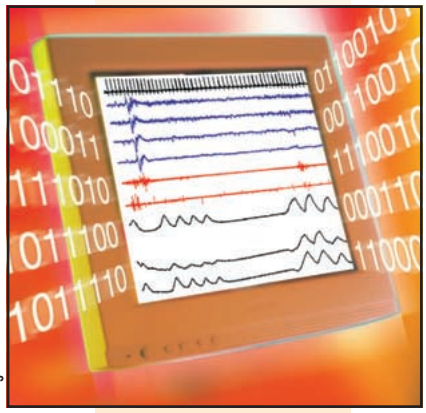

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Acquisition of Biomedical Signals Databases

Aspects to Consider when Building a Database, Based on Experiences from the SIESTA Project

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Biomedical signal databases generally are built for reference purposes. In order to make use of such reference databases, a physiological or medical question first has to be specified. Like in any medical study, hypotheses have to be formulated before setting up a biomedical signal database. The questions posed and the hypotheses formulated naturally lead to the design of a study protocol. The study protocol specifies the recording equipment and details the type and number of signals and the sampling rates of the signals. The questions also allow the estimation of the number of subjects from whom the data should be collected ("power analysis"). The number of subjects and the number of total investigations then determine whether a single center can collect the data or whether a multicenter study is needed to collect the data within a reasonable period of time. One other reason supports the selection of multicenter studies. Different sites do use different equipment and follow slightly different protocols in terms of diagnosis and treatment. A study with many different partners can reflect these differences and may result being more general than it ever could be derived in a single-center study.

With a thoughtful design the resulting database can answer the questions posed in the beginning. Due to the large amount of collected information, being the nature of biomedical signal databases, the database can also answer more questions by applying new analysis methodologies or hypotheses to the gathered data. But in general, any database, even with extensive data, cannot answer all questions in the field. Very often new data have to be acquired with different protocols, different channel configurations, different sampling rates, or different signal preconditioning, etc.

As biomedical signal databases are used for scientific and reference purposes, one specific aim is to obtain the best signal quality possible. Therefore, quality assurance during data acquisition is a very important task and has to follow structured guidelines. However, there is a lack of such general guidelines and often they need to be database specific at least to some extent.

Often, signal databases are created in multicenter studies. Multicenter studies require additional specifications in terms of recording equipment and protocol compatibility. Special care must be taken for continuous quality assurance during the recording period at the different sites. Site visits at all recording laboratories are a very useful method to harmonize recording conditions. Such site visits should follow a checklist of items being tracked. Although the checklist can be planned ahead of the recordings, its should be revised after the first round of recordings from each participating laboratory. This test series often reveals unforeseeable deviations from the intended protocol.

Usually, the first objective of recording biomedical data is not to make a database but to monitor or diagnose a patient, or to do research. The recorded data strongly depend on this first objective. For instance, monitoring the vital signs of a patient in acute life-threatening states or being under surgical procedures or anesthesia conditions requires online analysis and immediate visualization. This is needed to allow immediate intervention by personnel trained for such situations. When data is recorded for research or diagnosis, then immediate visualization of analyzed data is usually not required, but continuous storage of data is.

Annotations and expert scorings of the signals recorded are as important as the data itself. Only through the evaluation of

