
# Manual 6
# Sleep Monitoring

## January 15, 2008 - Version 1.0

**Study website - http://www.cscc.unc.edu/hchs/**

**Sleep Monitoring**
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# 1. BACKGROUND

## 1.1 Purpose of Sleep Monitoring

One goal of the HCHS/SOL is to measure the association between Sleep Apnea as a risk factor for a number of diseases, including hypertension, cardiovascular disease, and diabetes, in the Hispanic adult population.

## 1.2 Sleep Apnea

Sleep Apnea is a condition characterized by repeated episodes of partial (hypopneas) or complete (apneas) obstruction of airflow due to pharyngeal narrowing or collapse occurring during sleep. With breathing obstruction, oxygen saturation levels drop and sleep continuity is disrupted. These influences often cause surges in blood pressure and increased levels of inflammatory and stress molecules-thus, explaining why sleep apnea may contribute to risk of hypertension and diabetes. The most common symptoms of sleep apnea are snoring (due to the turbulence of airflow in a narrow throat) and daytime sleepiness (due to poor sleep quality related to breathing disturbances causing sleep disruption). The prevalence of sleep apnea in adult US populations is estimated to be approximately 10%. However, very few studies have addressed this in Hispanic populations. Risk factors for sleep apnea include: obesity, male gender, and older age. Sleep apnea is usually diagnosed by overnight polysomnography (a sleep study where multiple channels of physiological signals are monitored) performed in a hospital setting and attended by an overnight sleep technician. However, new technology provides the ability to measure relevant physiological signals in unattended (in-home) settings.

Participants in the HCHS/SOL will undergo a single night of unattended, in-home monitoring with a sleep apnea monitor. The data obtained will identify those individuals with frequent breathing pauses and oxygen desaturation, including those with clinically significant levels of sleep apnea (more than 5 breathing pauses per hour of sleep; AHI). Quantitative data will be available for each participant, describing levels of oxygen saturation, number of saturation dips, number of breathing pauses, frequency of snoring, number of nocturnal movements.

# 2. CHOICE OF SLEEP APNEA MONITORING EQUIPMENT

The HCHS/SOL Sleep Subcommittee reviewed several monitors amenable for use in a large cohort, balancing feasibility and subject burden issues, with the desire to acquire physiologically relevant and validated data. The equipment chosen for sleep apnea monitoring is the *Apnea Risk Evaluation System (ARES*, Unicorder, Advanced Brain Imaging, Carlsbad CA - See Appendix 7 for equipment specifications). This device uses a novel pulse oximeter with highly accurate recording characteristics compared to gold standard Remco-oximetry (measuring oxygen saturation and heart rate), and sensors which measure: airflow (by nasal a cannula and pressure transducer; i.e., considered the "gold standard" for airflow assessment during polysomnography), snoring sounds (by microphone), and head movement and body position (by accelerometry). All sensors are housed within a small unit stabilized on the forehead with a self applied band. The unit is powered by a rechargeable battery that can support 14 hrs of recording. The data collected enable computation of the apnea hypopnea index (AHI), an index associated with important health outcomes for this study, including, hypertension, impaired glucose tolerance, cardiovascular disease and sleepiness and functional impairment. Published data indicate the

validity and reliability of this device for quantifying these indices. It is minimally invasive, can be self-applied, returned to clinic via a mailer, and has a low failure rate. Alarms are available to warn of any malfunction or disconnection. Although commercial software provides algorithms for apnea detection, the data are "full disclosure" and can be exported as edf files for flexibility of analyses. Reported failure rates are <1%. In a study of 284 subjects monitored concurrently with in-lab polysomnography and the Unicorder, the AHIs were almost identical (r=0.96); AHIs from in-lab polysomnography and at-home Unicorder, determined on two different monitoring nights also showed excellent agreement (n= 187; r=0.88), with no evidence of bias between the two records.

Each site will receive 20 sleep monitors (30 monitors as of 12-20-07) in which to collect approximately 40 sleep studies per week. Each site will also receive the necessary software which will be used to upload participant information, download studies, and transmit studies to the Case Sleep Reading Center (CSRC) for review and scoring.

## 3. ROLE OF FIELD SITES

Field sites will be responsible for collection and transmittal of sleep data to the CSRC, maintaining the sleep units, instructing the participant in use of the sleep monitor, and follow-up with appropriate site staff for Urgent Sleep Alerts.

### 3.1 Collection and Transmittal of Data

There will be a total of four (4) field sites for data collection. Each field site will be responsible for preparing the sleep monitors for each use, properly fitting the monitor as well as instructing the participant in use of the sleep monitor. Upon return of the monitor, recorded data will be downloaded, reviewed for quality standards and transmitted to the CSRC. Proper working order of the sleep monitor will be confirmed at the time of each download. If a problem is detected, further maintenance checks and unit calibration will be performed; CSRC and/or the manufacturer will be contacted regarding monitor problems the site is unable to resolve and/or monitors that fail calibration checks.

### 3.2 Maintenance and Tracking of Sleep Monitors

Sleep monitor units will be cleaned and disinfected between participants. The sleep monitors will undergo routine maintenance every 60 nights of use as well as maintenance checks every six (6) months. A log record book of all maintenance checks as well as problems with individual units and problem resolution will be maintained at each local field site. Field sites will track the use, location and status of each monitor, assuring timely retrieval after study completion. *(See Appendix 1 for ARES Tracking and Maintenance Logs).*

### 3.3 Follow-up of Urgent Sleep Alerts

In the event that a sleep recording submitted to the CSRC meets criteria for Urgent Sleep Alert, the field site, after notification from CSRC, will be responsible for assuring that the appropriate follow-up has been accomplished, which in most cases will require that the participant be contacted and urged to follow-up with their physician. A disposition log for Urgent Sleep Alerts will be maintained at each local field site.

## 4. FIELD SITE TECHNICIAN TRAINING AND CERTIFICATION

Every collection site must have at least one (1) research assistant or study coordinator at central training who will be responsible for overseeing the sleep data collection. This staff member will be the first at each site to certify for sleep collection and then become ultimately responsible for training and oversight of any additional technicians to certify for field collection at the site. Sleep collection training requires the technician to become familiar with the purpose of HCHS/SOL, the purpose of sleep monitoring and relevance to the overall study goals; how to use the sleep monitor hardware and software; how to transmit data to CSRC; how to maintain relevant study documents; interpret unit-generated quality control checks; perform calibrations, routine maintenance checks and other unit troubleshooting methods; and how to act on identified Urgent Sleep Alerts.

### 4.1 Staff Certification for Sleep Monitoring

Staff certified at central training for performing HCHS/SOL sleep studies will be required to pass a written examination and demonstrate proficiency in using the sleep monitor for collection and transmitting data by submitting one (1) acceptable night time recording on a volunteer. This serves both as part of the technician certification and as practical experience in using the equipment in the study environment. Certification studies also allow for verification that sensors and equipment are functioning properly before being used on a study participant. Centrally certified sleep technicians will be permitted to train others at the local level. Additional staff trained locally must complete the certification process before performing these duties at the collection site. A checklist for training on site is provided to ensure technicians that have not attended central training will have basic understanding of collecting sleep data. This checklist must be signed off by the trainee and the certified technician and submitted to the CSRC as part of the certification process. (See Appendix 6 - Certification Packet.)

To be considered acceptable for certification the sleep recording must: 1) Have good quality signal on each channel (i.e.: all sensors must work and be relatively free from artifact); 2) Proper naming of study recording (Site ID followed by six consecutive numbers and a check digit – SNNNNNNC; eg. B0000019); and 3) Electronic file must include Technician ID, head measurement and strap setting, and times the monitor was turned on and off. The performance of the download must result in successful data transmission to the CSRC.

### 4.2 Maintaining Certification

After initial certification, sleep certification can be maintained by performing successful data collection and transmission of a minimum of two (2) sleep studies per month. If field collection work does not permit the technician to perform these duties at such a rate certification may be maintained by submitting enough practice studies to equal two (2) submissions a month. A practice study is defined as successful data collection (at least 4 hours in length) and transmission on a non-participant volunteer.

### 4.3 Field Site Technician Training and Certification Process

In order to obtain certification for sleep data collection the following must be met:

1. Attendance at Central Training or training under the close supervision of a centrally trained staff member. Technicians that have not attended central training must submit an At-Site Training Checklist signed off by the trainee as well as the overseeing certified staff member.
2. Submission of a written exam.
3. Submission of one acceptable overnight (volunteer non-participant) sleep recording performed at the field site.

## 5. OVERVIEW OF SLEEP DATA COLLECTION PROTOCOL

The certified Sleep Technician will be responsible for following all aspects of the protocol during collection of sleep data. Proper equipment maintenance, disinfecting, and tracking of all equipment are important to obtain high quality data in this population.

Each field site will be responsible for preparing participants to collect a one-night sleep study using the sleep monitor (called "Unicorder"). The Sleep Technician will work closely with the CSRC. CRSC will provide feedback on the quality of the data and assist with troubleshooting equipment issues. Sleep data reports for the participant, quality reports, and receipt summary reports will be posted on the study website.

Table 5.1 - Sleep Protocol

| | |
|---|---|
| Pre-Clinic Visit<br>(1 to 2 days prior to Clinic Visit) | Prepare ARES Unicorder<br>Verify battery fully charged and Unicorder clean and disinfected<br>Upload Participant information to the Unicorder<br>Place Participant ID labels on head strap and storage box<br>Verify necessary sleep study supplies in storage box |
| Clinic Visit | Describe purpose of sleep study<br>Demonstrate basic unit parts and how to use<br>Review Alarms and who to contact if questions<br>Provide written instructions for return of unit<br>Log Monitor Number, Date and Participant ID |
| Retrieval of Ares Unit<br>(Morning after Use) | Upon receipt verify Sleep Log is complete and accurate, and phone participant if necessary to complete.<br>Remove, discard disposables, and clean unit.<br>Download, save and transmit sleep file to CSRC.<br>Reformat Unicorder<br>Recharge Unicorder Battery<br>Apply New Disposables to Unicorder |
| Data Transmittal<br>(24 to 48 hrs. after receipt of monitor) | Take appropriate troubleshooting actions if needed in response to quality messages generated at download<br>Backup Data<br>Confirm CSRC receipt on website |
| Reports | Check website for sleep reports and quality summaries<br>Follow-up on Urgent Sleep Alerts |

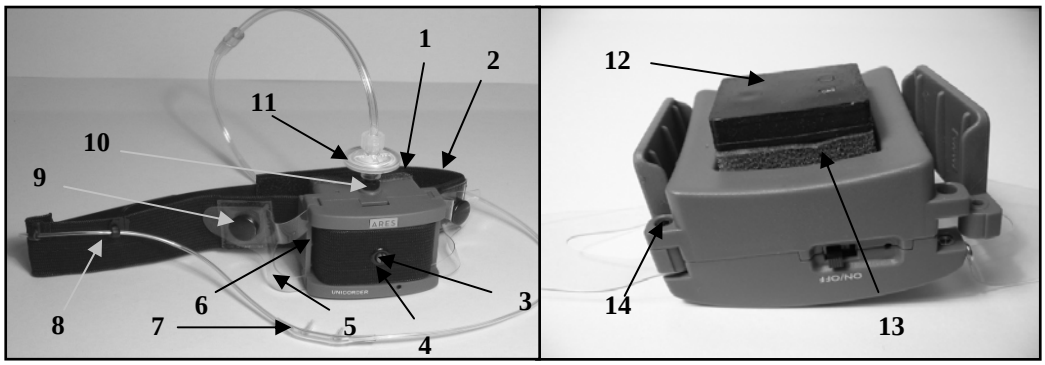
## 6. PRE-CLINIC VISIT PREPARATIONS FOR SLEEP DATA COLLECTION

Prior to participant arrival for the clinic visit the technician should prepare the Unicorder for data collection and gather a complete packet of supplies, instruction sheets, and data forms to be given to the participant at the clinic visit.

### 6.1 Recorder Components and Sleep Study Supplies

Table 6.1a - Unicorder Components

| Number | Description of component | Number | Description of component |
|---|---|---|---|
| 1 | Enclosure foam | 8 | Cannula clip |
| 2 | Enclosure strap | 9 | Stabilizing strap snap |
| 3 | Eyelet connector | 10 | Enclosure luer lock |
| 4 | Strap Eyelet | 11 | Nasal cannula luer lock |
| 5 | Stabilizing strap | 12 | Forehead Sensor |
| 6 | Strap Arm | 13 | Sensor Foam |
| 7 | Cannula tip | 14 | Enclosure Screw |




Each site will be responsible to maintain sufficient supplies in stock for use with the Unicorder sleep monitor. Unicorder disposable supplies (Salter cannula, enclosure strap, enclosure foam, sensor foam) are intended for single participant contact only and must be discarded after use. These disposable supplies specific to the recorder are supplied by Advanced Brain Monitoring. Each participant kit should be assembled and contain the following basic supplies:

Table 6.1b - Sleep Study Supplies for Participant

| Unicorder Specific Supplies | General Sleep Study Supplies |
|---|---|
| Unicorder (reusable)<br>Black storage box (reusable)<br>Blue sensor foam (disposable)<br>Black Enclosure foam (disposable)<br>Universal size enclosure head strap (disposable)<br>Custom Salter nasal cannula (disposable) | Alcohol Wipes<br>Re-sealable plastic bag, such as Ziploc<br>Instruction Sheet<br>Mailer Envelope or Courier Instructions |

Table 6.1c – Additional Supplies Needed at Test Site

| Unicorder Specific Supplies | General Sleep Study Dispensing Supplies |
|---|---|
| Ziplinc Battery Charger<br>Data download cable<br>Functional Test Rig<br>NiMH Rechargeable Battery<br>Replacement Forehead Sensors | Measuring Tape<br>Mirror<br>Labels for head strap and Unicorder case<br><br>Supplies for Disinfection:<br>Caviwipes<br>Disposable surface protector (i.e.: underpad)<br>Scissors<br>Latex-free gloves |

***(See Appendix 3 for ARES Disposables/Replacement Parts Order Form and information on ordering general supplies.)***

## 6.2 Unicorder Preparation

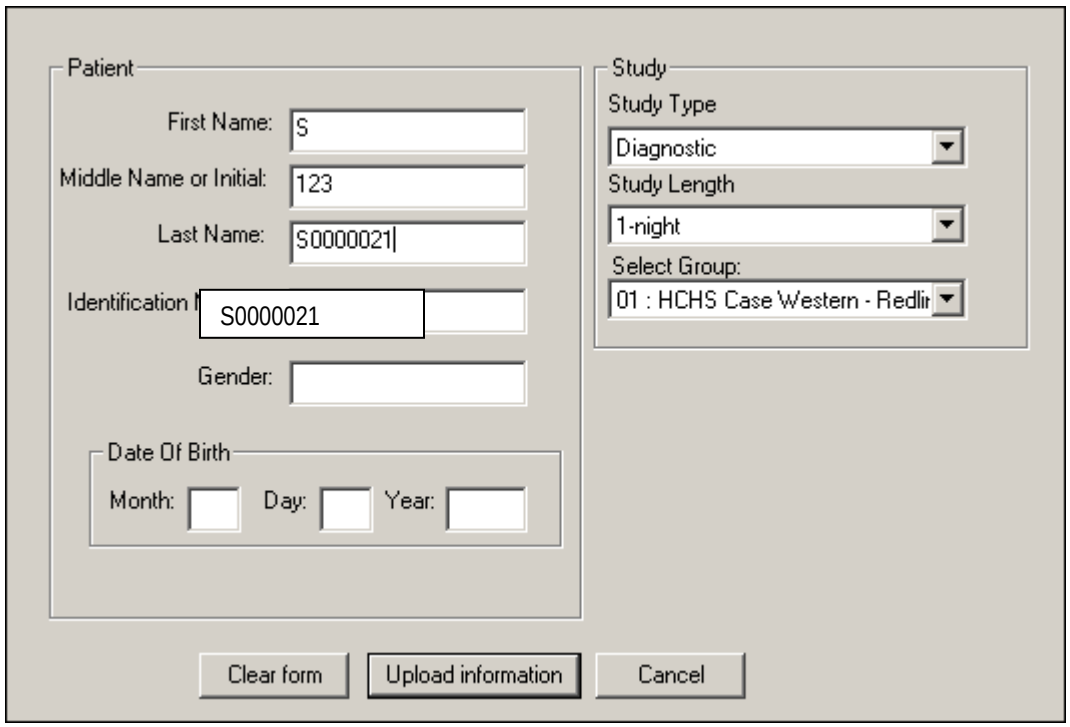
Preparation of the Unicorder prior to the clinic visit requires the participant identification information be uploaded and that participant ID labels to be placed on the storage case and head strap. The Unicorder will not permit a new participant set up if the battery has not been fully recharged. After download of a prior study, allow 3 hours of battery charging time before resetting for a new participant; charging may be accomplished in less than 3 hours if the battery has not been fully depleted.

