Department of Electronics and Telecommunication Engineering
University of Moratuwa

BM2210 - Biomedical Device Design

Feasibility Proposal

by

Group D

Submitted by

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1. Introduction

This report details the steps taken to resolve the issue that was previously identified. We do the ideation and concept-screening stages outlined in the book 'Biodesign: The Process of Innovating Medical Technologies'.

2. Need Statement

"A way to monitor saline flow rate in patients remotely for enhanced patient management."

Pumps for delivering intravenous saline solutions in hospitals are crucial for patient care. An IV line is established during the procedure to allow for the controlled infusion of saline for fluid balance, medication administration, and hydration. The circulatory system and veins are components of typical anatomy. Abnormalities like infiltration or phlebitis can cause pain and irritation. Inadequate setup can lead to air emboli and infections, and inappropriate flow rates can be uncomfortable and have negative effects. These issues arise in various healthcare settings at varying rates. High healthcare costs are a result of improper pump use, including additional hospital stays and impeded workflows from manual monitoring. The vital role that modern pumps play in improving healthcare outcomes is highlighted by the fact that they are outfitted with cutting-edge technology that enhances patient care, decreases interruptions, and maximize healthcare efficiency.

3. Ideation

On 19th September 2023, a brainstorming session was held to produce ideas to address the requirement. The ideas offered are listed below as part of the process of identifying answers.

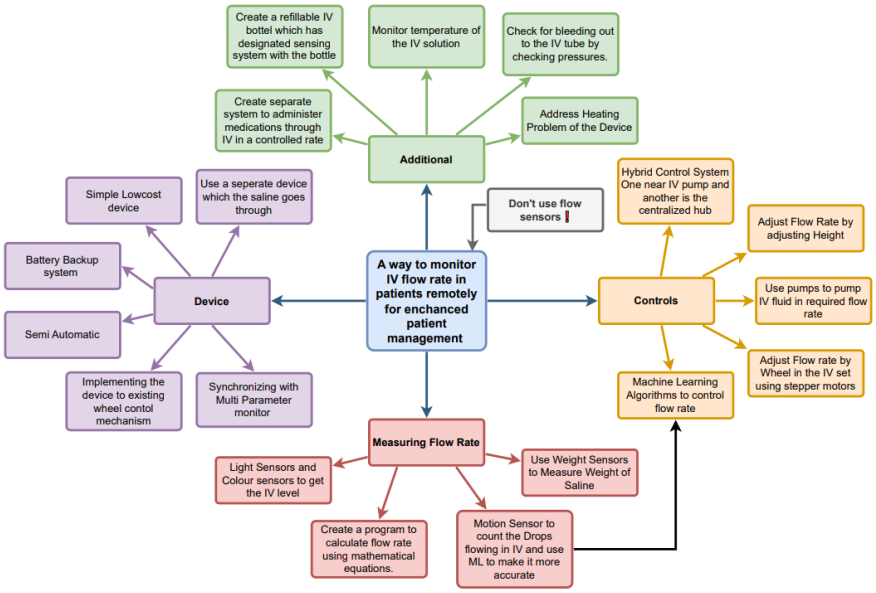

Figure 01: Brainstorming Session Ideas

4. Initial Concept Screening

We have carefully considered and chosen a selection of concepts from the ideas presented above that are viable for further development. We simultaneously identified and disregarded any concepts that we felt wouldn't help us achieve our goals. It's important to highlight that for each of the problems mentioned, we independently obtained solutions. We have adopted a strategic approach because we require a comprehensive solution that addresses each of the three issues mentioned in the need statement. We have developed three separate concepts that, when combined, offer a whole solution framework to our overall challenge by combining certain compatible ideas and synthesizing them.

The problems we mentioned were,

- Automate the monitoring saline flow rate process.
- Design a system to automatically control the flow rate.
- Centralized control systems can help nurses to observe all the saline levels in wards from a computer.

Three ideas listed below are the solutions we are about to examine and decide which is the most feasible solution for the problem we addressed.