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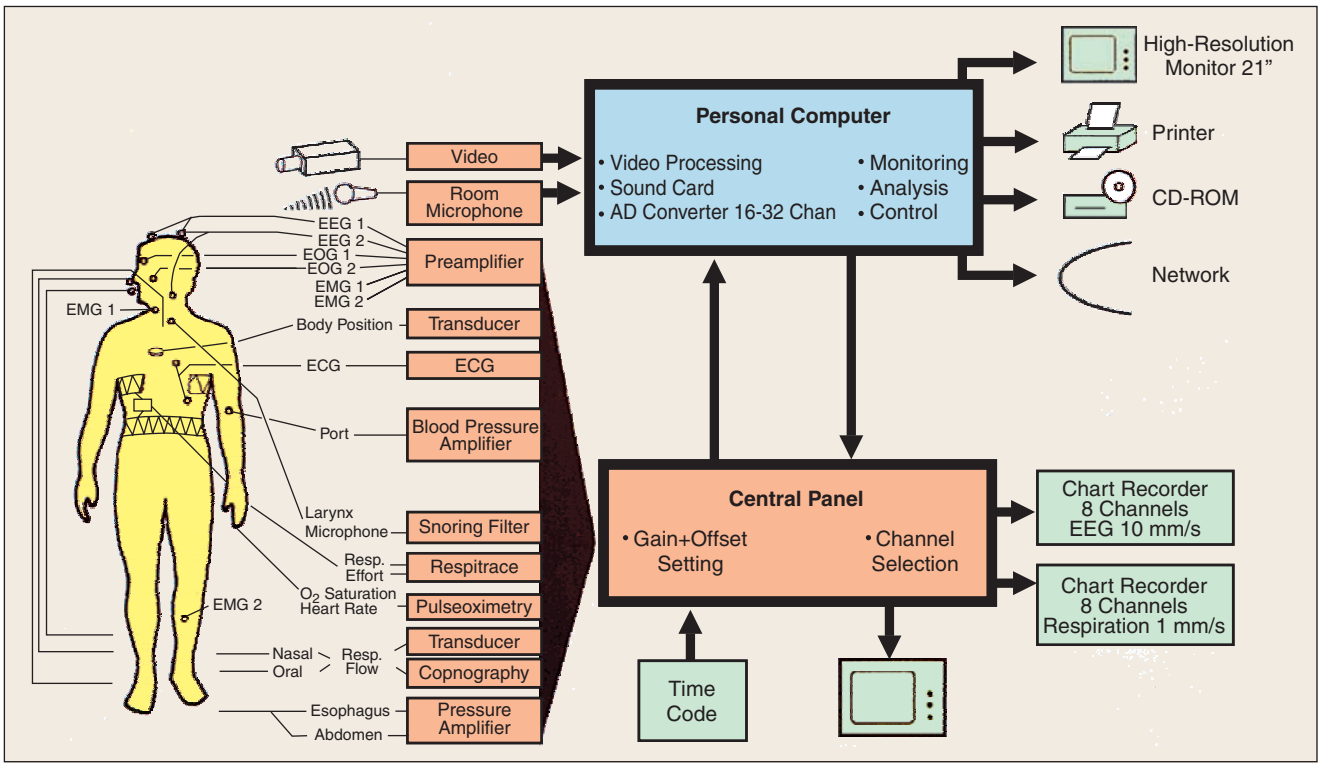
annotations a human user or a computer algorithm can learn the meaning of specific signal patterns. Therefore, annotations and visual evaluation, by experts, of the recorded signals can be regarded as the key for further signal processing and analysis [1]. Especially in complex settings such as intensive care, it is often impossible to judge on the basis of recorded data only what was really happening.

A Case Study—the SIESTA Project

As a case study for a biosignal database, the European project SIESTA is introduced here. Sleep recordings in sleep laboratories are performed in order to objectify sleep disorders after having evaluated the subjective symptoms of insomnia ("I cannot sleep") and hypersomnia ("I am always tired and I do fall asleep even when trying to stay alert"). The International Classification of Sleep Disorders (ICSD), which was developed in 1990 and revised in 1997,

Table 1: Minimal and optimal requirements for digital polysomnography as a basis for automatic sleep scoring. The digital amplitude resolution is chosen according to the measurement precision of the underlying instrument (n.a. = non applicable).

Function	Signal	Minimum Sampling Rate	Optimal Sampling Rate	Digital Resolution
Neurophysiology	Electroencephalogram Electro-oculogram Electromyogram	100 Hz 100 Hz 100 Hz	200 Hz 200 Hz 200 Hz	0.5 µV / Bit 0.5 µV / Bit 0.2 µV / Bit
Respiration	Oro-Nasal Airflow Respiratory Movements Oesophageal Pressure Capnography Oxygen Saturation Transcutaneous pO_2, pCO_2 Breathing Sounds	16 Hz 16 Hz 16 Hz 16 Hz 0.5 Hz 0.5 Hz 1 Hz	25 Hz 25 Hz 100 Hz 25 Hz 1 Hz 1 Hz 5000 Hz	n.a. n.a. 0.5 mmHg / Bit 0.1% / Bit 1 % / Bit 0.1 mmHg / Bit n.a.
Cardiovascular	ECG Heart Rate Blood Pressure	100 Hz 1 Hz 50 Hz	250 Hz 4 Hz 100 Hz	10 µV / Bit 1 bpm 1 mmHg / Bit
Auxiliary	Body Temperature Body Position	0.1 Hz 0.1 Hz	1 Hz 1 Hz	0.1 ° Celsius / Bit n.a.



1. The diagram illustrates the modules comprising a cardiorespiratory polysomnography with all necessary transducers for signals acquired during sleep studies, amplifiers, and data storage options. Paper chart writers are used for signal quality control proofing at the time of the recording.

defines 88 sleep disorders based on symptoms and findings from sleep recordings [2]. In order to objectify a diagnosis, a sleep recording must be done in a sleep laboratory. Biosignals reflecting neurophysiological, respiratory, and cardiac activities are recorded for eight to ten hours during the night. During the recording, the signals are also monitored, thus allowing the attending personnel to make notes on movements, talking during sleep, or other events being of possible relevance. These data are evaluated by sleep experts using rules developed by a committee chaired by A. Rechtschaffen and A. Kales in 1968 [3]. The rules were based on chart recordings of electroencephalography, electro-oculography, and electromyography in 30-s epochs. This visual scoring results in four non-REM (rapid eye movement) sleep stages, with 1and 2 being light sleep, 3 and 4 being deep sleep, and REM sleep. Wakefulness and body movements are also scored and noted. This scoring is still state of the art in the evaluation of polygraphic sleep recordings.

