



SLEEPTRACKER® Evaluation Study

ANALYSIS REPORT

Submitted by

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Introduction

SLEEPTRACKER® continuously monitors signals from the body that indicate whether the person is asleep or awake. SLEEPTRACKER® finds the best waking moments, so that waking up has never been easier. The average adult experiences 4-5 full sleep cycles over an 8-hour period. Many factors can influence sleep cycles, including diet, exercise, medications, drugs or alcohol, stress, sleep disorders, and sleep deprivation. A typical sleep cycle has five stages and takes 90-110 minutes. During Stage 1 of the sleep cycle, one sleeps lightly. At Stage 2, the sleep gets progressively deeper. At Stages 3 and 4, also known as "Delta Sleep," the person sleeps most heavily. Stage 5 of sleep, also known as REM (rapid eye movement) sleep, is marked by extensive physiological changes, such as accelerated respiration, increased brain activity, rapid eye movement, and muscle relaxation. In the first third of the night, Delta sleep stages last longer than REM stages. As the night progresses, Delta sleep diminishes in length. By the last third of the night, Delta sleep usually ceases, while REM stages lengthen.

SLEEPTRACKER® uses a tiny accelerometer to measure certain types of lateral motion that correlate to lighter stages of sleep. It uses those times to give the user a picture of how many restless or light sleep periods they have throughout the night. The more recorded events, the worse the sleep. It also uses those almost awake moments to detect lighter stages of sleep within the alarm window to wake the user at the optimal time. SLEEPTRACKER® may find multiple almost-awake moments within the sleep cycle. Almost-awake moments may also vary in frequency throughout the night.

The purpose of this evaluation study is to compare SLEEPTRACKER® with advanced sleep laboratory equipment in the proper detection of movement events.

Methods

Data collection was independently conducted by Douglas W. Puryear, MD, FCCP, D. ABSM, Director of Sleep Disorders Centers of Pulmonary Associates located at 2354 Colony Crossing Place in Midlothian, VA 23112. A total of 20 subjects were used to collect sleep data during one night each. The SLEEPTRACKER® on two of the subjects was not turned on correctly so no data were recorded for comparison. Those two subjects were subsequently removed for data analysis purpose leaving a total of 18 subjects with full data. Dr. Puryear randomly selected the subjects among patients at the sleep center seen for apnea like symptoms. Consenting participants were paid \$25 each in the form of a gift card.

A battery of measurements was recorded in the lab on each subject for a duration of one night for each subject. Measurements include the following:

- EEG (C3,C4, F3,F4, O1, O2, FPZ, A1, A2,) LEOG & REOG (EYE LEADS)
- CEMG1 & CEMG2 (CHIN LEADS)
- LEMG & REMG (LEG LEADS)
- THORASIC BELT (BREATHING CHEST)
- ABDMONINAL BELT (BREATHING)

- NASAL FLOW
- THERMISTER FLOW
- PAP FLOW (CPAP IF NEEDED)
- EKG1 & EKG2
- SPO2 (PULSE OX)
- RR (HEART RATE)

Movements were monitored and recorded by both SLEEPTRACKER® and the lab equipment. The sleep data was summarized to compare event detection between SLEEPTRACKER® and the lab equipment, considered the “gold standard” in the study.

Results

The sample was formed so as to span different ages and gender combinations as shown in the following table.

Gender	Male	Female	Total
Number of Subjects	9	9	18
Minimum Age	37 yrs	37 yrs	37 yrs
Maximum Age	73 yrs	69 yrs	73 yrs
Mean Age	53.67 yrs	53.67 yrs	53.67 yrs
Standard Deviation	11.55 yrs	10.04 yrs	10.50 yrs

Across all 18 patients, a total of 203 "events" were recorded (either by the sleep lab equipment or by SLEEPTRACKER®). Of those, based on the column labeled "sleep lab equipments movement detection", 11 are no-movement and should not have been "detected" by SLEEPTRACKER®. In addition, based on the column labeled "Notes", 16 (or 17 if we include the micro event that lasted only 10.10 seconds) were not detected (missed) by SLEEPTRACKER®.

Thus, if the sleep lab equipment is considered the "gold standard" for this study, there were a total of $203 - 11 = 192$ "true" events detected by the lab equipment.

SLEEPTRACKER® missed 16 of those 192, thus leading to a 8.33% "false-negative" defined as an event that sleep tracker wrongly classifies as a non-event. In other words, of the 192 true events, SLEEPTRACKER® correctly recorded 176 of them and missed 16. Thus, SLEEPTRACKER® overall correct positive detection to incorrect positive detection ratio is 176 to 16 or 10.9 to 1. That is, for about every 11 correct positive detections, SLEEPTRACKER® misses one.

Regarding "false-positive" defined as a non-event that SLEEPTRACKER® wrongly classifies as an event), we know that SLEEPTRACKER® recorded 11 of them. However, we do not have a denominator (the total number of "non-events" to calculate a percentage. Obviously, the total number of "non-events" is infinite since, presumably, both SLEEPTRACKER® and the sleep lab equipment are "continuously" monitoring movement. In any case, the rate would be infinitely small (11 divided by a very large number, or infinity) and therefore is meaningless.

Thus, in addition to the false-negative rate of 8.33%, another way to look at the accuracy of

SLEEPTRACKER® is as follows.

Of the 203 total events, SLEEPTRACKER® correctly recorded 176 of them. SLEEPTRACKER® missed 16 true events and over-recorded an additional 11 non-events. Thus, SLEEPTRACKER® overall misclassification rate for all 203 events detected by either piece of equipment is $27/203=13.3\%$. In terms of a ratio, this translates to 176 to 27 or 6.52 to 1. Thus, for every 6.52 correct positive detections, SLEEPTRACKER® makes 1 mistake (either misses a positive detection or detects something that should not be detected).

All percentages and odd ratios are statistically significant at the 0.01 confidence level.

Conclusion

SLEEPTRACKER® performance in detecting events is excellent, as compared to state-of-the-art sleep laboratory equipment. Of a total of 203 total events detected by either SLEEPTRACKER® or the sleep equipment, SLEEPTRACKER® correctly recorded 176 true events, missed only 16 true events, and wrongly reported 11 non-events. Thus, SLEEPTRACKER® overall misclassification rate is 13.3%. In other words, for every 6.52 correct positive detections, SLEEPTRACKER® makes 1 mistake.

In terms of positive detections only, SLEEPTRACKER® correctly detects and records 91.67% of 192 true events (a false positive rate of only 8.33%). In other words, for every 11 correct positive detections, SLEEPTRACKER® misses one. Thus, the overall performance of SLEEPTRACKER® is excellent.