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## Validation of a portable single-channel EEG monitoring system

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### 携帯型1チャンネル脳波計の性能検証

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**Objectives:** The aim of this study was to validate the accuracy of a newly developed single-channel electroencephalogram and sleep staging by signals obtained from the device by comparing the sleep scoring results to those of simultaneously recorded full polysomnography.

**Methods:** Sleep stages were scored using the American Academy of Sleep Medicine Manual for Scoring Sleep 2007. The participants (age,  $52.4 \pm 11.9$  years; five women, 53 men) were Japanese clinic outpatients with an apnea-hypopnea index  $\leq 5$ .

**Results:** The average percent agreement and kappa coefficient of sleep stages between single-channel electroencephalogram and polysomnography were  $86.9\% \pm 4.42$  and  $0.75 \pm 0.081$ , respectively. In epoch-by-epoch analysis, the kappa coefficients showed strong agreement for stage R, stage W, and stage N1+N2 (0.80, 0.77, and 0.74, respectively) but weak agreement for stage N3 (0.25).

**Conclusions:** This single-channel electroencephalogram facilitates unattended sleep monitoring with results that acceptably agree with those of polysomnography. This feature may meet the needs of large epidemiological and interventional studies.

**Key words:** electroencephalogram, portable device, single channel, home monitoring, sleep  
(脳波計, 携帯型, 1チャンネル, 在宅計測, 睡眠)

### Introduction

Sleep duration is reportedly associated with mortality<sup>1)</sup>. However, studies citing this finding were based on self-reported data and not on sleep architecture data obtained from polysomnography (PSG) recordings<sup>1)</sup>. The PSG sleep scoring montage includes six electroencephalogram (EEG) channels, left and right electrooculogram (EOG), a bipolar submental electromyogram, and respiration monitors. PSG

provides comprehensive information about sleep duration and architecture, but it is too expensive and cumbersome for large-scale or repeated-measures evaluations<sup>2)</sup>. This makes PSG unsuitable for screening large populations or performing repeated evaluations. Actigraphy is a simple method for monitoring locomotor activity and can be used to estimate sleep/wake time but cannot access sleep architecture and sleep staging<sup>3, 4)</sup>.

Recent advances in electronic technologies and sensor

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interfaces have enabled a significant reduction in the size and weight of the recording equipment, resulting in a small EEG unit with only a few EEG electrodes<sup>5)</sup>. Using such devices, subjects can objectively monitor their sleep quality at home in their usual sleep environments. Single-channel EEG is reportedly effective for monitoring sleep<sup>6-11)</sup>. Most studies reporting this finding were based on single-channel EEG data derived from full PSG recordings<sup>6-10)</sup>, all of which used the Rechtschaffen and Kales sleep staging criteria<sup>12)</sup>.

The objective of the present study was to validate the accuracy of a newly developed single-channel EEG (PORTABLE EEG; SleepWell Co., Ltd., Osaka, Japan) and sleep staging by signals obtained from single-channel (1ch) EEG by comparing its results with those of simultaneously recorded PSG using the sleep staging criteria of the American Academy of Sleep Medicine (AASM) 2007<sup>13)</sup>.

## Methods

### Subjects and study design

The participants were outpatients of the Toyohashi Mates Sleep Disorder Treatment Clinic in Aichi, Japan, who underwent attended PSG to diagnose sleep apnea syndrome or calibrate continuous positive airway pressure (Alice 5, Philips Respironics, Amsterdam, Netherlands; Sleep Watcher E-series, Compumedics, Abbotsford, Australia; SomnoStar z4 Sleep System, CareFusion, San Diego, CA, USA; Sandman N7000, S4500, Mdrive, Titanium, SD32+, Embla, Thornton, CO, USA). The subjects were asked to wear the 1ch EEG (PORTABLE EEG, SleepWell Co., Ltd., Osaka, Japan) at the same time as the PSG. This study was conducted from April 17, 2009 to February 8, 2010. The data from participants with an apnea-hypopnea index (AHI)  $\leq 5$  on PSG were used in this study.

### Single-channel EEG system

The single-channel EEG system uses self-adhesive and disposable electrodes with gel to collect electrophysiological signals from the forehead and mastoid with a bipolar derivation signal. The EEG device contains a 12-bit analog to digital converter and preprocessing unit that amplifies and filters the electrophysiological signal. The sampling rate and filter setting were 128 Hz and 0.5-64 Hz, respectively. The device was powered by a chargeable AAA battery.

