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**Design Process of a Constant Epilepsy Monitoring
Wearable Device**

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To all those living with chronic conditions,
whose resilience inspires me every day to
contribute towards a better future.

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keywords

Epilepsy, continuous monitoring, user experience, wearable, textile electrodes.

abstract

Epilepsy is one of the most common neurological conditions, affecting over 70 million individuals worldwide, with life-long neurobiological, psychological, psychiatric, physical, and social consequences, and associated with higher risks of mortality and developing commodities. Monitoring aids in diagnosis, seizure characterization, and treatment planning, enhancing patient safety and quality of life. Wearable devices with healthcare applications present as a solution for continuous, every day, monitoring with little impact to patients' lives, a technological advancement, including textile-based solutions, represent new opportunities for developing comfortable, non-intrusive, non-obstructive, and non-stigmatizing wearable products for PWE. Given the extended use of this kind of monitoring wearable, user experience is particularly pivotal in its development; thus, this work focused on a user-centric process of conceptualizing a wearable for epilepsy monitoring, by considering both the user experience and expert feedback. In this sense, the main objective of the research is to explore a user-centric development process of an epilepsy monitoring wearable device. The research followed a double diamond methodology in each of the four stages of projects development, during which we explored the process of conceptualizing, defining and evaluating an epilepsy monitoring wearable product, through the insights and finding of experts and epilepsy patients. As a conclusion, an introduction to a new complementing avenue of development was also provided, concerning a smartphone app, which would pair with the proposed wearable device. While this project was limited by time and

resource constraint, limited access to patients with epilepsy, and inability to apply techniques in prototyping which are only available in industrialized processes, this research and collected insights throughout the development process contribute to the area of design for health and wellbeing as well as future developments of design of medical wearable devices for epilepsy monitoring.

palavras-chave

epilepsia, monitorização contínua, experiência do utilizador, *wearable*, eléktrodos t  xteis.

resumo

A epilepsia   uma das doen as neurol gicas mais comuns, afectando globalmente mais de 70 milh es de indiv duos, com consequ ncias neuro-biol gicas, psicol gicas, psiqui tricas, f sicas e sociais que perduram durante toda a vida, e   associada a maiores riscos de mortalidade e de desenvolvimento de doen as associadas. A monitoriza  o de epilepsia contribui para o diagn stico, para a caracteriza  o das crises e para o estabelecimento de um plano de tratamento, aumentando a seguran a e a qualidade de vida dos pacientes. Os dispositivos *wearable* com aplica  es na  rea da Sa de apresentam-se como uma solu  o para a monitoriza  o cont nua e quotidiana, com pouco impacto na vida de indiv duos com epilepsia. Os avan os tecnol gicos, incluindo as solu  es baseadas em t  xteis, representam novas oportunidades para o desenvolvimento de produtos *wearable* confort veis, n o intrusivos, n o obstrutivos e que n o contribuam para o estigma associado   condi  o neurol gica. Dado o uso prolongado deste tipo de *wearables* de monitoriza  o, a experi ncia do utilizador   particularmente importante no seu desenvolvimento; assim, este trabalho consistiu num processo de conceptualiza  o de um *wearable* para monitoriza  o da epilepsia centrado no utilizador, considerando tanto a experi ncia do utilizador como o *feedback* de especialistas na  rea. Neste sentido, o principal objetivo da investiga  o   explorar um processo de desenvolvimento centrado no utilizador de um dispositivo desta natureza. A investiga  o aplicou a metodologia *double diamond* em cada uma das quatro fases de

desenvolvimento, através das quais explorámos o processo de conceptualização, definição e avaliação de um produto *wearable* de monitorização de epilepsia, através das percepções e conclusões de especialistas e pacientes. Ao concluir, foi também apresentada uma nova via de desenvolvimento complementar, relativa a uma aplicação de *smartphone*, que seria emparelhada com o dispositivo *wearable* proposto. Embora este projeto tenha sido limitado por restrições de tempo e recursos, acesso limitado a pacientes com epilepsia e incapacidade de aplicar técnicas de prototipagem que só estão disponíveis em processos industrializados, esta investigação e conhecimentos recolhidos ao longo do processo de desenvolvimento contribuem para a área do Design para a Saúde e o bem-estar, bem como para o desenvolvimento futuro do Design de dispositivos médicos *wearable* para a monitorização da epilepsia.

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Acronyms

AED	Anti-epileptic Drug
ANS	Autonomic Nervous System
ASM	Anti-seizure Medication
BLE	Bluetooth Low Energy
CNS	Central Nervous System
ECG	Electrocardiogram
EDA	Electrodermal Activity
EEG	Electroencephalogram
EMG	Electromyography
EMU	Epilepsy Monitoring Unit
GSR	Galvanic Skin Response
HRV	Heart Rate Variability
MRI	Magnetic Resonance Imaging
PCB	Printed Circuit Board
PDS	Product Design Specifications
PPG	Photoplethysmogram
PWE	People with Epilepsy
QoL	Quality of Life
RMSD	Root-Mean-Square Deviation
SCR	Skin Conductance Response
SNR	Signal-to-Noise Ratio
SNS	Sympathetic Nervous System
SUDEP	Sudden Unexpected Death in Epilepsy
UCD	User Centred Design
UI	User Interface
UX	User Experience
v-EEG	Video-Electroencephalography

Chapter 1

1 Introduction

1.1 Epilepsy Monitoring

Epilepsy is a common neurological disorder that causes a predisposition to generate spikes of abnormal neuronal activity, expressed through unprovoked, recurrent seizures. Depending on their onset location and affected neuronal networks, seizures exhibit different symptoms, and are classified accordingly, such as focal or generalized onsets, referring to whether seizures begin in one or both brain hemispheres, and motor and non-motor, referring to whether seizures affect neuronal networks related to bodily movement and muscle control. The level of consciousness impairment is also considered in seizure classification. For instance, a patient may suffer from an absence seizure, which is characterised by a momentary loss of awareness, also referred to as petit-mal; on the other hand, grand-mal seizures are characterised by bilateral motor manifestations, such as stiffening and jerking of muscles, also referred to as tonic-clonic seizures (Johnson, 2019). While seizure occurrence represents a direct cause for increased risk of injuries and mortality, the burden of epilepsy extends beyond this symptomology, with cognitive, neurological, psychiatric, psychological, and social consequences for people with epilepsy (PWE); additionally, more than half of PWE suffer from comorbidities, such as migraines, diabetes, high cholesterol, mood and anxiety disorders, depression, and heart disease, amongst others, which affect the progression of the disease, the patient's response to treatment, and their quality of life (QoL) (Mula, 2020). PWE score lower than the general population in various domain of QoL, including employment, general health, both physical and psychological, self-esteem and social relationships (Strzelczyk et al., 2023). While anti-seizure medication or antiepileptic drugs (ASM, AED) are the first line of treatment once the diagnosis is established, more than a third of patients are not able to achieve seizure freedom, and are considered pharmacoresistant, or drug resistant. Additionally, AEDs present numerous side-effects that impact the physical and emotional health of PWE. More common alternative treatments to medication include surgery, where the epileptogenic area is identified and resected; neurostimulation, in which a vagus nerve is stimulated through an

implanted stimulator; and dietary. Despite pharmaceutical advancements and an increase in the availability and heterogeneity of AEDs, the number of PWE with drug-resistant epilepsy has not changed significantly over the years (Johnson, 2019).

Seizure activity monitoring integrates and greatly contributes to epilepsy diagnosis and management, allowing more accurate characterization of seizures and the condition, as self-reporting, due to the nature of seizure activity, may be unreliable (Karoly et al., 2018); better understanding of the effectiveness of the current epilepsy treatment and possible adjustments; the possibility for timely interventions, improving PWE safety and overall QoL; and the personalization of patient care. The electroencephalogram (EEG) plays a crucial role in epilepsy diagnosis, providing direct measurements of brain activity; and facilitating accurate seizure characterization, and it can be combined with simultaneous video monitoring, video-electroencephalogram (v-EEG), to better understand the physical manifestations of the seizure activity. Currently, video-electroencephalography (v-EEG) represents the gold standard; however, this technique is resource consuming, possibly stigmatizing, and increases the burden on both epilepsy patients and caregivers (Tang et al., 2021). Continuous v-EEG monitoring is commonly applied in in-patient context, particularly, in epilepsy monitoring units (EMUs), with an average stay duration of five days, in order to improve diagnosis, seizure characterization, surgery candidacy, or treatment adjustments (Sauro et al., 2016). However, in order for this technique to be effective, seizure activity must occur, and, as such, protocols are applied involving the decreasing or withdrawal of AEDs, in order to provoke seizures, or increase their frequency, during patient's stay (Smith, 2005), which has a negative impact and increases the burden on the patient, while also being possibly unsafe and ineffective (Cascino, 2002). This equipment and technique are not patient-friendly for long-term application and are not viable for daily life monitoring (Bruno et al., 2018).

Everyday life monitoring represents a crucial seizure data gathering and monitoring technique (Vergara et al., 2017) and can be facilitated through the use of wearable monitoring devices, representing an alternative to the EEG and v-EEG methodologies. In fact, a more digital approach to self-management and self-monitoring can be beneficial, enhancing and personalising patient care, through passive approaches such as the use of digital journals and diaries, and active, through the use of wearable devices, including smartwatches, Brain Sentinel, or Embrace, to validate and/or detect seizures (Shegog et al., 2020).

As it is feasible to monitor and detect seizure activity through a multimodal wrist or ankle worn wearable device, particularly through the application of machine learning on the data collected from monitoring accelerometry, photoplethysmography, and electrodermal activity (Tang et al., 2021), and PWE, overall, favour their long-term usage (Bruno et al., 2018), it is crucial to include the experience of epilepsy patients, as well as caregivers and medical personnel, in the development process of seizure monitoring devices (Sivathamboo et al., 2022), as it is the positive user experience of these stakeholders that ensures the adoption of these technologies. By incorporating of the preferences of PWE, as well as understanding their everyday experience, that is, overall emphasizing user experience in the development process, we are able to improve user acceptance (Bajracharya et al., 2019). It is essential to aim at developing a product that compliments users' lifestyle and daily routine seamlessly, without any necessary additional effort (E. Park, 2020), as long-term monitoring should not contribute to the burden of the condition, particularly considering the challenges that PWE already face with epilepsy management, thus developing a comfortable, discreet, and non-obtrusive product that promotes adherence to the technology and contributes to the improvement of their overall QoL.

1.2 Motivation

Technological advancements accompanying the growing need for wearable eHealth devices have created new development opportunities and promoted an increasing number of commercially available digital solutions in the medical field. In particular, novelty fabric-based solutions offer new opportunities in user experience due to their flexibility, elasticity, comfort, and ease of integration with sensing technologies. As such, this research aims to define and develop a textile-based epilepsy monitoring device, with the overall goal of improving the everyday well-being, and potentially the QoL, of PWE, by combining textiles and electronics in a user-centric development process. Continuous collection of specific physiological signals allows detection, and potentially prediction, of epileptic seizures, providing the possibility of timely interventions, but also an increased sense of security and autonomy, particularly for patients who have not yet achieved seizure freedom. Additionally, the collected data can contribute to a more comprehensive diagnosis and, subsequently, a more accurate treatment of the condition, supporting greater patient care. By defining a wearable product that carries out this functional performance with a human-centred approach, we ensure a positive long-term monitoring experience, taking into account the

multitude of challenges faced by PWE (particularly issues such as perceived and enacted stigma, as well as anxiety, fear, and lack of autonomy), in the development of a comfortable, unobstructive, discreet, and adaptable product; ultimately, the user experience will heavily influence the acceptance of, and the adherence to, the device and monitoring protocol.

In addition to the motivation of positively and meaningfully impacting the everyday well-being of PWE, psychologically and physically, we aim to contribute to the continuous advancements in health and well-being design. Furthermore, as the scope of this development is multidisciplinary, it is crucial to foster and strengthen collaboration between interdisciplinary fields and promote knowledge exchange. As such, this work was also developed in collaboration with Instituto Superior Técnico, specifically the team ScientISST, who provided the knowledge and resources necessary for data acquisition. This collaboration's aim was to help develop a biosignal wearable that could be useful and correspond to the needs of their current or future projects, specifically in biomedical engineering, not limited to the epilepsy monitoring scope, as these also involved data acquisition of modalities that coincide with the ones explored within epilepsy monitoring. While needs did not always converge with the main motivation of this work, it is important to foster a relationship between institutions, of mutual support and exchange of knowledge and resources.

1.3 Objectives

The primary goal of this research is to showcase the design process of a wearable device for constant monitoring of epilepsy patients, during which we will explore the process of conceptualising and defining a solution for epilepsy monitoring using textile electrodes with a focus on extended user experience. In addition to our primary goal, the secondary objectives include:

- Understanding comprehensively the condition, its impact on patients, and current practices in and out of clinical or research contexts, including similar solutions.
- Identifying user and product requirements for a wearable device meant to be worn daily.
- Validating the feasibility of data acquisition for the proposed solution.
- Evaluating and refining design solutions through collaboration with users and experts.
- Gaining valuable insights from epilepsy patients regarding the long-term usability and functionality of the wearable.

- Defining the content and features for the wearable's accompanying application, ensuring it meets the specific needs of users and patients.

1.4 Critical factors for success and limitations

The main components of development that should be considered fall into the categories of Experience and Functionality, and for each we can define key factors that allow us to validate the conceptualized solution:

- Experience – user experience should be ensured through the validation of end-users, through testing and feedback phases in each design decision, collecting both qualitative and quantitative data.
- Functionality – factors that ensure the correct and effective functionality of the conceptualised solution should include validation from experts, through their insights from interviews and questionnaires, and verification that the chosen location and desired functionalities are viable, through data acquisition testing.

Due to the time available for development, as well as resources and access to epilepsy patients, some of these key factors were adapted throughout. While our goal required the development process to focus on PWE, due to challenges associated with recruiting participants with a condition of this nature, the number of epilepsy patients available was reduced. This situation is worsened by the restriction that participants could only participate in a singular stage of this research, in order to avoid skewed or invalid results consequential of recurrent participation.

Given this limited access to epilepsy patients, validation with PWE was only performed in the final stage of the study; consequently, earlier stages of development and respective design choices did not include the direct involvement of epilepsy patients. While, in order to mitigate this limitation, other important stakeholders were involved in the preceding steps (experts in the areas of biomedical engineering, as well as collaborating researchers in the field of epilepsy monitoring), we acknowledge that the absence of feedback and validation from PWE in early development choices remains a limitation of the developed solution and may result in a biased or less comprehensive design process (by not holistically capturing the needs and requirements of patients with epilepsy).

1.5 Document structure

This document is structured in six chapters, following the course of research development. The first chapter provides a brief introduction to current epilepsy monitoring and management approaches, leading to the derived motivations and objectives for this work, while reflecting upon the necessary key factors to ensure validity as well as limiting factors. The second chapter provides a more comprehensive look into the fundamentals of epilepsy and its impact on patients, an overview of biosignal monitoring, including the relevant modalities and respective sensors and electrodes for this work, and a reflection on the role and factors of patient and user experience during development. The third chapter reflects on current approaches for epilepsy monitoring in both clinical and everyday contexts, including relevant and currently available solutions. The fourth chapter defines the structure for the development process and applied methodologies, and the fifth chapter details the practice aspect of the thesis by presenting the execution of the different development iterations with an in-depth look into each stage. The sixth and final chapter discusses the main conclusions and insights derived from the development and reflects on future steps.

1.6 Contributions

The outcomes of this thesis' research and development represent several significant contributions:

- Enhanced patient care – the defined wearable solution, conceptualised for epilepsy patients, will support continuous monitoring, resulting in timely detection and medical interventions, contributing to the prevention of *status epilepticus* and SUDEP, and improvement seizure documentation, leading to betterment of the epilepsy diagnosis and improvements of treatment plans.
- Improved patient well-being and QoL – a solution for constant monitoring contributes to patients' perception of safety, autonomy, and independence, potentially improving their state of mind with minimal impact to their daily lives, due to a development focused of user experience.
- Insights for future projects – this exploration contributes to advancements in the wearable design process, particularly those incorporating textile electrodes in data acquisition, insights which may be applied to the development process of other medical monitoring solutions. The findings and design process can serve as a valuable reference for future endeavours in designing wearables for medical conditions. The lessons learned and best

practices established can be applied to similar works and lead to more efficient and effective development processes.

- User-centric design – the development process involving users and experts ensures the wearable device is tailored to meet the specific needs and preferences of epilepsy patients. This user-centric approach can lead to more effective and user-friendly products.
- Research contribution: the findings and insights gained from multiple stages of this research, particularly from expert interviews, user testing and extended testing with participants with an epilepsy diagnosis, can contribute to the existing body of research in wearable healthcare technology and the associated preferences, routines, and challenges of PWE.

Findings related to user preferences on hand-worn wearable shapes and coverage areas research were submitted as abstract and accepted by the Conference on Design Principles and practices. The same findings were submitted in full to the Senses&Sensibility Conference. This thesis was also submitted to the Fraunhofer Portugal Challenge.

Chapter 2

2 Background

The following chapter concerns theoretical research necessary to contextualise the developed work, comprising four sections. The first section will focus on understanding epilepsy, characterising the symptoms, available treatment, and impact of the condition. The second section concerns the biosignal modalities, and their activity in seizure occurrence, which integrate epilepsy monitoring and are considered in this research. The third section provides an overview of conductive fabrics and their properties. User experience, particularly in healthcare, will be explored in the fourth section.

2.1 Epilepsy

Characterization. Epilepsy is a chronic condition and one of the most common neurological diseases, affecting over 70 million people of different sexes, age groups, races, and socioeconomical contexts (Beghi, 2020; Fiest et al., 2017; Löscher et al., 2020; Thijs et al., 2019). Its prevalence and incidence, however, vary according to those factors. In terms of sex and age, epilepsy prevalence and incidence are slightly higher in the male population than the female population, possibly due to the prevalence of risk factors (Fiest et al., 2017). They are also highest in the elderly age-group due to the higher frequency of cardiovascular and neurodegenerative diseases, while children and adult age-groups are those in which focal seizures are most common (Beghi, 2020). Disparities related to socioeconomical factors can be found; rates of epilepsy prevalence and incidence are higher in low and middle-income countries, as well as in the lowest socio-economical classes in high-income countries, possibly due to the demographic structure of the population, environmental risk factors, reduced quality of health management and access to the health care system, hygiene and sanitation, infections, and traumatic injuries (Banerjee et al., 2009; Beghi, 2020; Thijs et al., 2019). In fact, improvements in the quality of health care, both access and treatment, can be associated with the observed reduction in mortality rates in the

population suffering from idiopathic epilepsy (Beghi, 2020). It is possible that incidence and prevalence may be greater than documented for specific regions in which, due to cultural and social stigma, condition and symptom concealment occur, leading to undiagnosed or unreported cases (Banerjee et al., 2009).

Epilepsy diagnosis is a comprehensive process encapsulating multiple criteria such as history, age of onset, status of the patient, seizure characterization, and various ECG, EEG, and, possibly, MRI exams (Moshé et al., 2015). Epilepsy can be classified according to its origin as idiopathic, in cases where no causing factor is identified and genetic predisposition is assumed; symptomatic, when a brain insult is responsible for epilepsy onset; cryptogenic, where the condition is presumed to be symptomatic, but the underlying factor has to be identified through further investigation (Banerjee et al., 2009). The genetic contribution to epilepsy development can be a spectrum, varying from primary cause (more commonly associated with generalized epilepsy) to an underlying predisposition to develop epilepsy after a brain insult (Thijs et al., 2019). And while genetic predisposition and environmental factors can explain the heterogeneity of epilepsy distribution, the cause of close to half of epilepsy cases is unknown (Beghi, 2020).

The disease is characterized by a predisposition to generate recurrent unprovoked epileptic seizures (Beghi, 2020; Löscher et al., 2020; Thijs et al., 2019). Unprovoked seizures occur in the absence of underlying factors, while acute symptomatic, or provoked, seizures occur as symptoms of an acute central nervous system insult, and do not integrate epilepsy diagnosis (Beghi, 2020). Recurrent, unprovoked seizures are thought to be originated by an abnormal, transient, synchronous, and oscillatory excitatory and inhibitory activity in a neuronal network, resulting in a pattern of electric discharges and disrupting the normal functioning of that and possibly other neuronal networks (Fisher et al., 2017; Moshé et al., 2015; Thijs et al., 2019). Seizures are associated with an abnormal cortical activity (Thijs et al., 2019) and can be categorized as focal or generalized, according to the area of the brain in which they originate, depending on whether the epileptogenic networks are distributed in one hemisphere of the brain, in the case of focal epilepsy, or bilaterally distributed, in the case of generalized epilepsy (Beghi, 2020; Blumenfeld, 2005; Thijs et al., 2019). Seizures can also be categorized as motor or non-motor (Fisher et al., 2017) according to the exhibited symptoms. While motor and non-motor symptoms may be observed in both

generalized and focal onset seizures (EFEPA¹), generalized seizures are characterized and categorized according to their motor symptoms – tonic, atonic (for, respectively, stiffness and relaxation of body muscles), myoclonic, and clonic (respectively, occurrence and periods of body shaking) (CDC²). For instance, tonic-clonic seizures are typically characterized by motor symptoms that include limb stiffness, contraction of the extremities, and unresponsiveness. On the other hand, generalized onset absence seizures have few or non-motor impacts and are characterized by a period of impaired consciousness (Blumenfeld, 2005). The physical symptoms of generalized onset motor seizures are commonly referred to as convulsions, however, this ambiguous term does not integrate the ILAE³ seizure classification (Fisher et al., 2017).

Comorbidities. When two or more conditions are simultaneously present in a patient, this condition is described as comorbidity. Comorbidities are common in the population with epilepsy and can be up to eight times more frequent than in the general population, affecting treatment outcomes and patient's QoL. These include cognitive impairments, psychiatric comorbidities, such as depression, anxiety, and autism spectrum disorders, and somatic comorbidities, such as diabetes, arthritis, digestive, cardiovascular, and pulmonary issues (Kerr, 2012; Moshé et al., 2015; Shlobin et al., 2022; Thijs et al., 2019). In particular, the population with epilepsy registers a higher prevalence of psychiatric comorbidities (mood disorders and anxiety are the most common conditions) and a ten times higher suicide rate when compared to the general population (Tombini et al., 2020). The causative relationship between some comorbidities and epilepsy can be established as bidirectional, in which the comorbidity may be the precipitating factor or the result of epilepsy and its treatment (Moshé et al., 2015; Thijs et al., 2019). In fact, a bidirectional relationship has been well established between psychiatric comorbidities, such as depression or anxiety, and epilepsy (Kerr, 2012; Löscher & Stafstrom, 2023; Shlobin et al., 2022), indicating a possible neurological mechanism in common (Moshé et al., 2015), where psychiatric issues are indicated as a consequence of epilepsy but also represent a higher risk factor for developing epilepsy, and, in some cases, resistance to its treatment (Tombini et al., 2020). Additionally,

¹ Epilepsy Foundation Eastern PA: <https://www.efepa.org>

² Centers for Disease Control and Prevention: <https://www.cdc.gov>

³ International League Against Epilepsy: <https://www.ilae.org>

comorbidities seem to be the most important contributing factor to premature death in people with epilepsy (Thijs et al., 2019).

In general, population with epilepsy is at higher mortality risk than the general population (Kerr, 2012), and one third of premature deaths are associated with the neurological condition, whether directly from status epilepticus or sudden unexpected death in epilepsy (SUDEP), or indirectly from, for instance, drowning or suicide (Beghi, 2020; Moshé et al., 2015; Thijs et al., 2019). SUDEP is the unexpected death triggered, in most cases, by an epileptic seizure, and in which there is no evidence for an additional cause of death such as traumatic, toxicologic, anatomic, and/or status epilepticus related factors (Beghi, 2020). In general, while evidence suggests that it follows seizure occurrences, the cause is unknown (Thijs et al., 2019). SUDEP risk factors are related to the nature and persistence of seizures, including tonic-clonic seizures and with a strong correlation to nocturnal seizures, for which supervision is the only effective preventive measure (Beghi, 2020; Thijs et al., 2019).

Treatment. Comorbid conditions also affect the efficacy of treatments for epilepsy (Moshé et al., 2015). The main treatment modality is pharmaceutical, with antiseizure medication or drug, also referred to as antiepileptic drug (respectively, ASM, ASD, and AED), but it is not effective in about one third of the patients due to pharmacoresistance (Löscher et al., 2020; Moshé et al., 2015; Thijs et al., 2019). This drug resistance is observed in monotherapy and polytherapy and refers to the inability to achieve a significant seizure-free period, to the uncontrollable recurrence of seizures after a seizure-free period, to an alternating pattern between controlled and uncontrolled seizure periods, or an initial drug resistance period followed by a successful response to treatment. Pharmacoresistance is multifactorial, and likely caused by multiple mechanisms; hence, it is necessary to consider individual factors at play during treatment, such as aetiology, medical and family history, drug response, and comorbidities, amongst others (Löscher et al., 2020). Non-pharmacological solutions are employed as alternative treatments and include surgery, electrical neurostimulation, brain cooling to reduce inflammation, immunosuppressant agents and inhibitors of mTOR pathways, and dietary changes, such as a ketogenic diet (Löscher et al., 2020; Thijs et al., 2019). The surgery consists of removing or disconnecting the epileptogenic zone in focal epilepsy to reduce or eliminate seizure occurrence. While being effective in terms of cost and seizure control, it is only an option for a few pharmacoresistant patients, and it requires a comprehensive evaluation and identification of the epileptogenic zone, as the zone and its location

accuracy determine the effectiveness of the procedure. The neurostimulation alternative is a palliative technique where electric stimulation is rhythmically applied, in either a scheduled or in-response manner, to specific brain areas and nerves, such as the vagus nerve, to counteract the process of seizure generation and propagation (Moshé et al., 2015; Thijs et al., 2019).

Antiseizure medication is also associated with side effects, most commonly neuropsychiatric (Thijs et al., 2019), but also of, and not limited to, cardiovascular, gastrointestinal, cognitive, dermatological, and visual nature (Moshé et al., 2015). These epilepsy treatment drugs carry a negative impact on patient's physical and emotional health, depending on both their level of effectiveness and severity of side effects (Kerr, 2012), and there is a significant correlation between number of administrated AEDs, stigma perception and emotional regulation issues (Tombini et al., 2020). Around 90% of patients report experiencing ASM side effects to some degree, as these side effects can be disabling and significantly impact patients' QoL (Kerr, 2012). The severity of the epilepsy condition, polytherapy, and psychological issues, such as depression or anxiety, are correlated to a higher number or severity of reported side effects from epilepsy medication (Sajobi et al., 2021).

Impact. QoL is multidimensional and, for epilepsy patients, not only includes health-related QoL factors (such as epilepsy severity and disability, seizure control and severity, and perception of medication treatment and its side effects), which are interrelated (Sajobi et al., 2021), but also involves their physical, mental, and social well-being (Yogarajah & Mula, 2019). QoL for epilepsy patients includes factors of the social dimension – the quality of their social life, their external support, and their autonomy or independence; the psychological dimension – the impact of social stigma and isolation, self-esteem and coping skills; the cognitive dimension – cognitive capacities such as memory, communication, and attention; the impact of comorbidities, especially psychiatric; their education and employment (Szemere & Jokeit, 2015). When compared to the general population, people with epilepsy tend to have a lower QoL, and while QoL is multifactorial, this deficit is mainly associated with factors such as depressive symptoms, anxiety, and perceived stigma (Ridsdale et al., 2017). In fact, anxiety or depression diagnoses are twice as prevalent in people with epilepsy, reaching one third of the epilepsy population (Moshé et al., 2015), and pharmacoresistant patients report a higher frequency of depressive symptoms. Psychological aspects impact not only the patient's mood, but also their perception of epilepsy

medication side effects, which, in turn, influence their willingness to carry out treatment and their condition severity, due to potentially lower seizure control (Sajobi et al., 2021). A causal correlation can be established between depression and increased drug treatment side-effects, accidents, injuries, and mortality. (Tombini et al., 2020).

Epilepsy, its symptoms, and its treatment result in neurobiological, neurocognitive, psychosocial, social, and physical challenges for patients, and these problems and limitations have a significantly negative impact on their well-being and QoL (Beghi, 2020; Henning et al., 2019; Jacoby, 2002; Thijs et al., 2019). The impacts of epilepsy are interrelated, for instance, cognitive issues can influence social difficulties (Szemere & Jokeit, 2015). Overall, patients with epilepsy, particularly those who have not achieved seizure freedom, report life challenges in relationships, education, and employment due to social stigma, seizure consequences (including fear), and functional disabilities (Asadi-Pooya et al., 2020).

In general, cognitive issues occur with higher frequency in the population with epilepsy, including memory and concentration difficulties. The decline of cognitive capabilities is especially associated with tonic-clonic seizures (Henning et al., 2019). Psychosocial issues include depression and depressive symptoms, anxiety, sexual, social, and communication difficulties. While studies discussing loneliness in people with epilepsy are rare, this feeling is reported more frequently in younger patients, possibly due to a struggle to meet the social expectations associated with their age-groups. Physical limitations associated with epilepsy are related to a higher level of physical inactivity, reportedly attributed to fear of seizures (Henning et al., 2019). Epilepsy has a significant impact on the brain areas responsible for social cognition, affecting both focal and generalized onsets (Yogarajah & Mula, 2019). Impairment of social skills (as an effect of fear or stigmatization), higher rates of psychiatric conditions, and neurocognitive issues (such as attention, memory, and communication impairments) are interrelated causes of social deficits in people with epilepsy. Deficits in social well-being in people with epilepsy affect external support, family constitution, employment, and social engagement and reward, leading to a reduced QoL and coping capabilities (Yogarajah & Mula, 2019). Hence, epilepsy management must go beyond seizure control and minimization of side effects and include social and psychological interventions (Cianchetti et al., 2015).

The burden of epilepsy goes beyond the condition itself, and social stigma associated with the disease is a main contributor to this burden, presenting additional challenges and distress for

patients (Jacoby, 2002), such as social exclusion and education or employment difficulties (Kerr, 2012). Its impact and perception significantly contribute to emotional dysregulation and depressive symptoms in people with epilepsy (Tombini et al., 2020). Stigma can be characterized as felt or enacted, corresponding respectively to the fear or shame of facing social stigma and the actual instances of public discriminatory attitudes (Kerr, 2012). Felt stigma tends to weigh more than enacted stigma, indicating that the belief in social discrimination and stigma prevails in patients despite the improvements in public attitudes (Jacoby, 2002). While this is the case for developed countries, in developing countries, enacted stigma is a bigger priority and concern (Kerr, 2012), possibly due to the aforesaid cultural beliefs. Despite effective seizure control and knowledge of their condition and prognosis seemingly leading to a decrease in felt stigma (Jacoby, 2002), patients with epilepsy and their families tend to have negative feelings and concerns regarding social discrimination and stigma excessively in view of a favourable prognosis (Cianchetti et al., 2015), highlighting the significant weight of patient's fears of prejudice and discrimination.

It is crucial to approach epilepsy care in a personalized and comprehensive way (Löscher et al., 2020; Sajobi et al., 2021). Unfortunately, this may be complicated by the existing gaps in knowledge, diagnosis, treatments, education, and research (Moshé et al., 2015).

2.2 Biosignal monitoring

A seizure log is a valued asset for clinical diagnosis, and condition characterization. However, seizure self-reporting and logging can be challenging for epilepsy patients, as some seizure types involve a partial or complete loss of awareness and/or consciousness, or occur during sleep (Safavi et al., 2019). As such, continuous seizure monitoring devices facilitate higher quality reporting and documentation, promoting the development of better, more timely treatment and intervention strategies (Thijs et al., 2019; Vieluf et al., 2020). Additionally, continuous monitoring and risk assessment can help understand the patient's risk of SUDEP, and the evolution of its associated predisposing factors over time, contributing to its prevention (Casanovas Ortega et al., 2022; Thijs et al., 2019). Seizure monitoring and detection present great clinical contributions, while also reducing the burden of epilepsy for those afflicted by the condition (Vieluf et al., 2020). EEG-based techniques are commonly used in seizure onset studies and remain the gold standard in seizure monitoring; however, their use is cumbersome and challenging in continuous outpatient monitoring contexts, commonly involving head-worn EEG devices. As such, wearable multimodal

devices combining multiple sensors (particularly wrist-worn or wristband-like sensors) that offer Autonomic Nervous System (ANS) activity monitoring and seizure detection with less impact on patients' lives are a highly desirable, non-invasive, non-stigmatising, and user-friendly alternative to EEG-based monitoring techniques (El Atrache et al., 2020; Safavi et al., 2019; Vieluf et al., 2020). While diagnosis and monitoring can be improved through the development of non-EEG based, multimodal, wearable monitoring devices, a recognised limitation is the variable performance by seizure type (Safavi et al., 2019), where the detection of non-convulsive seizure types is still unreliable (Thijs et al., 2019).

Common sensors for epilepsy monitoring include factors related to accelerometry, thermoregulation, electrodermal activity, and hemodynamics monitoring (El Atrache et al., 2020; Vieluf et al., 2020), in order to capture physiological responses to ANS dysfunction caused by epileptic activity, particularly during seizure occurrence, which includes a pre-ictal stage (comprising early symptoms and aura), ictal stage (active stage), and a postictal stage (corresponding to recovery). Accelerometry concerns the measurement of acceleration through an accelerometer sensor, which allows us to detect velocity, position, and movement changes. This is particularly relevant for detecting body movement patterns during motor seizures. Thermoregulation monitoring by measuring the patient's temperature is relevant for epilepsy monitoring, as seizures frequently induce body temperature fluctuations, particularly an increase (Sohn et al., 2016).

Considering hemodynamics, the imbalanced activity of the Autonomic Nervous System during the pre-ictal and ictal phases of a seizure generally leads to heart rate variability (HRV) and fluctuations of heartbeat intervals, thus they can be adopted as a marker for seizure detection. Additionally, during a seizure, catecholamines, neurotransmitters that act as anticonvulsants, are excessively released as a response, affecting autonomic responses concerning vascular modulation, through constriction and dilation of blood vessels. The vasoconstriction caused by the excess release of these neurotransmitters can be measured by a small photoplethysmogram (PPG) optical sensor (Figure 1), which emits light and captures its reflection with a photo detector. By detecting the alterations in the reflected light waves, it consequently detects blood flow volumetric changes; as the volume increases, less light is reflected. As such, the PPG signal, which is commonly used to measure heart rate and blood oxygenation, reflects the variations occurring in the cardiovascular system triggered by ANS alterations, including the possibility to derive HRV

information. Hence, as a seizure occurs, a consistent pattern of increased variation in hemodynamics can be observed and measured by PPG sensors (including during the onset stage), with seizure detection performance comparable to electrocardiogram (ECG) techniques (El Atrache et al., 2020; Safavi et al., 2019). However, high motion sensitivity is a challenge in PPG monitoring, even in well-established epilepsy monitoring devices, with little more than a third of the data being considered high quality. As such, hand movements must be limited, and further processing must be performed on the acquired data in order to remove artifacts (El Atrache et al., 2020). While, in clinical settings, the gold standard in PPG signal acquisition is a fingertip placement, experimental results also validate a palmar placement for PPG sensors, specifically in the thenar eminence of the palm, as an alternative, as it is less affected by hand and finger movement. Palm placement also promotes the possibility of combining multiple sensors in the same area, for multimodal monitoring devices (Silva et al., 2012).



Figure 1. Example of an PPG optic sensor (back and front).

Electrodermal activity (EDA) refers to the sympathetic responses of eccrine sweat glands, and while it presents regular, long-term fluctuations over time, internal or external stimuli can trigger phasic responses, which are transient changes in EDA. These changes can be measured as a Skin Conductance Response (SCR) or, more broadly, as Galvanic Skin Response (GSR), referring to an event-related physiological response during which changes occur in the skin's electrical conductance and resistance. During epileptic seizures, detectable electrodermal responses resulting from ANS activation occur – sweat gland activity increases, increasing skin conductance. As such, EDA signal monitoring can contribute to seizure detection and

differentiation. In clinical context, EDA is commonly monitored through the measurement of the GSR response by applying two electrodes, commonly disposable Ag/AgCl gel electrodes (Figure 2), which adhere onto the skin in the face, palms, or soles, as these are body locations with the highest electrodermal responses. (Casanovas Ortega et al., 2022) Hand-based EDA signal acquisition varies among the different fingers (Haddad et al., 2018; Janka et al., 2022). Additionally, wrists have been proven to provide good EDA signal measurements, while also being a more convenient location for outpatient monitoring. In terms of limitations, EDA responses are variable and are impacted by seizure types (including awareness, and laterality). An EDA response is detected in focal and generalized seizures, (with the highest response in tonic-clonic seizures) and motor and non-motor seizures (higher in motor ones); however, it is seemingly not elicited in seizures with an awareness state. Additionally, EDA sensors on a specific side seemingly do not detect lateral focus seizures on the opposing side (Casanovas Ortega et al., 2022).



Figure 2. EDA sensor (PLUX) connected to hydrogel electrodes (Cardinal Health).

The overall physiological responses to seizures present a common pattern, such as sequence of heart rate changes, motor response, followed by EDA response. These patterns in evolution and the relationships between the different responses may improve seizure monitoring detection accuracy (Casanovas Ortega et al., 2022). When considering seizure prediction in daily-life scenarios, particular challenges arise, including low sampling rates, sensor location, and artifacts from poor fitting or movement. Particularly concerning electrodermal activity, EDA

entropy can be considered a promising predictive feature; this marker reflects the degree of disorder and complexity of the EDA signal, and its increase tends to precede changes in specific neural networks. While the changes occurring in the Central Nervous System (CNS) and ANS in the pre-ictal stage of seizures could be potentially captured by EDA entropy (Vieluf et al., 2020), current knowledge on pre-ictal electrodermal responses is limited, and contradictory (Casanovas Ortega et al., 2022). As such, further research is necessary on the pre-ictal EDA changes, and the factors that impact EDA responses.

2.3 Textile electrodes

Skin conductance is a versatile biosignal; it allows us to monitor responses from the sympathetic nervous system (SNS, part of the ANS), integrating health monitoring in various dimensions, such as emotional or neurological, as an indicator. Commercialized wearable devices that integrate EDA monitoring employ rigid electrodes, which can become uncomfortable. Silver/Silver Chloride (Ag/AgCl) gel electrodes are the most commonly employed, especially in clinical and laboratory contexts, as they are cost and functionally effective. However, they are not appropriate for prolonged, daily use, as they are adhesive and can cause skin reactions. Additionally, they are not a sustainable option, as they are single use (Janka et al., 2022), and their performance degrades due to the gradual dehydration (Nigusse et al., 2020). Thus, dry electrodes can be a beneficial, sustainable, and unobtrusive alternative, and can easily be integrated into fabric and clothing (Janka et al., 2022). Textile-based wearables, such as wrist bands with fabric electrodes, offer a flexible, user-friendly, sustainable, alternative for long-term monitoring contexts with positive functional performance (Das et al., 2019). Dry, textile electrodes can be integrated through embroidering plated yarn (such as Shieldex multifilament threads), in a dense or cross-hatched surface pattern, or by application of a metal-based conductive fabric, such as copper or silver (Janka et al., 2022). Other production and integration techniques for textile electrodes include knitting and weaving the conductive threads, or direct application on an existing material, through coating (plating or printing) (Nigusse et al., 2020). Direct integration of the conductive yarn can produce unsatisfactory results concerning fabric flexibility; thus, application or coating methods may be more suitable (Tseghai et al., 2020). Nevertheless, knitting can help provide flexibility to the section where stretchiness and elasticity are necessary; on the other hand, weaving creates a

more rigid section, and can be performed in sections where structure is necessary (Ismar et al., 2020).

When employing contact-based electrodes, there is direct contact between the skin and the electrode; this contact must be ensured, otherwise data acquisition will be disrupted. Additionally, movement creates artifacts and acquisition disruptions. While performance may be poorer in dynamic contexts, movement or loss of contact issues can be mitigated through the application of the electrodes on elastic materials, and the tension applied to the contact improves signal quality (Nigusse et al., 2020). Considering substrates, woven cottons seem to be the most appropriate for signal quality with stitched textile electrodes when compared against nylon and polyester fabric substrates, possibly due to increased breathability, flexibility, and interface stability due to moisture absorption (Haddad et al., 2018). In comparison to standard Ag/AgCl gel electrodes, copper-based conductive fabric and densely embroidered Silver-based conductive yarn performed the best. Denser and larger contact areas largely improve performance due to reduced resistance; in fact, in larger contact areas, copper-plated fabric and densely embroidered conductive yarn perform better than standard wet electrodes (Janka et al., 2022). However, surface resistance is not only affected by the contact area with the fabric, but also by deformations caused by stretching or reactions to external environmental factors (Tseghai et al., 2020). Dry, solid electrodes, such as silicone electrodes, on the dorsal wrist, have a comparable performance to wet electrodes on the thenar eminence (van der Mee et al., 2021); solid electrodes, such as silicone or rubber electrodes, promote the retention of fluids and moisture, serving as an electrolyte (Janka et al., 2022). However, contrary to solid electrodes, textile electrodes do not affect skin temperature (Haddad et al., 2018), which is relevant when temperature is also being monitored.

While palm-based EDA remains superior in terms of signal quality and is thus preferred in clinical contexts, it is important to weigh the limitations on wrist acquisition quality against the benefits of daily monitoring of the SNS (van der Mee et al., 2021). Textile EDA electrodes facilitate long-term monitoring, due to the wearability they provide, as they are comfortable and unobtrusive (Das et al., 2019).

In wearable applications of textile-based systems, factors related to breathability, weight, comfort, stability, resistance to washing, chemicals, abrasion, and light, amongst others, must be ensured and balanced with performance (Das et al., 2019; Tseghai et al., 2020). Particularly with washing cycles, the surface tension of textile electrodes increases; however, these maintain their

stability and acceptable acquisition quality after washing (Nigusse et al., 2020). Additionally, in order to improve durability, encapsulating or coating the conductive fabric with a polymer can be performed, in order to increase resistance to washing and other external factors. Optimization for dry EDA electrodes, particularly in stabilization, can be done by adjusting the configuration and the distance between both electrodes in arm and wrist-based monitoring (Anusha et al., 2018).

2.4 User and patient experience

In the context of healthcare and, particularly, epilepsy monitoring, it is crucial to emphasise the significance of user and patient experience in the design and functionality of medical devices. Medical devices directly interact with patients and medical staff, making their design vital for effective treatment and safety, as poorly designed devices can lead to discomfort, considerable effort for operation, medical errors, improper diagnosis, and treatment, and potentially harm to the patients. Both ergonomic principles and usability are integral aspects to the design process, focusing on ease of use, safety enhancement, efficiency increase, risk reduction during use, and simplified maintenance and repair. During development, it is also important to acknowledge the different target user groups of medical devices (including patients, doctors/medical staff, caregivers, and general users), as well as the context in which these devices are applied (as environmental factors will condition the design of the product as must be taken into consideration) (Bitkina et al., 2020).

Thus, in order to ensure the medical device's safety, convenience, and efficiency, and the subsequent quality of patient care, the incorporation of efficient and effective usability and UX research methods, both quantitative, which target objective parameters and conclusions of statistical nature, and qualitative, which target the subjective dimension of user feedback and conclusions of an emotional dimension, is essential. Research methods include observations, questionnaires, interviews, focus groups, among others (Bitkina et al., 2020).

The role of eHealth applications is also significant in enhancing patient experience by providing engaging and interactive platforms for healthcare delivery. Ensuring these applications are user-centric and engaging is vital for optimizing their effectiveness, as poor engagement could lead to mistakes and compromised functionality. As such, the application of a holistic and pragmatic approach such as User-Centered Design (UCD), plays a pivotal role in optimizing eHealth applications; by focusing on real end-users, validating requirements and designs, iterative

development, UCD enables us to understand and design for the holistic user experience (Mival & Benyon, 2015).

Concerning, particularly, the experience in the context of healthcare, we can discuss patient experience, which reflects the experience of a patient, not in a singular encounter, but over time and including multiple touch points and interactions, which demands a more comprehensive and responsive approach to healthcare delivery. It includes meeting the emotional needs, ensuring engagement, and providing a continuity of care, which are essential components of enhancing patient experience; it is influenced by factors such as autonomy, choice, communication, confidentiality, dignity, prompt attention, and quality of basic amenities (Wolf et al., 2014). Ensuring these elements within the design and use of medical devices for epilepsy monitoring can contribute to an enhanced patient experience, subsequently leading to better healthcare outcomes.