Several limitations of this paper-oriented approach became apparent in the last 30 years and did lead to multiple approaches for using computer-based sleep analysis in order to overcome the limitations [4]. The SIESTA project was initiated to acquire a large reference database of sleep recordings from healthy volunteers in different age groups and from patients with sleep disorders selected according to their prevalence. The aims of this multicenter study were:

- to develop an enhanced computer-based system for analyzing polysomnographies in a reliable, reproducible way based on a small temporal resolution and a high-amplitude resolution;
- to obtain an increased understanding of the contribution of well-defined and computed variables to sleep analysis;
- to achieve an improved description of sleep for subjects which do not fall into the categories of Rechtschaffen and Kales—e.g., elderly persons, patients with sleep disorders;
- to develop a methodology to make the new system adaptable and refinable to sleep disorders other than those already included here;
- to compile a sleep scoring manual with the definitions of the procedures and terms developed in the SIESTA project.

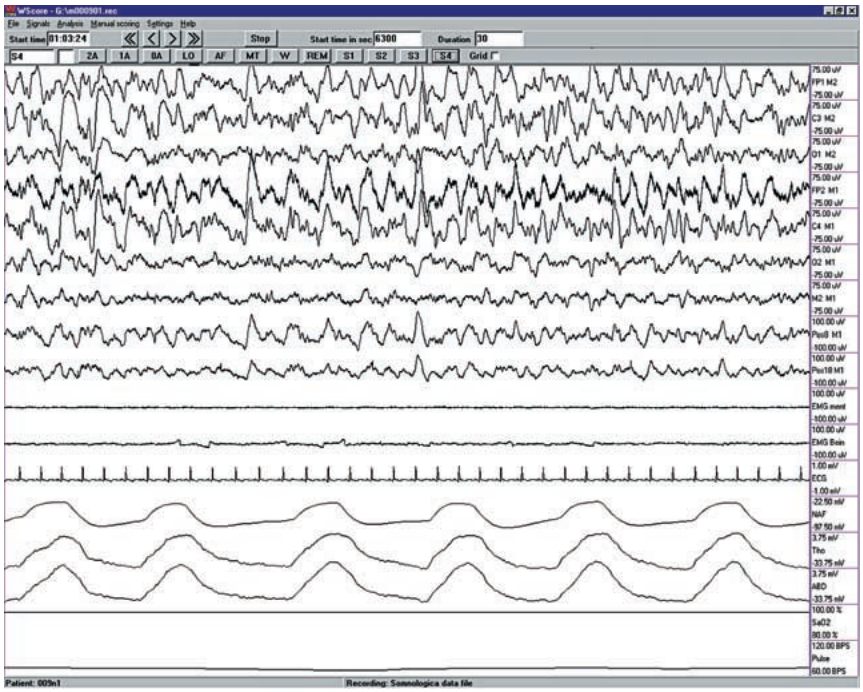
Signal Acquisition Conditions

Acquisition of raw physiological signals is highly dependent on the settings of amplification and filtering. This affects signal-to-noise ratio for the information obtained. Despite similar settings, the resulting signals recorded by equipment from different manufacturers often differ. This is due to different implementation of sensors, amplifiers, and filters by different manufacturers. Signal-to-noise ratio in low-voltage signals such as brain waves is especially sensitive to the implementation of amplifiers and the circuits chosen. Therefore, the resulting data are device dependent and the device specification has to be documented with the data.

As different signal channels are interpreted together, the inter-signal synchronization is also important and must be thought of when selecting the recording equipment (or the analog-digital converters) used throughout the study. Inter-signal synchronization becomes a serious problem when different data are recorded using different devices with independent clocks to different data files. This is the case in sleep recordings and parallel activity recording using a wrist-worn actigraph. In intensive care it is a regular scenario to record data with different devices in parallel. One has to guarantee that the start time matches and one has to correct for a drift between clock rates of the devices.

Sampling rates must be chosen in such a way that the requirements of subsequent analysis are covered [5]. The specifications as they were applied for polysomnographic recordings and as they were used in the SIESTA project are presented in Table 1. The different biomedical device modules needed for polysomnography are depicted in Fig. 1. Once all conditions are set, different recording sites were free to use their own equipment for the study. In the SIESTA project, minimal sampling rates and the filter settings for all physiological data were fixed. Due to the different equipment being in use in the different laboratories, different sampling rates were accepted. Processing of the signals using the different sampling rate was done using two approaches. For many analysis methods applied, resampling of the raw signals was performed to come up with the agreed minimum sampling rate of 100 Hz. In the case of QRS detection in the ECG, the original sampling rate was preserved and the analysis was adapted to the conversion rates 100 Hz, 128 Hz, 200 Hz, 250 Hz, 256 Hz, and 400 Hz, respectively.

