Polysomnographic validation of an under-mattress monitoring device in estimating sleep architecture and obstructive sleep apnea in adults

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Introduction

Consumer home devices have gained rising popularity among the general population for sleep monitoring [1]. Yet most currently available home sleep monitoring devices lack validation [2]. The objective of this study is to evaluate the validity of an under-mattress monitoring device (Fullpower Technologies) in estimating sleep continuity and architecture, as well as estimating obstructive sleep apnea in an adult population.

Methods

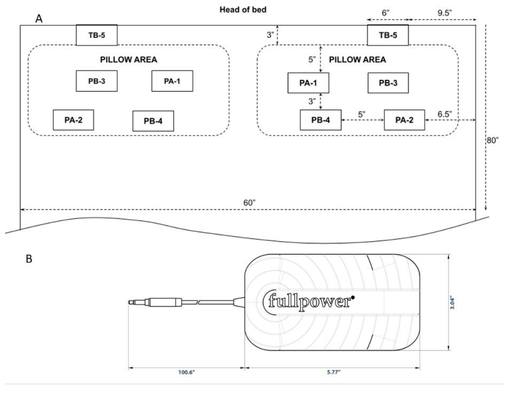
Adult volunteers (n=102, 55% male and 45% female, aged 40.6 ± 13.7 years with a mean body mass index of 26.8 ± 5.8 kg/m^2) each participated in a one-night unattended in-lab study conducted by Fullpower Technologies. Each participant slept on a queen-sized bed with Sleeptracker-AI Monitor sensors placed underneath the mattress. Standard polysomnography (PSG) was simultaneously recorded on the same night. Researchers (FD and CK) were provided de-identified sleep studies and datasets by Fullpower Technologies for analysis. Sleep continuity measures, 30-second epoch-by-epoch sleep stages, and apnea and hypopnea events estimated by an automated algorithm from the Sleeptracker-AI Monitor were compared with the PSG recordings, with the PSG recordings serving as the reference.

Demographics

Characteristic	Mean ± SD (range), or n (%)
Age, years	40.6 ± 13.7 (range 18 – 72)
Male / Female	55 (53.9%) / 47 (46.1%)
BMI, kg/m^2	26.8 ± 5.8 (range 17.7 – 44.6)
BMI < 25	50 (49.0%)
25 ≤ BMI <30	28 (27.5%)
BMI ≥ 30	24 (23.5%)

N = 102, BMI = Body Mass Index.

Device Setup



One Sleeptracker-AI Monitor setup consists of two Sleeptracker-AI Monitor sensors placed between the mattress and foundation, each connected to one Sleeptracker-AI Monitor processing unit.

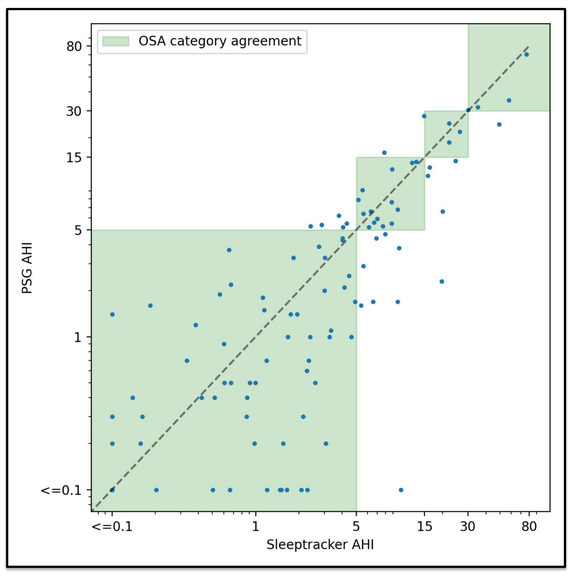
A) Sleeptracker-AI Monitor sensor positions tested. Each position corresponds to an independent Sleeptracker-AI Monitor, with independent predictions.

B) Dimensions of Sleeptracker-AI Monitor.

