Portable Monitoring in the Diagnosis and Management of Obstructive Sleep Apnea

Polysomnography Scoring Manual

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Sleep and Epidemiology Research Center

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1.0 Certification

1.1. Certification of Scorers

Each certified scorer will be required to:

- Demonstrate a complete understanding of scoring rules and ability to articulate reasons for assigning epoch-by-epoch codes for sleep staging and respiratory events scoring. Understanding will be judged by review of several records with the chief polysomnologist (CP) and/or physician investigator (PI).
- Demonstrate a level of agreement (within 10% for summary respiratory disturbance index (RDI) and sleep stages and 15% level of agreement for arousal index) with a second experienced polysomnologist (each scoring the same 10 records "blinded").
- Demonstrate a 5% level of agreement (within scorer reliability) by scoring the same 10 records at least one week apart.

Each novice scorer will be required to score 50 records under the supervision of a certified scorer. Ten of these records will be selected from a standardized score set. Data from these 10 records must show a 10% level of agreement with a senior scorer for summary respiratory disturbance index (RDI) and sleep stages and a 15% level of agreement for arousal index.

A certified scorer will review (epoch-by-epoch) the first 10 records scored by each novice scorer after certification. After that, a random 20% of the first 100 records will be checked.

2.0 Training and Certification of Field Sites

2.1 PSG Technician Certification

The Case Sleep and Epidemiology Research Center (CSERC) requires the lead polysomnography (PSG) technician, who will supervise field center PSG technicians, to obtain protocol certification prior to performing data collection. PSG certification is awarded upon (1) demonstration of basic understanding and application of specific sensors and equipment specific to HomePAP PSG acquisition (including lab PSG and portable monitoring (PM)), and (2) demonstration of compliance with the study protocol for data collection, and (3) demonstration of appropriate data transmittal via file transfer protocol (FTP) to CSERC, including removal of identifier information.

In order to gain PSG certification, the following criteria must be met:

- Attendance at Central Training of a local polysomnologist who performs sleep studies or who supervises others who perform sleep studies.
- Submission of written exam.
- Adherence to standard placement of electrodes and sensors, including placement of the ground and reference electrodes for lab PSG, as per the HomePAP PSG manual of procedures.
- Submission of one acceptable overnight (non-subject) split night PSG recording, one autoadjusting positive airway pressure (APAP) recording and one PM study performed at the clinical site using the HomePAP recording protocol. Submission 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 all sensors and equipment are functioning properly before being used on a study participant and that the site is scoring respiratory events and determining positive airway pressure (PAP) consistent with the protocol.
- Conversion to electronic deliverable format (EDF) after de-identifying per protocol and placed on CSRC FTP server.

To be considered acceptable, the recording must:
- Have good quality signals on each channel (i.e., all electrodes must work) and signals must be relatively free from artifact.
- Reflect HomePAP PSG protocol and procedure and include:
    1. Correct study identification.
    2. Impedance check for lab PSGs.
    3. Documentation (paper log or printed electronic log) of events, including physio-cals, impedance measurement values, tech comments and signal checks throughout the recording for lab PSG.
    4. Completed Signal Verification (SV) and Signal Evaluation (SE) forms.
    5. PAP pressures within 2 cm water of centrally determined pressures.
    6. Diagnostic RDI within disease severity range as centrally determined RDI (<5, 15-40, > 40).

2.2 Lab PSG Acquisition Instrument Certification

- Completion of one Equipment Survey for each identified PSG unit in participating laboratories, including sensors used for each requisite channel.
- Ability to standardize each identified unit to the HomePAP PSG montage.
- Ability to convert PSG files to EDF format
- Capability to interface with electrodes, sensors and auxiliary devices specified in the HomePAP PSG standardizations.
- Approvable signal quality (as deemed by CSERC).
- Ability to de-identify previously recorded patient information and assign an appropriate identification (ID) to the PSG file.
- Submission of a sample tracing converted to EDF for each identified HomePAP PSG unit. This converted EDF file must minimally contain the requisite signals, at standardized sampling and filter rates, and use similar sensors to a standard HomePAP montage.
- Along with the sample EDF submissions, the site must send a minimum of five sample pages from the same recording prior to EDF conversion. One page must illustrate machine calibration and reflect the standardized calibration display montage. All other pages must reflect the standardized PSG display montage. One page should capture the first epoch of the recording, and one page should capture the last epoch of the recording. Two other pages should be chosen randomly but show a waveform event that can be easily located and compared to the EDF file. An example of such an event would be a large K complex, sleep with arousal, or unusual artifact. The paper sample pages must clearly show epoch number and clock time.

3.0 Polysomnography

All HomePAP participants will undergo a PSG or PM study as part of study protocol.

3.1 Standardized Collection Procedures

Each clinical site will use a standardized approach established at training. Existing laboratory equipment will be used. Data will be standardized using the same montage and comparable sensors, sampling rates, and filters across sites. Local sleep technicians who are supervised by a centrally certified sleep technician will monitor participants. All PSG data will be edited, scored and summarized at the CSERC using well-developed quality assurance approaches.

3.2 Montage

Polysomnography will reflect the new 2007 American Academy of Sleep Medicine (AASM) standards as closely as acquisition instruments will allow. PSG will be collected using 15 EEG electrodes with face and scalp placements: E1, E2, F3, F4, C3, C4, O1, O2, M1, M2, L Chin, R Chin, C Chin, patient ground and common reference, electro-oculography (E1, E2), submental electromyography (EMG) (L Chin/C Chin), F_3/M_2, F_4/M_1, C_3/M_2, C_4/M_1, O_1/M_2, O_2/M_1,

In addition, the following cardio-respiratory and other ancillary data will be continuously recorded: chest and abdominal wall motion by inductive plethysmography with a sum signal if available; oronasal airflow; nasal airflow by nasal pressure cannula; pulse oximetry (SpO_2) numeric and plethysmograph waveform; heart rate by ECG; right and left leg movements by EMG; position sensor (mercury gauge). Snore microphone may be included at discretion of the site but will not be mandatory.

3.3 Sensors and Placement

Sensors, sampling rates, filter and notch settings, and peak-to-peak ranges will be standardized with respect to the limitations of various recording instruments. In brief, EEG and EOG signals are sampled at a minimum of 200 Hz, ECG and EMG (chin and leg movement) channels at 200 Hz, and respiratory signals at 32 Hz, except for nasal pressure which is collected at 128 Hz. Respiratory belts and airflow cannulae are placed using standardized placements. Oximeter sensors are attached to a finger of the non-dominant hand. Scalp electrodes are attached according to the International 10-20 system as well as behind the ears at the left (M_1) and right (M_2) mastoid areas and three over the submental muscles. EOG electrodes are applied 1 cm below and 1 cm lateral to the outer canthus of the left and right eye and will be referenced to an electrode at FPz. Eye electrode placement may also follow the standard AASM guideline (with one lateral and lower and the other upper to the outer canthus).

