Department of Biosystems and Agricultural Engineering
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Biosystems Design Projects

Medical Device Irrigation System Innovations (Under NDA)

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Background

Sonopet iQ® Ultrasonic Aspirator System

- A medical device shown in Figure 1 used in surgeries that vibrates to resect tissue and bone without harming non-target tissue (Stryker, 2023)
- The aspirator function in the handpiece works to remove the resected bone, tissue, and blood
- Saline bags are the source of irrigation as well as temperature control
  - Therapeutic benefits
  - Lubrication prevents buildup of debris in tubing
  - Metal tip warms due to the ultrasonic vibrations, saline cools it
- Lack of saline can cause issues during operations
- Currently, there is no alert system in place to monitor the liquid levels
- Medical staff can accidentally neglect replacing the irrigation bag promptly

Figure 1: Sonopet iQ® Console (Stryker, 2020)

Problem Statement

To conceptualize, design, and prototype a method to detect and alert when irrigation is running low such that hospital personnel can replace the irrigation bag in a timely manner to prevent patient injury.

Objectives

Specific objectives to fulfill to accomplish this goal relate to safety and efficiency, such as:

- Must notify hospital personnel when saline left in irrigation bag reaches 100 mL to ensure enough time to replace bag
- Perform tests to collect data on the device, before and after integration
- Ensure the solution is commercially practical via surveys
- Add a visual and audible alert system to console

Constraints

To be conscientious of patient safety, customer satisfaction, and accessibility, the constraints are:

- Must be an integrated solution into the disposable cassette or the console
- $1.25 maximum cost addition to the disposable cassette
- $500 maximum addition to the console
- Device and add-ons < 50 lbs
- Must follow current medical grade safety regulations: LFL Medical Device Classifications from FDA, China RoHS Standard SJ/T 11364 and GB/T26572
- Alert must not be too distracting to staff (Nasri et. al., 2023)

Design Alternatives

The five feasible sensor designs include the incorporation of

1. A pump revolutions counter
2. A load cell
3. A smart IV pole
4. An optical sensor
5. A capacitive sensor

These five designs were evaluated in a decision matrix based on six different categories: cost addition, weight addition, accuracy/effectiveness, user experience, size, and ease of integration.

Table 1: Feasible design alternatives decision matrix

Metrics	Accuracy/ Effectiveness	Ease of Integration	User Experience	Cost Addition	Size	Weight Addition	Total
Weight	20	20	20	15	15	10	100
Alternatives							
Pump revolutions sensor	5	4	5	5	5	4	470
Strain gauge sensor on console bracket	5	4	5	4	4	4	440
Strain gauge sensor in IV pole	5	4	4	4	4	4	420
Optical sensor	5	4	4	3	4	4	405
Capacitive sensor	4	4	4	4	4	4	400

As for the alert system, the options were either a screen pop up, audio alert, light alert, the handpiece stopping, or different combinations of these.

The key metrics for the alert system were user experience, effectiveness, ease of integration, and size. A team of nurses were surveyed for their opinion on the first two criteria for each alert option.

Table 2: Alert system decision matrix

Metrics	User Experience	Effectiveness	Ease of Integration	Size	Total
Weight	30	25	25	20	100
Design Alternatives					
Screen Pop Up & Audio Alerts	5	5	4	5	475
Audio Alert	3	5	5	5	440
Screen Pop Up & Light Alerts	4	2	4	5	370
Audio & Light Alerts	2	3	4	5	335
Light Alert	2	1	5	5	310
Screen Pop Up & Handpiece Stops	1	2	1	5	205

Selected Design

Pump revolutions sensor design

Using the revolutions counter in the peristaltic pump within the irrigation cassette holder shown in Figure 2 is the optimal choice. Some benefits of this are:

- Counts the revolutions of the peristaltic pump within the console
- Estimates the amount of liquid left in saline bag using displacement
- Most cost-effective, all hardware already exists in the machine
- Implemented through software updates
- Requires code to instruct the console to control and count the pump revolutions
- Saline amount input can be changed to be 500 mL or 1000 mL through a prompt

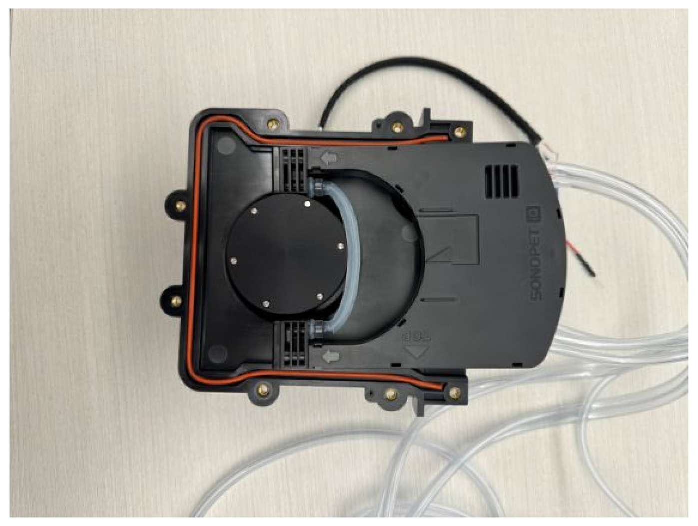

Figure 2: Sonopet iQ® Peristaltic pump

Alert system design

The screen pop-up with an audio alert was found to be the most practical alarm system. Some features of this are:

- Screen pop-up has 2 stages displayed in Figures 3 and 4
  - Warning page
  - Reset page
- Audio chime
  - 6 second melodic chime
  - Repeats every 45 seconds until reset
  - Effectively draws attention, but does not incite fear or distraction

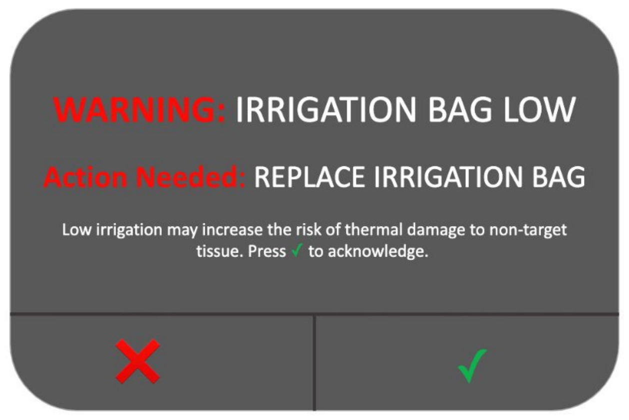

Figure 3: User interface acknowledgement screen

Figure 4: User interface reset screen

Design Model

A model of the Sonopet iQ® irrigation system to test the volume output per pump revolution was created. The complete prototype is shown in Figure 5.

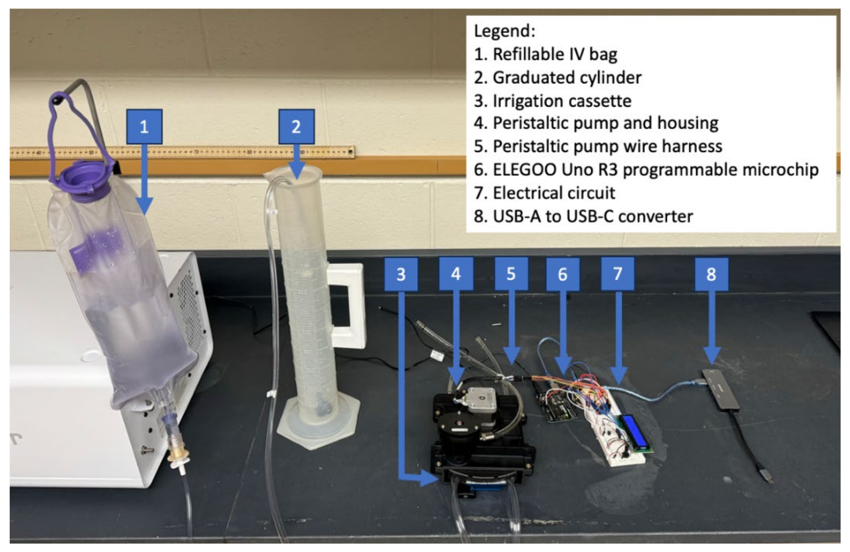

Figure 5: Prototype design overview

Prototype components

- Pump driver board wired to an Elegoo Uno (microchip) was connected to the Sonopet iQ® peristaltic pump via a wire harness
- Alert components wired on breadboard
- Arduino IDE was used to send and gain information from the driver board
- Model was utilized to estimate the number of pump rotations needed for a target volume depletion
- Once the target number of revolutions is reached, both the LCD screen displays "REPLACE BAG" and the audio alert is triggered until reset

The schematic of the electrical board circuit used to control the system is shown in Figure 6.

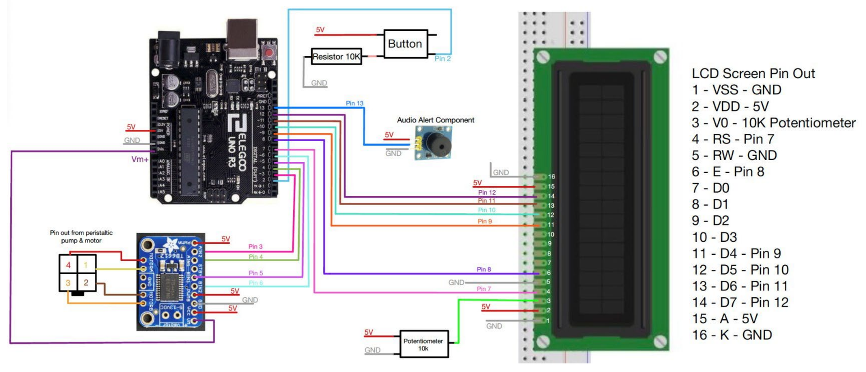

Figure 6: Schematic of model components

The prototype uses a programmable microchip to control a stepper motor. The principle of the coding for this chip is outlined in the flowchart shown in Figure 7.