### Recording protocol

The PSG recorded biosignals as follows: EEG with recommended derivations (F4-M1, C4-M1, and O2-M1) and

back-up derivations (F3-M2, C3-M2, and O1-M2); left and right EOGs; chin electromyography (EMG); leg EMGs (recorded from linked electrodes placed at the left and right musculus anterior tibialis to monitor leg movements); and electrocardiogram and respiratory signals (airflow, chest and abdominal respiratory movements, and oxygen saturation). The PSG sampling rates for the SomnoStar, Sleep Watcher, Alice 5, and Sandman were 200, 256, 500, and 512 Hz, respectively. The PSG filter settings for the Sleep Watcher, Alice 5, SomnoStar, and Sandman were 0.3-30, 0.5-50, 0.3-35, and 0.3-30 Hz, respectively.

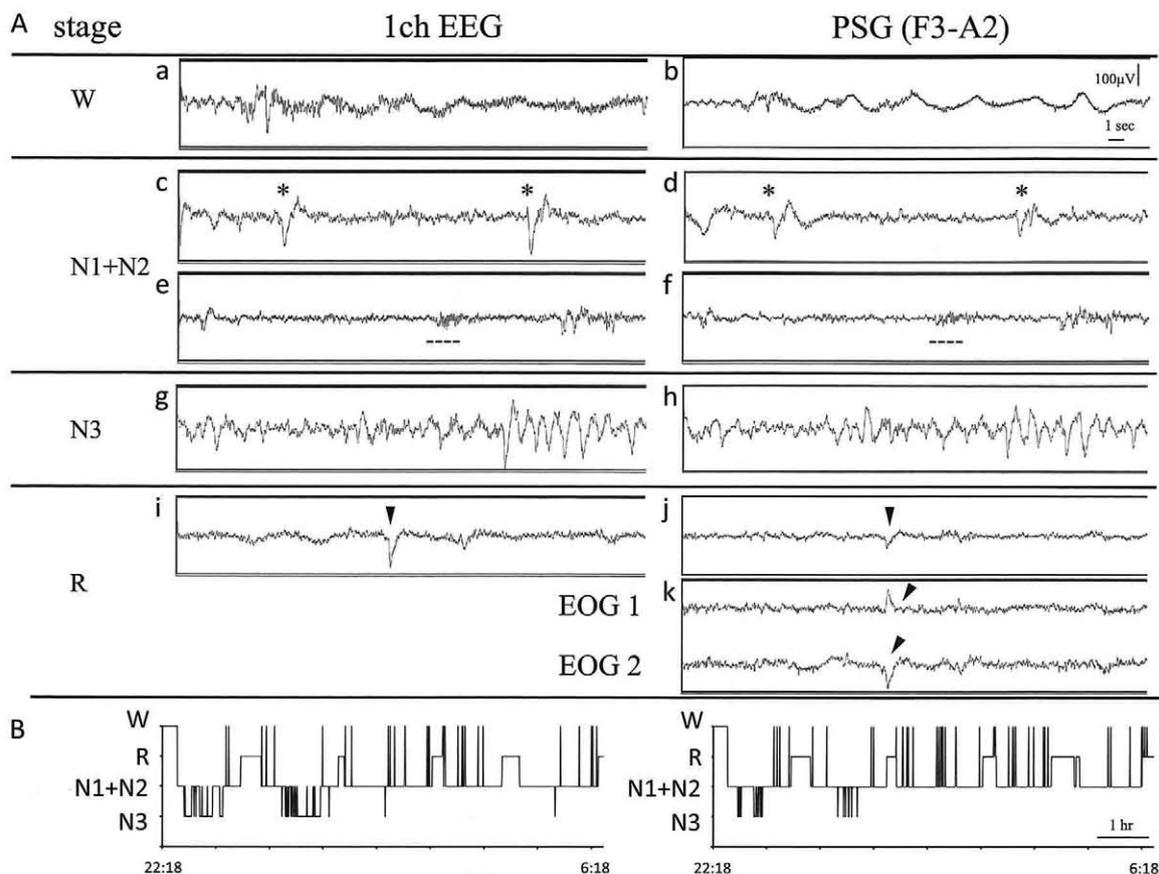
The channel located at approximately Fpz-M1 was recorded for the 1ch EEG system simultaneously with the recorded PSG.

The sleep technologists who attended the recordings were asked not to reattach the 1ch EEG electrodes when they disconnected during the recordings to determination of data loss rate of the self-adhesive electrodes.

