

E4

EINTHOVEN'S TRIANGLE ELECTROCARDIOGRAM FOR EPILEPTIC EMERGENCIES

PREDICTION AND MANAGEMENT OF EPILEPTIC SEIZURES



AAZAM | GUNNY

Executive Summary

This Design Journal summarizes the design process and development of a Prediction and Detection device for the management of Epilepsy, more precisely Drug-Resistant Epilepsy.

Following field research, ethnographic research and exchanges with People With Epilepsy (PWE) as well as healthcare professionals, a preliminary set of requirements was derived to serve as backbone for the development of the product.

The main objective of this research was to identify and isolate the biomarker that would reflect a change in the human body with the potential of predicting a seizure. Through literature review the Biomarker was identified as being the Heart-Rate Variability which is the variation in the time intervals between heartbeats.

Following the identification of the Biomarker a means of monitoring and implementing the monitor into a device that could be worn by an individual with Epilepsy had to be found.

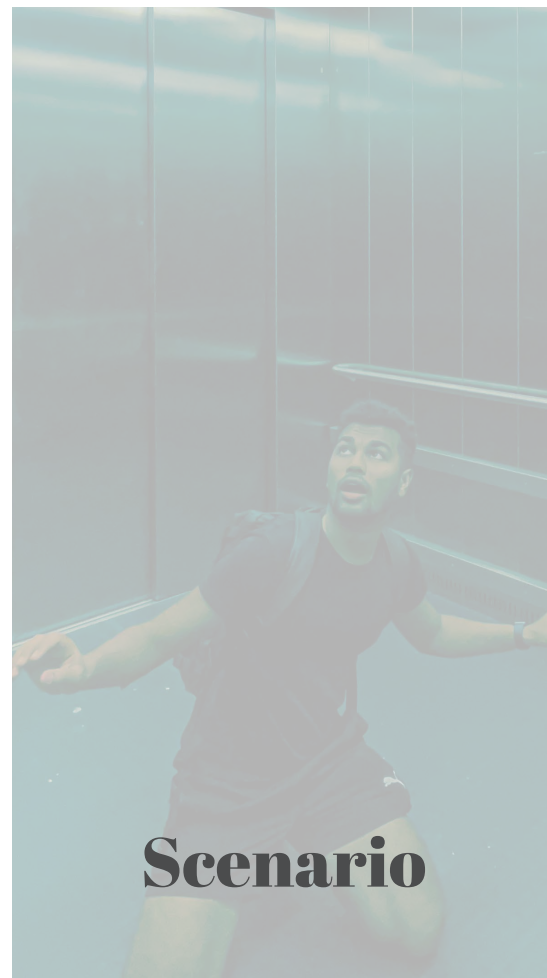
A 5-leads ambulatory Electrocardiogram ECG was the monitoring device selected for the task due to its ability to monitor the HRV which, with the help of a patient-specific algorithm, can allow for predictions of up to about 15 minutes prior to an episode.

For ease of use and ensuring constant correct placement of the ECG electrodes a vest was designed for the electronic components to be mounted upon.

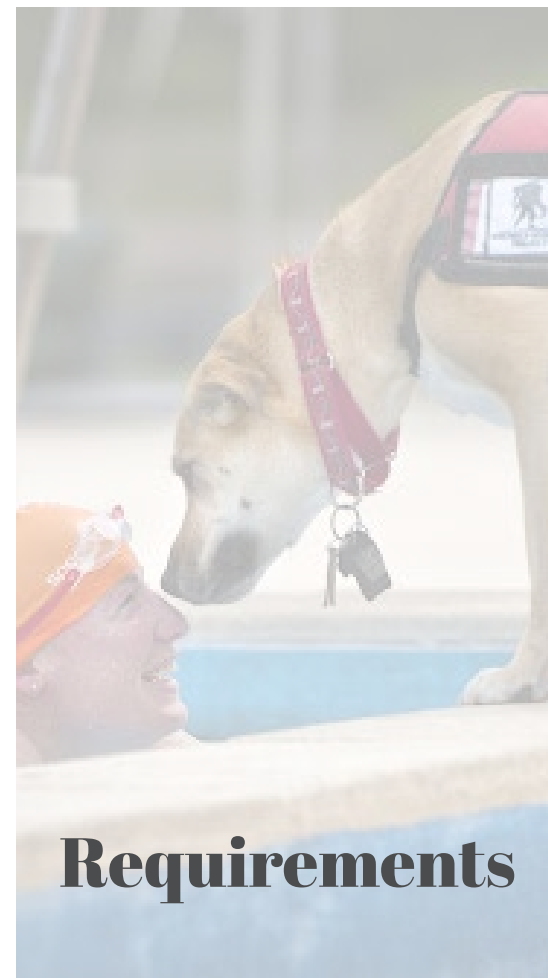
User testing was carried out with low-fidelity prototypes and a 3D CAD model was created as a proof of concept for the Prediction Device henceforth referred to as E4.



