13 Biosignal Monitoring and Recording

Thomas Penzel[1], *Karl Kesper*[1], *Heinrich F. Becker*[1]

[1] Department for Internal Medicine, University Hospital of Philipps-University, Marburg, Germany

Biosignal monitoring and recording is the extension of medical investigations taking into consideration the development over time. The usual practice for medical tests is the investigation at one particular time point when the physician sees the patient. Besides the clinical interview the physician checks the pulse, measures blood pressure, takes a blood sample and sometimes urinary sample, and perhaps also measures body temperature and sweating. This collected information is used to develop a diagnosis or if it is not sufficient, to request more investigations. The additional investigations are in many cases functional tests or image-producing examinations. Such examinations can be radiology or ultrasound investigations or endoscopic or angiographic investigations. Functional investigations being requested can be electrocardiography, lung function test or a physical stress test. All these investigations are really point measures even if they involve image generation or a functional test over a short period of time. These point measures are used to generate a medical diagnosis. Based on the diagnosis the physician tries to predict changes over time (e.g. development of a disease or a treatment outcome). In order to verify these predicted changes often a second or a third investigation follows after a couple of days or weeks, again being point measures in essence. This type of measurement is always restricted to a few time points (Figure 13-1).

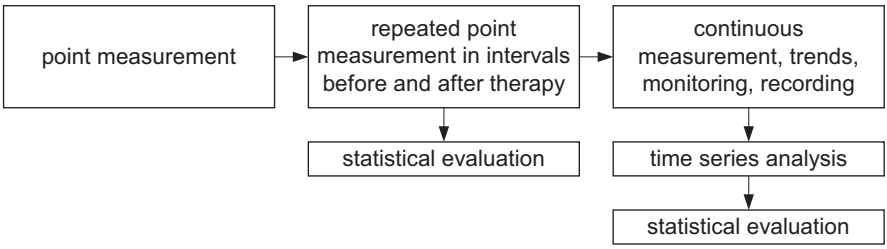

Figure 13-1 Biosignal monitoring and recording marks the move from point measurements to continuous measurement in terms of time. Thus biosignal monitoring means time series analysis in the medical field.

By its nature it cannot give any conclusion about the dynamic behavior of physiological systems. Functional tests are the only and still limited approach to dynamic behavior. To extend the investigations of physiological variables in the time domain is the primary aim of biosignal acquisition or in other terms time series analysis in medicine. By this approach a better understanding of physiological control systems can be achieved. Predictions can be improved by considering the dynamic behavior of physiological regulation.

1 Basics of Monitoring and Recording

During the last few decades biosignal monitoring and recording became essential in many areas of modern medical services. This reflects the recognition of the importance of physiological control systems. The best known case for biosignal monitoring is electrocardiography (ECG). ECG has certainly the longest tradition in biosignal monitoring and recording because it is a strong (amplitude near 1 mV) and relatively robust signal [14]. Electrocardiography can be monitored for diagnostic purposes in a general physician's office with relatively simple and inexpensive devices. It may be recorded with 6 or 12 leads by a cardiologist for a comprehensive diagnosis of specific heart problems (e.g. signs of ischemia or heart attack). This type of ECG is still time limited and it may last a couple of minutes only. This examination can be regarded as a functional investigation which still represents a point measure based on a limited time segment of the continuous signals. In addition to this category of point measures based on functional investigations the ECG may be recorded over much longer periods of time (e.g. 24 hours) in order to detect and possibly explain arrhythmias. This long-term recording allows one to investigate dynamic properties and regulation mechanisms of heart rate for at least one 24-hour period. A 24-hour period is often chosen to obtain information on the circadian changes and the changes observed during sleep compared to daytime activities. Some ECG problems may become manifest only during the sleep period.

In another completely different category of investigations the ECG may be monitored in an operating room or under anesthesia as the primary vital sign to judge patient condition for the attending physician. In this case the continuous monitoring and an optional alarm management is most important. An immediate diagnosis related to the ECG is not done and a recording with permanent storage of the signal is usually not required.

