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EMERGING TECHNOLOGIES

# Validation of Contact-Free Sleep Monitoring Device with Comparison to Polysomnography

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**Study Objectives:** To validate a contact-free system designed to achieve maximal comfort during long-term sleep monitoring, together with high monitoring accuracy.

**Methods:** We used a contact-free monitoring system (EarlySense, Ltd., Israel), comprising an under-the-mattress piezoelectric sensor and a smartphone application, to collect vital signs and analyze sleep. Heart rate (HR), respiratory rate (RR), body movement, and calculated sleep-related parameters from the EarlySense (ES) sensor were compared to data simultaneously generated by the gold standard, polysomnography (PSG). Subjects in the sleep laboratory underwent overnight technician-attended full PSG, whereas subjects at home were recorded for 1 to 3 nights with portable partial PSG devices. Data were compared epoch by epoch.

**Results:** A total of 63 subjects (85 nights) were recorded under a variety of sleep conditions. Compared to PSG, the contact-free system showed similar values for average total sleep time (TST), % wake, % rapid eye movement, and % non-rapid eye movement sleep, with 96.1% and 93.3% accuracy of continuous measurement of HR and RR, respectively. We found a linear correlation between TST measured by the sensor and TST determined by PSG, with a coefficient of 0.98 (R = 0.87). Epoch-by-epoch comparison with PSG in the sleep laboratory setting revealed that the system showed sleep detection sensitivity, specificity, and accuracy of 92.5%, 80.4%, and 90.5%, respectively.

**Conclusions:** TST estimates with the contact-free sleep monitoring system were closely correlated with the gold-standard reference. This system shows good sleep staging capability with improved performance over accelerometer-based apps, and collects additional physiological information on heart rate and respiratory rate.

**Keywords:** actigraphy, home sleep monitoring, polysomnography, sleep architecture

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## INTRODUCTION

Fifty to 70 million Americans suffer from chronic disorders of sleep and wakefulness that can adversely affect daily functioning, safety, quality of life, health, and longevity.[1] Increasing healthcare costs and the declining fiscal state of healthcare systems worldwide prompt a need for low-cost means of assessing sleep-related complaints.[2] There is particular demand for validated patient-centered and outcome-based delivery models that provide user-friendly, accurate, and noninvasive monitoring. The technological potential exists for contactless home sleep monitoring that could be used for initial screening evaluations of sleep-related complaints, as well as continuous follow-up to assess the benefits of treatment or lifestyle changes over time.

Polysomnography (PSG) is the gold standard for sleep monitoring, but has several obvious disadvantages, including intensive resource consumption,[3] cost,[4] discomfort,[5] limited availability,[6] and limited accuracy of interrater interpretation.[7–9] A home sleep monitoring device with the accuracy of PSG would be an ideal solution to enable a combination of cost-effectiveness and ease of use along with reliability and accuracy.

Among the available alternatives, actigraphy has the disadvantage of requiring body contact. A variety of smartphone apps are available to satisfy the consumer-driven need for personal health information; however, such devices and software often lack validation. Several portable home sleep monitoring devices have also been developed to evaluate sleep staging, overall sleep time, and sleep quality.[10–13] Of these, the EarlySense (ES) contact-free sensor has been validated for measuring movement, heart rate, and respiration[14] and is currently used in hospitals in the United States.[15,16]

The primary objective of the current study was to validate the accuracy of a new home-adapted sensor (**Figure 1**) for reliably determining sleep/wake state and sleep parameters as compared to PSG. The secondary objective was to determine whether this device could detect sleep architecture under different home sleeping conditions, including different mattress types and sizes, and in the presence of a bed partner.

## METHODS

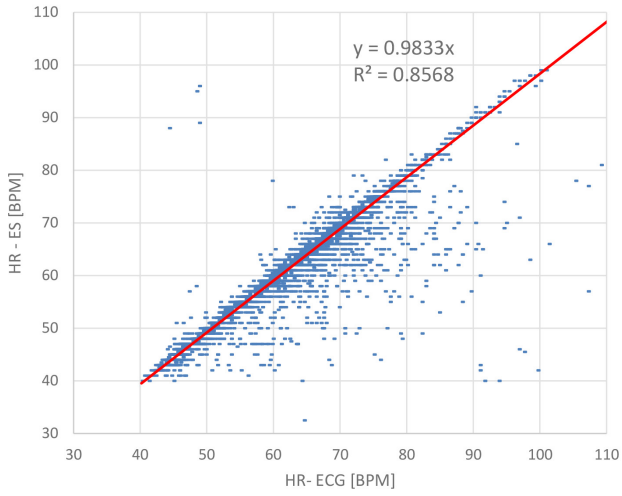
### Study Design and Participants

We compared the performance of the ES contact-free sensor (EarlySense, Ramat Gan, Israel) located under any mattress, with the gold standard PSG using three different setups. For the sleep laboratory setup we recruited patients who were referred for PSG, mainly for evaluation of sleep-disordered breathing.