Problem



Scenario



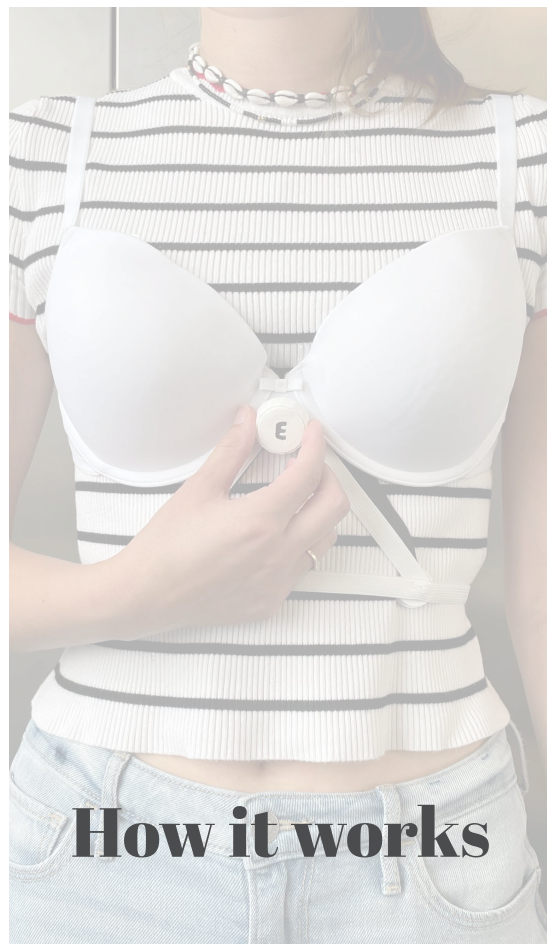
Requirements



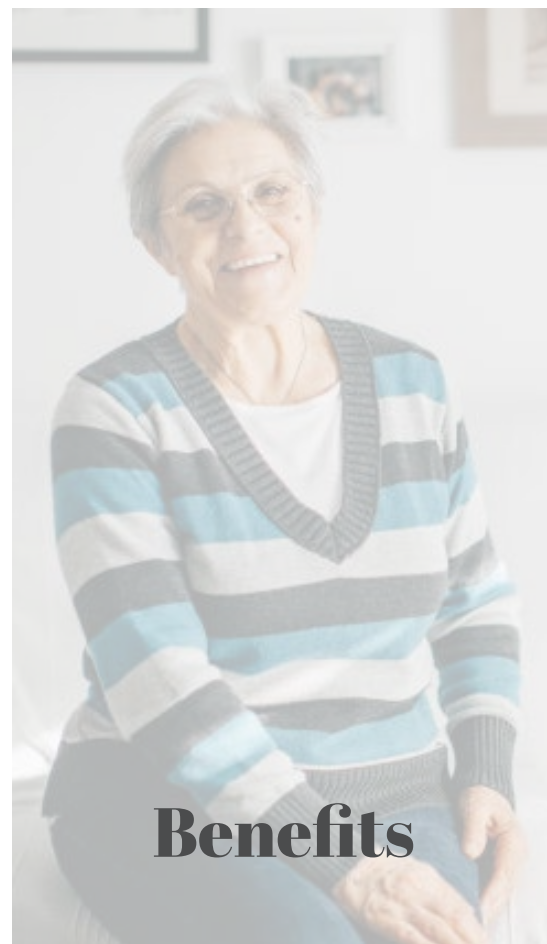
Development



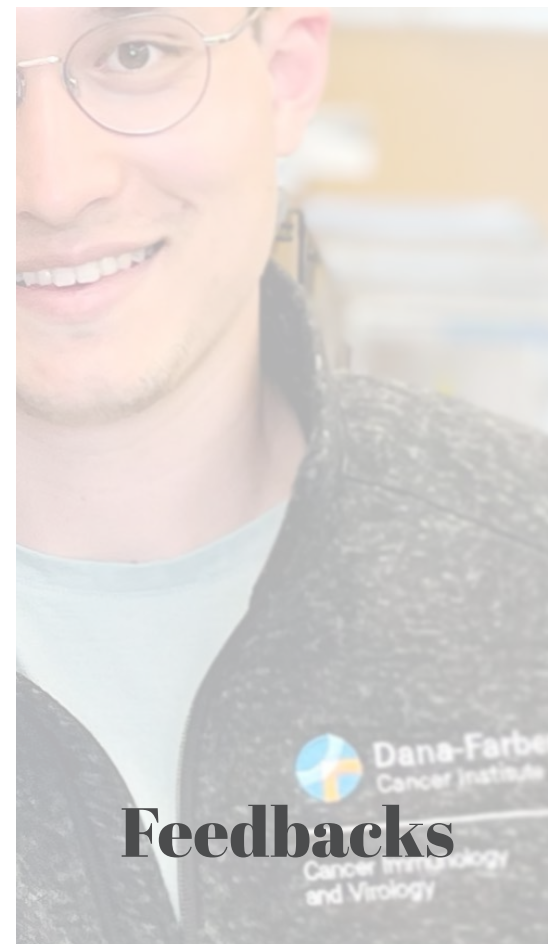
Evaluation



How it works



Benefits



Feedbacks



Refinement



Final Concept

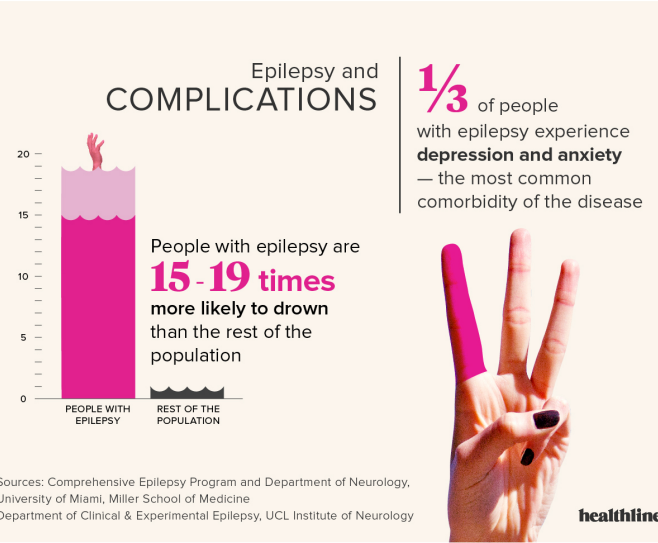
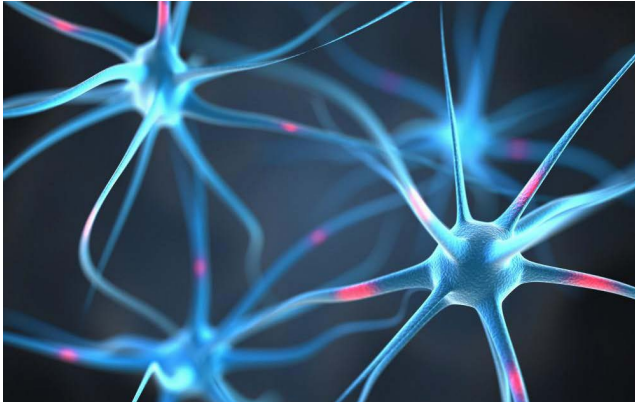
Problem

“Epilepsy is a central nervous system (neurological) disorder in which brain activity becomes abnormal, causing seizures or periods of unusual behavior, sensations, and sometimes loss of awareness.”(Mayoclinic.org)

Among the different kinds of Epilepsy is the **Drug-Resistant Epilepsy** which as the term suggests, the kind that does not respond to medication. Consequently, individuals with Drug-Resistant Epilepsy are **at the mercy of the unpredictable nature of their seizures**. It affects their lives and restricts their activities largely and leaves them vulnerable to **life-threatening injuries and situations**.

Why is it a problem worth solving?

In the UK alone there are 600,000 people living with Epilepsy and 1/3 of those people live with uncontrolled Seizures. In 65% of the people the cause is unknown and there are 21 Epilepsy-Related deaths every week.



Scenario

ACCOUNT OF EVENT

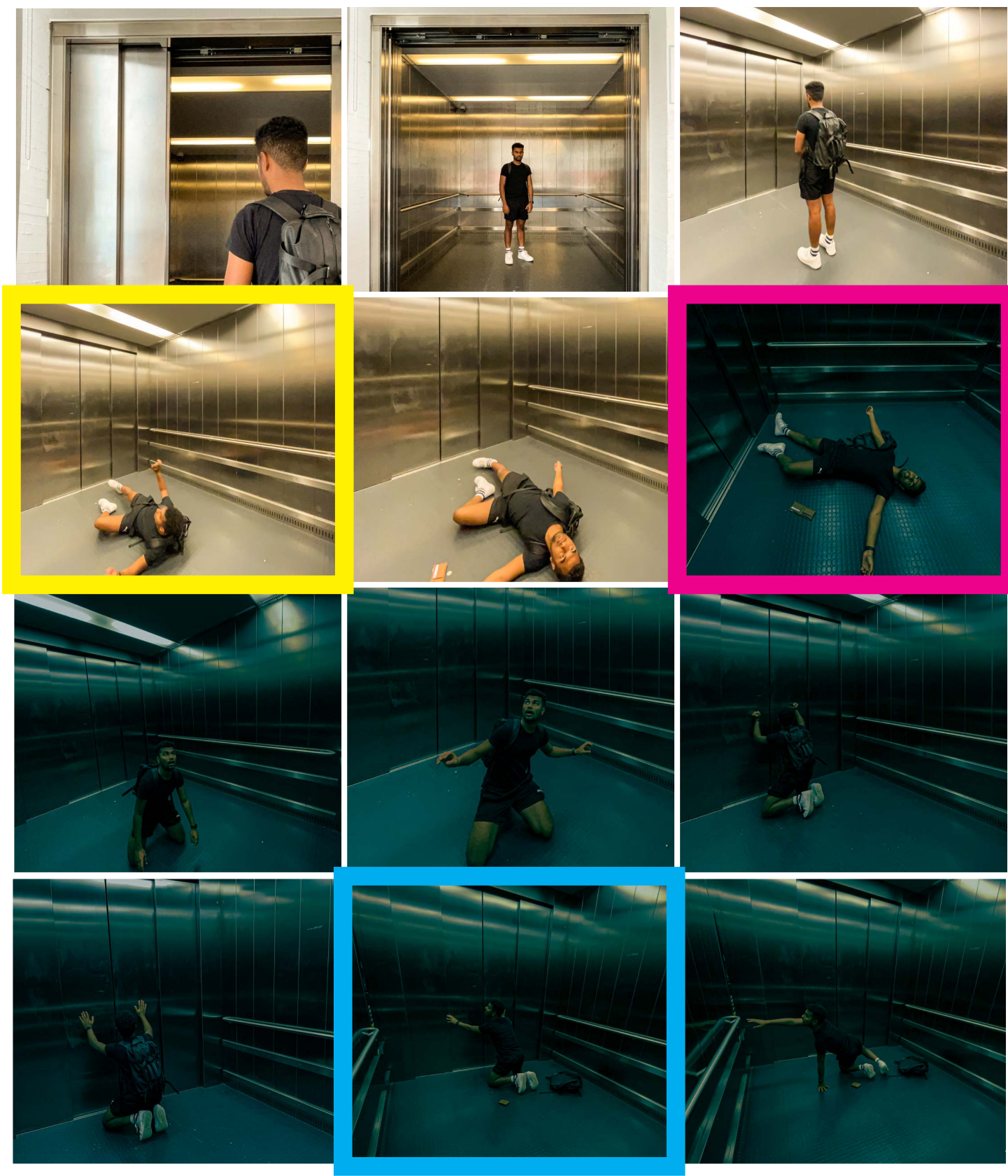
For illustrative purposes a real life situation experienced by a trusted source was reenacted. This was done in order to segment the episode and identify the potential friction points and touch points that would serve as backbone to further design explorations and decisions.

The episode as it was described by the individual without any intermediary was reenacted as accurately as possible to capture and deliver the essence of it.

As it can be seen in the first 3 photographs the individual got onto an elevator and everything was fine until they had an Epileptic seizure and fell on the floor. They were unconscious for about 20 minutes and on the floor long enough for the elevator to go on Power Saving mode and all the lights went off. After their seizure stopped and they regained consciousness they found themselves trapped in a black box terribly disoriented and panicked.

