec), EMG, ECG, PR and the bottom screen displayed as a 5 minute page for Airflow, Thoracic, Abdomen, SaO2, Position, and Light.

**Epoch by Epoch review**

Use the PgUp and PgDn keys to move backward and forward through the study. If study is reviewed on the split screen pressing these keys will advance 30 seconds if the top window is active or 5 minutes if the bottom window is active.

**Thirty Minute Interval Review**

Use Ctrl + G or click on the icon on the tool bar with two arrows pointing right. A dialog box will appear, prompting you for an epoch number. Type "60". Each time you call this function, add 60 to the previous number (view epochs 60, 120, 180...).

7.3. Sleep Data Retrieval

7.3.5. Using the Compumedics Replay Software to View Signal Quality

**View Oximetry Summary Graph.**

From the View menu select "SaO2/TcCO2 overview." The graph that appears represents oximetry thru the whole study and can be used to evaluate and complete Sleep Study Evaluation Form noting whether there were at least 4 hours of oximetry data.

For each technician it is recommended the initial 10 studies reviewed be scanned epoch by epoch. After this, you can use the "Jump to" key to review every 60 epochs (or every half hour of the study).

When the review is completed, Exit the Compumedics Replay Program.

**7.3.6. Transfer of Data to Sleep Reading Center**

Data should be sent to the Sleep Reading Center on a weekly basis. This will enable the Sleep Reading Center to evaluate the signal quality and equipment functioning in a timely manner. It is recommended that each Field Site advise the SRC which day they plan to send studies and always mail on that day. If a Field Center is not going to mail on their regularly scheduled day, they will inform the SRC and indicate when the next mailing will be done.

The site will keep a Sleep Study Review and Transfer log of each study downloaded. A copy of this log will be sent to the SRC with the "A" zip cartridges containing the sleep studies. The cartridges should be sent by overnight mail in a padded envelope to:

Susan Surovec  
Sleep Heart Health Study  
The Triangle Building  
11400 Euclid Avenue - Suite 260  
Cleveland, Ohio 44106-6003.

A copy of the Signal Verification Form and Sleep Evaluation Form for each study downloaded and reviewed should be included.

7.3. Sleep Data Retrieval

7.3.7. Sleep Study Review and Transfer Log

When sending Zip cartridges to the RC include a transmittal sheet showing what studies are being sent. Due to variations in the setup at individual sites and development of specialized tracking mechanisms already in place, it is not necessary to follow a specific format. However, the following items MUST be included on the log sheet sent with the zip cartridges to the Sleep Reading Center:

**Study ID, Alpha Code, Tech ID, Monitor/PIB ID,  
PSG Study Date  
Zip Disk # .**

All studies that have been downloaded and reviewed should be listed on the Sleep Study Review and Transfer Log Sheet.

7.4. Medications

See Data System Manual

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## 8. Medical Alerts and Participant Feedback

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### 8.1. Medical Alerts and Adverse Events

#### 8.1.1. Background and Rationale

Certain findings made at the time of the home visit, or during local or central reading of the ECG, or during analysis of the PSG, may require medical intervention. Although the PSG, ECG, and blood pressure measurements, performed as part of the SHHS are not considered diagnostic studies, the SHHS investigators have an obligation to refer special cases to their local source of medical care. Therefore, a referral system has been established that is based on the urgency of the finding - either IMMEDIATE (prior to the technician leaving the participant's home), or URGENT (within 10 days).

#### 8.1.2. Documentation of alerts and adverse events

An "Alerts and Adverse Events" form (AE) is to be completed for **all participants at the home visit, regardless of whether or not an alert condition value or adverse event takes place.** Additionally, for every instance in which an alert condition value or an adverse event occurs, the "Alerts and Adverse Events Action" form (AA) is to be completed, in order to document what, if any, action was taken. Alert conditions to be recorded on the AE form will be those determined by the blood pressure measurement and those determined at the time of PSG hook-up. Three other study forms, also, will be used to document the occurrence of alert conditions and actions taken if the alerts arise as a result of the ECG reading, or as a result of the central PSG reading. The EP form (ECG Physician Review) and the EC form (Electrocardiogram) are used to document results, alerts, and actions arising from the ECG (by the physician-reviewer at the Field Site, and by the central ECG Reading Center, respectively). The SS (Sleep Study Status) form is used to document alerts found by the central Sleep Reading Center, and actions taken at the Field Site upon receipt of the Sleep Reading Center report.

#### 8.1.3. PSG determined values

The SHHS approach minimizes the use of specific threshold levels of apneic activity (e.g., AHI > 15%) to judge "severity" or to trigger a recommendation for physician follow-up. Avoid the words "abnormal" or "normal" in these community volunteers. Emphasize that, other than at the high extreme, a given AHI, by itself, should not be used to grade abnormality. Rather, participants should be told that, if symptomatic, they should consider further medical evaluation (regardless of level of apnea).

There are levels of apneic activity/hypoxemia so high that the likelihood of health risks/functional impairment may be substantial. SHHS elected an AHI level of  $\geq 50$  and level of hypoxemic stress, defined as the time in desaturation ( $< 75\%$  sat.) for  $> 10\%$  sleep time, as levels that merited individual physician/investigator review (within 10 days of the sleep study), with tailoring of

8.1. Medical Alerts and Adverse Events

8.1.3. PSG determined values

specific feedback to participants, and to the physicians caring for these participants. Very low heart rates (<30 BPM for > 2 minutes) or very high heart rates (150 BPM > 2 minutes) should trigger a review of the participant's record, with consideration of notifying the participant that a finding was noted that may require medical intervention.

8.1.4. Blood Pressure

The blood pressure immediate alert values are lower than those used at the SHHS Baseline visit. (Baseline values were 200 systolic or 120 diastolic.) In the interim, the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure published its sixth report (see Home Visit Procedures chapter), and established that a systolic pressure of 180 or a diastolic pressure of 110 requires either immediate referral, or referral within one week, depending upon the clinical situation. Therefore, these values will be handled as immediate alert values (regardless of whether the participant is or is not taking anti-hypertensive medications). Values falling in the range of 171-179 systolic or 101-109 diastolic will be treated as urgent alert values.

8.1.5. AAI

The Ankle Arm Blood Pressure Index will not be used to generate medical alerts.

8.1.6. ECG

The ECG will be read by a local Field Site physician reviewer within 48 hours of the measurement, preferably the next morning. The parent study protocol may dictate different alert conditions than the SHHS guideline alerts and abnormalities. If so, the local Field Site protocol may be followed. Also, the local Field Site protocol regarding actions should be used to determine the actions to be taken when alert conditions occur. The SHHS guideline alerts (see also EC form) are the following:

Alert condition values:

- Heart rate <45 or >120 beats per minute
- Ventricular tachycardia
- Acute myocardial infarction
- Complete AV block
- Second degree AV block



Abnormalities that are require notification:

- Any finding which includes a reference to ischemia or pericarditis
- Wolff-Parkinson-White (WPW) or ventricular pre-excitation pattern
- Left bundle branch block
- Prolonged QT interval
- Atrial fibrillation or flutter
- RBBB + LAH (Bifascicular block)
- Frequent/Multifocal PVC's

## 8.2. Referrals

While findings that fall into a SHHS alert category require *documentation* as SHHS alerts at every field site, the SHHS *referral protocol* (sections 8.2.1, 8.2.2) is followed by all field sites except for the three Strong Heart Study field sites. The referral protocol for Strong Heart Study sites is outlined in section 8.2.3)

### 8.2.1. Immediate Referrals

Immediate referrals are potential medical emergencies which may require immediate notification of both the participant and his/her primary physician or other available health care provider. These are findings made at the time of the home visit, or PSG study setup in the participant's home. Because the technicians performing the physical measurements and PSG setup are neither trained nor licensed to perform clinical diagnostic assessments, all findings requiring immediate referral will be referred by the technician to a physician-investigator of the SHHS. This physician, based on information obtained from the technician and/or the participant, will determine whether immediate referral is indicated. Participants receiving immediate referrals are those who would be advised to go directly from home to their physician or to a hospital.

Notification of the participant should be performed by the SHHS physician-investigator and should occur prior to the technician's departure from the home. Notification of the participant's physician, or other available health care provider (such as a hospital Emergency Department physician), will occur as deemed necessary by the SHHS physician-investigator. A follow-up letter documenting the information discussed by telephone may also be sent to the participant's physician.

8.2. Referrals

8.2.1. Immediate Referrals

Findings requiring immediate referral at the time of the home visit/PSG setup are as follows, unless the parent cohort specifies different criteria (see “local” manuals and see section 8.2.3 for Strong Heart sites referral procedures):

- Blood pressure (awake, seated) (on EITHER the second or third reading):  
systolic blood pressure  $\geq$  180 mm Hg  
OR  
diastolic blood pressure  $\geq$  110 mm Hg
- Oximetry (awake):  
oxygen saturation  $<$  80% for longer than 2 minutes while at rest
- Heart rate (awake):  
> 150 beats/minute for longer than 2 minutes at rest  
< 30 beats/minute for longer than 2 minutes at rest

8.2.2. Urgent Referrals

Urgent referrals are related to abnormalities detected at the time of home visit/PSG hook-up or on review of the ECG or PSG which require medical attention but not on an emergency basis. Notification of the participant and his/her physician should be sent by mail within 10 days.

