Sentinam
Innovations

School of Engineering Science
Simon Fraser University
Burnaby, British Columbia

October 19, 2015

Andrew Rawicz
School of Engineering Science
Simon Fraser University
Burnaby, British Columbia
V5A 1S6
Re: ENSC 440 Functional Specifications - Remote Monitored IV for Home Care

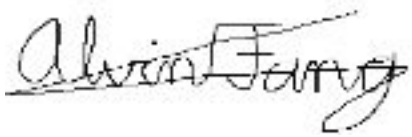
Dear Dr. Rawicz,

Attached is our functional specifications report for a Remote Monitored IV for Home Care, which outlines our detailed functional specifications for our ENSC 440W Capstone Engineering Science Project. We are building a device that allows caregivers to intravenously administer substances to patients with greater control, flexible monitoring capabilities, and user-friendliness.

The function specifications document outlines the functional requirements for the prototype and final version of our project. We describe in detail the features we will develop in our system in each development phase, the components that we use for our system, and the standards and requirements we plan to incorporate into this project. The members of Sentinam Innovations will design the project with the enclosed functional specifications in mind.

We look forward to your review and feedback of our project. If you wish to contact me, please reach me at kpfang@sfu.ca. Thank you for your time and consideration.

Sincerely,



Alvin Fang
Chief Operational Officer
Sentinam Innovations

Enclosed: *Functional Specifications for Remote Monitored IV for Home Care*

Sentinam Innovations

# Functional Specification for a Remote Monitored IV for Home Care

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## Glossary

| | |
|---|---|
| GUI | Abbreviation for Graphic User Interface |
| Infusion pump | A medical device that delivers fluids, such as nutrients and medications into a patient's body in controlled amounts. |
| IV | Abbreviation for intravenous, is the infusion of liquid substances directly into a vein. |
| FDA | Food and Drug Act |
| LCD | Liquid Crystal Display |
| EMI | Electromagnetic interference |
| EMC | Electromagnetic compatibility |
| IEC | International Electrotechnical Commission, international standards organization |
| CSA | Canadian Standards Organaziation, international standards organization. |
| PVC | Polyvinyl Chloride |
| PCB | Printed Circuit Board |
| DEHP | Di(2ethylhexyl) phthalate (DEHP), a plasticizer for PVC |
| Underinfusion | A state in which less fluid/medication is delivered to the patient than intended |
| Overinfusion | A state in which more fluid/medication is delivered to the patient than intended |

## Executive Summary

Intravenous (IV) therapy is the delivery of fluids directly into the bloodstream, through injection into a vein. It is a common practice in hospitals in Canada, and is used to administer saline solutions, antibiotics, or other medication that cannot be taken orally. Blood transfusions are also administered via IV. Infusion pumps are used in IV to regulate the amount of fluids delivered to a patient. Infusion pumps help accurately set the amount of drugs administered to patients, and the rate at which they are delivered.

Many infusion pumps are equipped with safety features, but are expensive and not readily available for usage at home. In addition, safety issues may arise when patients need to use IV over an extended period of time outside the hospital. Therefore, to improve the safety of patients, we want to integrate a mobile app into our system, which will help track the status of the IV system and provide wireless feedback to the medical practitioner, who can then respond immediately.

The prototype for Sentipump is currently being developed, and will contain functional requirements that are marked with I or II in this document. Due to a constraint in time and budget, the highest priority features will be implemented in our prototype. Development of Sentipump will occur in three phases. In the first two phases, the following high priority features will be implemented:

- The system will be able to pump and maintain a steady infusion rate
- The amount and the flow rate will be monitored and controlled from a mobile device

In the final phase, the auxiliary features listed below will be developed:

- The system will be able to monitor the body temperature and the heart rate of the patient
- The system will send an alert to the supervisor when there is a dangerous change in the patient's health status

Our team has done thorough research for this project, and we believe we have come up with a solid product design. Safety and reliability are the two important features

we incorporate into our product design and we are aware of the safety standards required to manufacture a medical device. The finished product will improve upon features of current IV systems, have an affordable price, and include remote monitoring capabilities.

# 1. Introduction

Sentinam Innovation sets out to develop Sentipump, an in-home operated infusion pump system, which medical practitioners can use to remotely supervise and control IV therapy through WiFi. Existing equipment used in IV therapy have issues such as having limited control over the infusion process, high retail price, lack of remote monitoring capabilities, and flexibility to add attachments for improved monitoring. Through our infusion pump design, we seek to improve the effectiveness of IV therapy that caregivers provide, by making infusion pumps more affordable, designing for home usage and control, and allowing medical practitioners to respond to patient health status through remote monitoring. In this document, Sentinam Innovations outlines the functional specifications for both the prototype and final version of the in-home operated infusion pump, which will be labeled with the classification described in 1.3.

## 1.1. Scope

The scope of this document explains in detail the functional specifications that will drive the design for the infusion pump system being developed by Sentinam Innovations. The functionality and requirements of the components that are used in our design are described, namely the infusion pump, microcontroller, sensors, user interface, casing, and other parts used for IV therapy. The functional specifications described will distinguish between features that we plan to include in our prototype from those of the production version.

## 1.2. Intended Audience

This document is intended for members of Sentinam Innovations. Our team will design the in-home operated infusion pump with the functional specifications described

in this document in mind, and will refer to this document in our phases of development to ensure we meet our predefined functional requirements.

## 1.3. Classification

The classification of the functional requirements in our document will be represented in the following form: **[Rn-p]**, where **R** is short for requirement, **n** is the number of the functional requirement, and **p** indicates the version of our product the requirement falls under.

The 3 values defined for **p** are,

I: Prototype version

II: Both prototype and production versions

III: Production version

# 2. Full System Requirements

## 2.1. System Overview

In the system overview model of Sentipump, shown below in Figure 1, the roller clamp is modified to include a peristaltic pump and flow rate sensor. The precise rate can be set by simply entering the desired rate on a mobile device or adjusting the potentiometer on the control unit. Once the flow rate is set, the peristaltic pump will adjust the flow rate slowly, until it reaches the preset value detected by the sensor from

the tube. The system will also ask the user to input the volume of the IV bag in order to generate a completion time at that flow rate. For the purpose of clarity, the drip rate displayed on the system will be in drops per minute (gtt/min), which is the current standard unit for IV drips.

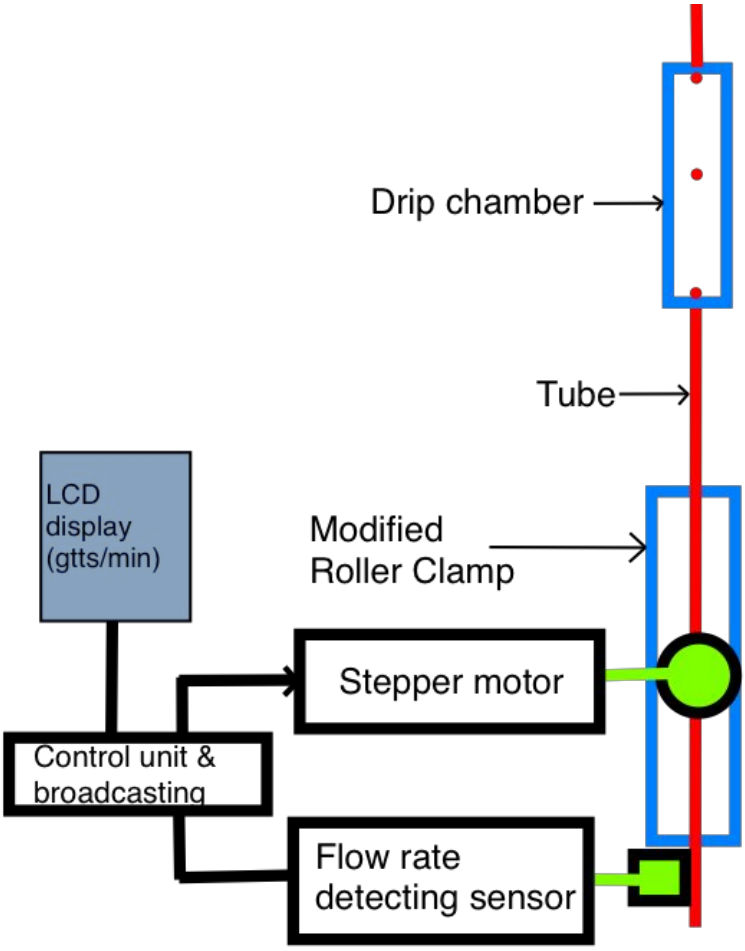


**Figure 1: System overview of the Sentipump.**

The development phases for Sentipump are shown in Figure 2 below.

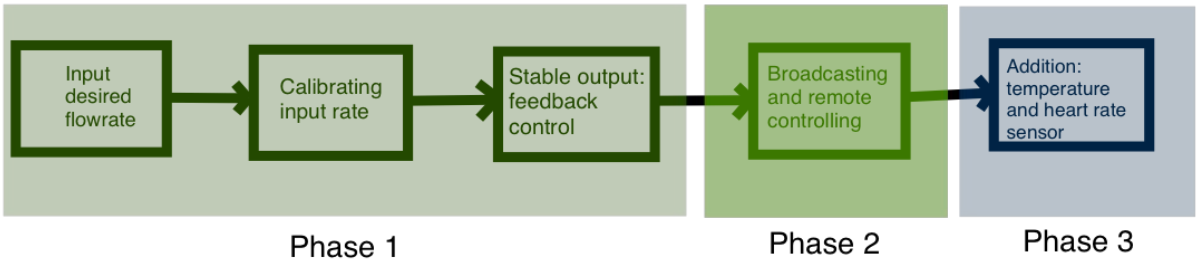


**Figure 2: Development phases for the Sentipump.**

For our prototype, we will be implementing the highest priority functions, due to constraints in time and budget. The constraints are to completely implement the system by the demonstration date in December, and having to build the system with limited amount of funding. Our system will go through 3 phases of development. The main functions will be added in our first 2 phases of development.