Biosignal recording in medicine is not only restricted to the ECG (Figure 13-2). It includes blood pressure, respiration, electroencephalography (EEG), gastrointestinal variables, and many other parameters [8]. In general biosignals may be derived either from electrical body sources with appropriate amplification (nerves, muscles) or through specific transducers (pressure, flow, tension) which may be simple (piezo elements) or rather sophisticated signal processing systems in (oxygen saturation) themselves.

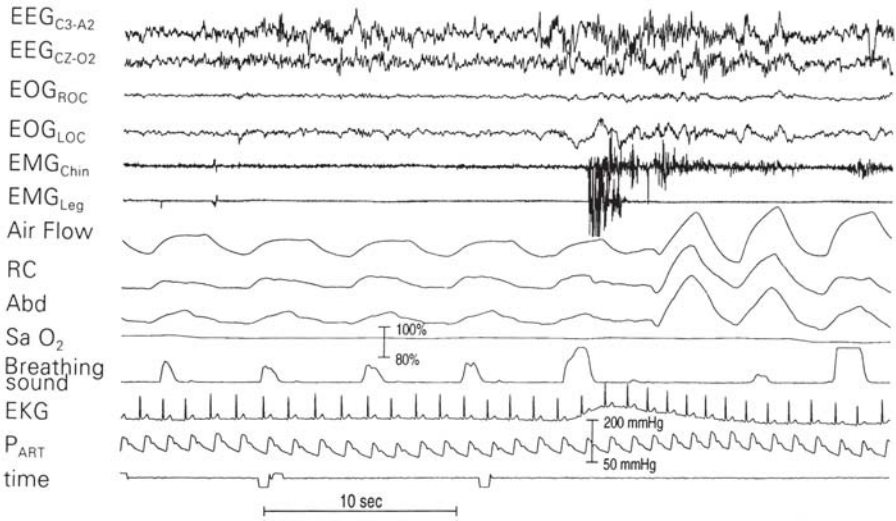

Figure 13-2 The recording of many different physiological parameters is required in several medical settings. This recording example with a multi-parameter recording was acquired in a sleep laboratory. The figure presents a 30-second segment of digital recorded data.

Biosignals may be monitored in acute and intensive care environments or recorded (stored for later analysis) for diagnostic purposes [5]. Applications using the recording of biosignals did increase much in recent years based on the technical possibilities provided by miniaturized and powerful digital recording and processing equipment. The recording of biosignals is now regularly done for diagnostic procedures in cardiology (ECG, blood pressure) and in neurology/neurophysiology (EEG, EMG). Specialty sleep medicine particularly

requires the recording of multiple biosignals from different physiological systems (brain, heart, circulation, respiration) due to its interdisciplinary approach [7]. The recording methodology in this context is called cardiorespiratory polysomnography (Figure 13-3).

