e-PUPP

Electronic Pressure Ulcer Prevention Pads

Project Summary

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The Problem: Pressure Ulcers

What are they?

A pressure ulcer is a localised breakdown of the skin and underlying tissue caused by prolonged exposure to pressure, shear and friction. Pressure ulcers are responsible for a significant reduction in the quality of life, and cause a huge amount of pain and discomfort for those that suffer them.

Who do they effect?

It is estimated that just under half a million people in the UK will develop at least one pressure ulcer in any given year. They are most likely to occur in people who are already seriously ill and have impaired mobility. **A patient's lack of mobility**, or awareness of the need to move, **is generally the main reason for pressure ulcer development**, however other health factors such as those that come with age can escalate the problem. Therefore those who are chair or bed-bound are most at risk.

What are the causes?

The extrinsic factors which cause pressure ulcer development are pressure, shear and friction. These all contribute to the occlusion of blood vessels and hence **a restriction of oxygen and other vital nutrients** reaching areas of tissue. This restriction of oxygen, known as ischemia, is most prevalent in tissue around bony prominences and hence it is in these areas that ulcers are most common.

How are they treated?

The primary approach to pressure area care is through **reducing risk to the patient**. This comes through improving controllable aspects of the patient's health, such as their diet, but more pragmatically it comes through **regular nursing attention**. High risk patients are regularly repositioned by nurses to redistribute pressure from an area of skin. There are also technological approaches, such as the use of 'high-tech' airflow mattresses, to reduce the effects of pressure.

PREVENTION IS KEY

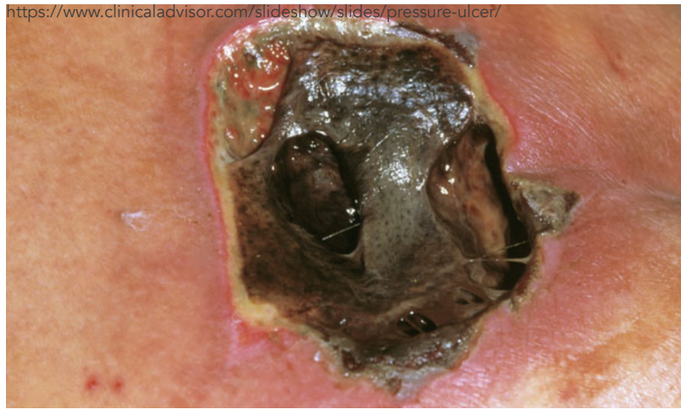
The impact of pressure ulcers

Pressure ulcers have significant consequences for patients, but they also have major financial implications to healthcare providers.

50% of patients who develop a serious ulcer die within 4 months.

£1.4 million/day
Cost of treatment for the NHS

https://www.clinicaladvisor.com/slideshow/slides/pressure-ulcer/



An example of a severe infected pressure ulcer.

Notable insights from preliminary research

Existing Technology

Technology is already being implemented in pressure area care, most notably with the use of 'high tech' dynamic mattresses that use alternating airflow to shift pressure around the body. Despite their significant cost, these mattresses have limited benefit, and are only proven to be effective for patients with pre-existing pressure ulcers.

Nursing Care

Where there is adequate nursing care, pressure ulcers are less prevalent. The flip-side of this is where the problem lies: **a lack of nursing care creates risk**. With nursing staff increasingly stretched, especially during the current pandemic, an improved method of pressure ulcer prevention that is not so reliant on nursing care would be hugely beneficial.

"Pressure ulcers remain a concern and they are mainly an avoidable harm. There is a profound impact on the overall wellbeing of the patient and they can be both painful and debilitating."

Nikki Proctor, Senior Nursing Manager

"They are a massive strain on nursing staff, in both time and physical effort"

Hilary Dereham, Senior Nurse

"It would be lovely to see something technical that would reduce the duplication of nursing time"

Liz Deutsch, Consultant Nurse

"The cost of prevention is half the cost of treatment"

Nikki Proctor, Senior Nursing Manager

Research and Concept Development

Research: Interviews

Due to the nature of the project, insights from clinical practitioners and experts in tissue viability were instrumental in the development process. Despite not being able to visit the user group in-person, these insights enabled a broad understanding of the user environment, and indicated where a solution might be most appropriate.

