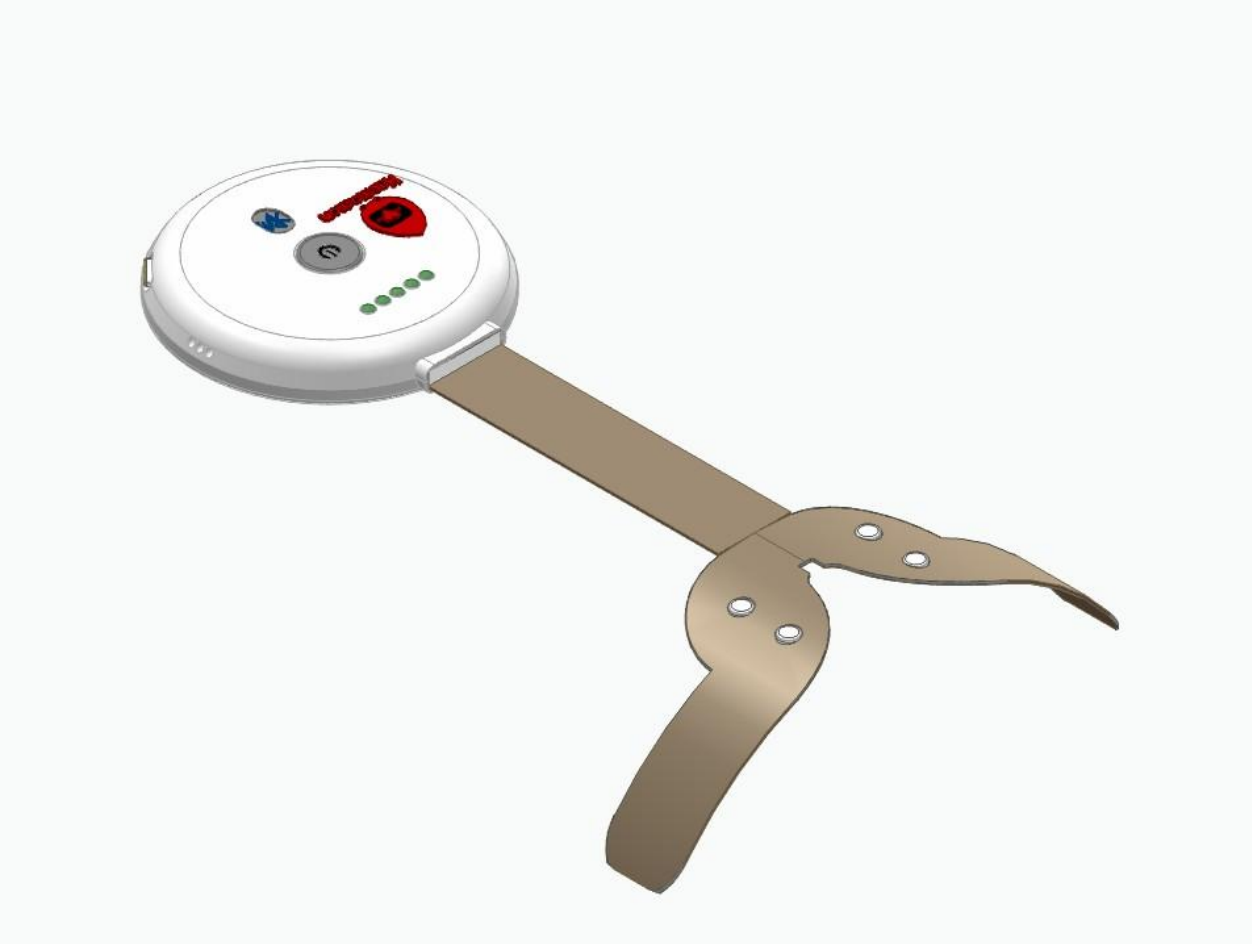
Group 2 Project Report

“Haemo.mon.” Bio monitor



Date: 03/04/2025 **Module**: MEC365

Lecturers: Dr Gregory Tierney, Dr Calvin Ralph, Dr Krzysztof Rodzen

Team Members: Kacper Bartkowiak, Sarah Beattie, Aidan Bradley, Joshua Belvis, Conor Bonsall, Komal Bairwa, Sai Adharsh, Andrew Bourke, Matthew Bell.

Team Number: Group 2

Executive Summary

Haemo.mon is an innovative surveillance system that is designed to elevate the monitoring of blood parameters and to combat venous needle dislodgement. Our project aims to tackle restrictions in blood monitoring systems by creating a reliable and easy to use model that integrates existing hemodialysis equipment, with the intention of improving patient outcome.

The design process involved a considerable amount of research into blood monitoring devices and their requirements. Intricate sensors, cloud-based analytics and a user-friendly interface are all key components for an efficient monitor. Haemo.mon provides improved accuracy and response time compared to other devices. Our prototype allows for prompt detection of any sudden changes during hemodialysis, allowing for quick intervention. This device is accessible and practical due to the remote accessibility and automated data logging.

Through continued research and clinical trials, future improvements will focus on the enhancement of sensor accuracy and power efficiency. The Haemo.mon device marks a significant breakthrough in blood monitoring for Haemodialysis, providing a simple and reliable solution to venous needle dislodgement.

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1. Introduction

1.1 - Background

This report details the development and creation of a safety device for Haemodialysis patients, addressing the threats of a venous needle dislodgement (VND) which results in the dialysis needles after a procedure, shifting out of place. This can cause sudden blood loss which can be life-threatening. This document will outline the project's goals, plans and methods to create a reliable and affordable solution to such a substantial issue affecting patients globally. Our final solution will be targeted towards individuals, post Haemodialysis treatment. Those who have freshly stitched wounds, or any other risks of blood loss will be considered later in the development process.

Haemodialysis is essential for patients with kidney failure, helping purify the blood and temporarily reducing the load on the liver and kidneys. VND will always pose serious risks as these procedures cannot be done any other way. Existing safety devices such as sensor alarms struggle with false alerts, high costs, and limited compatibility with dialysis machines. Our aim is to overcome these problems by developing a solution that instantly detects blood leaks and integrates with already available systems to automatically stop the dialysis procedure, preventing risks of blood loss.

2. Project Definition

2.1 - Problem Statement

Haemodialysis is the most dominant dialysis procedure globally, with approximately 4 million patients worldwide requiring haemodialysis treatment because of kidney and liver failures. The procedure itself is already too expensive and unaffordable for many people. Those who can afford the procedure still have a handful of side effects that they must stay on top of to prevent any further difficulties that can be lethal if ignored and untreated.

These side effects include low blood pressure, muscle cramps, itchy skin, nausea and potential infections because of fluid overflow or discomfort in the access site.

From the article published by Healthcare Technology Letters it states that, “More than 40% of adult blood volume can be lost in just a few minutes, resulting in morbidities and mortality” (Healthc.Technol. Lett. 2018). The aim of our project is to ensure that blood leakage within a patient can be diagnosed instantly, and preventative measures can be acted on the patient immediately.

2.2 - Existing Product Research

From conducting research on existing blood leakage monitors, patients prefer a less bulky and highly sensitive monitor (Hemodialert, 2018). Our aim is to make it as simple and compact as possible to satisfy the patients during the procedures while also avoiding the risk of it getting in the way or caught in any of the medical equipment in the surrounding area. To ensure our device is accredited and reliable, we aim for the device to operate at the highest accuracy and sensitivity possible. In a study conducted in 2019 it states that an existing blood leak detection device achieved 100% and 98.9% accuracy rates on the phantom arm test and clinical test (Int J Environ Res Public Health, 2019). By allowing the patients to trust the accuracy and reliability of the device, it can help reduce any anxiety during the dialysis process.

In terms of the user interface of the product, we can gather components from existing products to enhance the user experience. An easy-to-read screen showing the patient’s heart rate and blood loss indicators can help detect anomalies and predict whether blood loss could occur, making it easier for healthcare workers to deal and avoid the situation and a clear visual and audible alarm system to alert the healthcare professionals that blood leak has been detected, for example an existing product ‘HEMOdialert’ has a sensor system that emits a loud alarm at approximately 3.3 kHz, a frequency that has been known to be sensitive to human hearing (Anzacare, 2013).

Figure 1: HEMODialert Hemodialysis Device

Haemodialert: The Haemodialert is a blood leakage detection alarm system designed to enhance patient safety during haemodialysis by promptly identifying venous needle dislodgement (VND) or blood leaks at the fistula site. It is manufactured using medical grade high-impact ABS plastic or polycarbonate, Printed Circuit Board (PCB), Medical-grade plastic, Flexible PVC or silicone rubber, Stainless steel, reinforced plastic, and copper/tinned copper.

