

AUTOMATED SALINE PUMP SYSTEM



FlowGuard

NEED STATEMENT

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

INTRODUCTION

- Increase the efficiency through proper management of human resources.
- Saline therapy is one of the most basic treatments in which a bottle of saline water is fed to patients as a solution for dehydration for maintaining their immune system.
- The associated problem is that the patient needs to be continuously monitored by the nurse during the whole time, as there is a possibility of the patient's blood flowing back into the tube unconditionally which may lead to fatal conditions, the proposed system has developed to mitigate those errors and to automate the process.



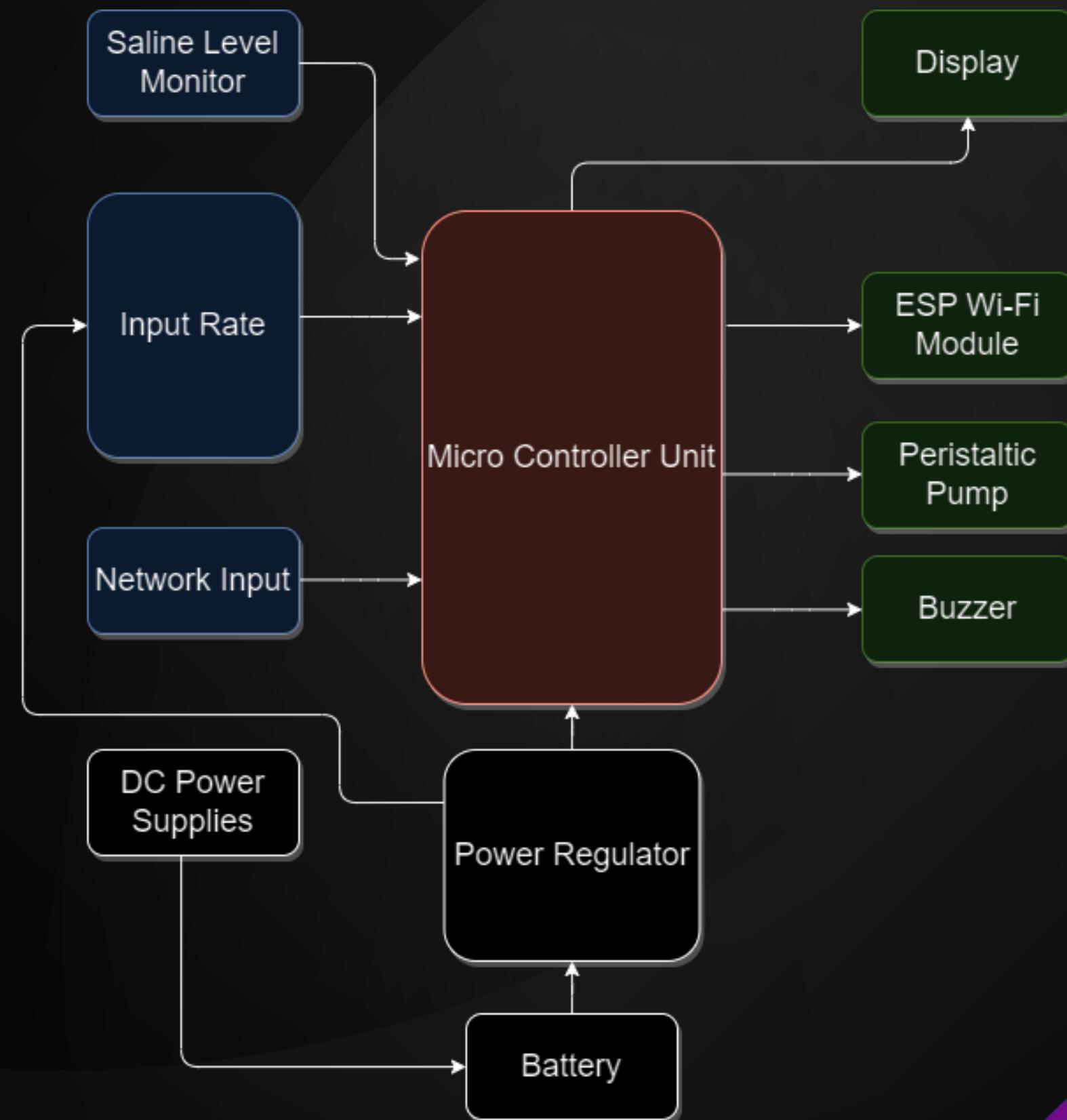
PROPOSED SYSTEM

- Has a suitable method of measuring the saline flow rate and remotely monitoring it using the IoT platform.
- Notifies the low saline levels with the help of a buzzer and notification to the hospital staff/control room.
- Stop reverse flow when the bottle goes empty.
- Compact, cheap, and can be implemented in rural as well as urban hospitals.

