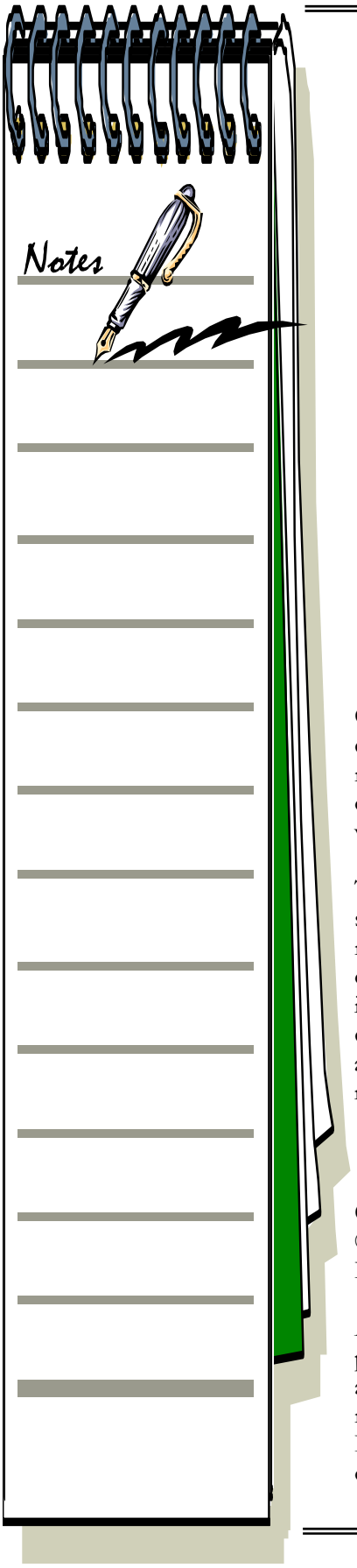
271212

Scoring Sleep Studies

3 Contact Hours



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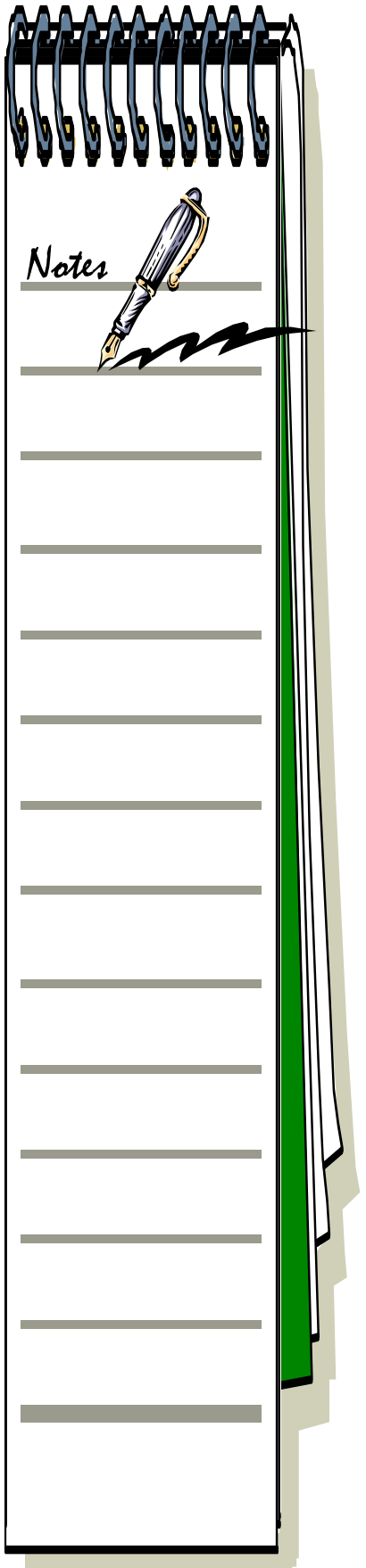

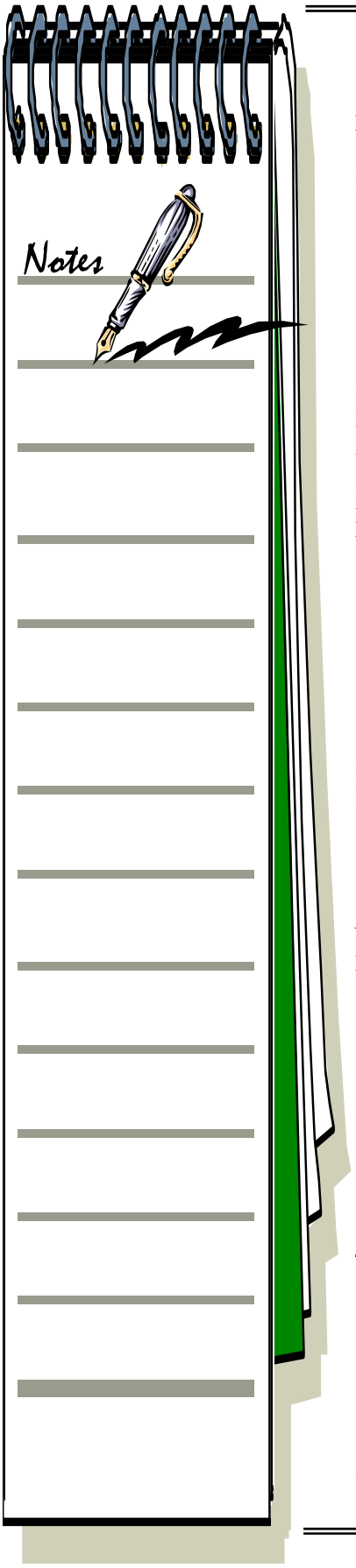

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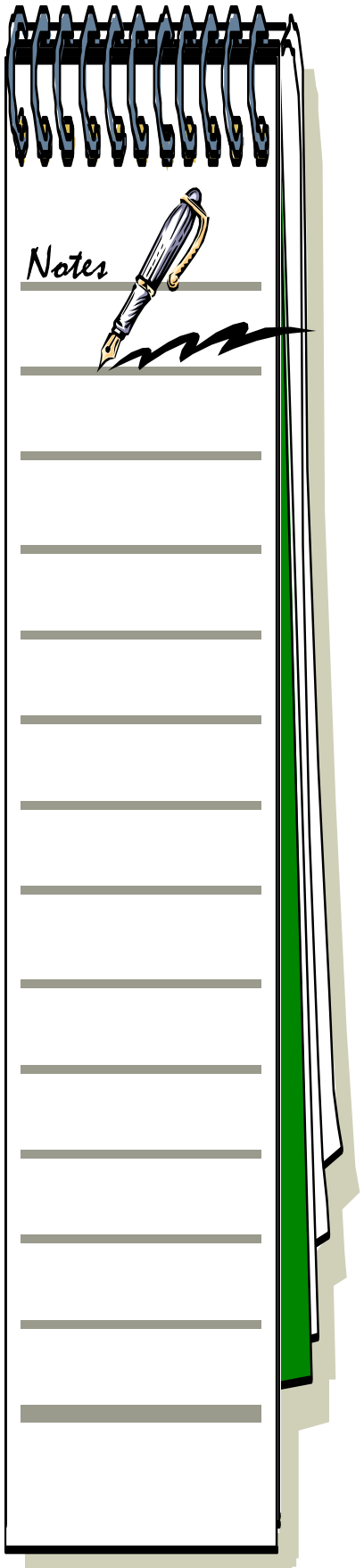
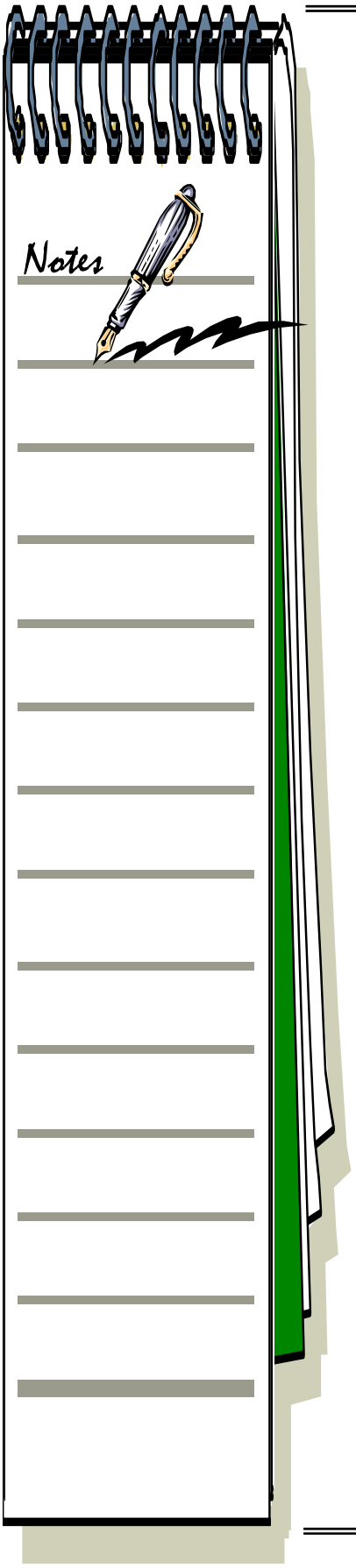



Notes

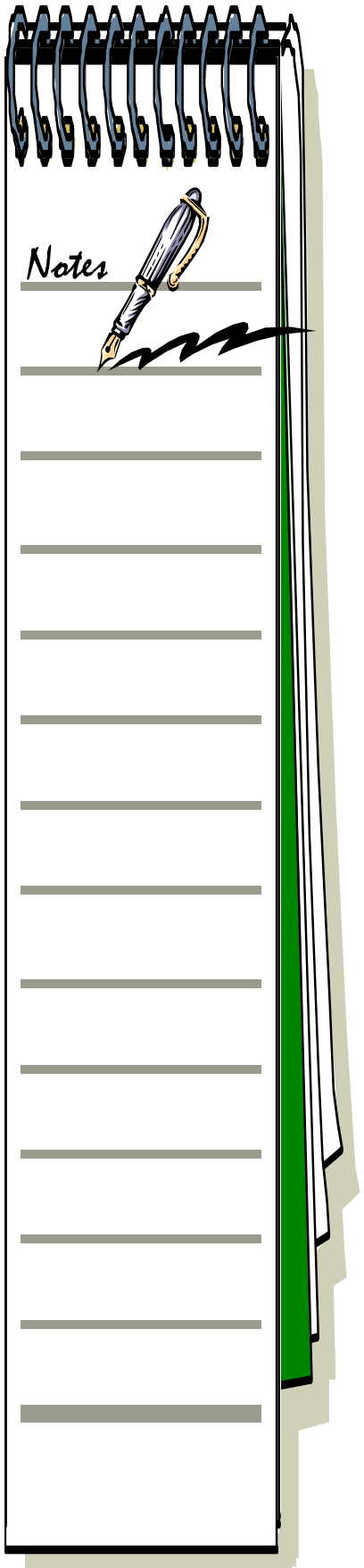
Scoring Sleep Studies

Course # 271212 **3 CEUs**

Learning Objectives

Upon successful completion of this course, you will be able to:

- Define what is meant by "scoring" sleep studies.
- Identify what changes were made in the new 2008 scoring "rules"
- Identify the differences of manual and auto-scoring.
- Identify what is meant by "Polysomnographic Interpretation".
- Define what is meant by "REM Scoring Subtleties".
- List the definitions of sleep-related respiratory events.
- Outline the new AASM Scoring Guideline Requirements.

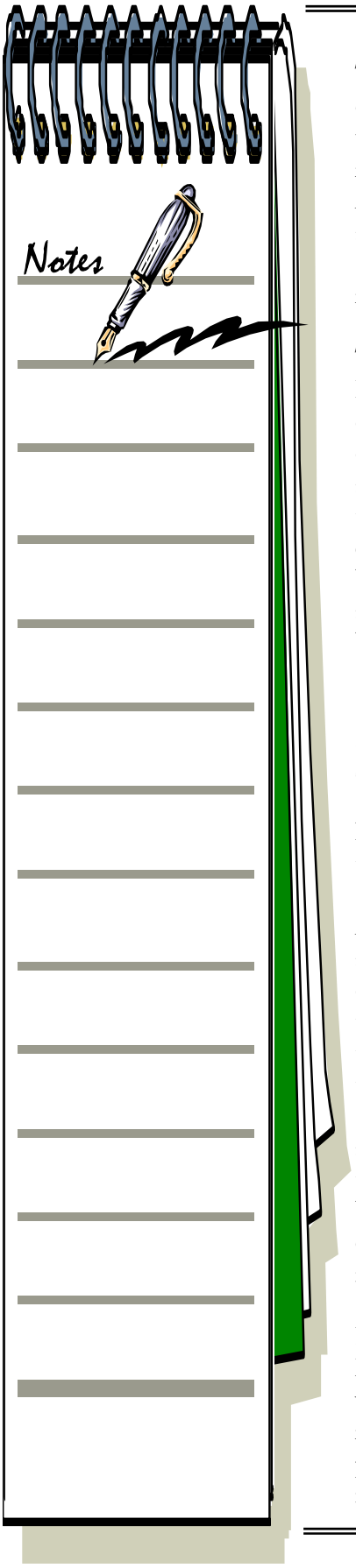


Introduction

New AASM Recommendations for Sensors: A Simple Guide for the Sleep Technologist

The implementation of new rules for scoring and summarizing sleep recordings has finally arrived and marks one of the most important milestones in the history of sleep medicine. The American Academy of Sleep Medicine published the first comprehensive and standardized scoring rules for sleep recordings in 2007. The AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology, and Technical Specifications is the result of years of deliberations and research among colleagues and industry concerning standardization of practices and technology in the field of sleep medicine. The final development of the new scoring manual includes changes in sleep stage terminology, technical specifications for recording and data management, and the standardized scoring of sleep. Since the publication of the AASM scoring manual, sleep disorders centers, physicians and sleep technologists have been preparing to comply with the new rules that became effective for all accredited sleep disorders centers on July 1, 2008. Understanding the changes and the use of new technology for sleep recordings presents a challenge for many technologists as well as sleep physicians.

The new scoring manual includes both recommendations and alternatives for parameters used in polysomnographic recordings. This article addressees two of the recommendations related to technical considerations and sensors used for recording of respiratory effort noted in section VIII of the scoring manual.



The AASM Scoring manual recommends that sensors used for detection of respiratory effort are "either esophageal manometry, or calibrated or uncalibrated inductance plethysmography." Recommendations are also included in the new scoring manual for detection of apnea and hypopnea. An oronasal thermal sensor is recommended for detecting absence of airflow to identify apnea, and a nasal pressure transducer (with or without square root transformation of the signal) is recommended for identification of hypopnea.

This article addresses the recommendations related to the use of Respiratory Inductance Plethysmography (RIP) to measure respiratory effort and the recommendation that nasal pressure be used in conjunction with an oronasal thermal sensor. The following discussion is an effort to bring some clarity for the sleep technologist concerning RIP technology. It is important for sleep technologists to understand the difference in RIP technology and piezo technology which has previously been used to record respiratory effort for the past few years. We will also address the rationale for the AASM recommendations for the use of both thermal and pressure sensors during PSG recordings.

Respiratory Effort Sensors

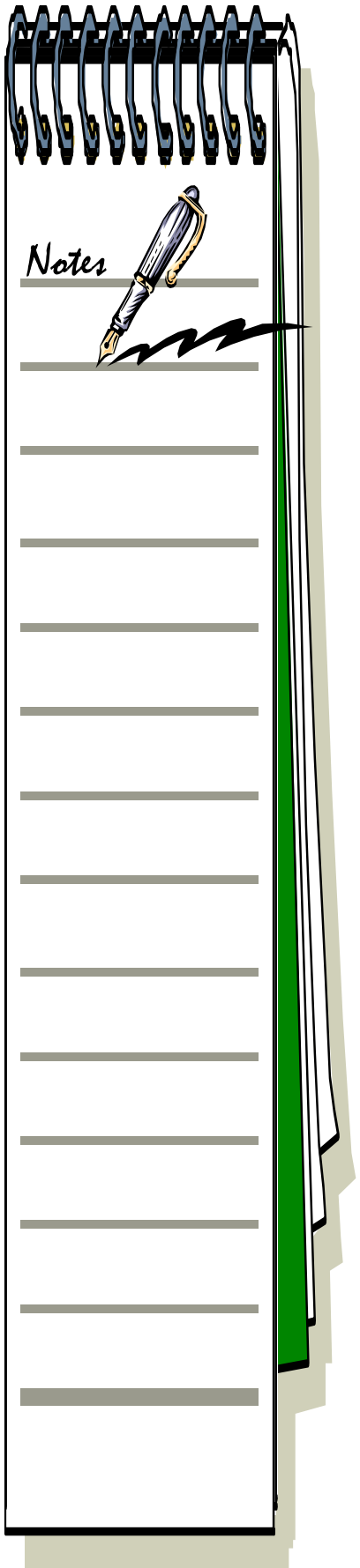
Sleepmate Technologies introduced the first piezo respiratory effort sensor the "Resp-Ez" in 1989. It replaced the mercury strain gauge that had been the standard for many years with a small, convenient package that did not run the risk of mercury contamination.

A piezo crystal is essentially a ceramic material that is capable of emitting a weak electrical signal when it is flexed. The little LED lights on children's shoes are often powered by a small piezo crystal in the sole of the shoe that is stressed with each footstep. When the stress is removed the electrical output stops. The repeated stress and release transmitted by the rise and fall of a patient's chest through an elastic band creates the familiar sine wave pattern on the recorder. The waveform is only an approximation of the movement of the chest and abdomen. In particular the output of the piezo is not linear. In other words the output created by a 1 inch change in chest or abdomen circumference is not twice the output from a ½ inch change. This lack of a linear response makes it more difficult to assess hypopneas.

Piezo-based effort belts also measure the tension where the crystal is located, a single point, where the band pulls during breathing. Problems with accuracy of the signal can occur when the patient moves and tension is lost. Piezo belts also can produce a phenomenon known as false paradoxing, particularly when the tension on the belt is altered by patient movement.

The AASM likely believed that the above mentioned problems associated with piezo technology were significant enough to warrant finding a more reliable way to measure respiratory effort. As a result of the new AASM recommendations the piezo respiratory effort sensor, though it has proven its reasonable accuracy over millions of sleep studies, is now replaced in AASM accredited sleep centers with RIP technology (the recommended AASM standard).

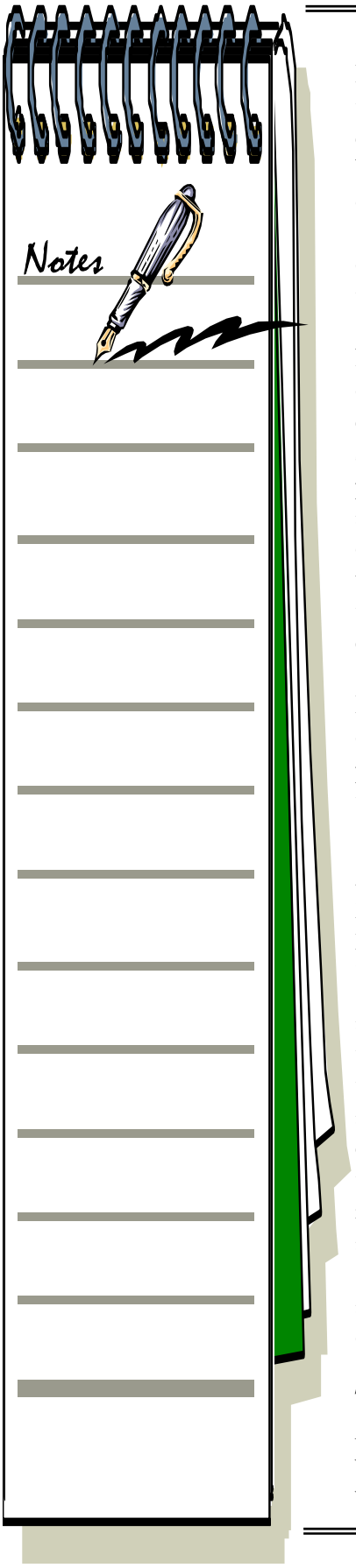
It should be noted that the AASM recommendation for RIP is Respiratory Inductance Plethysmography. There is currently another existing technology known as Respiratory Impedance Plethysmography which is not what the AASM recommends. There may be some confusion as both go under the RIPmoniker, but they work very differently. Accredited sleep centers that must use the new AASM scoring should be aware of the difference and insist on Inductance Plethysmography.



Respiratory Inductance Plethysmography

Inductance Plethysmography employs sensors that are able to measure changes in a cross-sectional area of the patient, specifically the thorax and abdomen during a respiratory cycle. The RIP sensor consists of a belt with a wire woven or sewn in a sine wave or zig-zag pattern along its length, and a driver module with a circuit board, oscillator and battery that passes a weak current through the wire in the band creating a small magnetic field. As the band is stretched and relaxed by the patient's breathing the cross-sectional area within the band changes slightly. This change in cross-section produces a slight change in the magnetic field that results in a change in the frequency of the current. This change can be measured and converted to a voltage output that creates the waveform on the PSG recorder. The science behind this phenomenon has to do with currents induced by changing magnetic fields and certain laws attributed to physicists, none of which really matters for the purposes of our discussion here. The key concept is that the stretching and relaxing of the band can be measured accurately and depicted as a waveform.

The circuitry in the processor module detects the change in the frequency and produces a signal waveform that is represented on the PSG recorder. An important quality of Inductance Plethysmography is that the signal depicted is linear, that is to say it changes in proportion both when the band is stretched and when it is relaxed. Thus, if a 1 inch stretch of the band creates a 1 volt output then a 2 inch stretch would create a 2 volt output and the difference would be clearly seen in the size of the waveform on the PSG recorder.



It should be noted that with RIP there is no electrical current passing through the patient, and only a weak magnetic field is created. The signal does not require a specific tension in the band, making the fitting of the band less critical than with a piezo belt. The bands need only be tight enough to stay in place and in fact a band that is too tight can loose signal quality. The belts should be placed in the standard locations at mid chest and just below the umbilicus to assure maximum expansion during the respiratory cycle.

By placing the bands over the abdomen as well as the thorax, the sensor can measure the phase relationship between the two bands and can help distinguish central apnea from obstructive apnea during sleep studies. Some RIP systems also include a sum channel that is useful in detecting paradoxical breathing or slight phase shifts. When the thorax and abdomen signals are completely out of phase in theory they will cancel each other out and the sum channel will be flat. In practice this is highly unlikely given the signal processing requirements, but it is useful for the technologist to be able to note a decrease in the sum channel output during these out-of-phase or paradoxical breathing episodes.

RIP can also be calibrated to measure the actual volume of airflow to create a "flow-volume loop". Calibrated RIP systems have not been as popular because of the time required to calibrate and the expense of these more sophisticated systems.

Pressure and Thermal Airflow

In addition to piezo effort belts being replaced by Inductance Plethysmography, the AASM has recommended that an oronasal thermal sensor be used to detect the absence of airflow for identification of apnea. As an alternative, the recommendations state that when the thermal signal is unreliable, technicians may use a nasal air pressure transducer. The AASM is recommending one sensor for apnea detection and another sensor for hypopneas. The recommended sensor for detection of airflow for identification of hypopnea is a nasal air pressure transducer, with or without square root transformation of the signal. The reasoning behind the recommendation for using two different types of airflow sensors is that nasal pressure transducers are more sensitive to slight changes in airflow (hypopneas), but may result in overestimating apneas, while thermal sensors are less sensitive to minor breathing changes, but are more reliable for identifying apnea.

Thermal sensors are generally either a thermistor or a thermocouple. Athermistor is a variable resistor that responds to temperature changes, while a thermocouple is made of dissimilar metals that generate a variable voltage in response to temperature fluctuations. Thermocouples are

generally thought to produce a more stable signal and to react better to small changes in airflow. Pressure transducers are even more sensitive than thermocouples, but require a cannula to be purchased with each study, and are less comfortable for the patient. In addition, mouth breathing is difficult to detect with a cannula and can cause a loss of the signal.

In the past, practitioners have either used an oronasal sensor or nasal pressure for recording airflow, often based on personal preference. Thermocouples are the choice of many sleep labs as they represent a fair compromise between a pressure transducer and a thermistor. Thermocouples are small, generally fit well on the patient, and pick up both nasal and oral flows. It is not practical to detect oral airflow with a pressure transducer.

Although the new recording recommendations present a challenge because of the requirement of using both a thermal sensor and a pressure transducer, the technology is not new. Sleep technologists will eventually become accustomed to using both sensors and will devise innovative techniques for obtaining good quality sleep studies. Manufacturers will ultimately develop oronasal sensors that can easily be used in conjunction with nasal pressure. As the field of sleep medicine continues to grow, the technology also continues to improve. The new scoring and recording rules represent a step in standardizing techniques, terminology and rules in sleep medicine—a step that is long overdue. Sleep medicine technology is on the path to continued growth in the next decade.

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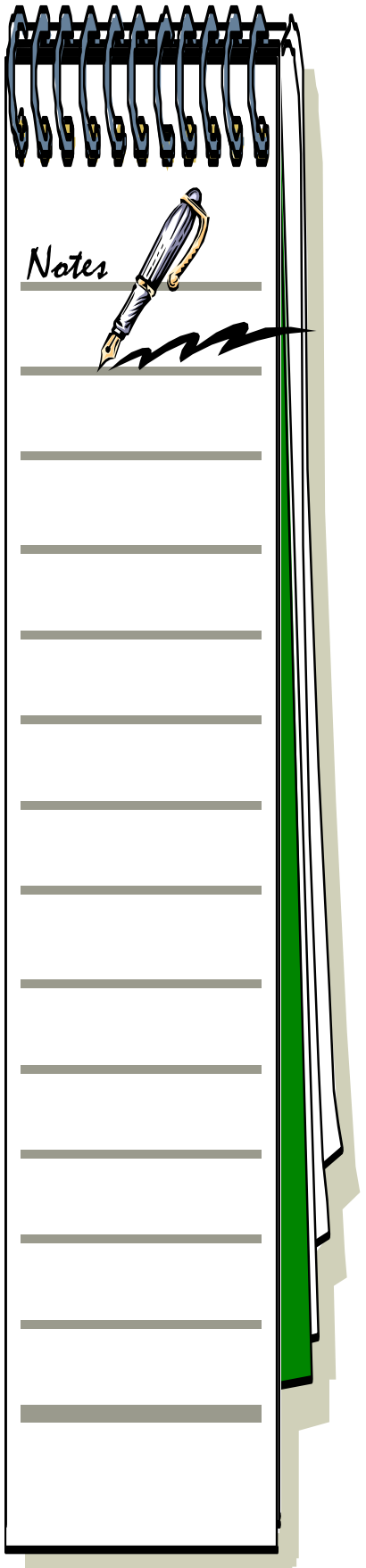
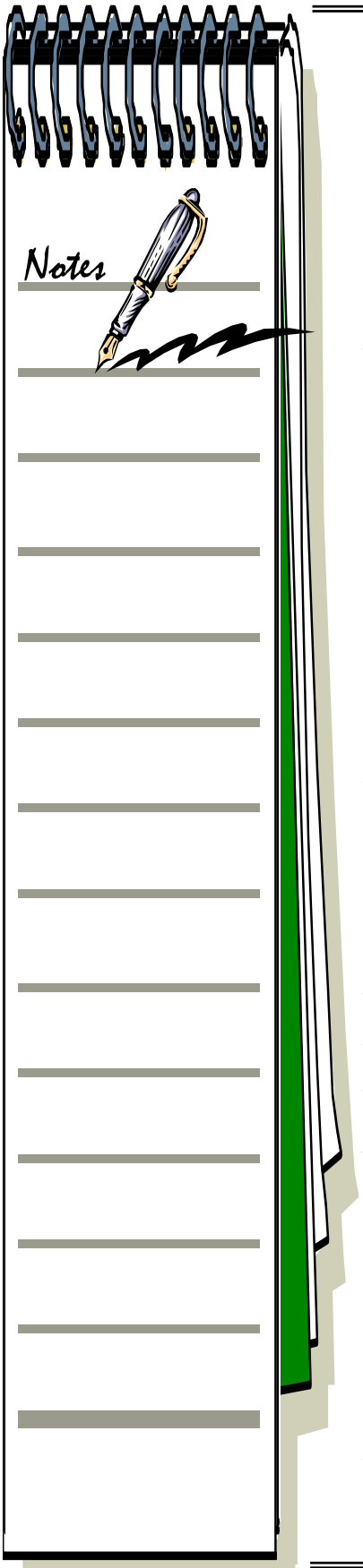


References

1. Iber C, Ancoli-Israel S, Chesson A and Quan SF for the American Academy of Sleep Medicine. The AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology and Technical Specificatiions, 1st. ed: Westchester, IL: American Academy of Sleep Medicine, 2007.
2. SleepMate Technologies—A history of Innovation. (http://www.sleepmate.com/about_us/index.jsp)



In reviewing the field of sleep scoring, it is valuable to review the following:

"Sleep Disorders, EEG-Changes, Altered Cognitive Functions – Is there a Connection with the Exposure to Mobile Communication RF Fields?" Stuttgart, Germany 5th-7 th November 2007

This workshop was organized by FGF E.V., EMF-NET, and the State Ministry of Environment, Baden-Württemberg. About 60 expert persons attended giving 30 lectures, each followed by open discussion over two and a half days.

Dr G. Friedrich, Managing Director of the FGF and Mr. P. Brunner, representing the State Ministry of Environment, Baden-Württemberg, made welcome and introductory remarks.

Mr. Brunner reminded us of the purpose of our meeting. 'Solid scientific knowledge must be the basis for the evaluation of possible risks from radiofrequency exposures. He said, although the German Radiation Protection Commission concludes that there is no need to change the limits in the range of radio frequency electromagnetic fields due to evidence for potential effects found in single research projects and studies, the conference experts need to evaluate the relevance of these single results in this meeting and advise the Ministry on further research to close the existing gaps of knowledge on RF effects on sleep by further focused research.

The workshop brought together representatives of the RF research groups that have worked on the topics of sleep/EEG and cognitive research and offered a public forum for open discussion of their results. This meeting continued on the progress in this area of the previous FGF, COST 281 and the State Ministry of Environment, Baden-Württemberg Workshop: 'Can electromagnetic fields used in mobile communications provoke sleep disorders?' in Immenstaad Germany 7-10 December 2003.

Introductory lectures explained the topic of the awake and sleep electroencephalograms [EEG] and the biology of sleep. They explained that medical sleep clinicians use an established international protocol to characterize, record, and score sleep polysomnograms. As well, sleep clinicians use the World Health Organisation [WHO] adopted 'International Classification of Sleep Disorders' [ICSD-2, 2005] for identifying and treating sleep disorders. Signals of base stations and mobile phones were reviewed including new technology signal measurement reports. The published EEG cognitive and sleep studies

with RF exposures were reviewed and the newly conducted and ongoing studies were presented and discussed. At the end of the conference after a general discussion, overall consensus conclusions were made.

I have focused this report on the introductory lectures by two invited experts in sleep research outside of the RF research area since their presentations were most helpful for the conference purposes [see Bruner above]. Firstly, Dr M. Kiefer outlined the specifics of the nature of brain EEG recordings. Secondly, Dr Thomas Penzel outlined the methods of evaluating the polysomnography [PSG] scoring of sleep research, specifically to revise *'The American Academy of Sleep Medicine [AASM] Manual for the Scoring of Sleep and Associated Events: Rules, Terminology and Specifications*'. This thorough, open, expert evaluation of sleep scoring methodology and evidence in the sleep publications, outside the RF field, may be directly applicable to designing, conducting and evaluating human RF sleep research. It is the 'solid scientific knowledge' we need to progress in human RF sleep research.

The human being has detectable, recordable, electroencephalogram [EEG] brain activity continuously as long as alive. The recording of the EEG is divided into wake and sleep EEG. Sleep EEG has unique features, making it easier to record as an individual is naturally unconscious in a reclined position throughout, e.g., sleeping, confined to a bed for 8 hour periods, daily. Because of the importance to RF sleep research of this unique opportunity to learn about quality polysomnographic sleep recording introduced in Dr Penzel's presentation I have confined my rapporteur's review mostly to quality polysomnographic sleep recording rules as revealed by the results of *The American Academy of Sleep Medicine [AASM] Manual for the Scoring of Sleep* Task Force for the revision on the R & K [1968] Sleep Recording Manual.

The rapporteur's report ends with 'Overall Conclusions' and,' Dr Brunner's Purposes of the Workshop: Answers.'

Measuring cognitive function in the human brain with EEG

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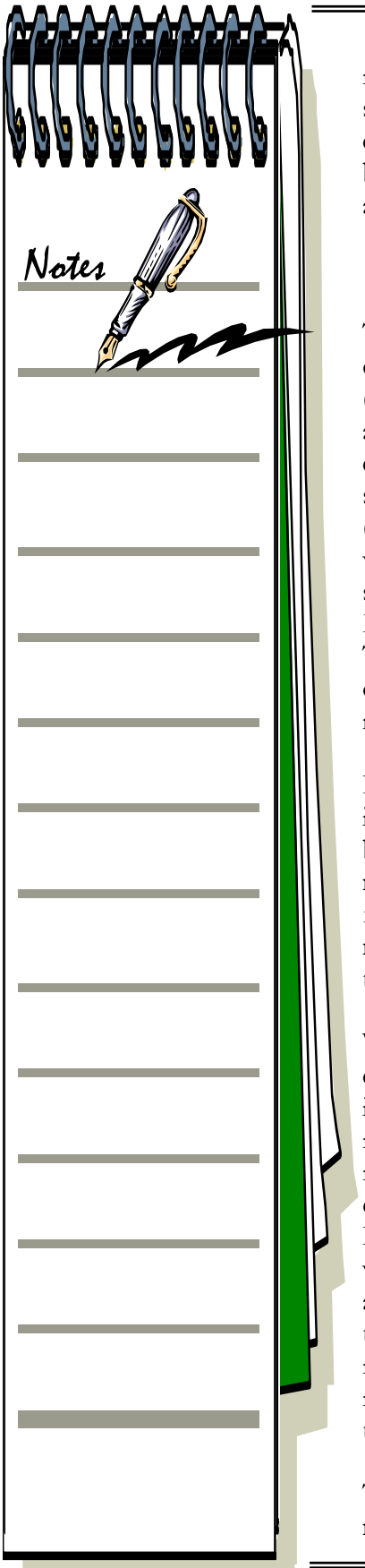
Summary [Derived from Dr Kiefer's slides, abstract and SAJ's notes]

Brain function can be studied non-invasively by measuring its electrical activity on the intact scalp. The possibility to record the electroencephalogram (EEG) had been discovered in the 1920's by the German psychiatrist and neurologist Hans Berger. The EEG arises from



rhythmic changes of scalp voltages generated by a summation of post-synaptic potentials from a large number of neurons. Since its first discovery, EEG recordings have been widely used in clinical settings as a brain function test of a **gross** correlate of brain activity for monitoring and diagnostic purposes. The EEG is typically described in terms of

1. rhythmic activity and
2. transients, e.g. single events.

The rhythmic activity is divided into bands by frequency. The frequency composition of the EEG typically depends on the state of the individual (e.g., degree of alertness, sleep stage, cognitive processing); it might be altered in neurological and psychiatric disorders and is affected by certain drugs and foods such as caffeinated coffee. There is a different cognitive significance associated with each of the frequency bands. The alpha band (8-12 Hz) is recorded from electrodes at the back of the head from the visual cortex when the eyes are closed during relaxation this wave signifies cognitive inhibition, and visual relaxation. The beta band (12-30 Hz) arises from a different form of mental activity for instance, speech. The gamma band (30-100 Hz) is recorded during visual perception and object recognition. And the theta band (4-7 Hz) is associated with memory consolidation in the hippocampus in the temporal cortex.

In research settings, the EEG is used as a non-invasive technique to investigate brain function. It allows determining the orchestration of brain activity with a **high temporal resolution in the range of milliseconds** in contrast to other brain imaging techniques such as functional magnetic resonance imaging (fMRI). However, **EEG has a relatively poor spatial resolution** so that the brain electrical sources of the potentials recorded at the scalp can only be approximately identified.

With the sleep polysomnograms you only record correlation information, descriptive information, not causal information. To move to causal information you have to stimulate and record a related response. For research purposes studying awake cognitive processes, mostly the event-related potential (ERP) technique is employed. ERPs contain only electrical brain activity, which is time-locked to a stimulus or an event. Most ERP experimental paradigms involve a subject being presented with a stimulus to which an overt or covert reaction is required. There are often at least two conditions that vary in some manner of interest to the researcher. As this stimulus-response is going on, an EEG is being recorded from the subject. The ERP is obtained by extracting the event-related activity from the background EEG activity by an averaging technique in each of the trials within a certain experimental condition.

The advantage of EEG or ERP recordings in research settings is their **non-invasive nature** and their high temporal resolution so that subtle

activity changes that last only a few milliseconds can be detected. EEG recordings may reveal subtle differences in brain function, which are not always accompanied by behavioral performance differences.

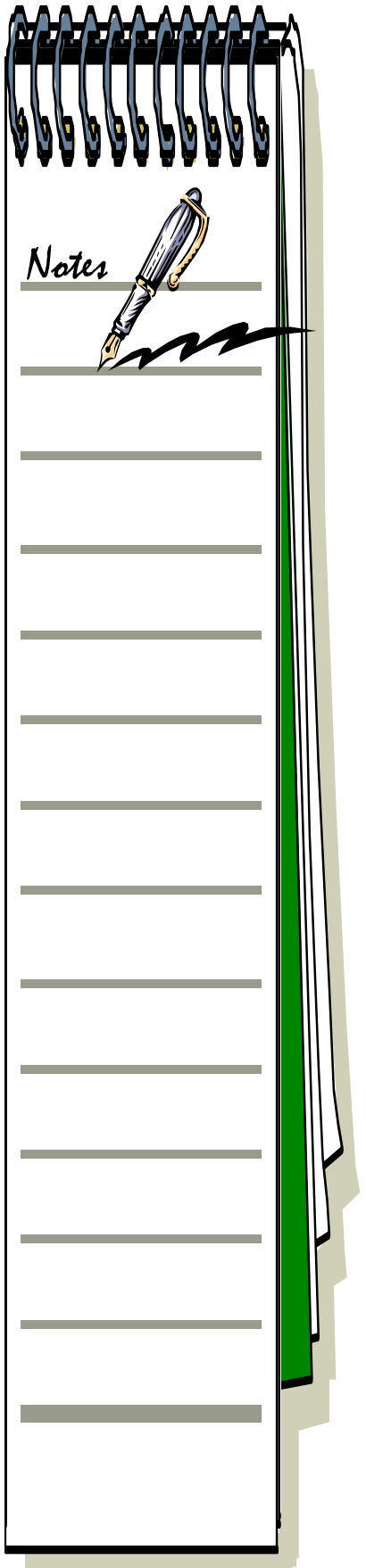
The disadvantage of EEG measurements is their low spatial resolution and the fact that they only reflect synchronous electric activity of large neural assemblies. For a fine-grained analysis, intracranial recordings of single cells are necessary. It should also be noted that contamination of EEG recordings by artifacts (eye or head movements, muscle movements, and external electrical noise) could compromise the interpretation of the data if such artifacts are not properly removed or rejected. Despite these limitations, EEG measurements are an important tool to elucidate cognitive and sleep functions in the human brain non-invasively.

