HUMAN BIOVIBRATIONS METHOD

This patent application is a continuation-in-part application of PCT Application Number PCT/US2007/008219 filed on Apr. 2, 2007 and published in the English language on May 2, 2008. PCT Application Number PCT/US2007/008219 claims the benefit of U.S. provisional patent application No. 60/788,759 filed on Apr. 1, 2006.

I. FIELD OF THE INVENTION

This invention relates to the detection of human biovibrations using a digital signal processing (DSP) actigraph worn by the individual. Human biovibrations result from the human body having reverberations and oscillations from bodily functioning. The DSP actigraph has been shown to be able to identify heart beat and breathing of an individual.

II. BACKGROUND OF THE INVENTION

Actigraphy was originally developed in the 1920s to objectively measure and quantify sleep based on body movements. The first such study was performed in 1922 by Szymansky, who constructed a device that was sensitive to the gross body movements of subjects as they lay in bed. Szymansky J S, *Aktivitaet und ruhe bei den menschen*, Z Angew Psychol 1922; 20:192-222. However, the advent of electroencephalograph (EEG) recording along with the development of EEG-based polysomnographic (PSG) standards for the scoring of sleep stages resulted in a shift away from movement-based measurements of sleep. Dement W, Kleitman N., *Cyclic variations in EEG during sleep and their relation to eye movements, body motility, and dreaming*, Electroencephalogr Clin Neurophysiol 1957; 9:673.

A resurgence of interest in the use of movement-based measurement of sleep occurred when wrist-mounted accelerometry was developed in the 1970s and 1980s at the Walter Reed Army Institute of Research and the National Institutes of Health. Wrist-mounted accelerometers were based on technological advances that, for the first time, made long-term portable measurement and recording of movement data feasible. Redmond D P, Hegge F W, *Observations on the design and specifications of a wrist-worn human activity monitoring system*, Behav Res Methods Instrum Comput 1985; 17:659-69.

The primary research question at the time was whether wrist-mounted actigraphy could reliably and validly measure sleep/wake states in comparison to the EEG gold standard. Several validation studies, using different scoring algorithms, employing subjects with various age ranges, sample sizes, and subjects with sleep and/or movement-related disorders were performed. An early pilot study to address validation issues was conducted by Kripke et al. Kripke D F, Mullaney D J, Messin S, Wyborney V G, *Wrist actigraphic measures of sleep and rhythms*, Electroencephalogr Clin Neurophysiol 1978; 44:674-6. Using five normal subjects, they reported excellent agreement (correlation of 0.98) between actigraphically-derived, manually-scored and polysomnographically-determined measures of sleep duration. Webster et al. published the first algorithm that could be used to automatically score wrist-mounted actigraphic data. Webster J B, Kripke D F, Messin S, et al., *An activity-based sleep monitor system for ambulatory use*, Sleep 1982; 5:189-99. This algorithm was an important development because manually scoring actigraphic data on 30 second epoch-by-epoch bases was labor-intensive and tedious and partially obviated the advantages of the data collection technique. Sadeh, Lavie, et al. applied automatic sleep-wake scoring to home-monitoring of pediatric patients. Sadeh A, Alster J, Urbach D, Lavie P., *Actigraphically based automatic bedtime sleep-wake scoring: Validity and clinical applications*, J Ambul Monit 1989; 2(3): 209-16. They determined a correlation of 85% between conventional polysomography and actigraphically-scored sleep and demonstrated the utility of the wrist-mounted actigraph for ambulatory monitoring. In 1995, Sadeh, Hauri et al. provided a review for the American Sleep Disorders Association (now named the American Academy of Sleep Medicine) that provided validation for the use of wrist-mounted actigraphy as an adjunct in the diagnosis of sleep-related disorders. Sadeh A, Hauri P, Kripke D, Lavie P., *The role of actigraphy in the evaluation of sleep disorders*, Sleep 1995; 18(4):288-302. FIG. **1** shows wrist-mounted actigraphically-determined sleep and wake using a commonly applied algorithm (Action W, Ambulatory Monitoring, Inc, Ardsley, N.Y.). The actigraphy counts are based upon 30 second epochs. The sleep/wake score per epoch is shown below the tracing.

Current conventional actigraph design represents an optimization of past technology based on two key considerations: 1) consistent reliability of the output data (counts of threshold crossings) as input for the detection of sleep/wake state transitions using validated weighted moving average algorithms such as that of Cole et al. Cole R J, Kripke, D F, Gruen W, et al., *Automatic sleep/wake identification from wrist actigraphy*, Sleep 1992; 15(5):461-9; and 2) small size, low weight and power requirements, computational capacity, and other electrical and electronic features realizable as a user-accepted device of reasonable cost. This optimization produces very sharp and deliberate limitations of the information originally contained in the movement signal and passed on to the scoring algorithm. As discussed in Redmond and Hegge (*Observations on the design and specifications of a wrist-worn human activity monitoring system*, Behav Res Methods Instrum Comput 1985; 17:659-69), there are four main areas of design constraint:

1. The sensitivity of the sensor must be such as to respond to "normal" arm movements, but not be "swamped" by the waking movements of a very active person, or by sources of external noise and vibration. This limitation of dynamic range is also a function of digitization, whether it is 8, 12, or 16 bits. Information from very fine, subtle movement is sacrificed.

2. The frequency response of the accelerometric sensor system is sharply confined to a band of 2 to 3 cycles per second (Hz). At the low end, this is to eliminate counts from undulating, slow-wave excursions of the sensor (e.g., due to breathing, or rocking of the device in the gravitational field, or vehicle motion) that are not actually due to motor activity. At frequencies above 3 Hz, this response helps eliminate false counts due to tremor, external noise and vibration, and "ringing" due to sharp impulses.

3. The translation of a complex movement signal into a simple measure, readily computed and expressed digitally in microprocessors of 1985-1995 vintage, resulted in the use of threshold-crossing counts, but eliminated far more descriptive measures of the signal characteristics, such as duration, amplitude, and power.

4. The use of extended (relative to movement rates) periods of measure, i.e., 1- or 2-minute bins, keeps data sets down to workable length in electronic memory, and matches the temporal scale expected by validated sleep/wake algorithms. This integration of sensor data over time smoothes over both rhythmic signals (e.g., tremor) and transient bursts of sensor activity (aperiodic movements). This restriction is advantageous only if such signals are not themselves physiologically relevant.