**Phase 1**

After completion of this phase, the system will be able to function with the following two main features:

1) The system will be able to operate with a highly accurate rate of flow (gtt/ min aka drop/min).

2) The system will be able to maintain the desired flow rate.

As seen in Figure 1, the user will be able to set the desired flow rate by entering the appropriate value using the keypad on the control unit. The rate of flow at any given time will be displayed on the LCD attached to the control unit. Once the input value is set, the system will maintain the set value until changed manually.

**Phase 2**

In this phase there will be 4 more criteria added to the previous phase:

1) The flow rate will be monitored from a mobile device,

2) The user will be able to change the flow rate via a mobile device,

3) There will be an alert on the mobile device when the IV fluid reaches a level of 5% remaining,

4) The amount(percent and ml) of IV fluid infused to the patient will be displayed**.**

Once a new IV bag is assembled, the system will broadcast the flow rate to the mobile device. The user will be able to monitor and change current flow rate by using their mobile app. For the issue of safety of the patient, the user will have to provide patient ID, medical practitioner ID and password to connect to the system for the first time. After that, the user will be able to instantly access the system until the current IV bag is used up fully. In addition, the user will receive an alert on their mobile device when IV bag is 95% empty. For liability reasons, there will be an activity log where the system will trace all the changes made by the user.

**Phase 3**

In this phase, there will be 2 additional features:

1) Body temperature and heart rate measured by auxiliary devices can be monitored on the LCD as well as on the mobile app,

2) An alert will be sent to the caregiver if there are dangerous changes in the patient's health statistics like spike in body temperature or drop in heart rate.

Two small sensors (a pulse oximeter and a temperature sensor) will be attached to the patient's fingertip and the resulting statistics will be observed on the LCD screen. For the metric standard, the system will use Celsius for body temperature and pulse per minute for the heart rate. In case of an emergency situation like extreme body

temperature or dropping heart rate, both the control unit and the mobile device will trigger an alert until the user responds to the alert.

These phases are the primary system overview and more applications will be added to manually calculate the flow rate. The foundation of our system is a simple closed loop feedback system. As shown below in Fig.5, the IV tubing enters the system, is constricted by the system to change the rate of flow, and then a flowmeter provides feedback on accuracy of the setting. The details of this part of the system are expanded on in Section 3.1: Setting IV Flow rate.

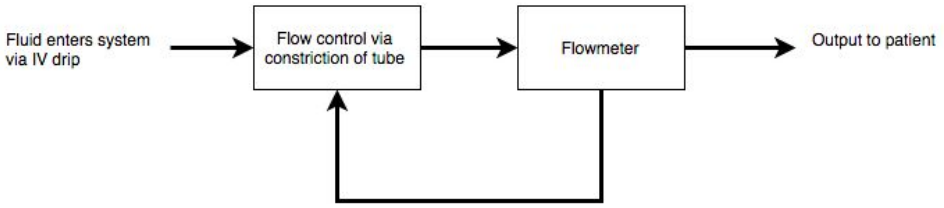


**Figure 3: SImplified overview of infusion pump.**

The proposed system in this section is the primary system overview and more applications will be added during the actual product implementation.

## 2.2. General System Requirements

**[R01-II]** The device shall deliver fluids at a constant rate as set by the user, with high accuracy.

**[R02-II]** The interface shall be simple with a small learning curve for the user.

**[R03-I]** The retail price of the IV system shall be under $500.

**[R04-III]** The sensors, motors and other hardware shall be enclosed in a water-resistant and tamper-resistant case.

**[R05-II]** The device shall be able to communicate via Wifi to the remote mobile app.

**[R06-II]** The system shall comply with and fulfill the requirements of a medical device as stated by FDA.

**[R07-II]** The device shall meet the IEC 60601-1 international standards. [1]

## 2.3. Physical Requirements

**[R08-II]** The device shall accommodate standard IV tubing with an inner diameter in the range of 0.633 - 1.291 mm.

**[R09-III]** The device shall be smaller than the ones available in the hospitals.

**[R10-III]** All the hardware shall be enclosed in a case and there shall be no loose wires.

**[R11-II]** The device shall withstand any mechanical stress like collision and vibration.

**[R12-III]** The device shall be lightweight and portable for easy mobility

## 2.4. Electrical Requirements

**[R13-II]** The device shall use an IEC 60601-1 compliant power supply. [2]

**[R14-II]** The power supply shall work with any power outlet designed according to North American standards.

**[R15-III]** The device shall have a backup battery in case of power outage.

**[R16-III]** The battery shall power the device for at least 4 hours on a full charge.

**[R17-III]** The battery shall have a lifespan of at least 2 years before being replaced.

## 2.5. Mechanical Requirements

**[R18-II]** All adjustable parts, such as valves, will be adjusted automatically by the system according to the user settings.

**[R19-II]** All adjustable parts, such as valves, will be adjusted manually while in error mode.

**[R20-II]** The device shall be unobtrusive.

## 2.6. Environmental Requirements

The Sentipump must be durable, and function correctly in the environmental conditions it may be used in. It must be capable of providing the correct volume, despite changes in temperature or any other typical environmental factors.

**[R21-II]** The device shall operate normally under room temperatures ranging from 0-30°C.

**[R22-II]** The device shall operate normally under typical room humidity conditions.

**[R23-III]** The device shall not malfunction due to EMI and shall be EMC tested under IEC 60601-1-2 standards. [1]

**[R24-II]** The device shall not make any unbearable or annoying noise for the user.

## 2.7. Sustainability Requirements

Wherever possible, the Sentipump should follow cradle-to-cradle design, however, the Sentipump will generate biomedical waste such as IV tubing, catheters,

and needles which cannot be recycled in any way in Canada. The biomedical waste the device generates must be incinerated according to the Environmental Management Act [3]. The plastics used in IV tubing, bags and catheters are also highly regulated and must be made from all new materials. One ingredient in polyvinyl chloride (PVC) plastic tubing, di(2ethylhexyl) phthalate (DEHP) which is used as a plasticizer for PVC, is a known carcinogen, and should be omitted from any tubing used in this project [4].

In the production version of the device, other parts of the Sentipump may be recycled as technical nutrients, such as the plastic casing for the device or the printed circuit boards (PCB). Any PCB parts must be recycled with a licensed disposal company, as the boards may contain heavy metals. Parts like the flowmeter and peristaltic pump should be salvaged for use in other devices (non-medical and non-critical devices) if they are still in good condition. To enable the salvage and sorting of the different materials, the parts should disassemble easily.

**[R25-II]** The IV tubing and IV bag shall not contain the chemical di(2ethylhexyl) phthalate (DEHP).

**[R26-II]** The casing shall be made of recyclable plastic.

**[R27-II]** The device shall be easily disassembled for recycling purposes.

## 2.8. Safety Requirements

**[R28-II]** The device shall not contaminate any fluids delivered to the patient.

**[R29-II]** All electrical and mechanical components of the device shall be encased.

**[R30-II]** The device shall not cause drug overdoses.

**[R31-II]** The infusion pump shall not increase the risk of injury due to extraversion of medication.

**[R32-II]** The electrical components of the device shall not cause interference with any other device.

**[R33-II]** The device shall not be prone to interference from other electrical devices.

**[R34-II]** The device shall not rely on wifi for its core functions.

**[R35-II]** The device shall run a calibration cycle upon startup to ensure that all components are calibrated correctly.

**[R36-II]** The device shall enter into error mode if any components are not working correctly.

**[R37-II]** The error mode shall halt the flow of any fluids and alert the patient's caregiver.

**[R38-II]** In error mode, the device shall be only manually adjustable.

## 2.9. Standards

**[R39-II]** The device shall meet the National Standard of Canada CAN/CSA-ISO 13485:03, Medical devices — Quality management systems — Requirements for regulatory purposes. [1]

**[R40-II]** The device shall meet the hardware safety standard IEC 60601-1.[6]

**[R41-II]** The device shall meet the IEC 60601-2-24 standard for the basic safety and essential performance of infusion pumps and controllers. [1]

**[R42-II]** The device shall meet the ISO-10993 standard for biological evaluation of medical devices. [6]

**[R43-II]** The device shall meet CAN/CSA-C22.2 NO. 60601-1:14 standard for basic safety and essential performance of electromedical devices. [1]

## 2.10. Reliability and Durability

**[R44-II]** The system shall be able to function continuously for four days using a portable power source, when the main power source is disabled