### Staging

The PSG records were visually inspected and scored using the sleep staging criteria of the AASM 2007 (Iber et al. 2007) by sleep technologists certified by the Board of Registered Polysomnographic Technologists and/or the Japanese Society of Sleep Research. All data were recorded digitally in European Data Format<sup>14)</sup>.

The records of the 1ch EEG system were visually inspected. Each sleep EEG was staged according to AASM 2007 criteria<sup>13)</sup>. A reduced set of sleep stages was applied for the staging reported that included wakefulness, rapid eye movement (REM) sleep, N1+N2 (combined N1 and N2), and N3. This simplified scoring strategy was previously used in another portable EEG system<sup>11)</sup>. Briefly, the epochs were scored as stage W when  $> 50\%$  of the epoch had a sinusoidal alpha rhythm or eye blinks, reading eye movements, or body movement was recorded. The epochs were scored N1+N2 when the alpha rhythm was attenuated and replaced by low-amplitude mixed-frequency activity for  $> 50\%$  of the epoch. If K complex unassociated with arousal or sleep spindle trains occurred, we scored N1+N2. We continued to score N1+N2 with low amplitude and mixed-frequency activity until transition to stage W, N3, or R. Epochs were scored N3 when  $\geq 20\%$  of an epoch consisted of frequency waves of 0.5-2 Hz and a peak-to-peak amplitude  $> 75 \mu V$ . Epochs were scored stage R when low-amplitude, mixed-frequency activity and/or eye movements were suspected (Figure 1A). We continued to score R if the EEG showed low-amplitude, mixed-frequency activity without K complexes or sleep spindles. We ended



**Figure 1** Simultaneous recordings by 1ch EEG and PSG

A : Representative raw EEG waveforms of the same time frames scored as W (a, b), N1+N2(c, e and d, f), N3 (g, h) and R (i, j) obtained from the 1ch EEG (Fpz-M1) and the PSG (F3-A2), respectively. Raw EEG waveforms with PSG (k). 1ch EEG, single-channel electroencephalogram; PSG, polysomnography; EOG, electrooculogram; Asterisk, K-complex; dotted line, spindle; arrowhead, eye movement.  
B : Hypnograms from the 1ch EEG (left) and the PSG (right).

stage R when the epoch transitioned to stage W, N1+N2, or N3. If two or more stages coexisted during a single epoch, we assigned the stage comprising the greatest portion of the epoch. The PSG and 1ch EEG were scored independently from each other.

The Ethics Committee of the Toyohashi Mates Sleep Disorder Treatment Clinic approved the study protocol. Informed consent was obtained from each participant before the study.

### Statistical analysis

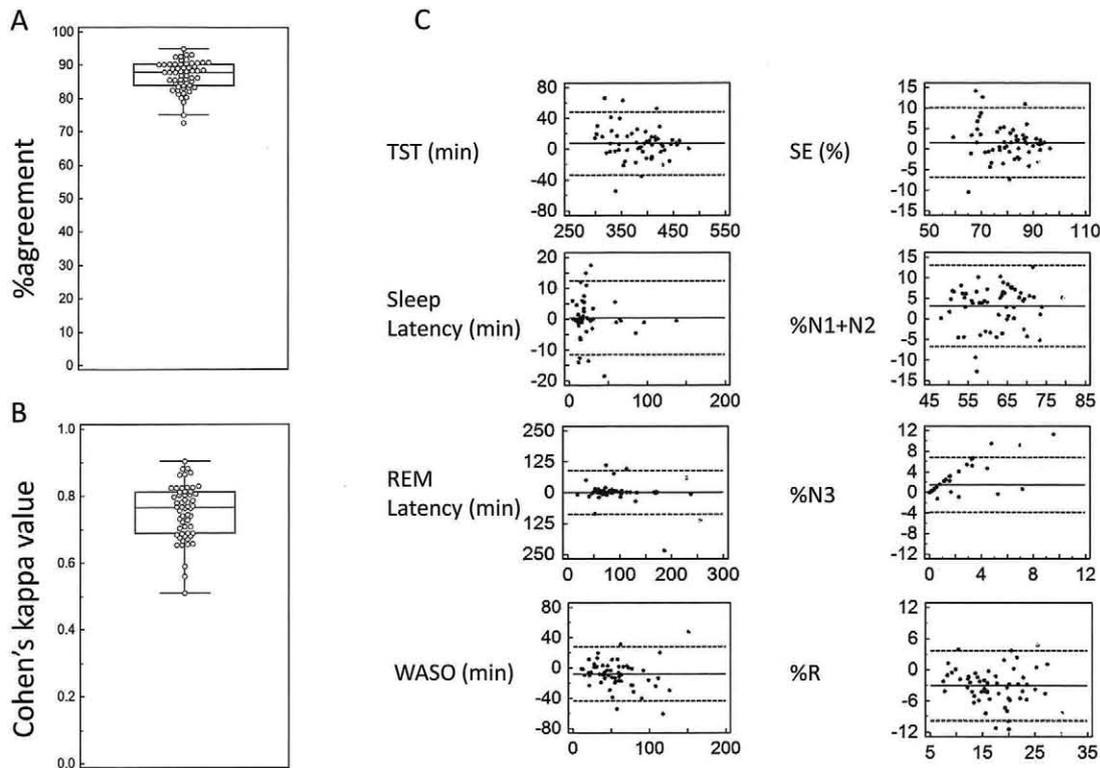
Categorical data are presented as proportions, and continuous data are presented as means and standard deviations. To compare sleep stages between the 1ch EEG system and the PSG, the PSG data scored as N1 and N2 were combined into N1+N2. The night-to-night variability and inter-scoring reliability were estimated using the intra-class correlation coefficient. Pooled epoch-by-epoch