It became also clear that the influence of sensors and transducers was important in respiration and oxygen saturation re-



2. Visual evaluation of biosignals of a sleep recording is performed using segments of 30 s. Sleep stages are classified based on the patterns, and then one of the buttons (each corresponding to a sleep stage) is activated. Here a signal data viewer is presented that was developed for EDF data used in the SIESTA project.

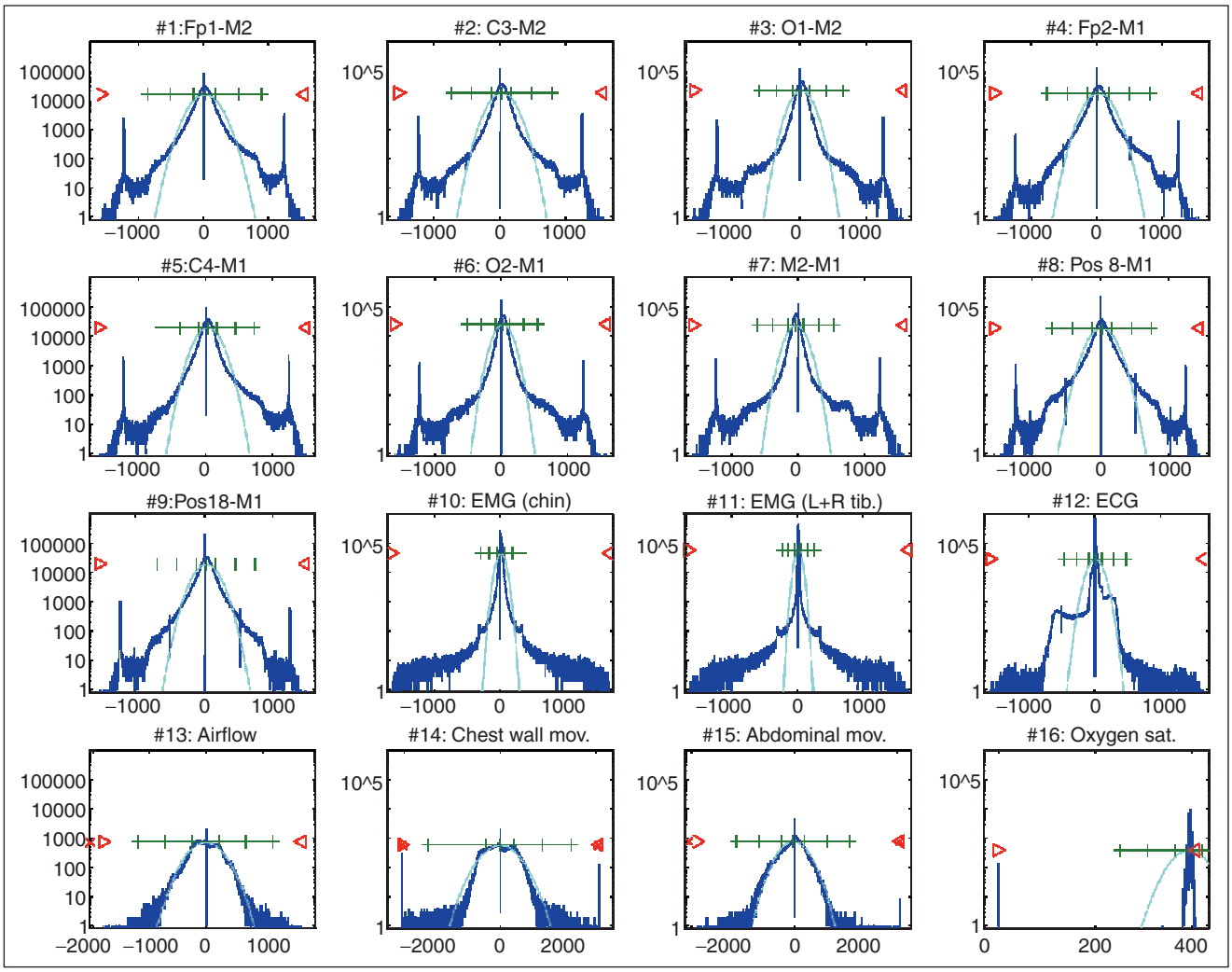
cording. For respiratory movement recording, piezo transducers of different kinds, pneumatic belts, and inductive plethysmography were used. The resulting waveforms had different signal characteristics, so that no uniform analysis of respiration could be implemented. For respiratory flow, different kinds of thermistors and thermocouples were used. The differences between the resulting waveforms were smaller than the differences found in respiratory movement signals.