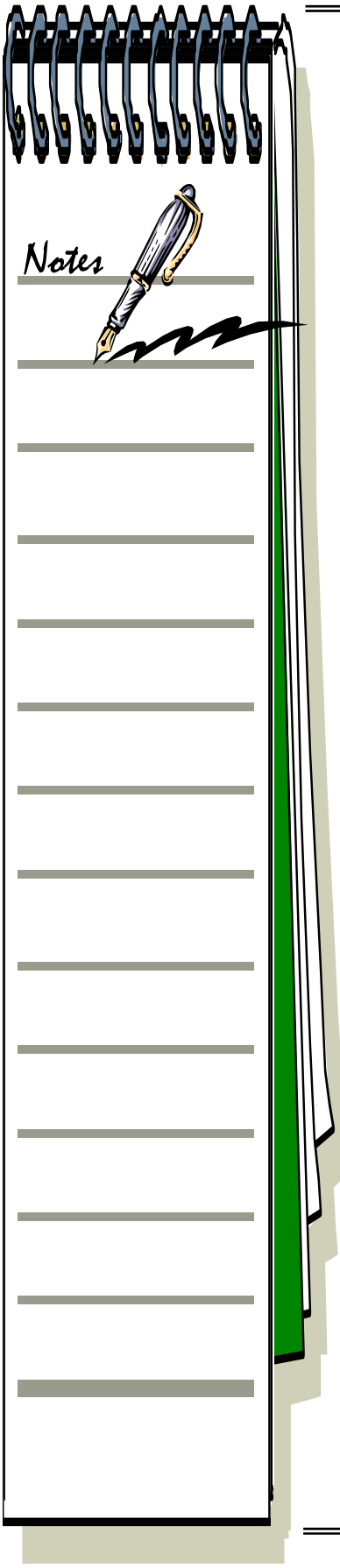
Humans spend a third of their life asleep. Sleep has its own internal structure with a well- programmed sequence of sleep stages. Important tasks being fulfilled during sleep are physical recreation, mental recreation, consolidation of memory, hormonal regulation, immune system activation, and restoration of performance [See: *Nature,* Issue July 2004; *Nature Insight Special Issue,* 27 Oct 2005; *Time Magazine*, July 2005]. Sleep is not a steady state of unconsciousness but has an internal structure with a cyclical time course. Sleep is a very dynamic and complicated behavior. Sleep begins over the daily circadian period when core body temperature is reaching its lowest level and ends when core body temperature is rising again [Kräuchi et al., 2007a,b]. Over the sleep period homeostasis is being restored.

The basic measurements of sleep diagnosis may include: sleep recording; sleep stage evaluation [according to Rechtschaffen and Kales, 1968] and cardiorespiratory recordings or ambulatory sleep recording.

In order to quantify sleep and sleep stages, polysomnography (PSG) is the chosen electrophysiological recording method in the sleep laboratory. The PSG recordings of sleep should include the left and right eye electromovements (electro-oculogram, EOG), the electroencephalogram (EEG, brain electrowaves recorded on the skin of the scalp), and the electromyogram submentalis (EMG of the chin muscle).

Sleep parameters such as percentages of sleep stages, latencies, wake times, and awakenings are measured. There are sequences of the sleep stages across the night from light sleep to deep sleep to rapid eye movement [REM] sleep with about 6 cycles of these periods of 90 minutes across about 8 hours of sleep. Sleep changes with age; older people have less slow wave sleep (SWS) time and more waking after sleep





onset and total slow wave sleep time decreases. [See Appendix A, N3, at the end of this document]

The classification of sleep stages according to Rechtschaffen and Kales (1968) is defined as follows:

- **AWAKE**: has beta waves and alpha waves that make up greater than 51% per recording epoch (30 seconds), with rapid eye movements and muscle tone at its highest;
- **REM**: has theta waves with some alpha, and rapid phasic eye movement, and muscle tone at the lowest;
- **NREM 1**: has theta waves, and alpha waves are less than <50% per epoch, and slow eye movements and muscle tone are reduced;
- **NREM 2**: has theta waves, spindles, K-complexes, no eye movements and muscle tone is low;
- **NREM 3**: has theta waves, delta is greater than 20% and less then 50%, there are no eye movements, and muscle tone is much lower; and
- **NREM 4**: has theta waves, delta is greater than 50% per epoch, there are no eye movements, and muscle tone is very low.

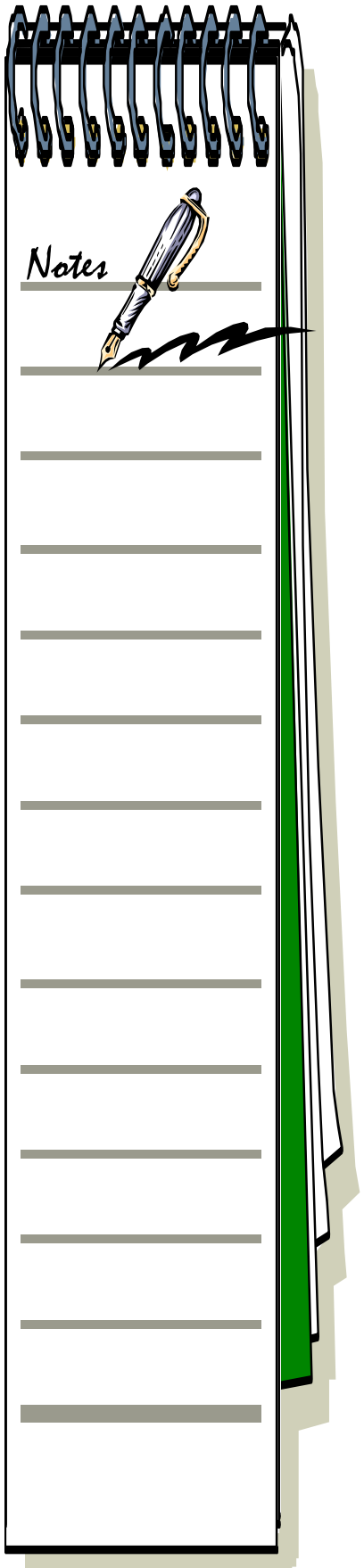
Digital Scoring

In the revision of the Rechtschaffen and Kales (1968) Manual by *The AASM Manual for the Scoring of Sleep* [2007] expert scientific Task Force for the standard of practice of PSG recording the issue of digital acquisition, display, and analysis was addressed. 'The evidence review suggested that computer scoring and quantitative analysis of sleep is still in the stage of development. Assessment of computer/digital capacity to mimic the well-trained visual scorer may be useful, but research is still needed to determine whether this [digital] technology will contribute new methods for understanding sleep and its disorders' [Penzel et al., 2007].

Visual Scoring

The well-trained visual scorer of sleep PSG is still considered the most reliable method for interpretation of the recordings [Silber et al., 2007; Iber et al. 2007a]. The R & K rules are extended by aspects of cardiorespiratory polysomnography. *The AASM Manual for the Scoring of Sleep* [2007] expert Task Force recommend more EEG leads; EOG and EMG scores should be more specific; merging of stages 3 NREM and 4 NREM to N3; new abbreviations for the stages namely, W, N1, N2, N3 and R to replace awake, NREM1, NREM2, NREM3 [and NREM4] and REM, respectively; discarding the stage 'Movement'; and they

recommend simplification of many context rules. They define new recommendations for sampling rates and filter settings; no automatic sleep analysis should be used. There is a new recommendation for PSG reporting and for user interfaces of computer-assisted systems (Iber et al., 2007a; See Appendix A, Appendix B, below).



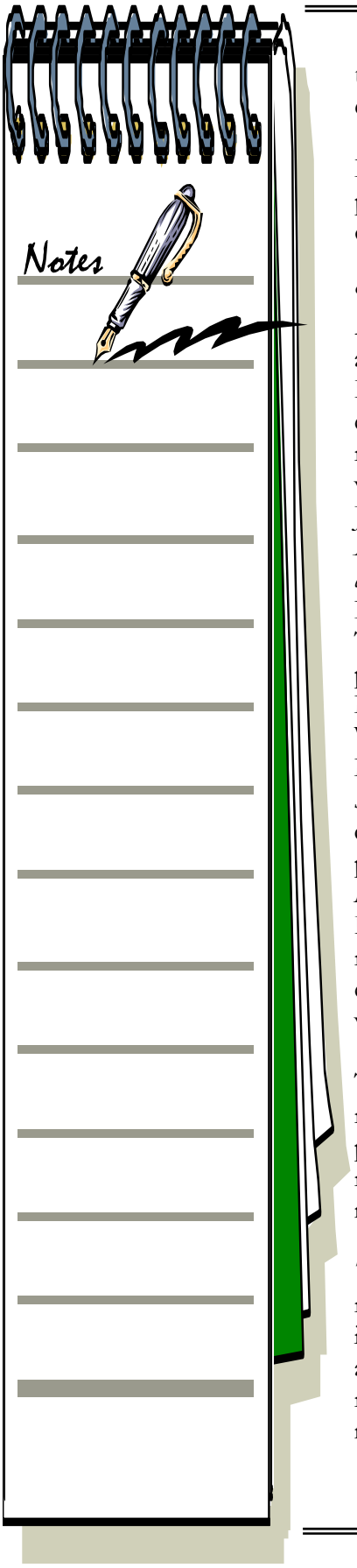
Ambulatory Sleep Investigation [Portable, non-laboratory, recording]

There are systems for ambulatory one channel sleep recording including ambulatory PSG (e.g., Embla), ambulatory EEG recording, special systems for sleep apnea, Quisi, and Biosomnia. But with one to two channel EEG sleep recording, no standardized leads, no visual inspection and automatic analysis, the ambulatory sleep recording has limitations because of lack of supervision, video, correction of electrodes and raw data and quality control. The discussion of ambulatory sleep recording is relevant to the interpretation of some of the RF sleep research reported at the Workshop (See the discussion below of the presentation by Leitgeb et al., 2007)

Penzel's Conclusions

1. Quantitative [digital] sleep analysis can give an objective diagnosis of sleep disorders but there is no accepted defined digital recording or scoring procedure and there are no estimates of the validity or reliability of the various digital recording methods.
2. There are, however, gold standards for the cardiorespiratory PSG and the visual evaluation of the sleep recording.
3. A limited [ambulatory] sleep recording with a one channel EEG gives only limited and not reliable results.
4. There are well-defined sleep disorders that are now part of ICSD-2 [2005] coding with eight main groups.
5. There are contradictory results on the influence of RF on sleep and the effects are much smaller than effects of known sleep disorders.

Dr Penzel's presentation was followed by many questions focusing on the variability of sleep recordings and the likely measurement limitations that would make recording, small RF effects near impossible. What is the variability of polysomnograms across a month for any one individual? What is the error in measurement, the natural variability of the EEG? How do you control for all the external factors such as caffeine consumption, alcohol consumption, noise, and emotional factors that are known to cause large enough effects to be detectable? Would caffeine or noise be a good positive control? How likely is it to pick up small effects if the natural variability in polysomnograms is large? In that case, since



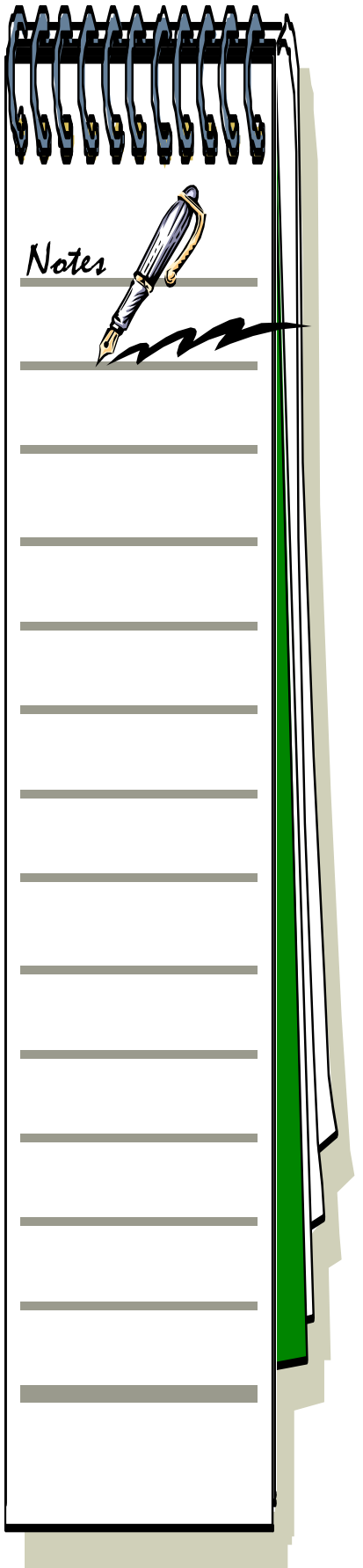
the effects of RF on sleep appear to be small, would it be a poor endpoint to study?

Dr Penzel agreed it would be difficult to pick up small RF effects in polysomnograms and he agreed noise [or caffeine] could be a positive control.

'***The AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology, and Technical Specifications***' Iber et al., [2007a,b] have revised the sleep scoring Manual of Rechtschaffen and Kales, [1968] with new scoring rules based on literature review and expert consensus on the evidence. The PSG scoring evidence behind the rules in '*The AASM Manual for the Scoring of Sleep*' was presented in seven white papers in a special edition [March 2007, Volume 3 Issue 2] of 'The Journal of Clinical Sleep Medicine' [JCSM] [Iber et al., 2007b]. "*The AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology, and Technical Specifications*" was published separately [Iber et al., 2007a]. Dr Iber was chairman of the Steering Committee of the revision Task Force. The revision Task Force topics were digital analysis and reporting parameters [chair T. Penzel], visual scoring [chair M Silber], arousal [chair M Bonnet], cardiac events [chair M Caples], movements [chair A Walters], respiratory events [chair S Redine], and pediatric scoring [chair MM Grigg-Damberger]. The charge of *The AASM Manual for the Scoring of Sleep* Task Forces was to develop reference material to support the development of a more comprehensive Scoring Manual. The Task Forces participated in consensus decision making for revision of *The AASM Manual for the Scoring of Sleep* [Iber et al., 2007a,b]. Similar chairs, Task Forces and procedures were followed for the earlier [Iber et al., 1999] revision of Rechtschaffen and Kales [1968] [R & K]. Standardized evidence tables (which can be accessed on the web at www.aasmnet.org) were prepared and evidence levels assigned to each study.

The revision of the R & K method of sleep recording as specified in the revised *AASM Manual for the Scoring of Sleep* [2007] was an iterative process; future editions of the Manual will undoubtedly require a reexamination of evidence to address the rapidly evolving science of the metrics for sleep recording [Iber et al., 2007a, b].

The AASM Manual for the Scoring of Sleep [2007] Task Forces openly reviewed the evidence for the accuracy of their scoring methods and this is most helpful to us reviewing the RF sleep research to use their results as the basis for, and a guide to, reviewing the quality of RF sleep recording evidence. Below I focus on digital and visual recording methods.



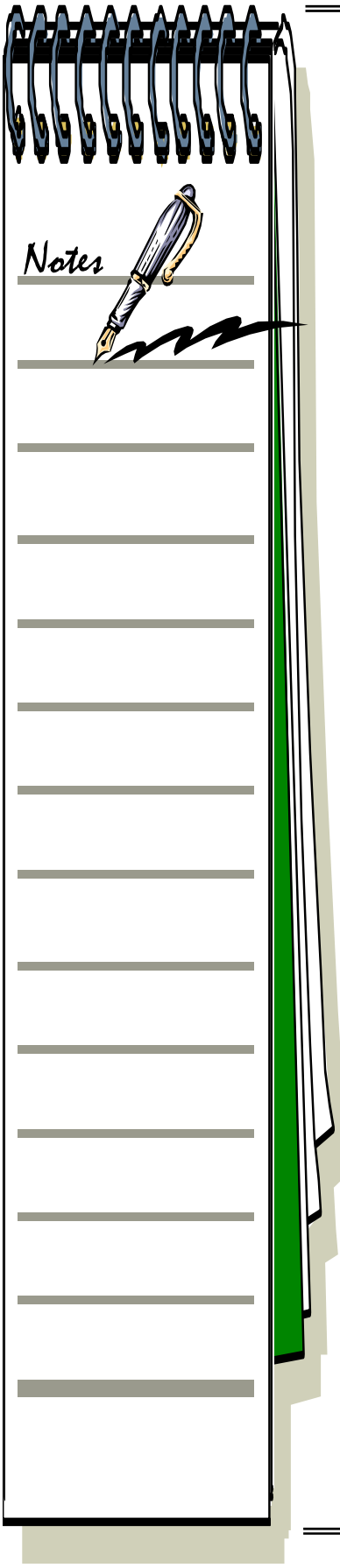
Digital Scoring:
Excerpted digital scoring comments below arise from a chapter on 'Sleep' by Dr Achermann and from a chapter on the 'Sleep Laboratory' by Dr Penzel in the recent book '*Wiley Encyclopedia of Biomedical Engineering*' [2006]. The digital scoring excerpts also come from the white paper of *The AASM Manual for the Scoring of Sleep* [2007] Task Force on digital scoring chaired by Dr Penzel [Penzel at al., 2007] and the section in *The AASM Manual for the Scoring of Sleep* [Iber et al., 2007a] on digital scoring rules. [See Appendix B, addendum recommended digital specifications, below]

No optimum method of digital recording has been identified. The methods are based on rules, neural networks, or fuzzy logic approaches. All methods try to mimic the visual classification of Rechtschaffen and Kales [1968]. Algorithms based on sleep EEG alone have difficulties distinguishing wake, sleep stage 1, and REM sleep [Penzel, 2006; Iber et al., 2007a].

'It is important to note that spectral analysis is a mathematical approach to quantify the EEG and does not provide a biophysical model of EEG generation. The sleep EEG is a non-stationary signal with typical changes in total power as a function of the non-REM-REM sleep cycle. Nevertheless, by selecting short epochs in which the parameters of interest vary little, the requirements for stationarity may be fulfilled (quasi-stationarity). The choice of the epoch length is a compromise between frequency resolution and stationarity. For spectral analysis, [of an entire night's sleep] epochs of 2 s to 10 s usually are used ' [Achermann, 2006].

'A shortcoming of spectral analysis is the loss of temporal information. The frequency spectra do not indicate the time point of a specific change within the analyzed interval. In an effort to overcome this shortcoming, Gabor (1946) adapted the Fourier transform so that only short sections of the signal are analyzed at a time. This technique is called short-time Fourier transform (STFT). STFT is a compromise between time- and frequency-based views of the signal; time and frequency resolution are fixed' [Achermann, 2006].

Validity and reliability of digital analysis: *The AASM Manual for the Scoring of Sleep* [2007] Task Force consensus: 'While [digital] findings suggest discernible relationships between sophisticated computerized EEG parameters and both normal and abnormal sleep, the understanding is minimal at this time. Much more work is needed in this area before the sleep specialist will have an acceptable [digital] clinical tool.' '..validation remains a question. It is critical that the [digital] measurements reflect details about extant phenomena and not artifact…The continued



variation and non-sinusoidal nature of EEG can, in some cases, generate information that does not really exist' [Penzel et al., 2007].

'Some computer based systems [quantitative EEG measures, fast Fourier transformation (FFT), period amplitude analysis (PAA), spectral analysis, zero crossings for frequency bands,] allow users to modify analysis settings. If users with limited knowledge modify these settings, it is not clear whether scoring results will be valid. Studies of software provided by manufacturers, independent investigators, and by national funding sources will be needed to assure clinically valid information' [Penzel et al., 2007].

Digital scoring conclusions:

1. No optimum method of digital recording has been identified.
2. Much more work is needed to validate digital recording before the sleep specialist will have an acceptable clinical tool.
3. *The AASM Manual for the Scoring of Sleep* sets out recommended digital recording methods as a first step to see if these methods may lead to accumulating evidence to support their validation in the future [see Appendix B].

Visual Scoring:

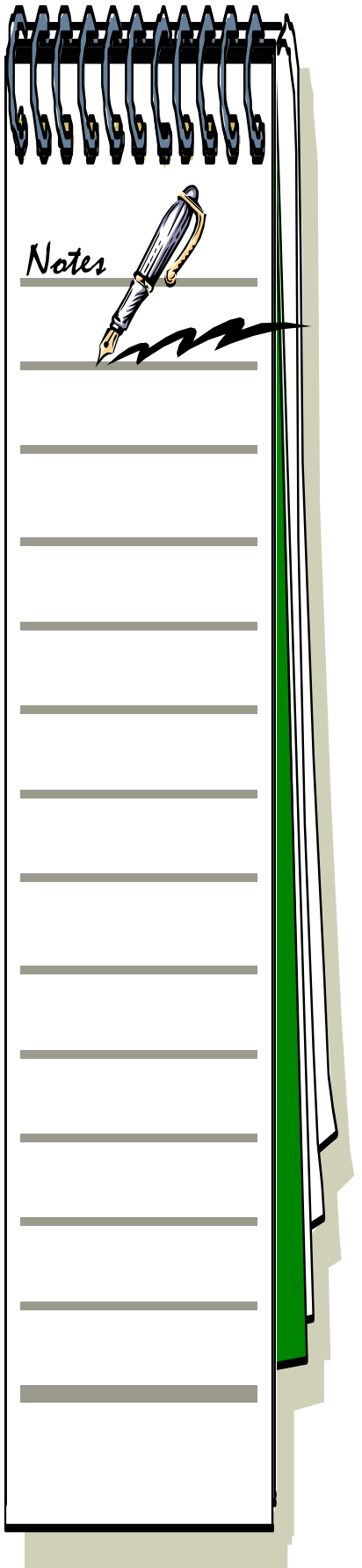
The visual scoring excerpts below come from the white paper of *The AASM Manual for the Scoring of Sleep* [2007] Task Force on visual scoring chaired by Dr Silber [Silber at al., 2007] and the section in *The AASM Manual for the Scoring of Sleep* [Iber et al., 2007a] on visual scoring rules. [See also Appendix A, on visual scoring rules, below]

Inter-rater and intra-rater reliability overall:

With the 1968 Rechtschaffen and Kales (R & K) sleep scoring Manual, the well-trained visual scorer of the sleep PSG is still considered the most reliable method for interpretation of the recordings (Silber et al., 2007). 'The AASM Visual Scoring Task Force concluded that inter-rater and intra-rater reliability were substantial for staging of records as a whole with the use of the R & K montages [up to and over 90% agreement]. This suggested that the R & K method could be used as a basis for a revised scoring system' [Silber et al., 2007].

Inter-rater and intra-rater reliability of each sleep stage:

Greatest inter-rater accuracy was achieved for REM sleep followed by stage 2 sleep. Lowest reliability was found for stage 1 sleep, while reliability for wake and slow wave sleep [SWS] was moderate. Similar results were noted in the one study examining intra-rater reliability [Danker-Hopfe et al., 2004]. 'It was concluded that scoring rules for stage 1 and SWS sleep needed reassessment' [Silber et al., 2007].



EEG electrode placement: (sleep characteristics at specific scalp locations)
'Evidence from these studies suggests that sleep spindle activity is optimally recorded with central electrodes, while K complexes and delta activity are optimally recorded with frontal electrodes. The predominant localization of alpha rhythm over the posterior head regions, and especially the occipital cortex, has been unchallenged since the days of the early EEG pioneers' [Silber et al., 2007].

Failure to record frontal activity may result in reduced identification of K complexes and thus inaccurate scoring of stage 2 sleep, especially in older subjects, and the absence of an occipital derivation may hamper the determination of sleep onset. As a result, the Task Force determined through the consensus process that a minimum of three EEG derivations will be required, sampling activity from the frontal, central, and occipital regions. …It was also recommended that appropriate backup electrodes for each standard electrode be applied in case of electrode malfunction during the sleep study' [Silber et al., 2007].

EOG electrodes (placement):
The R & K Manual recommended at least two electro-oculogram (EOG) derivations to record eye movements during sleep [Silber et al., 2007].

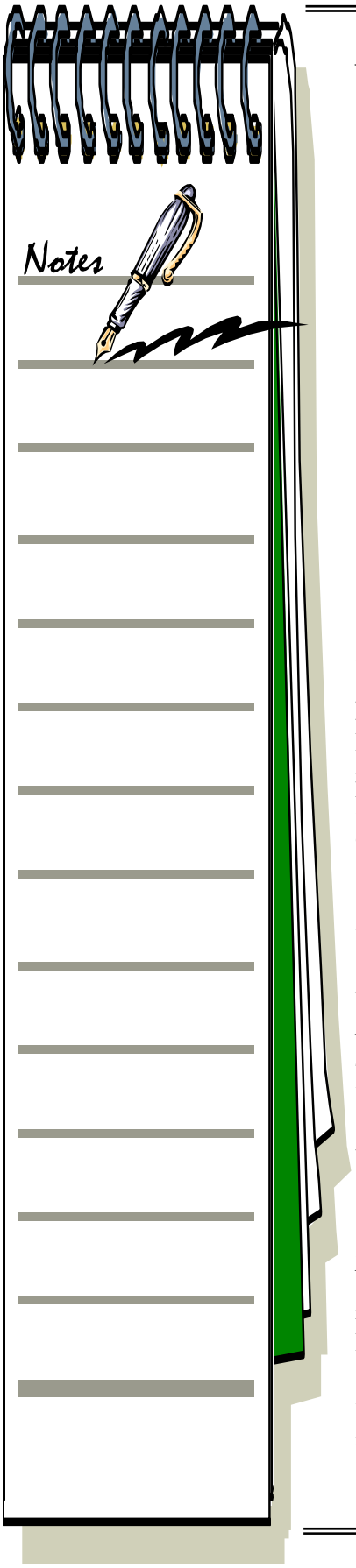
EMG electrodes (placement):
Given the uniformly accepted practice of using EMG derivations specified in the R & K Manual, the Task Force recommended continuation of the standard bipolar single chin surface EMG derivation. Chin EMG should be recorded from electrodes placed above and below the chin with a backup electrode placed below the chin close to the primary electrode [Silber et al., 2007].

Scoring epochs:
A recommendation was made to retain the traditional epoch based scoring method. The group also voted to recommend that an epoch length of 30 seconds continue to be used for stage scoring, finding no compelling evidence to change it [Silber et al., 2007].

Sleep stage terminology revision [Silber et al., 2007]:

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

[See Appendix A, on visual rules for scoring of sleep stages W, N1, N2, N3, R, excerpted from *The AASM Manual for the Scoring of Sleep*, Iber et al., 2007 a].



Visual scoring conclusions

1. 'No visual based scoring system will ever be perfect, as all methods are limited by the physiology of the human eye and visual cortex [alpha wave artifacts], individual differences in scoring experience, and the ability to detect events viewed using a 30-second epoch' [Sibler et al., 2007]. Nevertheless, Silber et al., found it is possible to develop a rigorous, biologically valid visual scoring system that can be applied meaningfully in clinical and research settings.
2. 'The new scoring system is presented as a step forward along this path' [Silber et al., 2007].
3. 'Studies are needed to test the reliability of the new rules. Future advances in technology may require modification of these rules with time' [Sibler et al., 2007].

RF Sleep Review Based on the Quality of RF Sleep Recording Evidence –SAJ

[Iber et al., 2007a,b; Penzel, 2006; Penzel et al., 2007; Silber et al., 2007].

Digital scoring in RF sleep studies

In accordance with the lack of validation of the digital sleep recording methodology in the clinical sleep studies [Achermann 2006; Penzel, 2006; Penzel et al., 2007; Iber et al., 2007a], the various digital methodologies employed by sleep researchers using RF exposures, (i.e. Borbély et al., [1999], Huber et al., [2000], [2003], Regel et al., [2007], Loughran et al., [2005]), must also be considered presently unvalidated and consequently their associated digital sleep data must also be considered unvalidated. Algorithms based on sleep EEG alone have difficulties distinguishing wake, sleep stage 1, and REM sleep [Penzel, 2006; Iber et al., 2007a]. [See Appendix B: In order to move forward in *The AASM Manual for the Scoring of Sleep* the first digital recording recommended rules are specified; they have been created, by consensus, to incorporate set techniques to facilitate a process for revision if accumulating evidence supports their utility' [Iber et al., 2007a].]

RF scoring artifact problems

We must take into consideration that the analysis of the sleep EEG first requires the removal of artifacts [Silber et al., 2007; Penzel et al., 2007; Iber et al., 2007a; Kiefer, 2007 above; Penzel, 2007 above]. The digital sleep recorders have particular difficulty removing these artifacts from their automated digital records [Achermann, 2006; Penzel 2006; Penzel et al., 2007; Iber et al., 2007a].

There may be ECG, EOG, and EMG artifacts in the EEG signal. As much as possible, these influences have to be removed. 'Automated [digital] sleep analysis primarily focuses on the sleep EEG signal. Several analysis algorithms restrict themselves to the analysis of one EEG only but the recording from at least 6 electrodes is required for accuracy of EEG recording [R & K, 1968; Iber et al., 2007a]. The definition of sleep stages, according to the recommendations of Rechtschaffen and Kales, do require the interpretation of EOG and EMG in addition' [Penzel, 2006]. *The AASM Manual for the Scoring of Sleep* recommends at least 7 polysomnograms to be recorded [Iber et al., 2007a]. [See Appendix A and B, below]. Thus, digital scoring does not record sufficient information to remove the artifacts to accurately score sleeping.

Artifacts can occur as a result of many causes. Electrode lead movements are a common cause. Electrode impedance changes result in waves that can be misinterpreted. Degrading electrode impedance over the course of the night significantly affects EMG signal quality, which is difficult to recognize with automatic analysis [Penzel, 2006, 2007; Penzel et al., 2007].

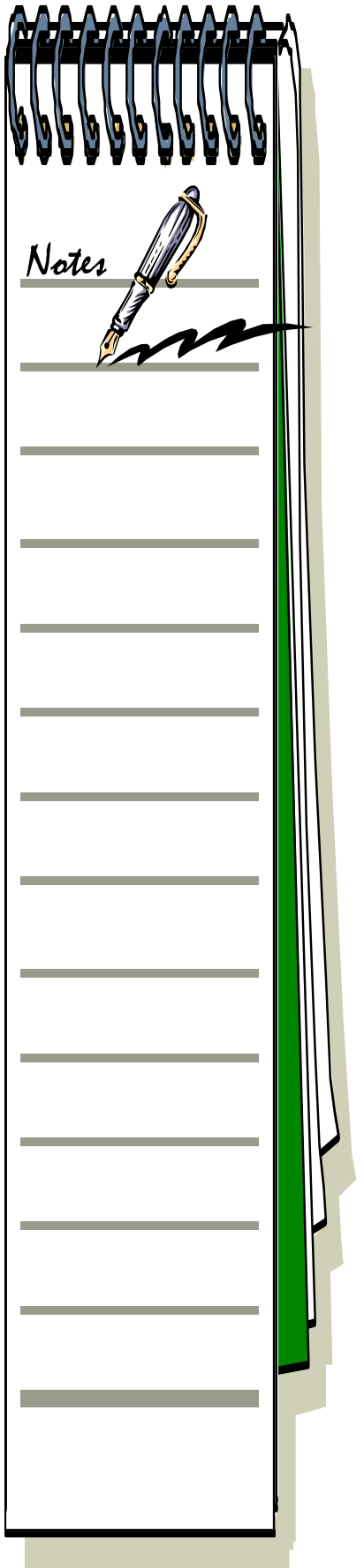
Furthermore, an artifact unique to RF studies may occur when the RF exposure takes place with the electrodes attached to the subject's head. In this exposure scenario, it is possible for the RF energy to interact with the recording electrodes producing artifacts in the measurement [Foster, 2007; Tattersall et al., Rostock, Sept 2006/ London ICES Conference, March 2007; Angelone et al., 2004; Chou and Guy, 1979].

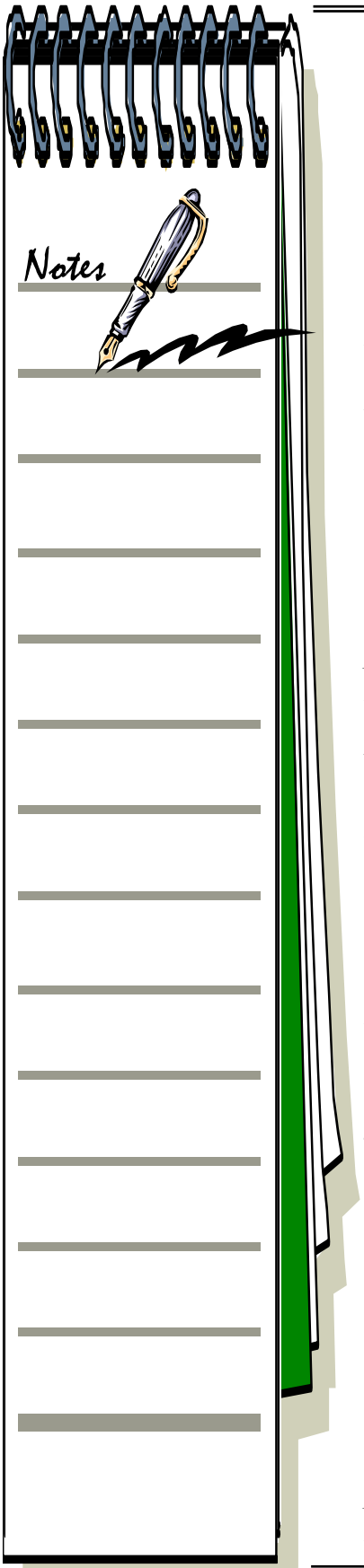
Alpha band results

The stage NREM 1 sleep [N1] with alpha rhythm has the worst scoring agreement [Penzel et al., 2007; Danker-Hopfe et al., 2004; Iber et al., 2007a; also see Appendix A]. Where the number of subjects is well below 60, the reliability of the reports is decreased markedly [Penzel et al., 2007].

These factors lower the quality of the reports of alpha band effects [i.e. Borbély 1999; Hubel et al.; 2000; 2003; Regel et al., 2007; Loughran et al., 2005]. Overall, in these RF studies, the alpha band effects are small, variable and may lack scoring validity. The health consequences are unknown and are not identifiable in the visible scoring range of sleep disorders [ICSD-2, 2005] for instance as compared to the effects of caffeine on sleep.

There were several presentations at the Workshop reporting no effect of RF exposure on the alpha band [i.e. Danker-Hopfe et al., 2007; Sauter et





al., 2007; Wiholm et al., 2007; Hinrichs et al., 2007; Hinrichs et al., 2005; de Seze 2007; Besset et al., 2005].

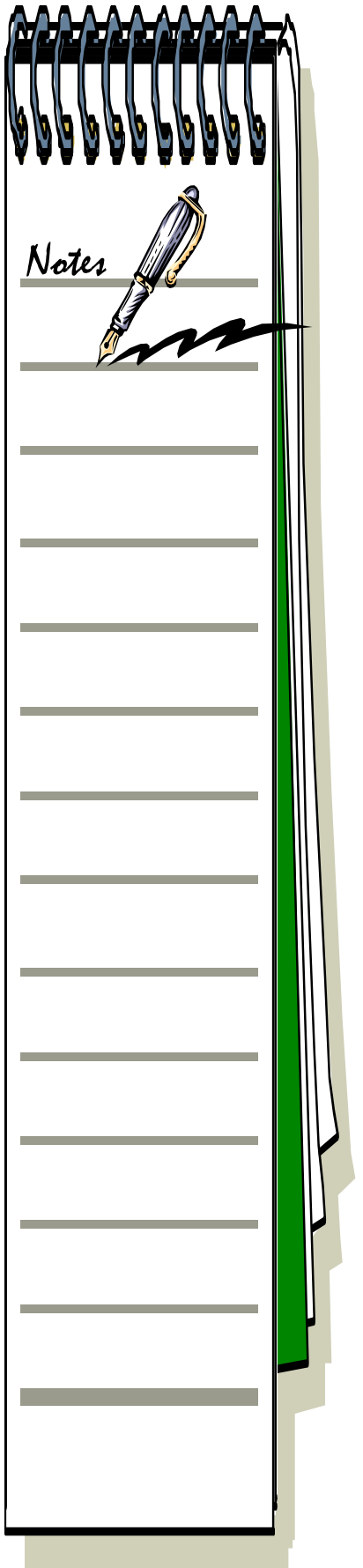
Visual Scoring of PSGs according to R & K [1968] during RF exposure

Loughran et al., [2005]

Loughran et al., [2005] have reported using the visual scoring method of R& K, 1968. However their number of electrodes for scoring sleep EEG is 2 [C4-A1 and C3-A2] whereas *The AASM Manual for the Scoring of Sleep* [following R & K 1968] recommends six, [F4-M1, C4-M1 and O2 M1 [on the left side of the scalp], with backup electrodes at F3-M2, C3-M2 and O1 M2, [on the right side of the scalp]. Loughran et al., [2005] appear to have recorded with one central-anterior [central, top] electrode on the left side of the scalp and one central-anterior electrode on the right side and did not report recording from frontal-medial [FM], central-medial [CM] and occipital-medial [OM] electrodes as specified by *The AASM Manual for the Scoring of Sleep* [Iber et al., 2007a]. This may result in limitations and distortions in their EEG recorded data. 'Evidence from these studies suggests that sleep spindle activity is optimally recorded with central electrodes [C], while K complexes and delta activity are optimally recorded with frontal [F] electrodes [see Appendix A]. The predominant localization of alpha rhythm over the posterior head regions, and especially the occipital cortex [O], has been unchallenged since the days of the early EEG pioneers' [Silber et al., 2007].

Considering Loughran et al., [2005] reported their visually scored data shows no effects except on REM sleep onset, this could be due to the lack electrodes over the frontal and posterior regions. This could account for their reporting an effect in the first REM onset [with a large standard deviation].

There is presently no validation for Loughran et al.'s, [2005] digitized scoring method and analyses [Iber et al., 2007a; Penzel et al., 2007] that suggest an effect on enhancing power in the 11.5–12.25 Hz frequency range. This reported effect could be a result of recording only with electrodes over the central region since 'sleep spindles with frequency 11-16 Hz are usually maximal in amplitude over the central regions' [Silber et al., 2007]. In their favour, Loughran et al., [2005] had a subject number of 50, which is near to the recommended number of around 60 subjects for sleep studies [Penzel et al., 2007]. They also used both visual and digital scoring allowing some possible cross validation of the digital scores. In the future, following the visible sleep scoring rules of *The AASM Manual for the Scoring of Sleep* could improve this research to the level of validated reports [Iber et al., 2007a].



Danker-Hopfe et al., [2007]

In ongoing RF exposure during sleep, Danker-Hopfe et al., [2007] are using the R & K visual recording method in their sleep laboratory with 30 subjects. The subject level is well below 60. Danker-Hopfe et al., have previously published sleep research [not in the RF field] that was judged level one [Danker-Hopfe et al., 2004] by the Visual Scoring Task Force.

A possible, but *unproven [Foster and Repacholi 2004; IEEE 95.1- 2005; ICNIRP 1998], reservation in regard to Danker-Hopfe et al., RF sleep on-going research is that they did not report using the same 8 Hz signal modulation that some groups report may be source of biological effects of GSM modulated 900 MHz signals [Bach Andersen group, 2007; Achermann / Kuster group, 2007].