Connect the Unicorder to the computer using the Ares USB Cable. Make sure the Unicorder is powered on. Double click the ARES Organizer Shortcut on your desktop. In the "Upload, Download and Send View" screen, click on the "Create and Upload Study" icon box.

In the Create and Upload Study screen (See Figure 6.2a), place the one letter Site ID in the “First Name” field, three-digit Tech ID in the “Middle Name” field and eight-character Participant ID in the "Last Name" and “Identification Number” fields. *(See Appendix 5 – Participant ID Naming Convention for more information on assigning ID’s.)* Leave the other fields on this screen blank. Do not use any identifying data on this screen. Study Type should default to Diagnostic, Study Length to 1-night, and Select Group to Bronx, Chicago, Miami or San Diego. When complete click on the Upload Information button.

When the status message states "Study Underway and the Unicorder is now prepared for use", the sleep monitor should be turned off and removed from the USB cable. Place a participant ID label on the inside of the head strap, on the paperwork and in the window of the black storage case to ensure the monitor is dispensed to the correct participant. Record the participant ID in the Unicorder tracking log. (See Appendix 1) Place the recorder in a re-sealable plastic bag and then into in the storage case so the nasal cannula is facing the short end of the case. Ensure that the case also contains an instruction sheet and alcohol swabs. The Unicorder is now ready for the participant.

Figure 6.2a - Create and Upload Study Screen




## 7. CLINIC VISIT – SLEEP STUDY INSTRUCTIONS

### 7.1 Overview of Study Goals and Unicorder *(See Appendix 2 - Script)*.

Explain the purpose of the sleep study and how assessment of the quality of sleep can help provide information about sleep apnea and its link to health. Explain the importance of collecting representative data of a normal night of sleep. *(See sample Script in Appendix 2)*. The ARES Unicorder collects: airflow data from the nasal cannula placed in the nose and oxygen levels through the sticky black pad that is placed on the forehead. The monitor also records the position of the head through an accelerometer and snoring through a noise microphone within the monitor. The noise microphone is built to record only snoring sounds in a quiet background and cannot record what the participant says when speaking.

### 7.2 Demonstration of Unicorder to Participant

The Unicorder should have been assembled for a new study, and uploaded with information for the new participant prior to the demonstration. If protective plastic has been placed on the forehead sensor, remove this before performing the demonstration.

Explain that we would like a night of sleep that is most likely to represent a normal night's sleep for them. During the demonstration, show the participant the basic parts of the unit: The on/off switch, the cannula and slip tube, the strap, the location of the snore microphone, and the oximeter.

## 7.3 Measurements

Measure the participant's head size with the tape low on the back of the head, just above the top of the ears, and one inch above the eyebrows. (Figure 7.3a). Repeat the measurement to ensure accuracy and then using the Strap Settings Chart (Table 7.3b) determine the proper setting and adjust the band as needed. Enter this measurement and the strap setting on the Sleep Log Form (Appendix 1). To keep the strap from slipping up during the night (causing alerts to sound), participants with long hair should be advised to wear it up at bedtime or the sleep monitor strap should go under their hair.

Figure 7.3a - Measurement of Participants Head

Table. 7.3b - Strap Settings Chart

| HEAD SIZE | | Universal Strap Setting |
|---|---|---|
| Inches | cm | |
| <21.5 | <55 | 0 |
| 21.5 | 55 | 1 |
| 22 | 56 | 3 |
| 22.5 | 57 | 5 |
| 23 | 58 | 7 |
| 23.5 | 59.5 | 9 |
| >24 | 61 | 10 |

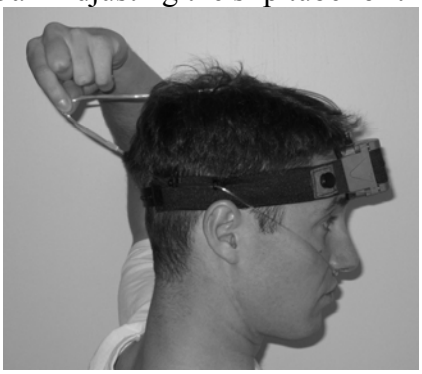
## 7.4 Applying Sleep Monitor

The Unicorder should be centered over the participant's nose and slightly above the eyebrows on the flattest region of the participant's forehead so the entire sensor makes contact with the skin. Demonstrate how to wipe the central area of the forehead with an alcohol pad before applying the monitor. Explain this will ensure that the sleep monitor acquires accurate signals all night long. Show how the unit is placed over the head with the proper strap setting assuring appropriate snugness. Make sure the black sensor (oximeter) is placed on a flat portion of the forehead. Pull any hair out of the way to ensure that it does not interfere with the oximetry signal.

## 7.5 Placement of Cannula and Slip Tube Adjustment

After the strap setting has been adjusted for the participant, explain the nasal cannula will be placed in the outer areas of the nostrils to record breathing through the night. Show how the cannula is placed in the nostrils with the tubing prongs curving downward to lay on the floor of the nares. Show the participant how to adjust the cannula tubing in case it gets twisted. Instruct the participant that the slip tube must be adjusted to make sure that the cannula does not fall out of the nose during the night (which would cause an alarm to sound). Demonstrate how the slip tube can be used to tighten or loosen the cannula tubing (Figure 7.5a) and explain if properly tightened it cannot be pulled out of the nose. Demonstrate proper positioning of the slip tube in the back of the head at the strap adjustment of the headband. Have the participant look at himself in the mirror to see the proper placement of the unit and the cannula

Figure 7.5a - Adjusting the slip tube for the cannula



## 7.6 Demonstrating Start of Study

Explain to the participant that the monitor should be placed on the head, in the fashion just demonstrated, 15 minutes before bedtime. The time the Unicorder was turned on should be noted in the Participant Instruction Summary. (See Appendix 5) After attaching the monitor and getting into bed, the unit should be powered on. The unit will produce a single chirp after powering on. The participant must lay on his back with his head facing straight upward for 30 seconds in order for the Unicorder to calibrate the position sensor. The participant will know that calibration has been completed when the unit chirps two (2) times and the green indicator light will be steady. After the two chirps, any position of sleep is acceptable. If the participant wakes and leaves the bed for any reason during the night the monitor should remain on the head and turned on. The Unicorder should only be removed and turned off after the participant wakes for the day.

## 7.7 Review of Alarms

The Unicorder chirps one (1) time when powered on and two (2) times when it begins to record data. In addition to this there are alerts to indicate when the unit needs adjustments during the recording. These need to be reviewed with the participant and included in the written instruction sheet.

A two (2) beep alert during the night indicates the head sensor is off place. For this, the participant needs to reposition the sleep monitor on the forehead, assuring the main sensor is flat and secure over the middle forehead. Three (3) beeps indicate the nasal cannula is off place. The participant needs to adjust the cannula tubes to the floor of the nares and may need to tighten

the slip tube. If any alert continues to sound after adjustments are made, or the Unicorder repeatedly sounds a four (4) beep alert, the participant should turn the Unicorder off and contact the site in the morning or at an after-hours emergency number provided by the site.

Otherwise, participants should be instructed to only remove and power off the monitor after rising for the day. Removing or powering off the monitor during the night may invalidate the study. It is important to collect at least 4 hours of data.

### 7.8 Instructions for Removal and Return of Equipment

The Technician should give the participant the Instruction Summary sheet (See Appendix 5) and a phone number and instructions on whom to contact if any alert sounds keep repeating and/or if they have questions. Remind participant to turn off the Unicorder after removal. Participant should be informed that in order to acquire accurate signals, the Unicorder may leave a mark on their forehead that usually disappears in a few hours and that this is normal. Indents on the cheeks from the cannula are also normal and should disappear in a few hours, as well.

After the participant has removed and turned the unit off, the entire unit, including the headband and cannula should be placed in the re-sealable bag and then into the black storage box. The time the Unicorder was turned on at night, and the time it was turned off in the morning should be noted on the Participant Instruction Summary sheet and it should be placed in the box with the Unicorder. The box should then be placed in the envelope provided and returned to the Field Site via the prearranged service. Sites should provide the participant with specific instructions and mailing supplies for retrieving the sleep monitor based on the use of a courier service or other means such as UPS or FedEx.

## 8. RECEIPT OF MONITOR, DOWNLOAD OF DATA, QUALITY REVIEW

Because the Unicorder was returned bagged with the used cannula it may have been exposed to viral, bacterial or tuberculosis organisms present in the mucous membranes of the user. To protect others coming in contact with the recorder, gloves must be worn when it is unpackaged, and the Unicorder must be cleaned and disinfected before downloading the study. After cleaning and disinfecting the recorder, the study should be downloaded promptly and unit plugged in for recharging using the Ziplinc Wall Battery Charger. Timely downloading provides the opportunity to ascertain that the study was successful; and if not, provides the opportunity to troubleshoot for any defective equipment prior to assigning the unit to the next participant. Immediate reformatting of the Unicorder and recharging of the battery allows for the monitor to be re-used for another participant.

### 8.1 Receipt of the Unicorder

When a package containing the returned Unicorder is received disposable gloves must be worn before unpacking and a work area suitable for cleaning and disinfecting the monitor should be prepared by opening and placing a clean disposable surface protector, such as a large paper towel or Chux under pad on the work surface. The surface protector must be large enough to hold the entire Unicorder and cannula. Have the canister of CaviWipes to provide intermediate-level disinfection and an appropriate trash receptacle ready.

## 8.2 Unpacking, Cleaning and Disinfecting the Unicorder

Open the package containing the monitor and accompanying paperwork. Remove the paperwork and set aside from the surface protector. Remove the plastic bag containing the Unicorder from the package, and then remove the Unicorder from the plastic bag. Discard the plastic bag and inspect the monitor and cannula for signs of damage in case the corresponding sleep study has poor quality. Check that the power switch has been turned off; if the monitor is on, turn it off. Check that the cannula is properly connected to the top of the recorder and the condition of the forehead oximeter sensor pad. Do not let the cannula hang loose during the inspection or other objects may become contaminated with any pathogens it may harbor. Continue to hold the Unicorder as you use scissors to cut both sides of the cannula tubing beneath the slip tube label and pull on the cannula to remove. Do not cut the tubing near the nasal prongs. Place the cut tubing onto one side of the protective work surface, keeping the other side of the surface clean.

## 8.3 Removing the Sensor Foam and Disinfecting the Enclosure Strap

Continue to hold the Unicorder in your hand, unsnap the clear plastic stabilizing strap and open the strap arms on each side of the recorder. Unsnap the headband at the adjuster strap. While performing this step ensure that the name on the headband matches the paperwork. Remove the headband from the recorder and place it on top of the cannula.

Gently lift the forehead sensor to gain access to the sensor foam. Pull downward on the sensor foam to peel it away from the underside of the sensor. Grasp the corners of the sensor foam and pinch slightly until the slit in the foam opens. Gently extract the sensor foam from the sensor foam cavity and discard. Clean the entire surface of the enclosure with a CaviWipe towelette. CAUTION: Pulling upward too hard on the forehead sensor when removing or replacing the sensor foam can cause permanent damage to the forehead sensor and/or Unicorder connector.

Grasp the corner of the black enclosure foam, remove and place it with the other disposables that have been removed. The Unicorder should now be simply the blue unit with the stabilizing straps and the sticky black forehead oximetry sensor. Be sure to treat the black forehead sensor gently, as it now is not stabilized and protected by the blue sensor foam. Set the unit down on the clean side of the surface protector; away from the used parts that have just been removed.

**Figure 8.3a Disinfecting Unicorder - Removing Sensor Foam**

Remove and discard your gloves; put on new gloves. Use the CaviWipe towelette to wipe the Unicorder. Wipe each side thoroughly, including all sides of the enclosure strap, stabilizing straps, Luer lock, on/off switch, forehead sensor and the entire body of the Unicorder. During this cleaning, turn the towelette frequently.

## 8.4 Cleaning the Forehead Sensor

Continue to thoroughly provide a second wipe of the Unicorder, including the forehead sensor with the CaviWipe. Ensure that all surfaces of the recorder, including the forehead sensor have been wiped. Excessive rubbing is not necessary and will reduce useful life of sensor.

To avoid damaging the sensor, do not rub it with your finger when the sensor is dry. The forehead sensor must be replaced after 60 nights of use or when the sensor surface becomes pitted or cracked.

After the Unicorder has been disinfected place it on its corresponding paperwork. Allow it to air-dry. Remove gloves, placing them with the dirty items on the protector. Placing your hands under the protector, gather or roll it up to enclose all the dirty disposable items. Discard into the appropriate trash receptacle. Before downloading the data, wash your hands and apply a blue sensor foam to the bottom of the forehead sensor.

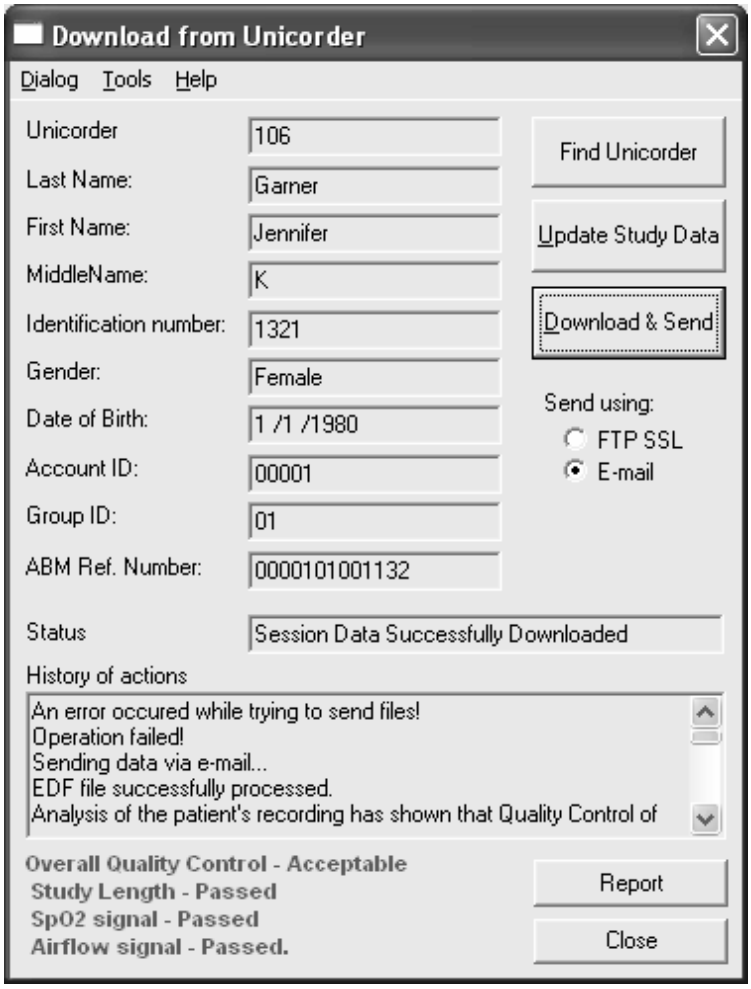
## 8.5 Download and Transmittal of Data to CSRC

Carry the Unicorder and its paperwork to the downloading computer. Connect the Unicorder to the ARES Cable and from the computer desktop open the **ARES Organizer**. Power the Unicorder on. Download and Transmittal involves three key functions. At download, a review of any quality messages will determine if the Unicorder can be prepared for re-use, or if trouble-shooting and/or unit testing will need to be done. After review of quality messages a data entry screen needs to be filled from the Sleep Log Data, including any comments regarding the quality review results. Finally, the **ARES Express** window will open and you will select **Sent to CSRC** after signing in to the FTP connection with your password. Click the "Download data from Unicorder" button and verify the participant information downloaded matches the label and paperwork.

