

# Clinical validation of the Bedbug™ in detection of obstructive sleep apnea

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**OBJECTIVE:** To validate the accuracy of the Bedbug™, a new home monitoring device for diagnosis of obstructive sleep apnea.

**STUDY DESIGN AND SETTING:** Simultaneous sleep monitoring was performed by formal polysomnography and by Bedbug. Monitoring was performed in a university sleep center in 42 subjects who had previously been scheduled for polysomnography.

**RESULTS:** The correlation for the apnea-hypopnea index (AHI) between polysomnography and Bedbug was  $r = 0.96$ . The sensitivity of Bedbug for detecting an AHI > 15 was 85.7%. The specificity of Bedbug for detecting an AHI < 15 was 95.2%.

**CONCLUSION:** The Bedbug device provides an accurate assessment of the apnea-hypopnea index.

**SIGNIFICANCE:** Accurate home monitoring for sleep apnea may provide access to care for a higher proportion of undiagnosed sleep apnea patients. (Otolaryngol Head Neck Surg 2001;125:227-30.)

Obstructive sleep apnea (OSA) has become increasingly recognized as a common disorder, with prevalence estimates of 2% to 4% of a middle age population.<sup>1</sup> Most Americans with OSA are not currently being diagnosed or treated. In the Wisconsin data, Young et al<sup>2</sup> reported that 7% to 12% of patients with moderate-to-severe OSA were being diagnosed. In a retrospective chart review, Kramer et al<sup>3</sup> estimated that only 0.13% of an HMO population were referred for sleep apnea evaluation and emphasized the need to educate primary care physicians.<sup>3</sup> Polysomnography (PSG)

remains the gold standard for diagnosis of sleep apnea, but may not be the optimal approach for studies in larger populations. Portable testing devices are an appealing vehicle to reach larger populations of undiagnosed individuals.

The goals of portable monitoring include accurate diagnosis and increased access to low-cost diagnosis of OSA, but stimulate debate regarding level of monitoring, accuracy, and cost. Devices are available to perform complete PSG monitoring including an electroencephalogram (EEG) in the home, but home PSG with EEG still involves greater time and cost for personnel and equipment.<sup>4</sup> Simple respiratory monitoring generally provides highly accurate results<sup>5,6</sup> and has gained wider acceptance as a screening device. An accurate computer scoring system combined with a simple respiratory monitor could increase access to screening in a larger percentage of the population.

The Bedbug™ is a device cleared by the Food and Drug Administration for diagnosis of obstructive sleep apnea in adults; it uses a computer algorithm to score apneas and hypopneas. It is a noninvasive, 5 channel, Level III device.<sup>7</sup> It consists of a respiration (breath) sensor, finger pulse oximeter, snoring detector, thoracic effort sensor, Patient Module, and a recording unit. It has been designed to be comfortable to wear and simple to operate. The aim of this study was to correlate the apnea-hypopnea index between PSG and Bedbug, and to evaluate the sensitivity, specificity, and accuracy of Bedbug for the diagnosis of OSA.

## MATERIALS AND METHODS

### Study Design

A consecutive sample of 42 volunteer subjects were recruited from a patient population who had been referred for a formal sleep study to evaluate suspected OSA. PSG was performed in the UCSF/Mount Zion Sleep Disorders Center, using Grass amplifiers and the Sensormedics computer system. This study involved human subjects, and the protocol was approved by the UCSF Committee of Human Research. Inclusion criteria were age over 18 years, clinical suspicion of uncomplicated OSA, and patients already scheduled for full polysomnography. Subjects were excluded if they exhibited flu-like symptoms, had a primary complaint of insomnia, had suspected respiratory failure or hypoventilation, or had sus-

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**Table 1.** Patient characteristics ( $\pm$  standard deviation)

Gender	31 Male, 11 female
Age (years)	54 (12.9)
BMI (kg/m <sup>2</sup> )	30.6 (6.7)
AHI (PSG)	25.5 (28.1)
AHI (Bedbugg)	22.9 (31.2)

pected narcolepsy or idiopathic hypersomnia. In addition, patients who had a family member present during the sleep study period were excluded, since the Bedbugg monitor is sensitive to ambient sound.

