EXPERIENCE Physiological Integrated System: a Smart Wearable System for Mid-term 32-channel EEG, 1-lead ECG, and Motion Recording using Dry Electrodes

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Hereafter a neurophysiology wearable monitoring prototype is presented, developed in the context of the EXPERIENCE EU project which, together with the devices developed by the other project partners, aims at creating a new generation of multimodal neuroimaging/electrophysiological biomarkers and methodological tools for the redefinition of psychiatric illnesses and disorders, unveiling for instance, new subtypes of anxiety and depression.

To achieve the project goal, CSEM contributes with the development of the EXPERIENCE physiological integrated system, composed of the EXPERIENCE Wearable System (EWS) and the related infrastructure: the EXPERIENCE Cloud and the linking communication means. The EWS records the physiological signals and uploads the recorded sessions to the cloud. The EXPERIENCE physiological integrated system has been completely developed, verified, and delivered on September 2023 to the partners for integration with their contribution. Once the paperwork is ready, the full system will be submitted for clinical trials at the University Hospital of Pisa in Italy.

EWS design and development

The EWS consists of a 32-dry electrode EEG cap, a digitalization module (EEG-AFE), an EEG, ECG, MOTION, and event recorder, a harness, a mobile app (eX App) (signal visualization, electrode positioning), a docking station (recorder battery recharge, recorded sessions upload to a secure cloud) and software drivers to decrypt and convert the downloaded sessions to BDF format. According to MDR 2017/745/EU, Annex VIII, the devices were classified as follows: EEG-AFE, Active Medical Device, Class IIa; recorder, Accessory of Active Medical Device Class IIa and the other parts, Class I.

Figure 1 shows the EWS parts finalized.

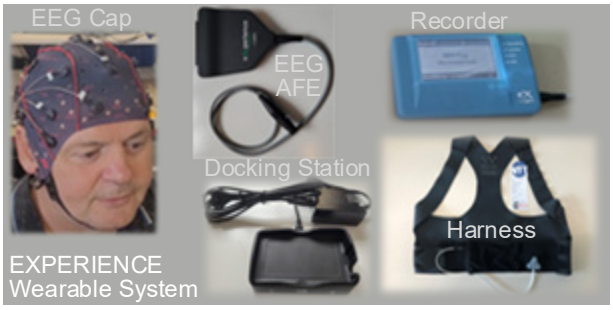

Figure 1: EXPERIENCE Wearable System (EWS) parts.

System verification – signal quality evaluation

The EWS successfully passed all the verification tests, including per-device and integrated functional tests, followed by Safety and EMC evaluations. Finally, to verify the quality of the signals the system acquires, an internal campaign with users was performed. A simple protocol was defined and executed on six candidates. Each participant underwent several recordings with the EWS, each one with a specific cognitive protocol, designed to elicit a particular brain activity and/or artifacts in a systematic manner. Each participant underwent three subsequent recordings as follows: sitting eyes-open still, standing (eyes open still, alternate eyes open and closed still, alternate eyes open and closed with head, eye, arm, jaw movements, then still) and walking (eyes open, alternate eyes open and closed).

The recordings were processed offline, where quality metrics were computed and compared across conditions and participants. The signal evaluation included metrics from both the temporal and frequency domain, some specific to the cognitive protocol and others more general, mainly RMS at specific frequencies and alpha peak amplitude.

Given the small group size, no statistical analyses were applied.

Results and discussion

Spectral properties: With users standing still, the RMS signals at 1–100 Hz range were about one order of magnitude stronger than that of the gold-standard, the disparity being caused by a stronger presence of broadband random noise and possibly motion artifacts at the lower frequencies. The RMS were strongest at 1–30 Hz and weaker at 65–85 Hz. Alpha modulation: when standing still, alpha peaks could be identified for each subject with the eyes-closed but were not identifiable with the eyes-open, becoming clearer in the ICA-derived data. When walking, the spectral background strongly masked the alpha peaks for both eye conditions. However, in the ICA-derived signals, the peaks could be identified once again, and they correctly demonstrated the amplification effect of closing the eyes, as shown in figure 2 for two of the participants.

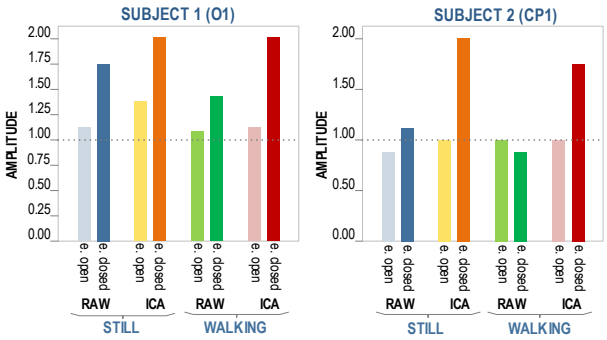

Figure 2: Alpha peak amplitude for two participants, for both raw EEG and ICA-derived signals selecting alpha components.

Conclusion

The tests demonstrate that the EWS can detect true meaningful aspects of brain activity (alpha waves). As expected, the signals are noisier than with gel electrodes. However, the use of multi-channel denoising techniques such as ICA may help with cleaning/separating part of these artifacts, allowing information to be extracted from periods of large motion.

The project partners are Universita Di Pisa (IT), Universitat Politécnica De Valencia (ES), Universita Degli Studi Di Roma Tor Vergata (IT), Commissariat à l'Energie Atomique et Aux Energies Alternatives (FR), Universita Degli Studi Di Padova (IT), Karolinska Institutet (SE), Quatechnion S.L. (ES). This project receives funding from the European Union's Horizon 2020 Research and Innovation program under grant agreement 101017727.