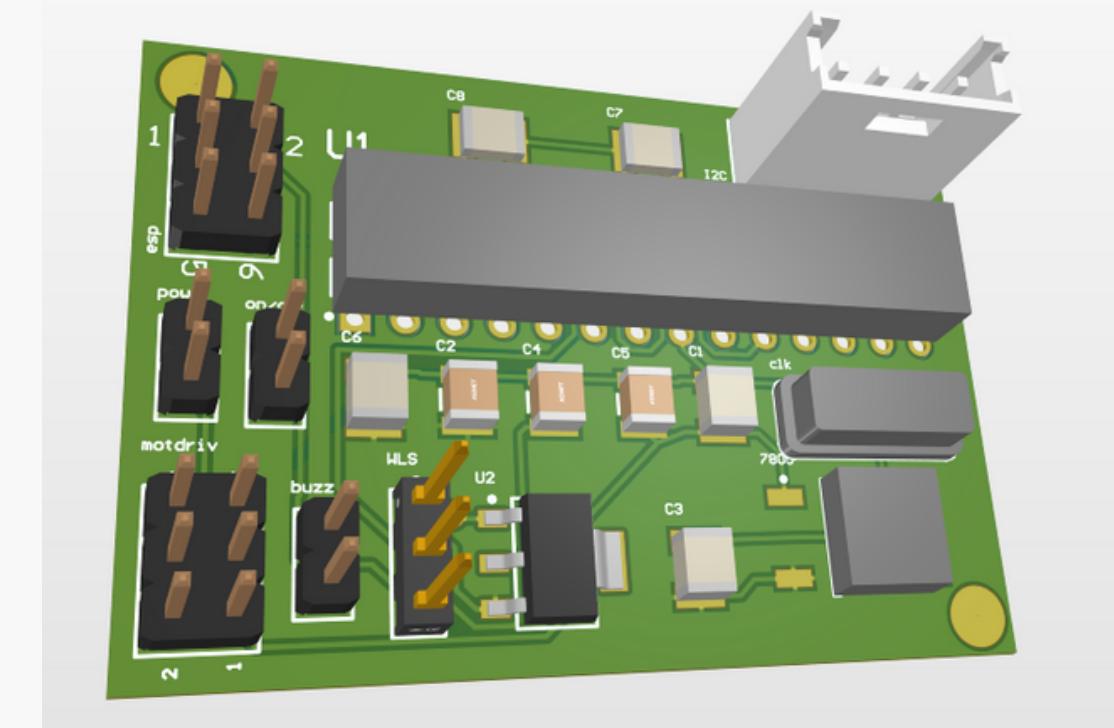