They tried to get ahold of themselves and fumbled in the darkness and started banging on the walls of the elevator until they managed to reach the buttons and reactivate the elevator.

To this day this episode in the elevator remains a gruesome experience and adds to the anxiety they face in their daily life.



“Post-traumatic stress disorder (PTSD) is a psychiatric disorder that may occur in people who have experienced or witnessed a traumatic event such as a natural disaster, a serious accident, a terrorist act, war/combat, or rape or who have been threatened with death, sexual violence or serious injury.”(psychiatry.org)

KEY INFORMATION EXTRACTED

- A fall from loss of motor control can lead to serious injuries, the gravity of which increases with age and physical composition of the individual.
- Loss of motor control, depending on the location at the seizure time, could lead to collision or falls from heights from which life-threatening injuries might ensue.
- Even more when alone and unattended, being unconscious for an extended period of time can be dangerous and can lead to irreversible damage to the brain and the body overall
- As we can see in the picture highlighted in pink the belongings of the individual are often spread out and might be stolen or just disappear after being projected away during violent motions.
- Following a seizure individuals wake up disoriented and sometimes have trouble understanding or remembering what happened. This could lead to more complications as it could trigger a panic attack and result in further injuries
- Depending on the environment the individual is in, by the time they regain consciousness the environment might have changed or may no longer be hospitable. For example in the case of a fire lack of oxygen might lead to death.

Requirements

A **set of requirements** were derived from the Scenarios and information exchanges previously explored.

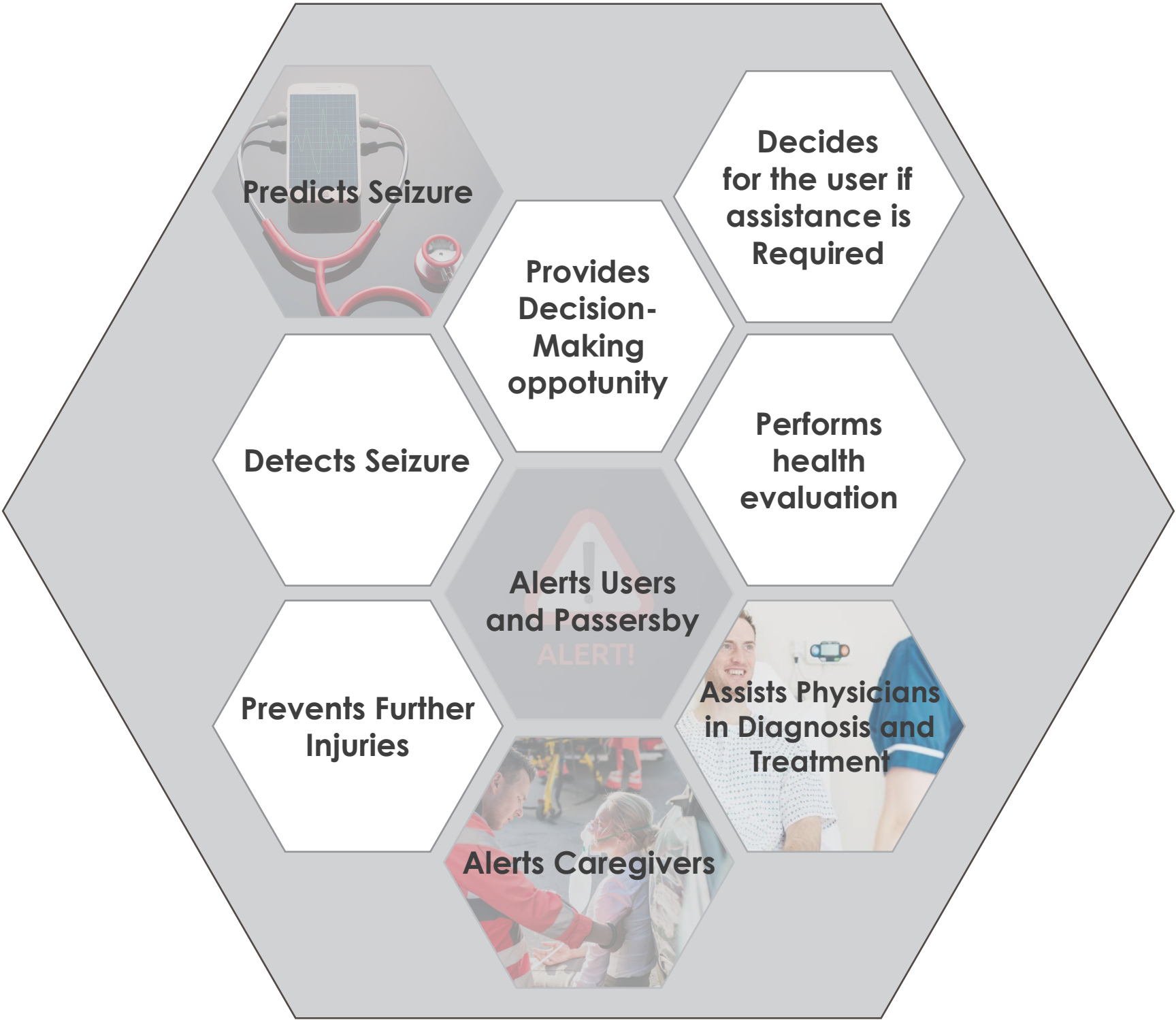
Among those are:

The **prediction of seizure**, as it would allow the individual the opportunity to decide whether they want to engage in an activity or not. Also it would allow them the possibility of getting into a safe position or place to wait out their seizure Episode.

Detecting Seizure as it is happening is for the purpose of tracking the duration of the seizure because even if generally seizures stop within 5 minutes there are occasions where it lasts more than 5 minutes and those are referred to as **Status Epilepticus** and are categorized as a **Medical Emergency**

Alerting the user in different ways to make them aware of an impending seizure. Alerts, however, can remain discreet while audible and detectable only by the user because some of them would rather keep their invisible disability invisible.

On the otherhand, during a seizure Episode **passersby** are often panicked and confused and communicating to them about the reason behind the behaviour of the individual, might reduce their confusion and potentially involve them in assisting the person in need.



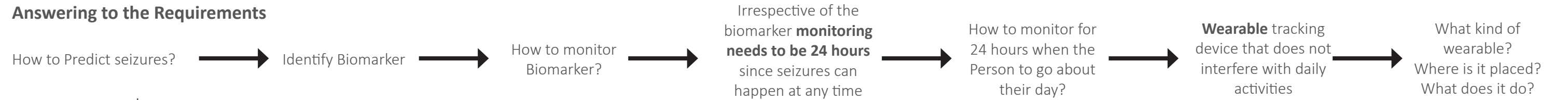
But I will argue that knowing complete product requirements up front is a quite rare exception, not the norm.

— Fred Brooks —

Key Facts that were discovered during the research on how to answer to the requirements:

- Generally before biological events the body emits certain signals in different forms and they are usually referred to as **Biomarkers**.
- **Biomarkers offer the potential to predict and detect the onset of biological events** and identifying the correct one can contribute to the prediction of Epileptic Seizures.
- **Heart-Rate Variability (HRV)** which is the measure of the Variation in time between each heartbeat can be used in combination with Patient-Specific algorithms to **predict Seizures to up to about 15 minutes prior**.
- An **Electrocardiogram (ECG)** can be used to monitor the (HRV) but in order to be useful in the case of a prediction device it needs to be **ambulatory**.
- An Electrocardiogram operates by having connections to different places on the body using **Electrodes**.
- Generally 1 lead, 3, leads, 5 leads and 12 leads ECG are used and the higher the number of leads the more accurate are the readings.
- In the case of an **ambulatory ECG** a 5 leads setup is a reasonable compromise.

Answering to the Requirements



Development

RESEARCHING

MOODBOARDING

SKETCHING

LOW-FIDELITY PROTOTYPING

CAD MODELLING

ITERATING

Prior to the decision to employ technology to answer to the requirements. The feasibility had to be investigated through research. The biomaker and its tracker had to be identified.

