

Department of Electronic & Telecommunication
Engineering
University of Moratuwa



BM 2210 - Biomedical Device Design

Investigation report

Group B:

Alwis W.K. - 210029J

Fernando W.W.R.N.S. - 210169L

Nethmal W D I - 210421E

Contents

1	Introduction/Stratergic Focus	2
1.1	Our mission	2
1.2	Effect on improving healthcare	2
1.3	Our strength and capabilities	2
1.4	Affordability	3
1.5	Time and resource allocation	3
1.6	Anticipated market	3
2	Need Finding	4
2.1	Problem : Difficulty in managing medication adherence for patients, particularly those with memory issues.	4
2.1.1	Need Statement 1	4
2.1.2	Design Fundamentals	4
2.1.3	Existing Solutions	5
2.1.4	Stakeholder Analysis	5
2.1.5	Market Analysis	5
2.2	Problem : Improving the quality of ultrasound scanning process using deep learning.	6
2.2.1	Need Statement 2	6
2.2.2	Problem State Fundamentals	6
2.2.3	Existing Solutions	7
2.2.4	Stakeholder Analysis	7
2.2.5	Market Analysis	7
2.3	Problem : Identify Diabetic Foot Ulcers in early stages.	8
2.3.1	Need Statement 3	8
2.3.2	Problem State Fundamentals	8
2.3.3	Design Fundamentals	9
2.3.4	Existing Solutions	9
2.3.5	Stakeholder Analysis	9
2.3.6	Market Analysis	9
3	Need Selection	9
4	Conclusion	10

1 Introduction/Strategic Focus

our startup company, Healthy is dedicated to revolutionizing the future of medicine by seamlessly blending technology with our new ideas. We want to push ourselves to collaborate with real-world needs and complexity. This report is to select a device to design that fulfills our requirements. A few of them are provided below.

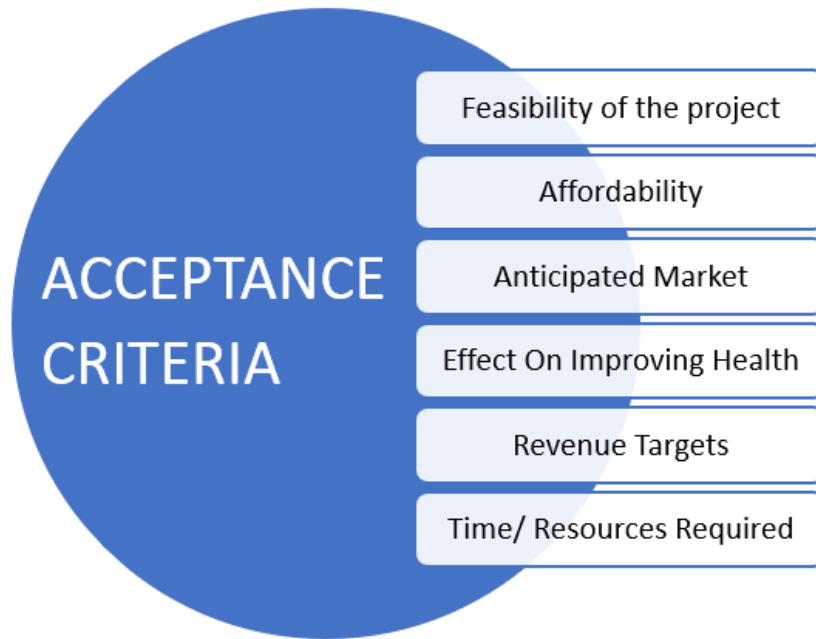


figure 1

1.1 Our mission

our mission as a startup is to improve health care by making scientific discoveries, solving problems, and advancing technology using our skills and knowledge.

1.2 Effect on improving healthcare

The products we develop must answer a problem that affects a considerable amount of target parties.