Findings requiring urgent notification are as follows, unless the parent cohort specifies different criteria (see “local” manuals and see section 8.2.3 for Strong Heart sites referral procedures):

- Blood pressure (awake, seated) (on EITHER the second or third reading):  
systolic blood pressure 171 through 179 mm Hg  
OR  
diastolic blood pressure 101 through 109 mm Hg
- Oximetry (awake):  
baseline awake oxygen saturation  $<$ 85% (but  $>$  80%)
- Oximetry (during sleep):  
oxygen saturation  $<$  75% for  $>$ 10% of total sleep time
- Apnea-hypopnea index (during sleep):  
AHI  $\geq$  50 events/hr

8.2. Referrals

8.2.2. Urgent Referrals

- Heart rate (during sleep):
  - > 150 beats/minute for longer than 2 minutes
  - < 30 beats/minute for longer than 2 minutes

8.2.3. Strong Heart Study (SHS) Sites Referrals

An immediate alert is noted if systolic blood pressure is  $\geq 180$  mmHg or diastolic blood pressure is  $\geq 110$  mmHg. According to SHS protocol, the participant is immediately escorted to a physician or an emergency squad or ambulance is summoned if the systolic pressure is  $\geq 260$  mmHg or if the diastolic pressure is  $\geq 130$  mmHg.

Consistent with SHHS protocol, an immediate alert is noted if the participant's heart rate is  $>150$  beats/minute for  $>2$  minutes at rest, or if the heart rate is  $<30$  for  $>2$  minutes at rest. In this event, the participant is escorted to a physician, or an emergency squad or ambulance is summoned.

Consistent with SHHS protocol, an immediate alert is also noted if the participant's oxygen saturation is  $<80\%$  for 2 minutes at hook-up. In this event, the participant is escorted to a physician, or an emergency squad or ambulance is summoned.

Consistent with SHHS protocol, an urgent alert is noted if systolic blood pressure is 170-179 mmHg or if diastolic blood pressure is 100-109 mmHg. According to SHS protocol, the participant is told to consult with his or her physician within one month or at the first convenient appointment to confirm the reading and determine appropriate action.

Consistent with SHHS protocol, an urgent alert is noted if the participant's oxygen saturation is 80-85% at hook up. If this is noted, both the participant and his/her physician are notified by mail within 10 days.

8.2.4. Immediate Referrals Methods

These measurements have been initiated as a result of a research initiative (to which the participant consented, but which s/he did not initiate because of specific health concerns). Studies will be performed in free living members of their community. Thus, the occurrences of true medical emergencies are likely to be rare. It is of great importance that if an abnormality during PSG hook-up is detected, the technician first ascertain whether the abnormal signal was an artifact from faulty sensor placement or faulty equipment. Only after this is ascertained (see instructions for channel 2, oximetry), is s/he to contact a SHHS investigator. The participant should be calmly informed that a finding was made during hook-up or blood pressure measurements that required him/her to discuss a possible problem with his/her supervisor. Technicians are not authorized to provide any medical advice; instead they need to encourage participants to speak with their own physicians about any such issues raised.

8.2. Referrals

8.2.4. Immediate Referrals Methods

The SHHS investigator, upon receiving a call regarding a possible immediate referral, may ask to speak with the participant (over the telephone) to assess other medical conditions, place of routine care, etc. that will help in determining the level of acuity and form of specific evaluation (emergency room, doctor's office, etc.). The SHHS investigator should use his/her clinical judgment to determine how to proceed at this point. Possible responses are: advising the participant to go directly to the nearest emergency room; immediately telephoning the participant's physician; advising the participant to contact his/her physician within the next several days; or taking no action based on the investigator's judgment that the condition is already known to the participant and his/her physician. The investigator will complete an Emergency Contact Form (EM), documenting the time/date of contact, the problem identified, and the action taken or recommended to the participant. This form should be returned to the Field Site within 24 hours.

The Field Site coordinator will transfer information from the completed Emergency Contact Form onto the Alerts and Adverse Events Action (AA) form. Within 48 hours of the referral, the coordinator also will contact the participant by telephone and ascertain what follow-up was taken and document this in the "Other action taken" items of the AA form. Both the AE and AA forms should be keyed into the data system. If these forms require update for later emerging Urgent Referral conditions, the form may be updated and edited in the data system at that later date.

8.2.5. Urgent Referrals Methods

Urgent Referrals Initiated by the Technician (based on findings at the home visit/ or during PSG hook-up)

Within 48 hours of the home visit, the Study Coordinator will identify any values noted on the data collection forms that met criteria for Urgent Referral. After confirming these values with the home technician, s/he will complete an Urgent Referral Form (UR). This will be reviewed with a SHHS investigator.

Within 10 days of the home visit, letters (see Physician's Optional Urgent Referral, Participant's Optional Urgent Referral letters on pages 135 and 136) will be sent to the participant and his/her physician, if the participant has requested it. Note that approval needs to be obtained from a SHHS investigator or polysomnologist for urgent referrals stemming from ECG's or oxygen saturation.

Urgent Referrals Initiated by the Sleep Reading Center

Within 10 days after the sleep study, the record will be reviewed at the Sleep Reading Center. The SRC Chief Polysomnologist will identify any records meeting the heart rate, oximetry or AHI criteria indicated above for Urgent Referrals. S/he will review the findings with the Director of the SRC (or her designee). The SRC then will fax a report to the Field Site coordinator. She will complete on Urgent Referral Form (UR), review it with a SHHS investigator, then complete the Sleep

**8.2. Referrals**

**8.2.5. Urgent Referrals Methods**

Study Status form (SS). S/he will key the SS form into the data system. The SS form documents the presence of Sleep Alerts and provides a means of documenting actions taken for PSG-dependent alerts not discovered at the time of PSG hook-up.

Within 10 days of the home visit, letters (see Physician's Optional Urgent Referral, Participant's Optional Urgent Referral letters) will be sent to the participant and his/her physician, if the participant has requested it. The Physician's Optional Urgent Referral Letter, and Participant's Optional Urgent Referral Letter follow this section. Note that approval needs to be obtained from the Director of the SRC or designee for urgent referrals stemming from PSG's. Forms are in the Forms Manual.

**PARTICIPANT'S OPTIONAL URGENT REFERRAL LETTER**

[Date]

[Participant's Name]

[Participant's Address]

Dear [Participant's Name]:

Thank you for agreeing to participate in the Sleep Heart Health Study [and to have had a recording of your sleep at night]. We have recently reviewed some of the results of your visit and have noted the following finding[s] which we believe you should discuss with your physician in the near future.

[The following should be deleted or included as required]:

Your blood pressure was [Systolic Pressure/Diastolic Pressure] which is elevated.

Your electrocardiogram findings are as follows: [ECG findings and comment].

The oxygen level in your blood while awake was [oxygen saturation]. This lower than normal.

The oxygen level in your blood while asleep was <75% for [% total sleep time spent with saturation less than 75%] of the time they were asleep. This is lower than normal.

You had more than 50 breathing pauses per hour of sleep. The number is much greater than normal.

You had episodes where your heart beat was faster than 150 beats/minute for longer than 2 minutes. This does not occur in most people.

You had episodes where your heart beat was slower than 30 beats/minute for longer than 2 minutes. This does not occur in most people.

These findings have been sent to your personal physician if you previously have requested us to forward study results to [him/her]. If you wish your study results sent to your personal physician, but you have changed your personal physician or have not identified one to us, please contact us so we may send these findings to [him/her].

If you have difficulty finding a personal physician, your local medical society may be of assistance.

If you require additional information or you wish to discuss these findings further, please do not hesitate to call Dr. [Investigator's Name] at [Investigator's Phone Number]. Thank you again for your participation in the Sleep Heart Health Study.

Sincerely yours,

[Investigator Name/Names]

[Investigator Titles]

8.2. Referrals

8.2.5. Urgent Referrals Methods

**PHYSICIAN'S OPTIONAL URGENT REFERRAL LETTER**

[Date]

[Physician's Name]  
[Physician's Address]

Re: [Participant's Name]

Dear Dr. [Physician's Name]:

Your patient, [Participant's Name], is a participant in the Sleep Heart Health Study at [Field Center Name]. Sponsored by the National Heart, Lung and Blood Institute and the National Sleep Center, the purpose of this study is to determine the cardiovascular consequences of sleep apnea. As part of this study, participants may undergo an ambulatory polysomnogram (PSG) in their homes. Your patient, [Mr./Mrs./Ms] [Participant's Last Name], had a [PSG, ECG, and measurement of their blood pressure] performed on [Date(s)]. An analysis of these data has revealed the following finding[s] which may require your further evaluation.

[The following should be deleted or included as required]

[Mr./Mrs./Ms] [Participant's Name] blood pressure was [Systolic Pressure/Diastolic Pressure].

[Mr./Mrs./Ms.] [Participant's Name] ECG findings were as follows: [ECG findings].

[Mr./Mrs./Ms.] [Participant's Name] oxygen saturation while awake was [oxygen saturation].

[Mr./Mrs./Ms.] [Participant's Name] oxygen saturation while asleep was <75% for [% total sleep time spent with saturation less than 75%] of the time they were asleep.

[Mr./Mrs./Ms.] [Participant's Name] had more than 50 apneas or hypopneas per hour of sleep.

[Mr./Mrs./Ms.] [Participant's Name] had episodes of tachycardia exceeding 150 beats/minute for longer than 2 minutes.

[Mr./Mrs./Ms.] [Participant's Name] had episodes of bradycardia less than 30 beats/minute for longer than 2 minutes.

[Mr./Mrs./Ms.] [Participant's Name] has been sent a letter notifying [him/her] of these findings.

[He/She] may be contacting you to discuss them. However, these results were obtained as part of a research protocol and should be interpreted in the context of your patient's current clinical symptoms and condition. If you require additional information or you wish to discuss these results further, please do not hesitate to call Dr. [Investigator's Name] at [Investigator's Phone Number].

[I/We] appreciate the opportunity to have your patient [Mr./Mrs./Ms] [Participant's Name] participate in the Sleep Heart Health Study.

Sincerely yours,

[Investigator Name/Names]  
[Investigator Titles]

### 8.2.6. Reports to the Participants

Participants will receive a Participant SHHS Study Summary, which will include PSG results. At the request of the participant, their physician may receive a copy of the report. These summaries will include total sleep time, time spent dreaming (REM), sleep efficiency, Apnea-Hypopnea Index (AHI), average heart rate, and oxygen profile. Those summaries with  $AHI \geq 50$  will include additional heart rate and oxygen profile data. In the cover letters, the tertiles of the preliminary RDI distribution at 3% desaturation, from SHHS 1 will be provided. This will give the participant information to which s/he may relate his/her individual score. The cover letters will differ for those participants whose PSG results generated a medical alert ( $AHI \geq 50$ ).