## 8.6 Quality Review

When the Download data from Unicorder button is selected, verify the participant information downloaded matches the label and paperwork. During the download the software performs a preliminary quality review of the study. Quality problems identified at this stage will be noted in the dialog box labeled "**History of Actions**" (See Figure 8.6a - Download Screen). This will indicate whether or not the study should be flagged for troubleshooting before reuse. If quality codes indicate a need for review, the CSRC should be notified by email. Quality messages that display will include problems with key collection signals such as study length, airflow channel quality and valid SpO2 time..

Figure 8.6a Download Screen



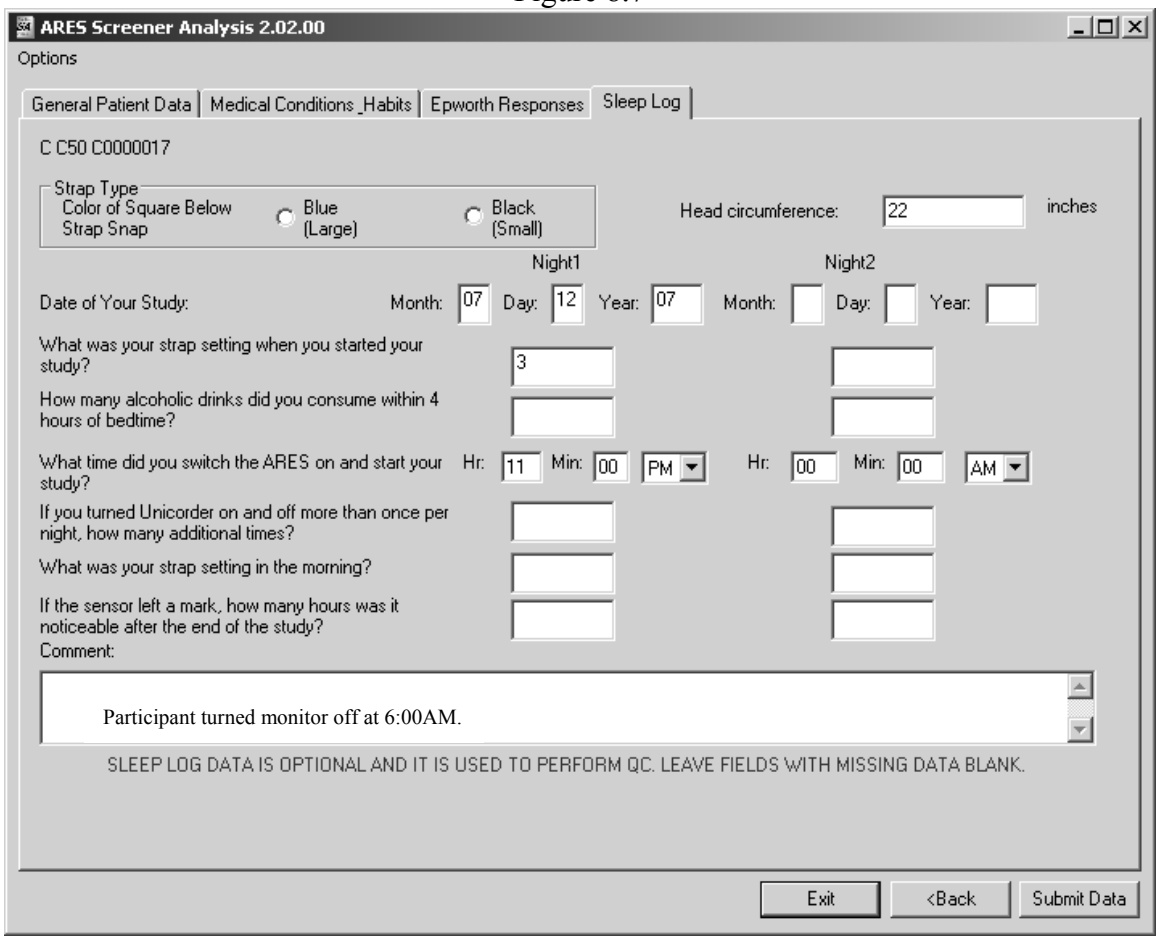

If any of these codes appear, check the recorder again for any signs of damage and indicate this or any other issues that were noted at the time of the receipt and cleaning. Include a note in the Sleep Log data entry screen regarding the quality issue and what, if anything, you were able to discover that caused the problem. Check for signs of damage to sensors. The CSRC will prioritize problem studies for troubleshooting review. Unicorders that have generated problem studies should not be re-used until what caused the quality code violation is identified. For example, if the participant indicates he shut off the unit early or never turned it on, it is most

likely that the problems were participant and not recorder-related. Any Unicorder with a failed recording must be tested before its next use in the field. *(See Appendix 8 – Calibration and Testing Equipment)* If no quality issues are identified at the download, monitor can be prepared for re-use and the battery recharged.

## 8.7 Data Entry Sleep Study Log Form and Download Notes

After download the next screen will ask for data entry of the information on the Sleep Study Log form. The only fields that need to be entered are Head Circumference, Date of Study, Strap Size Setting, and Start Time of Study. The Comment field should include study end time and notes to the CSRC regarding any quality issues noted at download that need to be communicated.

Figure 8.7




## 8.8 Transmit to CSRC

Transmittal of the studies to the CSRC will be done using the ARES Study Data Exchange System. This allows for your sleep study files and data to be uploaded to the CSRC FTP server over a secure SSL FTP server. On the "Send" screen that appears after the Data Entry is completed, make sure that FTP SSL is selected under Send Using. Click on Down Load and Send. The FTP server Login screen will pop up. Enter your user name and password and the Data is then uploaded to the appropriate folder at the CSRC for your site. Confirmation that all

has been received will be available for viewing at the CC website. Each site will receive the website address and specific login and passwords for site personnel to access the data available on the website.

## 9. PREPARING MONITOR FOR RE-USE

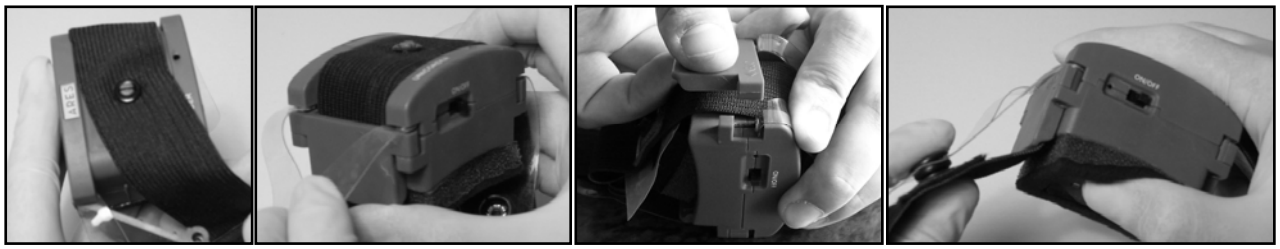
### 9.1 Replacing the Sensor Foam and Enclosure Foam

Peel the backing off the new piece of blue sensor foam. Lift the forehead sensor with one hand to gain access to the sensor foam cavity. Slip the sensor foam into the sensor foam cavity, sticky side facing the back of the sensor, allowing the sensor cable to slip through the slit in the foam. Make sure the foam fits correctly into the cavity and press it in to the back of the sensor. Peel the backing away from the new black enclosure foam and place the foam, sticky side down, to fit around the forehead sensor. The forehead sensor should be further protected by cutting a small sheet of plastic (use a fresh plastic bag) and placing this over the sticky forehead sensor.

### 9.2 Replacing the Head Strap

Completely unsnap the new head strap and make sure the numbers on the adjustment band are upright. Hold the Unicorder upright and snap the eyelet of the new strap onto the round connector in the center of the enclosure. Thread each strap end under the strap arms of the enclosure. The clips that hold the cannula tubing should be at the top of the strap. Snap the enclosure arms closed to hold the head band. Inspect each clear plastic stabilizing strap for any tears as you snap it to the headband. If any damage was noticeable, replace the plastic stabilizing straps before continuing. Stabilizing straps can be ordered from Advanced Brain Monitoring (See Appendix 3.)

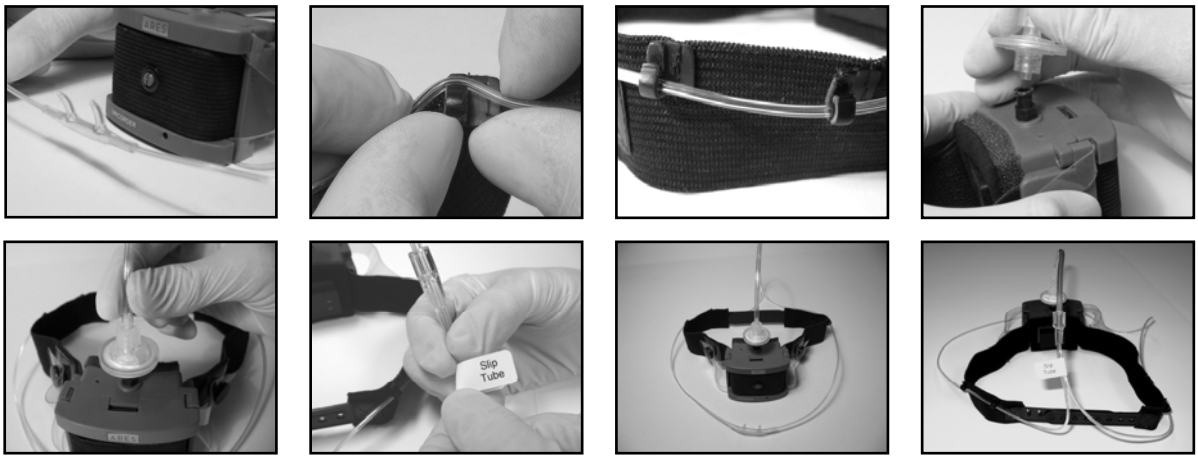
Figure 9.2



### 9.3 Replacing the Nasal Cannula

Place the Unicorder on a flat surface with the luer lock connector pointing upward. Place the two cannula tips in front of the Unicorder with the tips curving away from the device. Begin affixing the cannula tubing into the four cannula clips on the strap. Pull down slightly on the tubing on both sides of the clip until the tubing slides into the clip. Take care not to tear the cannula tubing. Attach the Nasal Cannula luer lock to the enclosure luer lock receptacle and rotate it clockwise until it stops. Check to be sure the Nasal Cannula luer lock is firmly seated in the lock receptacle. Affix the label to the cannula slip tube.

Figure 9.3




If the monitor has been uploaded with new participant information, place a participant label on the inside of the head band. If the monitor has not been uploaded and assigned to a participant it may be uploaded now, and the participant sticker placed.

After the monitor and paperwork has been made ready for the participant place the Unicorder into the reseal-able plastic bag and place into the carrying case. Include the participant paperwork, instruction sheet and make sure the case contains an alcohol swab. Slide a participant sticker under the window at the front of the case and snap the case closed securely until the participant demo.

### 9.4 Reformatting the Unicorder and Charging the Battery

Before reformatting the Unicorder verify that all data has been downloaded. Access the ARES Software and click on the Format Unicorder icon. Formatting takes approximately one minute. When the formatting is complete, click OK. At this point the Unicorder will need to be recharged. The Unicorder will not permit new data to be entered for the next participant if the battery is not fully charged. Allow up to 3 hours for the recharge, although this may be shorter depending on the length of power usage from the last use. If the last participant failed to turn the unit off resulting in a completely depleted battery the recharge will take 3 hours to complete.

To recharge the battery, plug the ARES cable into the Ziplinq wall charger, plug the Unicorder into the ARES cable, plug the wall charger into a standard outlet, and switch the Unicorder ON. The light on the ARES Cable box will turn on, and the flashes on the front of the Unicorder will follow a two flash per second pattern. When charging is complete, the light on the ARES Cable box will no longer be illuminated.

### 9.5 Sleep Study Data, Participant Feedback and Urgent Alert Identification

The site will receive the following information from the CSRC: 1) Quality Signals (including Pass/Fail status; 2) Urgent Alert Identification; 3) Participant/Physician Feedback. Copies of each are found in Appendix 2 and are detailed in section 11.

Data from any studies flagged as failed quality grades or noted to have marked drops in oxygen levels will receive priority scoring, with reports generated within 48 work hours of receipt at the CSRC. The CSRC Manager will contact the site by phone or email with information on possible equipment malfunction, participant acquisition problems (possibly requiring repeat studies), or urgent alerts (requiring timely feedback to the participant and/or the participants' physician). Reports for these studies will be emailed to the site.

All other studies will be triaged for complete scoring within 2 weeks. Study reports, including quality grades and information for participant feedback will be posted on a study web site.

**Quality Codes**
The performance of each technician, monitor and site will be reported on a monthly basis. Each study receives an overall study quality grade based on the artifact-free recording time that is present in the air flow (cannula) and saturation (SpO2) channels, which are considered key for scoring apneas and hypopneas.

**Urgent Alerts**
The site will receive email notification of any study that meets the following alert criteria: 1) AHI >50; 2) Oxygen saturation <90% for > 10% of Total Sleep Time; 3) Baseline oxygen saturation < 90%; or 4) Heart rate > 150 bpm for ≥ 2 minutes or < 30 bpm for ≥ 2 minutes.

Studies so identified will require timely feedback to the participant who should be advised to consult with their physician. A copy of the sleep record should be made available to such participants at the time they are notified of a possible sleep concern.

**General Feedback**
On a weekly basis, each site will receive copies of sleep reports amenable for use in feedback letters (See Appendix 2). In general, such reports will be made available within 2 weeks of the receipt of the sleep study at the CSRC.

## 10. Case Sleep Reading Center

### 10.1 Description and Role of Case Sleep Reading Center (CSRC)
The Case Sleep Reading Center (CSRC) will:

- Work with study investigators to select sleep monitoring devices and recording montage most appropriate for meeting the study goals.
- Develop a standardized protocol for data acquisition, processing, scoring, and urgent alert identification.
- Provide training for technicians, research assistants and study coordinators for four collection field sites, dedicated to sleep study acquisition, staff certification, and data transmission to CSRC.
- Provide ongoing technical feedback to study sites relative to acquisition of sleep data.
- Monitor the quality of submitted sleep studies; assign quality codes; report findings of study quality and performance to study investigators.

- Review and score sleep studies by certified scorers, following a standardized protocol.
- Establish routines for reporting results to the Coordinating Center and clinical sites. Monitor the quality of central reading and scoring.
- Generate electronic reports from scored records; prepare customized data files for data analysis; transmit these reports periodically to the DCC analysis center.
- Electronically archive all scored data
- Maintain a data dictionary relevant to polysomnographic variables.

## 10.2 Structure of Reading Center

The Case Sleep Reading Center (CSRC) will be directed by Susan Redline, MD, MPH. She will direct the activities of the CSRC Administrator, Quality Control Manager/Chief Polysomnologist, Sleep Study scorers, Data Manager, Systems Administrator and ultimately be responsible for all goals specified above.

***The Quality Control Manager/Chief Polysomnologist*** will be directly responsible for certification of scorers and central training of field research assistants. She will participate in the development of teaching materials for training and for procedures for certifying scorers and assuring high levels of accuracy and reproducibility of scoring procedures. She will monitor the performance of the scoring staff and field technicians, and provide support for interpreting ambiguous studies. She will prepare reports on scoring accuracy and reliability, assist in troubleshooting equipment problems, tracking study quality at various sites and scoring quality at the CSRC. She will implement on-going procedures for assuring accuracy and reproducibility of scored procedures. The Manager will triage studies for formal scoring to the scorers. She also plays a key role in developing, implementing and modifying procedures for managing the data from multicenter studies. She is responsible for tracking data flow from clinical sites to the Reading Center and then providing reports to the sites and the Coordinating Center.