1.3 Our strength and capabilities

As 2nd-year undergraduates, our expertise lies in a constricted section of the biomedical industry. However, we are capable of doing medical electronic equipment design and biomechanical designs up to a certain extent.

1.4 Affordability

The products we develop must be in a considerable price range. However, when considering manufacturing costs, it becomes crucial in third-world countries like ours. Finding sponsorships may have a significant effect on affordability and as a startup, we will be obligated to create opportunities.

1.5 Time and resource allocation

Since we are advised to complete this within a single semester, the time will be limited from designing to having a working prototype. so that we have to thoroughly look at its complexity.

1.6 Anticipated market

As a startup company market approach will be very crucial for us. Predicted growth of the product market and Similar products already in the market are thoroughly researched before getting into a project.

2 Need Finding

2.1 Problem : Difficulty in managing medication adherence for patients, particularly those with memory issues.

source : physician in national hospital and few medical students

Adhering to prescribed medication schedules is crucial for effective medical treatment, ensuring patients receive the intended therapeutic benefits. Yet, a widespread issue, especially among those with memory deficits, challenges patients to consistently follow intricate medication regimens. This struggle is particularly evident in demographics like the elderly and individuals with cognitive impairments.

Modern life's complexities, coupled with busy schedules and the prevalence of polypharmacy, compound this problem. For patients needing multiple daily doses such as "three times a day" dosing—accurate adherence becomes increasingly demanding. Missed doses, incorrect amounts, and irregular timing can compromise treatment efficacy, leading to adverse health outcomes.

The consequences of medication non-adherence are extensive, encompassing reduced therapeutic effects, prolonged illness, increased healthcare expenses, and even hospitalizations. Patients facing memory lapses or complex routines need innovative solutions to ensure precise dosing and timely administration. Addressing this issue is pivotal in improving patient well-being, particularly for vulnerable groups, and enhancing overall healthcare outcomes.

2.1.1 Need Statement 1

- **Problem** : Difficulty in managing medication adherence for patients, particularly those with memory issues.
- **Population** : Patients of all ages, especially those prone to forgetting medication schedules.
- **Outcome** : Efficient medication management and improved adherence through an electronic pill bottle cap.

“Addressing the challenge of medication non-adherence by developing an electronic pill bottle cap that ensures accurate dosing, timely reminders, and enhanced accessibility.”

2.1.2 Design Fundamentals

The electronic pill bottle cap aims to revolutionize medication management:

Accurate Dosage: A precise release mechanism guarantees the correct medication dosage as prescribed by the doctor.

Timely Reminders: Audible and visual reminders alert users when it's time to take their medication.

Dosing Validation: The feedback system confirms successful medication dispensing and records the event.

Customized App Interface: A user-friendly mobile app enables patients to input prescription details such as dosage, frequency, and instructions.

Bluetooth Connectivity: Cap connects with the mobile app, ensuring synchronization of prescription data and usage events.

2.1.3 Existing Solutions

Currently, there is a lack of specialized electronic pill bottle caps in the market:

- Traditional pill bottles rely on manual tracking.
- Few automated pill dispensers exist, but they lack customization and connectivity.
- Smart medication management systems are limited and do not provide real-time dosing validations.

2.1.4 Stakeholder Analysis

Patients: Elderly individuals and those with memory challenges will benefit from accurate dosing, reminders, and simplified medication routines.

Caregivers: Family members and healthcare providers can monitor adherence through the app and intervene if needed.

Healthcare Professionals: Doctors can review patients' adherence patterns and adjust prescriptions accordingly.

2.1.5 Market Analysis

The lack of comprehensive electronic pill bottle caps presents an opportunity:

- Emerging trend of digital health solutions.
- Growing aging population demands user-friendly medication management tools.
- Potential challenges include user adaptation and ensuring secure data transfer.