4.1. Automated Saline Pump System

Create a sophisticated, automated control-equipped infusion pump system with flow rate sensors. These infusion pumps would be able to precisely and continuously monitor patient needs to modify saline flow rates. Install a wireless connection module (like an IoT device) in each smart infusion pump to enable real-time data transmission to a centralized control system about saline levels, flow rates, and any anomalies. Create a central control system that nurses, and other healthcare personnel can access from desktops or mobile devices. This system would show real-time data from each smart infusion pump in the hospital, enabling nurses to remotely check and change saline levels and get alerts in the event of problems.

4.2. Saline Containers Based on RFID Technology

Give saline containers Radio-Frequency Identification (RFID) tags with data about the saline solution and the required flow rates. Install RFID readers across the ward, including at the infusion pumps. A saline container linked to an infusion pump would be immediately detected and recognized by the RFID reader. To enable nurses to monitor the status and flow rates of each saline container on a computer interface, create a central control system that collects data from RFID readers. Additionally, the system might have automated notifications for low levels or flow rate variations.

4.3. Using Machine Learning Techniques and Predictive Analysis

Using historical data and ongoing flow rate monitoring, implement machine learning techniques to forecast the depletion of saline bottles and calculate the remaining flow time. Add preventive maintenance capabilities to the infusion pumps. When a saline bottle is about to expire, the system can swap to a backup bottle automatically or notify the nurse to get a new one. Create a centralized control system that continuously analyses data from

each infusion pump in the ward using a machine learning component. To improve proactive patient care, nurses can use laptops to access this system and get alerts about when to change saline bottles or adjust.

5. Concept Screening

5.1. Intellectual Property (IP)

5.1.1. Automated Saline Pump System

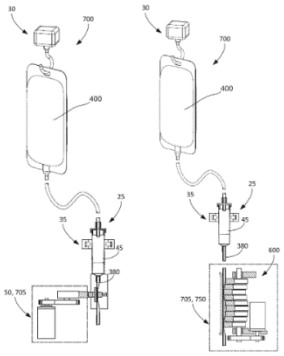

Figure 02: Flowrate Measuring System

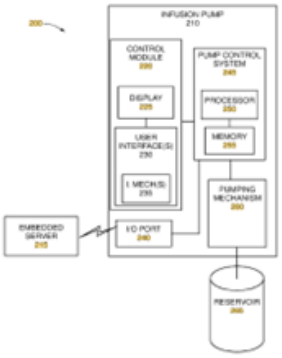

Figure 03: Flowrate Measuring System Block Diagram

Our innovative system introduces an automatic flow control mechanism within a centralized network of these pumps. This technology allows healthcare providers to dynamically adjust the required flow rate, responding to the patient's evolving medical needs. The automated functionality of the system can adapt and decide the precise saline flow rate based on specific parameters or patient conditions, further enhancing the efficiency and safety of saline delivery.

How It Works: The Automated Saline Pump System operates by delivering saline solutions with precision and automation. It employs a pump mechanism to draw saline from a reservoir and safely delivers it through medical tubing to the patient. Healthcare providers configure the desired flow rate and volume, ensuring consistent and sterile saline delivery, making it indispensable in clinical settings.

Data Collection: While data collection is not directly related to the operation of this system, it's important to note that accurate data about patient parameters and medical history may contribute to optimizing the automated flow control mechanism.

Real-Time Monitoring: Real-time monitoring is a key aspect of this system. It continually assesses patient parameters and allows dynamic adjustments to the saline flow rate, responding to evolving medical needs. This real-time adaptability further enhances the efficiency and safety of saline delivery. Monitoring can be accessed through centralized control interface also.

