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SleepMinder: An Innovative Contact-Free Device for the Estimation of the Apnoea-Hypopnoea Index.

Alberto Zaffaroni MEng, Philip de Chazal PhD *Member, IEEE*, Conor Heneghan PhD *Member, IEEE*, Patricia Boyle BSc, Patricia Ronayne MPPM, Walter T. McNicholas MD

***Abstract* — We describe an innovative sensor technology (SleepMinder™) for contact-less and convenient measurement of sleep and breathing in the home. The system is based on a novel non-contact biomotion sensor and proprietary automated analysis software. The biomotion sensor uses an ultra low-power radio-frequency transceiver to sense the movement and respiration of a subject. Proprietary software performs a variety of signal analysis tasks including respiration analysis, sleep quality measurement and sleep apnea assessment.**

This paper measures the performance of SleepMinder as a device for the monitoring of sleep-disordered breathing (SDB) and the provision of an estimate of the apnoea-hypopnoea index (AHI). The SleepMinder was tested against expert manually scored PSG data of patients gathered in an accredited sleep laboratory. The comparison of SleepMinder to this gold standard was performed across overnight recordings of 129 subjects with suspected SDB. The dataset had a wide demographic profile with the age ranging between 20 and 81 years. Body weight included subjects with normal weight through to the very obese (Body Mass Index: 21-44 kg/m^2). SDB severity ranged from subjects free of SDB to those with severe SDB (AHI: 0.8-96 events/hours). SleepMinder's AHI estimation has a correlation of 91% and can detect clinically significant SDB (AHI>15) with a sensitivity of 89% and a specificity of 92%.

I. Introduction

Obstructive sleep apnoea syndrome (OSAS) is associated with significant cardiovascular morbidity [1] and is one of the leading identifiable causes of hypertension. However, although OSAS is relatively prevalent in middle-aged adults [2] and preschool children [3], up to 90% of sufferers remain undiagnosed [4] due to resource constraints in many countries. Diagnosis and treatment are important as effective therapy leads to significant reductions in cardiovascular mortality and non-fatal cardiovascular events. The standard for OSAS diagnosis is overnight attended polysomnography (PSG).

The diagnosis of Sleep Apnoea is based on the combination of the Apnea-Hypopnea Index (AHI), a clinical index measuring the average number of sleep disordered breathing (SDB) events per hour, and of a subjective measure of daytime sleepiness. According to a landmark study from the American Association of Sleep Medicine (AASM) [5] it is estimated that 4% of the male and 2% of the female adult population are affected by sleep apnoea.

Moreover, the AASM [5] reports that mild forms of sleep apnoea can result in hypertension, sleepiness, and motor vehicle accidents, while more severe forms can induce severe sleepiness and strongly affect neurocognitive functions, producing marked impairment in social or occupational function. Changes in respiration during sleep are a leading indicator of deteriorating condition in patients with chronic diseases such as chronic heart failure (CHF) or chronic obstructive pulmonary disease (COPD).

The laboratory-based PSG analysis is the accepted reference standard for the assessment of sleep apnoea. PSG studies are very expensive, due to the need of both a well-equipped structure and of trained personnel. Also, PSG studies are obtrusive and are not a representative sample of a person's sleep, due to the laboratory setting, the extensive amount of sensors on the patient, and the limitations arising from basing a diagnosis on a single night's recording.

SleepMinder™ (Biancamed Ltd., Dublin, Ireland) [6] is a novel sensor technology for contactless and convenient measurement of sleep and breathing in the home (see Fig.1). It contains a non-contact radio-frequency sensor that continuously measures the biomotion due to breathing and body-movement of a subject in bed. The sensor operates in a license-free band at 5.8 GHz, emits an average power less than 1 mV and is capable of sensing movement and breathing over a distance ranging from 0.3 to 1.5 meters; in the case of two people in the bed, a combination of sophisticated sensor design and intelligent signal processing results in measuring only the respiration of the person nearest to the sensor.

The goal of this study was to validate SleepMinder as a device capable to accurately estimate the AHI in a population with suspected sleep apnoea.

