



University of Moratuwa

BioMedical Device Design

BM2210

Investigation Report

Team Members:

Rajapaksha N.N	210504L
Kavishan G.T	210285M
Madugalle M.R.K.J.M.M.S.B	210351M

August, 2023

Table of Contents

1. Introduction.....	3
2. Strategic Focus.....	3
2.1 Mission.....	3
2.2 Strengths and Weaknesses.....	3
2.3 Acceptance Criteria.....	3
2.3.1 Alignment with the Mission and Requirements	3
2.3.2 Effect on the Field of Healthcare	3
2.3.3 Time and Resource Needed.....	4
2.3.4 Target Population	4
2.3.5 Market analysis	4
2.3.6 Affordability.....	4
3. Need Findings	4
3.1 Noninvasive method for monitoring lung functions for detecting COPD.	4
3.2 Continuous weight measurements of the patients who are unable to stand.	5
3.3 Higher bleeding risk in surgeries or other medical procedures in patients on Warfarin	7
4. Need Selection	8
5. Conclusion	8
6. References.....	9

1. Introduction

We are planning to improve the healthcare industry with new bio medical ideas. we need to push ourselves to meet the needs and requirements of the medical industry. This investigative report is to select a device to design that falls under our company’s acceptance criteria.

2. Strategic Focus

2.1 Mission

Our objective is to pave the way for the future of healthcare by developing revolutionary biomedical devices. We intend to transform the field of healthcare by increasing accessibility, accuracy, and patient outcomes. Also, we aim to help medical professionals and personnel by solving their problems by introducing our technologies to them.

2.2 Strengths and Weaknesses

Our team of biomedical undergraduates has the technical prowess to create cutting-edge biomedical devices, thanks to a solid foundation in electronics, signal processing, and machine learning. This knowledge enables us to create sophisticated hardware, analyze complex data, and implement advanced algorithms, all of which improve device functionality and performance.

Financial constraints offer a challenge as undergraduates, potentially limiting investment in research and development. Furthermore, material availability may present difficulties in prototyping. We understand the need to bridge the industry experience gap, ensuring a thorough awareness of regulatory subtleties and client objectives.

2.3 Acceptance Criteria

Acceptance criteria serve as the standard for determining the sufficiency and quality of a product or service. They ensure congruence with expectations and facilitate successful evaluation by outlining specific requirements and circumstances.



2.3.1 Alignment with the Mission and Requirements

A product must be mission-aligned since it reflects the company's basic values and aims. A mission-aligned product is more likely to resonate with target audiences, creating customer loyalty and distinguishing the brand in a competitive market.

2.3.2 Effect on the Field of Healthcare

Biomedical technologies are changing the face of healthcare by allowing for early detection, precise diagnostics, and individualized therapy. Real-time data enables quick treatments, whilst remote monitoring improves accessibility and lowers healthcare costs.

2.3.3 Time and Resource Needed.

Time and resource allocation within a project is a meticulous process that involves distributing available time, manpower, financial, and material resources efficiently to various project activities and tasks. This allocation is important for ensuring the project's successful completion within defined timelines and budget.

2.3.4 Target Population

We are planning a project which will help to get benefits for a significant audience. Project refers to the specific group of individuals, communities, or entities that the project aims to benefit, serve, or impact. We would consider such a project only if those groups of potential consumers are a special group of people with a special need for that kind of equipment.

2.3.5 Market analysis

When doing market analysis, there are certain aspects that should be looked after; It is important to evaluate the present market environment with an emphasis on how well-existing solutions currently meet customer needs and the criticality of unmet needs. Both the overall market size and growth trends within particular solution categories should be assessed. There are some key characteristics that should be done such as classifying clients with similar needs that will be determined through segmentation, along with the potential size and expansion of each sector. Competition intensity, new entrant success, and ties to established businesses are just a few of the competitive aspects that will be researched. The target market should be identified, focusing on the categories that will benefit most from the new technology while considering the needs of users, investors, and innovators. And it is important to deliver a personalized value to stakeholders.