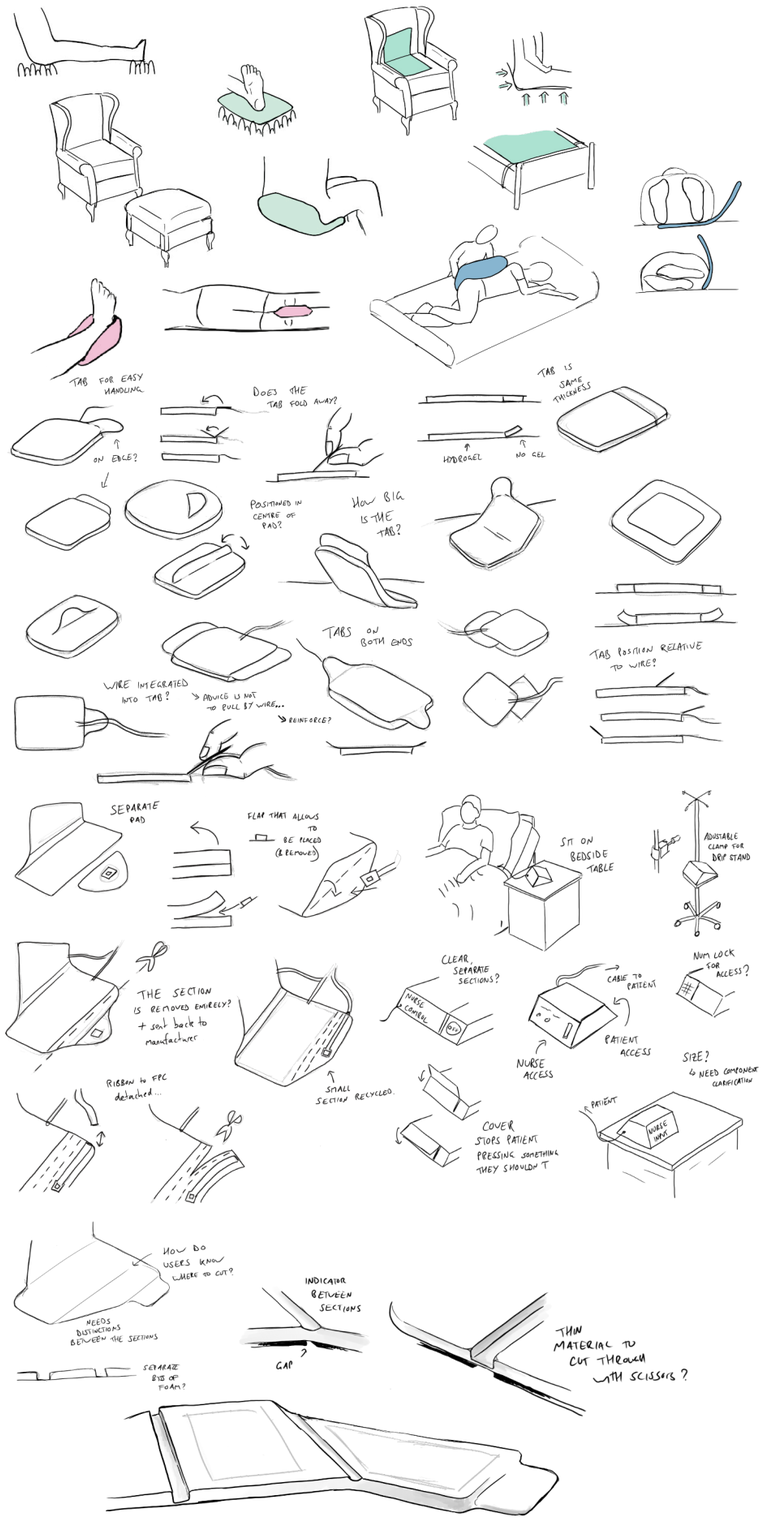
An example of this was through an interview with a physiotherapist, Rosie Bartlett, whose alternative approach to repositioning patients changed the course of the project. The emphasis from Rosie's perspective was on repositioning patients for the sake of movement, not purely to redistribute pressure. Movement activates joints, muscles and tissues, encouraging the flow of blood and reducing the chance of ischemic injury. This insight was instrumental to the discovery of using extrinsic therapy to simulate exercise and promote oxygenation to those at risk of developing pressure ulcers.

