Raghava Ravi
Ankit Patel
Sankruth Kota

Single Infusion Intravenous Fluid (IV) Regulator

Introduction

Objective

Single infusion IV drips are currently manually regulated, or use an electric pump. Electric pumps, also known as infusion pumps, range from $1,800 to $4,500 in cost, might have an annual software subscription license, and require an additional $150-250 annual contract for maintenance if there is no in-house repair department. [4] Hospitals in first world countries have a limited supply of pumps due to the cost. During the COVID pandemic, the FDA issued an Emergency Use Authorization [5] for an increased supply of infusion pumps and accessories. Many hospitals reverted to using gravity IV pumps due to a shortage of infusion pumps. Many third world countries or medical camps have even fewer available. Infusion pumps also require training to learn how to operate.

Our goal is to create a low cost and easy-to-use solution to measure the rate of drips for gravity IV drip systems, and provide an alert when a certain amount of IV fluid has been consumed or if the IV supply has been depleted, and control the rate of flow of IV fluid at a per unit price below $20 once scaled.

Background

An infusion pump has the ability to deliver fluids in controlled quantities. According to the FDA, there are many types of specialty infusion pumps. An Enteral pump delivers nutrients and medications to a patient's digestive tract. A PCA (patient-controlled-analgesia) pump allows the patient to self-administer a set amount of medication. There are many other varieties as well, but all pumps can neatly be classified into two categories; one category are large stationary bedside pumps and the other is mobile pumps. [6]

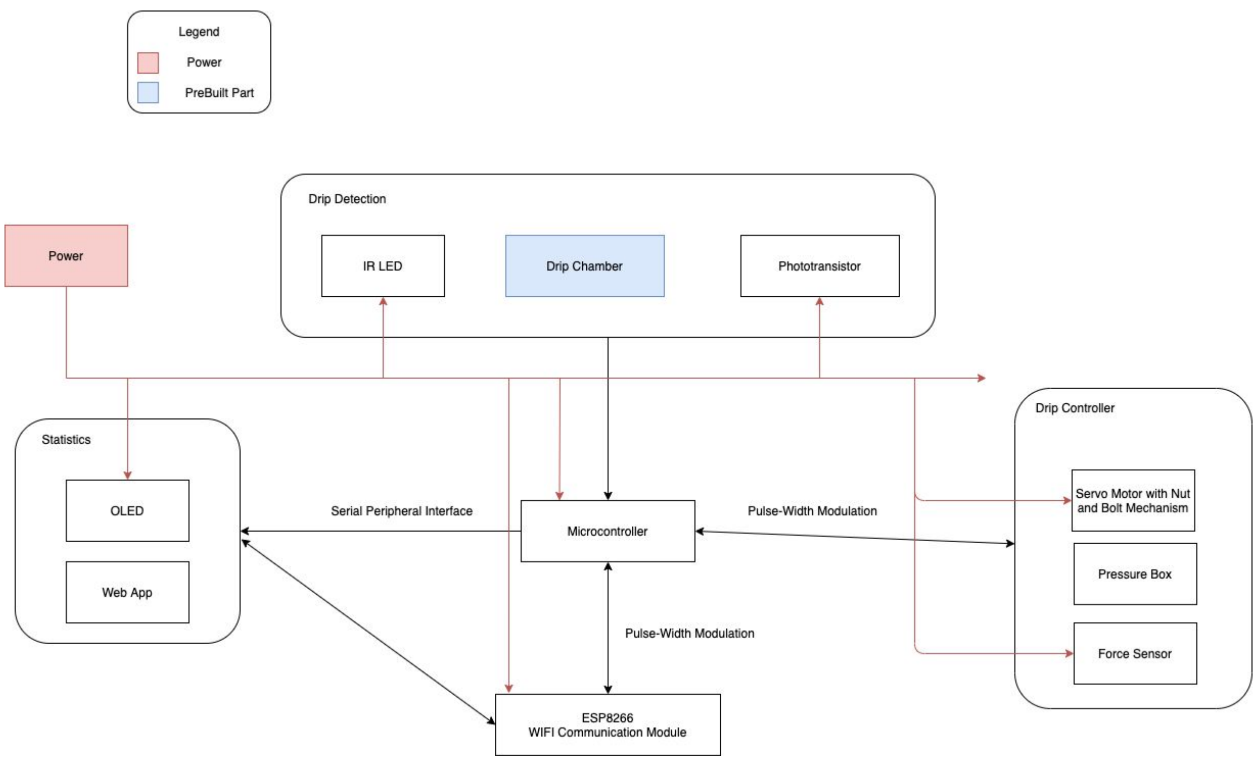
Errors in IV administration can lead to harmful patient outcomes. A study was done at a teaching hospital in Brisbane, Australia. All patients received a continuous IV infusion. Of the 687 observations, 124 (18%) had at least one administration error. The most common error was the wrong administration rate. It was concluded that errors could be mitigated with the use of infusion control devices and frequent monitoring of the administration rate. [1]