In the context of smart wearable devices for epilepsy monitoring, understanding, and meeting users' expectations is paramount. Factors such as hardware, software, value, and design influence users' continuance intention to use these devices. Ensuring the users' perceptions of service and system quality meet their expectations can lead to higher satisfaction and intention to continue using the devices, ultimately enhancing the user and patient experience in epilepsy monitoring (E. Park, 2020).

These insights emphasize the need for a multi-faceted and patient-centric approach to design and implementation in the context of medical devices and eHealth applications for epilepsy monitoring, underscoring the significance of usability, engagement, and meeting users' expectations for optimizing patient and user experience (Bitkina et al., 2020; Mival & Benyon, 2015; E. Park, 2020; Wolf et al., 2014).

Chapter 3

3 State of Art

The following chapter discusses current practices epilepsy monitoring, both inpatient and outpatient contexts, that is, monitoring practices in clinical environment and at-home, autonomous health and epilepsy monitoring through epilepsy management wearables.

3.1 In-patient epilepsy monitoring

In-patient epilepsy monitoring plays a crucial role in the comprehensive assessment of the condition and in its management. The initial diagnosis of epilepsy often relies on clinical descriptions of seizures and medical history; further information can be obtained from routine outpatient EEG or neuroimaging. The EEG remains a gold-standard tool for epilepsy, offering high temporal resolution of brain activity and providing crucial insights into the condition and treatment approaches used for different types of epilepsy. Both outpatient and inpatient EEG, along with other imaging studies, aid in establishing and further characterising the condition, particularly when the diagnosis is uncertain or in need of redefinition (Maganti & Rutecki, 2013). The ILAE recommends long-term EEG monitoring in such cases to correctly classify the type of epilepsy, and for surgical preparation (Maganti & Rutecki, 2013). Due to transient nature of seizures, these are rarely observable in out-patient settings, which highlights the significance of inpatient v-EEG monitoring, which allows for the simultaneous recording of behavioural events and EEG, which is particularly valuable for diagnosis and pre-surgical planning, as it allows for a distinction between epileptic and non-epileptic seizure, and their localisation (Maganti & Rutecki, 2013; Shih et al., 2018).

During in-patient v-EEG monitoring, individuals are often admitted to an Epilepsy Monitoring Unit (EMU) for continuous, monitored evaluation, for an approximate 5 days stay for diagnosis or seizure characterization purposes (Sauro et al., 2016). In this setting, scalp EEG electrodes are applied, and in cases where seizures cannot be adequately localised, intracranial electrodes may be applied. The EMU environment is designed to ensure a more controlled and

comprehensive environment, taking into account patient safety and reliability of recorded data, making it more efficient and effective than bedside v-EEG monitoring (Shih et al., 2018). Certain processes used within these units, such as anti-seizure medication withdrawal or sleep deprivation, may increase the risk of adverse events for patients; despite these risks, EMU admissions have been found to be reasonably safe (Sauro et al., 2016).

With advancements in technology, the field is also exploring seizure detection systems for EMUs, for real-time and reliable automatic seizure detection, which is fundamental for timely intervention strategies such as electrical stimulation or drug infusion to interrupt seizures (Hartmann et al., 2011). However, while the technological and methodological aspects of in-patient epilepsy monitoring continue to advance, certain challenges and concerns, particularly regarding patient safety and care protocols, remain. Drug withdrawal, a common practice in EMUs, as well as treatment for *status epilepticus*, do not follow a general protocol, often varying by physician and case, which may indicate aspects in which patient safety could be at risk (Buelow et al., 2009).

3.2 Epilepsy management and wearables

The emergence of wearable devices with healthcare applications has created new opportunities for leveraging the possibility of acquiring large amounts of continuously collected data, particularly for enhancing patient care by monitoring their health status in their everyday contexts. Thus, this shift presents new ways of improving patient care and epilepsy management for PWE, by continuously monitoring, detecting, reporting and documenting seizures which improves patient safety, improves treatment decisions (Bruno et al., 2020), and enhances patient care outside hospital settings, by providing objective data on seizure logging, given that self-reporting is unreliable due to impaired awareness or consciousness during seizure incidents (Sivathamboo et al., 2022). These wearable devices with clinical and healthcare applications, particularly seizure-detecting devices, with sensors such as PPG, EDA, temperature, accelerometer, gyroscopes, GPS, among others, can be useful to timely report and alert caregivers and medical professionals. However, it is still difficult to effectively acquire quality data, as this technology is in progress and there are many challenges to data acquisitions outside clinical setting, which challenge the reliability of the acquired data (Rukasha et al., 2020). Currently, wearables encompass a range of form factors in the context of epilepsy monitoring, particularly: smartwatches, smart rings, arm bands, smartphone

integrated, and stick-on sensor patches. While wrist-worn devices are appreciated for comfort and ease of use, small ring devices are limited by their battery capacity and real-time data linkage capabilities. Additionally, the quality of PPG data is compromised by subject movement. Arm band sensors are generally less comfortable and accepted by users, while facing quality problems due to movement and unsecured devices. Adhesive sensors, although versatile in their placement location, may not be suitable for prolonged monitoring (in the scale of multiple weeks, months or years) due to loss of adherence, and skin irritation issues (Brinkmann et al., 2021).

Wearables devices such as the Empatica E4, the SPEAC system of Brain Sentinel, Nightwatch, and Epi-care (Figure 3) are examples of already existing wearable solutions for tackling epilepsy management and seizure detection. The E4 is unobtrusive, wrist-worn monitoring device, where a wristband is attached to an acquisition module, with a watch-like form factor, which pair with a smartphone application via Bluetooth connection, allowing for the alert of emergency contacts in the case of a detected seizure. Seizure detection is facilitated by sensors such as EDA (with stainless steel and silver electrodes placed on the volar wrist), PPG, accelerometer, and temperature, where specific patterns in data associated to tonic-clonic seizures indicate the possibility of a seizure. This device is currently marketed in the context of clinical research studies. The Brain Sentinel SPEAC is a monitoring device, attached to the user's arm, particularly the bicep area, where the acquisition unit is attached through an adhesive pad with gel electrodes. Conversely to the E4, this device uses surface EMG signals to detect patterns associated to tonic-clonic seizure activity, and is paired with a laptop throughout Wi-Fi connection, rather than an application. In the event of seizure detection, emergency contacts are alerted; this device is currently applied in rest periods of epilepsy patients, both in and out of clinical context. NightWatch is also worn on the bicep area of the arm, in the form of a lightweight acquisition module attached to an elastic armband; it utilises PPG and an accelerometer to detect motor seizure activity, and it is connected to an external base station which provides the necessary feedback on monitoring activity. This device is marketed for both personal and clinical use, allowing for at-home monitoring during night-time rest periods. The Epi-care is a wrist-worn lightweight acquisition module attached to an adjustable wrist strap, which connects to a smartphone application through Bluetooth connection. This device utilised sensors based on body motor activity, accelerometer and gyroscope, to detect tonic-conic seizure based on analysed motion

patterns; when a seizure is detected, the emergency contacts are alerted through the app (Bruno et al., 2020).



Figure 3. Seizure detection wearables, respectively, E4⁴ (top, left), Brain Sentinel SPEAC⁵ (top, right), NightWatch⁶ (bottom, left) and Epi-Care⁷ (bottom, right).

While epilepsy patients are generally acceptant of epilepsy management wearables (Sivathamboo et al., 2022), and despite their technological advancements, many high-tech wearables face short life cycles and limited user acceptance; these issues arise from the neglect of human factors in their design, which are an often overlooked critical component in wearables development (Francés-Morcillo et al., 2020). The aesthetic characteristics of the seizure detection device highly impacts patient's self-image, their outlook on the condition and its severity, and their routine experiences, by reminding them of their condition, causing them to feel different from others, observed, vulnerable and exposed, even in contexts where they did not report feeling as such before (such as among family and friends). While the use of monitoring wearable allows patients to maintain their everyday lives, improving their comfort and well-being, particularly

⁴ Image retrieved from Empatica website <https://www.empatica.com/en-gb/research/e4/>.

⁵ Image retrieved from <https://www.epilepsygroup.com/notes6-35-203/the-brain-sentinel-detecting-seizures-anywhere-and-anyt.htm>.

⁶ Image retrieved from NightWatch website <https://nightwatchepilepsy.com/nightwatch/>.

⁷ Image retrieved from <https://danishcare.co.uk/epicare-free>.

when compared to inpatient monitoring settings, such as the EMU, their visual appearance (particularly, the visibility) of these devices significantly impacts patients, and can deter them from adhering to the technology (Olsen et al., 2021). In order to enhance long-term adherence to medical wearable device usage, aesthetics according to user preferences and comfort must be ensured (Brinkmann et al., 2021). Epilepsy patients' preferences and experiences, as well as those of caregivers and medical professionals, must be taken into account during the development of epilepsy monitoring devices (Bruno et al., 2020; Sivathamboo et al., 2022). By integrating requirements such as physical (comfort, safety, and durability), cognitive (usability and reliability) and emotional (engagement and aesthetics) ergonomics, a synergy is created between technology and human factors (Francés-Morcillo et al., 2020).

There is large preference for epilepsy management solutions that are of discreet, unobtrusive, non-stigmatising, non-intrusive design and easily integrate patients' daily lives (Bruno et al., 2020; Olsen et al., 2021), such as devices integrated with smartphones, wristbands, smartwatches, jewellery, clothing and other everyday items, with a preference for wristwatch-like designs; conversely, items more intrusive or noticeable, such as head-worn devices and sensors, or cameras, were least preferred due to being more stigmatising (Bruno et al., 2018; Sivathamboo et al., 2022). It is important to ensure a familiar-looking, comfortable, and fashionable design, that can be easily hidden or covered, and do not present any exposed electronic components, nor a bulky and large shape or size; otherwise, such devices may attract unwanted visibility, and lead to discrimination and stigma (self, perceive or enacted) (Bruno et al., 2020).

Users have a lower threshold for discomfort for wearables worn on extremities, being more sensitive to the device's weight and movement; thus, issues such as the wearable being of excessive weight, not ensuring a correct weight placement or distribution, or not being securely attached more easily trigger discomfort for users, than in areas such as the waist area (closer to the centre of their body mass). Additionally, it is important to ensure the weight of placement the wearable does not impact the posture of users, causing long term discomfort or even orthopaedic issues. In order to uniformly distribute the pressure and the weight of the objects, and to allow a comfortable and secure fixation, wearable devices should be produced using flexible materials (H. Park et al., 2019).

In terms of functionality and usability, there is a preference for customisation of alert and feedback (prevents the device's alerts from becoming excessively intrusive or disturbing users in

particular periods or contexts) and that the device is waterproof (Bruno et al., 2020), with a battery life superior to 24 hours (Sivathamboo et al., 2022), as the task of charging these devices, which are meant to be worn continuously during the day and night time, presents a significant challenge to user compliance (Brinkmann et al., 2021). Other functional preferences include highly sensitive real time detection with short delay, and low rate of false positives. In terms of collected data, physiological data included heart rate, respiration, oximetry, and muscle movements; psychological data included mood, concentration, and attention, as well as tracking the user's sleep (Sivathamboo et al., 2022).

The design process of wearables may present many trade-offs, where users' expectations for aesthetics and comfort may not align with functional priorities from a medical and technological perspective; therefore, the costs and benefits of each design solution must be weighed, in order to meet user needs and expectations while addressing medical and functional requirements (Motti & Caine, 2014). Wearable verification and validation must be both quantitative and qualitative, as well as performed iteratively, where prototypes are important exploratory tools in early stages, as indicators of preferences, performance measuring tools in later stages, as indicators of interactivity (Francés-Morcillo et al., 2020).

There is a growing desire among PWE to gain a holistic view of their health status, particularly in the context of seizure risk assessment (Bruno et al., 2020). That is, while wearable devices for epilepsy tend to focus on seizure detection (in which false alarms posing a significant challenge), with seizure forecasting, the emphasis shifts towards informing individuals of their current seizure likelihood, reducing the disruptive impact of false alarms, through an holistic approach to long-term tracking of risk factors; it focuses on the probabilities of seizure occurrence, communicating this likelihood, allowing PWE to take proactive measures in such situations (Brinkmann et al., 2021). Risk assessment mechanisms are highly valued; in fact, PWE prioritise receiving information that can help patients mitigate the unpredictability of seizures over automatic alerting of emergency contacts in the event of seizure occurrence. This is accompanied by a preference of combining multiple measurements into a single wearable device, which highlights the importance of combining active and passive, physiological and contextual, information in order to facilitate seizure forecasting through risk assessment, rather than focusing solely on seizure detection (Bruno et al., 2018).

Chapter 4

4 Methodology

The fourth chapter describes the methodology applied in this research – four iterations of the development process, which followed the Double Diamond design methodology (Design Council, 2022), characterized by four non-linear diverging and converging thinking stages: Discover, Define, Develop and Deliver.

This framework encompasses two core design principals that correspond to the scope and needs of this research. One of them corresponds to people prioritization, understanding the end-users of the product, their needs, and requirements; this human-centric approach is especially important when designing a product for long-term, daily and continuous wearing. Furthermore, epilepsy patients may have additional and different struggles, needs and journeys than the general population, which highlights the importance of focusing and understanding this user group. The second core design principal which aligns with the developed work is iteration, which is time and cost effective, allowing us to change and improve quickly in a short period of time.

Each stage of the followed Double Diamond structure (Figure 4) encompassed specific tools and steps. At the Discover stage, our goal is to understand the scope and context of the iteration, by collecting all necessary information, both indirectly, through desk research, and directly, by contacting and observing the relevant stakeholders⁸ (end-users and/or experts). The Discover stage is a consolidation of the previously performed research and collected information, and in which we summarize our findings, defining elements such as development requirements and constraints, user and/or expert insights, and identify themes. These two stages encompass the problem space, allowing us to identify and define the problem or gap, but also to consolidate the known information necessary to tackle it. The third stage, Develop, focuses on conceptualising one or multiple solutions that target the issues raised in the previous stages, taking into account

⁸ ‘Stakeholders’ was the chosen term to encapsulate both epilepsy patients and experts, in order to represent those concerned in the outcomes of this project.

the identified requirements and constraints; in this stage, the solution design can be of an idealised nature, being conveyed through sketches and concept, or materialised one, through models and prototypes. Deliver, the fourth stage, encompasses the evaluation of the conceptualised, or materialised, solution against previously established requirements and insights. This evaluation is performed with relevant stakeholders, through tests, questionnaires or interviews; their behaviour and feedback allow us to identify and define necessary improvements, and the subsequent steps in development. These two last stages encompass the solution space, in which a solution is conceptualised, possibly materialised, and evaluated by users and/or experts, ensuring that the design process is user and human-centric and is constantly guided by the stakeholders' needs and requirements.

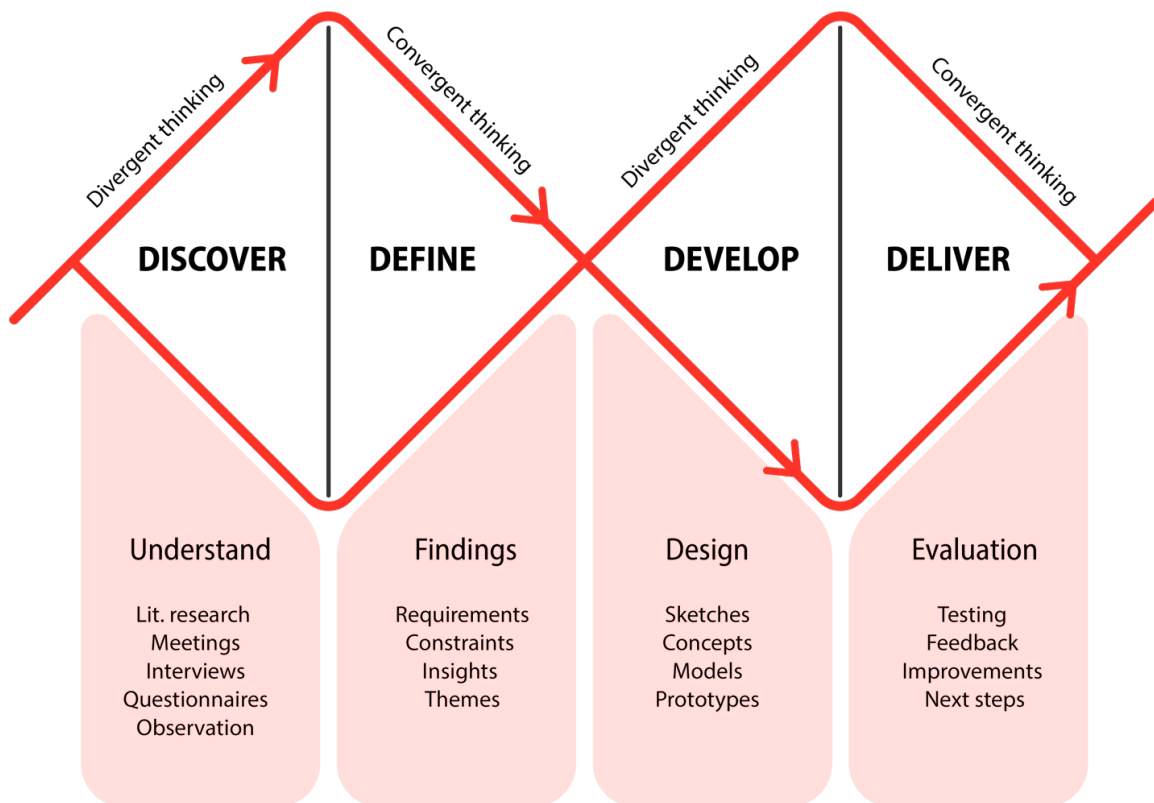


Figure 4. Double Diamond methodology⁹.

⁹ Adapted from the Design Council (2022).

During the course of this research, the Double Diamond structure was iterated a total of four times, each iteration referring to a different stage of the development (Figure 5). The feedback, insights and identified improvements, derived from the evaluations performed at the Deliver stage of an iteration, integrated the Discovery stage of the following iteration as a baseline of new, learned information. Overall, methods of observation, questionnaires, interviews, and user diaries were applied, and each phase of the research collected both quantitative and qualitative data.

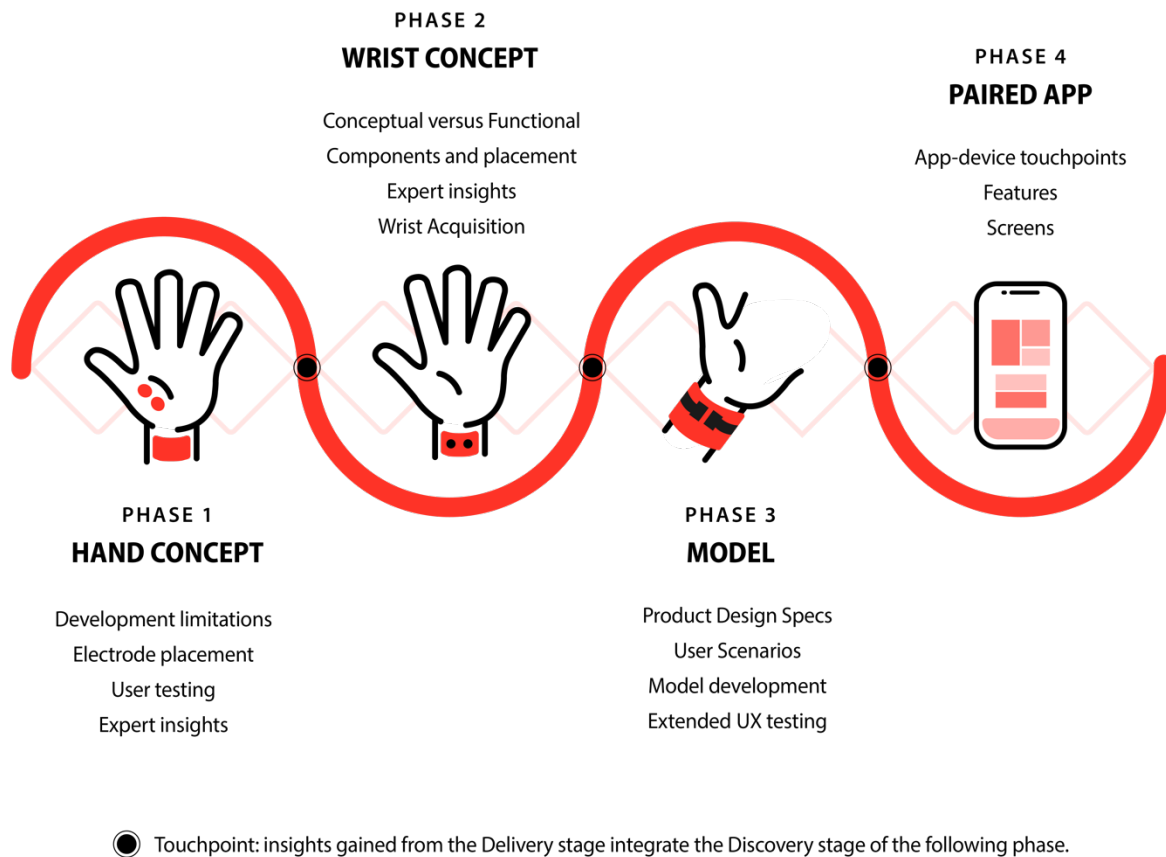


Figure 5. The four phases of development.

The first development phase, i.e., the first iteration of the Double Diamond process, encompassed the initial concept development for a hand-worn epilepsy monitoring wearable. During this phase, our goal was to define the electrode placement, and the subsequent size and shape of the palm coverage area, as a first step towards defining the hand-worn device. Methods such as observation, questionnaires and interviews were employed, in order to collect both quantitative and qualitative data; evaluation methods involved both users and experts.

The following phase consisted in the shift from hand-worn to wrist worn, following evaluation result from the previous stage. During this second phase, our goal was to define and validate the electrode and sensor placement in the wrist. Quantitative and qualitative data was collected by performing, respectively, bio-signal acquisition tests and interviews with experts, in order to validate wrist data collection and electrode and sensor placement.

The third phase of development consisted of further defining the wrist-worn solution from the previously consolidated and functionally validated concept, by developing a dummy model, i.e., a non-functioning model, and performing an extended user experience testing with epilepsy patients, our end-users. During this phase, our goal was to validate the conceptualised solution in terms of experience, in particular, continuous, long-term monitoring. This extended user experience testing included the methods of user diaries and interviews, in order to collect both quantitative and qualitative data.

The final phase of development concerned the idealisation of features and the development of screens for a smartphone app, which pairs with the conceptualised long-term epilepsy monitoring device. During this phase, the evaluation of app was achieved through questionnaires and interviews, collecting both quantitative and qualitative data.

Chapter 5

5 Project development

The fifth chapter will describe in greater detail the process of development and each of the phases, outlined and summarised in the previous chapter, consisting in four sections, each an iteration of the Double Diamond process, and structured according to its stages (Discover, Define, Develop, Deliver).

5.1 Phase 1 – Hand wearable concept

This section will discuss the first iteration of the development process, during which, starting from the briefed position – the hand – three alternatives for electrode placement in the palm and fingers, and subsequent device coverage area and shape, were tested and discussed with users and experts.

5.1.1 Discover

The initial brief for this research defined the wearable as hand-worn, which derived from both current in-lab practices and functional performance maximisation; and provided a differentiating factor from the current epilepsy monitoring wearable solutions.

In the context of the collaboration with Instituto Superior Técnico, multiple meetings were set up with professors and students, with expertise in the areas of Biomedical Engineering and Electronics Engineering. These meetings allowed us to further understand current practices, and how they could be improved, related projects (concluded or in development) as well as deepen the understanding of specific sensors, electrodes and devices in use. At this stage, two specific related projects became relevant: the epilepsy monitoring sock, a project developed by my MSc student Afonso Ferreira (Instituto Superior Técnico), where textile electrodes were applied to regular socks to perform EDA data acquisition, and the acquisition module was attached to the ankle area; and the EmotiphAI emotional response¹⁰ system, developed by Ph.D. student Patrícia Bota (Instituto

¹⁰ Project overview available at <https://www.scientisst.com/projects/emotiphai>

Superior Técnico), which is used to monitor physiological data, during video visualisation (such as movie screenings) in order to correlate it to the emotional response of participants. In the latter, gel electrodes are applied to the palm of participants, and the PPG sensor on the fingertip of the index finger, both locations considered the gold standard, in order to maximise the quality and efficacy of the data acquisition. Considering our initial briefing, these placement locations could be a starting point for the definition of the overall shape of the monitoring wearable device.

By attending two of the data acquisition sessions of the EmotiphAI system, we were able to ask participants a few questions regarding their experience with the current system (Figure 6).

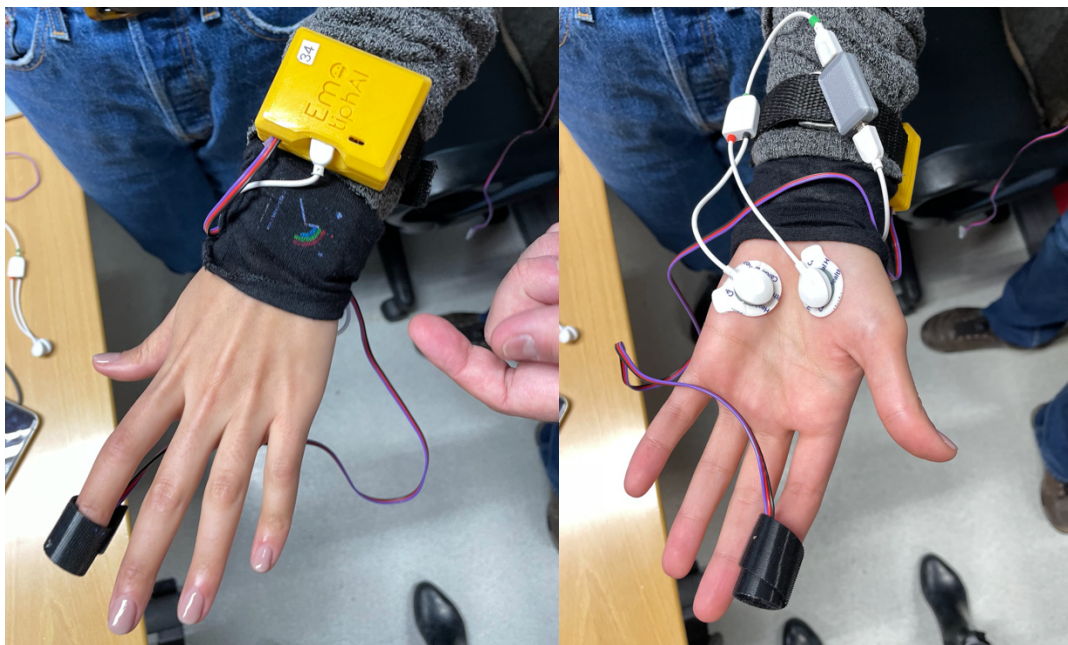


Figure 6. EmotiphAI system; back of hand view (left) and palm view (right).

The questionnaire had a duration of one to two minutes and was included in the closing procedure of Patrícia Bota's EmotiphAI data acquisition sessions. Eighteen participants participated overall, all of whom were students at Instituto Superior Técnico (site of the data acquisition session), consisting of 9 female and 9 male participants, and ages ranging from 19 and 25 years old ($\mu = 20.67$, $\sigma = 1.50$). The presented questions, and respective results, are the following:

1. Rate your perception of the device on the following 5-point Likert scale:
 - a. Fragile (1) to Robust (5): $\mu = 3.33$, $\sigma = 1.14$;

- b. Safe (1) to Dangerous (5): $\mu = 1.17$, $\sigma = 0.51$;
 - c. Impractical (1) to Practical (5): $\mu = 3.27$, $\sigma = 0.83$;
 - d. Tolerable (1) to Intolerable (5): $\mu = 1.78$, $\sigma = 0.88$;
 - e. Comfortable (1) to Uncomfortable (5): $\mu = 2.16$, $\sigma = 0.92$;
2. Rate how impactful the monitoring device was to your movie viewing experience, from Not influenced at all (1) to Highly influence (5): $\mu = 1.61$, $\sigma = 0.61$
 3. Rate each sentence from Strongly Disagree to Strongly Agree, in a 5-point Likert scale (results in the following Table 1).

Table 1. Results for the last question of the EmotiphAI data acquisition study.

Sentence	Strongly disagree	Disagree	Neutral	Agree	Strongly Agree
I was concerned about my privacy	10	5	0	0	0
I was afraid to cause damage to the device	4	6	1	6	1
I felt like I couldn't move freely	4	9	3	2	0
I forgot I was wearing it	1	2	5	8	2
This device was obstructive	6	4	7	1	0
I would use the device in my daily life	13	1	3	1	0

The overall results were quite positive; despite the system presenting the exposed electrodes and sensors, and respective connecting wires, participants found it to be moderately robust (average of 3.33), practical (average of 3.27) and safe (1.17). Additionally, the system does not cause any tolerability or comfort issues, presenting minimal impact to the movie viewing experience, which corresponds to a significant portion of participants being able to forget they were wearing the device (56% agreed or strongly agreed). Results also demonstrate that there were no significant privacy concerns associated with the acquisition device. While the obstruction of the device (reflected in two of the statements) presented mixed results, these were still associated moderately low concerns. It is important to note that participants answered the previous questions in the context of a movie-length monitoring experience, rather than in the scope of everyday monitoring. In fact, this is validated by the results pertaining to the last rated statement, where the vast majority of participants (78% disagreed or strongly disagreed) reported they would wear this device routinely.

In terms of technical issues, two students reported that one or both EDA gel electrodes lost adherence and become unattached from their palm during the study; this situation was consistent with a common issue reported in literature.

5.1.2 Define

Through this initial stage, we were able to define some early-on characteristics of the wearable device, such as the possible configurations of components and electrodes; given the increased performance and efficacy of the data acquisition when EDA electrodes would be placed in the palm of the hand, being the gold standard for signal acquisition. By utilising textile EDA electrodes, in a fabric hand-worn wearable with glove features, we could mitigate the adherence issues of the gel electrodes, which are not suitable for prolonged, everyday use. As learnt previously, the areas for electrode placement in the palm encompassed, mainly, the thenar eminence and hypothenar eminence of the palm; in the literature, it was also indicated that the phalanges are also appropriate locations for reliable signal acquisition. As such, these three alternative areas must be validated in order to further define the configuration of electrodes, and the resulting wearable shape.

The PPG sensor's location, in research and clinical context, tends to be the index fingertip, which is not feasible in daily life contexts, due to the noise introduced from finger movements and contact with other surfaces. Thus, and similar to other wearables such as smartwatches, the PPG can be collected from the wrist area, and incorporated into the acquisition module, rather than external and connected through wires or textile pathways. This acquisition unit will also incorporate other necessary sensors, such as gyroscope, accelerometer or temperature.

5.1.3 Develop

Following the definition of requirements and location, including possible electrode and acquisition unit placement in the hand and wrist areas, the first step was to define the extent and shape of the fabric-covered area wearable. The aim was to create a minimal coverage area size, in order to make the product as discreet as possible, while still facilitating functional performance.

Due to the textile nature of the electrodes, these would not, by default, maintain contact with the skin (contrary to standard hydrogel electrodes, which are stuck onto the skin), which would disrupt or even preclude electrodermal activity monitoring, in the cases where electrodes

drag on the skin, introducing noise to the readings, or become loose from the skin. As to address this requirement, not only the fabric covering the hand should be skin-tight and elastic, but the coverage area should also be adapted in order to minimize movement interference and immobilize the electrodes during natural hand movements. Unfortunately, this could translate in a larger amount of coverage than just the necessary for the conductive fabric pathways. In order to understand these implications and visualise the minimal possible fabric coverage area necessary to facilitate functionality, sketches were created for each electrode placement alternatives (Figure 7).

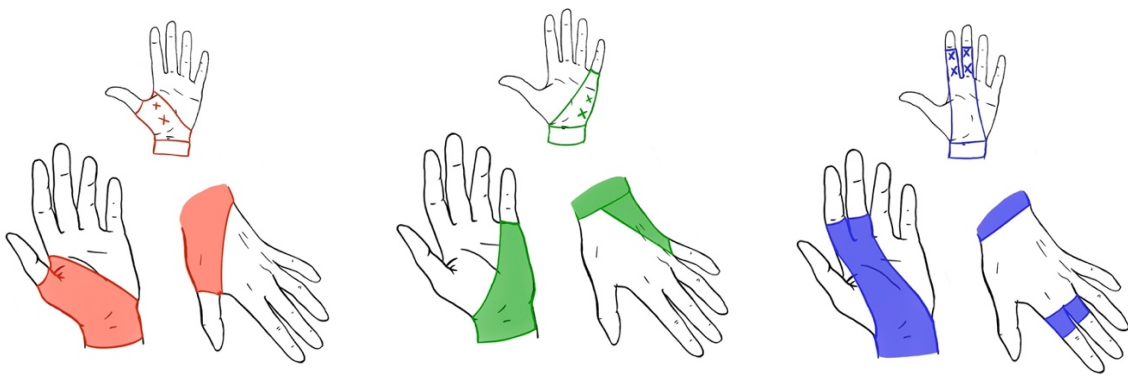


Figure 7. Sketches for the three shape and coverage area alternatives.

The first alternative, also referred to as the thumb alternative, focused on the textile electrodes being placed on the thenar eminence of the palm, at the base of the thumb, as the conductive fabric pathways would lead to the wrist, where the acquisition unit would be placed, similarly to a wrist bracelet. During hand movements, including thumb movements or bringing the thumb and little finger closer together (oblique arch), natural skin folds and creases are created in the palm, particularly radial tension creases in the thenar area, which can cause the skin to drag from under the fabric, the fabric to move, and/or it would create gaps between the fabric and the skin. As such the fabric in this alternative should be large enough to cover and tightly hug all the skin and muscle area around the thumb, in order to immobilize, as much as possible, the skin during these types of movement, and reduce creases in the thenar area. Additionally, the seam should be elastic, and run along the longitudinal thenar crease, naturally separating the immobilized area from the instability of the rest of the palm, avoiding fabric folding in that area.

This also implicates a larger coverage in the back of the hand to create the necessary tension in the fabric and, more importantly, in the seam. The resulting coverage area for the thumb alternative is represented in red, in Figure 7.

The second alternative, also referred to as the little finger alternative, focused on the external of side of the hypothenar eminence of the palm, where the textile electrodes would be in line with the little finger but below the distal palmar crease. That area would be less influenced by hand and finger movements, and with less tension creases that, for instance, the thenar area. The conductive fabric pathways then run down the hypothenar area, from the electrodes towards the acquisition unit on the wrist. During specific hand movements along the longitudinal and oblique arches, the palmar gutter deepens, which results in a gap between the skin and the fabric and textile electrodes. Creating a tight, elastic seam, between the ring and little fingers, and along the ulnar area of the hand, could mitigate the deepening of the palm concavity during these movements; however, it will not eliminate it, and can create an uncomfortable tension and disturb the hand during other movements or in resting position. Instead, the fabric should hug the ulnar side of the hand, maintained by a stiffer seam that anchors that tension to the wrist band. As such, if the electrodes are sufficiently close to the side of the hand, the less likely they are to be affected by the gap between the fabric and skin in the middle of the palmar area.

The third alternative focused on the distal and middle phalanges of the index and middle fingers, which would require ring-like bands to maintain contact between the textile electrodes and the skin – this would be a very small and unnoticeable coverage area. However, to connect the electrodes to the wrist acquisition, it is necessary to run the pathways down, which would require a bridge-like coverage of either the palm or the back of the hand, towards the wrist band. In terms of noticeability, decreasing visible coverage would be preferable; as such, creating a bridge over the palm would be appropriate. However, this situation would be particularly challenging as hand movements involving any arches, and deepening the palm gutter, could create a possibly obstructive excess of loose fabric in the bridge, which would require a heavier dependence on fabric composition and cutting pattern to mitigate this issue. Nevertheless, the coverage area would be minimal, less than the previous alternatives.

Given that these three alternatives already reflected functional concerns for data acquisition, it was necessary to validate them through user testing and expert interviews in the following stage, in order to understand which would be more adequate within the scope of this research. As such,

these coverage areas were produced as tangible models of a beige fabric, of organic cotton and elastane composition (Figure 8; right). Initial moulds were made using latex gloves, paper and painter's tape in order to create the patterns (Figure 8; left). Then measurements were adjusted to produce two different glove sizes per alternative, which combined with the elasticity of the fabric, could fit multiple hand sizes.



Figure 8. Tangible thumb glove recreated using tape for pattern creation (left) and elastic fabric (right).

5.1.4 Deliver

At the last stage of the first development iteration, the objective was to establish the preferred overall shape and extent of the coverage area, and the consequent electrode positioning, as a first step in defining the wearable product. An evaluation of the three developed alternatives was performed, collecting qualitative and quantitative data; while the evaluation would require two different studies, concerning both end-users and experts, access to epilepsy patients was challenging and limited (as previously discussed as a limitation), and each patient would only be able to participate once throughout the development, to ensure unbiased results and findings. As such, the user evaluation of this stage was performed with participants without an epilepsy diagnosis; the impact of this limitation, at this stage of development, was not considered to be great enough to compromise the results, as there were no documented shape and placement preferences for this type of product particular to PWE. Nevertheless, in order to mitigate this limitation, during study introduction, topics of social stigma, discrimination, discretion and condition concealment were presented in order for participants to empathise and understand the impact of visibility and

obstruction in the scope of long-term, continuous epilepsy monitoring, to a sufficient degree. With this acknowledgment that participants do not represent the end-users, the established term ‘user’ will still be applied for practicality and standardization purposes.

User testing. This first study focused on understanding the user experience of the three alternatives, and which would be preferred, in order to establish a starter shape and coverage area, as well as electrode placement.

Design of the study: The conducted study followed a mixed design approach, assessing user preference through questionnaires, providing quantitative data (user experience related questions with Likert scale, and user acceptance related statements with multiple choice provide) and short semi-structured interviews, providing qualitative data. The study was structured into three separate stages:

- Sample characterization – quantitative stage with questions regarding age, sex, occupation, expertise, wearable and glove experiences for each participant.
- Single model assessment – mixed stage, between-subject design. Each participant performs tasks using only one of the three alternatives, answering a questionnaire on user experience, followed by a short interview.
- Multiple model comparison – mixed stage, within-subject design. Participants perform the same tasks using all three alternatives, answering a forced-choice questionnaire related to user acceptance, followed by a short interview.

Materials: The tangible models, produced in the same elastic cotton fabric, for the three alternatives in coverage areas (thumb, index and middle finger, and little finger), as well as the respective sketches, were available to participants. Other materials included a 33ml bottle of water, a standard pen and a notebook, which were available during task execution. The study also required three questionnaires, each for one of the mentioned stages. The first questionnaire focused on sample characterization, the second questionnaire (adapted from the UEQ) focused on assessing user experience of participants with one specific model, and the third questionnaire focused on user acceptance, with a multiple choice for the different statements, creating a comparison between the three alternatives. These questionnaires are available in Appendix A.

Participants: Thirty participants took part voluntarily in the study, recruited from various areas of expertise with a sample consisting of 15 female and 15 male participants, and ages ranging from 19 and 62 years old ($\mu = 37.83$, $\sigma = 11.32$).

Procedure: This user testing phase occurred in separate individual sessions, over the course of two weeks; took place in a separate room, with natural lighting and negligible noise. Each participant was welcomed in, seated next to the researcher, and introduced briefly to the context and objective of the study. After the brief introduction, all participants read and signed an Informed Consent document. Sample characterization data was then collected through the first questionnaire. Afterwards, each session was separated into two parts:

- I. Single model evaluation: During the first phase, each participant interacted with, and evaluated, one of the three alternatives. The models were distributed consecutively, per participant, which resulted in ten individual evaluations of each alternative. Participants were introduced to their physical model and respective sketches, with a brief explanation of their coverage area and shape. Afterwards, they were requested to perform the following tasks:
 - a. Free exploration, up to one minute.
 - b. Put on and take off the glove on their own.
 - c. Put on the model to non-dominant hand and handle the following personal items: smartphone, keys, and wallet. Participants used their smartphones to write, navigate, dial, take a picture, pretend to make a call. Keys were handled in the following manner – shuffle through keys, hold the keys in different manners, pretend to open a lock, twirl the keys with different fingers. Finally, participants were asked to open and close their wallets, remove and handle cards, existing coins and bills.
 - d. Grab, grip, open and close a water bottle.
 - e. Grab, grip and handle a pen.

These tasks allow us to understand whether the model would constrain their movement, obstruct, or get caught in other objects, as well as if the participant experienced any difficulties in putting on and taking off the glove. The glove model was always worn on the participant's non-dominant hand. After the first experience questionnaire, a small

interview was conducted where participants were able to give feedback and justify some of their answers.

- II. Multiple model comparison: The second stage of the testing session followed a within-subjects design approach, in which the participant was introduced to the remaining two models and respective sketches. Each participant repeated the previous tasks with each new model – they were also able to explore at their will their originally assigned model, including repeating the same tasks. They were then asked to answer the third questionnaire that targeted specific identified concerns for user acceptance, in the form of statements, related to social stigma and discretion; participants performed a forced choice of which model best corresponded to each statement. A small semi-structured interview was conducted, where participants justified their choices, discussed their preferences, and gave feedback.

Results. The questionnaire and interview data were analysed according to the two stages of the study – user experience and user acceptance. Considering the first stage, participants were asked to evaluate their model individually, unaware of other alternatives, through an adapted UEQ. We took into account the average score results in the evaluated dimensions of attractiveness, perspicuity, efficiency, dependability, stimulation, novelty and comfort, for each different alternative.

Table 2. Average scores for each glove in the dimension of Attractiveness.

Measurement	Category	Thumb	Little finger	Double
Attractiveness	Annoying — Enjoyable	4.0	3.7	2.3
	Good — Bad	1.3	1.9	2.2
	Unlikeable — Pleasing	4.2	3.4	3.1
	Unpleasant — Pleasant	4.2	3.6	3.1
	Attractive — Unattractive	2.4	2.5	2.8
	Friendly — Unfriendly	1.5	1.8	2.7

In terms of attractiveness (Table 2), the thumb alternative was ahead in all categories. While no models were significantly perceived negatively, rated as unlikeable, unattractive, unfriendly and/or unpleasant, the index and middle fingers model was rated closer to annoying,

which was associated with observed challenges, specifically movement obstruction during task performance.

Table 3. Average scores for each glove in the dimension of Perspicuity.

Measurement	Category	Thumb	Little finger	Double
Perspicuity	Understandable — Not understandable	1.2	1.8	2.0
	Complicated — Easy	4.6	4.4	3.9
	Clear — Confusing	1.6	1.6	2.2
	Cumbersome — Not cumbersome	4.8	4.7	2.9

While all models were rated positively across the perspicuity dimensions (Table 3), the third model demonstrated a lower rating in terms of cumbersome nature, averaging close to a neutral score and quite lower than the other alternatives. While there were no significantly poor scores across the dimensions, the short interviews at the end of the user experience stage relayed strong opinions from the participants. Multiple users mentioned that the index and middle fingers model had a “complex” or “awkward” appearance, partly due to its “detached manner” which was also associated with a lack of robustness and higher visual complexity. Participants mentioned that its shape conveyed how it was supposed to be worn, “easy to perceive how to put it on” – which was associated with it being fairly clear and understandable. However, while performing the tasks, it was a common occurrence the middle and index model was put on differently than intended. Most participants would put it on with the bridge on the back of the hand, instead of the palm. There was only one instance in which a participant had to be alerted to the incorrect wearing of this model before proceeding with the tasks. The task of putting on and taking off also revealed some mishaps for the little finger model, where a few participants would initially fit the glove with the hole to the thumb, and, only afterwards, rotating the model to insert the little finger. The thumb model did not register this type of occurrence. Despite these observations, the models scored overall positive results in perspicuity.

Table 4. Average scores for each glove in the dimension of Efficiency.

