RIVISTA ITALIANA DI

ERGONOMIA

ORGANO UFFICIALE DELLA S.I.E. - SOCIETÀ ITALIANA DI ERGONOMIA

N.29 - 2024

- RETHINKING NEONATAL CARE
- NEW FRONTIER IN HOME-CARE EEG MONITORING
- ENHANCING HOSPITAL NAVIGATION THROUGH GAMIFICATION
- NEIGHBORHOOD EDUCATIONAL CENTER
- A CLASSROOM TAILORED TO STUDENTS WITH CHRONIC MEDICAL CONDITIONS

Poste Italiane S.p.A. – Sped. in Abbon. Post. DL 353/2003 conv. in L.27/02/2004, n.46, art.1 comma 1 DCB Milano – rivista quadrimestrale - anno 13 - n. 29, 2024

RIVISTA ITALIANA DI
ERGONOMIA

RIVISTA QUADRIMESTRALE
NUOVA EDIZIONE
NUMERO 29 - 2024

Organo ufficiale della
SOCIETÀ ITALIANA DI ERGONOMIA
www.societadiergonomia.it

SEDE LEGALE REDAZIONE, AMMINISTRAZIONE
Segreteria SIE c/o R.M. Società di Congressi srl
Via Ciro Menotti 11, 20129 Milano
tel. +39 02 70.12.63.67 – segreteria@societadiergonomia.it

GRAPHIC DESIGN AND LAYOUT
Frush [Design sostenibile] – www.frush.it

ISSN 2531-8845
Rivista Italiana di Ergonomia

RIVISTA ITALIANA DI ERGONOMIA

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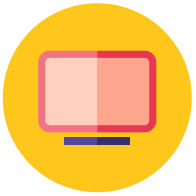
Cosmo+: New Frontier in Home-Care EEG Monitoring



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Keywords: Paediatric Neurophysiology, Wearable EEG devices, Usability, Human-Centred Design, User Experience, Home care

Abstract

Modern neurophysiological techniques have expanded the understanding of cortical dysfunctions in paediatric neurological diseases, such as brain injuries and epilepsy, which are associated with high rates of mortality and disability. Electroencephalography (EEG), a crucial method for diagnosing and monitoring critical patients, presents significant challenges in paediatric use due to usability and comfort issues associated with traditional systems. The research at the Meyer Children's Hospital in Florence aimed to develop innovative solutions to optimise brain activity monitoring in paediatric patients. The interaction between the patient and the device was analysed using Human-Centred Design (HCD) and User Experience (UX) approaches. The investigation revealed critical issues in the current workflow, highlighting usability problems and discomfort caused by traditional EEG devices. These findings led to the design of the Cosmo+ EEG System, a modular device that offers personalised monitoring, providing a more user-friendly and less invasive experience. This device could improve workflow

and patient satisfaction, representing a significant advancement in neurophysiology with potential clinical and research applications, including home use.

Introduction

Advancements in neurophysiological techniques have greatly improved the understanding of cortical dysfunctions underlying neurological conditions such as traumatic brain injuries, status epilepticus, hypoxic-ischemic lesions, stroke, and meningitis/encephalitis, which are increasingly prevalent and linked to higher mortality and disability rates in paediatric patients (Williams et al., 2019; Chang & Rasmusen, 2022). Emerging neuro-monitoring technologies, particularly continuous, non-invasive electroencephalography (EEG), are vital in diagnosing acute brain injuries and monitoring critically ill patients, including those without neurological injuries (Kirschen et al., 2022; Caricato et al., 2018). EEG offers a reliable method for various clinical applications, such as detecting seizures, psychological evaluation, and anaesthesia monitoring (Reyes, 2018). Despite its advantages, the use of EEG in paediatric patients faces challenges related to usability and acceptability, especially in current systems that rely on wired electrodes with conductive gel, limiting mobility and patient comfort (Webster, 2009). Though gel-based electrodes are still the standard, studies indicate that portable, gel-free EEG systems can offer comparable signal quality with faster, more straightforward setup and better comfort (Di Flumeri et al., 2019). Recent developments have led to the creation of wearable, wireless, flexible EEG devices that maintain high signal quality while being discreet and minimally invasive, making them suitable for everyday use (Sciaraffa, 2022; Guermandi et al., 2018; Celik, 2017). However, wearable EEG devices still lag behind other wearable technologies, with challenges in balancing comfort, usability, aesthetics, and adaptability for long-term home-based monitoring (Jamil et al., 2021). These challenges prompted a multidisciplinary team from the University of Florence and Meyer Children's Hospital in Florence to develop a next-generation wearable EEG device designed to meet the needs of both patients and healthcare professionals. The main objective of this research was to optimise the EEG monitoring system and improve the overall experience for patients and medical staff by developing a new wearable medical device for EEG monitoring