**Figure 1**—The EarlySense (ES) contact-free sensor and the smartphone/tablet interface for analyzing signals and displaying the results.


The ES sensor (left) is placed under the mattress under the estimated location of the patient's chest. The ES device is considered a nonsignificant risk device because the sensor is placed under the mattress, does not come in contact with the subject, and does not require subject compliance.

**Figure 2**—Heart rate from the EarlySense (ES) sensor (y-axis) compared to heart rate from gold standard electrocardiogram (ECG; x-axis). BPM = beats per minute.




For the home setups, we recruited healthy volunteers with no major sleep disorder, which was confirmed by PSG. Subjects were studied for 1 night in the sleep laboratory (setup I), with one person in bed at home (setup II), or with two persons in bed at home (setup III) (**Figure S1** in the supplemental material).

The tested variables included heart rate (HR), respiratory rate (RR), and sleep stage (**Table S2** in the supplemental material). The sleep stage results obtained from the ES sensor were compared with the sleep stage determinations by PSG. This study was approved by the Institutional Review Ethics Committee of the Soroka University Medical Center (IRB Approval Reference Number: 0231-13-SOR; 24 Oct 2013). All subjects gave their written consent.

### Reference Device Recording and Scoring

In setup I, each subject was recorded for 1 night at a nationally accredited sleep laboratory (Millennium Sleep Laboratory, Beer Sheva, Israel), using the ES contact-free sensor as well as full PSG (Respironics Alice 5 Diagnostic Sleep System, USA) as the reference. Full PSG included three electroencephalogram (EEG) leads sampled at 100 Hz; two respiratory inductance plethysmography (RIP) respiratory belts (abdomen and thorax); an accelerometer for snore assessment (sensing sound), pulse oximetry, and body movement; two electro-oculogram (EOG) leads (left and right) sampled at 100 Hz; two electromyogram (EMG) leads (submental and leg) sampled at 100 Hz, an airflow monitor; and one electrocardiogram (ECG) lead II sampled at 200 Hz. The home setups included one of two models of portable PSG: Embletta Gold or X100 (Embla Corp, Bloomfield, CO, USA). These portable PSG devices include EEG, EOG, EMG, and ECG leads; two RIP respiratory belts (abdomen and thorax); and monitoring of pulse oximetry, air flow, snoring, and body movement.

The ES contact-free sensor and application analyzed sleep using an algorithm based on HR, HR variability, RR, RR variability, and movement. To validate the detection rate and accuracy of vital signs measurement, we used data from the subjects of home setup III (two persons in a bed, which represents the most challenging scenario, as interference of the bed partner might impair the accuracy), comparing a 1-min manual count of thorax RIP belts and the 1-min average of ECG lead II heart rate to the ES sensor's measurements of RR and HR. All sleep laboratory studies were scored by an expert sleep technologist, according to American Academy of Sleep Medicine guidelines, and the scores were reviewed by one of the authors (AT). Each epoch was assigned as: wake, rapid eye movement (REM), light sleep (N1+N2 ) or slow wave sleep (SWS). For each epoch, the score attained from PSG was compared to the score of the same epoch obtained automatically by the ES contact-free sensor. Only for epochs that were scored as wake, according to PSG, we allowed 1-epoch (30-sec) shift when comparing to ES score, i.e., an epoch scored as "wake" according to PSG was considered true positive if ES score for the same epoch or any of the two adjacent epochs was marked "wake." This method was necessary because the PSG recorder and the ES device had different clocks, and the drift between the two clocks was almost 1 min per night.