Measurement	Category	Thumb	Little finger	Double
Efficiency	Fast — Slow to put on/take off	1.4	1.2	2.6
	Easy — Hard to put on/take off	1.2	1.5	2.3
	Impractical — Practical	4.8	4.1	2.2

Efficiency measurements (Table 4) demonstrated an advantage for the thumb model, followed by the little finger glove, with similar average scores. All models had positive scores for speed and ease of putting it on and off the gloves, while the two fingers model yielded the worst scores for practicality – during task performing, participants who evaluated this model experienced difficulties handling loose personal objects, such as keys and coins, as they would occasionally get caught on palmar area of the glove. Additionally, during interviews, participants mentioned that the palmar coverage of the model was not only impractical due to those occurrences, but also associated it to the lack of sensitivity and feel in that area due to the coverage, which led to feeling “less in control” over object handling as well as obstructing their tasks. This obstruction, which was both observed and confirmed by participants, is also associated with the negative score in the Obtrusive-Supportive dimension for Dependability (Table 5).

Table 5. Average scores for each glove in the dimension of Dependability.

Measurement	Category	Thumb	Little finger	Double
Dependability	Obtrusive — Supportive	4.8	4.0	1.6
	Secure — Not secure	1.0	1.1	1.3
	Meets — Does not meet expectations	1.2	1.7	3.0

On the other hand, the thumb model and little finger models obtained quite positive results in that same dimension, indicating that, unlike the third alternative, they properly support participants during task performance. During the short interviews, a few participants indicated that the little finger model would “slightly restrain” or “offer resistance” to their finger during the gripping and handling tasks, interfering with their movements.

Table 6. Average scores for each glove in the dimension of Stimulation.

Measurement	Category	Thumb	Little finger	Double
Stimulation	Valuable — Inferior	1.2	1.3	1.8
	Boring — Exciting	3.0	3.8	4.0
	Not interesting — Interesting	3.1	4.1	3.9
	Motivating — Demotivating	1.3	1.7	2.0

Table 7. Average scores for each glove in the dimension of Novelty.

Measurement	Category	Thumb	Little finger	Double
Novelty	Creative — Dull	3.3	2.4	2.2
	Inventive — Conventional	3.5	2.2	1.3
	Usual — Leading edge	2.8	3.6	4.2
	Conservative — Innovative	3.4	4.0	4.5

Considering Stimulation and Novelty (Table 6 and Table 7), the thumb model averaged neutral scores for dimensions that we can associate or attribute to familiarity, such as boring, conventional, usual, amongst others. This perception of familiarity towards the coverage shape of the thumb model was described during user interviews, where many participants mentioned that the model was similar to other medical or compression gloves they had frequently seen or worn before, thus not associating them with novelty or innovation. It was perceived during interviews that three participants had experienced guilt and avoided voting more expressively towards adjectives such as conventional, usual or conservative. Despite these results, the thumb model averaged high results for value and motivation. Questioned on this duality, most participants expressed that they valued familiarity and conventionality in the context of discretion and everyday use. Multiple participants mentioned that if they wore that glove, it would not raise questions, strangers would most likely not stare, since most would assume it would be for a muscle or ligament lesion. While, similarly, the little finger model averaged very positive values for value and motivation, the remaining fields such as the Novelty dimensions, performed better than the thumb model. A few participants mentioned in interviews that it looked “cool” and “interesting” while still being discreet due to the reduced coverage area and its placement. The index and middle

finger model averaged close to neutral ratings in value and excitement, motivation, but the highest results in qualities such as interesting, inventive, innovative and leading edge. During interviews, it was described as “weird but interesting”, looking “futuristic” but participants didn’t associate it with an increased motivation to wear it. Interestingly, multiple participants described it as prominent, which would catch the attention of strangers, despite its coverage area being mostly in the palmar region. When questioned further, a few mentioned that the palmar region is often visible to others, and two participants pointed the finger bands as weird and unusual (“looking like Band-Aids”). Overall, the little finger model was favoured in both Stimulation and Novelty.

Table 8. Average scores for each glove in the dimension of Comfort.

Measurement	Category	Thumb	Little finger	Double
Comfort	Bothersome — Not bothersome	4.7	4.0	3.2
	Tolerable — Intolerable	1.2	1.3	1.9
	Comfortable — Uncomfortable	1.2	1.8	3.3

Finally, the Comfort results (Table 8) averaged higher scores for the thumb model across the different dimensions, particularly in the Bothersome — Not bothersome one. All models scored positively in tolerability (below 2). While the index and middle fingers model performed worse than the other alternatives across Comfort dimensions, its average scores were still positive to neutral. During the interview stage, the lack of palm sensitivity associated with this model was also referenced as a source of discomfort and intolerability. The existence of a fabric bridge connecting finger, the palm and then the wrist was also perceived as restrictive, and consequently bothersome during prolonged usage. Participants also raised concerns of the fabric tension when the hand was stretched out, becoming a source discomfort. While the little finger model averaged positive scores for comfort, the majority of participants who evaluated it mentioned sensory issues with the seam between the ring and little fingers. Participants who evaluated the little finger model with lower scores also mentioned that they were not used to having something attached to their little finger, describing it as “awkward” and “unfamiliar”, as well as restricting. One participant mentioned that their little finger seemed “trapped or caught on something”. During thumb model evaluation interviews, participants did not mention any awkwardness or discomfort, while three participants mentioned that the fabric tension was high between the thumb and index finger, which could be uncomfortable in the long-term.

During the first interview stage, a few participants from different backgrounds and expertise demonstrated concern for the protection of sensors; specifically, four participants that evaluated the little finger model mentioned the external side of the palm as being more likely to rest on surfaces, or to hit against objects, which could interfere with sensor monitoring, either by damaging the sensors or by creating multiple artifacts in the reading.

During the second stage of the study, where participants were able to test and directly compare the three glove alternatives, the questionnaire and interview were focused on user acceptance, with statements related to everyday life factors, such as discretion, privacy, and exposure (which related to the social and cultural issues faced by epilepsy patients). Additionally, some user experience themes were revisited during interviews, since model comparison evaluation could allow more expressive results than those obtained during single model evaluation. The user acceptance questionnaire results indicated that, in discretion related items, the two fingers model is perceived as the least discreet model (60%), the most likely to cause users to be stared at by others (63.3%) and to stare at others using the model (50%). The first alternative, the thumb model, was rated as the most discreet alternative (70%) and most indifferent to others (90%). Interference related prompts also favoured the thumb model as the least interfering in both daily life (80%) and hand movement (73.3%), and the index and middle finger model as the most obstructive one (93.3%). Prompts related to the impact of the glove alternatives on the daily life of participants indicated a preference for the thumb model in terms of practicality, ease to put on and take off, and reduced impact in their daily life, with 86.7% of participants indicating that they could see themselves wearing it every day. Comfort related statements also indicated a preference for the thumb model; 86.7% chose this model as most comfortable. Furthermore, 66.7% of participants chose the index and middle finger model as most uncomfortable. In questionnaire items that related to participants' feelings, the thumb model was the most liked (83.3%) and the index and middle finger model was most disliked (63.3%). 70% of participants chose the index and middle finger model as the alternative that made them feel weird, and the remaining participants chose the little finger model. Finally, 90% of participants indicated the index and middle finger model as the alternative that could be a constant reminder of a medical condition.

During the interview stage, while most participants reiterated their opinions from previous interviews, their preferences shifted towards the thumb model. This was very common among participants that reported a positive experience with the little finger model during individual

evaluation, but then preferred the thumb model during direct comparison. A suggestion was also offered by a participant during their interview to create a single model that unified the thumb and little finger alternatives, where users could choose to rotate it and wear it one way or the other. During final interviews, the reported preferences were relatively consistent with the individual scores in user experience dimensions, indicating an overall preference for the thumb model, and the index and middle fingers model with the worse performance.

Conclusion. During both interview stages, a relation between familiarity and coverage was established from participant feedback, indicating that familiarity is prioritized over the extent of coverage area. That is, participants would often prefer a larger exposed coverage (more visible to others) to a smaller and less noticeable one, if the placement and coverage area resembled a familiar product. Generally, the discretion and noticeability of the models were associated more commonly to how much it resembled already existing products than to how much fabric was visible to others, indicating that, while visible coverage area may be smaller, if the placement of covering is unusual or uncommon, it may lead to stronger feelings of exposure. There were some cases in which participants had initial difficulties evaluating their models, mostly in the evaluation of user experience dimensions such as Attractiveness, Stimulation and Novelty. In addition, it is also important to note as a limitation the reduced number of participants, none suffered or had suffered from epilepsy. While 7 of them reported having a family member, friend or acquaintance with epilepsy, and 28 participants reported efforts to empathize with epilepsy patients throughout their evaluations, it is still crucial to validate these results with epilepsy patients.

Expert insights. Following user testing, where a preference for the thumb coverage was established, along with other insights, it was important to validate these findings with experts in the biomedical and electronic engineering areas; as such, a study was conducted, covering this validation, as well as development priorities and technical information.

Design of the Study. The study followed a qualitative design approach, consisting of a semi-structured interview on four different themes. Three interviews were conducted online and the remaining in person.

Materials. In order to complement the previously performed user test, regarding hand wearable coverage areas and consequent sensor placement, the three sketches and physical models were presented to the participants in this study.

Participants. Six experts took part in this study, one male and five females, ages ranging between 23 and 28, consisting of experts in the area of Biomedical Engineering, including MSc in Biomedical Engineers, PhD students, and PhD candidates, working within the scope of biomedical and electronic engineering and wearables. At the time of the study, Experts 1 and 2 integrated a wearable PhD project, with EDA and PPG sensors, for biosignal monitoring; Expert 3 integrated an epilepsy monitoring wearable MSc project with PPG and textile EDA electrodes; Expert 4 integrated an epilepsy monitoring wearable PhD project with EDA and PPG sensors in in-patient settings; Expert 5 integrated a grip-strength wearable PhD project; and Expert 6 integrated an epilepsy monitoring and epileptic seizure prediction MSc project.

Procedure. This qualitative study occurred in separate interviews with an average duration of 20 minutes, where each expert was initially introduced to the context and objective of the study and provided information about their expertise and education. Afterwards, the semi-structured interview covered the following themes:

1. Wearable development priorities — understand which are the developmental and conceptual aspects prioritized by the participant in their own projects, or in general, within the biomedical scope, in order to comprehend how they may differentiate from the current approach, and what elements could possibly be missing, should be integrated and how.
2. Ideal coverage area shape — recommendations on a specific product shape, as well as opinions and validation of the previously, user tested, concept sketches.
3. Sensors and their placement — expert opinion on which should be the important sensors to be integrated and their placement, from a technical and functional standpoint and a user experience perspective (or other perspectives they may offer), also allowing the validation of literature and previous product concepts.
4. Expected technical issues — given the sensors, their placement, the product shape, or other factors of the development, which can be the expected issues of the system. Alternatively, technical issues that these experts currently face, or have faced in similar projects. This allows us to understand possible needs, requirements or error factors that could be mitigated early in development.

Additionally, after these topics have been discussed, some time was dedicated to additional feedback, opinions, or recommendations. Given the nature of the study, the order, depth, and duration of each discussion topic varied amongst participants.

Results. The relevant transcripts of the interviews, discussed in the following sub-section, are available in Appendix **B**. During the first discussion topic, related to wearable development priorities within the scope of this development, the overall two priority factors mentioned were user experience and functionality; both were referenced by all but Expert 4. Concerning the prioritization of UX, comfort was commonly mentioned; Expert 2 defined comfort as (“(...) non-invasive, doesn’t hurt, doesn’t look weird, or like a strange body (...)”). Experts 5 and 6 also mentioned the importance of comfort in prolonged wearing scenarios. Noticeability and discretion were referred to by Experts 1 and 6 as another priority in the scope of epilepsy monitoring – this was consistent with a recommendation by Expert 3 to validate form factor with epilepsy patients. Concerning the prioritization of functionality, data acquisition efficacy was mentioned; Expert 2 highlighted that “its preferable to have a functional, robust and efficient” equipment, alerting to the difficulty of correctly capturing the EDA signal, and the need to maximize this functionality. Expert 4 mentioned the priority to be an “adaptable and adjustable form factor” that could fit most subjects, easily reproducible and assembled. Other UX related aspects were also mentioned, such as the breathability of the materials and the importance of sanitation and hygiene of the product. The breathability aspect was also mentioned by Experts 1 and 2, but in the scope of functionality, where excessive sweating caused by the material could disrupt and create artifacts in EDA monitoring, generating false positives. The following hierarchy (Figure 9) summarizes the themes and concepts discussed in the interviews.

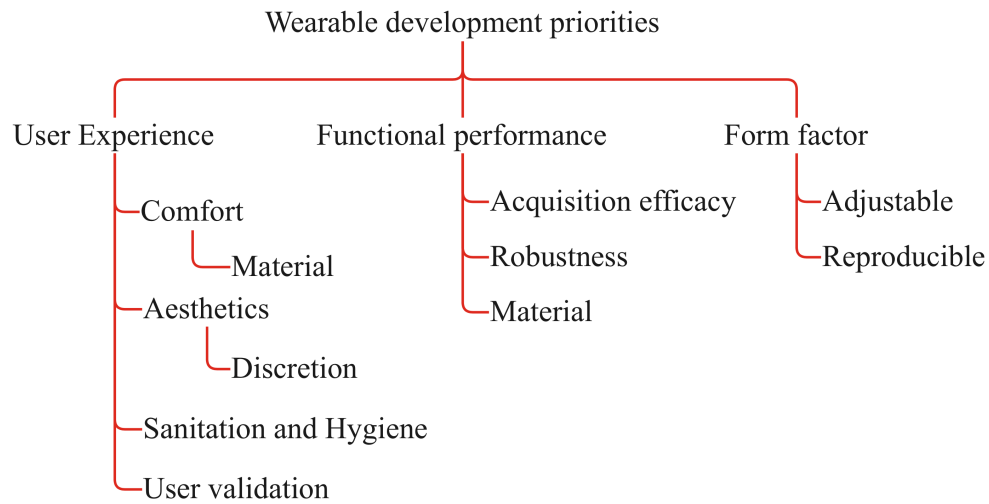


Figure 9. Expert insights – themes and subthemes for wearable development priorities.

Insights for the second discussion topic, ideal coverage area shape, included both expert opinion on previously user tested concept models, as well as recommendations on a form factor they found more appropriate. Considering the hand-wearable models, the thumb and little finger models were preferred. While Expert 1 and 3 had no preference between the two, Expert 3 suggested an alteration to the thumb model, to “raise the fabric on the external side of the palm”, in order to increase tightness to the skin and avoid creating fold in the fabric during hand movement, which can disrupt the data acquisition. Experts 2 and 4 recommended the little finger model from a functional perspective. Expert 2 justified it due to a higher sensor safety, while Expert 4 also suggested the thumb model since it “would be easier to produce in a universal size”. Conversely, Expert 5 and 6 recommended the thumb model for functionality, indicating that the remaining models would create higher noise and higher probability to disrupt data acquisition. Expert 6 added that the little finger model could be best in terms of user experience, as “people tend to move that side less, so they wouldn’t feel as restricted”, referring to the external side of the palm. Considering their own recommendations, Expert 5 did not have any additional opinions, while all the remaining experts suggested a band-like wearable. Expert 1, in particular, suggested a palm worn band (such as the product Mediaprobe, Figure 10) that “could be adjustable and worn on other places, like the upper arm”. Expert 3 suggested a non-rigid wrist worn band, adding “it’s hard to get people to wear a watch every day, let alone a glove”; they also mentioned that, while

the hand and foot are body locations where signal acquisition is better, the wrist area would be best in terms of user experience. Expert 4 also suggested a wrist-worn bracelet as it is more discreet, and gloves are harder to produce (complex sizing), degrade faster, are harder to sanitize and produce higher noise during data acquisition; however, this expert warned that a “wrist wearables are so common, it is harder to innovate”. Experts 2 and 6 recommended a band due to user comfort, without a specific placement recommendation. Figure 11 summarizes discussed themes and subthemes during this interview stage.

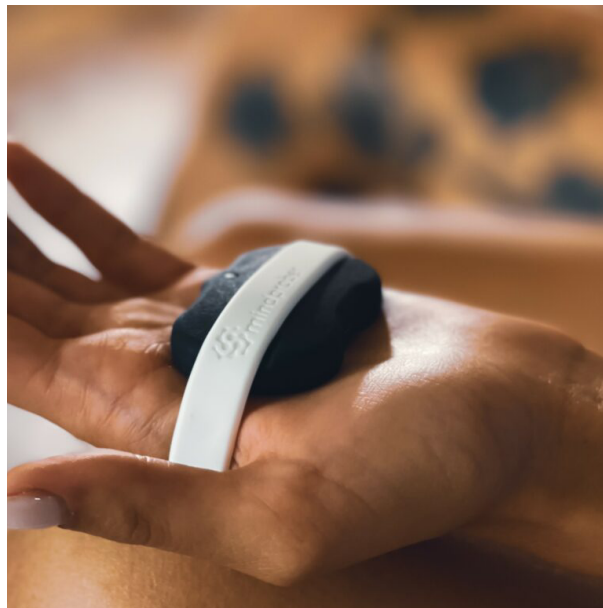


Figure 10. Mediaprobe¹¹ device (previously called MindProber).

¹¹ Image retrieved from the Mediaprobe website: <https://www.mediaprobe.com/technology-sensor-mobile-app-platform/>

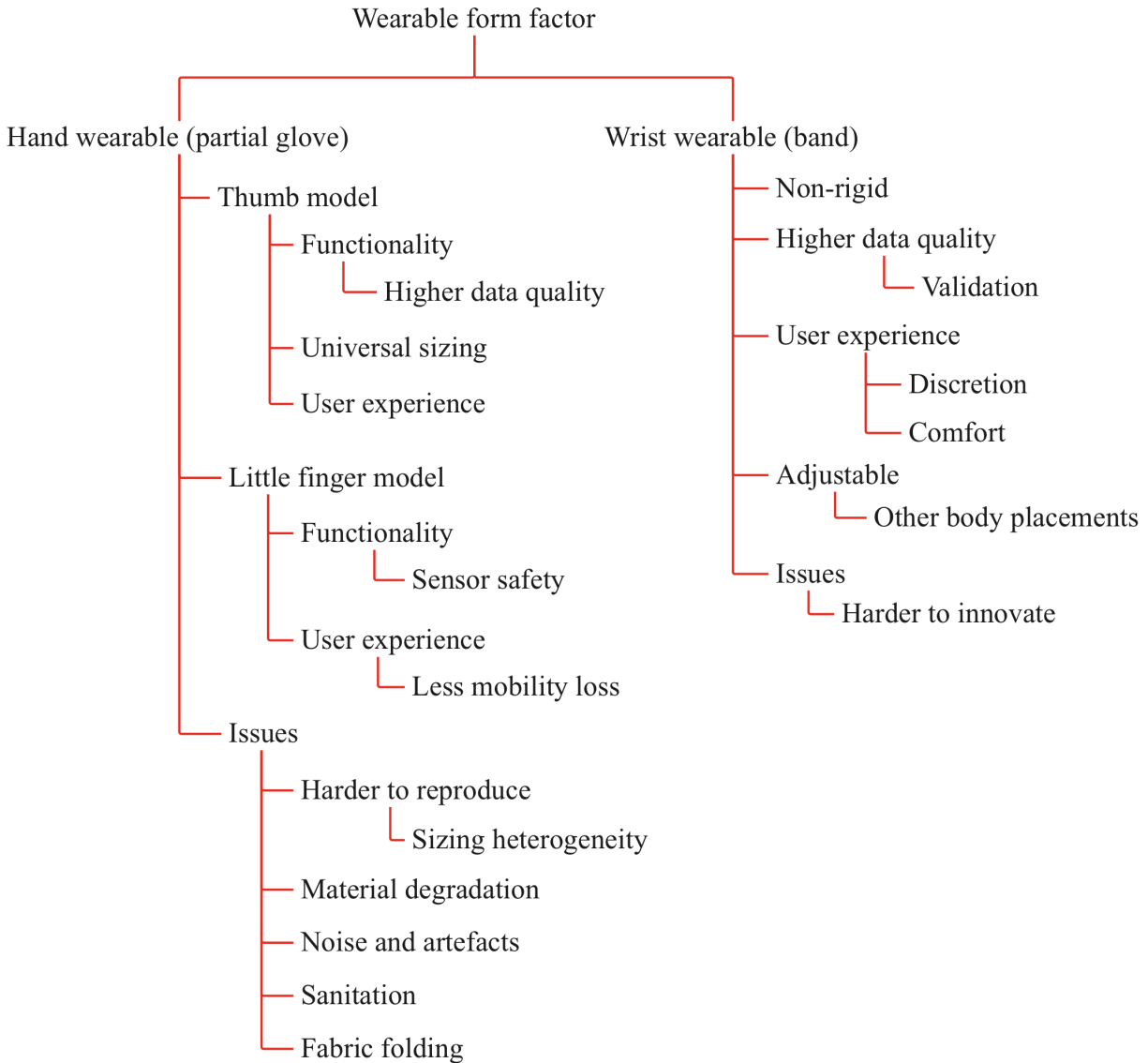


Figure 11. Expert insights – themes and subthemes for coverage, shape and/or form factor.

Considering the third topic of discussion, which was related to appropriate sensors, their placement, and other recommendations, the interviews discussed both hand and wrist contexts following the previous discussion topic. In terms of mentioned sensors, Expert 4 explicitly recommended integrating sensors that are present in the Empatica E4, which are PPG, EDA, temperature (“(...) temperature readings let you know if the user is wearing the product correctly (...)”) and accelerometer, while the remaining Experts mentioned only information related to EDA and PPG sensors. Concerning the positioning of the PPG sensor, Experts 4 and 6 discouraged

positioning it in the usual reading place, the finger, for usability reasons, alerting that “it introduces a lot of noise unless a person is perfectly still” and that “the finger is not doable for daily wear”, respectively. These two experts, as well as Expert 3, recommended using the PPG sensor on the wrist. Expert 5 mentioned that the PPG sensor can be worn either on the hand or wrist. Both Experts 1 and 2 mentioned their own projects, in which the PPG sensors have only been used on the finger, but PPG sensors “should work” on the wrist. Additionally, Expert 4 also mentioned “there are different types of PPG sensors with different characteristics to improve reading” in the context of PPG sensors in different body placements. Concerning the EDA sensor and electrodes, Experts 1, 2 and 5 reported to be unsure whether they are able to effectively acquire data in a place such as the wrist, as Experts 1 and 2 mentioned they had only studied EDA signals acquired in the hand (thus recommending in-hand acquisition). Expert 1 highlighted their preference for functionality above conceptualisation, referring that “it’s best to have something tested and functional than conceptual and futuristic”. Experts 3, 4 and 6 recommended EDA signal acquisition on the wrist for usability, as hand acquisition would immobilize the user’s hand. While all confirmed that it is doable, Expert 4 alerted to “EDA varies from person to person, and wrist acquisition may work for some and not for others”, and Expert 6 mentioned that while “wrist acquisition would be best (...) it is trickier”. Reiterating their opinion from the previous discussion topic, Experts 3, 4 and 6 recommended moving and combining all sensors to the wrist area, similarly to the Empatica E4. Experts 3 and 6 were then questioned further on textile EDA electrodes, where both alerted to the distance between the electrodes and the acquisition board. Expert 3 recommended the electrodes be “placed close to each other, and at the same distance of the acquisition board”, due to the signal resistance that increases as the travelled distance increases, reminding however that “the disposable gel ones don’t really have this issue, mainly textile ones”. Expert 6 also mentioned this issue, referring “signal carrying in textile electrodes has a higher resistance if the travelled distance is too large; the farther from the board, higher the likelihood of signal loss”. In Figure 12, a summary organized by identified themes and subthemes for this interview topic is illustrated.

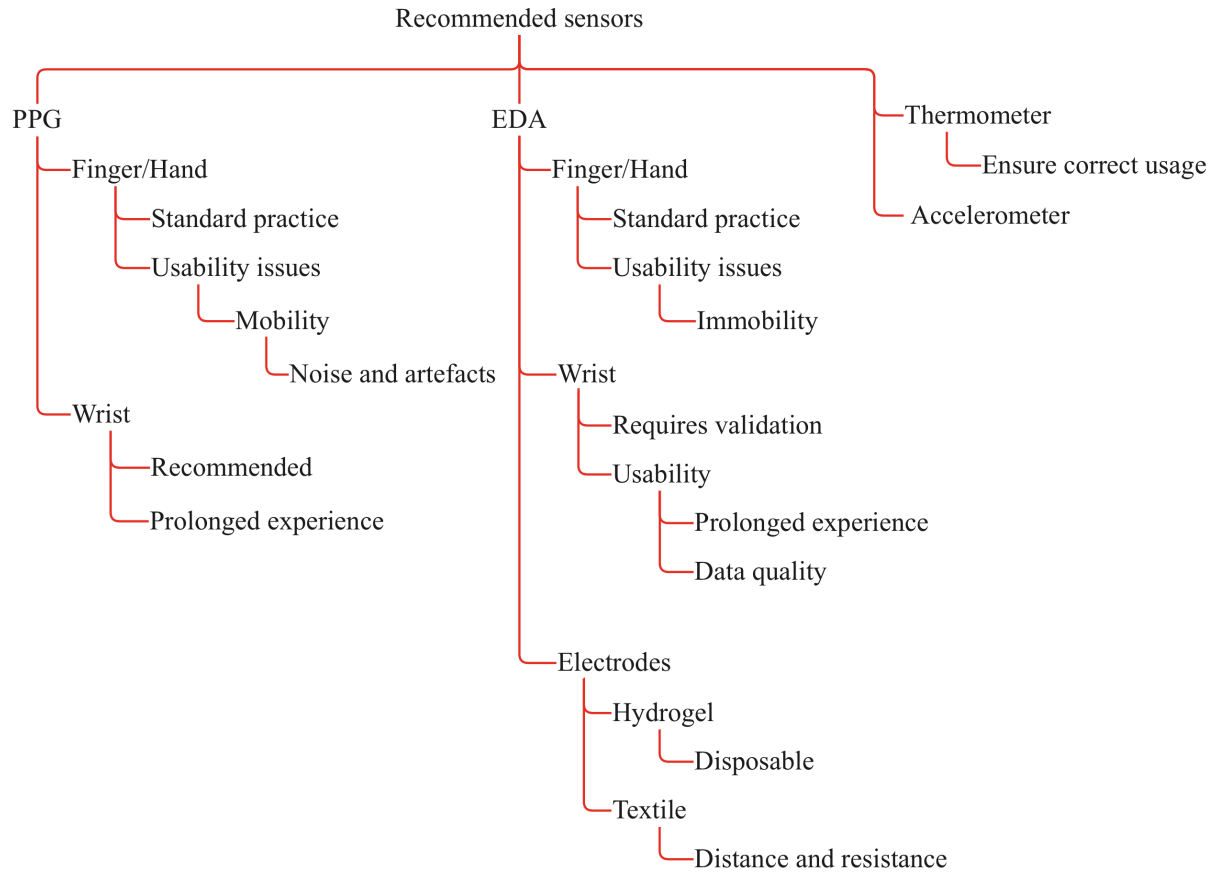


Figure 12. Expert insights – themes and subthemes for recommended sensors.

Considering the expected, current, or solved technical issues, Expert 1, 2, 3 and 4 referenced mainly their own projects to indicate technical issues they currently face or had faced, while Experts 5 and 6 opted to speak more broadly, relating to the sensors or data transmission. Expert 1 mentioned PPG sensors cable breakage, but also maintaining robustness in device miniaturization. Experts 1, 2, and 6 mentioned the same issue with disposable EDA gel electrodes, which is frequently, and easily, coming off the user's skin and, added by Expert 1, "once they come off they rarely stick onto the palm again". Expert 2 alerted that user related factors can worsen this issue, such as hyperidrosis, but also contextual factors, such as warm environment or physical activity, which can increase perspiration. This expert additionally suggested that while the proposal of textile glove would solve the issue of disposable electrodes coming off, as a more sustainable alternative, the product itself could generate increased perspiration. Concerning textile wearables issues, Expert 3 reported irregular textile electrodes when sewing, but also stiff and

brittle conductive yarn that breaks under tension. Expert 5 suggested noise as the biggest challenge, due to incorrect tightness of the PPG and EDA sensors, leading to incorrect measurements. This concern related to PPG sensor stability was also mentioned by Expert 6, who also mentioned communication issues and data loss during transferring, related to wireless communications such as Wi-Fi or Bluetooth, as well as the latter's antenna sensitivity. Sanitation in devices or acquisition products that are not washable was an issue also raised by Expert 2. Finally, Expert 4 presented their current device for data acquisition indicating issues such as lack of access to the electronic part (it would be necessary to unstitch the fabric part of the product), including the LED light that conveys system status, as well as a past issue they face related to usability: the band was previously bulky due to the acquisition unit, so they “took it apart and glued on its different parts spread across the band, making it more comfortable and flexible”. Figure 13 summarized the identified themes and subthemes of this discussion.

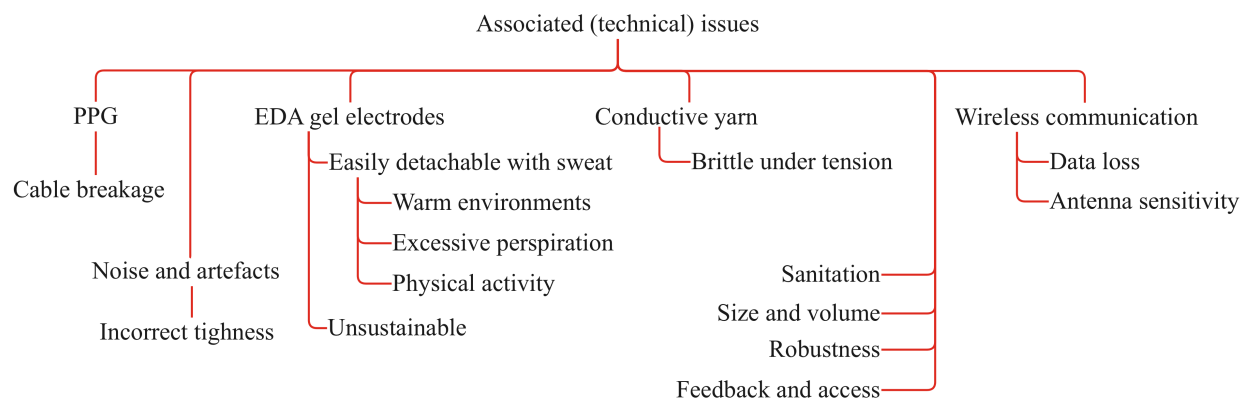


Figure 13. Expert insights – themes and subthemes for technical issues.

Additional to the four main points of discussion, some suggestions were made additionally by Experts 3, 4 and 5. Regarding product sizing, Expert 3 suggested the determination of a few standard sized, and alerted to the fact that, while an adjustable piece could solve the lack of universal sizing in gloves and glove-related products, it would become “an extra variable” to consider in prototyping. Regarding product's composition, Expert 3 advised on conductive lycra as a better alternative to conductive yarn, due to its elasticity. Expert 4 suggested the use of modular design to separate the washable components from the non-washable ones; additionally, offered another alternative to reduce the volume of the data acquisition unit by “separating and

spreading out” its components, attaching them on a more extensive area of fabric, reducing its stiffness and allowing the fabric to fold, bend and adapt to the body location more easily.

Considering product prototyping, Expert 4 advised on printing module cases in a rubbery material to improve its elasticity. In a discussion about time and technical constraints, Expert 5 suggested the development of two separate prototypes; a more functional, proof of concept, model where functionality is prioritised, and a second one in which “comfort is the priority, not necessarily measuring” for user testing stages.

Moving forward, and concerning the varied topics of discussions, particularly the wearable’s form factor, while the hand models were validated (particularly the thumb and little finger models) and different challenges discussed, a wrist worn wearable and wrist worn sensors were suggested as an alternative frequently and with less associated challenges to both experience and functionality. Human-related factors to take into account include mainly the long-term comfort of the wearable, a non-invasive, adjustable and discreet form factor, and breathable materials; these must be achieved without sacrificing the quality and efficacy of data acquisition, particularly, EDA signal capturing. Additionally, the device should be robust, and easy to sanitise. Identified technical issues indicate a need to focus on improving robustness, partial immobilisation of the contact area to avoid artefacts and signal noise, easy access to the data acquisition unit, and that textile electrode present a more sustainable and durable alternative to currently used gel electrodes.

5.2 Phase 2 – Wrist wearable concept

5.2.1 Discover

From the previous Delivery stage, particularly through expert insights, a new direction for development became clear, in which it would be preferable to shift from a hand-worn monitoring device to wrist-worn, which aligned with the performed research of other epilepsy monitoring wearable solutions available in the market (research integrates chapter 3.2) comprising of wrist-worn devices. To follow up on this shift, a meeting was set up at Instituto Superior Técnico in order to observe, in more detail, the current solution of the epilepsy monitoring sock, and, particularly, the prototyping process and application of conductive lycra; this material is presented in Figure 14, where a discoloration caused by oxidation, due to prolonged usage, is visible,

particularly when compared with conductive lycra not previously used (bottom fabric in Figure 14). However, the observed discoloration did not seem to be associated with a loss of efficacy.



Figure 14. Conductive lycra. Discoloured from oxidation (top).

During this session¹², a wristband was produced applying a similar process to the one applied in the epilepsy monitoring sock project (Fortes Raposo Ferreira et al., 2022), during which the conductive lycra pathways are applied using interlining, and further stitched onto to the fabric of the wristband, and the electrodes and pathways are in opposite sides of this band. The interface between the acquisition unit and pathways is performed through male NSR/NDR pin strips (Figure 15, left), and magnetic pogo pin connectors (Figure 15, right) which allow for a modular solution where the acquisition module case can be fit onto a 3D printed socket (Figure 16, left), which is stitched onto (and facilitates the interfacing with) the wristband (Figure 16; right).

¹² Prototyping session lead by Afonso Ferreira to explain the manufacturing process of the epilepsy monitoring sock.



Figure 15. Brass, male, NDR pin strips (left) and magnetic pogo pin connectors (right).



Figure 16. Acquisition unit from IST (left) and produced wristband (right).

When the acquisition unit was assembled with the wristband, and worn (Figure 17; left), it was apparent that the solution was rather bulky and voluminous, limitative of movements and would obstruct most daily tasks, leading to a long-term, near immobilization of the hand and arm, which would not be feasible for continuous, every day monitoring, thus, not aligning with the scope of this research. Further discussion on the possibility to miniaturise the acquisition unit

revealed that such processes could only be performed on an industrial level, which was not feasible for this project, due to time and financial constraints.



Figure 17. Wrist-worn acquisition module (left) and impromptu PPG acquisition test (right).

Nevertheless, the understanding of the process of interfacing between textile electrodes and the acquisition unit set the groundwork for future developments, allowing us to understand the fundamentals of systems of this kind. Additionally, an impromptu testing session demonstrated positive measurements of the PPG signal on the dorsal wrist.

5.2.2 Define

From the previous stage of development, and the demonstration of the production process of an artisanal biosignal monitoring textile wristband, we solidified the shift in the definition of the wearable to wrist-worn; thus, it was crucial to understand the configuration of the electronic components, particularly, PPG, EDA electrodes, and the acquisition unit integrating the remaining sensors, in order to understand certain aspects of the wearable's design (for instance, the placement and type of the clasp, the length of the adjustment, or whether reinforcing the fabric would be necessary in specific areas). The greater difference will be related to the PPG sensor, as it requires skin contact; thus, we can define three alternatives for further validation, where the PPG sensor is either on the volar wrist, the dorsal wrist, both integrated into the acquisition module, or separated from the acquisition module and on the volar wrist (the latter addresses the possibility that the PPG

signal acquisition is more effective on the volar wrist, while that may not be the appropriate location for the acquisition module).

During the previous production process, and expert insights from the previous development phase, it became apparent that the device should be modular; an acquisition module contains the sensors and electronic components, and it is inserted or removed into a fabric wristband, which must open or close (as inserting it through the hand will lead to a faster breakdown of the fabric).

Additionally, it also became apparent that a fixed location of the wearable may not be appropriate in both usability and user experience perspectives: during daily tasks, the proximity of the device to the hand may increase the probability of the it becoming dirty, wet, or retaining odours; users may wear other wrist-worn accessories, and the simultaneous use may be uncomfortable and crowded; additionally, users may want to conceal the device by, for instance, pulling it towards the upper arm, where it is more likely to be covered by clothing. Thus, it became crucial that the wrist-worn device be adjustable enough (or different sized bands be provided) that users may relocate it to other body parts; this adjustability aligns also with the previously identified need for accommodating multiple sizes, in order for the device to fit every patient correctly. This implies that the clasp, which allows users to open and close the wristband, must also facilitate the adjustability of the band length.

5.2.3 Develop

In order to decide on the better alternative for the configuration of components on the wrist, it was necessary to question experts in the fields of Electronic and Biomedical Engineering to understand which alternative could be best in terms data acquisition efficacy, durability, monitoring experience, and other aspects, according to their opinions. As such, in order to facilitate these interviews, three sketches were created (Figure 18), each illustrating one of the alternatives for configuration of components.

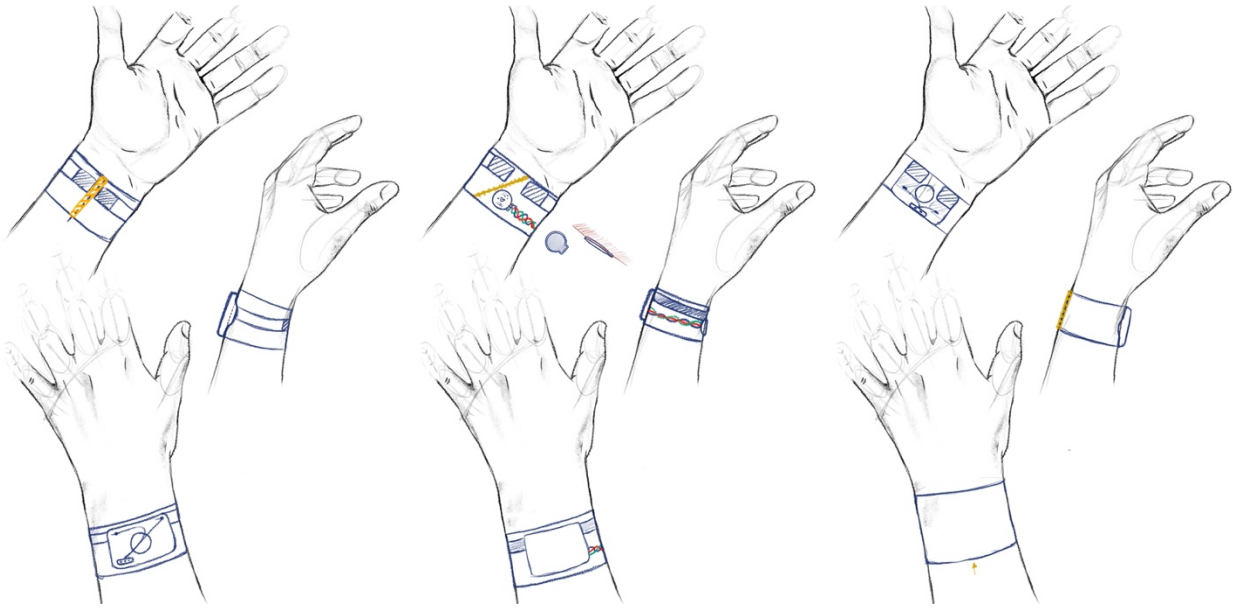


Figure 18. Three alternatives for component configuration in wrist wearable with a fabric wristband (Left to right: configuration/Option 1, 2 and 3, respectively).

5.2.4 Deliver

Quick-and-dirty Expert Interviews. In order to understand which configuration of components in the wrist would be more appropriate, particularly in terms of functionality, short quick-and-dirty interviews were conducted with experts in the areas of Electronic and Biomedical Engineering, in order to decide on a configuration before proceeding to further developments.

Materials. The previously created sketches (Figure 18) were provided, in order to illustrate the alternatives for sensor and electrode placement.

Participants. Seven experts took part in these interviews, three male and four females, ages ranging between 24 and 27, consisting of experts in the areas of Electronic and Biomedical Engineering, including MSc Engineers, PhD students, and PhD candidates, working within the scope of biomedical and electronic engineering and wearables.

Procedure. These interviews individually with an approximate duration of 8 minutes, where each expert was initially introduced to the scope of the research and the objectives of this stage of development and discussed freely their opinion on the provided alternatives.

Results. When discussing the different alternatives with each expert, concerning mainly aspects of robustness concerns (particularly regarding contact with other surfaces, dragging, brushing or bumping the device against other objects, and the deterioration of the material), the first configuration, Option 1, was discussed as the, overall, best alternative from the three configurations; additionally, it did not raise as many concerns as the remaining. Nevertheless, Experts 1 and 5 alerted to the fact that, by introducing a clasp between the electrodes would only work if either no adjustment was introduced, or the excess which facilitates the adjustment is correctly attached to the wristband:

E1: “If the person zips it in the middle, buttons it, or similar, something that is static, it works. But if you want to adjust it, one of the sides will inevitably hold the excess fabric.”

E5: “When you tightened the wristband, the remaining should be tucked and secured, similar a regular watch. Otherwise, it might create a bulge and interfere with the electrodes.”

Expert 4 also mentioned that the visual appearance of Option 1, a case on the dorsal wrist and a strap, is too similar to other watches or smartwatches, where the visible difference is the fabric strap.

E4: “The first option has the best aesthetic and might not have so many issues in terms of durability, but it might be too standard—derivative. Like a smartwatch but with a fabric bracelet, which is challenging if you’re trying to innovate.”

Considering the second configuration, Option 2, where the PPG sensor is placed on the volar wrist, close to the textile electrodes, and the acquisition unit placed on the volar wrist, Expert 1, 2, and 7 raised issues regarding the lack of available space to introduce a clasp, or an adjustment to the length of the wristband. Concerning the same aspect of removing and putting on the band, Experts 4 and 7 alerted to necessity to have a clasp, and an elastic wristband would decrease the product longevity.

E1: “You can’t really adjust the strap; you would probably need to do it on the sides since there is not much space in either side of the wrist. But then it will cut the paths of the electrodes, and the PPG.”

E2: “Not sure how the adjustment would work, there is not have enough space for size adjustments, the usable sides of the wrist become too crowded. And the opening would not be aligned, because of the PPG, so it is a little awkward, visually.”

E4: “If the fabric is elastic, to keep it tight to the skin, the PPG wires can break when you slide it through the hand. Even if they’re weaved this way, in waves, the elasticity is not enough long term.”

E7: “Options 1 or 2 are more protective of the module, but the second one seems quite difficult to fit an adjustment. (...) You would have to make it elastic to go over the hand, which will wear down the band faster.”

Experts 6 and 7 also alerted that, unlike Options 1 and 3, Option 2 featured the PPG outside the module, becoming too exposed and unprotected; regarding the PPG, Expert 3 added that there was no particular gain in moving the sensor to the volar wrist.

E3: “The PPG on the inner wrist is not necessary because you can get quality PPG sensors to read it effectively on the top, like other smartwatches (...) the trade-off between the PPG exposure and efficacy gains is not worth it.”

E6: “The PPG is too exposed, in my opinion, every sensor and component should be inside the case, otherwise it is unprotected and not as robust.”

E7: “The PPG should not be exposed or easy to bump against things, the data will not be reliable. Even with a second fabric barrier, it is too exposed.”

Finally, regarding Option 3, Experts 1 alerted to the exposure of the module, particularly to contact with other surfaces, due to its location on the volar wrist, while Expert 2 indicated that that location could cause the band to deform over time due to the weight of the module.

E1: “If the module is too heavy, there’s going to be some deformation here with prolonged usage, because the weight will constantly tug on the fabric, and it may not support that kind of tension

over time. (...) If the weight pulls the fabric down, it is likely that the electrodes will have a lot of noise and invalid data.”

E2: “People tend to use their volar wrist a lot, to rest their hand, to write, it frequently drags across surfaces, and so it is very likely that it hits other objects. (...) It will create artefacts in the data.”

On the other hand, Experts 5 and 6 raise positive aspects associated with the third configuration, particularly due to the protection of the EDA electrodes and the reduced visibility to others.

E5: “The case here also protects the and hold the electrodes against the skin, so it ensures constant contact. Also, there would be less resistance since the electrode are so close to the module.”

E6: “The last one is more discreet, which is important for patients. If you glance at it, it’s just a bracelet.”

Given the analysed advantages and disadvantages for each of the configurations, Option 1, while being harder to innovate, would not present as many challenges in other areas of development and functionality, being the better alternative for placement of components in the wrist.

EDA wrist acquisition. The goal of this study is to validate the measurement of electrodermal activity (EDA) on the wrist, by comparison with palm measurements of the same signal.