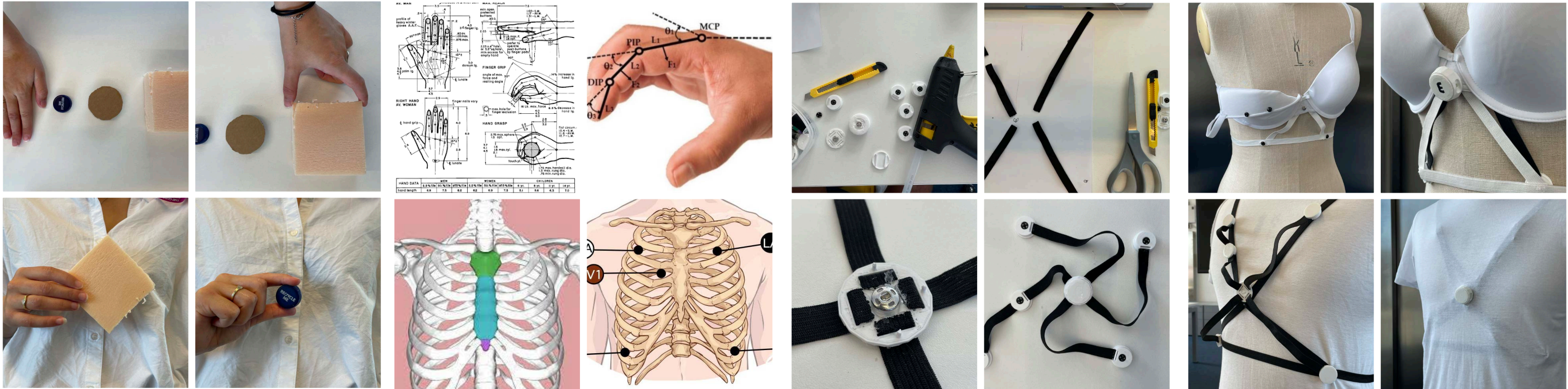
Moodboarding has allowed for the discovery of shapes and arrangements of devices that share some similarities.

Through sketches the establishment of a preliminary layout of the components and explore the different combination and evaluate them from a functional and aesthetic perspective.

The low-fidelity prototypes have allowed me to explore the user interaction and possible friction points and make discernible the touch points that would affect the usability.

CAD modelling has allowed for an understanding of the specific sizes and fitting of the components as well as the fitting onto a subject.

Moodboarding has allowed me to discover shapes and arrangements of devices that share some similarities.



Shape and size Justification

Epilepsy is categorized as an invisible disability. People with people might often want their condition to remain invisible as much as possible. For that reason, the size, concealability and aesthetics of the product were vital aspect of the design considerations. After the decision to make a wearable that would fit on the chest area several shapes and sizes of a device that could contain all the necessary electronics were explored. Initially from bought-in components a massive square like casing was derived which would have been in contradiction with all these considerations but also made it very unlikely to be adopted by people with epilepsy. Assumptions that custom made PCBs could be integrated in the device allowed for a smaller more aesthetically-pleasing form factor.

Human Factors

For increased adequacy of the product, its ease of use and the optimization of its touch points to avoid discomfort Human-factors had to be taken into consideration. The size of the device should be able to be worn and handled by individuals from a broad range of age, gender, sizes and preferences. As the development of the product progressed it was determined that the device would need to be worn for extended periods of time and that the electrodes should always be in contact with the skin at the intended placement. Allowance has therefore been made for flexibility of the materials as well as making available different sizes of the vest. As for the detachable ECG component a size that allows for comfortable interaction and that does not hurt the individual were they to sleep on their front was chosen.

Prediction Device Prototype

The development of Prototypes 3D printed from CAD models with appropriate sizes was to get a sense of the real arrangement and placement of the different component and visually understand their sizes in relation to the body in order to develop the vest, the accessories and the wireless charger. The device has also allowed for user testing and different attachment options were explored and their weaknesses identified so as to avoid them and account for different possibilities of failure.

Making it wearable

Following discussions with healthcare professionals the need for consistent correct placement was understood. For that reason a vest developed to assist in holding the electrodes in place throughout the day. With the help of 3D printed parts, elastic bands, a cotton t-shirt and a bra a prototype was made to explore the feel of a wearable of that size. Pressure clips were placed on the the elastic harness stitched to the t-shirt and the bra. The previously developed prediction device prototype was then easily clipped onto the two items. When trying out the prototype several strengths and weaknesses were identified. Of the weaknesses that needed to be addressed was the entanglement in the leads of the electrodes while putting on the vest.

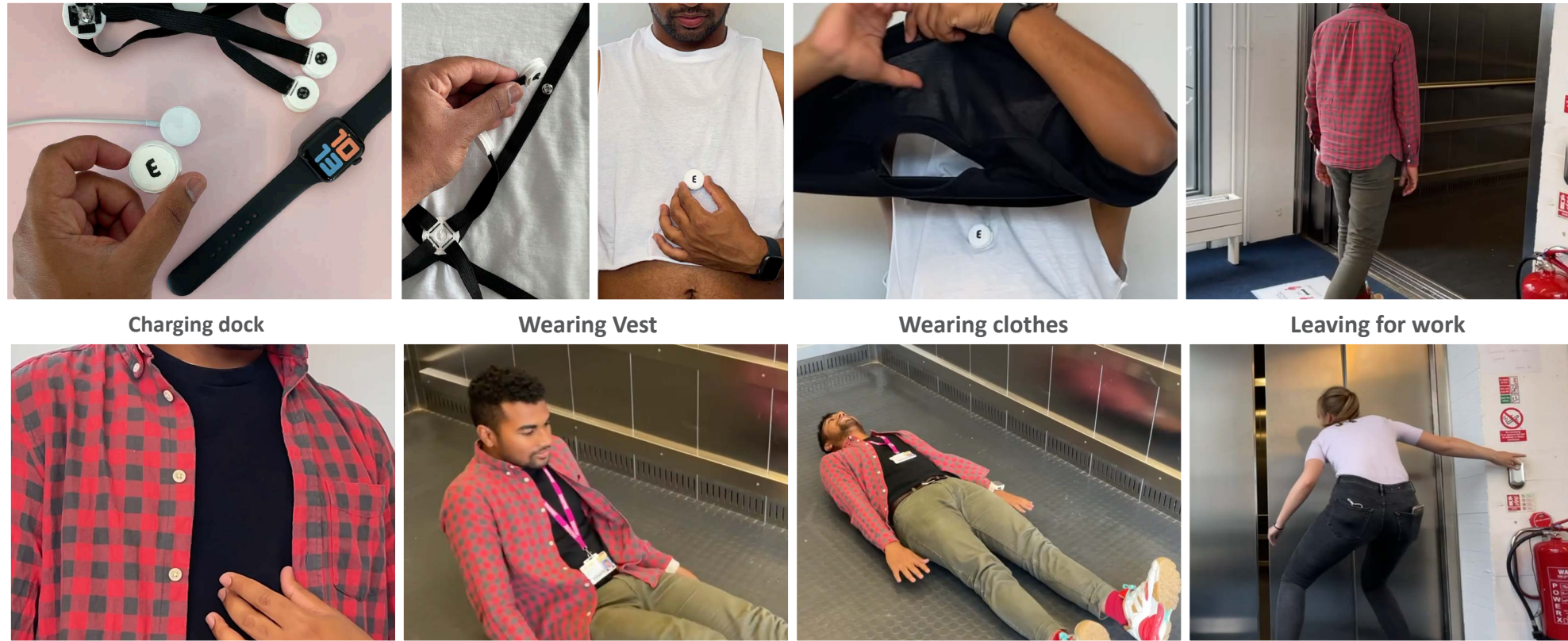
Evaluation



User Testing

For the scope of this project testing was limited to only the observation and evaluation of the interaction, ease of use, size and shape suitability, satisfaction and preferences of the users with the product rather than a technical evaluation of the function of the product. Evaluation subjects were a range of potential users, people with drug-resistant epilepsy as well as healthcare professionals. There were presented with a concept which they evaluated and responded with comments, concerns and suggestions for what they believe might be useful additions and substitution in the design proposed.

USER JOURNEY



Charging dock **Wearing Vest** **Wearing clothes** **Leaving for work**

Vibrates+Notification **Gets into safe space and sends alert** **Seizure is longer 5 minutes. Emergency services contacted.** **Emergency arrives**

BRIEF

The user journey walks us through a typical day in the life of a user. It starts off with picking up the device from the wireless charging station. The device and the electrodes are then clipped onto the vest which is flexible and washproof. The individual then wears his clothes on top of the vest making it seemingly invisible. He then moves on to go to work and on the way receives an alert through vibration on his chest and also as a notification on his watch and phone which he responds to by single pressing on the button on the side of the device. By doing so he acknowledges receipt and the device pings nearby caregivers about the possibility that assistance might be required in the near future so they can be ready to intervene if needs be. He then lies down to avoid falling down from loss of motor control. As his

seizure starts the device starts recording the magnitude of the seizure and its timings using the accelerometer and the ECG. The seizure, however, does not stop within 5 minutes and since that is categorized as medical emergency the device automatically contacts the emergency services and sends the GPS location of the individual to make it possible for him to be found promptly.