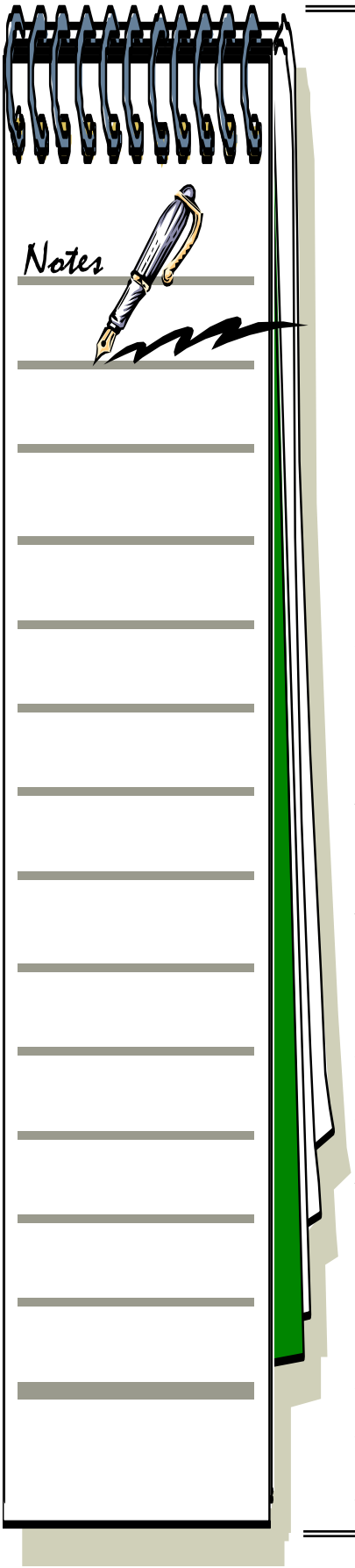
** There is no established biophysical reason to expect a more likely biological non-thermal effect of RF with an amplitude modulated signal than a continuous wave signal at the same exposure level, below guideline limits [Foster and Repacholi 2004; IEEE 95.1- 2005; ICNIRP 1998].*

Hinrichs et al., [2005] also report that they used the R & K [1968] visual recording method in their sleep laboratory, with 14 subjects exposed to a GSM 1800, 1736 Hz base site signal. They have acquired 8 EEG signals. It would require an expert RF Sleep Task Force to evaluate whether the polysomnograms recorded in this paper included the 7 different types of signals suggested for level 1 diagnosis [see the Penzel summary above, page 7]. They found no effects on sleep.

Leitgeb et al. [2007] reported, in ambulatory RF sleep studies, sleep onset effects in 14% [6 subjects] of a possible 43 subjects. This work is presently unpublished, and tentative comment below is based his presentation. Considering the reports of *The AASM Manual for the Scoring of Sleep* Task Force, stage one sleep, is the most unreliable to score [Silber et al., 2007a] and ambulatory sleep recordings are not considered reliable sleep evidence [See Penzel summary above, page 7, re: limitations of ambulatory recordings]. As noted below, about 10-20 % of the population has little or no alpha rhythm [Appendix A, N1] and this is the way to identify sleep onset. This natural lack of alpha rhythm could result in a failure to record sleep onset accurately in 14% of his subjects. Also 'inward anger' of 'electrosensitive' persons could affect sleep onset [See 'Emotional measurements' below Kräuchi et al., 2007a]. The tentative RF effect on sleep onset, [Leitgeb et al., 2007], reported is much less than for instance the effect of caffeine on sleep. This appears to be at most, a small, weak, unreliable report of an RF effect on sleep.

Summary on the quality of RF sleep recording

1. Although the rapporteur's report is not the appropriate format to re-evaluate the entire RF sleep literature according to *The AASM*



Manual for the Scoring of Sleep Task Forces' findings, with this brief introduction above, it is already clear that their findings [Iber et al., 2007a; Penzel et al., 2007; Silber et al., 2007] highlight the weaknesses of the RF sleep research methodology.

2. During the workshop several expert speakers reviewed the RF sleep literature [i.e. Loughran et al., 2007; Hämälainen, 2007; Danker-Hopfe et al., 2007] with various evaluation criteria. But, in the future, once the ongoing RF sleep research is published, an expert RF Sleep Task Force may undertake a complete evaluation, by using the reliable and validated scoring criteria as set out by *The AASM Manual for the Scoring of Sleep* white papers and *The AASM Manual for the Scoring of Sleep* to reach a consensus scientific conclusion, and make expert recommendations and rules for future RF sleep research.

General Discussion/Consensus Statement

[Leader Dr. Jürgen Kiefer]

During the concluding Workshop discussion, three questions related to these sleep and cognitive EEG studies were discussed and an answer to each question was developed based on a consensus of the participants attending the final session of the Workshop.

Are there any proven effects? There are no proven effects on either cognition or sleep. Generally there are both negative and positive results that are not replicated [by different laboratories].

What is the relevance of the present results to human health? None of the positive results are established evidence and all appear to be very small effects. Although there was disagreement, it was generally agreed that none of the small positive effects if established appear to be of any likely health consequence.

Mechanisms? There are no known mechanisms by which low level RF exposure below ICNIRP limits could cause effects on sleep or cognition. Above limits, heat is the known mechanism that could affect human cognition or sleep. Further research would be of greater importance if a new mechanism could be identified.

Future Developments –Considerations [SAJ]

Electrodes

New wireless recording techniques are now being investigated in sleep laboratories to free the patient from the leads between the body and a head-box or a bedside box. Efforts are underway to develop sensors with integrated wireless data transmission, which allows even less wires on the

body. Efforts are being made to improve sensors and electrodes (e.g., dry electrodes) in order to minimize artifacts caused by movements and low impedance [Penzel, 2006]. Possible RF interaction artifacts with the electrodes require elucidation and elimination [Foster, 2007].

The AASM Manual for the Scoring of Sleep [2007] rules of visual scoring In the medical clinical sleep field, as a result of the fact that considerable differences between visual sleep scoring and automated sleep analysis are always reported, none of the current automated sleep analysis methods has been accepted as an alternative for visual sleep analysis [Penzel, 2006]. Thus future RF sleep researchers could be required to follow *The AASM Manual for the Scoring of Sleep* rules of visual scoring of sleep EEG recordings to achieve validated sleep reports [Iber et al., 2007a; See Appendix A].

The AASM Manual for the Scoring of Sleep [2007] recommendations for digital scoring:

If digital scoring of RF sleep recordings is desired, it could be done as set out in *The AASM Manual for the Scoring of Sleep*, [Iber et al., 2007a; III Technical and Digital Specifications; See Appendix B], in parallel with the visual scoring, as set out by *The AASM Manual for the Scoring of Sleep*, [Iber et al., 2007a; See Appendix A], to allow for cross validation of digital methods. In such a way, they would incorporate digital techniques that may in the future lead to 'accumulating evidence to support their utility' [Iber et al., 2007a].

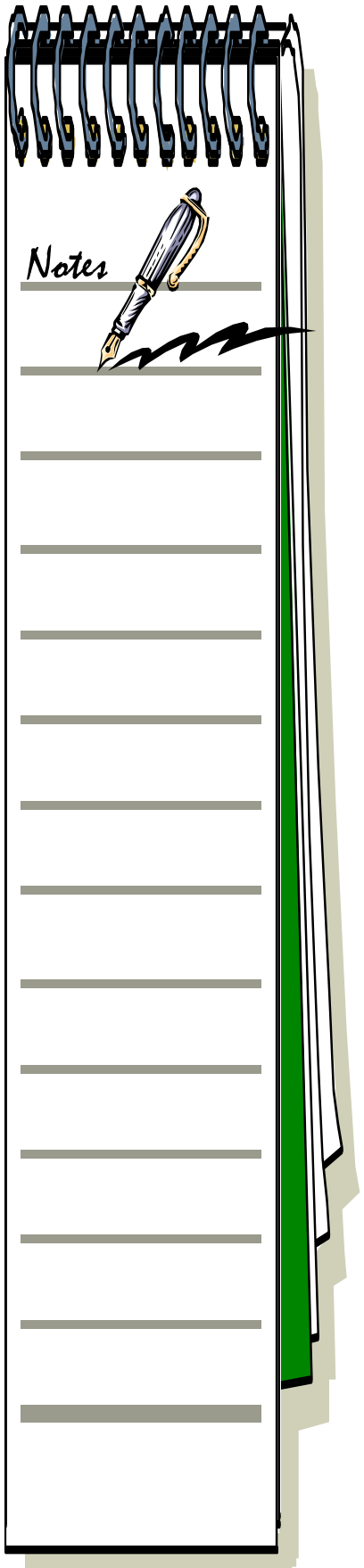
RF Exposures

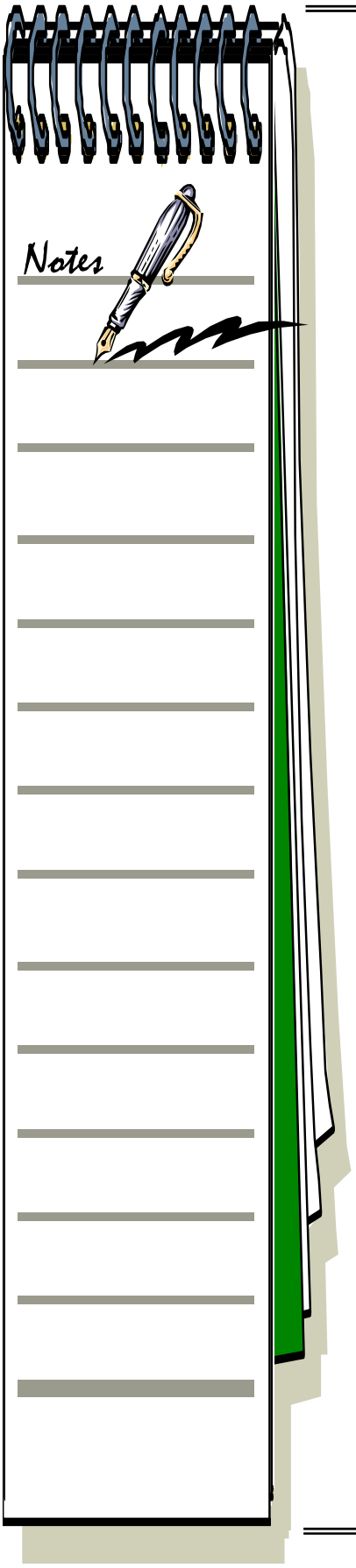
Future sleep researchers using RF exposures need to establish by international consensus standard exposure protocols for GSM 900, 1800 and UMTS [and emerging technology signals] and use them in the same way among inter-laboratory replications. Presently each sleep study laboratory has had their own exposure protocols making study comparison and interpretation difficult.

Additional points:

1. Temperature measurements.
   In *The AASM Manual for the Scoring of Sleep* [Iber et al., 2007a], thermoregulation measurements over the sleep night are not required.

   The human circadian rhythm of the core body temperature is relevant to sleep onset latency and thus influences N1; it is also





relevant to sleep duration. The core body temperature and distal [skin temperatures] and their ratio and changes are relevant to sleep onset latency and the duration of the sleep.

Sleep duration is longest when in sync with circadian rhythm of the core body temperature. 'Sleep is then typically initiated on the declining portion of the core body temperature [CBT] curve when its rate of change, and body heat loss, is maximal. In the morning when heat production is dominant over heat loss, CBT increases, as does the propensity to wake-up…. These preferred zones for falling asleep and for waking up have a profound effect on sleep duration — sleep length is maximal (circa 14 h) when sleep is initiated around the CBT maximum. All these findings indicate that sleep propensity and sleep duration are tightly coupled with the thermoregulatory system. However, in contrast to the sophistication of sleep EEG analyses, including spectral decomposition of the EEG-signal, the thermoregulatory system has not been adequately studied in parallel' [Kräuchi, 2007b].

'Body heat loss before lights off, via selective vasodilatation of distal skin regions, promotes sleepiness and the rapid onset of sleep. This thermophysiological effect represents the cement between the circadian clock and the sleep–wake cycle, and in turn determines phase of entrainment and sleep onset latency. These interrelationships have been recently studied in a particular subset of the general population, mainly women, who suffer from cold hands and feet (the so-called vasospastic syndrome, VS). Women with VS exhibit not only a lower capacity to lose heat during the daytime but also a prolonged sleep onset latency, a disturbed phase of entrainment of the circadian clock with respect to the sleep–wake cycle and psychologically, a disposition to turn experienced anger inwards. This naturalistic model leads us to a more general conclusion that regulation of distal skin blood flow may have clinical relevance for insomnia, in particular sleep onset insomnia' [Kräuchi 2007a].

Disorders of the circadian rhythm are relevant; the recording of core body temperature can give insights on the actual circadian phase of the patient. Core body temperature [CBT] is closely linked to the circadian system and its recording will allow conclusions on jet lag, delayed, or advanced sleep phase problems [Penzel, 2006].

Since an established mechanism of RF bioeffects is heating, it would be relevant to maintain and report the sleep recording room temperature and air circulation and also measure core body

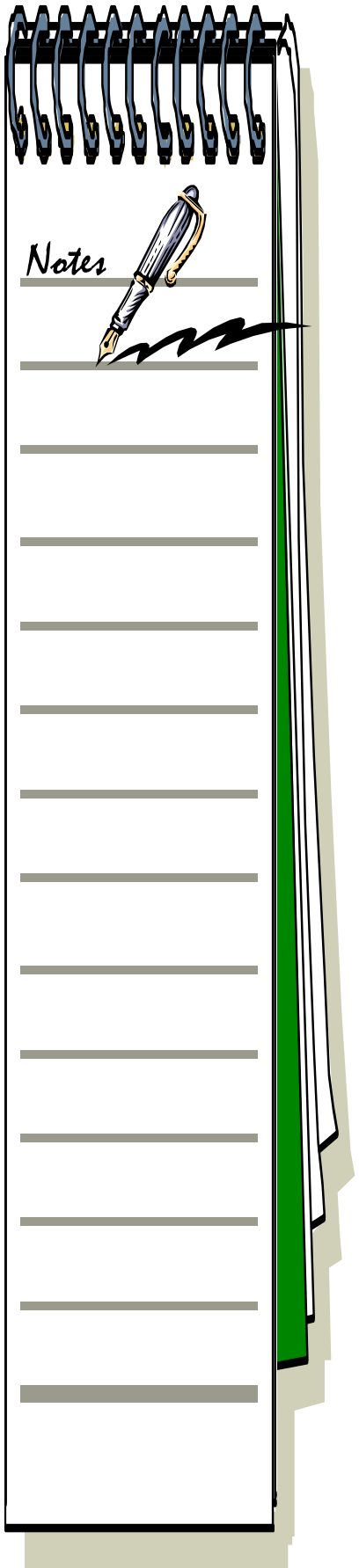
temperatures and distal skin temperatures of subjects throughout the sleep period.

2. The Emotional Measurements
   Sleep is a desired state of unconsciousness, a state of disconnection, expecting to be restored and comforted upon awakening many hours later [Iber et al., 2007a].

   "Sleep that knits up the ravell'd sleave of care,
   The death of each day's life, sore labour's bath,
   Balm of hurt minds, great nature's second course,
   Chief nourisher in life's feast"
   [Macbeth Act II Sc ii. Shakespeare, ~1606].

   These three authors [Kräuchi, Iber and Shakespeare] spanning some 400 years suggest one dimension of sleep not yet recorded in *The AASM Manual for the Scoring of Sleep* revision of the R& K Sleep Scoring Manual that may influence sleep scores, the emotional context ['anger inwards' 'the comforter' 'the balm of hurt minds'] in which we sleep [Iber et al., 2007a]. Kräuchi [2007a] suggests above an impact on sleep scoring of prolonged sleep onset in women who turn anger inward.

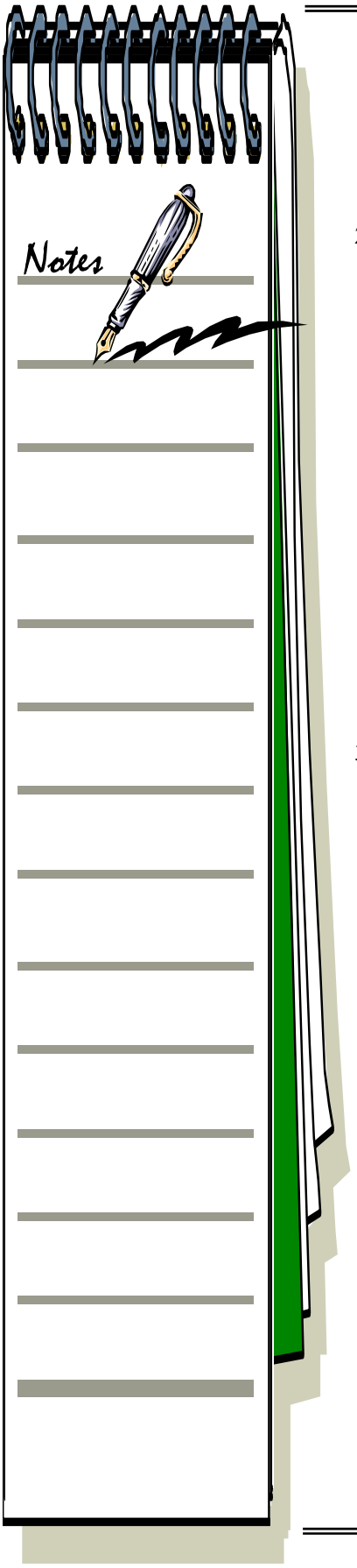
   Presently *The AASM Manual for the Scoring of Sleep* does not record emotional measurements but they may be relevant to a delayed sleep onset [N1]. The idiopathic environmental intolerant [IEI] 'electrosensitive' persons in sleep recording may have inward anger and thus delayed sleep onset. Should emotional state before sleep be recorded in RF sleep studies?



Overall Conclusions

I have confined my rapporteur's review mostly to quality polysomnographic sleep recording rules as revealed by evaluation of clinical sleep research by the American Academy of Sleep Medicine [AASM] Task Force [Iber et al., 2007a,b] for the revision of the R & K [1968] Sleep Recording Manual as introduced by Dr T. Penzel because of the 'rules' great importance to RF sleep research.

1. General comments on brain electroencephalogram recordings
   - The advantage of EEG and ERP recordings is their non-invasive nature and their high temporal resolution so that subtle activity changes which last only a few milliseconds can be detected. EEG recordings may reveal subtle differences in brain function, which are not always accompanied by behavioral performance differences.

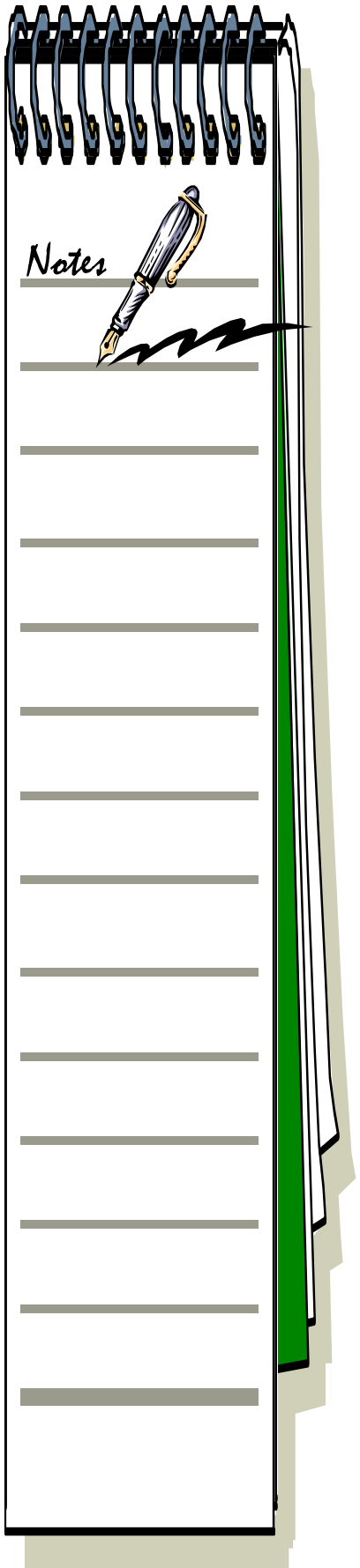


- The disadvantage of EEG measurements is their low spatial resolution since the location in the brain of the electrical potentials recorded at the scalp can only be approximately identified. And the potentials only reflect synchronous electric activity of large neural assemblies.

2. *The AASM Manual for the Scoring of Sleep* [2007]
   The R and K, [1968] Sleep Recording Manual was revised in 2007 [*The AASM Manual for the Scoring of Sleep*, Iber et al., 2007a]. The AASM expert Task Forces [Iber et al., 2007a,b] evaluated the sleep evidence for the accuracy of their scoring methods and this information could be most helpful in future evaluation and planning of RF sleep research.
   - Visual sleep scoring remains the preferred reliable and valid method [90% agreement] but the new small changes in *The AASM Manual for the Scoring of Sleep* [2007] need validation.
   - Computer/digitized scoring of sleep is not yet an established method; any such method requires future validation [Iber et al., 2007a].
   - The AASM Task Force found Stage N1 [NREM1-alpha rhythm] sleep scoring is the least reliable record of all the sleep stages and scoring of stage R [REM] is the most reliable.
3. Summary of RF studies presented at the Workshop
   Some RF sleep studies appear to follow the visual scoring methodology in the R and K [1968] Manual at least to some extent [i.e. Danker-Hopfe et al., 2007; Hinrichs et al., 2005; Loughran et al., 2005]. These visual studies mostly show no effect of RF exposure on sleep.
   - Replicated visual scoring RF sleep results that follow the R & K, [1968], scoring rules would be a valid level of scientific evidence (see the AASM Task Forces' publications).
   - Digital recordings of sleep scores provide weak reports (see the AASM Task Forces' publications) and presently lack validity. Many of the digital scoring RF sleep studies report various positive small effects of RF on sleep.
   - There are no proven effects of RF exposure on either cognition or sleep EEGs. Generally there are both negative and positive results that are not replicated [by different laboratories].
   - None of the positive results are established evidence and appear to be very small, and of much less significance to health than, for instance, caffeine before sleep. The RF positive sleep results are much smaller than any of the sleep disorder effects identified in the ICSD-2, 2005: The International Classification of Sleep Disorders.

- Although there was disagreement, it was generally agreed that none of the small positive effects if established appear to be of any likely health consequence.

4. Future research
   - Researchers would be well advised to use *The AASM Manual for the Scoring of Sleep* [2007] Task Forces' evaluation results and visual scoring rules to guide the design of quality RF sleep recording studies.
   - Future RF sleep replication studies should be designed using RF signal exposures with characteristics specified on the basis of consensus among international experts.
   - RF researchers could investigate the usefulness of new wireless recording techniques now being investigated for sleep laboratory use in order to free the patient from the leads between the body and a head-box or a bedside box. This could help minimize electrode artifacts. RF electrode interaction artifacts require expert investigation and elimination.
   - Improvement in thermal measurements during sleep recording could advance the quality of sleep recording overall and may be essential in sleep research during RF exposures.

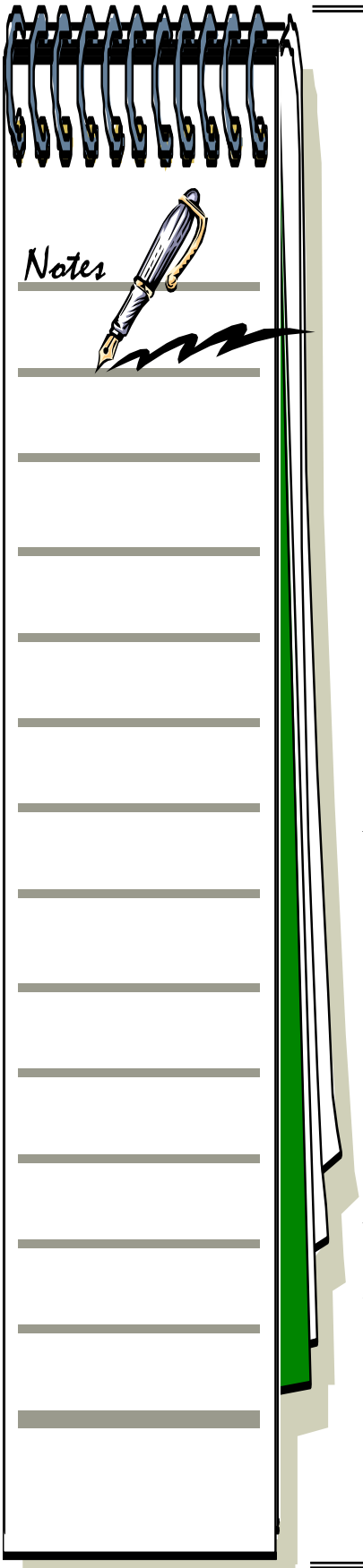


Dr Brunner's, Purposes of the Workshop: Answers [SAJ]:

1. RF sleep researchers could build 'solid scientific knowledge' about the effect of RF exposures on EEG through the use of *The American Academy of Sleep Medicine [AASM] Manual for the Scoring of Sleep* visual scoring rules that give well-validated scientific evidence [90% agreement] [Iber et al., 2007a,b].

'The relevance of the single RF positive studies on EEG' has been evaluated. The RF EEG experts at the workshop reached the consensus conclusion that the reports of potential RF effects found in single EEG research projects are not validated, are variable, weak and of small and unknown health concerns, [and less than i.e. the effects of caffeine on sleep, less than the effects of Sleep Disorders identified in the ICDS-2, 2005]. The Workshop results affirm the opinion of the German Radiation Protection Commission that there is no need to change the limits in the range of radio frequency electromagnetic fields.

The consensus advice to the Ministry on further research to close the existing gaps of knowledge on RF effects on EEG would be that at present results are not of sufficient quality to make a strong conclusion. Once ongoing RF sleep research is published an expert Task Force could evaluate the RF EEG literature, guided by *The AASM Manual for the Scoring of Sleep* [2007] visible scoring rules and guided by international dosimetry experts, using consensus conclusions.



If such a future RF Sleep Task Force concludes there is still a lack of quality RF sleep research literature to make a strong conclusion then future replicated quality research on sleep EEG may be warranted and is feasible. It is feasible because we have validated visual rules for sleep EEG scoring in *The AASM Manual for the Scoring of Sleep,* [Iber et al., 2007a]. Such an RF Sleep Task Force could also draw up rules for future RF research with validated methods on the basis of solid science, by consensus.

Solid Science Research would include, for instance:

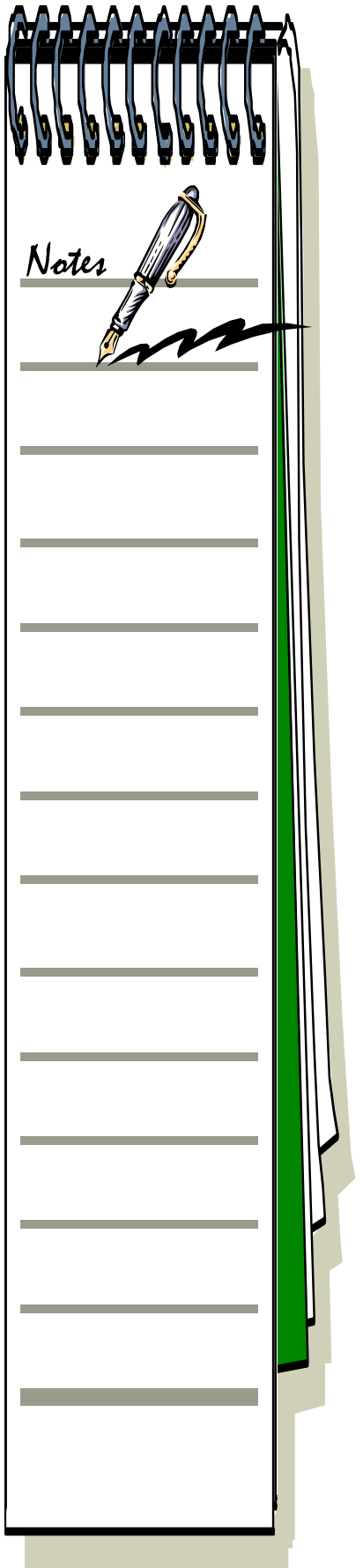
- Validated visual scoring of sleep following the rules of *The AASM Manual for the Scoring of Sleep* [Iber et al., 2007a], recording electrodes verified to be free from RF interference and artifacts, RF exposures that are agreed by international consensus to measure relevant human exposures, and room and body thermal measurements through out the sleep period, testing around 60 subjects. The work should be conducted in a recognized international medical clinical facility by sleep medicine clinicians with the support of radio engineers and simultaneously replicated in another independent expert sleep recording medical clinical facility, by similar staff.

Appendix A

Excerpts from: IV Visual Rules from The AASM Manual for the Scoring of Sleep and Associated Events. Rules Terminology and Technical Specifications, [Iber et al., 2007a, pages 23-31] and [Silber et al., 2007].

Defining the wake-sleep boundary: Criteria for stages W and N1

Proposed criteria for stages W and N1 in subjects who are good alpha rhythm generators (80%-90% of the population) are largely unchanged, and sleep onset is defined as the start of the first epoch of sleep other than stage W. The "alpha rhythm" is an electrical rhythm which oscillates at a frequency of 8-13 Hz generated over the occipital scalp regions in humans during a state of relaxed wakefulness with eyes closed [Berger, 1929]. The issue of definition of stage N1 and sleep onset in subjects who generate little or no alpha rhythm (10%-20% of the population) was carefully considered. This group most probably accounts for the low inter- and intra-rater reliability for scoring of stage 1 sleep. Through the consensus voting process, the Task Force chose to concentrate on the development of slow eye movements in the EOG as the best measure of early sleep in the absence of any visually discernable alterations in EEG [no alpha waves] [Silber et al., 2007; Iber et al., 2007a].



Defining stage N2

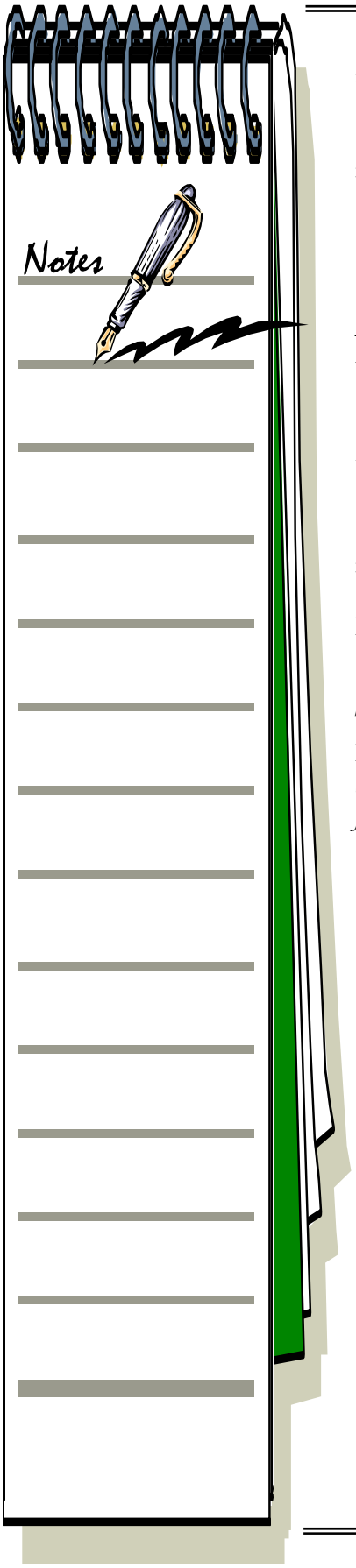
The N2 sleep stage is characterized by low amplitude mixed frequency background with two morphologically distinct waveforms superimposed: K complexes and sleep spindles. The presence of these waveforms defines stage N2 sleep. The Task Force voted to define a K complex as a well delineated negative sharp wave immediately followed by a positive component standing out from the background EEG with total duration ≥0.5 seconds. Sleep spindles are comprised of a group of rhythmic waves which progressively increase and then gradually decrease in amplitude. Following review of the literature, the Task Force voted to define a sleep spindle as a train of distinct waves with frequency 11-16 Hz (most commonly 12-14 Hz) with a duration ≥0.5 seconds, usually maximal in amplitude over the central regions [Silber et al., 2007; Iber et al., 2007a].

Defining slow wave sleep: Stage N2

'Stage N3 represents slow wave sleep and replaces the R & K nomenclature of stage 3 and stage 4 sleep' [Iber et al., 2007a]. Slow wave sleep is high voltage [> 75 μV, < 2Hz] delta activity. Stages 3 and 4 are the only stages in which the R & K Manual specifies amplitude criteria. This was felt to be important, as there were no distinctive morphological features of slow waves in contrast to K complexes and sleep spindles. The R & K Manual defines the low frequency filter setting as a time constant not shorter than 0.3 seconds.

'After about age 40 years -age-related drops in amplitude or spectral power have been noted in the theta, alpha, and spindle frequency bands, suggesting that this is a nonspecific phenomenon.' 'Both the Visual Scoring Task Force and the Geriatric Task Force voted to retain the 75 μV criterion for all ages. Data discussed earlier in the EEG derivation section indicate that slow wave amplitude is higher when recorded by frontal compared to central derivations. As a result, the Task Force voted to recommend the use of a frontal rather than a central derivation to measure slow wave amplitude. Since no evidence could be found to indicate validity or biological significance in the subdivision of SWS into stages 3 and 4 based on the percentage slow waves in each epoch, they voted not to subdivide SWS. The group found no reasons to change from the current definition of stage 3 sleep. It was therefore recommended that stage N3 sleep be scored when 20% or more of an epoch consists of waves of 0.5-2 Hz frequencies with peak-to-peak amplitude >75 μV in the frontal derivation' [Silber et al., 2007; Iber et al., 2007a]. Defining sleep stage R (formerly REM sleep)

'As discussed earlier, inter- and intra-rater reliability for scoring according to R & K rules is highest for R sleep compared to other stages. The Task Force addressed scoring of the onset and termination of periods of stage R sleep by consensus voting, with the aim of simplifying the current rules



and giving clear guidelines for most circumstances. In summary, stage R sleep commences when chin EMG tone falls, unless K complexes or spindles persist, in which case stage N2 persists until rapid eye movements develop. If chin EMG tone is low in stage N2 as well as R sleep, the transition to Stage R occurs after the last K complex or spindle' [Silber et al., 2007; Iber et al., 2007a].

Appendix B

Excerpts from: III Technical Digital Specifications from The AASM Manual for the Scoring of Sleep and Associated Events. Rules Terminology and Technical Specifications, [Iber et al., 2007a]

The AASM Manual for the Scoring of Sleep RE: New Digital Recording Recommendations [Quoted from AASM, Iber et al., 2007a]

'Quantitative electroencephalography, cyclic alternating pattern, and methods characterizing autonomic events have not been incorporated [in *The AASM Manual for the Scoring of Sleep*] although a process for revision has been created to incorporate techniques if accumulating evidence supports their utility' [Iber et al., 2007a].

These recommendations are found in the section 'III Technical and Digital Specifications'. They list the following recommendations in Sections A, B, C and D [See brief quotes below from *The AASM Manual for the Scoring of Sleep*, Iber et al., 2007a pages 20-21].

'A. 'Digital Specifications for Routine PSG Recordings [Notes]'

' The recommended practice includes the maximum electrode impedances [5 K Ω], minimum digital resolution [12 bits per sample], sampling rate for EEG, EOG, EMG, ECG [desirable 500 Hz, minimal 200 Hz]; there are also specifications for sampling rates of airflow, nasal pressure, oximetry, esophageal pressure, body position, snoring sounds, and ribcage and abdominal movements. There are specifications for routinely recorded low frequency and high frequency filter settings for EEG, EOG, EMG ECG, respiration and snoring.'

'B. Digital PSG Recording Features: Recommended are the following 7 features:'

'1. A toggle switch permitting visual on screen standard 50uV DC calibration signal for all channels to demonstrate polarity, amplitude and time constant settings for each recorded parameter.
2. A separate 50/60 Hz filter control for each channel.
3. The capability of selecting sampling rates for each channel.

4. A method of measuring actual individual electrode impedance against a reference.
5. The capability of retaining and viewing the data in the exact manner in which it was recorded by the attending technologist [i.e. retain and display all derivation changes, sensitivity adjustments, filter settings, temporal resolution].
6. The capability of retaining and viewing the data in the exact manner it appeared when it was scored by the scoring technologist [i.e., retain and display all derivation changes, sensitivity adjustments, filter settings, temporal resolution].
7. A filter design for data collection which functionally simulates or replicates conventional [analog-style] frequency response curves rather than removing all activity and harmonics within the specified bandwidth.'

'C. Rules for PSG Display and Display Manipulation: Systems must include 10 listed PSG features.'

'Features 1-4 are recommended

1. Resolution of a digital screen and video card must be at least 1600 X 1200 for display and scoring of raw PSG data
2. Histogram with stage, respiratory events, leg movement events, 0_2 saturation, and arousals, with cursor positioning on histogram and ability to jump to the page
3. Ability to view a screen on a time scale ranging from the entire night to windows as small as 5 seconds
4. Recorded video data must be synchronized with PSG data and have an accuracy of at least one video frame per second.

PSG features 5-10 are optional:

10. Fast Fourier Transformation or spectral analysis on specifiable interval (omitting segments marked as data artifact).'

'D. Digital Analysis of PSG.'

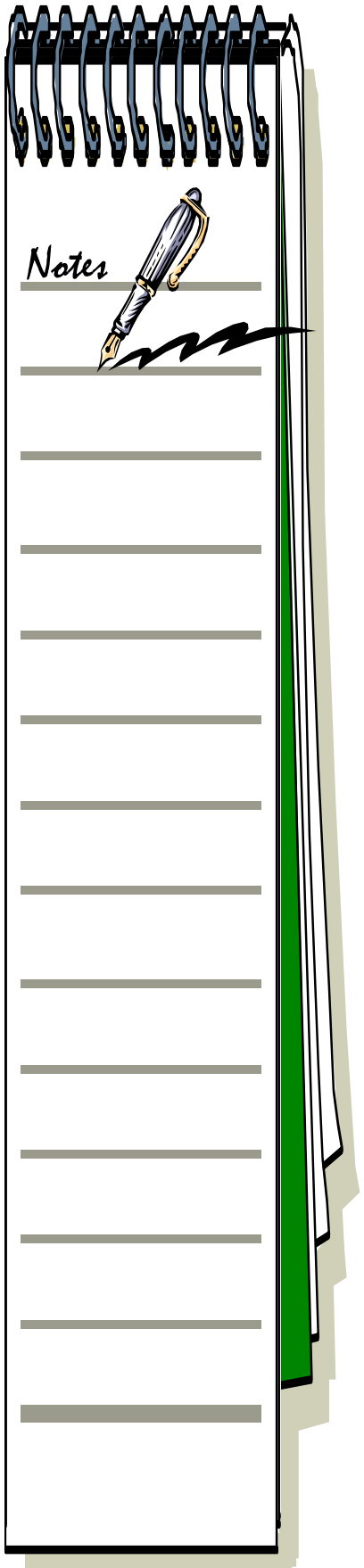
'Digital systems must include the ability to:

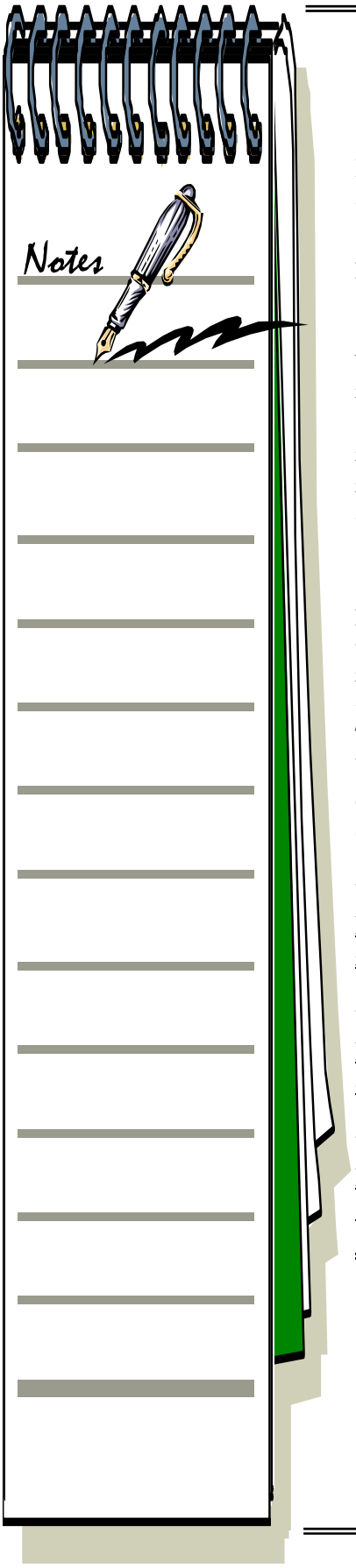
1. Identify whether sleep stage scoring was performed visually or computed by the system. [Recommended]'

'Digital systems should include the capability to turn off and on, as demanded, highlighting for: 2-4 [Optional]

2. Patterns identifying sleep stage decisions [i.e., sleep spindle, K complex, alpha, delta].
3. Patterns identifying the respiratory analysis (for example apneas, hypopneas, desaturations)
4. Patterns identifying the movement analysis (for example periodic limb movements of sleep).'