### Bedbugg™

The Bedbugg respiration sensor houses 2 microphones, 1 to measure respiration based on sound characteristics, and 1 for recording snoring intensity and ambient noise. The respiration sensor rests on the patient's upper lip and detects both nasal and oral airflow. The pulse oximeter is attached to the patient's index finger to measure blood oxygen saturation levels. The effort sensor is a soft, thin, Tygon tube that is placed around the patient's upper midsection to detect respiratory effort. The pressure in the tube is transduced, and fluctuations in pressure are used to assess respiratory effort, and to classify apneas as obstructive or unclassified. An unclassified apnea is associated with an 80% or greater reduction in baseline respiratory effort. Due to the small number of these apneas observed, the FDA did not approve use of the term central apnea. The Bedbugg has sufficient memory to record 3 consecutive nights of sleep. In clinical practice, the Bedbugg is mailed directly to the patient and then returned to Sleep Solutions. The data are scored by computer algorithm, and a detailed Sleep Study Summary of scored data is sent to the physician for diagnostic interpretation. For this validation study, a single night sleep study was performed for a direct comparison to PSG.

### Procedures

Technologists performed PSG in the usual manner, including EEG, EOG, and EMG for sleep staging. Respiratory events were classified based on thermistor airflow, and thoracic and abdominal piezobands for effort. The Bedbugg system performed a simultaneous recording using 3 additional sensors that provide 5 channels of data: airflow based on sound characteristics, snoring volume in dBA, respiratory effort, oxygen saturation, and heart rate derived from the oximetry signal. Raw data are stored in the bedside unit. Each subject was hooked up to the 3 additional Bedbugg sensors (respiration, effort, and Nonin 8500 finger oximeter) for the 1-night sleep study, in addition to the electrodes used for a regular PSG study. The PSG airflow sensor and the Bedbugg respiratory effort sensor were both placed between the upper

**Table 2.** Cross-tabulation of AHI results from PSG and Bedbugg

PSG/Bedbugg	<10	10-15	15-20	>20
<10	16	3	0	1
10-15	1	0	0	0
15-20	0	2	1	1
20	0	1	1	15

lip and nose. The PSG data were hand scored by the technologist, using usual guidelines for sleep staging. Apnea was defined as lack of airflow for 10 seconds. The hypopnea criteria was a 50% reduction in airflow accompanied by at least a 4% oxygen desaturation.<sup>8,9</sup> The data from the Bedbugg recording unit were analyzed using the Bedbugg software. An event by event comparison was made between Bedbugg and PSG. Outcome measures included number and duration of apneas and hypopneas, apnea-hypopnea index (AHI), and oxygen saturation as derived by PSG standard and by Bedbugg. The body mass index (BMI) was computed as: BMI = Wt(kg)/(ht[m<sup>2</sup>]).

### Data Analysis

For PSG, the AHI was determined based on sleep time. For Bedbugg, the AHI was determined based on the total duration of recorded data. The AHI scored by the Bedbugg was compared with the AHI scores from the PSG using a correlation coefficient. Sensitivity and specificity for the detection of OSA using Bedbugg were determined, using a PSG determined AHI of greater than 15 as positive for apnea, and AHI less than 15 as negative for apnea.

### RESULTS

Table 1 outlines the anthropometric data and sleep data for the 42 subjects.

For the 42 subjects, the AHI correlation between Bedbugg and PSG was calculated using Pearson's correlation coefficient. The correlation coefficient was  $r = 0.96$  (Fig 1).