Design of the study. Quantitative study, dealing only with measurements from the materials.

Materials. Two BITalino (r)evolution acquisition boards were used for synchronous sampling, in order to avoid signal interference. The acquisition boards communicate through Bluetooth; hence a Bluetooth dongle was also used in order to improve signal strength and extend the connectivity range. Two EDA sensors, one for each board, were used, and for each session four disposable hydrogel electrodes were required. In situations where the electrodes would lose adherence and come loose from the skin, medical tape was used to ensure they would remain on. In order for participants to wear both boards simultaneously, a custom case (Figure 19, right) was sketched,

modelled (Appendix C) and 3D printed, and a Velcro band was produced in order to adjust and attach the case to the participants' non-dominant arm. Figure 19 (left) presents all necessary physical materials; additional to these, the software OpenSignals (r)evolution from PLUX Biosignals was necessary to perform and record the signal acquisition.



Figure 19. Data acquisition materials (left) and 3D printed case (right).

Participants. Eleven participants took part voluntarily in the study, with a sample consisting of 5 male and 6 female participants, and ages ranging from 20 and 59 years old ($\mu = 29.27$, $\sigma = 10.94$).

Procedure. Each session was performed individually, with an average length of approximately 30 minutes, where participants were accompanied by the researcher during the entirety of the experiment. Before starting, participants were introduced to the experimental study, and asked to fill an Informed Consent Form (Appendix D). The study then consisted of the following steps:

1. On the participant's non-dominant hand and wrist, the EDA monitoring device was positioned (Figure 20), adjusted, and tested for functionality.
2. Participants were required to sit with headphones on and watch three movie trailers for approximately seven minutes.
3. For the following ten minutes, participants were asked to sit still and use their laptop, phone, or notepad, relaxing, or engaging in other comparable low-movement, low-effort activities (Figure 21).

4. Then, participants were instructed to stand up and perform a five-minute light stretching session while watching a video that includes the required movements, carefully complying with the directions on the video to the best of their abilities.
5. After the ending of the stretching session, and for the following five minutes, participants were asked to remain seated, while using a laptop, smartphone, notepad, or engaging in other comparable low-movement, low-effort activities.
6. Finally, the monitoring device was taken out and the data acquisition was interrupted.

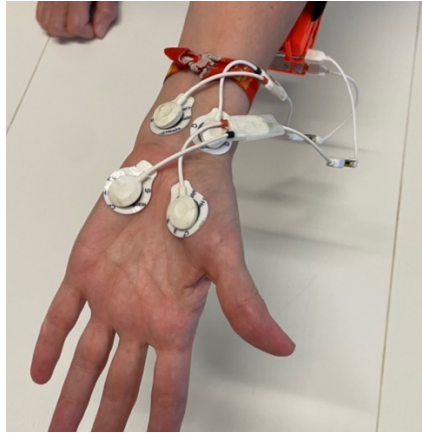


Figure 20. Electrode positions when the device is placed on participant's hand and wrist.

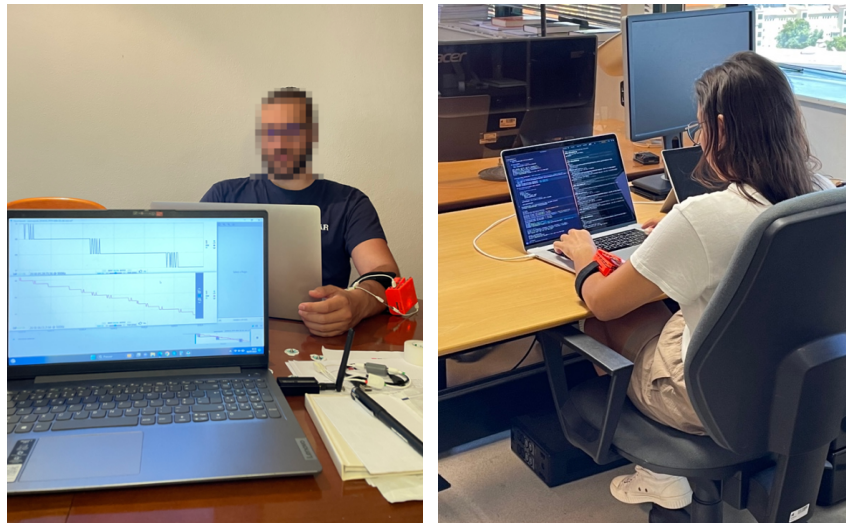


Figure 21. Photos from rest stages of the data acquisition study.

Throughout the afore mentioned steps, OpenSignals (r)evolution was operated in a separate laptop in order to perform and record the data acquisition from each participant, where data was gathered simultaneously from both acquisition boards.

Results. The average acquisition time was 28.03 minutes ($\sigma = 0.38$); data signal was acquired with a sampling rate of 100Hz. The treatment of the collected data files from all participants was automated through a script provided by PhD student Patrícia Bota. Results were analysed through the following metrics:

- Pearson correlation: this is a measure of linear correlation between the two data sets, indicating the strength and direction of how they change in relation to one another. Measurements vary between -1 and 1, where values tending to -1 indicate an inverse correlation, to 1 a perfect correlation, or zero in case they are not significantly correlated.
- Cosine similarity: can be used to determine the level of similarity between two signals, in terms of direction and not magnitude, by comparing the cosine of the angle between each two signals over time. This measure varies between 0 and 1, where zero indicates complete dissimilarity (vectors are orthogonal) and 1 indicates perfect similarity (vectors are identical, forming an angle of zero degrees).
- Euclidean distance (RMSD) which provides complementary information to Pearson correlation and Cosine similarity. While Pearson correlation and cosine similarity concern the similarity in their patterns of evolution over time, Euclidean distance tackles the absolute differences between the two signals, that is, the difference in magnitudes between them, by calculating the distance between each pair of data points. The smaller the value of RMSD, the closer the signals are.
- Signal to noise ratio (SNR): this metric provides a quantification of the quality of the signal, by measuring the level of the signal against the level of background noise. SNR is a crucial metric because it allows us to understand how much of the collected data can be considered valid, relative to the noise, allowing us to understand the level of clarity, robustness and reliability of the signal. Higher values of SNR indicate a more significant presence of the signal compared to the presence of noise.

- Zeros: percentage of time during which signal was lost, in incidents such as when electrodes come off the skin. This measure can also reflect the reliability of the data, the device and/or the location of collection.
- Saturation: percentage of time during which the signal reaches the maximum or minimum values that the sensor is able to measure. High saturation percentage can indicate that the sensor does not have the necessary reading capacity, or, in the scope of EDA, the participant may suffer from hypohidrosis or hyperhidrosis.
- Number of peaks: after a filter is applied to smooth the signal, the number of peaks reflects the number of events during which the GSR was heightened. By comparing the number of events between signals, we are able to evaluate the reliability and efficacy of the measuring location.
- Number of matching peaks: after the identification of peaks, they are compared within a 0.51 second range in order to understand whether the signals are identifying the same peaks, and how many they are. The time range accounts for the natural delay in GSR between palm and wrist.

Other descriptive metrics applied were mean, standard deviation, minimum value reached, and maximum value reached. The following Table 9, Table 10 and Table 11 present the results of these metrics applied to the data files of each participant, followed by the mean results for all participants. The graphical representation of each participant's collected signals, hand and wrist, is available in Appendix E.

Table 9. Results for comparison and quality metrics of the signals for each participant.

	Pearson correlation	Cosine Similarity	Normalized RMSD		SNR (dB)	Zero (%)	Saturation (%)
1	0,384	0,985	135,660	Wrist	79,136	0,000	0,014
				Palm	107,924	0,000	1,221
2	0,725	0,814	74,080	Wrist	135,482	0,041	0,000
				Palm	150,108	0,000	0,000
3	0,686	0,986	63,788	Wrist	142,429	0,000	0,000
				Palm	151,937	0,000	0,000
4	0,104	0,977	138,361	Wrist	121,104	0,000	0,000
				Palm	115,762	0,000	18,509
5	0,662	0,963	48,128	Wrist	147,815	0,000	0,000
				Palm	122,202	0,589	0,000
6	0,682	0,965	95,484	Wrist	113,721	0,000	0,000

				Palm	158,088	0,000	5,592
7	0,823	0,947	110,419	Wrist	107,068	0,000	0,000
				Palm	75,380	0,103	0,007
8	0,441	0,893	142,799	Wrist	115,031	0,000	0,000
				Palm	142,002	0,000	0,000
9	0,460	0,641	147,363	Wrist	129,692	0,000	0,000
				Palm	149,938	0,000	0,000
10	0,546	0,739	159,561	Wrist	163,748	0,000	9,153
				Palm	151,264	0,000	0,000
11	0,309	0,981	51,723	Wrist	116,909	0,000	0,058
				Palm	113,994	0,005	0,000

Table 10. Descriptive results for comparison of the signals for each participant.

		Mean	Standard deviation	Minimum	Maximum	Peaks	Matching Peaks
1	Wrist	5,621	0,963	4,541	24,902	178	61
	Palm	16,453	2,224	12,012	24,902	312	
2	Wrist	1,640	1,766	0,000	7,104	97	34
	Palm	9,801	3,297	5,615	20,972	177	
3	Wrist	4,661	1,060	3,027	10,913	210	88
	Palm	13,497	2,524	8,691	24,365	254	
4	Wrist	5,096	0,858	2,710	7,617	196	69
	Palm	20,460	3,165	9,961	24,902	305	
5	Wrist	7,123	1,071	4,272	10,913	196	29
	Palm	8,047	2,915	0,000	18,774	202	
6	Wrist	4,208	1,612	0,854	11,304	154	51
	Palm	15,296	4,291	6,299	24,902	172	
7	Wrist	12,927	2,614	5,811	23,438	316	51
	Palm	3,759	1,927	0,000	24,902	241	
8	Wrist	1,573	0,842	0,513	5,200	107	8
	Palm	6,753	2,838	0,879	12,793	234	
9	Wrist	0,996	1,657	0,098	5,688	63	24
	Palm	5,912	3,204	1,074	14,062	194	
10	Wrist	7,124	9,242	1,099	24,902	115	53
	Palm	8,168	4,049	1,831	16,016	176	
11	Wrist	16,484	1,842	8,423	24,902	229	111
	Palm	9,929	2,011	0,000	19,995	311	

Table 11. Relevant results for comparison of the hand and wrist signals.

Pearson correlation	Cosine Similarity	Normalized RMSD		SNR	Zero (%)	Saturation (%)	Peaks (%)	Matching Peaks (%)
$\mu = 0,53$ $\sigma = 0,21$	$\mu = 0,90$ $\sigma = 0,12$	$\mu = 106,12$ $\sigma = 41,33$	Wrist	$\mu = 124,74$ $\sigma = 22,78$	$\mu = 0,00$ $\sigma = 0,01$	$\mu = 0,84$ $\sigma = 2,76$	$\mu = 72,15$ $\sigma = 27,24$	$\mu = 21,62$ $\sigma = 10,07$
			Palm	$\mu = 130,78$ $\sigma = 25,79$	$\mu = 0,06$ $\sigma = 0,18$	$\mu = 2,30$ $\sigma = 5,63$		

It was expected that the registered skin conductance level would be generally higher in the palm of hands than or the inner side of the wrist; palms, and soles, have a higher concentration of eccrine glands, which increases the quality and robustness of the signal. By analysing the differences in individual results, both in the chosen metrics and the graphic representation of the signal over time, it is observable the heterogeneity of the EDA signal and the level of difference between measurements in the palm versus the wrist. Some participants demonstrated a much lower skin conductance in the wrist, when compared to the palm, than other participants (for instance, participant P1), while others demonstrated relatively similar levels in both locations (for instance, participants P5 or P3), and one participant, P7, demonstrated higher EDA measurements in the wrist than the palm. Heterogeneity is also observed when comparing the raw EDA values (pre-normalisation) between participants, in both wrist and palm acquisitions.

Additionally, participants P2, P9 and P10, who initially registered a lower skin conductance in the wrist when compared to the palm, demonstrated an observable improvement in the last third (approximately) of the experiment. This improvement was registered after the initiation of stretching session. A potential explanation is that, during physical exercises, the increase blood flow, body temperature, and particularly, activation of the SNS, lead to the increase of sweat glands and, consequently, changes in skin conductance. These results possibly indicate that measurements of the EDA signal in the wrist post physical exercise provide a more robust reading, however, its values (and conclusions derived) must take into consideration the context of physical activity.

Observable spikes in P1, P2, P7 and P11 are attributed to brief malfunctions and artefacts in the data transfer during acquisition, or the sensors themselves. Additionally, participant P5's palm electrodes lost adherence from the skin and peeled off during the physical exercise, which corresponds to the null values in palm readings before and after the 125000 s mark; there were subsequently glued on using medical tape. Participant P7's palm electrodes also had to be reattached using medical tape (loss of signal visible approximately between the 25000 and 50000 seconds mark). Zero percentages in participants P2 and P11 correspond to error spikes in the acquisition; similarly, saturation percentages registered in participants P1's wrist, P7's palm and wrist, and P11's palm and wrist were partially, or completely, attributed to these errors.

Considering the overall results for all sessions of the experiment, the Signal to Noise Ration was similar in both wrist and palm EDA measurements, however, the signal is marginally clearly

or less noisy in the palm. Conversely, palm measurements presented a slightly higher number in percentage of zeros and saturation. Considering the percentage of zeros, and excluding the errors (registered spikes) in acquisition, this was due to the gel electrodes losing adherence and coming off the participant's skin (relatively common incident, previously reported in expert interviews), most likely due to the higher mobility of the palm and fingers; the higher percentage in saturation, excluding the registered errors, may be due to the higher density of eccrine glands in the hand, the activity of which is increased during physical activity, reaching levels outside the capabilities of the used sensors. Nevertheless, both values were minimal.

The Pearson correlation of 0.53 indicates a moderately positive direct relation between the two signals, that is, there is a tendency for the wrist signal to follow a trend of increase or decrease of the signal in the hand, but not exactly linear. On the other hand, Cosine Similarity presents a very positive result, 0.9, indicating a great similarity in their overall trends or patterns despite different absolute values (this metric is not influenced by the amplitude of the signal, and indicates a high similarity between the time series). The difference in absolute values is observable in the value of the normalised Euclidean distance, which is consistent with a moderate Pearson correlation. This difference was expected due to the difference in concentration on eccrine glands, as mentioned previously; this may be improved with higher sensitivity, higher quality sensors.

In terms of event detection, considering only the numbers of detected peaks (that is, with no temporal matching), the EDA acquisition on the wrist detected a relatively high number of the peaks (72.15% of those detected through the hand, which the gold standard). However, when matching the detected event with an interval of 0.51 seconds, the value drops to 21.62%; due to the large difference between these values, further adjustments must be performed to the interval used in the matching analysis, and the data re-analysed.

Overall, opting for the wrist as an EDA signal acquisition location alternative to the palm seems viable, particularly considering the potential positive impact on the user monitoring experience. While the palm remains the gold standard, the general patterns and trends are captured through the wrist to a moderately positive degree. Nevertheless, further improvements can be made, particularly in terms of the quality of the EDA sensors and data treatment processes, in order to improve the quality of the results.

5.3 Phase 3 – Wrist wearable prototype

5.3.1 Discover

From the Delivery stage of the previous development phase, we were able to obtain information on advantages and disadvantages for different configurations of wearable components around the wrist, from the opinions of experts in the field. Thus, for this new phase of development, we consider to Discover the better configuration of components, where all sensors are integrated into a single acquisition module, located on the dorsal wrist, connected to the electrodes on the volar wrist through conductive fabric pathways. This also presents an easier way to integrate a clasp to open and close the wristband, by locating it between the EDA electrodes. We consider the location of EDA measurements in the volar wrist partially validated (from both results obtained for gel electrodes in the past Delivery stage, and the from similar solutions available in the market, such as the E4, analyzed in the State of Art) and thus passible of being applied in the following definition stage.

It is important to consider the discovery of prototyping limitations uncovered during the past and present stage; this limitation was mentioned by experts, during expert interviews, as well as by colleagues at Instituto Superior Técnico, and validated by colleagues at FCT (Foundation for Science and Technology), and concerns the inability of producing a smaller, fully functional acquisition unit. Necessary miniaturization and assembling techniques are only available at an industrialized manufacturing level, and requesting such production would require a large amount of time and financial resources, with was not viable. Thus, and as previously mentioned, it was discussed and determined the development of a dummy model which would present the desired design characteristics and allow us to evaluate the user experience associated to its continuous, daily monitoring without functionality constraints.

5.3.2 Define

At this stage of development, it was possible to determine key characteristics and specifications which would integrate the long-term, continuous monitoring product. In accordance with a modular design, users should be able to attach and detach the acquisition unit from its holder, which is safely placed and covered withing the adjustable textile band (Figure 22), which allows them to not easily sanitize both, but to easily exchange or replace the strap.

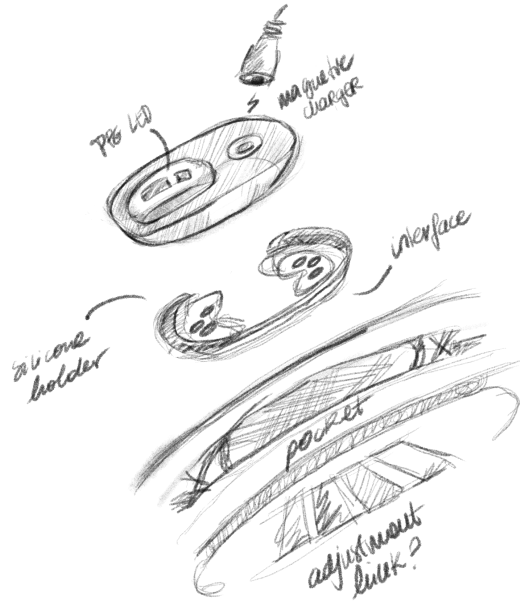


Figure 22. Sketch illustrating the structure of the product.

As such, we can reflect upon the three core elements of the product:

- Band (also refer to as strap or bracelet): a fabric, adjustable band with non-magnetic clasp and textile-based conductive pathways and electrodes. It contains a pocket-like opening, in which a silicone socket in which the acquisition unit is secured. Must be machine-washable, and its materials should be biocompatible and sustainable. In specific contexts, body locations other than the wrist may be preferred by users; as such, through multiple sizing (in this case, user exchanges the band for another size) and fine adjustments, it must be possible for the user to relocate the band to other places. Additionally, and depending on the contexts, users may prefer a specific aesthetics; thus, bands must also be commercialized separately and with multiple variations in color, material or texture and patterns.
- Acquisition unit: a small pod, pebble-like module incorporating EDA, PPG, temperature and accelerometry sensors. Its top has a slight curvature which aids in blending the module with the bracelet; additionally, the charging port should be installed in an indented area, to avoid skin contact and friction, with the opposite occurring in the PPG area, to improve contact with the skin. To facilitate the curvature and shape of the unit, a flexible PCB may be used. Its LiPo battery must ensure at least 48 hours of consecutive acquisition and data

transmission, the latter which occurs via Bluetooth (as it is a short range, point-to-point, low-power communication). Data is stored temporarily on the unit; default location is an external device, particularly, a smartphone. In order to facilitate miniaturization and increase battery life, the module does not have a screen; additionally, as it is inserted into the bracelet, is it not easily observed by the user. Thus, visual feedback is not fit for the context; in situations in which an alert is required, such as for low battery level, incorrect placement, or seizure detection, the unit alerts the user through haptic feedback, particularly, specific vibration patterns.

- **Application:** collected data must be stored and further analyzed in an external device, as well as communications with emergency contacts and emergency services. Due to the simplicity in terms of feedback (haptic only) of the acquisition unit, an additional component is necessary to present more comprehensive alerts and information on the status of the acquisition and the device itself. Thus, a smartphone application is also required as a core component of the product. Since it will accompany the monitoring product at all, or most, times, the user experience related to the interactions with the application must be further explored and validated; other features may be useful, such as an autonomous seizure diary, medication alert and integration with external health services, public and/or private.

In the commercialized package, these components would also be accompanied by a thorough instructions manual and a quick-start guide. An overview for specifications of the conceptualized product is presented in a product Design Specifications (PDS) table (Table 12), divided according to its core elements.

Table 12. Product Design Specifications.

Product	Epilepsy monitoring wristband
Components	Main components include the strap and the acquisition unit which constitute the wrist-worn device, and the paired smartphone app that allows additional feedback, and data visualization and sharing.
Strap/Band/Bracelet	
Components	Non-magnetic, adjustable clasp for opening, closing and adjusting the wristband size and fabric wristband. Socket when the data acquisition unit is secured should be further researched and defined.

	Materials	Knitted silver-based yarn for pathways, densely embroidered in the electrode zones; non-magnetic clasp; non-conductive fabric should allow some degree of stretch to make tight skin contact more comfortable (possibly a blend) and breathability.
	Sanitation	Hand wash is recommended. Machine washable, below 40° in a protective wash bag or delicate cycle. Mild detergents and soaps. No centrifugation. Not sui for dryer, air dry only. Drying times depends on the chosen material.
	Aesthetics	Multiple aesthetics commercialized, block colours (including a comprehensive skin tone spectrum), patterns and textures.
	Size (length)	Multiple standard sizes, with intervals of sizing for adjustments. Users may acquire different sizes to be able to relocate the band to another body location. Size categories from XS to XL such as: 130mm to 145mm, 146mm to 163mm, 165mm to 180mm, 183mm to 198mm, and 200mm to 216mm.
Detachable acquisition unit/module		
	Materials	Biocompatible materials. Enclosure of polycarbonate, and silicone coating. Adhesive-less flexible PCB of polyimide, and gold connectors (for durability and conductivity; coated copper alternative).
	Sanitation	Use a humid cloth to wipe the surface, dry with microfiber cloth.
	Sensors	Minimum requirements include transmissive photoplethysmography sensor, electrodermal activity sensor, accelerometer, and temperature sensor.
	Size and weight	Approximate weight of 30 grams, maximum of 50 grams. Optimal size would be 35 x 20 x 15 mm.
	Battery and battery life	Lightweight lithium polymer battery (as they can be manufactured in customizable size and shape). Minimum battery life should be of 48 hours.
	Charging	Wireless charging (induction) through dock.
	Data storage	Activated when connectivity is lost; should hold measurements up to 48 hours (battery life). Should flush after connectivity is restored and data is transferred to the paired smartphone.

Connectivity	Minimum Bluetooth 5.0 (due to enhanced BLE).
Water and dust resistance	IP67 certification; due to the nature of EDA measurements, data collection/alerts are interrupted when in water.
Feedback	Haptic feedback: vibration patterns alert for high risk of seizure detected (preictal, aural or ictal stages), obstructed reading and low battery. Visual feedback must be further researched and validated.
Application	
Features	Feedback on device status (battery, connection, correct functioning); notification on seizure detection; seizure logging; live vis of bio-signals; live location of user.
Communication and Integration	Possible integration with Health systems, both public and private, (access to medical history/health records/profile) to facilitate sharing the collected seizure log information. Communication channel with emergency/health support lines and forwarding of user information (status and location) in case of emergency. Send message/phone call through user's phone system to emergency contacts with pre-defined message/audio in case of emergency.
Packaging	Package should contain the data acquisition unit, two wristbands, device induction charger, case, instructions manual and a download QR code for smartphone app access.
Safety and Regulations	Compliance with EMA and FDA regulations; Regulation (EU) 2017/745, CE marking certification, and Premarket notification 510(k).

5.3.3 Develop

Given time and resource constraints, as mentioned previously, the concept would be materialised through a dummy prototype, a model with no electronic functionality but built using a form, size and weight approximate to the concept, allowing us to validate the development choices thus far through user testing with a focus on daily wear experience, rather than device performance.

The development of the model concerned the development of differently sized wristbands, and a mock acquisition unit.

The wristbands were developed using a cotton and Lycra blend, which would provide breathability and elasticity; the colour of the fabric was a darker beige shade, which, from the

available colours, was a more muted, and potentially more discreet tone. To recreate the adjustment clasp, a metallic hook, commonly used to attach bra straps, was used.

The first iteration of the band model was a simple fabric wristband, in which there was no adjustability; the goal was test the elasticity of the fabric, the stitching of the hook, the ability to open and close the band using said hook, and the comfort and feel of the fabric. The fabric was folded in half, machine stitched together along the length (a few millimetres from the edge); it was then turned inside out with a crochet needle. Due to the nature of the fabric, it tends to curl causing the band to puff into a tube; as such, using an iron on low temperature, the band was flattened with the seam running through its middle. The middle seam would facilitate the installation of the acquisition unit, as it could simply be unstitched in the middle of its length to fit the socket and the unit inside the bracelet; additionally, the middle seam would be completely hidden once the bracelet was put on (Figure 23; right). In one of its ends, the hook was inserted and the fabric was hemmed by hand (due to the thickness of the fabric, small area and meticulousness necessary); the opposite end was folded over, hemmed and double stitched along the width of the bracelet while leaving a small gap at the end, which would create the loop where the hook would be secured (Figure 23; left).

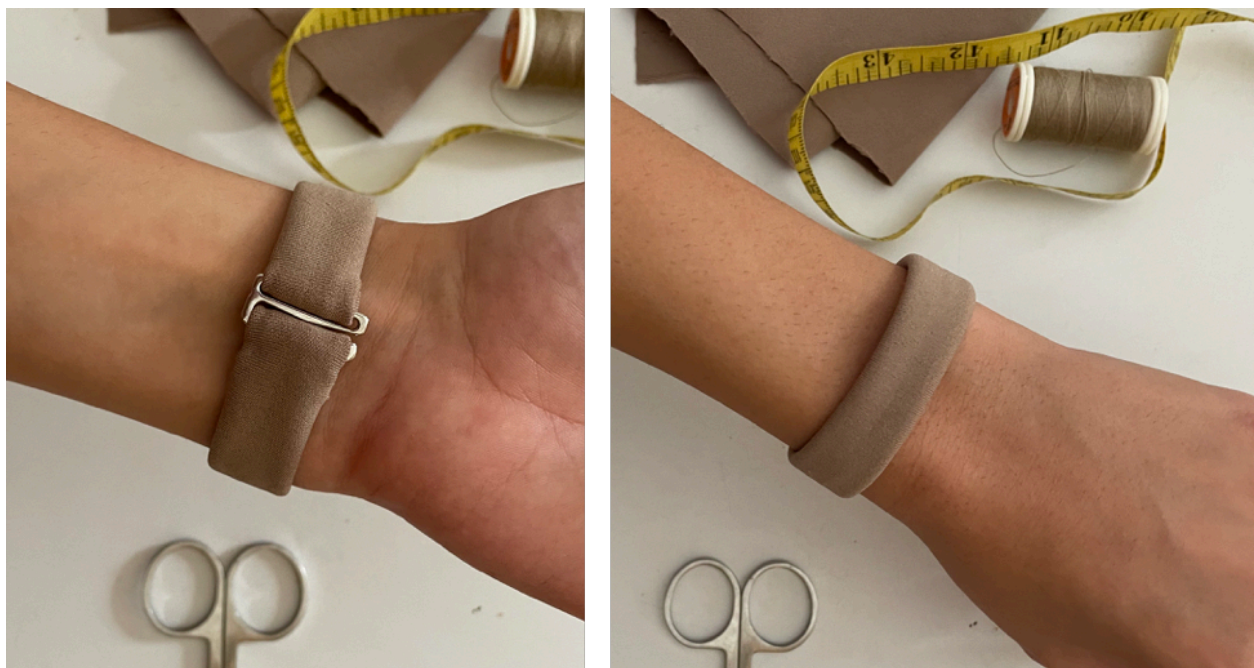


Figure 23. Fabric band put on; anterior view (left) and posterior view (right).

Opening and closing the band proved to be slightly challenging due to the both the lack of width in the loop, making it difficult to fit the hook, but also due to the thickness of the fabric, from the hem and fold. Additionally, despite using the iron to flatten the band, it seemed to easily puff and reverse to a tube-shaped bracelet; due to the fabric, but also due to the middle seam, the band would not easily retain its shape. This could result in an additional challenge for user to upkeep the wristband, particularly after washing.

Concerning the challenge in securing and removing the hook, for the second iteration in model development, the same process was performed, with the exception that the end of the band, where the loop would be, was not hemmed and folded after turning the bracelet inside out, but instead stitched close before prior to it. This resulted in significantly less volume in that end of the band. Additionally, this second iteration concerned the possibility to adjust the length of the bracelet, and the level of tightness to the skin, through multiple loops (Figure 24; left).



Figure 24. Fabric band; loops for adjustment (left) and hook stuck in the seam (right).

The individual loops are created by stitching dividers, and then opening holes on both sides of each loop (Figure 24; left). However, it still proved to be a challenge to insert e remove the hook, as it would frequently get caught, or be obstructed by, the stitches of the middle seam running through one of the sides of the bracelet (Figure 24; right). Additionally, the loops were, once more, too tight. While the middle seam made it easier to create the pocket for the acquisition device, by

unstinting it in the middle and inserting the socket into the band, it was not feasible for hook and unhooking the band or retaining the shape of the fabric.

As such, the third iteration would feature side seams. Instead of one piece of fabric folded and stitched, two pieces of fabric were used, stitched on both sides, and turned inside out. In order to insert the acquisition unit in the middle of the band, a pocket was then created. The pocket opening was marked by tacking the fabric of one of the band's sides and a second, smaller piece of fabric to create the edges of the opening. The outline is then double stitched, and after the pocket opening is cut, the second piece of fabric is tucked through the hole. After tucking, it is then tacked and stitched with a fold, in order to create the edges of the pocket. The excess fabric is then stitched, and we're left with the two sides of the band, one of them with the pocket opening (Figure 25).

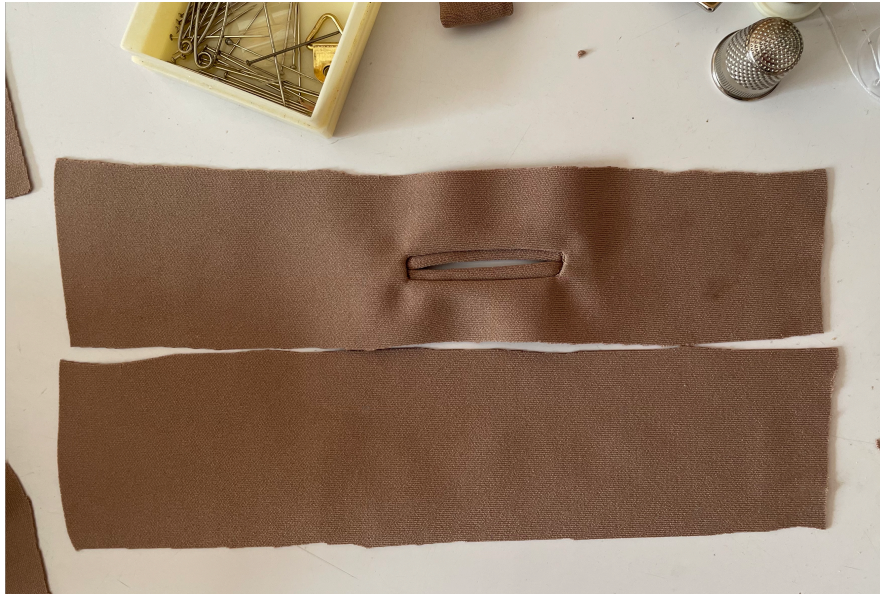


Figure 25. Fabric pieces for the two sides of the band after creating the pocket-like opening.

These two pieces of fabric were stitched together, the excess was trimmed, and the band was then turned inside out with the help of a crochet needle, at which point it tends to puff lightly (Figure 26); thus, it was ironed at low temperature to become flatter.



Figure 26. Band after being turned inside out, with one open end.

Using the open end of the band (Figure 26), hook by tucking the fabric through the piece, and hand stitching it tightly, without folding the fabric, to reduce volume (Figure 27).



Figure 27. Hook secured, hand stitched.

In the closed end of the band, the seams along the length of the adjustment area were unstitched; the dividers were then double stitched, to create the loops where the hook is fastened.

This last iteration presented loops with a better finishing on the edges, as the holes are opened by unstitching the lateral seams, before the dividers are stitched (opposed to cutting them open). Furthermore, the lateral seams resulted in no obstruction for the hook, which is secured and removed more easily (Figure 28).



Figure 28. Finished band, highlighting the hook fastened in one of the loops.

It is important to mention that, due to the elastic nature of the fabric, it can be challenging to sew, particularly to keep it secured during hand stitches, including when closing the ends of the band. Additionally, the material tends to puff, and requires ironing.

To model the mock acquisition unit, clay was used, as it would harden after drying and create some weight (as opposed to using a polystyrene with a hard coverage) but would also allow to work on a small scale and model the specific shape quite easily, as well as facilitate inserting

other small pieces into the model (as opposed to a mock made of plastic or wood). Initial shapes were created using the clay, and, after 12 hours drying, they were sanded to create the desired shape (sandpaper of medium grit, 80, and then fine, 220). Afterwards, a small section is gradually humidified, small holes are carved and the magnetic connector for the charger, as well as a small piece of red plastic, are introduced and cemented with *lamбуje* (Figure 29).



Figure 29. Unit mock after inserting the magnetic connector.

The area where the charger connector was placed was shaved in order to create a small indentation (to avoid it coming into contact with the skin and causing irritation from friction); the opposite was done for the area where the small red piece was inserted, to create a slight height where the PPG sensor would be located, facilitating contact with the skin. After drying, the piece was sanded with fine sandpaper, and painted using an acrylic-based spray paint (for more seamless adhesion, coverage, and colour vibrancy), in three layers, with approximately 12 to 18 hours of drying time in between. Before varnishing, the mock-up was lightly sanded using extra fine sandpaper (440 grit) to remove imperfections on the paint job. The concluded mock acquisition unit (Figure 30) was varnished twice (12-hour interval) and left to dry for more than 24 hours. Dimensions followed the guidelines of the PDS (Table 12).



Figure 30. Finalised acquisition unit mock-up: top view (left) and bottom view (right).

Additional figures of the development process are available at Appendix F. Both components, wristbands and mock-up acquisition unit, were included in the evaluation of the concept in terms of user experience, detailed in the following section.

5.3.4 Deliver

Extended UX user testing. The goal of this study is to understand the user experience of participants with epilepsy, particularly, the impact of the developed device mock-up in participant's daily life, for approximately 72 hours, in order to validate and improve the concept.

Design of the study. The conducted study followed a mixed design approach, where user diaries and short structured interviews were used to provide both quantitative data and qualitative data on the user experience of participants throughout three days.

Materials. A short instructions manual (Appendix G) was developed concerning the specific daily tasks in which users must interact with the device, and in which evaluation and validation was necessary: charging the acquisition unit and replacing, and washing, the band/strap. Similar to other user manuals, a first section illustrated which elements of the product were in the acquired packaged. Additionally, a small section detailing the use of the device, particularly incompatibility with water, positioning and time of wear. Throughout the manual, multiple illustrations were provided to improve users' cognitive perception.

The validation and evaluation of user experience intended for user testing would require users to use the device for a relatively long period of time and in an autonomous way; as recollection may not be comprehensive and reliable enough, a user diary or journal must be provided, allowing users to document their experience as it evolves. As such, it must be correctly structured and organized, comprehensibly concerning specific contexts and activities of the users' daily lives, providing both closed questions for quantitative analysis, and open questions for free writing, for a more in-depth and individual qualitative analysis. A user diary (Appendix H) was developed to for participants to evaluate the following for each day:

1. The overall experience of the user with the device throughout the day, using illustrations for the 14 emotions of the Premo tool¹³ (female and male versions), as well as Likert scales for comfort, obstructiveness, and safety. This section would allow us to monitor the overall emotional response and how it evolves throughout the days; additionally, it was selected as the first section to invite users to reflect on their overall day from the beginning.
2. The experience in public spaces where the participants visited wearing the prototype and scales describing their emotions in those public spaces; additionally, the evaluation on how many times participants were asked about the device and the respective impact on users. This section was crucial to evaluate how the device may impact users' mental state by possibly contributing to the felt or enacted stigma.
3. Impact on daily activities, including fitness and sports, house upkeep, working, among others, in order to detect a pattern of specific activities in which characteristics of the device may be challenging or impactful.
4. Impact on user's quality of sleep, which is particularly important given that sleeping issues are a common epilepsy trigger; additionally, nocturnal seizures are commonly associated with SUDEP, so it is crucial to ensure that the product provides a positive user experience that encourages participants to maintain a routine of wearing the device during sleep.
5. Device-specific experience, particularly related to interactions such charging the device, changing, washing, putting on and taking off the band. Additionally, participants are asked to indicate whether they removed or changed the location of the product, and why. This section allows us to understand whether participants are complying with the study, and

¹³ Retrieved from the Delft Institute of Positive Design website: <https://diopd.org/premo/>

whether they are being deterred from wearing the device (from obstruction, uncomfortableness, embarrassment, sensory issues, among others), as well as if there are any challenges related to daily tasks.

6. Any additional issues not mentioned in previous sections (optional section).
7. A free writing space for users to document any thoughts or opinions they might have (optional section).



Figure 31. Materials for the extended UX user testing.

The described user manual and user diary, the developed wrist model with three straps (two adequate to the participants wrist size, and one sized up), and one magnetic charger, incorporated the package each participant received to perform the experiment (Figure 31).

Participants. Six participants, with an epilepsy diagnosis, took part in this experimental study. The sample consisted of 4 females and 2 males, ages ranging between 22 and 59 ($\mu = 35.50$, $\sigma = 15.79$).

Procedure. The experimental study is structured in three main stages, before, during and after:

- I. Before. This stage refers to a short briefing session prior to the beginning of the experimental study, including the following steps:

1. Introduction to the study, explanation of requirements and procedures, and voluntary agreement to participation (Appendix I).
 2. Short interview, during which the following information is obtained:
 - i. Age, sex, occupation, familiarity level with technology, frequency with which they wear wristwatches (including smartwatches) and are physically active, and how long their diagnosis was established.
 - ii. Personal outlook regarding their diagnosis, and the impact of the condition on their life.
 - iii. Personal opinion on epilepsy monitoring devices, as well as familiarity with devices in-market, willingness to wear one and justification.
 3. A package containing the necessary material (Figure 31) is provided and explained thoroughly.
 4. A meeting is set up to mark the end of the study (time and location set according to the preference of the participant). The participant leaves in possession of the materials at the end of the briefing session.
- II. During. This stage refers to the approximately 72 consecutive hours during which the participant carries out their daily routine, while:
1. Wearing the device daily, for as long periods as possible.
 2. Performing necessary upkeep tasks according to the provided user manual, such as charging the device, washing or changing the strap.
 3. Documenting the experience with the device through the provided user diary.
- Throughout this stage, participants were able to contact the researcher, if necessary, in which case, the time, frequency and motive(s) for contact were registered.
- III. After. This stage refers to the previously arranged closing meeting, marking the end of the experimental study, during which:
1. The provided material was returned to the researcher.
 2. A short interview was conducted, during which the diary entries were reviewed, and the following topics were discussed:
 - i. Difficulties with daily device-related tasks and suggested improvements.

- ii. Impact of the device in their everyday life – were participants able to forget they were wearing the device? Did the device obstruct their tasks? Among other topics.
 - iii. Impact of the device on their emotional state, mood, feeling of safety, particularly related to noticeability/discretion.
 - iv. Evolution of their experience, in terms of novelty versus familiarity, and the impact on their willingness to wear the device every day.
 - v. Additional feedback and suggestions.
3. The participants were asked to answer a short questionnaire pertaining to the concept of a smartphone application which pairs to the evaluated device. This questionnaire, and its results, will be analyzed in the next development phase.

Results. Participants' experiments followed a pattern of two working days and one weekend day (or non-working day), which would allow us to evaluate their experience in different contexts and environments. The resulting data for each filled diary is available in Appendix J.

Considering the first section of each journaled day, the participants' overall experience with the device, participants P1, P3, P5 and P6 selected positive emotions in all three days of the study (particularly, pride, desire, joy, hope, fascination and satisfaction); remaining participants P2 and P4 both reported a negative emotion on the first day (respectively, embarrassment and fear), followed by positive emotions (joy and satisfaction). Through the analysis of P2's first day, we observe that the participant was at work and used public transportation, in which reported a high degree of feeling exposed and observed, leading us to assume that that was the source of their negative experience (reported as embarrassment). In the closing interview, this was discussed with the participant, who confirmed it and clarified that while there was no enacted stigma, they felt "hyperaware of others' gaze", particularly in their commute by public transport. Participant P2 also added that the first day was hardest due to anticipation and fear, feelings which then improved. This relates to the fact that P2 performed that same commute on the second day of the experiment and reported an improved experience (positive emotion in Premo, hope, and decrease feelings of being exposed and observed). Participant P4 was also asked to discuss the negative experience (fear) reported on the first day, as there were no negative feelings related to public spaces or being asked about the device. During the closing session. P4 clarified that he selected the emotion unaware that it was associated to fear; the negative experience was due to interactions with the

product at the beach; the necessity to remove it to swim and dry the arm before putting it on again, as well as the discomfort and itchiness caused by the sand (which became trapped between the wrist and the strap, causing friction) cause the participant to become dissatisfied and question how viable it would be to constantly remove it to shower or swim. Despite these two instances of reported negative experience on the first day of the study, both participants reported an improvement. By performing a non-parametric Cochran's Q test, through SPSS statistics, we can state that the frequency of these reported negative emotions is not statistically significant. That is, as illustrated by Figure 32, while the first day presented approximately 33% of negative reports, the differences between the three days are not statistically significant (the test does not reject the null hypotheses, $Q_{(2)} = 4.000$; exact p-value = 0,333; $N = 6$).

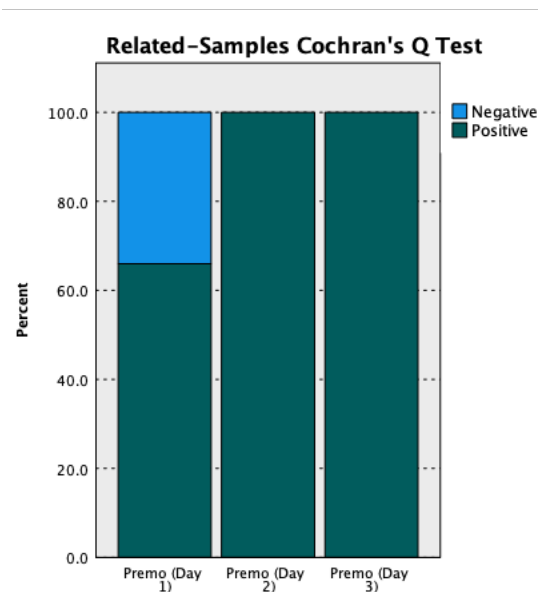


Figure 32. Percentages of reported negative and positive emotions of Premo throughout the days as analysed through Cochran's Q test.

Prior to the end of the study, it was hypothesised that the emotional response to the device could be influenced by the duration of the diagnosis, that is, participants who had been diagnosed for longer could present a statistically different emotional response of those with more recent diagnosis. However, through a non-parametric Fisher's exact test, we found no statistically significant correlation between the time of diagnosis and the emotional response (classified through Premo), that is, these variables are independent ($F = 4.461$, exact p-value = 0.200 > 0.05);

this test was solely performed for the Premo reports of the first day, as in the second and third day all participants reported positive emotions. Through this analysis, we can conclude that the overall emotional response to the wearable was positive across participants.

The experience section also concerned other subjects: comfort, obstructiveness, safety, and impact. Comfort and obstruction scored consistently very positive results across participants. Specific events related to discomfort or obstruction of tasks due to the wearable were reported by participants P4 (aforementioned friction due to sand) and P5 (excessive heat during exercise, and discomfort when wrist was rested during typing in a keyboard), which still reflected in neutral scores of overall comfort rather than negative. P6 also reported slightly overheating in the wristband area during physical exercise, but it did not impact their rating of comfort. Overall, these results are quite positive; the wristband was seemingly not obstructive to participants' daily tasks and did not cause significant discomfort; the elimination of polyester from the material composition might improve the feelings of overheating during physical exercise. No participants rated the wearable negatively in comfort or obstructiveness.

Questioning participants about the degree to which the wearable impacted their feelings of safety was assumed to depend on their own interpretation of the experimental study. While all participants were made aware that the wearable was a *dummy* model, not functional, neutral feelings of safety were expected, as there was no real contribution to the participant's safety. However, some participants were able to, at some level, abstract from that fact and answered according to their experience with a functional wearable; as such, participants P1, P2 and P6 rated consistently higher levels in felt safety, while the remaining reported neutral levels (no impact to their perceived safety). No participant reported feeling less safe with the device.