[Quoted from AASM, Iber et al., 2007a]





The AASM Scoring Manual: A Critical Appraisal

Grigg-Damberger, Madeleine M

Recent findings: Only a few retrospective studies have been published evaluating the new AASM Scoring Manual. These have shown that when scoring polysomnograms (PSGs) using the AASM rules compared to previous standards and guidelines: increased amount and percentage of sleep time in Non-Rapid Eye Movement Sleep (NREM) 1 (N1) and N3 sleep, and decreased NREM 2 (N2) sleep; improved interscorer reliability when scoring sleep stages in adults; large differences in apnea-hypopnea indexes (AHIs) using different hypopnea scoring definitions; and PSGs scored using the 'recommended' hypopnea definition in the new manual identified no significant sleep disordered breathing in 40% of lean individuals with symptomatic OSA (AHI ≥5/h by 1999 'Chicago' criteria) and a favorable response to treatment.

Summary: Two years have passed since the AASM Scoring Manual was published, garnering less criticism than was feared by those who developed it. The improvement in interscorer reliability using the Manual is heartening since this goal shaped many of the choices made. The alternative hypopnea rule should be endorsed as a recommended option. The AASM Scoring Manual provides a foundation upon which we all can build rules and methods that quantify the complexity of sleep and its disorders. Multicenter validation and refinement of the Manual is encouraged.

Practice Parameters: Circadian Rhythm:
http://www.aasmnet.org/Resources/PracticeParameters/Review_CircadianRhythm.pdf

Practice Parameters: Polysomnography:
http://www.aasmnet.org/Resources/PracticeParameters/PP_Polysomnography.pdf

Practice Parameters: OSA
http://www.aasmnet.org/Resources/ClinicalGuidelines/OSA_Adults.pdf

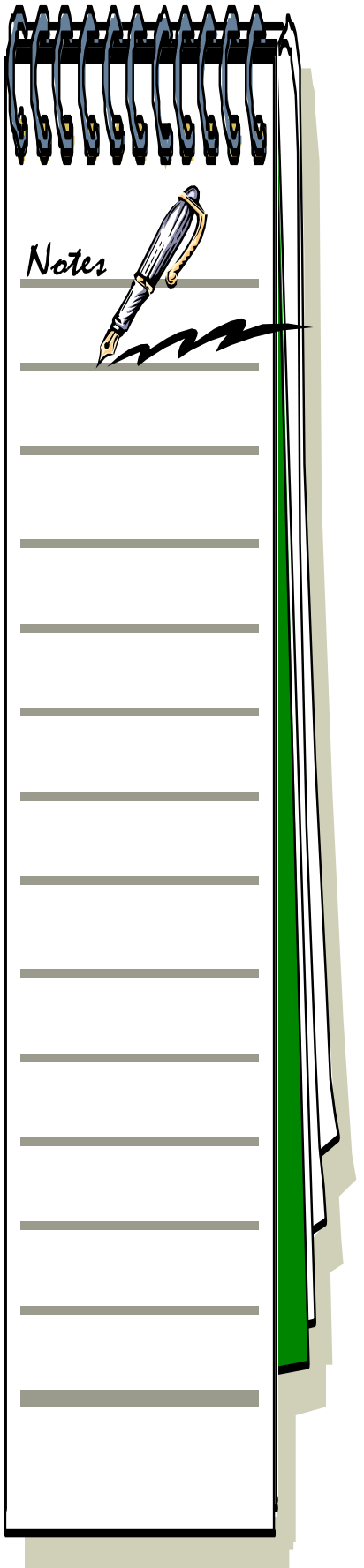
There are numerous reasons and techniques for "scoring" sleep studies—here is one example:

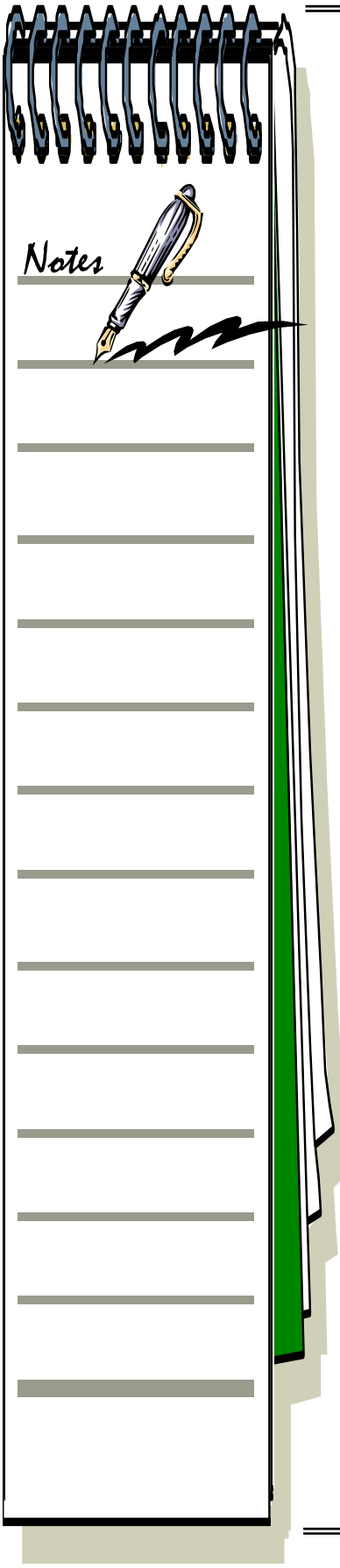
Sleep disordered breathing in children: Recording techniques

Cinzia Castronovo (Italy)

Obstructive sleep apnea syndrome (OSAS) in childhood is a disorder of breathing during sleep characterized by prolonged partial upper airway obstruction and/or intermittent complete obstruction that disrupts normal ventilation during sleep and normal sleep patterns. A spectrum of severity related to the degree of upper airway resistance, to the duration of the disease, to the presence or absence of hypoxemia episodes, and to certain clinical features can be described. Symptomatic children may not fit the criteria for diagnostic establishment for OSAS in adults; age-specific standards are needed. Both anatomical factors that increase upper airway resistance (e.g. adenotonsillar hypertrophy, and functional processes that decrease upper airway tone (e.g. REM sleep) contribute to the pathogenesis of pediatric OSAS. Sequelae of OSAS in children include neurobehavioral abnormalities, problems of growth, and cor pulmonale. Both the history and physical examination should target the sleeping child; parents often report loud snoring, difficulty breathing, and obstructive apneas. The gold standard investigation to establish the diagnosis and to quantitative assess disease severity is overnight polysomnography. Home cardiopulmonary sleep studies have been shown to be an accurate and practical alternative to overnight laboratory polysomnography for routine evaluation of non-complex children with adenotonsillar hypertrophy. Children with documented severe OSAS are at increased post-operative risk for airway compromise and should be observed and monitored carefully. Adenotonsillectomy is the most common therapy for OSAS in children; as a second-line treatment, the use of nasal CPAP in children with OSAS has been very successful in experienced hands. Different methodologies for recording sleep disordered breathing in children can be used:

1. Asking the parents to obtain an audio or audio-visual tape of the child sleeping may prove to be an efficient means of observing the child asleep. Whether such recordings are representative or worst case data should be ascertained.
2. Portable devices (MesamIV, Polymesam) and overnight oximetry;
3. Diurnal PSG with at least 2.5 hours of sleep that have to include at least one REM period.
4. For children with a history and/or physical examination suggestive of obstructive sleep apnea, the gold standard investigation for confirmation of both diagnosis and disease severity is overnight polysomnography (PSG).





Studying children in this manner presents unique challenges. Skilled and experienced technicians are essential in order to win the cooperation and trust of young children. The laboratory settings must be soothing and non-threatening. A typical hospital sleep laboratory setting may frighten a child, thus preventing the technicians from obtaining even the most elementary set-up. Removing all non-essential hospital equipment from the immediate area, the display of colorful and interesting posters, diversion with favorite video shows and a relaxed, non-threatening approach to lead application all help to gain the cooperation of the child. Parents should be encouraged to bring favorite toys or items from home that may help to create normal bed-time routines in the sleep laboratory. We strongly recommend that a parent be required to stay with the child in the laboratory. The American Thoracic Society recently established standards and criteria far cardiopulmonary sleep studies in children. These include measurements of respiratory movements, airflow, ventilation and oxygenation, sleep staging, electrocardiogram, electromyogram and audiovisual recording. Supervision by a trained technician is required throughout the study with additional record keeping of unusual event or behaviours during the night. Additional information regarding sleep positioning, snoring, and arousal frequency is easily obtained by adding videotaping during PSG. Unfortunately, few scientific data examining the correlation between PSG abnormalities, clinical symptoms, and sequelae of OSAS in children are currently available. The American Thoracic Society recommended further investigation of abbreviated testing such as unattended home monitoring of oxygen saturation and respiratory pattern. In some countries as our (Italy) home cardiopulmonary sleep studies were shown to be an accurate and practical alternative to overnight laboratory polysomnography for routine evaluation of non-complex children with adenotonsillar hypertrophy that helps the diagnosis where only few labs perform laboratory PSG.

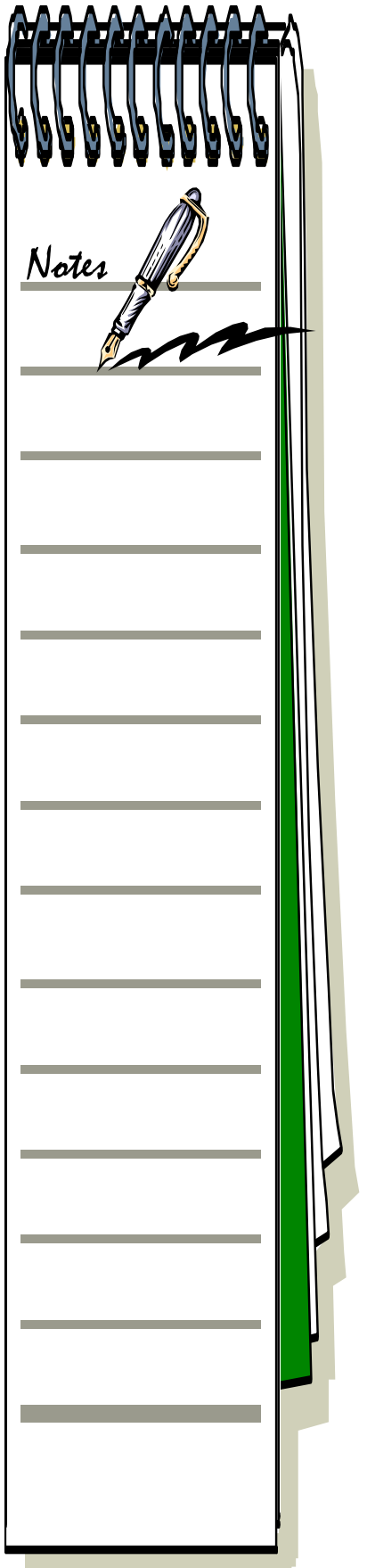
Lessons from the Forefathers of Sleep

by Max Hirshkowitz, PhD, DABSM
Sleep Review Magazine: Issue: November 2007

The new AASM Scoring Manual: Learning from R&K about achieving consensus and acceptance.

The new *AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology and Technical Specifications*[1] represents a giant step toward standardization of clinical polysomnography. Some of the challenges for making it the "New Standardized Manual" can be easily met while others will require more effort. Looking at the challenges faced approximately 40 years ago when Allan Rechtschaffen and Anthony Kales developed A

Manual of Standardized Terminology, Techniques and Scoring System for Sleep Stages of Human Subjects, the sleep community can learn valuable lessons about how to proceed with consensus and acceptance of the new AASM Scoring Manual.

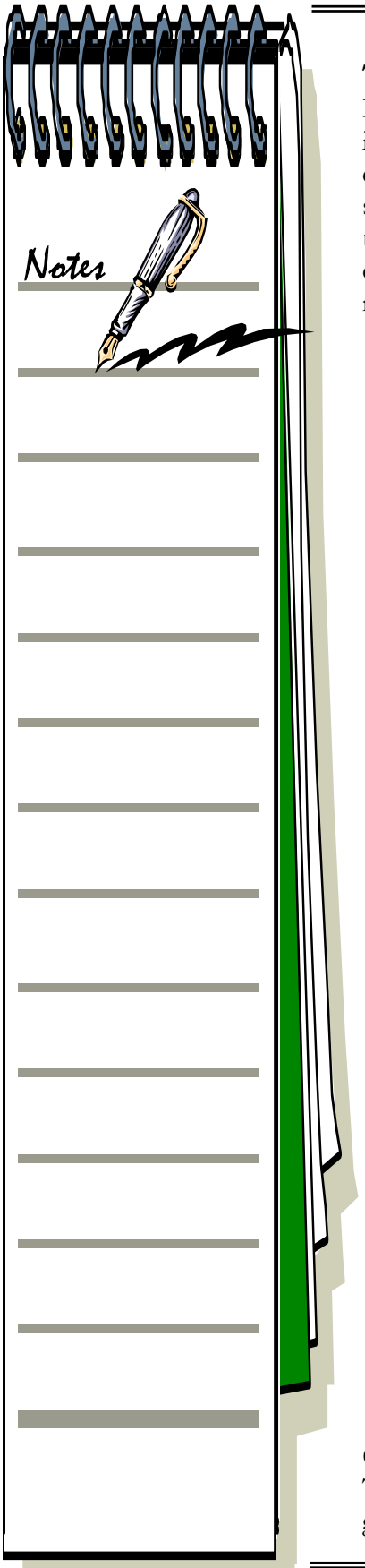


Background

In 1968, *A Manual of Standardized Terminology, Techniques and Scoring System for Sleep Stages of Human Subjects* was published by the United States Government Printing Office.[2] This "standardized manual" was developed by an ad hoc committee of sleep experts and was chaired by Rechtschaffen and Kales; the manual thereafter was often referred to as "R&K." R&K defined recording technique, terminology, and scoring rules for normal human sleep that lasted 40 years. The key word here is normal.

As the need arose to detect sleep pathophysiologies associated with specific sleep disorders, clinical researchers developed additional guidelines. One of the best compendia of additional rules was to be found in the book *Sleeping and Waking Disorders: Indications and Techniques*, edited by Christian Guilleminault.[3] This volume contained rules for scoring breathing, leg movements, abnormal EEG, nocturnal tumescence, and other sleep phenomena. This book became a standard desk reference and citation for those of us engaged in clinical sleep research; however, it was out of print by the next decade.

Later, the rules for scoring central nervous system (CNS) arousals were formalized by the American Sleep Disorders Association (ASDA) Atlas Task Force and published in the journal *Sleep*.[4] A year later, the leg movement scoring rules from Richard Coleman's chapter in *Indications and Techniques* were reviewed, slightly modified, illustrated, and endorsed by the Atlas Task Force.[5] Finally, the "Chicago" group considered sleep-related breathing and proposed a set of guidelines that were adopted as a recommended clinical research technique.[6] Even as scoring rules were evolving with changing methodology, no official guidelines emerged concerning computerized polysomnography. By the millennium, sleep recordings had migrated from special-purpose, analog-circuit, EEG machines attached to paper chart drives to digital amplifiers interfaced with personal computers programmed to capture, display, and manipulate data. Until the introduction of the new AASM Scoring Manual, no recommendations from professional organizations have specified even the most basic, minimal operational characteristics for such machinery in application for polysomnography.



The New Manual

In a bold move, the American Academy of Sleep Medicine (AASM) initiated a large-scale project to revise the Standardized Manual and develop a unified guideline for terminology, recording method, and scoring rules for sleep-related phenomena. A task force was also formed to review and recommend guidelines related to functional aspects of digital system polysomnography. The following illustrates the areas where modifications occurred.

- The task force concerned with staging renamed the stages, combined stages 3 and 4, and eliminated stage "movement time." Also, some of the "smoothing rules" governing specifics of stage transition were simplified. More controversial, perhaps, was the mandate that an additional EEG channel (from a frontal derivation) be routinely recorded.
- Recording and scoring of CNS arousals were essentially re-endorsed without modification.
- Leg movement scoring underwent minor modification and clarification without major changes. More significant, however, was the addition of rudimentary approaches to scoring other sleep-related movements, including teeth grinding, hypnagogic foot tremor, excessive fragmentary myoclonus, and rhythmic movement disorders.
- The respiratory task force managed to formalize technique and define sleep apnea episodes. For hypopnea, the recommended definition accords with Medicare's specifications requiring an associated 4% drop in oxygen saturation. An optional definition that considers events with either desaturation (3%) or arousal is also provided (and accords better with how clinical sleep specialists traditionally defined hypopnea). Rules for scoring respiratory events in children were also developed and included.
- Newly covered is a list of definitions of important electrocardiographic events that should be delineated, tabulated, and reported as part of a comprehensive polysomnographic assessment.
- Finally, the digital PSG task force made recommendations concerning specifications for digital recordings, display, reporting, and operational characteristics. The body of work and new recommendations and guidelines were published in a single volume entitled the *AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology and Technical Specifications.*[1]

Challenges for the Future

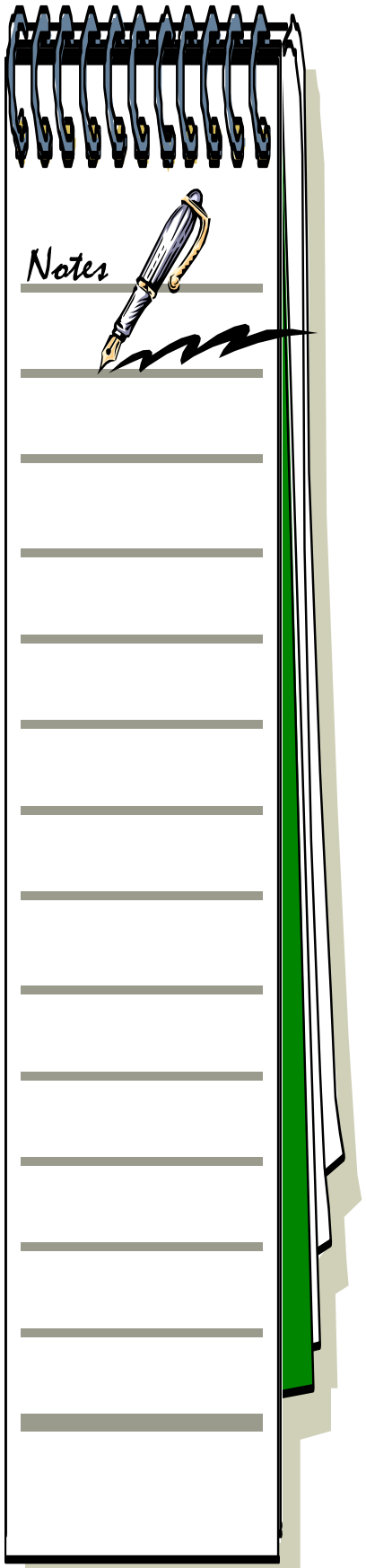
The main challenge for making this long-awaited and much-needed guidebook the New Standardized Manual will be consensus and

acceptance. This challenge was also the primary challenge facing the previous manual, and the framers of that work were keenly aware of this fact. Rumor had it (and was confirmed by Rechtschaffen) that during the deliberations of the ad hoc committee in the 1960s, Rechtschaffen barred the meeting room door and declared, "No one can leave until we all agree!" Because of Rechtschaffen's demand that consensus take place, the framers were eventually able to come to an agreement.

While it may not be immediately apparent, this was the key to the original standardized manual's success. If each committee member had returned to their respective laboratories and continued to use their own home-grown methods, the R&K manual would merely be an asterisk in the history of sleep medicine. Furthermore, we would still be discussing synchronized sleep, paradoxical sleep, d-sleep, orthodox sleep, desynchronized sleep, and dreaming sleep.

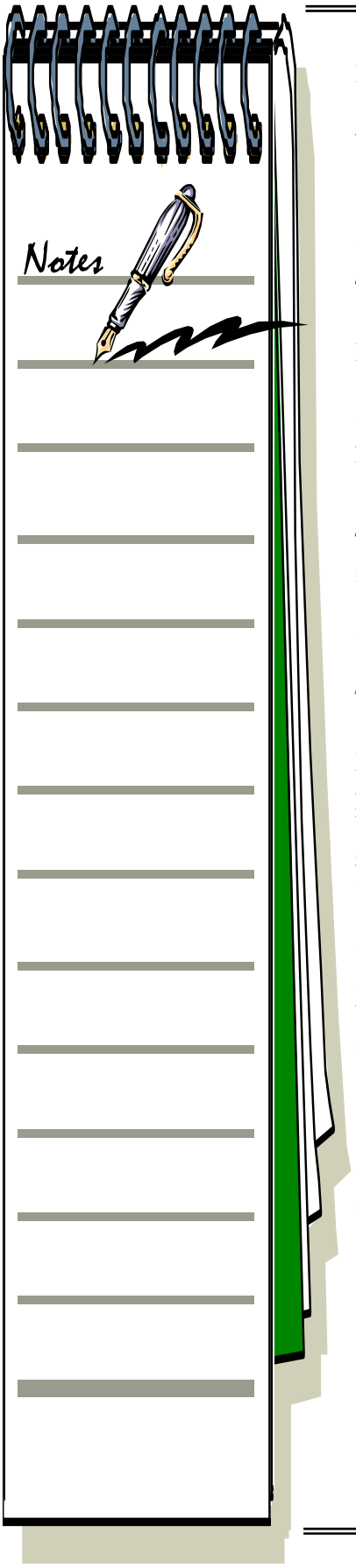
The second challenge will be disambiguation of some of the rules and terminology. For example, frontal EEG recordings are mandated for routine use for determining slow wave sleep, now called N3. However, the somnologist can choose between monopolar or bipolar derivations. Furthermore, minimum amplitude criteria are specified, but not differentially, for the two recording types.

The third challenge to acceptance will be influenced by how the AASM manual responds to future needs. As with all projects, particularly ambitious ones, there are always things that have not been fully covered.



References

1. *AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology and Technical Specifications*. Westchester, Ill: American Academy of Sleep Medicine; 2007.
2. Rechtschaffen A, Kales A. *A Manual of Standardized Terminology, Techniques and Scoring System for Sleep Stages of Human Subjects*. Washington, DC: US Government Printing Office; 1968. NIH Publication No. 204.
3. Guilleminault C, ed. *Sleeping and Waking Disorders: Indications and Techniques*. Menlo Park, Calif: Addison-Wesley; 1982.
4. Arousal Scoring ASDA Report. Bonnet M, Carley D, Carskadon M, et al. EEG arousals: scoring rules and examples. *Sleep*. 1992;15:173-184.
5. PLMS ASDA Report. Bonnet M, Carley D, Carskadon M, et al. Recording and scoring leg movements. *Sleep*. 1993;16:748-759.
6. AASM Task Force. Sleep-related breathing disorders in adults. Recommendations for Syndrome definition and measurement techniques in clinical research. *Sleep*. 1999;22:667-689.



Many sleep centers are mired in backlogs of sleep studies which need scoring. The following is some helpful information regarding dealing with such backlogs:

Organizing Your Outsourcing

By Andrew Korbel, RPSGT

To ease the patient backlog afflicting many sleep centers, managers are searching for outside sources to score sleep studies. Here's a primer on how to do it.

Sleep disorder sufferers are banging down sleep centers' doors with their pillows. To ease this patient backlog, sleep center managers are searching for outside sources to score sleep studies.

This environment is potentially a flash fire of business because little regulation currently exists regarding qualifications for collecting and scoring these records. Also fueling this blaze is affordable, cutting-edge technology that makes the most out of scoring technologists' time.

The first reason many sleep center managers seek outsourcing for scoring studies is the reduction of operating costs. Sending records out allows a limited staff to focus on the many overlooked issues of a center, such as patient follow-up, patient and physician education, and marketing. And because study scoring is the most standardized task between institutions, it's the most logical job to pass along and help alleviate the day technologists' workload.

Outsourcing also adds experience and knowledge to a new facility. By carefully choosing scoring contacts, a sleep center can get the maximum benefit in a short amount of time. This can be a lifesaver for small, new centers that seek resources normally out of reach.

Getting Started

Once a sleep center manager has decided to use outsourcing (whether on a temporary or a permanent basis), there are a few things he or she should keep in mind:

- **Get started early.** Waiting until the center is swamped to ask for help only will cause bigger headaches. Begin contacting remote scoring technologists as soon as possible. Be honest — tell them if you want them as backup or on a regular basis.

  Given the relatively small intellectual community, finding qualified scoring technologists locally to score the records can be nearly impossible. For those with contacts in the field, your

personal and professional network always should be the first choice to finding reliable help. Word-of-mouth recommendations remain the most consistent method of hiring qualified people. Secondary to that, place an ad on the Internet or in trade magazines.

- **Set up a screening process.** The same qualities you look for in full-time employees also should be characteristics of remote scoring technologists.

  Ask the candidate to score a short sleep study. Every scoring technologist in the lab should score this study, and the medical director should review the final results. Keep in mind that when you settle on a technologist's scoring particularities, you're compromising the sleep center's inter-scorer reliability.

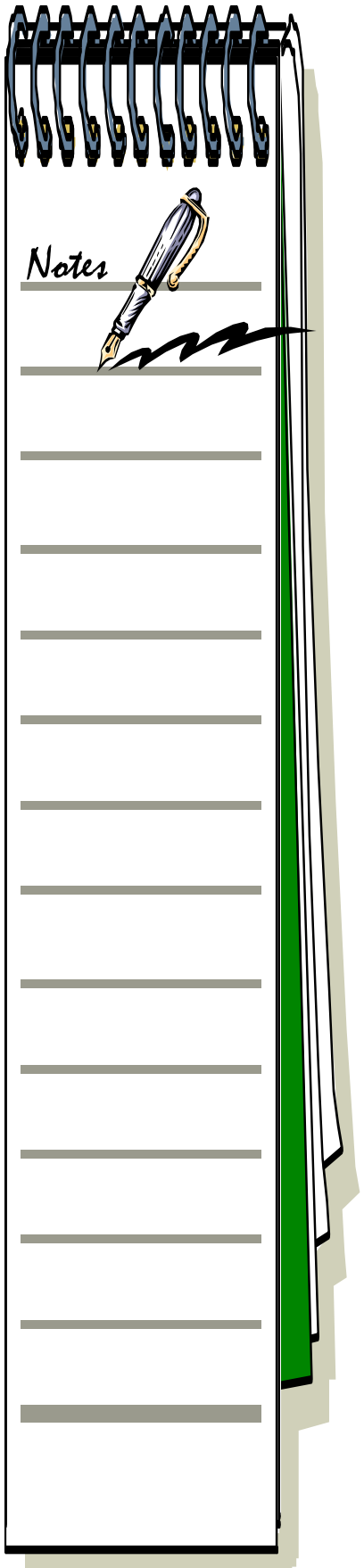
  Also, it would be professional to offer some sort of reimbursement for the candidate's time, but it's not unheard of for the technologists to score an example study for free. If you choose the latter option, don't make the sample study too long.

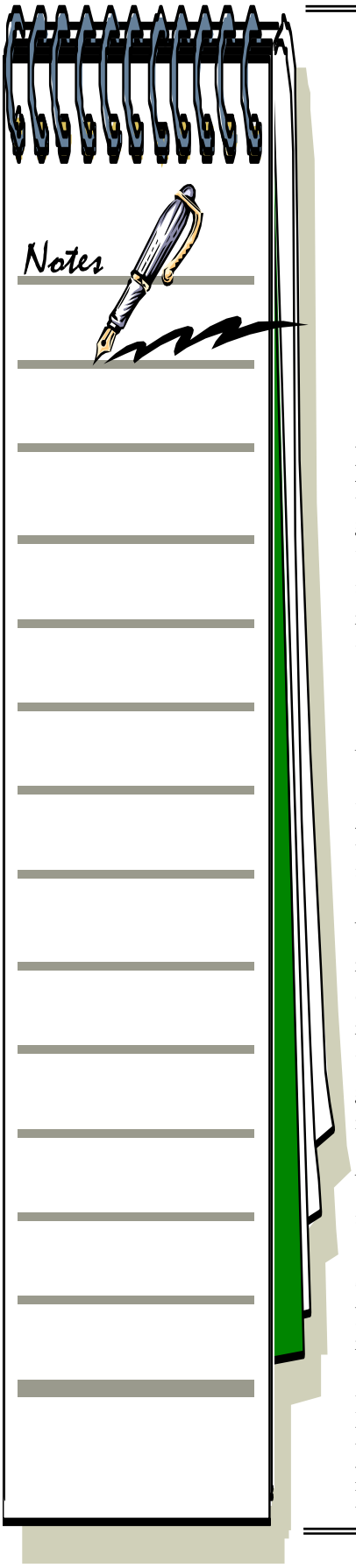
- **Make sure a contract defines all of your terms and expectations.** This includes standards for scoring (respiratory events, arousals, leg movements, etc.), turnaround time, compensation, and a dispute resolution policy that's fair to both sides for difficult-to-score studies.

  Most (but not all) manufacturers tightly control software programs designed to score the studies. Some sort of hardware (often called a "dongle") prevents exchanging the software without the designer's consent. The scoring technologist must use his or her own software, or the sleep lab can provide the scoring technologist with a licensed copy.

  Compensation for each study scored can vary greatly. When considering how much to pay an outsourced technologist, you might consider their point of view.

  How many studies can you guarantee they will receive each week? Perhaps you only want a temporary technologist for quick scoring, performed within 12 hours to 24 hours. Obviously, the more consistent long-term work you can provide and the more time you give them to score, the lower you can expect to pay them per record.





On this end of the spectrum, rates average around $50 to $75 per record, with about a two-day to three-day turnaround time. On the other side, a 12-hour turnaround time for a last-minute request easily can reach $200 or more per record.

- **Always have a backup scoring technologist who you've interviewed and screened previously.** This is one of the beauties of outsourcing sleep scoring. When backlogged with studies to score, relying on a backup technologist can be helpful to full-time employees and keep your reputation intact.

Exchanging Data

Now that you've found a few technologists to work with, how are you going to exchange the sleep data? With the explosion of Internet-related technology over the last decade, outsourcing has become even more appealing to those who are willing to adapt their business systems to integrate even faster turnaround time. Sleep center managers and technologists who have embraced the digital age are setting a new standard for sleep.

An Internet transfer system enables all the parties involved with a sleep study (patient, referring physician, sleep center director, sleep technologist, insurer, etc.) to track all dealings with a particular patient. Not only does this electronically account for each step of the study, but it also frees up the sleep center's day crew from phone calls.

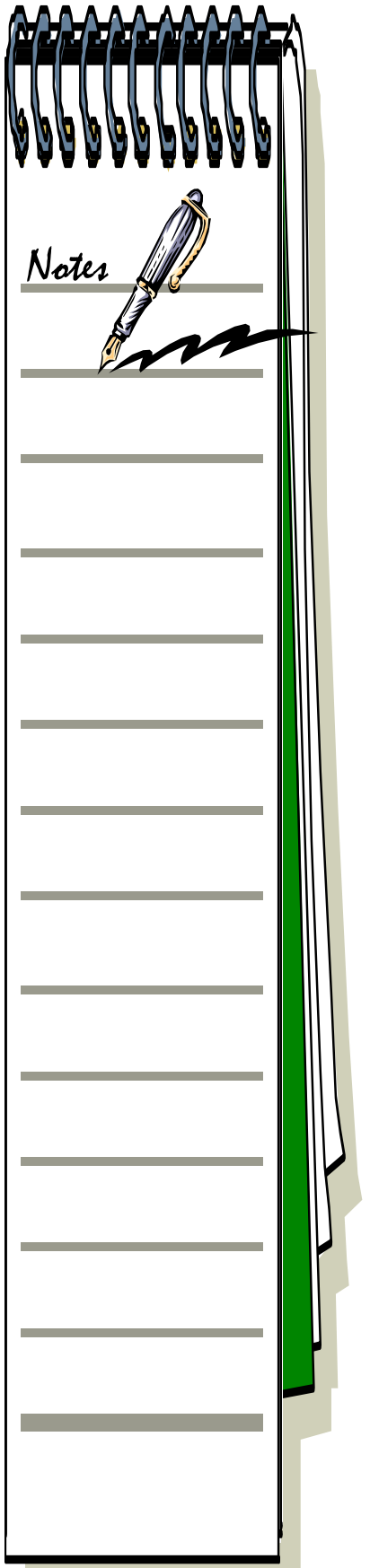
Yet another beauty to the Internet transfer system is the flexibility it gives interpreting physicians to work while on vacation or at a conference. For example, one physician at our center consistently produces detailed interpretations within six hours to 24 hours of receipt. This quick turnaround time not only motivates the staff to work harder but also gives our sleep center an excellent reputation for quick and accurate results.

With any mention of electronic transfer, the Health Insurance Portability and Accountability Act (HIPAA) always is close behind.

Simply put, HIPAA legislation asks that you inform your patients what you're doing with their information, ask their permission to release their information, and that you take steps to protect their information.

In the office, this includes: having compliancy letters from anyone who has access to the data, ensuring you have all necessary patient rights and privacy policies available to patients and employees, and common-sense habits of locking up patient files to prevent unnecessary access to them.

But when these things are coupled with using the Internet, some people become dumbfounded. It's quite simple: encrypt, encrypt, encrypt. Simply encrypting your connection or encrypting the file you're sending will exceed HIPAA's standards for protection.



Auto-scoring Appeal

Once the sleep studies have been transferred securely via the Internet, the remote scoring technologist can go to work. Auto-scoring features now common on most computerized systems have become more and more appealing to a technologist seeking to maximize time. After all, he or she is getting paid the same price whether it takes 30 minutes or four hours to score a study.

When considering the auto-score function, the two most significant questions at hand are:

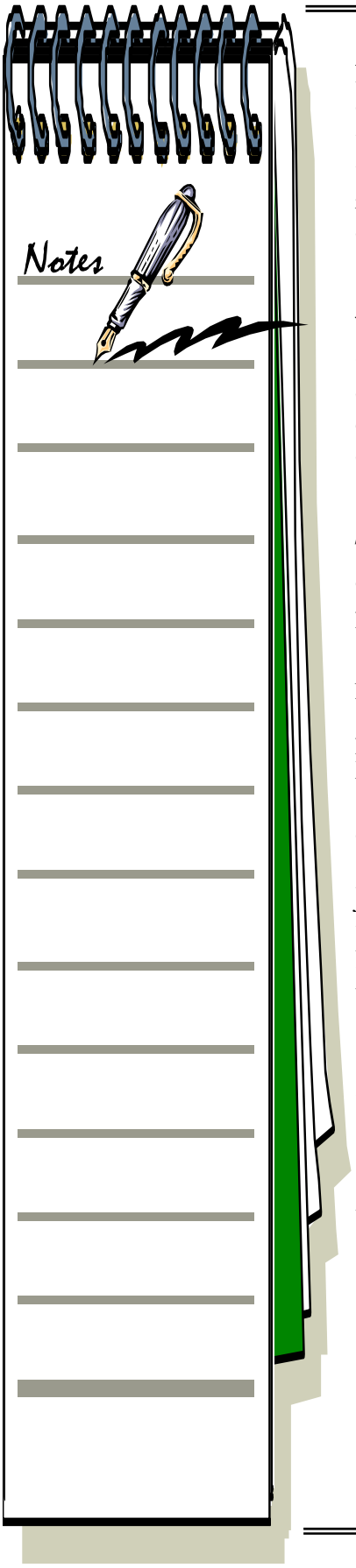
1. How statistically accurate is the system you're evaluating?
2. Does the confidence interval meet the expectations of the technologist and medical director?

Accuracy (statistically speaking) is how close the auto-scoring software is to the true value. While most computers are "precise" (a measure of consistency), the accuracy can vary greatly depending on what's being scored.

Quantitative measurements, such as leg EMGs, are well suited to auto-scoring. The scoring technologist simply has to validate or unvalidate the auto-scored leg movements (or any other quantitative measurement). This is providing that the system has been previously compared to hand scoring, with a margin of error acceptable to the record scorer. Qualitative measurements, such as the EEG signals, prove more troubling.

While the leading software writers have made significant strides, sleep professionals always must evaluate the confidence interval associated with a hand-scored record versus the auto-scored one. A margin of error of just 10 percent or 20 percent can significantly distort apnea-hypopnea indices.[1]

Further complicating the decision to rely on auto-scoring (for qualitative measurements) are factors such as changes in patient population, how much fine-tuning is required to get accurate results, medicated versus nonmedicated patients, and the purpose of the PSG. [2]



No matter how much a sleep system is pre-tested for accuracy and confidence interval, the scoring technologist must take responsibility for that report. If auto-scoring is used in any form or fashion, a statement to that extent, along with the calculated margin of error, should be included in the final summary for the interpreting physician. Nothing less easily could be construed as fraud.

When to Think Twice

Outsourcing isn't for everyone, though, and a significant issue of contention for many facilities is overcoming technical issues with outsourcing. Some labs don't want to install high-speed Internet connections in their offices, and some can't afford to purchase new software keys (often $2,000 or more) to allocate to remote technologists.

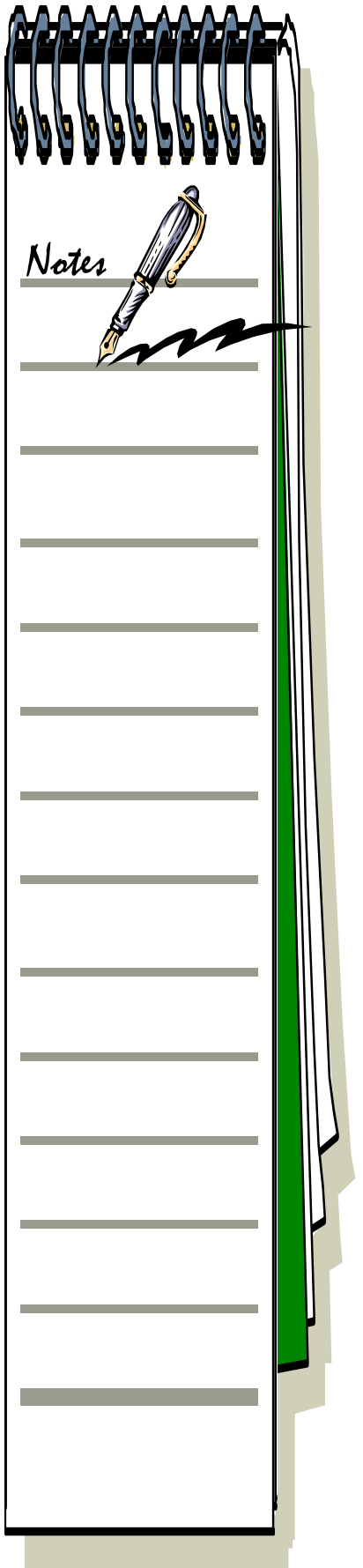
Trying to find a remote technologist after you're behind in your scoring only will make matters worse. As explained earlier, without proper planning and screening, you'll only set yourself up for failure.

Another issue to contend with is the fact that technologists and labs are becoming more regulated. Some states have already legislated who can perform sleep studies, and more states are likely to follow. While legislation might not address outsourcing directly, any rule governing a sleep lab's operation will obviously have to carry over to whomever contracts to score with them.