[Patent 01] US11623041B2 - Flow rate measurement and control of infusion devices - Google Patents, 2020-02-27, https://patents.google.com/patent/US11623041B2

5.1.2. Saline Containers Based on RFID Technology

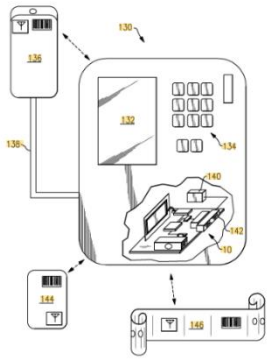

Figure 04: Infusion Pump having RFID Technology

The optical imaging and RFID-enabled infusion pump is an example of cutting-edge medical technology that provides a flexible option for improving the accuracy and safety of medicinal fluid administration. This ground-breaking gadget, which was initially intended for the delivery of medications, may easily fit into saline pump systems. It can provide precise saline bag identification, patient verification, and dosage validation by combining optical imaging and RFID technology. It gives medical staff the ability to compare patient information, confirm authorization, and check saline flow rates, greatly lowering the possibility of mistakes when administering saline. This cutting-edge device is a great asset in healthcare settings since it can be integrated into saline pump systems to increase patient safety while also streamlining the saline administration process. To adapt the technology to saline pump requirements while abiding by healthcare rules and standards, customization and validation would be necessary.

[Patent 02] US20070210157A1 - Infusion Pump Having Radiofrequency Identification and Optical Imaging Capabilities – Google Patents,
2006-04-11, https://patents.google.com/patent/US20070210157

5.1.3. Using Machine Learning Techniques and Predictive Analysis

How It Works: The Automated Saline Pump System operates by automatically delivering precise saline doses. It employs a pump to draw saline from a reservoir and delivers it through medical tubing to the patient. Healthcare providers configure the desired flow rate and volume, ensuring constant and sterile saline delivery, making it an essential tool in clinical settings.

Data Collection: Incorporating machine learning requires extensive data collection. This data encompasses patient-specific parameters, medical history, and other relevant information. It's crucial to maintain structured data collection for accuracy and reliability.

Machine Learning Analysis: Machine learning techniques analyze collected data to create predictive models. These models adapt to patient-specific parameters, ensuring the precise flow rate for saline delivery. Machine learning enhances the system's efficiency and accuracy.

Real-Time Monitoring: Real-time monitoring is integral, continually assessing patient parameters and dynamically adjusting the saline flow rate. This feature ensures patient well-being by responding to real-time needs and changes.

[Patent 03] US10438354B2 - Deep learning medical systems and methods for medical procedures - Google Patents,

2019-03-20, https://patents.google.com/patent/US10438354B2/en?oq=US10438354B2

5.2. Regulatory

When all suggested solutions are put into practice, the resulting devices are classified as Class II devices, more precisely as non-invasive devices. Unless specifically exempted by regulatory rules, Class II devices normally go through the 510(k)-clearance process to be allowed to enter the market. These devices must adhere to a set of "special controls" in addition to meeting all the standards that apply to Class I equipment. These unique controls may cover a range of topics, including but not restricted to:

- Certain labelling specifications.
- Obligatory performance criteria.
- Design decisions.
- Post-market monitoring

5.3. Reimbursement

In Sri Lanka, where most patients lack insurance and government funding sustains most hospitals, only around a quarter of facilities are privately owned. Among the three ideas, the Automated Saline Pump System and Saline Containers Based on RFID Technology are expected to have more favorable reimbursement potential. Using Machine Learning Techniques and Predictive Analysis might involve higher initial costs and training, potentially making it less cost-effective within Sri Lanka's healthcare framework.

5.4. Business Model

5.4.1. Automated Saline Pump System

While automated saline pumps exist in Sri Lanka primarily within ICUs, we aim to introduce an affordable solution for regular hospital wards by joining with local manufacturers. Our user-friendly system, familiar to healthcare staff, integrates a GUI for quick adaptation. We'll provide thorough training and support to ensure seamless implementation. This approach improves affordability and efficiency in standard wards.

5.4.2. Saline Containers Based on RFID Technology

Beyond cost and time savings, RFID technology enhances saline flow monitoring and streamlines inventory management, reducing waste and improving resource utilization. Nurses' workloads are lightened as RFID allows for direct inventory control. Collaboration with local medical supply vendors ensures effective distribution of RFID-equipped saline containers.

