Nocturnal Recording with **Ultra Long-Term Subcutaneous EEG** Recorder Is Effortless and Shows High Adherence

Lykke Blaabjerg[1,†], Esben Ahrens[2], Jonas Duun-Henriksen[1], Helle W. S. Borregaard[2], Sofie Sylvest Nielsen[1], Bjarki Ditlev Djurhuus[3,4], Preben Homøe[3,4], Troels W. Kjær[1], Martin Christian Hemmsen[2]

[1]UNEEG medical, Alleroed, Denmark; [2]T&W Engineering, 3450 Alleroed, Denmark; [3] Zealand University Hospital, Zealand, Denmark, [4]University of Copenhagen, Copenhagen, Denmark;
†Contact: lybl@uneeg.com

Key Points

- **Nocturnal recording subcutaneous EEG (sqEEG) over a 1-year period is feasible in a real-world setting**

- **The 24/7 EEG™ SubQ is easy to use and overall, a positive experience**

Introduction

- Minimally invasive devices are emerging to meet the need for long-term, real-world EEG recordings to provide objective data and aid in epilepsy management.[a]

- These devices must be easy to use and have low interference with everyday-life activities as patients need to use them daily for extended periods of time.

- Here, we report the adherence and user perspective on the minimally-invasive subcutaneous EEG (sqEEG) recording device, 24/7 EEG™ SubQ.

Methods

- A clinical study was set up to record sqEEG in healthy adults for 365 consecutive nights to investigate sleep.[b]

- Daily usage pattern and adherence, calculated as the percentage of nights with at least 4 hours of sqEEG, were obtained.

- The 10-item System Usability Scale (SUS) questionnaire is a widely accepted method for subjective assessment of device usability and was used in this study to evaluate the 24/7 EEG™ SubQ system.

- Discomfort related to the UNEEG SubQ implant and Ease of Use of the 24/7 EEG™ SubQ system were assessed with a 5-point scale ranging from "Strongly agree" to "Strongly disagree".

- The SUS, Discomfort and Ease of Use questionnaires were evaluated in the beginning of the study (6 weeks after start of sqEEG recording) and at the end of the study (1 year after start of sqEEG recording).
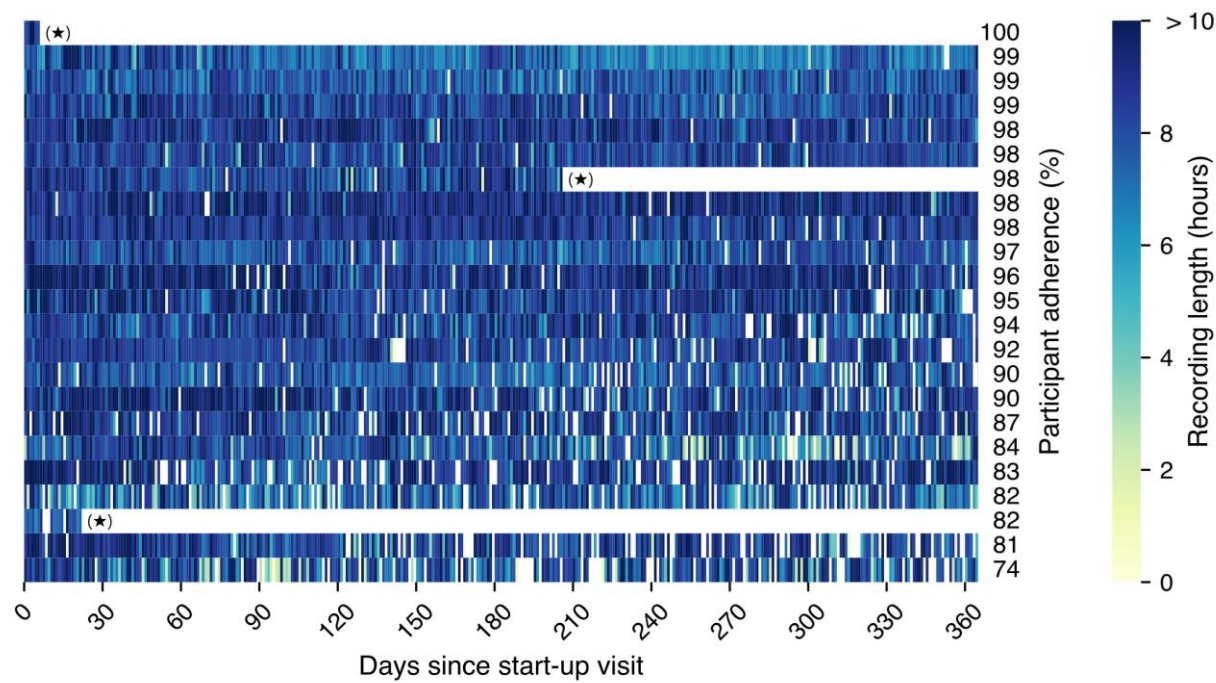