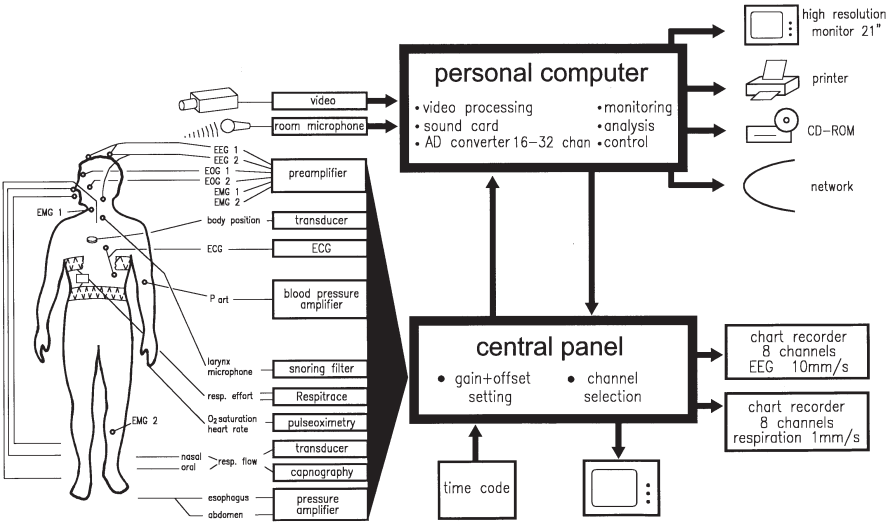

Figure 13-3 Multi-parameter biosignal recording is performed in a sleep laboratory or a neurophysiological laboratory. This includes many options for different signals. All signals are stored digitally by a personal computer. The interface to the amplifiers is usually given through an application software, here denoted as "central panel". Paper chart writers may be used for monitoring purposes and documentation at the same time. For later processing and archiving the possibilities of network access and CD-ROM writing are essential.

The biosignals need careful interpretation by well trained experts in their specific fields of medicine. Thus annotations and expert scorings of the signals recorded are as important as the raw digital data itself. Only through the evaluation of annotations can a human user or a computer algorithm learn the meaning of specific signal patterns. Therefore annotations and visual evaluation as assigned by experts to the recorded signals can be regarded as the key for further signal processing and analysis. Especially in complex settings such as intensive care it is often impossible to judge on the basis of recorded data only without explanatory annotations on recording conditions and actual medical interventions.

2 Signal Acquisition Conditions

Primary focus has to be given to the type of signal derived. Several signals are of electrophysiological origin and are electric by nature (e.g. ECG, EEG). These signals need careful amplification and filtering in order to obtain them with a minimum of artifacts. Other signals need transducers which are close to the physiological variable to be studied (flow, force, tension, movement, biochemical components). The transducers should have high signal-to-noise ratio and should be efficient in terms of power consumption. If possible sensors should be placed non-invasively on the skin. This issue implies the aspect of single or multiple use sensors as well as sterilization issues for the sensor.

All acquisition of raw physiological signals is dependent on the settings of amplification and filtering. This determines 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 specific circuits chosen. Therefore the resulting data are often 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 even 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. This is the case in sleep recordings and parallel recording of long-term ECG, long-term blood pressure, or activity using a wrist-worn actigraph. In intensive care it is very common to record data with different devices in parallel. Besides the bedside vital signs monitor this may be a ventilator, infusion pumps, and a fluid management system. For exact evaluations one has to guarantee that the start time of the different devices matches and one has to correct for a drift between clock rates of the devices. Differences of one minute over a 24-hour period are commonly observed. For normal clinical service this time shift is not important but for scientific studies looking for causal relationships this is important.

Sampling rates must be chosen in such a way that the signals can be reproduced in sufficient quality and that the requirements of subsequent signal analysis are covered. The specifications are appropriate for intensive care, cardiology, neurology and for polysomnographic recordings are presented in Table 13-1.

Table 13-1 Requirements for digital biosignal recording are specified for some major areas of monitoring and recording. The digital amplitude resolution is chosen according to the measurement precision of the underlying instrument (n. a. = not applicable) [7].

function	signal	optimal sampling rate	digital resolution
neurophysiology	electroencephalogram	200 Hz	0.5 μV/bit
	electrooculogram	200 Hz	0.5 μV/bit
	electromyogram	200 Hz	0.2 μV/bit
respiration	oro-nasal airflow	25 Hz	n.a.
	respiratory movements	25 Hz	n.a.
	esophageal pressure	100 Hz	0.5 mmHg/bit
	capnography	25 Hz	0.1%/bit
	oxygen saturation	1 Hz	1 %/bit
	transcutaneous pO_2, pCO_2	1 Hz	0.1 mmHg/bit
	breathing and lung sounds	5000 Hz	n.a.
cardiovascular	ECG	250 Hz	10 μV/bit
	heart rate	4 Hz	1 bpm
	blood pressure	100 Hz	1 mmHg/bit
auxiliary	body temperature	1 Hz	0.1 ° C/bit
	body position	1 Hz	n.a.
	esophageal pH	1 Hz	0.1 pH/bit

