ULTEEM—Ultra-long-term EEG Monitoring

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ULTEEM project showcases a sensor solution which transforms ordinary eyeglasses into smart glasses, by simply clipping two stand-alone devices onto the frame, to non-invasively record the brain activity generated by the temporal lobes. Temporal electroencephalogram (EEG) provides valuable information for long-term generalized epilepsy monitoring while electrooculogram (EOG) signals are commonly used in vigilance monitoring.

Electroencephalography (EEG) is an electrophysiological monitoring method that is used to characterize the type of epilepsy syndrome and epilepsy seizures. A subset of these seizures, namely primary generalized seizures, is characterized by the bi-hemispheric simultaneous onset of epileptiform signals. Clinically they typically involve sudden impairment of consciousness. As patients often do not realize or remember that they had a seizure, the treating physician is faced with incomplete or inaccurate information. Reliable long-term monitoring of these seizures by EEG is therefore expected to significantly improve the personalized treatment of epilepsy patients by providing objective information about the individual pattern of seizure occurrence.

Patient compliance is the key factor for success to achieve reliable long-term EEG monitoring. In the context of epilepsy patients, who suffer a lot from social stigmatization, it is essential to provide an inconspicuous solution to ensure patient adherence (Figure 1). Today, neither bulky multi-channel EEG devices nor consumer-grade EEG headbands found in the market satisfy this demand. The project ULTEEM [1] sets out to address this unmet medical need by placing the patient and their comfort in the center of the solution. The proof-of-concept device (Figure 2) comprises two dry-electrode sensors that can be clipped onto the metallic frame of eyeglasses. Such a solution is only possible thanks to the unique technology of CSEM (EP2101408) allowing the connection of sensors using a single wire which does not need to be shielded nor insulated. Although the connection is simplified, the signal quality is not compromised. This feature differentiates the ULTEEM device from consumer-grade EEG solutions, providing the clinicians with a signal quality obtained with dry electrodes equivalent to clinical-grade EEG devices with gel/wetted electrodes. Applicable medical device standards (IEC 60601-1 and IEC 80601-2-26) were followed during the design and verification phases of the development.

Figure 1: ULTEEM device provides an inconspicuous solution to boost patient adherence, a key success factor for long-term EEG monitoring.

Using dry electrodes, ULTEEM device acquires 1-lead EEG between two temporal lobes. The sensors are powered by a rechargeable battery and communicate with portable devices via Bluetooth Low Energy, which allows recording and real-time visualization of the data.

The pilot study of the device was performed at NeuroTec [2] with 10 healthy volunteers (KEK Bern No 2020-01979). The objectives of the evaluation were to assess the usability of the ULTEEM device in clinical settings as well as benchmark the performance of the device with certified EEG devices used for clinical purposes. For each subject, brain signals were recorded simultaneously for 20 minutes with a certified EEG device using gel electrodes and with ULTEEM using stainless steel dry electrodes. Both signals were compared by an experienced neurologist from Sleep-Wake-Epilepsy Center (Inselspital, Bern) who concluded that measurements acquired by the ULTEEM device matches well with the measurements obtained with the reference device. Moreover, similarity analysis was performed between the two waveforms using Pearson's correlation coefficient. For the cases where the subjects were instructed to perform lateral eye movements, a very strong correlation was observed (Pearson's $r > 0.97$). In the cases where the subjects were recorded still, similarly to clinical examination, a strong correlation was observed (Pearson's $r > 0.80$). All the 10 subjects who participated in the study expressed that it was comfortable to wear the ULTEEM device and they did not develop any headaches or discomfort during and after the recordings.

In conclusion, by simply clipping the ULTEEM device onto ordinary eyeglasses, EEG signals comparable to clinical grade could be obtained in the absence of an explicit wired connection. This patient-centric solution holds great promise to address the unmet need for reliable long-term EEG monitoring, and thus to improve the personalized treatment of epilepsy patients. The outlook is to combine the ULTEEM device with a new form factor suitable for night-use to achieve 24/7 monitoring.

Figure 2: ULTEEM device clipped on eyeglasses with metallic frames.

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[1] https://www.csem.ch/page.aspx?pid=161359

[2] https://www.neuro-tec.ch/projects/