Obstructive Sleep Apnea Comparison

Accuracy, sensitivity, and specificity of Sleeptracker-AI Monitor in estimating obstructive sleep apnea among 102 participants compared with polysomnography

	AHI ≥ 5	AHI ≥ 15
Accuracy (95% CI), %	87.3 (80.8, 93.7)	92.2 (86.9, 97.4)
Cohen's Kappa (95% CI)	0.723 (0.582, 0.864)	0.649 (0.414, 0.883)
Sensitivity (95% CI), %	85.7 (74.1, 97.3)	81.8 (59.0, 100.0)
Specificity (95% CI), %	88.1 (80.3, 95.8)	93.4 (88.3, 98.5)
Positive likelihood ratio (LR+) (95% CI)	7.18 (3.69, 14.0)	12.4 (5.44, 28.3)
Negative likelihood ratio (LR-) (95% CI)	0.162 (0.072, 0.368)	0.195 (0.055, 0.685)



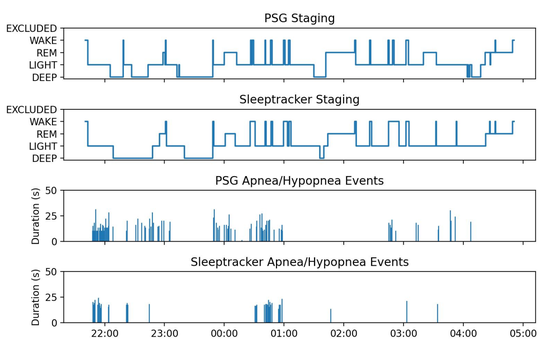
Sleep Staging Comparison

Epoch-by-epoch agreement, sensitivity and specificity between Sleeptracker-AI Monitor and polysomnography in 102 participants

Sleep stage	Accuracy (95% CI), %	κ (95% CI)	Sensitivity (95% CI), %	Specificity (95% CI), %
Multiple classes				
Wake/N1+N2/ N3/REM	79.0 (77.8, 80.2)	0.676 (0.656, 0.697)	n/a	n/a
Wake/NREM/REM	86.6 (85.4, 87.7)	0.733 (0.706, 0.756)	n/a	n/a
Single class				
Wake	93.3 (92.4, 94.1)	0.709 (0.672, 0.743)	71.3 (66.8, 75.7)	96.8 (96.1, 97.4)
Light	80.1 (78.8, 81.2)	0.601 (0.576, 0.625)	84.8 (83.6, 86.2)	75.3 (72.9, 77.2)
Deep	92.0 (91.3, 92.7)	0.673 (0.644, 0.702)	65.6 (62.1, 68.9)	96.9 (96.3, 97.4)
REM	92.6 (91.6, 93.5)	0.772 (0.743, 0.800)	80.0 (76.5, 83.3)	95.9 (95.2, 96.5)

Example Hypnogram

Median four-class sleep staging accuracy example



Stage by stage cross tabulation of Sleeptracker-AI Monitor compared with polysomnography

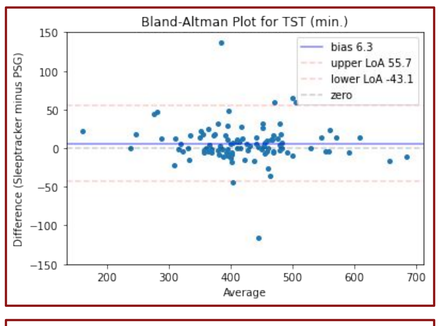
Sleeptracker-AI		PSG Wake	PSG Light	PSG Deep	PSG REM
Dichotomized accuracy, %		93.3	80.1	92.0	92.6
Cross Tabulation, %	Wake	71.32	4.87	0.71	0.92
	Light	23.42	84.92	33.59	19.04
	Deep	1.48	4.84	65.56	0.05
	REM	3.79	5.37	0.14	79.99