Research: Literature Review

A large aspect of this project is involved with the therapy implemented, and how it can benefit those at risk of pressure ulcer development. Literature review was essential in providing an understanding of how the technology can stimulate a natural physiological response capable of stemming the onset of pressure ulcers.

The therapy has has been proven effective at increasing levels of oxygenation in tissue through muscle contraction, and also by stimulating the release of Nitric Oxide (NO), a natural vasodilator that the body releases when blood flow is threatened, for example when exposed to external pressure.

Concept Development

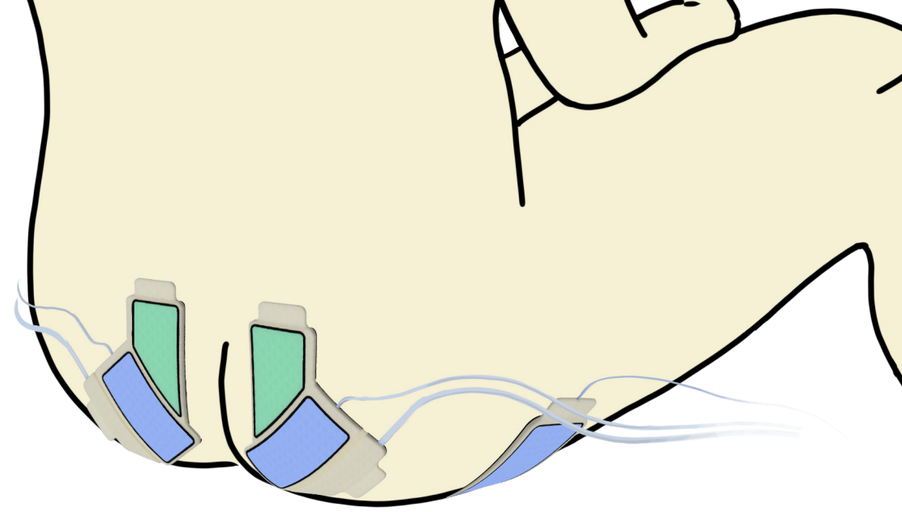


2D ideation was essential in exploring potential forms of the product, from wide-angle concepts to the refined details of the product.

The concepts were thoroughly evaluated against the requirements of the users, the patients and their care providers, whilst being guided by the application and feasibility of the technology. Various methods of the therapy were explored, for example integrating essential components into a surface rather than in a wearable. Ultimately a combination of technological and patient requirements determined that it was necessary for the these parts to be applied individually to the skin.

Prototyping through the use of a device capable of performing the desired therapy and iterations of physical modelling allowed the refinement of a product that provides a **novel, combative approach to preventing pressure ulcers.** Prototyping helped ensure that the solution **does not increase the workload for nursing and care staff, and intuitively and seamlessly integrates into their existing workflow.**

The Solution: Product Overview



E-PUPPs, or Electronic Pressure Ulcer Prevention Pads, offer a novel, combative approach to the prevention of pressure ulcers. Rather than relying solely on the nursing profession and pressure alleviating mattresses to prevent pressure injuries, this device approaches the issue from a more technological standpoint and coordinates extrinsic therapy with the appropriate physiological responses that keep pressure ulcers at bay.

Designed to work in conjunction with standard nursing care, this product reduces the risk of pressure ulcers forming on the sacrum and buttocks and extends the length of time between nursing turns (repositioning the patient). This helps to reduce the strain on nursing staff and allows them to make better use of their time.