For oxygen saturation, pulse oximetry devices from different manufacturers were used. The devices were modules partially integrated in the polysomnographic recording equipment itself. Pulse oximeters use different settings for the averaging of pulses and different algorithms when calculating oxygen saturation, based on backscattered or transmitted light in several wavelengths. The signal recorded is not the raw signal but the result of a first algorithm involved in feature extraction. These types of algorithms are an inherent part of the database. Care must be taken when the database contains signals acquired with various devices that may use different algorithms. Practically, it was not possible to assure that all recording sites did use the same preprocessing algorithm with their oximeters. In consequence, a careful documentation of the type and version of oximeters was required.

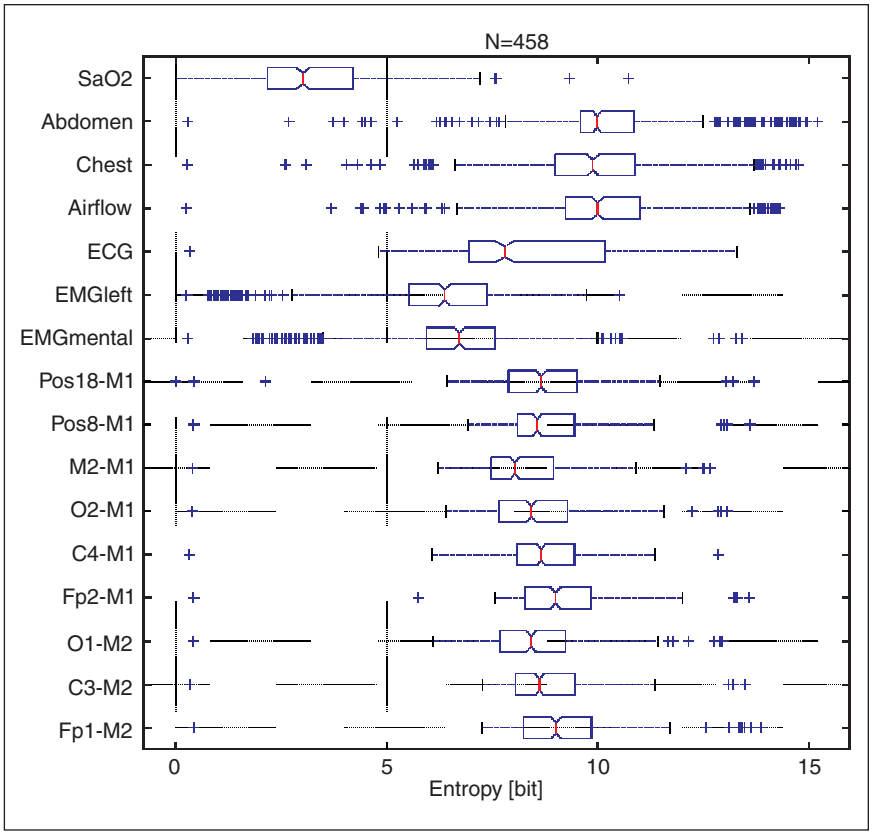
Algorithms that make use of the recorded signals, such as an automatic sleep staging, are not an inherent part of the database, and therefore it is not compulsory to include such algorithms in the database.

Database Structures

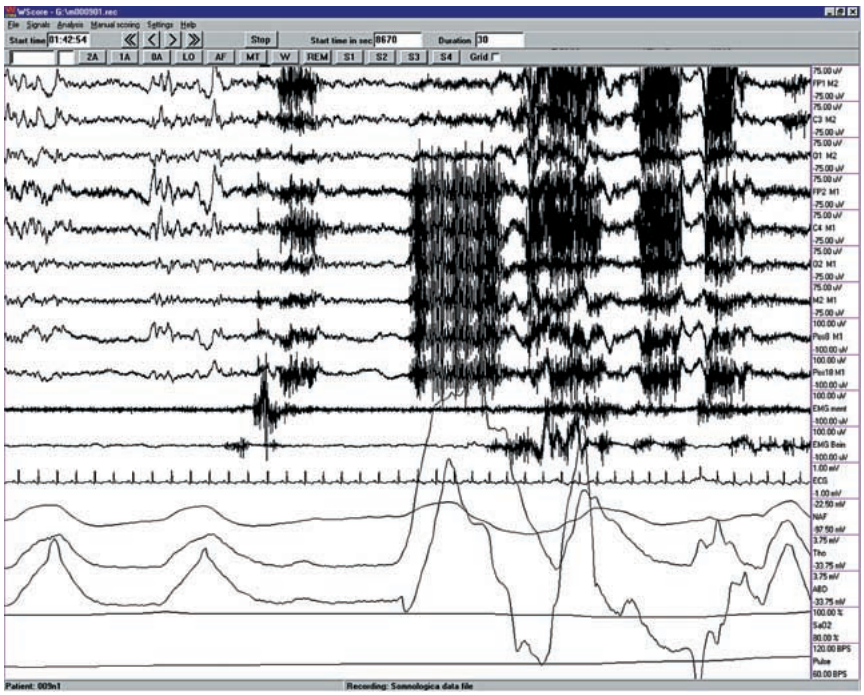
In order to have a systematic access to the recorded signals and the annotations, rules were settled in the study protocol, with minimum criteria for the signals recorded by all partners in a multicenter study. In the SIESTA project all signals were either directly recorded using the European Data Format (EDF) or they were converted into the EDF format after using the locally available equipment [6, 7]. One single file containing the continuously recorded signals was produced per sleep recording. Filename conventions specified the recording site, the running number of the subject, and the number of the night being recorded (either 1 or 2). The order of the signals in the file was also specified and it was agreed that the first 16