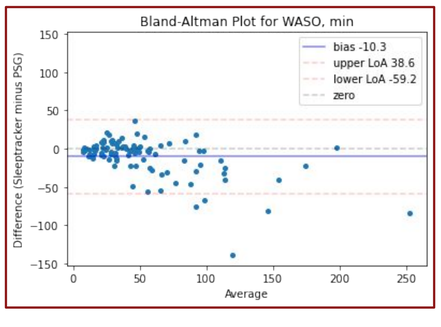
Sleep Architecture Comparison

Means and correlation of sleep parameters between Sleeptracker-AI Monitor and polysomnography in 102 participants

**p value < 0.0001. *p value < 0.05.

Sleep parameters	Sleeptracker-AI Mean (SD)	Sleeptracker-AI Range	PSG Mean (SD)	PSG Range	Correlation coefficient (Rho)
TST, min	423.9 (83.3)	172.0, 679.0	417.6 (85.2)	150.0, 690.5	0.96**
SOL, min	15.6 (27.0)	0, 205.5	11.6 (11.6)	0, 55.0	0.34*
WASO, min	46.2 (37.0)	5.5, 211.0	56.4 (50.3)	7.0, 294.5	0.88**
SE, %	87.6 (8.7)	55.4, 98.4	86.3 (9.7)	52.1,97.2	0.87**
Light, min	265.5 (62.2)	124.0, 465.5	241.6 (63.7)	64.5, 445.5	0.84**
Deep, min	62.8 (23.0)	4.5, 119.5	75.2 (32.5)	5.0, 173.0	0.61**
REM, min	96.3 (30.6)	30.0, 170.5	100.8 (39.6)	26.0, 223.0	0.76**





Results

Overall, the Sleeptracker-AI Monitor estimated similar sleep continuity measures compared with PSG. The Sleeptracker-AI Monitor overestimated total sleep time (TST) by an average of 6.3 minutes and underestimated wake after sleep onset (WASO) by 10.2 minutes. Sleep efficiency (SE) was similar between the Sleeptracker-AI Monitor and PSG (87.6% and 86.3%, respectively).

The epoch-by-epoch accuracy of Sleeptracker-AI Monitor to distinguish 4-stage sleep (wake, light, deep, and REM sleep) was 79.0% (95% CI: 77.8%, 80.2%) with a Cohen's kappa of 0.676 (95% CI: 0.656, 0.697).

Thirty-five participants (34.3%) were diagnosed with obstructive sleep apnea (OSA) with an apnea-hypopnea index (AHI) ≥ 5 based on PSG. Accuracy, sensitivity, and specificity for the Sleeptracker-AI Monitor to estimate OSA (an AHI ≥ 5) were 87.3% (95% CI: 80.8%, 93.7%), 85.7% (95% CI: 74.1%, 97.3%), and 88.1% (95% CI: 80.3%, 95.8%) respectively. The positive likelihood ratio (LR+) for AHI ≥ 5 was 7.18 (95% CI: 3.69, 14.0), and the negative likelihood ratio (LR-) for AHI ≥ 5 was 0.16 (95% CI: 0.072, 0.368).

Conclusion

The Sleeptracker-AI Monitor had high accuracy, sensitivity, and specificity in estimating sleep continuity measures and sleep architecture, as well as in estimating apnea and hypopnea events. These findings indicate that Sleeptracker-AI Monitor is a valid device to monitor sleep quantity and quality among adults. Sleeptracker-AI Monitor may also be a reliable complementary tool to PSG for OSA screening in clinical practice.

References

[1] Kelly JM, Strecker RE, Bianchi MT. Recent developments in home sleep-monitoring devices. ISRN Neurol 2012;2012:768794. https://doi.org/10.5402/2012/768794.

[2] Khosla S, Deak MC, Gault D, Goldstein CA, Hwang D, Kwon Y, et al. Consumer Sleep Technology: An American Academy of Sleep Medicine Position Statement. J Clin Sleep Med 2018;14:877–80. https://doi.org/10.5664/jcsm.7128.

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