Control Unit

Human factor influenced form
Accounts for varying angles of view of different users.

Patient & nurse Control
(Depending on the cognitive ability of the patient)

Intuitive UX design
No prior training is required.

Power supply
9V PP3 style batteries.

Hospital Compatibility
Flush surfaces enable easy cleaning.
Drip stand mount for use in ICU.

Wearable Pads

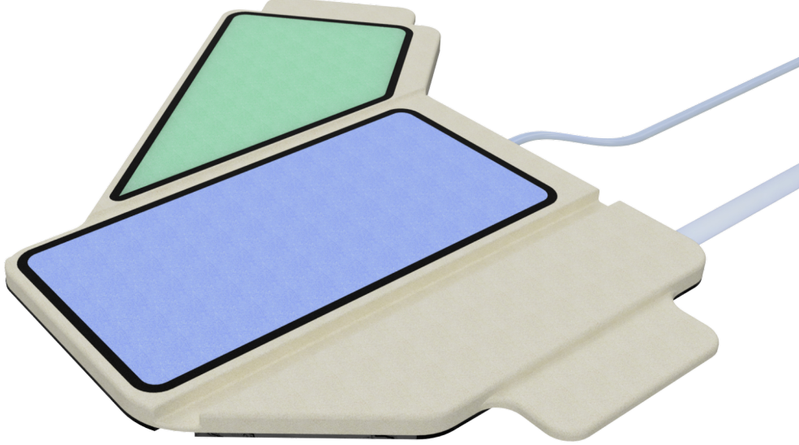
Integrated Therapy Feedback
Enables safe and effective therapy with the most vulnerable patients.

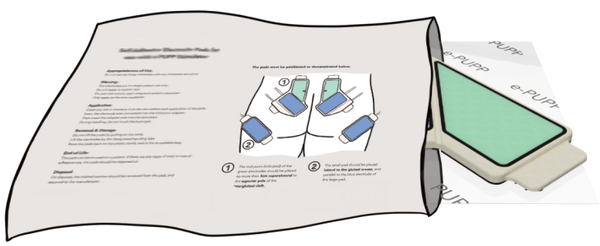
Foam Topping
Reducing pressure and protecting crucial components.

Handling tabs
Enable easy handling whilst wearing PPE.

Removable Technology
Encouraging recycling and reuse of valuable components.

Sealable packaging
Prolonging the lifetime of the pads, and providing a pad placement guide and instructions of use.





12
Cycles of use (10 hours each) on one battery.

Both the control unit and the pads conform to the medical device specifications of

BS EN 60601-1

User Journey

1

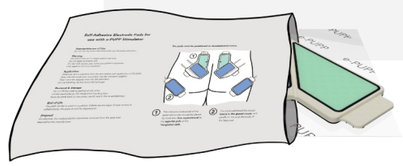
Patient is identified as being suitable for an e-PUPP device.

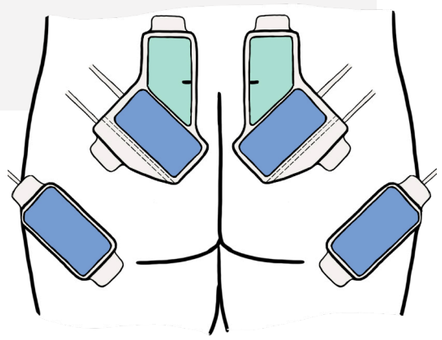
The patient has a Waterlow Assessment score of 20+ and is at risk of ulcers developing on their sacrum or buttocks.

2

e-PUPPs are removed from their packaging and applied to the patient.

The instructions for use on the packaging provide a placement guide.

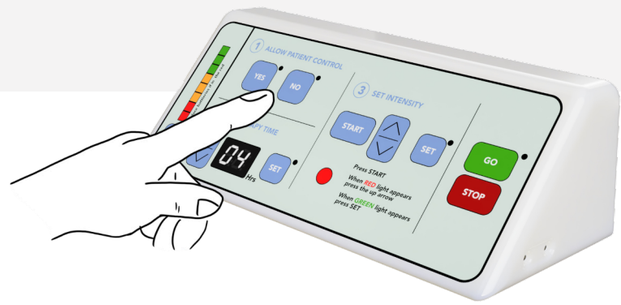




3

The nurse inputs the parameters of the therapy.