Alternative Scenarios

Several other scenarios were also explored in order to maximize the opportunity of finding potential improvement in the interaction of the user with the product and possibly add, tweak or substitute its functionalities.



Healthcare professional Review

Nico Muller from Harvard Medical School and Anna Gallagher from the School of Medicine at the University of Glasgow have given their insights and thoughts on the matter and have consequently brought several improvements to the design.



Environmental Factors

The product was evaluated from the perspective of its place in its environment of use and its possible impacts from the very first stages that is the design and manufacture to the usage and disposability. Materials and manufacturing techniques have a strong correlation with the environmental factors and for that reason the aim is to reduce energy consumption by choosing an energy efficient manufacturing process. Also materials waste should be minimized as much as possible. For electronic component such as the battery the raw materials and electrolytes have to be safe and disposed properly.

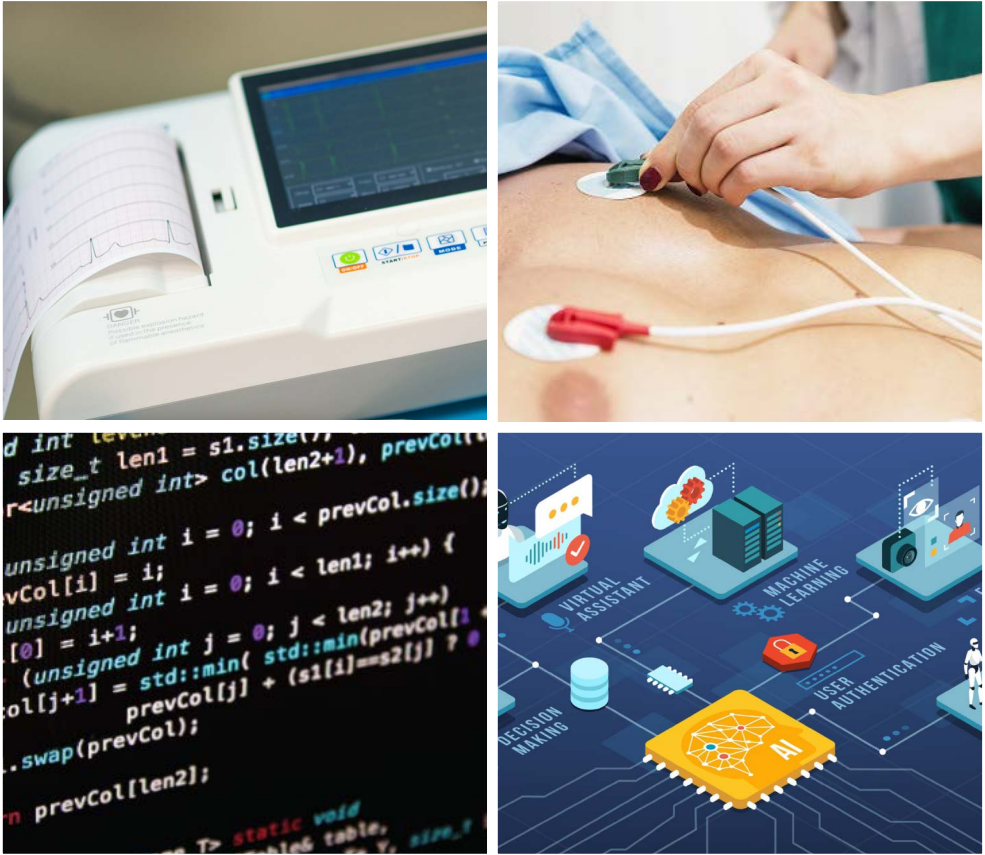
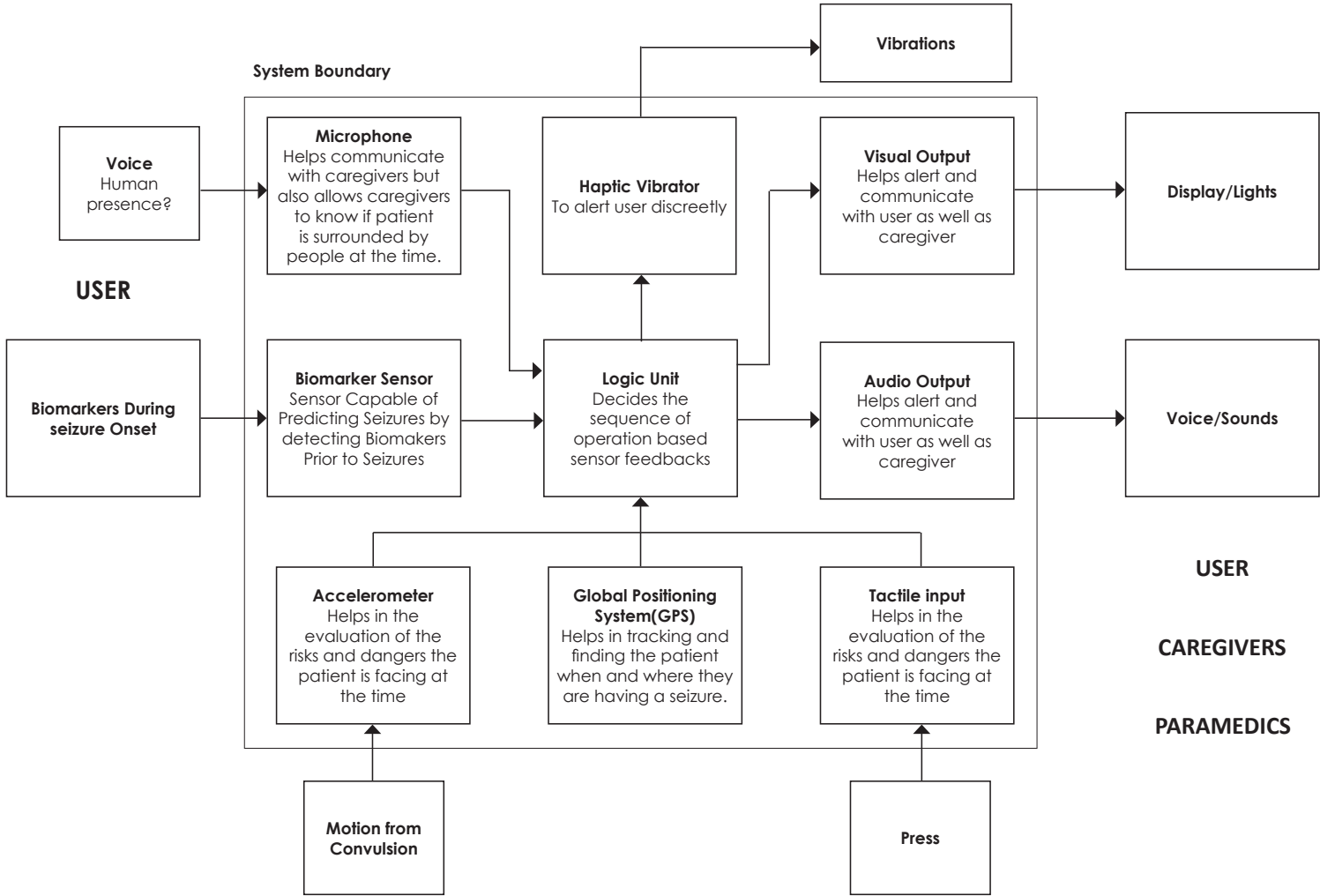


Market awareness

Through studies and surveys it is undeniable that there is a demand for such products. Currently there are devices of the same family but their limitations are the fact that they can only detect the seizures at the time they are happening which would not offer decision-making opportunities such as protecting oneself and alerting someone prior to the seizure.