in both hospital and home settings. Specific objectives included: (i) analysing the human-device interaction in paediatric EEG monitoring; (ii) identifying needs, workflow issues, and innovation opportunities; (iii) evaluating the effectiveness and usability of current EEG devices; (iv) defining the requirements for a new EEG device. The following outlines the applied methodology and the most significant findings of the research.

Methodology

In healthcare, many medical devices focus primarily on technical and regulatory aspects, often overlooking patient and staff needs. This lack of attention to human factors can lead to usability issues and user errors (Iacono et al., 2019). A design approach that considers the context of medical devices, phases of care and workflow is needed to address these challenges. The research at Meyer Children's Hospital in Florence applied Human-Centred Design and User Experience principles to improve the human-device interaction in EEG monitoring systems.

The study, developed in multiple phases, included field investigations and the involvement of various stakeholders (doctors, healthcare professionals, neurophysiology technicians, and biomedical engineers) who interact with the EEG monitoring service, particularly those using EEG devices in paediatric settings. The focus was placed on their needs and expectations, as well as the expertise and perspectives of professionals involved in the planning and designing of such products/services. The research precisely followed these operational phases:

- Phase 1: Literature review and benchmarking analysis;
- Phase 2: Evaluation of current EEG systems;
- Phase 3: Data analysis;
- Phase 4: Development of design concepts and intervention scenarios.

Literature review and benchmarking analysis

In the initial phase, the study involved a review of the literature related to the research topics to outline the relevant scientific background. The research was conducted on major platforms such as Google Scholar, PubMed, and ResearchGate, using the following search strings to identify relevant scientific articles: TITLE-ABS-KEY (“EEG Device”, “wearable device”, “Paediatric neurophysiolo-

gy", "medical device", "EEG technology", "emotional impact EEG"). It allowed the selection of national and international key research contributions that were most relevant to the study. In parallel, a benchmarking analysis was carried out, enabling the research team to examine various types of EEG devices available in the target market from functional, technological, and morphological perspectives. This analysis also included assessing each device's application areas (Soufineyestani et al., 2020) and understanding their operating principles. The main findings from this phase were summarised in data sheets (see Fig. 1), facilitating the subsequent research phases.