When possible, electrodes are secured using water-soluble pastes, increasing the holding power by using an adhesive enhancer and cleaning agent. Isopropyl alcohol is not used for any phase of participant preparation or electrode placement. Sensors are placed, calibrated, and signal quality/impedance checked, recording these data on study forms. Sensor positions are modified as needed to improve signal quality, replacing electrodes if impedances > 5 kohms.

4.0 Polysomnography Data Transmittal

Once properly de-identified and archived at the clinical site, the PSG data file and appropriate forms will be electronically transmitted to the CSERC via a secure FTP (FTP over SSL) connection. The Signal Verification Form, Sleep Tech Observation Form, and Signal Integrity Check Sheet should be scanned to create a PDF file named with the participant ID. Clinical sites will register at the website to activate their login and password for FTP access.
HOMEPAP web site: http://dceweb1.case.edu/dce/home.aspx?p=homepap

4.1 Study Receipt and Processing

All data placed on the FTP server by clinical sites are backed up daily and then moved to an Incoming Processing folder. The PSG study will be converted to a proprietary format compatible with scoring software. The study will be reviewed by the CP to assess criteria for minimal technical acceptability and urgent referral status. The CP will note any signal quality issues and record recommendations for sensor replacements or adjustment. . The CP will also notify the site if a study has failed, or if other technical problems occurred due to faulty technique or equipment not identified by the site. If urgent referral criteria are met, then the study will be reviewed by the CSERC Director and the site PI will be notified, who will subsequently alert the appropriate physicians and/or family.

4.2 Quality Assurance and Reporting

After full scoring, a Quality Signal Report indicating PSG eligibility and study quality assessment will be made available.

4.3 Data Security and Archival

The CSERC data systems are part of a local area network that is protected both by the campus-wide firewall of Case Western Reserve University and the CSERC's own software firewall. Study data will be housed on several existing servers which will have dedicated storage space for this project, with controlled access only to RC staff involved in this project. Users outside of the CSERC (including clinical site) will have limited access to designated areas of the FTP server and designated reports through the CSERC web site based on individual account information that will be supplied by the CSERC. The security of research data during transmittal will be achieved by using an FTPS (FTP over SSL) connection, which will encrypt files during upload. Nightly incremental backups and monthly full backups of data placed on the FTP server and all scored and processed data are made to SDLT tape. Monthly backups are stored in a secure off-site location.

5.0 Polysomnography Scoring

Each study will be assigned to the HomePAP CP for scoring of sleep and breathing on an epoch-by-epoch basis, visualizing each epoch on a high-resolution monitor, using customized software that allows flexibility in choosing specific signals for visualization. The scorer also completes quality code assessments (Signal Quality Form), assigning each data channel a quality code grade according to the duration and quality of signals collected, and each study will be given an aggregate quality grade based on the overall interpretability and duration of artifact-free signals. Other data are coded that are not

captured in the computerized scored report (e.g., periodic breathing, alpha intrusion, etc.). This form will be data entered on the website and available for the site and DCC to access using assigned passwords.

All scoring will be consistent with AASM 2007 recommendations.

5.1 Medical Monitoring and Reporting

Severity of OSA will be determined by PSG review at the CSERC. Any PSG study showing severe physiological abnormalities will be flagged. Such abnormalities include the following: arrhythmia (non-sustained ventricular tachycardia; paroxysmal atrial fibrillation or a fibrillation at ventricular rates > 120 or < 50; second degree Type II AV block; sustained bradycardia > 30 bpm (>2 minutes); sustained tachycardia > 150 bpm (>2 minutes). The Signal Review form will be completed and this information transmitted to the site study coordinator and local PI. Individuals found to have profound desaturation (suggesting hypoventilation syndrome) or unstable rhythms requiring interventions, will be considered ineligible for continued study participation.

5.2. Exclusion Criteria

AHI < 15

5.3 Quality Grading

The quality of each signal and overall study quality will be assessed at the time of scoring of the record. The Scorer will code each channel of information according to the duration of the following: i) scorable signals, ii) artifact-free signals during sleep, and iii) an overall QA grade to each study. The total duration of the study (from the edited lights off to the lights on) and the total duration of sleep will also be indicated. Scoring notes regarding staging, event identification, outliers, and specific physiologic signal issues are also recorded on the QS form. All data contained in the QS Form (quality grades and scoring notes) will be entered in the QS table database.

5.4 Scored Data

After full scoring, the scorer will generate:

- Participant Sleep Report containing summary sleep data, including the AHI (the number of apneas and hypopneas per hour of the sleep associated with a desaturation $\geq$ 4%), a summary of the desaturation profile, time in REM/non-REM sleep, stage distributions, and the arousal index.

- SAS Report containing all sleep variables. Summary data include the following: event type, duration, associations with level of desaturation, arousal, position, and sleep stage. Dividing the total number of specific events by sleep duration provides the obstructive apnea hypopnea index, central apnea index, and percent time in apnea or hypopnea. Oximetry: The S_pO_2 nadir, mean S_pO_2, and percent of total sleep time during which S_pO_2 is<95%, 92%, 90%, 85%, 80%, 75%, 70%. Sleep Architecture: Time in each

sleep stage; Sleep efficiency (% of the sleep period that the subject was asleep) and latency (time to onset of sleep); REM latency (onset of sleep to first REM); A periodic limb movement index is calculated based on the number and pattern of limb movements (>4 movements, each separated by 5-90 seconds). EEG arousals: Arousal index (number/sleep hour), number of upward stage shifts (from deeper to lighter) and wake shifts (number of sleep to wake transitions), expressed as total per hour of sleep and by sleep stage (REM vs. non-REM) and body position. Heart rate (HR) maximum, minimum and mean HR in sleep, associated with respiratory events and/or with arousals (REM vs. non-REM). Note on scoring and archiving: After studies are scored and initial reports and processing are completed, studies are removed from individual scoring computers and archived in duplicate at the CSERC..

- Split Night Studies: One file for the diagnostic portion of the study and one file for the titration portion.

- Embletta Study Reports: Contain similar respiratory variables but none of the sleep variables as the PSG reports.

5.5 Archived Data

After QS data have been entered and reports are posted to the CSERC website, the complete study folder containing the raw data file, scored files, sleep study report, and the SAS report are placed in a site directory, which is backed-up on a daily basis.

The summary scored SAS data are outputted as individual .txt files. After outlier checks, studies are imported on a monthly basis into a SAS file.

6.0 Scoring Procedures

6.1 Scoring Overview

Each study will be manually scored in two passes.

First pass: Verify Lights Off, Lights On, Sleep Onset and End of Sleep are set correctly. The EEG, EMG and EOG signals from each study will be reviewed on an epoch by epoch (30 sec screen) basis. Each epoch will be assigned a sleep stage. Periods of EEG change that meet the criteria for arousal will be marked.

Second pass: Respiratory data (airflow/abdominal/chest/saturation) will be reviewed on five- or two-minute page. The saturation channel will be edited for artifact and respiratory events will be marked manually according to the rules stated below.

