

Investigation Report BM2210

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Contents

1	Introduction	3
2	Our Mission	3
3	Need finding	3
3.1	Opportunity 1: Need based autonomous Drug Delivery System .	3
3.1.1	Background	3
3.1.2	Need statement	4
3.1.3	Existing Solutions	4
3.1.4	Stakeholder Analysis	4
3.1.5	Market Analysis	5
3.2	Opportunity 2: Smart Bandage	5
3.2.1	Background	5
3.2.2	Need statement	6
3.2.3	Existing Solutions	6
3.2.4	Stakeholder Analysis	7
3.2.5	Market Analysis	7
3.3	Opportunity 3: ECG power line filter	7
3.3.1	Background	7
3.3.2	Need statement	8
3.3.3	Existing Solutions	8
3.3.4	Stakeholder Analysis	8
3.3.5	Market Analysis	9
3.4	Opportunity 4: EEG based communication system for paralysed patients	9
3.4.1	Background	9
3.4.2	Need statement	9
3.4.3	Existing Solutions	10
3.4.4	Stakeholder Analysis	10
3.4.5	Market Analysis	11
3.5	Need Selection	11
3.6	Conclusion	11
3.7	References	11

1 Introduction

Finding unmet needs in healthcare is the starting point for designing effective biomedical devices. It's about listening to the challenges faced by patients and healthcare professionals and understanding where current tools and technologies fall short. In this report, we explore several such needs that we identified by visiting and consulting health care professionals, the key insights we gained, existing solutions to these unmet needs and the solutions that we could brainstorm to meet these needs in a unique way. By addressing these gaps, we aim to develop innovative solutions that can make a real difference in patient care and medical practice.

2 Our Mission

Our mission is to create biomedical devices that truly make a difference in people's lives. We focus on understanding the real challenges faced by patients and healthcare providers and turning those insights into innovative, easy-to-use solutions. Our goal is to improve patient care and make the work of medical professionals smoother and more efficient, ensuring our devices have a lasting positive impact.

3 Need finding

3.1 Opportunity 1: Need based autonomous Drug Delivery System

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3.1.1 Background

Autonomous drug delivery systems represent a significant leap in the field of personalized medicine. Traditional drug delivery methods often require patients to administer medication manually or rely on healthcare professionals for precise dosages, which can lead to issues such as non-adherence or incorrect dosing. According to research from Johns Hopkins University, autonomous drug delivery systems are designed to optimize the release of medication based on real-time data from the patient's body. These systems use sensors and AI to monitor physiological conditions, such as blood glucose or hormone levels, and adjust dosages automatically. This technology is particularly impactful for manag-

ing chronic conditions like diabetes, where maintaining tight control over drug delivery is crucial.

3.1.2 Need statement

Problem

Current drug administration methods rely heavily on manual intervention, which is prone to human error. These limitations lead to challenges in ensuring timely and precise drug dosing, which is especially critical in managing chronic diseases.

Population

The primary population affected includes individuals with chronic diseases such as diabetes or hypertension, where consistent and accurate medication management is essential for maintaining health. Healthcare providers also face challenges in monitoring and managing patients' drug administration.

Outcome

Autonomous drug delivery systems offer a solution by providing continuous, precise, and user-friendly drug management. These systems automatically monitor patient health, adjust drug dosages in real time, and reduce the burden on both patients and healthcare providers, improving overall disease management and patient outcomes.

3.1.3 Existing Solutions

Current drug delivery options include manual injections, oral medications, and insulin pumps, which require patient involvement and frequent monitoring. Insulin pumps, for example, offer improved control over diabetes management but still require manual input for dose adjustments. Smart pens and automated injectors are emerging solutions that simplify administration but still rely on user interaction. Autonomous drug delivery systems, however, take the next step by integrating sensors, AI algorithms, and automated pumps that continuously monitor patient data to adjust drug dosages without the need for manual input. This real-time response to changing physiological conditions offers more accurate drug delivery and minimizes the risk of overdose or underdose. While early models are under development, the potential for real-time monitoring and dosing is poised to revolutionize chronic disease management.