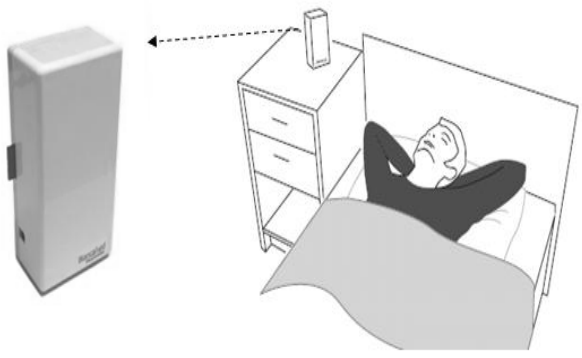

Fig.1. An example set up of SleepMinder in the home environment.

A. Zaffaroni, P. de Chazal, C. Heneghan are with Biancamed Ltd, NovaUCD, University College Dublin, Belfield, Dublin 4, Ireland. P. Boyle, P. Ronayne and W. T. McNicholas are with the Respiratory Sleep Disorders Unit, St Vincent's University Healthcare Group, Dublin 4, Ireland. Corresponding author: Alberto Zaffaroni, telephone: +353(0)17163753, email: alberto.zaffaroni@biancamed.com.

II. METHODS

SleepMinder's Sleep/Wake analysis [6] and integrated movement detector proprietary algorithms [7] were run over the recording and sleep state and movement flags were used during the further stages of analysis.

A new event based algorithm was developed for the detection of SDB events, using phase demodulation and amplitude and correlation based signal processing methods. The fundamental requirement defining the detection of a disturbed breathing event was the reduction of 50% or more in the amplitude of the non contact measure of overall body breathing effort, lasting 10 or more seconds.

Finally, the AHI is estimated by averaging the total number of detected events over the Total Sleep Time (TST), as estimated by the Sleep/Wake algorithm. An overview of the different stages and the interactions between each steps of signal processing is shown in Fig. 2.

The database for the study consisted of subjects who were sequentially admitted in St. Vincents Private Hospital, Dublin, between November 2007 and June 2009.

The study had hospital ethics approval and written consent was obtained from each subject beforehand. Each subject had been referred to the sleep laboratory because of suspected sleep apnoea, suspected disordered sleep, or both, and underwent full PSG analysis (Jaeger, SleepLab 1000E [8]), manually scored by a sleep expert. SleepMinder was installed in the sleep laboratory and its biomotion signal was recorded simultaneously with the PSG signals. SleepMinder was placed, facing the subject, in line with chest at a distance of approximately 0.2 meters and with an elevation of approximately 0.5 meters from the edge of the bed.

Table I shows the signals acquired by SleepMinder and the PSG. Data analysis was performed using Matlab v6.5 [9]. The biomotion signal was recorded at 64Hz; on the other hand, the sensor signal has a low-pass hardware characteristic with a cut-off point at 1.6Hz. As no movement components are present at 5 Hz, the signal is then down-sampled to 10 Hz before further processing.

All in all, 159 sequentially admitted subjects underwent full PSG analysis. 157 recordings were accepted for data analysis with a technical issue causing the signal not to be recorded for one subject. One subject, according to the expert PSG annotations, slept for 6 minutes and was also excluded, as AHI could not be reliably clinically determined.

Recordings were grouped into 4 different classes according to the AHI obtained by Expert PSG scoring: Normal (AHI<5), Mild (5≤AHI<15), Moderate (15≤AHI<30) and Severe (AHI≥30) SDB.

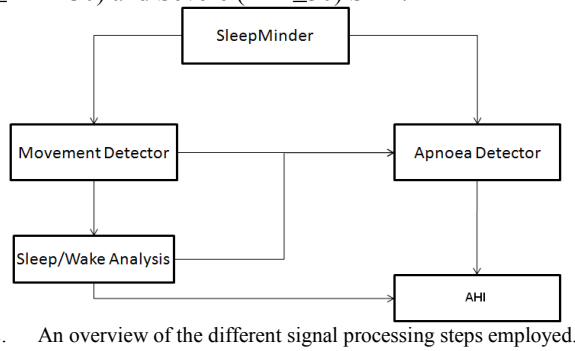

Fig.2. An overview of the different signal processing steps employed.