5.4.3. Using Machine Learning Techniques and Predictive Analysis

Use of Machine Learning Techniques in Healthcare industries is scars in countries like Sri Lanka. Our approach includes key elements for our predictive analysis solution in healthcare. We focus on data integration, offering a subscription model with competitive fees, and collaborating with governments for cost reduction incentives. We provide extensive training and support to healthcare professionals and suggest outcome-based payments for improved patient care.

5.5. Screening Matrix

The preceding analysis has evaluated the viability of the products, and the subsequent screening matrices elucidate this process. In the matrix, the following abbreviations are employed:

I. IP: Intellectual Property
II. RR: Regulatory Requirements
III. RI: Reimbursement
IV. BM: Business Model

The objective and concept abbreviations are as follows:

(01) Automated Saline Pump System
(02) Saline Containers Based on RFID Technology
(03) Using Machine Learning Techniques and Predictive Analysis

Idea	**IP**	**RR**	**RI**	**BM**
(01) Automated Saline Pump System				
(02) Saline Containers Based on RFID Technology				
(03) Using Machine Learning Techniques and Predictive Analysis				

Table 01: Risk Analysis

Accuracy: Capable of providing the required accuracy

Non-invasive: Able to take measurements invasively

Continuous: Provide a continuous diagnosis for the patient

Accessibility: Easy to use by the patient or the medical staff

Objective	**Weight**	**Notification Alarm Saline System (Baseline)**	**(01)**	**(02)**	**(03)**
Accuracy	5	0	+1	0	+1
Non-invasive	4	0	+1	+1	+1
Continuous	3	0	+1	-1	+1
Accessibility	5	0	+1	+1	0
Final Score		0	+17	+6	+12

Table 02: Objective and Concept Screening

6. Final Concept Selection

The Automated Saline Pump System approach was discovered to be the most practical of the three based on the screening study. Additionally, it had the fewest hazards.

6.1. Concept Exploration and Testing

6.1.1. Prototyping

The temperature sensor, load cell, solenoid valve, water pump, and ESP 8266 Wi-Fi module make up the Automated Saline Pump System. The load cell measures how much saline is still in the bottle. The user chooses one of the three flow rates via the online application according to the patient's needs as we attach the saline bottle and begin the flow, and the water pump starts with the chosen voltage of the flow rate. A message indicating that the solenoid is going to open, and the saline is about to empty will be generated at the server side once the saline reaches 30ml or more. As the valve approaches, a relay will activate, stopping the flow processes. The extra voltage regulator works with the microcontroller and the full set of connected sensors to satisfy the sensor's operating voltage requirements. The controller is set up such that when it receives information about the data from the sensor is transmitted to the ESP Wi-Fi module, which then transmits it to the server. AWS is utilized from the server side from which a static IP address is obtained. JavaScript is used to program a socket at the software design stage, and a simple web application is created utilizing. We are managing the flow rate of the saline bottle for the specified IP address using HTML and CSS. Below is a block diagram of the system.

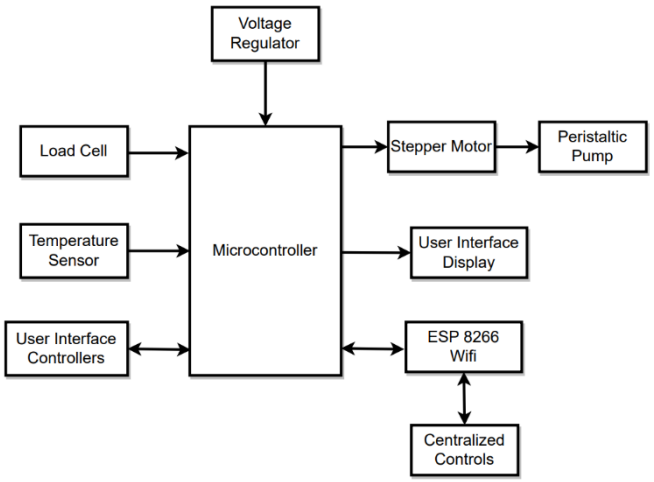

Figure 05: System Block Diagram

6.1.2. Technical Feasibility

Many of the parts used in this system are basic components frequently used in IoT-based projects. The design and execution processes may be completed quite easily, and sourcing the essential components should be a simple operation. This project is approachable and enticing because of its simplicity, which guarantees a quick and efficient development process.