They choose: whether to give patient control, the time limit, and the therapy intensity level.



4

During use, patients have the ability to alter the therapy.

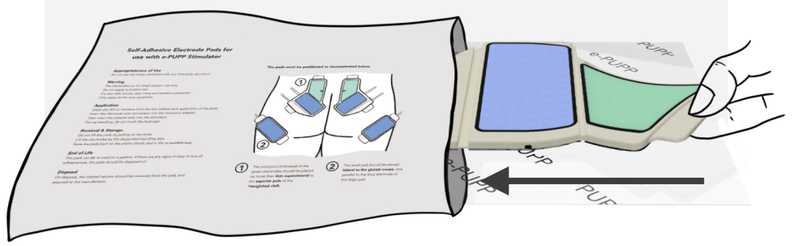
Depending on their cognitive ability they can stop the therapy, reduce the intensity or send an alert to a nurse.

or

5

If they are to be used again on the same patient…

After use the pads are placed back in the sealable storage for reuse.



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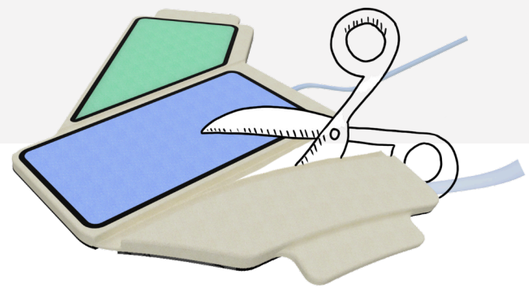
If the patient is not to use the pads again…

The technology section is removed and returned to the manufacturer.

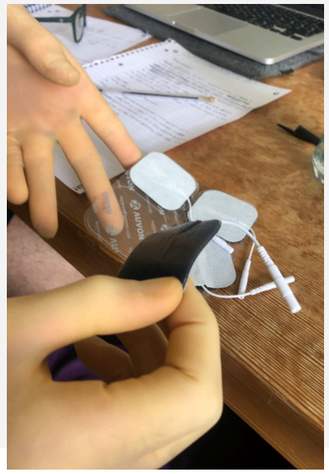


Nursing Considerations

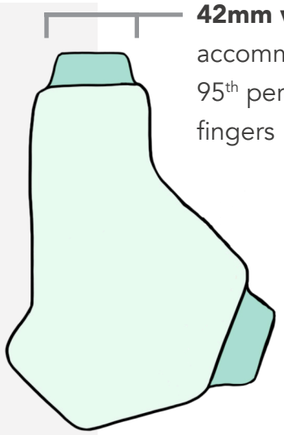
Handling Tabs

PPE has become an everyday challenge of working in hospitals. There are many fiddly jobs that are made even more so by PPE.

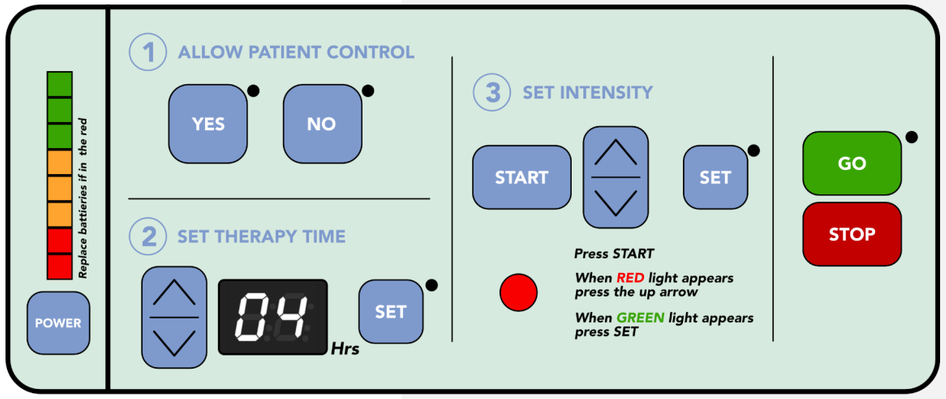
PPE gloves cling to the hydrogel adhesive used on the wearables making what should be a straightforward process a painstaking task.