The last question of the section of their experience asked patients to rate the degree to which the device made them feel better or worse than usual. Participants P3, P4 and P6's reports remained consistent throughout the three days, with P4 reporting neutral/no impact to their mood, and P3 and P6 a positive improvement. Participant P5 demonstrated a decrease from positive to neutral reporting, which was seemingly due to both the experiences of discomfort aforementioned; conversely, participant P2 reported increasingly positive impact throughout the days, which corresponds to their reported experience, previously mentioned.

The second section of user diaries focused on their experience with the device on public spaces, concerning specifically which public places participants visited, whether the device

impacted them and in which ways, and, finally, how many times they were asked about the wearable and how it impacted the participants. The reported public places included professional settings (their places of work or study), social settings (public parks and beaches, coffee shops, restaurants), and or routine settings (grocery stores and public transportation). Considering the second question, which allows users to classify the impact of the device through statements from 1, “not at all”, to 5, “definitely”, in the statement “I felt the same”, participants P1, P2 and P3 presented some variation in their feelings but generally reported left to middle scale values, indicating a moderate perception of feeling different; P3’s results indicate they felt increasingly less different. The remaining participants consistently reported feeling the same, with rating ranging between 4 or 5. The statement “I felt better” did not elicit expressive results from participants P1 and P2; when questioned further during the interview stage, it was noted that the question was not clear, as lower answers and results could imply that the device made them feel worse rather than simply not improving their mood significantly. This situation was also observed with participant P3, who showed a significant drop in this statement over time, which coincided with high ratings in “I felt the same”; in interview, participant P3 explained the device had less and less impact over time, rather than having a negative impact. P5 and P6 registered overall low to medium results, which is consistent with higher rating in the previous statement. Participant P4 reported a high positive impact on their mood in the third day, which was consistent with a reported positive experience while teaching at a school (which will be mentioned in further analysis). The third and fourth statements, respectively, “I felt more exposed” and “I felt more observed”, allowed us to understand whether there was an increased perception of vulnerability, discrimination, or stigma. Regarding feelings of exposure, P1 and P3 reported low to moderate ratings throughout the days, with P2 demonstrating an improvement over time. Participants P4, P5, and P6 consistently reported not feeling exposed at all. Concerning the feeling of being observed, P2, P3, P4, P5 and P6 generally did not feel more observed in public places due to the device; P2 demonstrated a significant drop after the first day, which was discussed during interviews, where P2 described that the first day coincided with using public transportation, which increased her perception of being observed; this feeling seemingly decreased as familiarity with the device increased. In order to understand whether there would be a relationship between the time of the epilepsy diagnosis and the feelings of exposure and being observed, a Fisher’s exact test for both variables. We found no statistically significant correlation between the time of diagnosis and the

reported degree of feelings of exposure (classified from 1 to 5), that is, these variables are independent for each day ($F_{\text{Day1}} = 6.043$, $p\text{-value}_{\text{Day1}} = 0.200$, $F_{\text{Day2}} = 4.656$, $p\text{-value}_{\text{Day2}} = 0.600$, $F_{\text{Day3}} = 5.467$, $p\text{-value}_{\text{Day3}} = 0.200$); the same conclusion was reached regarding the time of diagnosis and the reported degree of feelings of being observed ($F_{\text{Day1}} = 4.081$, $p\text{-value}_{\text{Day1}} = 1.000$, $F_{\text{Day2}} = 2.182$, $p\text{-value}_{\text{Day2}} = 1.000$, $F_{\text{Day3}} = 4.081$, $p\text{-value}_{\text{Day3}} = 1.000$), as results revealed these variables are not correlated. The final statement, “I felt safer” in the context of public spaces, elicited consistent results throughout the days for each participant. Participants P3, P4, P5 did not report feeling safer in public spaces due to the device, while P1, P2 and P6 reported moderate to moderately higher feelings safety. It was assumed previously that there would be no impact as all participants were aware that the device was not functional; however, P1, P2 and P6, reported efforts to behave and perceive the device as functioning, which was reflected on higher results in rating feelings of safety. The third question of the public spaces section questioned participants on how many times they were asked about the device, and how it impacted them. Contrary to our previous expectations, no participant reported a negative impact on their mood or wellbeing due to being questioned about the wearable. A Fisher’s exact test was performed to verify whether the number of times participants were asked was positively correlated to a worse reaction, a negative impact to the participants. We found no statistically significant correlation between the number of occurrence and the impact to the participant (classified from -2 to 2), that is, these variables are independent for each day ($F_{\text{Day1}} = 7.167$, $p\text{-value}_{\text{Day1}} = 0.733$, $F_{\text{Day2}} = 7.505$, $p\text{-value}_{\text{Day2}} = 1.000$, $F_{\text{Day3}} = 4.081$, $p\text{-value}_{\text{Day3}} = 1.000$). During interviews, most participants expressed a certain enthusiasm in showing the device, and explaining the experimental study to others, with participants P5 a P6 reporting being somewhat surprised and slightly disappointed that they were not asked about it more frequently. Participants P2 reported a very positive impact to not being asked, and neutral on one occurrence. P1 was consistent across the three days, reporting null impact. Generally, participants had very few occurrences of being questioned the wearable, with exception of participants P3 and P4. These interactions were originated in, respectively, university and their places of work (a gym and an elementary school), which tend to have higher density of people. Participants P3, who demonstrated being an advocate for the normalisation of epilepsy during the initial interviews, reported a positive impact to being asked about the device, and reported viewing it, mainly during the first day, as a tool and opportunity for education. Participant P4 reported a very positive impact to being asked on the third day (asked six times by their

students), due to the device creating new interactions with the children, who revealed heightened interest.

The third section concerned the degree to which the device impacted specific activities performed daily by the participants. The activities which revealed more consistently issues were cleaning and cooking, which was related, during the analysis of the answers in the final interviews, to the proximity of the device to the water, food, cleaning products, and others, leading participants to worry, be more aware or careful than usual, and relocate the device to avoid getting it wet or dirty, particularly due to the textile strap (which, contrary to other material such as plastic, metal or silicone, cannot be wiped to remove stains). Exercising also revealed to be impacted negatively due to fabric of the bracelet, which could create overheating or discomfort, particularly when sweating. Participant P5 also reported discomfort from the fabric during work, as their wrist rests on the table when they are using their computer. However, the results for most activities performed were not expressive, with generally neutral results; additionally, no activity was physically, partially or completely, obstructed by the device.

Concerning the quality of sleep of participants, the fourth section presented to questions concerning the degree to which the device impacted them during night-time. Results were generally positive, impacting neutrally or positively all participant, with only one instance or a participants (P5) report a slightly negative impact, which was then related to a difficulty in falling asleep, due to the unfamiliarity of wearing a wrist accessory to bed. Additionally, participants P4 and P5 did not report data for this section on one night of their experimental studies, as both left the device charging through the night; this was related to a routine of charging their own smartwatches.

The fifth section concerned aspects related to direct interactions with the device. The first two questions concerned the relocation of the device; questions three and four concerned the removal of the device; questions five and six concerned the level of difficulty in putting on and taking off the strap; the last question focused on the daily tasks and whether any issues or difficulties arose. Concerning moving the wearable, participants P1, P5 and P6 relocated the band to other body parts; while participant P6 moved it once, pushing it up closer to elbow, to protect the device from becoming dirty or wet (consistent with their reports of it being concerned during cooking or washing the dishes), P1 used the device every day on their upper arm, with the same justification as P6. When questioned further in interview, this participant explained that it was a

constant worry, particularly at work as a chef, that while on the wrist, it could easily become dirty, burnt or wet. Participant P5 moved device in two of the days, during the time they would exercise, to the ankle of his left foot; this was not only because participant P5 found it uncomfortable to wear a wrist accessory during exercising, but that the bracelet would create some discomfort due to heat.

The following two questions, concerning whether participants would remove the wristband, were included with the goal of understanding whether any situation of discomfort, physical or emotional, discrimination, obstruction, or other issues, could be a deterrent to the adoption of the wearable, causing users to remove it during the study. All participants removed the devices at different times for routinely reasons (showering, charging the device, changing the band, among others), as expected, except for three situations which were out of this norm. P5 reported removing the device to wash dishes, which is consistent with previously mentioned reports on participants' concerns on causing the wearable to become dirty or wet. They also removed the device to due to the discomfort caused while using the computer for an extended period at work (previously mentioned). In one of the situations in which P4 removed the wristband, they reported feeling "uncomfortable or itchy"; in further discussion, the participant indicated that it was related to the discomfort caused by the sand and salt at the beach (previously mentioned).

Concerning the ease with which participants took off and put on the device, taking off the device revealed itself to be a generally easier task. Participants P1, P2, P4, and P6 reported consistently high ratings in ease; additionally, participants P3 and P5 demonstrated an improvement from moderate rating to higher ratings. In contrast, the task of putting on the wristband revealed itself to much harder for participants in general, except for participant P6; during interviews, P6 alerted that while they found it relatively easy to do so, others with less dexterity might find it hard to put on the device without help. By analysing the evolution in the results of the remaining participants, we can observe a trend in the increase of ratings, from low to moderate. To verify this evolution (and due to the reduced sample, $N = 6$) a Friedman test was performed (Figure 33; left), which leads us to reject H_0 with a 5% significance level ($F(2) = 10.300$; $p\text{-value exact} = 0.002$; $N = 6$), concluding that the average of ranks of the variable, throughout the three days, are not similar; additionally, a pairwise comparison (Figure 33; right) indicates a statistically significant different between the first and the last day (adjusted $p\text{-value} = 0.012$).

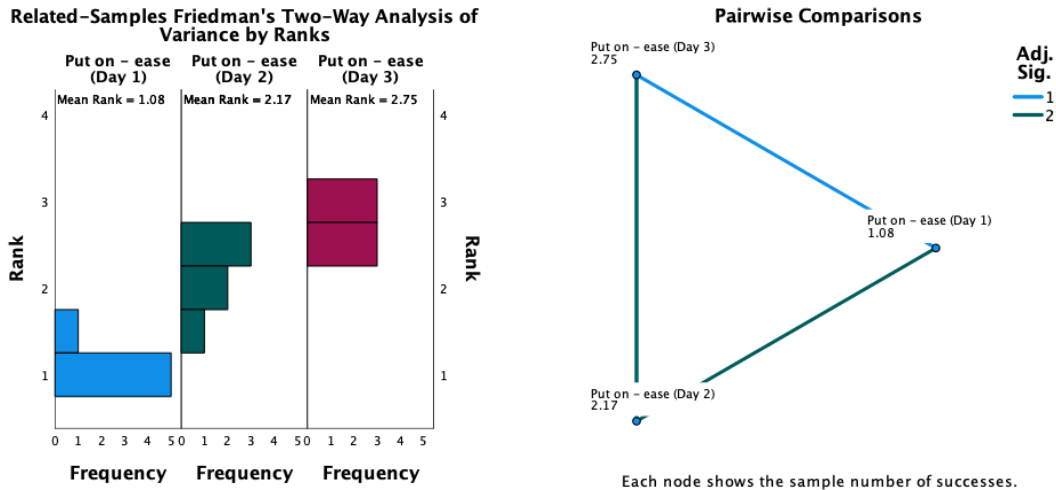


Figure 33. Results for the Friedman's Test and respective pairwise comparisons.

The final question of this section, which concerned the daily tasks of the device, such as charging, changing the wristband, or washing the wristband, did not reveal any issues or challenges for participants.

The sixth section allowed participants to report additional problems, which may not have been covered by previous sections of the user diary. In this section, only P5 reported forgetting the bracelet. The final section allowed users to register any additional feedback, through which a few aspects were brought up or revisited. One additional feedback was a difficulty finding time to charge the device was reported. As the device should be worn continuously, allocating time can be challenging, particularly given that PWE, particularly suffering from nocturnal seizures, primarily benefit from night-time monitoring, which coincides with the time when, routinely, people may charge their devices. The difficulty in putting on and taking off the strap, which consists with results previously discussed, was also mentioned. Discomfort was reported when the wrist is rested for prolonged periods of time, such as when using a computer, which can be mitigated by utilising a different fabric; discomfort from overheating during warm weather or exercise was also mentioned in this section. Regarding aesthetics, it was mentioned that it would be valuable to provide straps with different aesthetics. Finally, one participant reported quick drying time after washing the bracelet.

During the closing interviews, specific themes were approached: difficulties and improvements related to daily device-related tasks, impact on daily tasks and routine, impact of

the device's visibility or noticeability on the participants' emotional state and mood, and additional comments, feedback, and suggestions. Concerning the first discussion theme, the following aspects related to difficulties and improvement were addressed:

- Clasp difficulties: many participants found it challenging to use the clasp and adjust the band on their own, especially with one hand. This highlights the need for a more user-friendly clasp mechanism which allows users to put on and take off the device independently.
- Charging time: participants noted that finding extended periods for device charging was difficult, particularly since they needed to wear it during the day and the night. This highlights the importance of optimising the device's power management system to reduce charging time.
- Water limitations: participant P4 expressed frustration at having to remove the device for water activities. This limitation should be addressed in the final product by making the device water-resistant or waterproof, and temporarily disabling the EDA acquisition, as the electrodes will be saturated.
- Aesthetics: participants mentioned a desire for more aesthetic options to make the device less conspicuous and more appealing. This indicates an opportunity for customisation to make the device blend with everyday attire.
- Robustness concerns: some participants expressed initial concerns about the security of the device pod, fearing it might fall off.

Regarding the third theme of discussion, concerning the possible impact of the device on participant's routine, we can conclude the following:

- Minimal disruption: Most participants reported that the device did not significantly disrupt their daily routines or tasks, and they were able to carry on with their activities as usual. However, Participants identified that activities, like cooking and washing dishes, made them more conscious of the device, leading them to adjust its placement to prevent it from getting wet or retaining odours.
- Comfort: Several participants noted that they were initially aware of the device's presence, but they were able to forget about it. This suggests that the device, once worn for a period, became less obtrusive and more comfortable. A few participants mentioned mild discomfort during exercise, particularly when running. They also noted that the device

generated some heat on their wrists, which prompted them to move it to a different location, such as the upper arm or ankle.

Regarding the second theme of discussion, concerning the possible impact of the device's visibility, we are able to conclude the following:

- Increased initial awareness and concern: some participants noted that they were more aware or concerned about the device's visibility, especially in public settings like the public transportation. However, they recognised that this heightened awareness might have been a projection of their own feelings and not necessarily reflective of how others perceived them.
- Perceived safety: this was mentioned by participants who were able to abstract from the lack of functionality in the device, and this perception contributed to a sense of security.
- Lack of noticeability: many participants reported that the device did not have a noticeable impact on their emotional state or mood. They felt that it neither signalled a specific issue nor attracted attention from others. This inconspicuousness was seen as a positive aspect, allowing them to go about their daily lives without significant emotional disruptions.

Finally, participants P4, P5, and P6 provided additional comments and feedback regarding their experience. Participant P4 emphasized the importance of making the device water-resistant or waterproof, and alerted to the fact that changes in their routine can be challenging to stick to, expressing concerns about forgetting to wear the device. Participant P5 expressed concern about the pod of device falling off during physical activities like running, which highlight the importance of ensuring the device remains securely attached during various movements and exercises. Finally, participant P6 expressed a strong interest in using a functional device like this for monitoring their epilepsy. They mentioned potential benefits, such as being able to detect nocturnal seizures and providing valuable data to their doctors, especially during medication changes. This feedback underscores the potential clinical utility of the device. Additionally, they suggested integrating the device with existing smartwatches or accessories to reduce the need for multiple wrist-worn devices.

Conclusion. The previously analysed results highlighted specific areas which must be further explored and improved in future development. The hook system utilised to allow users to open, close and adjust the length of the bracelet was a clear challenge to most participants; while we

observed an improvement over time, some participants needed help from another person which does not contribute to the improvement of patient's perception of autonomy. Additionally, the dexterity required to use this mechanism may also be a challenge for the elderly population.

It is pivotal that such a feature does require any training or familiarity. Not being able to autonomously close the wristband is a challenge users will face in first interactions; thus, it can deter PWE from adopting the technology early on, in which case, users may stop using the device before they become familiar enough, and more able to use the hook system. Modifying the adjustment piece must be done while considering that the excess length of the fabric must not be tucked between the wristband and the wrist, as it will cover one of the textile electrodes. A possible solution might be to apply the mechanism used in resizing watch strap, where it is possible to remove or add metal links to the bracelets in order to adjust the length and make the watch fit comfortably on their wrist. Additionally, adjusting the wristband must be tested with multiple lengths; if the adjustment is too great, for instance, when we tighten the wristband, the distances between some components will drastically decrease. This implicates that resizing the wristband will result in components becoming placed in different locations depending on the wrist size, which can create consequences to both functional (for instance, placement of electrodes or PPG sensor on an area which yields less reliable data) and user experience aspects (for instance, placement of the pod in a less stable or comfortable area of the wrist). To mitigate this issue, we suggest that when manufacturing the wristband in different sizes, the length to which the band can be tightened or loosened for each available size must be small enough that the changes to component placement are minimal.

While EDA acquisition is not feasible in humid environments, such as showering and swimming, due to sensor saturation, other alternatives to removing the device should be explored and validated with users. We suggest the possibility of temporarily disabling the acquisition and processing of the EDA signal through the complementing digital product until electrodes have dried completely, or the wristband is changed.

Another development to explore is the improvement of the structural integrity of the fabric band, particularly through the use of different fabric blends or manufacturing techniques which provide some rigidity and firmness to area of the bracelet where the pod is inserted.

We suggest that future developments prioritise the use of validated technologies available in the market, to ensure reliable and effective functional performance, pivotal in the scope of

medical monitoring wearables, while also being aware of more innovative solutions and technological advancements which may help improve the monitoring experience for patients (for instance, lightweight, flexible, textile batteries – a concept in the research and development stage – which can be seamlessly integrated in clothing and textile accessories; an alternative power which offers greater comfort and eliminates the need for bulkier, exterior batteries). It is also important to prioritise product sustainability, particularly in the field of textiles, and ensure the chosen fabrics can be obtained from renewable and biodegradable materials, can be responsibly recycled at the end of the product lifetime, and can be produced through manufacturing processes with reduced environmental footprint and non-impactful dyes. It is important to ensure that the developed product is of high-quality, long-lasting textiles and other materials, as it improves its durability and longevity, reducing the need for frequent replacements. Growing advances in textile technology, such as 3D knitting or biofabrication, may also present viable solutions in the future for more sustainably sourced and produced textiles.

5.4 Phase 4 – App screens

After the development and evaluation of the concept for two of the core elements of the proposed solution, the strap and the acquisition unit, the third core element, the application, is further detailed in this chapter. Given that the scope of this research concerns mainly the wearable product, and given the time constraints, the proposed for the digital product in this chapter will serve as an introduction, a minor contribution to future developments and research of this thesis.

5.4.1 Discover

As an initial phase in the research and development of the application, it is paramount to understand the needs and preferences of primary users, in order to ensure a user-centred, tailored solution, improving the resulting user experience and the adherence to that solution. Thus, to understand and prioritise specific features and characteristics, a short questionnaire (Appendix K) was provided to, and answered by, the same six participants at the end of the previous study. This questionnaire aims to provide initial information for a first concept of the digital solution. Overall results have shown to be relatively diverse and are available in Appendix L. Features such as seizure detection, confirmation of seizure detection, alert emergency contacts, seizure prediction, medication reminders and feedback on the status of the device were, in general, attributed high levels of importance. These results indicate a generally strong prioritisation of functional abilities that enhance the users' well-being and safety. Results for the feature of live visualisation of data acquisition are evenly split between lower and higher degree of importance; this divergence may need to be addressed by offering this feature but not in a spotlighted or commonly visible screen of the application (such as the home screen). Daily summaries of health data presented a majority of votes for a higher degree of importance, indicating a relatively strong preference in receiving concise and regular updates on their health status. Features such as seizure log, integration with other health and wellness applications, personal seizure journal, and community forums, scored diverse ratings in prioritisation and importance; due to the small sample and its heterogeneity in background and diagnosis, these features should be further validated with people with epilepsy. Finally, information and tips on epilepsy management was a feature rated with a majority of a moderate to higher importance, which indicates that, while not all consider this feature a priority, reflects a general interest in educational resources.

Suggested features in the free-write answer included feedback on the status of the acquisition (that is, feedback on whether the acquisition is in progress, if the sensors are correctly placed, etc.) and sending the user's GPS location with the alert of emergency contacts.

Participant 4 (P4) also requested that the app would recognise that they are in physical activity; later, P4 clarified that, due to their occupation as a personal trainer, physical activity is intensive and biosignal activity such as elevated heart rate and increased sweating might constantly trigger seizure detection and prediction (false detection).

Concerning the notification in the user's phone of detected and predicted seizure, in both instances there was a clear preference for a banner or screen notification, followed by phone vibration. Alarms were overall less preferred. Additionally, notifications were slightly preferred for seizure prediction rather than seizure detection; this may be due to the fact that, in seizure detection, the user may be already in a stage of impairment, in which the notification/alarm will be less valued or prioritised.

Alerting emergency contacts and services was overwhelmingly preferred for seizure detection rather than prediction, with only participant preferring alert of emergency contact and services on both instances. We can assume these results may be due to the fact that, during seizure detection, the user may be significantly impaired, unable to guarantee their own safety, and in need of further assistance for potential injuries or potential status epilepticus (unrequested, such as from passers-by, or requested, through emergency services and contacts). On the other hand, with a seizure detection mechanism, users are empowered to guarantee their own safety first, and then having the ability to still notify emergency services or contacts when the state of seizure detection is triggered. In terms of contacting overall, emergency contacts seemed to be preferred (4 votes for seizure detection, 1 for prediction) over emergency services (2 votes for seizure detection, 0 for prediction).

Concerning data and information visualisation, iconography (4 votes) and graphs (5 votes) were the most preferred options, followed by text (2 votes); tables were not voted by any of the participants. In terms of the complexity of the information, the preferences were split, where three participants voted for simplified information, and the remaining three for comprehensive and detailed information. Given this result, it should be provided the option to visualise information in both manners, through either a definitive setting, which configures the application, or the existence of two different screens, one for each.

In this question, an option to download their data was suggested by Participant 6, which was then reinforced by their answer on data privacy and sharing, where they opted for manual sharing (which involves extracting their data and manually choosing when and with whom they wish to share). Data privacy and sharing answers divided between automatic synchronisation with their medical records, to external public and private health systems, with 4 votes, and manual sharing, with the remaining 2 votes. In order to comply with these preferences, users may opt in or out of automatic synchronisation in application settings and have manual sharing as an offered option at any time through a “share” or “export” button.

Analysis of similar solutions. There are already available in-market many other applications related to epilepsy management and epilepsy monitoring (Figure 34); we will discuss the E4 Realtime, a research application; Empatica Care, targeting participants and patients; and Alert for Embrace Watch, an alert application, all of which are part of the Empatica ecosystem. Additionally, other applications such as SeizAlarm and Epsy are also considered.

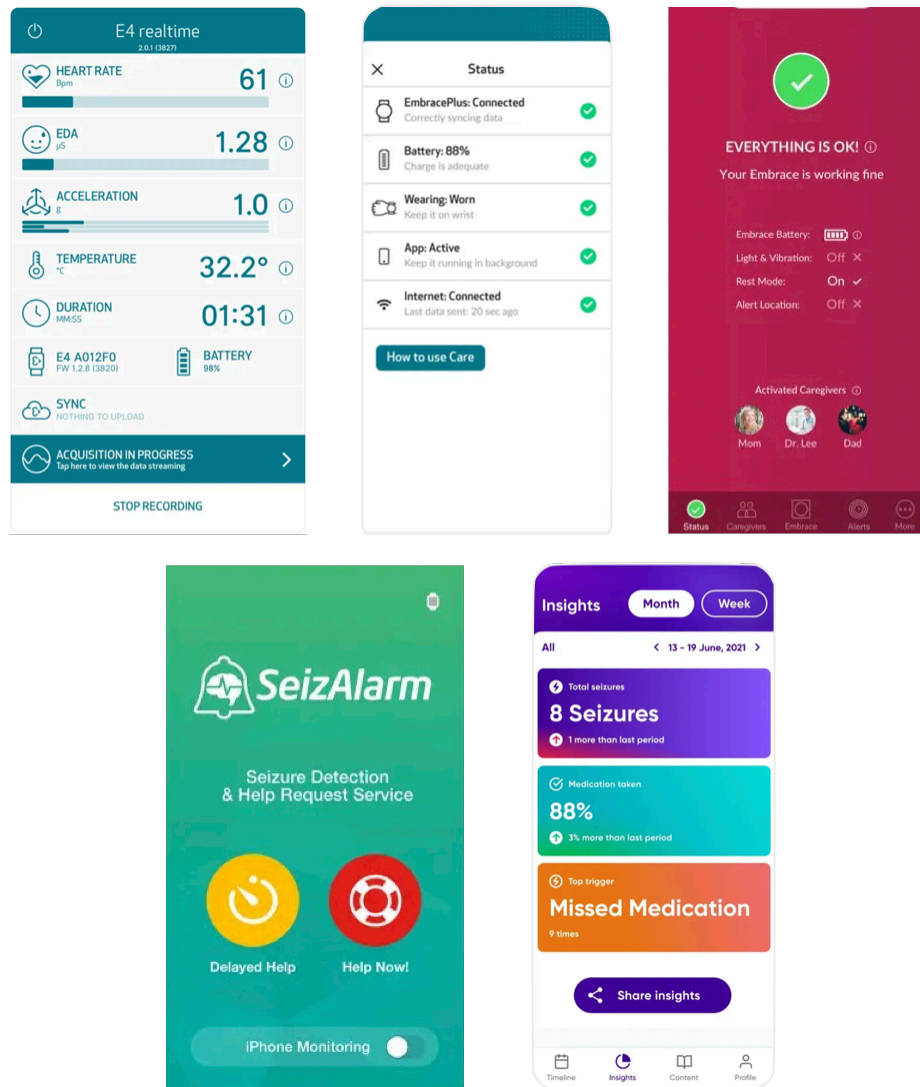


Figure 34. Analysed applications' illustrative screens (respectively, Empatica E4 Realtime¹⁴, Empatica Care¹⁴, Alert for Embrace Watch¹⁴, SeizAlarm¹⁴, and Epsy¹⁵).

The Empatica E4 Realtime is targeted primarily at researchers, with a main feature of real-time display of the collected physiological data. This is reflected on the presented utilitarian UI design; the main screen depicts a dashboard, with listed elements, of the current data on heart rate, EDA, accelerometry and temperature, as well as information on the device (serial and battery

¹⁴ Image retrieved from the App Store page of the digital product.

¹⁵ Image retrieved from the Epsy website: <https://www.etsyhealth.com>

level), acquisition control and synchronisation control. A secondary screen allows users to visualise the live acquisition in real-time graphical form, for the different modalities, in a landscape orientation. Iconography is used as support to text, rather than substitution, and easily recognisable. As this application is developed mainly for professionals, the data is not interpreted for the user; that is, there is not textual conclusion or feedback on the meaning of data.

Conversely, the Empatica Care app, associated with the Care Portal, is primarily directed towards patients, as a support tool during remote data acquisition; this is reflected in a cleaner and more simplistic UI, and a much more simplified view of information. The main screen presents the overall status of the device, which uses the colour, particularly of the background, and iconography to convey this information, finding the perception of users. It is possible to view the status of the device in detail, such as status of different connections and battery. These are also colour coded accordingly and use iconography to aid in textual information. Verifying the status of the device, including the running time of the acquisition session, is the key feature of the digital solution, and the information presented is concise, and conveyed through multiple signals; while not fully possible to assess the application due to access constraints, the digital solution seemingly obeys to multiple usability heuristics (Nielsen's Heuristics), such as visibility of system status, minimalist design, helping users recognise, diagnose, and recover from errors, help and documentation (as the application offers comprehensive troubleshooting and onboarding), among others.

Alert for Embrace Watch is also directed towards patients and people with epilepsy, rather than researchers or professions, and presents a key feature of contacting emergency contacts (with a period of confirmation of a few seconds), referred to as caregivers, including the option to share the user's location with that alert; a log of seizures is also documented, and users are able to review it. These features correspond to those discussed in the previous participant questionnaire. Concerning the UI of the application, the design is minimalistic and clean; with enough negative space to improve readability. Related elements are grouped together and present similar features. Despite constrained access to the full application, it is possible to verify that the UI complies with the Gestalt principals of visual perception, particularly similarity, proximity, and symmetry and order. A menu bar offers quick navigation and organisation, with the information structured in five screens: homepage with status of the device, the list of caregivers and their contacts, the device, alerts, and other settings. Critical alerts and notifications are displayed prominently. Similar to the Empatica Care app, information is displayed in a simplified and concise manner, with recognisable

iconography and colour to convey the status of the device. Interestingly, and contrasting the previous two applications, the main colours of the application palette are deep tones in the red and pink range rather than the blue spectrum, the latter commonly associated to caregiving and healthcare.

The application SeizAlarm also tackles autonomous seizure detection; however, unlike the previous three applications, which integrate the Empatica environment, it does not utilise a proprietary device, but rather provides a detection system based on information collected through the sensors of the Apple Watch and iPhone. SeizAlarm presents a key feature similar to Alert for Embrace Watch, which is the notification of emergency contacts with the user's GPS location, in case of a detected event, which has a period of cancelation (false positive scenario), or scheduled with a delay, in case users begin to demonstrate symptoms or aura in a pre-ictal stage.

Additionally, events are logged, and presented in a dashboard with a graphical information on frequency of events and requests for help, data which can be exported and shared with medical professionals; users are also able to edit or add their own events to the log, which includes a journal, where they are able to document additional information, notes, triggers, symptoms, and others. Overall, SeizAlarm presents a very neutral palette, with a main neutral and accent colours vary depending on the information presented; the main screen is the exception, with a gradient background (green and blue hues). Information on seizure logs is relatively comprehensive, with graphic representation over time; the main screen is very simplified, with two quick access options, both related to help requests.

Finally, Epsy tackles a different aspect of epilepsy management, self-reporting; as this application does not pair with a seizure detection device, it covers other important key features which support users in their daily, autonomous management. These key features include medication support (plans and reminders), seizure diary (allowing users to report events, as well as associated triggers, symptoms, and side-effects), insights report from the collected data (which can be shared with medical professionals), and a forum with articles and information on the condition. Additionally, Epsy provides integration with the Health app and Apple Watch. These features can be extremely useful for users to feel more in control, informed and involved in the management of their condition, while supporting and improving the quality of self-reporting. The app also presents a menu bar, allowing users to quickly access to a timeline (where logged data, medication, and other journal entries are registered in a calendar-like access), insights screen,

which presents important extracted metrics and statistics, educational forum, and settings. Epsy presents a primary scheme of purple, pink and a contrasting neutral colour, utilising then a colour code for specific information categories and iconography to support recognition. Information is also provided in multiple formats, both simplified and comprehensive, text and graphic.

Through this analysis, we can validate the suggested features in the questionnaire as they are already present and developed in in-market solutions; we are also able to define, in the following subsection, not only the architecture, but also the priorities of development based on the attributed levels of importance obtained through the performed questionnaires. The possibility of combining features from applications paired with seizure detection devices with those from applications which target self-reporting, should be explored; such combination allows for both a degree of control over information revision, validation and condition management, and the autonomy and freedom provided by the autonomous detection from an external device.

5.4.2 Define

From the results obtained in the user preference questionnaire and brief research on available applications, concerning some of the functionalities and features of the digital product, we are able to define, on a simplified level, the system and interactions (Figure 35) between devices, and between devices and stakeholders. The two main products of the epilepsy monitoring solution are the wearable device, which collects the biosignal data, and the smartphone application, which interprets and displays the collected biosignal data. The wearable device, the defined wristband in previous sections, continuously transfers the data collected from the PPG, EDA, temperature, accelerometer, and possibly gyroscope, to the user's smartphone through Bluetooth connection, along with information on the device status (such as battery level, storage, status of the acquisition).

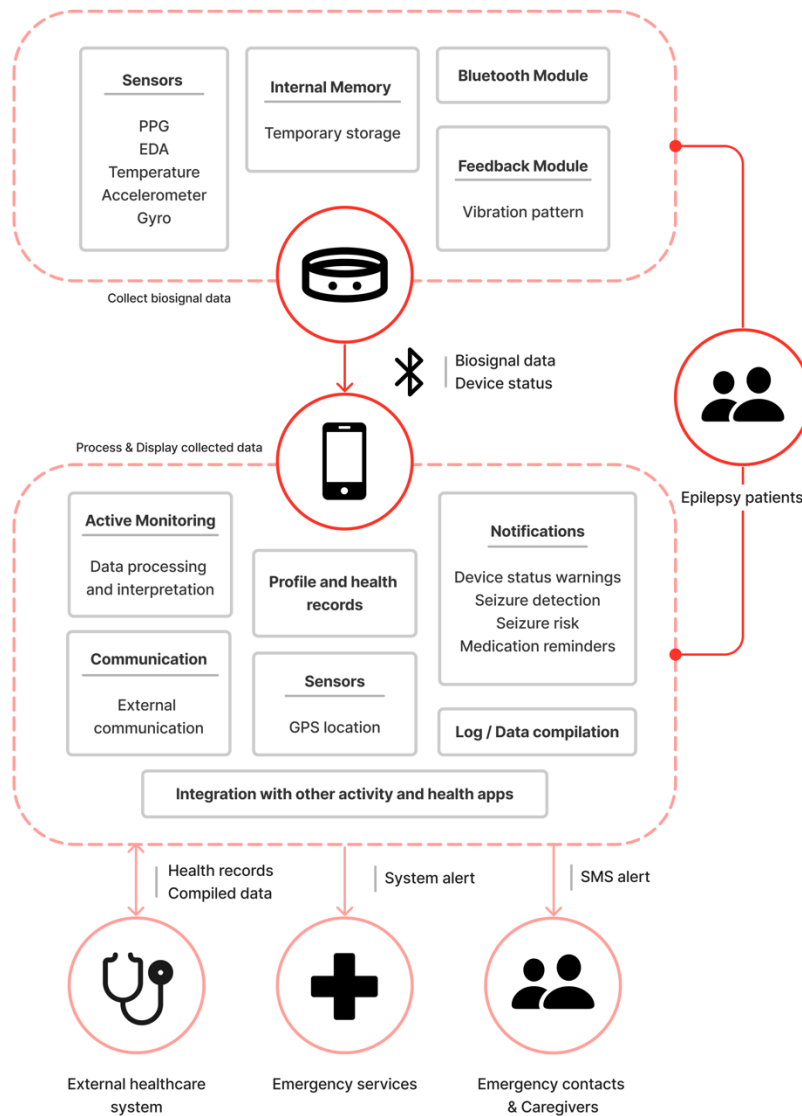


Figure 35. Overview of the system.

The application is then responsible for continuously processing and interpreting the biosignal data, which allows for seizure monitoring and verification that the device is correctly worn. In case of a detected seizure, the application must present an emergency screen with vibratory and/or auditory alarm; if confirmed, must alert emergency contacts through a preferred communication channel (it is also possible to do so with emergency services, given integration with their request system), with information on the user's profile, and their current location, provided by the smartphone's GPS location. Protocols for external communication must be established. Additionally, warnings related to the received device status, medication reminders and high

assessed level of seizure risk must also be facilitated by the application notification system, according to user preferences. Integration with other health and activity applications on the patient's smartphone is crucial, as their data (along with the collected and compiled data on seizure history and associated patterns) is applied in seizure risk assessment processes.

The smartphone stores not only the record of confirmed, detected seizures (date and time, duration, physiological manifestation, among others), but allows users to add to this data with their own notes, which improves the characterisation of the seizures (aura, triggers, post-ictal consequences, among others). If it is possible to establish data transfer protocols with external healthcare systems, this compiled data can be synchronised to the medical records of the patients, and accessed by their medical team, and the patient can access important health information related to their medical records, such as diagnosis, notes from past appointments, prescriptions, and treatment plans.

Furthermore, and based on the results from the user questionnaires pertaining to the preferred application characteristics, as well as information retrieved from the different solutions available, we are able to identify specific features and their content and categorize them into an initial information architecture (Figure 36). Particularly, the following categories and features can be defined:

- Dashboard: this category encompasses all the simplified information users should have quick access to, in order to be informed of their current health status and the basic status of their paired wearable device. As such, it should include simplified information, which should be represented visually through easily recognizable iconography and short texts (in order for users to easily capture all information), on the device status (battery, connection, acquisition status), biosignal status (information solely on the interpretation, no raw information), risk of seizure (indication of a level); it should also include a button for autonomously reporting an emergency, which is crucial as not all seizure are detected by the device, and a quick access to medication reminder (scheduled for the time of their choosing, with the option to immediately check the medication as “taken”).
- Device: this category is an expansion on the simplified information which integrates the previous category, encompassing detailed information on the device status, access to a troubleshooting guide, and the live visualisation of the collected biosignals in the form of graphs.

- Log/Diary: this category contains the information from two different sources, the application and the user. The former contributes to this information with data on confirmed seizure occurrences (date, time, duration, physiological data in pre-ictal, ictal and post-ictal stages); the latter contributes through self-reporting, subjective data, where patients are able to register symptoms, auras, lifestyle choices, triggers, and other information which complements the seizure data, allowing for a more comprehensive and holistic view of the condition.
- Personal area: this category pertains to the information of emergency contacts, including list of contacts, and preferences for contacting each; and the integration with external healthcare systems which provides access to the user's medical records and profile, and allows for a synchronisation of the data compiled (previous category).
- Community: this category pertains to the content of epilepsy management information, for the purpose of educating and providing new information and tools to patients with epilepsy; community forum may also be encompassed here, allowing users to interact with posts of other patients with the same condition, strengthening the sense of community and allowing an exchange of knowledge.
- Settings: this category encompasses the settings for the application itself (allowing users to change the language, appearance, font size), the wearable device (battery saving options, pairing and unpairing the device), and, more importantly, notifications for seizure detection, seizure risk assessment, and medication, ensuring that the notification system can be tailored to meet to each user preferences.



Figure 36. Information architecture.

The definition of this information architecture serves as a foundation to define the structure of the application flow, particularly different screens and how they interact with each other. It is important to note that this is an early-stage information architecture and might not directly translate to the architecture of the application, as some categories might be integrated and become contained by others (particularly as not all categories present the same level of prioritisation).

5.4.3 Develop

From the defined information architecture, where we were able to understand certain hierarchies of information, sketches for the initial flow of screens were created (an example on Figure 37); at this stage, the application would open from the main dashboard, and a navigation menu on the right bottom corner of the screen (easily accessible) allows users to access their journal, the detailed information on the device; top options allowed users to access their profile, and settings. This was then refined, as it was important for the main screen to contain much more information in order for users to quickly gather simplified information and understand their health status, and the spreading of menu options in multiple corners provided an unwanted level of complexity to the screen. While using rapid sketching to refine the flow of the application, it was also noted that specific decisions must be further evaluated; for instance, to understand whether the access to the feature of data and should be available in the Log screen (where the compiled data is presented and edited) or the Profile screen (the touchpoint with healthcare systems, where the medical records are accessed). Until further evaluation, it was decided that manual sharing would be available at the Log screen, allowing users to export their data to a PDF file, and sharing through synchronisation would be provided on the Profile screen; we acknowledge that this may be, however, unnecessary separation of feature access.

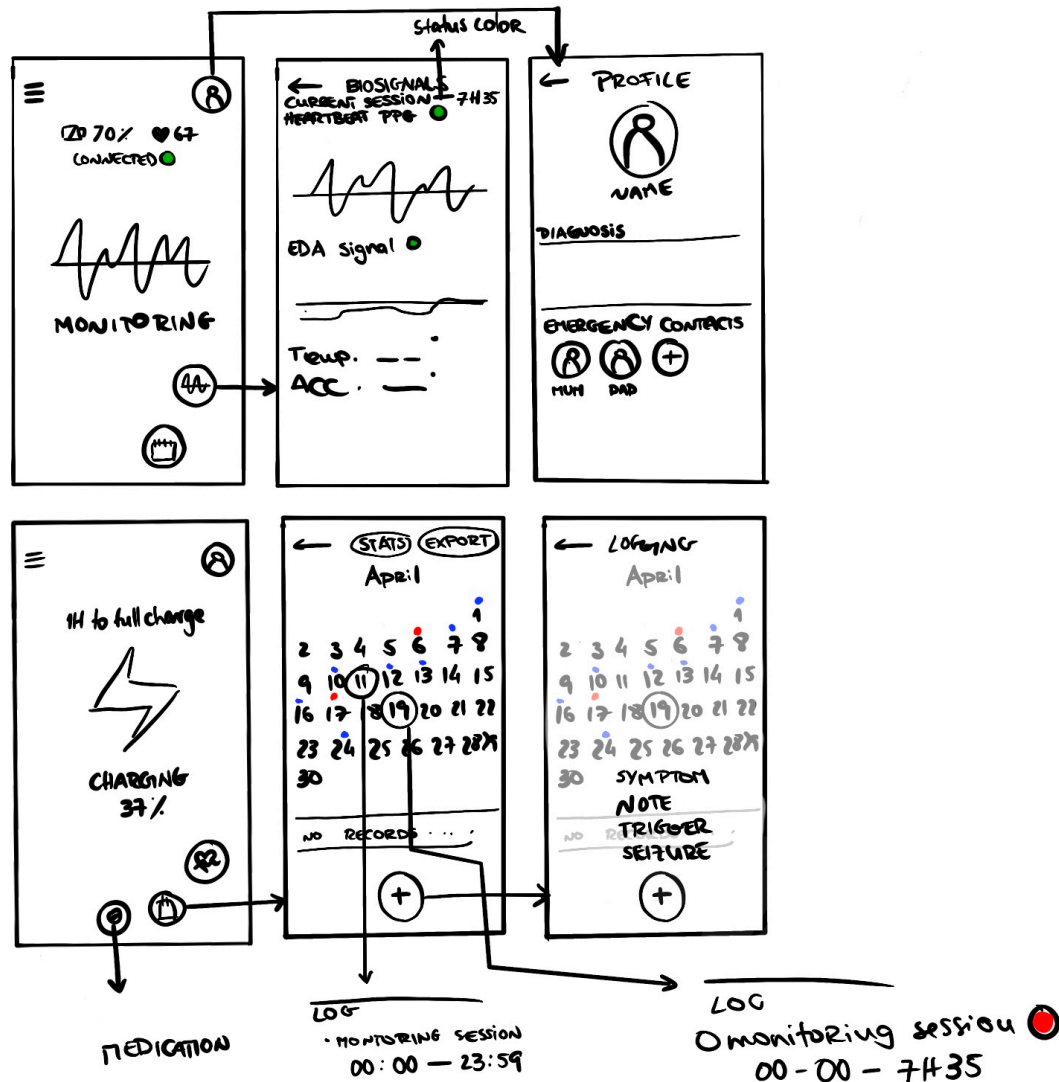


Figure 37. Initial sketches of different screens.

After rapid prototyping through sketches, corresponding wireframes were produced in Figma for the more relevant screens, to create a foundation for future developments of the digital solution. Each wireframe, and its analysis and annotations are available from Figure 38 through Figure 42; they are also available in Appendix M (without annotations). The developed wireframes refer to the categories of Dashboard, Log, Profile and Settings. Community was not included at this stage, due to a reduced priority when compared to other features. The wireframes present a navigation menu on the bottom of the screen; the expected interaction for the navigation menu is that, by clicking the icon of the desired screen, the bubble expands with its title.