Just as a registered technologist's signature on a scored report certifies the standards and professionalism set by the Board of Registered Polysomnographic Technologists, a sleep facility's management is ultimately responsible for the work that bears its name.

References

1. Hirshkowitz M, Moore CA. Computers in sleep medicine. In: Kryger MH, Roth T, Dement WC, editors. Principals and practice of sleep medicine, 3rd edition. W.B. Saunders: Philadelphia; 2000. p. 1302-7.
2. Carskadon MA, Rechtschaffen A. Monitoring and staging sleep. In: Kryger MH, Roth T, Dement WC, editors. Principals and practice of sleep medicine, 3rd edition. W.B. Saunders: Philadelphia; 2000. p. 1197-1215.



Sleep Stage Scoring

Last Updated: March 8, 2007

INTRODUCTION

This article is based on the rules of the definitive sleep scoring manual (Rechtschaffen and Kales). For situations not defined by Rechtschaffen and Kales, other expert polysomnographers have developed logical rules, which are presented in this text as supplementary information to facilitate scoring. The contents of this article reflect only the opinions of the author and do not constitute official policy of the United States Department of Defense.

Sleep-stage scoring is a rule-based art requiring an understanding of the basic mechanisms underlying the generation of cephalic electric potentials. Signals of interest are generated from the brain (i.e., cortex and deeper structures) and the facial muscles (i.e., signals picked up by periorbital and electromyographic [EMG] leads).

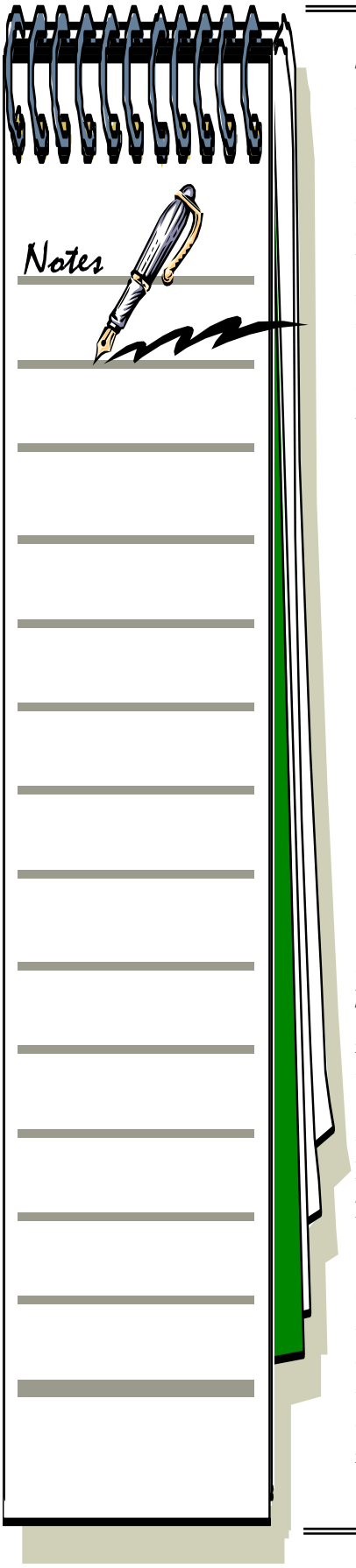
Interference with the signals of interest is encountered through many mechanisms, including physiological attenuation of the cerebral electric potentials by scalp muscle and bone; intrusion into the signal by slow cyclic respiration, movement, ECG signal, or external electric fields; and impaired contacts between the recording electrodes and the skin surface. Discriminating true signal from artifact can be one of the most challenging aspects of scoring the stages of sleep.

At a paper speed of 10 mm/s, 1 page equates to 30 seconds and is defined as 1 epoch. Computerized polysomnography usually displays one video screen as one 30-second epoch.

Polysomnographic Interpretation

Cortical signals

The electroencephalography (EEG) signal is of primary importance in interpreting polysomnographic studies. It records electric potentials generated by the interaction between the cortex and the deeper brain structures, especially the thalamus. Two centrocephalic and two occipital cortical channels are recorded. Measurement of EEG signals is possible because of the relative difference in potential between the two recording electrodes; one electrode is considered negative with respect to the other. Negative discharges, by convention, are represented by an upwardly deflecting wave.



The polysomnograph references the left and right centrocephalic electrodes (C3, C4) or the left and right occipital electrodes (O1, O4) to electrodes on the opposite right and left ears (A2, A1). The general rule is to read only from the left cortical channel. However, when the left channel develops artifact or the validity of the signal is suspected, comparison is made with the right cortical channel. By convention in the United States, the left channels are odd numbers and the right channels are even numbers. By convention in the United Kingdom, the opposite is true, with the left channels described by even numbers.

Cortical signals are defined slightly differently according to the reference used. The following convention is used here:

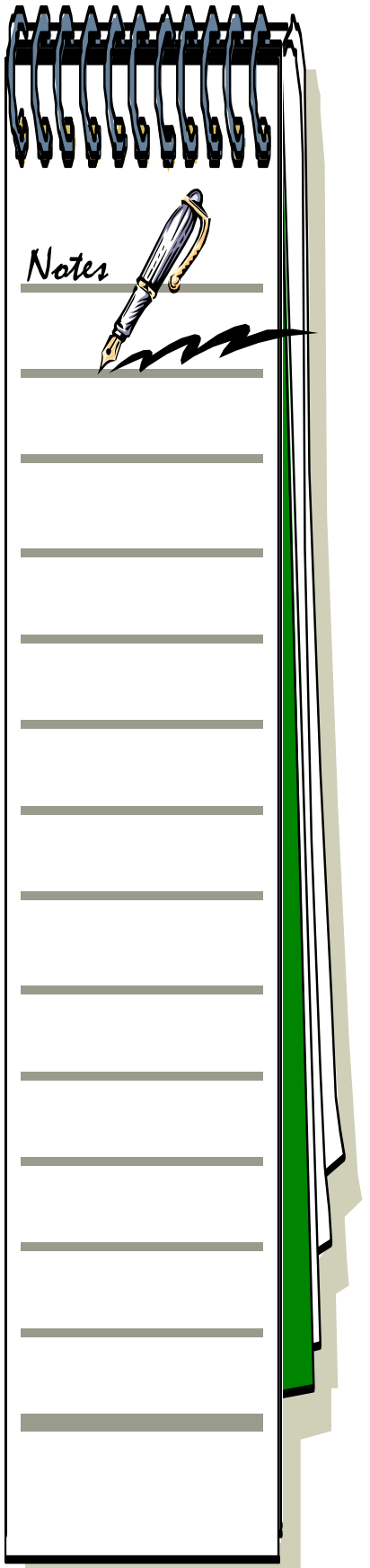
- Delta is the slowest activity at less than four counts per second (cps).
- Theta is between four and eight cps.
- Alpha is between eight and 14 cps.
- Beta is greater than 14 cps.
- Another range occasionally mentioned is gamma, which is part of the high end of the beta frequency and has been described to range from 30-45 cps.
- High frequency signals above 50 cps are finding increased mention in the literature. High frequency bands (HFB) are described in the ranges 51-100 Hz (HFB1), 101-200 Hz (HFB2), and 201-500 Hz (HFB3) for analysis purposes. Frequencies in these bandwidths are reported as being associated with cognitive processing and alertness.

Muscle signals

The EMG signals are muscle twitch potentials that are of secondary importance in polysomnography. Their utilization is based on the finding that, during sleep, muscle activity decreases. During rapid eye movement (REM) sleep, muscle activity is at its nadir. However, in many cases appreciating the decreasing tone is difficult. The relative silence during REM sleep may not be of help in distinguishing REM sleep from the preceding or subsequent sleep stages.

Compounding the problem of interpreting EMG channels is intrusion of artifact into the signal. This has many etiologies. Some examples include cyclic chewing movements, irregular teeth grinding, steady high-amplitude noise generated by increased pressure on the electrode (egg, as caused by lying on the chin). Additionally, muscle artifact may spill over into the cortical leads. ECG signal is a specific type of cardiac artifact

that can appear in all or several channels; it can be recognized by the QRS complexes in the cortical or other channels.



Eye movements

The electro-oculographic (EOG) signals measure changes in the electric potential of the positive anterior aspect of the eye relative to the negative posterior aspect. Horizontal axis electrodes are placed near the outer canthi and vertical axis electrodes below and above the eye to measure transient changes in potential during the actual eye movement. During any eye movement, the cornea (positive) moves toward 1 electrode, while the fundus (negative) moves away. When the eye is not moving, the change in relative position is zero, and the eye leads do not record a signal.

Slow, rolling eye movements are recorded as long gentle waves, while rapid jerking movements are represented by sharply contoured fast waves. Blinking of the eyes produces rapid vertical movements. Eye movements during drowsiness and stage I sleep may be jerky, irregular, or gently rolling. In deeper stages of sleep, macro eye movements cease altogether. During REM sleep, eye movements again become active and jerky. The intensity of the bursts of activity is used to describe the density of REM sleep.

Sleep Stages

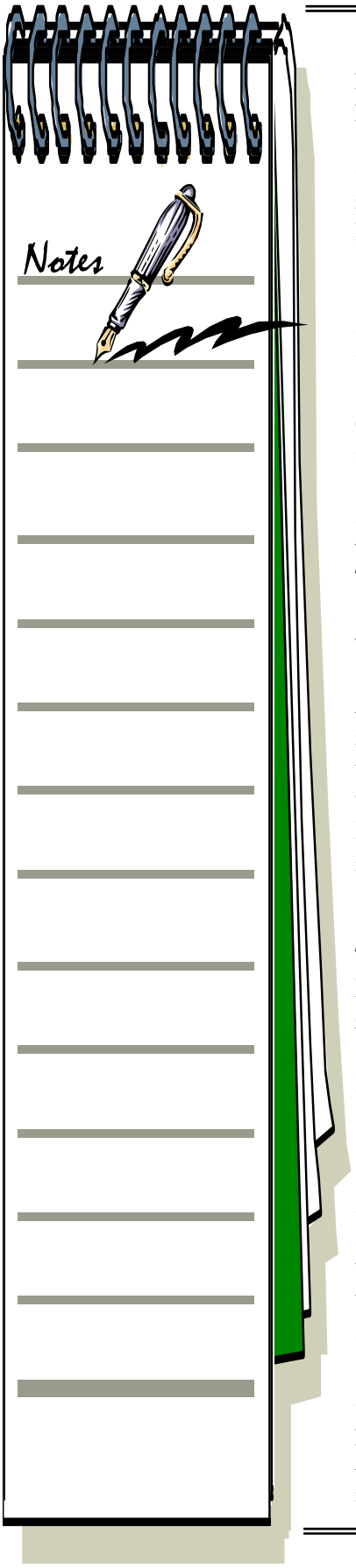
Initially, the clinician should scroll through the entire record quickly to evaluate the quality of the recording and the usefulness of specific channels. Observe sections that represent the major stages to learn the specific shape of the features that represent the stages in that particular individual and to gain an overall picture of the cycles for that record. Specifically observe for sleep spindles, K complexes, slow waves, and REMs.

Wake stage

The first several epochs of the record will be the wake stage. The EEG will show mixed beta and alpha activities as the eyes open and close and predominantly alpha activity when the eyes remain closed. The EMG will reflect the high-amplitude muscle contractions and movement artifacts. The EOG will show eye blinking and rapid movement. The record will slow in frequency and amplitude as the subject stops moving and becomes drowsy.

Drowsiness

This stage is defined as sleepy but awake with eyes closed. The EEG will show predominant alpha activity, while the EMG activity becomes less



prominent. The EOG may show slow, rolling eye movements. If, at any point, the subject rolls over, the record will reflect this as paroxysmal sustained increased artifact and high-amplitude activity. The subject may enter stage I of sleep for 1 or 2 epochs and then reawaken. Transitions may be difficult to score. From wake, sleepers normally proceed to stage I, but infrequently they may enter REM sleep or stage II sleep directly.

Stage I

Stage I sleep is scored when the alpha activity in the EEG drops to less than 50%. A transition is observed from alpha activity to a lower frequency activity, such as theta, possibly intermixed with low-amplitude delta activity. Amplitudes are less than 50-75 μV. Paroxysms of 2-7 cps activity up to 75 μV may occur.

Stage I is usually brief, lasting for one to seven minutes. Vertex sharp waves may occur, but no sleep spindles or K complexes are recorded. The EOG may show slow, rolling eye movements, especially early in the stage. No REMs are observed. The EMG shows less activity than in wake stage, but the transition is gradual and of little assistance in scoring.

Arousals are paroxysms of activity lasting 3 seconds or longer. The minimum arousal is simply a paroxysmal burst in the EEG channel, usually to alpha or theta activity. Arousal from stage I is common and usually is represented by a burst of activity on the EEG, EOG, and EMG. If the burst results in alpha activity for greater than 50% of the record, then the epoch is scored as wake.

Stage II

The EEG shows predominant theta activity with minimal alpha activity. Delta is permitted for less than 20% of the record. Amplitude may increase from that seen in stage I.

K complexes appear for the first time. K complexes are sharply negative (i.e., up-deflecting) monophasic or polyphasic waves followed by a slower, positive (i.e., down-deflecting) wave. The complex must persist for at least 0.5 seconds. No minimum amplitude is defined, but characteristically the waves stand out clearly from the background. K complexes can occur in response to a sudden sound and were so named because they were appreciated as following the knocking sound produced by knuckle rapping. In this respect, they may represent a form of cortical evoked potential in a brain still minimally responsive to external stimuli.

Sleep spindles may appear. These are paroxysms of 12-14 cps activity persisting for at least 0.5 seconds (that is, 6-7 small waves in 0.5 seconds). Although classically described as spindle shaped, they vary in morphology and may attach as a tail to a K complex.

No specific criteria exist for EOG and EMG in this stage.

Arousal from stage II may be into stage I or into wakefulness. If the arousal is 3 seconds or longer in duration, and the resulting alpha activity persists for less than 50% of the record, the epoch is scored as stage I. If the alpha persists for greater than 50% of the record, the epoch is scored as stage wake. If the first half of the following epoch demonstrates stage II characteristics (i.e., spindles, K complexes, high-amplitude theta/delta activity), that epoch is scored as stage II.

Once in stage II, that score is maintained unless a reason to exit presents. One such reason to exit is described as the 3-minute rule. If no specific stage II indicators appear, and in the absence of arousals and muscle tone changes that would alter the staging, continue to score all epochs as stage II for up to 3 minutes. At 3 minutes, if no specific indicators for stage II have occurred, scroll back 3 minutes and score those epochs as stage I.

Stage III

The EEG shows 4 cps or slower activity, with peak-to-peak amplitudes greater than 75 μV for between 20% and 50% of the epoch. Both K complexes and sleep spindles may be seen in stage III sleep. No specific criteria exist for EOG and EMG. The transition to stage III from stage II may be gradual, and stage III may alternate with stage I.

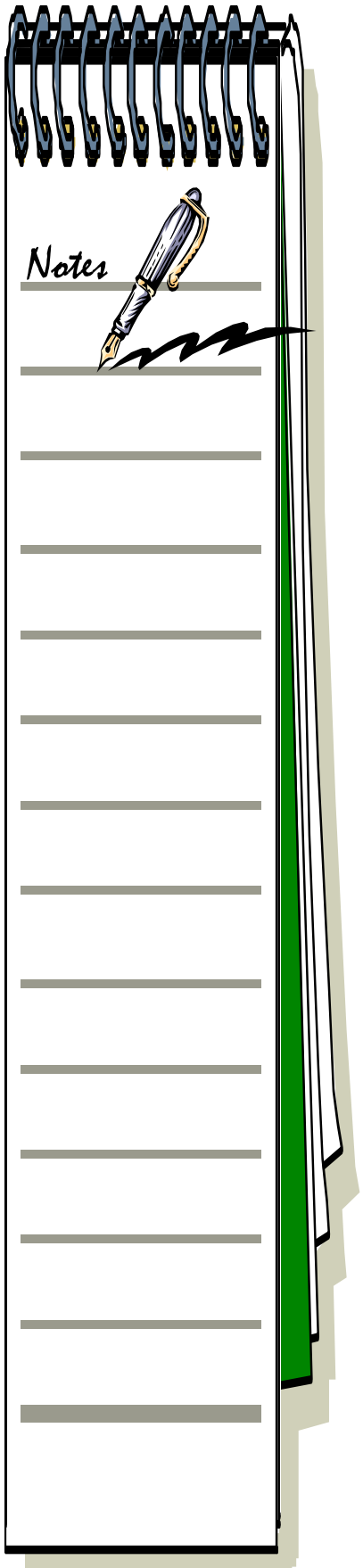
Stage IV

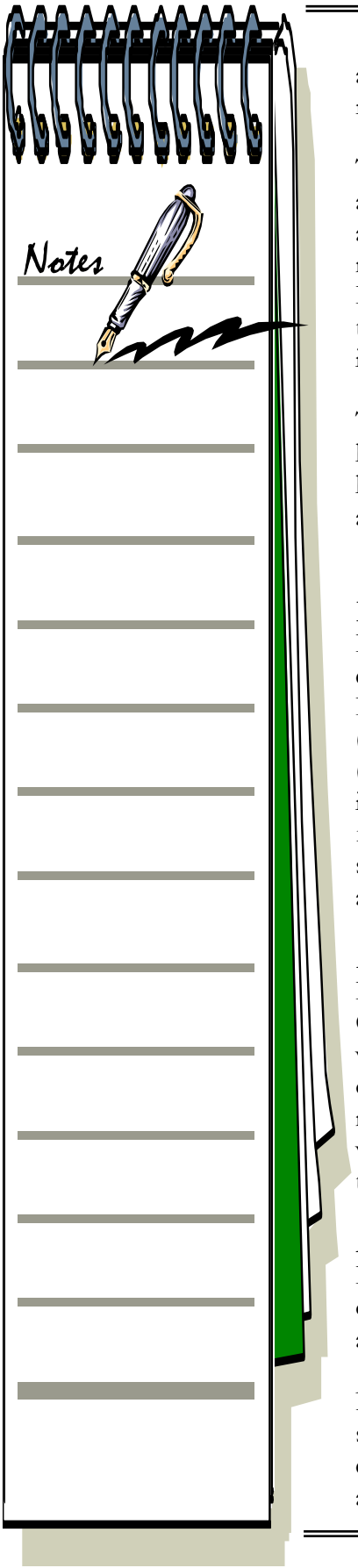
The EEG shows 4 cps or slower activity, with peak-to-peak amplitudes greater than 75 μV for at least 50% of the epoch. Both K complexes and sleep spindles may be seen in stage IV sleep. No specific criteria for EOG and EMG exist. In general, muscle tone decreases gradually from stage II to stage IV. The transition from stage III to stage IV may be gradual, and stage III may alternate with stage IV.

Stage REM

The EEG of REM sleep shows relatively low-voltage and mixed-frequency activities and may resemble the EEG of stage I. Sawtooth-shaped waves may occur before or with REM EOG bursts. Slow alpha activity may occur, resembling that of wake stage.

Sleep spindles and K complexes are not part of the REM EEG; when they occur, they are reason to consider moving from REM to stage II. If 2 K complexes or spindles occur without REM activity between them, the epochs between the complexes are scored as stage II. If REM activity occurs on both sides of the K complexes or spindles, then the epoch is scored as REM and the complex is considered to represent a momentary breakthrough into REM rather than a change of stage. No high-





amplitude activity may be counted as REM. Bursts of delta activity are reason to change sleep stage.

The EOG of REM shows paroxysmal, relatively sharply contoured, high-amplitude activity occurring in all eye leads simultaneously. The EOG activity is not needed to mark the start of an REM period. REM epochs may be recognized by EEG activity before EOG movements start. Small REMs on EOG may serve as a harbinger of REM stage and can indicate the actual onset of REM in another area where interscorer concordance is lower.

The EMG of REM shows an appreciable decrease in tone but may differ little from the EMG of stages III or IV. The EMG should show the lowest tone in the record, but no specific amplitude or frequency criteria are in place.

REM Scoring Subtleties

REM can alternate with stage wake, stage I, or stage II. Rules to help differentiate REM-spindle-K complex intermixing include the following: If a single sleep spindle or K complex occurs during an REM period (REM on both sides of the complex), and the EMG remains unchanged (low amplitude), continue to score REM. If the EMG amplitude increases with the spindle or K complex and REM is not clearly apparent following the complex, score stage II from that point forward. If 2 spindles or K complexes occur in the absence of EMG changes (i.e., low amplitude continues), score them and the intervening period as stage II.

Beginning scoring REM

REM periods may begin before the characteristic EOG movements. Occasionally, low-voltage, mixed-activity EEG, sometimes with sawtooth waves and low-amplitude EMG, may begin several epochs prior to the onset of the characteristic EOG movements. When the EOG movements are recognized clearly as REMs, scroll back to the point where the record became REM-like on both EEG and EMG and score those epochs as REM. REM may begin after a brief arousal.

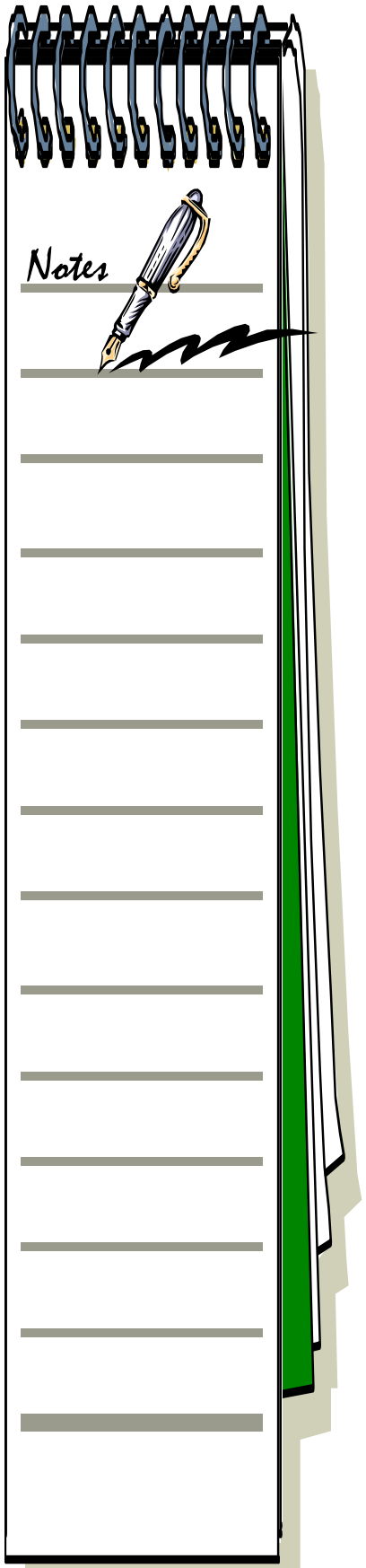
Ending scoring REM

REM may end with a brief arousal, after which the EEG looks qualitatively different, with higher amplitude and slower frequency activity. In the absence of arousal, the transition may be subtle.

Because the EEGs of REM, stage I, and stage wake can be similar, several criteria are available to help differentiate the stages. Look for development of bursts of higher amplitude and slower frequency EEG activity, which may be associated with EOG eye movements similar in

morphology to those of REM. Score the epoch according to the applicable stage criteria from the onset of the EEG bursts of slow activity. Remember that REM does not have high-amplitude, slow-EEG activity and that eye movements may occur in all stages. For example, if paroxysms of K complexes begin, score stage II.

Refer to the EMG and EOG as adjuncts to help confirm staging. For example, if the EMG increases in amplitude briefly and without warning, the period may be stage I. If higher amplitude EMG discharges persist and are accompanied by increased alpha activity (for >50% of the record), the epoch may be scored as wake.



General Considerations

Once in a stage, remain in that stage until given an unambiguous reason to change.

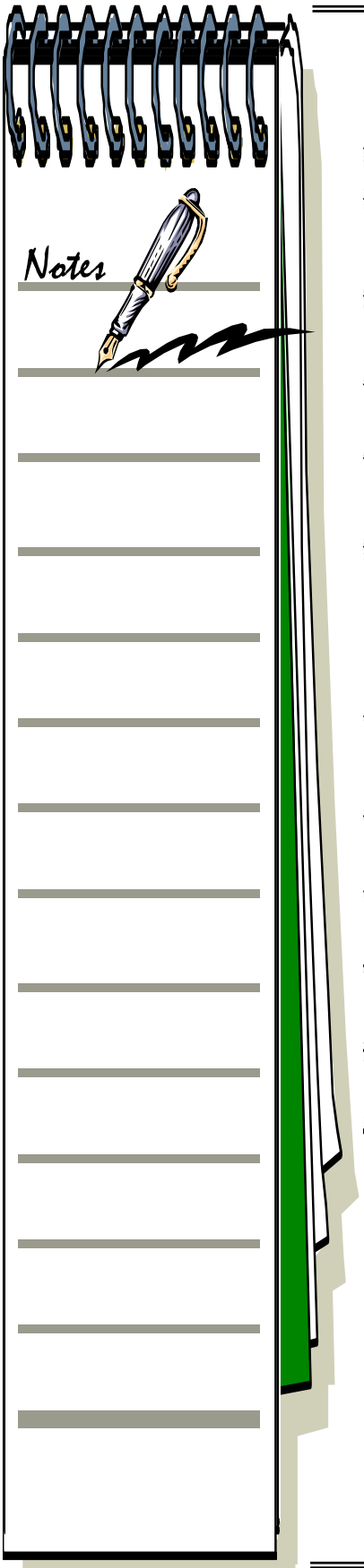
Arousal of greater than 3 seconds occurring in the first half of the epoch (from stages II, III, IV, or REM) is reason enough to consider changing the stage.

Arousals may be observed only on EEG, characterized by the development of theta or alpha activity.

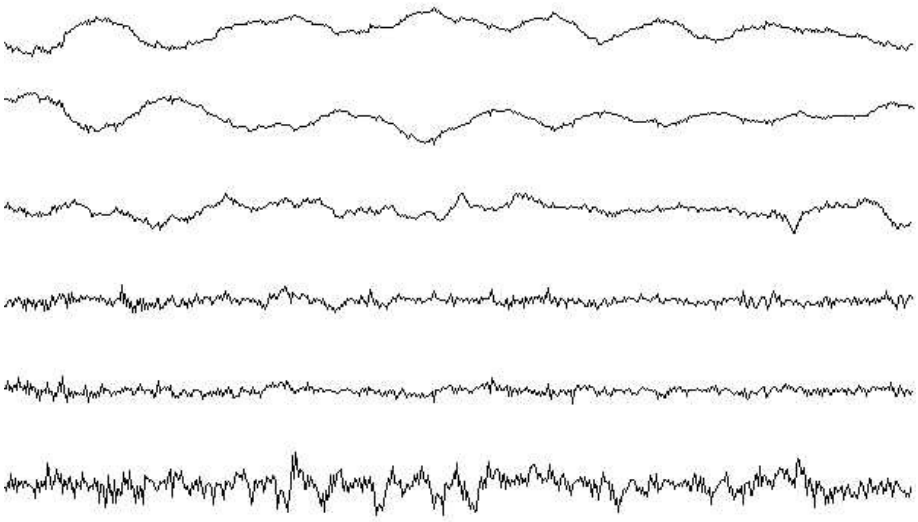
Arousals may have EEG activity with EMG activity increases, or they may have EEG, EMG, and EOG activity. For example, if an arousal occurs during stage III, score stage II if the arousal is less than half the record, stage I if the arousal is greater than half the record, and stage wake if the arousal is greater than half the record and associated with sustained alpha activity.

In a given epoch, if an arousal occurs from stage II, normally the remaining epoch would be scored as stage I or wake depending upon the characteristics of the arousal.

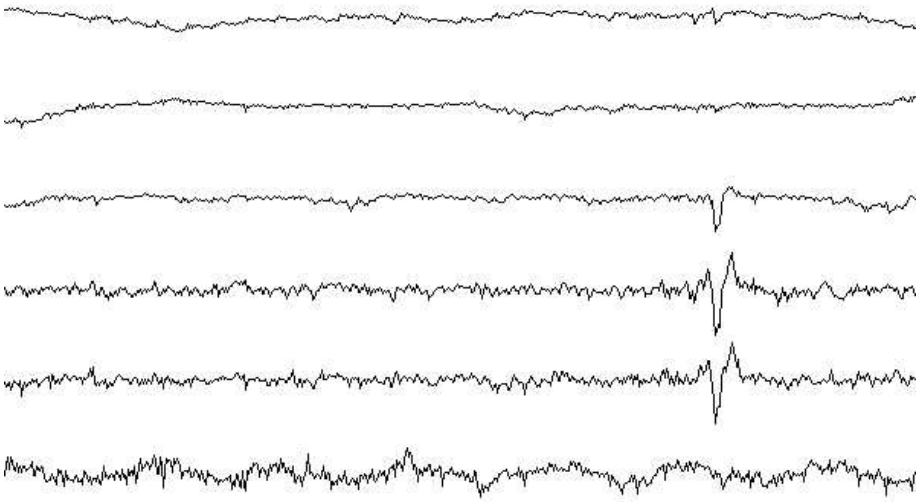
An exception to this might be if a K complex or a sleep spindle occurs within 15 seconds of the end of the arousal, in which case the epoch is scored as stage II.



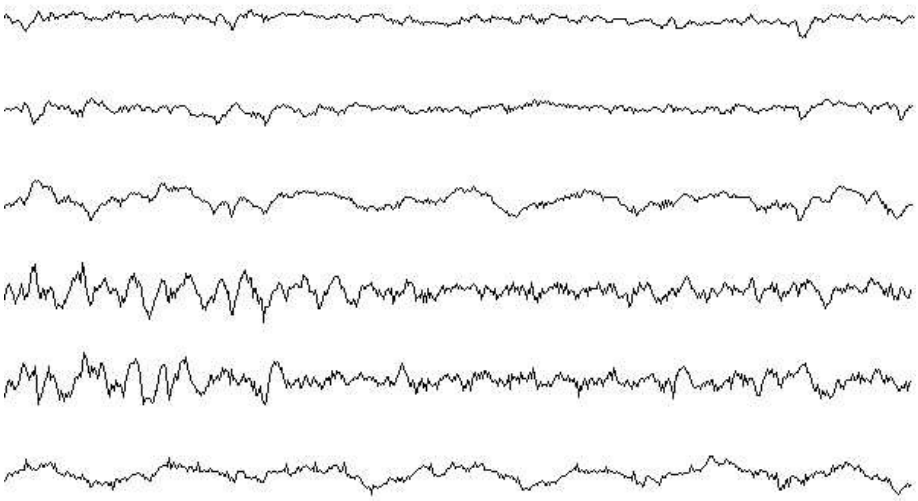
Sleep stage I EEG sample.



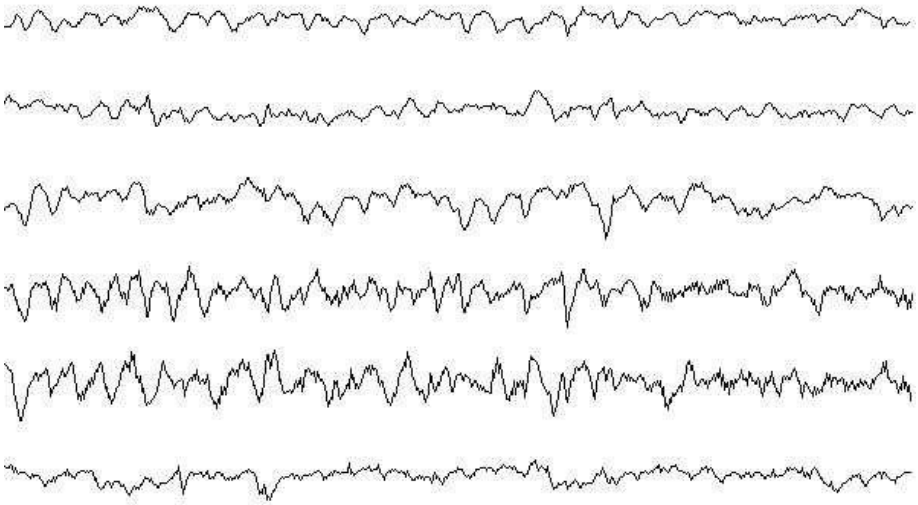
Sleep stage II EEG sample.

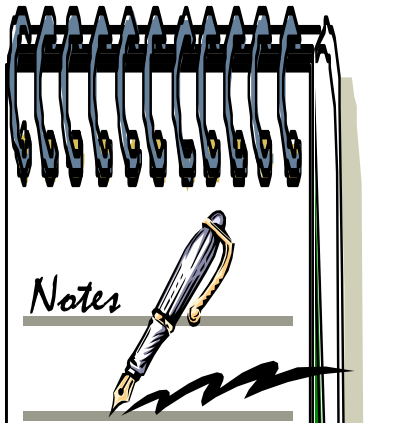


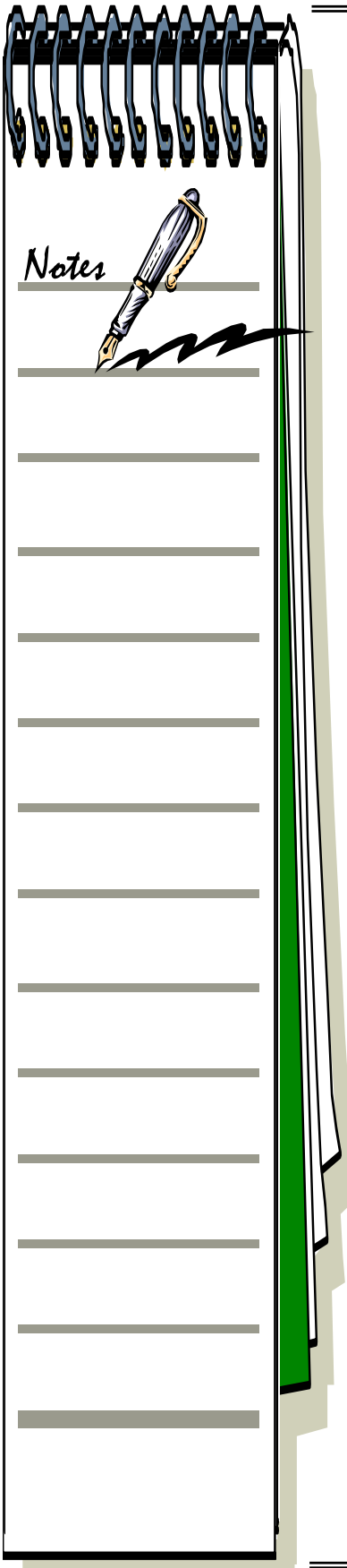
Sleep stage III EEG sample.



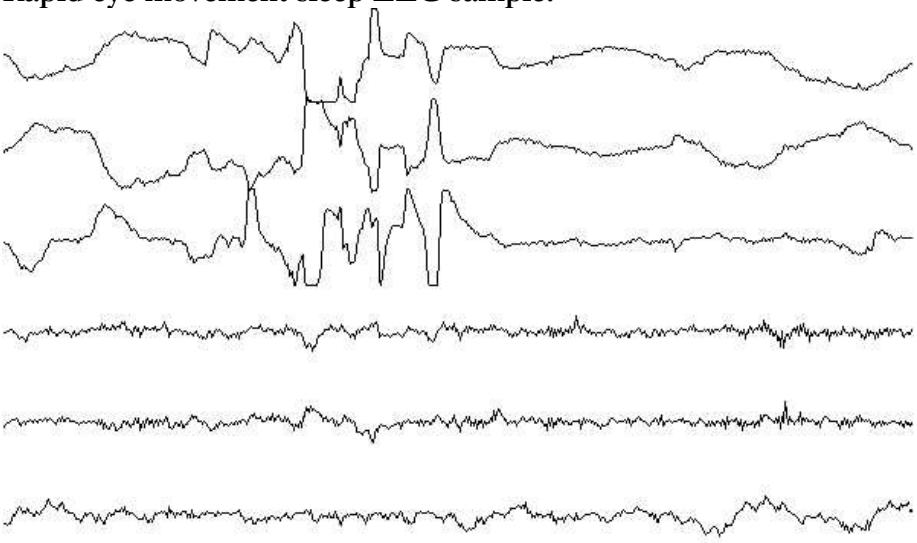
Sleep stage IV EEG sample.







Rapid eye movement sleep EEG sample.



References:

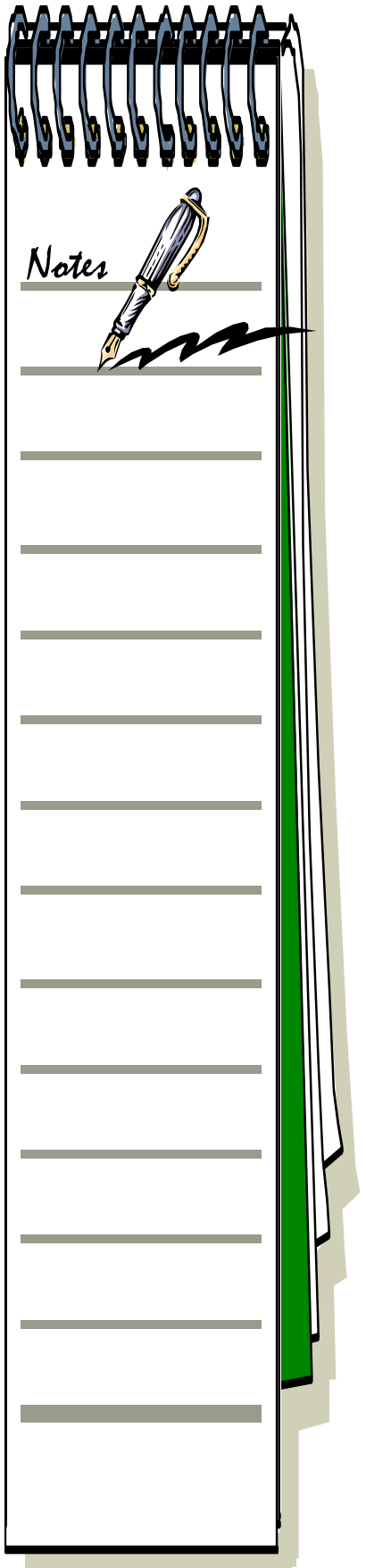
1. Butkov N: Atlas of Clinical Polysomnography . Ashland, Ore: Synapse Media; 1996.
2. Kumano-go T, Mikami A, Suganuma N, et al: Three components of obstructive sleep apnea/hypopnea syndrome. Psychiatry Clin Neurosci 2003 Apr; 57(2): 197-203
3. Marzec ML, Malow BA: Approaches to staging sleep in polysomnographic studies with epileptic activity. Sleep Med 2003 Sep; 4(5): 409-17
4. Niedermeyer E, Lopes Da Silva F: Electroencephalography: Basic Principles, Clinical applications, and Related Fields. 3rd ed. Baltimore, Md: Williams and Wilkins; 1993.
5. Rechtschaffen A, Kales A, eds: A Manual of Standardized Terminology, Techniques, and Scoring System for Sleep Stages of Human Subjects. US Department of Health, Education, and Welfare Public Health Service - NIH/NIND. 1968.
6. Sing HC, Kautz MA, Thorne DR, et al: High-frequency EEG as measure of cognitive function capacity: a preliminary report. Aviat Space Environ Med 2005 Jul; 76(7 Suppl): C114-35

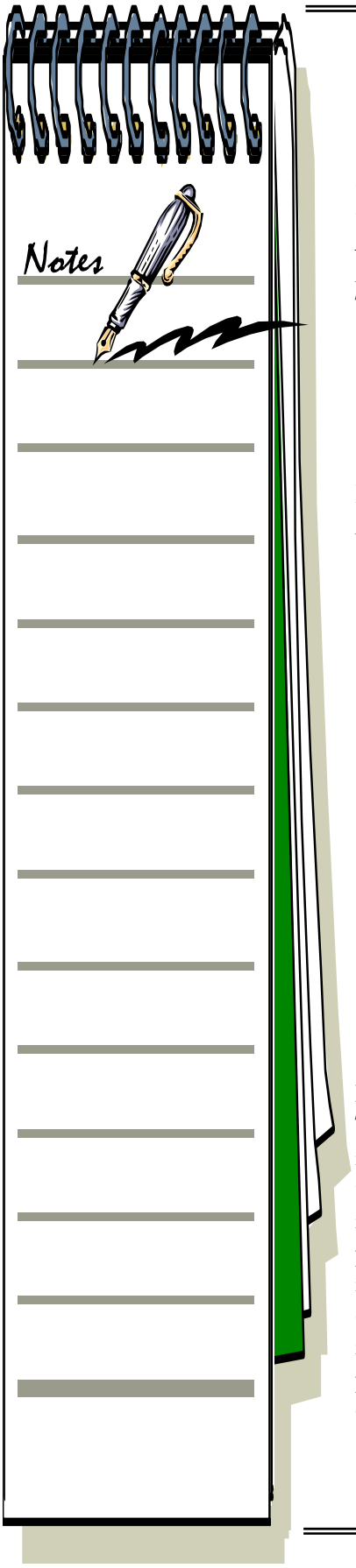
SLEEP STUDY SCORING: VISUAL VERSUS AUTOMATED; QUALITY CONTROL

In recent years computer based systems have largely replaced the traditional method of continuous recording on a multi-channel paper chart recorder with subsequent visual analysis. While these computerized systems offer a satisfactory method of recording information, the accuracy of software analysis packages provided for automated sleep

staging and the detection and characterization of disordered breathing events in general remains undefined. One recent study of an automated scoring system in a sleep apnea population reported that for sleep and respiratory events the level of agreement between automatic and manual scoring was similar to that between trained manual scorers[37], but these findings await confirmation by other laboratories. The difficulties of automatic scoring relate primarily to defining the stages of sleep and wakefulness, for which the definitions of Rechtschaffen and Kales[38] remain the standard. The main difficulty with computerized systems is in adequately programming the computer to recognize, with the same accuracy as the trained observer, the inter-subject variability in EEG waveforms that exist independently of variations in the state of sleep or wakefulness. Thus, at this time the committee considers that fully automated sleep and respiratory event scoring is not an acceptable alternative to careful scrutiny and staging of the raw data by appropriately trained personnel. However by presenting the data in provisionally analyzed and summarized forms these systems offer significant aids to analysis and allow a reduction in time taken for sleep staging. For similar reasons it is necessary to score arousals visually, using relevant criteria[39]. Automated respiratory event analysis is better than for automatic sleep scoring, but again difficulties can arise because of inter-subject variability in signal quality or changes over a single night in signal amplitude or quality in an individual. Considerable error can arise in calculation of respiratory disturbance indices and the characterization of events (e.g. obstructive or central) unless the threshold and diagnostic criteria for computer analysis are frequently reviewed. Consequently the computer scoring must be reviewed visually against the raw data and rescored manually.