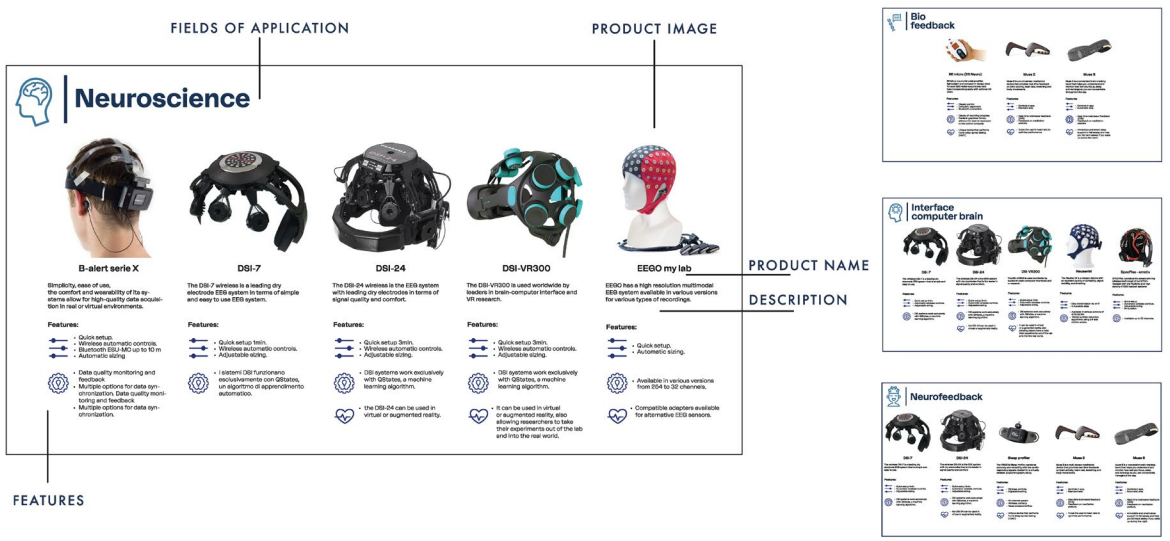

Figure 1. Visualization of the structure of the summary sheets developed for different types of EEG devices on the market, based on six application areas identified in the literature (Neuroscience, Biofeedback, Ergonomics and Biometry, Computer Brain Interface, Neuromarketing, Neurofeedback).

Evaluation of current EEG systems

Building on the involvement of healthcare professionals and patients, the subsequent phase of the research focused on evaluating the EEG monitoring service and the equipment used in the paediatric units. The primary aim was to assess the usability of the current EEG devices. To achieve this, the research team employed a combination of observational and participatory methods, which provided valuable insights into the overall user experience. The methods used included:

- *Direct User Observations* (Stanton et al., 2014). Observations were conducted during all operational steps before, during, and after the EEG monitoring process in the clinical setting. The actions performed by patients (ages 6-14), parents, and healthcare personnel were filmed, photographed, and documented to capture their thoughts, feelings, and behaviours. This observational data helped to better understand the users' experience, identifying pain points and emotional responses, which are crucial for redesigning the device to improve usability.
- *Semi-Structured Interviews* (Wilson & Sharples, 2015). Interviews with healthcare experts and professionals provided deeper insights into the operational activities, revealing unexpressed needs, challenges, and information about the interaction between users and the product/service. These discussions enriched the overall analysis and pointed out areas where improvements could be made to enhance the user experience.
- *Questionnaires* (Wilson & Sharples, 2015). A set of questionnaires was distributed to neurophysiology technicians, neurologists, and paediatric epileptologists at Meyer Hospital, as well as professionals from other national and international institutions. The survey included Likert-scale questions (5 points) and open-ended questions to gather feedback on user satisfaction and opinions regarding various aspects of the EEG monitoring process. The responses provided valuable quantitative and qualitative data that informed the design considerations for the new EEG device.
- *Personas*, *Scenarios* (Hanington & Martin, 2019) (see Fig. 2) and Task Analysis (Tosi, 2020). These tools were pivotal for analysing the activities of healthcare operators in the paediatric units. Storyboards were used to visualise the operational phases of EEG monitoring, identifying potential issues in the interaction between the users and the product. This method helped to better define the users' needs and expectations, ensuring a comprehensive design approach.
- *User Journey Maps* (Hanington & Martin, 2019) (see Fig. 3). These maps helped visualise the users' actions, emotions, and perceptions during their interaction with the EEG device. They provided a clear picture of weak points in the current system and highlighted opportunities for improving the user experience. By identifying pain points, the team was able to determine key areas for optimisation in the design process.