It has a portable alarm unit device that attaches to the patient's clothing, a reusable plastic sensor that detects blood leakage, a connection cable that allows for real-time signal transmission when a blood leak is detected, and a clip for securing the alarm unit to the patient's clothing. It weighs 40kg and consists of a 482mm X 508mm X 660mm rectangular shape.

The HEMOdialert™ alarm and HEMOsensor™, will detect a blood leak from the fistula site of less than 1mL in 1 to 2 seconds or less[1]. (“HEMOdialert Venous Needle Alarm - Linc Medical”). It is impervious to blood and other fluids and so can be reused after cleaning with alcohol or any proprietary antibacterial/antiviral cleaner.

The alarm responds to small amounts of blood, by emitting a loud alarm at approximately 3.3 kHz, a frequency that has been established as one to which the human ear is especially sensitive (“Haemodialysis Alarm - Blood Leak Detector for Needle Dislodgement ...”). If battery power is below a predetermined level (this has been established with a high degree of safety with regard to battery power required to operate the alarm), then the alarm will beep at 10 second intervals to warn of the need to replace the batteries.

While the HEMOsensor™ is reusable, after 6-9 months the flexing of the wires may require it to be replaced. For this reason, a spare sensor is supplied with the package. The Hemodialert meets the following standards: (“Haemodialysis Alarm - Blood Leak Detector for Needle Dislodgement ...”)

1. “UL International Report No 13870A 16 July 2008: Anzacare Body Fluid Detection Alarm with Reusable Plastic Sensor Model: HEMOdialert.” (“Haemodialysis Alarm - Blood Leak Detector for Needle Dislodgement ...”)
2. ISO 226:2003 Acoustics -- Normal equal-loudness-level contours
3. “UL International Report No 13870A 16 July 2008: Anzacare Body Fluid Detection Alarm with Reusable Plastic Sensor Model: HEMOdialert.” (“Haemodialysis Alarm - Blood Leak Detector for Needle Dislodgement ...”)
4. IEC/ EN 60601-1:2006 Medical Electrical equipment. “Part 1: General requirements for basic safety and essential performance.” (“IEC 60601-1:2005+AMD1:2012+AMD2:2020 CSV | IEC”)
5. ISO 14971:2007 Medical devices - Application of risk management to medical devices (“Application of risk management to medical devices - iTeh Standards”)
6. IEC/EN 60601-1-2: 2006 and 2007. Medical Electrical Equipment Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic compatibility - Requirements and tests. (“IEC 60601-1-2 - Medical electrical equipment - Engineering360”)
7. IEC 60601-1-6: 2006 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.

Figure 2: Redsense Hemodialysis Device

Redsense: The Redsense is a system for monitoring the vein or arterial needle during haemodialysis. “Redsense consists of an alarm unit and infrared sensor incorporated into an adhesive patch.” (“Redsense Medical T A C 0 1 C F K071013 - Food and Drug Administration”). The sensor patch is placed around the vein or arterial needle and detects any blood that drips onto the patch if the needle has been accidentally pulled out or if there is leakage during dialysis. If blood loss is detected, the device will alarm.

The manufacturing cost of Redsense ranges between £45 and £79 per unit, depending on production scale and component sourcing. Key components include:

- Optical sensors - £8–£20 per unit
- Microprocessors - £3–£8
- Alarm modules - £2–£5
- Medical-grade plastic housing - £5–£10
- Assembly and quality control - £8–£12 per unit

R&D expenses for the device, including sensor calibration and ISO 13485 compliance, account for 10-15% of total costs. Large-scale production (10,000 or more units) can lower unit costs by up to 20%. The gadget is normally sold for between £160 and £250 to cover distribution costs, regulatory compliance, and commercial margins.

The dialysis machine is connected to Redsense, complying with the IEC PAS63023, closing the venous clamp when blood is detected (“KidneyBuzz.com: Chronic Kidney Disease Information, Dialysis Tips ...”).

A unique feature of the sensor patch is its ability to absorb up to 2 ml of blood that may leak/ooze during a treatment without triggering a critical blood loss alarm. This helps to deter nuisance alarming.

The entire device is portable, weighing 500 grams, compatible with standard dialysis equipment. Its primary function is to reduce risks associated with unnoticed venous line disconnections, which can lead to significant blood loss or infection. Clinical studies have shown that the use of such devices can reduce adverse events by up to 90% in dialysis situations.

3. Product Definition

3.1 - Stakeholder Requirements

The following are the key stakeholders for the haemodialysis monitoring device:

1. *Patients* – who require an inexpensive, user-friendly, and dependable monitoring system to ensure early detection of any issues and real-time alerts. Additionally, non-invasiveness and comfort of patient are essential components.
2. *Healthcare professionals* – who require the device to be inter-operable with existing healthcare systems, accurate data readings, and minimal maintenance.
3. *Regulatory authorities* - the device must conform to medical safety standards, and data security regulations must be fulfilled.

3.2 - Engineering Specifications

The haemodialysis safety device prevents dangerous blood loss from the patient by detecting bleeding from the fistula site immediately, in case of venous needle dislodgement (VND) or line disconnection. The device contains a patented, reusable plastic sensor, which is placed over the fistula site and secured with tape. The sensor is blood and waterproof, allowing it to be reused after proper sanitation with alcohol or antibacterial fluids (excluding bleach).

Additionally, the device includes a small, comfortable sensor patch which sticks to the skin near the needle site. If blood begins to leak, the sensor quickly detects it and triggers an alarm to alert the patient, caregiver, or medical staff. If connected to a dialysis machine, the device can also stop blood flow automatically, preventing further blood loss.

The system is designed to be affordable, easy to use, and compatible with all dialysis machines. This device offers precise detection, reliability, and comfort for patients. It is suitable for both hospitals and home dialysis, ensuring accessibility for a wide range of patients. We will aim to produce a high-quality solution using similar designs that can be improved on, instead of “reinventing the wheel” and starting from the ground up. This is partially due to the time frame we have been given to produce this product. We will do this by designing and manufacturing a lifesaving, user-friendly, and cost-effective proof of concept. This will help dialysis patients feel safer and more confident during treatment while easing the burden on caregivers and healthcare providers.

3.3 - Product Specifications

Design Goals:

- **Data Accuracy and Reliability** - High precision sensors with ±0.05% accuracy for detecting blood leaks. Real-time error correction for enhanced reliability. Automated calibration and redundancy mechanisms to prevent data loss.
- **Comfort and Safety** - Non-invasive design with hypoallergenic, skin-safe materials. Ergonomic form factor for comfortable wear during dialysis. Compliance with safety regulations (CE, FDA, ISO 13485). An audible alarm at 3.3 kHz for immediate caregiver and patient alerts.
- **Technical Performance** - Fast detection response time under 2 seconds. Energy-efficient components for prolonged operation. Adaptive monitoring with adjustable sensitivity settings.
- **Data Transmission and Processing** - Secure wireless connectivity via Bluetooth 5.0 and Wi-Fi. End-to-end encryption for data protection. Cloud synchronization and local storage options for historical analysis.

- **Durability and Maintenance** - Water and dust resistance (IP67 rating) for reliability. Reusable, easy-to-clean sensor technology. Self-diagnostic alerts and modular design for easy maintenance.

Specifications:

- **Size and Adaptability** – It is lightweight and compact for ease of use. Flexible attachment accommodates for different patient needs.
- **Integration and Compatibility** - Interoperability with healthcare systems (any dialysis machine.
- **Cost-effectiveness** - Long lifespan with minimal maintenance costs. Affordable pricing model for healthcare providers, patients, and low-resource areas.
- **Regulatory Compliance** – IEC/EN 60601 for medical electrical equipment, ISO 14971:2007 for medical device risk management.
- **Simple and Easy to Use** – Designed for medical staff, caregivers, and home dialysis users.