How it works

Functional Topology
Moodboarding has allowed me to discover shapes and arrangements of devices that share some similarities



TECHNICAL DESCRIPTION

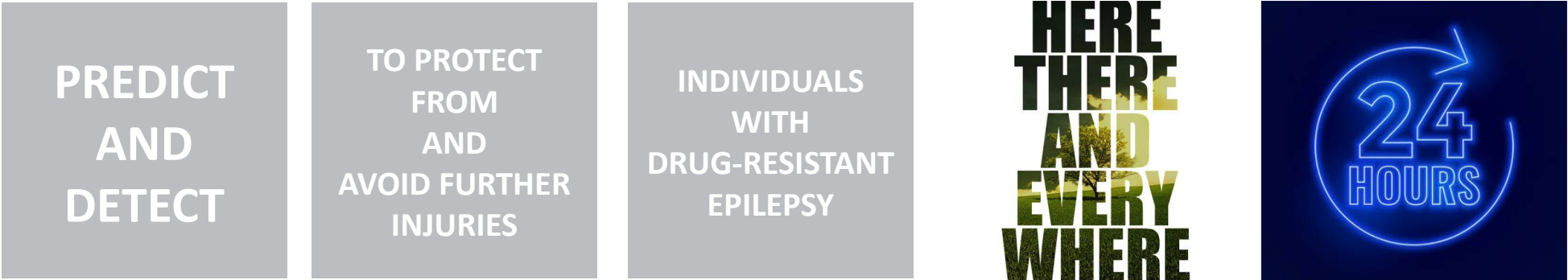
Proof of Technology adequacy
From research performed by a team of experts at the University of Modena and Reggio Emilia, ITALY, Heart-Rate Variability which is monitored using an ECG can be used in combination with the Mathematical Technique Recurrence Quantification Analysis in a Patient-Specific algorithm had the potential to predict seizures up to about 15 minutes prior to a seizure with a very low level of false positive.(number of false positive per hour (FP/h) of 0.41)

Implementation of the Technology
Currently the technology is restricted to stationary medical grade ECG in healthcare establishment but an attempt to recreate the functionalities of an ECG to implement it in a wearable could make all the difference as it would allow 24/7 monitoring while allowing the users to go about their lives uncumbered.

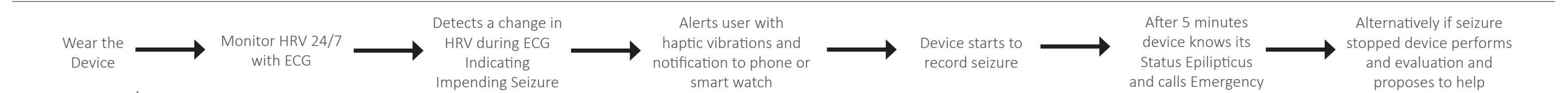
Principles of an ECG
ECGs usually operate on subjects at rest to minimize interference due to muscle artifacts and a 12 leads setup is commonly used in hospital for a thorough evaluation. In the case of an ambulatory ECG, however, 12 leads, some on the upper half of the body and some on the lower half would be hard to make and to wear. For that reason a compromise was made and a 5 leads ECG was chosen. From the Einthoven’s triangle for ECG and studies for the optimized placement of the electrodes there are promising results to expect.

Communication Technology
For communication to the user and the emergency services haptic feedbacks, smart device notifications and GSM have been selected.

CONTEXT OF USE



WHAT	WHY	WHO	WHERE	WHEN
Providing an early-detection method for epileptic seizures in individuals irregardless of the nature of their epilepsy and particular triggers.	Allows individuals the time to sit or reach a safe space before a seizure to avoid injuring themselves during loss of motor control. Helps in requesting assistance.	Individuals with drug-resistant epilepsy who are and about throughout the day and are at the risk of falls, injuries, other complications and even death.	At home, At work, on the road, Medical Establishments, Schools, Elderly care establishments.	Virtually all day, everyday depending on environment, occupation, lifestyle and severity of the epilepsy.



Benefits

“If I could know before I have a seizure I could be able to start driving again!”
(Ibrahim Gunny, Interior Architect)

“The best chance we’ve got at helping and potentially saving someone is early detection and prompt responses”
(NHS Worker)

“Now I can have peace of mind knowing that my child will be safe on his way to work!”
(Marie Christiane, Mother to a child with Epilepsy)

Don’t find customers for your products, find products for your customers.

– Seth Godin –



To the User

To relatives and caregivers

To the Emergency Medical Services

To bystanders and passersby

Because of the unpredictability of the seizures People with Epilepsy often find themselves restricted in their mobility and cannot engage in potentially risky activities such as driving.

- A device monitoring their HRV and alerting an impending seizure would allow people with epilepsy to allow go about their days without worrying about running into an accident or being in an unsafe place at the time of the seizure.
- A device assisting in alerting the emergency medical services in the case of an accident or medical emergency could mean the difference between life and death in some circumstances
- Usually for patients with Epilepsy medication dosage is based on the record they make of their episodes but very often in the seizure diary they keep there is a lack of accurate information and sometimes some of the seizures even go unnoticed during sleep. For that reason a device that keeps track of the seizure episodes could allow for better evaluation of their condition by their physicians and more appropriate medication dosage can be prescribed.

Relatives and caregivers of people with epilepsy are very often left to worry about the well-being of the latter when they leave the house and go about their day in a world full of unexpected situations and danger.

- Relatives and caregivers cannot always be by the side of the person with epilepsy and even if they are in the same house epilepsy is not particularly loud enough to be noticeable except maybe in the case of a fall and that might be already too late a sign to help someone as the fall might have lead to serious injuries in elderly individuals and those with compromised bone strength. For that reason a device that would allow for prediction, early alerts to the relatives and caregivers could help prevent complications.
- For cases where direct assistance is not possible the fact that they would be alerted about the seizure and condition of the person they care for would be a great way to allow them peace of mind. This is specially true in the case of parents who have children with epilepsy.

In most medical situations early discovery and intervention is the best hope for helping and saving someone.

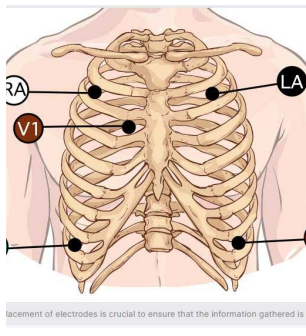
- Very often contacting emergency services is done by someone in the presence of the person requiring assistance and in the confusion and panic it is often very hard for them to describe the situation. With a device that is designed for people with epilepsy that would be registered with Emergency Medical Services they would already know that its for a person with epilepsy and data being recorded from the device could be fed to them as live updates of the patients condition while they are on their way and could help prioritize in case there are other people more in need of assistance.
- The device is also equipped with a GPS which would help the emergency medical services to navigate to the person in need promptly and accurately.

Passersby are very often confused and terrified at the sight of a seizure episode and can sometimes even mistake it for the effects of recreational drugs and alcohol leading them to mistreat the individual in need of help.

- As the individual having a seizure episode falls to the ground or willingly lies down but is unable to communicate the reason for his involuntary and voluntary action the device paired with their phones communicates to the passersby though the phone loud-speaker allowing them to understand that the person is having a seizure.
- Also as the device communicate to the bystanders and passersby it offers the potential of notifying a healthcare professional in the vicinity to assist the person faster than the emergency medical services.

“All in all I believe this device has the potential to help not only the user but also the range of stakeholders affected by this condition”
(Anna Gallagher, NHS worker)

Feedbacks



Polls from Potential Users

When presented the different concepts and asked to choose and rate the different combinations the potential user responded as follows:

- 7 out 11 would wear the device only if it is concealable while the rest would not mind even if it was not.
- 3 out 8 have not been in a situation where their lives were at risk but were always anxious that it could happen.
- 5 out of 8 would prefer a watch over vest.
- 7 out of 11 are willing to invest in such a product.

General Comments and Concerns from Potential Users

Potential users expressed several comments and concern in relation to the product both in its design and reliability.

- They were concerned about the comfort and wondered if it would be itchy
- They wonderered if they had to wear it all the time.
- They wondered how often they had to charge it.
- They wondered if they could do physically intensive activities while wearing it
- They are more focused on the reliability rather than the aesthetics.

Healthcare Professionals feedbacks

Healthcare have expressed their concerns and suggestions as to what they believe need to be considered and guaranteed.