If not previously reported, the participant's Right and Left Ankle Arm Indexes (AAI) will be reported in the participant letter. These values are automatically calculated by the SHHS data system during data entry. (Instructions for obtaining a printout of calculated Ankle Arm Indexes for this report are detailed in SHHS Manual of Procedures, Volume 5, Data System Manual data entry chapter, 5.4.). Because the date of the observation could have been at any time within the previous 5 years (1,826 days), the date of the observation should be included in the letter. A statement that an Ankle Arm Index ratio of less than 0.9 (90%) may indicate a problem with circulation in the legs will be included. Note: If the AAIs have already been reported to the participant as right and left values (i.e., not as an average value) omit mention of AAI in report.

Additionally, some Field Sites may choose to include blood pressure and weight measurements and ECG findings in the report letters. The decision as to which additional information should be included in report letters at an individual site is made by the Principal Investigator of the site. When making this decision, Principal Investigators should keep in mind that participants may have certain expectations of what will be included in the report letter based on the feedback they receive from a parent study visit.

Sample cover letters to participants and physicians and the Participant Sleep Study Summaries follow:



**PARTICIPANT LETTER AND REPORT FOR NON-PSG HOME VISIT**

Dear [Mr./Mrs./Ms.][Participant's name]

Many thanks for participating in the Sleep Heart Health Study being done in conjunction with the [parent study]. We appreciate the effort, time, and patience you have contributed to this research. The results of your ankle-arm blood pressure measurement is summarized below.

The ankle-arm index (ankle brachial index) is the ratio of the blood pressure at the ankle compared to the arm and is one of the tests used to evaluate the circulation in the legs. A ratio of less than 0.9 (90%) may indicate a problem with circulation in the legs. Your ankle-arm blood pressure index was measured on [date]. Your right ankle-arm blood pressure index was [x%] and your left ankle-arm blood pressure index was [x%].

Please feel free to call me at [telephone number] if you have any questions about this study.

Thank you again for your participation in the Sleep Heart Health Study. The contribution you make to research into the causes of heart disease is enormous.

Sincerely,

[Investigator]

[Investigator titles]

### 8.3. Serious Adverse Events

Serious adverse events are any incidents that occur in the research setting which are life threatening or result in death, disability, or inpatient hospitalization. Adverse events may be unexpected or expected. Unexpected events are of a specificity or severity not consistent with risk information described previously in the protocol, manual of procedures, or consent form. Expected events are of a specificity or severity consistent with previously disclosed risk information. The site principal investigator (or other designee) should be informed immediately after observation or report of unexpected serious adverse events that occur during (or are connected with) a home or clinic SHHS visit. A Serious Adverse Event Report (SR) Form should be completed by the principal investigator or co-investigator within 48 hours of notification and faxed both to the SHHS Coordinating Center and to the project officer at NHLBI. A copy should be retained in the participant's folder.

Serious, unexpected adverse events should also be documented on the AE (Section B, Question 3c.) and AA (Section C, Questions 6-7) forms.

**PARTICIPANT LETTER AND REPORT, FOR RDI < 50**

Dear [Mr./Mrs./Ms.][Participant's name]

Many thanks for participating in the Sleep Heart Health Study being done in conjunction with the [parent study]. We appreciate the effort, time, and patience you have contributed to this research. The results of your ankle-arm blood pressure measurement, and your sleep study are summarized below, and a copy has been sent to your doctor, if you requested that we do so.

The ankle-arm index (ankle brachial index) is the ratio of the blood pressure at the ankle compared to the arm and is one of the tests used to evaluate the circulation in the legs. A ratio of less than 0.9 (90%) may indicate a problem with circulation in the legs. Your ankle-arm blood pressure index was measured on [date]. Your right ankle-arm blood pressure index was [x%] and your left ankle-arm blood pressure index was [x%].

It is common for adults to have a few brief oxygen dips as a result of breathing pauses or shallow breaths. In our study, one third of the participants have fewer than 5.7 of these pauses or shallow breaths per hour, one third between 5.7 and 14.7 per hour, and one third greater than 14.7 per hour. One of the purposes of this research is to determine if a mild or moderate elevation in the number of breathing pauses or shallow breaths has any effect on health.

After you went to bed on [date of PSG study] you slept for a total of [sleep hours] hours and [sleep minutes] minutes. You spent [total REM (in minutes)] minutes in the dream stage of sleep and slept for [sleep efficiency] percent of the time you were in bed. During the night you had [RDI] breathing pauses or episodes of shallow breathing per hour. Your heart rate averaged [average HR] beats per minute.

The sleep study we performed was done for research purposes. Regardless of the results of your sleep study, if you experience unsatisfactory or restless sleep, or are often troubled by daytime sleepiness, you may want to discuss this with your doctor to determine if further evaluation is needed. Please feel free to call me at [telephone number] if you have any questions about this study.

Thank you again for your participation in the Sleep Heart Health Study. The contribution you make to research into the causes of heart disease is enormous.

Sincerely,

[Investigator]

[Investigator titles]

**PARTICIPANT LETTER AND REPORT, FOR RDI  $\geq$  50**

Dear [Mr./Mrs./Ms.][Participant's name]

Many thanks for participating in the Sleep Heart Health Study being done in conjunction with the [parent study]. We appreciate the effort, time, and patience you have contributed to this research. The result of your ankle-arm blood pressure measurement is summarized below. The results of your sleep study are attached, and a copy has been sent to your doctor, if you requested that we do so.

The ankle-arm index (ankle brachial index) is the ratio of the blood pressure at the ankle compared to the arm and is one of the tests used to evaluate the circulation in the legs. A ratio of less than 0.9 (90%) may indicate a problem with circulation in the legs. Your ankle-arm blood pressure index was measured on [date]. Your right ankle-arm blood pressure index was [x%] and your left ankle-arm blood pressure index was [x%].

It is common for adults to have a few brief oxygen dips as a result of breathing pauses or shallow breaths. In our study, at the first sleep study, one third of the participants had fewer than 5.7 of these pauses or shallow breaths per hour, one third between 5.7 and 14.7 per hour, and one third greater than 14.7 per hour. Oxygen levels in the blood are normally greater than 90%. Your study shows greater than 50 shallow breaths or breathing pauses per hour, a level which is markedly elevated and may be associated with side effects.

The sleep study we performed was done for research purposes and does not allow a definite diagnosis to be made. We recommend that you discuss these results with your doctor, who may wish to obtain further evaluation and to determine if treatment is needed. Please feel free to call me at [telephone number] if you have any questions about this study.

Thank you again for your participation in the Sleep Heart Health Study. The contribution you make to research into the causes of heart disease is enormous.

Sincerely,

[Investigator]  
[Investigator titles]

**Template for a report to a participant with RDI  $\geq 50$ . It will be accompanied by an explanatory letter.**

**SLEEP STUDY REPORT - TEST PERFORMED FOR RESEARCH PURPOSES**

Participant name: [full name]

Date of sleep study: [Date]

You slept for [total sleep period (hr:min)] hours during the night of your sleep study, and spent [total REM (in minutes)] minutes in the dream stage of sleep. You slept for [sleep efficiency] percent of the time you were in bed.

Throughout the night you had [RDI] breathing pauses or episodes of shallow breathing per hour. During some of these episodes you oxygen level fell briefly to a low level with a minimum of [minimum SaO<sub>2</sub>] percent. The oxygen level in your blood was below 90% for [SaO<sub>2</sub><90] percent of the time you were asleep and below 75% for [SaO<sub>2</sub><75] percent of the time.

Your heart rate averaged [average HR] beats per minute.

### PHYSICIAN LETTER

Dear Doctor,

Your patient is a participant in a research project called the Sleep heart health study (SHHS) being conducted at the [name of parent study]. The SHHS is sponsored by the National Heart, Lung and Blood Institute and the National Sleep Center, and is designed to determine the cardiovascular consequences of sleep apnea.

Participants undergo an overnight polysomnogram in their homes which includes monitoring of oxygen saturation, respiratory effort, heart rate and sleep stage. A respiratory disturbance index (RDI), the number of apneas or hypopneas per hour of sleep which are associated with a 3% or greater drop in oxygen saturation, is calculated for each participant. In our study, at baseline one third of the participants have an RDI below 5.7, one third between 5.7 and 14.7, and one third greater than 14.7. An RDI of greater than 50 is markedly elevated; however, in the absence of symptoms attributable to sleep apnea, the clinical significance of an elevated RDI, even of this magnitude, is unknown.

A copy of your patient's Sleep Study Summary is attached. This test was performed for research purposes and does not allow a definitive diagnosis to be made. The results should be interpreted in the context of your patient's clinical condition. Please feel free to call me at [telephone number] if you have any questions about this study.