4.0 Conceptual Designs

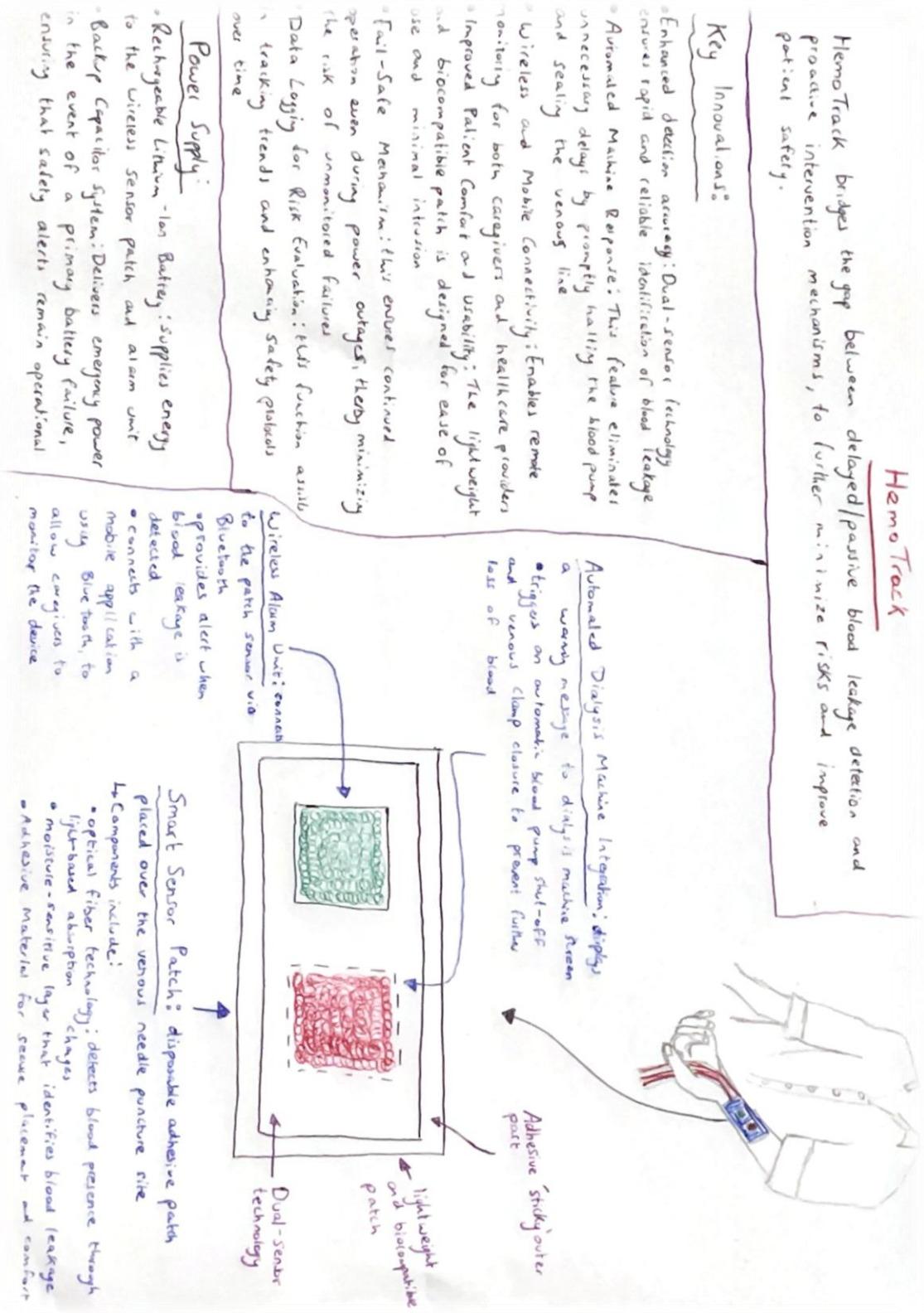


Figure 3: Concept Design 1

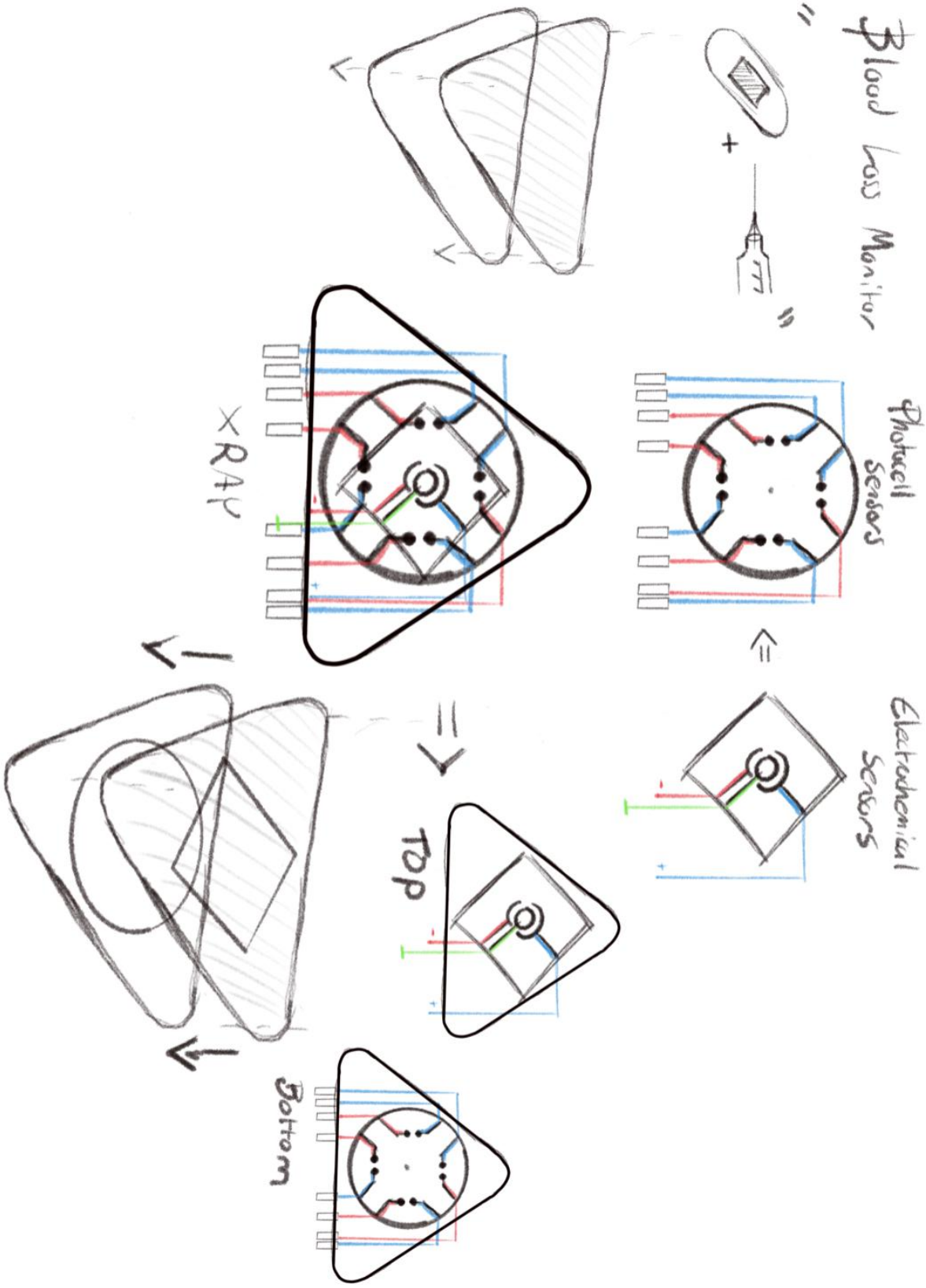


Figure 4: Concept Design 2

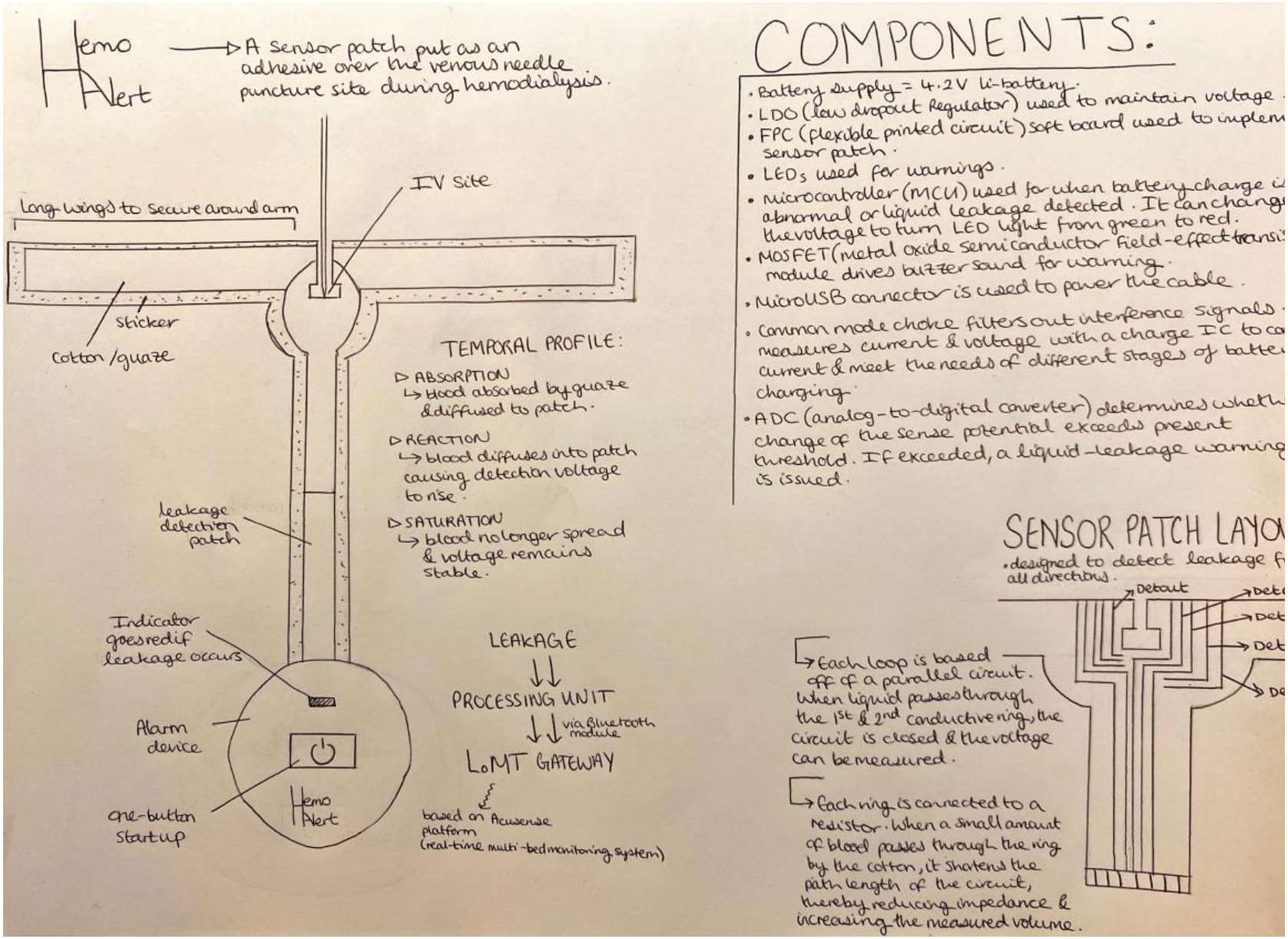


Figure 5: Concept Design 3

Figure 6: Concept Design 4

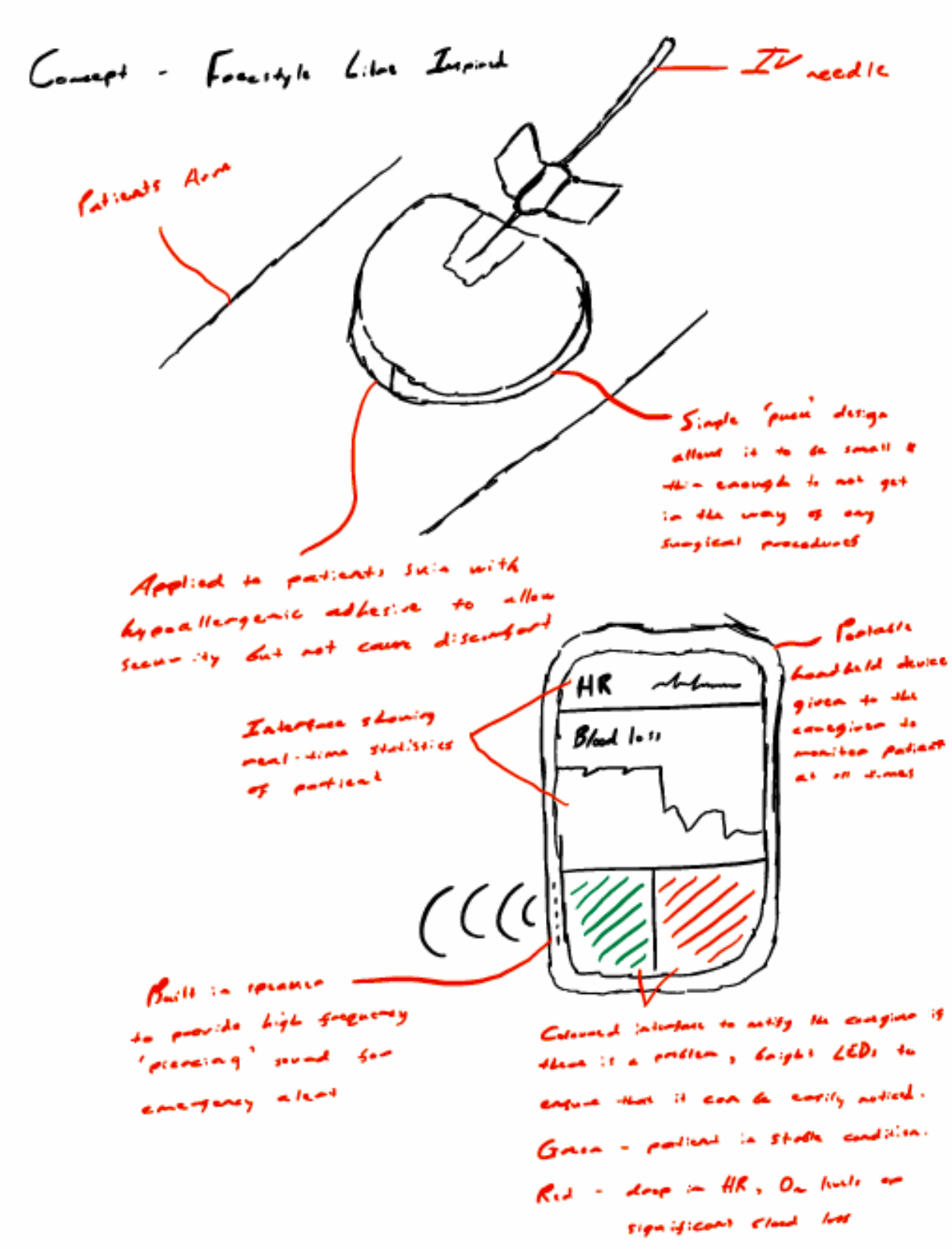


Figure 7: Concept Design 5

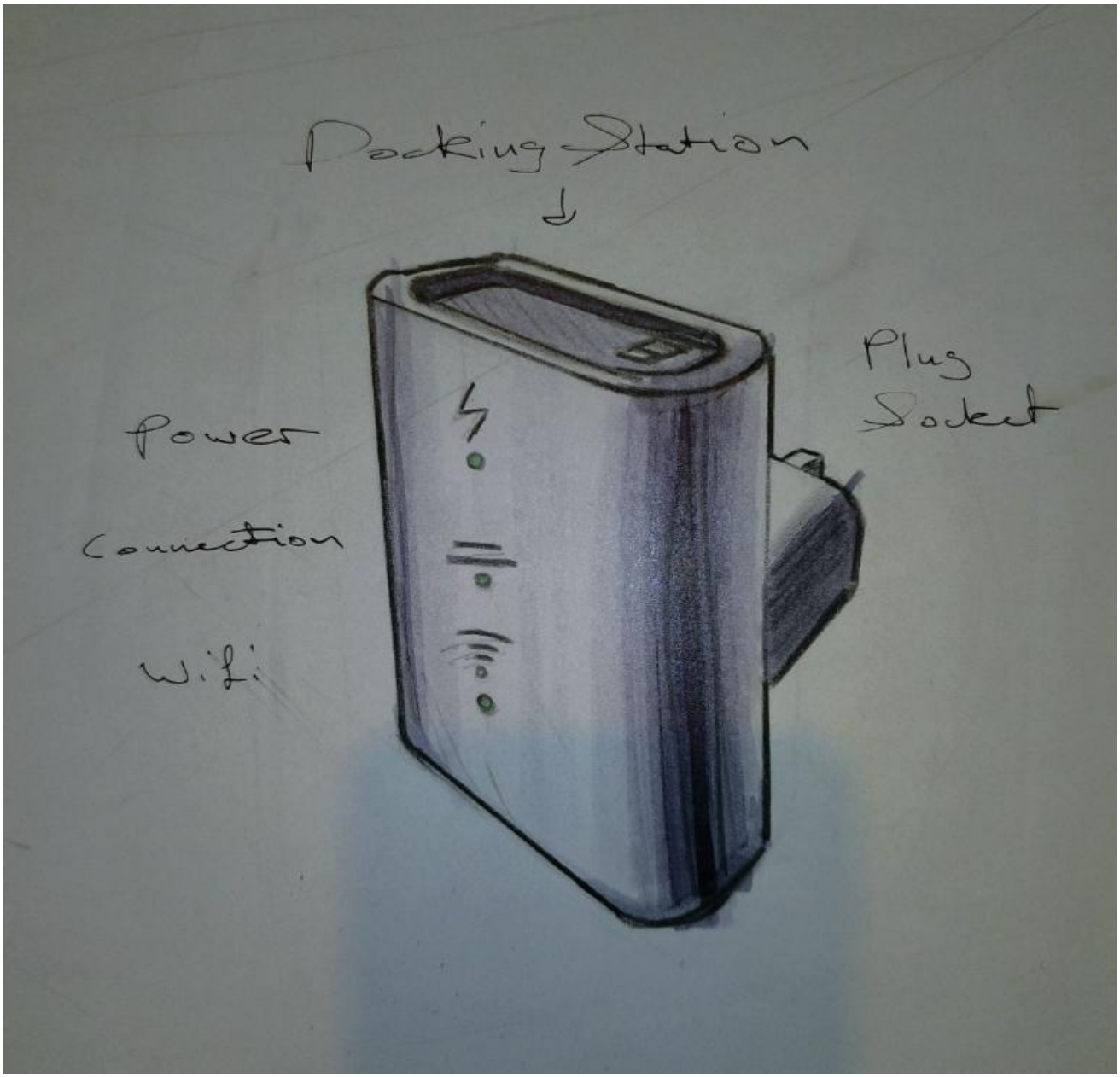
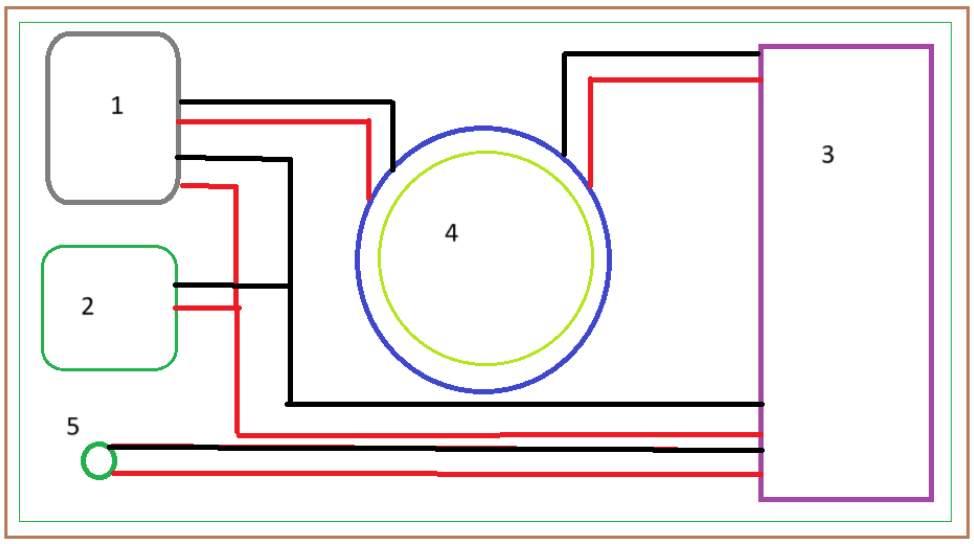


Figure 8: Concept Design 6



1. Components Selection:

Sensors & Detection Unit:

Bioimpedance Sensor or Optical Sensor: To detect blood loss from the central patch

Conductive Hydrogel Electrodes: For direct blood detection

Processing Unit:

Microcontroller (MCU): ESP32C3

Analog to Digital Converter (ADC): For signal processing of blood loss detection

Internal Clock (RealTime Clock): DS3231 (for time tracking)

Wireless Communication:

WiFi Module: ESP32 has builtin WiFi

Bluetooth Module: BLE 5.0 (integrated in ESP32)