2.3.6 Affordability

A biomedical device design's affordability relates to its capacity to be produced, maintained, and accessed at a reasonable and accessible cost for a wide range of users, including individuals, healthcare facilities, and communities. Achieving affordability involves optimizing the manufacturing process, utilizing cost-effective materials, and minimizing the need for complex maintenance or specialized training.

3. Need Findings

3.1 Noninvasive method for monitoring lung functions for detecting COPD.

Chronic obstructive pulmonary disease (COPD) is a chronic inflammatory lung disease that causes obstructed airflow from the lungs. It's typically caused by long-term exposure to irritating gases or particulate matter, most often from cigarette smoke. People with COPD are at increased risk of developing heart disease, lung cancer, and a variety of other conditions. The main reasons for COPD are mainly smoking and air pollution. In addition, it may be caused by Occupational exposure- Intense and prolonged exposure to workplace dust, chemicals, and fumes.

COPD symptoms often don't appear until significant lung damage has occurred, and they usually worsen over time, particularly if smoking exposure continues.

- Shortness of breath, especially during physical activities
- Wheezing
- Chest tightness
- A chronic cough that may produce mucus (sputum) that may be clear, white, yellow, or greenish.
- Frequent respiratory infections
- Lack of energy
- Unintended weight loss (in later stages)
- Swelling in ankles, feet or legs



Problem

Observing lung functions and detecting lung diseases.

Source

A Doctor from Deniyaya Base Hospital.

Need Statement

measuring the volume of air inspired and expired by the lungs during breathing.

Population

People who can't breathe regularly and who want to know about their lung functions.

Outcome

Non-invasive monitoring of lung functions

The base idea of this method is to measure lung function by assessing the volume and flow of air that a person can inhale and exhale. Chronic obstructive pulmonary disease (COPD) is a chronic inflammatory lung disease that causes obstructed airflow from the lungs. It's typically caused by long-term exposure to irritating gases or particulate matter, most often from cigarette smoke. People with COPD are at increased risk of developing heart disease, lung cancer, and a variety of other conditions. It would be more beneficial if a device is produced to monitor the respiratory activities of the lungs that could automatically detect and alert complications.

3.2 Continuous weight measurements of the patients who are unable to stand.

Peritoneal dialysis (PD) is a treatment method used for patients with kidney dysfunction, including those with conditions like chronic kidney disease (CKD) or chronic kidney disease of Unknown etiology (CKDU). In peritoneal dialysis, the patient's abdominal cavity is used as a natural filter to remove waste products and excess fluids from the blood.

First, the saturated solution containing waste is drained using a catheter. Subsequently, it is refilled with the dialysis solution. Therefore, the measurement of the patient's weight is an essential task in this process. While weight measurement is a routine procedure, it can pose challenges when dealing with patients who are unable to stand.

The issue at hand is not confined solely to Peritoneal Dialysis; rather, it extends to various medical scenarios where accurate weight measurements are crucial.

Problem

Continuous weight measurements of the patients who are unable to stand.

Source

Ward personnel of Nephrology unit Peradeniya Hospital. (18/08/2023)

Need Statement

Measuring the weight of the patients while they are in their resting position.

Population

Patients who can't stand, but need treatments that include continuous weight scaling.

Outcome

A flexible, continuous weight scaler.

Technical fundamentals.

Introduction:

Accurate and continuous weight measurement is essential in various medical scenarios. This technical fundamental introduces a method to measure patient weight using load cells and impedance-based technology. By monitoring weight distribution and utilizing load cell outputs, this approach offers a viable solution for weight measurement in stationary rest positions.