Each laboratory should aspire to meet international benchmarks for accuracy and inter- and intra- scorer reliability for the scoring of parameters such as respiratory events, sleep stages, leg movements and arousals. This can be achieved in each laboratory by using internationally agreed scoring definitions[8] and by using a set of sleep studies that have been scored as standard to which other staff can measure their ability to score the various parameters. As a guide agreement of 80% or greater should be achieved for most sleep and respiratory parameters[40]. The exception to this is arousal from sleep which may achieve a concordance of only 55% to 60%[40]. Programs designed to monitor between laboratory scoring differences and encourage their reduction are strongly endorsed.





DEFINITIONS OF SLEEP-RELATED RESPIRATORY EVENTS

Standardized criteria are essential for scoring sleep-related respiratory events (AASM-Chicago criteria)

Apnea

An apnea is defined as cessation of breathing for 10 seconds or longer. Three types are recognized:

1. Obstructive: apnea associated with evidence of persisting respiratory effort
2. Central: apnea associated with cessation of breathing effort
3. Mixed: mixture of central and obstructive features

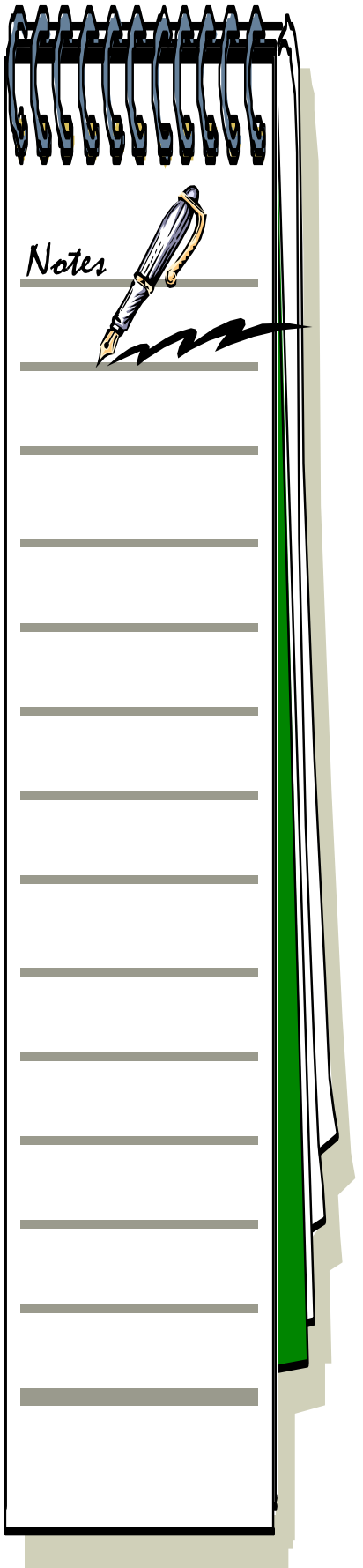
Hypopnea

A hypopnea is defined by the presence of the first or second of the following criteria, plus the third (1 or 2, plus 3):

1. A clear decrease (>50%) from baseline in the amplitude of a valid measure of breathing during sleep (quantitative or semi quantitative flow (e.g. pneumotachography, nasal pressure or thoraco-abdominal motion (e.g. summed rib cage plus abdominal respiratory inductance plethysmography) - see reference 7 for details). Baseline is defined as the mean amplitude of stable breathing and oxygenation in the two minutes preceding onset of the event (in individuals with a stable breathing pattern during sleep) or the mean amplitude of the three largest breaths in the two preceding minutes where breathing pattern is unstable.
2. A clear amplitude reduction of a valid measure of breathing during sleep that does not reach the above criterion but is associated with either an oxygen desaturation of>3% or an arousal.
3. The event lasts 10 seconds or longer.

Distinguishing obstructive from central hypopneas

These may be distinguished by observation of a concordant reduction in respiratory effort and flow in the case of central hypopneas. However, this separation is problematic even with the aid of oesophageal pressure measurement as there is no relative or absolute reduction in oesophageal pressure which can be used to distinguish them. Precise measurement of reduction on oesophageal pressure and flow are both required to detect changes in airway resistance associated with obstructive events and this is not possible with currently available clinical devices. The presence of paradoxical rib cage motion can be useful in helping distinguishing obstructive hypopneas (where it is often present) from central hypopneas (where it is not).



Respiratory effort-related arousal (RERA)
A RERA is defined as an arousal from sleep that follows a 10 second or longer sequence of breaths that are characterized by increasing respiratory effort, but which does not meet criteria for an apnea or hypopnea. Snoring, though usually associated with this condition need not be present. Respiratory effort is measured via oesophageal pressure monitoring. Where oesophageal pressure is being monitored the pattern is one of progressively more negative pressure terminated by a sudden change to a less negative level and an arousal. A useful surrogate for oesophageal pressure monitoring is the use of nasal pressure signal with progressive inspiratory flattening followed by an arousal.

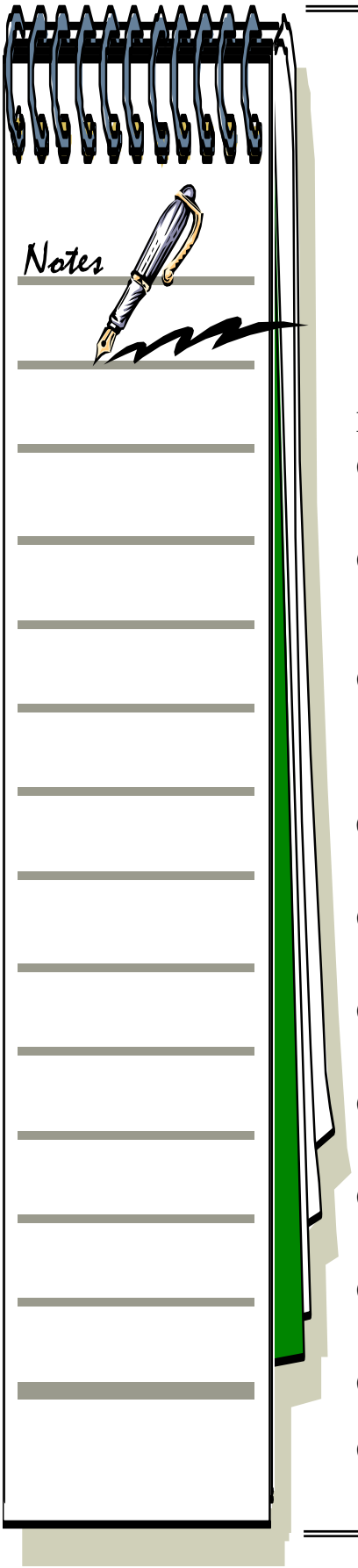
RERA's have the same implications for sleep fragmentation and consequent daytime sleepiness as do apneas and hypopneas. Some patients who have symptoms suggestive of OSA have few apneas or hypopneas on polysomnography, but frequent respiratory effort related arousals to which their clinical presentation can be related. This condition has been termed Upper Airway Resistance Syndrome[44], although the basis of its separate status from OSA syndrome appears related to sensitivity of the respiratory measurements, as they have a shared clinical and pathophysiological basis[45].

Similarly, the distinction between obstructive apneas and hyponoeas is not particularly important clinically as both types of events have similar pathophysiology and consequences. They both usually produce desaturation and end in arousal. There are no current data to suggest different long or short term outcomes in patients with predominantly apneas as compared to hypopneas.

LABORATORY REPORT

A written report should be issued at the completion of all sleep studies detailing:

1. the variables measured.
2. sleep staging (if performed), including total sleep time, sleep efficiency, sleep latency, percentage of time in the various sleep stages, and frequency of arousals.
3. frequency and type of abnormal respiratory events (e.g. central or obstructive).
4. relationships of disordered breathing to posture (if measured), sleep stage or treatment intervention when relevant.
5. oxygen saturation, described in quantitative terms using either a continuous saturation versus time plot or by using discrete intervals (e.g. sleep time spent within various ranges of saturation). The lowest saturation recorded during abnormal respiratory events should be noted.



6. transcutaneous PCO_2 trends, where measured.
7. any disturbance of cardiac rate or rhythm, and its relationship to abnormal respiratory events, if measured.
8. the frequency of periodic limb movements and any associated sleep fragmentation.
9. medications (including sedatives) and alcohol that may have influenced the results.
10. technician's comments.
11. physician's interpretation/conclusions.

REFERENCE LIST

(1) Practice parameters for the indications for polysomnography and related procedures. Polysomnography Task Force, American Sleep Disorders Association Standards of Practice Committee. Sleep 1997; 20(6):406-422.

(2) Chesson AL, Jr., Anderson WM, Littner M, Davila D, Hartse K, Johnson S et al. Practice parameters for the nonpharmacologic treatment of chronic insomnia. An American Academy of Sleep Medicine report. Standards of Practice Committee of the American Academy of Sleep Medicine. Sleep 1999; 22(8):1128-1133.

(3) Flemons WW, Littner MR, Rowley JA, Gay P, Anderson WM, Hudgel DW et al. Home diagnosis of sleep apnea: a systematic review of the literature. An evidence review cosponsored by the American Academy of Sleep Medicine, the American College of Chest Physicians, and the American Thoracic Society. Chest 2003; 124(4):1543-1579.

(4) Littner M, Hirshkowitz M, Kramer M, Kapen S, Anderson WM, Bailey D et al. Practice parameters for using polysomnography to evaluate insomnia: an update. Sleep 2003; 26(6):754-760.

(5) Littner MR, Kushida C, Wise M, Davila DG, Morgenthaler T, Lee-Chiong T et al. Practice parameters for clinical use of the multiple sleep latency test and the maintenance of wakefulness test. Sleep 2005; 28(1):113-121.

(6) Kushida CA, Littner MR, Morgenthaler T, Alessi CA, Bailey D, Coleman J et al. Practice parameters for the indications for polysomnography and related procedures: An update for 2005. Sleep 28[4], 499-521. 2005.

(7) Hillman D.R., Bowes G., Grunstein R.R., McEvoy R.D., Pierce R.J., Saunders N.A. et al. Guidelines for Respiratory Sleep Studies. Thoracic Society of Australia and New Zealand . 1994.

(8) Sleep-related breathing disorders in adults: recommendations for syndrome definition and measurement techniques in clinical research. The Report of an American Academy of Sleep Medicine Task Force. Sleep 1999; 22(5):667-689.

(9) Flemons WW, Douglas NJ, Kuna ST, Rodenstein DO, Wheatley J. Access to diagnosis and treatment of patients with suspected sleep apnea. Am J Respir Crit Care Med 2004; 169(6):668-672.

(10) Pack AI. Sleep-disordered breathing: access is the issue. Am J Respir Crit Care Med 2004; 169(6):666-667.

(11) Manser RL, Rochford P, Naughton MT, Pierce RJ, Sasse A, Teichtahl H et al. Measurement variability in sleep disorders medicine: the Victorian experience. Intern Med J 2002; 32(8):386-393.

(12) Hill NS. Noninvasive ventilation. Does it work, for whom, and how? Am Rev Respir Dis 1993; 147(4):1050-1055.

(13) Hukins CA, Hillman DR. Daytime predictors of sleep hypoventilation in Duchenne muscular dystrophy. Am J Respir Crit Care Med 2000; 161(1):166-170.

(14) Young IH, Crockett AJ, McDonald CF. Adult domiciliary oxygen therapy: position statement of the Thoracic Society of Australia and New Zealand. N Z Med J 1999; 112(1080):15-18.

(15) Chaouat A, Weitzenblum E, Kessler R, Schott R, Charpentier C, Levi-Valensi P et al. Outcome of COPD patients with mild daytime hypoxaemia with or without sleep-related oxygen desaturation. Eur Respir J 2001; 17(5):848-855.

(16) Chaouat A, Weitzenblum E, Kessler R, Charpentier C, Enrhart M, Schott R et al. A randomized trial of nocturnal oxygen therapy in chronic obstructive pulmonary disease patients. Eur Respir J 1999; 14(5):1002-1008.

(17) Grunstein RR, Ho KY, Sullivan CE. Sleep apnea in acromegaly. Ann Intern Med 1991; 115(7):527-532.

(18) Sin DD, Fitzgerald F, Parker JD, Newton G, Floras JS, Bradley TD. Risk factors for central and obstructive sleep apnea in 450 men and women with congestive heart failure. Am J Respir Crit Care Med 1999; 160(4):1101-1106.

(19) Bradley TD, Floras JS. Sleep apnea and heart failure: Part II: central sleep apnea. Circulation 2003; 107(13):1822-1826.

(20) Bradley TD, Floras JS. Sleep apnea and heart failure: Part I: obstructive sleep apnea. Circulation 2003; 107(12):1671-1678.

(21) Kaneko Y, Floras JS, Usui K, Plante J, Tkacova R, Kubo T et al. Cardiovascular effects of continuous positive airway pressure in patients with heart failure and obstructive sleep apnea. N Engl J Med 2003; 348(13):1233-1241.

(22) Hukins C. Comparative study of autotitrating and fixed-pressure CPAP in the home: a randomized, single-blind crossover trial. Sleep 2004; 27(8):1512-1517.

(23) Masa JF, Jimenez A, Duran J, Capote F, Monasterio C, Mayos M et al. Alternative methods of titrating continuous positive airway pressure: a large multicenter study. Am J Respir Crit Care Med 2004; 170(11):1218-1224.

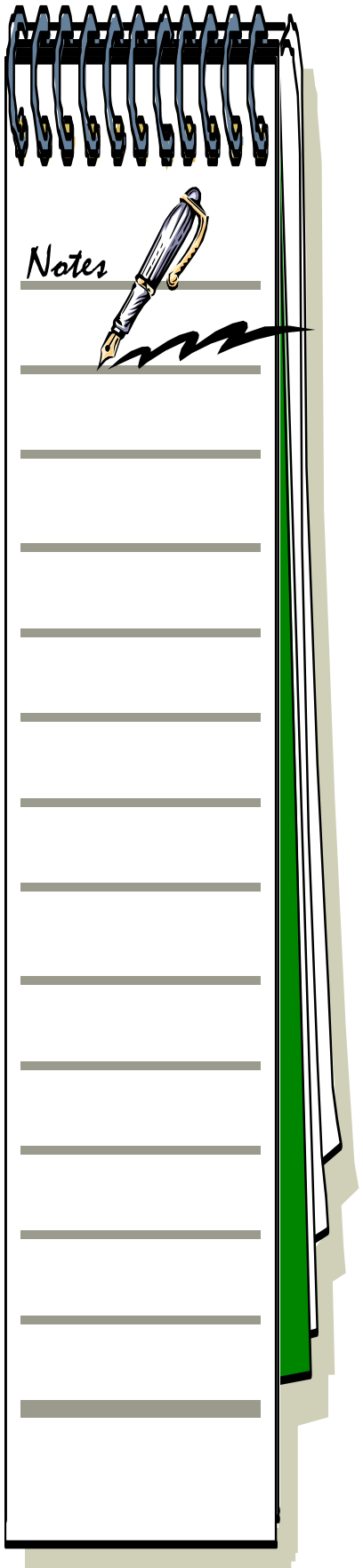
(24) Hukins CA. Arbitrary-pressure continuous positive airway pressure for obstructive sleep apnea syndrome. Am J Respir Crit Care Med 2005; 171(5):500-505.

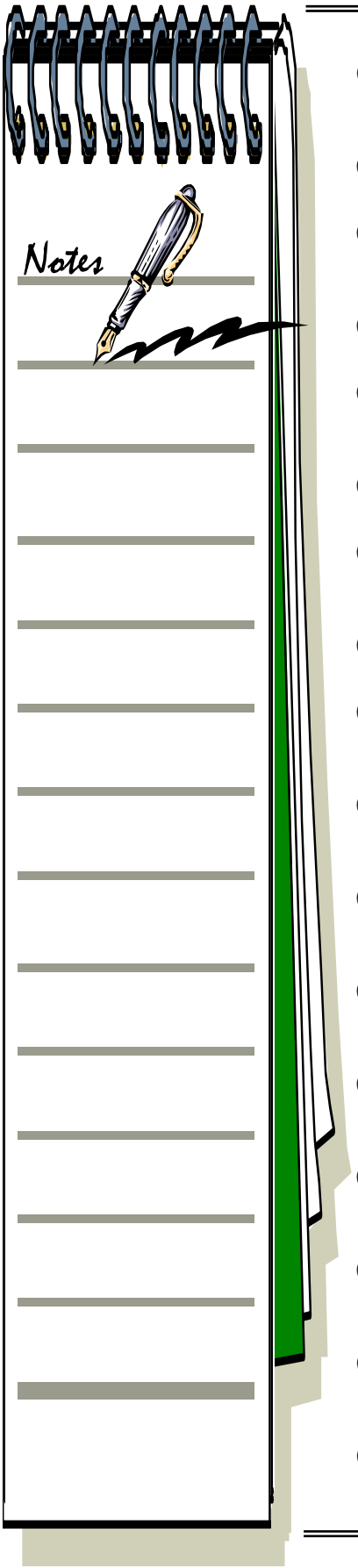
(25) Redline S, Sanders MH, Lind BK, Quan SF, Iber C, Gottlieb DJ et al. Methods for obtaining and analyzing unattended polysomnography data for a multicenter study. Sleep Heart Health Research Group. Sleep 1998; 21(7):759-767.

(26) Quan SF, Griswold ME, Iber C, Nieto FJ, Rapoport DM, Redline S et al. Short-term variablility of respiration and sleep during unattended nonlaboratory polysomnogaphy--the Sleep Heart Health Study. Sleep 2002; 25(8):843-849.

(27) Iber C, Redline S, Kaplan Gilpin AM, Quan SF, Zhang L, Gottlieb DJ et al. Polysomnography performed in the unattended home versus the attended laboratory setting--Sleep Heart Health Study methodology. Sleep 2004; 27(3):536-540.

(28) Executive summary on the systematic review and practice parameters for portable monitoring in the investigation of suspected sleep apnea in adults. Am J Respir Crit Care Med 2004; 169(10):1160-1163.





(29) Chesson AL, Jr., Berry RB, Pack A. Practice parameters for the use of portable monitoring devices in the investigation of suspected obstructive sleep apnea in adults. Sleep 2003; 26(7):907-913.

(30) Flemons WW, Littner MR. Measuring agreement between diagnostic devices. Chest 2003; 124(4):1535-1542.

(31) Elshaug AG, Moss JR, Southcott AM. Implementation of a split-night protocol to improve efficiency in assessment and treatment of obstructive sleep apnoea. Intern Med J 2005; 35(4):251-254.

(32) Rodway GW, Sanders MH. The efficacy of split-night sleep studies. Sleep Med Rev 2003; 7(5):391-401.

(33) Farre R, Montserrat JM, Ballester E, Hernandez L, Rotger M, Navajas D. Importance of the pulse oximeter averaging time when measuring oxygen desaturation in sleep apnea. Sleep 1998; 21(4):386-390.

(34) Strohl KP, House PM, Holic JF, Fouke JM, Cheung PW. Comparison of three transmittance oximeters. Med Instrum 1986; 20(3):143-149.

(35) West P, George CF, Kryger MH. Dynamic in vivo response characteristics of three oximeters: Hewlett-Packard 47201A, Biox III, and Nellcor N-100. Sleep 1987; 10(3):263-271.

(36) Barker SJ. "Motion-resistant" pulse oximetry: a comparison of new and old models. Anesth Analg 2002; 95(4):967-72, table.

(37) Pittman SD, MacDonald MM, Fogel RB, Malhotra A, Todros K, Levy B et al. Assessment of automated scoring of polysomnographic recordings in a population with suspected sleep-disordered breathing. Sleep 2004; 27(7):1394-1403.

(38) Rechtschaffen A, Kales A. A manual of standardized terminology, techniques and scoring system for sleep stages of human subjects. Los Angeles: Brain Information Service/Brain Research Institute, University of California at Los Angeles. 1968.

(39) EEG arousals: scoring rules and examples: a preliminary report from the Sleep Disorders Atlas Task Force of the American Sleep Disorders Association. Sleep 1992; 15(2):173-184.

(40) Whitney CW, Gottlieb DJ, Redline S, Norman RG, Dodge RR, Shahar E et al. Reliability of scoring respiratory disturbance indices and sleep staging. Sleep 1998; 21(7):749-757.

(41) Kristo DA, Lettieri CJ, Andrada T, Taylor Y, Eliasson AH. Silent upper airway resistance syndrome: prevalence in a mixed military population. Chest 2005; 127(5):1654-1657.

(42) Hosselet JJ, Norman RG, Ayappa I, Rapoport DM. Detection of flow limitation with a nasal cannula/pressure transducer system. Am J Respir Crit Care Med 1998; 157(5 Pt 1):1461-1467.

(43) Ayappa I, Norman RG, Krieger AC, Rosen A, O'malley RL, Rapoport DM. Non-Invasive detection of respiratory effort-related arousals (REras) by a nasal cannula/pressure transducer system. Sleep 2000; 23(6):763-771.

(44) Guilleminault C, Stoohs R, Clerk A, Cetel M, Maistros P. A cause of excessive daytime sleepiness. The upper airway resistance syndrome. Chest 1993; 104(3):781-787.

(45) Douglas NJ. Upper airway resistance syndrome is not a distinct syndrome. Am J Respir Crit Care Med 2000; 161(5):1413-1416.

(46) Young T, Blustein J, Finn L, Palta M. Sleep-disordered breathing and motor vehicle accidents in a population-based sample of employed adults. Sleep 1997; 20(8):608-613.

(47) Young T, Peppard P, Palta M, Hla KM, Finn L, Morgan B et al. Population-based study of sleep-disordered breathing as a risk factor for hypertension. Arch Intern Med 1997; 157(15):1746-1752.

(48) Barnes M, McEvoy RD, Banks S, Tarquinio N, Murray CG, Vowles N et al. Efficacy of positive airway pressure and oral appliance in mild to moderate obstructive sleep apnea. Am J Respir Crit Care Med 2004; 170(6):656-664.

(49) Engleman HM, Kingshott RN, Wraith PK, Mackay TW, Deary IJ, Douglas NJ. Randomized placebo-controlled crossover trial of continuous positive airway pressure for mild sleep Apnea/Hypopnea syndrome. Am J Respir Crit Care Med 1999; 159(2):461-467.

(50) Redline S, Adams N, Strauss ME, Roebuck T, Winters M, Rosenberg C. Improvement of mild sleep-disordered breathing with CPAP compared with conservative therapy. Am J Respir Crit Care Med 1998; 157(3 Pt 1):858-865.

(51) Effectiveness of nasal continuous positive airway pressure (nCPAP) in obstructive sleep apnea in adults. National Health and Medical Research Council . 2000. Commonwealth of Australia, AusInfo.

(52) Consens FB, Chervin RD, Koeppe RA, Little R, Liu S, Junck L et al. Validation of a polysomnographic score for REM Sleep Behavior disorder. Sleep 28[8], 993-997. 2005.

(53) Aldrich MS, Chervin RD, Malow BA. Value of the multiple sleep latency test (MSLT) for the diagnosis of narcolepsy. Sleep 1997; 20(8):620-629.

(54) Mignot E, Chen W, Black J. On the value of measuring CSF hypocretin-1 in diagnosing narcolepsy. Sleep 2003; 26(6):646-649.

(55) Sangal RB, Thomas L, Mitler MM. Maintenance of wakefulness test and multiple sleep latency test. Measurement of different abilities in patients with sleep disorders [see comments]. Chest 1992; 101(4):898-902.

(56) Banks S, Barnes M, Tarquinio N, Pierce RJ, Lack LC, McEvoy RD. The maintenance of wakefulness test in normal healthy subjects. Sleep 2004; 27(4):799-802.

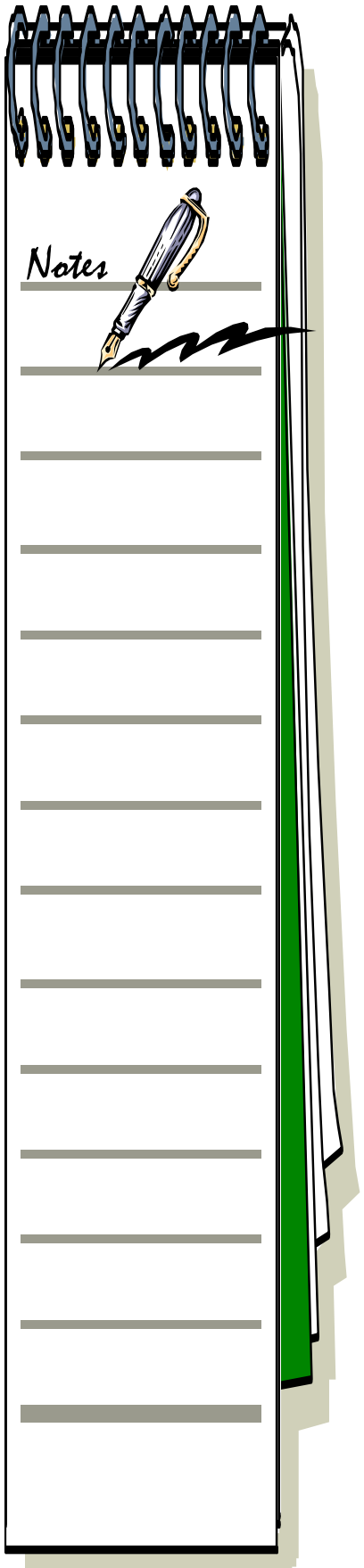
(57) Bennett LS, Stradling JR, Davies RJ. A behavioural test to assess daytime sleepiness in obstructive sleep apnoea. J Sleep Res 1997; 6(2):142-145.

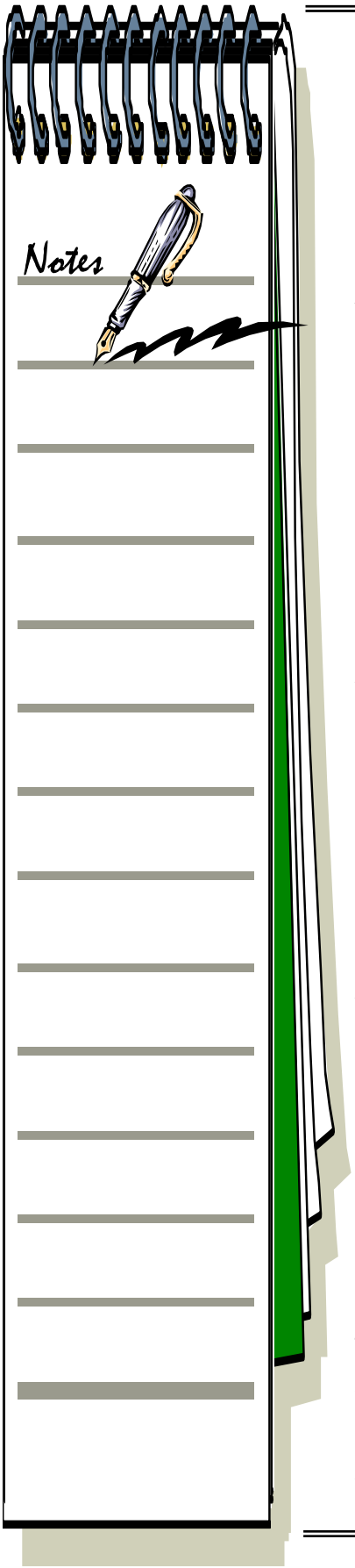
(58) Krieger AC, Ayappa I, Norman RG, Rapoport DM, Walsleben J. Comparison of the maintenance of wakefulness test (MWT) to a modified behavioral test (OSLER) in the evaluation of daytime sleepiness. J Sleep Res 2004; 13(4):407-411.

(59) Practice parameters for the use of polysomnography in the evaluation of insomnia. Standards of Practice Committee of the American Sleep Disorders Association. Sleep 1995; 18(1):55-57.

(60) Chesson A, Jr., Hartse K, Anderson WM, Davila D, Johnson S, Littner M et al. Practice parameters for the evaluation of chronic insomnia. An American Academy of Sleep Medicine report. Standards of Practice Committee of the American Academy of Sleep Medicine. Sleep 2000; 23(2):237-241.

(61) Accreditation of Sleep Disorders Services - Standards and Guidelines. Thoracic Society of Australia and New Zealand/Australasian Sleep Association. 1997.





Sharing the Load

by Tor Valenza

Outsourcing sleep scoring helps many laboratories be more efficient and flexible, but a lack of industry standards concerns some.

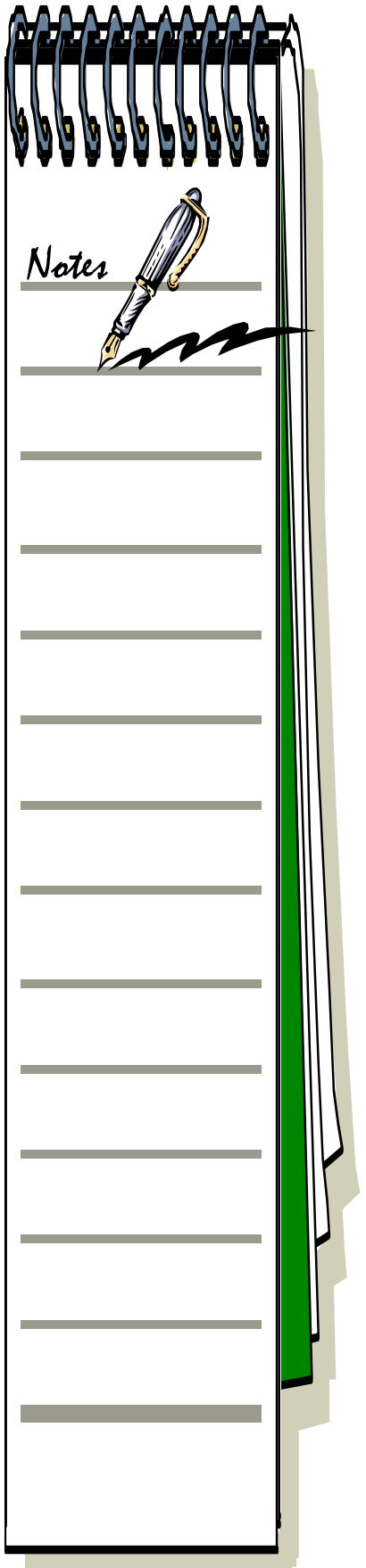
For sleep center managers, staffing can be one of the biggest challenges. As the demand for sleep-disorder testing grows, so does the demand for qualified technologists to administer the testing, and this can create a real bind. For example, in the small community of Dover-Foxcroft, Me, Kim Havea, RRT, director of cardiopulmonary services at the Mayo Regional Hospital Sleep Disorders Center, had to find a way to efficiently score just a small number of studies a day without an RPSGT on staff. In the San Francisco Bay area, Mehran Farid, MD, medical director and CEO of the Peninsula Sleep Center in Burlingame, needed to provide quality scoring while also controlling costs in an area where chief technologist salaries tend to match the high cost of living. For both, the solution was outsourcing a portion of their sleep studies, a trend that some see as encouraging and others see as possibly troubling because of the lack of independent national standards in outsourcing services.

Companies providing outsourcing for sleep studies say their services relieve sleep facilities of the costs of salaries and benefits for skilled technologists, while giving timely turnaround at affordable rates. Each scored study is typically returned in 12 to 72 hours and runs between $50 and $150. Most outsourcing companies employ contracted scoring technicians that are experienced RPSGTs and are adept at handling all brands of sleep software. However, some sleep laboratories forgo large outsourcing companies and simply find local technicians seeking extra income. Neither of these solutions is regulated by any guidelines from accrediting sleep medicine associations.

Choosing Outsourcing

Farid, a board-certified physician in sleep medicine and pulmonary diseases, considered the staffing needs of the four-bed facility and the typically high salary and benefits paid for a chief technologist in his area. Instead of hiring one chief technologist to provide all of the aspects of the operation, in addition to local scoring, he hired four part-time RPSGTs and gave most of the scoring responsibilities to outsourcers. The part-time technologists assist him and three other pulmonary physicians and score approximately 30% of the studies. The business model has helped him cut costs while still maintaining a turnaround and reporting of the study 48 hours after the test is completed. Farid also likes being able to transfer more of the scoring workload to the outsourcing company as needed.

Another case where outsourcing seems to work well is for small or rural sleep clinics that find it difficult to justify the expense of hiring a full-time RPSGT to score a small number of daily sleep studies. One such center is Kim Havea's two-bed facility in a small community an hour from Bangor, Me. Havea says, "When you're a little place like us, it would cost quite a bit of money to have another tech here to just score a couple of studies full time in the day." Instead, the center employs a technician to stage the test during acquisition. The data is then uploaded via a secured server to Sleep Strategies, an outsourcing company located in Toronto. Sleep Strategies gives Havea different turnaround options, from 24 hours to 72 hours, depending on the urgency.



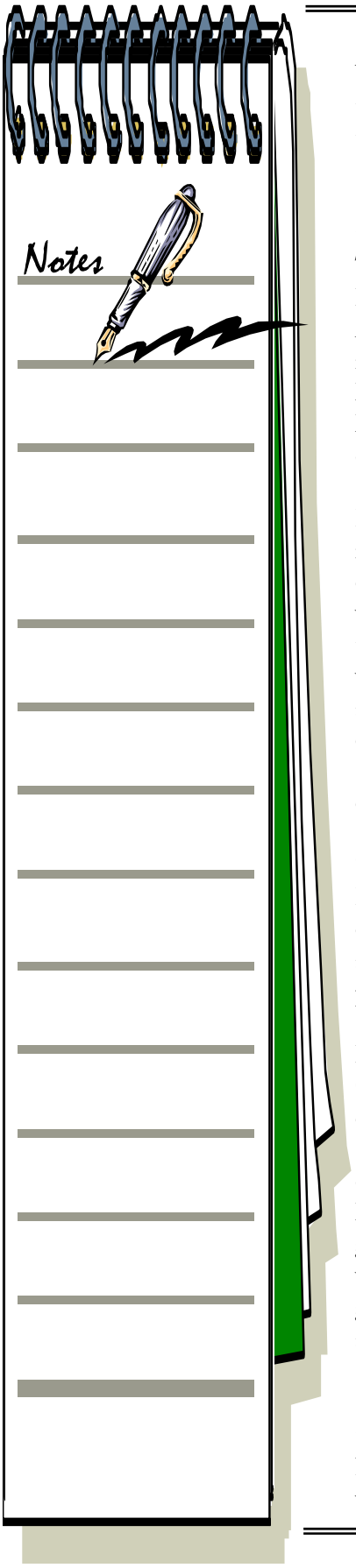
Choosing to Invest in Recruitment and Training

While outsourcing can be a boon to some facilities, for others it is not the right option. Robert Lindsey, RPSGT, director of neuromedical services for Memorial Health Care System in Chattanooga, Tenn, considered outsourcing. In the end, he decided to develop an in-house long-term training program to up the number of full-time RPSGTs at his facility. Today Memorial Health Care System's sleep laboratory has 14 beds and 15 sleep technicians.

Much of the reasoning for Lindsey's decision was because of the way Lindsey's center scores its studies. While some sleep laboratories train their technicians to stage their studies during acquisition, then review and score sometime after the test, Lindsey's technicians use the method that takes advantage of the "look-back" feature of most Microsoft Windows-based acquisition software. Utilizing the look-back feature, each technologist stages and scores two patients per night during data acquisition, and then reviews and finishes the scoring before leaving the next morning. Typically, the night technologist stays a half hour to an hour after the patient has left the laboratory. Consequently, an outsourcer is an unnecessary expense, even for a sudden increase in the number of studies. "We'd rather pay inside people and know that we've got a strong team," Lindsey says.

Similarly, Kendal White, RPSGT, director of sleep disorders at the Diagnostic Center for Sleep Disorders, decided to recruit and train, rather than consider outsourcing. White's 10-bed sleep laboratory, also located in Chattanooga, uses the look-back feature as well.

"An hour's worth of sleep scoring takes less than 5 minutes to score," White says. "So if the tech, just once an hour, sat down for 5 minutes, they could have everything that happened in the previous hour staged, scored, and ready."



White allows that his beginning technicians may have to stay later into the morning to finish scoring, but that their efficiency improves over time.

Outsourcing and Quality Control

The American Academy of Sleep Medicine (AASM), the Board of Registered Polysomnographic Technologists (BRPT), and the Association of Polysomnographic Technologists (APT) all lack requirements that sleep studies be scored directly after acquiring the data. Many AASM-accredited sleep laboratories accurately score sleep studies long after acquisition. However, it is the quality of the scoring that most concerns sleep specialists.