6.1.3. Testing

An automated saline pump system must undergo extensive testing in a medical setting to ensure its use, dependability, and, most importantly, patient safety. A detailed assessment of numerous components and capabilities is part of the testing process. This entails making certain that the system precisely gauges and regulates the saline flow rate, reacts to low saline levels by closing the solenoid valve, and keeps steady connection with the server via the Wi-Fi module. Testing also includes evaluating the system's capacity to handle unforeseen circumstances, user interfaces, and emergency functions. For tracking performance and spotting any irregularities, thorough data logging and analysis are essential. In addition to technical evaluations, acceptance testing and user training are equally important to guarantee that healthcare professionals can utilize the system efficiently in real-world settings. Additionally, throughout the testing process, adherence to medical device rules and standards is given priority, reaffirming the dedication to patient safety and system integrity.

7. Conclusion

In conclusion, the automated saline pump system stands out as the most practical and adequate answer to the problems posed by saline monitoring. Our criteria, which include automating the monitoring of saline flow rates and creating a method for the automatic regulation of these rates, are successfully met by this system. A centralized control system also makes it simple for nurses to check the saline levels on different wards from a computer, streamlining saline management in general and improving efficiency in healthcare settings.

References

[1] Paul g. yock, stefanos zenios, josh makower, todd j. brinton, uday n. kumar, f., “biodesign: The process of innovating medical technologies", 2nd edition, new york: cambridge university press, 2009.

[2] Rajveer Shastri, Aparna Shastri, Sarika Shende, Nikita Swami, Rohini Yadav,, "JETIR January 2019, Volume 6, Issue 1, CONTROLLER BASED AUTOMATIC SALINE INFUSION PUMP," Department of Electronics and Telecommunication Vidya Pratishthan’s Kamalnayan Bajaj Institute of Engineering and Technology Baramati, India, 2019.

[3] ACHRAF HAIBI, KENZA OUFASKA, KHALID EL YASSINI, MOHAMMED BOULMALF AND MOHSINE BOUYA, "Systematic Mapping Study on RFID Technology," IEEE, 2022.

[4] O. T. K. N. S. Patrick Loola Bokonda, "Predictive analysis using machine learning: Review of trends and methods," in *Conference: International Symposium on Advanced Electrical and Communication Technologies - IEEE ISAECT 2020*, 2020.

Appendix: Brainstorm Canvas

The original image taken from the brainstorming session on 19th September 2023 is given below.