Sensitivity and specificity for the detection of OSA using Bedbugg were determined with a PSG-determined AHI of greater than or less than 15. Based on the PSG-derived AHI, 21 subjects had AHI > 15. Of these 21 subjects, 18 had a Bedbugg AHI > 15. Using the PSG AHI as the "gold standard," the sensitivity is the number of subjects with AHI > 15 by Bedbugg ( $n = 18$ ), divided by the number of patients with AHI > 15 by PSG ( $n = 21$ ). The sensitivity was 85.7% (18/21), with 14.3% (3/21) false-negative results. The 3 false-negative results all had an AHI determined by Bedbugg between 10 and 15. One false-negative result showed a significant underestimation of the AHI, with a PSG AHI = 30.45, and a Bedbugg AHI = 13.3.

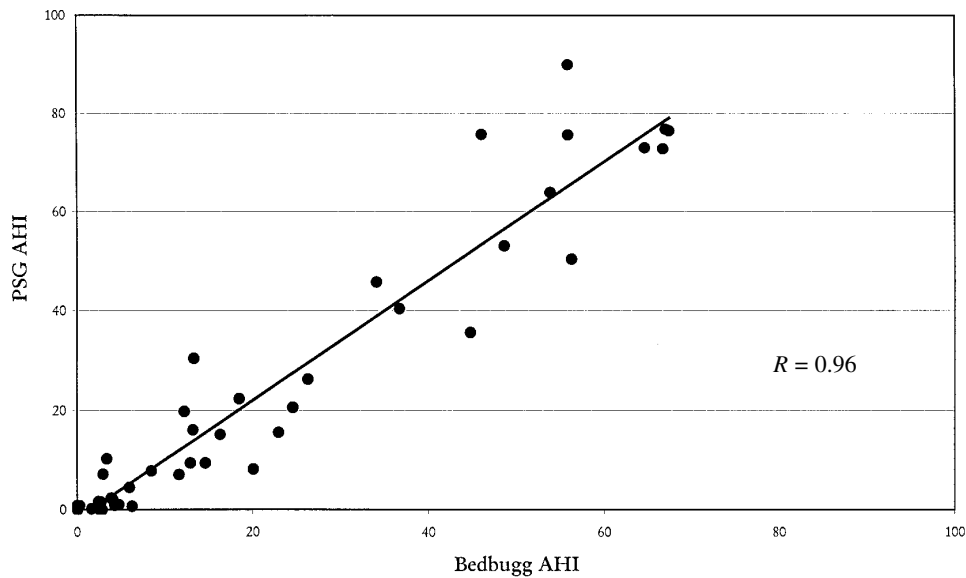


Fig 1. Graph shows AHI correlation between PSG and Bedbug.

Specificity was also calculated. Based on the PSG-derived AHI, 21 subjects had AHI < 15. Of these 21 subjects, 20 had a Bedbug AHI < 15. Specificity is the number of patients with AHI < 15 by Bedbug (n = 20), divided by the number of patients with AHI < 15 by PSG (n = 21). The specificity was 95.2% (20/21), with 4.8% (1/21) false-positive results. The 1 false-positive result showed a significant overestimation of the AHI, with a PSG AHI = 8.17 and a Bedbug AHI = 20.1.

The prevalence of OSA in this subject group, based on PSG AHI > 15 was 50% (21/42). Based on that prevalence, the positive predictive value (TP/TP + FP) for Bedbug AHI > 15 is 94% (17/18), and the negative predictive value (TN/TN + FN) for Bedbug AHI < 15 is 87.5% (21/24). Overall accuracy is 90% (38 of 42 studies yielded accurate AHI).

The cross-tabulation of AHI results based on PSG and Bedbug based on AHI <10, 10 to 15, 15 to 20, and >20 is shown in Table 2. The AHI was essentially the same in 32 of 42 subjects.

In 5 subjects, Bedbug overestimated the AHI relative to the “gold standard” RDI based on PSG. In 5 subjects, Bedbug underestimated the AHI. As noted above, there was one significant false-positive result, and one significant false-negative result.