## RESULTS

Comparison of 2,162 points between the ES sensor and the RIP thorax belt revealed a detection rate of 94.2%, with 93.3% accuracy and 4.7% absolute relative error. Comparison of 10,773 points between HR determined from the ES sensor and the ECG reference lead II showed a detection rate of 92.2%, with 96.1% accuracy and 1.83% absolute relative error. **Figure 2** shows the correlation between the 1-min average HR obtained from a reference ECG and the 1-min average acquired from the ES sensor. The correlation factor was 0.98 with $R^2 = 0.86$, equivalent to the ES medical grade system.[14]

**Table 1**—Patient demographics.

| | Sleep Laboratory Setup I | Home Setup II | Home Setup III |
|---|---|---|---|
| Subjects | | | |
| Number | 43 | 7 | 13 |
| Sex (M/F) | 34/9 | 3/4 | 8/5 |
| Nights (number) | 43 | 15 | 27 |
| Age, y | | | |
| Mean (standard deviation) | 45.9 (14.4) | 31.2 (10.8) | 40.0 (10) |
| Minimum | 17 | 24 | 29 |
| Maximum | 72 | 65 | 59 |
| Body mass index, kg/m$^2$ | | | |
| Mean (standard deviation) | 34.6 (9.6) | 23.0 (4.6) | 24.1 (2.9) |
| Minimum | 19 | 15 | 19 |
| Maximum | 57 | 30 | 28 |

**Table 2**—Contingency tables comparing values obtained with the piezoelectric contact-free system to those acquired with full polysomnography for all subjects in all three setups (85 nights).

| A | | Reference Values (full PSG) | | | |
|---|---|---|---|---|---|
| | Piezoelectric contact-free system | Awake | REM | LS | SWS |
| | Awake | 9,482 (80.4%) | 588 (5.4%) | 3,710 (9.7%) | 114 (1.1%) |
| | REM | 569 (4.8%) | 5,844 (53.7%) | 4,224 (11.1%) | 308 (3.0%) |
| | LS | 1,477 (12.5%) | 4,190 (38.5%) | 24,771 (64.9%) | 4,014 (39.7%) |
| | SWS | 265 (2.2%) | 254 (2.3%) | 5,471 (14.3%) | 5,684 (56.2%) |

| B | | PSG Reference | |
|---|---|---|---|
| | Piezoelectric contact-free system | Wake | Asleep |
| | Wake | 9,482 (80.4%) | 4,412 (7.5%) |
| | Asleep | 2,311 (19.6%) | 54,760 (92.5%) |

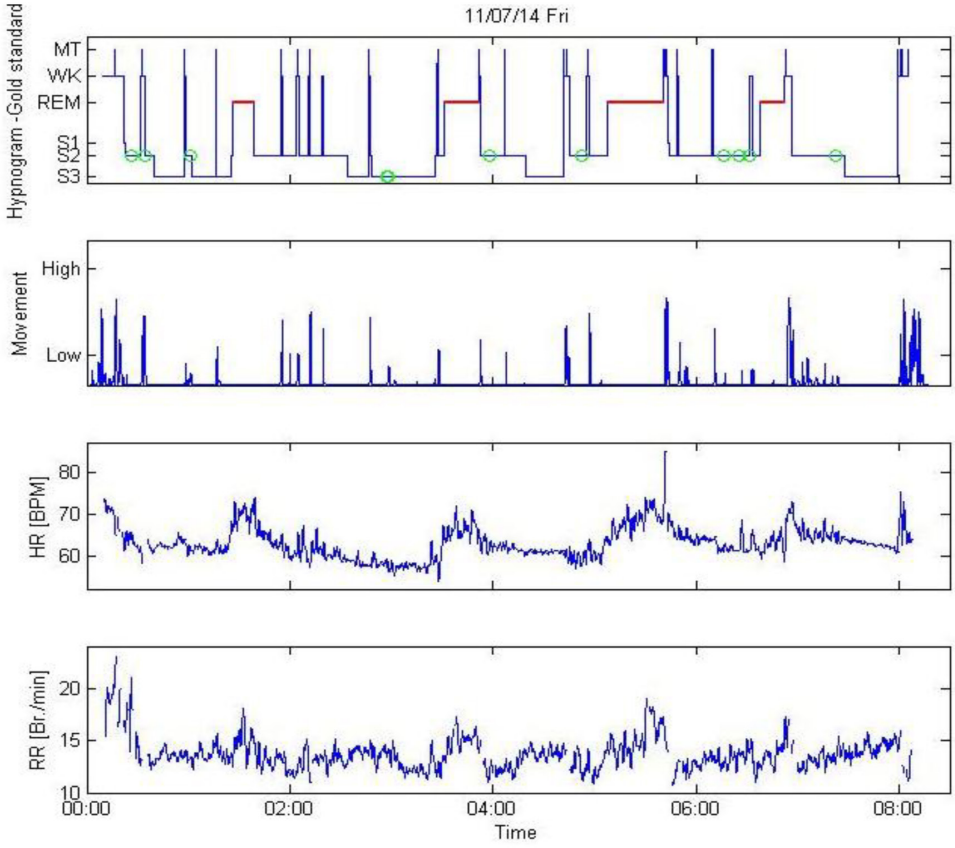
Values are presented as epoch count (percentage of reference recordings in that category). LS = light sleep (N1+N2), PSG = polysomnography, REM = rapid eye movement, SWS = slow wave sleep. In both tables, columns represent sleep stage according to reference PSG. Rows represent sleep stage according to piezoelectric sensor. Values on the diagonal represent sleep stages recorded the same by both devices. In Table 1B, collapsing the 4 × 4 contingency table into a 2 × 2 table (wake/sleep only) reveals wake sensitivity of 80.4%, sleep (REM + LS + SWS) sensitivity of 92.5%, and overall agreement of 90.5%.