3.1.4 Stakeholder Analysis

A stakeholder analysis for autonomous drug delivery systems identifies and evaluates the interests and impacts of various groups:

- **Patients:** These systems significantly improve patient quality of life by reducing the need for manual drug administration and ensuring precise

dosing, which can lead to better management of chronic diseases and reduced complications.

- **Healthcare Providers:** Autonomous drug delivery systems streamline treatment by offering continuous real-time monitoring of a patient's condition, allowing for more accurate and timely interventions. This reduces the frequency of hospital visits and frees up healthcare professionals to focus on other aspects of patient care.
- **Regulatory Bodies:** Regulatory agencies ensure that autonomous drug delivery systems meet stringent safety and efficacy standards before they can be marketed. Approval from bodies such as the FDA is critical for widespread adoption.
- **Researchers and Developers:** These stakeholders are crucial for advancing the technology behind autonomous drug delivery systems. They focus on improving the sensors, AI algorithms, and hardware to create systems that can adapt to a wide range of medical conditions.
- **Investors:** Investors are interested in the market potential of these systems, as the increasing prevalence of chronic diseases creates a growing demand for more sophisticated drug delivery methods. Their financial backing is essential for the development and commercialization of these systems.

3.1.5 Market Analysis

The market for autonomous drug delivery systems is expanding rapidly, driven by increasing demand for advanced and precise drug administration technologies. With the rising incidence of chronic diseases such as diabetes and cardiovascular conditions, there's a clear need for continuous monitoring and more effective drug delivery systems. The global drug delivery market, estimated to be worth 100 billion in 2023, is expected to grow at a rate of 6 percent annually over the next decade. Key factors fueling this growth include advancements in AI, wearable health technology, and patient demand for personalized medicine. However, challenges such as high development costs, regulatory hurdles, and ensuring patient safety remain. Despite these challenges, autonomous drug delivery systems offer vast potential for innovation and improved health outcomes.

3.2 Opportunity 2: Smart Bandage

3.2.1 Background

Smart bandages offer a groundbreaking solution to the challenges of monitoring and treating chronic wounds. Traditional bandages don't provide real-time data on wound conditions and often need to be removed frequently, which can slow down healing and increase the risk of infection. According to research from the Keck School of Medicine, smart bandages are designed with sensors that

can monitor key metrics like temperature and pH, which are important for detecting infections early. These bandages can also release medication and even use electrical stimulation to speed up healing, making them a game-changer, especially for people with chronic conditions like diabetes, where wound care is more complex.

3.2.2 Need statement

Problem

Traditional wound care methods involve manual inspection and frequent bandage changes, which can slow down healing and increase the risk of infection. This approach is not optimal, especially in cases where frequent interventions are required, potentially delaying recovery and increasing complications.

Population

Individuals with chronic wounds, such as those caused by diabetes, are particularly affected by these shortcomings in wound care. The healthcare providers managing these patients also face challenges due to the need for constant monitoring and manual wound care procedures.

Outcome

Smart bandages provide a solution by allowing continuous monitoring, early problem detection, and minimal disruption to the wound. These innovations improve patient outcomes by promoting faster healing and reducing infections, while also alleviating the burden on healthcare providers.

3.2.3 Existing Solutions

Existing solutions in wound care include traditional bandages and advanced dressings like hydrocolloids or antimicrobial patches, which help with healing but still need manual inspection. Negative pressure wound therapy (NPWT) has also been used to create a vacuum environment that speeds up healing in chronic wounds, but it doesn't provide continuous feedback on the wound's condition.

According to recent research, smart bandages are a significant step forward. They use sensors to monitor important factors like temperature and pH, which are crucial for detecting infections early. These bandages can also release medication and apply electrical stimulation directly to the wound to enhance healing. While there are early versions of smart bandages, this new technology, which combines real-time monitoring with automated treatment, promises to greatly improve wound care compared to current methods.

3.2.4 Stakeholder Analysis

Stakeholder analysis for the smart bandage project involves identifying and evaluating the interests and impacts of different groups involved.