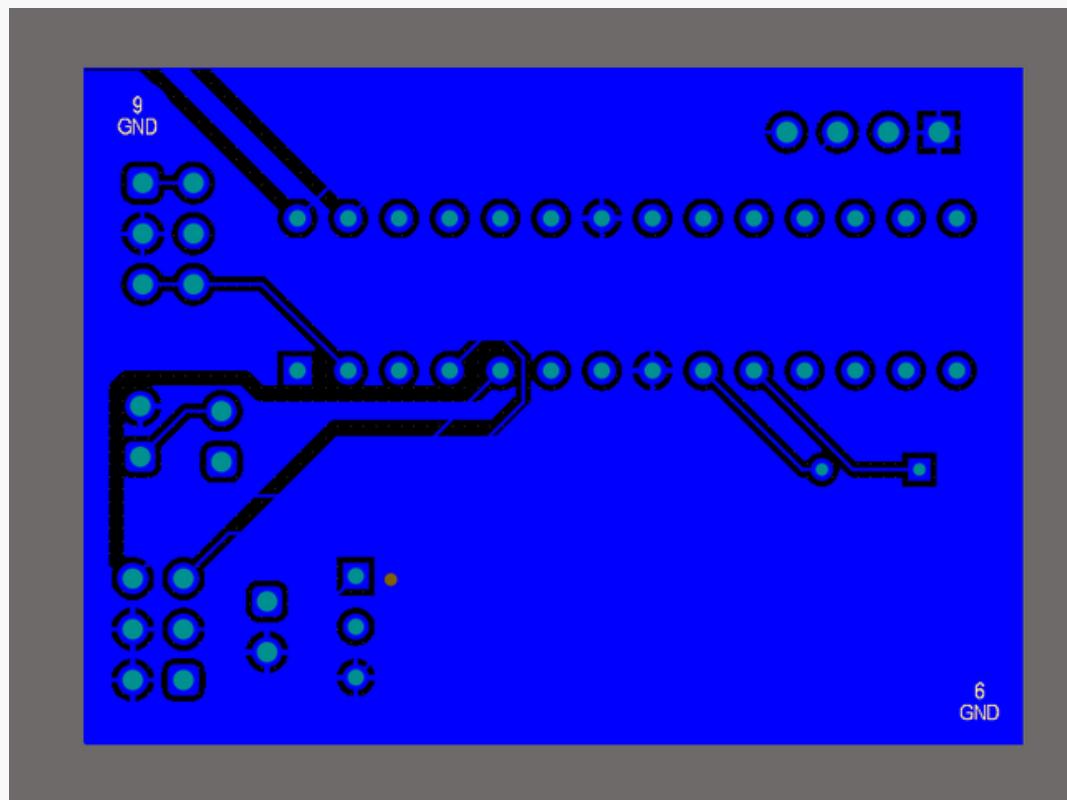
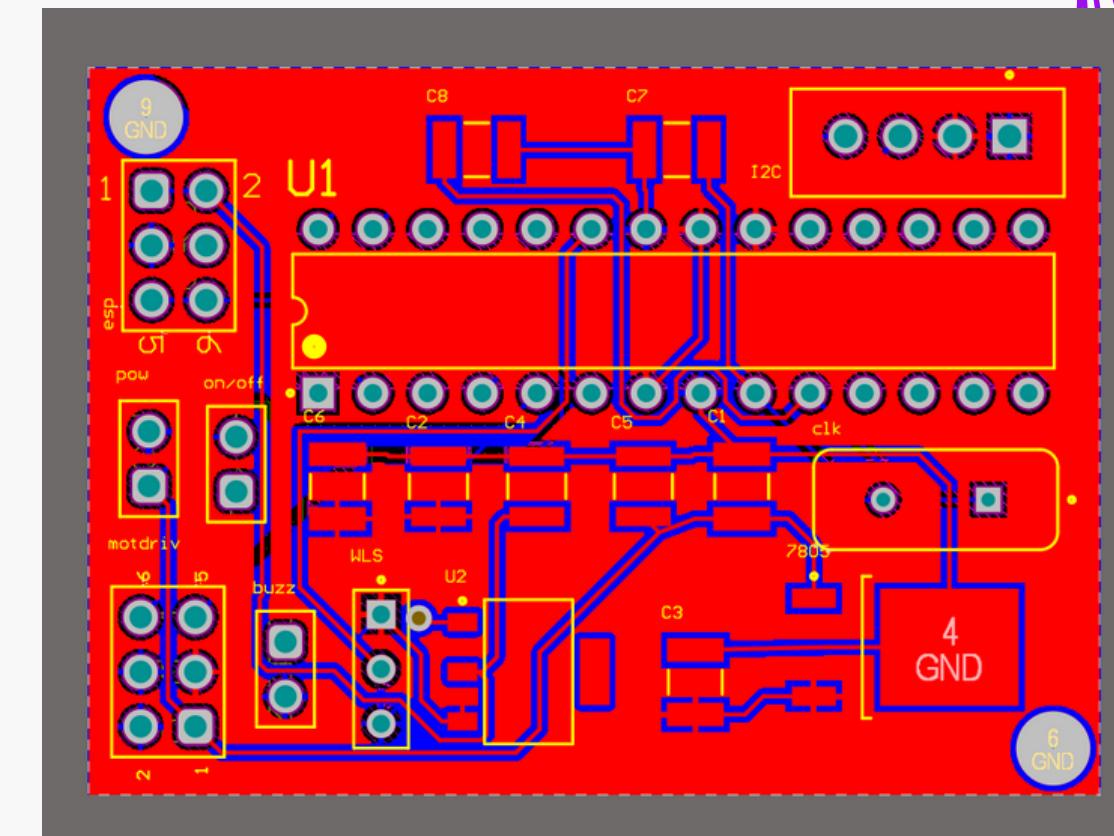