Sincerely,

[Investigator]

[Investigator titles]

**Physician Report, RDI < 50: To be accompanied by generic physician letter**

**Sleep Study Summary – Test performed for research purposes**

Participant name [full name]

Date of sleep study: [Date]

Total Sleep Time: [total sleep period (hr:min)]

Total Time in REM: [total REM (in minutes)] minutes

Sleep Efficiency: Asleep for [sleep efficiency] % of time in bed

Respiratory Disturbance Index

(apneas or hypopneas associated

with  $\geq 3\%$  oxygen desaturation): [RDI] per hour

Average Heart Rate: [average HR] bpm

% Sleep time with oxygen saturation < 90%: [SaO<sub>2</sub><90%]

**Physician Report, RDI  $\geq$ 50: To be accompanied by generic physician letter**

**Sleep Study Summary – Test performed for research purposes**

Participant name: [full name]  
Date of sleep study: [Date]

Total Sleep Time: [total sleep period (hr:min)]  
Total Time in REM: [total REM (in minutes)] minutes  
Sleep Efficiency: Asleep for [sleep efficiency] % of time in bed

Respiratory Disturbance Index  
(apneas or hypopneas associated  
with  $\geq$ 3% oxygen desaturation): [RDI] per hour

Average Heart Rate: [average HR] bpm

% Sleep time with oxygen saturation < 90%: [SaO<sub>2</sub><90%]  
% Sleep time with oxygen saturation < 75%: [SaO<sub>2</sub><75%]  
Minimum SaO<sub>2</sub>: [minimum SaO<sub>2</sub>]%

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## 9. Quality Assurance/Quality Control

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### 9.1. General

In the Sleep Heart Health Study, quality assurance (QA) includes those activities designed to assure data quality that take place prior to data collection. Quality control (QC) includes data quality monitoring efforts that take place at identified points during data collection and processing.

### 9.2. Certification and Training

#### 9.2.1. Overview

One of the SHHS quality assurance strategies is certification of staff to conduct SHHS procedures. Certification of at least one staff member for each of the SHHS procedures is required before a field site may participate in SHHS Follow-up 2. A field site may not begin screening participants, have participant sign any consent statements, conduct home visit procedures, or complete any SHHS forms until the field site has a full complement of certified personnel.

The primary purpose of certification is to help assure consistent conduct of SHHS procedures over time, within and across Field Sites. SHHS specific procedures for data collection may be required, as may specific items of equipment.

Certification is also a managerial tool for the study. It provides a mechanism for tracking who is responsible for the overall conduct of data collection procedures and who is carrying out selected data collection procedures. Certification identifies to the staff member that he/she is a part of SHHS. In addition, certifying staff helps to assure that the staff have acquired a basic level of training in the SHHS protocol. All personnel who request certification must agree to abide by the design tenets of the trial. The process of obtaining certification may help a clinic prepare for SHHS activities by presenting the training, facility, and equipment needs in an organized fashion and requiring acquisition or completion of these items before SHHS Follow-up 2 activities may be started. Procedures requiring certification include:

- Polysomnography
- Ankle Arm Index
- Electrocardiogram
- Blood pressure
- Anthropometry (height, weight, neck girth)
- Site Coordination
- Consenting
- Interviewing
- Data and data system management

9.2. Certification and Training

9.2.1. Overview

To be certified in SHHS, all staff members must:

- Complete a Personnel Certification (PC) form. (NOTE: If a staff member is requesting certification for more than one procedure, all certification materials may be submitted with a single PC form; ie, a separate PC form is not required for each procedure when being submitted at the same time.)
- Read the protocol and participant consent statements
- Fax completed PC form to Coordinating Center. The Certification Coordinator will issue a unique three character Personnel Identification Number (PIN) to be used by the staff member when completing SHHS forms or as otherwise needed.
- Practice the procedures and forms pertaining to the procedure for which certification is being requested
- Complete the number of procedures required for certification and the required paperwork
- Submit the materials to the Certification Coordinator at the Coordinating Center
- Submit PSG materials to the Sleep Reading Center, for PSG certification

The initial training for SHHS Follow-up 2 of key staff was partially completed through training and practice at the SHHS Training Meeting in Cleveland, 6-10 November 2000. Backup personnel and personnel joining the SHHS subsequent to this initial training meeting will be trained by other SHHS certified personnel at the Field Site.

After training is complete, a Personnel Certification (PC) form, and any other documents required for the functions for which certification is requested are to be completed. The Personnel Certification (PC) form, which staff members are required to sign, includes a statement indicating an understanding of the rules by which SHHS is to be conducted.

The forms and supporting documentation submitted for Non-PSG certification are to be sent to:

Certification Coordinator  
SHHS Coordinating Center  
Center for Clinical Trials  
615 North Wolfe Street, Room 5010  
Baltimore, MD 21205

Certification forms and certification PSG studies should be sent to:

Sleep Reading Center  
Attention: Susan Surovec  
UH-Division of Clinical Epi  
11400 Euclid Avenue, Suite 260  
Cleveland, OH 44106

**9.2. Certification and Training**

**9.2.1. Overview**

The materials will be reviewed by the Certification Coordinator and other staff as appropriate. If found to be in order, the Certification Coordinator will issue a memo stating that the certification requirements have been met and that the staff member's participation in SHHS is approved. The memo will also specify a unique three character Personal Identification Number (PIN) to be used by the staff member when completing SHHS forms or as otherwise needed. A staff member may be certified for more than one function, and more than one staff member may be certified for the same function. Each staff member will have a single PIN even if certified for more than one function. It is recommended that at least two staff members be certified for each function so that there is backup in case of illness, during vacations or other absence.

**9.2.2. PSG**

**9.2.2.1. Training Requirements**

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

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

- An overview of Sleep Physiology and Sleep Apnea
- An overview of the Study Protocol
- An overview of Polysomnology
- Detailed training on use of the Compumedics SleepWatch PS, including hands-on activities.
- Detailed training on all aspects of the SHHS protocol specific for performing and processing sleep studies.

**9.2.2.2. Certification Requirements for PSG Studies**

Only SHHS certified personnel may conduct PSG studies on study participants.

PSG personnel that have attended central training will demonstrate requisite knowledge and ability of technical performance with a written and practical examination (requiring a grade of  $\geq 75\%$  to pass). After passing these examinations, personnel will be required to perform a minimum of 5 practice overnight certification PSGs that must be sent to the Sleep Reading Center for review of acceptable quality. The practice PSGs accomplished for certification are evaluated differently (more stringently) than actual participant studies.

PSG personnel trained locally will be required to pass the written and practical examinations

**9.2. Certification and Training**

**9.2.2.2. Certification Requirements for PSG Studies**

administered by a centrally trained certified PSG field technician as well as to perform 5 hook-ups (i.e.: measure, mark and place sensors) under the same supervision. The non-certified technician must, then, perform the minimum 5 practice certification PSGs that are sent to the Reading Center in order to become SHHS certified.

Certified PSG technicians are required to perform a minimum of 4 studies each month. Any technician that fails to meet this performance quota for 2 consecutive months will be required to re-certify. In order to re-certify, the technician must submit 2 practice certification PSGs to the Reading Center.

Certified PSG field technicians are expected to maintain quality scores (assigned by scorers at the reading center) of at least 85% or better. The Director of the Reading Center, after consulting with the PI of the Investigative Center, will determine actions necessary for technicians that fail to maintain quality standards. Such actions may include recertification.

**9.2.2.3. Re-certification Requirements for PSG Studies**

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

**9.2.3. Ankle Arm Index**

**9.2.3.1. Training Requirements**

- Read and study manual
- Attend training session on techniques (or observe administration by experienced examiner)
- Practice on volunteers
- Compare measurements with those made by experienced colleagues (Goal: obtain measurements within  $\pm 2$  mm Hg of that observed by a trainer)
- Discuss problems and questions with local expert

**9.2.3.2. Certification Requirements**

- Complete training requirements
- Recite exclusion criteria
- Conduct exam on two volunteers while being observed by AAI-certified personnel listening with Doppler

9.2. Certification and Training

9.2.3. Ankle Arm Index

9.2.3.2. Certification Requirements

- Perform exam according to protocol
- Three simultaneous readings of systolic measurements recorded by the staff member must agree with those of certified AAI personnel within  $\pm 4$  mm Hg, with the average of the three readings within  $\pm 3$  mm Hg
- Have AAI certified observer complete the Ankle Arm Index Certification Checklist (AC Form)
- Submit PC form, 2 PM forms, and a AAI Certification Checklist to the Certification Coordinator at the SHHS Coordinating Center

9.2.3.3. AAI Quality Assurance Checklist

Right Arm Systolic BP Measurement

- Explains procedure
- Uses cuff size determined during blood pressure measurement, or, if blood pressure has not been taken, determines cuff size using directions in Home Visit Procedures chapter of MoP
- Five minute rest period before measurement
- Turns unit on
- Palpates brachial artery
- Applies ultrasound jelly over brachial artery
- Locates brachial artery using Doppler
- Determines maximal inflation level
- Measures the systolic blood pressure using the Doppler and standard manometer:
- Inflates cuff quickly to maximal inflation level
- Deflates at 2 to 3 mm Hg/second to 10 mm Hg below the appearance of systolic pressure
- Deflates cuff quickly and completely

Ankle Systolic BP Measurement

- Places manometer between participant's ankles

Right and Left Ankles:

- Places blood pressure cuff (appropriate size) on ankle
- Locates posterior tibial artery by palpation
- Applies ultrasound jelly over posterior tibial artery
- Locates posterior artery using Doppler

**9.2. Certification and Training**

**9.2.3. Ankle Arm Index**

**9.2.3.3. AAI Quality Assurance Checklist**

- Measures the systolic blood pressure using the Doppler and standard manometer:
  - Inflates cuff quickly to maximal inflation level
  - Inflates further by 30 mm Hg increments if sounds are still present
  - Deflates at 2 to 3 mm Hg/second to 10 mm Hg below the appearance of systolic pressure
  - Deflates cuff quickly and completely

Repeat of Ankle-Arm Measurements

- Repeats sequence of measures in reverse order of initial sequence, as below:
  - Left ankle
  - Right ankle
  - Right arm

Completion

- Removes cuffs and conducting jelly
- Turns Doppler unit off immediately
- Reviews form for completeness
- Correctly completes “Physical Measurements, Blood Pressure, Ankle-Arm Index, ECG” (PM) form

**9.2.4. Electrocardiogram (ECG)**

**9.2.4.1. Training requirements**

- Read and study manual
- Attend training session on techniques (or observe administration by experienced examiner)
- Practice on volunteers
- Discuss problems and questions with local expert