2.2 Problem : Improving the quality of ultrasound scanning process using deep learning.

source : Local radiologist and few medical students

Ultrasonic scanning is a widely used imaging technique in medical diagnostics. The incorporation of deep learning into this process has the potential to enhance its efficiency, accuracy, and usability. This will help to improve the state of the typical process by reducing the scanning duration and giving live feedback to sonographers.

2.2.1 Need Statement 2

- **Problem** :Improving the quality of the ultrasound scanning process using deep learning.
- **Population** : All patients undergo ultrasounds.
- **Outcome** : Reduce the scanning duration and ease the diagnosing process to meet the growing demands, minimize costs, and enhance patients experience.

“The way to improve the quality of ultrasound scanning process using deep learning of all patients undergo ultrasounds that reduce the scanning duration and ease the diagnosing process. ”

2.2.2 Problem State Fundamentals

This process will address the below concerns in the field:

1. **Operator dependency** : As US imaging depends on the ability of the operator to position the transducer and interpret the images correctly, it can be difficult to obtain consistent and reliable results from different operators, requiring long and specialized training.
2. **Subjectivity in image interpretation** : The interpretation of the US images is quite subjective. Unlike other imaging modalities, which produce objective, quantitative data, the interpretation of US images depends heavily on the experience and skills of the person performing the scan.
3. **High false-positive and false-negative rates** : Ultrasonic scanning processes may produce false-positive or false-negative results, leading to unnecessary follow-up investigations or missed abnormalities. Reducing these rates is crucial to avoid unnecessary costs and ensure accurate diagnosis and treatment.
4. **Variations in scanning quality** : The quality of ultrasonic scans can vary due to multiple factors such as operator experience, hardware limitations, patient factors, and image artifacts. These variations can impact the reliability and consistency of diagnoses, requiring improved standardization.
5. **Limited availability of expert opinions** : Access to expert opinions and consultations in ultrasonic scanning interpretation may be restricted, particularly in remote or underserved areas. The lack of availability hampers the quality and reliability of diagnoses and limits learning and development opportunities.

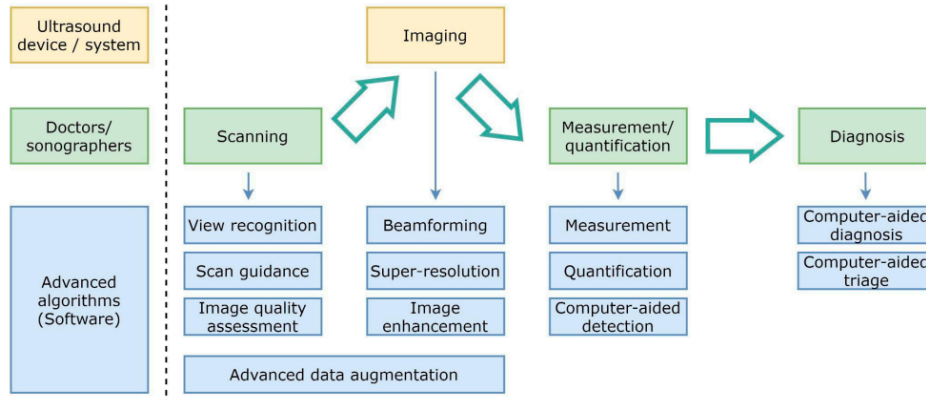


figure 2

2.2.3 Existing Solutions

There are a few algorithms available. Currently, ultrasound image-based diagnoses are widely used for the detection of kidney abnormalities including cysts and tumors. For the early diagnosis of kidney diseases, DNN and SVM are used as machine learning models for abnormality detection and classification.

Furthermore, researchers have proposed a CAD system that consists of the feature extraction of Lung Ultrasound images through a residual network (ResNet) to assist radiologists in distinguishing COVID-19 syndrome from healthy and non-covid pneumonia. We couldn't find any fully optimized data sets or algorithms related to this and they are more likely to be built within the next era.