The study included a total of 66 subjects (**Table 1**). Of these subjects, 43 were studied in the sleep laboratory (setup I), including 34 men and 9 women, with an average age of 45.9 y (range, 17 to 72 y), average weight of 105.2 kg (range, 63 to 188 kg), and an average body mass index (BMI) of 34.6 kg/m$^2$ (range, 19 to 57 kg/m$^2$). In this group, we examined a total of 35,070 epochs of 30 sec each (equivalent to 292.25 h). Data analysis for this group showed a wakefulness sensitivity of 83.4%, sleep sensitivity of 89.7%, and overall sleep accuracy of 88.5%. Detailed sensitivities for each sleep state were 40.0% for REM, 63.3% for light sleep (LS), and 53.6% for SWS.

Studies in the home setting included 23 subjects, in whom 7 were recorded with 1 person in bed (setup II). This group included 3 men (recorded for a total of 6 nights) and 4 women (recorded for 9 nights), with an average age of 32.1 y (range, 24 to 65 y), average weight of 66.6 kg (range, 45 to 88 kg), and average BMI of 23.0 kg/m$^2$ (range, 15.4 to 30.1 kg/m$^2$). The remaining 16 subjects were recorded with two individuals in a double bed (setup III). This group included 9 men (recorded for a total of 19 nights) and 7 women (recorded for 13 nights), with an average age of 42.7 y (range, 29 to 65 y), average weight of 73.8 kg (range, 49 to 90 kg), and average BMI of 24.2 kg/m$^2$ (range, 19.4 to 28.2 kg/m$^2$).

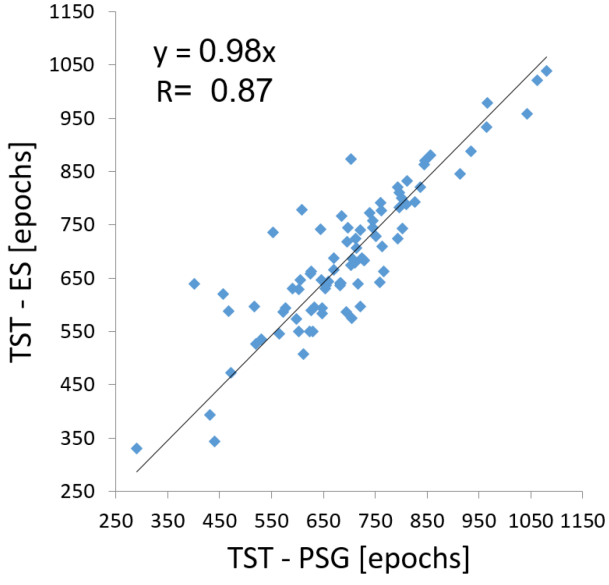
**Table 2** summarizes the data from the ES sensor for all subjects in all three setups (85 sleep studies), with comparison to full PSG using a contingency table. Epoch-by-epoch comparison with four-state disclosure (wake, REM, LS, and SWS) are presented in **Table 2A**. **Table 2B** presents the same results collapsed into two states (wake and sleep). The overall wake sensitivity (i.e., wake epochs according to reference that were detected as wake by the ES sensor) was 80.4%, sleep sensitivity (i.e., sleep epochs according to reference that were detected as sleep by the ES sensor) was 92.5%, and overall agreement was 90.5%. Separate analysis for the subgroups presented similar results. In setup I (sleep laboratory; 43 nights; 35,070 scored 30-sec epochs; 292.25 h), the overall wake sensitivity was 83.4%, sleep (REM + LS + SWS) sensitivity was 89.7%, and overall agreement was 88.5%. For setup II (single subjects in bed at home; 15 nights; 12,423 scored 30-sec epochs; 103.5 h), the overall wake sensitivity was 72.1%, sleep (REM + LS + SWS) sensitivity was 95.4%, and overall agreement was 92.1%. In setup III (one patient is recorded when two persons are in a double bed at home; 27 nights; 23,472 scored