**9.2.4.2. Certification requirements**

- Complete training requirements
- Conduct examination on 5 volunteers while being observed by an ECG-certified staff member
- Perform exam according to protocol
- Submit a PC form, the 5 ECG recordings, completed EC-forms (including the local physician review portion), and a Electrocardiogram Certification Checklist (EK Form) to the Certification Coordinator at the SHHS Coordinating Center

**9.2. Certification and Training**

**9.2.4. Electrocardiogram (ECG)**

**9.2.4.3. ECG Quality Assurance Checklist**

- Twelve lead resting ECGs conducted
- ECG taken with participant in supine or semi-recumbent position
- Explanation given as to why the ECG is being conducted
- Participant asked to avoid movement
- Checks that participant is comfortable and relaxed
- Limb lead electrode is placed on the right leg, then the left leg, then right arm followed by the left arm
- Proper lead placement identified and marked before lead attached chest electrodes positioned properly

**9.2.5. Blood Pressure**

**9.2.5.1. Training requirements**

- Read and study manual
- Attend training session on techniques (or observe administration by experienced examiner)
- Practice on volunteers
- Discuss problems and questions with local expert

**9.2.5.2. Certification requirements**

- Complete training requirements
- Conduct examination on 2 volunteers while being observed by a BP-certified staff member
- Perform exam according to protocol
- Submit a PC form, 2 BP recordings, completed EC forms (including the label physician review portion), and a Blood Pressure Certification Checklist (BC Form) to the Certification Coordinator at the SHHS Coordinating Center

**9.2.5.3. Blood pressure quality assurance checklist**

- Explains procedures
- Measures for cuff size
- Wraps cuff snugly, centering bladder over brachial artery
- Five minutes rest period before measurements
- Palpates brachial artery
- Determines maximal inflation level

9.2. Certification and Training

9.2.5. Blood Pressure

9.2.5.3. Blood pressure quality assurance checklist

- 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 taken after one minute standing rest period
- Records reading and disconnects tubes
- Reviews form for completeness
- Correctly completes form
- Tells participant BP reading and refers as indicated

9.2.6. Anthropometry (height, weight, neck girth)

9.2.6.1. Training requirements

- Read and study manual
- Attend training session on techniques (or observe administration by experienced examiner)
- Practice on volunteers
- Discuss problems and questions with local expert

9.2.6.2. Certification requirements

- Complete training requirements
- Conduct examination on 2 volunteers while being observed by a SHHS staff member certified in anthropometry
- Perform the procedures according to protocol
- Submit a PC form, 2 PM forms with results of height, weight and neck girth procedures, and a Anthropometry Certification Checklist (NC Form) to the Certification Coordinator at the SHHS Coordinating Center

9.2.6.3. Anthropometry quality assurance checklist

**Weight measurement**

- Conducted per protocol
- Scale positioned at zero
- Participant not wearing shoes
- Participant's weight equally distributed on both feet
- Participant not being physically supported
- Examiner's eyes level with the point of measurement



**9.2. Certification and Training**

**9.2.6. Anthropometry (height, weight, neck girth)**

**9.2.6.3. Anthropometry quality assurance checklist**

**Height measurement**

- Conducted per protocol
- Procedures explained to participant
- Participant not wearing shoes
- Record the highest measurement

**Neck circumference**

- Conducted per protocol
- Participant sitting upright with head in Frankfort Horizontal Plane
- Tape is applied around neck just below laryngeal prominence
- Measurement is made perpendicular to long axis of neck
- Tape is not too loose or too tight, but enough to maintain skin contact
- Measurement is completed in less than 5 seconds
- Measurement is recorded to the nearest 0.5 centimeter, rounding up

**9.2.7. Project Coordination**

The function of the project coordinator is to oversee, organize, and coordinate home visit and data collection activities. The coordinator also is responsible for the overview of all data collection forms for consistency, completeness, and accuracy. In addition, the project coordinator is to be the primary liaison between the field site and the Coordinating Center on SHHS non-PSG issues at that site.

**9.2.7.1. Certification training and requirements**

- Read the protocol, consent statements, and Manual of Field Site Procedures
- Complete the Personnel Certification form and submit to the Certification Coordinator at the SHHS Coordinating Center

**9.2.8. Consenting**

The function of the consentor is to review the study procedures and consent statements with the participant, answer any questions the participant may have about the study, and obtain the participant's signature on the consent statement.

#### 9.2.8.1. Certification training and requirements

- Read the SHHS protocol, consent statements, and Manual of Field Site Procedures
- Practice giving the consents
- Present the consent to 3 people as if you were obtaining consent for SHHS participants
- Provide a written description of the 3 practice sessions including to whom the practice consents were presented (e.g., participant, colleague, relative), what questions or issues arose, and how you responded
- Submit PC form and written description of practice sessions to the Certification Coordinator at the SHHS Coordinating Center

#### 9.2.9. Interviewing

The interviewer is to explain the study interview documents to the participant and conduct the interviews as they are worded in the study documents. In addition, the interviewer must explain study self administered interviews to the participant such that the participants fully understands how to complete the instruments. The interviewer is to review the self administered questionnaires in the presence of the participant to ensure that all data has been collected.

#### 9.2.9.1. Certification training and requirements

- Read the SHHS protocol, consent statements and Forms (MOP, Volume 6)
- Practice giving interviews and explaining self administered interviews
- Interviewer administered questionnaires
  - Health Interview (HI)
- Self Administered questionnaires
  - Morning Survey (MS)
  - Sleep Habits and Lifestyle Questionnaire (SH)
  - Quality of Life Survey (QL)
- Administer the HI and provide instruction for the QL, MS, and SH to 3 practice participants
- Submit the practice questionnaires and a completed Personnel Certification form to the Certification Coordinator at the SHHS Coordinating Center

**9.2.10. Data system operator**

The data system operator is responsible for keying data forms, assisting with quality assurance by bringing form completion problems to the attention of the project coordinator, keying changes to data forms resulting from edits, generation of lists and reports required by the Coordinating Center, transfer of data to the Coordinating Center, and system maintenance as directed by the Coordinating Center.

**9.2.10.1. Certification training**

- Review the protocol and consent statements
- Read the Data System Manual (MOP, Volume 5)
- Read the section of the MOP discussing completion of data forms (MOP Volume 6: Forms)

**9.2.10.2. Certification requirements**

- Complete training requirements
- Complete the data system tutorial
- Submit output from the tutorial along with a completed Personnel Certification form to the Certification Coordinator at the SHHS Coordinating Center

**9.2.11. Integrated home visit certification (pilot studies)**

In addition to the above certification requirements, personnel to be certified to conduct home visit procedures must do two of each procedure for which they are applying for certification as part of a complete home visit (pilot study). A pilot study (complete home visit) is to include:

- Consenting of participant (volunteer)
- Health Interview
- Medications Survey
- Sleep Habits and Lifestyle Questionnaire
- Anthropometry measurements
- Seated blood pressure
- Ankle-Arm Index blood pressure
- ECG
- PSG hook-up
- Retrieval of monitor and forms, and removal of electrodes the next morning

Procedures conducted as part of a pilot study will be counted toward the total number of practice procedures required for certification.

9.2. Certification and Training

9.2.11. Integrated home visit certification

9.2.11.1. Changes in Clinic Personnel Certification

When personnel certified for SHHS functions are no longer employed by the study or when current employees cease performance of certified functions, a Personnel Status Change (PS) Form should be submitted to the Coordinating Center. The field site coordinator (or other study designee) should use the PS form to record 1) the name and PIN# of the employee and 2) the function(s) for which certification no longer desired. The form should be completed and either faxed or mailed to the Coordinating Center within 14 days of the change in certification status.

9.3. Field site supervision

9.3.1. Quality Control Responsibilities of Supervisors

As a part of ongoing SHHS quality control (QC) procedures, the designated QC supervisor is responsible for: 1) Bimonthly observation of blood pressure and anthropometry procedures, 2) Daily inspection of blood pressure equipment, and 3) Monthly inspection of the measuring tape, weight scale, and sphygmomanometer. This section, 9.3.1, outlines required actions and reports. Form samples follow in sections 9.3.2 – 9.3.5 (consult *MOP, Volume 6, Forms* for paper copies).

1. Observation of technicians:

Frequency:	bimonthly for each procedure
Required reports:	Supervisor Form for Simultaneous Blood Pressure Observations Blood Pressure Examination and Anthropometry Check List
Send reports to:	Coordinating Center

2. Maintenance of equipment:

Name of machine/equipment	<b>Blood Pressure Cuffs</b>
Frequency:	daily
Action required:	make sure all sizes of cuffs are available
Required reports:	none
Send reports to:	NA

Name of machine/equipment	<b>Standard Sphygmomanometer</b>
Frequency:	daily (before each use)
Action required:	check for correct zero
Required reports:	none
Send reports to:	NA

9.3. Field site supervision

9.3.1. Quality Control Responsibilities of Supervisors

Frequency:	monthly; more often if problems suspected
Action required:	check tube for oxide dust, check cap for tightness, check that mercury is at zero with no pressure, check inflation system
Required reports: List	Blood Pressure, Weight, and Neck Circumference Check
Send reports to:	Coordinating Center
Name of machine/equipment	<b>Measuring Tape (for cuff size and neck circumference)</b>
Frequency:	monthly
Action required:	check for worn or stretched tape
Required reports: List	Blood Pressure, Weight, and Neck Circumference Check
Send reports to:	Coordinating Center
Name of machine/equipment	<b>Scale</b>
Frequency:	monthly
Action required:	check for accuracy
Required reports: List	Blood Pressure, Weight, and Neck Circumference Check
Send reports to:	Coordinating Center

9.3. Field site supervision

9.3.2. Supervisor Form for Simultaneous Blood Pressure Observations

DATE:    \_\_\_    \_\_\_    \_\_\_  
           mo    day   year

Field Center:

Supervisor:

1st Technician ID#:

2nd Technician ID#:

Every other month each technician should, with a second technician, simultaneously measure blood pressure with a sphygmomanometer using a Y-tube on a volunteer, not a participant. Each technician should separately (and out of the other s view) record his or her measurements on a Technician Form for Simultaneous Blood Pressure Observations. The Blood Pressure Supervisor should then transfer the results to this form (Supervisor Form for Simultaneous Blood Pressure Observations), calculate the differences between the two sets of measurements, and record the results below. If the difference on any individual measurement is greater than 4 mmHg, or if the averages of the readings for each technician differ by more than 3 mmHg, the supervisor should take corrective action and continue testing until the technicians succeed. A copy of this supervisor form should be sent to the Coordinating Center.