Load Cells and Impedance Technology:

Load cells are transducers that convert mechanical force or pressure into an electrical signal. They are widely used for measuring loads in various applications. In this context, load cells are employed to capture the weight distribution of a patient in rest positions. Impedance-based technology, commonly used in load cells, offers a precise means to assess pressure variations. This approach can be likened to pressure mats used for various applications. The sum of individual pressure points provides an approximation of the overall pressure distribution, which in turn is correlated with the patient's weight.

Advantages and Applications:

- Non-intrusive: Patients are not required to perform any specific actions, ensuring comfort and ease of use.
- Continuous Monitoring: Enables real-time weight tracking, beneficial for conditions requiring regular weight measurement.
- Medical Settings: Suitable for patients unable to stand, including those undergoing peritoneal dialysis, post-surgery recovery, or critical care.

Existing solutions

- Bed Scales: Some beds come with inbuilt weight scalers. There are some limited beds, and they are very expensive.
- Hoist Scales: These scales are used to measure the weight of a patient who cannot stand with their legs, they lift the patient and measure the weight. However, it needs a mounting process, and it is not a continuous scaling method.
- Wheelchair scales: Some wheelchairs with weight sensors are there; they can be used to measure the weight of a patient who can't stand. But the patients need to sit in wheelchairs.
- Large weight scales: large weight scales can measure the weight of both the patient and bed, and then the weight can be calculated. It is not a continuous scaling technique.

Stakeholder Analysis

- Doctors: Doctors require precise and reliable weight data for accurate medical assessment, dosage determination, and tracking of treatment progress. And also, they want to get measurements most comfortably.
- Patients: Measuring continuously while patients are in their resting position is much more comfortable than walking to scales, using hoists, or distracting when their beds are rolling to scales, and disconnecting from the machines
- Ward personals: it is easy if the weight can be measured continuously, while patients are resting. No need to interrupt patients from time to time. Once a flexible weight scale is established no need to do anything to measure the weight. Just noting down the measurements is enough.
- Hospital administrative: The technology can be implemented even to the existing normal hospital beds, no need to buy separate beds.

Market Analysis

Target Population

All the medical centers can be targeted. Especially the rural hospital which can't afford a technical hospital bed.

Market Opportunities

Telemedicine, Hospital Management systems, and Electronic Health Records (EHR) are some of the market opportunities.

Challenges

Resistance to change from the traditional methods, Educating and training health care professionals, and being approved by the authorities.

3.3 Higher bleeding risk in surgeries or other medical procedures in patients on Warfarin

Source

A doctor from Kalubowila Teaching Hospital (21/08/2023)

Problem:

The physician is discussing a concern regarding individuals who are taking the drug Warfarin. Warfarin is a blood clot preventative, but it can also make people more prone to bleeding. The problem is that people on Warfarin frequently need to cease taking the drug for around 5 days before surgery or other medical procedures. This is because the blood-thinning effects of Warfarin take time to wear off, and having surgery while the patient's blood is still too thin can be dangerous. According to the doctor, it would be extremely beneficial if a new technology—possibly based on nanotechnology—could instantly modify the effects of Warfarin. Warfarin's dosage may be adjusted with this technique, or its blood-thinning effects could be neutralized. Patients wouldn't have to wait days to receive surgery or other medical procedures because of this.

Need Statement

Problem: Patients on Warfarin have a higher bleeding risk in surgeries or other medical procedures.

Population: patients on warfarin such as pregnant mothers

Outcome: Develop a new technology that quickly adjusts the effects of Warfarin

“A way to address the higher bleeding risk in surgeries or other medical procedures in patients on Warfarin such as pregnant women to develop a new technology that quickly adjusts the effects of Warfarin”

Disease state fundamentals

What is the medication?

Anticoagulant drugs like warfarin are frequently recommended to treat clot-related illnesses like strokes and blood clots. It functions by preventing the body from forming blood clots.

Cause of Medication Use:

Atrial fibrillation, deep vein thrombosis, and heart valve replacement are just a few of the disorders for which warfarin is given. The development of hazardous blood clots, which can result in major health issues, must be avoided.