It has to be considered that the sensor and transducer specific characteristics are very important in respiration recording if subsequent comparisons of analysis results are made. The gold standard methodology consists of pneumotachography for quantitative airflow and esophageal pressure for quantitative respiratory effort. Both methods pose some discomfort on the patient and for long-term recording less intrusive and semi-quantitative methods are preferred. For respiratory movement recording, piezo transducers, pneumatic belts, impedance and inductive plethysmography are used as alternatives. The resulting waveforms have completely different signal characteristics, so that no uniform analysis of respiration can be implemented. For respiratory airflow different kind of thermistors, thermocouples and nasal pressure sensors are in use. The pressure sensors deliver a signal which has a quadratic relation to actual airflow. This must be corrected prior to further

analysis. Thereafter the differences between the resulting waveforms are smaller than the differences found for respiratory movement signals.

For oxygen saturation pulse oximetry devices from different manufacturers were used. Pulse oximeters use different settings for the averaging of pulses and different algorithms when calculating oxygen saturation, based on reflected or transmitted light in several wavelengths. The signal finally recorded is not the raw signal used by the oximeter but the result of a signal processing algorithm used in feature extraction.

3 Signal Processing Algorithms

The application of signal processing methods and the development of new methods is one of the most important tasks in biosignal monitoring and recording. Signal processing methods have been developed to extract heart rate from the ECG, to detect and to classify arrhythmias, and to derive more information such as respiration, physical and mental stress signs [14]. Signal processing may help to derive a medical diagnosis or may help to simplify the monitoring task during anesthesia by giving alarms in case of abnormalities of the ECG waveform or of the heart rate as the result of a real-time analysis. Biosignal monitoring is therefore the application of general methods developed for time series analysis and signal processing to the biological and specifically to the medical field.

Biosignal processing implies filtering of the digital acquired signals and continues with feature extraction in the time domain and the frequency domain. New algorithms apply concepts derived from statistical physics in order to detect and characterize non-linear processes underlying the physiological variations [6]. Again the ECG and heart rate play a pioneering role in applications of biosignal processing [1]. Many of the methods are also applied to EEG signals and in recent years to more signals mentioned earlier.

The analysis of the heart rate is often done using frequency domain methods. Fourier transform and alternative methods to estimate spectral power had been applied and specific frequencies had been identified as reflecting physiological information. The low-frequency component (0.04 – 0.15 Hz) of the heart rate power spectrum has been attributed to baroreflex sympathetic control of blood pressure. The high-frequency component (0.15 – 0.4 Hz) has been attributed to the respiratory rhythm and is believed to be related to parasympathetic control of heart rate [1], [13]. The very low frequency component (< 0.04 Hz) has not been related to physiological rhythms with much success. There are still different hypotheses to be tested. Some parts of these very low frequency components are related to specific disorders, such as obstructive sleep apnea

characterized by respiratory cessations with a one-minute rhythmicity during sleep. The identification of this specific rhythm can be used as a diagnostic approach for a disorder having its causes in sleep and respiration [10]. In this case the analysis of heart rate can serve as an indirect diagnostic tool based on signals much easier recorded than sleep and respiration itself (Figure 13-4).