	1st Tech	2nd Tech	Difference
• initial arm circumference (cm)	_____	_____	_____
• initial cuff size selected	_____	_____	_____
• palpated systolic pressure	_____	_____	_____
• first SBP	_____	_____	_____
• first DBP	_____	_____	_____
• second SBP	_____	_____	_____
• second DBP	_____	_____	_____
• average SBP	_____	_____	_____
• average DBP	_____	_____	_____

Overall Comments of Supervisor

Instructions to Technicians/Corrective Actions

9.3. Field site supervision

9.3.3. Technician Form for Simultaneous Blood Pressure Observations

DATE:    \_\_\_    \_\_\_    \_\_\_  
          mo    day    year

Field Center:

Technician ID#:

Every other month each technician should, with a second technician, simultaneously measure blood pressure with a standard sphygmomanometer using a Y-tube on a volunteer, not a participant. Each technician should separately (and out of the other s view) record his or her measurements on a copy of this form. The Blood Pressure Supervisor should then transfer the results to the Supervisor Form for Simultaneous Blood Pressure Observations and calculate the differences between the two sets of measurements.

- initial arm circumference (cm) \_\_\_\_\_
- initial cuff size selected \_\_\_\_\_
- palpated systolic pressure \_\_\_\_\_
- first SBP \_\_\_\_\_
- first DBP \_\_\_\_\_
- second SBP \_\_\_\_\_
- second DBP \_\_\_\_\_
- average SBP \_\_\_\_\_
- average DBP \_\_\_\_\_





9.3. Field site supervision

9.3.4. Blood Pressure Examination and Anthropometry QC Supervisor Check List

**Seated Blood Pressure Measurement**

- |   |   |  |
|---|---|--|
| y | n | <ul style="list-style-type: none"><li>Measures the systolic blood pressure using the standard manometer:<br/>Inflates cuff quickly to maximal inflation level<br/>Deflates at 2mmHg/second to appearance of systolic pressure.<br/>Deflates cuff quickly and completely.</li></ul> |
|---|---|--|

**Weight Measurement**

- |   |   |   |
|---|---|---|
| y | n | <ul style="list-style-type: none"><li>Scale is positioned at zero.</li></ul>                              |
| y | n | <ul style="list-style-type: none"><li>Participant is not wearing shoes.</li></ul>                         |
| y | n | <ul style="list-style-type: none"><li>Participant s weight is equally distributed on both feet.</li></ul> |
| y | n | <ul style="list-style-type: none"><li>Participant is not supporting himself or herself.</li></ul>         |
| y | n | <ul style="list-style-type: none"><li>Examiner s eyes are level with the point of measurement.</li></ul>  |
| y | n | <ul style="list-style-type: none"><li>The measurement is recorded to the nearest 0.1 kilogram.</li></ul>  |

**Neck Circumference Measurement**

- |   |   |   |
|---|---|---|
| y | n | <ul style="list-style-type: none"><li>Participant is sitting upright with the head in the Frankfort Horizontal Plane.</li></ul> |
| y | n | <ul style="list-style-type: none"><li>The tape is applied around the neck just below the laryngeal prominence.</li></ul>        |
| y | n | <ul style="list-style-type: none"><li>The measurement is made perpendicular to the long axis of the neck.</li></ul>             |
| y | n | <ul style="list-style-type: none"><li>The tape is not too loose or too tight, but enough to maintain skin contact.</li></ul>    |
| y | n | <ul style="list-style-type: none"><li>The measurement is completed in less than 5 seconds.</li></ul>                            |
| y | n | <ul style="list-style-type: none"><li>The measurement is recorded to the nearest 0.5 centimeter, rounding up.</li></ul>         |

**Overall Comments of Supervisor**

**Instructions to Technicians/Corrective Actions**

---

**Signature, Supervisor**

9.3. Field site supervision

9.3.5. Blood Pressure, Weight, and Neck Circumference Equipment Check List

Field Center:

QC Supervisor:

Standard Sphygmomanometer(s):

Enter date checked in table

Sphyg. ID#	Check cap for tightness	Check that mercury is at zero with no pressure	Check Inflation system	Check tube for oxide dust

Scale(s) for Weighing

- Set scale at zero mark. Place 50-pound known weight on scale. If weight falls outside 49.5-50.5 pound range, the scale should be serviced.

Scale ID #	Weight recorded	Date Checked

9.3. Field site supervision

9.3.5. Blood Pressure, Weight, and Neck Circumference Equipment Check List

**Measuring Tape(s) for Arm and Neck Circumference:**

- Hold the zero mark on the tape against the 150 cm mark on a height ruler. If the 30 cm mark on the tape falls outside the range 119.5 to 120.5 on the ruler, the tape should be replaced.

Tape ID #	Point on height ruler where 30 cm mark on tape falls	Date Checked

List problems with any equipment and corrective action taken:

For unresolved problems, contact the Coordinating Center for instructions before proceeding. For repair information and shipping instructions, contact the manufacturer (for Baum sphygmomanometers, contact W. A. Baum Co., 626 Oak Street, Copiague, New York 11726; 516/226-3940).

\_\_\_\_\_  
 Signature, Quality Control Supervisor

#### 9.4. Equipment maintenance

Refer to chapter 3

#### 9.5. Reports

##### 9.5.1. Sleep Reading Center (SRC)

Reports: Upon receipt of studies at the Reading Center all zip cartridges will be scanned for viruses. The integrity of received data will be checked to ensure that the Sleep Study Review and Transfer Log sheet and paperwork received match the studies on the zip cartridge. Discrepancies in the received data will be handled in the following manner:

- If there is a discrepancy between the paperwork received and the Compumedics recorded file, the ID and Date in the Compumedics file will be entered in the Receipts table of the QASN database until corrected information is received from the site.
- An e-mail will be sent to the Site Coordinator requesting clarification
- An e-mail will be sent to the Site Coordinator if a study is received that is not a valid ID based on the ID List obtained from the Data Coordinating Center.
- An entry will be made in the SRC Participant ID Discrepancy Log Book containing the following information: Participant ID, date of the study, date of entry, nature of the problem, date site notified, date correct information received and a notation when the database was corrected.
- These entries will be maintained by Site and if any site is noted to have a significant number of discrepant entries, the Coordinator will be contacted by the RC to request they identify source and report action taken to correct.

The "Receipt" database table entry will include the following information: Study ID, Alpha Code, Field Center ID, Technician ID, Monitor/Headbox ID, date received at the Reading Center, and Zip Cartridge Number. The Chief Polysomnologist will then review each study to determine if the overall quality is sufficient to be scored (passed/failed), and identify any potential medical alerts (defined as preliminary RDI >45).

Codes will be entered into the Receipt database table indicating P (passed), F (failed) with notes indicating reason(s) study was not acceptable for scoring. Passed studies will be triaged to the scorers for full scoring and will be scored in the order in which they are received. Possible medical alert studies will be scored within 48 hours of being identified and reviewed by a Sleep Reading Center physician. During this review, the Chief Polysomnologist will note any significant signal problems and contact the site to troubleshoot the equipment, sensors, or application issues.

**9.5. Reports**

**9.5.1. Sleep Reading Center (SRC)**

On a weekly basis the following reports will be sent to the Site Coordinator:

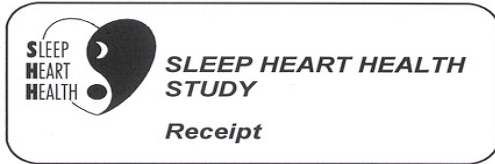
- Listing of studies received that week and preliminary Pass/Fail codes for studies that have been processed by Chief Polysomnologist.
- Studies received that were failed by the Chief Polysomnologist will include comments on the reasons for failure.
- Overall Quality of Study report containing completed information on the QS Form for studies that were scored that week.
- The two part Sleep Study Report containing information on the sleep study to be reported back to the participant and more detailed information that can be sent to a physician.

Samples of the Receipt Report, Quality Assurance and Scoring Notes (QS Form), and the two page Sleep Study Reports follow.