***The Sleep Scorers*** will review each assigned sleep study record within 72 hours of its receipt at the CSRC, identifying Urgent Medical referrals, completing the quality assessment, and provide complete scoring and report generation following standardized rules. The scorer will participate in regular reliability exercises.

## 10.3 Certification of HCHS/SOL Sleep Scorers

Each scorer will be trained by the Chief Polysomnologist and demonstrate ability to recognize artifact and events on each channel. The scorer must demonstrate the independent ability to score apneas and hypopneas that agree to within 5% of the number of events scored by a reference standard. Maintenance of certification requires demonstration of levels of agreement of >95% relative to prior scoring and scores of other certified scorers.

## 10.4 Quality Control Sleep Scoring

A minimum of 1.5 hrs per week is dedicated for the scorers to participate in QA exercises, which include reviews of scoring rules and problem studies, and performance of scoring reliability exercises of records that are randomly chosen or selected to represent specific challenges. Disagreements between scorers in event designation are discussed until a “consensus”

designation is achieved. Levels of agreement among scorers and the consensus designation are tracked over time. Any scorer who systematically differs from the others over 3 consecutive weeks is further assessed for potential re-training. The results of the deliberations are documented, including copies of ambiguous records and summaries of arbitration. To track scoring reliability, monthly data from the actual scored research records (for any given study) are summarized and reported to the Coordinating Center, Steering Committee and relevant subcommittees (e.g. QA Subcommittee). Reports include summary statistics of key sleep parameters, calculated for each scorer over discrete time periods (monthly to quarterly). Intra- and inter-reader differences are also reviewed by the CSRC staff. If differences between scorers can not be explained or resolved, scorers noted to score differently score together, concentrating on the areas where differences were noted. Subsequent scoring is monitored until conformity is demonstrated, with determination of any need for re-training. Studies are also assigned to the same reader at defined time periods to define intra-reader reliability. As appropriate, the Coordinating Center monitors intra- and inter-reader reliability to determine further thresholds for requiring remediation, including retraining or removing a scorer, or implementation of a formal reliability study of within and between scorer reliability. Site visits to the CSRC, coordinated by the CC, occur as directed by the Steering Committee.

### 10.5 Assignment of Studies to Scorers

Studies identified as potentially problematic (based on preliminary quality checks) or containing medical alerts will be triaged for immediate scoring (within one working day). Assignment of alerts will be on a rotating basis so they are distributed among scorers equally. Weekly assignments of incoming studies will be made for each scorer to ensure equal distribution of site specific studies among the three designated scorers.

## 11. Scoring Procedures

### 11.1 Overview of Scoring

The ARES Insight software will be used to process and score the sleep recordings. The ASI file reduces a 25 MB EDF file to approximately a 4 MB ASI file. The Insight software does not allow technician editing of an EDF file. The ASI file must be used for editing of events detected the ARES algorithms.

Preliminary processing by the Insight Software takes approximately 4 minutes and during this time the SpO2 and pulse rate are computed from the optical signals, events are detected across all signals and the data are compressed and saved in the ASI file.

During scoring, respiratory "events" or breathing pauses are identified by the scorer. To be classified as a respiratory event, there must be at least 50% reduction in the Nasal Flow signal for at least 10 seconds.

The study is reviewed in 2 or 5 minute pages to assess any respiratory events. Events that are at least 10 seconds in duration are to be marked as respiratory events with their appropriate level of desaturation.

Computer analysis will link data from varying channels to identify desaturation levels and permit the calculation of traditional measures of the Apnea Hypopnea Index (AHI). For primary analyses and participant feedback, the primary AHI (Apnea/Hypopnea Index) will be defined as the total number of all respiratory events with $\geq$ 3% desaturation (AASM 2007 criteria). In addition, analyses for secondary analyses will include the AHI calculated using various thresholds for corroborative desaturation ( 0 to 5%), indices of time in desaturation, and indices derived using the Insight software which provides novel indices which combine SpO2 desaturation events with changes in airflow and other arousal indicators to derive a hierarchy of respiratory events. These provide summary measures that utilize desaturation dips relative to baseline, and factor in confidence ratings that any given event is an obstructive event (based on airflow and snoring).

### 11.2 Summary of Scoring Process

During the first pass, the scorer will review the overall pattern in the data across the night's recording, and will review the ARES generated quality reports for potential signal problems that may have been identified during processing. The scorer will note the duration of sleep period and document if the study is less than 4 hours which will result in a failure of the study. During the second pass, respiratory events will be manually scored.

Finally, a QS (Quality of Signal) form will be filled out indicating unusual patterns and signal/study quality grades and a Feedback Sleep Report will be generated (See Appendix 2). Reports will be available for viewing on the CC website. The raw and scored files and summary reports will be saved to the CSRC network drive and backed up on a nightly basis.

### 11.3 Lights Out and Lights On; Sleep Onset and Offset

Lights Out and Lights On will be documented based on data provided on the participant's Sleep Log. If the Sleep Log is not available, then Lights On and Lights Off will correspond to the times the scorer estimated corresponded to Sleep Onset and Sleep Offset.

Sleep Onset will be defined as a time after Lights Off when head movements are first absent for 5 minutes, and heart rate and breathing patterns appear to be lower or more regular than the initial wake monitoring.

Sleep Offset will be defined as a time at or after Lights On, when movement and heart rate increase, motion artifact increases, or the study stops recording.

### 11.4 Sleep Duration and Quality of Signals

Each signal will be reviewed for quality and a quality grade will be assigned for each channel that gauges the duration of artifact free data (See Appendix 2). Any questionable or absent signal will be noted in the quality report. An overall study quality grade is also assigned that reflect the absolute duration of artifact free signals for the two primary signals: nasal pressure and oxygen saturation.

### 11.5 Urgent Alert Categories

Urgent alerts from the Unicorder recording are defined as: 1) RDI/AHI >50; 2) Oxygen saturation <90% for > 10% of Total Sleep Time; 30 Baseline Saturation < 90%; or 4) Heart rate > 150 bpm for ≥ 2 minutes or < 30 bpm for ≥ 2 minutes.

A physician investigator will be asked to review the study and if after scoring it meets the alert criteria it will be logged in the Scoring Alert Log and an e-mail sent to the designate site personnel with a copy to the Coordinating Center.

### 11.6 Reporting

Study data will be transmitted to the CC and a report will be generated and posted to the website for each sleep study. AHI, oximetery statistics and sleep time will be reported. (See Summary of Sleep Study Results in Appendix 2.)

## 12. Data Management

### 12.1 Study Receipt

The Case Sleep Reading Center (CSRC) upon receipt of the studies via the ARES Study Data Exchange System will generate summary data of all receipts on a weekly basis and distribute to the appropriate staff at each site either via e-mail or by posting on the CSRC website.The Receipt information includes: Subject ID, Study Date, date received, Unicorder ID, and Technician ID. If there is a discrepancy regarding the ID or any missing data an e-mail will be sent to the designated Site Coordinator requesting clarification. Sites also have the responsibility to review the Receipt Summaries and notify CSRC if any data is incorrect or missing.

CSRC tracks all problems. The problem studies are monitored and if any pattern is observed study wide we will contact ARES to assist in resolving.

### 12.2 Preliminary Review

The ARES Insight software will be used to provide an initial overview of study quality. During initial review, the scorer will note any signal quality issues, possible monitor malfunctions, and recommendations for replacements in the Quality database. The feedback on all studies submitted will be available on the website for viewing by the site as soon as they are completed. If any situation warrants urgent feedback the Study Administrator will e-mail the designated Site Coordinator.

The record must contain at least 4 hours of useable artifact free data during sleep period. Artifact free requires that all key signals be classified as reliable sleep data. Studies containing less than the minimal requirements will not be processed for scoring and the site will be notified to request a repeat study from the participant if feasible. Studies that do not meet minimal requirements will not be archived at the CSRC.

### 12.3 Assignment of Urgent Referrals to Scorers

Studies identified as potential urgent referrals will be triaged for immediate full scoring (within 48 hours of assignment to the scorer). Once fully scored and determined to meet criteria for

Urgent Referral, a physician investigator will be asked to review the study. If an Urgent Referral is ascertained, it will be logged into an Urgent Referral Log and the site will receive the full report and quality grades (Quality Report) within a week after final scoring is completed.

### 12.4 Quality Grades

The overall study quality will be assessed at the time of scoring of the record. The Scorer will code each channel of information according to the duration of i) scorable signals; ii) duration of artifact free signals during sleep, and iii) an overall QA grade to each study. Scoring notes regarding event identification and specific physiological signal issues are also recorded on the QS form. The Quality Report will be available for viewing and downloading on the CC website.

### 12.5 Scored Sleep Data

After full scoring, the scorer will generate:

The Summary of Sleep Study Results that contains summary data. Data in the report will include the AHI (the number of apneas and hypopneas per hour of the sleep associated with a desaturation) and a summary of the desaturation profile. A sample of the Summary of Sleep Study Results is in Appendix 2. This report will also be available on the Site specific website for viewing and downloading.

A SAS report containing all ARES generated sleep variables together with the Quality Report data containing all quality grades and scoring notes will be generated for each study.

The Summary Sleep Data Reports and Quality Reports are posted generally within 2 weeks of receipt of the sleep study at the CSRC. Urgent Alert sleep and quality reports will be sent to the site via e-mail as soon as they are processed, and will also be posted.

After QS data has been entered and reports are posted to the website, the complete study files containing the raw data sleep file, scored files, sleep study report, and the SAS reports are placed in site specific directories for the creation of data backup. Two copies of scored data will be retained at the CS RC (one copy will be stored at an off site location). One copy will be sent to the Coordinating Center on a weekly basis along with a SAS file containing the data collected to date.

# Appendix 1 - Logs

## Sleep Study Log
## ARES Tracking Log
## ARES Maintenance Log

# Sleep Study Log

Participant ID _____ Date of Study _____

Tech ID _____

Head Circumference: _____

Strap Setting: _____

| HEAD SIZE | | Universal Strap Setting |
|---|---|---|
| inches | cm | |
| <21.5 | <55 | 0 |
| 21.5 | 55 | 1 |
| 22 | 56 | 3 |
| 22.5 | 57 | 5 |
| 23 | 58 | 7 |
| 23.5 | 59.5 | 9 |
| >24 | 61 | 10 |

What time was the Sleep Monitor turned On to start the study? _____ (Hour/Min)

What time was the Sleep Monitor removed and turned Off? _____ (Hour/Min)

Did the participant experience any problems while wearing the Sleep Monitor?

# ARES Unicorder Tracking Log

**Unit#: 152**

| Test # | Participant ID | Tech ID | Date Dispensed | Date Returned | Study Quality | | Data to CSRC | Comments |
|---|---|---|---|---|---|---|---|---|
| | | | | | Acceptable | Questionable | | |
| 1 | B0000019 | B14 | 9/10/2007 | 9/12/2007 | x | | 9/13/2007 | |
| 2 | B0000027 | B02 | 9/15/2007 | 9/16/2007 | x | | 9/16/2007 | |
| 3 | B0000035 | B14 | 9/18/2007 | 9/20/2007 | x | | 9/20/2007 | |
| 4 | B0000042 | B09 | 9/23/2007 | 9/25/2007 | | x | 9/26/2007 | Poor SpO2. Unit Tested - See Maintenance Log. |
| 5 | B0000057 | B01 | 10/1/2007 | 10/3/2007 | x | | 10/3/2007 | |
| 6 | | | | | | | | |
| 7 | | | | | | | | |
| 8 | | | | | | | | |
| 9 | | | | | | | | |
| 10 | | | | | | | | |
| 11 | | | | | | | | |
| 14 | | | | | | | | |
| * | | | | | | | | |
| * | | | | | | | | |
| * | | | | | | | | |
| 48 | | | | | | | | |
| 49 | | | | | | | | |
| 50 | | | | | | | | |
| ****PERFORM ROUTINE TESTING OF UNIT**** | | | | | | | | See Maintenance Log - 12/15/07 |
| 51 | | | | | | | | |
| 52 | | | | | | | | |
| 53 | | | | | | | | |

ARES Tracking Log


# ARES Unicorder Maintenance Log

**Unit #: 152**

| Date | Tech ID | Reason for Maintenance | | Type of Maintenance | | Comments |
|---|---|---|---|---|---|---|
| | | Routine *50 use/6 mo* | Troubleshooting *damage/malfunction* | In-House Test *with test rig* | Sent to ABM | |
| 9/22/2007 | 125 | x | | x | | Passed testing. Prepared for reuse. |
| 10/12/2007 | 132 | | x | x | | Poor Oximetry quality. Failed Reflectance. |
| 10/13/2007 | 132 | | x | | x | Repaired unit returned from ABM 10/20/07. |
| | | | | | | |
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# Appendix 2 - Reports

## Quality/Urgent Referral Report
## Physician/Participant Feedback Report

# Site Feedback
# Sleep Study Quality and Urgent Referral Report

| ID NUMBER: | | | | | | | | | STUDY YEAR | 1 8 | SEQ # | 0 0 | 11/XX/04 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|

Participant ID: _____
Study Date: _____
Monitor #: _____
Tech ID: _____

**SIGNAL QUALITY**

| | Hours Recording Time | Hours Artifact-Free Recording Time |
|---|---|---|
| Nasal Cannula | | |
| Oxygen Saturation | | |

**OVERALL STUDY QUALITY**

| | |
|---|---|
| ☐ 4 | EXCELLENT – Both cannula and saturation artifact free for > 4 hrs. |
| ☐ 3 | GOOD – Saturation artifact-free for >= 4 hrs; cannula artifact free for >= 3 and < 4hrs. |
| ☐ 2 | FAIR – Saturation artifact-free for >= 4 hrs; cannula artifact free for >= 2 and < 3hrs. |
| ☐ 1 | POOR – Saturation artifact-free for >= 4 hrs; cannula artifact free for <2 hrs. |
| ☐ 0 | FAIL – Saturation artifact-free for < 4 hrs. |

| **URGENT REFERRALS** | N | Y |
|---|---|---|
| AHI > 50 | ☐ | ☐ |
| Baseline Oxygen Saturation <90% | ☐ | ☐ |
| Oxygen Saturation < 90% for > 10% of recording | ☐ | ☐ |
| Heart rate > 150 bpm > 2 minutes | ☐ | ☐ |
| Heart rate < 30 bpm for > 2 minutes | ☐ | ☐ |

***For urgent referrals, complete Urgent Notification Form.***

Comments:

_____
_____
_____
_____

| ID NUMBER: | | | | | | | | | STUDY YEAR | 1 8 | SEQ # | 0 0 | 11/XX/04 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|

# Summary of Sleep Study Results
# For HCHS/SOL Participants and their Physicians

Participant's name: _____ Birth date: _____/_____/____

Date of visit to the HCHS/SOL center: _____/_____/_____

**SLEEP APNEA STUDY RESULTS**

As part of the HCHS/SOL examination, you underwent an overnight sleep apnea screening study. In this study, your breathing, oxygen levels, head position, and snoring level were measured using a portable recorder. Please note that the study performed was for research purposes and not for diagnostic reasons. Therefore, you and your doctor should use this information to point out areas that may require further evaluation. Also, regardless of the results of the sleep study, if you regularly experience poor sleep or daytime sleepiness, you should discuss these findings with your doctor.

***The results of research sleep studies include:***

**Total Recording Time:** This is the total time that information was collected on your sleep and breathing patterns. Generally, recording times of at least 4 hours are needed to make sure the information that was collected is reliable.

**Oxygen Saturation Levels ($SpO_2$):** The monitor on your forehead contained an oximeter, which uses light rays to measure the amount of oxygen in your blood. Oxygen levels are one indicator of general health, and low levels may indicate problems with the heart, lungs, or of breathing problems occurring at night. Normal oxygen levels are usually >92%.