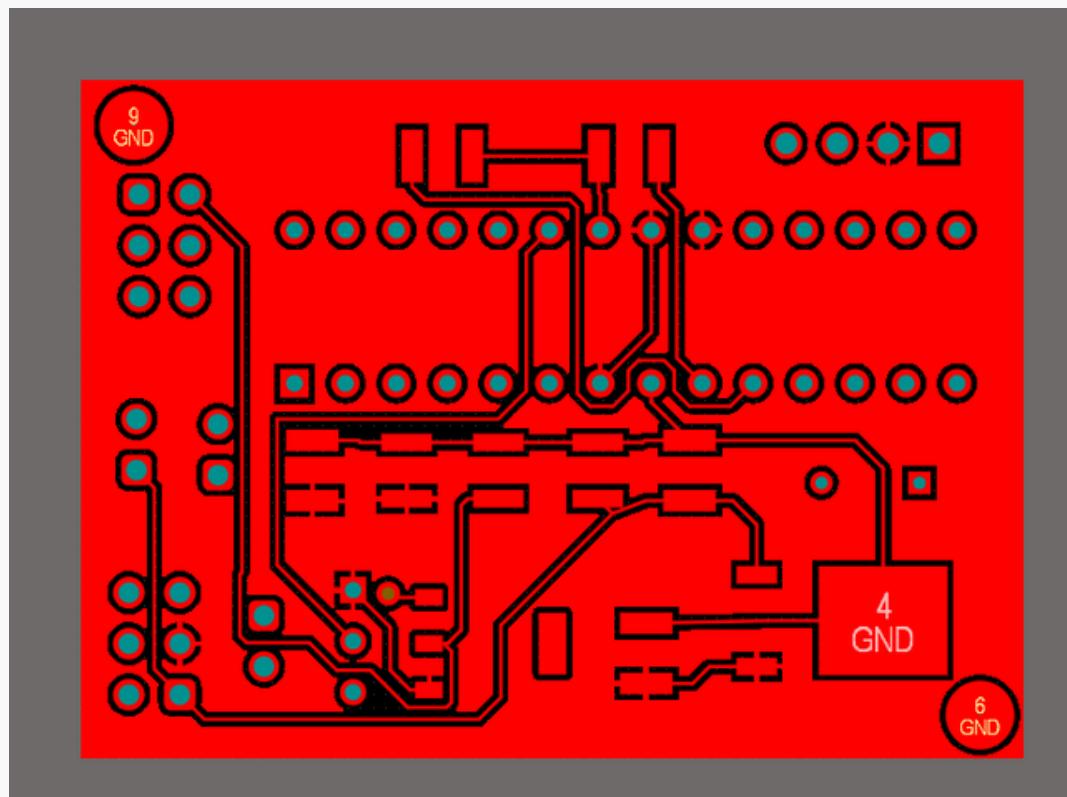
DEVICE OVERVIEW