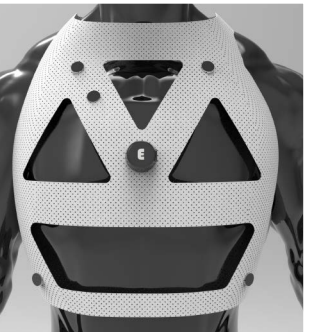
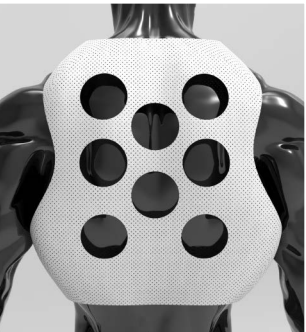
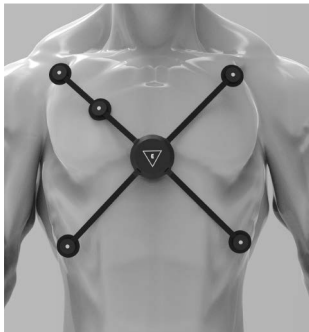
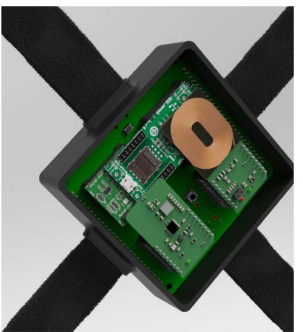
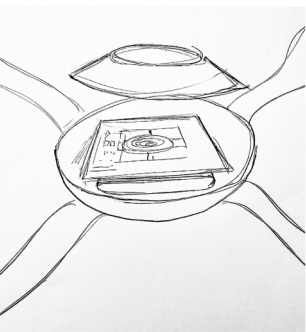
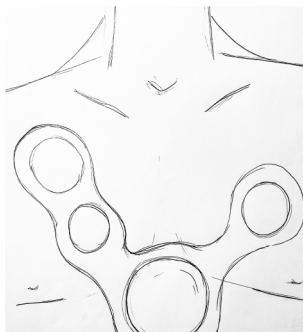
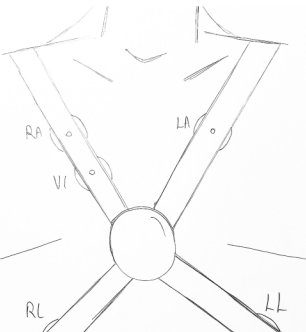
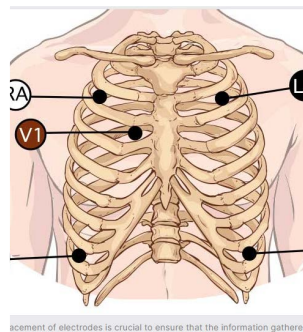
- Worries about false positves were expressed.
- Concerns about the impacts of motion on the recordings of the ECG and wondered about what was being done to answer to that problem.
- Discussed the tolerance and optimization of the electrode placement for better results.
- Discussed the principles of the ECG.
- Wondered about biocompatibility of the material.

Ideas Brought forward

Device was designed to be as concealable as possible. It is intended to be placed underneath the clothes. As for the preference for the watch a compromise had to be made for the sake of accuracy over aesthetics as a watch would offer only a single lead ecg while a vest can offer a leads ECG bringing the number of false positives to a minimum. Breathable and biocompatible materials were explored and employed to answer to the needs of comfort. Wireless fast charging was implemented for convenience. A vest with a predetermined placement of electrodes was designed to ensure consistent correct placement at optimized locations.

Refinement

DESIGN EVOLUTION



Engineering

For the development of this product several engineering best practices were employed both for proper time management, prioritization and to answer the requirements from a technical perspective ensuring feasibility.

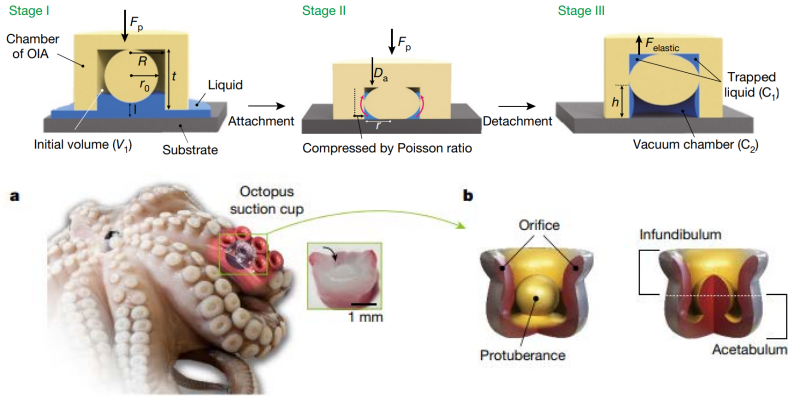
A special attention was given to the technical aspects of the design of the electrodes as from Quality Function Deployment the sensor component of the product was identified a crucial one in order to fulfill the requirement previously established.

Adhesion is an important aspect of the electrode design as it is crucial that it is constantly in contact with the body and as stationary as possible to minimize signal disruption and consequently inconclusive readings from the ECG.

Proposed by a team of expert adhesion is usually attained by three methods of which is the creation and replication of microstructures to create dry adhesive. The octopus inspired architecture (OIA) was therefore explored in relations to it potential for application in the electrodes for the prediction device.

Simulations were performed with the following equation as the relationship of the different parameters with the suction stress which in laymen terms is its stickiness.

$$\sigma_{suc,wet} \cong -2.145 \left(\sqrt[3]{\frac{1-\nu^2}{E}} \right) \left(\frac{(2R+l)Rkn}{\sqrt[3]{tr_0}} \right) \Delta P \times F_p^{1/3}$$



The outcome of these simulations were the understanding of the impacts of the number of OIA per unit area, the radius of the OIA, the Poisson's Ratio and the Young's Modulus of the material used for the electrode.

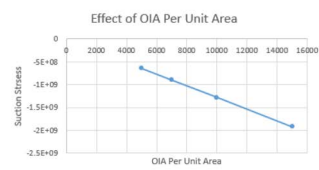


Figure 9: 5 Effect of OIA per unit Area on Suction Stress

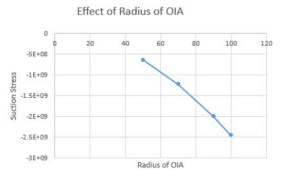


Figure 10: Effect of Radius of OIA on Suction Stress

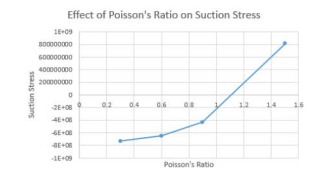


Figure 11: Effect of Poisson's Ratio of Material on Suction Stress

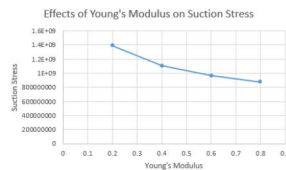
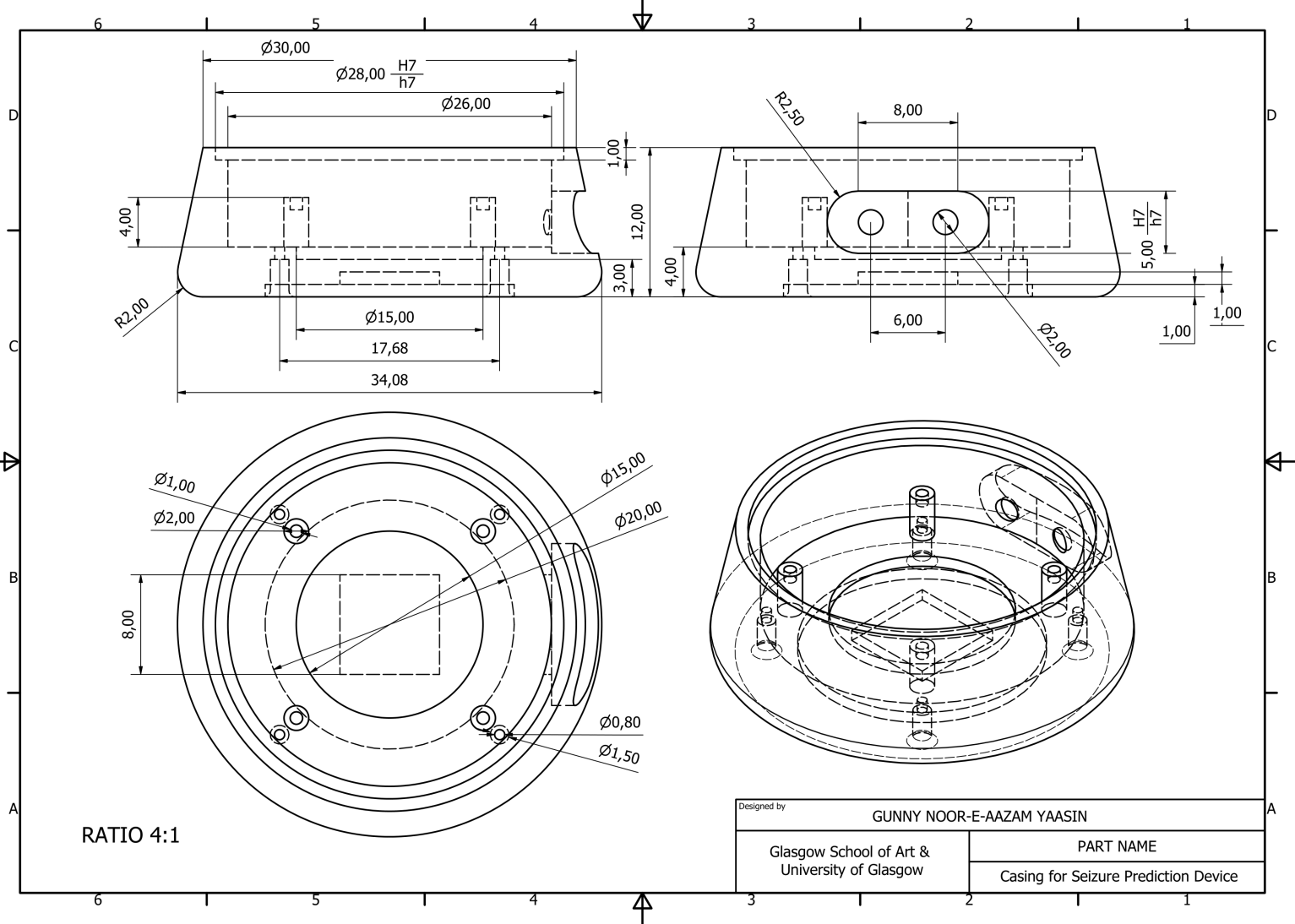


Figure 12: Effect of Young's Modulus of Material on Suction Stress

Other aspects of the design were also considered and the assumptions for the battery selection and other technology technical information were briefly introduced.