It was determined that two handling tabs positioned on either end of the pad would provide the best handling experience. These tabs should also be large enough for both the index and middle finger.



42mm wide, accommodating two 95th percentile male fingers



Control Unit UX

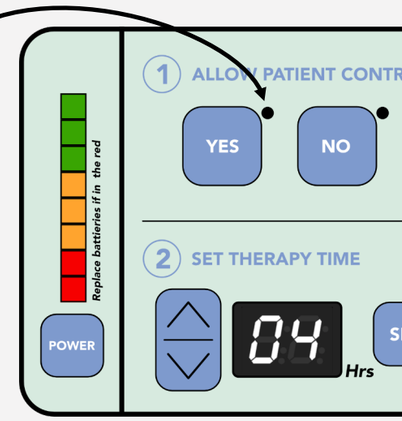
In order to fit seamlessly into the nursing workflow, the control unit user interface must be cognitively compatible and be usable with no prior training.

The design leads the nurse through each stage of setting the therapy parameters, ensuring each task is completed before continuing to the next.

LEDs are a visual signifier that each parameter has been entered.

The state of the power source is available at the click of a button (requirement of BS EN 60601-1)

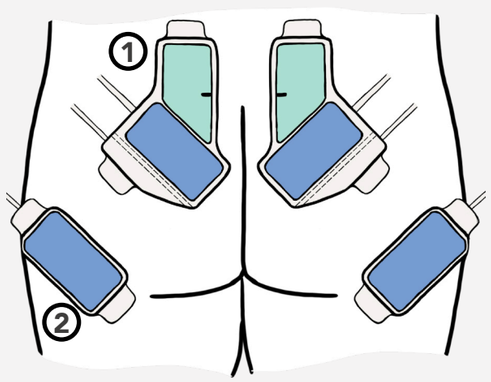
The smallest button size accommodates the 95th percentile male finger, ensuring the ease which which the device is used.



Placement Guides and Packaging

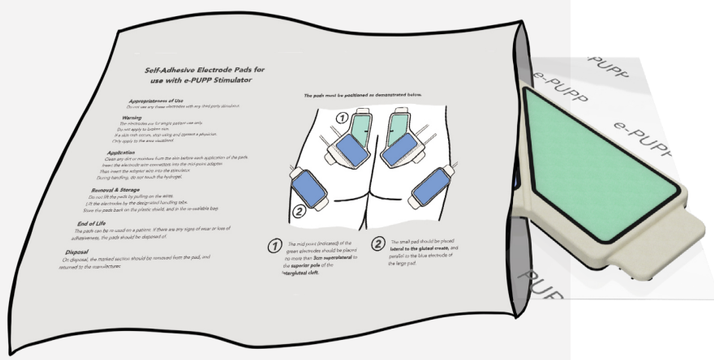
BS EN 60601-1 states that instructions for use shall include:

- "Easily understood diagrams, illustrations, or photographs showing proper connection of the PATIENT to the ME EQUIPMENT." (7.4.3)
- "The nature of the HAZARD, likely consequences that could occur if the advice is not followed, and the precautions for reducing the RISK." (7.4.1)



The pad packaging covers both of these requirements. The correct pad positions are described according to physiological reference points and visually represented in context of the human body.

These details are positioned so that it is impossible for the nurse to remove the pads without reading the instructions.