3. Histograms of 16 channels (7 EEG, 2 EOG, 2 EMG, 1 ECG, 3 respiration, 1 oxygen saturation) from one polygraphic recording in logarithmic scale. The horizontal line and the vertical markers (green) indicate the mean μ ±1,3,5 times of the standard deviation (μ ±1,3,5*σ); the left and right triangles indicate the maximum and minimum value; the light (blue) parabolic line indicates the Gaussian distribution with the same *N*, μ and σ^2; cross markers (x) indicate the digital minimum and maximum values as provided in the EDF header information.



4. Box-whisker-plot of entropy values of polygraphic recordings. The boxes indicate the 0.25 and 0.75 quantile, and the whiskers indicate the 1.5 inter-quantile range (IQR). The polygraphic data was stored in EDF format [6] using 16-bit integer values. Each channel of each recording (458 in total) was calculated by the histogram and the entropy [10]. The polygraphic SIESTA database [8] was used.



5. This example of a sleep recording gives muscle artifacts and movement artifacts that are found at major transitions from one sleep stage to another one. This is accompanied by a change in body position, which is annotated in the sleep log written by the attending technicians.

signals must be arranged in that particular order to simplify access for analysis algorithms. The possible sampling rates for the different signals were specified. The filename convention was further used for accompanying files, which were used for descriptive data of all subjects and for additional test data [8].

Quality Control of Recorded Signals

In the SIESTA project, site visits were performed to check the recording conditions at the different sites. This helped in harmonizing the recording practice in the different laboratories and thereby improved comparability and overall quality of the recorded data.

Having acquired the data, quality control first checked the formal criteria of the signal database. It was advantageous here that there existed only one data file of biosignals for each recording. The first check tested the filename conventions. The second check tested the contents of the fields in the global header and the signal headers according to the EDF file format definition [6, 7]. The fields were checked in terms of correct characters in the various places. The order of signals was checked by investigating the labels written in the signal headers. The allowed set of labels was defined in the study protocol of the SIESTA project. When the entries of all header fields were checked, deviations from the strict definitions for the contents were found regularly. Some typing errors could be corrected automatically whereas others, such as a shuffled order of signal channels, needs visual inspection prior to corrections.

If the contents of the file headers were correct, but the data itself were shuffled within one signal channel, this could become obvious when checking signal properties automatically. This was the third step in checking the data files.

The digitized recordings were tested automatically using a histogram analysis in order to identify technical failures and artifacts. The bin-width of the histograms was chosen to be the quantization of the analog-digital converter (ADC). In case of 16-bit signed integer numbers, as used in the EDF format, the histogram $H(i)$ has bins in the range $-32768 \le i \le 32767$.

When the total number of samples N goes to infinity, the normalized histogram is the probability distribution $p(i)$. For large N, the probability distribution may be approximated by the normalized histogram:

$$\hat{p}(i) = \frac{H(i)}{N} \tag{1}$$

and the entropy of information I [9] in binary digits (bits) is defined as:

$$I = \sum_i p(i) \log_2 p(i). \tag{2}$$

The mean μ, variance σ^2, and the standard deviation σ can be obtained from the histogram $H(i)$:

$$\mu = \sum_i i\, p(i) \rightarrow \hat{\mu} = \frac{1}{N} \sum_i i\, H(i) \tag{3}$$

$$\hat{\sigma}^2 = \frac{1}{N} \sum_i (i - \hat{\mu})^2 H(i). \tag{4}$$

The results of the quality control are given as an example in Fig. 3. This shows the histograms of 16 channels from one polygraphic all-night sleep recording stored in EDF format [6]. For each channel, the header information contained a digital minimum and maximum of –2048 and +2047, respectively. Hence, a 12-bit ADC was used. The "sidelobes" of the histogram are clipping peaks due to saturation of the input. It can be caused by a limited dynamic range of the input amplifier and/or the ADC. The "smearing" of the peaks is probably due to digital filter or a temperature drift of the dynamic range of the input amplifier. Several channels show also a peak at the value zero.