**[R45-II]** The system shall be waterproof and cleanable

**[R46-II]** The user interface shall be able to endure interaction from regular usage

**[R47-II]** The values calculated by the system shall be accurate to within 2 decimal places

**[R48-II]** When the system delivers unreasonable values, it shall alert the caregiver immediately

## 2.11. Performance Requirements

**[R49-II]** The system requires high accuracy (+/- 0.1 mL/min) in IV flow volume control

**[R50-II]** With household wifi connection, the system will be accessed remotely from within a 22m - 33m radius

**[R51-II]** Remote mobile app control response time shall be less than 3 seconds.

**[R52-II]** The system shall be able to sense the body temperature as accurately (+/- 0.1 C) as possible

**[R53-II]** The system shall be able to yield maximum efficiency of ( +/- 3 pulse/min)

**[R54-II]** The system's mobile app shall have minimum complexity level for users to adapt easily.

**[R55-II]** The system's alert triggering component shall be designed to make sure that the users receive and acknowledge the alert properly

**[R56-II]** In case of power outage, the system shall transition smoothly into backup power system

## 2.12. Usability Requirements

**[R57-II]** The user shall be able to set up the system with instructions

**[R58-II]** The user shall be able to operate the equipment in a home

**[R59-II]** The equipment shall have an intuitive interface to control the system

**[R60-II]** The system shall be easily operated by one able-bodied person

**[R61-II]** The system shall be able to function even without WiFi

## 2.13. Additional Functions

**[R62-II]** The infusion pump shall support easy attachment of body temperature and heart rate sensors

**[R63-II]** The infusion pump shall provide drug concentration calculations

# 3. Individual Component Requirements

## 3.1. IV Pump Requirements

The pump's primary purpose is to provide an adjustable pressure, so that the pump does not need to rely on gravity. Gravity fed pumps are unreliable, because if there is any resistance added to the system, a gravity fed system would not be able to increase the pressure and would cause under-infusion of the drug [7]. The pump should have a small flow rate, to ensure accurate infusions, and current IV infusion pump flow rates are typically between 1mL and 1000mL per hour [7], or 16µL per minute to 16mL per minute. If the pump has good resolution, small volumes can be infused in increments rather than continuously, which can lower the flow rate. Any non-disposable parts of the pump must not come into contact with the solutions delivered to patients, as it is not feasible to sanitize a pump. The pump's signal response is also important, as too high an overshoot could result in over-infusion of the drug.

### 3.1.1 General Requirements

**[R64-II]** The pump shall pump fluid at a rate of 16µL to 16mL per minute.

### 3.1.2. Physical Requirements

**[R65-II]** The pump shall accommodate the standard size tubing of an IV drip.

**[R66-II]** The pump shall be completely encased.

### 3.1.2 Electrical Requirements

**[R67-II]** The pump shall use less than 50mA of current.

**[R68-II]** The pump's motor shall have a resolution of 5° degrees or less.

**[R69-II]** The pump shall have a rapid settling time.

### 3.1.4. Reliability Requirements

**[R70-II]** The pump shall work for at least 2 years.

### 3.1.3 Safety Requirements

**[R71-II]** The pump shall not contaminated the fluids delivered to the patient.

**[R72-II]** The pump shall not have a large overshoot in its response.

## 3.2. Microcontroller Requirements

In this design, a microcontroller plays the most important role of acquiring inputs and yielding the most efficient output. Since the Arduino Uno I/O pins can only allow a maximum current of 20 mA , it is necessary to add a motor shield to operate the peristaltic pump which consumes more than the allowable current limit. To channel the remote connection between control unit and mobile device , it is required to add a wifi shield which will allow the Arduino Uno board to access a WiFi network via a household wireless router. Both the motor and WiFi shields' working voltages have to be in the 6V-12V range because that is the range of power that the Arduino board can provide.

### 3.2.1. General Requirements

**[R73-II]** The microcontroller needs software configuration to match with sensors and motor attachment as well as proper functioning and synchronization of the whole system.

**[R74-II]** The system requires an Arduino motor shield to link with the peristaltic pump and Arduino Uno controller board.

**[R75-II]** The controller shall be encased in a protected waterproof case.

**[R76-II]** The system requires Arduino WiFi shield to channel between the mobile device and the controller.

### 3.2.2. Electrical Requirements

**[R77-II]** The controller requires AC to DC adapter with working voltages from 6V to 12 V.

**[R78-II]** In case of backup battery use, the controller will need a voltage of 12V, either single or a combination of batteries.

**[R79-II]** Maximum allowable DC current per I/O pin is 20 mA.

**[R80-II]** Maximum allowable DC current for power pin is 50 mA.

## 3.3. Sensor Requirements

We plan to utilize flowmeter, body temperature, and pulse rate sensors in Sentipump. The sensors will be connected to an Arduino Uno on one end. On the other end, the flowmeter will be attached to IV tubes, and the body temperature and pulse rate sensors will be attached to a patient's fingers. Since the sensors are used to measure the health status of a patient, they will need to be very accurate to deliver reliable results. Each sensor we use has power specifications given in the subsections below.

### 3.3.1 General Requirements

**[R81-II]** All the sensors shall have an electronic output compatible with the Arduino Uno

**[R82-II]** The flowmeter shall detect flow rates above 2.5 mL/minute

**[R83-II]** The body temperature shall be able to detect maximum deviation of +/- 0.1 C

**[R84-II]** The pulse rate sensor's deviation should be less than +/- 3 pulse/min

### 3.3.2. Physical Requirements

**[R85-II]** Flowmeter has to attach to the IV tubing

**[R86-II]** Body temperature and pulse rate sensors shall be flexible to attach to the patient's fingertips

### 3.3.3. Electrical Requirements

**[R87-II]** All the sensors shall work properly in both 50 and 60 Hz frequency levels.

**[R88-II]** Body temperature sensor will require 4V-12V working voltage and the maximum current will be 0.01mA

**[R89-II]** Flowmeter will require a 5V power supply and a maximum current of 10mA

**[R90-II]** Pulse rate sensor will require a 5V power supply and a maximum current of 4mA

## 3.4. User Interface Requirements

Users will be able to control the device with the help of a LCD and a keypad. The LCD will display necessary patient statistics, and the keypad will be used to change required settings by doctors, nurses or caregivers.

### 3.4.1 General Requirements

**[R91-II]** The system will be usable by one person

**[R92-II]** The system will be easy and intuitive to use

**[R93-II]** The system will have a minimalistic design intended for quick use, primarily with the help of buttons and dials

**[R94-II]** The system will use a seven segment display LCD (Liquid Crystal Display)

**[R95-II]** The LCD should clearly display the units required, in order to avoid confusion

### 3.4.2. Physical Requirements

**[R96-II]** There will be 2 buttons to scroll menu options

**[R97-II]** There will be a select button that allows setting of values, and choosing of menu options

**[R98-II]** There will be a dial that can be rotated, to choose from, and set the required numeric values

**[R99-II]** The buttons would be adequately spaced in order to prevent accidental button presses

**[R100-II]** The size of the display will be less than 5 in. X 4 in.

**[R101-II]** There will be a switch on the side acting as a lock, which will prevent unintended changes to the IV requirements

**[R102-II]** There will be a switch to turn off the pump, in case of emergency

### 3.4.3. Electrical Requirement

**[R103-II]** The LCD and the keypad shall be powered by the Arduino board

**[R104-II]** The operational voltage of the display and keypad shall be within a range of 5V - 12V, and the operational current shall be less than 20 mA

**[R105-II]** For backup purposes, the display could also be powered by using rechargeable batteries in the Arduino board

## 3.5. Casing Requirements

The basic purpose of the case is to enclose all the necessary hardware of the device. It needs to be sturdy and robust and has to be manufactured from recyclable materials to account for the environmental requirements. The case will have a power switch and a usb connection port at the back. The requirements in the following subsections provide more detailed information regarding the case.

### 3.5.1 General Requirements

**[R106-III]** The casing shall be water resistant and dust resistant.

**[R107-III]** The casing shall be robust and rigid to withstand any mechanical stress.

**[R108-III]** The case shall hold all the components in their place so they do not interfere with each other.

### 3.5.2. Physical Requirements

**[R109-III]** The casing shall enclose all the hardware and other parts and at the same time not be too bulky.

**[R110-III]**The casing shall be designed keeping in mind the repairing and replacement of all the components inside.

### 3.5.3. Electrical Requirements

**[R111-II]** The case shall be electrically neutral so as not to pose any threat to its user.

**[R112-II]** The casing shall be an insulator so that it does not interfere with the electronics of the device.

## 3.6. IV Bag Requirements

The IV bag is a sealed plastic bag that has an attachment for tubing and a hanger so it can be placed on a holder. It will store the fluid that needs to be infused intravenously into the patient's body. It will be connected to the tubing to deliver intravenous fluids, so the dimensions must be compatible with the tubing.

### 3.6.1 General Requirements

**[R113-II]** The bag will not be susceptible to leaks and tears

**[R114-II]** The bag will be easy to clip onto the stand and connect to the tubes

### 3.6.2. Physical Requirements

**[R115-II]** The IV bag shall be made up of a material that is flexible, reliable and durable, like PVC or copolyester ether

## 3.7. Tubing Requirements

The tubing connects the infusion pump to the IV bag, so its dimensions must be compatible with the IV bag. Intravenous fluids are infused through the tubing.