Storage Unit:

Flash Memory (2MB 8MB): To store patient data logs

EEPROM (optional): For long term storage

Power Management:

Small Rechargeable LiPo Battery

Battery Management Circuit (TP4056)

2. Severity Classification Algorithm:

Case 1 (Low Severity): Slow blood loss detected (small variation in sensor data over time)

Case 2 (Moderate Severity): More rapid blood loss trend detected

Case 3 (Severe Condition): Sudden, rapid loss detected, triggering emergency alert via WiFi/Bluetooth (for jugular, subclavian, femoral vein)

Final Design:

Uses Polyamide to create a flexible circuit board that is attached to the adhesive patch with an external alert system.

Figure 9: Concept Design 7 and specifications

4.1 Final Design Concept

- Concept better than baseline concept it was scored as 1.
- Concept worse than baseline concept, it was scored as -1.
- Concept similar, it was scored as 0.

Pugh Matrix Group 2										
		Concepts								
		Sai	Aidan	Komal	Andrew	Sarah	Casper	Conor	Matthew	Joshua
Critical to Quality	**Weight /10**					*Benchmark				
Ease of Maintenance	10	0	1	1	1	0	-1	0	-1	0
Cost of Maintenance	5	-1	0	1	1	0	1	1	-1	-1
Lightweight	6	1	1	1	1	0	1	-1	1	1
Simplicity	9	0	1	1	1	0	-1	1	0	1
Integration	5	1	1	1	0	0	1	1	1	1
Alarm System	6	1	0	0	1	0	-1	0	-1	0
Practicality	8	1	1	1	1	0	0	0	1	1
Accessibility	7	0	1	1	0	0	1	-1	0	1
Conectivity	8	1	1	1	0	0	1	1	1	1
Reliability	10	1	1	1	0	0	1	0	-1	0
Biocompatibility	9	1	1	1	1	0	1	-1	1	1
Safety	10	1	1	1	1	0	1	0	1	0
		Summary Table								
	Total Qty of +1's	8	10	11	8	0	8	4	6	7
	Total Qty of 0's	3	2	1	4	12	1	5	2	4
	Total Qty of -1's	1	0	0	0	0	3	3	4	1
	Overall Weighted Score	57	82	87	63	0	35	5	15	47

Figure 10: Pugh Matrix

We decided to go with **Komal Bairwa's** idea as her design met our expectations and set standards. It is the easiest to manufacture and integrate into existing systems within the researched field.