**Figure 3**—Data from a single night, with EarlySense sensor data shown versus polysomnography (PSG) reference data.




Green circles mark arousals. N1, N2, and slow wave sleep (SWS) indicate non-rapid eye movement stages 1, 2, and 3 according to American Academy of Sleep Medicine criteria. The data showed a close correlation between movement and the various sleep stages, with movements being abundant during wake and sparse during rapid eye movement (REM) and SWS stages. Respiration rate (RR) variability, heart rate (HR), and heart rate variability were increased during REM cycles. MT = movement, WK = awakening.

**Figure 4**—Correlation of total sleep time (TST; measured in epochs) according to the EarlySense (ES) sensor versus that derived from polysomnography (PSG) data for all recorded nights (n = 85).

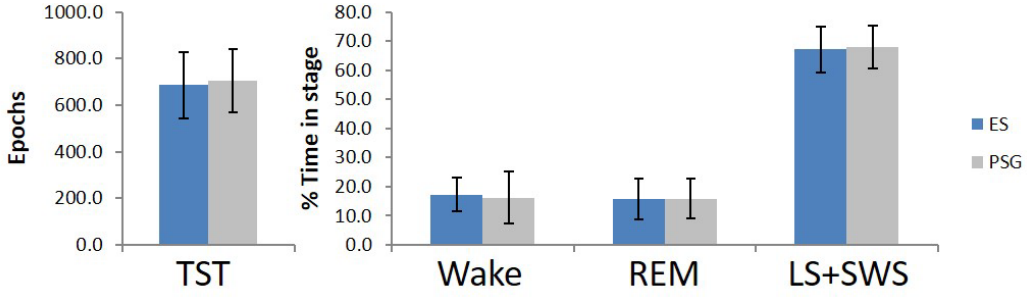



30-sec epochs; 195.6 h), the overall wake sensitivity was 79.0%, sleep (REM + LS + SWS) sensitivity was 95.1%, and overall agreement was 92.5%. Combined analysis of the results for both home setups showed a 76.7% sensitivity to wake, 95.2% sensitivity to sleep, and overall accuracy of 92.5% (**Tables S3–S5** in the supplemental material).

**Figure 3** presents an example of a single night, with a PSG reference hypnogram (top panel) versus movement, HR, and RR measurements with the ES contact-free sensor (lower three panels). The data show a close correspondence between movements and the various sleep stages, as well as increases of HR, HR variability, and RR variability during REM cycles. TST measurement by the ES sensor and PSG showed an overall correlation factor of 0.98 (R = 0.87) (**Figure 4**). Comparison of average TST and sleep stage revealed that, on average, the per night distribution of sleep stages was similar as determined by the PSG reference and the contact-free ES sensor device (**Figure 5**).

**Figures S2–S4** in the supplemental material show examples of using the ES contact-free sensor to monitor circadian rhythm, and its possible use for long-term monitoring—displaying movement, heart rate, and respiration rate for 12 consecutive days and nights. In the example, delayed sleep onset can be observed during the weekends (Friday and Saturday).

**Figure 5**—Comparison between data assessed by the EarlySense (ES) sensor (blue bars) and that derived from polysomnography (PSG) data (gray bars) for all nights (n = 85), including in the sleep laboratory and at home.




## DISCUSSION

The results of our current validation study demonstrated that the ES contact-free sensor was highly accurate in detecting sleep and wake states relative to the gold standard, PSG. Moreover, the ES contact-free sensor measured HR and RR throughout the night with accuracy similar to that of the ES sensor that is currently used in general wards in hospitals for this purpose.[14] The monitoring of these two vital signs (HR and RR) integrated with motion detection give this system an advantage over simple activity trackers, such as actigraphy or wrist bands, and enable analysis of four sleep stages: wake, REM, LS (N1+N2), and SWS.