### 3.7.1 General Requirements

**[R116-II]** The tube should be able to be cleaned easily using water and soap

**[R117-II]** The tube should be easy to disconnect in case of malfunction of equipment

**[R118-II]** The tube should be able to function well in normal room temperature (0 degrees to 30 degrees celsius)

**[R119-II]** The tube shall be easy to set up and connect with the other components

**[R120-II]** The material of the tube shall be strong and flexible.

### 3.7.2. Physical Requirements

**[R121-II]** The size of the tube shall be compatible with the pump

**[R122-II]** The tube should be made of non-corrosive and rust-free material

**[R123-II]** The tube shall be strong enough to bear the stress of the rollers of the peristaltic pump.

## 3.8. Software Application Requirements

We plan to allow monitoring of the patient and infusion status remotely, by communicating to our WiFi attachment through smart phone and/or desktop apps. The primary data we want the app to display includes infusion duration, infusion rate, delivery volume, dosage concentration, patient and practitioner ID, and data from attachments such as body temperature and heart rate. When values reach the provided thresholds, the practitioner can be warned about it immediately. The figure below shows a conceptual drawing of the application's user interface on a mobile device.

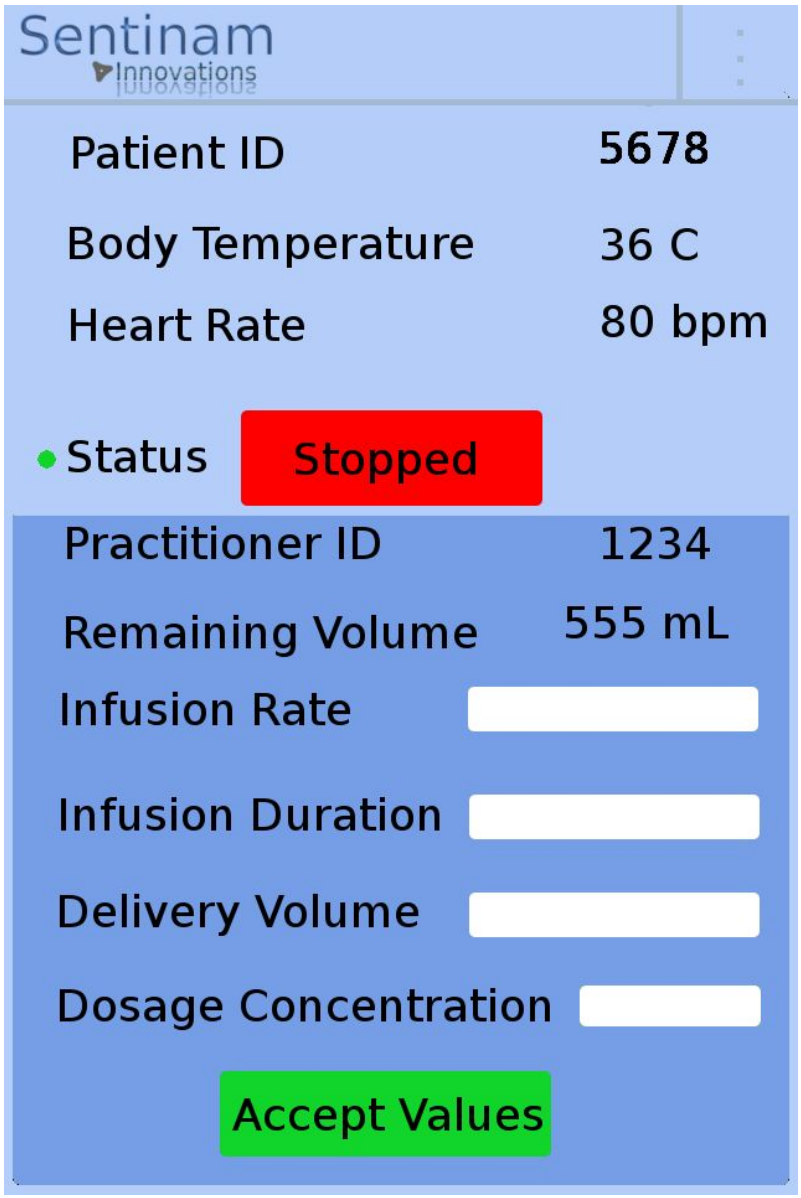


**Figure 4: Conceptual drawing of the application's user interface.**

### 3.8.1 General Requirements

**[R124-II]** The interface will provide information for practitioners to monitor a patient's health status

**[R125-II]** The interface will provide a button for practitioners confirm values to control the infusion process

**[R126-II]** The colour and style design of the interface will be intuitive

**[R127-II]** An alarm will sound when the health status of the patient reaches a threshold value

**[R128-II]** There will be a button to start and stop the infusion process

**[R129-II]** There will be a settings page to change the alarm threshold value, alarm sound

**[R130-II]** There will be a login page to enter patient and practitioner ID, to prevent unauthorized access

**[R131-II]** Internet connection will be required to access the application

# 4. User Document Requirements

**[R132-II]** The User Document will provide users of our product with information to use the system effectively as intended.

**[R133-II]** The document should provide detailed explanations on how to use each component of the system, and contain charts and images as necessary to clearly educate the reader on how to use the system

**[R134-II]** The document will be provided in English

**[R135-II]** The document will provide detailed installation instructions

# 5. Conclusion

This document presents the functional specifications of Sentipump, a remote monitored IV infusion pump, intended for home care use. The Sentipump is designed to improve upon existing IV infusion pumps. We intend to attain this objective by making our product smaller and more portable than other products, and available at a lower retail price than infusion pumps designed by other manufacturers. In addition, the remote monitoring aspect of our design will make it extremely convenient for doctors, nurses, and at home caregivers to keep a track of the patient's blood pressure, heart rate and rate of infusion of the IV fluid.

The system's core functionality, performance requirements, reliability and durability, and adherence to necessary safety and environmental standards have been outlined in this document. The requirements mentioned are tentative, and are subject to to changes and improvements during the course of completion of this project.

Development of our project will occur in three phases. In the first two phases, the main features will be implemented for Sentipump, and in the final phase, auxiliary features will be developed. The main features are being able to pump and maintain a steady infusion rate and monitor and control the infusion rate from a mobile device. The auxiliary features are to support more sensor types and remotely alert the caregiver of any dangerous changes in the patient's health status. The prototype for Sentipump is currently being developed, taking into account our constraint in time and budget, and will contain the highest priority features and functional requirements that are marked with I or II in this document.

Ensuring that the system delivers an accurate infusion rate is the highest priority. The system will be put through various stages of design and development, and a rigorous testing phase to ensure it operates safely and reliably. We are confident that our product, with its special features and monitoring capability, will stand out among other competitors.

# References


[1] FDA, (2014, Dec 2), Infusion Pumps Total Product Life Cycle [Online].

Available:http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm209337.pdf

[2] Dr. A. Turnbull, (2007, Sep 12), Medical Eco Design [Online]. Available:http://www.medical-ecodesign.com/files/Use%20of%20IEC%2060601%20in%20supporting%20medical%20device%20approval.pdf

[3] Government of British Columbia (2015). Hazardous Waste: Legislation and Regulation [Online]. Available: http://www2.gov.bc.ca/gov/content/environment/waste-management/hazardous-waste/legislation-regulations

[4] B. Eckle. (2012, April 24). GreenHealth Magazine [Online]. Available: http://greenhealthmagazine.org/do-no-harm/

[5] Health Canada, (2015, Sep 11), List of Recognized standards for medical standards [Online].

Available:http://www.hc-sc.gc.ca/dhp-mps/md-im/standards-normes/md_rec_stand_im_norm_lst-eng.php

[6] J.B. Polin, (2002, April 18), *Alternatives to PVC for IV Bags* [Online]. Available: http://www.pmpnews.com/article/alternatives-pvc-iv-bags

[7] C. Quinn. "Intravenous flow control and infusion devices," in *Intravenous Therapy in Nursing Practice* (2nd ed.), L. Dougherty and J. Lamb, Eds. 2009.

## Appendix A.

## Proposal Revision 1.2


# Project Proposal for a

# Remote Monitored IV for Home Care

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**Issue Date:** September 28, 2015

**Revision:** 1.2

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## Executive Summary

Infusion pumps are used in Intravenous therapy (IV) to regulate the amount of fluids delivered to a patient. Infusion pumps help accurately setting the amount of drugs administered to patients, and the rate at which they are delivered. There are a number of electronic infusion pumps available in the market. While some infusion pumps are equipped with many safety features, they tend to be expensive and are not readily available for at home usage. In addition, safety issues may arise when patients need to use IV over an extended period of time outside the hospital. To address the issues of existing IV systems, Sentinam Innovations is committed to developing an in-home operated IV system that can be supervised by medical practitioners remotely through WiFi.

Existing IV systems have reliability issues, such as not being able to maintain preset values. This can occur due to a number of factors, such as change in the patient's arm position, difference in viscosity of two infused fluids, or the infusion of the wrong drugs at wrong rate. If this happens, the patient needs immediate attention to correct the issue, and this help will not be readily available for patients using an IV at home. This is why we want to integrate a mobile app into our system, which will help track the status of the IV system and provide wireless feedback to the medical practitioner, who can then respond immediately.

Our team has done thorough research for this project, and we believe we have come up with a solid product design. Safety and reliability are the two important features we incorporate into our product design and we are aware of the safety standards required to manufacture a medical device. Our team proposes to design and build the IV system and mobile app with great reliability and effective testing. The finished product will improve on features of current IV systems, have an affordable price, and include remote monitoring capabilities.

Sentinam Innovations (SI) consists of five versatile Engineering Science students with in-depth knowledge of circuit design, microfabrication, 3D modelling, microfluidics, real-time software development, and microcontroller programming. With our knowledge

and skill set, we aim to complete the project within the specified period of time. The project will cost approximately $500, which we hope to cover with different funding sources.