**Number of Breathing Pauses During Sleep (AHI):** The Apnea/Hypopnea Index (AHI) is the average number of breathing pauses per hour of estimated sleep time. A pause is when breathing becomes shallow or breathing stops for 10 seconds or longer. A high number of breathing pauses may indicate a condition called ***"sleep apnea,"*** in which breathing pauses disrupt sleep, and may be associated

with loud snoring, daytime sleepiness or tiredness, as well as increase risk for high blood pressure and heart disease. When breathing stops, oxygen levels may drop for a short time.

***The results of your research sleep study showed:***

| | Your Results | Interpretation |
|---|---|---|
| Total Recording Time | | If **less than 4 hours**, the information collected may need to be repeated on another night to make sure this information provided a good estimate of your usual breathing at night. |
| Baseline Oxygen ($SpO_2$) | | Baseline Oxygen level **less than 90%** is considered low and indicate a need to check with your doctor. |
| Percentage of time with a low oxygen level (% sleep time with SpO2 < 90%) | | Spending **more than 10%** of time at a low oxygen level is considered low and indicate a need to check with your doctor. |
| Lowest Oxygen During Sleep | | Generally, oxygen levels should stay above 90% during sleep. If they fall **below 90%**, this may be because of sleep apnea or another breathing problem. Values below 90% indicate a need to check with your doctor. |
| Apnea / Hypopnea Index (AHI) | | An AHI of less than 5 is considered normal.<br>An AHI of 5-15 is considered mildly increased.<br>An AHI of 16-30 is considered high.<br>An AHI of 31 and higher is considered very high.<br>If your AHI is **above 5** or if you experience poor quality sleep or daytime sleepiness (regardless of your AHI level), we suggest you speak with your doctor. |

# Appendix 3 – Unicorder Supplies

## ARES Disposables/Replacement Parts Order Form
## Additional Supplies

**ARES Disposables/Replacement Parts Order Form**


Shipping Address

Billing Address

Purchase Order #

# ARES Price list for Hispanic Community Health Study

| Part # | Description | Order quantity | Price per unit | Quantity Ordered |
|---|---|---|---|---|
| AD-17 | ARES study kit - 30 studies – includes all disposables, 1 battery and 1 forehead sensor will be provided with every two kits. | 30 / kit | $ 510 | |
| 1090 | Stabilizing straps - 5 series ** | pair | NC | |
| 1080-3 | Strap arms - 5 series | pair | NC | |
| 1180-4 | Hex screws | 12 / pack | NC | |
| Extra-ordinary items that may be required on a limited basis | | | | |
| 1140 | Data cable - 48" * | each | $ 75 | |
| 1141 | Fast charging cable - 15" * | each | $ 75 | |
| 1070 | Forehead sensor ** | each | $ 100 | |
| ZL1205 | Zip-Linq AC to 5V USB Adapter * | each | $ 9 | |
| 1060 | NiMH Rechargable Battery - 5 series ** | each | $ 6 | |
| 1170 | Hex screwdriver | each | $ 10 | |
| 1160 | Functional test rig | each | $ 225 | |
| 1150-1 | Shipping box - black plastic | each | $ 15 | |

Shipping: FOB Carlsbad

Terms: Net 15 days

FAX orders to 760.720.3337

2237 Faraday Ave., Suite 100
Carlsbad, CA 92008
Tel: (760) 720-0099 Fax: (760) 476-3620
Email: info@b-alert.com Website: http:/ / www.b-alert.com

# List of Additional Supplies Needed for HCHS/SOL Sleep

Check with your hospital to see if these are available. Most items are standard stock-room items with better pricing due to contract ordering. If not available via hospital storeroom they are carried by vendors such as MVAP, NSI, ElectraMed, or directly from the manufacturer.

| SUPPLY ITEM | Needed per PPT | Amount for 30 PPTs |
|---|---|---|
| **Caviwipes XL Disinfecting Towelettes**<br>(manufactured by Metrex Research Corp<br>Provides intermediate-level disinfection after unit is returned | 1 wipe per unit being cleaned | 30 wipes |
| **Moisture Resistant Underpads**<br>(i.e.: "Chux") Used during disinfection procedure after unit is returned | 1 per unit being cleaned | 30 underpads |
| **Latex-free exam gloves**<br>(non-sterile) Used during disinfection procedure after unit is returned | 4 gloves per unit being cleaned | 120 gloves |
| **Medical Tape Measure**<br>Disposable (paper) tape measure or reusable tape measure that wiped with alcohol between participants. Used to properly fit the Sleep recorder | 1 per ppt if disposable/ 1 per tech if reusable | 30 paper tapes, if disposable/ 1 per tech if reusable |
| **Alcohol Wipes**<br>Included in case when unit is dispensed to participant. Also may be used to wipe tape measure | Allow 2 per ppt | 60 wipes |
| **Hand Mirror**<br>Used during initial instruction before dispensing unit. This item should remain in the clinic. | Allow 1 per tech | 1 per tech |
| **Re-closable plastic bags** (i.e.: "Ziplock" or "Glad" half-gallon or larger in size). Used monitor and cannula will be placed in the bag and returned to collection site. Bag to be discarded during cleaning. | 1 bag per unit being dispensed | 30 bags |
| **Participant Labels**<br>Pre-written ID labels will be placed on recorder headband, recorder case, ppt diary and tech form | Allow 4 labels per ppt | 120 labels |

## Appendix 4 – Dispensing Script

### Study Explanation

Sleep Apnea is a condition characterized by repeated breathing pauses occurring in sleep, occurring between 5 to as many as 100 times per hour. Most people with sleep apnea snore and some make gasping or snorting noises during sleep. Because sleep is interrupted by these breathing pauses, many people with sleep apnea may feel as though their sleep did not refresh them, and they may feel sleepy or tired during the day. Also, oxygen levels may drop when a breathing pause occurs, and drops in oxygen levels may cause stresses on the body's normal functions. Because of this, sleep apnea may increase a person's risk for high blood pressure, heart disease and diabetes. A major goal of HCHS/SOL is to understand risk factors for high blood pressure, heart disease, diabetes and other health problems. Therefore, as part of this study, we would like you to wear a small device to sleep while at home that will measure your breathing, snoring and oxygen levels during sleep, which are indicators of your risk for sleep apnea.

### Demonstrating the Unicorder.

The device is called the ARES Unicorder. It is worn on your head while you are sleeping. The recorder is fairly light weight, so it will feel like you are wearing a cap or hat to bed.

This is what the unit looks like. **(*Show participant the unit.)*** The main part of the recorder rests on your forehead, and the strap goes around your head. There are plastic tips that are gently placed into your nose measure breathing. The recorder also measures snoring sounds, head movements, and oxygen levels (this is done by the use of modern technology where a light from the device is shown onto the forehead skin and can this light reflected back to the device can estimate oxygen in your body.) There are no needles, glue, or anything that needs to be worn in other places on your body.

### Measuring/Fitting the Unicorder

I will measure your head first to determine the strap size that fits you the best. It is important that the strap fit around your head firmly, but not be uncomfortable. We want things to be comfortable enough so you can wear this AND get your typical night's sleep.

***(If participant hair is long)*** It is usually recommended that you wear your hair up during recording to prevent the Unicorder from slipping down during the night. Will you be wearing your hair up for the study? ***(If so)*** Can you hold your hair up for me, so I can get an accurate measurement?

***(Measure the circumference of the participant's head. Enter the measurement on the Sleep Log Form and look up the proper setting in Strap Setting Chart. )***

Your initial strap setting should be X. ***(Show participant how the holes on the Unicorder strap should line up and MARK this with a marker.)*** If this setting at any point in the study feels uncomfortably tight, you can loosen it one notch. Or, if it should feel too loose so that it is slipping on your forehead, you can tighten it one notch.

## Putting on the Unicorder

The Unicorder should be placed on your head about 15 minutes before bedtime. Before putting the Unicorder on, it is important to wash and dry your forehead where the sensor will be resting and wipe it thoroughly with an alcohol wipe we will give you.

***(If an extra unit is available, tech should demonstrate on self as well as walking the participant through the following steps.)***

To position the Unicorder, hold the plastic tube tips against the on/off label at the bottom of the unit. With the strap set at the correct setting, slide the strap around your head and remove any hair from under the forehead box. Center the Unicorder sensor over your nose and slightly above your eyebrows on the flattest part of your forehead, so the entire forehead box touches your skin.

Place the two plastic tips in your nose and pull the tubing at the back of your head until it is snug. Grasp the slip tube label at the back of your head and slide it downward until the cannula is snug and in place. To test the cannula for correct tightness, try and pull the tips away from your nose. If they barely move, it should mean the fit is good. If they come out of the nose, readjust the slip tube to make it tighter. Remember, it is important that the plastic tubing tightens at the back of your head to keep the cannula from slipping during the night.

## Starting the Sleep Study

Once the Unicorder is properly positioned and you are ready for bed, turn off the TV or radio. (Noise in the room will interfere with the recorders microphone that measures snoring sounds.) .

With the switch at the bottom of the unit, turn on the Unicorder. ***(Show participant on the demo unit.)*** You will hear one chirp. This lets you know the unit is on. Once the unit is on, it is important that you not turn it off during the night. If you need to get out of bed during the night for any reason, leave the unit on. Do not turn the unit off for any reason during the night.

Next, lie flat on your back as still as possible until the Unicorder chirps twice. This usually takes between 30 seconds and two minutes. When you hear the two chirps, it means that the Unicorder is ready to begin collecting information. It will not record if this step is not completed. After you hear the two chirps, you can lie in any position that is comfortable.

## Special Alerts

If you should hear a two beep alert at any time during the night after the Unicorder has begun recording, it means the Unicorder needs to be adjusted on your forehead. Move it slightly, so the sensor is in full contact with the flattest part of your forehead. If necessary, tighten the strap one position smaller.

If you should hear a three beep alert during the night, it means the cannula is too loose. Readjust the cannula in your nose, and tighten the slip tube at the back of your head.

If you should hear a four beep alert, it means that there may be a problem with the unit. Remove the unit, turn it off and notify the site in the morning.

Otherwise, do not turn off the unit or take it off during the night.

## In the Morning

When you wake up in the morning, turn the Unicorder off. Remove the Unicorder and put it in the plastic bag, being careful not to damage the forehead box. Put the unit back in the supply box, along with all the other supplies that you were given. Note the time you went to sleep and woke up in the Sleep Log and put that in the supply box with the recorder, as well.

## Common questions and answers:

1. Can I get the device wet?
    a. No. It is important not to get the device wet. Do not use it in the shower and be careful it does not fall into the sink.

2. Is there any danger to using the device?
    a. It is run by a battery and there is no chance it will cause any electrical problem. However, the place where the box sits on your forehead can cause some mild redness of the skin. If this should happen, the red mark usually goes away within a day after the study.

3. What information will I get? Will you diagnose my insomnia? Will you diagnose me with sleep apnea?
    a. Insomnia is a condition where people have trouble getting to sleep, wake up too early, or wake up a lot during the night. It can be caused by a number of different problems. If you have these symptoms and feel as though your sleep is not refreshing or you have daytime sleepiness, you should speak to your doctor. This test will tell you if you are at high risk for sleep apnea, but will not tell you about other reasons for poor sleep.
    b. This test is called a screening test for sleep apnea. It does measure the most important aspects of sleep apnea- breathing pattern and oxygen levels. However,

usually to make a definite diagnosis of sleep apnea, you will need to talk to your doctor. We can arrange to have your doctor get the results of this test. Your doctor will then decide whether to arrange for further testing, such as spending the night in a sleep laboratory.

c. The staff here and I are not trained to make any diagnoses. We are trained to collect accurate research information which will help us understand health patterns in the Hispanic community. However, we will work with study doctors and investigators to make sure you, and if you wish, your doctor, receives information that will be helpful in your health care.

4. Will I need to repeat the study?
    a. We need to get at least 4 hours of information from your sleep time to provide a report that is reliable. If something goes wrong and we do not get this information, we may ask you to wear this on another night.

5. What if I forget or cannot use the monitor tonight?
    a. Please let me know and we can see what is the best night for you to use this.

6. How do I return the device?
    a. ---NOTE: This will be customized at each site, re couriers, mailers, etc.

## Appendix 5 – Summary Sheets

Technician Summary Sheet for Sleep Recorders
ARES Order Processing Flowchart
Participant Instructions Summary Sheet
Participant ID – Naming Convention

## Technician Summary Sheet for the Sleep Recorder

1. **Prepare the Sleep Recorder and case:**
    - Replace foam components on the Unicorder
    - Replace the head strap
    - Interface nasal cannula. Make sure prongs will curve downwards when unit is applied.
    - Access ARES organizer: Upload participant information
    - Attach participant labels to headband, recorder case, paperwork.
    - Prepare the carrying case: alcohol wipe, skin tape, plastic bag, instruction sheet, return mailer, if appropriate

2. **Instruct the Participant:**
    - Measure head circumference, set and mark strap setting,
    - Demonstrate the unit and obtain a return demonstration for application, on/off, instruction sheet and writing bedtime.

3. **Dispense the Unit and Log Monitor out**.

4. **Receive Returned Unit**
    - Prepare area to disinfect unit. Unpack items while wearing gloves, separate paperwork from recorder, verify the sleep monitor to paperwork.
    - Visually inspect unit, discard replaceable foam items and headstrap, disinfect unit.
    - Re-match the recorder to correct paperwork
    - Log Monitor in

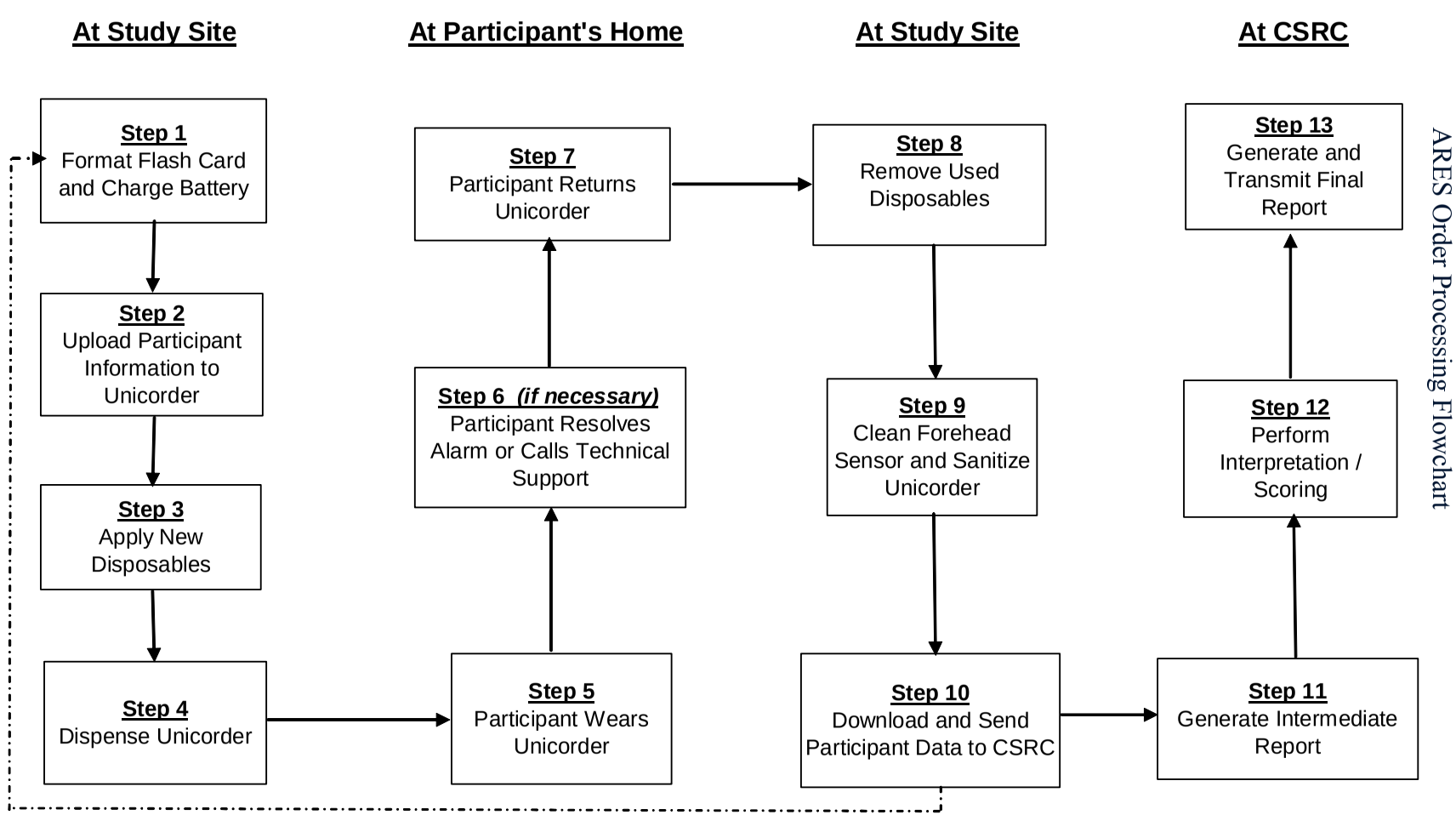
5. **Download Sleep Study**
    - Open Ares Organizer
    - Verify the Participant ID
    - Download and transmit the sleep file, check for quality codes
    - E-mail CSRC for any quality codes at download