agreement was established for sleep stages between the 1ch EEG system and PSG by calculation of the percent agreement and Cohen's kappa<sup>15)</sup>. A kappa value of 0–0.2 is considered essentially no agreement, 0.2–0.4 is considered low agreement, 0.4–0.6 is considered moderate agreement, 0.6–0.8 is considered high agreement, and 0.8–1.0 is considered almost perfect agreement<sup>16)</sup>. A Bland-Altman plot<sup>17)</sup> was drawn to present the relationship between the mean of two individual values and the difference between those values. Statistical analyses were performed using MedCalc version 9.3.1 (MedCalc Software, Mariakerke, Belgium).

## Results

### Participants' characteristics

During the study period, 1,572 outpatients underwent PSG at the Toyohashi Mates Sleep Disorder Treatment



**Figure 2 Agreement between PSG and 1ch EEG by subject**

Box-Whisker plot of the percent agreement (A) and Cohen's kappa value (B). Bland-Altman analysis of sleep parameters (C) from 58 subjects. In the Bland-Altman analysis, the differences between the two methods (vertical) are plotted against the averages of the two methods (horizontal). The mean difference and limit of agreement ( $\pm 1.96$  SD) are represented as dotted lines. PSG, polysomnography; 1ch EEG, single channel electroencephalogram; TST, total sleep time; REM, rapid eye movement; WASO, wake after sleep onset; SE, sleep efficiency; %N1+N2, N1+N2/TST (%); %N3, N3/TST (%); %R, REM/TST (%).

Clinic in Aichi, Japan. Subjects suspected to have sleep disorders other than sleep apnea were excluded. A total of 235 subjects were asked to participate. Of these, 233 patients agreed. All PSG recordings could be analyzed. No data were obtained from the 1ch EEG in 18 of 233 recordings because the self-adhesive electrodes detached during the recordings. Fifty-nine of the 215 participants had an AHI  $\leq 5$ , and their PSG data were analyzed. In one of these 59 participants, data were not analyzed by the AASM 2007 standard and were, therefore, discarded. Data from 58 subjects were ultimately used in this study.

Among the participants (five women, 53 men), the mean age was  $52.4 \pm 11.9$  years (range, 29–79 years); height,  $167.07 \pm 6.95$  cm; weight,  $73.26 \pm 11.98$  kg; body mass index,  $26.21 \pm 3.79$  kg/m<sup>2</sup>; AHI,  $1.92 \pm 1.57$ ; and Epworth Sleepiness Scale score,  $6.07 \pm 3.87$ .

**Durability, safety, and reliability (data loss) of the 1ch EEG**

No devices required repairs during the survey period for the 235 simultaneous recordings. No safety complaints or serious problems from the devices were reported by the participants, nor were any electrical problems reported.

Data were analyzed from 215 of 233 recordings (92.27%) from the 1ch EEG. The other 18 recordings could not be analyzed because of electrode disconnection. No data were lost from the PSG recordings because the attending sleep technologists immediately resolved any problems that occurred during the recording.