- **Patients:** Smart bandages offer patients improved wound care by providing real-time monitoring and reducing the need for frequent bandage changes. This helps in faster healing and minimizes the risk of infection, enhancing overall treatment outcomes.
- **Healthcare Providers:** These professionals benefit from smart bandages as they streamline wound management by offering continuous data on the wound's condition. This reduces the time spent on manual inspections and allows for more efficient patient care.
- **Regulatory Bodies:** Regulatory agencies are responsible for ensuring that smart bandages meet stringent safety and efficacy standards. Their approval is crucial for the product's market entry and widespread adoption.
- **Researchers and Developers:** These stakeholders are involved in the research and development of smart bandages, aiming to advance technology and improve functionality. Their work ensures the product integrates cutting-edge innovations and performs effectively.
- **Investors:** Investors are interested in the financial return and market potential of smart bandages. Their support is essential for funding the development and commercialization of the product, influencing its success in the marketplace.

3.2.5 Market Analysis

The market for smart bandages is growing rapidly as demand increases for advanced wound care solutions. With the rise in chronic wounds due to diabetes and surgical procedures, there's a clear need for continuous monitoring and improved healing products. The global wound care market, valued at around 20 billion dollars in 2023, is projected to expand at a 5 percent annual growth rate over the next few years. This growth is driven by advancements in wearable technology and increased healthcare spending. However, challenges like high development costs and regulatory requirements exist. Despite these, smart bandages offer significant opportunities for innovation and improved patient outcomes.

3.3 Opportunity 3: ECG power line filter

3.3.1 Background

ECG devices play a vital role in keeping track of heart health by recording the heart's electrical signals. Unfortunately, these devices often pick up unwanted

noise from powerlines and nearby electronics. This interference can make the ECG readings less accurate. To help ensure that these readings are clear and reliable, we need a way to filter out this powerline noise.

3.3.2 Need statement

Problem

Many ECG devices struggle with interference from power line noise, which can distort readings and lead to incorrect results. This interference delays proper diagnosis and treatment, forcing healthcare institutions to turn off nearby devices to mitigate the issue. While this might not be a significant problem in a ward, it becomes a critical concern in an ICU where nearby medical devices, such as ventilators, are vital for patient care.

Population

Patients in ICUs are particularly affected, as they rely on multiple medical devices essential for their well-being. Healthcare providers are also impacted, as they must manage the conflict between using necessary devices and obtaining accurate ECG readings.

Outcome

A new power line filter is needed to specifically target this issue, improving the accuracy of ECG readings and supporting better healthcare. This solution would allow continuous operation of vital medical equipment in ICUs without compromising the quality of ECG monitoring.

3.3.3 Existing Solutions

There are some methods out there to deal with power line noise, like using filters or shielding, and digital processing techniques. While these can help, they might not fully meet the unique needs of ECG devices. Many current solutions are either too complicated or not perfectly suited to solving this specific problem, so there's room for a better, more focused filter.

3.3.4 Stakeholder Analysis

- **Patients:** They will benefit from more accurate ECG readings, leading to better and more timely treatment.
- **Healthcare Professionals:** Doctors and technicians will receive clearer data, which will aid in making better clinical decisions.
- **ECG Device Manufacturers:** Companies producing ECG devices will be interested in integrating effective filters into their products to enhance performance.

- **Regulatory Bodies:** Organizations that oversee medical device standards will need to review and approve any new filtering technology.

3.3.5 Market Analysis

The market for ECG devices is growing as people become more aware of heart health and technology continues to advance. There's a strong demand for high-quality, accurate diagnostic tools. A specialized powerline filter designed for ECG devices could offer a valuable new solution, filling a need in both existing and future devices.

3.4 Opportunity 4: EEG based communication system for paralysed patients

3.4.1 Background

Effective communication is a fundamental human need, yet for individuals with severe physical disabilities, it can be a challenge. Our project aims to address this issue with an EEG-based communication system specifically designed for paralysed patients. System utilizes electroencephalography (EEG) technology to enable users to communicate by interpreting their brain signals.

The core functionality of the system involves presenting patients with simple questions or statements and providing a limited set of response options, such as "yes" or "no," or a limited vocabulary choices. By analyzing the patient's EEG readings, the system determines their intended response. This offers an effective way for individuals with severe mobility issues to interact and communicate with the environment.