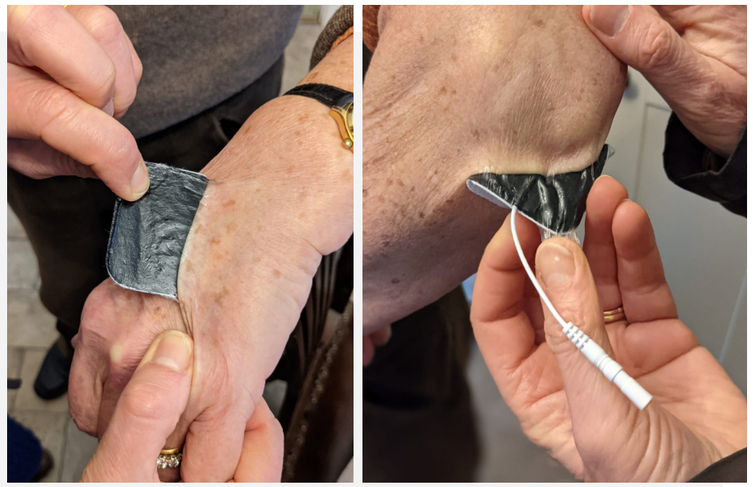


Patient Safety

Hydrogel Analysis

A commonly raised concern from clinicians was the safety of using an aggressive hydrogel adhesive with the potentially frail skin of the user group.

It was decided that the **AG700** hydrogel is safe and suitable for the user group of this product. All hydrogels pass the **ISO 10993-1** biocompatibility tests for intact skin contact.



After testing, the participants and healthcare professionals were both happy with the quality of the hydrogel.

"The sticky sites are all fine, no sign of any redness or anything. They were easy to peel off leaving no sticky patch"

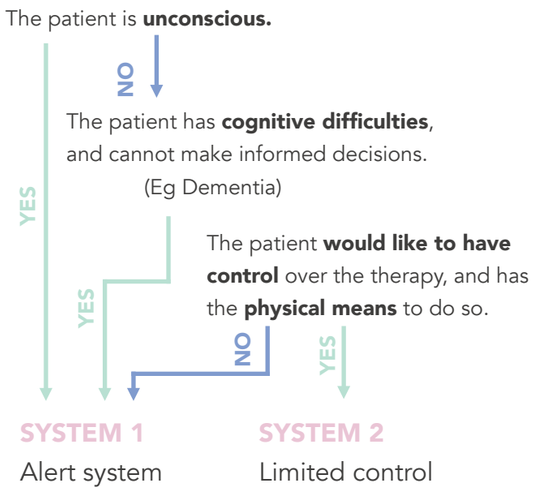
Safety Function

Another issue raised by clinicians is the level of control that patients have over the therapy.

A phrase often used in clinical practice when discussing this issue is:

"Respecting the patient's autonomy"

People feel differently about whether they want to be in control of their own treatments, and whether they can be in control depends on their **cognitive ability**, and their ability to make **informed decisions**.



This decision over whether the patients have more or less control over the system is ultimately decided by the care provider, guided by this decision tree.

Pressure Risk Mitigation

If the wearable pads increase the risk of pressure injury, they have failed at the first hurdle. Considerations have been made in both the form and material selection to mitigate these risks.

The foam protective layer is ultimately used to mitigate any risk that result from the rigid electrical components.

The material must be a compromise between being firm enough to offer protection whilst remaining as thin as possible, and soft enough to provide enough comfort to the user. It was decided that *Zotefoam's* **Supazote** medical grade foam offered the best compromise between these properties.

"The product MUST NOT increase risk!"

Cost Analysis

Based on assumptions gathered from the estimated raw material and component costs, the estimated sales price of a single set (of 4 pads) of an e-PUPP consumable is:

£27.36

To be cost-effective (based on assumptions of patient requirements) the device must prolong the time between nursing turns by **16 minutes**. If the device prolongs the time between turns by **30 minutes,** using e-PUPPs could save the NHS an estimated

£103400 every day.