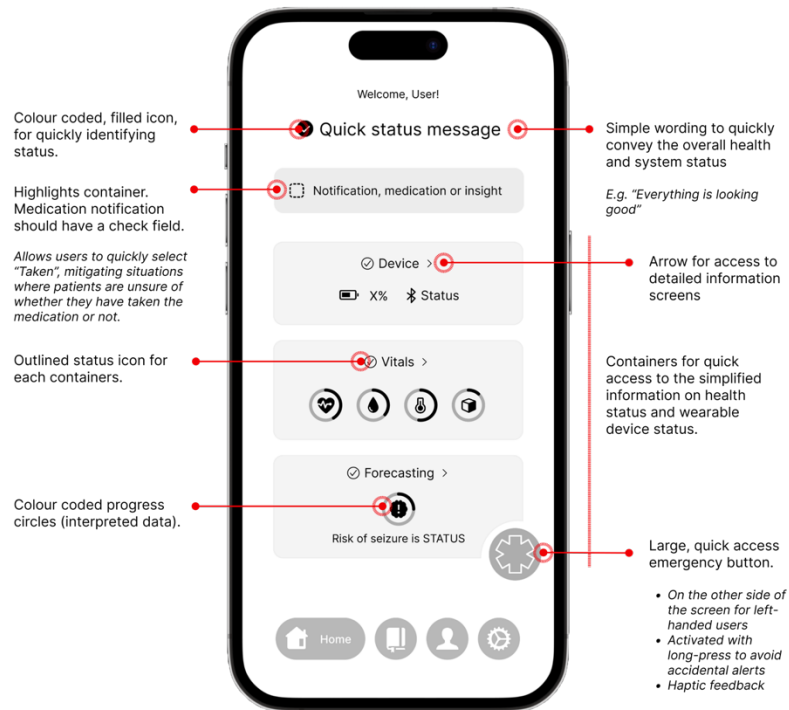


Figure 38. Wireframe for Home screen (Dashboard).

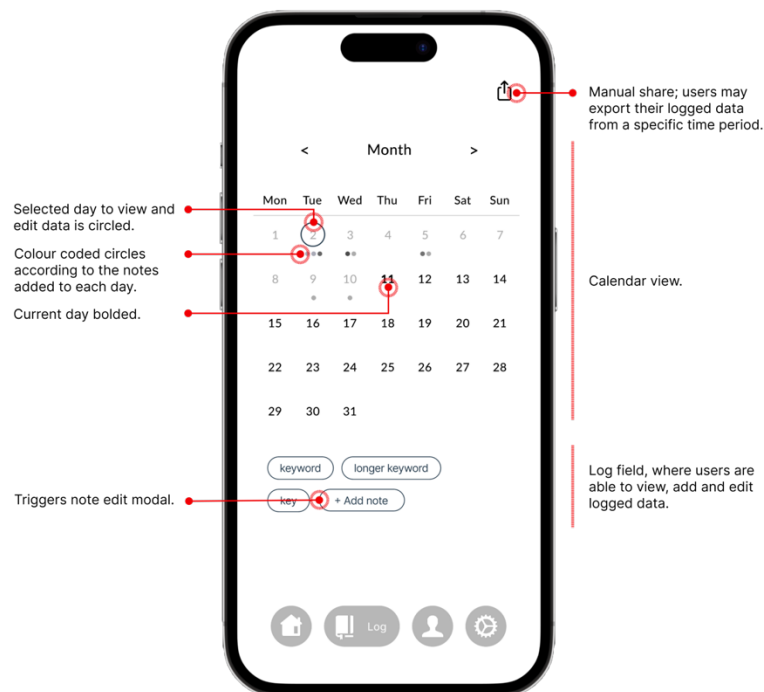


Figure 39. Wireframe for Log screen (seizure diary).

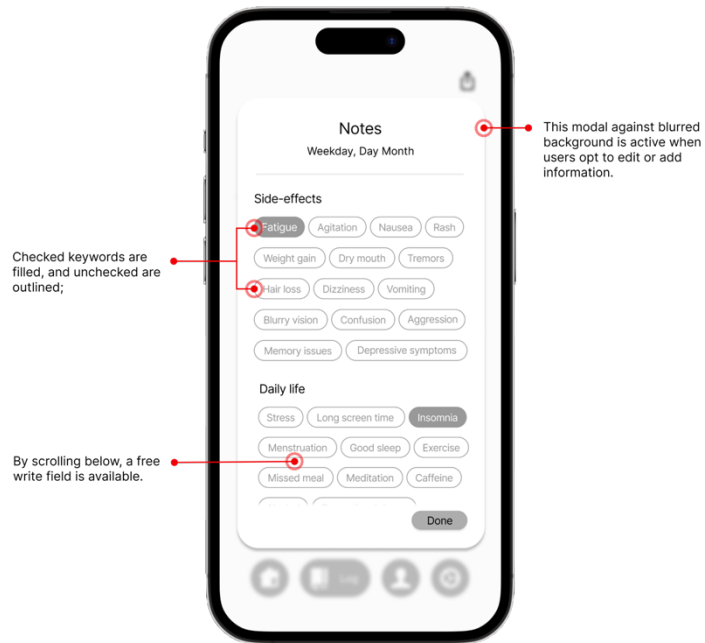


Figure 40. Wireframe for note editing modal (seizure diary).

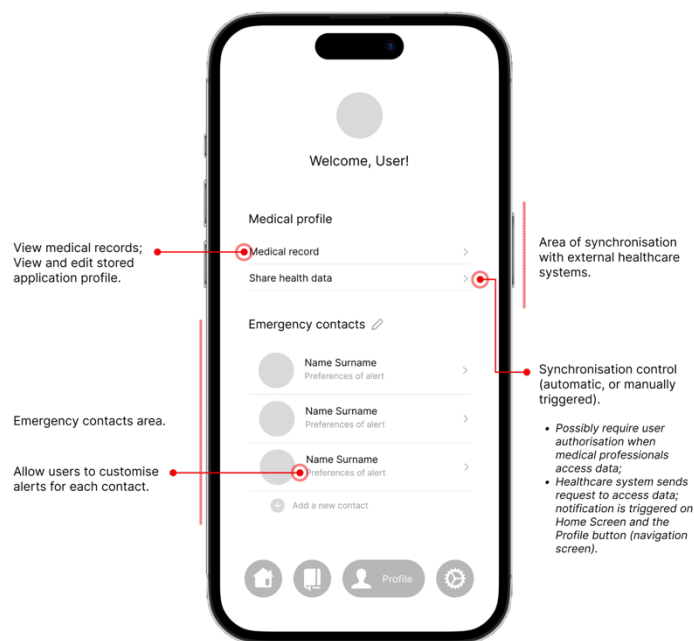


Figure 41. Wireframe for profile screen.

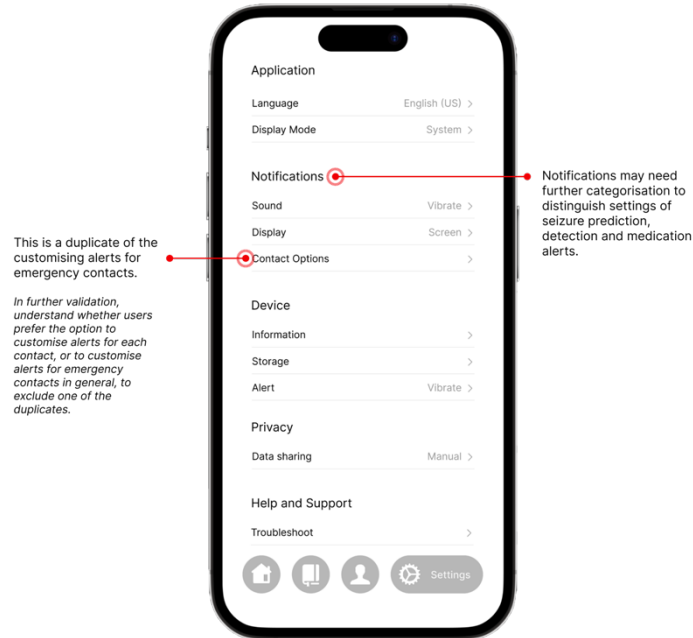


Figure 42. Wireframe for settings screen.

In future developments, it is also important to consider the creation of a colour palette consistent with the scope of the application; our suggestion would be to apply a palette encompassing neutral and blue colours, as blue is often associated with the identity archetype of Caregiver/Caretaker and to medical and health related environments and products. It is also important to consider the accessibility of the app at each design decision, taking into account the appropriate font sizes (important information should be presented at a minimum 16px to ensure readability), component sizes (buttons and icons should be visible, with a minimum clicking area of 45px by 45px), and offer screen reading.

5.4.4 Deliver

In this subsection, we will discuss the assessment of the application's viability and functionality in the perspective of user experience. While the development of the application itself lies beyond the scope of this thesis, we will focus on providing an outline and suggestions regarding the testing stage in order to validate and evaluate the digital application, should it be part of future developments. It is important to note that, alike the explored process throughout this work, the smartphone application development should follow an interactive design methodology, where user

testing should be applied at each iteration, in order to ensure that user preferences, needs and requirements are met, and overall positive user experience, as it will impact the adherence of the digital solution. For testing stages, we suggest A/B testing, usability testing (including user flow/ task completion, and possibly the analysis of user interaction heatmaps and analytics analysis, in the case of autonomous user testing), and heuristics evaluation.

A/B split testing should be applied to evaluate different variations of the UI elements; we suggest the application of this test to evaluate the layout of the home page/dashboard, particularly the structure and amount of information that may be preferred, as well as variations for the colour scheme of the application. The type of text, such as a different wording for the feedback message regarding the overall health and device status, as well as the notification and insights text, displayed on the home page, which may help determine whether specific wordings are more effective at communicating the necessary tone (may that be at conveying relaxation, or emergency).

We suggest that usability testing should be applied at every iteration, including evaluation and validation of wireframes, and throughout the iterations of mock-ups, and the high-fidelity prototypes. While usability testing should be tailored to each different stage of the digital product, a qualitative and quantitative approach must be taken in order to obtain more comprehensive results, where qualitative feedback can be correlated to statistical results. In order to facilitate qualitative results, usability testing sessions must be accompanied by the researcher, in order to ask questions throughout; this is useful as particularly in situation where a participant is seemingly blocked, taking longer than expected, or repeating similar mistakes during a task. In situations where usability testing is performed autonomously, that is, without the presence of a researcher, we suggest the utilization of an external platform, to allow the recording of the full interaction of the participant with the digital solution and the analysis of resulting heatmaps, in order to identify problematic areas and usage patterns to evaluate and validate the application and support design decisions. For quantitative measures, specific metrics can be defined, such a level of completion, time taken to perform a task, number of taps, number of errors or deviation from the user flow. While tasks, and their complexity, must be tailored depending on the development stage or the specific features or design choices performed in a specific iteration, we suggest the following tasks/scenarios and associated user flows:

- Request immediate help: this task concerns the ability to quickly, in case of emergency, such as an undetected seizure, manually alert emergency contacts and/or emergency services. Given being an emergency feature, it should be easily available on the main screen. Suggested user flow would be for the participant to open the app, to the default main screen, and long-press an emergency alert button.
- Log a symptom and a trigger on the previous day: this task concerns the log feature, where users are able to visualise and edit their data on seizure occurrences, symptoms, auras, side-effects, triggers, and other important notes. This scenario would require the participant to open the app to the default home screen, use the navigation menu to select the Log or Diary screen, select the correct day on the calendar and select the button to add a note to that day. Following that, they must scroll the list which appears on the modal, check select a symptom, check select a trigger, and confirm (selecting two options allows us to verify whether participants do it in the same modal, or whether they select a symptom, confirm, and repeat the process for the trigger).
- Check your current heartrate (bpm): this task concerns the access to the live visualization of the data acquisition, rather than observing the simplified version on the main screen. Suggested user flow requires the user to open the app to the default main page, select a button in the area of the simplified biosignals which allows them to see in higher detail (or similar indication); this will navigate the user to the modal or screen of live biosignal monitoring, where they must verify the value next to the heartrate.
- Export your data to a PDF: this task concerns the ability to manually export the data to a PDF file and share it at their leisure. By performing this task, we are able to understand and define whether it is more intuitive that the share option is on the Log/Diary screen, or the Profile, depending on the interaction flow of participants and whether or not it deviated from the user flow.
- Change your notifications to audio alarm: this task concerns the ability to change the feedback of the application according to user preferences. The expected flow would be for the participant to navigate to the Settings screen from the main page, select sound from the category of notification settings, and selecting the correct choice. Another variation may request users to customise it further, by changing the sound of alarm, volume, and a specific time in which it may play.

- Cancel the seizure alert and verify if it was logged: this task concerns the emergency scenario in which a seizure is detected, and an emergency screen is presented. During this scenario, users are using the app (free exploration) when the emergency screen will appear (scheduled). The expected interaction will be for users to long press the cancel/false positive button before the countdown for the alert of emergency contacts runs out. After the disappearance of the emergency screen, users should use the navigation menu to select the Log/Diary screen and verify that there is no report of that seizure in the current date.
- Check that you have taken your medication: this task concerns the scenario in which the notification for medication appears at the scheduled time. Suggested user flow would be for the user to open the app to the default main page, find the medication notification, and check the option for Taken, causing the notification to disappear.
- Add and remove a contact to your emergency contacts: this task concerns the ability to edit the emergency contacts, who are alerted in the event of a confirmed detected seizure. The suggested user flow would be for the participant to navigate to the Profile screen from the main page, select the option for emergency contacts, select the plus button, or analogous, and selecting a contact from the list of contacts of the phone. Afterwards, the participant would select the edit option, or similar, and erase one of the contacts from the list.

Finally, Heuristics evaluations allow us to identify and assess the severity of potential usability issues in the digital product; it may be applied throughout the iterative development process, but given the possibly elevated effort to perform Heuristics evaluation, as it is necessary to recruit experts in the field of UX/UI, or similar expertise, and the same expert must not participate in more than one stage of evaluation (to avoid skewed results), we suggest the application of Heuristics evaluations to validate the last iteration in mock-up development, and in high fidelity prototype development.

Chapter 6

6 Conclusion

This thesis explored the design process of a long-term, continuous epilepsy monitoring wearable device which incorporates textile electrodes for EDA signal acquisition; the process followed a double diamond methodology in each of the four stages of development. The first stage consisted in defining three shape and coverage area alternatives for the initial briefing, which was a textile-electrode hand-worn wearable; a stage of user testing was performed, using sketches and tangible models, to evaluate which would be the preferred alternative. The preferred area of coverage overall involved placing the textile electrodes on the thenar eminence of the palm, with the acquisition unit on the wrist; from interviews, participants also revealed a preference of familiarity over less extensive coverage area, that is, larger coverage area is preferred to a smaller, less noticeable one, if its placement and shape resemble a familiar product. This testing stage was followed by expert interviews, where the themes of development priorities, coverage area shape, sensors and technical issues were discussed; wrist-worn wearables were suggested as a preferable alternative to hand-worn ones, particularly considering human-related factors, such as comfort, invasion, and discretion. However, it was suggested that user experience should not sacrifice functionality and data quality. Priorities such as adjustability, robustness, breathability, and sanitisation were also mentioned. From the collected feedback, the second phase of development concerned the shift from a hand-worn device to a wrist-worn one; during this stage, three alternatives for the placement of components were discussed with experts, with the preferred alternative included placing the acquisition unit, which included a PPG sensor, on the dorsal area of the wrist, and the textile electrodes on the volar area of the wrist. To validate electrode placement, an experimental study was conducted with eleven participants, using standard hydrogel electrodes in the palm, the gold standard, and the volar wrist, for a direct comparison. EDA results demonstrated a higher quality signal in the palm, as expected, but validated the viability of the wrist, with a Pearson correlation of 0.53 and cosine similarity of 0.9; improving the quality of

sensors could yield better results for wrist readings. The third phase of development concerned the definition of the conceptualised solution, production of a non-functioning model (due to resource constraints it was not possible to produce a functioning prototype) which allowed us to evaluate user experience for three days, through user diaries, with six participants with an epilepsy diagnosis. Quantitative and qualitative analysis of the extended user experience study demonstrated an overall positive reaction to the device, considering obstruction, discretion, and comfort; a positive evolution in their experience with the product was also identified in some participants. The necessity of allowing users to move the wrist wearable to other body locations, such as the upper arm, in specific contexts, particularly situations in which the wrist is exposed such as washing dishes or cooking, was validated. The clasp used for opening, closing, and adjusting the bracelet, was identified as in need of improvement, where, despite users becoming more accustomed with time, it revealed itself to be difficult to close and requiring some level of dexterity, which can be particularly challenging for the older population. It was observed that participants' personality traits and lifestyles impacted their reported experience, particularly their initial reaction to the experiment. The final phase of development concerned the initial definition of a smartphone app, which would pair with the proposed wearable solution, where the six participants from the previous study identified their priorities and preferences for the digital product. System and information architecture was defined, and wireframes were produced, as an initial contribution for future developments

Through this process we were able to identify and define requirements and preferences for extended use wearable, through feedback of participants without an epilepsy diagnosis, experts in related fields, and epilepsy patients, at each stage of this work. An important aspect to this work was a concern for the incorporation of textiles in this solution, in the perspective of sustainability (the effective sanitisation of components presents an alternative to single use medical electrodes in the clinical setting), and of user experience, as a comfortable, breathable, washable, and elastic and adjustable material (which may be particularly appropriate for children) which also creates more opportunities for a discreet and less noticeable¹⁶ form factor. Additionally, while our main

¹⁶ It is important to acknowledge that reduced noticeability does imply reduced visibility; for instance, by developing the product with the visual appearance of a familiar accessory, this product can blend seamlessly to the patient's attire. As such, we can associate reduced noticeability to not attracting unwanted attention from others, or reduced recognition of the product as a different or strange object.

focus throughout the exploration was the tangible wearable device, it was clear to us that it was not possible to discuss the physical product without introducing the complementing digital product, through which many required features are facilitated, as an epilepsy monitoring solution should involve both the physical and the digital components.

A central aspect of our exploration approach was to maintain a focus on user experience without compromising functionality, both identified as key factors in developing a medical solution, which was achieved through the involvement of experts, non-experts, and epilepsy patients in the process. Throughout this exploration, we were able to reach the secondary objectives: understand the epilepsy condition, its impact, associated practices, and the role of wearable monitoring technology; identify user and product requirements through valuable insights collected at multiple stages of the process, and apply those findings in defining and redefining design solutions; gather valuable insights from epilepsy patients and experts regarding long term monitoring functionality and experience; and propose a solution, including both physical and digital products, to serve a contribution to the foundation of future developments of a wearable device for continuous epilepsy monitoring. Thus, while we able to carry through the main and secondary objectives we proposed to achieve at the beginning of this work, certain limitations influenced the degree to which each objective was accomplished. In addition to the time constraints, which are associated with a master's thesis, two particular limitations were very impactful throughout the process. The first concerned the access to our target user group, epilepsy patients. Establishing a formal protocol with partner institutions would require a prolonged waiting time; in turn, access to patients would still be limited under said protocol, as there would be a protracted patient recruitment process. These unanticipated obstacles lead us to independently recruit people with epilepsy willing to volunteer and take part in this research; unfortunately, the number of volunteering participants remained extremely low, six patients with a confirmed epilepsy diagnosis, who, in order to avoid skewed or biased results, would only be able to participate in one stage of the development. As such, the explored process of designing an epilepsy monitoring wearable did not involve PWE throughout, but rather solely on the last phase of development, where we explored the daily life impact of the proposed solution through an extended user testing stage. The second impactful limitation concerned functional prototyping, which was also not feasible due resource constraints; access to the necessary materials, manufacturing processes, but particularly the ability to miniaturise the necessary electronic

components, would require processes and practices only available at the industrial level (which would require partnerships with manufacturers) and at great financial expense. Producing an artisanal data collecting device would be possible, utilising already available electronic components, particularly as it is already being explored at Instituto Superior Técnico; however, given the scope of this work, which was to develop this device with a focus on user experience, rather than functional validation, it would not be feasible to produce a working prototype with the defined design requirements and characteristics, without access to the aforementioned resources. In order to circumvent this obstacle, we produced a non-functioning, *dummy*, model, which allowed to evaluate the daily life impact of the conceptualised device concerning, particularly, its form rather than its function.

The explored process throughout this work revealed itself to be vastly multidisciplinary and of high complexity, requiring the collaboration of specialised expertise of multiple scientific domains, including biomedical engineering, material engineering, neurology, electronics, signal processing, data analysis, clinical validation, among others, in order to ensure a successful development. The necessary multidisciplinary approach, abundant resources, significant time and effort investments go beyond what was feasible to achieve in this research; as such, it is pivotal to acknowledge that much more must be explored, researched, performed, and achieved, and that we propose this research as a contribution to the foundation for those required future developments. To overcome the limited inclusion of epilepsy patients in the performed exploration, we propose improvements in the adopted methodology as design decisions at every stage should be validated with epilepsy patients; insights and perspectives of PWE are invaluable for creating solutions which address their unique challenges and needs, leading to a greater acceptance and adoption of the monitoring device, but also contributing to the establishment of guidelines in this field. This incorporation of epilepsy patients should be performed prior to the design stage, through user interviews, focus group, and journey mapping; during the design stage, through methods such as co-design sessions and participatory design; and through validation after the design stage, through interviews and user testing. The application of fabric materials and textile electrodes in this product must also be concerned in future developments, particularly in three areas: functional testing, user testing, and research on the improvement of conductivity. Functional testing concerns primarily the conductive fabric, used to create the electrodes and pathways which allows the device to acquire the EDA signal, and can be important not only to validate the location of acquisition (volar

wrist) but also to independently test and understand which kind of conductive thread or fabric, and type of application method would improve the quality of the signal. User testing concerns primarily the non-conductive fabric that composes the adjustable strap, and should be marketed in different materials, textures and aesthetics; these tests include comfort, feel, fit, mobility, temperature and moisture regulation, breathability, durability, skin reaction and sensitivity, door resistance, ease of care and sanitation, and colour retention; these must concern user preferences and their satisfaction with different fabrics and blends. Environmental impact of the product throughout its lifecycle must also be researched for each strap alternative provided (including recyclability and its associated cost), as well as mechanical properties which may impact the structure or performance of the product. Finally, concerning the improve the performance of conductive fabrics, further research must be conducted into chemical treatments which may be applied to reduce resistivity and remove impurities in order to enhance conductivity; this should be accompanied by experimental studies in order to understand which particular treatment may be more effective in improving the quality of the data acquisition.

Concerning the proposed solution, future developments should not only revisit the extended user testing stage with a large sample of epilepsy patients and a lengthier experimental study period but should also aim to include the user experience of the children and the elderly with a confirmed epilepsy diagnosis, in order to understand whether there are specific challenges, needs or requirements particular to these age groups. Extended user experience highlighted the importance of being able to relocate the device to other body parts; as such, further research must be done to ensure functional performance is viable in these situations. The stage of development concerning the smartphone application, which pairs with the wearable device, was proposed in order to introduce a necessary path of development for the future, which must explored through its own process and methodology, with a focus on both interface design and user experience design; while contamination between physical and digital products will always occur, as they integrate the same solution, the application must not be viewed a secondary aspect to the wearable device.

It is important to acknowledge that the functionality of these types of medical devices is also heavily dependent on the quality of the sensors, the components, and the processing of the multiple biosignals acquired; thus, as technological advancements are constantly occurring, future developments should strive to explore and include new sensing technology, alternate energy

sources, new miniaturisation techniques, and other progressive features, when these do not compromise functionality or user experience, with the aim of constantly improving the quality of the epilepsy monitoring solution.

Considering the chosen development methodology, we found it a challenge to correctly follow and apply the Double Diamond. The development process revealed itself to be more effort-intensive in the Develop and Deliver stages, as these produced the results which were then directly applied in Discover and Define, leading to an imbalance of elaboration across the methodology stages. Additionally, and as a result, the Discover stages tended to be a collection of knowledge and conclusions produced in Deliver stages, rather than a collection of newfound and newly sourced knowledge particular to that stage. The overall challenge to converge the development process and the chosen methodology is also visible in the execution of four iterations of the Double Diamond as a whole, rather than returning to previous stages with new results and conclusions, leading to a linear application of the methodology, which is not the intended one; this also resulted in near non-existence of the Problem/Challenge, Problem/Challenge Definition and Solution touchpoints. As such, we conclude that the Double Diamond, as applied throughout the development process, is not the most appropriate application of the methodology; future work regarding the showcased design process should consider applying a tailored version of the Double Diamond, or applying a different methodology that best compliments the needs and flow of the design process.

Since the nature of this research requires a multidisciplinary approach, the collaboration established with Instituto Superior Técnico played a pivotal role in this work, by not only facilitating access to necessary materials and protocols, but also by providing invaluable expertise in different fields; thus, we highlight the importance of maintaining collaborations with institutions of other areas of expertise in future developments, as this significantly enhances the quality of the, not only the development process, but of the solution.

This exploration's findings contribute to the area of design for health and wellbeing as well as future developments of design of medical wearable devices for epilepsy monitoring. The overall aim should be the development of a long-term, continuous epilepsy monitoring wearable device which not only follows user experience stuff to improve the well-being of patients, but also ensures effectiveness and performance to improve their safety, while pairing with a digital product that facilitates interaction with the wearable product, and complies with the medical standard and

protocols in order to be marketed and available to patients and medical professionals as an effective medical device.

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Appendix

A – Applied questionnaires in the user preferences study.

Questionnaire 1 – Sample characterization		
Variable	Question	Answer type
Sex	Indicate your sex.	Multiple choice
Age	Indicate your age.	Number
Area of expertise	Indicate your area of expertise.	Multiple choice
Occupation	State your current occupation.	Free text
Wearable experience	How would you describe your familiarity with wearable devices?	5-point Likert scale between “Very unfamiliar” and “Very familiar”
Wearable devices	Which wearable devices are you familiar with, use or have used?	Multiple selection
Glove familiarity	Approximately, how often do you wear gloves (of any type)?	Multiple choice
Glove types	Which types of gloves are you most familiar with?	Multiple selection
Questionnaire 2 – User experience; single model		
<i>Attractiveness. Overall impression. Do I like or dislike it?</i>		
Annoying ☐ ☐ ☐ ☐ ☐ Enjoyable		
Good ☐ ☐ ☐ ☐ ☐ Bad		
Unlikeable ☐ ☐ ☐ ☐ ☐ Pleasing		
Unpleasant ☐ ☐ ☐ ☐ ☐ Pleasant		
Attractive ☐ ☐ ☐ ☐ ☐ Unattractive		
Friendly ☐ ☐ ☐ ☐ ☐ Unfriendly		
<i>Perspiciuity. Is it easy to get familiar with the product and learn how to use it?</i>		

Not understandable	☐	☐	☐	☐	☐	Understandable
Complicated	☐	☐	☐	☐	☐	Easy
Clear	☐	☐	☐	☐	☐	Confusing
Cumbersome	☐	☐	☐	☐	☐	Not cumbersome
Efficiency. <i>Can I solve my tasks without unnecessary effort? Is the interaction efficient and fast?</i>						
Fast to put on and take off	☐	☐	☐	☐	☐	Slow to put on and take off
Easy to put on and take off	☐	☐	☐	☐	☐	Difficult to put on and take off
Impractical	☐	☐	☐	☐	☐	Practical
Dependability. <i>Do I feel in control of the interaction? Do I feel safe when wearing the product?</i>						
Obstructive	☐	☐	☐	☐	☐	Supportive
Secure	☐	☐	☐	☐	☐	Not secure
Meets expectations	☐	☐	☐	☐	☐	Does not meet expectations
Stimulation. <i>Is it exciting and motivating to use the product? Is it fun to use?</i>						
Valuable	☐	☐	☐	☐	☐	Inferior
Boring	☐	☐	☐	☐	☐	Exciting
Not interesting	☐	☐	☐	☐	☐	Interesting
Motivating	☐	☐	☐	☐	☐	Demotivating
Novelty. <i>Is the product innovative and creative? Does it capture my attention?</i>						
Creative	☐	☐	☐	☐	☐	Dull
Inventive	☐	☐	☐	☐	☐	Conventional
Usual	☐	☐	☐	☐	☐	Leading edge
Conservative	☐	☐	☐	☐	☐	Innovative

Comfort. <i>Would I feel comfortable wearing this for long periods of time?</i>			
Bothersome ○ ○ ○ ○ ○ Not bothersome			
Tolerable ○ ○ ○ ○ ○ Intolerable			
Comfortable ○ ○ ○ ○ ○ Uncomfortable			
Questionnaire 3 – User acceptance; model comparison			
For each statement, indicate which model/shape best applies.			
	Thumb/Inner palm	Little finger/Outer palm	Index and middle fingers
I would feel uncomfortable	☐	☐	☐
I would feel comfortable	☐	☐	☐
It is practical	☐	☐	☐
It would be easy to put on/take off everyday	☐	☐	☐
It is complicated to put on/take off	☐	☐	☐
Makes me feel weird	☐	☐	☐
I feel like people would stare	☐	☐	☐
Makes me feel different	☐	☐	☐
Interferes a lot in daily activities	☐	☐	☐
Does not interfere with daily activities	☐	☐	☐
Makes it hard to go about my daily life	☐	☐	☐
Would have no influence in my daily life	☐	☐	☐
This seems the most discreet	☐	☐	☐
This seems the least discreet	☐	☐	☐
I like this glove	☐	☐	☐

I dislike this glove	☐	☐	☐
It seems a constant reminder of a condition	☐	☐	☐
I would forget that I am wearing it.	☐	☐	☐
It does not interfere with my hand movement	☐	☐	☐
It is obstructive	☐	☐	☐
I would stare if someone else would wear this glove	☐	☐	☐
I feel like other people would be indifferent	☐	☐	☐
I would never wear this daily	☐	☐	☐
I could see myself wearing this everyday	☐	☐	☐

B – Relevant transcriptions from Expert interviews.

Theme 1 — Wearable development priorities	
Expert 1	<i>Comfort, and functionality of course. Visibility, in the case of epilepsy patients, is very important to consider. Not in our project, since acquisition is for a couple of hours, and it's not something worn on the day-to-day, it's used in a specific context, so visibility is not a concern, necessarily. But for daily wearing, for subjects with epilepsy, it's important for it to be discrete, or hardly noticeable. (...) Functionality is crucial, it's important to make sure the PPG and the EDA signals are strong, and that they don't create artifacts. The PPG can't be too loose or too tight. And same with the EDA, if the product doesn't allow the skin to breathe or if it's too tight, it's going to influence results and false positives.</i>
Expert 2	<i>In the project we're developing, our priorities are the comfort of our users, that is, non-invasive, doesn't hurt, doesn't look weird, or like a strange body. But also, functionality and the quality, it's preferable to have a functional, robust and efficient device, that is long-lasting and transmits efficiently. The EDA signal is a very difficult signal to capture correctly, it's less studied, and it's heterogeneous, it varies a lot amongst subjects. It's already hardly reliable, so it's necessary to ensure and maximize that functionality. (...) If the material gets warm, or it's too tight, it can make them sweat excessively, which can interfere with the EDA signal, create fluctuations and incorrect results.</i>
Expert 3	<i>The priorities are signal acquisition but also form factor. In fact, the form factor should be validated with users without epilepsy, but specially patients with epilepsy. That's crucial. An idea for testing the form factor is to simulate the product, like a dummy version, simulate size, weight, compression, everything.</i>
Expert 4	<i>I believe the main priority is to produce an adaptable form factor that can be adjusted to multiple individuals, and easy to reproduce. For instance, a 3D printed model. With a model you can easily and quickly produce copies. That's crucial in a hospital environment, because you need a prototype for each patient. (...) It's also very important that it's breathable and easy to assemble. In the hospital, patients are in closed rooms, it's warm inside, and our product acquires a bad smell with usage, so it's important to consider fabric hygiene and sanitation.</i>
Expert 5	<i>I think the priority should be data acquisition but also the comfort of the patients, since they're going to use the product every day.</i>
Expert 6	<i>User experience is very important in long term use cases, the comfort of the materials, and discretion. But given the scope of your project, epilepsy monitoring and seizure detection, the quality of the signals and the acquisition is very important as well.</i>

Theme 2 — Ideal coverage area shape	
Expert 1	<i>I think either the first or the second ones could work. However, I think the ideal would be a band, one that goes around the middle area of the hand, similar to the Mindprober. You could remove it, could be adjustable and worn on other places, like the upper arm. Move it to the wrist, to the arm, maybe. However, just like what happens with Mindprober, it can become too bulky of a device.</i>
Expert 2	<i>Best option would be a band, or like a strip, something adjustable. It's better secured, adaptable. (...) From the models you have shown me, the little finger model seems sensor safe and best in functionality.</i>
Expert 3	<i>It could be both the thumb and the little finger models, either. The problem with these models during hand movement is that there's moments where distance between opposing sides of the hand decreases, such as when someone closes their hand or moves them in a specific way, this will create loose and/or folding fabric. This means that the sensors won't be tight to the skin and can disrupt the acquisition. However, if you raise the fabric on the external side of the palm, it will have a larger coverage area, but it will be better secured, tighter. (...) An idea would be like a tennis bracelet, electrodes and PPG, everything, in the wrist. Might not be the best place in terms of signal, the hand and the foot tend to be the best place scientifically, but in terms of experience and comfort of the user, the wrist is better. Like the rigid Empatica bracelets. Everyone speaks a lot about comfort, but we're actually pretty limited. I mean, it's hard to get people to wear a watch every day, let alone a glove. (...) No, I haven't seen or know of something like that but textile. (...) A semi-rigid, or actually soft, band or bracelet would be ideal.</i>
Expert 4	<i>A glove or glove-like product is harder to produce than a band, let's say. The diversity of sizes, higher noise generation, the fabric degrades faster. The wrist hides better than the hand. Another thing is hygiene, which for hospital environments, is mandatory. A glove can be harder to sanitize, and also cause users to sweat more, for instance. In terms of product, a band or bracelet are easy to replicate than a glove, easier to get a universal size. But it's also the most seen type of products, wrist wearables are so common, it is harder to innovate. (...) In terms of functionality, the green model would be best. The blue one can have loose fabric in the palm, and movements can be uncomfortable. For usability either the red or the green ones. Actually, the red one, since in terms of sizing, would be easier to produce in a universal size.</i>
Expert 5	<i>On the hand, best model could be the one that involves either the thumb or little finger areas. Although, I believe the little finger one and the last one, the one with the two fingers, can generate much more noise. So perhaps, the thumb one.</i>

Expert 6	<i>I don't think the one with sensors on the fingers is doable. The thumb one, in terms of functionality, is better. The other may create noise or disruption. But it can represent loss of mobility. In that sense, the little finger one is more practical, better for users, as people tend to move that side less, so they wouldn't feel as restricted. (...) Ideal format, I believe it would be like a wristband, definitely, more comfortable.</i>
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Theme 3 — Sensors and their placement	
Expert 1	<i>Our data acquisition device measures both PPG and EDA where they're signals are easier to capture, so PPG is on the fingertip, and EDA on the palm. (...) PPG sensors should be able to measure on the wrist, I'm just not sure the ones I use can, or if the signal's good. EDA, on the other hand, I'm not sure you can read it on the wrist, I've never tried. Electrodes in the hand may not be as user friendly, but it's best to have something tested and functional than conceptual and futuristic. It's important to have the best measurements possible.</i>
Expert 2	<i>I don't have experience measuring EDA or PPG anywhere other than the hand. We use the PPG sensor on the finger, and EDA electrodes are both on the palm, but yes, PPG sensors should work on the wrist, as plenty of other devices do so. However, EDA on the wrist I'm not really sure, I'm not sure it can effectively measure the signal, so I'd recommend in-hand measurements.</i>
Expert 3	<i>Electrodes on the hand will not work for people in terms of everyday use. I would suggest, instead of the hand, placing the EDA electrodes either on the very bottom of the palm or, preferably the wrist; place the PPG sensor also on the wrist, basically pull all sensors to the wrist like Empatica. (...) Textile electrodes need to be placed close to each other, and at the same distance of the acquisition board. That is, like two electrodes on the external side of the palm instead of one on each side. The disposable gel ones don't really have this issue, mainly textile ones; they can stay farther away from the board, because the gel makes up for that distance.</i>
Expert 4	<i>Adequate sensors would be the ones you find in E4, PPG, EDA, accelerometer, and temperature. Temperature readings let you know if the user is wearing the product correctly, or whether the person is wearing it at all. (...) PPG is usually measured on the finger. It introduces a lot of noise unless a person is perfectly still during the whole acquisition; daily hand and finger movements will create noise. The PPG sensor doesn't really have to be in the finger at all, it should be in other places, and there are different types of PPG sensors with different characteristics to improve reading. (...) EDA would be great on the wrist in terms of user experience (...) however EDA varies from person to person, and wrist acquisition may work for some and not for others. It can also be too tight or too loose depending on the person, so it's uncertain. (...) But getting it all on the wrist, like Empatica, would be best in terms of usability.</i>

Expert 5	<i>I don't have actual experience with EDA signal, but I understand it's usually measured on the hand, the palm, although the ideal situation for continuous use would be to measure it outside the hand, like on the wrist. However, I believe EDA is not that easy to collect on the wrist, I'm not sure it's possible, but again, I'm not sure because I'm not very familiar with the EDA signal. (...) PPG is usually measured on the finger, but it can also be collected on the wrist to make the experience easier.</i>
Expert 6	<i>For the PPG, it's most common to place it either on the fingers or the pulse. However, a PPG sensor on the finger is not doable for daily wear, most people wouldn't wear it at all. The wrist is the appropriate place for usability in this context. (...) For the EDA, it's usually in the palm, but it partially immobilizes the hand. Wrist acquisition would be best, but it is trickier. It's possible to get an EDA reading on the wrist but, yes, can be trickier. In fact, it's best to combine it all on the wrist, like Empatica E4. (...) Signal carrying in textile electrodes has a higher resistance if the travelled distance is too large; the farther from the board, higher the likelihood of signal loss.</i>

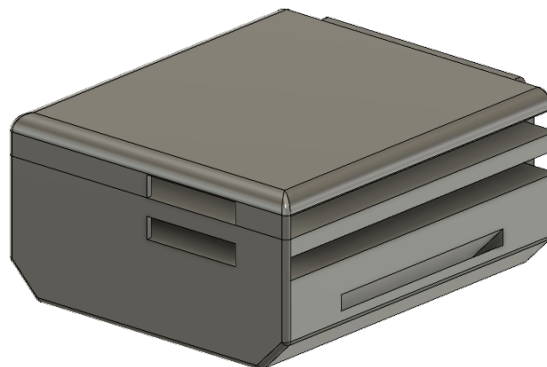
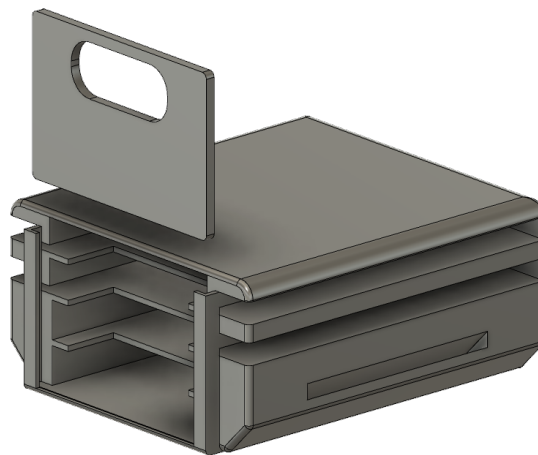
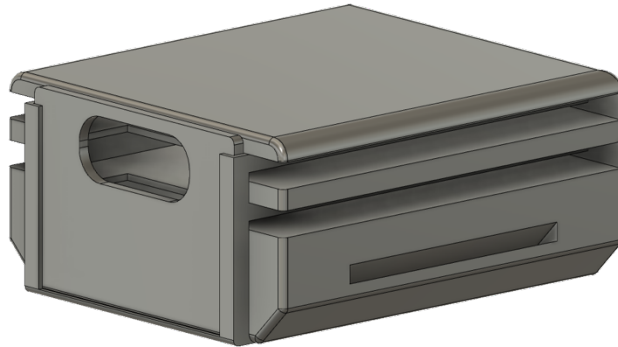
Theme 4 — Expected technical issues	
Expert 1	<i>The issues I face currently in the project are braking cables, especially the PPG cables. And there's challenges with miniaturizing everything while maintaining robustness. Additionally, the gel electrodes for EDA acquisition fall easily, it's a constant occurrence, and once they come off, they rarely stick onto the palm again.</i>
Expert 2	<i>The main issues are sanitation, the current prototype is not washable, but also sustainability, which should be a concern and taken into account, since the EDA electrodes we currently use are disposable gel ones, they're the most common. The electrodes also come off the skin frequently, especially when users suffer from hyperhidrosis, which is relatively common. Approximately, I would say, 1 in 30 of our users suffer from it. Nevertheless, sweating can also be very influenced by the environment and not the person, like the climate - a warm environment - or sweating more due to activity. These situations cause the sensors to easily come off. The textile glove you propose would solve this issue, since electrodes would still be tight to skin when sweating, but also the sustainability issue. However, the glove itself can create excessive perspiration, due to a thick material. It has to be breathable.</i>
Expert 3	<i>Main issues I encountered were during prototyping, especially the textile part, like irregular electrodes, or, especially, the conductive wires that you can weave into the fabric, they are stiff, they're not elastic, so become brittle and break when the overall fabric is pulled or, like, tensioned.</i>

Expert 4	<i>The band we use, it's seen together, so access is problematic. In case there is a functional issue, like a loose sensor or cable, we need to unstitch to open the band, and stitch it back together. For the same reason, there's no access to the LED inside that gives feedback on the status of the acquisition, on whether it's working. (...) Initially, we had some issues also because the acquisition device on the band was bulky and rigid, so we took it apart and glued on its different parts spread across the band, making it more comfortable and flexible, especially important for when users sleep.</i>
Expert 5	<i>Noise in acquisition will probably be the biggest issue. Considering the PPG, it may not be tight enough; similarly with the EDA sensor, it may have that problem as well. In fact, I face that problem with everyday fitness bracelets and smartwatches. They don't allow me to tighten it enough, correctly, so they are unable to measure my bio signals correctly. So, in that sense, size adjustment should be a priority.</i>
Expert 6	<i>In terms of technical issues, the type of communication for data transferring can generate faults and issues. Wireless communication can definitely have loss of data issues, like Wi-Fi and Bluetooth. Additionally, in the case of Bluetooth, the antenna is very sensitive and needs to be protected and probably can't be obstructed. Disposable gel EDA electrodes are also prone to coming off the skin easily. And the PPG sensor needs to be stable, can't be on too tight or too loose.</i>

Suggestions	
Expert 3	<i>Sizing for gloves can be tough, there's no universal size, every hand is different. Research the standard sizing for both men and women, see what are the sizes a big, but not out-of-the-ordinary, hand, a medium one, a small one but not out-of-the-ordinary small, you get it. Then make prototypes per each size, like clothing. Of course, having the possibility to adjust would be great, it would solve the sizing issue, like velcro or similar. But keep in mind that it's an extra feature, an extra variable that you need to worry about during specs and prototyping. (...) Conductive yarn can be weaved in a wave pattern so that it can stretch with the fabric. However, it's still brittle and when someone puts the glove or the band on too fast, or pulls too hard, it will break. So conductive lycra is a better alternative.</i>
Expert 4	<i>Separating and spreading out the electronic components can help you obtain more flexibility and less volume. (...) Using modules can be helpful, dividing the device into two modules, so you'll have your textile, washable, module and then the electronic module. (...) If you 3D print the case of the module, you can print it on a rubbery and flexible material, so it bends, especially around the wrist. I'm not sure how much it will bend, but it's an improvement.</i>

Expert 5	<i>For a proof of concept, it is okay that your setup is complex, that your prototype is bulky or is not clean as it should be, because then, for prolonged use testing, you can create a different prototype in which comfort is the priority, not necessarily measuring.</i>
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C – Images of the 3D modelled double BITalino case.



D – Informed consent (data acquisition study).



Informed Consent Form

Title. Epilepsy monitoring wearable - EDA signal measuring on palm and wrist

Context. You are invited to voluntarily participate in an experimental study developed in a collaboration between UE- IADE and Instituto Superior Técnico, conducted by the IADE MSc student Mafalda Morgado (mafaldapmorgado@gmail.com). The supervising researcher is UE- IADE Prof. Hande Ayanoglu (hande.ayanoglu@universidadeuropeia.pt) and Prof. Gianni Montagna (g.montagna@gmail.com), FAUL. This study is also in collaboration with Instituto Superior Técnico PhD student Patrícia Bota, fellow research intern Joana Brito, and Prof. Hugo Silva, who provided not only the materials necessary but also support for the operation of data acquisition.

This experimental study integrated the MSc project for the development of a wearable device for epilepsy monitoring, and epileptic seizure detection, alert and prediction.

EDA is one of the biosignals used in epileptic seizure detection, measuring the skin conductance which changes according to sweat glands activity. The preferred locations for EDA measurements are the palm or the sole of the foot.

Objectives. The goal of this study is to validate the measurement of electrodermal activity (EDA) on the wrist, by comparison with palm measurements of the same signal.

Procedure. Each session will be performed individually, with an average length of approximately 30 minutes. You will be accompanied at all times by the researcher conducting the experience.