6. **Reformat the Recorder**

7. **Recharge the Battery**

8. **Perform testing every 50 studies or if a QC flag appears at download.**

# ARES
# ORDER PROCESSING WORKFLOW




ARES Order Processing Flowchart

## Instruction Summary for Sleep Recorder

1. Clean your forehead with an alcohol wipe.

2. If there is a plastic covering on the black sticky forehead sensor of the recorder remove it.

3. Wipe the forehead sensor with an alcohol wipe.

4. Hold the cannula tips (2 short prongs extending from clear plastic tubing) against the on/off label on the bottom of the Unicorder with your thumb. ***(See photo - #1)***

5. Place the recorder on your head so the tubing faces up over your forehead and the power switch is facing down above your eyebrows. The recorder box should be in the middle of your forehead. ***(See photo - #2)***

6. Place the tips of the cannula just inside of your nose.

7. Grasp the cannula with one hand and pull it away from the back of your head until it is snug. ***(See photo - #3)***

8. Reach behind your head for the slip tube. Tighten the slip tube gently until it meets the back of your head. Do not make it too tight. ***(See photo - #4)***

9. Place a small piece of skin tape over the tube on each side of your face. This helps hold the cannula in place if you move your head on the pillow.

10. Try to pull the cannula tips away from your nose. If the tips barely move, the slip tube is correctly tightened. ***(See photo - #5)***

11. Turn the recorder on by the switch above your eyebrows. You should hear it "chirp."

12. Keep your head still while the recorder calibrates. This can take up to 30 seconds. When you hear the unit chirp twice, you may take your pillow and lie as you usually do for sleep.

13. Remember the time you go to bed and wake up next morning. Write the times on this form below.

14. In the morning, remove the recorder from your head. Turn the unit off. Place it in the plastic bag and seal the bag.

15. Write down the times you went to bed and woke up.

16. Return the unit.

**I turned the unit on and went to bed at: _____**

**I woke up and turned the unit off at: _____**


**Photo - #1**

**Photo - #2**

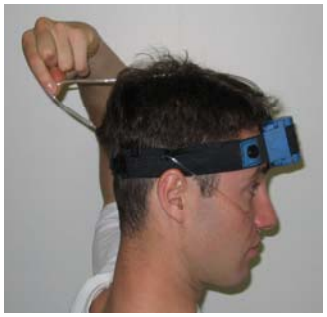


**Photo - #3**

**Photo - #4**

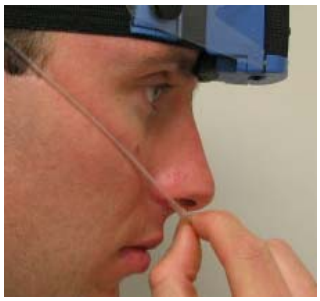


**Photo - #5**

## SLEEP RECORDER ALERT GUIDE

| | Alert | Green Light | Repeats Every | Indication |
|---|---|---|---|---|
| Start-up | 1 chirp | Fast blink | - | Calibration started. |
| | 2 chirps | No blink | - | Calibration ended, recording started. |
| During night | 2 chirps | 2 blinks | 1 second | Adjust/tighten Unicorder on forehead. |
| | 3 chirps | 3 blinks | 1 second | Adjust/tighten cannula in nose. |
| | 1 chirp | 1 blink | 3 seconds | Battery not charged. |
| | 4 chirps | 4 blinks | 3 seconds | Service needed. Turn off/remove unit. |

# Naming convention for assigning Participant ID

## In Create and Upload Screen:

**Site ID *(put in First Name field)***

B = Bronx
C = Chicago
M = Miami
S = San Diego

**Tech ID *(put in Middle Name field)***

Three digits to be assigned to technicians by study sites.

**Participant ID *(put in Last Name field)***

8 character ID in the following format – SNNNNNNC

S = Site ID
NNNNNN = Sequential 6 digit numeric beginning with 000001
C = check digit based on preceding sequential number

***Note: Participant ID is assigned by the Coordinating Center.***

## Appendix 6 - Certification Packet

Field Site Technician Training and Certification Process

At Site Sleep Technician Training Checklist

Sleep Technician Certification Exam

Sleep Tech Practical Exam

## Field Site Technician Training and Certification Process

If not in attendance at Central Training, to obtain certification for sleep data collection the following must be met:

1. Training under the close supervision of a centrally trained sleep technician. Submission of an At-Site Training Checklist signed off by the trainee as well as the overseeing certified technician.

2. Submission of a written exam.

3. Submission of 1 acceptable overnight (non-subject) sleep recording performed at the field site. To be considered acceptable for certification the sleep recording must:
   - Have good quality signal on each channel (i.e.: all sensors must work) and signals must be relatively free from artifact.
   - Have correct study identification as a certification recording
   - The electronic recording file must be accompanied with paperwork that matches this naming convention and additionally includes the technician identification.
   - The performance of the download must result in successful data transmission to the CSRC

4. Submission of the Practical Observation evaluated by a certified sleep tech that attended central training.

5. Certification for the Sleep Technician will remain effective unless the quality grades for more than 85% of monthly data submissions for that technician are less than "good." Technicians who fall below this quality standard (determined by CSRC) must re-train and re-certify by accomplishing steps 1, 3 and 4 above.

Name:_____
Site:_____
Date:_____

# At Site Sleep Technician Training Checklist

Topics to be covered during at site training for additional sleep technicians by a centrally trained and certified HCHS/SOL sleep technician. Please indicate date subject was presented followed by instructor and trainee initials. When training is complete, send this form to CSRC (attn: Nancy Scott) as part of the certification packet.

| Topic | Date | Instructor | Trainee |
|---|---|---|---|
| Introduction to the HCHS/SOL Study<br>• Objective of Study<br>• Study duration, number of field sites, participant size, inclusion criteria. | _____ | _____ | _____ |
| Sleep Data as part of HCHS/SOL<br>• Restless Leg Syndrome<br>• Usual length of sleep<br>• Napping<br>• Sleep Disordered Breathing (apnea/hypopnea)<br>• Changes in Blood Oxygen levels resulting from apnea/ hypopnea<br>• Apnea/ hypopnea as risk factor in hypertension, diabetes, cardiovascular disease | _____ | _____ | _____ |
| The Unicorder sleep monitor<br>• Types of data recorded<br>• Interfacing the nasal cannula to the Unicorder<br>• Turning the unit on/off<br>• Understanding and completing the monitor log | _____ | _____ | _____ |
| Instructing the participant:<br>• Measuring head circumference and fitting the sleep monitor<br>• Demonstrating the unit to the participant, including return demonstration<br>• Instructing the participant in risk of temporary mark on forehead from forehead sensor<br>• Instructing participant how to return the monitor<br>• Logging the monitor out (monitor log)<br>Instructing participant on how to complete forms | _____ | _____ | _____ |

Receiving the returned sleep monitor

- Possible infective organisms that may be carried on the used monitor
- Preparing a suitable area for un-packing, cleaning and disinfecting the unit
- Treating the monitor as a contaminated item including wearing gloves during unpacking
- Verifying the sleep monitor to paperwork
- Visual inspection of the monitor for signs of damage
- Removing and discarding disposable items
- Correct procedures to accomplish intermediate-level disinfection
- Removing dirty gloves before touching clean surfaces or items after disinfecting the monitor
- Re-matching the Unicorder to the correct paperwork after disinfecting
- Logging the monitor in (monitor log) _____ _____ _____

Downloading data from the Unicorder

- Verifying the participant ID
- Downloading, transmitting the sleep data file
- Checking for software quality codes
- Notifying CSRC of quality code issues
- Transmitting the sleep log
- Reformatting the Unicorder
- Recharging the battery _____ _____ _____

Preparing the Unicorder for a participant

- Replacing disposable components with new
- Uploading information
- Attaching participant labels
- Preparing the carrying case
- Properly packing the Unicorder in the carrying case

_____ _____ _____

Routine Maintenance of the Unicorder

- Testing and Calibration of Unicorder
- How often to calibrate the Unicorder
- Replacing the flashcard, battery and forehead sensor
- How often to replace forehead sensor
- Logging the maintenance for each Unicorder

_____ _____ _____

Troubleshooting Problems with the Unicorder

- Recognizing problems with the Unicorder
- Troubleshooting problems with the Unicorder
- Understanding Functionality Indicators _____ _____ _____

Performance review:

- Practical exam
- Written exam
- Submission of practice studies for certification
- Submission of check off list for at site training _____ _____ _____

# Sleep Technician Certification Exam-HCHS/SOL

Name:_____
Site:_____
Date:_____

1. HCHS/SOL is expected to study a total of how many participants?
a. up to 5000
b. up to 16,000
c. up to 14,000
d. up to 20,000

2. One of the overall objectives of the HCHS/SOL study is to:
a. learn the health effects of changes in cultural settings and environment
b. to collect census information which will be shared with the US government
c. to identify the prevalence of protective and harmful risk factors on the health of Hispanics
d. a and c

3. The age range for participation in the HCHS/SOL study is:
a. 21-75
b. 25-80
c. 18-74
d. 18-65

4. US Hispanic populations overall have a lower prevalence than non-Hispanics for:
a. coronary heart disease
b. cancer
c. diabetes
d. a and b, but not c

5. How many field centers will be collecting data for the study?
a. 6
b.10
c. 4
d. 5

6. HCHS/SOL will collect sleep monitoring data primarily in order to measure:
a. sleep apnea as a risk factor for diseases such as hypertension, diabetes and cardiovascular disease.
b. the mean night time sleep duration in the Hispanic adult population
c. the relation of snoring to daytime sleepiness
d. if older, obese Hispanic males have increased risk factors for sleep apnea

7. How many nights of in-home sleep monitoring will HCHS/SOL participants undergo?
a. 7 (1 week)
b. 2
c. 1, repeated every year until the collection ends
d. 1

8. The sleep monitor will identify what type of data?
a. fluctuations in blood pressure during sleep
b. leg kicks associated with periodic limb movements of sleep (PLMS)
c. breathing pauses and oxygen desaturations
d. heart rate

9. Each field site will receive how many sleep monitors?
a. 10 in order to collect approximately 50 sleep studies/week
b. 30 in order to collect approximately 40 sleep studies/week
c. 5 in order to collect approximately 21 sleep studies/week
d. 25 in order to collect approximately 80 sleep studies/week

10. When preparing the Unicorder where should the Participant ID label be placed?
a. on the body of the Unicorder
b. on the cannula slip tube and black Unicorder case
c. on the inside of the headband and outside of the Unicorder case
d. on the disposable blue enclosure foam

11. What is the purpose of the Unicorder's Quality Checklist?
a. To make sure the Unicorder functioned properly on the last use
b. To see if the last study was a Sleep Urgent Alert
c. To verify that the Unicorder has been returned, downloaded and is set up and ready for use.
d. a and c but not b

12. How much time should be allowed to fully recharge the Unicorder battery after night time use?
a. 12 hours
b. 6 hours
c. overnight
d. 3 hours

13. You are instructing a participant on the use of the Unicorder. After powering on the unit it chirps once, followed by 4 chirps. What should you do?
a. Attach the monitor to the computer and check the Ares Organizer. The unit has not been set up with a participant ID and will not record data.
b. Assign a new unit to the participant. This unit has a battery that has not been recharged.
c. Give it to the participant, it is ready to record sleep data.
d. Assign a new unit to the participant; 4 chirps indicate that the unit is malfunctioning.

14. A Unicorder has just been returned to the field site. What is the HCHS/SOL order of procedure?
a. Unpack the unit, download the study, put on gloves, discard disposables, upload the next study
b. Put on gloves, unpack the unit, download and transmit the study, upload the next study, discard disposables and ready the monitor for the next use
c. Put on gloves, unpack the unit, discard disposables, and disinfect the Unicorder before downloading
d. Unpack the unit, download and transmit the study, discard disposables and ready the monitor for the next use

15. You have plugged the Unicorder into the computer, opened the Ares Organizer but cannot download. The most likely problem is:
a. The Unicorder is broken and needs to be repaired
b. There is no information on the Unicorder to download
c. The Unicorder has not been powered on
d. The Unicorder needs to be calibrated

16. The Unicorder must undergo intermediate-level disinfection as soon as it is removed from the return package because:
a. It has been touching the used cannula while in the plastic bag, and may be harboring disease pathogens such as, but not limited to, influenza, staph, strep, MRSA or TB
b. A contaminated Unicorder can transmit pathogens to anyone that handles it or anything that touches it.
c. The PI, research assistant and field tech have a responsibility to ensure that the participant is not harmed and kept safe during the course of the study.
d. all of the above

17. How often should the sensor foam and the enclosure foam be replaced?
a. every 60 participants
b. every participant
c. once a month
d. these are not disposable

18. How often should the sticky black forehead oximeter sensor be replaced?
a. every 60 uses or sooner if there is a problem
b. every participant
c. these are not replaceable, the unit must go back to the manufacturer
d. every 10 uses

19. You are downloading the data from a Unicorder and the software identifies a quality issue. What should be done?
a. Call your supervisor
b. Don't send the data, the study will fail. The sleep study must be repeated
c. Call the participant and ask if there were any problems during the recording
d. Continue to download and transmit but send an e-mail to the CSRC about the study

20. What is the purpose of the sleep monitor log?
a. To take up time and create paperwork
b. To track the usage and location of each Unicorder
c. To track the maintenance and repairs of each Unicorder
d. b and c

Name:_____
Site:_____
Date:_____
Evaluator: _____

**Sleep Technician Certification Practical-HCHS/SOL**

Observe and Evaluate the Following:

| Y | N | Was the technician able to successfully | Additional Comments |
|---|---|---|---|
| | | Manipulate the Unicorder sleep monitor<br>• Interface the nasal cannula to the Unicorder<br>• Turn the unit on/off<br>• Understand and complete the monitor log | |
| | | Interface with the participant and dispense unit:<br>• Measure head circumference and fit the sleep monitor<br>• Demonstrate the unit to the participant, including a return demonstration<br>• Discuss with the participant the risk of temporary mark on forehead (from forehead sensor) and cheeks(from nasal cannula)<br>• Instruct participant how to return the monitor<br>• Instructing participant on how to complete forms<br>• Log the monitor out as it is dispensed (monitor log) | |
| | | Receive and disinfect the returned sleep monitor<br>• Prepare a suitable area for un-packing, cleaning and disinfecting the unit<br>• Treat the monitor as a contaminated item including wearing gloves during unpacking<br>• Verify the sleep monitor to paperwork<br>• Visually inspect monitor for signs of damage<br>• Remove and discard disposable items<br>• Accomplish intermediate-level disinfection<br>• Remove dirty gloves before touching clean surfaces or items after disinfecting the monitor<br>• Discard used items appropriately | |

| | | | |
|---|---|---|---|
| | | • Re-match the Unicorder to the correct paperwork after disinfecting<br>• Log the monitor in (monitor log) | |
| | | Download data from the Unicorder<br>• Verify the participant ID<br>• Download and transmit the sleep data file<br>• Check for software quality codes<br>• Notify CSRC of quality code issues<br>• Transmit the sleep log<br>• Reformat the Unicorder<br>• Recharge the battery | |
| | | Prepare the Unicorder for a participant<br>• Replace disposable components with new<br>• Upload information<br>• Attach participant labels to headband, case, paperwork<br>• Prepare the carrying case (alcohol wipe, tape, plastic bag, paperwork, instruction sheet)<br>• Properly packing the Unicorder in the carrying case | |
| | | Understand routine maintenance of the Unicorder<br>• Testing and Calibration of Unicorder<br>• How often to calibrate the Unicorder<br>• Replacing the flashcard, battery and forehead sensor<br>• How often to replace forehead sensor<br>• Logging the maintenance for each Unicorder | |
| | | Understand troubleshooting of problems<br>• Recognizing problems with the Unicorder<br>• Troubleshooting problems with the Unicorder<br>• Understanding Functionality Indicators | |