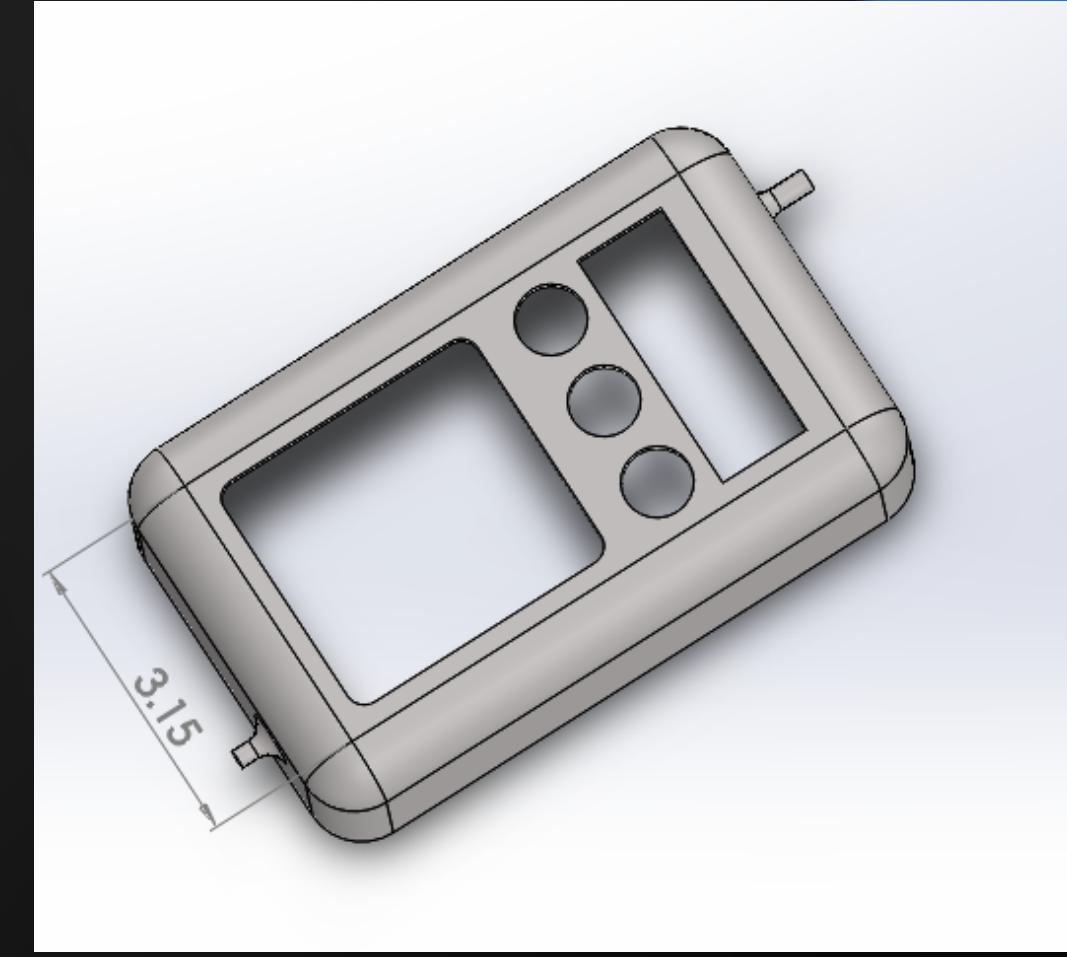
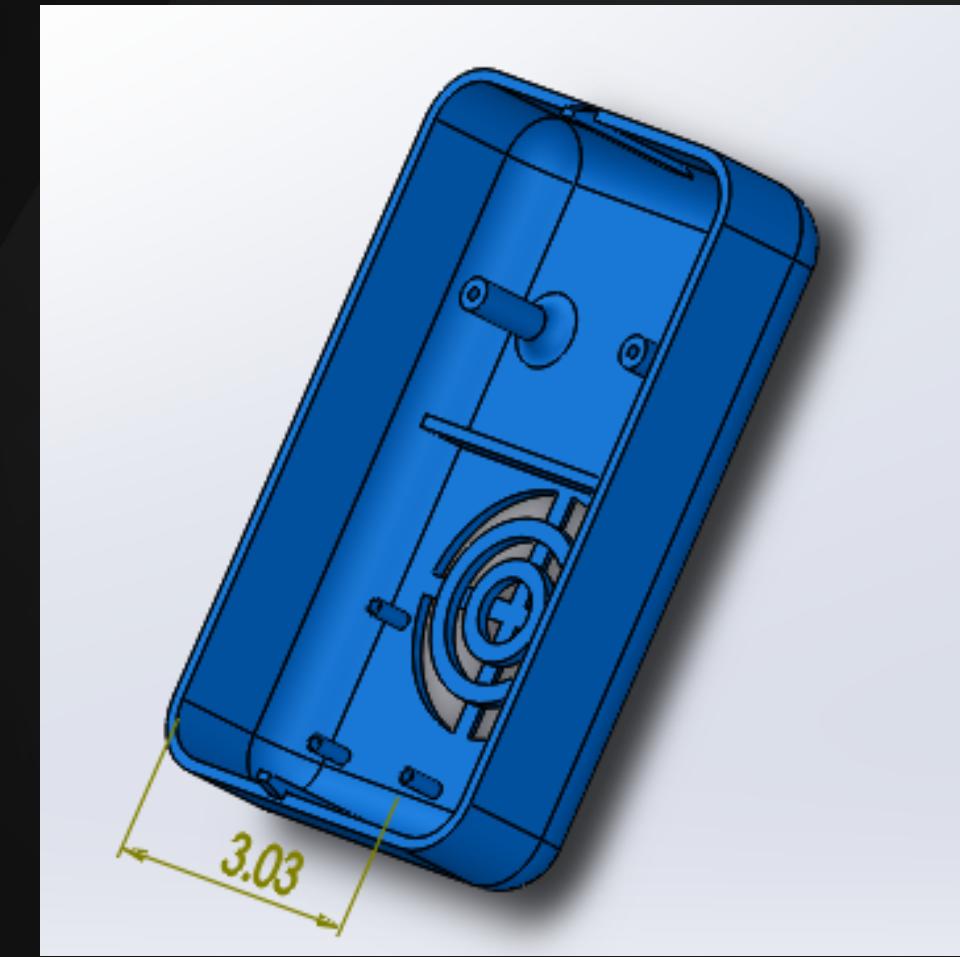