---

9.5. Reports

9.5.1. Sleep Reading Center (SRC)



**Field Center ID:** \_\_\_\_\_  
**Participant ID#:** \_\_\_\_\_  
**Alpha code:** \_\_\_\_\_  
**Study Date:** \_\_\_\_/\_\_\_\_/200\_\_  
**Visit ID Code:** F 0 2  
**Form & revision:** Receipt 1

**Received on zip #** \_\_\_\_\_ **Mon ID** \_\_\_\_ **Hbx ID** \_\_\_\_  
**Date received at RC** \_\_\_\_/\_\_\_\_/200\_\_ **Tech ID** \_\_\_\_\_

Date receipt entered: \_\_\_\_/\_\_\_\_/200\_\_

Initials ( )

**Study passed?**  (1) Yes  (0) No

- |                                |                                  |                                 |
|--------------------------------|----------------------------------|---------------------------------|
| <b>Problems with lights?</b>   | <input type="checkbox"/> (1) Yes | <input type="checkbox"/> (0) No |
| <b>Recording short?</b>        | <input type="checkbox"/> (1) Yes | <input type="checkbox"/> (0) No |
| <b>Problems with EEG?</b>      | <input type="checkbox"/> (1) Yes | <input type="checkbox"/> (0) No |
| <b>Problems with EMG?</b>      | <input type="checkbox"/> (1) Yes | <input type="checkbox"/> (0) No |
| <b>Problems with ECG?</b>      | <input type="checkbox"/> (1) Yes | <input type="checkbox"/> (0) No |
| <b>Problems with Airflow?</b>  | <input type="checkbox"/> (1) Yes | <input type="checkbox"/> (0) No |
| <b>Problems with Belts?</b>    | <input type="checkbox"/> (1) Yes | <input type="checkbox"/> (0) No |
| <b>Problems with oximetry?</b> | <input type="checkbox"/> (1) Yes | <input type="checkbox"/> (0) No |
| <b>Equipment issue?</b>        | <input type="checkbox"/> (1) Yes | <input type="checkbox"/> (0) No |
| <b>Other problems?</b>         | <input type="checkbox"/> (1) Yes | <input type="checkbox"/> (0) No |

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

**Reason code:**

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

**Assigned Scorer:** \_\_\_\_\_

**Date Assigned:** \_\_\_\_/\_\_\_\_/200\_\_

**Date status entered:** \_\_\_\_/\_\_\_\_/200\_\_

Receipt form  
Revision 1 1/5/01

9.5. Reports

9.5.1. Sleep Reading Center (SRC)



**Study Quality Report**

Field Center ID:

Participant ID:

Alpha Code:

Study date:

Tech ID

Mon ID

Hbx ID

Date scored:

Total Rec. Time:

Total Sleep Time:

RDI:

Channels	Hours of usable signal	Signals quality:
EEG		
EEG(sec)		
EOG L		
EOG R		
Chin EMG		
ECG		
Airflow		
Thoracic		
Abdomen		
Oximetry		

Code for sleep signals quality:

Good for entire sleep time(> 95 %)	5
Good for 75 - 94 % of sleep time	4
Good for 50 - 74 % of sleep time	3
Good for 25 - 49 % of sleep time	2
Good for < 25 % of sleep time	1

**Lights calibration appropriate:**

(0 - No, 1 - Yes)

**Sleep latency reliable:**

(0 - No, 1 - Yes)

**Position signal changing during study:**

(0 - No, 1 - Yes)

**Was study scored sleep - wake only:**

(0 - No, 1 - Yes)

**Overall study quality:**

Code for Overall study quality:

7 – Outstanding. All channels good for  $\geq$  5 hours and entire sleep time

6 – Excellent. At least one EEG channel, one EOG channel, EMG, oximetry, all respiratory channels usable for  $\geq$  5 hours and  $\geq$  75% of the sleep time

5 – Very good. At least one EEG channel, oximetry, airflow and either chest or abdomen usable for  $\geq$  5 hours and  $\geq$  50% of the sleep time

4 – Good. At least one respiratory channel (airflow or either band), oximetry and one EEG usable for  $\geq$  5 hours and  $\geq$  50% of the sleep time

3 – Fair. At least one respiratory channel, oximetry and one EEG usable for  $\geq$  4 hours or study scored sleep-wake only (because of the EEG artifact).

Study quality report

Created on 11/1/00 4:52 PM

Page 1 of 2

Field Center ID:

**Participant ID:**

**Alpha Code:**

**Study date:**

**Was entire sleep captured:**

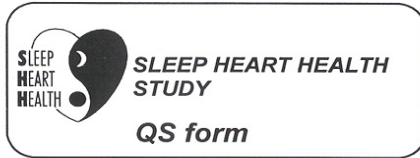
Recording started after sleep onset	(0 - No, 1 - Yes)
Recording ended before participant awoke	(0 - No, 1 - Yes, 8 - N/A)
Loss of the data at the beginning of the study	(0 - No, 1 - Yes, 8 - N/A)
Loss of the data at the end of the study	(0 - No, 1 - Yes, 8 - N/A)
Loss of the data during the study	(0 - No, 1 - Yes, 8 - N/A)

**Comments:**

**Medical Alert:**

Heart rate > 150 bpm for $\geq$ 2 minutes	(0 - No, 1 - Yes)
Heart rate < 30 bpm for $\geq$ 2 minutes	(0 - No, 1 - Yes, 8 - N/A)
Oxygen saturation < 75% for > 10% TST	(0 - No, 1 - Yes, 8 - N/A)
RDI > 50	(0 - No, 1 - Yes, 8 - N/A)





Field center ID: \_\_\_\_\_  
Participant ID#: \_\_\_\_\_  
Alpha code: \_\_\_\_\_  
Study Date: \_\_\_/\_\_\_/200\_\_

1. Scorer ID: \_\_\_\_\_ Total Rec. Time (hr:min) \_\_\_\_\_  
2. Date scored: \_\_\_/\_\_\_/\_\_\_ Total Sleep Time (hr:min) \_\_\_\_\_  
3. CD #: \_\_\_\_\_ 4. RDI \_\_\_\_\_

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

**Code for signals quality:**

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

**15. Overall Study Quality:**

(7) **Outstanding.** All channels good for  $\geq 5$  hours and entire sleep time.

(6) **Excellent.** At least one EEG channel, one EOG channel, EMG, oximetry, all respiratory channels usable for  $\geq 5$  hours and  $\geq 75\%$  of the sleep time.

(5) **Very good.** At least one EEG channel, oximetry, airflow and either chest or abdomen usable for  $\geq 5$  hours and  $\geq 50\%$  of the sleep time

(4) **Good.** At least one respiratory channel (airflow or either band), oximetry and one EEG usable for  $\geq 5$  hours and  $\geq 50\%$  of the sleep time

(3) **Fair.** At least one respiratory channel, oximetry and one EEG usable for  $\geq 4$  hours or study scored sleep-wake only (because of the EEG artifact).

16. Was lights calibration appropriate?  (1) Yes  (0) No

17. Was sleep latency reliable?  (1) Yes  (0) No

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

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

9.5. Reports  
9.5.1. Sleep Reading Center (SRC)



Participant ID#: \_\_\_\_\_  
Study Date: \_\_\_\_\_

<b>20. Medical Alert?</b>	<input type="checkbox"/> (0) No	<input type="checkbox"/> (1) Yes	Initials of reviewing physician
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 < 70% for > 10% TST	<input type="checkbox"/> (8) N/A	<input type="checkbox"/> (1) Yes <input type="checkbox"/> (0) No	
d) RDI > 50	<input type="checkbox"/> (8) N/A	<input type="checkbox"/> (1) Yes <input type="checkbox"/> (0) No	

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

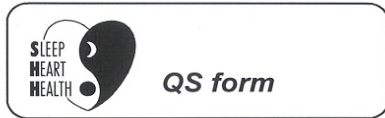
<b>22. Was study scored Sleep/Wake only?</b>	<input type="checkbox"/> (0) No	<input type="checkbox"/> (1) Yes
<b>23. Were there problems with scoring sleep stages?</b>	<input type="checkbox"/> (1) Yes	<input type="checkbox"/> (0) No <input type="checkbox"/> (8) N/A
a) Wake / Sleep unreliable	<input type="checkbox"/>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

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

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

9.5. Reports

9.5.1. Sleep Reading Center (SRC)



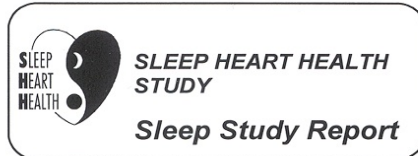
Participant ID#: \_\_\_\_\_  
Study Date: \_\_\_\_\_

28. Were unusual occurrences during sleep?	<input type="checkbox"/> (0) No	<input type="checkbox"/> (1) Yes	Initials of reviewing physician
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	<input type="checkbox"/> (8) N/A	<input type="checkbox"/> (1) Yes <input type="checkbox"/> (0) No	
e) CSB type breathing	<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 of reviewing physician
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) Min HR < 30 bpm or max HR > 150 bpm real	<input type="checkbox"/> (8) N/A	<input type="checkbox"/> (1) Yes <input type="checkbox"/> (0) No	
f) Poor ECG quality or computer not picking up	<input type="checkbox"/> (8) N/A	<input type="checkbox"/> (1) Yes <input type="checkbox"/> (0) No	
g) Other - see Notes	<input type="checkbox"/> (8) N/A	<input type="checkbox"/> (1) Yes <input type="checkbox"/> (0) No	

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

31. Date entered \_\_\_/\_\_\_/200\_\_\_  
Initials ( )



Participant ID [ @1 ]  
Study Date [ @50 ]

PARTICIPANT'S FEEDBACK INFORMATION

Lights out	= [ @9000,t ]
Sleep onset	= [ @9001,t ]
Sleep latency	= [ @9002,s ]
Total time in bed	= [ @9005,s ]
Total sleep period	= [ @9006,s ]
Sleep efficiency	= [ @9007,f ] %
Total time for NREM sleep	= [ @9041,s ]
Total time for REM (dreaming) sleep	= [ @9015,s ]
RDI	= [ @9040,f ]
(Total number of apnea and hypopnea associated with $\geq 3\%$ desat per hour of sleep)	

## 9.6. Data audits and edits

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The Coordinating Center will conduct periodic data audits as a quality control measure. Audits may be done by mail or on-site. During an audit, the forms will be reviewed to see if they are completed and keyed correctly. When applicable, the forms will also be checked against the source documents to be sure that values were transcribed correctly.

Computerized data edits, also known as Data Quality Queries (DQQs), will be sent to the field sites monthly. These edits will check inconsistent and questionable values in the database. Specific instructions for data edits are listed below:

- Edit (DQQ) listings are prepared and distributed by the SHHS Coordinating Center
  - Resolution of the listed queries requires review of the specified forms on a participant by participant basis. Data edits are to be completed by the field site coordinator as soon as possible.
  - All resulting corrections and/or annotations must be recorded onto the clinic forms and onto the edit listing sent by Coordinating Center.
  - The corrections to the forms should be recorded according to usual form completion standards. In addition to being initialed and dated, changes made as a result of an audit or edit should be marked 'per audit' or 'per edit'.
  - The edit listings on which the corrected items were recorded should be faxed to the Coordinating Center editor.
  - The database should be updated accordingly. Edits that are not updated in the database will continue to appear on the subsequent data edit listings.
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### 9.6.1. Coordinating Center Reports

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The CC will provide reports on participant contact, follow-up visits, and data collection to all sites on a monthly basis.