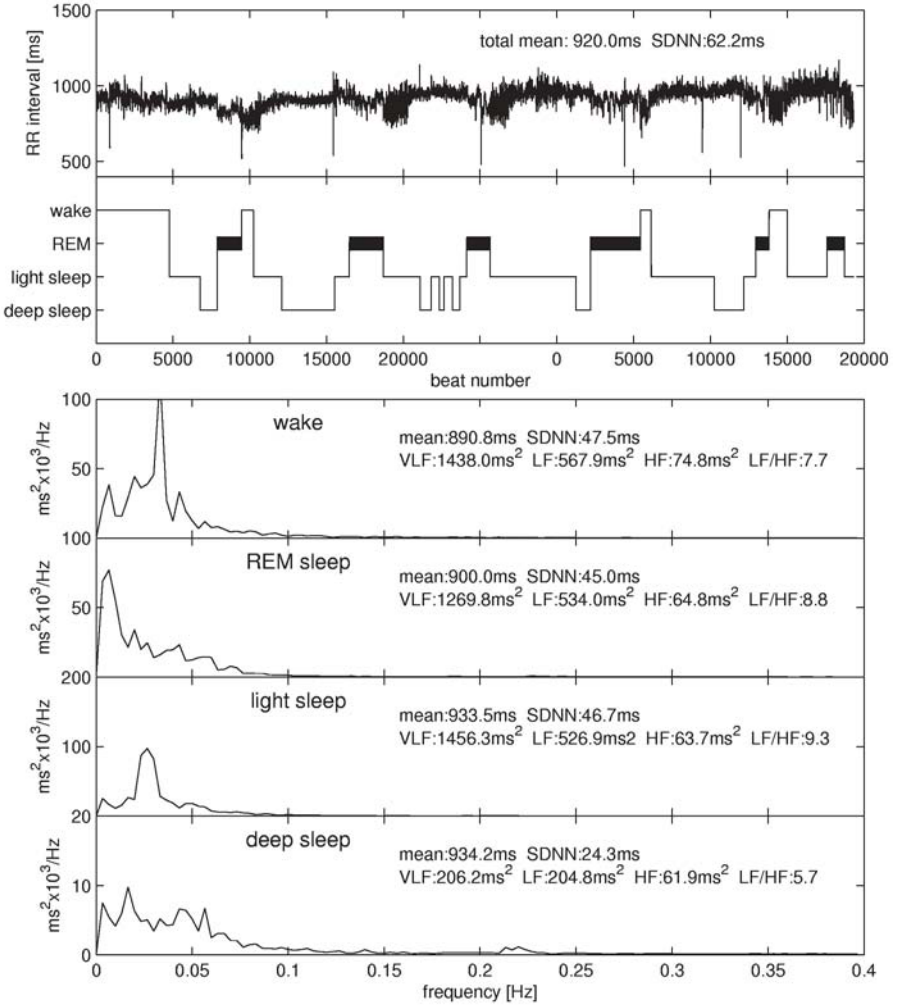

Figure 13-4 A frequency analysis of heart rate variability can help to identify a specific sleep disorder known as sleep apnea. This disorder is characterized by respiratory cessions with a one-minute periodicity. This periodicity is found in the power spectra of heart rate again. To apply the power spectra successfully it is necessary to analyze heart rate for the different sleep stages separately [10].

Statistical physics methods start with the assumption of random processes and underlying processes controlling the random behavior. These underlying processes may influence the correlation within the time series. Correlation within a time series is also investigated using autocorrelation analysis. But biological time series often bear additional influences over short or long terms which can be denoted as trends [12]. A detrended fluctuation analysis can first remove the trends and then investigate the correlation behavior within the time series [6]. This was done for heart rate time series again [6].This type of analysis could reveal that one important contribution to correlation behavior during sleep are the different sleep stages [2]. This uncovered that the different sleep stages really go along with different regulation of the physiological functions. These differences are so characteristic that they are now used to differentiate the sleep stages based on heart rate analysis. This approach marks the transition from data analysis to models and then a prediction of physiological regulation. The prediction in this case still needs validation studies in order to show that it is reliable under well described conditions.