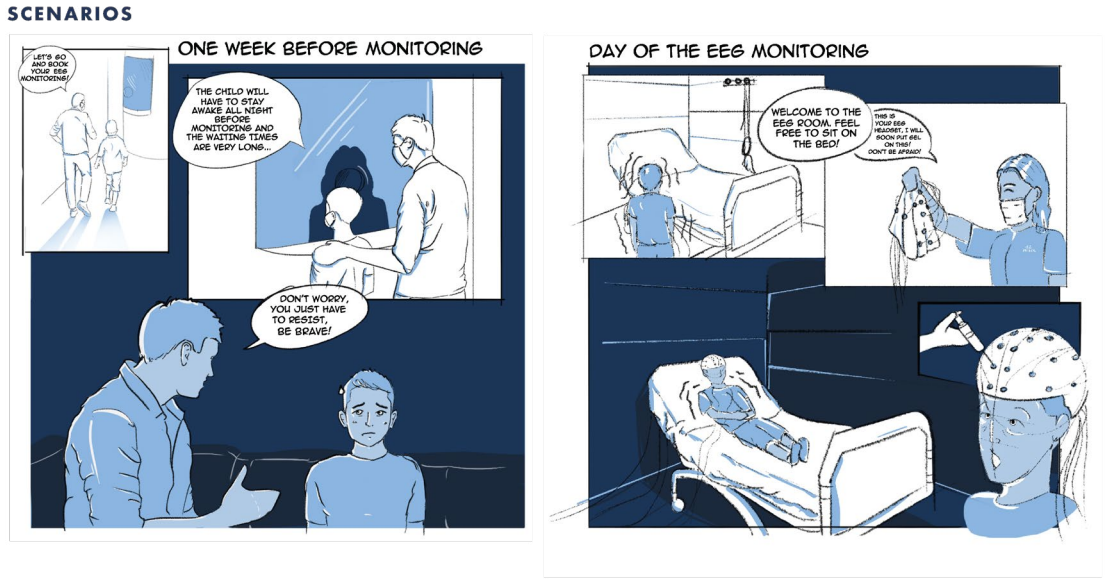

Figure 2. Scenario of some EEG monitoring phases within the paediatric hospital.

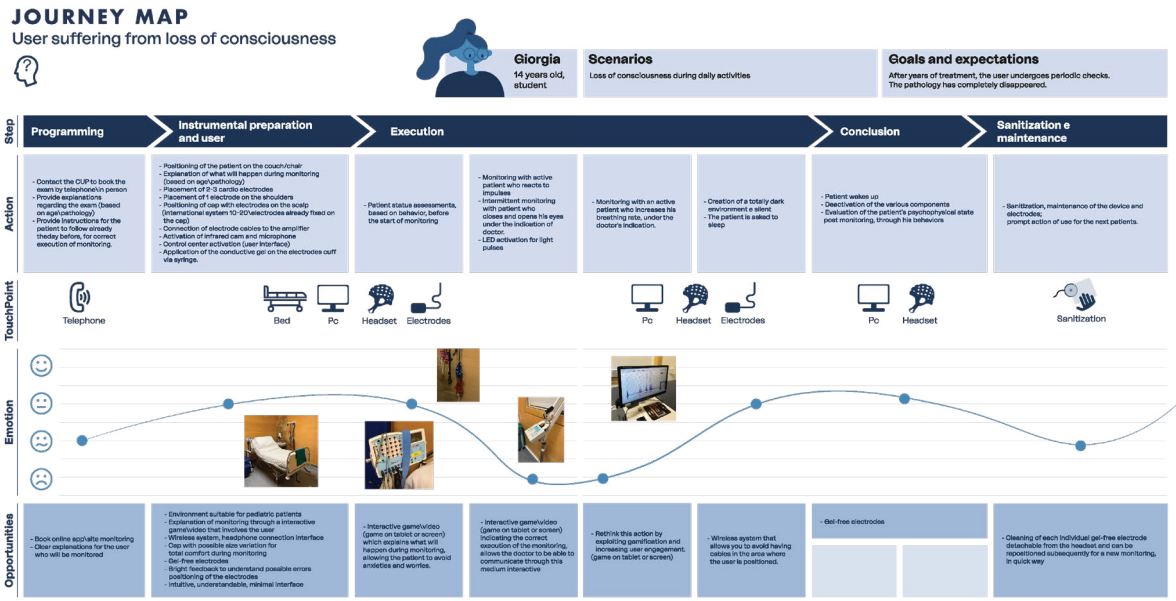

Figure 3. An example of a User Journey map relating to a patient suffering from loss of consciousness during daily activities, developed by the team.