# 1. Introduction

Intravenous therapy (IV) is the delivery of fluids directly into the bloodstream, through injection into a vein. It is a common practice in hospitals in Canada, and is used to administer saline, antibiotics, or other medication that cannot be taken orally. Blood transfusions are also administered via IV. [1]

At home use of IV therapy is most common for patients that have chronic infections. Home use of IV's for chronic infections was first advocated in the 1970's, when Ruckter and Harrison [2] showed that home use of intravenous antibiotics successfully and safely treated chronic bronchopulmonary infection in children with cystic fibrosis. Approximately 95% of at home use of IV's is for antibiotics for people with chronic infections.[1] Home use of an IV is particularly appropriate for patient's with chronic infections or chronic conditions because these patients would otherwise undergo long hospital stays to complete their run of intravenous medicine. Some patients need up to 6 weeks of intravenous antibiotic therapy to clear their infection [3]. Patients that live in rural areas, and bedridden patients also benefit from home IV therapy, as the trip to the hospital would be a hardship [[3].

To use an IV, a health-care provider inserts a needle with an attached catheter into a vein, then the needle is removed leaving the catheter tapped into the patient's vein. Tubing is then connected to the catheter, which connects the patient to the rest of the IV drip system. The IV drip system works by suspending a bag or bottle of fluid on an IV stand. The fluid flows down the tubing because of gravity, with the rate of flow controlled by roller clamps. These roller clamps constrict the tube, which allows the rate of flow to be manipulated. If there are multiple solutions to be administered to the patient, then the solutions meet at a Y-connect just before the drip chamber. This is the air filter, which allows trapped air to escape from the tubing. There the solutions mix via diffusion, and then travel through the drip chamber, which serves as another safety feature to protect the patient from air bubbles entering their system. Nurses also use the rate of drips in the drip chamber to manually calculate the flow rate. After the drip

chamber, the fluids may flow into the patient via the catheter previously inserted into a vein.

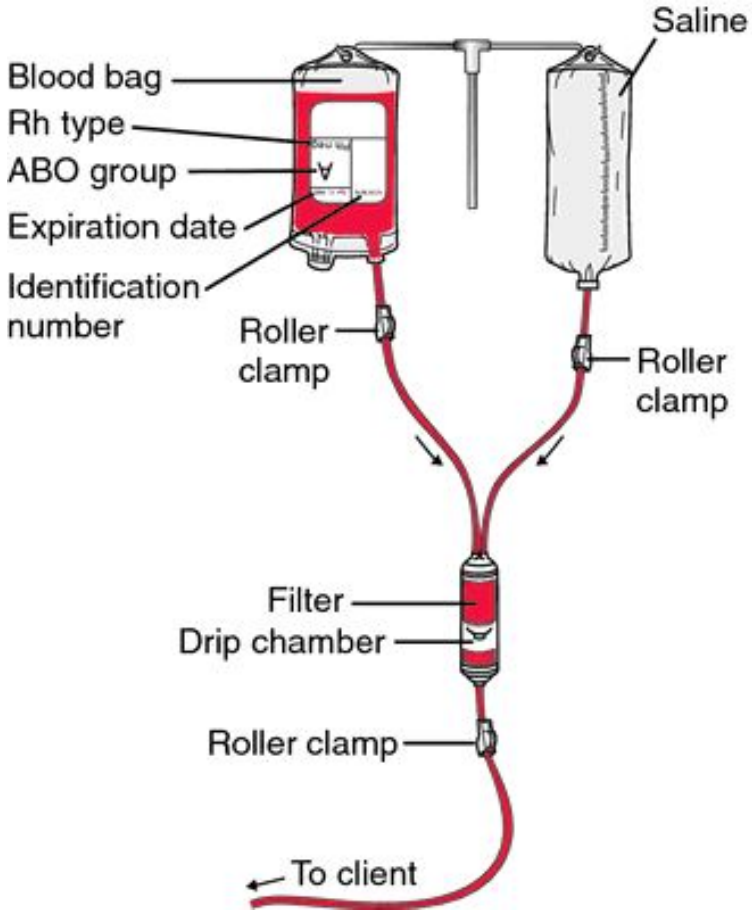


**Figure 1: IV drip system with Y connector. [4]**

The *Figure 1* above shows the two different solutions mixing at the air filter, however, medication may also be infused into the saline bag directly. This is shown in *Figure 2* below. The drug is added to the saline solution and allowed to diffuse through the solution.

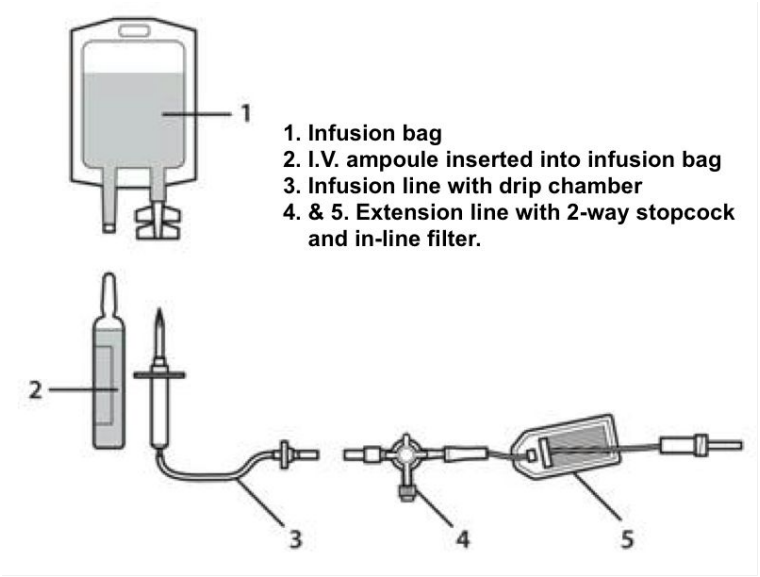


**Figure 2: Direct Infusion into saline bag. Image modified from source.** [5]

The IV drip may be manually calculated by a health-care provider or controlled using an infusion pump. An infusion pump is a device that controls the delivery of fluids; it can control the flow rate, the time over which to deliver the drug, and the volume of the drug.[6]

There are several types of infusion pump for an IV drip. A syringe pump controls the flow rate of a drug into the patient by controlling the depression of the syringe plunger [4]. The syringe pump uses a small motor to depress the syringe plunger at the set rate [7]. An example of this pump is shown below in *Figure 3.*

**Figure 3: Syringe pump and motor. [8]**

A gravity control infusion pump controls flow by electronically restricting the tubing [7]. Gravity feeds the system, as in the original IV drip system, except the roller clamps in the IV drip system are replaced with electronically controlled clamps. This allows the flow rate to be set more accurately and with less user error [7]. Because of their simple design, gravity infusion pumps are significantly cheaper than other options on the market. Gravity infusion pumps are, however, prone to under-infusion if there is resistance to flow in the system, which may be caused by kinks in the tubing or other issues[7].

A volumetric infusion pump may be used for a large volume IV drip, and tend to deliver fluids at a medium to high flow rate. The volumetric infusion pump can also be used at slow, precise flow rates [7], [9]. Current volumetric infusion pumps can be set between 1mL and 1000mL per hour [7]. Peristaltic pumps are commonly used in volumetric pumps, and pump fluid by using rollers to pinch the tube and rotating [9]. An example of a peristaltic pump is shown below.

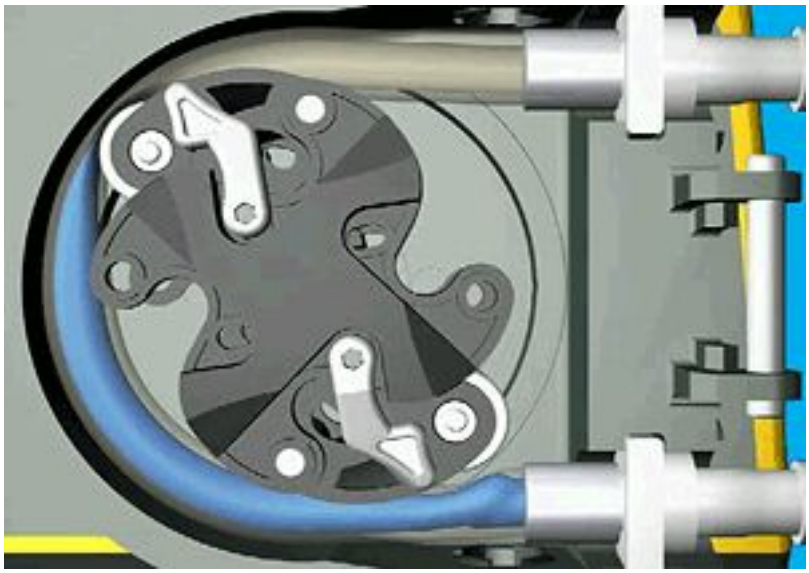

**Figure 4: A peristaltic pump. [10]**

In this project, we endeavor to build a volumetric infusion pump that controls the flow of several fluids via a peristaltic pump. “Smart” features such as flow rate monitoring, delay timing and remote monitoring will make the device simple for at home use. The remote monitoring application will allow caregivers and health-care professional to view the status of the patient’s IV therapy on a cell phone or computer. In the app, the health-care professional may adjust the controls if needed, and the app will push alerts to the caregiver when the IV is finished.