The QS Form will then be completed, indicating unusual patterns, reliability problems, and signal/study QA grades. Participant Feedback Sleep Reports will be generated.
The raw and scored files and summary reports will be saved to the appropriate scored sections on the Network.

6.2. Sleep Stages and Arousals

Scoring will be based on the *American Academy of Sleep Medicine Manual for the Scoring of Sleep and Associated Events Rules, Terminology, and Technical Specifications* (2007).

6.3 Epoch-by-Epoch

Epoch-by-epoch approach: The polygraph record is divided into consecutive segments of equal size (30 seconds, each termed an "epoch"). Each epoch has assigned a single sleep stage score. The epoch duration is maintained for the duration of the recording.

- When more than one stage is present in an epoch, that epoch is assigned a single stage score reflecting the stage that occupied the greatest portion of the epoch.
- When two stages of sleep are evenly distributed on the epoch, and one of these stages was the same stage as in the preceding epoch, then that epoch will be assigned the same sleep stage as the preceding epoch (*).
- Portions of two epochs may not be combined to create a new epoch.
- When an arousal of <15 seconds occurs within an epoch, the time in arousal is not counted when determining the predominant sleep stage time in that epoch.

Terminology for stages of sleep:

- Stage W (Wakefulness)
- Stage N1 (NREM 1)
- Stage N2 (NREM 2)
- Stage N3 (NREM 3)
- Stage R (REM)

Note: Stage N3 represents slow wave sleep and replaces R & K nomenclature of Stage 3 and Stage 4 sleep.

6.4 Sleep Onset

Sleep onset is defined the start of the first epoch scored as any stage other than Stage W.

6.5 EEG Arousal

The scoring of EEG arousals is independent of the scoring of sleep stages (i.e., an arousal can be scored in an epoch of recording that would be classified as wake by R & K criteria). An arousal can proceed to the wake stage (by R & K criteria) or can be followed by a return to sleep.

<u>Definition of Arousal:</u>

An EEG arousal is an abrupt shift of EEG frequency including alpha, theta and/or frequencies greater than 16 Hz (but not spindles) lasting at least 3 seconds, and starting after at least 10 continuous seconds of sleep.

Artifacts, K complexes and delta waves are included in meeting the 3 second duration criteria only when they occur within the EEG frequency shift (change in frequency must be visible before these waveforms). A K complex or spindle occurring immediately prior to the EEG shift or following is not included in the arousal duration.

Parts of the EEG totally obscured by EMG artifact are considered an arousal if the change in background EEG in addition to the area obscured by EMG is at least $\geq$ 3 seconds.

Alpha activity of less than 3 second duration in non-REM sleep at a rate greater than one burst per 10 seconds is not scored as an EEG arousal. Three seconds of alpha sleep is not scored as an arousal unless a 10 second episode of alpha free sleep precedes this activity.

Arousals lasting > 15 seconds and containing awake EEG within an epoch cause the epoch to be classified as AWAKE.

7.0 Detecting Arousals

- When unsure if change in background EEG represents an abrupt change, look at a 60-second epoch and note if there is a discrete change from background EEG.
- Note whether changes were evident on both EEG channels.
- Be careful to distinguish an increase in EEG frequency from EMG artifact (esp. in delta sleep).
- Isolated bursts of delta activity or sawtooth-like waves do not constitute an arousal. In contrast, slow waves intermixed with fast activity that differs from background do qualify as arousals.
- Occasionally, EEG acceleration is superimposed on slower waves. The slowing may be an artifact secondary to movement or burst of delta waves. If there is evidence of embedded EEG acceleration for $\geq$ 3 seconds, then mark as an arousal.

7.1 Arousal Length

Some studies with high RDIs have many arousals that may appear to last > 15 seconds within given epochs. If all such epochs were classified as AWAKE, then the respiratory events would not be included in the RDI, and the RDI will be underestimated. When faced with this situation, and when <1 second duration would change the epoch from sleep to wake, the scorer may attempt to keep the duration of the arousal to as short as feasible to maintain the epoch as sleep (e.g., corresponding to the length of the waking EEG in that epoch). This will maximize the number of epochs containing arousals that are captured as "sleep."

7.2 Arousals in REM

In stage REM, an EEG frequency shift must be accompanied by a simultaneous increase in amplitude of the chin EMG (lasting at least 1 second). An arousal starts when a definite change in background EEG is visualized. The increase in the chin EMG can occur anytime during the arousal (can be at the end) and is not a marker for the beginning of the arousal however, increased EMG activity without a change in background EEG does not constitute an arousal.

- If the level of REM EMG appears to be fluctuating, then the increase in EMG in the area of a putative arousal needs to be more than the background level of fluctuations in order to identify this as a REM arousal.

- A long period of alpha activity before an EMG increase may mark the beginning of the arousal if the alpha activity represents the change in the background pattern.

8.0 Episodic Events in Sleep

8.1 **Sleep spindles**: Clearly visible, rhythmic bursts of activity 12-14 Hz, duration at least 0.5 seconds. One should be able to count six or seven distinctive waves within a half-second period. The amplitude variability appears sinusoidal.

Sleep spindle activity occurs in adults with a frequency of about three to eight bursts per minute in Stage N2 sleep. These are absent in wakefulness and Stage N1. Spindles may be rarely observed in Stage R and N3. Spindle rate appears to be a fairly stable individual characteristic. In the elderly and in individuals with various medical conditions, sleep spindles tend to lose their classic morphology and may have a slightly slower frequency, lower amplitude, and shorter duration.

8.2 **Medication effects:** Can introduce beta range activity that may be confused with spindles.
Tips to alert to the presence of drug effects mimicking spindles are two or more of the following:

- Increased beta activity (spindle-like) in well defined REM sleep and wakefulness.
- Increased spindle duration (often > 1 sec.)
- Increased frequency of spindles per epoch (>5/epoch).
- Spindle-like activity with amplitude variability that is NOT sinusoidal.
  Fast frequencies (often > 13 Hz).
- When identifying atypical “spindle activity,” review previous epochs to ascertain if stage was properly scored.
- When atypical spindle-like activity is observed, then such activity cannot be used to distinguish Stage 2 from other sleep stages. This may lead to some underscoring of Stage 2 from 1.

8.3 **K complexes**: EEG waveforms having a well-outlined negative sharp wave, immediately followed by a positive component. Total duration of the K complex should exceed 0.5 seconds. Waves of 12-14 Hz (sleep spindles) may or may not constitute part of a K complex. K complexes can occur as a response to sudden auditory stimuli. K complexes may be reflected on the EOG channels. When in doubt about whether a particular polyphasic wave is a true K complex, record is scanned for clear Stage N2 sleep. Questionable K complexes are only designated as K complexes if their morphology closely matches those seen in unequivocal Stage N2 sleep. For an arousal to be associated with a K complex, it must commence no more than one second after termination of the K complex.

8.4 **Hypersynchrony**: Bursts of high voltage delta (< 4 Hz) or theta (4 - 7 Hz) waves lasting 2-3 s. with a comb-like morphology with a positive polarity (points up going). Hypersynchrony is not considered an arousal. May need to be distinguished from seizure discharges. In children, this actually may be exaggerated. It is relatively more common during the transition from wakefulness to sleep.