## DISCUSSION

This report describes a new home respiratory monitoring device, with an accurate computer algorithm that provides a high correlation ( $r = 0.96$ ) with the PSG-derived AHI. The low rate of false-positive and false-negative AHI results gives Bedbug a high positive

predictive value of 94%, and an excellent negative predictive value of 87.5% in providing accurate clinical studies.

The device is simple to use in an unsupervised setting, which is important for an ambulatory device, and the accurate computer scoring algorithm may reduce cost by decreasing technologist and physician time.

As is true in general for all portable monitoring devices, clinical correlation with symptoms is essential. Bedbug does not provide EEG monitoring, EMG monitoring, or sleep staging.

Patients with severe sleepiness who are suspected of having narcolepsy, idiopathic CNS hypersomnia, upper airway resistance syndrome, or periodic limb movements of sleep should have formal sleep testing. Given the high predictive values in this study, patients with a Bedbug AHI consistent with their clinical symptoms can be safely and accurately diagnosed with Bedbug.

Some patients who have “borderline” AHI results, particularly in the 10 to 20 range, may benefit from formal PSG to confirm Bedbug AHI results.

The high correlation between PSG and Bedbug for AHI ( $r = 0.96$ ) is important for an ambulatory device because there is little clinical distinction between AHI = 13 and AHI = 17. The cutoff of AHI = 15 is clinically arbitrary but is necessary for validation studies, in order to calculate positive and negative predictive values. This study monitored subjects simultaneously by the 2 methods on a single night, which eliminates night-to-night variability as a confounding factor. The high correlation for AHI was observed despite the absence of EEG and sleep staging. Other portable monitors have been

reported to have adequate correlation with PSG-derived AHI.

This study required an apnea to last for 10 or more seconds, and the hypopnea criteria included at least a 50% decrease in airflow and a 4% oxygen desaturation. There is no universal criteria for hypopnea, and a recent American College of Chest Physicians consensus statement suggested that a 3% desaturation criteria be incorporated into future clinical and research work in order to standardize results.<sup>10</sup> The data in this study specifically used the AHI, which does not include respiratory-effort-related arousals (RERA). RERAs are now often included in the respiratory disturbance index (RDI), in order to address the issue of upper airway resistance syndrome. This device does not provide information about RERAs; upper airway resistance syndrome is best diagnosed by PSG.<sup>11</sup>

The impact of the computer-scoring algorithm is important to discuss. The data are scored by the proprietary computer algorithm after Bedbugg is returned to the company (Sleep Solutions), and the scored data are then sent to the physician for diagnostic interpretation. The breath-to-breath data are not available for review by the physician, so that the computer results cannot be visually confirmed in every case. The algorithm must be accurate, as it was in this study, and the test results should be consistent with the patient's clinical symptoms, which involves clinical judgment. A nonexpert physician may be able to manage a patient who has either a highly abnormal or a completely normal result that is consistent with clinical symptoms, but a board-certified sleep specialist would likely exercise the best clinical judgment in any borderline or atypical case.

No studies were lost because of data acquisition problems, but this study took place in a sleep center that performs PSG, and the Bedbugg sensors were placed by the sleep technologists. Other portable monitors have been reported to lose data in 9% to 33% of studies. In a recent "ease-of-use" study of the Bedbugg device, 42 of 44 subjects were able to follow the instructions and obtain adequate sleep study data (personal communication, B. A. Adornato). This suggests that the goal of a simple, affordable, and convenient

home-testing system has been met, which could provide access to care for a higher proportion of undiagnosed sleep apnea patients.

## SUMMARY AND CONCLUSIONS

The Bedbugg has been evaluated in a clinical setting with statistical analysis performed on 42 patients. The Bedbugg AHI correlated highly with the AHI derived by simultaneously performed PSG, with an excellent  $r = 0.96$  for the 42 subjects studied. In 38 (90%) of 42 patients, the Bedbugg scored a clinically accurate result. The results also indicate a high degree of both specificity and sensitivity with respect to overall RDI values. Based on these results, the Bedbugg has met the study objectives by demonstrating to be accurate in diagnosing sleep apnea.

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