# Appendix 7 - Equipment Specifications

ARES Unicorder Specifications
ARES Signal Quality Parameters

## ARES Unicorder Specifications

| **System Specifications – subject to change** | |
|---|---|
| Oxygen Saturation Range | 1 to 100% |
| Pulse Rate Range | 20 to 250 pulses per minute |
| Saturation Accuracy | SpO2 Range Error (± 1 SD)<br>70 – 100% 2.3<br>60 – 100% 2.4 * Up to 32% of the reading may<br>90 – 100% 1.5 fall outside the listed error range<br>80 – 90% 2.6<br>70 – 80% 2.6<br>60 – 70% 2.7 |
| Pulse Rate Accuracy | 20 to 250 bpm ± 5 bpm |
| Power Supply | AAA 900 mAH NiMH battery |
| Airflow via Nasal Pressure | Range +/- 0.55 cm/$H_2O$ Accuracy +/- 2% |
| Head Position via accelerometers | Position accuracy $3^o$ @ $30^o$ C |
| Snoring Level | 20 dB @ 10% of dynamic range<br>60 dB @ 50% of dynamic range<br>90 dB @ 80% of dynamic range |
| Battery Charging | External, via ARES cable connected to USB port |
| Recharging Time | 3 – 5 hours |
| Operating Time | Days after Charge Hours of Use<br>0 – 4 Days 14.0<br>5 – 10 Days 12.0 |
| User Control | ON/OFF |
| Indicator LED | Green |
| Case Material | ABS |
| Dimensions | 4” long x 2” wide x 1” deep |
| Weight | 3.6 ounces with batteries |
| **ARES Cable** | |
| Dimensions | 5” long x 2.25” wide x 1” deep |
| Connector Interface | 8-pin Hi-Rose connector |
| Recharging Indicator | LED – Green, pattern - blinking |
| Data Transfer Rate | 2 – 4 MB per minute |
| **Software** | |
| Compatibility | Personal computer with Pentium/MMX 750 MHz or higher processor (or equivalent) with Windows Operating System |
| Estimated File Size per Minute | ~ 184 KB/Min |

# ARES Unicorder Specifications (continued).

| Environmental Conditions | Operation | Transportation | Storage |
|---|---|---|---|
| Temperature | 5°C to 40°C<br>41°F to 104°F | -20°C to 70°C<br>-4°F to 140°F | -20°C to 70°C<br>-4°F to 140°F |
| Altitude | -390m to 3,012 m<br>-1,254 ft. to 9,882 ft. | -390m to 3,012 m<br>-1,254 ft. to 9,882 ft. | -390m to 3,012 m<br>-1,254 ft. to 9,882 ft. |
| Atmospheric Pressure | 70 kPa to 106 kPa<br>20.6 in. Hg to 31.3 in. Hg | 70 kPa to 106 kPa<br>14.7 in. Hg to 31.3 in. Hg | 70 kPa to 106 kPa<br>14.7 in. Hg to 31.3 in. Hg |
| Relative Humidity | 15% to 95% non-condensing to be compliant with IEC 60601-1, sub-clause 44.5 | 15% to 95% non-condensing | 15% to 95% non-condensing |

## General Compliance

| Item | Compliant With |
|---|---|
| Equipment classification | Safety Standards: IEC 60601-1, CSA 601.1<br>UL 2601-1, EN865, EN/IEC 60601-1-2 2nd edition |
| Type of protection | Class II, Internally powered by battery |
| Degree of protection against electrical shock | Type BF – Applied part |
| Mode of operation | Continuous |
| Degree of protection against ingress of water/liquids | IEC 60601-1, sub-class 44.6 IPXO |
| Degree of Safety in presence of flammable mixtures | UL 2601-1, sub-clause 5.5, Not suitable |
| Applied sensor label to indicate Type BF applied part | IEC 60601-1 Symbol 2 of Table DII of Appendix 4 |
| Attention Symbol, consult accompanying documentation | IEC 60601-1 Symbol 9 of Table DI of Appendix 4 |
| External case made with non-conductive plastic | IEC 60601-1, sub-clause 16(b) |
| Case mechanically strong | IEC 60601-1 |
| Electromagnetic compatibility | IEC 60601-1, sub class 36 IEC/EN 60601-1-2 2nd edition |
| Electrostatic discharge immunity | IEC 60601-1-1-2, EN 61000-4-2 |
| Radiated magnetic field emissions | IEC 60601-1-1-2, EN 61000-4-3 |
| Magnetic filed susceptibility | IEC 60601-1-1-2, EN 61000-4-8 |

Table 201

| Guidance and manufacturer's declaration – electromagnetic emissions | | |
|---|---|---|
| The ARES Unicorder is intended for use in the electromagnetic environment specified below. The customer or the user of the Unicorder should assure that it is used in such an environment. | | |
| **Emissions Test** | **Compliance** | **Electromagnetic environment - guidance** |
| RF emissions<br>CISPR 11 | Group 1 | The Unicorder does not use RF energy only for its internal function and is not likely to cause any interference in nearby electronic equipment. |
| RF emissions<br>CISPR 11 | Class B | The ARES Unicorder is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions<br>IEC 61000-3-2 | N/A | |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | N/A | |

Table 204

| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
|---|---|---|---|
| The ARES Unicorder is intended for use in the electromagnetic environment specified below. The customer or the user of the Unicorder should assure that it is used in such an environment. | | | |
| **Immunity Test** | **IEC 60601 test level** | **Compliance level** | **Electromagnetic environment - guidance** |
| Conducted RF<br>IEC 61000-4-6<br>Radiated RF<br>IEC 61000-4-3 | 3 Vrms<br>150 kHz to 80 MHz<br>3 V/m<br>80 MHz to 2.5 GHz | 3 Vrms<br><br>3 V/m | Portable and mobile RF communications equipment should be used no closer to any part of the Unicorder, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br>**Recommended separation distance**<br>$d = 1.2\sqrt{P}$<br>$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz<br>$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz<br>where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $d$ is the recommended separation distance in meters (m).<br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]<br>Interference may occur in the vicinity of equipment marked with the following symbol:  |
| NOTE 1 At 80 MHz, the higher frequency range applies.<br>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | | |
| [a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Model 603 is used exceeds the applicable RF compliance level above, the Model 603 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Model 603<br>[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m. | | | |

## ARES Signal Quality Parameters

### SpO2 quality estimation

Raw SpO2 signal quality is assigned good, marginal, poor and bad based on three criteria: raw SpO2 variability, percentage time of resynchronization periods and optical signals' correlation.

### Variability

Sample variability is computed as absolute value difference between current sample and previous one. Average variability is computed over the window of size, with an application of overlapping windows. (The same window size and overlapping window characteristics is also used for the % desync SpO2 quality measure). Average variability is compared to variability thresholds for marginal, poor and bad SpO2. Based on comparison results, the current window is assigned the corresponding quality. If two overlapping windows are assigned different quality, overlapping region is assigned the worse quality of two.

### Percent desync

A desync region is defined as a minimum/maximum pair that are not detected in the region of expectation (i.e., based on past pulse rate next pulse rate should appear within a physiological maximum beat to beat change in pulse rate. Marginal, poor or bad SpO2 for desyncs is based on thresholds applied to the percentage of desyncs in a detection region relative to the total number of heart beats in the window.

### Correlation

A cross correlation analysis is applied to every SpO2 sample to compare the red and infrared optical signals. The first step is to create a sum of cross correlation results for each sample that includes a fixed number of previous, current and subsequent samples. The summed values are then compared to cross correlation thresholds to determine if the sample is marginal, poor and bad SpO2. If the sample is classified as poor or bad it is not used to calculate SpO2. A region is classified with marginal, poor or bad SpO2 when contiguous samples are classified as marginal, poor or bad.

# Appendix 8 - Calibration and Testing Equipment

Functional Testing of Unicorder
Warranty Claim Return

## Functional Testing of Unicorder

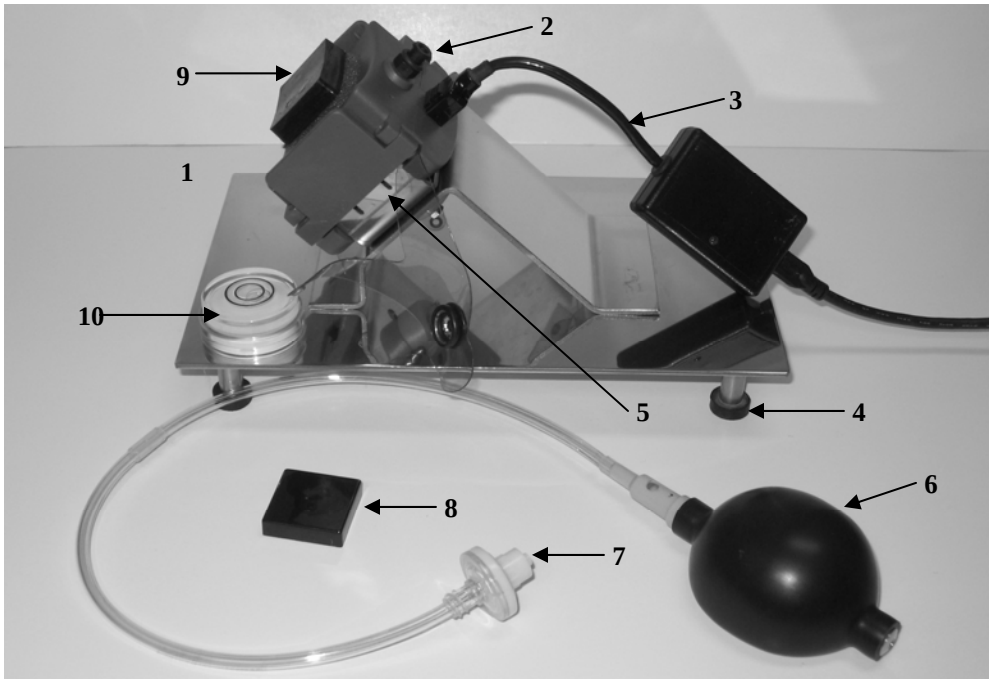
Unicorders should be tested routinely every 50 uses and or 6 months, whichever comes first. Additionally, any Unicorder that has an unresolved quality issue should be tested before it is prepared for reuse on a new participant. This will ensure that study quality is not affected by malfunctioning units and alleviate the need to repeat studies.

Units that fail any part of the test program should be sent to ABM for repair under Warranty Claim Return.
*Note: Testing of the Unicorder can only be done prior to formatting it for reuse.*

**Unicorder Test Rig Components**

| Number | Description of Component | Number | Description of Component |
|---|---|---|---|
| 1 | ARES Unicorder | 6 | Nasal Pressure Test Bulb |
| 2 | Enclosure Luer Lock | 7 | Nasal Pressure Test Bulb Luer Lock Connector |
| 3 | ARES Cable | 8 | Optical Test Surface |
| 4 | Adjustable Legs | 9 | Forehead Sensor |
| 5 | Unicorder Holder | 10 | Level Indicator |

**Figure 2.1**

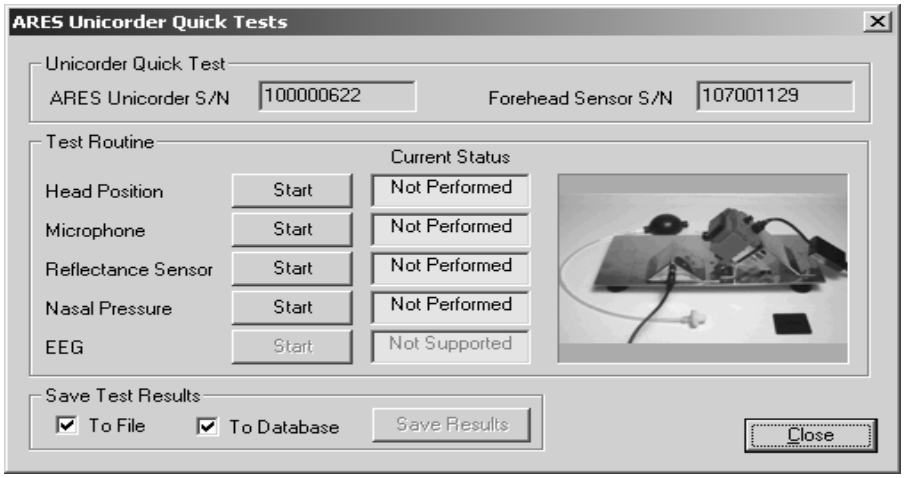



**1. Testing Setup**

a.) Open ARES Organizer software and click on ARES Manager icon.
b.) Place the Unicorder test rig on a flat surface and using the level indicator (10) adjust the legs (4) until the test rig is level.
c.) Connect the Unicorder to the ARES cable (3), and switch the Unicorder to the "on" position.
d.) Place the Unicorder on the Unicorder Holder (5) with the Forehead sensor and ARES Cable pointing upward as shown in Figure 2-1.

e.) Click on the "Select" radio button in the ARES Manager Main Menu to the left of the Unicorder to be tested.
f.) Click on "Perform ARES Testing".
g.) The "ARES Unicorder Quick Tests" dialog box will appear. (See Figure 2-2)
h.) Make sure both the "To File" and "To Database" boxes are checked in the Save Test Results section.

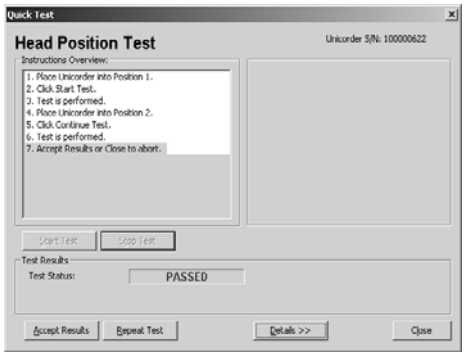
Figure 2.2




## 2. Head Position Test

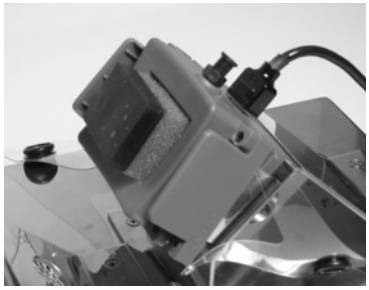
a.) Click the "Start" button to the right of the "Head Position" label. A Quick Test dialog box will open (Figure 2-3). Follow the on-screen instructions to run the test. The prompts will ask you to place the Unicorder in the two positions shown in 2-4a and 2-4b.