8.5 **Seizures:** Manifested by an abrupt change in background EEG. This usually requires a wider sampling of areas of the brain than is provided with our montage. Two patterns are

commonly seen: 1) high voltage, rhythmic activity in the 2-6 Hz range, or 2) diffuse sustained beta activity. A seizure is often accompanied by prominent muscle artifact. A seizure is usually followed by low to moderate voltage irregular slowing. On the 10 second screen, characteristic spike and wave pattern may be seen. If a possible seizure is identified, a PI will be immediately asked to review the study.

9.0 Assigning Sleep Stages

9.1 EEG Frequencies

EEG frequencies are divided into following bandwidths:

- β (beta) > 13 Hz
- 13 Hz $\geq \alpha$ (alpha) $\geq$ 8 Hz
- 8 Hz $> \theta$ (theta) $\geq$ 4 Hz
- 4 Hz $> \delta$ (delta)

An alpha wave is any wave that has the frequency in alpha range.
Alpha rhythm (also known as posterior background rhythm, trains of sinusoidal 8-13 Hz activity) has the following characteristics:

- Is seen in the relaxed waking state with the eyes closed.
- Attenuates with eye opening, anxiety or mental activity such as mental calculations
- Slows in drowsiness (occasionally <8 Hz) and then disappears in sleep.
- The slowing may be so brief as to be unnoticed.
- Generated by occipital lobes and has a broad reflection to temporal and mastoid areas.

9.2 Stage W : Waking State

Stage W, when eyes are open, is defined by low voltage, mixed frequency EEG in the alpha and beta ranges (> 8 Hz). When eyes are closed, wake is defined by the presence of the alpha rhythm. There is usually (but not necessarily), a relatively high tonic EMG. Waking shows frequent eye movements and eye blinks. Some subjects may have virtually continuous alpha activity; others may show little or no alpha activity in the waking record. Scoring will be done primarily from C4-M1, F4-M1, and O2-M1 with backup electrodes C3-M2, F3-M2 and O1-M2. Occipital leads will be used for alpha rhythm detection for transitions from wake to sleep.

9.3 Stage W: Scoring Rules

Score epochs as stage W when more than 50% of the epoch has alpha rhythm over the occipital region. Score epochs without visually discernable alpha rhythm as stage W if any of the following are present:

- Eye blinks at a frequency of 0.5-2 Hz
- Reading eye movements
- Irregular conjugate rapid eye movements associated with normal or high chin muscle tone.

9.4 Stage 1: N1

Stage N1 sleep occurs most often in transition from wakefulness to other sleep stages. Stage N1 is defined by a background of relatively low voltage, mixed frequency EEG activity with noticeable activity in the 4-7 Hz range with no clearly defined non-arousal associated K complexes or sleep spindles in the first half of the epoch. Faster frequencies are mostly lower voltage (amplitude). High voltage (50-75 μV) 4-7 Hz activity tends to occur in irregularly spaced bursts mostly during the later portions of the stage. There are slow eye movements, each of several seconds duration, usually most prominent during early portions of the stage. No rapid eye movements or blinks are present. During the latter portion of the stage, vertex sharp waves, occasionally as high as 200 μV, are often seen in conjunction with high amplitude 4-7 Hz activity. The amount of alpha activity combined with low voltage activity comprises less than half of the epoch. Finally, the tonic EMG level may be lower than observed during relaxed wakefulness.

Traces of low voltage activity at 12-14 Hz may begin to appear as the transition to Stage N2 approaches, but this activity is not defined as a sleep spindles until the rhythmic bursts are clearly visible for at least 0.5 s.

9.5 Stage 1: Scoring Rules

In subjects who generate alpha rhythm, score stage N1 if alpha rhythm is attenuated and replaced by low amplitude, mixed frequency activity for more than 50% of the epoch.

In subjects who do not generate alpha rhythm, score stage N1 commencing with the earliest of any of the following phenomena:

- Activity in range of 4-7 Hz with slowing of background frequencies by >=1 Hz from those of stage W
- Vertex sharp waves
- Slow eye movements

9.6 Stage 2: N2

Stage N2 is defined by a background similar to Stage N1 sleep with the presence of the non-arousal associated K complexes and/or sleep spindles. It is impossible to define the difference between Stage N1 and Stage N2 sleep on the basis of background activity alone. Bursts of other polymorphic high voltage slow waves, which do not have the precise morphology of K complex, are also frequently seen. Delta waves: high amplitude (> 75 μV), slow (≤ 4 Hz; duration 0.5 s. and longer) activity occupy no more than 19% of the epoch.
At the beginning of the Stage N2, slow eye movements may infrequently, and only briefly, persist after the appearance of sleep spindles and non-arousal associated K complexes.

K complexes associated with an arousal or imbedded within an arousal do not constitute evidence of Stage 2.

9.7 Stage 2: Scoring Rules

The following rule defines the start of a period of stage N2 sleep: Begin scoring stage N2 (in absence of criteria for N3) if one or both of the following occur during the first half of that epoch or the last half of the previous epoch:

- One or more K complexes unassociated with arousals
- One or more trains of sleep spindles

Note: Continue to score stage N1 for epochs with arousal-associated K complexes but no spontaneous K complexes or sleep spindles.

The following rule defines continuation of a period of stage N2 sleep: Continue to score epochs with low amplitude, mixed frequency EEG activity without K complexes or sleep spindles as stage N2 if they are preceded by a) K complexes unassociated with arousals or b) sleep spindles.

The following rule defines the end of a period of stage N2 sleep: End stage N2 sleep when one of the following events occurs:

- Transition to stage W
- An arousal (change to stage N1 until a K complex unassociated with an arousal or a sleep spindle occurs)
- A major body movement followed by slow eye movements and low amplitude mixed frequency EEG without non-arousal associated K complexes or sleep spindles (score the epoch following the major body movement as stage N1; score the epoch as stage N2 if there are no slow eye movements; the epoch containing the body movement is scored using the criteria in section 8.1.5; has definition and rules for Major Body Movement)
- Transition to stage N3
- Transition to stage R

9.8 Deep Sleep: N3

No attempt is made to distinguish Stage 3 from Stage 4. Both are combined into a single category: Deep Sleep [N3].

Deep Sleep is scored when 20% or more of the epoch consists of delta waves, which are 0.5 Hz-2 Hz and have amplitude greater than 75 μV [irrespective of age]. The 20% criteria refers specifically to the time occupied by the high amplitude, slow waves, and does not include intervening waves of higher frequency and lower amplitude or K complexes. To fulfill the criteria for Deep Sleep, one should be able to find at least 5-6 high voltage delta waves in the 30 second sleep epoch. Delta waves embedded in increased frequency activity (an arousal) do not contribute to the calculation of time in delta sleep.

Sleep spindles and non-arousal associated K complexes may or may not be present in Deep Sleep. Eye movements do not occur in Deep Sleep, although the EOG may reflect the high voltage slow wave activity. The EMG is tonically active, although the tracing may achieve very low levels, indistinguishable from that of REM sleep.