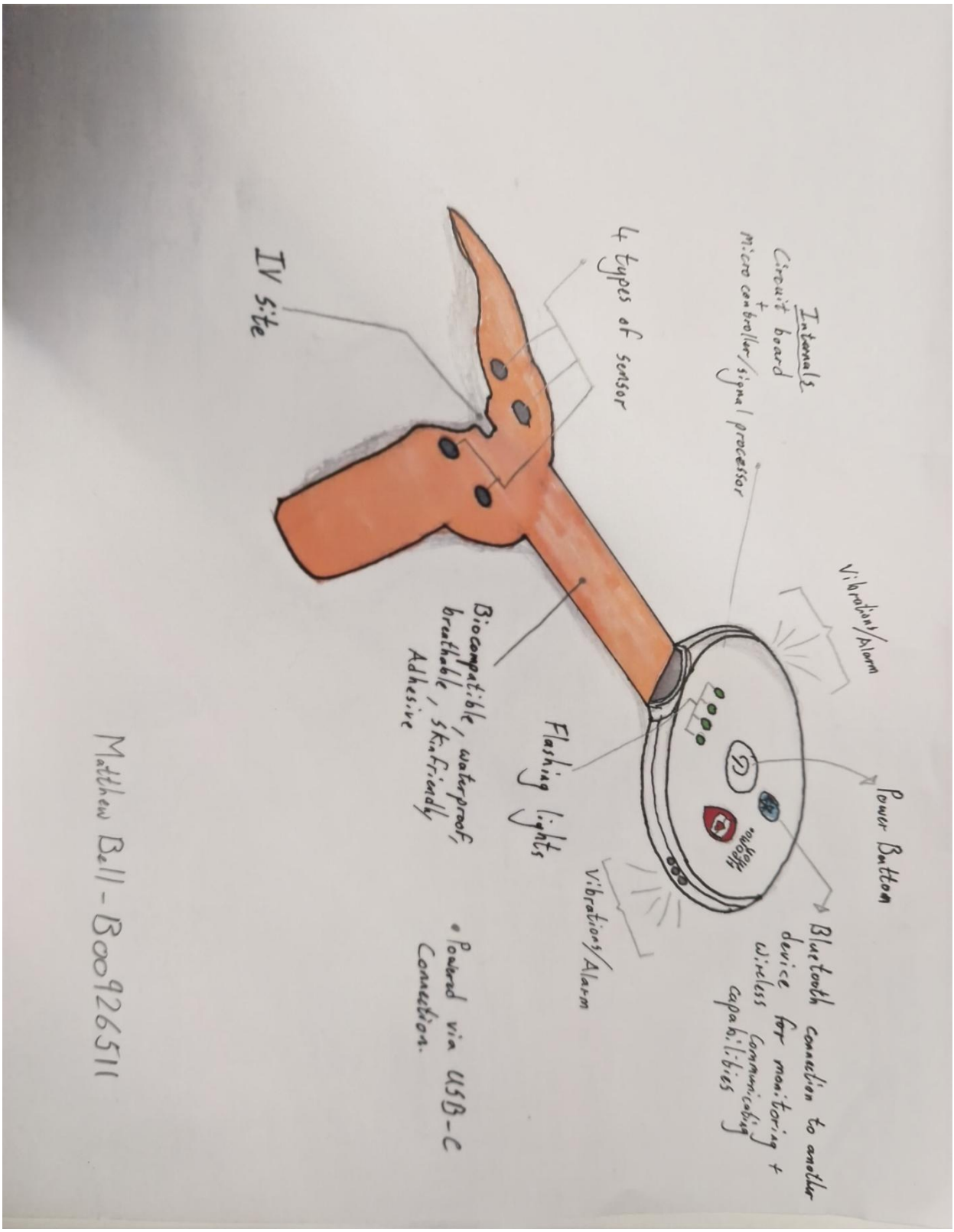


Figure 11: Finalized Design for Haemo.mon

Figure 12: 3D View of the Device's Main Unit

To manufacture a prototype for redundancy, compatibility, and general testing, the utilisation of additive manufacturing would typically be considered as it is a reliable, and cost-effective solution to help portray ideas quickly. Materials used could range from PETg to PLA as they have excellent structural rigidity, can withstand environmental decay through factors such as material degradation through UV radiation. Depending on their uses, they can also be manufactured into products and finished for additional waterproofing and insulation. Smaller and more finite parts could also be manufactured through this additive process; however, the quality of the final product may vary depending on the design. PETg is usually the more expensive of the two, costing approximately £18/Kg whereas PLA would cost approximately £14/Kg. Considering the advantages of PETg in comparison to PLA, this small price difference could be the difference between a reliable, high quality final product and another wasted prototype.

PETg is also commonly used within medical and pharmaceutical applications for its ability to prevent contamination and insulate external products such as liquids, medication, and other substances. Considering the cheap costs, flexibility in manufacturing techniques, and its easy recyclability, PETg does not have any other competing materials with similar properties.

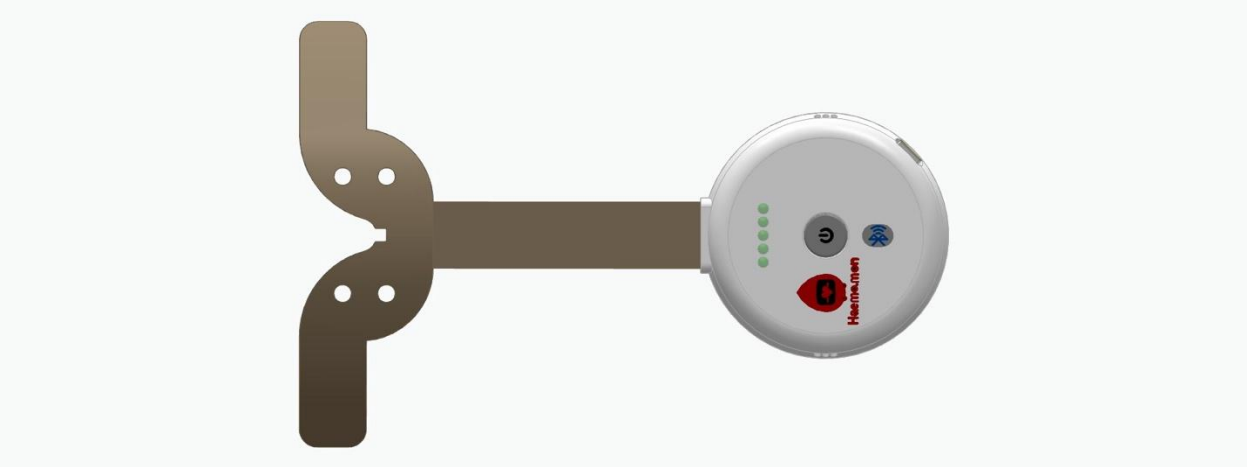


Figure 13: Top view of the 3D model

For larger scale manufacture, the external chassis of the product can be injection moulded to save on manufacture time, costs and to help increase production accuracy. Electrical components can be designed and sourced externally to accelerate the rate of production and to meet demands. However, PETg requires a lot of heat energy to transform it from a raw material into its use case because of its high melting point. The appendage that adheres the product on to the skin will be manufactured from a robust, woven fabric layered on top of a non-toxic, body safe adhesive layer. This adhesive layer could also be fabricated from a hydrogel to help moisturise the skin and prevent irritation if the product were to be applied to the body for longer periods of time.

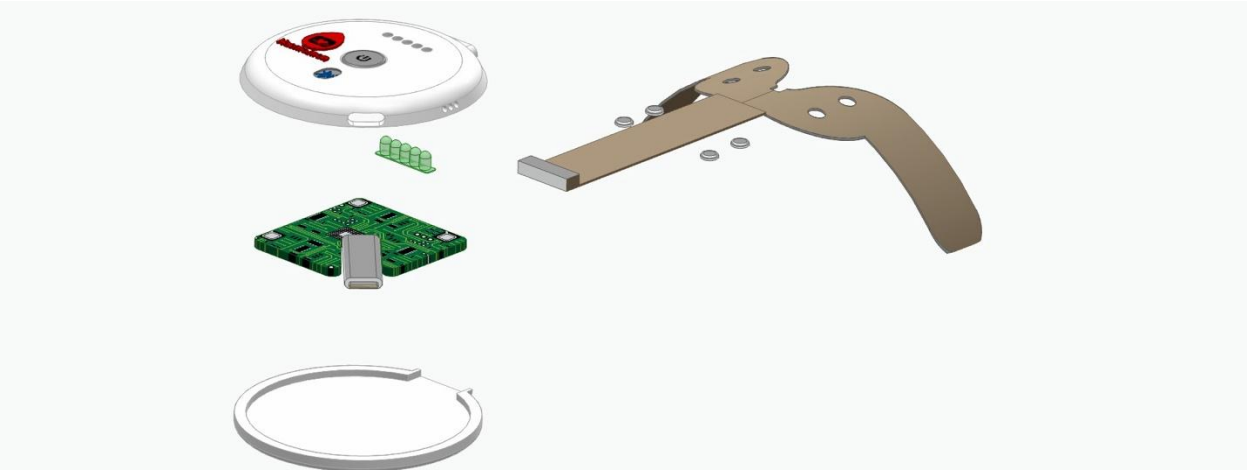


Figure 14: Exploded View of the Haemo.mon Device

4.3 Testing & Validation Plan

For FDA clearance (US):

To get FDA clearance we must demonstrate substantial equivalence (SE) to a legally US-marketed device with similar intended use. Proving SE to the reference device affirms that our device is as safe and effective as predicate devices such as RedSense and HaemoDialert. The key criteria for determining SE include the following parameters: type of device, intended use, manufacturer, technology, blood amount for detection, area of detection, tolerance, size of sensor, optical fiber type, components parts, single use, sterile, usage time and patient contact. This will be combined into an FDA 510k file containing sufficient information about our device, demonstrating that our device proves to be substantially equivalent. As our product is a Class II device in accordance with FDA standards, and is also intended for human use, we must submit a 510(k). Pre-market approval is not required for Class II devices. If the FDA finds the device to be substantially equivalent, it will grant clearance for our device with a '(k)' number. ("FDA 510k Clearance for Medical Device & IVDs - I3CGLOBAL") The process should be completed within 90 days.

For European clearance:

To successfully gain the CE marking, we must self-assess our device for compliance with applicable directives by writing up a technical file detailing its technical specifications/performance and our risk assessment procedures. As a group we will refer to Chapter V, Section 2, Article 52 of the MDR: 'Manufacturers of class IIa devices, other than custom-made or investigational devices, shall be subject to a conformity assessment as specified in Chapters I and III of Annex IX, and including an assessment of the technical documentation as specified in Section 4 of that Annex of at least one representative device for each category of devices'.