Before starting, you will be introduced to the experimental study, and asked to fill this Informed Consent Form.

The experiment will follow the following steps:

1. On your non-dominant hand and wrist, the EDA monitoring device will be positioned, adjusted, and tested for functionality.
2. You will be required to sit with headphones on and watch three movie trailers for about seven minutes.
3. You will sit still for the next ten minutes while using your laptop, phone, or notepad, relaxing, or engaging in other comparable low-movement, low-effort activities.
4. Following that, you will be instructed to stand up and perform a five-minute light stretching session while watching a video that includes the movements. You should carefully comply with the directions on the video.
5. You will then be asked to sit down once more. For the following five minutes, you must remain seated while using a laptop, smartphone, notepad, or engaging in other comparable

low-movement, low-effort activities.

6. The monitoring device will be taken out and the data acquisition will be stopped.

Data registration and privacy. The data acquisition device will be measuring your physiological signal in real-time throughout the experiment, and storing that data locally on the researcher's computer. This data will be anonymous, only identified by age and gender.

You may request to access and eliminate the data at any time, by contacting the researcher conducting the study, Mafalda Morgado (mafaldapmorgado@gmail.com). Unless permitted by the participant, the data will only be accessed by the researcher conducting the study, Mafalda Morgado (IADE, UE), PhD student Patrícia Bota (IST, UL) and fellow research intern Joana Brito (IT-IST, UL). The data will be kept for future studies for up to 1 year or until requested elimination.

Risks. The voluntary participation in this experimental study does not represent risks greater than those of everyday life.

Participation. Your participation in this study must be done voluntarily and in an informed way. You may choose to withdraw it at any time with no consequence.

Participation and Use of Data Agreement

I have read and understood this study, and agree to participate voluntarily in this experiment by signing below.

Name:.....

Signature:..... Date:

The collected data will be anonymous, and will not be associated with your name or other information that can be used to identify you.

By writing my initials next to each purpose, I indicate which ways I allow the researchers stated as part of this study (and below referred to as "team") to use my physiological data.

I agree that the team can view and analyze my data

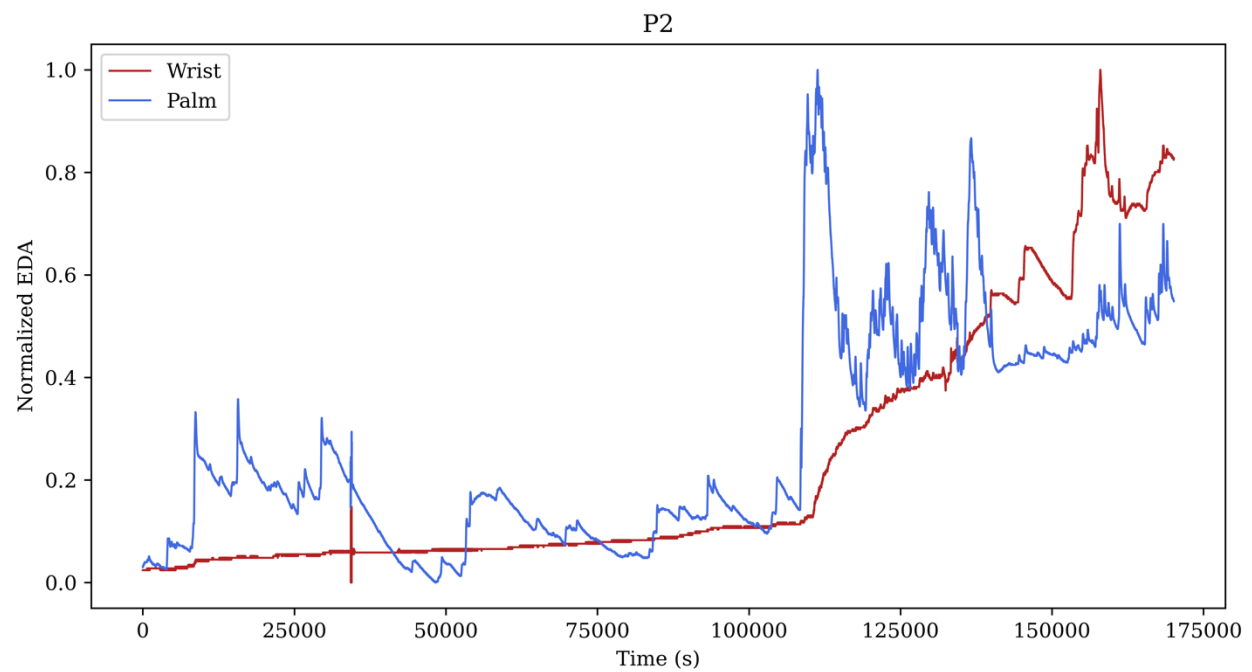
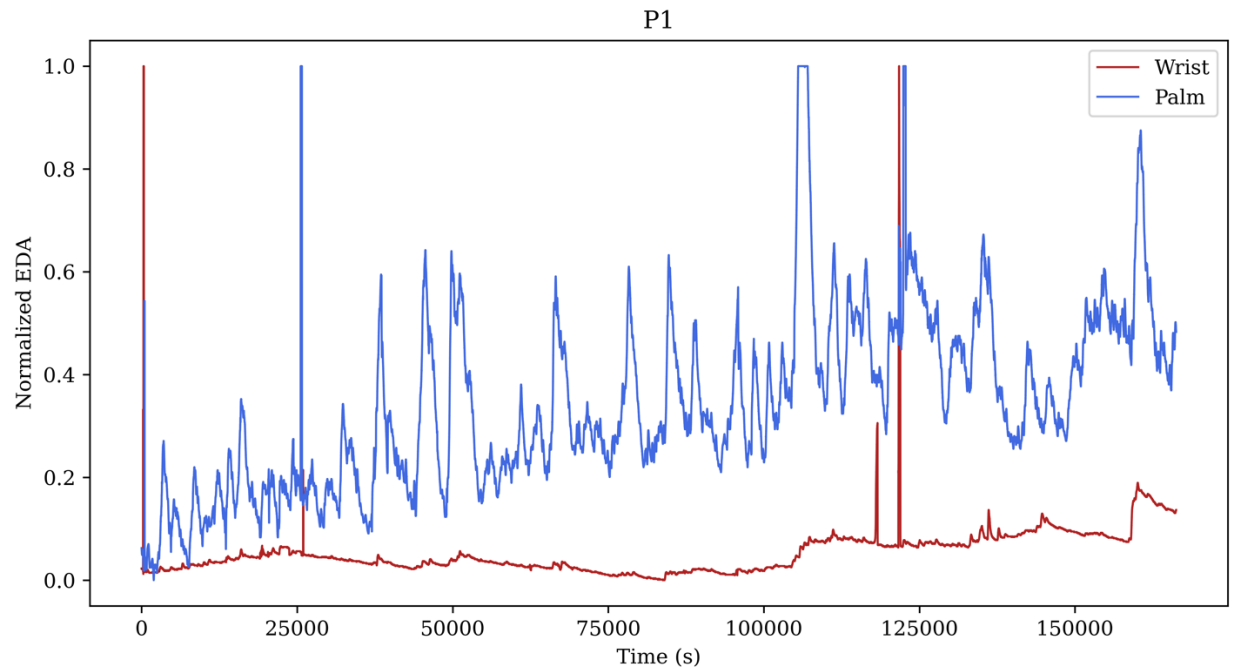
I agree that the team can share my data with partners for further analysis

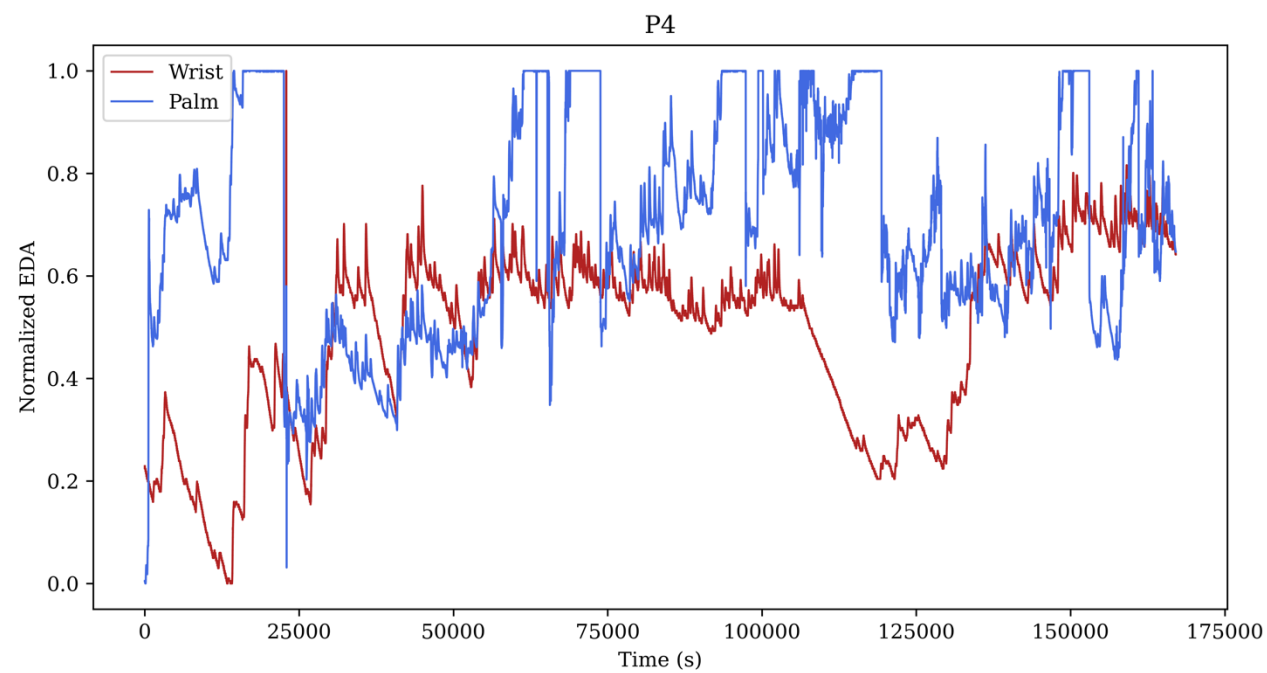
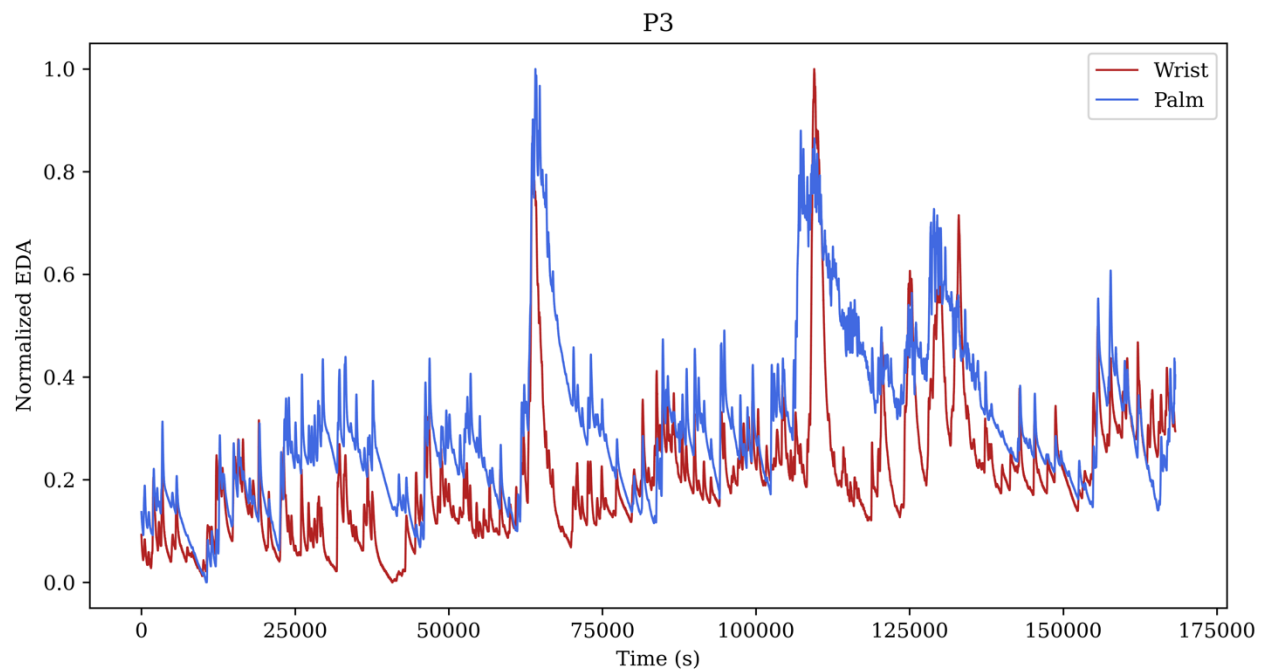
I agree that my data can be published as part of an academic study

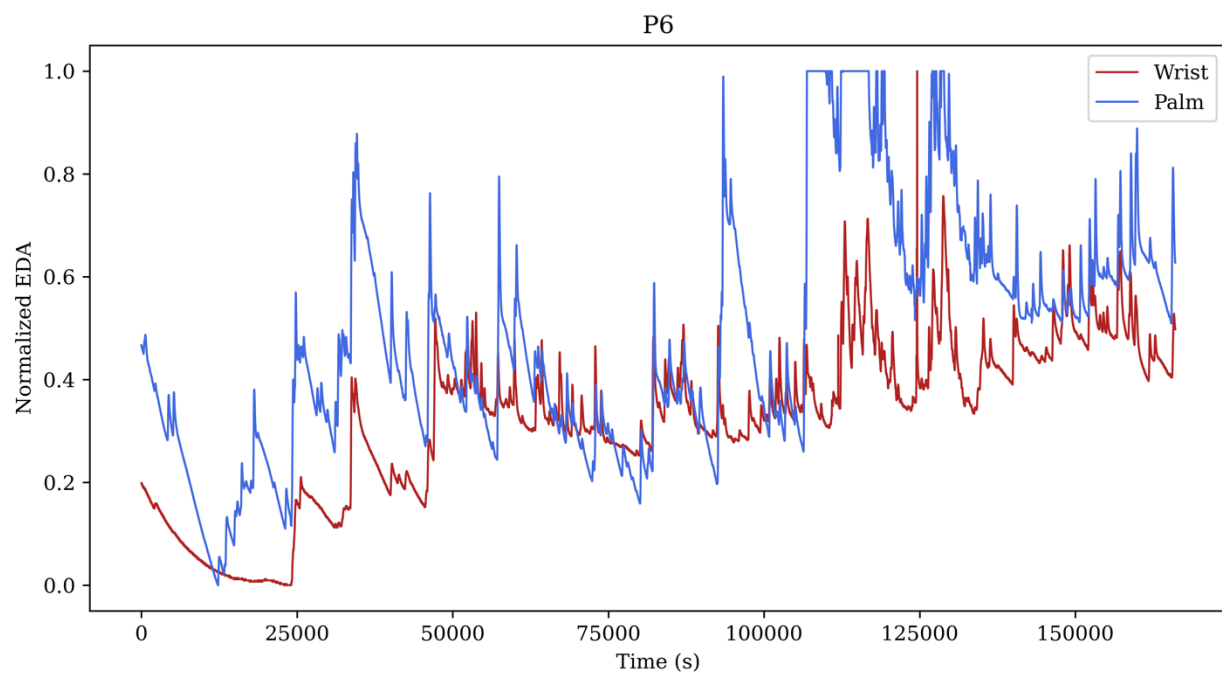
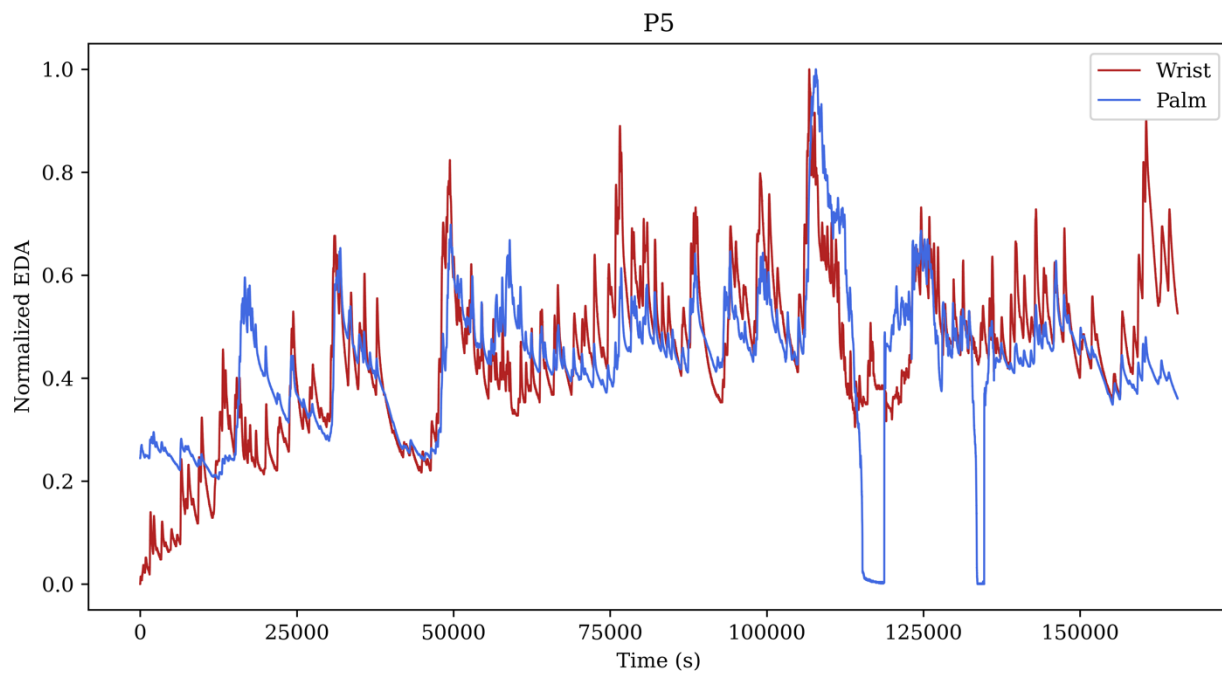
I agree that my data can be shown at conferences

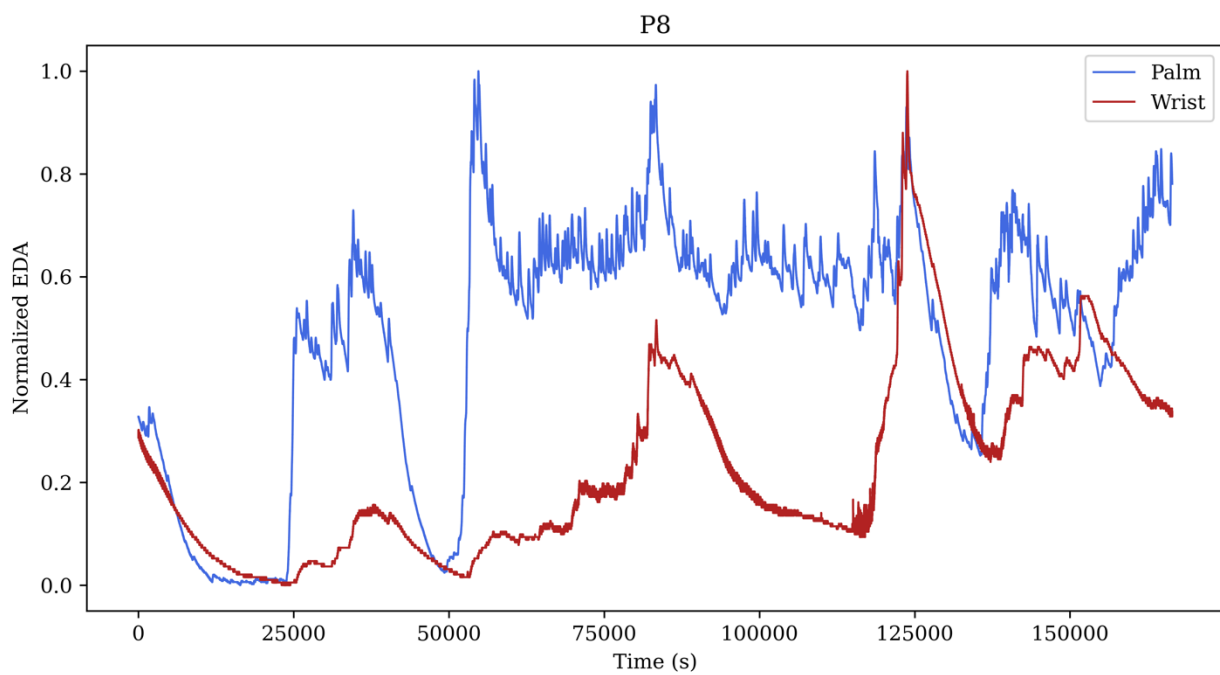
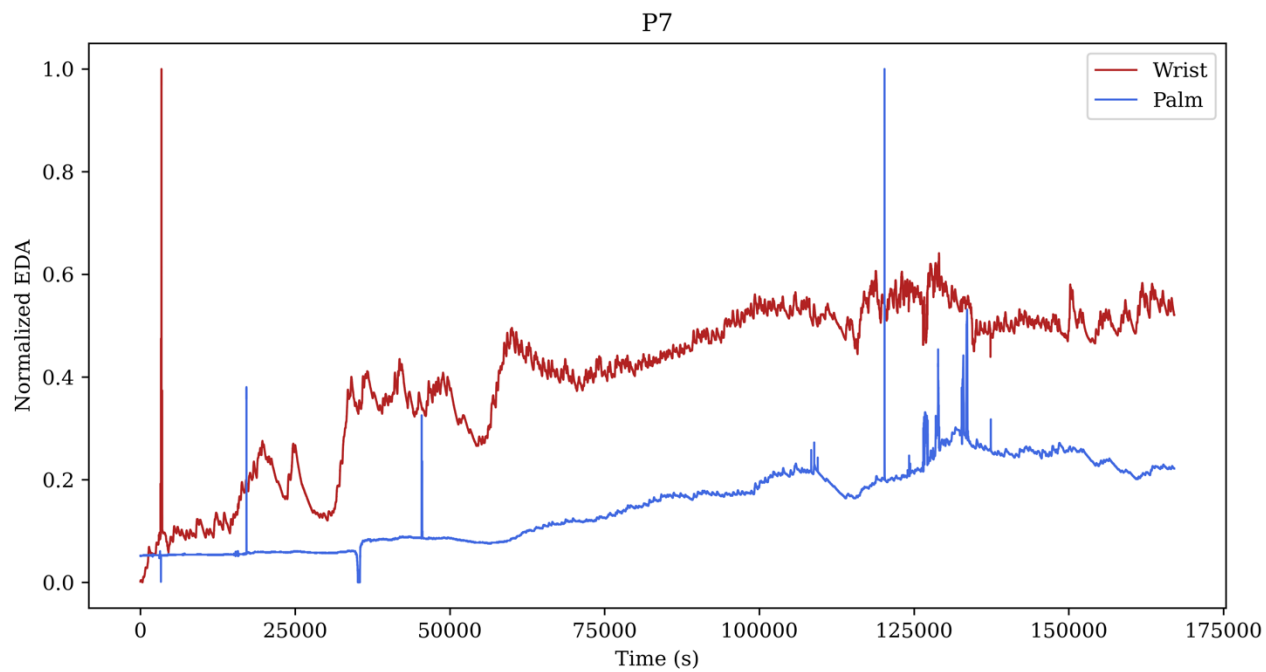
Age: Gender: Participant number:

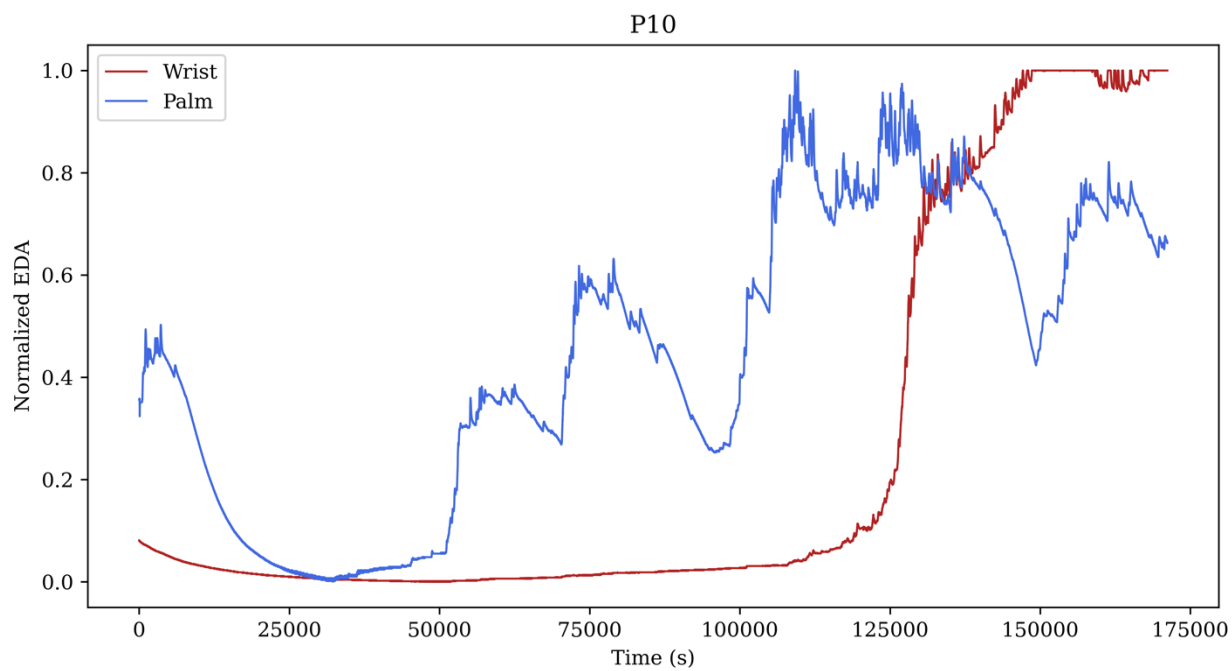
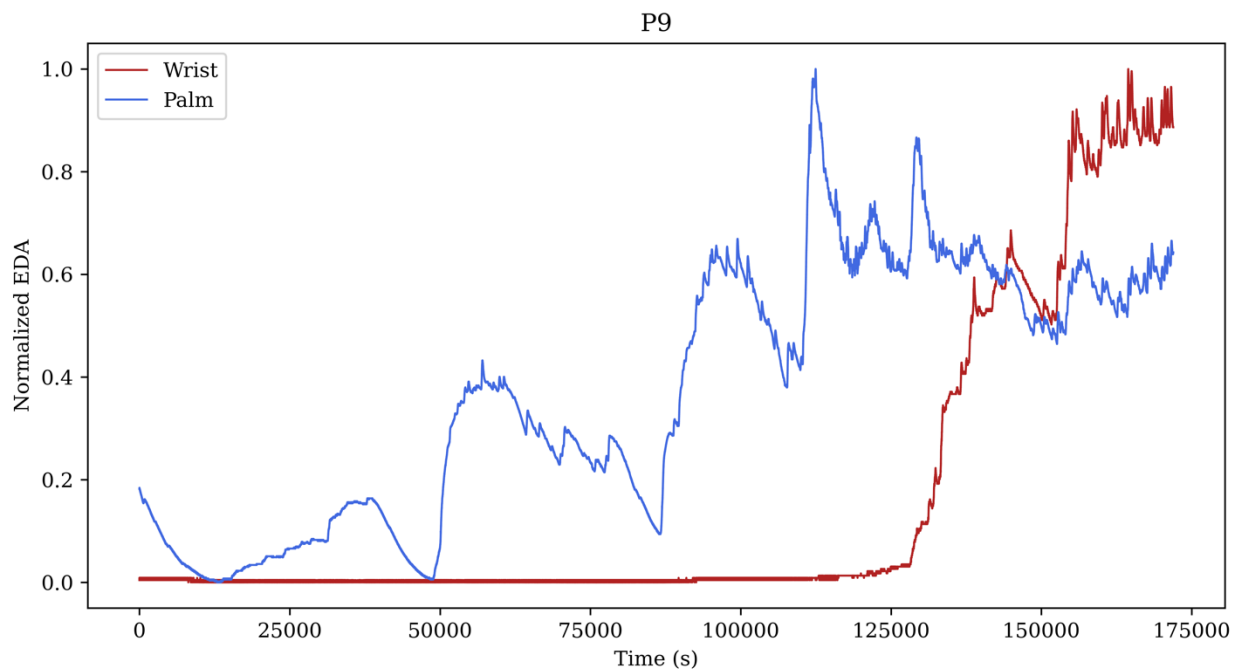
E – Graphical representation of the EDA signal collected at both hand and wrist for each participant (data acquisition study).

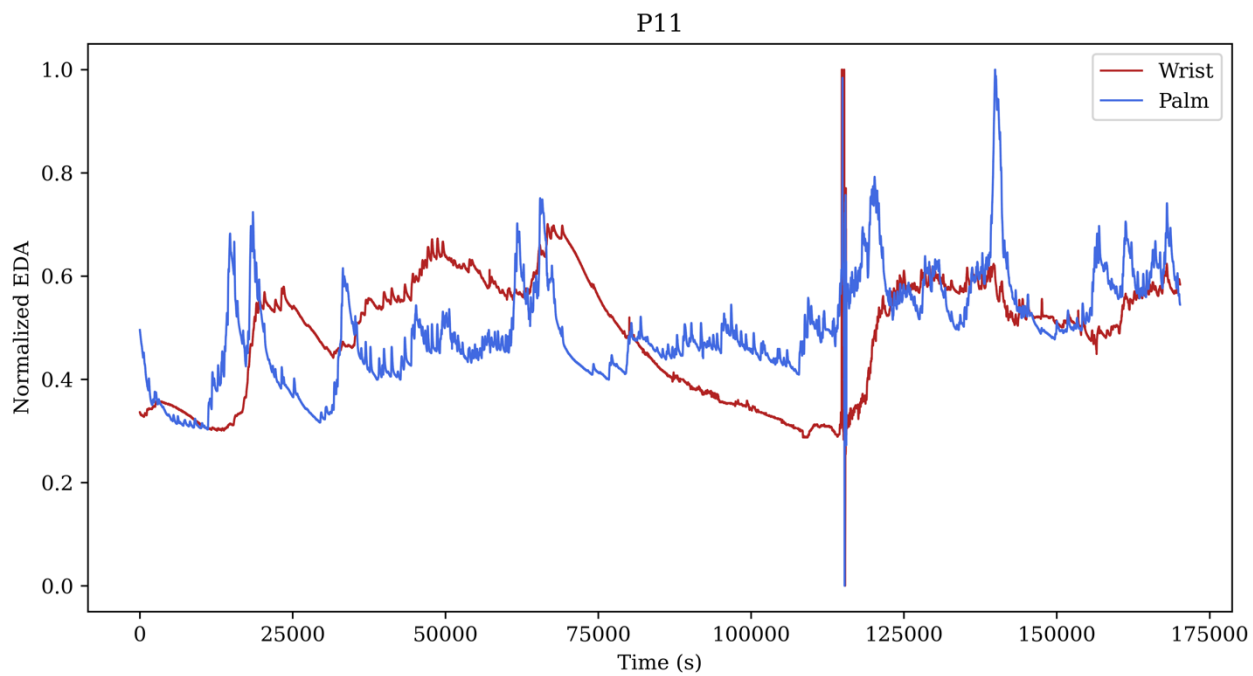












F – development process photos of the wrist model.



Figure 43. Fabric band (first iteration).

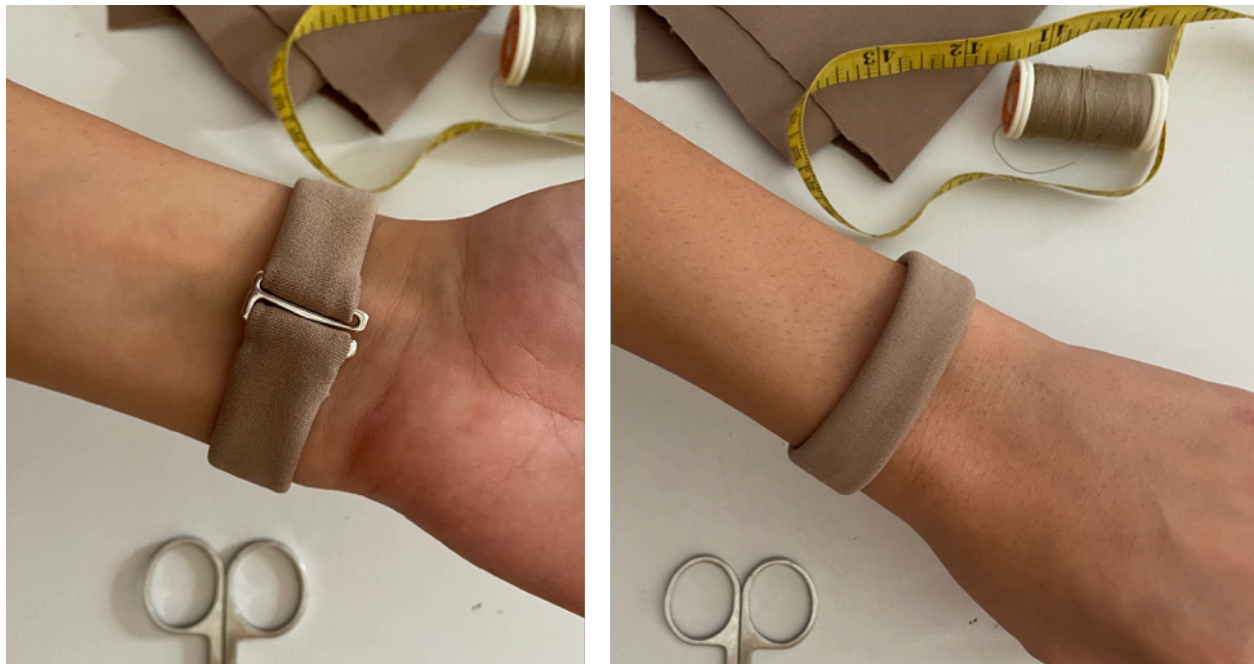


Figure 44. Fabric band put on; anterior view (left) and posterior view (right).



Figure 45. Fabric band (second iteration).

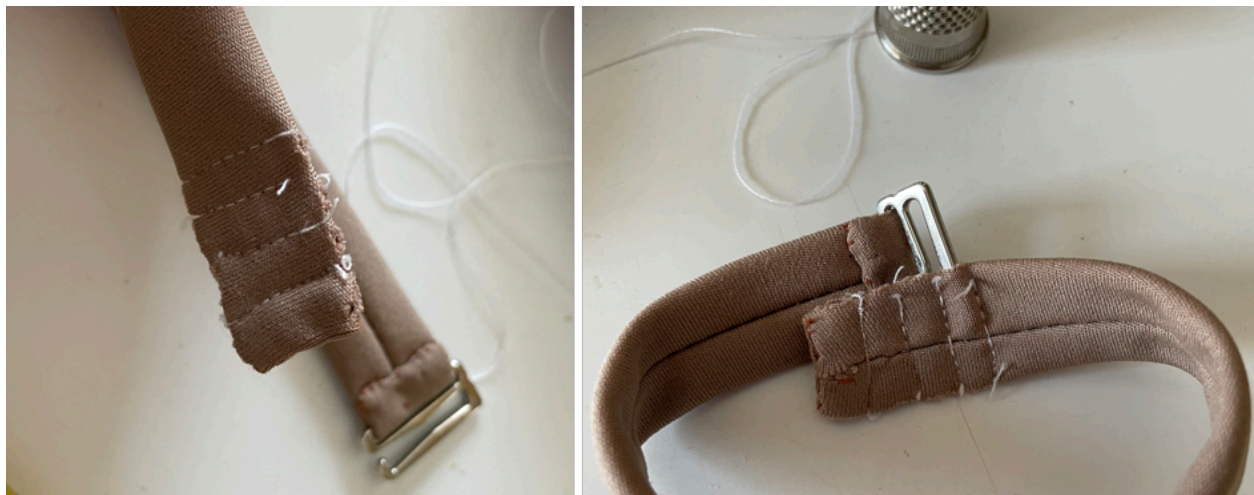


Figure 46. Fabric band; loops for adjustment (left) and hook stuck in the seam (right).



Figure 47. Pocket opening marking (band's side and a second piece of fabric tacked).

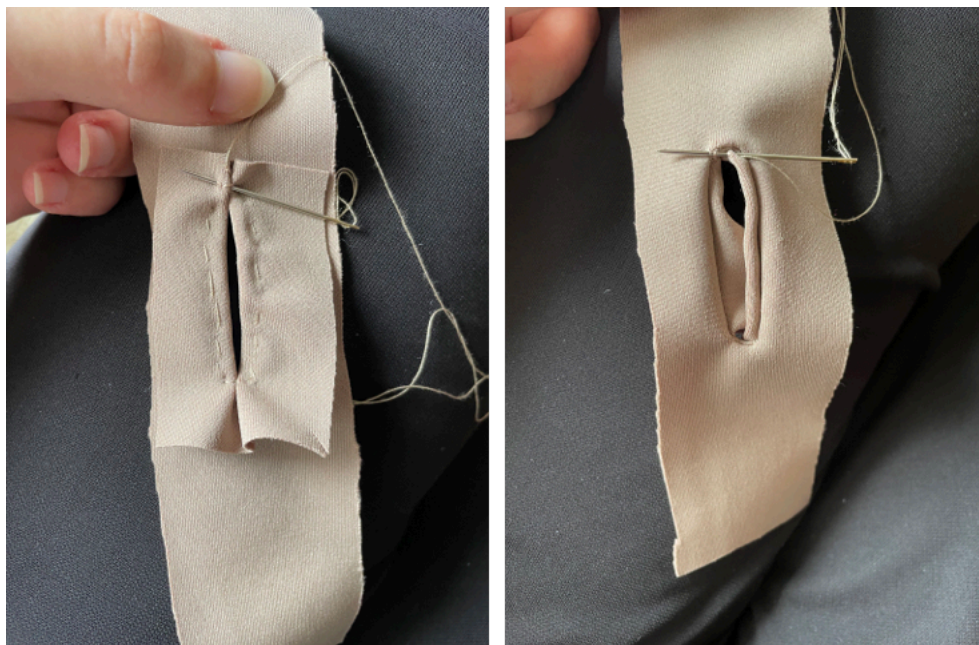


Figure 48. Fabric pieces for the two sides of the band after creating the pocket-like opening.



Figure 49. Band tacked and machine stitched together, before being turned inside out.



Figure 50. Band after being turned inside out, with one open end.



Figure 51. Hook secured, hand stitched.



Figure 52. Machine stitching the dividers of the loops.



Figure 53. Finished band, highlighting the hook fastened in one of the loops.



Figure 54. Multiple shapes in the process of sanding.



Figure 55. Unit mock after inserting the magnetic connector.

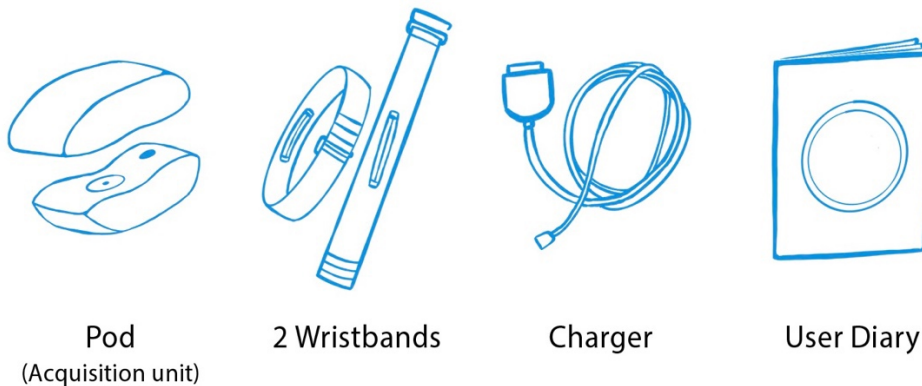


Figure 56. Finalised acquisition unit mock-up: top view (left) and bottom view (right).

USER MANUAL

Welcome to your new epilepsy monitoring band. Please consult all the information present on this pamphlet before starting. Contacts for user support in the back. Thank you.

1 Package contents

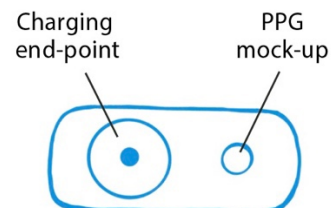


2 Everyday use

This device is meant for long term, continuous, everyday wearing.

Sensors integrated on the pod and textile electrodes incorporated onto the fabric of the band continuously monitor for seizure detection.

For best performance, we recommend maintaining the band on your non-dominant wrist, everyday, for as longer periods as possible.



⚠ Warning! Please remove your wristband before any activity that may result in your wrist and wristband becoming fully wet, such as showering or swimming.

H – User diary (female version).

Extended experience of an epilepsy monitoring device

My User Diary

Researcher contact | Mafalda Morgado +351 915 079 816 mafaldapmorgado@gmail.com

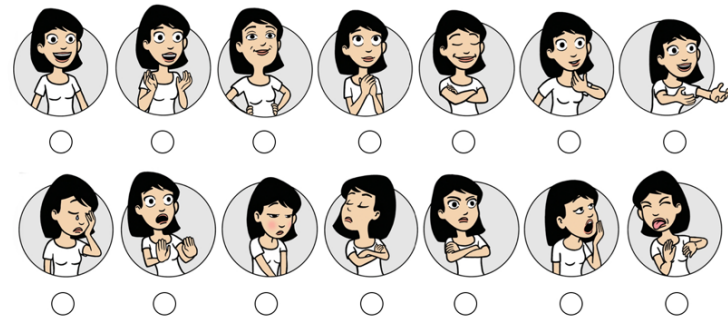
May _ _

DAY 1

1 EXPERIENCE

1. My overall experience today was ...

Closely analyze each following image. Check the **one** which best describes your overall experience with the device throughout the day.



2. The device was ... uncomfortable ○○○○○ comfortable
obstructive ○○○○○ not obstructive

3. The device made me feel ... less safe ○○○○○ safer ... than usual
worse ○○○○○ better

2 IN PUBLIC

1. Today I was in the following public spaces:

2. When wearing the device in these spaces I felt...

		Not at all			Definitely		
the same	☐	☐	☐	☐	☐	☐	
better	☐	☐	☐	☐	☐	☐	
more exposed	☐	☐	☐	☐	☐	☐	
more observed	☐	☐	☐	☐	☐	☐	
safer	☐	☐	☐	☐	☐	☐	

3. I was asked about my device ____ time(s)

and that had a ☐ ☐ ☐ ☐ ☐ impact on me

negative neutral positive

3 ACTIVITIES

1. Today, I performed these activities, with the following impact from the device:

	negative	neutral	positive
☐ working/studying	☐	☐	☐
☐ jogging/running	☐	☐	☐
☐ cycling	☐	☐	☐
☐ weight exercising	☐	☐	☐
☐ yoga or pilates	☐	☐	☐
☐ cleaning	☐	☐	☐
☐ cooking	☐	☐	☐
☐ driving	☐	☐	☐
☐ going out to eat	☐	☐	☐

4 SLEEPING

1. The device impacted my sleep

☐ ☐ ☐ ☐ ☐

negatively neutral positively

2. Throughout the night, the device was

☐ ☐ ☐ ☐ ☐

uncomfortable neutral comfortable

5 DEVICE

1. Today, I moved the device to a different place ____ times,

and I moved it from the wrist to _____

2. I moved the device because ...

- ☐ I was uncomfortable
- ☐ I wanted to try it
- ☐ I like it better in a different place
- ☐ it was restricting my movements
- ☐ it was obstructing my tasks
- ☐ I wanted to hide it
- ☐ it would get dirty or wet
- ☐ it was itchy
- ☐ of sensory issues/intolerance
- ☐ _____

3. Today, I took off the device ____ times,

and I was not wearing the device for a total time of _____

4. I took the device off because I ...
- ☐ did not want to sleep with it
 - ☐ showered
 - ☐ charged it
 - ☐ changed its band
 - ☐ re-adjusted its size
 - ☐ showed it to someone else
 - ☐ was embarrassed to wear it
 - ☐ was uncomfortable or itchy
 - ☐ was too hot
 - ☐ _____

5. Taking off the device was

difficult easy

☐ ☐ ☐ ☐ ☐

6. Putting on the device was

☐ ☐ ☐ ☐ ☐

7. Today's experience with ...

	How	When	Instructions	Issues
Charging	☐ On my own ☐ With help ☐ I couldn't do it ☐ _____	_____ h	☐ I followed them ☐ I tried on my own ☐ I didn't need them ☐ _____	
Changing	☐ On my own ☐ With help ☐ I couldn't do it ☐ _____	_____ h	☐ I followed them ☐ I tried on my own ☐ I didn't need them ☐ _____	
Washing	☐ On my own ☐ With help ☐ I couldn't do it ☐ _____	_____ h	☐ I followed them ☐ I tried on my own ☐ I didn't need them ☐ _____	

Researcher contact | Mafalda Morgado +351 915 079 816 mafaldapmorgado@gmail.com

6 PROBLEMS

1. I had other problems today:
- ☐ I was unable to take off the device
 - ☐ I was unable to put on the device
 - ☐ I was unable to change the band
 - ☐ a part of the device broke
 - ☐ I had a skin reaction
 - ☐ _____
 - ☐ _____
 - ☐ _____
 - ☐ _____

7 FREE WRITE

Write any other thoughts you have on your day with the device, and on the overall experience with the device so far. This field is optional.