An attempt should be made to distinguish between spontaneous K complexes and delta waves, although this distinction is not always easy. When a K complex distinction is in doubt, comparison should be done with the K complex in unambiguous Stage N2.

9.9 Stage R: REM

Stage R is defined by a background of relatively low voltage, mixed frequency EEG with accompanying episodes of REM (rapid eye movement). The EEG pattern resembles Stage N1, except that vertex sharp waves are not readily noticeable. Bursts of

characteristic sawtooth waves may appear, appearing as notched waves in the theta range. Alpha activity is usually more prominent than in Stage N1 and its frequency is 1-2 Hz slower than the alpha rhythm in wakefulness. The EMG reaches its lowest levels (it cannot be higher than the level during the preceding stage). Phasic twitches and intermittent increases of EMG activity may be observed but intervening baseline must remain low. Phasic twitch (EMG) defined as: short (no longer than 10 second) burst of EMG activity superimposed on suppressed muscle tone which physically manifests as a twitch (contraction) of a muscle or jerk of a limb. In Stage R, such muscle contractions may be isolated or become repetitive, but they remain distinctive. Periods of relatively low voltage, mixed frequency EEG and EMG at Stage R level but without eye movements may follow unambiguous Stage R and is considered Stage R unless criteria for a state change are met.

The EOG shows bursts of rapid eye movements; often the density of such bursts increase as sleep progresses. Thus, earlier Stage R episodes usually contain fewer REM than later episodes.

Rarely, delta waves may be observed in an epoch that is within a period of REM. If occurring within period of REM, a low EMG, continue to score as REM. Large sawtooth waves also may be confused with hypersynchrony.

Note: Excessive beta activity may be observed in REM and should not be confused with spindles. Medications (benzodiazepine or barbiturate ingestion) may induce excessive beta activity in both REM and non-REM sleep. This beta activity can mimic sleep spindles. Their frequencies often are faster than those seen with the true sleep spindles (see above Stage N2 sleep section for guidance on identifying spindles). Rarely, sleep spindles can be seen in Stage R in subjects with substantial sleep deprivation.

9.10 Start of REM

At the start of Stage R, non-arousal associated K complexes, sleep spindles and delta waves end, characteristic sawtooth waves can appear. EMG levels tend to be the lowest after eye movements begin. The fall in EMG may not coincide with the EEG changes.

- If the EMG drops before the last sleep spindle, non-arousal associated K complex or delta wave: Score Stage R from the point the last sleep spindle, non-arousal associated K complex or delta wave was seen.
- Otherwise, score Stage R from the point where EMG drops. The period of the record before the EMG drop is scored according to the rules for NREM sleep.

9.11 Elevated EMG During REM

When EMG is elevated above the REM level for longer than .5 seconds, then this portion of the record is scored as a non-REM sleep or WAKE. If phasic twitches or sawtooth waves are seen but intervening EMG is low, the epoch remains Stage R.

9.12 Stage R: Scoring Rules

Score stage R sleep in epochs with all the following phenomena:

a. Low amplitude, mixed frequency EEG
b. Low chin EMG tone

c. Rapid eye movements

A. The following rule defines the continuation of a period of stage R sleep:
Continue to score stage R sleep, even in the absence of rapid eye movements, for epochs following one or more epochs of stage R as defined in A above, if the EEG continues to show low amplitude, mixed frequency activity without non-arousal associated K complexes or sleep spindles and the chin EMG time remains low.

B. The following rule defines the end of a period of stage R sleep. Stop scoring R sleep when one or more of the following occur:
1. There is a transition to stage W or N3
2. An increase in chin EMG tone above the level of R is seen and criteria for stage N1 are met
3. An arousal occurs followed by low amplitude, mixed frequency EEG and slow eye movements (score as stage N1; if no slow eye movements and chin EMG tone remains low, continue to score as stage R)
4. A major body movement followed by slow eye movements and low amplitude mixed frequency EEG without non-arousal associated K complexes or sleep spindles (score the epoch following the major body movement as stage N1; if no slow eye movements and the EMG tone remains low, continue to score stage R; the epoch containing the body movement is scored using criteria in section 8.1.5)
5. One or more non-arousal associated K complexes or sleep spindles are present in the first half of the epoch in the absence of rapid eye movements, even if chin EMG tone remains low (score as stage N2)

C. Score epochs at the transition between stage N2 and stage R as follows:

1. In between epochs of definite stage N2 and definite stage R, score an epoch with a distinct drop in chin EMG in the first half of the epoch to the level seen in stage R as stage R if all of the following are met, even in the absence of rapid eye movements:
a. Absence of non-arousal associated K complexes
b. Absence of sleep spindles

2. In between epochs of definite stage N2 and definite stage R, score an epoch with distinct drop in chin EMG in the first half of the epoch to the level seen in stage R as stage N2 if all of the following criteria are met:
a. Presence of non-arousal associated K complexes or sleep spindles
b. Absence of rapid eye movements

3. In between epochs of definite stage N2 with minimal chin EMG tone and definite stage R without further drop in chin EMG tone, score epochs as stage R if all of the following are met, even in the absence of rapid eye movements:
a. Absence of non-arousal associated K complexes
b. Absence of sleep spindles

9.13 Stage R: Scoring Issues

Identification of the Stage REM may be difficult when there are prolonged bursts of elevated EMG seen during eye movements or the EMG increases with snoring. In such cases:

EMG increases clearly related to snoring (changing with breathing) may be ignored, as long as intervening EMG is low.

The portion of the record with unquestionable Stage R should be reviewed to provide a visual reference of the characteristic Stage R EEG pattern. Stage R is scored when EEG pattern changes to the pattern characteristic for Stage R regardless of the level of the EMG. When EEG is consistent with Stage R, and there is no evidence of wake (blinking), no evidence of Stage N1 (vertex waves, slow rolling eye movements), or the presence of REM,, then score stage Stage R from the last non-arousal associated K complex, sleep spindles or delta wave. Distinguishing between Stage N1 and Stage R is unreliable and noted as such on the PSG scoring notes form.

10.0 Scoring Respiratory Events

The scorer will identify the following categories of discrete breathing events: obstructive apneas, central apneas and hypopneas. Additionally, periodic breathing will be identified. Central hypopneas and increased upper airway resistance (RERAs) will not be identified because of controversies in the defining these events and the probable need to use invasive monitoring to identify these accurately.

10.1 **Obstructive Apneas** are identified when the amplitude (peak to trough) of the airflow (thermistry) signal decreases to a flat or almost flat signal (showing a 90% reduction of the amplitude of "baseline" breathing for 90% of the duration, this will be known as the 90% criteria) if this change lasts for $\geq$ duration of 10 seconds. It will be classified as an obstructive event unless it meets the criteria for a central apnea (absence of effort on both bands). *Baseline breathing* is defined as a period of regular breathing with stable oxygen levels. Without reliable airflow, the event will default to hypopnea. Identification of an apnea does not require a minimum desaturation criterion.