Figure 4 shows that the entropy of the signal channels is most often between 7 and 11 bits. Only the oxygen saturation shows a median value of 3 bits. This indicates that the quantization resolution is low. Pulse oximeters theoretically produce digital-analog converted values between 0% and 100% saturation with steps of 1%. During the recordings of our subjects the range of values was found to be much lower due to oxygen saturation being in normal ranges, and this results in the very low entropy.

Unfortunately, the saturation values of the input amplifiers and the ADC used are often not specified with the signal data [10]. This lack of information makes it difficult to perform an automated quality control using an overflow check for the signals. In order to overcome this difficulty, it is recommended that the initial saturation values are stored together with the data.

The final check of the signal quality is the visual inspection of the signals by an expert (Fig. 5). During the inspection phase, quality-related annotations can be added to the database. Signal artifacts and biological artifacts are noted. Polygraphic recordings may be superimposed by many different types of noncortical sources. In order to describe the sleep process, these noncortical sources must be removed, or at least detected. For a systematic evaluation of various artifact processing methods, 90-minute segments out of 15 randomly selected sleep recordings were visually analyzed and annotated. Nine types of artifacts (EOG, ECG, muscle, movement, failing electrode, sweat, 50 Hz, breathing, pulse) were visually identified, resulting in a total of 563192 1-s epochs. Different artifact detection methods (least mean squares algorithm, regression analysis, independent component and principal component analysis, etc.), which are able to remove technical and signal artifacts, were tested on the selected set of recordings with the annotated artifacts (Table 2). After validating different artifact processing algorithms [11], adaptive FIR filtering, regression analysis, and template removal were recommended to minimize the ECG interference, 50-Hz notch filtering for minimizing the line interference, adaptive inverse filtering for muscle and movement detection, and combined overflow and flat line detector for failing electrode artifacts (Fig. 6).

Archiving Considerations

Signal data need storage space. Luckily, digital storage space becomes less expensive and more condensed in terms of physical volume dimensions. Using the signal specifications given in Table 1, a digital recording of one night of sleep with 16 channels being recorded for eight to ten hours requires approximately 130 MB of digital memory. A recordable CD-ROM can hold four recordings of this size. Sleep recordings require two consecutive nights with recording of all signals. The first night is called "adaptation night" and is examined to investigate the "first-night effect" compared to the second recorded night. Often subjects need

Table 2. Possible artifacts in the EEG signal. The methods to detect and remove these and the solution chosen within the SIESTA project. (ICA = independent component analysis, PCA = principal component analysis)

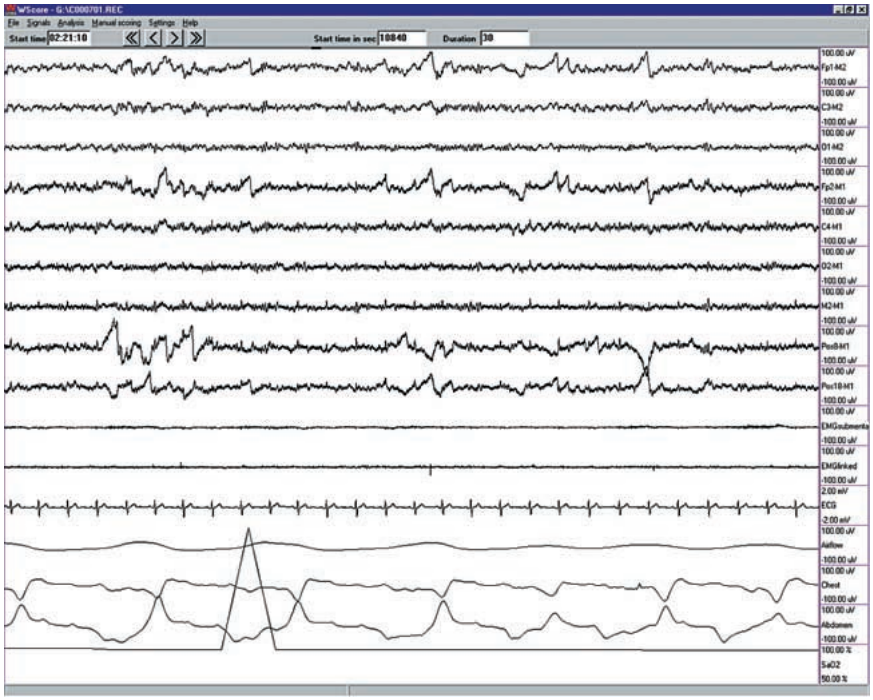
Artifact	Detection and Removing	Solution Chosen
EOG	Regression Analysis, PCA, ICA	Minimizing
ECG	Regression Analysis, PCA, ICA, Template Removal	Minimizing
Muscle Activity	Adaptive Inverse Filtering	Detect and Mark Data
Movement	Adaptive inverse filtering, overflow check	Detect and Mark Data
Failing Electrodes	Detect Typical Step Function with Exponential Decay, Combined Overflow and Flat Line Detector	detect and mark data
Sweating	High-Pass Filtering	None
50 Hz interference	Notch Filter	Off-Line Filter
Breathing	Not Important for EEG	No Action
Pulse	Cross Correlation in Time, (did not appear in the SIESTA artifact database [11])	—