Figures 2.3, 2.4a, b




(Figure 2-3)

Position 1 (Figure 2-4a)

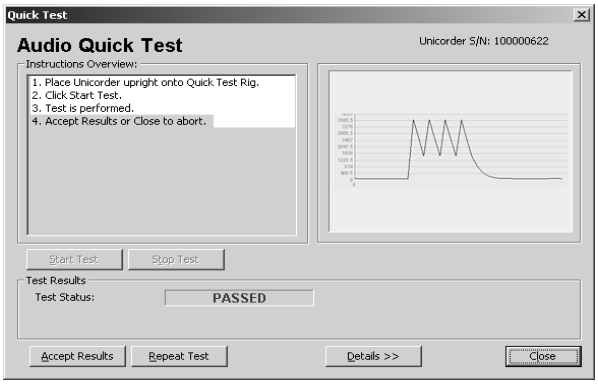


Position 2 (Figure 2-4b)

b.) If the test status appears as PASSED, then press the "Accept Results" button and close the quick test dialog box. If test status appears as FAILED, then click "Details" for more information and repeat the test or click "Close" to abort the test.
c.) Make sure an error bias is not the result of not properly leveling the Test Rig prior to performing the test. If the differences are extreme, make sure that the Unicorder in the Unicorder Holder has the same device number as the one selected in the ARES Manager Main Menu screen.

### 3. Microphone Test

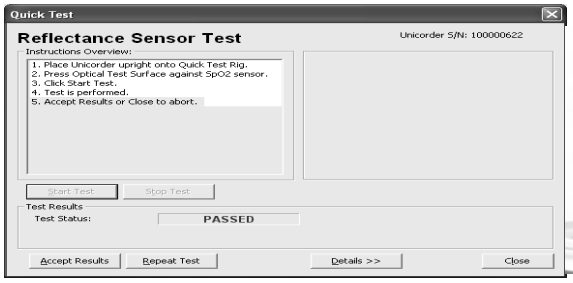
a.) Leave the Unicorder in Position 2.
b.) Click the "Start" button to the right of "Microphone Test." Follow the onscreen instructions to run the test. (Figure 2-5)
c.) If the Microphone Test Results display as PASSED, "Accept Results" and close the dialogue box. If the test status appears as FAILED, then click "Details" for more information and repeat the test, or click "Close" to abort the test. Limit ambient noise in the room during the repeat test.




(Figure 2-5)

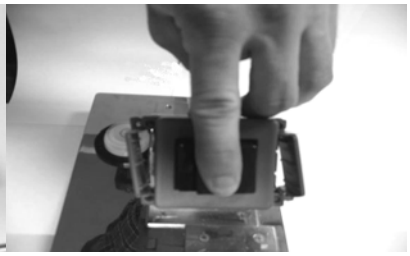
### 4. Reflectance Sensor Test

a.) Leave the Unicorder in Position 2.
b.) Click the "Start" button to the right of "Reflectance Sensor Test" label. The Reflectance Sensor Test dialog box will appear. (Figure 2-6)
c.) Hold the optical test surface with the silicone surface facing down. Set the optical test surface on the forehead sensor so the right edge, the top and the bottom edges of the optical test surface are flush with the right edge, top and bottom edges of the forehead sensor. (Figure 2-7)
d.) Press down on the optical test surface so it sticks to the forehead sensor and release the optical test surface. (Figure 2-8).
e.) Press "Start Test" and wait until the test stops automatically. If it passes, then accept results. If the test fails, click "details" for more information. Remove the optical test sensor and replace back onto the forehead sensor and repeat the test. (To remove the optical test surface, hold the sides of the forehead sensor with one hand and lift off the optical test surface with the other.)
f.) If the Reflectance Test does not pass, the forehead sensor and/or the optical test surface may need to be cleaned. Gently wipe the surface of each component with an alcohol swab. Once the components are dry, replace the optical test surface on the forehead sensor and repeat the test.




(Figure 2-6)

(Figure 2-7)



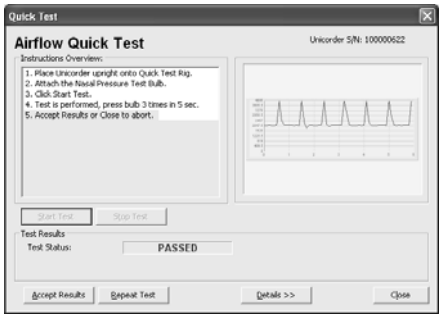
(Figure 2-8)

**5. Nasal Pressure**

a.) Attach the Nasal Pressure Test Bulb to the Unicorder luer lock. (Figure 2-9)

b.) Place the bulb on a flat surface

(Figure 2-9)



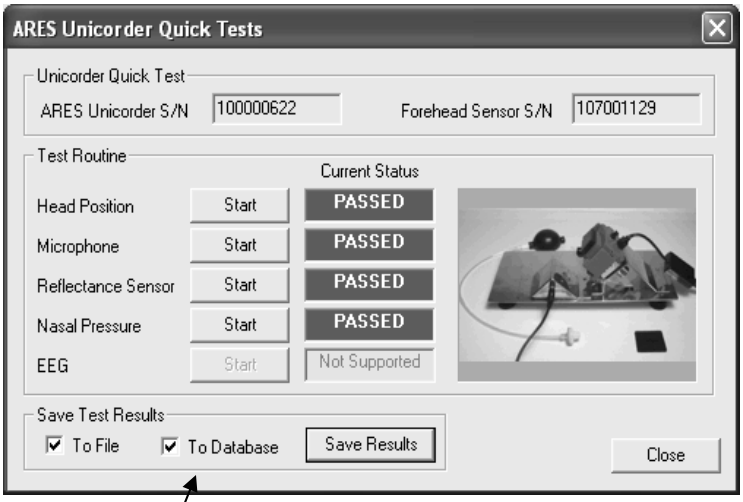

(Figure 2-10)

c.) Click the "Start" button to the right of "Nasal Pressure". Follow the on-screen instructions to run the test.

d.) If the test passes, accept results. (Figure 2-10)

e.) If the test fails, click "Details" for more information or click "Close" to abort the test

**6. If all tests are "PASSED", click on "Save Results" in the Test Main Dialog and return to The ARES Manager main menu. The Unicorder is now ready for formatting.**




(Figure 2-11)

***Note: Uncheck "To Database" box and Save Test Results "To File" only.***

## Warranty Claim Return

To return an ARES product to ADVANCED BRAIN MONITORING, INC. under a warranty claim, the Purchaser must first contact ADVANCED BRAIN MONITORING, INC.'S Customer Support at (866) 677-2737 and receive a Return Merchandise Authorization (RMA) number. The Purchaser must place the RMA number on the outside of the package containing the ARES product being returned and ship the package to ADVANCED BRAIN MONITORING, INC.'s facility, freight prepaid. Any returned ARES product received by ADVANCED BRAIN MONITORING, INC. without a RMA number shall be sent back to the Purchaser.

## Appendix 9 – Sleep Glossary

Overview of Sleep Disorders
Respiratory Monitoring- Measurement Tools
General Glossary of Sleep Terms

# Overview of Sleep Disorders

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

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

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

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

levels are thought to cause to stress on the heart, and possibly contribute to high blood pressure, to other heart ailments (heart attacks, angina, irregular heart rhythms) or stroke. However, very few studies have carefully examined these issues.

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

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

**Insomnia**

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

**Periodic Leg Movements Disorder (PLMD)**

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

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## Respiratory Monitoring – Measurement Tools

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

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

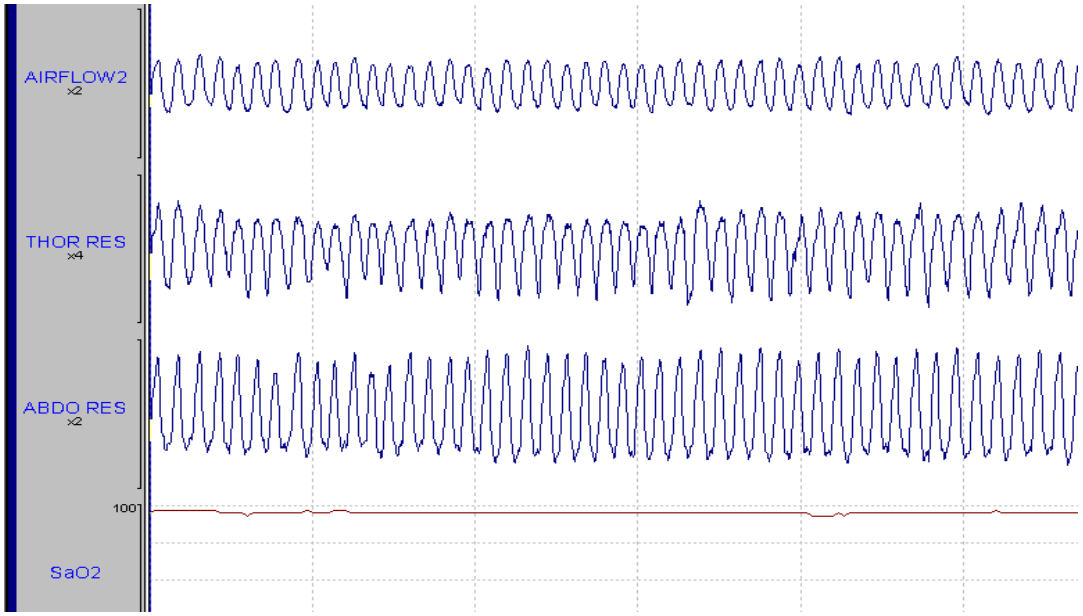
A **hypopnea** is a reduction in airflow (< 70% of a "baseline" level), associated with desaturation or arousal.

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

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

1.2

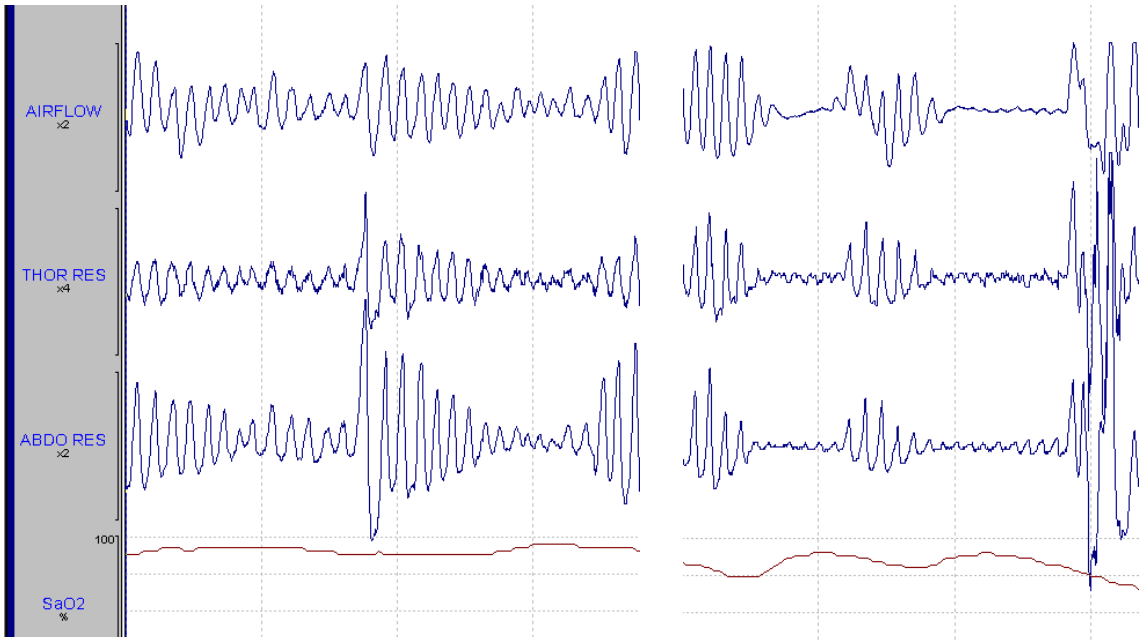
NORMAL BREATHING




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

Hypopnea

Apnea



Thus, accurate recording of these events requires measurement of airflow, oxygen saturation, respiratory effort:

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

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

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

**Oximetry**. Measures oxygen saturation levels in the blood by the reflectance of light from the capillaries under the skin. By use of a computer, the amount ot oxygen contained in the red blood cell is estimated by measuring absorption patterns of light.

**Body Position**. To distinguish supine (on back), prone (on front), and side positions. This permits identification of the extent to which any sleep-related breathing problems are positional.

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

## General Glossary of Sleep Terms

| | |
|---|---|
| Alpha rhythm: | EEG rhythm, usually with frequency of 8-12 Hz. in adults; most prominent in the posterior areas; present most markedly when the eyes are closed; attenuated during attention, especially visual. (Characteristic of relaxed wakefulness with the eyes closed.) |
| Alpha wave: | Individual component of an alpha rhythm. |
| Amplifier: | An electronic instrument used to increase the strength of an incoming signal. |
| Apnea: | Period ($\geq$10sec) with no airflow. |
| Apnea/Hypopnea Index (AHI): | Number of apneas + hypopneas per hour of sleep. |
| Artifact: | A non-biological signal that appears in an EEG or sleep recording; or a signal that interferes with the derivations being recorded. |
| Beta rhythm: | EEG rhythm with a frequency higher than 12 cps. Can be increased by certain medications |
| Bioelectric potentials: | Electrical changes originating from living tissue. |
| Bipolar derivation: | Signals obtained by comparing voltages from 2 electrodes. |
| Body movement: | Scored during any sleep stage when a phasic increase in the amplitude of the EMG lead of 1 sec or longer is accompanied by muscle artifact in an EEG or EOG trace. |
| Canthus: | Corner of the eye (plural: Canthi) |
| C3: | A symbol of the International 10-20 electrode system, identifying left central electrode placement site. |
| C4: | A symbol of the International 10-20 electrode system, identifying right central electrode placement site. |
| Cz: | A symbol of the International 10-20 electrode system, identifying a central electrode placement site. |
| Central Apnea (Hypopnea): | Cessation (or reduction) of respiratory effort $\geq$ 10 secs |
| Channel: | The linear (signal) output of an amplifier |
| Collodion: | An ether-based substance used for gluing electrodes to the scalp. Not used in this protocol |
| Delta Rhythm: | EEG rhythm with frequency of 4 Hz. or less. |
| Delta Sleep: | Sometimes used as a synonym for stages 3 and 4 sleep. |
| Delta Wave: | EEG wave with duration of .25 sec. or more |
| Derivation: | Recording from a pair of leads. |
| Drowsy sleep: | Sometimes used as a synonym for stage 1 sleep. |
| Duration of a wave: | Time interval from beginning to end of a waveform. |
| Electrical silence: | Absence of electrical activity. |
| Electroencephalogram (EEG): | A record of the electrical activity of the brain. |
| Electromyogram (EMG): | A record of the electrical activity of muscles. |
| Electrooculogram (EOG): | A record of the electrical activity of eye movements. |
| Frequency: | The number of complete cycles of a waveform within 1 second. Defined in Hz. |
| Gain: | Voltage ratio of amplifier input to output. |
| Ground electrode: | Electrode (or pair of electrodes) connected directly to the polysomnograph to provide for electrical safety or artifact reduction. |
| Hertz (Hz): | Cycles per second; a measure of frequency . |

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

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| | sharp waves may be seen; EMG activity is not suppressed. |
| Stage 2 sleep: | 12-14 Hz. sleep spindles and K complexes on a background of relatively low-voltage, mixed-frequency EEG activity. |
| Stage 3 sleep: | Moderate amounts (20%-50%) of high amplitude (75 μV or greater), slow-wave (2 Hz. or slower) EEG activity. |
| Stage 4 sleep: | Predominance (greater than 50%) of high-amplitude (75 μV or greater), slow-wave (2 Hz. or slower) EEG activity. |
| Thermocouple: | Sensor measuring changes in temperature with inspiration and expiration, used to assess airflow. |
| Theta activity: | Series of waveforms with durations of .14 to .25 sec. (May be seen in stage 1 or REM sleep). |
| Theta rhythm: | EEG rhythm with a frequency of more than 4 Hz to less than 8 Hz. |
| Theta wave: | EEG wave with duration of .14 to .25 sec. |
| Topography: | Distribution of activity with respect to anatomic landmarks. (Synonym: spatial distribution). |
| Transducer: | Devise used to convert non-electrical physiological variables into electrical signals. |
| Unilateral: | Occurring on one side of the head or body. |
| Vertex sharp wave: | Sharp wave, maximal at the vertex and negative in relation to other areas (often occurring during later portions of stage 1 sleep). |
| Wave: | Any transient change of potential difference in the EEG. |