10.2 **AASM Hypopneas** will be identified if ≥30% reduction of amplitude is visualized on either the nasal cannula or the respiratory SUM channel for a duration of at least 10 seconds and associated with >=4% desaturation. If the SUM and nasal cannula are not present, if a 30% reduction is seen on both belts (thoracic and abdominal), or 30% reduction on the airflow, and associated with >=4% desaturation, then a hypopnea may be scored. Discernable changes with desaturations that do not meet the rules of hypopnea are NOT scored as hypopneas. Identification of a hypopnea does require a minimum desaturation ≥4%.

10.3 **Distinguishing Between Hypopneas and Apneas**

This distinction only can be made for events in which airflow by thermistry is interpretable. (If airflow is uninterpretable, the event-based on inductance data is considered by default to be a hypopnea but must be associated with >=4% desat to be scored as a hypopnea.). Apneas are marked if >90% of the event shows absent or nearly absent airflow on the thermistor channel (and this reduction is 90% the amplitude of the surrounding breaths).

10.4 A **Central Apnea** event is scored if NO displacement is noted on both chest and the abdominal inductance channels. Minimum duration of event is ≥10 seconds. Identification of an apnea does not require a minimum desaturation criterion.

10.5 Distinguishing Between Central and Obstructive Events

Only events in which there is clear data from both the abdominal and chest signals can be distinguished as central or obstructive. (Events where one or both of these channels are missing or contain artifact are considered obstructive or hypopneic, but a hypopnea must be associated with ≥4% desaturation).

Often determining whether an event is central or obstructive is influenced by where the event is noted to begin and end. Sometimes small efforts are seen following a completely flat area, followed by a large (”breaking”) breath. If a single non-artifactual deflection less than 25% of baseline breathing is seen at the beginning or the end of the period of flat signal, the event will be marked as central. (This recognizes that shortening the event slightly would make it a central event). However, if two or more consecutive small breaths less than 25% of baseline breathing (providing airflow is flat) are seen in the period in question, the event is marked as obstructive.

Determining whether an event is central or obstructive in areas of periodic breathing can be difficult because of uncertainties in deciding when to start and end such events. Often these areas contain breaths that gradually increase and decrease, sometimes decreasing to an imperceptible level. Marking longer events in these areas would result in identifying obstructive events; shorter events are more likely to appear central. When it is unclear as to when to start an event, look for evidence of paradoxical breathing. Change in phase angle between thoracic and abdomen is an indicator of upper airway obstruction (such events will be designated as obstructive). When still unclear, the event duration will be marked using the airflow channel. Identify the areas where airflow stops and starts, then assess whether the period is also associated with effort on either channel/band. Then the inductance channels will be visualized to decide whether during this period, any effort occurred. If any effort was visualized, the event will be considered “obstructive,” otherwise, “central.”

Duration criteria: The beginning of an Apnea/Hypopnea is marked at the end of the last “normal” breath; the end of the event is identified as the beginning of the first breath that exceeds the amplitude of the first reduced breath used to mark the beginning of the event. Duration is based on a “trough to trough” marking lasting at least 10 seconds.

10.6 Additional Notes on Central Apnea Scoring

Clarification of amplitude threshold relative to baseline: If one non-artifactual deflection is less than 25% of baseline breathing, then it is a central. If two deflections are less than 25% of baseline breathing providing airflow flat, then it is obstructive or mixed. Flat excludes cardiogenic oscillation. If airflow reliable and not flat or airflow unreliable, then default to hypopnea if hypopnea is associated with ≥4% desaturation.

11.0 Nasal Flow Limitation

Nasal flow limitation is derived from the nasal cannula signal. A normal flow signal will present as a regular sinus rhythm and curve. Flow limitation may occur with increase upper airway resistance, not sufficient enough to cause discrete apneas and hypopneas. A regular sinus curve will transform into a signal that resembles a lowercase ‘H.”

12.0 Scoring Periodic Leg Movements

The AASM rules for scoring Periodic Limb Movements in Sleep (PLMS) for 2007 will be used.

12.1 Scoring Rules

The following rules define a significant leg movement (LM) event:
1. The minimum duration of a LM event is 0.5 seconds
2. The maximum duration of a LM event is 10 seconds
3. The minimum amplitude of a LM event is an 8 microV-increase in EMG voltage above resting EMG
4. The timing of the onset of a LM event is defined as the point at which there is an 8 microV-increase in EMG voltage above the resting EMG
5. The timing of the ending of a LM event is defined as the start of a period lasting at least 0.5 seconds during which the EMG does not exceed 2 microV above resting EMG

The following rules define a PLMS series:
1. The minimum number of consecutive LM events needed to define a PLM series is 4 LMs.
2. The minimum period length between LMs (defined as the time between onsets of consecutive LMs) to include them as part of a PLM series is 5 seconds.
3. The maximum period length between LMs (defined as the time between onsets of consecutive LMs) to include them as part of the PLM series is 90 seconds.
4. Leg movements of 2 different legs separated by less than 5 seconds between movements onsets are counted as a single leg movement.

Events that occur simultaneously or within one half second on both limb traces will be reported as one event. Intervals between limb movement events are measured between the end of the previous limb movement event and the commencement of the next limb movement event. Minimum peak-to-peak amplitude for a Limb Movement to be detected and marked. This applies when using EMG electrodes to measure limb movements. Leg movements that are exclusively associated with the termination of respiratory events will not be considered in the PLMI. (Will be deleted if occurring in clusters.)

Delete all the PLMs in awake.

12.2 Mixture of Periodic Leg Movements and Respiratory Events

Delete all clusters of four or more leg movements in row if all of them clearly terminate a respiratory event. However, when a mixture of LMs are seen where some occur at the termination of a respiratory event and others appear unrelated temporally to a respiratory event, retain such events other than ones where a sequence of three occur associated with respiratory termination.

13.0 Quality Scoring

The following are coded on the QS Form during the scoring of each study:

Lights out time, Sleep onset time, and Lights on time: The time of lights out, sleep onset and lights on are recorded by the scorer on the QS form to assist in analysis of accuracy of reported time to bed and sleep latency.

13.1 Grade Review

The quality assurance (QA) grades of the signal and study are assigned at the time of scoring. It is recognized that the scorer, who spends a longer time with each study, may disagree with the preliminary pass/fail review of the Chief Polysomnologist. This will be re-reviewed with the Chief Polysomnologist and final determination made. Unusual signals and/or questions not addressed in Manual of Operations will be addressed at weekly scoring meeting

13.2 Limited Scoring

Study is scored sleep-wake only when the technical quality of the EEG does not allow distinction between sleep stages, but allows a differentiation between sleep and wake. The time considered sleep will be marked as Stage 2. No arousals will be scored for these studies. Respiratory events will be scored as usual. Scoring a study "sleep-wake" requires approval by the CP. Any study scored sleep - wake only will be given grade Fair regardless of the hours of scorable signal.