2.2.4 Stakeholder Analysis

Patients: They expect accurate and reliable results from the scanning process aided by deep learning. Their primary concern would be the safety and effectiveness of the scans.

Medical Professionals: : Radiologists, sonographers, and other medical professionals involved in conducting and interpreting ultrasonic scans require aid from AI to enhance their diagnostic capabilities and workload management. However, there may be concerns about job displacement and the need for training to effectively use the new systems.

Healthcare Institutions: Hospitals, clinics, and medical centers have a stake in using AI for ultrasonic scanning as it can improve their efficiency and diagnostic accuracy

2.2.5 Market Analysis

The overall ultrasound market is expected to grow significantly in the coming years. According to a report by MarketsandMarkets, the global ultrasound market was valued at \$8.2 billion in 2020 and is projected to reach \$12.3 billion by 2025, growing at a CAGR of 8.5%. Several companies are working on developing AI-assisted ultrasound scanning solutions, including established medical imaging companies.

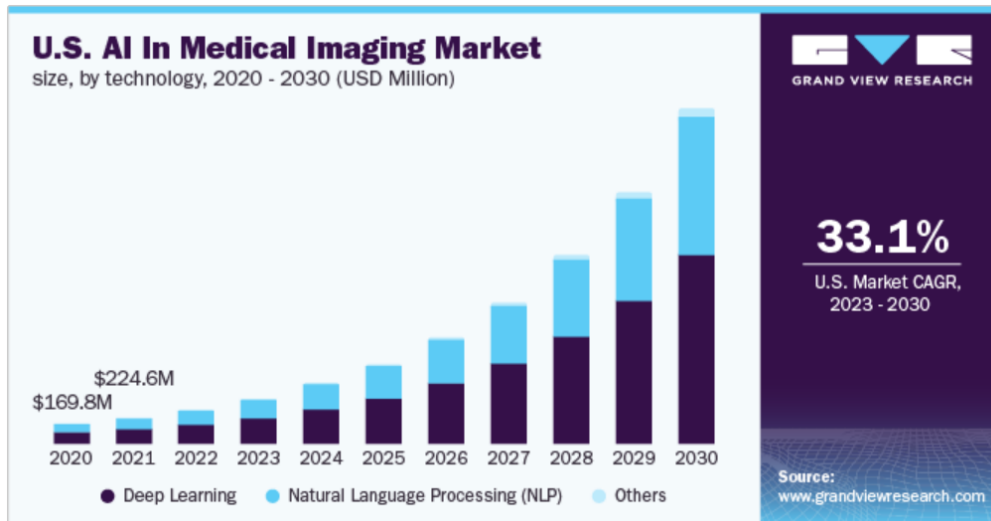


figure 3

2.3 Problem : Identify Diabetic Foot Ulcers in early stages.

source : physician in national hospital and few medical students

The delayed detection of diabetic foot ulcers (DFUs), Can result in severe complications such as infections, amputations, and increased healthcare costs. Diabetic patients with neuropathy often lack sensation in their feet resulting in challenging to identify ulcers in their early stages.

2.3.1 Need Statement 3

- **Problem :** The delayed detection of diabetic foot ulcers (DFUs)
- **Population :** The individuals with diabetes, particularly those with neuropathy or vascular complications.
- **Outcome :** Enable early detection of DFUs, preventing complications and improving patients' overall quality of life.

“A method to identify the potential risk of getting diabetes foot ulcers to preventing complications and improving patient care.”

2.3.2 Problem State Fundamentals

Diabetic foot ulcers (DFUs) pose a serious threat to the well-being of individuals with diabetes, often resulting from neuropathy and reduced blood flow to the lower extremities. These ulcers can lead to severe complications such as infections, gangrene, and even amputations if not detected and managed in a timely manner.

Currently, DFUs are often diagnosed at an advanced stage when patients experience pain or visible symptoms. This delayed detection leads to increased morbidity and mortality rates among diabetic patients, coupled with elevated financial burdens on healthcare systems.