**Waveform obtained from the PSG and 1ch EEG**

Representative EEG waveforms staged for W, N1+N2, N3, and R obtained from the PSG and 1ch EEG are shown in Figure 1A. Fast, irregular, and low-voltage waves and body movement noises were detected (a, b). K complex,

**Table 1 Sleep Parameters monitored with PSG and 1ch EEG**

	PSG	1ch EEG	ICC
TIB (min)	478.0 ± 21.3	478.0 ± 21.3	1.00
TST (min)	380.7 ± 48.3	388.3 ± 44.6	0.887
Sleep Latency (min)	24.2 ± 24.5	24.6 ± 24.0	0.969
REM Latency (min)	92.1 ± 59.9	92.6 ± 48.4	0.669
N1+N2 (min)	288.9 ± 36.2	303.5 ± 36.9	0.723
N3 (min)	2.3 ± 6.3	9.3 ± 15.6	0.348
REM (min)	89.5 ± 28.1	75.5 ± 26.8	0.743
WASO (min)	59.7 ± 32.9	51.8 ± 30.9	0.812
N1+N2/TIB, (%)	60.5 ± 7.3	63.6 ± 7.7	0.716
N3/TIB (%)	0.5 ± 1.3	1.9 ± 3.2	0.349
REM/TIB (%)	18.8 ± 5.8	15.8 ± 5.4	0.708
Sleep Efficiency (TST/TIB, %)	79.7 ± 9.5	81.3 ± 8.8	0.878

Values are presented as mean ± SD.

PSG, polysomnography; 1ch EEG, single channel electroencephalogram; ICC, intra-class correlation coefficient; TIB, time in bed; TST, total sleep time; REM, rapid eye movement sleep; WASO, wake after sleep onset.

typically a high-amplitude, long-duration biphasic waveform (c, d), and sleep spindles with short-lived rhythmic activity (e, f) were seen on the 1ch EEG at the same time as the PSG. Slow-wave sleep with predominant delta activity was detected, especially in the last third of the each epoch of the 1ch EEG and PSG recordings (g, h). Rapid eye movement was seen in the 1ch EEG and in two channels of the EOG in the PSG (i and k, arrowheads). Eye movements were detectable in the EEG of PSG, but the signals were small (j, arrowhead).

#### Comparison of sleep parameters from the PSG and 1ch EEG

Figure 1B shows representative four-state hypnogram data analyses from the PSG and 1ch EEG. For this staging, the percent agreement and kappa coefficient between the PSG and 1ch EEG were 83.5% and 0.65, respectively.

The box-whisker plots in Figures 2A and 2B show the distributions of the percent agreement and kappa value of data from 58 participants. The average percent agreement and kappa coefficient were 86.9% ± 4.42 and 0.75 ± 0.081, respectively.

Comparison of average of sleep parameters with data from the PSG versus the 1ch EEG showed a slight increase in stage N1+N2, significant increase in stage N3, and slight decrease in stage R (Table 1) for the 1ch EEG. No

statistically significant differences were found for any other sleep scoring summary statistics.

The Bland-Altman plots in Figure 2C show the differences in sleep parameters. No apparent proportional bias was found except for N3.

#### Epoch-by-epoch comparison of PSG and 1ch EEG

The pooled accuracy by stage is shown in Table 2. Each row represents the stages from the PSG scorings, while each column represents the stage from the 1ch EEG. The stage-specific agreement presented by each kappa coefficient was substantial except for stage N3. In 35.9% of cases, epochs staged as N3 by the PSG were misclassified as N1+N2. In 17.5% and 3.5% of cases, epochs staged as W by the PSG were misclassified as N1+N2 and R, respectively. In 20.9% of cases, epochs staged as R by the PSG were misclassified as N1+N2. Kappa coefficients showed strong agreement for R, W, and N1+N2 (0.80, 0.77 and 0.74 respectively) but weak agreement for N3 (0.25).

#### Discussion

In this study, we compared 1ch EEG recordings with simultaneously recorded PSG in a clinical setting. The sleep stage scoring results from the signals obtained from the 1ch EEG showed reasonable agreement with the manually

Table 2 Pair-wise epoch by epoch agreement between PSG and 1ch EEG

		1ch EEG				Total	No. epochs	% epochs
		W	N1+N2	N3	R			
PSG	W	78.9%	17.5%	0.1%	3.5%	100%	11125	20.1%
	N1+N2	4.2%	92.0%	2.7%	1.1%	100%	33690	60.7%
	N3	2.1%	35.9%	62.0%	0.0%	100%	284	0.5%
	R	1.9%	20.9%	0.0%	77.2%	100%	10363	18.7%
No. epochs		10395	35207	1101	8759			
% epochs		18.7%	63.5%	2.0%	15.8%			
Kappa value		0.77	0.74	0.25	0.80			

PSG, polysomnography; 1ch EEG, single channel electroencephalogram.

scored PSG.