Arousals are not scored when the technical quality of the EEG does not allow differentiation of background changes in EEG from discrete periods of EEG acceleration. Studies may still be of sufficient quality to stage sleep.

13.3 Urgent Referrals/Medical Alerts:

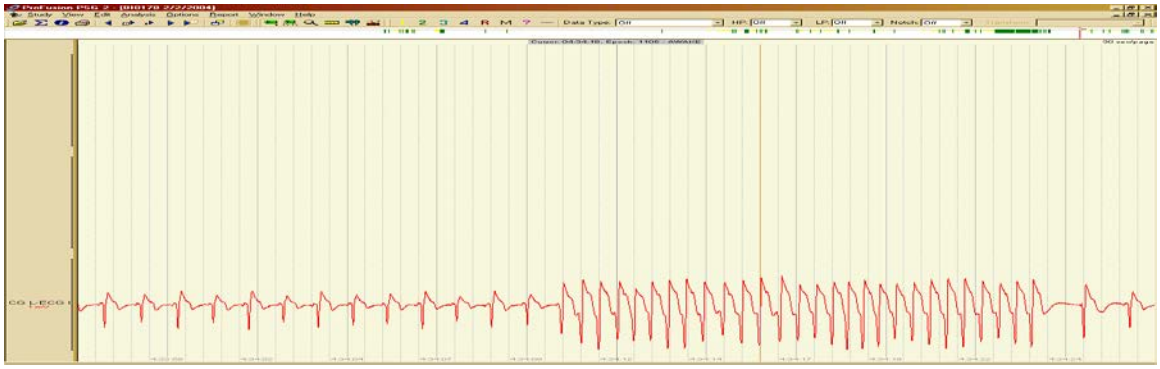
Check "yes" for any of the following criteria:

- Heart rate > 150 bpm for $\geq$ 2 minutes
- Heart rate < 30 bpm for $\geq$ 2 minutes
- Ventricular tachycardia (NSVT) observed
- Atrial flutter/fibrillation noted with no known diagnosis (as recorded at the clinic and communicated to CSERC) or known atrial flutter/fibrillation occurred with heart rate exceeding limits (>120 or <50).
- Oxygen saturation <85% for >15% TST

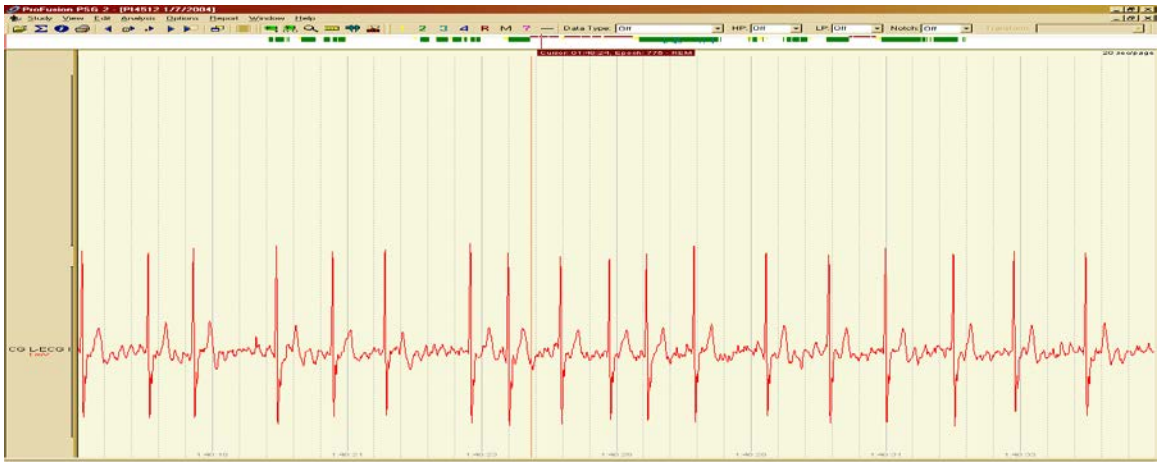
Note: An urgent referral/medical alert event **during PSG study** does not constitute an adverse event; therefore, completion of the HomePAP Adverse Event Form is not required.

13.4 Examples of Heart Rate Abnormalities Requiring Urgent Referral/Medical Alert

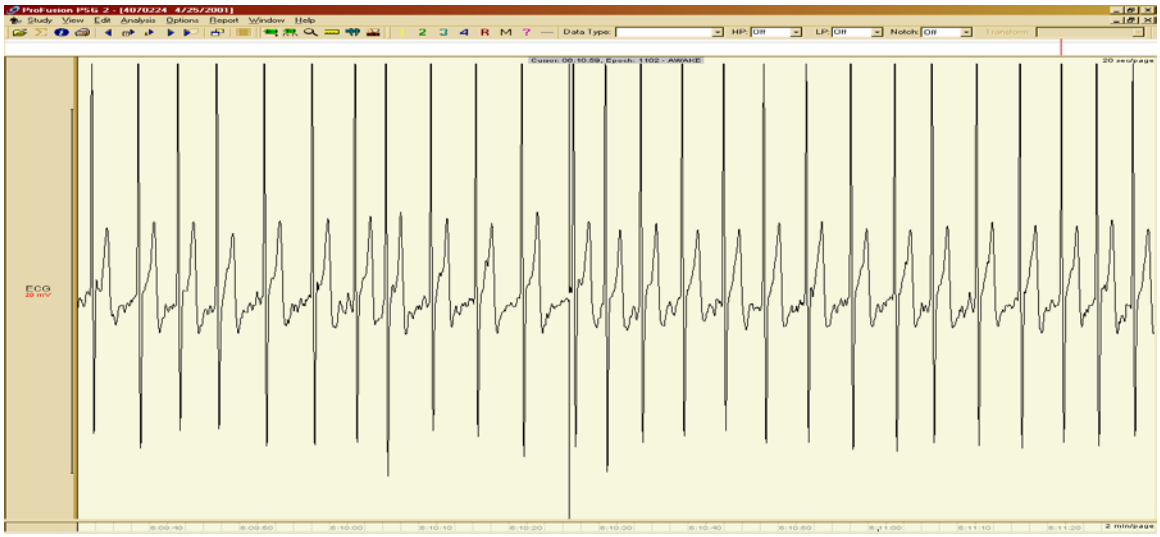
Non-sustained Ventricular Tachycardia (Rate≥120)