TABLE I
SIGNAL ACQUISITION

	Signal	Channel	Sampling rate [Hz]
SleepMinder	*Biomotion*	NC-I	64
		NC-Q	64
PSG	*EEG*	C3/A2	128
		C4/A1	128
	EOG	Left eye	64
		Right eye	64
	ECG	---	128
	RIP	Ribcage	8
		Abdomen	8
		Sum	8
	Flow	---	8
	Position	---	8
	Snoring	---	8
	Sp02	---	8

The dataset was split into a training set and a test set. The training set was composed of 28 recordings, including the first 7 recordings, following the admission order, for each of the above defined SDB degrees of severity. Information on training and testing set can be found in Table II and Table III. The period of evaluation was the total time spent in bed by the subjects undergoing the analysis.

The apnea algorithm was designed and calibrated using the recordings of the training set. Complete results are shown in Fig. 3. The correlation is 85% (CI [69.7-92.8%]) and 79% of results did not differ to the clinical one by more than 10 events/hours.

III. RESULTS

When measuring the algorithm's performance on the test set, the correlation between the SleepMinder and the PSG's AHI was 91% (CI [87.9-93.8%]); in 81% of the subjects the error was lower than 10 events/hour (grey band in Fig.5). A scatter-plot of the results can be observed in Fig.4.

The testing performance figures are higher than those of the training set: the reason is the presence, in the training dataset, of a subject with an AHI of 122 Events/hour that was clinically estimated from only 68 minutes of sleep. As such recording was used in the developing and training of the algorithm, it was included in the training database.

The Bland and Altman [10] plot in Fig. 5 shows good agreement between the SleepMinder and the PSG's AHI.

TABLE II
DATABASE INFORMATION

	Training	*Test*	*Overall*
Total subjects	*28*	129	157
Gender (M-F)	*23-5*	106-23	129-28
Age [yrs]	*49.3 (13.0)*	54.9 (13.6)	53.9 (13.7)
BMI [Kg/m^2]	*29.1 (4.8)*	31.0 (5.1)	30.7 (5.1)
AHI [events/hour]	24.3 (30.3)	20.4 (20.6)	21.1 (22.6)

TABLE III
DATABASE INFORMATION - OVERALL

Overall	*Normal*	*Mild*	*Moderate*	*Severe*
Total subjects	35	55	28	39
Gender (M-F)	21-14	44-11	27-1	37-2
Age [yrs]	48.1(14.7)	53.1(12.8)	55.4(11.7)	59.0(13.5)
BMI [Kg/m2]	29.2 (4.7)	29.9 (4.9)	30.3 (5.6)	33.4 (4.6)

Total subjects and Gender are presented in number.

Age, Body Mass Index (*BMI*) and Apnoea-Hypopnoea Index (*AHI*) are mean ± SD (Standard Deviation).

While a tendency towards under-estimating the apnoea-hypopnoea index can be observed for AHI levels above 30, the bias does not appear to significantly influence the diagnosis.

Receiver-operator characteristics curves were built for 4 different PSG diagnostic threshold, ranging from AHI>5 to AHI>20 events per hour.

Performance figures for four different diagnostic thresholds (AHI≥5, AHI≥10, AHI≥15 and AHI≥20) are shown in Table IV: sensitivity and specificity are as high as 89% and 92% for a diagnostic threshold of AHI≥15. The receiver-operator curve (ROC) area under curve (AUC) parameter shows that the best threshold is AHI≥15. For the first threshold (AHI>5) the high sensitivity confirms the usefulness of SleepMinder as a screening device. Furthermore, since the AUC remains close to or above 0.950 for all of the remaining three diagnostic thresholds, they can all be considered as reasonable choices.