These integrated methods not only allowed for a thorough understanding of the challenges faced by users but also provided a strong foundation for the redesign of the EEG monitoring system, ultimately aiming to create a device that meets the needs of both patients and healthcare providers.

Data analysis

As The data collected in the previous phase proved essential in identifying critical issues within the EEG monitoring workflow and outlining new requirements and innovation scenarios. One of the core challenges in the design process is accurately determining the proper requirements to address the identified problems. Thus, data collection aims to gather sufficient, relevant, and actionable information that can form a solid foundation for developing the system's specifications.

Data from interviews, questionnaires, and direct observations were systematically analysed and synthesised into maps and diagrams. These visual tools helped highlight the research's critical areas and essential system requirements. Additionally, to enhance the clarity and interpretation of the questionnaire data, the results were presented in graphical form, displaying the percentage distribution of user responses. This approach allowed for a more intuitive understanding of the data and facilitated the identification of patterns, preferences, and issues that required attention. Through this comprehensive analysis, the research team was able to pinpoint specific pain points in the EEG monitoring process, which ultimately informed the design of the new device, ensuring it addressed the real needs and expectations of both patients.

The data collected during the investigation phase played a crucial role in assessing the critical issues and defining the requirements for the new EEG monitoring device. The evaluations focused mainly on (a) the product's dimensions, functionality, and usability and (b) cognitive and emotional aspects related to service management and user interaction with the product.

In general, within the neurophysiology department, critical issues emerged regarding the bulkiness and excessive number of cables connecting to the patient, which made the examination uncomfortable and unfamiliar, especially during sleep monitoring. Additionally, the current use of the gel-based electrodes and cap is unpleasant to the touch, leaving the user with a wet sensation. The system often

appears unattractive and generates anxiety and fear in patients.
Beyond the general discomfort reported by patients and their families, healthcare providers also encountered difficulties, particularly with placing electrodes on the scalp, due to a lack of feedback from the device. Based on these challenges and others identified during the analysis, specific objectives and new requirements were defined and subsequently incorporated into the design of the Cosmo+ EEG monitoring device.

Development of design concepts and intervention scenarios

The final phase of this research focused on formulating and developing new design solutions. These solutions mainly focused on enhancing usability and addressing the emotional impact on users. A key element in this phase was the use of design-orienting scenarios, which enabled the development of innovative ideas tailored to all users' needs. This approach provided a strategic vision for the team regarding the potential development of a more user-friendly and familiar wearable EEG monitoring system. The following outlines the main results of the research.

Results

The new Cosmo+ EEG system

Cosmo+ is designed to diagnose and monitor brain activity anomalies in paediatric patients, such as detecting and managing seizures, monitoring wakefulness and sleep, and identifying brain dysfunctions. The primary goal of this device is to ensure long-term monitoring, even outside the hospital setting, such as in a home environment, making the technology more accessible and more comfortable to wear while also being highly emotionally acceptable. Key aspects that guided the design process were *user-friendliness*, *versatility*, and *modularity*.
Cosmo+ features three modules that can be placed on various areas of the scalp—frontal, occipital, parietal, and temporal lobes. This configuration allows for more accurate analysis and recording of electrical activity and provides a more comfortable and familiar system for both the patient and healthcare personnel.
Cosmo+'s *modularity and versatility* allow users to monitor specific areas of the scalp based on their needs and the doctor's instructions (see Fig. 4). For example, the first module, with dry electrodes placed