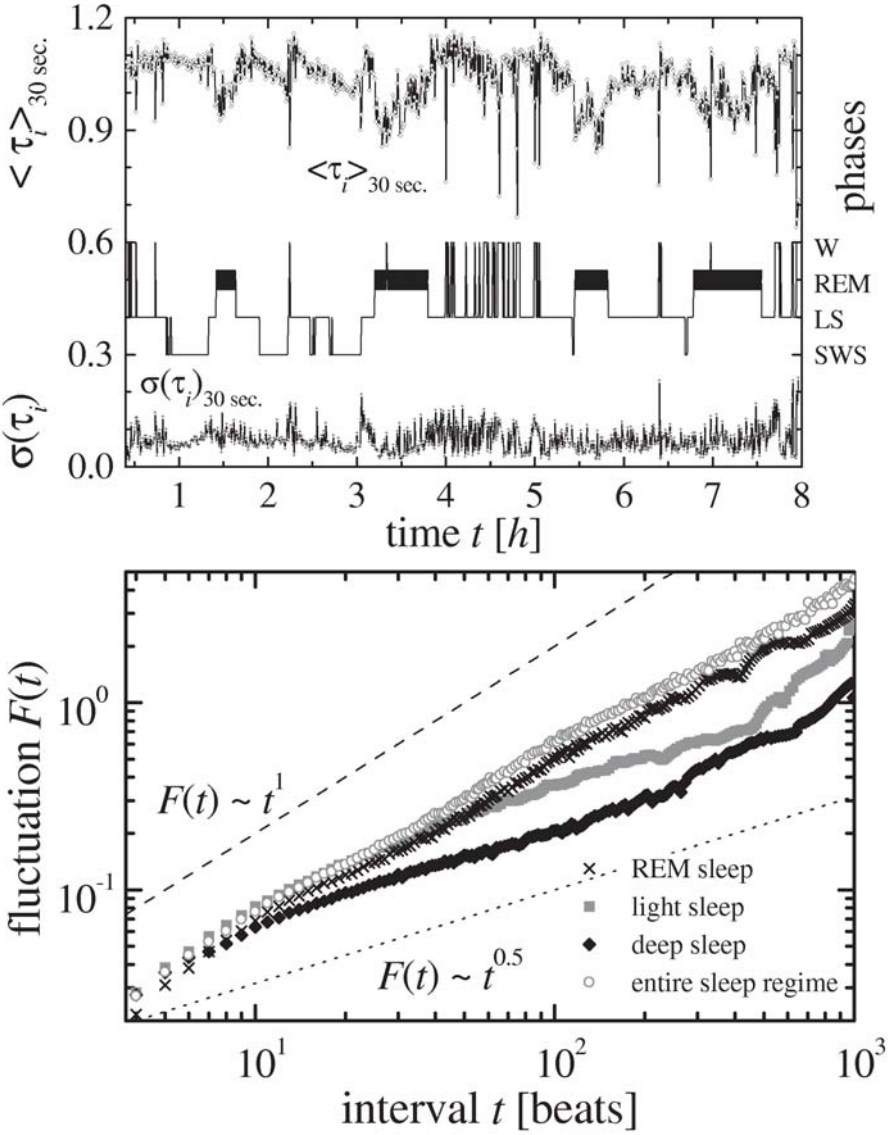

Figure 13-5 A correlation analysis of heart rate fluctuations reveals completely different beat-to-beat correlation for the different sleep stages. This difference is consistent over a wide range of heart beats and therefore is regarded as a reliable finding [2].

4 Multi-parameter Biosignal Database

As a case study for a biosignal database the European project SIESTA is introduced here [4], [9]. 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"). In order to objectify a sleep disorder diagnosis a sleep recording must be done in a sleep laboratory. Biosignals reflecting neurophysiological, respiratory and cardiac activities are recorded for 8-10 hours during the night. During the recording, the signals are also monitored, thus allowing the attending personnel to take notes on movements, talking during sleep or other events being of possible relevance. After recording the raw data are evaluated by sleep experts using rules developed by a committee chaired by A. Rechtschaffen and A. Kales in 1968. These traditional rules are based on chart recordings of electroencephalography, electrooculography and electromyography in 30-second epochs. This visual scoring of sleep signals results in four non-REM (rapid eye movement) sleep stages 1 and 2 being light sleep, 3 and 4 being deep sleep, and REM sleep. Wakefulness and body movements are also scored and noted. This visual scoring is still state of the art in the evaluation of polygraphic sleep recordings today. Several limitations of this traditional paper-oriented approach became apparent in the last 30 years and led to multiple approaches to use computer-based sleep analysis in order to overcome the limitations. The SIESTA project was initiated in 1997 to acquire a large reference database of sleep recordings from healthy volunteers covering different age groups and also patients with sleep disorders selected according to their highest prevalence [4]. The aims of this multi-center 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 that do not fall into the categories of Rechtschaffen and Kales – e.g. elderly persons, patients with sleep disorders,
- to compile a sleep scoring manual with the definitions of the procedures and terms developed in the SIESTA project.