2.3.3 Design Fundamentals

The solution seeks to combine advanced sensor technologies, data analytics, and real-time alerts to create an early detection system. The design should focus on providing continuous monitoring of temperature, pressure distribution, and skin integrity in patients' feet. The system's algorithms should identify patterns associated with early ulcer formation and notify patients and healthcare providers in real time.

2.3.4 Existing Solutions

Existing methods primarily rely on visual inspection by healthcare providers or self-examination by patients. These approaches are subjective, leading to missed ulcers in their initial stages. A need exists for a non-invasive solution that offers continuous monitoring and timely alerts.

2.3.5 Stakeholder Analysis

Patients: Seek early intervention to prevent complications and maintain a better quality of life.

Healthcare providers: Aim for effective patient care and prevention of advanced DFUs

Hospitals/clinics: Strive to reduce hospitalizations and healthcare costs.

Insurance Companies: Desire cost-effective solutions that minimize expensive treatments.

2.3.6 Market Analysis

The market potential for an early detection system for DFUs is substantial, given the increasing prevalence of diabetes and associated complications. As the healthcare industry focuses on preventive care and cost savings, innovative solutions that enhance patient outcomes and reduce the need for complex interventions are highly sought after. This need addresses a critical gap in the market, catering to a niche population that requires specialized attention and contributing to the broader trend of patient-centered care.

3 Need Selection

We went through the standard process including screening our three problems, assigning marks according to our analysis, and at last selected the best one.

Need	Estimated market	Patient Impact	Provider's Impact	Feasibility Index	Total	Rank
	out of 5	out of 5	out of 5	out of 5	out of 20	out of 20
1. Efficient medication management and improved adherence through an electronic pill bottle cap	3	4	3	5	15	3
2. Reduce the scanning duration and ease the diagnosing process to meet the growing demands, minimize costs, and enhance patients experience	4	5	4	4	17	2
3. Enable early detection of DFUs, preventing complications and improving patients' overall quality of life.	5	5	5	3	18	1

4 Conclusion

In conclusion, we identified problem identifying diabetic Foot Ulcers in the early stages, as the most needed and viable need. We will be planning to implement a method to identify them.

References

- 1.AI In Medical Imaging Market Size, Share, Trends Report, 2030. (n.d.). Retrieved August 27, 2023, from <https://www.grandviewresearch.com/industry-analysis/artificial-intelligence-medi> [PMC free article] [PubMed]
- 2.Armstrong DG, Boulton AJM, Bus SA. Diabetic Foot Ulcers and Their Recurrence. N Engl J Med. 2017 Jun 15;376(24):2367-2375. [PubMed]
- 3.Malhotra R, Chan CS, Nather A. Osteomyelitis in the diabetic foot. Diabet Foot Ankle. 2014;
- 4.Micucci, M., Iula, A. (2022). Recent Advances in Machine Learning Applied to Ultrasound Imaging. Electronics, 11(11), Article 11. <https://doi.org/10.3390/electronics11111800>
- 5.Mutluoglu M, Uzun G, Turhan V, Gorenk L, Ay H, Lipsky BA. How reliable are cultures of specimens from superficial swabs compared with those of deep tissue in patients with diabetic foot ulcers? J Diabetes Complications. 2012 May-Jun;26(3):225-9. [PubMed]
- 6.Singer AJ, Tassiopoulos A, Kirsner RS. Evaluation and Management of Lower-Extremity Ulcers. N Engl J Med. 2018 Jan 18;378(3):302-303. [PubMed]
- 7.Tenajas, R., Miraut, D., Illana, C. I., Alonso-Gonzalez, R., Arias-Valcayo, F., Herraiz, J. L. (2023). Recent Advances in Artificial Intelligence-Assisted Ultrasound Scanning. Applied Sciences, 13(6), Article 6,from <https://doi.org/10.3390/app13063693>