# 2. System Overview

These phases are the primary system overview and more applications will be added to manually calculate the flow rate The foundation of our system is a simple closed loop feedback system. As shown below in *Figure 5*, the IV tubing enters the system, is constricted by the system to change the rate of flow, and then a flowmeter provides feedback on accuracy of the setting. The details of this part of the system are expanded on in Section 2.1: Setting IV Flow rate.

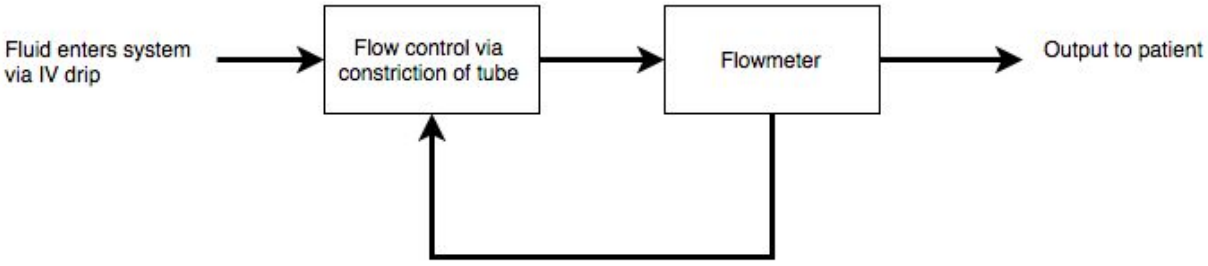


**Figure 5: SImplified overview of infusion pump system.**

The proposed system in this section is the primary system overview and more applications will be added during the actual product implementation.

## 2.1 Setting IV flow rate

In an IV drip system, a healthcare provider can adjust the infusion rate by adjusting the roller clamp up or down and observing the rate of drips in the drip chamber. The infusion rate is calculated by counting the number of drips that occur in a time interval. Even if the calculated infusion rates are close enough to the desired values when set, the real infusion rate may be influenced by changes in the patient's arm position or blood viscosity. Continuous care and continuous monitoring from an infusion pump can eliminate these issues. Some of the drugs administered by IV must be infused at a very precise rate that only an infusion pump can accomplish, or the patient may be at risk.

In this model, shown below in Fig.6, the roller clamp is replaced with a peristaltic pump (or potentially another type of positive displacement pump) and a flow rate sensor. The precise rate can be set by simply entering the desired rate on a mobile device or adjusting the potentiometer on the control unit. Once the flow rate is set, the pump will pump the fluid, until it reaches the preset flow rate value detected by the sensor from the tube. The system will also ask the user to input the volume of the IV bag in order to determine completion time at that flow rate. For clarity to healthcare providers, the drip rate displayed on the system will be in drops per minute (gtt/min), which is the current standard unit for IV drips.

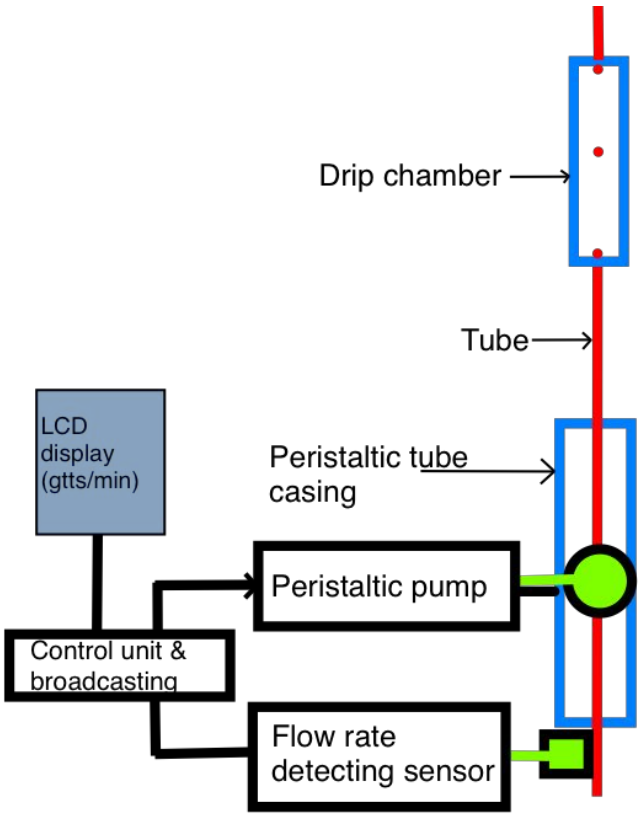


**Figure 6: System overview.**

In our design, we will try to address 3 main objectives. The flow process chart shown below in *Figure 7* illustrates how these directives would work in our system.

1. To get a more precise rate of flow that the patient needs. The rate & duration of a IV bag can easily be observed, both on the 7-segment display and also on a mobile device.

2. To continuously maintain a stable rate of flow is set by using feedback control system until the operator changes it to another value.

3. To be able to perform changes in rate of flow remotely on the practitioner's mobile device, through an active Internet connection.

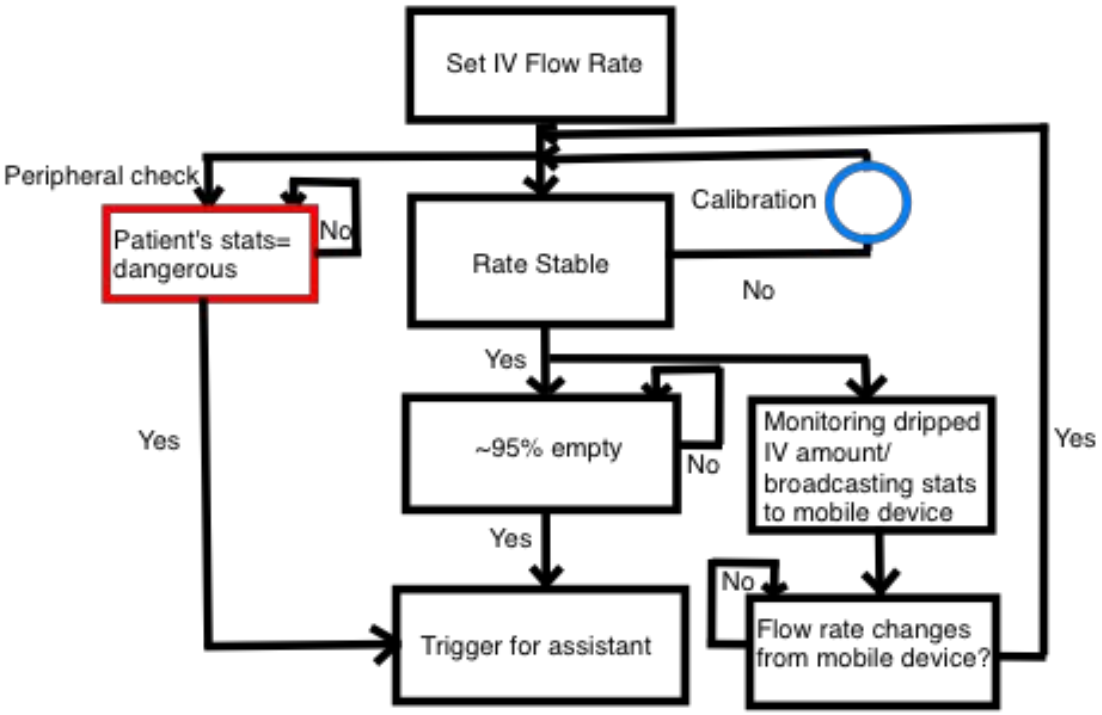


**Figure 7: Process flow chart.**

Basic patient statistics like body temperature, heart rate and IV flow rate will be transmitted through WiFi. The most recent statistics can be obtained on the mobile device by opening the app, which will be implemented as a real-time system. In case of an emergency, like a rise in body temperature or a drop in heart rate, an alert will be triggered on both the control unit and the mobile device.

For the safety of the patient, mobile device control app will be needed to provide information like product serial number, password, practitioner name and license number.

All the information and flow rate changes made by the person will be recorded in the controlunit.