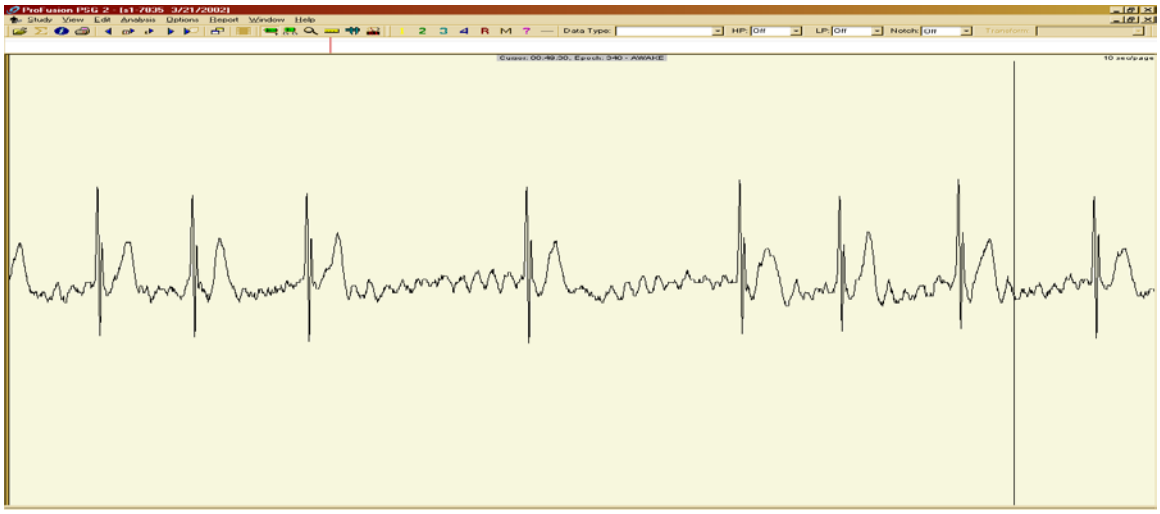
Atrial Flutter (Rate within Limits)



Atrial Fibrillation (Rate>120)



Atrial Flutter/Fibrillation (Rate<50)



13.5 Scoring Limitations

Was the study scored with minimal problem? The following boxes are checked when the scorer is unsure (approximately 20% of the time) about classifying epochs/events:

- Wake - Sleep unreliable: when the clarity of the EEG makes distinguishing the transition.
- Stage 1/Stage 2 unreliable: when K-complexes and sleep spindles do not have show their classical morphology and distinction between Stage 1 and Stage 2 is doubtful (characteristic for the studies with low voltage EEG).
- Stage 2/Deep Sleep unreliable: when distinction between Stage 2 and Deep Sleep is unreliable because of EEG artifact (usually due to the respiratory artifact on the EEG).
- REM/non-REM unreliable: when identification of Stage REM is unreliable (usually due to poor or missing EMG or when both EOGs are absent).
- Arousals unreliable: when the technical quality of the study does not allow one to distinguish discrete increases in EEG frequency from background changes in EEG. EEG still may be of sufficient quality to score stages. Studies with the physiological alpha intrusion will have arousals scored regardless of difficulty, Checking the “arousal unreliable”
- Arousals in REM unreliable: when EMG is artifactual or absent during all or REM portion of the study.
- Respiratory events/RDI unreliable: when due to the technical quality of the respiratory signals, distinctions between hypopneas and normal breaths are equivocal in over 20 % of scored events; also when the quality of the oximetry signal raises doubts about actual magnitude of desaturation linked with over 20 % of respiratory events (unstable baseline).
- Apnea/hypopnea unreliable: when airflow signal is artifactual or absent for over 20 % of scored respiratory events.

13.6 Unusual Sleep Occurrences

Abnormal Awake EEG: when the waking EEG background rhythm consists of waves in the theta range. This should be distinguished from presence of theta waves as a result of excessive sleepiness, which will disappear after some period of sleep, and may indicate a neurological disorder or toxicity

13.7 Data Loss

- Recording ended before participant awoke - the last epoch of the study is any stage of sleep; or when an arousal is seen in the last few epochs of the study and there is a question if the participant actually awoke or would have returned to sleep (i.e., lack of sustained activity indicating "out of bed.").
- Loss of the data at the beginning, end or during study - indicates a loss of the data due to poor technical quality of the signals for >30 minutes.

13.8 Flow Limitation

Flow limitation, as seen by the nasal cannula, which is not associated with respiratory events, and occurs in more than 10% of sleep time.

14.0 Quality Assurance and Quality Control

14.1 Weekly Quality Assurance Exercises

Weekly scorers' staff meetings will be conducted at the CSERC, with dedication of between one to two hours of time per week for the scorers to meet and discuss scoring issues. The weekly exercises will be organized by the Quality Control Monitor (QCM), with topics that will reflect ongoing needs as identified by the staff or by the Coordinating Center/PSG Committee. These exercises will include:

- scoring of randomly chosen epochs
- scoring of problem records/epochs
- discussions of any problematic rules/examples identified during scoring
- rotating "paired" scoring exercises

Exercises will include individual scoring with follow-up discussion of any discrepancies in assigned scores. A discussion, with participation of CSERC investigators, will establish a consensus score for discrepant records. Results of discrepancies between any scorers will be reviewed at weekly meetings with investigators. The results of the deliberations will be kept on file. This will include copies of ambiguous records and a summary of any arbitration.

Examples of organized meetings include:

- Quality Assurance (QA) Exercises: At least monthly, individual scorers will score the same 50 epochs from a selected study. Most studies for QA scoring will be chosen randomly; however, scorers also will identify problematic studies that may show useful training/teaching points during QA exercises. Scoring of such designated studies will be recorded on an epoch by epoch basis. Differences in any epoch or event assignment between scorers will be discussed during the weekly QA meeting. Results of this discussion will be noted on the separate form (group consensus).

When a group consensus cannot be reached, the epoch or event will be designated "indeterminate." Data will be entered into a database and summarized quarterly for internal QA tracking.

- Scoring Exercises: On the weeks when no QA exercise is performed, 30-60 minutes of paired scoring (one scorer scoring, one watching) or team scoring (with group members acting as a single unit) will be done. Noted differences will be discussed after the scoring exercise. Scorers will rotate roles, partners, and teams so that all interactions occur over any given time period.

- Studies which pose scoring difficulties or present interesting problems will be reviewed by the entire CSERC staff during weekly meetings. Minutes from these meetings and printed copies of problem epochs will be maintained.

14.2 Tracking Quality Assurance/Quality Control Data

The CP/QCM will track two types of data: data from the actual scored records and data generated during QA exercises. Using actual scored data, the overall mean RDI, sleep stage values and arousal indexes will be tracked for each scorer. If average values differ by > 15% for any given scorer, then those records will be reviewed by the CP/QCM. The CSERC Director will determine whether re-training and re-standardization are required. Using data from the QA exercises, levels of agreement will be determined among scorers and trends tracked over time. Any scorer identified to deviate excessively (>10% from the consensus statement) on three consecutive exercises will be "re-trained." "Re-training" will be considered successful if review of at least five additional studies demonstrates no deviation from scoring protocol, and the subsequent QA exercises show no deviations in performance compared to scoring assignments made by the other scorers.

At monthly QA meetings, the statistics summarizing inter-and intra-scorer variability will be reviewed by the CSERC staff. These data will identify any explanations for differences. If differences between scorers can not be explained by real differences in the studies assigned to any given scorer in any given time period, scorers noted to score differently will score together, concentrating on the areas where differences were noted. The QCM will assign a senior scorer to review consecutive records and reinstruct the scorer. Subsequent scoring will be monitored until conformity is demonstrated.