Three main steps we will follow:

1. Identify and comply with all applicable Directives and Harmonized Standards.

2. Affix the CE Marking to the product and draw up a Declaration of Conformity (DoC). (“CE Marking Directive: EEC Council Directive 93/68/EEC of 22 July 1993 ...”)
3. Prepare a technical file with documents on how we identified and applied these requirements.

5. Conclusion

The development of Haemo.mon marks a significant advancement in enhancing the safety of Haemodialysis patients. A potentially life-saving solution to the problem of venous needle dislodgement (VND) is provided by this bio-monitor. Through comprehensive research, our group has created an innovative and practical post-Haemodialysis device.

The project emphasizes how important it is to integrate patient safety requirements with advanced sensor technology. Haemo.mon offers real-time monitoring, this ensures that any dislodgment or issue can be dealt with promptly. The development process has also placed a strong emphasis on ease of use and affordability, making the device suitable for a broad range of users.

Although our design offers a promising solution, additional developments and clinical testing will be necessary to confirm its effectiveness. Future advancements could include the enhancement of sensor accuracy and improving power efficiency. In conclusion, Haemo.mon has the potential to completely transform patient safety in Haemodialysis, acting as a reliable defense against VND.

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- BSI Group *2024* MDR Conformity Assessment Routes

7. Appendix:

Appendix 1

Functional Decomposistion

Product Functional Decomposition		
Design Group No.: 2	**Module: MEC365**	**Date: 23/2/2025**
Product Decomposed: Hemodialert Blood Leak Detection Alarm		
Description: HEMOdialert is a blood leak detection system comprising two main components: • **HEMOsensor:** A patented, injection-molded, reusable plastic sensor placed over the fistula site and secured with tape. It is impervious to blood and other fluids, allowing for reuse after proper cleaning. • **HEMOdialert Alarm Unit:** A device that emits a loud audible alarm (~3.3 kHz) upon detecting blood on the HEMOsensor, alerting healthcare providers to potential blood leaks.		
How it works: 1. **Sensor Placement:** The HEMOsensor is positioned over the patient's fistula site and secured with medical tape. 2. **Detection:** In the event of a blood leak (as small as less than 1 mL), the sensor detects the presence of blood within 1 to 2 seconds. 3. **Alarm Activation:** Upon blood detection, the HEMOsensor sends a signal to the HEMOdialert alarm unit, which emits a high-pitched audible alarm (~3.3 kHz), immediately notifying medical staff. 4. **Maintenance:** After use, the HEMOsensor can be cleaned with alcohol or appropriate antibacterial/antiviral cleaners (excluding bleach) and reused. Over time (approximately 6-9 months), the sensor may require replacement due to wire flexing; a spare sensor is provided with the system. 5. **Battery Monitoring:** The alarm unit performs a battery check when the sensor is connected, emitting a beep if the battery level is sufficient. If the battery power drops below a		

predetermined level during use, the alarm beeps at 10-second intervals to indicate the need for battery replacement.

Interfaces with other objects

Part No.	Name of part	Other Object	Energy Flow	Information Flow	Material Flow
1	HEMOdialert Alarm Unit	Patient's clothing	Electrical (Battery)	Audio signal (alarm)	N/A
2	HEMOsensor Blood Leak Detector	Patient's skin/fistula site	N/A	Blood detection signal to Alarm Unit	Blood (if leak occurs)
3	Connection Cable	Alarm Unit to Sensor	Electrical (Signal transmission)	Blood detection data	N/A
4	Attachment Clip	Patient's clothing	Mechanical (clip holds device)	N/A	N/A
5	Battery	Alarm Unit	Electrical power supply	Low battery warning	N/A

Prepared by:	Sai Adharsh Babu, Sarah
Checked by:	Komal

Product Functional Decomposition

Design Group No.: 2	Module: MEC365	Date: 22/2/2025

Product Decomposed: Redsense Blood Leak Detection System

Description: Redsense is a blood leak detection system for haemodialysis, consisting of a reusable alarm unit and two types of single-use, disposable sensor patches:

- Venous Sensor Patch: Applied at the venous needle site.
- Catheter Sensor Patch: Applied at the central line luer lock connection.

Both patches use an optic fiber sensor embedded in an absorbent sponge-like material to detect blood leaks. If blood contacts the sensor, a visual (LED) and audible alarm (85 dB) is triggered, alerting staff immediately.

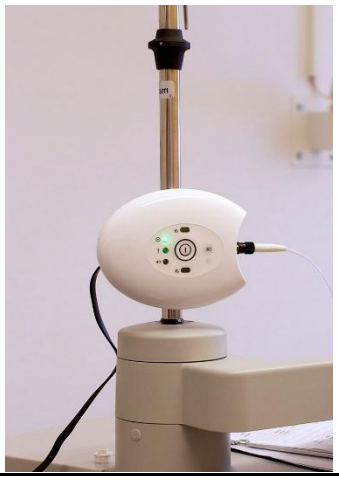
How it works:

1. Venous Sensor Patch Process:

- Applied over the venous needle site with the absorbent sponge directly over the needle.
- If leakage occurs, blood is absorbed into the sponge and reaches the optic fiber sensor.
- Sensor detects blood optically and sends a signal to the alarm unit.
- Alarm unit triggers both audible and visual alarms.
- The patch can absorb up to 2 mL of blood before critical alarms trigger, reducing false alarms.
- After dialysis, the patch is discarded according to clinic waste procedures.

2. Catheter Sensor Patch Process:

- Wrapped around the luerlock of the central bloodline, forming a pouch.
- If leakage occurs at the luerlock, the absorbent material soaks up the blood and transports it to the optic fiber sensor.
- Sensor detects the blood and triggers both audible and visual alarms.
- After dialysis, the catheter patch is discarded according to clinic waste procedures.



Interfaces with other objects

Part No.	Name of part	Other Object	Energy Flow	Information Flow	Material Flow
1	Alarm Unit	Dialysis machine (optional)	Electrical (Battery/Power supply)	Alarm signal to staff/dialysis machine	N/A
2	Venous Sensor Patch	Patient's venous access site	Optical (infrared detection)	Blood detection signal to Alarm Unit	Blood (if leak occurs)

3	Catheter Sensor Patch	Luer lock of central bloodline	Optical (infrared detection)	Blood detection signal to Alarm Unit	Blood (if leak occurs)
4	Absorbent Sponge Layer (both patches)	Patient's skin/luer lock	N/A	N/A	Blood (absorbed)
5	Adhesive Layer (both patches)	Patient's skin/luer lock	Mechanical (adhesion)	N/A	N/A
6	Optical Fiber Sensor	Inside sensor patch	Optical (light transmission)	Blood detection signal	N/A
7	LED Indicator	Healthcare Staff	Electrical	Visual alarm	N/A
8	Audible Alarm	Healthcare Staff	Electrical	Audio alarm	N/A
9	Redsense Clamp (optional)	Venous bloodline	Mechanical (clamps bloodline)	Signal from Alarm Unit	N/A

Prepared by:	Sai Adharsh Babu, Sarah
Checked by:	Komal

Appendix 2:

House Of Quality

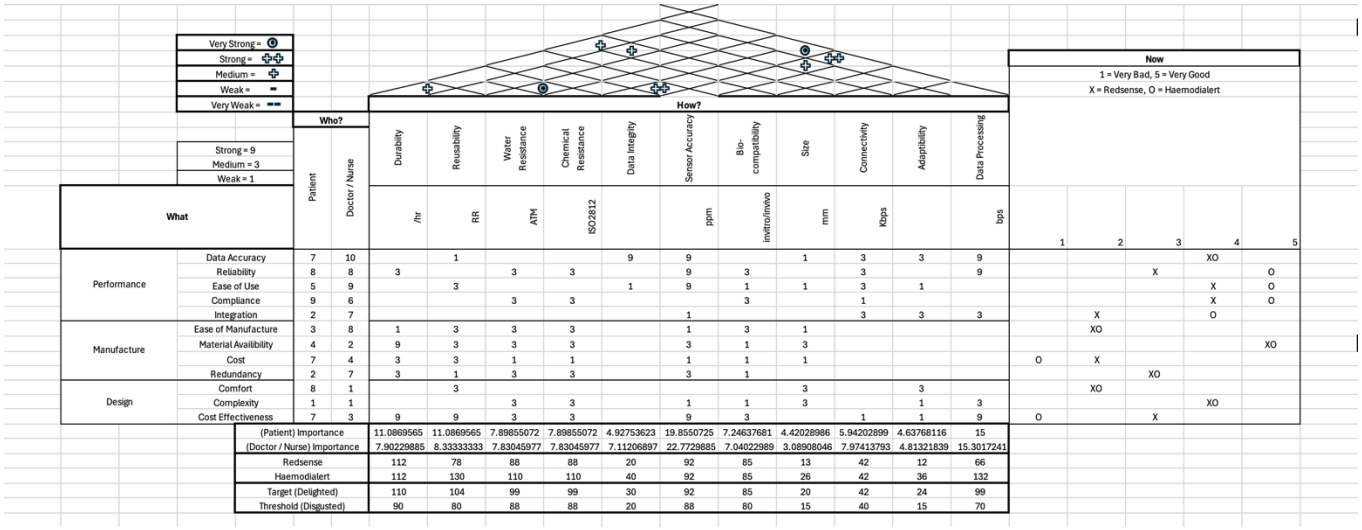


Figure 15: House of Quality Chart

Appendix 3:

Relevant Patent/6-3-5/TRIZ Information

- **US Patent 6,730,220 B2 –** Kidney Dialysis Machine
- **US Patent 4,601,830 A –** Method for Dialysis
- **EP Patent 0,615,760 A1 –** Hemodialysis Apparatus with Balancing Chamber
- **EP Patent 0,701,828 B1 –** Hemodialysis Machine with Vent Valve
- **CN Patent 1,129,152,87 A –** Hemodialysis Machine
- **US Patent 5,674,390 A –** Dialysis Machine with Leakage Detection
- **US Patent 5,671,892 A –** Dialysis Machine with Electrical Insulation for Variable Voltage Input
- **US Patent 4,601,830 A –** Method for Dialysis

- **EP Patent 0,615,760 A1 –** Hemodialysis Apparatus with Balancing Chamber
- **EP Patent 0,701,828 B1 –** Hemodialysis Machine with Vent Valve

Appendix 4:

Design for Manufacturability and Assembly (DFMA)

Regarding making each component's production more efficient, we have explored the use of PETG as our casing sensor as it is waterproof and chemically resistant, but expensive. As our product is not frequently exposed to acids and solvents, PVC acts as a more affordable option. Sterilizing our product with steam is a cost-effective method that doesn't damage our PVC. Our manufacturing method is injection moulding, providing us with a cheap, effective way to produce multiple components with lots of design flexibility for more complex shapes. Only thermoplastics and thermosets can be injection moulded, minimizing our possible materials, and directing us towards using PVC. The motherboard is screwed into the base plate. The two plates have interjoining clasps which click together and cannot be opened again.

A few eco considerations would exclude the use of PVC as it is a heavily processed petrochemical product that requires oil to extract the base components and lots of energy to react the chemicals together. Alternatives to PVC are recycled PU, similar in composition but less harmful since it is made from recycled materials and doesn't release toxic substances or dioxins during use or disposal.

Appendix 5:

Cost Estimations

Haemo.mon costs about £30 to £72 per unit, depending on production scale and component sourcing. Key components include:

- Optical sensors - £6–£25 per unit
- Microprocessors - £5–£9
- Alarm modules - £4–£8
- Medical-grade plastic housing - £5–£15
- Assembly and quality control - £10–£15 per unit

Appendix 6:

Engineering Drawings i.e., Detailed Part Drawing

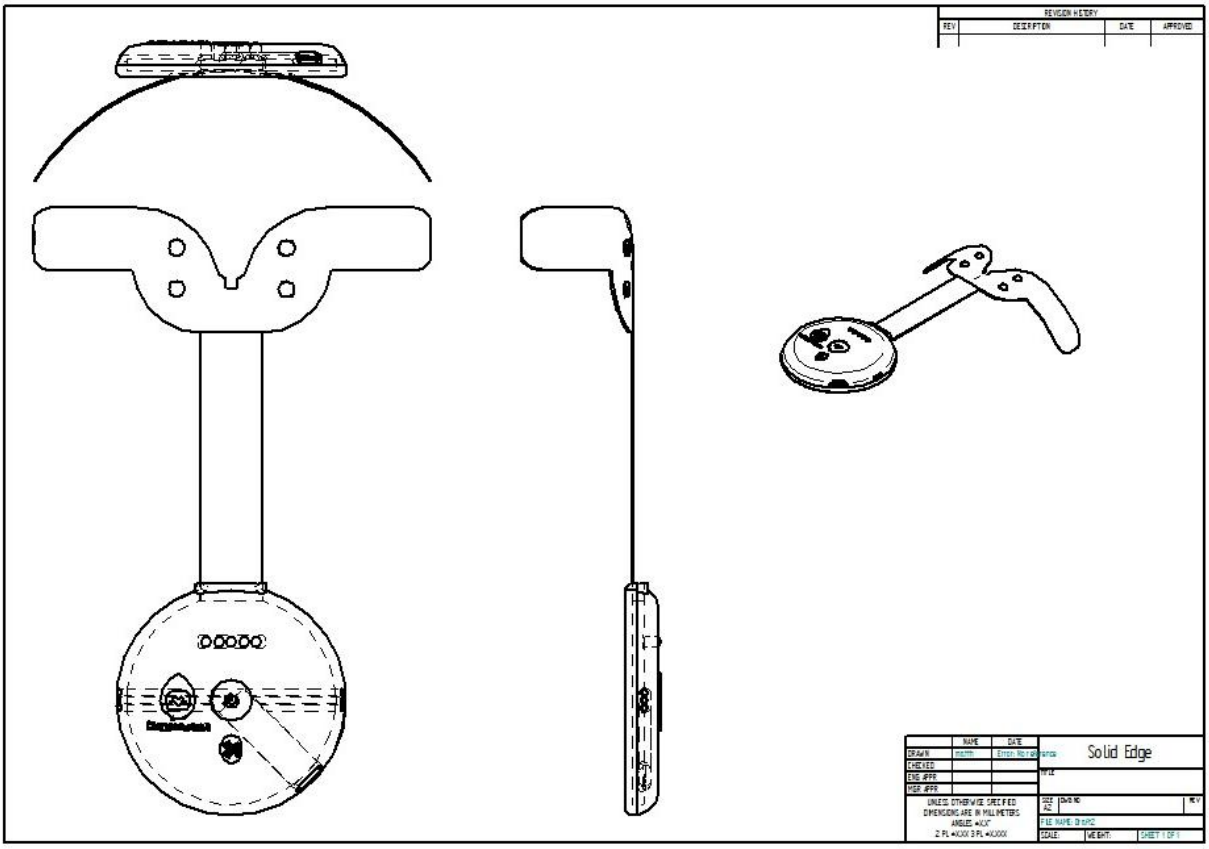


Figure 16: Detailed Part Drawing of the Haemo.mon Device

Appendix 7:

Gantt Chart and Team Contract

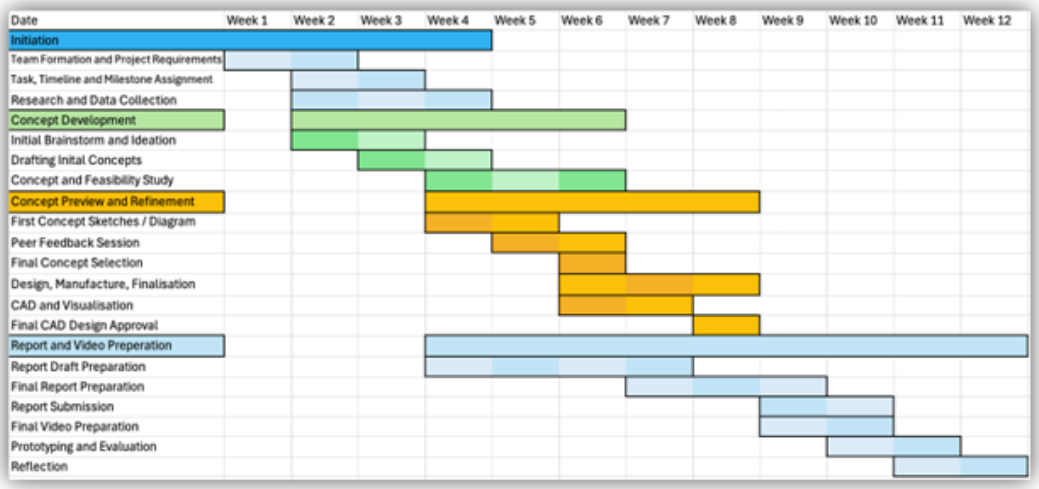


Figure 17: Gantt Chart