Further effort was put into measuring how such performance figures translated into a clinical output. Table V presents the results according to the relative clinical diagnosis, according to the 4 classes described above. It can be observed that, while some subjects were wrongly placed into a different class from their PSG equivalent, errors were limited to the adjacent class. Looking at the results in table V, 75 out of 129 subjects in the testing dataset were correctly diagnosed (58%), with most of the incorrect detections due to incorrect classification between Normal Breathing and Mild SDB (29, 22%).

IV. Discussion

From the results shown above, SleepMinder's performances are comparable to those of the screening devices which have been proposed and tested as an alternative to PSG studies.
A validation study [11] for ApneaLink™, an apnoea screener measuring airflow, on a database of 59 subjects with a similar demographic distribution (Age 57.3±12.0, BMI 32.6±6.8) reported AUC values of 0.863 for a diagnostic

TABLE IV
SleepMinder performance for the Test Dataset

	Sens	*Spec*	*PPV*	*NPV*	*AUC*
AHI≥5	86.1	46.4	85.3	48.2	0.858
AHI>10	83.6	84.0	87.1	79.7	0.940
AHI≥15	88.7	92.1	88.7	92.1	0.971
AHI≥20	77.3	89.4	79.1	88.4	0.948

Sensitivity (*Sens*), Specificity (*Spec*), Positive Predictivity Value (*PPV*) and Negative Predictivity Value (*NPV*) are expressed in percent value.

Receiving-operator characteristic (ROC) curve Area under Curve (*AUC*) is expressed in number (0 to 1).

TABLE V
Results, Diagnostic performance by severity class

PSG↓SM→	*Normal*	*Mild*	*Moderate*	*Severe*	*Tot*
Normal	13 (46.4)	15 (53.6)	0 (0.0)	0 (0.0)	28
Mild	14 (29.2)	28 (25.3)	6 (12.5)	0 (0.0)	48
Moderate	0 (0.0)	6 (28.6)	14 (66.7)	1 (4.8)	21
Severe	0 (0.0)	0 (0.0)	12 (37.5)	20 (62.5)	32

SleepMinder (*SM*) versus PSG output, based on a 4 classes severity division: *Normal* Breathing (AHI<5), *Mild* (5≤AHI<15), *Moderate* (15≤AHI<30) and *Severe* SDB (AHI≥30). Results are presented as number of patients (percentage). *Tot* is the total number of patients for each class, according to the PSG outcome.

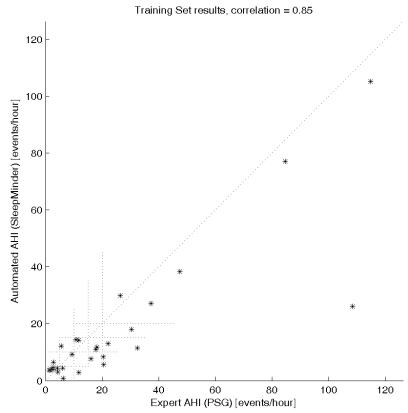

Fig.3. SleepMinder vs. PSG AHI estimation in the Training Set

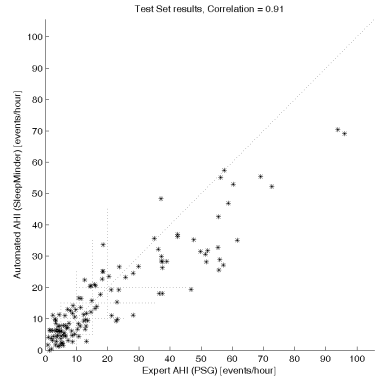

Fig.4. SleepMinder vs. PSG AHI estimation in the Test Set

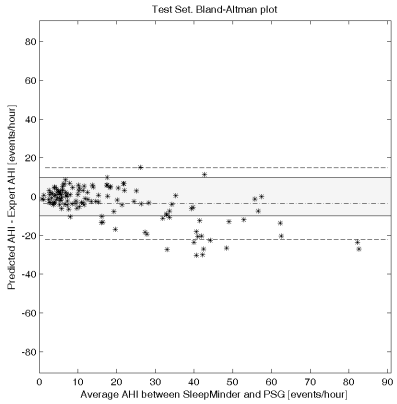

Fig.5. Bland-Altman plot of SleepMinder vs. PSG AHI in the Test Set. The grey sector represents an agreement band of ± 10 events/hour.