Farid's Peninsula Sleep Center, which is AASM-accredited, has three measures of quality control. First, before sending the study to the outsourcer, Farid personally reviews the data for any indication that would require immediate attention. When the scoring is returned from the outsourcing company 48 hours later, Farid compares his initial notes with the outsourcer's report. Second, the scored data will be screened again by one of his four part-time technologists to ensure proper tagging of the events. As a third quality control, Farid personally scores at least 1% of all the studies himself, and then matches his scoring against the outsourcer's scoring. These checks have revealed minor discrepancies.

"Sometimes you have to change the events tagging when it arrives," Farid says. "On the occasion that it has significance, we have given the outsourcing company feedback, and they have improved the tagging." He also notes that the outsourcing company scores according to Peninsula's protocols and that they use the same software.

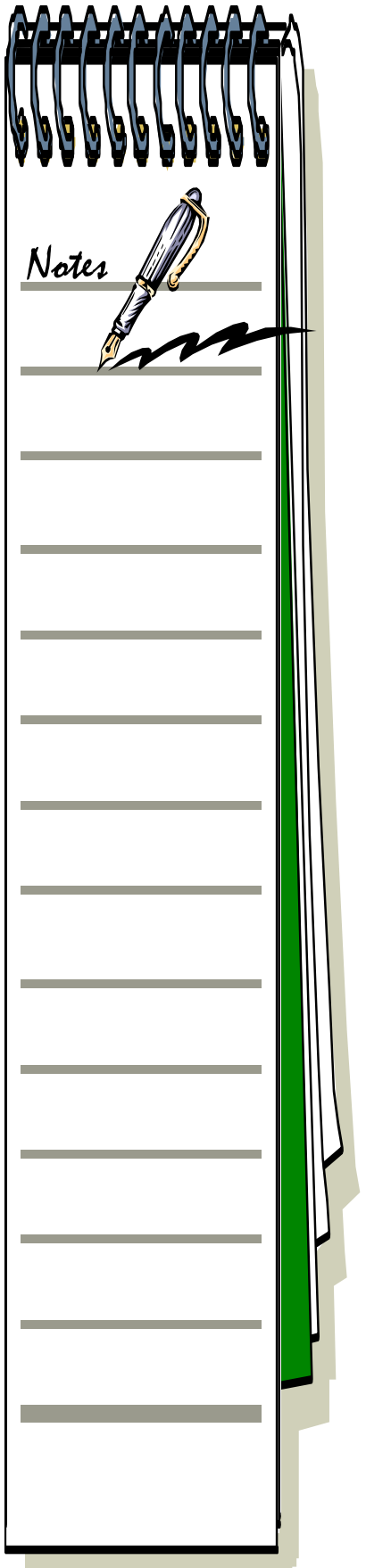
Roger Godbout, RPSGT, director of the Sleep Disorders Clinic for Children & Adolescents in Montreal, and a BRPT board member, uses outsourcers at the Rivière-des-Prairies Hospital, a research and clinical sleep laboratory also in Montreal. Aside from checking references and confirming that his outsourcer is a Technologiste en Électrophysiologie Médicale, the Quebec equivalent of being an RPSGT, Godbout also gives his outsourcers a quality-control study mixed with real cases. As with Farid's quality checks, the results of these quality-control tests are generally positive, but sometimes requires the outsourcer to make a few adjustments.

Outsourcing and the Nuances of Sleep

Because diagnosing sleep disorders can be highly nuanced, opinion does vary, however, on whether even the best quality-control program for the

outsourcing of sleep scoring can compete with direct observation and scoring. White says, "If you have a possibility that a patient has sleep apnea, or you're looking for signs of narcolepsy or central nervous system hypersomnolence, the night tech is going to know what the RDI [respiratory distress index] is in the morning. He'll know what the sleep architecture looked like during the night."

Lindsey agrees. "They [night technicians] have seen the morphology, they've seen the amplitude of that person's brain waves, and they've seen the patient that night, one-on-one, in real time. Things look a lot different the next day. It's a little intangible, but there is an advantage," says Lindsey.



Standards and Security

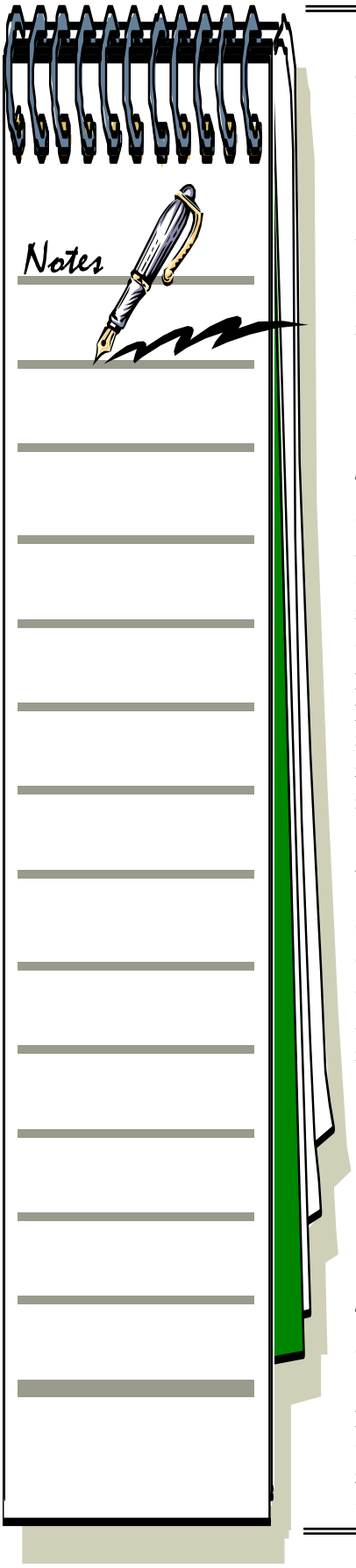
Godbout is more concerned about the lack of standards for outsourcing sleep scoring. "There are many possibilities for disaster," he says. "There are no guidelines, so you have to rely on your own way of doing things. I can imagine somebody hiring someone, training [that person] for a week or so, then taking over these files and doing something with it."

As for protecting privacy, most outsourcing companies use secure servers that protect patient privacy and comply with the standards of the Health Insurance Portability and Accountability Act (HIPAA), as well as screen their technologists.

The AASM and the APT elected not to comment regarding the outsourcing of sleep scoring. Though not speaking for the BRPT, Godbout is personally in favor of the AASM, APT, and the BRPT cooperating in developing some guidelines. "We have to apply some rules," he says. "We have to be sure that the job is well done, that it's done by someone who is accredited somehow, that the person has continuing education hours, and that the person's education level is optimal."

Scoring and Processing of Sleep Studies

Current scoring approaches use a system of epoch by epoch scoring (30 seconds per epoch) developed over 40 years ago when polysomnography used only paper-based systems based on analog data. This approach is recognized to be both labor-intensive and time-consuming. Further, reliance on human scorers using visual pattern recognition requires intensive and ongoing training to achieve high reliability (Whitney et al., 1998), which may be lower than that potentially attained by automated methods (which also have their limitations). Visual scoring also may not maximally utilize the spectral components of the electrophysiological



data, which may provide useful information on sleep architecture. Furthermore, there is a shortage of trained sleep technicians. Currently there are only 2,198 certified technicians to monitor and score sleep tests, far below the need (Association of Polysomnographic Technologists, 1999). Recognizing these issues, the AASM convened a task force in 2004 to reassess current scoring approaches, critically evaluate both sensors and scoring algorithms, and update scoring approaches as appropriate to include digital analysis of electrophysiological data. This report, scheduled for release in 2006, should provide important advances for the diagnosis of chronic sleep loss and sleep disorders.

Summary of Formal Evaluation Reviews

Three recent in-depth reviews have been performed to examine the effectiveness of portable monitoring devices (Ross et al., 2000; ATS, 2004; Tice, 2005). As described above, these reports were largely aimed at evaluating the literature regarding the accuracy of clinical diagnosis relative to reference in lab polysomnography, with some attempt at also evaluating the literature relative to cost-effectiveness and clinical prediction. In 1998, the Agency for Healthcare Research and Quality performed a literature review and meta-analysis on studies of portable monitoring for OSA. The review concluded that at the time there was insufficient evidence to make firm recommendations for use of portable monitoring for the diagnosis of sleep apnea (Ross et al., 2000).

An executive summary on the systematic review and practice parameters for portable monitoring in the investigation of suspected sleep apnea in adults was published in 2004 by an evidence review committee consisting of members from the American Thoracic Society, the American College of Chest Physicians, and the American Academy of Sleep Medicine (ATS, 2004; Flemons and Littner, 2003). In that summary, the following recommendations were made:

- Given the available data, the use of portable device was not recommended for general screening.
- The use of portable devices was not recommended in patients with comorbid conditions or secondary sleep complaints.
- The use of portable devices should require review of raw data by trained sleep specialists.

The review committee also recognized the need for further development of portable devices and suggested several goals for future research. It was found that most studies on portable monitoring were performed primarily on white males with OSA who had few comorbidities. The evidence review committee recommended that future studies should include more diverse populations, other than patients with sleep apnea, that are not subject to selection bias. Additional recommendations were

that future studies should address clinical predictive algorithms in combination with portable monitoring in the diagnosis of sleep apnea, and study design should assess the cost-effectiveness and outcomes associated with different diagnostic and management strategies.

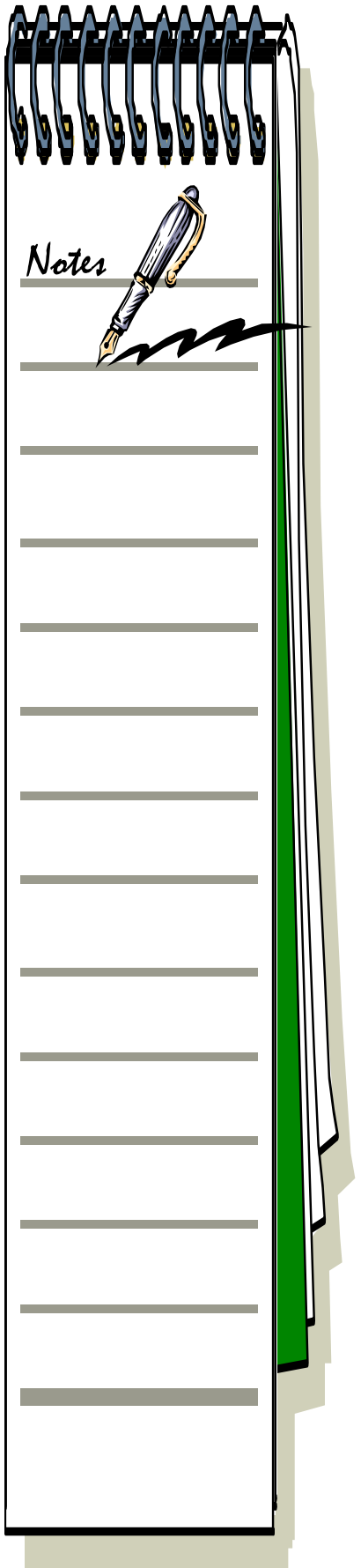
The California Technology Assessment Forum most recently evaluated the evidence that supported use of ambulatory devices over in-laboratory procedures for the purposes of diagnosing sleep apnea (Tice, 2005). The following five technology assessment criteria were identified:

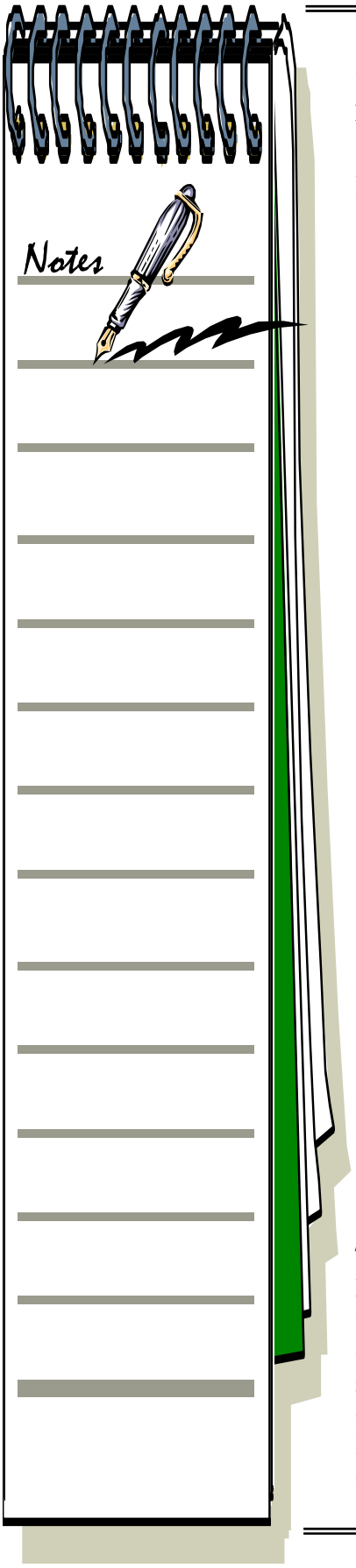
1. The technology must have final approval from government regulatory bodies.
2. The scientific evidence must permit conclusions concerning the effectiveness of the technology regarding health outcomes.
3. The technology must improve health outcomes.
4. The technical must be as beneficial as any established alternatives.
5. The technology must be attainable outside of the investigational setting.

They determined that only the first two criteria had been met, but the last three were not. This review also identified the paucity of data regarding the "reference standard" (laboratory polysomnography) as improving health outcomes and suggested that a therapeutic trial of CPAP therapy may be a more efficient and clinically relevant approach than use of either in-home or in-laboratory sleep monitoring.

FUTURE DIRECTIONS

Given the cumbersome nature and cost of the diagnosis and treatment of sleep disorders and sleep loss, the resultant inequities with regard to access, and in order to ensure future quality care, greater investment in the development of new, and validation of existing, diagnostic and therapeutic technologies is required. Improvement in portable monitoring techniques will likely enhance access to sleep diagnostic services. With the inadequate availability of sleep centers and sleep technicians, not only in the United States but more so worldwide, access to portable diagnostic screening procedures and streamlining initiation of treatment would clearly be advantageous. In particular, portable monitoring at level III (limited channel polysomnogram of four or more cardiopulmonary bioparameters) or level IV (testing of only one or two cardiopulmonary bioparameters) would help lower health costs and shorten waiting lists. In selected patient populations, portable monitoring in conjunction with inpatient split-night polysomnography or unattended autotitration of nasal CPAP could prove to be the most cost-effective and rational approach to most patients with a clinical profile for moderate to severe sleep apnea syndrome. Research in the design and evaluation of existing and novel diagnostic technologies is also needed in





the area of insomnia, hypersomnia, and restless legs syndrome and periodic limb movements.

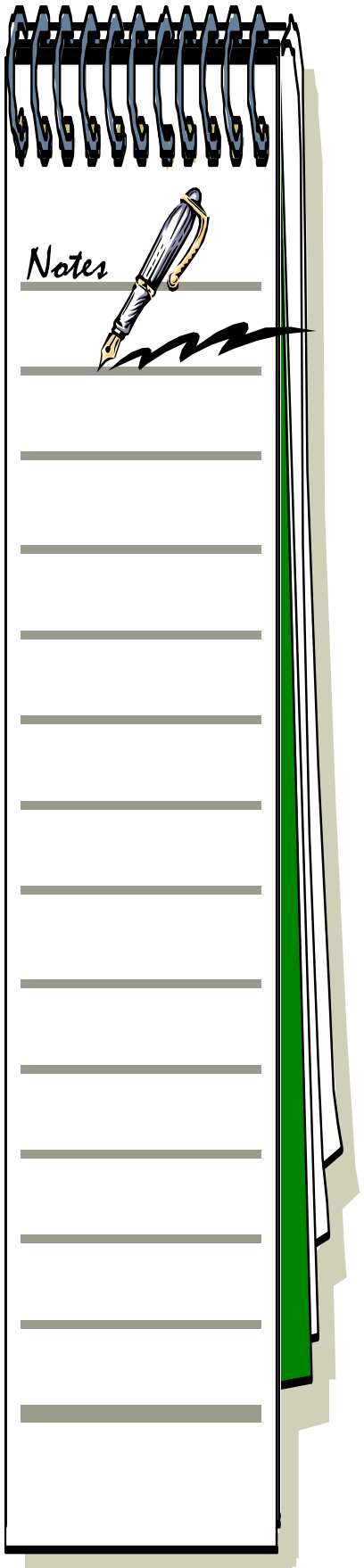
However, the rational application of technology needs to be coupled with the following:

- A reexamination of the role of diagnostic testing in case identification and disease management, clarifying optimal use of objective physiological monitoring data (including data obtained from portable monitors) in clinical diagnostic and management algorithms.
- Recognition that the development of new physiological monitoring tools needs to be guided by research that clarifies the short- and long-term clinical predictive information of specific channels (including responses to clinical interventions), or combinations of data. This should include consideration of the extent to which data from new technologies complement those from other techniques.
- Standardization of diagnostic and treatment criteria, language, and technologies.
- Investigation of how information from laboratory and portable diagnosis may interface as complementary rather than competitive technologies.
- Investment by industry and the NIH in rigorous evaluation and outcome studies that are designed to test specific questions regarding technology applications in improving the efficiency of screening, case identification, and disease management.
- Assessment of technologies utilizing indexes to examine their cost-effectiveness.
- Development of technologies keeping in mind that treatment of sleep disorders requires a chronic care management scheme.
- Specific efforts to develop and modify technologies for children.

The New AASM Scoring Manual: Learning from R&K about Achieving Consensus and Acceptance.

The new AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology and Technical Specifications1 represents a giant step toward standardization of clinical polysomnography. Some of the challenges for making it the "New Standardized Manual" can be easily met while others will require more effort. Looking at the challenges faced approximately 40 years ago when Allan Rechtschaffen and Anthony Kales developed A Manual of Standardized Terminology, Techniques and Scoring System for Sleep Stages of Human Subjects, the sleep

community can learn valuable lessons about how to proceed with consensus and acceptance of the new AASM Scoring Manual.



Background

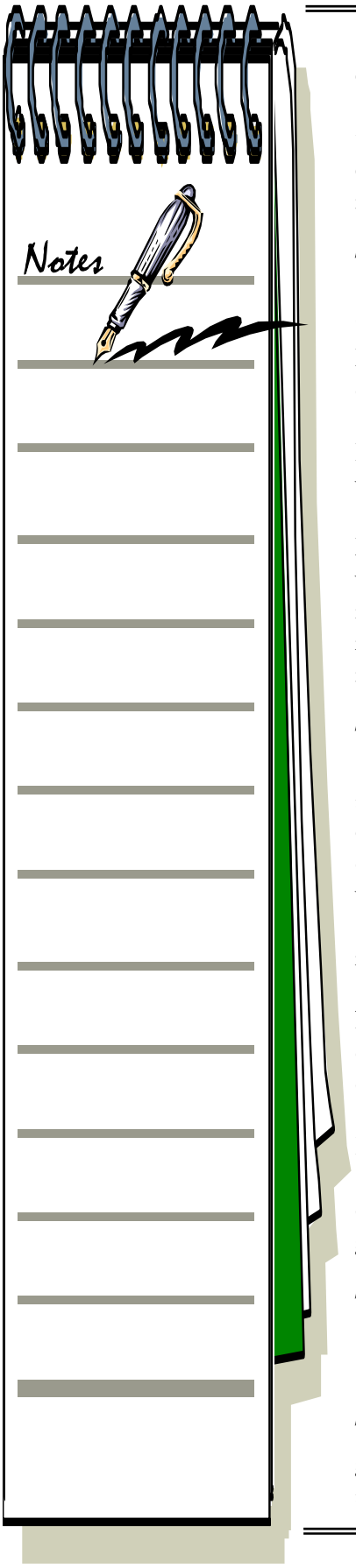
In 1968, A Manual of Standardized Terminology, Techniques and Scoring System for Sleep Stages of Human Subjects was published by the United States Government Printing Office.2 This "standardized manual" was developed by an ad hoc committee of sleep experts and was chaired by Rechtschaffen and Kales; the manual thereafter was often referred to as "R&K." R&K defined recording technique, terminology, and scoring rules for normal human sleep that lasted 40 years. The key word here is normal.

As the need arose to detect sleep pathophysiologies associated with specific sleep disorders, clinical researchers developed additional guidelines. One of the best compendia of additional rules was to be found in the book Sleeping and Waking Disorders: Indications and Techniques, edited by Christian Guilleminault.3 This volume contained rules for scoring breathing, leg movements, abnormal EEG, nocturnal tumescence, and other sleep phenomena. This book became a standard desk reference and citation for those of us engaged in clinical sleep research; however, it was out of print by the next decade.

Later, the rules for scoring central nervous system (CNS) arousals were formalized by the American Sleep Disorders Association (ASDA) Atlas Task Force and published in the journal Sleep.4 A year later, the leg movement scoring rules from Richard Coleman's chapter in Indications and Techniques were reviewed, slightly modified, illustrated, and endorsed by the Atlas Task Force.5 Finally, the "Chicago" group considered sleep-related breathing and proposed a set of guidelines that were adopted as a recommended clinical research technique.6 Even as scoring rules were evolving with changing methodology, no official guidelines emerged concerning computerized polysomnography. By the millennium, sleep recordings had migrated from special-purpose, analog-circuit, EEG machines attached to paper chart drives to digital amplifiers interfaced with personal computers programmed to capture, display, and manipulate data. Until the introduction of the new AASM Scoring Manual, no recommendations from professional organizations have specified even the most basic, minimal operational characteristics for such machinery in application for polysomnography.

The New Manual

In a bold move, the American Academy of Sleep Medicine (AASM) initiated a large-scale project to revise the Standardized Manual and



develop a unified guideline for terminology, recording method, and scoring rules for sleep-related phenomena. A task force was also formed to review and recommend guidelines related to functional aspects of digital system polysomnography. The following illustrates the areas where modifications occurred.

The task force concerned with staging renamed the stages, combined stages 3 and 4, and eliminated stage "movement time." Also, some of the "smoothing rules" governing specifics of stage transition were simplified. More controversial, perhaps, was the mandate that an additional EEG channel (from a frontal derivation) be routinely recorded.

Recording and scoring of CNS arousals were essentially re-endorsed without modification.

Leg movement scoring underwent minor modification and clarification without major changes. More significant, however, was the addition of rudimentary approaches to scoring other sleep-related movements, including teeth grinding, hypnagogic foot tremor, excessive fragmentary myoclonus, and rhythmic movement disorders.

The respiratory task force managed to formalize technique and define sleep apnea episodes. For hypopnea, the recommended definition accords with Medicare's specifications requiring an associated 4% drop in oxygen saturation. An optional definition that considers events with either desaturation (3%) or arousal is also provided (and accords better with how clinical sleep specialists traditionally defined hypopnea). Rules for scoring respiratory events in children were also developed and included.

Newly covered is a list of definitions of important electrocardiographic events that should be delineated, tabulated, and reported as part of a comprehensive polysomnographic assessment.

Finally, the digital PSG task force made recommendations concerning specifications for digital recordings, display, reporting, and operational characteristics. The body of work and new recommendations and guidelines were published in a single volume entitled the AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology and Technical Specifications.

Challenges for the Future

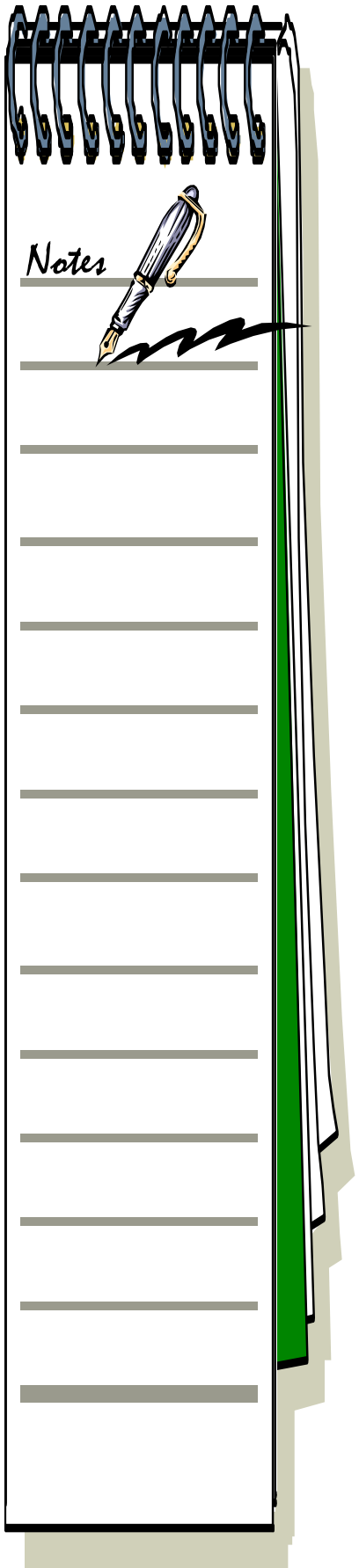
The main challenge for making this long-awaited and much-needed guidebook the New Standardized Manual will be consensus and acceptance. This challenge was also the primary challenge facing the

previous manual, and the framers of that work were keenly aware of this fact. Rumor had it (and was confirmed by Rechtschaffen) that during the deliberations of the ad hoc committee in the 1960s, Rechtschaffen barred the meeting room door and declared, "No one can leave until we all agree!" Because of Rechtschaffen's demand that consensus take place, the framers were eventually able to come to an agreement.

While it may not be immediately apparent, this was the key to the original standardized manual's success. If each committee member had returned to their respective laboratories and continued to use their own home-grown methods, the R&K manual would merely be an asterisk in the history of sleep medicine. Furthermore, we would still be discussing synchronized sleep, paradoxical sleep, d-sleep, orthodox sleep, desynchronized sleep, and dreaming sleep.

The second challenge will be disambiguation of some of the rules and terminology. For example, frontal EEG recordings are mandated for routine use for determining slow wave sleep, now called N3. However, the somnologist can choose between monopolar or bipolar derivations. Furthermore, minimum amplitude criteria are specified, but not differentially, for the two recording types.

The third challenge to acceptance will be influenced by how the AASM manual responds to future needs. As with all projects, particularly ambitious ones, there are always things that have not been fully covered.

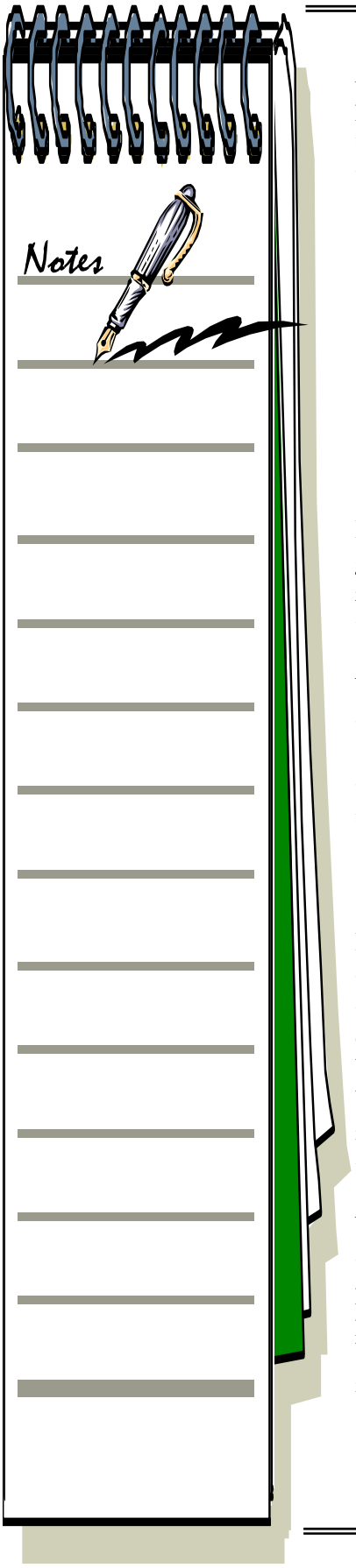


Review of a New AASM Scoring Guideline Requirement: Respiratory Inductance Plethysmography

In July 2008, the new AASM Scoring Guidelines[1] impacting accredited sleep centers across the United States will take effect. With the implementation of the new guidelines, there are many new procedures to become familiar with as sleep centers change equipment associated with a polysomnogram (PSG). One of the new pieces of equipment to be used is respiratory inductance plethysmography (RIP), which detects respiratory effort.

Methods to Assess Respiratory Effort

In the past, respiratory effort was determined by measuring esophageal pressure. The patient swallowed a pressure manometer which resided in the esophagus during the study to accurately assess thoracic effort. This process was uncomfortable for patients and rarely used in clinical practice.



A reasonable surrogate measure of respiratory effort, known as plethysmography, can be obtained by measuring changes in the chest and/or abdominal volume. There are three main methods of noninvasive chest and abdominal plethysmography:[2]

- Elastometric: evaluates changes in the tension of an elastic belt; this is typically achieved through the use of piezoelectric sensors or crystals.
- Impedance: evaluates how quickly or slowly electrical currents flow from a reference electrode to the receiving electrode.
- Inductance: relies on principles of magnetic forces and how they change with movement.

Respiratory Inductance Plethysmography(RIP)

RIP relies on the principle that a current applied through a loop of wires generates a magnetic field normal to the orientation of the loop. If there is a change to the area, the loop then creates an opposing current within the loop directly proportional to the change in the area.

With an RIP system, an alternating current is passed through the belt to create the magnetic field. The act of breathing will change the cross-sectional area of the patient's body, "inducing" an opposite current that can be easily measured by observing the change in the frequency of the applied current.

Comparing RIP Belts to Piezoelectric Belts

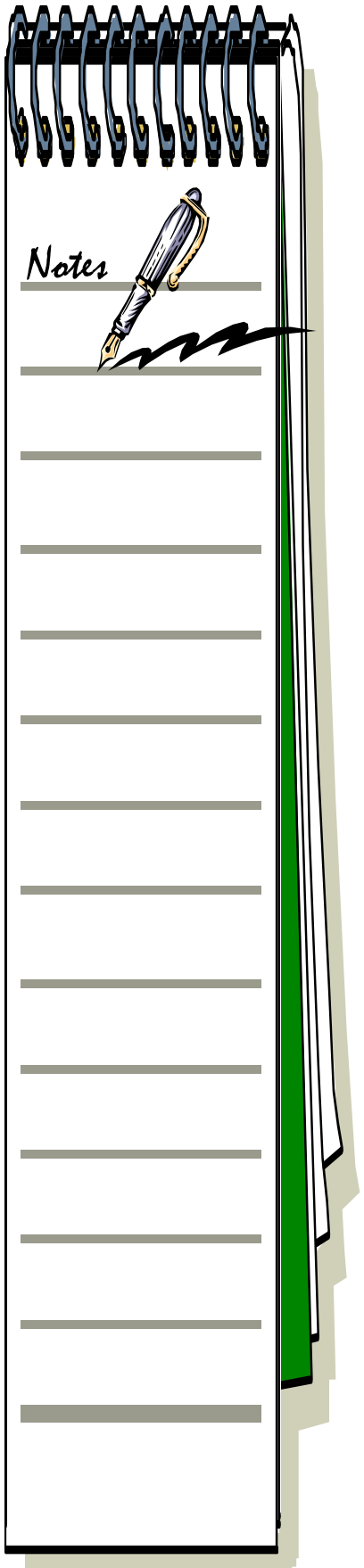
In an RIP belt, the sensing element is the zigzagging wire that runs the entire length of the belt. Once placed on the patient, the sensing element covers the patient's entire circumference. Changes in breathing will be detected regardless of the patient's position. Proper placement of the belts is around the nipple line (or mid chest) and just above the belly button. If the belts are placed too loosely or too tightly around the midsection, a change or restriction of the chest or abdomen can occur and result in an inaccurate measurement.

With piezoelectric belts, two sensors generate voltage directly when compressed or stretched. While this method is simple to use, it can also provide inaccurate information if the belt becomes "trapped" under the person as he or she turns from one side to the other. Also, changes in body position can impact the position of the electrode or belt tension, negatively impacting the signal being created.

Summary
Inductance Plethysmography was initially developed as a tool to noninvasively measure respiratory volumes in pediatric and asthma research. In the 1990s it was adapted for PSG use. In 2008 it will become a recommendation for detection of respiratory effort in patients undergoing PSG.

References

1. The AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology and Technical Specifications. Westchester, Ill: American Academy of Sleep Medicine;2007:45-50.
2. Mazeika GG, Swanson R, Respiratory Inductance Plethysmography; an Introduction. Pro-Tech Services 2007.



Scoring Manual Frequently Asked Questions

The following has been excerpted from the AAST website: http://www.aasmnet.org/SMFAQs.aspx.

GENERAL
G.1.
I see that the STANDARDS FOR ACCREDITATION states that we are to use the recommended AASM guidelines, when available. Does this mean, if our medical director chooses for us to use the alternative rule, that our accreditation is at risk?

A. The term "recommended AASM guidelines" in the accreditation standards refers to the set of guideline papers published by the AASM [http://www.aasmnet.org/PracticeParameters.aspx]. Each paper has recommendations based on evidence and/or consensus with terms that are used to reflect the strength of evidence and/or consensus. The AASM guidelines leave some discretion to implementation of guidelines within the context of these terms. In the case of the AASM scoring manual, the key on page 15 indicates that "recommended," "alternative," and "optional" rules are all methods acceptable by AASM for scoring and that "alternative" and "optional" rules may be used at the discretion of the clinician or investigator based on preference or logistics of a specific laboratory. Use of "alternative" or "optional" rules would not create any risk to accreditation.

TECHNICAL SPECIFICATIONS
T.1.
I have just bought NEW PSG EQUIPMENT. Do I need to change my equipment again to become compliant with the technical specifications on pages 19-21?

No, for AASM accredited centers and laboratories, all new equipment purchased after July 1, 2008 will need to be in compliance with the technical requirements on pages 19-21.

However, even with existing equipment, by July 1, 2008, you will need to:

1. be compliant with the new rules for EEG, EOG, EMG and respiratory signals, including using both thermal and nasal pressure sensors to record respiratory events (pages 45 and 48)
2. have modified your reporting software to reflect the parameters to be reported (pages 17-18) and the new sleep stage terminology (page 24)
3. be scoring stages and events according to the new rules

T.2.
Is there a requirement for CONTINUOUS AUDIO RECORDING during polysomnography under the new guidelines?

The manual does not specifically require audio recording. Most laboratories incorporate it within the required video recording process however because there are so many clinical situations in which audio is extremely useful, including but not limited to bruxism, snoring, behavioral disorders, parasomnias, seizures and catathrenia.

T.3.
If my AMPLIFIER, purchased prior to July 1, 2008, does not have enough inputs to allow for the additional EEG and EMG channels, and I am not required to replace this equipment, then how am I to stage sleep using the new criteria?

Please refer to FAQ T.1. The exception granted for equipment purchased prior to July 1, 2008 refers only to the technical requirements listed on pages 19-21. This does not include the number of amplifier channels. By July 1, 2008, you will need to have equipment enabling compliance with the new rules for scoring sleep using EEG, EOG and EMG signals. Therefore an adequate number of amplifier inputs to allow recording of the required number of EEG and EMG derivations will be needed.

T.4.
I AM BUYING NEW EQUIPMENT in May 2008 with capabilities that will not be compliant with some of the scoring manual specifications. When must I replace or modify the equipment?

Please note that it is only the technical specifications listed on pages 19-21 that need not be present in equipment purchased prior to July 1, 2008. All other requirements must be met as specified in FAQ T.1. The AASM has not set a specific date by which older equipment not fulfilling all the specifications on pages 19-21 need be replaced or modified. Any replacement equipment purchased after July 1, 2008 must be in full compliance with all technical requirements.

VISUAL RULES
V.1.
Is it permissible to use the RECOMMENDED EOG derivations AND the ALTERNATIVE EEG derivations for the same study, or must we use either the recommended or the alternate derivations for both EEG and EOG?

You may choose between the recommended and alternative derivations for EEG and EOG within the same study.

V.2.
I currently use EOG derivations similar to the alternative ones (page 24, B.2.) but the REFERENCE FOR EYE LEADS is Fz rather than Fpz. Is this permissible?

No, in the interests of standardization, the EOG derivations in the manual (recommended or alternative) should be followed exactly.

V.3.
I currently record LEFT-SIDED EEG (F3, C3, O1) and reference to M2. This is the mirror image of the recommended derivations (page 23, A.1.) Is this permissible?

No, in the interests of standardization, the routine EEG derivations in the manual (recommended or alternative) should be followed exactly. Exceptions are allowed only in individual cases when applications are prevented by local conditions such as scalp conditions or focal encephalomalacia.

V.4.
I plan to use the recommended EEG derivations (page 23, A.1.) If the C4 ELECTRODE BECOMES DISCONNECTED during the study, can I replace C4 with C3 and continue to record F4-M1 and O2-M1, or must I then change all 3 derivations to recording from the left side of the head?

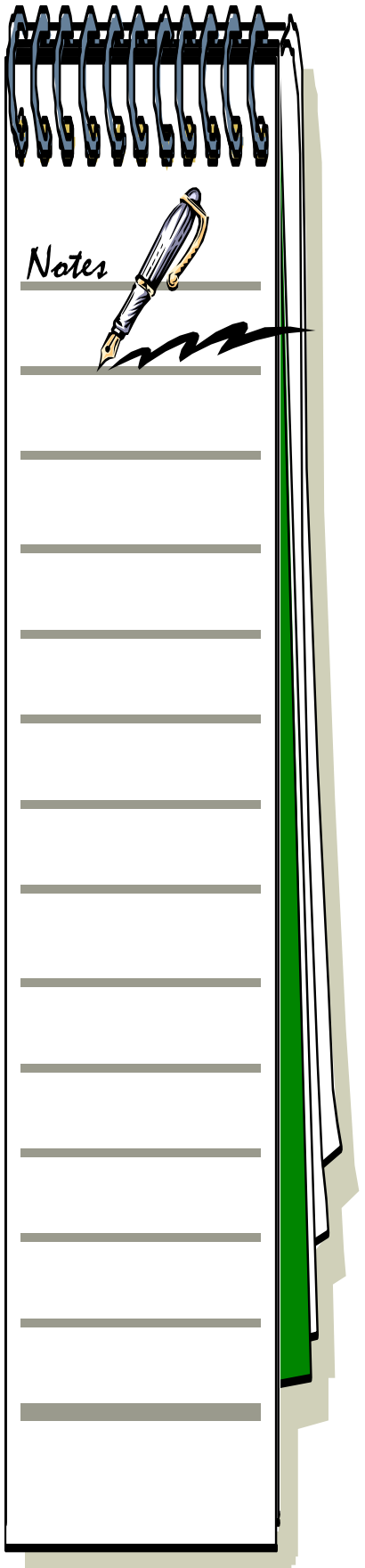
You need only change the derivation that incorporates the faulty electrode. However, in the scenario described above, you would change to C3-M2, rather than C3-M1, even if the M1 electrode is intact.

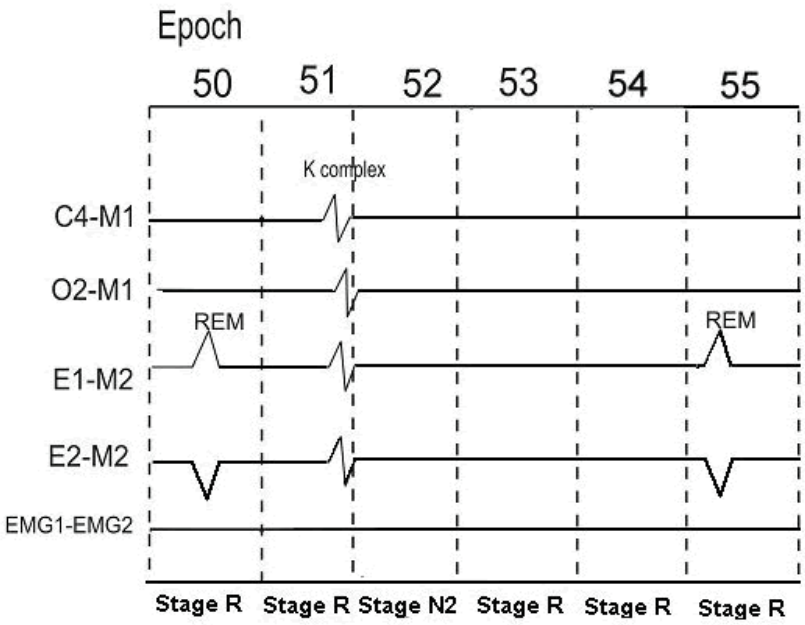
V.5.
I plan to use the alternative EEG derivations (page 23, A.2). The amplitude of EEG activity during stage N3 sleep should be measured using the frontal derivation (page 27, definition). Won't the use of the bipolar derivation Fz-Cz result in EEG CANCELLATION EFFECTS, reducing the amplitude of the signal compared to a referential derivation, such as F4-M1?