Figure 1
Adherence and daily usage pattern for the 23 participants is shown on the horizontal rows of the graph as a function of days in the study. The colors represent the recording length for each night. White means that no recording was made. The black star (★) marks the participants that did not complete the 1-year study. The adherence rate for each participant is shown to the right of each row in percentage

System Usability Score (SUS)				
Timepoint	n	Mean SUS score	Std Dev	Range
6 weeks	21	83.1	11.1	50-100
1 year	19	86.3	10.1	60-97.5

Table 1
Mean SUS scores, median and range across all participants are presented after 6 weeks and 1 year of sqEEG recording, respectively. n= number of participants who completed the questionnaire.
SUS scores between 84.1-100 are regarded as 'best imaginable' for a given device.[c]

[a]Duun-Henriksen et al. A new era in electroencephalographic monitoring? Subscalp devices for ultra–long-term recordings. Epilepsia 2020, Vol.61(9)
[b]Ahrens et al, The Ultra Long-Term Sleep Study: Design, Rationale, Data Stability, and User Perspective (Submitted to J. Sleep Res, 2023), NTC04513743
[c] https://measuringu.com/interpret-sus-score/

Results

- Adherence ranged from 74-100% across all participants (n= 23). Two-thirds recorded sqEEG ≥ 90% of all nights.

- The mean SUS score was high: 83.1 (±11.1) following 6 weeks of recording and 86.3 (±10.1) following 1 year of recording, respectively. This translates to a perceived usability of the 24/7 EEG™ SubQ system as 'best imaginable' after 1 year of use.[c]

- Overall, participants did not feel limited by the 24/7 EEG™ SubQ system, people around them reacted positively towards their use of the system and participants agreed to the use of the system being a positive experience, - even after 1 year of nightly recordings.

Discomfort Questionnaire	Timepoint	n	Mean	Range
1. I have experienced discomfort related to the UNEEG™ SubQ implant for the last 2 days	6 weeks	21	1.52	1-4
	1 year	19	1.89	1-4
Ease of Use Questionnaire	Timepoint	n	Mean	Range
1. Close friends and family have reacted positively to me using the 24/7 EEG™ SubQ system	6 weeks	21	3.62	1-5
	1 year	19	3.32	2-5
2. Colleagues and acquaintances have reacted positively to me using the 24/7 EEG™ SubQ system	6 weeks	21	3.57	3-5
	1 year	19	3.53	1-5
3. Using the 24/7 EEG™ SubQ system has limited me in my spare time	6 weeks	21	1.24	1-3
	1 year	19	1.89	1-5
4. Overall, using the 24/7 EEG™ SubQ system has been a positive experience	6 weeks	21	4.14	3-5
	1 year	19	3.89	1-5

Table 2
Discomfort related to the implant and Ease of Use are presented as mean score and range across all participants after 6 weeks and 1 year of sqEEG recording, respectively. n= number of participants who completed the questionnaire.
1= Strongly disagree, 2= Disagree, 3= Neither agree nor disagree, 4= Agree, 5= Strongly agree