Actigraphy is a well-established practice in sleep medicine, especially for detecting circadian disturbances. It is mainly used for sleep/wake cycle analysis in order to track sleep schedule. Sleep and wake states can also be monitored based on motion tracking using popular wrist bands. It is well established that heart rate analysis—specifically, heart rate variability methods—allow differentiation of four states: deep sleep (SWS), LS, REM, and awake state.[17,18] Studies have demonstrated that ECG-based analysis can produce an accurate per night distribution of these four states. [33]

The current sleep/wake analysis results meet or exceed the reported accuracy of actigraphy.[19,20,21] These findings indicate that the contact-free ES sensor may be used as an objective sleep diary. Compared to actigraphy, the ES device has the advantage of being conveniently installed under the mattress, enabling seamless monitoring without the burden of wearing or charging a device. The main limitation of the ES sensor is that it collects data only when the subject sleeps in the bed that has the sensor embedded underneath the mattress.

Because the four-state sleep analysis results in our study are lower than the interobserver agreement in PSG, the contact-free ES sensor cannot be considered for professional use. However, to our knowledge, the ES sensor shows the highest accuracy for four sleep-state analysis compared to any other published non-EEG system, including other contactless monitoring devices that use technology based on passive infrared,[22] sonography,[13] or pressure sensation.[23]

The current results demonstrate that the performance of the contact-free ES sensor was not impaired by environmental factors, such as home environment, mattress type, or a second person in the bed. These findings confirm the suitability of this device for consumer use, in keeping with the increasing trend of self-monitoring. Moreover, the performance of the ES system could potentially be further improved, to achieve even better results. We are currently investigating the accuracy of the ES contact-free sensor for the identification of sleep-disordered breathing. In the future, the ES system may be integrated into smart homes when biofeedback is required, and used as a reliable monitoring device in the emerging research field of improving sleep.

## CONCLUSIONS

The results of this study confirm that the ES contact-free sensor is highly accurate in detecting sleep and wake states relative to the gold standard, PSG. The ES sensor is a reliable, comfortable option, being a noncontact sensor that is installed under the mattress.

## ABBREVIATIONS

ES, EarlySense
HR, heart rate
LS, light sleep
PSG, polysomnography
REM, rapid eye movement
RR, respiratory rate
SWS, slow wave sleep
TST, total sleep time

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Authors' contributions: AT participated in the study design and patient recruitment, and drafted the manuscript. ZS developed the software algorithms for sleep detection and sleep pattern recognition, participated in data analysis, and drafted the manuscript. DS, SC, and AG contributed to the patient recruitment, data analysis, and discussions during the manuscript writing. All authors read and approved the final manuscript.

## SUBMISSION & CORRESPONDENCE INFORMATION

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## DISCLOSURE STATEMENT

This work was supported by funding from EarlySense, Ltd. Dr. Shinar is an employee of EarlySense, the company that developed the technology used in this study. Dr. Tal has participated in the speakers' bureau of Sanofi and Teva. Dr. Goldbart has recieved research support from the Israel Science Foundation (ISF grant 1344/15). The other authors have indicated no financial conflicts of interest. Ethics Statement: The study was approved by the Institutional Review Ethics Committee of Soroka Medical Center, Ben-Gurion University of the Negev, Beer Sheba, Israel (IRB Approval Reference Number: 0231-13-SOR; 24 Oct 2013). All records and information were anonymized and de-identified for analysis and publication. All subjects signed consent forms.

## EDITOR'S NOTE

The Emerging Technologies section focuses on new tools and techniques of potential utility in the diagnosis and management of any and all sleep disorders. The technologies may not yet be marketed, and indeed may only exist in prototype form. Some preliminary evidence of efficacy must be available, which can consist of small pilot studies or even data from animal studies, but definitive evidence of efficacy will not be required, and the submissions will be reviewed according to this standard. The intent is to alert readers of *Journal of Clinical Sleep Medicine* of promising technology that is in early stages of development. With this information, the reader may wish to (1) contact the author(s) in order to offer assistance in more definitive studies of the technology; (2) use the ideas underlying the technology to develop novel approaches of their own (with due respect for any patent issues); and (3) focus on subsequent publications involving the technology in order to determine when and if it is suitable for application to their own clinical practice. The *Journal of Clinical Sleep Medicine* and the American Academy of Sleep Medicine expressly do not endorse or represent that any of the technology described in the Emerging Technologies section has proven efficacy or effectiveness in the treatment of human disease, nor that any required regulatory approval has been obtained.