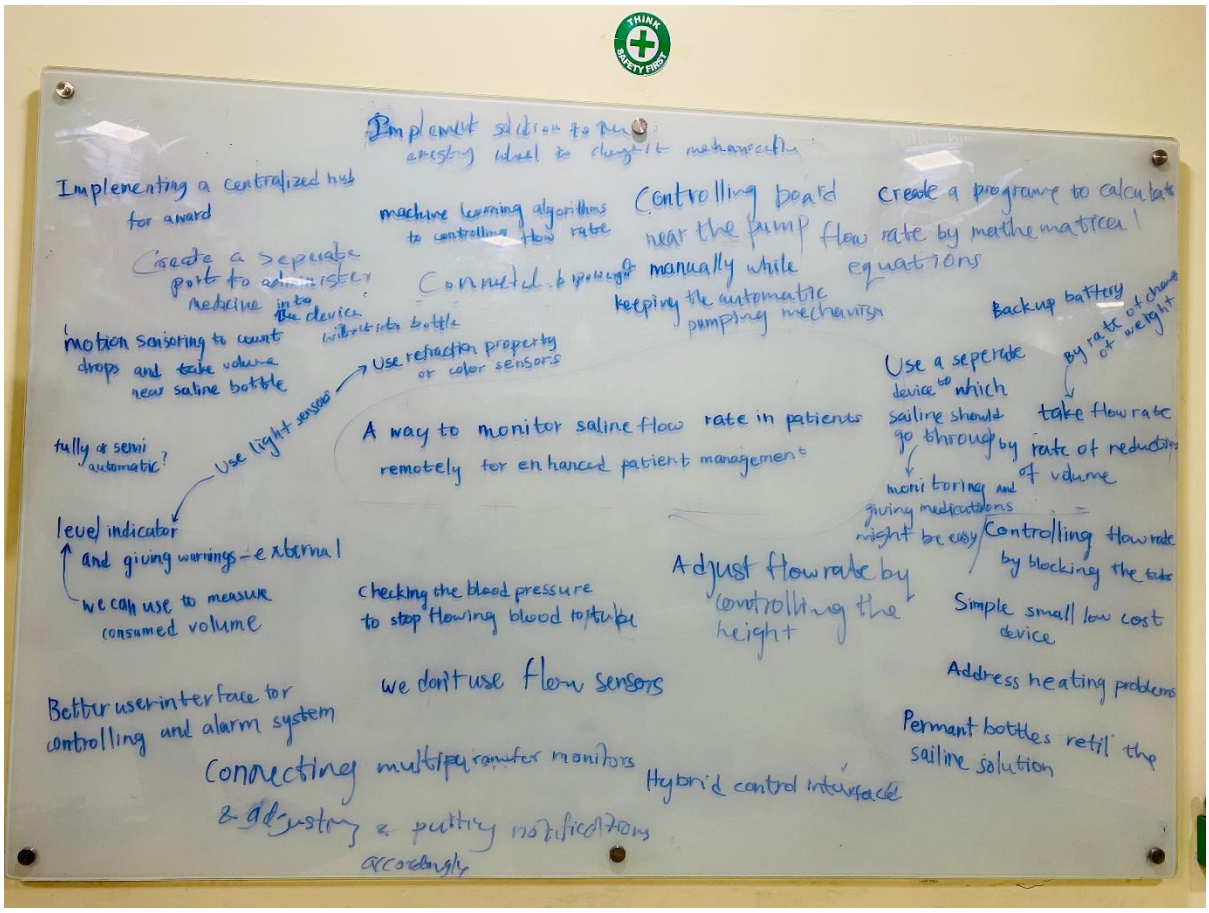

Figure 06: Brainstorming Canvas

Table 4.2.1 Device classification has direct implications on the number and complexity of the requirements imposed by the FDA.

Class	Examples	Description	FDA requirements
I	Bandages, tongue depressors, bedpans, examination gloves, hand-held surgical instruments	Class I devices present minimal potential harm to the person they are being used on and are typically simple in design.	With Class I devices, most are exempt from premarket clearance. There is no need for **clinical trials** or proof of safety and/or efficacy since adequate predicate experience exists with similar devices. However, they must meet the following "general controls": • Registration of the establishment with the FDA. • Medical device listing. • General FDA labeling requirements. • Compliance with quality system regulation (**QSR**), with the exception of design controls, unless specifically called out in the regulation.
II	X-ray machines, powered wheelchairs, surgical needles, infusion pumps, suture materials	**Class II** devices are often non-invasive, but tend to be more complicated in design than Class I devices and, therefore, must demonstrate that they will perform as expected and will not cause injury or harm to their **users**.	Class II devices are generally cleared to market via the **510(k)** process, unless exempt by regulation. They must meet all Class I requirements, in addition to the "special controls" which may include: • Special labeling requirements. • Mandatory performance standards. • Design controls. • Post-market surveillance.
III	Replacement heart valves, silicone breast implants, implanted cerebellar stimulators, implantable pacemakers	Class III devices are high-risk devices. These are typically implantable, therapeutic, or life-sustaining devices, or high-risk devices for which a predicate does not exist.	Class III devices must generally be approved by the **PMA** regulatory pathway, although a small number are still eligible for 510(k) clearance. (FDA has begun the process of requiring PMAs for all of these.) Class III devices must meet all Class I and II requirements, in addition to stringent regulatory approval requirements that necessitate valid scientific evidence to demonstrate their safety and effectiveness, before they can be used in humans.

Figure 07: Source: "Biodesign: The Process of Innovating Medical Technologies" [1]