5 Biosignal Database Quality

In order to have a systematic access to recorded signals and the annotations, rules were settled in the study protocol, with minimum criteria for the signals recorded by all partners in a multi-center study. In the SIESTA project all signals were either directly recorded using the EDF format or they were converted into the EDF format with the local equipment [3], [15]. One file containing the continuously recorded signals was produced per sleep recording.

Having acquired the data, a thorough quality control first checked the formal criteria of the signal database [11]. It was advantageous that only one data file of biosignals for each recording had to be checked. The check tested the contents of the fields in the global header and the signal headers according to the EDF file format definition. The fields were checked in terms of correct characters and the order of signals was checked by interpreting the labels in the signal headers. The set of labels was previously defined in the study protocol of the SIESTA project. Some typing errors could be corrected automatically whereas others such as a shuffled order of signal channels needed visual inspection prior to corrections.

The digitized raw signals were tested using a histogram analysis in order to identify signal characteristics, 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 a 16-bit signed integer number, as used in the EDF format, the histogram H(i) had bins in the range $-32768 \leq i \leq 32767$.

The final check of the signal quality is the visual inspection of the signals by an expert. During the inspection phase quality related annotations can be added to the database. Signal artifacts and biological artifacts were noted. Polygraphic recordings may be superimposed by many different types of non-cortical sources. In order to describe the sleep process, these non-cortical sources must be removed, or at least detected. Nine types of artifacts (EOG, ECG, muscle, movement, failing electrode, sweat, 50 Hz, breathing, pulse) were visually identified. Different artifact detection methods (least mean squares algorithm, regression analysis, independent component and principal component analysis, etc.) are able to remove technical and signal artifacts. They were tested on recordings with the annotated artifacts. After validating different artifact processing algorithms, 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.

6 Biosignal Archiving Considerations

Signal data need storage space. Digital storage space becomes low in terms of cost and is also more condensed in terms of physical volume dimensions. Using the signal specifications given in Table 13-1 a digital recording of one night of sleep with 16 channels being recorded for eight to ten hours requires approximately 130 megabytes of digital memory. A recordable CD-ROM can hold four recordings of this size. The database of sleep recordings produced by the SIESTA project consists of 200 healthy volunteers and 100 patients with selected sleep disorders [4]. Each subject was recorded for two nights resulting in 600 recordings. This equals approx. 150 CD-ROMs. In order to have an easy and systematic access to all data files and all information a database which holds all data recorded and the related files was installed. The database holds all medical information on the subjects, file information about the available data, technical reports and signal information with artifact annotations, quality annotations and interpretation results. The database with the large signal data files resides on a central server. Today DVDs are an alternative to CD-ROMs in order to reduce the number of separate disks. With these technical advances archiving and accessing a database of biosignals can be done in a convenient way.

7 Summary

Biosignal monitoring and recording are an integral part of medical diagnosis and treatment control mechanism. These methods mark the transition from point oriented measures to continuous measures in medicine. This transition is much more appropriate to the dynamics of physiological regulation in health and disease. Modern approaches for sensor technology, for new analysis algorithms and for database technologies help to move this emerging area forward. Technical advances originating in computer technology, in consumer electronics and microtechnology can support these technological advances.

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