

# Objective Assessment of Sleep using a 2-Channel Portable, Self-Applicable Device

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## Methodological Question:

Objective assessment of sleep in clinical trials requires the recording of various biological signals (at least electroencephalography - EEG, electrooculography - EOG and electromyography - EMG). This method – polysomnography (PSG) - is usually carried out at highly specialized sleep-centers requiring skilled personnel and full equipment, and limits the number of measurements to only a few nights in a protocol. This might not be representative for a patient's sleep. Portable solutions for sleep measurement are gaining increasing acceptance based on published evidence. Currently, most such solutions still rely on the availability of a full montage according to the published standards (AASM 2012), preventing the easy self-applicability and thus limiting the potential scope of those instruments. Thus, a portable, less intrusive and self-applicable solution for sleep measurement would allow for the acquisition of more nights in the patient's familiar environment. Recently, we presented a new method of sleep staging based on a reduced setting using two EOG channels only (Gruber et al. 2016). We could demonstrate, that the algorithm identified effectively the three main states wakefulness, NREM sleep and REM sleep from the two EOG channels as compared to the standard setting including additional EEG and EMG channels.

## Aims:

The aim of this paper is the application of the 2-EOG based algorithm in data acquired with a 2-channel, self-applicable recording device, and to compare the results to simultaneously recorded standard PSG.

## Methods:

20 healthy subjects (aged 20 – 29 years) participated in the experiment. Standard PSG was recorded using the EEG channels F4, C4, and O2 referenced versus the contralateral mastoid (A1), submental EMG, and 2 EOG electrodes placed one cm above the outer canthus of the right eye (ROC) and below the outer canthus of the left eye (LOC) referenced both versus A1. The reduced montage included 2 EOG electrodes placed one cm above LOC and below ROC respectively, referenced versus A2 (i.e. mirror-inverted to the standard montage) and was recorded using an Actiwave miniature recorder (Camnitech, Cambridge UK).

All 40 recordings were analyzed either using a validated computer assisted scoring system (Anderer et al. 2010) for the standard PSGs and a modified version adapted for the reduced 2-channel montage.

The calculated target variables included - among others - the sleep efficiency index (EFF), Wake after sleep onset (WASO), latency to persistent sleep (LCONT), and the percentages of sleep stages N1, N2, N3, and R.

## Results:

Data loss as a result of absent backup channels was minimal in the 2-channel recorder. The number of epochs not scoreable was 1.3 % in the portable device (0 % in the standard recording).

In general, the differences between the target variables between reduced and standard montage were marginal in absolute terms: EFF: -0.47 % (SD=2.6), WASO: -3.2 minutes (SD= 9.05), LCONT: +3.2 minutes (SD=8.28), N1%: - 0.24 % (SD=4.57), N2%: -0.61% (SD=7.36), N3%: -0.52% (SD=7.17), and R%: +1.44 (SD=4.5). As expected, no significant differences were found in a paired samples t-test in any variable. Bland-Altman plots showed no evidence of a systematic bias. However, it needs to be mentioned that this is yet no prove of equivalence, which could only be demonstrated by a non-inferiority design.

## Conclusion:

The results provide further indication that, with appropriate computer-supported sleep scoring, data obtained by means of a 2-channel portable device lead to sleep measurements comparable to a full PSG.

## References:

Anderer P, Moreau A, Woertz M, et al. Computer-assisted sleep classification according to the standard of the American Academy of Sleep Medicine: validation study of the AASM version of the Somnolyzer 24 × 7. *Neuropsychobiology*. 2010;62(4):250-64.

Gruber G, Parapatics S, Loretz E, Schmittner S, Dorffner, G. Validation of sleep staging based on a reduced montage using 2 EOG channels. *Journal of Sleep Research*. 2016; 25 (Suppl. 1): 344.

## Disclosure:

GG, SP, EL, GD are employees and shareholders, MK is employee of The Siesta Group.