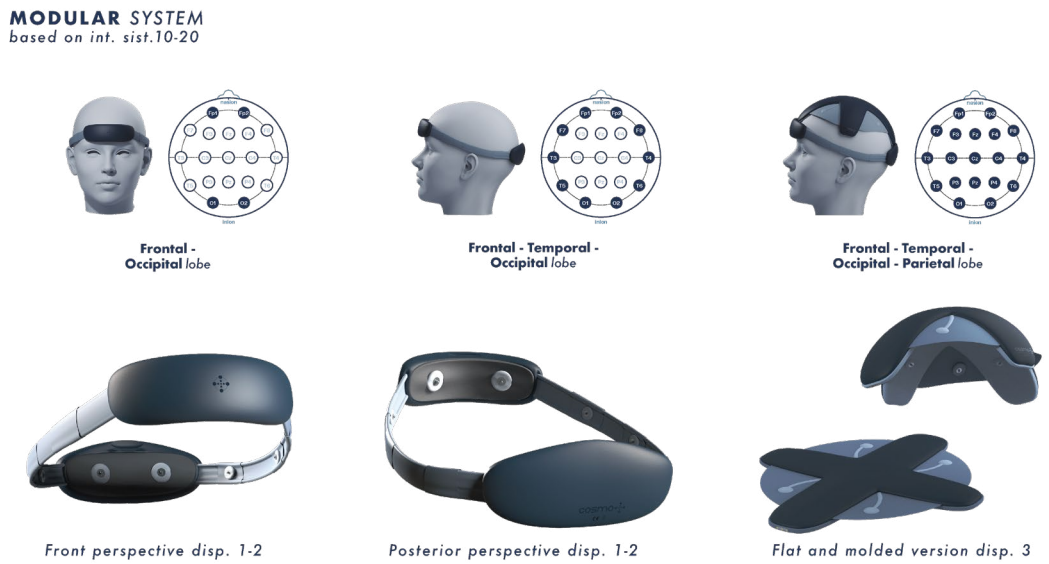

Figure 4. Modular Cosmo+ system, positionable at various points of the international 10-20 system.

on FP1 and FP2 of the 10-20 international system, enables monitoring of the frontal lobe activity, which is involved in higher cognitive functions such as executive control, planning, emotion regulation, and more. The second module, positioned on the O1 and O2 points of the 10-20 system, tracks the occipital lobe's electrical activity, primarily responsible for vision and visual processing. When used together, the two modules monitor the temporal lobe, which is involved in functions like memory, hearing, language, and facial recognition, through elastic bands placed on points F7, F8, T3, T4, T5, and T6.

The third module, placed on points F3, Fz, F4, C3, Cz, C4, P3, Pz, and P4, allows monitoring of the parietal lobe, which handles various cognitive functions such as sensory processing, spatial perception, attention, and working memory. These three modules, equipped with dry electrodes, are interconnected with adjustable elastic bands to accommodate the size of the scalp. Using dry electrodes eliminates the need for conductive gel, simplifying the procedure and enhancing comfort.

Moreover, the absence of connecting cables around the patient ensures accurate and reliable measurements, preventing movement artefacts. The dry electrodes detect electrical impulses and transmit them to an amplifier, which sends the brainwave signals to a com-

puter to visualise EEG tracings. The system also includes a physical interface with two different LED feedback (green and red) indicating correct or incorrect electrode placement, ensuring high usability and perceived reliability.

Cosmo+ is *portable, easy to use, and compatible with telemedicine services*. It enables home monitoring, storage of EEG traces, and real-time transmission of results to medical specialists via an app available for smartphones, tablets, and computers (see Fig. 5). It could positively impact the management of EEG monitoring services, optimising specialists' workflow, reducing patient wait times, and minimising department overcrowding.