After receipt of monthly data transmittals from the field sites, the CC will generate summary data reports specific to each field site. These reports will provide a count of participants who have been contacted. They also will indicate when forms have been entered for an expected visit, when visits are missed, and when visits appear incomplete (i.e., expected forms have not been entered). These monthly reports will be posted on the internal SHHS website. PIs and coordinators will be notified of new postings by e-mail.

On approximately a quarterly basis, the CC will generate reports summarizing the performance of all field sites. These reports will include information on recruitment and the percentage of expected visits for which documentation has been entered into the SHHS data system. Also, for those visits for which data have been entered, the report will show the percentage of missed visits, the completeness of data collection, and the timeliness of data entry. Performance reports will be reviewed by the Steering Committee, which will make decisions regarding actions to be taken in the event that a field site is performing poorly.

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### 9.6.1.1. Data Quality Query (DQQ)

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#### Purpose

The purpose of the Data Quality Query (DQQ) is to resolve problems discovered during review of the dataset. Problems include missing values, out of range values, inconsistencies among 2 or more items, or other difficulties in interpreting the response. The corresponding items in the database cannot be analyzed until the queries have been resolved.

#### Turnaround

1 month from receipt

#### Frequency

Monthly

#### Completed By

Field Site Coordinator

#### Instructions

DQQ reports are prepared by the SHHS II Coordinating Center (DCC) and distributed to the field sites via Federal Express. The list of queried items is sorted by participant ID, and within participant by form and item.

Query completion requires review of the form hard copy. If a correction is necessary, mark a single line through the existing response and write the correct one next to, or above, the original one. Other items to include: brief explanation for change, date of correction, and initials of the person making the correction. **It is important that all edits to the paper form are also included in the database.** After both the form and database have been corrected and/or annotated, record the corrected value in the space labeled "Action" on the DQQ form.

If a mutually agreeable solution to the problem cannot be reached in a reasonable amount of time, print "Pending" in the space provided on the DQQ, indicating that more time is needed to determine the correct value. Pending DQQs should not be filed in the participant's study folder until all queries have been resolved, i.e., "Pending" has been replaced with an appropriate response. Non-response or pending responses to a DQQ will result in the inclusion of the item(s) on subsequent DQQ reports.

Record "Blank" in the space provided on the DQQ form if a previous response should be deleted and the item left blank. A brief explanation for the response should be included. Note that if a response is required, future DQQ reports will query this item.

Finally, if the existing response is correct and requires no change to the database or data forms record "No Change" in the space on the DQQ and provide a brief explanation.

Each page of queries should be initialed and dated by the person who completed the queries on that page. After all queries have been completed, they should be reviewed and the name and ID# of the reviewer should be printed in the space labeled “Reviewer” and the date in the spaced labeled “Date.”

Fax the completed DQQ form(s) to the coordinating center.

Completed DQQ reports should be filed in the participant’s study folder.

For quick reference, the instructions are outlined on the following page.

### **DQQ Response Outline**

1. Item response is in error – a change to the database and data forms is required
  - a. Single line through original response
  - b. Initial and date
  - c. Record corrected response
  - d. Record explanation for change
  - e. Correct item in database
  - f. Record response on DQQ form
  - g. Sign and Date DQQ
  - h. Fax to Coordinating Center
  - I. File in participant’s study folder
2. Item response is correct – no change to the database and data forms is necessary
  - a. Record response “No Change” on DQQ form
  - b. Provide brief explanation
  - c. Sign and Date DQQ
  - d. Fax to Coordinating Center
  - e. File in participant’s study folder
3. Mutually agreeable response not available at time of query completion
  - a. Record response “Pending” on DQQ form
  - b. Sign and Date DQQ
  - c. Fax to Coordinating Center
  - d. This response will result in inclusion of the item on subsequent DQQ reports

**Note: Non-response, pending responses or responses remaining blank in required fields will result in inclusion of the item(s) on subsequent DQQ reports.**



## 10. Glossary

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Alpha rhythm:	EEG rhythm, usually with frequency of 8-13 cps in adults; most prominent in the posterior areas; present most markedly when the eyes are closed; attenuated during attention, especially visual. (Characteristic of relaxed wakefulness with the eyes closed.)
Alpha wave:	Individual component of an alpha rhythm.
Amplifier:	An electronic instrument used to increase the strength of an incoming signal.
Apnea:	Period (>10sec) with no airflow.
Apnea Hypopneas 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 13 cps.
Bioelectric potentials:	Voltages originating from living tissue.
Bipolar derivation:	Signals obtained by comparing voltages from 2 exploring electrodes.
Body movement:	Scored during any sleep stage when a phasic increase in the amplitude of the EMG lead of 1 sec or longer is accompanied by muscle artifact in an EEG or EOG trace.
Canthus:	Corner of the eye (plural: Canthi)
C3:	A symbol of the International 10/20 electrode system, identifying left central electrode placement site.
C4:	A symbol of the International 10/20 electrode system, identifying left central electrode placement site.
Central Apnea	Apnea or hypopnea with no associated respiratory effort (or Hypopnea)
Channel:	Group of components completing a pathway between input and output of recorded signal.
Collodion:	An ether-based substance used for gluing electrodes to the scalp.
Delta Rhythm:	EEG rhythm with frequency of less than 4 cps.
Delta Sleep:	Sometimes used as a synonym for stages 3 and 4 sleep. (Note that the frequency criterion for scoring slow EEG waves in stages 3 and 4 sleep is 2 cps or slower.)
Delta Wave:	EEG wave with duration of more than ¼ second.
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 wave.
Electrical silence:	Absence of electrical activity.
Electroencephalogram (EEG):	Record of the electrical activity of the brain.
Electromyogram (EMG):	Record of the electrical activity of muscles.
Electrooculogram (EOG):	Record of the electrical activity of eye movements.
Frequency:	The number of complete cycles of a rhythm in 1 second.
Gain:	Amplifier sensitivity.

Ground electrode:	Electrode (usually from forehead or (2) connected directly to the polysomnograph and to building grounds, prevents external interfering voltages.
Hertz:	Measure of frequency; cycles per second
Hypopnea:	Discrete decrease in airflow or thoracic effort for >10 sec. (usually <50% of baseline); partial airflow obstruction.
Impedance:	Opposition to the passage of fluctuating (AC) signals generated by the patient.
Inductive	Method for measuring changes on circumference.
Plethysmography:	
Inion:	A bony protuberance in the lower occipital regions.
K complex:	EEG wave forms having a well-delineated negative sharp wave immediately followed by a positive component; duration exceeds 0.5 seconds; waves of 12-14 cps (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 state 2 sleep.)
Lead:	Term used to denote a single electrode placement.
Light sleep:	Sometimes used as a synonym for stage 2 sleep.
Location:	Refers to a brain area.
Low-voltage EEG:	EEG in which no activity larger than 20 V can be recorded between any two points on the scalp.
Montage:	Combination of a number of derivations.
Morphology:	The shape (form) of a wave or activity.
REM sleep:	Sleep stages 1,2,3, and 4
Obstructive apnea (or hypopnea):	Apnea or hypopnea with associated respiratory effort.
Ohm:	Unit of electrical resistance.
Ohmeter:	A device used to measure impedance in a circuit.
Oximeter:	Sensor that emits infrared light band, sent across a tissue (e.g., nail, earlobe), to detect hemoglobin oxygen saturation.
Mastoid:	Lower portion of the temporal bone, behind the ear.
Nasion:	Indentation above the bridge of the nose.
Piezoelectric bands:	Bands containing a crystal which generates electrical current when subjected to stress.
Polysomnograph:	Multichannel instrument used to record physiologic parameters during sleep.
Preauricular point:	Small indentation in front of, slightly above, cartilage flap of ear canal.
Quiet sleep:	Sometimes used as a synonym for stages 3 and 4 sleep.
Random:	Occurring at inconstant time intervals.
REM sleep	A relatively low-voltage, mixed-frequency EEG in conjunction with episodic rapid eye movements and a low-amplitude EMG.
Respiratory Disturbance Index (RDI):	Number of respiratory disturbances (apneas plus hypopneas per hour of sleep).
Rhythm:	Activity of approximately constant period and morphology, but not necessarily of amplitude.

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Saw-tooth waves:	Notched wave forms in vertex and frontal regions that sometimes occur in conjunction with bursts of rapid eye movements in REM sleep.
Sleep spindle:	A waxing and waning wave form with a frequency of 12-14 cps, 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 eye movements are often present; vertex sharp waves may be seen; EMG activity is not suppressed.
Stage 2 sleep:	12-14 cps 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 V or greater), slow-wave (2 cps or slower) EEG activity.
Stage 4 sleep:	Predominance (greater than 50%) of high-amplitude (75 V or greater), slow-wave (2cps or slower) EEG activity.
Strain gauge:	Device used to detect movement or changes in body (body part) circumference.
Thermistor:	Sensor measuring changes in temperature with inspiration and expiration, used to assess airflow.
Theta activity:	Series of regular or irregular EEG waves with duration of ¼ to more than 1/8 seconds. (May be seen in stage 1 or REM sleep).
Theta rhythm:	EEG rhythm with a frequency of 4 cps to less than 8 cps.
Theta wave:	EEG wave with duration of ¼ second to more than 1/8 second.
Topography:	Distribution of activity with respect to anatomic landmarks. (Synonym: spatial distribution).
Transducer:	Device used to convert non-electrical physiological variables into electrical signals.
Unilateral:	Occurring on one side of the head.
Vertex sharp wave:	Sharp wave, maximal at the vertex and negative in relation to other areas (often occurring during later portions of stage 1 sleep).
Wave:	Any transient change of potential difference in the EEG.

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