You are correct. Fz-Cz is not appropriate for measuring the amplitude of frontal activity for the reason you describe. If you are using the alternative EOG derivations (page 24, B.2.), then we recommend you use the E1-Fpz derivation to measure frontal slow wave amplitude. Used in this way, Fpz will be the active electrode recording frontal activity and E1 the reference electrode in a referential derivation. If you are using the recommended EOG derivation (page 24, B.1.), then we suggest you measure EEG amplitude using the C4-M1 derivation.

V.6.
Regarding the END OF A PERIOD OF STAGE R SLEEP RULE [page 28, 7.C.]: Epoch 50 (see Figure 1 below) is typical R sleep, epoch 51 is R sleep with a K complex (but no arousal) in the 2nd half of the epoch, epoch 52-54 have low amplitude mixed frequency EEG activity and low muscle tone but no REMs or K complexes, epoch 55 has low amplitude mixed frequency EEG, low muscle tone and REMs in the first half of the epoch. Should epochs 52-54 be scored N2 or R?

According to the rules for ending a period of stage R sleep (page 28, C1.e and page 29, Figure 7), epoch 51 would be scored as R and epoch 52 would be scored as N2. According to the rules for the transition between stage N2 and R (page 30, D.3), epochs 53-54 would be scored as R (see Figure 1 below).



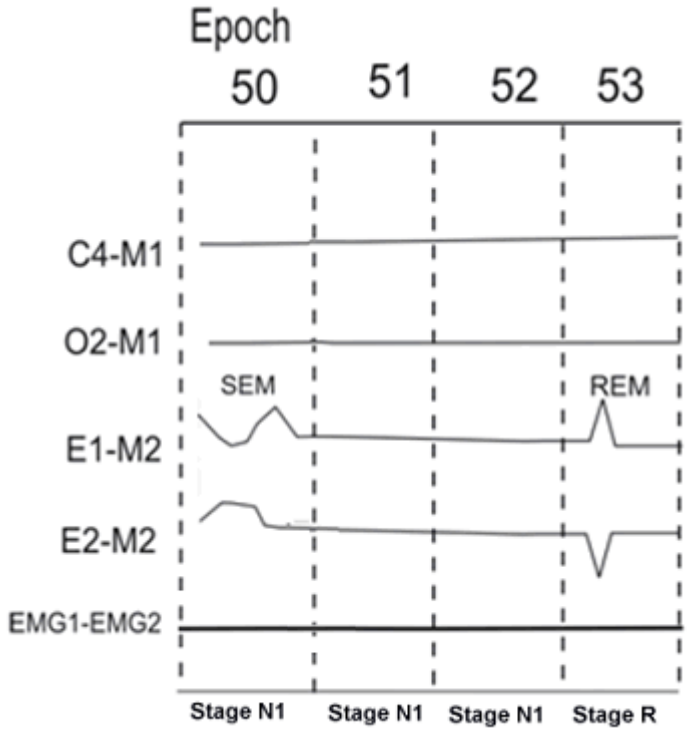


V.6A.
This question is in response to a previous question (V.6.) concerning the END OF A PERIOD OF STAGE R SLEEP RULE [page 28, 7.c]. In the figure shown for question V.6., epoch 52 has no K-complexes or spindles and maintains a low chin EMG. If we are indeed moving to an epoch by epoch scoring mandate then why would you score this epoch as N2 rather than REM? Rule 7 C specifically states ending stage R when the K-complex occurs in the first half of the epoch. The only exceptions I know of for the epoch by epoch staging mandate are those of when REM begins before eye movements are seen i.e. when chin EMG drops in the absence of K-complexes and spindles, and staging what used to be movement epochs which is now determined by the following epoch's stage provided there was sleep in the previous epoch.

The epoch 52 in V.6 should be scored as N2 because REMs do not appear following the epoch; this is consistent with both the right sided part of Figure 7 in the manual (p. 29) and the right sided part of Figure 9 (p. 30) which shows REM scoring if subsequent epochs demonstrate REMs. Please note also Rule 5.A.1 which mandates scoring stage N2 if a K complex or spindle occurred in the second half of the previous epoch. The Committee feels that their response to V.6 FAQ is a reasonable interpretation of an uncommon scenario.

V.7.
How are epochs BETWEEN an initial N1 with slow eye movements AND an epoch of R with rapid eye movements scored if all the epochs demonstrate low amplitude mixed frequency and there are no changes in the EMG?

There are no rules in the AASM manual specifically dealing with stage N1-R transitions. R will only commence when rapid eye movements are seen in association with low muscle tone and the typical EEG (Rule 7A. page 27):



Extra reply to sender: In contrast, the manual does specify rules for the transition between N2 and R. See Rule 7.D. and Figures 8 and 9.

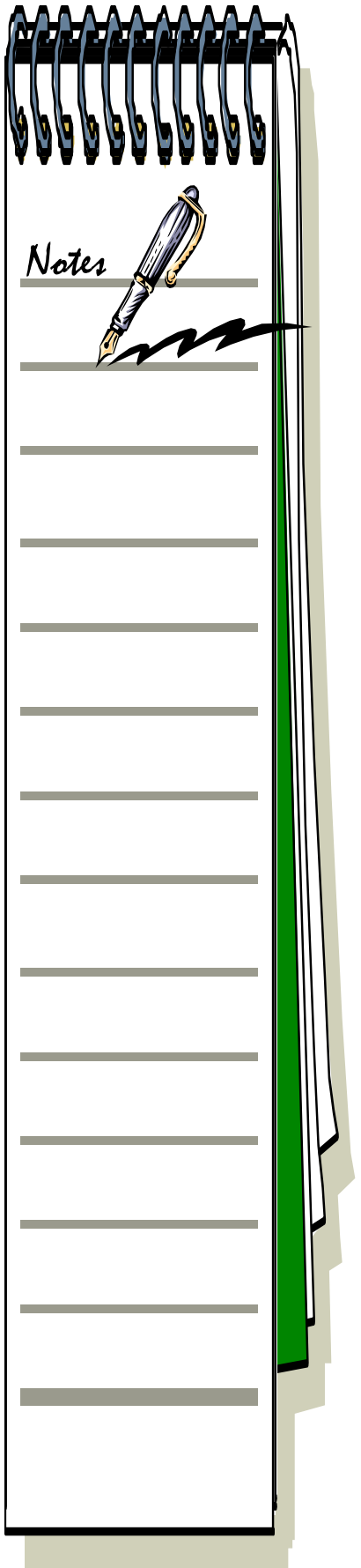
V.8.
Occasionally FRONTAL DERIVATIONS are the only derivations that DETECT SPINDLES, OR AROUSALS during an epoch. Can these events be used to score sleep even if they are only found in the frontal derivations? The scoring manual indicates that spindles are "maximal in amplitude using central derivations" and that arousal should be scored from "both the occipital and central derivations."

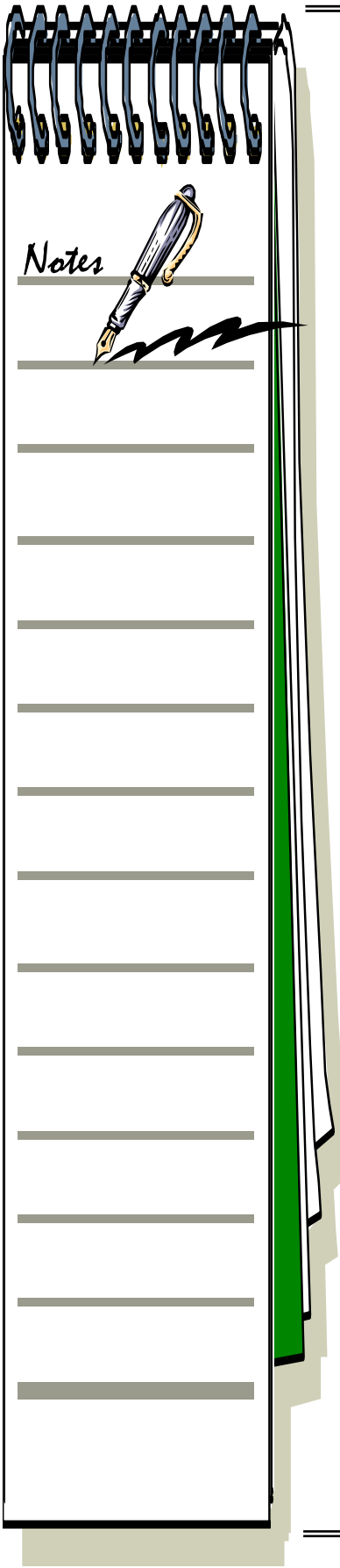
Yes. Although sleep spindles and frequency changes associated with arousals are more typically noted in the central and occipital derivations respectively, these events should be used to score sleep even if they are only noted in the frontal derivations.

MOVEMENT RULES
M.1.
In scoring the PSG FEATURES OF RBD, how many epochs of REM sleep must show either sustained or excessive transient muscle activity for REM sleep as a whole to be considered compatible with RBD?

The manual has deliberately not specified this as there are little normative data. Clinicians are encouraged to read the relevant section of the supporting paper (J Clin Sleep Med 2007;3:159-161) to help them decide how to address this issue in their own laboratories.

M.2.
There are numerous leg movement sensors available. We switched from electrodes to sensors several years ago and have been happy with the response. Will it be necessary to return to LEG ELECTRODES to score PLMS?





Bipolar EMG electrodes are required for PLM scoring as noted in Parameters to be reported (II. A. 4.) and the notes appended to PLM scoring rules (VII.1.notes).

M.4.
In our lab we score arousals associated with PLM's. Since you cannot score arousals unless there is 10 seconds of sleep preceding the arousal, can I score an arousal that is associated with a PLM when there can be as little as five seconds since the last PLM with arousal?

The short answer is no, you cannot score arousals with less than 10 seconds of intervening sleep. Members of the Movement Rules and Arousal Rule task forces were consulted on this question. The Movement Rules perspective was that conceptually it would be possible to have multiple limb-movement related arousals with the minimal interval between limb movements (five seconds from onset to onset). However, the Arousal Rule perspective is that the scoring of such arousals would be technically quite difficult. Since an arousal must last a minimum of three seconds, this would leave only two seconds to determine that sleep had resumed. The Steering Committee reviewed both perspectives and determined that the arousal rule should hold and that a minimum of 10 seconds is necessary to reliably determine that the patient has returned to sleep. When periodic limb movements occur with an interval of less than 10 seconds and each is associated with a three second arousal, only the first arousal should be scored though both limb movements may be scored. In this scenario, the arousal index and PLM index with arousal but not the Periodic Limb Movement Index would be influenced by not scoring the second "arousal".

RESPIRATORY RULES

R.1.
I perform epidemiologic studies of sleep apnea. It is very important that all research studies use the same criteria for hypopneas to allow valid comparisons between different protocols. How will this be possible with TWO RULES FOR HYPOPNEAS?

We strongly recommend that investigators use the alternative rule for hypopneas (page 46, 4.B.) in all prospective epidemiological and outcome studies. For clinical purposes, sleep specialists may select either the recommended (pg 46, 4.A.) or alternative (page 46, 4.B.) rule. Certainly, for comparison purposes in clinical research or practice, both methods may be reported.

R.2.
Right now, our laboratory only uses ONE FLOW SENSOR. With the new rules, are BOTH a thermal sensor and a nasal pressure transducer recommended for detection of airflow?

Yes. A thermal sensor is recommended for detection of the absence of airflow for the purposes of identifying apneas. A nasal pressure transducer with or without square root transformation of the signal is recommended for the detection of a flow reduction for the purpose of identifying hypopneas. As indicated in the supporting review paper, (J Clin Sleep Med 2007; 3:188), use of only a nasal pressure transducer can result in misclassification of hypopneas as apneas.

R.3.
What should be done when one AIRFLOW SENSOR FAILS? If I am monitoring with both a thermal sensor and a nasal pressure sensor and the nasal pressure sensor stops working, how can I now define hypopneas?

The manual recommends using back-up sensors when one fails. When the nasal pressure sensor fails, the oronasal thermal sensor should be used for scoring hypopneas. [pages 45 & 48, notes]

R.4.
Is CALIBRATED INDUCTANCE PLETHYSMOGRAPHY required for detection of respiratory effort?

No. The recommended sensors for detection of respiratory effort are either calibrated OR uncalibrated inductance plethysmography OR esophageal manometry.

R.5.
Are PIEZO BELTS acceptable as sensors for detection of respiratory effort?

No. The recommended sensors for detection of respiratory effort are calibrated OR uncalibrated inductance plethysmography OR esophageal manometry. As indicated in the supporting review paper, (J Clin Sleep Med 2007; 3:172), piezo belts are not felt to be a satisfactory reflection of respiratory effort.

R.6.
During CPAP TITRATION, are both thermal sensors and nasal pressure sensors required for scoring apnea and hypopnea?

The scoring manual does not specifically apply to scoring of respiratory events during CPAP treatment. Alternative methods for verifying flow such as flow output from the CPAP device will be necessary during treatment as nasal pressure and thermal sensor measures may no longer be reliable.

R.7.
Is arousal required for scoring RERAs in children?

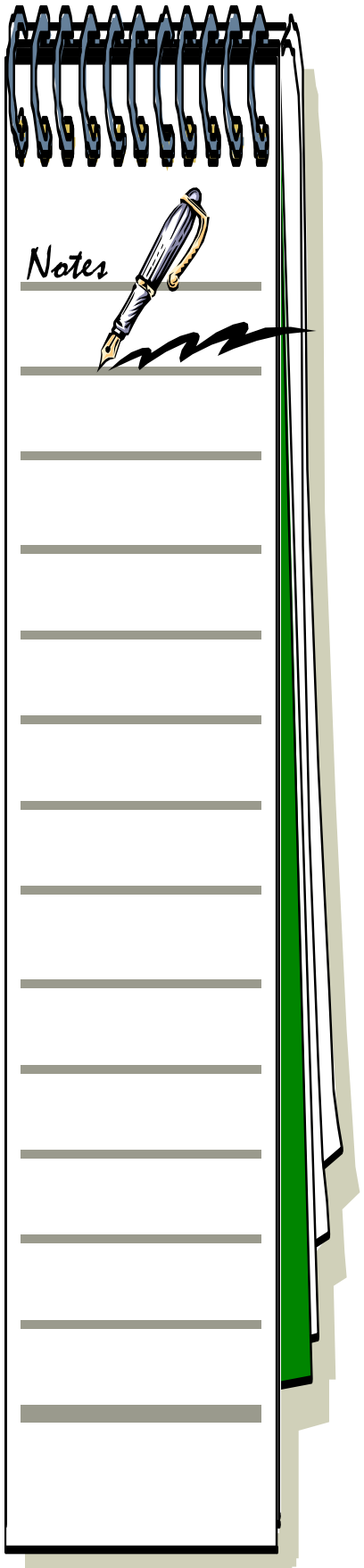
Yes. Scoring of RERAs in both adults and children requires that the RERA be associated with an arousal that conforms to the recommended AASM arousal rule.

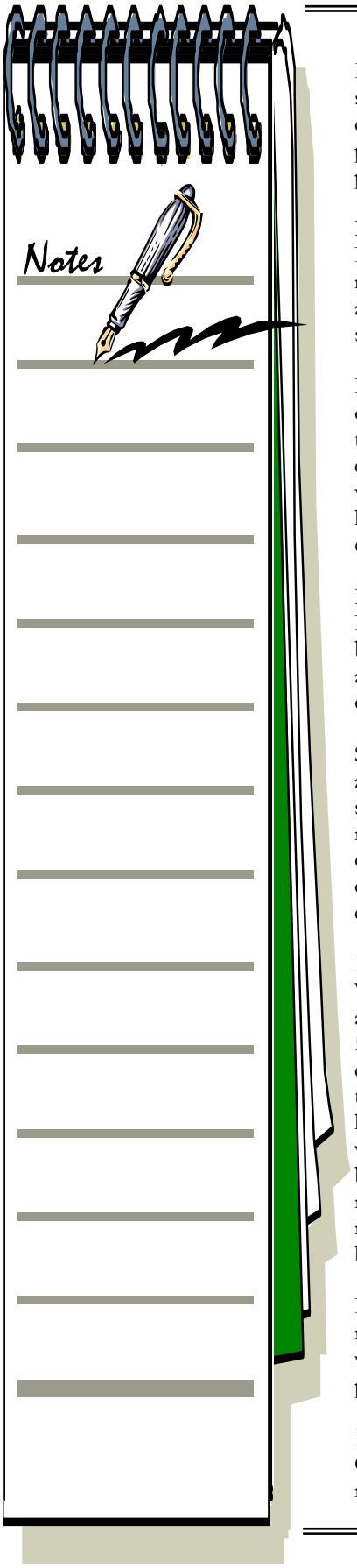
R.8.
The standards require an oximeter to have a maximum signal averaging time of 3 seconds. But some OXIMETERS' SAMPLING TIMES are linked to heart rate and thus may at times be longer during periods of bradycardia. Is this acceptable?

Yes, as long as the maximum signal averaging time at a heart rate of 80 beats per minute or more is 3 seconds or less.

R.9.
In some cases, APNEAS AND HYPOPNEAS may begin during an epoch scored as sleep, but end during an epoch scored as wake. Can these events be scored and used for the computation of apnea-hypopnea index?

Yes. If any portion of either the apnea or hypopnea occurs during an epoch that is scored as sleep, then the corresponding respiratory event can be scored and included in the computation of the AHI. This situation usually occurs when an individual has a high apnea hypopnea index with events occurring so frequently that sleep is very disrupted and epochs may end up being scored as wake even though there are brief seconds of sleep between the respiratory events.





However, if the apnea or hypopnea occurs entirely during an epoch scored as wake, it should not be scored or counted towards the apnea-hypopnea index because of the difficulty of defining a denominator in that situation. If these occurrences are a prominent feature of the polysomnogram and/or interfere with sleep onset, their presence should be mentioned in the narrative summary of the study as well.

R.10.
I am concerned about the requirement that 90% of the EVENT DURATION must meet the amplitude reduction criteria. I see that there was no evidence and no agreement by the respiratory task force, and that this criteria was adjudicated by the steering committee.

If the amplitude and/or desaturation criteria are met during any contiguous 10 seconds of an event that lasts longer than 10 seconds, then the event should be scored even if the duration of the amplitude reduction does not constitute 90% of the total event duration. In the example cited, any contiguous 10-second period during the 17 seconds would be scored and classified based on the amplitude and/or desaturation criteria for hypopnea or apnea. The event duration would be that measured for the length of the entire episode.

R.11.
It does not make sense to me that a 17-second reduction in AMPLITUDE would not be counted if the event is 20 seconds long, but that a 9-second reduction would be adequate if the duration of the event is 10 seconds. What is the rationale for this criterion?

Scoring of hypopneas and apneas requires a minimum duration of 10 seconds. If the amplitude criteria are met during any contiguous 9 seconds of an event that lasts 10 seconds or longer then the event should be scored even if the duration of the amplitude reduction does not constitute 90% of the total event duration. In the example cited, any contiguous 9-second period during the 20 seconds would be scored and classified based on the amplitude and/or desaturation criteria for hypopnea or apnea. The event duration would be that measured for the length of the entire episode.

R.12.
What is meant by "BASELINE" in the new AASM scoring manual. We are using the alternative definition for hypopnea in non-Medicare patients. Hypopnea is defined as > 50% drop in the nasal pressure signal compared to baseline associated with either a 3% desaturation or an arousal. I am meeting with our techs on a regular basis in an attempt to insure uniform scoring under the new criteria. I have attached a typical example. The labeled events are those scored by the technologist. There are other events present which are associated with arousals which the tech did not score because he did not believe that there was a 50% drop in flow. There is a 50% drop in flow compared to the recovery breaths but this may not be "baseline" in that the patient is hyperventilating in response to the event. Is it acceptable to use the amplitude of these three to four breaths following the event as "baseline" and compare the reduced breaths to these?

If there is no clear baseline breathing to measure, due to a high frequency of abnormal respiratory events, then the recovery breaths between the frequent apneas or hypopneas would be acceptable to use for an approximate baseline against which to measure the percent of drop for the next reduction in airflow.

R.13.
Can the INTERCOSTAL EMG be used as an alternative sensor for detection of respiratory effort?

As noted in Section VIII, 1, Note 3 of the scoring manual, "An alternative sensor for detection of effort is diaphragmatic/intercostals EMG." However, it should be emphasized that an interpretable diaphragmatic/intercostal EMG signal is sometimes difficult to obtain especially in obese patients. Thus, sole use of this sensor to assess respiratory effort is not encouraged.

R.14.
Can the HYPOPNEA RULES 4a and 4b on page 46 be combined to compute a single AHI?

No. Each AHI reported should be based on consistent application of either rule 4a or 4b. Scoring using 4a and 4b cannot be combined to compute a single AHI. Laboratories that choose to use both rules must report AHI for each rule separately.

R.15.
What, according to the new standards of the AASM, do they want us to do with SNORING? Are we mandated to measure it? How are we to measure it? Score it? Interpret it?

The presence of snoring should be commented in the text of the report with interpretation of severity left to the discretion of the clinician/investigator. The scoring manual does recommend methods for data acquisition but not for reporting. Since there was insufficient evidence to specify an objective measure of snoring, specific reporting measures are not required.

For example a statement such as follows may be an adequate way to handle the situation:
"There were frequent, almost continuous moderately loud to loud snores present. These occurred in all positions but appeared to be worse supine. Intermittent snore related arousals appear independent of definable apneas and hypopneas."

R.16.
What, according to the new standards of the AASM, do they want us to do with SNORING? Are we mandated to measure it? How are we to measure it? Score it? Interpret it?

The presence of snoring should be commented in the text of the report with interpretation of severity left to the discretion of the clinician/investigator. The scoring manual does recommend methods for data acquisition but not for reporting. Since there was insufficient evidence to specify an objective measure of snoring, specific reporting measures are not required.

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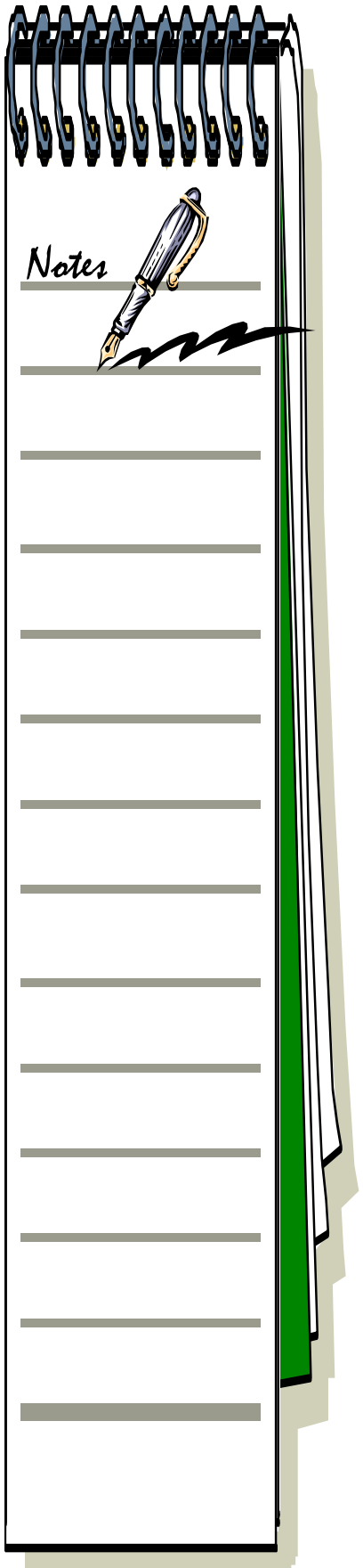
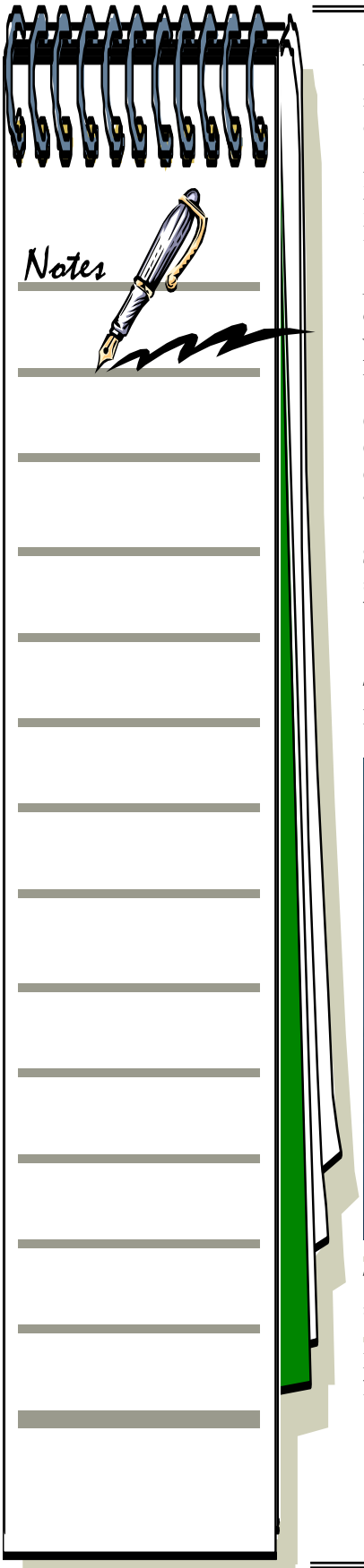
"There were frequent, almost continuous moderately loud to loud snores present. These occurred in all positions but appeared to be worse supine. Intermittent snore related arousals appear independent of definable apneas and hypopneas."

AROUSALS
A.1.
Can you score AROUSALS IN AN AWAKE EPOCH if 10 seconds of sleep precedes the event and all other criteria are met?





Yes. Arousals meeting all scoring criteria but occurring during an awake epoch in the recorded time between "lights out" and "lights on" should be scored and used for computation of the arousal index.

PEDIATRIC RESPIRATORY
P.R.1
Is $ETCO_2$ an acceptable air flow signal? Can it replace one or both of the others?

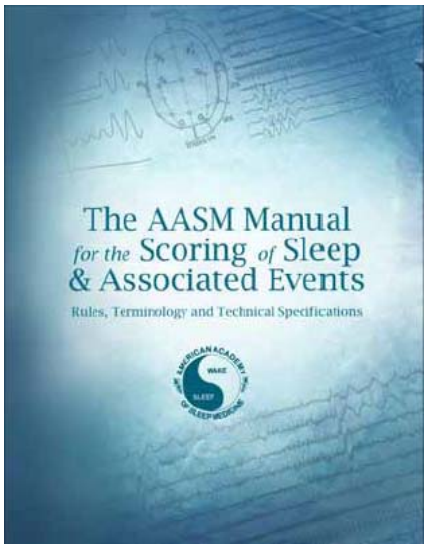
As specified in the notes following the technical considerations 1A and 1B on page 48, end-tidal PCO_2 may be used as an alternative sensor for the detection of apneas only when the oronasal thermal sensor is not reliable. It may not be used for detection of hypopneas.

CARDIAC
C.1.
On page 39, 2. A and B scoring of tachycardia and bradycardia, what is meant by "SUSTAINED"?

Sustained sinus bradycardia or tachycardia is defined by more than 30 seconds of a stable rhythm to distinguish it from transient responses associated sleep disordered breathing events or arousals.

Updated April 18, 2008

To purchase their manual, please go to the following website:
http://www.aasmnet.org/store/ProductDetails.aspx?pid=176



The AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology and Technical Specification

Member price: $50.00
Non-member price: $70.00

Examination

Select the ***best*** answer to each of the following items. Mark your responses on the Answer form.

1) Sleep disorder sufferers are banging down sleep centers' doors with their pillows. To ease this patient backlog, sleep center managers are searching for _____ to score sleep studies.

a) funding
b) outside sources
c) nurses
d) None of the above

2) An Internet transfer system enables all the parties involved with a sleep study (_____) to track all dealings with a particular patient. Not only does this electronically account for each step of the study, but it also frees up the sleep center's day crew from phone calls.

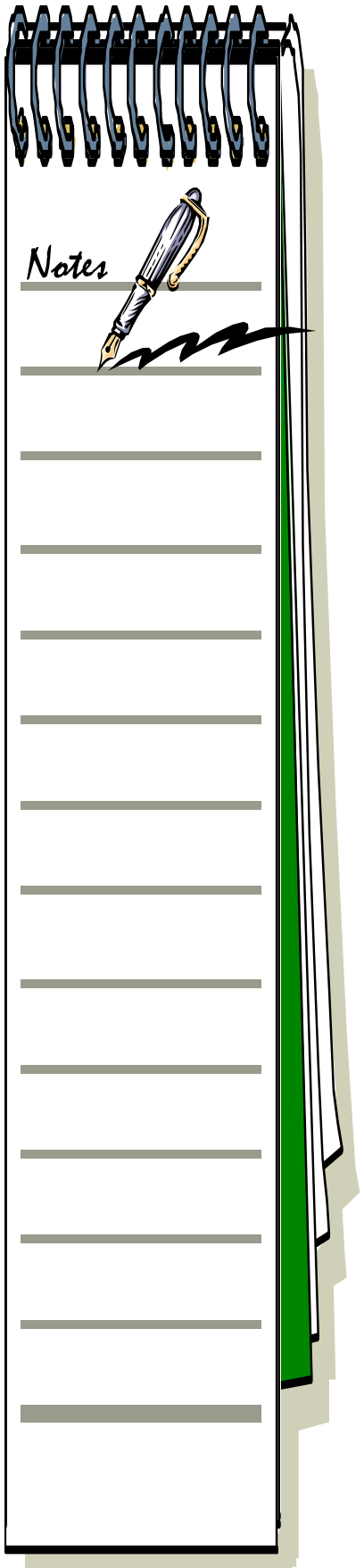
a) patient
b) referring physician
c) sleep center director
d) All of the above

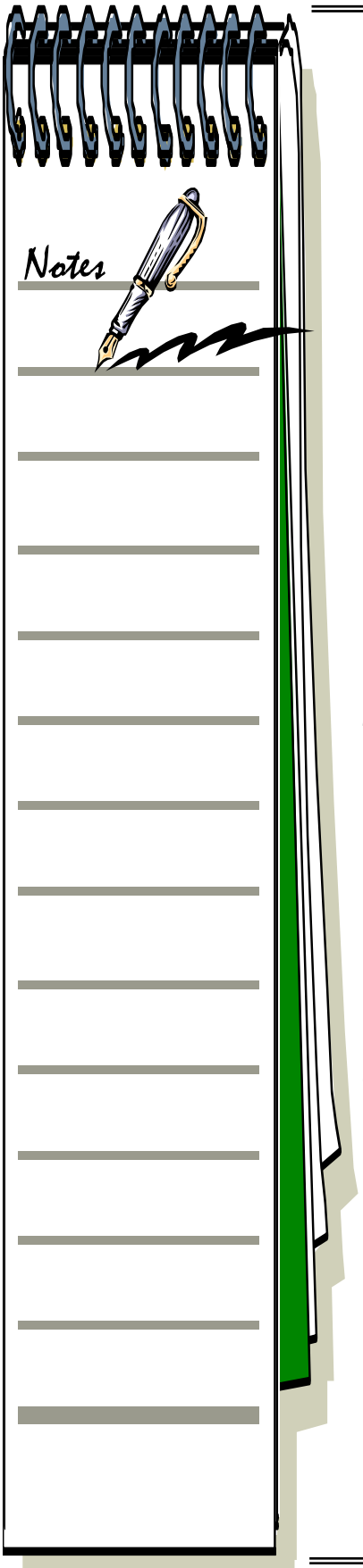
3) Simply put, _____ asks that you inform your patients what you're doing with their information, ask their permission to release their information, and that you take steps to protect their information.

a) HICFA
b) the AMA
c) HIPAA legislation
d) None of the above

4) Once the sleep studies have been _____ via the Internet, the remote scoring technologist can go to work. Auto-scoring features now common on most computerized systems have become more and more appealing to a technologist seeking to maximize time. After all, he or she is getting paid the same price whether it takes 30 minutes or four hours to score a study.

a) found
b) transferred securely
c) visualized
d) None of the above





5) Quantitative measurements, such as leg EMGs, are _____to auto-scoring. The scoring technologist simply has to validate or unvalidate the auto-scored leg movements (or any other quantitative measurement).
   a) well suited
   b) not suited
   c) not relevant
   d) None of the above

6) Another issue to contend with is the fact that technologists and labs are becoming _____. Some states have already legislated who can perform sleep studies, and more states are likely to follow. While legislation might not address outsourcing directly, any rule governing a sleep lab's operation will obviously have to carry over to whomever contracts to score with them.
   a) faster
   b) more skilled
   c) more regulated
   d) All of the above

7) Sleep-stage scoring is a _____art requiring an understanding of the basic mechanisms underlying the generation of cephalic electric potentials. Signals of interest are generated from the brain (i.e., cortex and deeper structures) and the facial muscles (i.e., signals picked up by periorbital and electromyographic [EMG] leads).
   a) regulated
   b) abstract
   c) rule-based
   d) random

8) At a paper speed of 10 mm/s, 1 page equates to _____ seconds and is defined as 1 epoch. Computerized polysomnography usually displays one video screen as one 30-second epoch.
   a) 10
   b) 20
   c) 30
   d) 45

9) The electroencephalography (EEG) signal is of primary importance in interpreting polysomnographic studies. It records electric potentials generated by the interaction between the cortex and the deeper brain structures, especially the _____.
   a) thalamus
   b) cortex
   c) hippocampus
   d) None of the above

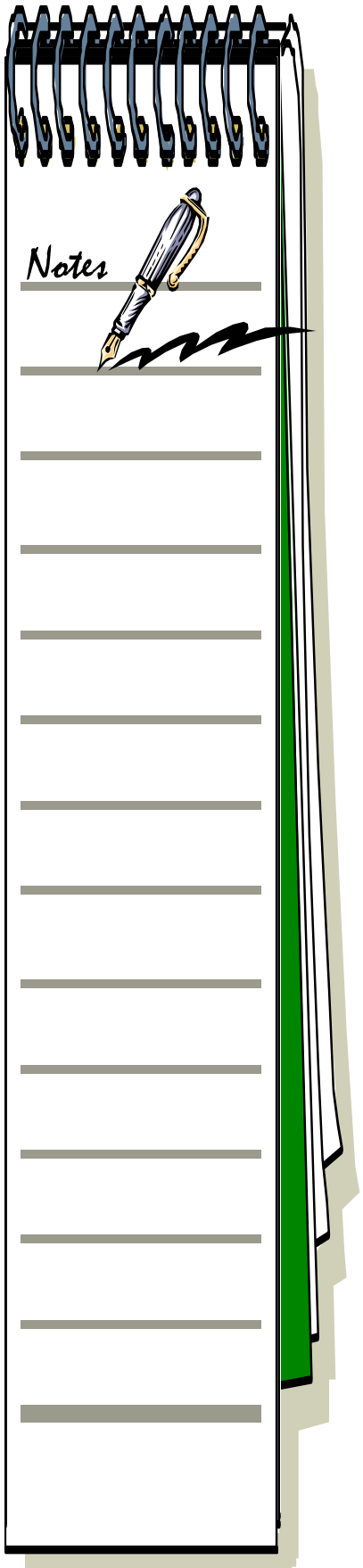
10) High frequency signals above 50 cps are finding increased mention in the literature. High frequency bands (HFB) are described in the ranges 51-100 Hz (HFB1), 101-200 Hz (HFB2), and 201-500 Hz (HFB3) for analysis purposes. Frequencies in these bandwidths are reported as being associated with _____ and alertness.

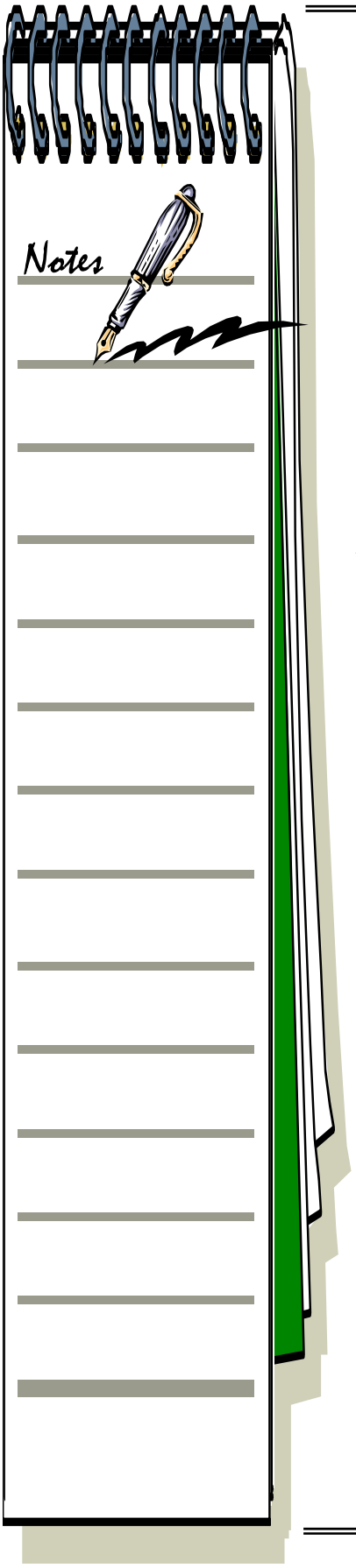
   a) Stage IV sleep
   b) REM sleep
   c) cognitive processing
   d) All of the above

11) The electro-oculographic (EOG) signals measure changes in the _____ of the positive anterior aspect of the eye relative to the negative posterior aspect. Horizontal axis electrodes are placed near the outer canthi and vertical axis electrodes below and above the eye to measure transient changes in potential during the actual eye movement.
   a) length
   b) electric potential
   c) width
   d) waves

12) Initially, the clinician should scroll through the entire record quickly to evaluate the quality of the recording and the usefulness of specific channels. Observe sections that represent the major stages to learn the specific shape of the features that represent the stages in that particular individual and to gain an overall picture of the cycles for that record. Specifically observe for _____.

   a) sleep spindles
   b) K complexes
   c) slow waves
   d) All of the above





13) This stage is defined as sleepy but awake with eyes closed. The EEG will show predominant alpha activity, while the EMG activity_____. The EOG may show slow, rolling eye movements.
   a) stops entirely
   b) becomes more prominent
   c) becomes less prominent
   d) none of the above

14) Stage I is usually brief, lasting for_____. Vertex sharp waves may occur, but no sleep spindles or K complexes are recorded.
   a) 20 minutes
   b) 1-7 minutes
   c) less than 40 minutes
   d) 50 minutes

15) The EEG of REM sleep shows _____ and mixed-frequency activities and may resemble the EEG of stage I. Sawtooth-shaped waves may occur before or with REM EOG bursts. Slow alpha activity may occur, resembling that of wake stage.

   a) relatively low-voltage
   b) relatively high-voltage
   c) slow development
   d) none of the above