DAY 1

Researcher contact | Mafalda Morgado +351 915 079 816 mafaldapmorgado@gmail.com

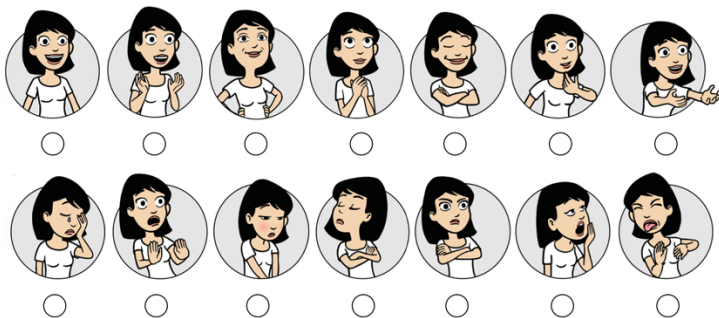
May __

DAY 2

1 EXPERIENCE

1. My overall experience today was ...

Closely analyze each following image. Check the **one** which best describes your overall experience with the device throughout the day.



2. The device was ... uncomfortable ☐ ☐ ☐ ☐ ☐ comfortable
obstructive ☐ ☐ ☐ ☐ ☐ not obstructive

3. The device made me feel ... less safe ☐ ☐ ☐ ☐ ☐ safer ... than usual
worse ☐ ☐ ☐ ☐ ☐ better

2 IN PUBLIC

1. Today I was in the following public spaces:

2. When wearing the device in these spaces I felt...

	Not at all			Definitely		
the same	☐	☐	☐	☐	☐	☐
better	☐	☐	☐	☐	☐	☐
more exposed	☐	☐	☐	☐	☐	☐
more observed	☐	☐	☐	☐	☐	☐
safer	☐	☐	☐	☐	☐	☐

3. I was asked about my device ___ time(s)

and that had a ☐ ☐ ☐ ☐ ☐ impact on me

negative neutral positive

3 ACTIVITIES

1. Today, I performed these activities, with the following impact from the device:

	negative	neutral	positive
☐ working/studying	☐	☐	☐
☐ jogging/running	☐	☐	☐
☐ cycling	☐	☐	☐
☐ weight exercising	☐	☐	☐
☐ yoga or pilates	☐	☐	☐
☐ cleaning	☐	☐	☐
☐ cooking	☐	☐	☐
☐ driving	☐	☐	☐
☐ going out to eat	☐	☐	☐

4 SLEEPING

1. The device impacted my sleep ☐ negatively ☐ neutral ☐ positively
2. Throughout the night, the device was ☐ uncomfortable ☐ neutral ☐ comfortable

5 DEVICE

1. Today, I moved the device to a different place ____ times,
and I moved it from the wrist to _____

2. I moved the device because ... ☐ I was uncomfortable
☐ I wanted to try it
☐ I like it better in a different place
☐ it was restricting my movements
☐ it was obstructing my tasks
☐ I wanted to hide it
☐ it would get dirty or wet
☐ it was itchy
☐ of sensory issues/intolerance
☐ _____
3. Today, I took off the device ____ times,
and I was not wearing the device for a total time of _____

Researcher contact | Mafalda Morgado +351 915 079 816 mafaldapmorgado@gmail.com

4. I took the device off because I ... ☐ did not want to sleep with it
☐ showered
☐ charged it
☐ changed its band
☐ re-adjusted its size
☐ showed it to someone else
☐ was embarrassed to wear it
☐ was uncomfortable or itchy
☐ was too hot
☐ _____

5. Taking off the device was ☐ difficult ☐ easy
6. Putting on the device was ☐ difficult ☐ easy

7. Today's experience with ...

	How	When	Instructions	Issues
Charging	☐ On my own ☐ With help ☐ I couldn't do it ☐ _____	_____ h	☐ I followed them ☐ I tried on my own ☐ I didn't need them ☐ _____	
Changing	☐ On my own ☐ With help ☐ I couldn't do it ☐ _____	_____ h	☐ I followed them ☐ I tried on my own ☐ I didn't need them ☐ _____	
Washing	☐ On my own ☐ With help ☐ I couldn't do it ☐ _____	_____ h	☐ I followed them ☐ I tried on my own ☐ I didn't need them ☐ _____	

Researcher contact | Mafalda Morgado +351 915 079 816 mafaldapmorgado@gmail.com

6 PROBLEMS

1. I had other problems today:
- ☐ I was unable to take off the device
 - ☐ I was unable to put on the device
 - ☐ I was unable to change the band
 - ☐ a part of the device broke
 - ☐ I had a skin reaction
 - ☐ _____
 - ☐ _____
 - ☐ _____
 - ☐ _____

7 FREE WRITE

Write any other thoughts you have on your day with the device, and on the overall experience with the device so far. This field is optional.

DAY 2

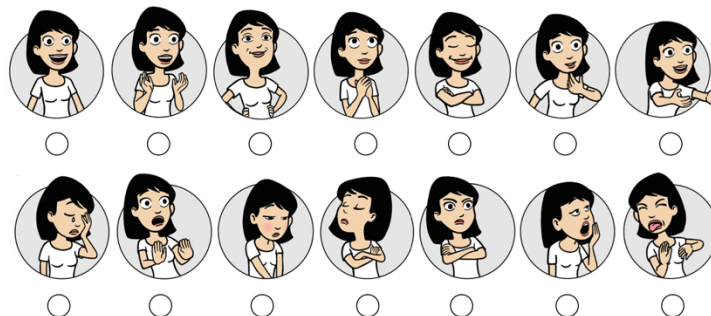
May __

DAY 3

1 EXPERIENCE

1. My overall experience today was ...

Closely analyze each following image. Check the **one** which best describes your overall experience with the device throughout the day.



2. The device was ...
- | | | |
|---------------|---|-----------------|
| uncomfortable | ☐ ☐ ☐ ☐ ☐ | comfortable |
| obstructive | ☐ ☐ ☐ ☐ ☐ | not obstructive |

3. The device made me feel ...
- | | | | |
|-----------|---|--------|----------------|
| less safe | ☐ ☐ ☐ ☐ ☐ | safer | ... than usual |
| worse | ☐ ☐ ☐ ☐ ☐ | better | |

2 IN PUBLIC

1. Today I was in the following public spaces:

2. When wearing the device in these spaces I felt...

		Not at all			Definitely		
the same	☐	☐	☐	☐	☐	☐	
better	☐	☐	☐	☐	☐	☐	
more exposed	☐	☐	☐	☐	☐	☐	
more observed	☐	☐	☐	☐	☐	☐	
safer	☐	☐	☐	☐	☐	☐	

3. I was asked about my device ____ time(s)

and that had a ☐ ☐ ☐ ☐ ☐ impact on me

negative neutral positive

3 ACTIVITIES

1. Today, I performed these activities, with the following impact from the device:

	negative	neutral	positive
☐ working/studying	☐	☐	☐
☐ jogging/running	☐	☐	☐
☐ cycling	☐	☐	☐
☐ weight exercising	☐	☐	☐
☐ yoga or pilates	☐	☐	☐
☐ cleaning	☐	☐	☐
☐ cooking	☐	☐	☐
☐ driving	☐	☐	☐
☐ going out to eat	☐	☐	☐

4 SLEEPING

1. The device impacted my sleep ☐ ☐ ☐ ☐ ☐

negatively neutral positively

2. Throughout the night, the device was ☐ ☐ ☐ ☐ ☐

uncomfortable neutral comfortable

5 DEVICE

1. Today, I moved the device to a different place ____ times,
and I moved it from the wrist to _____

2. I moved the device because ...

- ☐ I was uncomfortable
- ☐ I wanted to try it
- ☐ I like it better in a different place
- ☐ it was restricting my movements
- ☐ it was obstructing my tasks
- ☐ I wanted to hide it
- ☐ it would get dirty or wet
- ☐ it was itchy
- ☐ of sensory issues/intolerance
- ☐ _____

3. Today, I took off the device ____ times,
and I was not wearing the device for a total time of _____

4. I took the device off because I ... ☐ did not want to sleep with it
☐ showered
☐ charged it
☐ changed its band
☐ re-adjusted its size
☐ showed it to someone else
☐ was embarrassed to wear it
☐ was uncomfortable or itchy
☐ was too hot
☐ _____

5. Taking off the device was ☐ difficult ☐ ☐ ☐ ☐ easy

6. Putting on the device was ☐ ☐ ☐ ☐ ☐

7. Today's experience with ...

	How	When	Instructions	Issues
Charging	☐ On my own ☐ With help ☐ I couldn't do it ☐ _____	_____ h	☐ I followed them ☐ I tried on my own ☐ I didn't need them ☐ _____	
Changing	☐ On my own ☐ With help ☐ I couldn't do it ☐ _____	_____ h	☐ I followed them ☐ I tried on my own ☐ I didn't need them ☐ _____	
Washing	☐ On my own ☐ With help ☐ I couldn't do it ☐ _____	_____ h	☐ I followed them ☐ I tried on my own ☐ I didn't need them ☐ _____	

Researcher contact | Mafalda Morgado +351 915 079 816 mafaldapmorgado@gmail.com

6 PROBLEMS

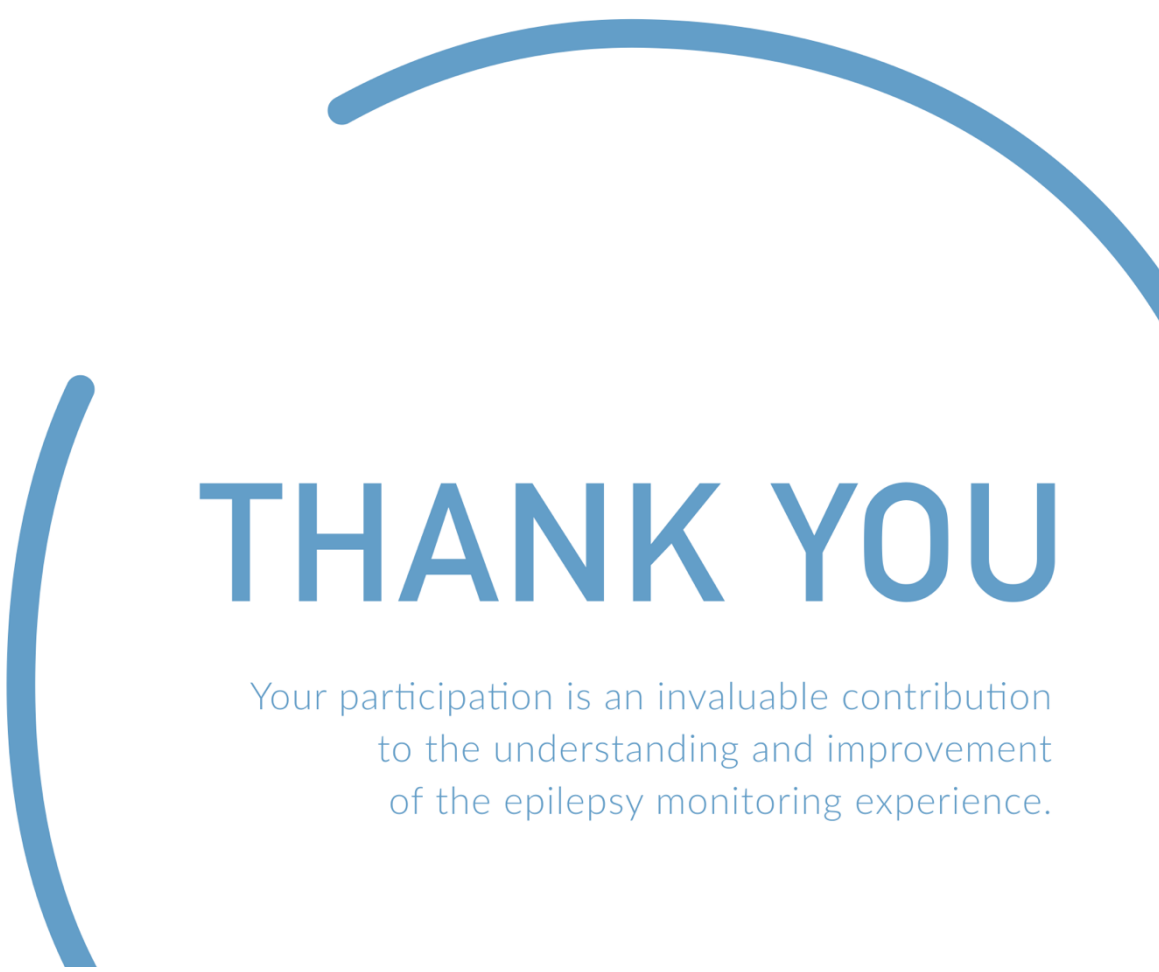
1. I had other problems today: ☐ I was unable to take off the device
☐ I was unable to put on the device
☐ I was unable to change the band
☐ a part of the device broke
☐ I had a skin reaction
☐ _____
☐ _____
☐ _____
☐ _____

7 FREE WRITE

Write any other thoughts you have on your day with the device, and on the overall experience with the device so far. This field is optional.

DAY 3

Researcher contact | Mafalda Morgado +351 915 079 816 mafaldapmorgado@gmail.com



THANK YOU

Your participation is an invaluable contribution
to the understanding and improvement
of the epilepsy monitoring experience.

I – Informed consent (extended UX study).



Informed Consent Form

Title. Extended User Experience testing — long-term epilepsy monitoring wristband (mock-up model)

Context. You are invited to voluntarily participate in an extended experimental study, conducted by the IADE MSc student Mafalda Morgado (mafaldapmorgado@gmail.com), during which you will evaluate and document your experience with a mock-up of an epilepsy monitoring wearable, for three consecutive days. The supervising researchers are UE-IADE Prof. Hande Ayanoglu (hande.ayanoglu@universidadeeuropéia.pt) and Prof. Gianni Montagna (g.montagna@gmail.com), FAUL.

This experimental study integrates the MSc project for the development of a wearable device for long-term continuous epilepsy monitoring, in order to detect epileptic seizures, notify emergency services, and possibly alert to these incidents just before they happen.

Your participation in this project is crucial as it will enable us to validate the prototype design and understand in which ways it can be improved in order to ensure a positive prolonged user experience.

Objectives. The goal of this study is to validate the design of the epilepsy monitoring wristband, in the context of continuous use.

Procedure. Each study session will be performed individually, with an average length of approximately 72h. Before starting, you will be introduced to the experimental study, and asked to fill this Informed Consent Form.

The experimental study will follow a three part structure:

III. Before

This stage refers to the briefing session before the experimental study begins, during which the study is introduced and detailed and your voluntary and informed participation is agreed upon.

1. A briefing session will be conducted, including a short interview, and during which the details of the study will be provided and explained.
2. A package with the necessary material, which you will take with you after the briefing session, will be provided. It will include: device mock-up, charger, two straps, user manual, user journal/diary.
3. A meeting marking the end of the study will be arranged, with an hour and location of your choosing.

IV. During

The study has an approximate duration of 72 consecutive hours, until the arranged meeting. During this time, you will be asked to carry out your usual routine, while:

1. Wearing the device daily, for as long periods as it is possible for you.
2. Filling out the appropriate sections of the diary, documenting your experience with the device, at the end of each day (preferably before going to sleep).

3. Performing necessary tasks according to the given user manual (charging, changing and washing the device).

You may contact the researcher (+351 915 079 816 and mafaldapmorgado@gmail.com) at any time during the study for any concerns and further clarifications.

You may withdraw your participation at any time and with no consequences, in which case a short meeting will be arranged, at a time and location of your choosing, to return the experimental study materials.

V. After

This stage refers to the arranged meeting that marks the end of your participation in this experimental study. During this meeting:

1. The provided materials will be returned to the researcher.
2. An interview of approximately 15 minutes will be conducted, during which the journal entries will be reviewed and discussed.
3. You will be asked to answer a short questionnaire, around 3 minutes, pertaining to a pairing smartphone application.

Data privacy. The data provided by the user diaries, the application questionnaire, as well as during the briefing and exit interviews, will be anonymous, only identified by participant number, age, gender and occupation. No physiological data is acquired. You may request to access and eliminate the data at any time, by contacting the researcher conducting the study, Mafalda Morgado (mafaldapmorgado@gmail.com). The collected data will be anonymous, and will not be associated with your name or other information that can be used to identify you.

Risks. The voluntary participation in this experimental study does not represent risks greater than those of everyday life.

Participation. Your participation in this study must be done voluntarily and in an informed way. You may choose to withdraw it at any time with no consequence.

Participation Agreement

I have read and understood this study, and agree to participate voluntarily in this experiment by signing below.

Name:.....

Signature:.....

Date:

Participant number:

J – Obtained results (extended UX study).

User Diaries.

	Section	Question	P1	P2	P3	P4	P5	P6
Day 1	1 Experience	1 Premo	Fascination	Embarrassed	Pride	Fear	Fascination	Joy
		2 Uncomfortable – Comfortable (1..5)	4	4	5	4	4	4
		Obstructive - Not obstructive (1..5)	5	5	5	3	5	5
		3 Less safe – Safe (1..5)	4	4	3	3	3	4
		Worse – Better (1..5)	3	2	4	3	4	4
	2 Public spaces	1 Places	Coffee shop; Grocery store	Office; Train; Train station	Café; Restaurant	Beach (Costa); football	Monsanto	IADE; Restaurant; Bar; Champalimaud Foundation
		The same (1..5)	2	2	2	4	4	4
		Better (1..5)	2	2	4	1	2	2
		2 More exposed (1..5)	3	4	3	1	1	1
		More observed (1..5)	1	4	1	1	2	1
		Safer (1..5)	3	3	1	2	2	3
		3 Occurrences	1	1	2	4	0	1
		Impact (-2..2)	0	1	2	0	0	1
	3 Activities	1 Activity and Impact (-2..2)	Cleaning 0; Cooking 0; Driving 0; Going out to eat 1	Working 0; Cleaning 0; Cooking 0	Studying 0; Going out to eat 1	Running 0; Driving 0	Running -1;	Working 0; Driving 0; Going out to eat 0
	4 Sleeping	1 Impact (-2..2)	0	1	1	0	-1	1
		2 Comfort (-2..2)	1	2	1	0	2	0
	5 Device	1 Occurrences	1	0	0	0	1	0
		Location	Upper arm	—	—	—	Ankle	—
		2 Moving reasons	I wanted to try it; It would get dirty or wet	—	—	—	Uncomfortable; heat	—
		3 Occurrences	4	2	1	4	1	1
		Duration	2 h	1 h	20 min	7 h	4 h 30 min	1 h

		4	Taking off reasons	Showered; Charged it; Showed it to someone else; Readjusted location	Did not want to sleep with it; Showered; Charged it; Not used to it	Showered	Shower; Charged; Was uncomfortable or itchy	Showered; Charged it	Showered; Showed it to someone else
		5	Take off difficult/easy (1..5)	4	5	3	4	3	4
		6	Put on difficult/easy (1..5)	1	2	1	2	1	3
		7	Charging	On my own; 19h; Didn't need them	On my own; 20h; Followed	—	On my own; 00h30; Didn't need them	On my own; 10h; Didn't need them	On my own; 7h; Followed
			Charging notes	—	—	—	—	—	—
			Changing	On my own; 21h; I tried on my own	—	—	—	On my own; 14h30; Didn't need them	—
			Changing notes	—	—	—	—	-	—
			Washing	—	—	—	—	On my own; around 10h; Followed	—
			Washing notes	—	—	—	—	—	—
	6 Problems			—	—	—	—	—	—
	7 Notes				Difficult to put on by myself. Difficulty getting used to it.			No issues so far, except needing help putting on the device, so not very practical in that sense. It's discreet.	
Day 2	1 Experience	1	Premo	Satisfaction	Hope	Satisfaction	Satisfaction	Satisfaction	Joy
		2	Uncomfortable – Comfortable (1..5)	4	5	4	5	3	4
			Obstructive - Not obstructive (1..5)	5	5	5	5	4	5
		3	Less safe – Safe (1..5)	4	5	3	3	3	4
			Worse – Better (1..5)	4	3	4	3	3	4
	2 Public spaces	1	Places	Work; Street	Office; Train; Train station; Groceries	University,, Restaurant	Gym	Office; Restaurant	IADE; Restaurant
		2	The same (1..5)	3	3	3	5	4	4

			Better (1..5)	2	2	2	1	3	2
			More exposed (1..5)	2	2	3	1	1	1
			More observed (1..5)	1	2	1	1	1	1
			Safer (1..5)	3	4	1	2	2	3
		3	Occurrences	0	0	1	2	1	1
			Impact (-2..2)	0	2	0	0	2	1
	3 Activities	1	Activity and Impact (-2..2)	Working 0; Cooking 0; Driving 0	Working 0; Cooking 0	Studying 0; Going out to eat 0	Working, -1; Running, 0; Weight exercises, 0; Driving, 0	Working -1; Driving 0; Going out to eat 1	Working 0; Cleaning -1; Cooking -1; Driving 0; Going out to eat 0
	4 Sleeping	1	Impact (-2..2)	0	1	1	—	0	1
		2	Comfort (-2..2)	4	2	2	—	2	0
	5 Device	1	Occurrences	1	0	—	0	0	1
			Location	Upper arm	—	—	—	—	Closer to elbow
		2	Moving reasons	It would get dirty or wet	—	—	—	—	It would get dirty or wet
		3	Occurrences	2	1	2	1	2	1
			Duration	—	1h 30 min	3 h 30 min	10 min	30 min	1 h
		4	Taking off reasons	Readjusted location	Showered; Charged it; Changed its band	Showered, Charged	Showered	Showered	Showered; Charged it
		5	Take off difficult/easy (1..5)	4	5	3	5	4	4
		6	Put on difficult/easy (1..5)	2	3	1	3	2	4
		7	Charging	—	On my own; 20h; I didn't need them	On my own; 10h; Didn't need them	—	On my own; 23h; I didn't need them	On my own; 7h; I didn't need them
			Charging notes	—	—	—	—	—	—
			Changing	—	—	—	—	—	—
			Changing notes	—	—	—	—	—	—
			Washing	—	—	—	—	—	—
			Washing notes	—	—	—	—	—	—
	6 Problems			—	—	—	—	—	
	7 Notes			—	—	It's hard to find time to charge because I want to wear it during the night.	—	There was some discomfort when using the computer.	—

Day 3	1 Experience	1	Premo	Satisfaction	Satisfaction	Satisfaction	Satisfaction	Satisfaction	Desire
		2	Uncomfortable – Comfortable (1..5)	4	5	5	5	3	4
			Obstructive - Not obstructive (1..5)	5	5	5	5	3	5
		3	Less safe – Safe (1..5)	4	4	3	3	3	4
			Worse – Better (1..5)	2	4	3	3	3	4
	2 Public spaces	1	Places	Public transport; Work; Restaurant	Restaurant	University	Gym; Work/School	Office	Supermarket; Friend's house
		2	The same (1..5)	2	2	4	4	4	4
			Better (1..5)	1	3	1	3	2	3
			More exposed (1..5)	3	1	2	1	1	1
			More observed (1..5)	3	1	1	2	1	1
			Safer (1..5)	2	4	1	1	2	3
		3	Occurrences	0	0	2	6	0	0
			Impact (-2..2)	0	2	1	2	0	0
	3 Activities	1	Activity and Impact (-2..2)	Working 1; Going out to eat 0	Working 1; Eating out 0	studying 0	Working 1; running 0; driving 0	Working -1; Driving 0; Cleaning -1	Working 0; Cleaning -1; Cooking -1; Driving 0; Going out to eat 0
	4 Sleeping	1	Impact (-2..2)	0	1	1	0	—	1
		2	Comfort (-2..2)	1	2	2	0	—	0
	5 Device	1	Occurrences	1	0	—	—	1	0
			Location	Upper arm	—	—	—	Ankle	—
		2	Moving reasons	It would get dirty or wet	—	—	—	Exercise	—
		3	Occurrences	3	2	2	2	3	1
			Duration	2h	30 mins	30 min	5h30	10h	3h
		4	Taking off reasons	Showered; Charged it; Changed it; Showed it to someone else; Readjusted location	Showered; Showed it to someone else; Changed its band	Showered; Changed it	Showered	Showered, Charged it; Washing dishes	Showered; Charged it; Washed its band
		5	Take off difficult/easy (1..5)	4	5	4	5	4	4
		6	Put on difficult/easy (1..5)	3	3	3	3	3	4

			Charging	On my own; 23h; I didn't need them	—	—	—	—	On my own; 9h; Followed
			Charging notes	—	—	—	—	—	—
		7	Changing	On my own; 00h; I didn't need them	On my own; 17h; I didn't need them	On my own; 10h; didn't need them	—	—	—
			Changing notes	—	—	—	—	—	—
			Washing	—	—	—	—	—	—
			Washing notes	—	—	—	—	—	—
	6 Problems			—	—	—	I forgot it at home	—	—
	7 Notes			—	—	It would be nice to have more styles.	—	I took it off while typing.	Opening of the band deforms a bit while wearing, but sensor stays in place. A bit uncomfortable with hot weather but no skin reactions. Band dries quickly after washing.

Closing interviews.

Question	P1	P2	P3	P4	P5	P6
What difficulties with daily device-related tasks? Or what would you improve?	<i>Pretty much just the clasp, to take it off and put in on, or to change the size, it was hard to do on my own, with just one hand. I would improve that. (...) More availability of colors and textures (...) Like a light or something to</i>	<i>I would say putting on and taking off the bracelet was a little difficult. (...) The last day I think it went a little better, but in the beginning, I needed help, which is not great for autonomy.</i>	<i>It was not easy to find time, long periods, to leave it charging. I have to use it during the nighttime, which is when I think people usually leave things charging; then I wanted to use it during the day, or I have a</i>	<i>Putting the bracelet on is not a huge issue, but I wasn't able to do it initially. (...) The fact that I have to remove it to do water activities is a little frustrating.</i>	<i>I had some difficulties putting the device on, on my own. Had to ask [my wife] for help, but then I got the hang of it, even though it is not super easy with just one hand. (...) I had some discomfort using the computer at work,</i>	<i>The first time the claps is a little hard to close, but you can get the hang of it. It should be simpler, but I think it's also because it is a prototype, so if it's stitched and finished better, it won't have that issue. (...) When I</i>

	<i>let me know that it's charging or not.</i>		<i>busy day, out of the house, and I don't want to leave it at home charging all day. (...) I don't think I would charge it while out, I don't usually do it. (...) Yes, one of the bands was very difficult to put on, and I needed help from my mom. When I used another one, that one was a little better, the holes to fit the hook were bigger, it was easier.</i>		<i>after a long time, dragging the wrist, writing, and typing.</i>	<i>was walking for a long time, I started to feel a little hot in the wrist. (...) It would like to have this is different colors, same shape, and everything, but different colors, because it can totally be mistaken by just a simple bracelet. (...) When you put the pod inside, it seems like it's going to fall off, but it doesn't. In the begging I was a little worried that it would.</i>
What was the impact of this device on your everyday life? Did it obstruct your tasks? Were you able to forget you were wearing it?	<i>I didn't really change my everyday life or make it more difficult (...) I would probably wear it on the upper arm more often because of work (...) I was very aware of it in the beginning, but quickly forgot it was there. Although you're also like excited or curious, so you're more aware of it</i>		<i>Yes, it didn't make much of a difference. Plus, if I use other bracelets, that one becomes lost in the middle, and it is not noticeable at all (...) it didn't bother me people asking about it, I liked it, I think it is important to take about epilepsy and try to normalize it, to reduce certain stigmas. But yes, it is likely that it could bother other people.</i>	<i>I don't think it really impacted me, it wasn't obstructive, so I forgot I was wearing it at times. (...) It can be a bit uncomfortable during exercise, but not too much.</i>	<i>I was a little uncomfortable running, I'm not used to using something like that, and it created some heat in my wrist. So, I changed it, and I didn't have any more issues. In fact, next time I went running, I put it on the ankle right from the start. (...) Like I mentioned, it was little uncomfortable during work, so I did end up taking it off a while. But other than that, it was pretty comfortable the fabric, most times I didn't notice it.</i>	<i>It didn't obstruct, no, the only time it made a difference was when I was cooking and washing the dishes, I felt the need to pull it up, so it wouldn't get wet or gain an odor. I think it's more in those tasks. I didn't feel it most times, I eventually forgot I was wearing it, except when I went for that walk in the heat, I felt like the bracelet was adding to the heat, but nothing major.</i>

What was the impact of this device on your emotional state and mood? Was it impacted by its noticeability, or its discretion?	<i>Overall, it made me feel a little safer, but also didn't have much impact, which is positive I think, the idea is that it's there but not really, right? (...) No, I don't think it was like something that signals that I have a specific issue.</i>	<i>Yes, in the bus I was definitely more aware or worried, but I think it's a projection, I don't think people behaved differently (...) it's like when you wear something new, or something out of your comfort zone, in public. No one really cares, but you're hyper aware. (...) I think it actually made me feel slightly safer, because I wanted to envision that it was real.</i>	<i>It didn't really create any issues, maybe in the beginning I was a bit more conscious of whether people were noticing or not, but it eventually went away.</i>	<i>No impact (...) didn't really make a difference.</i>	<i>Generally speaking, I don't think it had an impact of that sorts. (...) I was excited to talk about it actually, but it wasn't really brought up by others.</i>	<i>No, I thought people would care but they didn't, and they didn't notice at all. I went to have dinner at a friend's house, and no one mentioned it, I was even a bit disappointed to be honest.</i>
Do you have other feedback or suggestions in terms of improvements to be made?				<i>I would say that the not being able to take it into the water thing is what I felt made the biggest difference. (...) Changes in my routine are hard to stick, I think I would maybe forget it because I had to remove it, because I'm very forgetful. Eventually I think it would stick. (...) I really enjoyed the interactions with the kids [students], it was a completely different engagement, and they were very interested on the device.</i>	<i>I would suggest having a little more structure, because, as I was running, I was a little concern that the device could come off.</i>	<i>I would definitely buy something like this, if it was functional, because I've searched for products like this before. I could wear it at night, since during the day I can tell a certain degree when I'm going to have a seizure. Even to be able to tell my doctor about it, since I'm not aware if I had a nocturnal seizure or not, I always wake up wondering, particularly if I have a headache or another symptom. (...) It's really, very useful. (...) It can be very useful</i>

						<i>for when a person is changing epilepsy medication; sometime symptoms are abstract it is good to have data. (...) It would be very interesting if you could integrate this band with an already existing smartwatch or accessory, so you don't have to carry multiple things on the wrist.</i>
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K – Applied questionnaire in the digital solution preferences study.

Preferences and priorities					
Questionnaire at the end of the experimental study to understand which features would be most important in a smartphone application which pairs to the textile-based epilepsy monitoring device.					
Q1. How important to you are the following features and characteristics?					
	Not important at all	Slightly important	Moderately important	Very important	Extremely important
Seizure detection	☐	☐	☐	☐	☐
Confirmation of whether the seizure detection is correct	☐	☐	☐	☐	☐
Alert chosen emergency contacts	☐	☐	☐	☐	☐
Seizure prediction (a few minutes prior)	☐	☐	☐	☐	☐
Risk of seizure assessment	☐	☐	☐	☐	☐
Live visualisation of the biosignal acquisition data	☐	☐	☐	☐	☐
Daily summaries of health data	☐	☐	☐	☐	☐
Medication reminders	☐	☐	☐	☐	☐
Seizure log/record	☐	☐	☐	☐	☐
Integration with other health and wellness apps	☐	☐	☐	☐	☐
Personal diary of seizures, symptoms and side effects	☐	☐	☐	☐	☐

Community forums	☐	☐	☐	☐	☐
Information and tips on epilepsy management	☐	☐	☐	☐	☐
Status of the device (battery)	☐	☐	☐	☐	☐
Are there other features you consider important?	_____				
Q2. What type of actions would you prefer in the event of a detected seizure?					
☐ Audible alarm ☐ Vibration ☐ Banner/Screen Notification ☐ Notification of emergency services ☐ Notification of emergency contacts ☐ User confirmation prior to notification ☐ Other: _____					
Q3. What type of actions would you prefer in the event of predicted seizure?					
☐ Audible alarm ☐ Vibration ☐ Banner/Screen Notification ☐ Notification of emergency services ☐ Notification of emergency contacts ☐ User confirmation prior to notification ☐ Other: _____					
Q4. How would you prefer data to be presented? Data related to the different statuses, such as biosignals, risk assessment, device, history/record.					

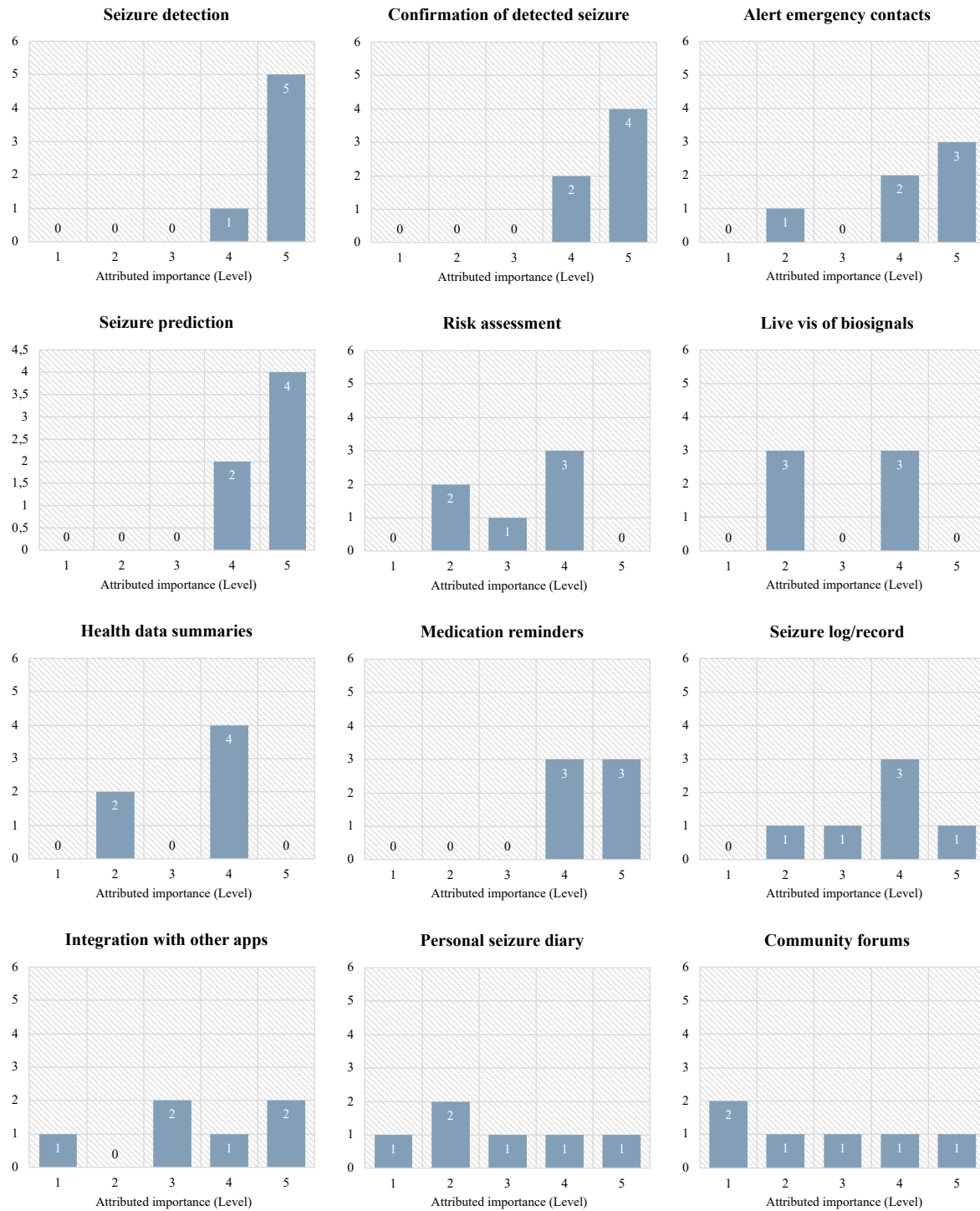
- ☐ Graphs
- ☐ Tables
- ☐ Text
- ☐ Iconography
- ☐ Simplified information
- ☐ Comprehensive and detailed information
- ☐ Other: _____

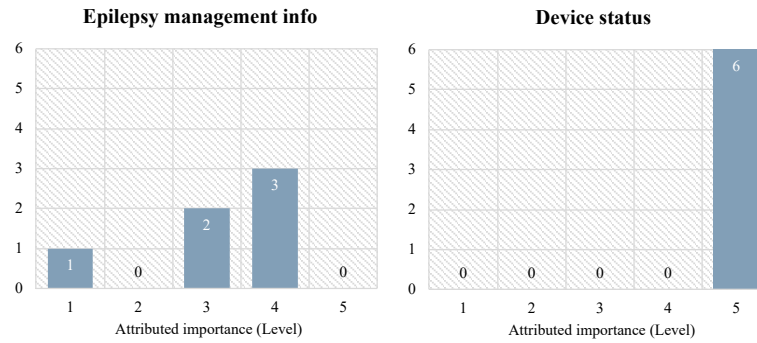
Q5. Concerning data privacy, what is your preference regarding the data collected with the device and your medical records (public or private health system)?

- ☐ Automatic sync: I would like data to sync automatically with my medical records
- ☐ Manual sync: I would like to choose when to sync my data with my medical records
- ☐ Manual share: I would like to be able to extract a report (such as a PDF) and personally send it to my doctor
- ☐ I don't want to share my data with medical records/personnel at all
- ☐ I have no preference
- ☐ Other: _____

L – Results of the digital solution preferences study.

1. Answers for Q1.

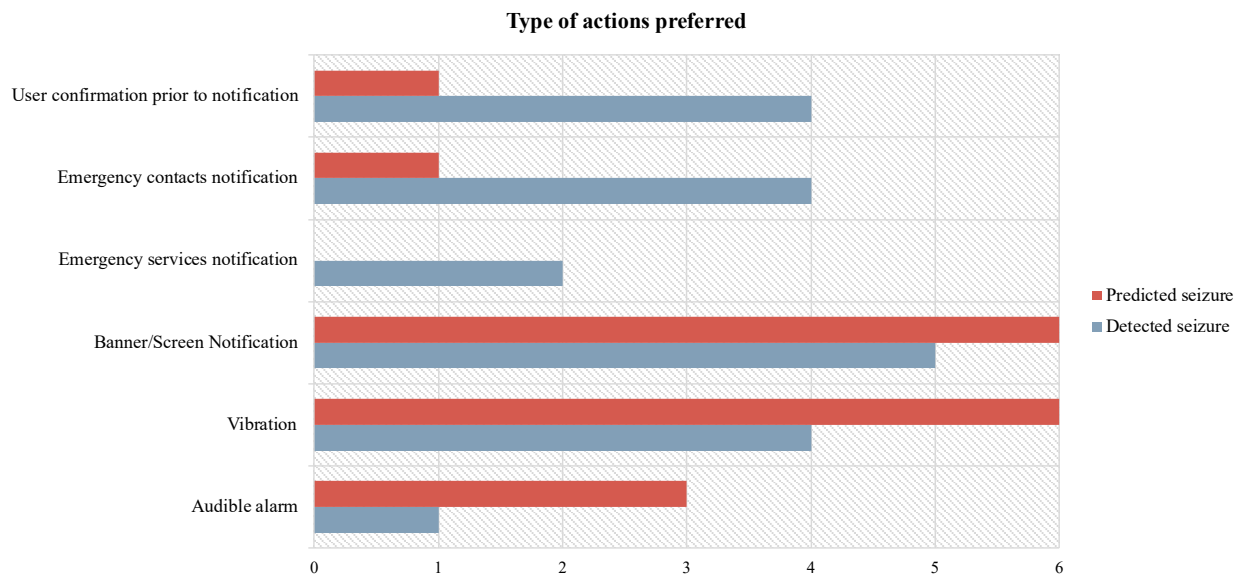




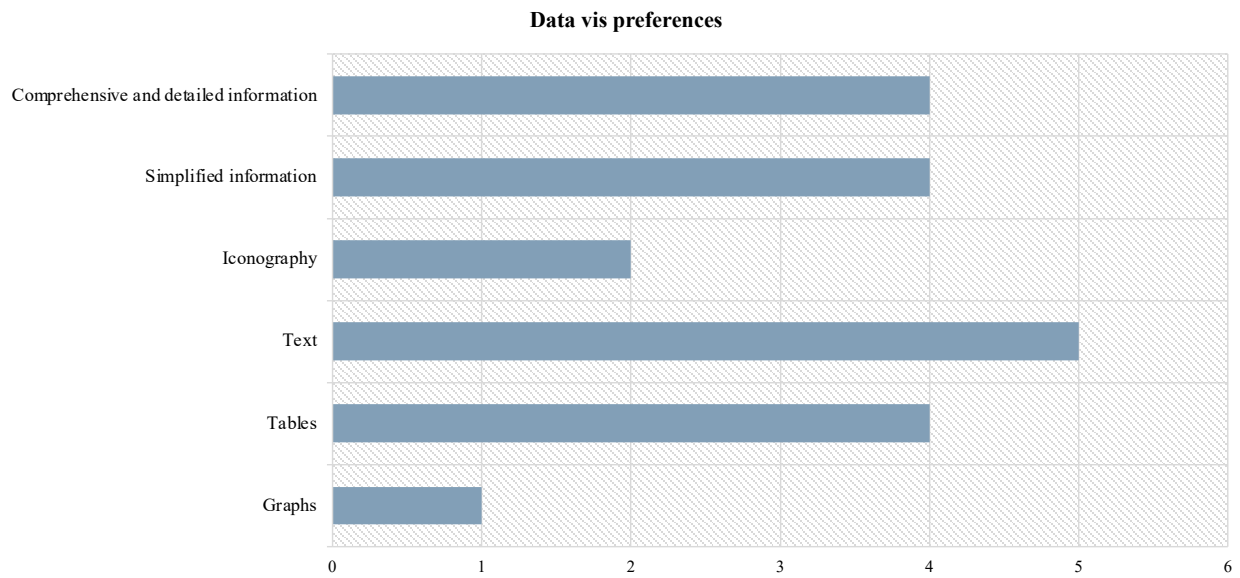
Suggestions:

- “Status of data acquisition (sensor in contact with skin, etc).”
- “Sleep track, avoid 2 devices during the night.”
- “Recognize activity.”
- “Send location with alert.”

2. Answers for Q2 and Q3.



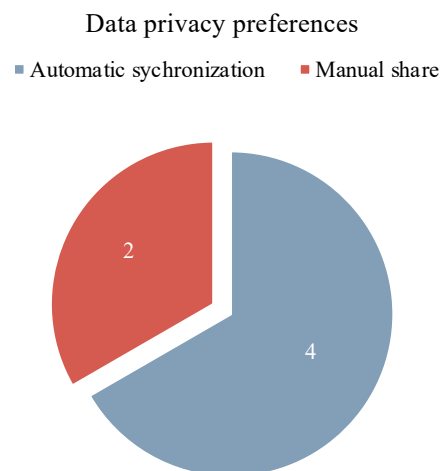
3. Answers for Q4.



Suggestions:

- “Option to download data.”

4. Answers for Q5.



M – Developed wireframes.