Engineering drawings to offer an understanding of the structure and assembly of the bottom part of the casing was also provided.



Reflective Summary and Future work

In hindsight more time could have been spent on the design in regards to the user interaction and comfort if the biomarker was identified sooner. A large amount of research has been made and a great deal of interesting information with great potential was gathered and if it were to go into development a with proper funding this device could actually be manufactured and made available for people with epilepsy and inevitably offer significant benefits to them.

If this was to be taken further then more research and decisions would have to be made about the sizes of the electronic components. An actual electrode design could be derived from the trends identified in the simulations. A working prototype would be the next step along with the understanding and development of the patient-specific algorithm used in the processing of the data collected by the electrocardiogram.

Final Concept

Brief

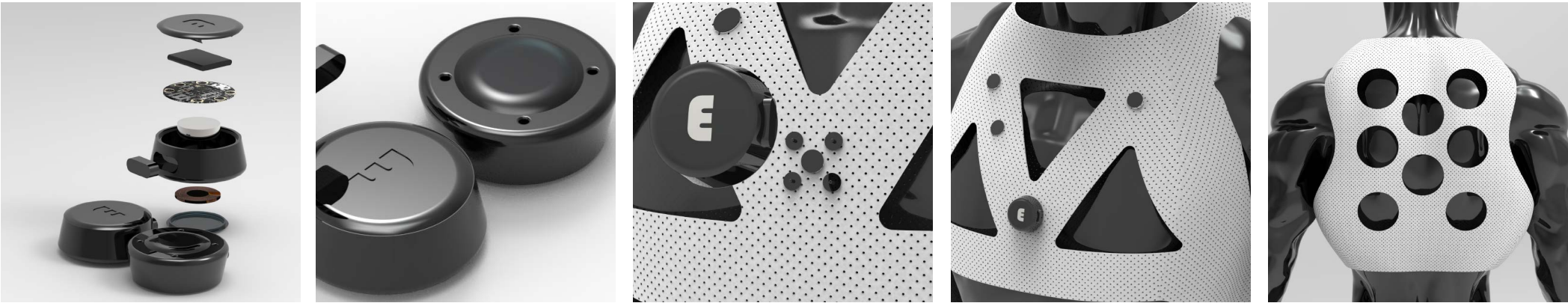
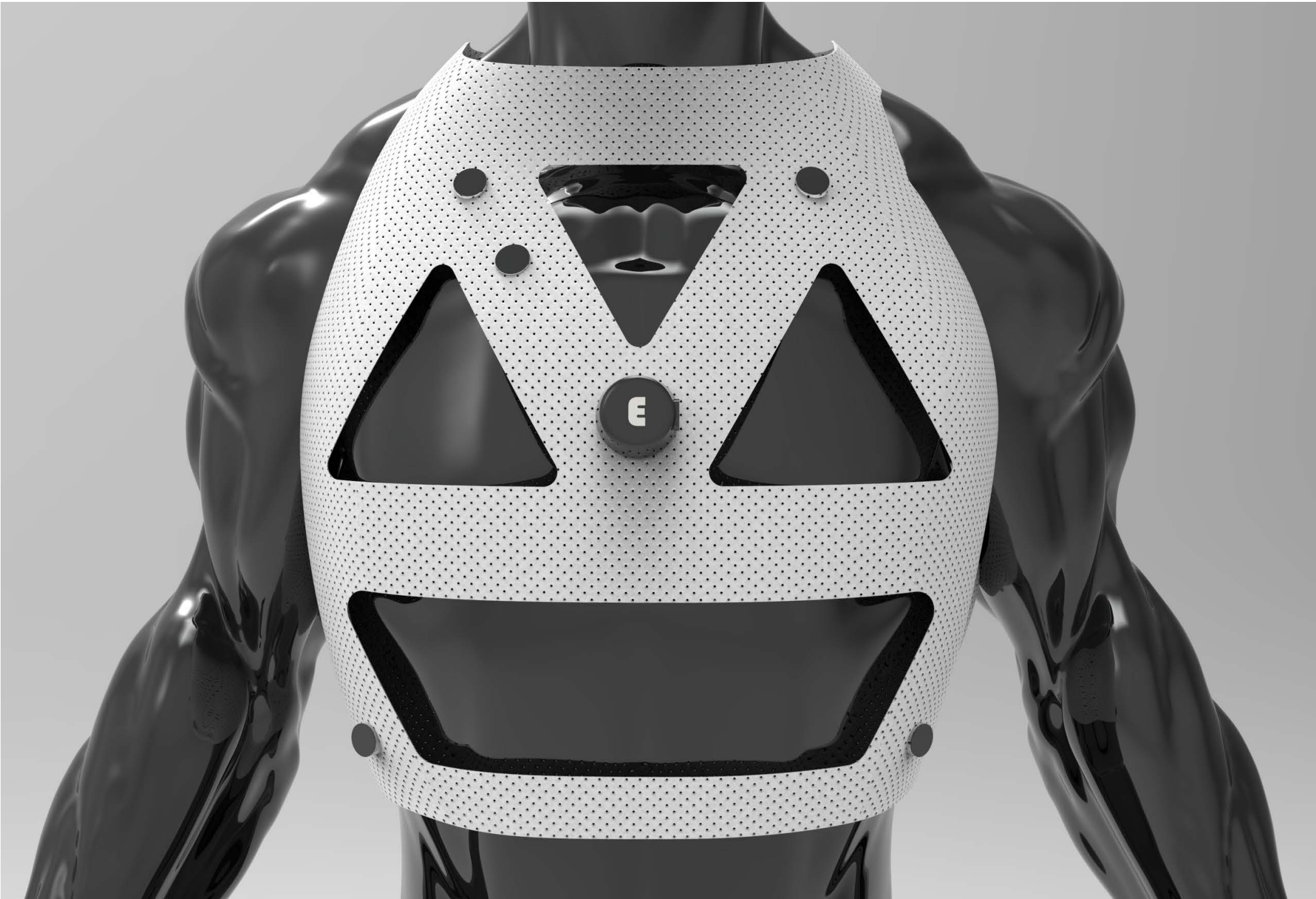
The final concept is the product of several iterations which started off as sketches and prototypes and ended up as the following 3D CAD renders.

The vest was designed to fit onto the upper-half of the body to hold the 5 electrodes at the pre-determined optimized locations. It is made of a biocompatible, flexible and breathable material and is available in different sizes both for men and women.

The central unit, where all the electronics are and where all the processing happens, is a detachable component. It was designed this way in order to allow easy charging through a wireless charger but also because the vest can then be washed without compromising the electronics.

It holds onto the vest securely with the help of a magnetic force and the 4 male pins leading to the electrodes.

The leads are embedded in the layers of fabrics of the vest for ease of use.



In user testing it was identified that dangling wires were a problem.

The flexible dry-electrodes on the opposite side of the black circles on the front side of the vest are made of biocompatible conductive material. The electrodes were designed using the Octopus-Inspired Architecture (OIA) for strong adhesion without the need for electro-gel or adhesives thereby eliminating the risks of skin irritation. These kinds of electrodes offer uncompromised signal capture under normal conditions as well as after physically intensive activities where sweat usually affects the signal in conventional electrodes.

The geometrical cuts on the front and back of the vest are meant for increased breathability especially in the case of physically intensive activities.

The ECG, the accelerometer, the GPS receiver, the GSM module, and the bluetooth module are all enclosed in the compact central unit. The central unit also contains a haptic vibrator in order to discreetly alert the user of an impending seizure. Connection to the electrodes are through pins on the surface of the vest which get into the central unit from underneath.

The device is powered by a rechargeable battery that is also enclosed in the central unit of E4.