The 1ch EEG recorded waves that were characteristic of specific sleep stages, such as spindles, K-complexes, and slow and rapid eye movements. Periorbital skin electrodes are reportedly useful for detecting both EEG and EOG<sup>2, 18)</sup>. We chose Fpz-M1 to detect both EEG and EOG signals in the 1ch setting. The use of self-adhesive and disposable electrodes and the Fpz-M1 position made it easy for the participants to set up the device by themselves. The differences in waveforms noted between the PSG and 1ch EEG may have resulted from differences in EEG electrode placement.

Epoch-by-epoch agreement of the staging results was  $86.9 \pm 4.42\%$ . The overall kappa was  $0.75 \pm 0.081$ , which suggests reasonable agreement. The epoch-by-epoch agreement in Table 2 shows that percent agreement and kappa value were both the lowest in stage N3. The PSG analyses represented only 0.5% of stage N3 in this study. The small number of stage N3 occurrences could have caused this discrepancy. In 62% and 81% of the participants, ages were  $> 50$  and  $> 40$  years, respectively. This may have reduced the number of N3 occurrences in this population. The PSG was recorded in F3-M2, while the 1ch EEG was recorded in Fpz-M1. This difference in position might have caused a difference in the amplitude of the delta waves and resulted in stage N3 identification discrepancies.

Although the AASM 2007 criteria recommended a sampling rate  $\geq 200$  Hz, the 1ch EEG was recorded at 128 Hz. Since waveforms of 0.5–45 Hz were analyzed, the sampling rate of 128 Hz may be sufficient to discern waveforms for the sleep analysis. The reduced sampling rate was suitable for reducing both electricity consumption

and EEG data file size.

A limitation of the 1ch EEG is its minimal number of electrodes without back-up derivations. No data can be obtained when one electrode falls off. We encountered an approximately 6% data loss (684/12,000 recordings) due to electrode malfunctions. After the application of additional adhesive tape or the use of larger electrodes, the data loss rate decreased to  $\leq 3\%$ .

The 1ch EEG was not developed to substitute for a full PSG for diagnosing sleep disorders; rather, it was designed to monitor daily sleep more easily in epidemiological and clinical settings. This device is durable and has been used under severe conditions such as those in Antarctic expeditions<sup>19, 20)</sup> and high-altitude expeditions (1,562 m above sea level)<sup>21)</sup>. The easy-to-use 1ch EEG device also may be useful in unattended home settings. Subjects can use the 1ch EEG on multiple nights to detect intervention- or therapy-related changes, such as monitoring hypnotic drug action<sup>7)</sup>. Sleep EEG abnormalities are observed in individuals with major depressive disorder<sup>22)</sup>, and insomnia may lead to depression<sup>23)</sup>. Home sleep EEG may be useful to predict changes in depressive symptoms. In many cases, family physicians treat only the subjective symptoms of patients with insomnia since they do not readily have access to easy-to-use devices for monitoring sleep quality. With 1ch EEG, physicians can more objectively monitor sleep and diagnose insomnia. This may help them consult sleep specialists more effectively when necessary, which may lead to an earlier diagnosis of a sleep disorder.

The present study was performed in a clinical setting, and validation studies in a general population may be required. We are now initiating a large sleep cohort study in both a general and a working population in Japan.

In conclusion, the 1ch EEG recorded appropriate waveforms for sleep staging, the findings of which showed acceptable agreement with the PSG findings. Thus, this 1ch EEG may meet the requirements of large epidemiological and interventional studies.

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### Conflict of authors

Mr. Yoshida and Dr. Urade are directors and stakeholders, Dr. Kashiwagi is an employee, Dr. Kadotani is an advisor, and Dr. Koike is a stakeholder of SleepWell Co. Ltd. Dr. Kadotani is also supported by a donation from Philips Respironics to Shiga University of Medical Science and a member of the Merck & Co. Inc. Advisory Board, which collaborates with the TEIJIN and NPO 0-degree Club. Mr. Yamamoto and Drs. Matsuo and Yamada report no conflicts of interest.

### Author contributions

Mr. Yamamoto and Dr. Koike conducted simultaneous recordings of 1ch EEG and polysomnography. Mr. Yoshida performed the sleep staging. Drs. Kashiwagi and Kadotani performed the statistical analysis. All of the authors contributed to the writing, editing, and final approval of the manuscript.

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