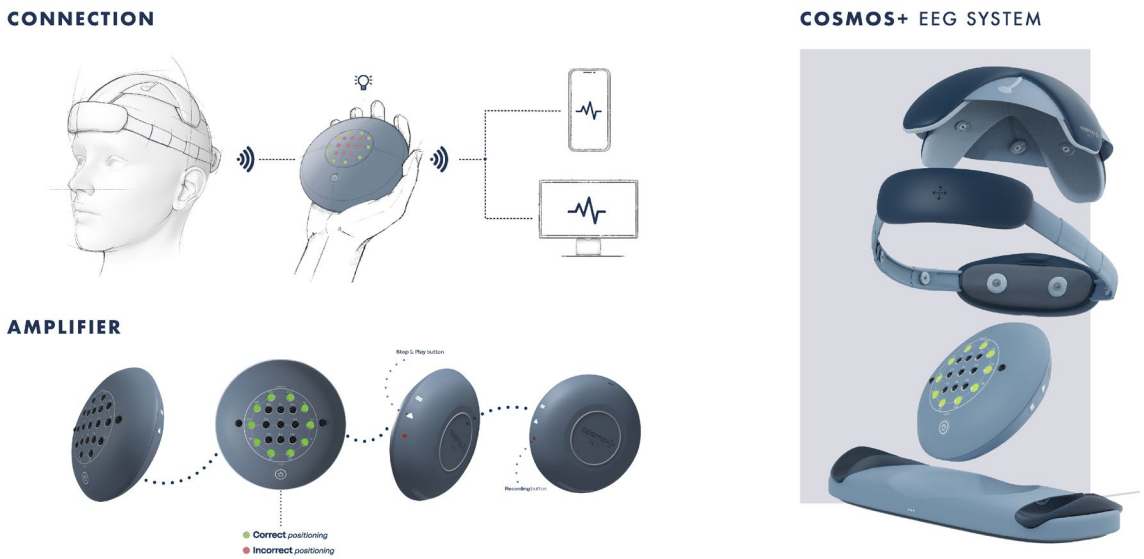

***Figure 5**. Ease of use of the device through light feedback (green or red) and the wireless connection of the Cosmo+ system via applications and external devices.*

From a morphological standpoint, the device's sleek design, colour choices, and finishes ensure better interaction with young patients, minimising negative impact and promoting a sense of calm. The use of Medical Grade materials, such as Tecafine PP for devices 1 and 2, medical-grade silicone for device 3, and Memory Foam padding, enhances the system's suitability for medical applications, ensuring excellent sterilisation, lightness, comfort, sensor wearability, and adaptability to the scalp.

Discussion and conclusions

The Cosmo+ concept represents a promising step forward in neurophysiology, introducing innovative ideas that redefine the design and functionality of EEG monitoring devices. The research focused on the device's usability and morphology, aiming to create a more user-friendly solution adaptable to the needs of patients and healthcare providers. Cosmo+ stands out for its modular system, which allows for personalized use based on specific clinical needs, and its light feedback system, which ensures an intuitive and hassle-free interaction. The dry electrode technology and the ability to connect to external devices via apps allow for overcoming the limitations of traditional hospital devices, offering continuous, remote brain activity monitoring, both in the ward and at home (see Fig. 6).