2.2 Control Unit & Broadcasting

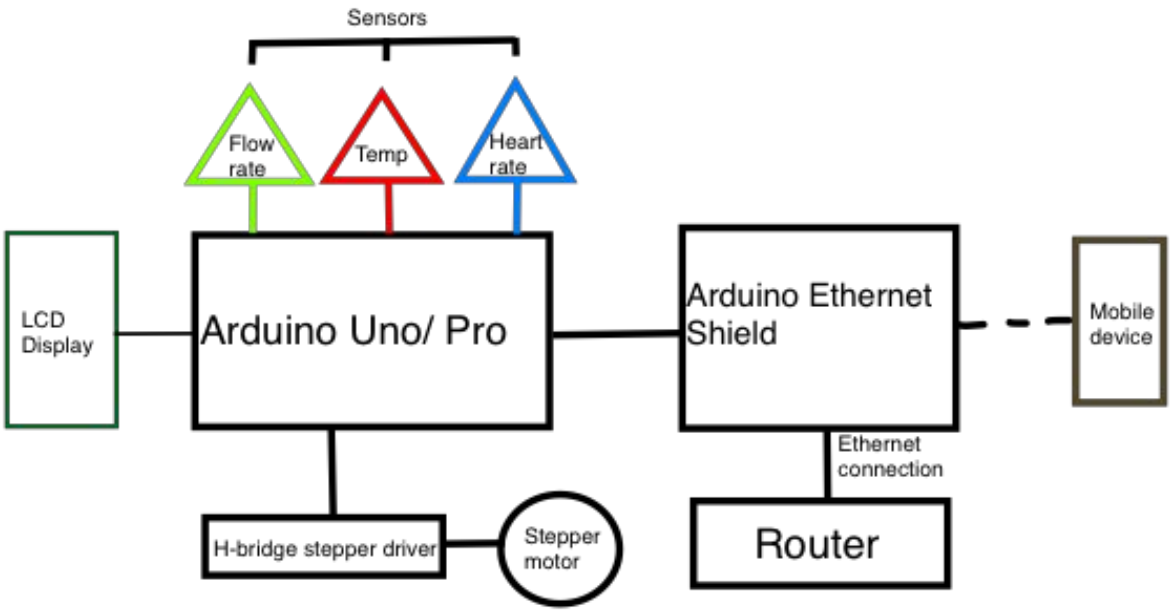


**Figure 8: Breakdown view of the control unit.**

The control unit will be implemented using either Arduino Uno or Arduino Pro depending on the power consumption of the peristaltic motor. There are 3 major reasons that an Arduino board has been chosen for this product implementation: it is cost effective, provides high precision for the peristaltic motor, and yields high efficiency with the sensors. Compared to the other controller boards, Arduino is the most cost effective. The availability of reference materials is also abundant. Since Arduino I/O pins can provide very precise output voltage, calibrating with peristaltic pump and flow rate sensor can be expected to yield desired outcome. In addition, an Arduino board is eco-friendly because the operating voltage of the board is 3.3V - 5 V.

Since Arduino board can only handle 50 mA, an H-bridge stepper driver will be used to link the peristaltic pump and the Arduino board. The peristaltic pump will synchronize with the flow rate detector, and for a new IV bag, it will start with flow rate equal to zero. Then the peristaltic pump will slowly increase the flow rate in the IV tube until it reaches the preset value, which is detected by the flow rate sensor. The system will maintain the preset rate until the operator changes it to a different value.

For temperature detecting, LMT70 will be used, because it not only provides a high accuracy of +/- 0.1C compared to other sensors but also claims to have the least error or malfunction. It is also easily wearable under a patient's finger, and works well with an Arduino board. A pulse sensor manufactured by Pulse Fun Electronics, which is

one of the most reliable components available in the market, will monitor the patient's heart rate. It can also easily be worn under the fingertips of the patient. These two sensors will directly connect to the Arduino board and the board will be implemented to generate the metric values, which can be seen on the LCD.

For broadcasting patient stats, Arduino Ethernet Shield will be used which allows the board to have access to the Internet. To implement this, a router with an active Internet line will be needed. The Ethernet Shield will allow the board to communicate with a mobile device. The board will update the mobile device whenever there is a change in the patient's statistics. In case of an emergency, the board will trigger emergency sounds and an alert message to the mobile device. To avoid conflicting change in flow rate, the control unit will be designed to have a higher priority than the mobile device. This means that in case of simultaneous changes from the control unit and the mobile device, the system will accept the value from the control unit.

## 2.3 Implement Remote Monitoring

We plan to allow monitoring of the patient and infusion status remotely, by communicating to our WiFi attachment through smart phone and/or desktop apps. The primary data we want the app to display include infusion duration, infusion rate, delivery volume, dosage concentration, patient and practitioner ID, and data from attachments such as body temperature and heart rate. When values reach provided thresholds, the practitioner can be warned about it immediately. *Figure 9* shows a conceptual drawing of the application's user interface on a mobile device.

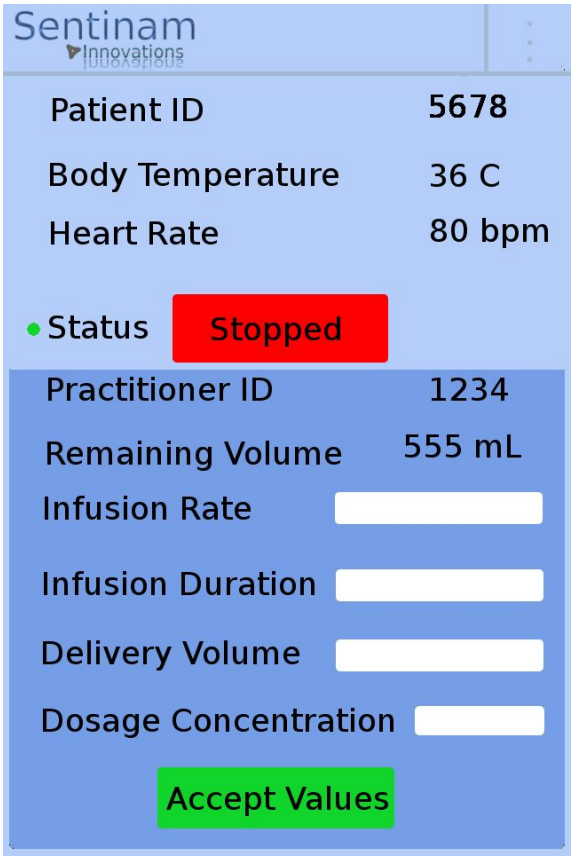


**Figure 9: Conceptual drawing of the app UI.**

# 3. Safety Standards

An IV infusion pump is a non-invasive device intended to channel fluids into the body. As such, the infusion pump is subject to Rule 5 of the Medical Devices Regulations, in the Food and Drug Act. This rule states that “A non-invasive device intended for channelling ... liquids, ... or body fluids for the purpose of introduction into the body by means of infusion ... is classified as Class II.” [11] However, since the infusion pump that we endeavour to build is an active device that includes drug delivery on closed loop system, the Infusion pump is also subject to rule 11 subrules 1 to 3 [11]. There is a potential for hazard in the substances used in this device; overdose of medication can cause serious injury, as such rule 11 subrule 2 is met. As the system is a closed loop system, the rule 11 subrule 3 applies, and the infusion pump is classified as a Class IV medical device. Rule 11 is quoted in full below, for the reader’s reference.

Rule 11:

1. Subject to subrules (2) and (3), an active device, including any dedicated software, intended to administer drugs, body fluids or other substances to the body or withdraw them from the body is classified as Class II.

2. If the administration or withdrawal by a device described in subrule (1) is potentially hazardous, taking into account the nature of the administration or withdrawal, the nature of the substance involved and the part of the body concerned, the device is classified as Class III.

3. A device described in subrule (2) that is intended to control the treatment of a patient's condition through a closed loop system is classified as Class IV.

-*Medical Devices Regulations*, Food and Drug Act. [11]

A Class IV medical device is subject to strict regulations. To obtain a Medical Device License for a Class IV medical device, the Food and Drug Act requires preclinical and clinical studies, process validation studies, software validation studies, and literature

studies to verify that the device meets the standards of safety and effectiveness (among other requirements).

# 4. Existing Solutions

There are a number of other products in the market that can provide infusion control for IV therapy. However, most, if not all of them, have issues that we plan to address with our product. Issues include having limited control over the infusion process, being expensive, and lacking remote monitoring capabilities and flexibility to add attachments for improved monitoring.

## 4.1 Gravity Drip Infusion

This method of infusion provides limited control over the infusion rate, because gravity drip rates are not accurate and precise, and a caregiver would be needed to count the patient's IV, leading to higher risk of human error. As a result, for patient safety and to improve the productivity of a caregiver, this solution cannot be used when precise infusion rates are required. [12]

## 4.2 Electronic Infusion Pump

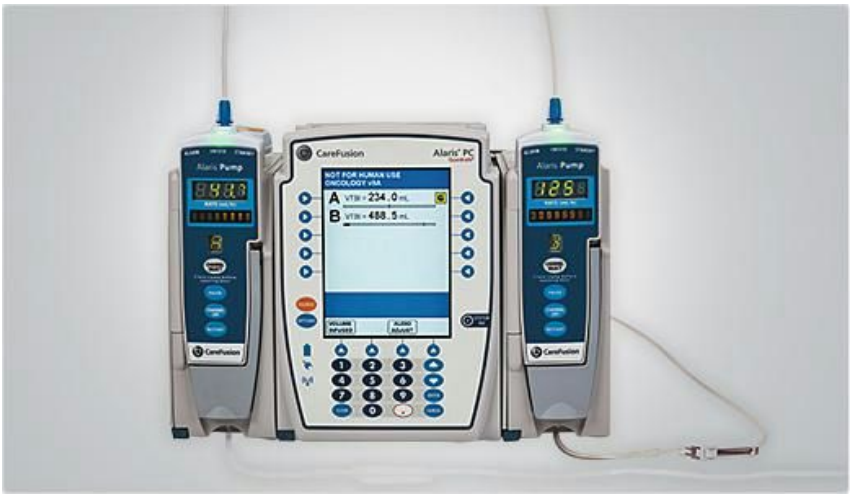


**Figure 10: Electronic infusion pump. [13]**

Infusion pumps provide control over infusion rate, dosage concentration, and delivery volume. However, existing options tend to very expensive, costing up to thousands of dollars. In addition, most existing solutions do not offer remote monitoring capabilities, and the flexibility to add attachments, to monitor the well-being of a patient with greater accuracy.[7]

# 5. Budget and Funding

## 5.1 Budget

The table below summarizes the projected costs in developing our product. This initial cost is a rough estimate since prices for some of the equipment are not displayed. Instead, prices of similar equipment are used to get an idea of the total initial cost. It is possible that the cost might increase as we go along.