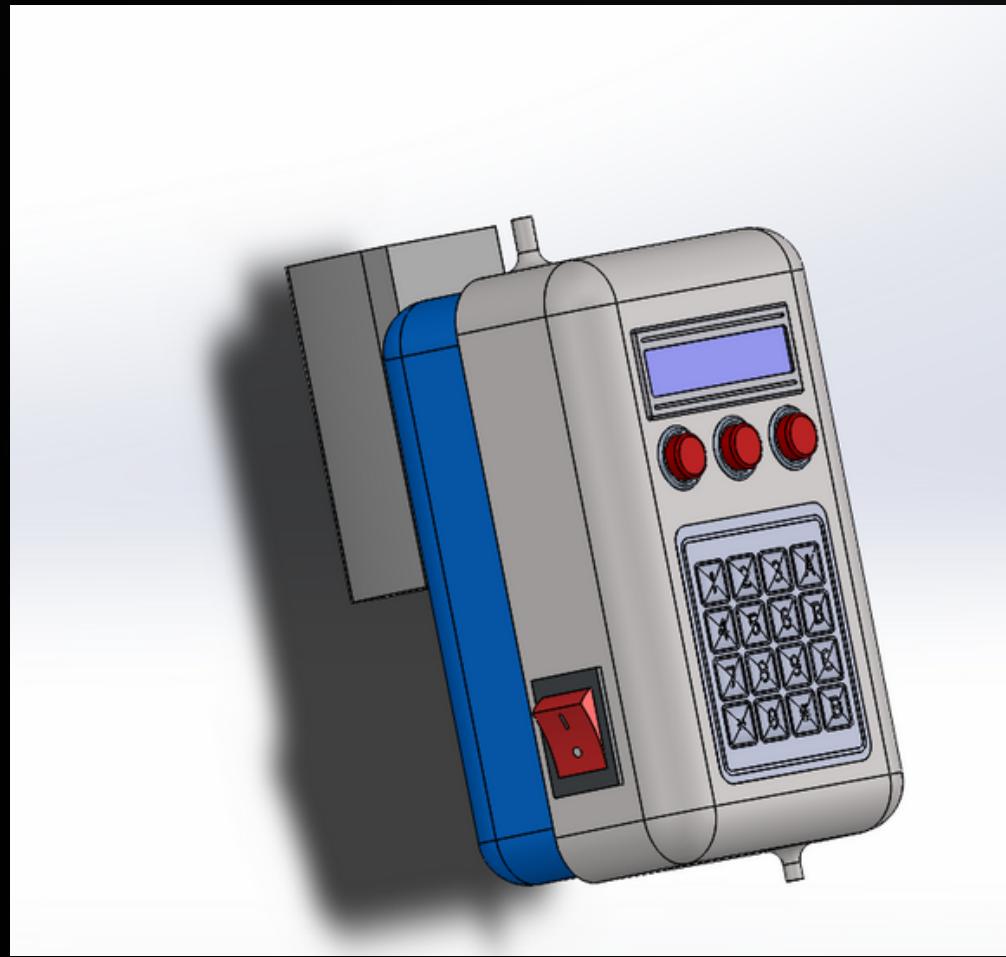
SYSTEM ARCHITECTURE