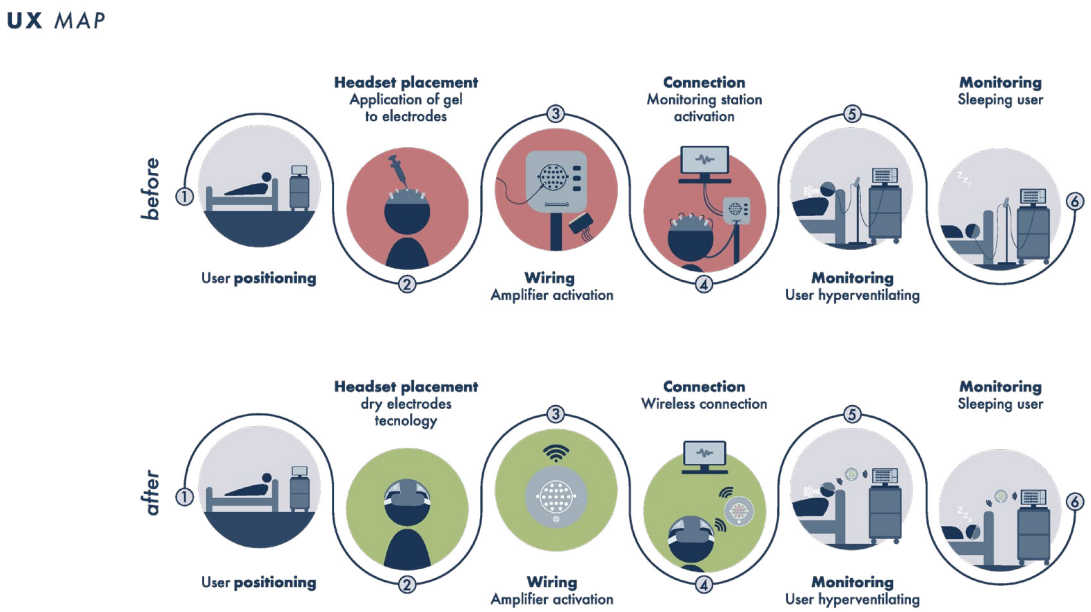

Figure 6. EEG Monitoring UX Map: Visualization of the activities planned for EEG monitoring before and after the design of Cosmo+.

In particular, Cosmo+ opens new perspectives in the field of EEG homecare, a sector that has the potential to transform the management of neurological and psychiatric disorders radically. Thanks to the possibility of continuous monitoring, improved comfort for patients, reduced costs related to hospital stays, and personalized treatment,

Cosmo+ could become a key tool in providing more accessible and less invasive healthcare. Home-based monitoring, for example, would allow patients to remain under observation continuously, avoiding long waits and frequent trips to the hospital, positively impacting both the psychological well-being of patients and the efficiency of healthcare services.

However, despite the clear advantages and innovative potential, there are still challenges to overcome to ensure the long-term success of this system. First, it is essential to guarantee the accuracy and reliability of the data collected by the device, preventing errors that could compromise diagnosis and treatment. Additionally, protecting privacy and securing sensitive data are crucial issues in a medical and digital context, requiring advanced cybersecurity solutions. The economic accessibility of the device represents another significant challenge, as the technology can be genuinely helpful to all population segments, including those with limited financial resources.

Looking to the future, Cosmo+ is not just a prototype intended for technological improvements but a continuously evolving system. Future iterations of the device could enhance its technical capabilities and integrate new forms of interaction, such as gamification, to make monitoring more engaging, particularly in the paediatric setting. By introducing interactive games or visual incentives, younger patients could be encouraged to cooperate actively during monitoring, improving the user experience and the accuracy of the collected data.

Furthermore, the introduction of augmented reality (AR) and virtual reality (VR) could be an additional step forward in the evolution of Cosmo+. These technologies could be used to visualize EEG data in real time or to create immersive environments that reduce patient anxiety during monitoring, especially in the paediatric setting. Adopting artificial intelligence for automatic EEG data analysis could make the system even more precise and responsive, enabling real-time monitoring and diagnosis of abnormalities without needing for constant human intervention.

Therefore, Cosmo+ has the potential to evolve not just as a monitoring device but as a digital healthcare ecosystem that adapts to the needs of patients, healthcare providers, and healthcare systems. With the introduction of new technologies and continuous improvements in user interfaces, the future of Cosmo+ appears rich in opportunities to revolutionize neurophysiology and expand accessibility to neurological and psychiatric treatments.

Future research activities will focus on developing functional prototypes to facilitate the transition from concept to realization and to validate the feasibility of the design and technology. This phase will be followed by usability and field tests conducted in clinical and home environments to evaluate the system's performance and reliability. Data collected from real-world use cases will then be observed and analysed to refine the device's functionality and enhance the user experience. Lastly, the focus will be on refining the system's engineering to enable scalable production while maintaining high quality and cost-efficiency standards.

Acknowledgements: The authors thank the medical staff of the Meyer Children's Hospital in Florence, in particular, Prof. Renzo Guerrini, Dr. Katia Romano, Dr. Martina Giudice and Nicola Rizzo (CTO of Micromed group).

Author Contributions

Conceptualization, E.I. and F.T.; methodology, E.I. and S.A.D.; infographics, rendering and data curation, S.A.D.; writing–original draft preparation, E.I.; writing–review and editing, E.I. (all sections except "The new Cosmo+ EEG system") and S.A.D.; Supervision, F.T, E.I. and C.M. (technical part). All authors have read and agreed to the published version of the manuscript.

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