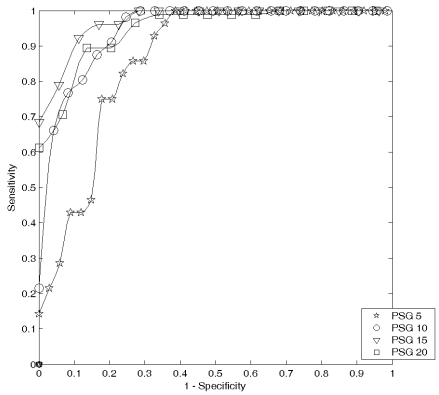

Fig.6. Receiver-operator characteristics curves for the SleepMinder estimated AHI versus the PSG AHI in the Test Set. The four curves with their related symbols refer to a diagnostic threshold of the expert annotated AHI>5 (AUC = 0.857), AHI>10 (AUC = 0.940), AHI>15 (AUC = 0.971), AHI>20 (AUC = 0.948)

threshold of PSG AHI≥5, 0.862 for PSG AHI≥10, 0.977 for PSG AHI≥15 and 0.967 for PSG AHI≥20.

SleepMinder performed in a similar way in the case of thresholds such as 5, 15 or 20, returning quite a stronger performance metric for a threshold of AHI≥10 (SleepMinder AUC 0.940 vs. ApneaLink AUC 0.862).

In a previous study, Portier [12] observed individual differences between the portable and the laboratory PSG AHI's values (made in consecutive nights) of less than 10 events/hour in 65% of the 78 subjects participating to the study. SleepMinder's AHI estimate was within 10 events per hour in 81% of the cases.

In another study, Vazquez [13] reported sensitivity of 98% and specificity of 88% for a diagnostic threshold of 15 events per hour for a digital oxymetry system from a slightly younger (Age 45.0±11.3, BMI 30.8±5.9) dataset of 245 subjects. These performance figures were calculated by applying a tolerance band of 5 points of AHI across the threshold used [13]. Using the same methodology, SleepMinder returns a performance of 92% for sensitivity and 95% for specificity.

Collop [14] reported high inter-scorer variability for laboratory PSG. Different experts returned diagnosis that in some cases differed by more than one severity class between each other. SleepMinder's incorrect responses were confined to the adjacent severity class.

Bittencourt [15] showed that the majority of the subjects analyzed showed variations in AHI of more than 10 events per hour. In another study, Westbrook [16] described how such variations are more common in patients with mild to moderate SDB (10<AHI<30), while the AHI values of subjects with normal breathing and severe SDB are steadier: such variations might produce an inaccurate diagnosis, given the same patient can potentially return AHI between 5 and 15 or more, spanning over the range of both normal breathing, mild SDB and moderate SDB. Not surprisingly, Le Bon [16] reported an increase of between 15% and 25 % in the number of patients diagnosed with SA for PSG recordings during consecutive nights.

V. Conclusion

SleepMinder™ is an unobtrusive device that provides contact-less and convenient measurement of the degree of sleep-disordered breathing severity in the home. The current results showed excellent performance in comparison to polysomnography. SleepMinder does not require any physical contact whatsoever with the patient.

SleepMinder's performances are comparable to those of much more obtrusive, expensive and less scalable systems, such as portable PSG systems [11]-[12] or those based on pulse oxymetry [13]. As SleepMinder monitors respiratory effort it may be used to separate apnoea and hypopnoea events.

The minimal interaction between the final user and the system make SleepMinder an ideal system to monitor sleep-disordered breathing over time.

The ability to perform analysis over many consecutive nights in the home-environment offers clear benefits over the sleep "snap shot" which is provided by the current hospital-based test. These benefits include convenience to the subject, significantly lower cost, and tracking of changes of the AHI estimate over time.

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