PCB DESIGNS



ENCLOSURE DESIGN



PROPOSED IMPLEMENTATIONS



KEY REGULATORY REQUIREMENTS FOR FDA APPROVAL



- Device Classification
- 21 CFR Part 820, the Quality System Regulation (QSR)
- 510(k) Premarket Notification
- Regulation of Labeling
- Biocompatibility - ISO 10993
- IEC 60601-1-2, Electromagnetic Compatibility (EMC)
- ISO 14971: Risk Management
- Software Validation - IEC 62304
- Clinical Evaluation
- Post-Market Surveillance



DEVICE CLASSIFICATION

Our device, FlowGuard is a Class II device with
the device code FRN - Infusion Pump

GAP ANALYSIS AND MITIGATION STRATEGIES

PREDICATE DEVICE

*Baxter SIGMA Spectrum Infusion Pump with
Master Drug Library Model 35700*

- An electromechanical, software-controlled device for the safe delivery of fluids, including blood products and medications.
- It uses a linear peristaltic pumping mechanism, which guarantees accuracy and fluid dynamics.
- Drug library management is made easier by the Master Drug Library (MDL) Editor.



Labeling Requirements

According to 21 CFR 807.87(e), premarket notifications must contain proposed labels, labeling, and advertisements that adequately describe the device, its intended use, and the usage instructions.

- 1** Including details about appropriate administration sets, reservoir volume, adjustable flow rates, and profiles in the directions for safe use.
- 2** Clearly identify the variables influencing flow accuracy and offer techniques for calibration confirmation.
- 3** List the tested products, their characteristics, and any known incompatibilities when describing the fluids to be administered.
- 4** Assure adherence to EMC standards and incorporate warning statements for patient safety during diagnostic procedures (MRI, x-ray, etc.).
- 5** Giving a thorough explanation of RF wireless technology, covering its features, frequency, range, and security precautions.(since we are using an ESP32)

BIOCOMPATIBILITY

Biocompatibility considerations

- Material Selection: Uses medical-grade plastics and silicones
- Conducting biocompatibility tests, such as cytotoxicity, sensitization, irritation, and systemic toxicity.
- Chemical Characterization and Particulate Evaluation
- Providing evidence to show that the route(s) of administration, materials, and post-manufacturing residuals align with those of the predicate device.
- Sterilization considerations