DripAssist by Shift Labs is a direct competitor. They advertise a IV monitoring system for gravity infusion pumps. The device can count drops, calculate the rate of fluid, and detect a depleted supply of fluid. The DripAssist retails for $480 for a human model and $335 for a veterinary model. This device lacks automatic pressure control to adjust the rate of flow on its own.

High Level Requirements

- Consistently deliver IV fluid at a rate, within a tolerance range, specified in our web app, by adjusting pressure of our clamping mechanism
- Accurately display and monitor how much fluid has been delivered, calculated rate of flow, and other similar statistics on an OLED display and on a web app
- Count drops of IV fluid dropping into the drip chamber to the amount of fluid administered.

Block Diagram & Physical Design



Functional Overview

Our project consists of 3 key subsystems, a microcontroller, and a WiFi communication module. First, we have our drip detection subsystem, which consists of an IR LED and a phototransistor as well as a drip chamber (which is pre-built and comes with the default IV infusion system). Here, we measure how much light is being transmitted to the phototransistor through the drip chamber, and when a water drop falls through the amount of light transmitted is reduced due to light scatter. By measuring this change, we are able to determine the number of drops of IV fluid falling into the drip chamber.

Along with the drip detection system is the drip controller subsystem, which applies varying pressure to the tube that is responsible for delivering the IV fluid and therefore controls the rate at which the fluid is administered to the patient. To implement this, we use a servo motor which rotates a threaded rod with a nut on the end. Attached to this nut is a plastic piece that applies pressure to the tube. Between this plastic piece and the tube is a force sensor to measure the amount of pressure exerted on the tube. As the servo motor begins to rotate, the nut slides forward, and the plastic piece attached to the nut applies the pressure.

Lastly, we have the statistics subsystem, WiFi module, and microcontroller. The statistics subsystem is responsible for displaying information about the fluid being administered, how much of the fluid is being administered, average flow rate, etc. The OLED focuses on displaying the current flow rate, while the web app will display all the statistics. The WiFi communication module is used to facilitate communication between the statistics module and the microcontroller. Our microcontroller will serve as the brain of the entire project and will be what each part is connected to to make sure all the subsystems work as intended.

Block-Level Requirement

1. ***Drip Detection***

   The drip detection system will consist of a phototransistor and LED that are placed around the drip chamber and are able to detect when drip has fallen from the IV bag into the drip chamber. This will be used to determine the rate of flow as well as how much fluid has been administered and is left.

   1.1. IR LED and Phototransitor

   The IR LED will point at the phototransistor which will be able to read how much light is being absorbed. In order to detect a drop, the phototransistor will have a lower reading of light when the drop falls due to the diffraction in light coming from the IR LED to the phototransistor. There is a risk of ambient light from the room affecting the readings from the phototransistor. Since light fixtures rarely

emit IR light, we plan to use an IR LED and a phototransistor which only recognizes IR light. This results in minimal noise from other light sources.
Requirements: Must provide 3.3V/5.0V depending on the specifications of the phototransistor and IR LED.

1.2 Drip Chamber

The drip chamber will continue to function the same way as it currently is but now we will just be detecting when a drip occurs. With this information, we will be able to adjust the drip rate and confirm it was adjusted properly.

2. Drip Controller

The drip controller will be used to adjust the rate of flow of the fluid. This will work through a rack and pinion system.