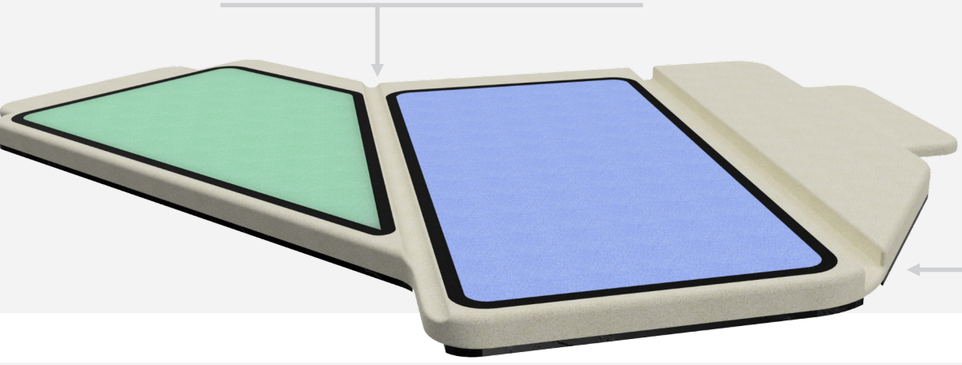
Design Detailing

Pad Details

When prototyping the form of the large pad, it was found that the unique shape (defined by the required locations of the internal components) was not a cognitively easy form to orientate and position, even when following instructions. Using a colour scheme that marries up with the placement guides proved a good way of encouraging users to position the pad correctly.

Incorporating features into the surface of the pad also helps users differentiate between the sections, and brings the fact that they have different roles to the forefront of their thought process when placing the pads.

This feature marries up with a gap in the hydrogel (there to eliminate continuity between therapy modalities) and will create a flex point in the pad. This will provide a sensory differentiation between the sections.

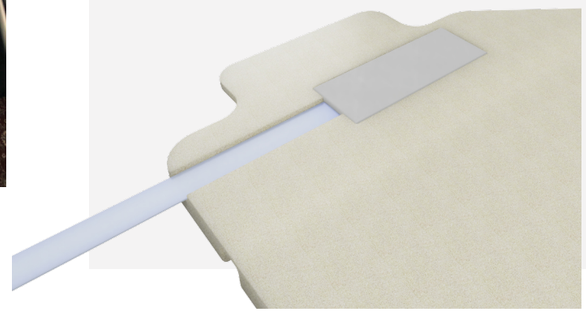


This more pronounced feature provides a section of the pad that is easy to cut through, allowing easy removal of the embedded technology.

Assembly

The technology housing containing the electrical components has an interference fit with the foam allowing it to be embedded prior to the whole pad assembly. The foam component is then mounted with specific foam acrylic tape onto the carbon substrate and hydrogel adhesive.

The assembly is outsourced to *Axelgaard*, who have the facilities to manufacture medical devices appropriately **(cleanliness ISO level 7)**.



The underside of the foam showing the embedded technology housing.

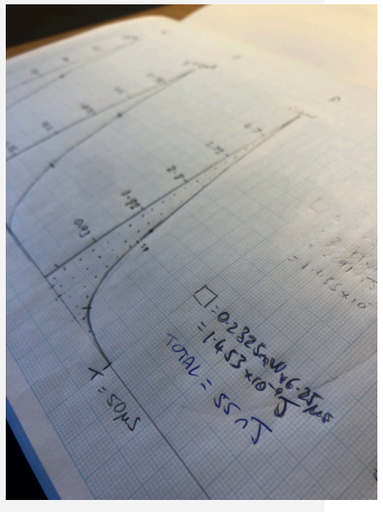
Power Requirements

In order to choose a suitable power supply, the power requirements for both the therapy and the control unit were calculated.

Based on the assumption that the intensity is set at roughly 50% of it's maximum intensity, a 9V PP3 battery will last:

125 **hours**, equivalent to

12 **cycles** of 10 hour uses.



Circular Economy

The circular economy is something that is often overlooked within medical devices. The vast majority of medical waste, which includes medical devices such as the e-PUPP pads, is deemed hazardous and is incinerated.

Whilst this cannot be changed, the embedded technology within the pad has been designed so that it, along with the associated wiring, can be removed from the device and remanufactured prior to the rest of the pad being incinerated.