Normal Anatomy Related to It and Abnormalities Caused by the Medication:

Blood clots play a protective role in preventing bleeding in a healthy person. On the other hand, some medical problems might cause irregular clotting, which can have negative health effects. Warfarin aids in preserving a healthy balance between bleeding and clotting.

Symptoms and signs:

Warfarin does not have any identifiable side effects or symptoms. Its main impact is to lower the risk of clot-related events such as deep vein thrombosis and strokes.

Amount of People Facing This Issue:

Millions of patients worldwide use warfarin to treat their diseases and avoid blood clots, making it a widely used drug.

Cost of the Problem to the Health Care Sector:

It can be challenging to manage patients using Warfarin, particularly when surgery or other medical procedures are necessary. Logistics issues, longer hospital stays, and potential problems can arise when Warfarin needs to be stopped or adjusted in order to undergo these treatments, raising the expense of healthcare overall.

Existing Solutions

There are some existing solutions; patients on Warfarin who require surgery can be managed in some ways. One strategy is to cease taking Warfarin five days prior to surgery to give the international normalized ratio (INR) time to return to normal. Before emergency surgery, anticoagulation can be promptly reversed using intravenous or oral vitamin K infusions or fresh-frozen plasma infusions.

These remedies are not without difficulties and restrictions, though. The benefits and hazards of "bridging" during this interval with a quicker-acting medication, such as heparin, are not clear. A more effective and efficient method of managing patients on Warfarin who require surgery may be made possible by the development of new technology.

Stakeholder Analysis:

Patients: Through this higher bleeding risk in surgeries or other medical procedures will be reduced and patients need not stop taking the medication before 5 days.

Doctors & Nurses: Since the higher bleeding risk in surgeries or other medical procedures will be reduced, it will be easier for doctors to treat the patient.

Market Analysis:

Since a new technology to achieve this, is not seen and there can be some nanotechnology or something like that can be involved as a solution the capital will be high.

4. Need Selection

Based on our research, given our financial limitations and other constraints, concentrating our efforts on a specific, impactful problem holds more promise than attempting a broad approach. This approach allows us to channel our strengths effectively towards the advancement of our product. By employing the accepting criteria to evaluate and prioritize needs, we can identify the most pressing and significant challenges to address.

	Need	Estimated Market	Patient Impact	Provider's Impact	Feasibility Index	Co-owner's preference			Total	Rank
		Out of 5	Out of 3	Out of 5	Out of 5	Out of 2 for each			Out of 24	
						1	2	3		
1	Non- invasive method for monitoring lung functions for detecting COPD	4	3	3	4	2	2	1	19	2
2	Continuous weight measurements of the patients who are unable to stand.	3	2	4	5	2	2	2	20	1
3	Patients on Warfarin have a higher bleeding risk in surgeries or other medical procedures.	3	4	2	3	2	1	2	17	3

5. Conclusion

In conclusion, we chose the problem of "continuous weight measurements of patients who are unable to stand" as the most important and practical necessity. We intend to put a method in place for it.

6. References

- Yock, P.G. (2015) *Biodesign (2nd edition)*. 2nd edn. Cambridgeshire: Cambridge University Press.
- “Load cell,” Wikipedia. Aug. 04, 2023. Accessed: Aug. 28, 2023. [Online]. Available: https://en.wikipedia.org/w/index.php?title=Load_cell&oldid=1168702072
- “COPD - Symptoms and causes,” Mayo Clinic. <https://www.mayoclinic.org/diseases-conditions/copd/symptoms-causes/syc-20353679> (accessed Aug. 28, 2023).
- N. K. de Andrade et al., “Bleeding Risk in Patients Using Oral Anticoagulants Undergoing Surgical Procedures in Dentistry: A Systematic Review and Meta-Analysis,” *Front Pharmacol*, vol. 10, p. 866, Aug. 2019, doi: 10.3389/fphar.2019.00866.