2.1 Servo Motor

The servo motor will be used to adjust the pressure on the roller clamp. By either tightening or loosening the IV tubing, we can increase or decrease the flow rate to the necessary value. The motor will be in a fixed positive to the roller clamp and will change the pressure on the tubing appropriately by turning a threaded rod which will move a plastic component in and out, to put pressure or release pressure on the tube.
Requirements: Must provide 3.3V/5.0V depending on the specifications of the motor

2.2 Force Sensor

The force sensor between the tube and the part that exerts compresses on the tube is necessary in order to determine how much pressure is being exerted on the tube. The amount of pressure on the tube determines the rate of flow and it can be adjusted until it matches the desired pressure.

2.3 Pressure Box

A roller clamp is part of a traditional IV set and is used to control the rate of flow. In our design, we are redesigning the roller clamp. There will be a box made out of delrin, a lightweight and rigid plastic, through which the tube passes through. Inside this box, there will be a moving delrin piece that can be pushed towards or away from the tube. This piece will be riding on a threaded rod which is rotated by the servo motor. The threaded rod will be 16 threads per inch or finer. A single rotation by the servo motor will translate to one-eight of an inch of horizontal movement. This mechanism will be built by the ECE Machine Shop.

3. Statistics

The statistics subsystem will consist of the OLED Display which will be used to display the information about the IV drip such as the flow rate. This screen will be visible so that it can be viewed in-person and without the app. The web app will be used to set the rate of flow and also view data.

3.1. OLED Display

The OLED display will display the current flow rate that the clamp is set to for easy viewing.

3.2 Web App

The web app will be connected to the system through WiFi and will be used to set the rate of flow that the IV needs to be administered at and will also contain information about how much of the fluid has been used and how much is left in the bag. Additionally, the app will notify the user when a bag is almost empty so that they can replace it.

4. Power

The power system will either be a power bank or wall adapter. The amount of voltage needed will be 3.3V or 5V depending on the requirements of the other subcomponents.

5. *Microcontroller*

The microcontroller will be used to ensure that the three subsystems and the WiFi communication module are all working together appropriately. It will also facilitate the data transfer between parts of the subsystems, either through the SPI or PWM interfaces.

Risk Analysis

The programmable flow rate clamping mechanism poses the largest risk in building our final project. It needs to be able to move linearly often without wearing down. Also, it needs to be able to successively communicate with the WiFi module and read incoming information with little delay to prevent the distribution of an improper dosage for too long. In order to tackle this issue, we will be using a responsive WiFi module that will be able to quickly transmit and receive information to be able to communicate with the WiFi module to understand info, and to keep in mind computational complexity when deserializing the WiFi module's output.

Being able to control the flow rate with a certain level of accuracy and precision is very important to the completion of our project. Because it is impossible to get the exact flow rate specified by the motor, we will have a range of acceptable tolerances that will be extremely small that will not take away from the final functionality of our project, but still prove to be acceptable in the real medical world.

IV tubing is made by various manufacturers and requires different amounts of pressure to achieve the same rate of flow. This is caused by differences in tube wall thickness, type of plastic used, tube diameter, etc. No matter the tube material, pushing the tube in by, for example, one-eight of an inch would result in the same rate of flow. Therefore, in order to calculate an accurate rate of flow, not only should we consider the reading from the force sensor, we also need to consider the amount of travel by the plastic part that exerts force on the tube.

Also, changing the amount of pressure applied to the tube can lead to the tube actually getting damaged and becoming permanently deformed. In these cases, the default flow rate will be altered since the tube is now bent. In order to mitigate this issue, we will measure the flow rate which causes tube deformation and specify that our product is useful up until a certain maximum flow rate.

Safety and Ethics

Automating the way IV fluid is delivered to the patient does pose certain, manageable safety hazards. Some of these hazards occur when a battery dies or when a motor fails. When it comes to part failure, we run the risk of creating an unconstrained flow of liquid into a person's body. In instances, when these occur we will have an emergency “shut-off” that will immediately cut-off all distribution of IV fluid, and notify the nurse by sending a push notification through the web app, as well as lighting a certain LED in the OLED panel to physically indicate this. The shutoff will be triggered either when the motor is unresponsive or when the battery dies.

There are times when internet connection at hospitals become unreliable due to geographical location, inclement weather or other unforeseeable issue. In these cases, the nurse can still manually adjust the clamp, as is the current default method.

In terms of ethics, there may be ethical concerns that we, as the developers of this product, may have access to the medical data of patients but we will not be storing any of this data ourselves in order to comply with HIPAA privacy rules and regulations.

References

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