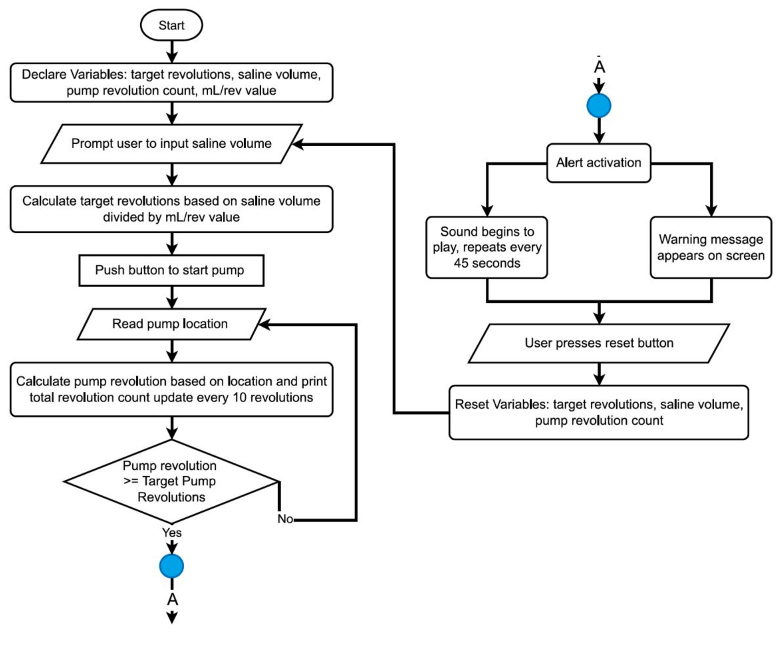

Figure 7: Coding principle flowchart

Model Testing

Height testing

The team performed testing to evaluate the effect of IV bag height on volume output per pump revolution. As seen in Figure 8, when increasing height between the IV bag with the peristaltic pump, the amount of saline output increases as well.

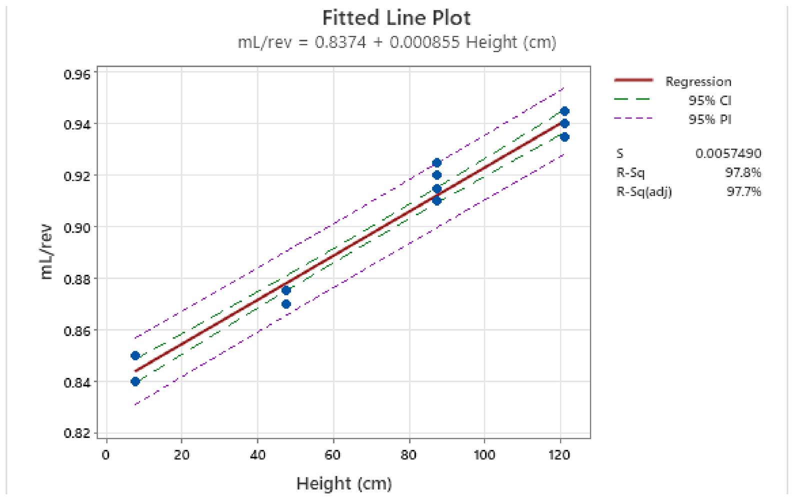

Figure 8: Linear relationship between volume per revolution and height of IV bag

Model optimization

Additional testing assessed the model's accuracy in estimating saline levels in IV bags and triggering the alert system. A capability analysis is seen in Figure 9. If using the 0.812 mL/rev value, the prototype will trigger the alert at 106.7 ± 3.77 mL.

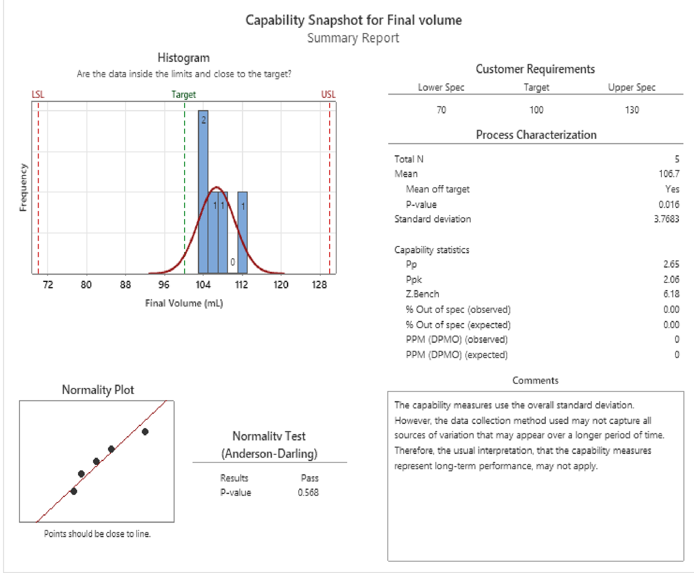

Figure 9: Capability analysis for 0.812 mL/ rev value

Economics

Cost to implement solution is very low.

- No hardware additions, no added cost in that regard
- Salary of employees to implement software updates are considered
  - Software engineers
  - Electrical engineers
  - Soldering technicians
  - Engineering lab technicians

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