one night to become comfortable with the recording equipment attached to their head and body. In order to evaluate the difference, both recorded nights need to be stored. Thus, recordings from two subjects will fit on one CD-ROM. The database of sleep recordings set up by the SIESTA project consists of 200 healthy volunteers and 100 patients with selected sleep disorders. This sums up to approximately 150 CD-ROMs, which in consequence require some physical space. Today, hard-disk capacities increase rapidly, but the ~100 GB needed to store the raw data recorded within the SIESTA project is still not the standard hard-disk size on desktop computers. In order to have an easy and systematic access to all data files and all information, it is favorable to set up a conventional database that keeps track of all subjects recorded and the related files. This core database holds medical information about the subjects, file information about the available data, technical errors and signal information with artifact annotations, quality annotations, and interpretation results. The large signal data files may either reside on a central server or on CD-ROMs where filename conventions are strictly followed. DVD can serve as a practical alternative to CD-ROMs in order to reduce the number of separate disks. With these rules in mind, archiving and accessing the database can be done in a convenient way.

Conclusion

When setting up a study design for the acquisition of a signal database, this has to be done on the basis of defined hypotheses with a fixed protocol. On the basis of a calculation on the number of subjects needed, the decision has to be made as to whether a multicenter study is need. For large signal databases this is usually the case. An agreement of all groups providing data must be obtained. Quality assurance in the beginning of the database collection period and during the recording is extremely important. Site visits are very useful and regular checks on signal files are necessary. The items to be checked are:

- filename consistency;
- adherence to the recording file format specification and agreed labeling conventions;
- entries in file header fields can show minor deviations and major inconsistencies;



6. The signals of this recording show a number of different artifacts. The most prominent is the artifact in oxygen saturation (the bottom-most channel)—values above 100% are not possible. This is a technical artifact. The respiratory movement channels, marked as "chest" and "abdomen" do move opposite, which indicates a inverse polarity in one of the signals. In the linked reference channel (M1-M2) and in the EOG channel (Pos8-M1) ECG artifacts are visible. In the frontal EEG channels (Fp1-M2 and Fp2-M1), EOG artifacts are very prominent. All these artifacts are neglected for visual analysis: this is a perfect sample of REM (rapid eye movement) sleep.

- saturation values should be always available in the file header information;
- entropy values calculated as automatic signal quality checks define possible compression rate and give quality indicators;
- visual inspection yields technical, signal, and biological artifacts.

The total volume of a signal database is so large that archival considerations have to be clarified in the beginning. This begins with filename conventions and ends at the specific information derived from analyzing the files in order to obtain new results for research and clinical work.

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Gerhard Klösch studied psychology and political science in Vienna. Since 1989 he has mainly been working in the field of sleep research (neurophysiology of sleep and dream research). He coordinated quality control and data management in the SIESTA project.

Alois Schlögl received his Dr. techn. degree for his PhD-thesis on "the electroencephalogram and the adaptive autoregressive model" in 2000 from the University of Technology Graz, Austria. During his Ph.D. study, he was a research assistant at the Institute of Biomedical Engineering. He was working for a project on an EEG-based Brain Computer Interface and for the SIESTA project on multicenter sleep analysis.

Joel Hasan studied medicine and computer science in Turku, Finland. He received his medical degree in 1977 and was certified as a specialist in clinical neurophysiology in 1987. He was the chief physician of clinical neurophysiology of Kanta-Häme Central Hospital from 1987-89, has been the staff neurophysiologist of the University Hospital of Tampere since 1990, and head of the Department of Clinical Neurophysiology since 1997. He has written more than 50 international and national papers, including book chapters. The main emphasis of his scientific work is computer analysis of sleep recordings. He has participated in the European research projects ComacBME and SIESTA.

Alpo Värri received the M.Sc. in electrical engineering in 1986 and the Dr.Tech. degree in signal processing in 1992, both from the Tampere University of Technology, Finland. Currently, he is a senior researcher and the vice head of the Signal Processing Laboratory of Tampere University of Technology. Since 1994 he has participated in health informatics standardization within CEN/TC251. His research interests include biomedical signal processing, particularly in sleep research and computer programming.

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