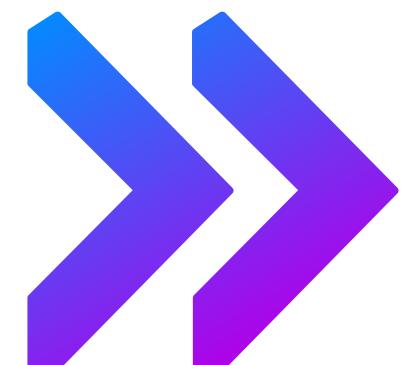
SYSTEM SOFTWARE, NETWORK INTERFERENCE AND ALARM SYSTEM

- We have designed a web server to control the saline pump system.
- Alarm will sound when the saline level is lower than the designated amount.
- We are still trying to implement a separate alarm system to notify when blood flows into the saline tube.
- Using serial communication to communicate with the web server
- Using wireless power supply module to power up the system

CLINICAL EVALUATION

Key steps to perform for clinical evaluation

- Collecting data
- Comparability with Predicate Instruments
- Create and carry out Clinical Studies
- Risk–benefit analysis
- Extensive Clinical Assessment Report (CER)



TESTING

Our device will confirm its suitability for the market through the successfullness achieved in bench testing and simulated use testing.

FUTURE IMPROVEMENTS

FUTURE IMPROVEMENTS

Hardware Modifications

- Implementing a way to detect and notify if blood flows into the saline tube.
- Integrating a valve controller to control the saline valve automatically – we tried to implement it still it in the research phase

FUTURE IMPROVEMENTS

Software Modifications

- Converting the web server into fully functioning software while ensuring security.
- Integrating a comprehensive drug library.
- Taking the smart monitoring system to the next level, enabling it to operate without continuous monitoring. This would require hardware support as well.

FUTURE IMPROVEMENTS

Enclosure Design Modification

- Since we are integrating new senses , we have to do modifications to the enclosure design as well.
- In order to prevent the hazard, “Biological/Chemical Contamination” we have to make our system more closed.

TECHNOLOGICAL CHARACTERISTICS

- The Baxter SIGMA Spectrum Infusion Pump([US8622979B2](#)) is substantially equivalent to the predicate device with regards to design, performance and intended use.
- This system uses a drop count measuring technique to take measurements of disposed liquid. Our device uses water level sensors to measure the distributed saline volume which makes the two devices differ. Also our device supports to program individual devices separately through web server.
- The following provides a comparison summary of the technical characteristics of each device



Characteristics	Proposed Device	Predicate Device(K133801)
Flowguard infusion pump		
Pump Type	Linear peristaltic pump	Linear peristaltic pump
Power	Input: 230V AC, 50 Hz Output: 12V DC Battery Powered	Input: 120V AC, 60 Hz Output: 9V DC Battery Powered
Infusion Modes	Continuous Primary and Secondary Rate Change Cyclic Specially programmed steps.	Continuous Primary and Secondary Multi-Step Cyclic TPN Rate Change Bolus Amount/Time

Intended Use

- used for the controlled administration of fluids.
- The intended routes of administration consist of the following clinically accepted routes; intravenous, arterial, subcutaneous, epidural or irrigation of fluid space.
- intended to be used in conjunction with legally marketed and compatible intravenous administration sets and medications provided by the user.
- not limited to hospitals and outpatient care areas.
- Intended to reduce operator interaction through guided programming.
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REFERENCES

1. [Infusion Pumps Total Product Life Cycle \(fda.gov\)](#)
2. [K133801.pdf \(fda.gov\)](#)
3. [Premarket Notification 510\(k\) | FDA](#)
4. [Spectrum IQ Infusion System | Baxter](#)
5. [Patent: Spectrum IQ Infusion System](#)
6. [510k summary Spectrum IQ Infusion System](#)

THANK YOU!