3.4.2 Need statement

Problem

Individuals who are fully or partially paralyzed and those with severe physical disabilities often face significant barriers in communication. Traditional methods, such as eye-tracking or speech-generating devices, may not always be practical or accessible for all users. This results in frustration, isolation, and a reduced quality of life.

Population

The target population for our EEG-based communication system includes individuals with severe physical disabilities who face challenges with existing communication methods. This group encompasses those who may have limited motor functions and find traditional assistive technologies inadequate.

Outcome

The EEG-based communication system aims to provide a simple and effective means of communication by leveraging brainwave technology. The anticipated outcome is a user-friendly interface that allows individuals to convey their needs and preferences with minimal effort and increased accuracy. By addressing the specific challenges faced by this population, the system has the potential to significantly enhance their ability to interact and communicate.

3.4.3 Existing Solutions

Several existing communication aids address the needs of individuals with severe disabilities, though each has its own limitations:

- **Eye-Tracking Systems:** These systems allow users to select letters or words by tracking eye movements. While effective, they may require precise calibration and can be affected by factors such as fatigue.
- **Speech-Generating Devices:** These devices use pre-recorded messages or text-to-speech technology, but they can be cumbersome and may require physical interaction.
- **Commercial EEG Systems:** Products like the Emotiv Epoc+ or NeuroSky MindWave offer EEG monitoring but can be expensive and complex for some users.

While these solutions have made notable advancements, they often fall short in terms of affordability, simplicity, or ease of use. Our EEG-based communication system aims to address these shortcomings by providing a more user-friendly and cost-effective alternative.

3.4.4 Stakeholder Analysis

- **Patients:** The primary users of the system who will benefit from enhanced communication capabilities. Their needs and preferences are central to the design and functionality of the system.
- **Healthcare Professionals:** Doctors, therapists, and caregivers who will assist in implementing and supporting the use of the system. Their insights are valuable for ensuring that the system meets practical and clinical needs.
- **Researchers and Developers:** Individuals involved in designing and refining the EEG-based system. Their expertise is crucial for developing a functional and reliable product.
- **Families and Caregivers:** Support networks who will interact with the system on behalf of the patients. Their feedback on usability and integration into daily routines will help improve the system's effectiveness.

3.4.5 Market Analysis

Our target group is individuals who are fully or partially paralyzed, as well as those with severe physical disabilities. This group requires specialized communication aids to interact effectively with their environment and the people around them. Further there are many applications for a EEG based communication device that transcend the medical field. Our EEG-based communication system is designed to meet the needs of the target patient group and the health professionals that are operating them. By providing a straightforward and cost-effective communication tool, we aim to enhance interactions and improve the quality of life for those with severe physical impairments.

3.5 Need Selection

Need	Estimated Market	Patient Impact	Providers Impact	Feasibility Index	Co-Owner Preference		Total	Rank
					i	ii		
Autonomous Drug Delivery System	3	4	4	4	3	4	22	2
Smart Bandage	4	4	5	2	2	2	19	3
ECG power line filter	2	2	4	3	1	1	13	4
EEG based communication system paralysed patients	3	4	5	4	4	3	23	1
	all marks are out of 5							
	5-highest							
	1- lowest							

Figure 1: Need Selection Process

3.6 Conclusion

In conclusion, we recognized the need for better communication solutions for paralyzed patients. There is a clear demand for an EEG-based system that can turn brain signals into meaningful communication for those with severe motor impairments. We aim to develop a device that uses EEG technology to help these patients communicate more effectively. Our focus will be on improving signal accuracy, making the system easy to use, and ensuring it responds in real-time to enhance communication and boost their quality of life.

3.7 References

1. **Keck School of Medicine.** (2024). *New Smart Bandages Hold Potential for Revolutionizing the Treatment of Chronic Wounds.* Retrieved from Keck School of Medicine
2. **Buchanan, J., & Laird, G.** (2010). *Alternative communication systems for people with severe motor disabilities: a survey.* Retrieved from NCBI

3. **Lebedev, M. A., & Nicolelis, M. A. L.** (2021). *Neuroprosthesis for Decoding Speech in a Paralyzed Person with Anarthria*. Retrieved from PubMed
4. **Reuters.** (2017). *Paralysed patients communicate thoughts via brain-computer interface*. Retrieved from Reuters