**Table 1: Proposed budget**

| Equipment | Estimated Cost |
|---|---|
| IV bags | $5 |
| IV tubing kit | $50 |
| Several valves | $20 |
| Flowmeter | $60 |
| Arduino | $60 |
| Mini LCD screen | $50 |
| Keypad | $30 |
| Casing for arduino and monitor | $25 |
| Temperature sensor | $15 |
| Pulse oximeter | $45 |
| Arduino wifi shield | $100 |
| Shipping and overhead costs | $50 |
| Total | $550 |

## 5.2 Funding

We plan to seek funding through the Wighton Fund, and may also talk to potential sponsors. In case of insufficient funding, our team members are ready to fund the project with equal share.

# 6. Schedule

The Gantt chart displayed below shows an ideal estimation of the time it will take us to reach the completion of this project. It is subject to change on the basis of various factors, such as availability of parts, coordination of individual team member schedules, and results of prototype testing. The chart will help us stay on track and compare our progress with the ideal timeline. We have allotted ample time for the research aspect of our project to allow for constant optimization of our idea and our prototype. Our aim is to start developing our prototype at the beginning of November, which will provide us with plenty of time to test the product and make our final modifications and improvements before our demonstration date. We plan on documenting all our meetings throughout the semester to keep a written record of all ideas and issues addressed during these meetings.

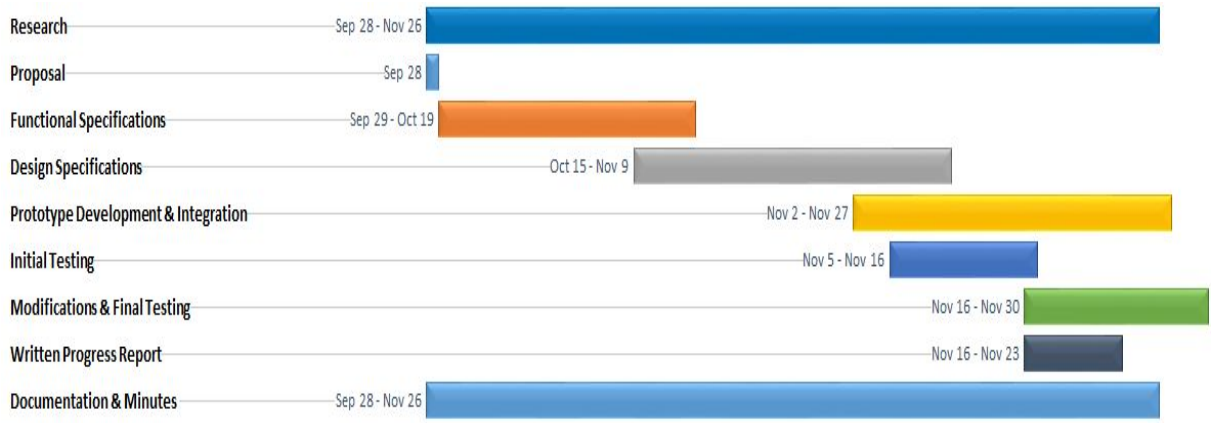


**Figure 11: Product development Gantt chart.**


**Figure 12: Key project milestones.**

# 7. Team Organization

Sentinam Innovations is composed of 5 dedicated and resourceful SFU engineering students. The team's diverse range of backgrounds enables us to tackle various technical development issues effectively. Each member of SI has a unique set of skills. Hence, to maximize efficiency, tasks are assigned based on the team members' professional experience and areas of interest.

As CEO, Chelsey Currie is the director and executive decision maker, and will see through the project from start to completion, tackling all obstacles along the way. With her background in medical devices, Chelsey will be responsible for the overall design and safety compliance of the product.

Alvin Fang will be taking on the role of COO. He will be working closely with the other members of the team, ensuring the team meets all necessary deadlines and also communicating our progress to the professors and teaching assistants. He will also be helping with the software aspect of the product and the development of the remote monitoring app due to his prior experience with software development.

Nyann Moe is the CTO and will be primarily taking on the programming and technical development of the product. He will troubleshoot any technical issues encountered along the way, and provide suggestions for the constant optimization of the infusion pump.

Because of his experience in sales and marketing, Pranav Malik will be taking on the role of CFO. He will be monitoring all strategic and tactical matters as they relate to budget management, cost-benefit analysis and financial planning. Marketing the final product and securing additional funding if necessary will also be his responsibilities.

As Chief Hardware Developer, Baljinder Singh is the head of the hardware design and implementation of the product. Meeting hardware and design standards, and using parts that ensure top-notch quality will be his primary responsibilities.

Since Sentinam Innovations is comprised of a fairly small team, all members try to help each other outside the tasks designated to their positions, taking into account each other's strengths and weaknesses. The team operates on a flexible schedule, and actively communicates through instant messaging and meetings as necessary, to handle tasks efficiently.

# 8. Company Profile

**Chelsey Currie- Chief Executive Officer (CEO)**

I am a fifth year Biomedical Engineering student in the Rehabilitative and Assistive Devices concentration at Simon Fraser University. Microfluidics is a particular interest of mine; I worked at the Institute for Microstructure Technology (IMT) at the Karlsruhe Institute of Technology for a co-op term and am also doing my bachelor thesis project at SFU's Microinstrumentation Laboratory. My background in microfluidics and medical devices gives me a solid foundation on which to make decisions on project direction. As CEO, I will oversee all parts of the project and aid team members with the challenges they encounter in their roles.

**Alvin Fang - Chief Operational Officer (COO)**

I am a fifth year SFU student enrolled in computer engineering, with four previous software co-op terms at SFU, IBM, and Blackberry, which helped me develop solid programming skills. I'm mainly experienced with coding in Java and C++, and developing cross-platform mobile and web applications on Windows, Linux, and OS X. From working with large tech companies, I have experience working with large codebases, a range of development tools, coding standards, systematic approach to testing, and structured approach to teamwork. I have limited but solid foundation in embedded system and hardware design, and would also be comfortable with working in these areas.

**Nyann Moe - Chief Technical Officer (CTO)**

I am a fifth year engineering student with previous coop experiences in software development and fabrication. Beyond my technical experience, I used to work as orientation Coordinator where I did supervise over 60 volunteers and event planning for over 900 students. My areas of expertise are programming in Real-time environment and

electronics design fabrication. As a CTO, I would make sure my design will be as safety and reliable as possible.

**Pranav Malik - Chief Financial Officer (CFO)**

I am a fourth year student enrolled in systems engineering. I have 8 months experience working as a system administrator and IT project coordinator at Glentel. I am also comfortable with sales and marketing, having volunteered for over 6 months at an online advertising startup, where I simultaneously managed 3 client accounts. As CFO, I will examine product functionality to ensure quality and efficiency for smooth release into the market. Also, I will be taking care of the budgeting in the development phase and marketing in the final stage of the product.

**Baljinder Singh - Chief Hardware Developer**

I am a fifth year Electronics Engineering student at Simon Fraser University with 8 month co-op experience in technical writing and 3D modelling using Solidworks at Allied Vision Technologies and 4 month research co-op experience under Dr. Ash at SFU. I have intermediate C++ and Matlab programming skills. I am an experienced user of lab equipments like Oscilloscope, Spectrum analyser and function generator. Courses in multimedia communication, digital communication, optics and laser and biomedical imaging have given me a wide variety of skills. I have good communication skills and love working in team.

# 9. Conclusion

Sentinam Innovation strives to create an eco-friendly product that greatly enhances the effectiveness of modern IV therapy. Current infusion pumps can have a number issues that make them unappealing to use, such as requiring certification to operate, lacking precision, and being too expensive. With our design, we plan to address all of these issues, and introduce features to further improve a practitioner's productivity, including remote monitoring capabilities and flexibility in using sensor attachments.

In this document, we provide background information to how IV works, the advantages and disadvantages of existing IV systems, and the deriving of our current design. An overview of our system design provides technical details of how our IV system will work. We also provide a Gantt chart and a timeline to describe how we plan to achieve our goals. Additionally, our estimated budget details are provided, along with how we plan to obtain funding to cover the costs.

Sentinam Innovation is formed by a team of experienced senior engineering students that are committed, and excited to develop a product that can make a difference and improve people's lives. By the end of the term, we aim to create a product with market potential, and can be seen as a viable alternative to existing IV systems.

# 10. References


[1] Moore, D., & Bortolussi, R. Home intravenous therapy: Accessibility for canadian children and youth. Paediatrics & Child Health 16(2), pp. 105-109. 2011. Available: http://www-ncbi-nlm-nih-gov.proxy.lib.sfu.ca/pmc/articles/PMC3043043/?tool=pmcentrez.

[2] R. W. Rucker and G. M. Harrison. Outpatient intravenous medication in the management of cystic fibrosis. *Pediatrics 54(3),* pp. 358. 1974. Available: http://proxy.lib.sfu.ca/login?url=http://search.ebscohost.com.proxy.lib.sfu.ca/login.aspx?direct=true&db=a9h&AN=6730090&site=ehost-live.

[3] L. Pearce. Intravenous therapy close to home. *Nursing Standard 28(44),* pp. 23. 2014. Available: http://proxy.lib.sfu.ca/login?url=http://search.ebscohost.com.proxy.lib.sfu.ca/login.aspx?direct=true&db=a9h&AN=97367070&site=ehost-live.

[4] Miller-Keane Encyclopedia and Dictionary of Medicine, Nursing, and Allied Health, *Y-Connector*. 2003 [Online]. Available: http://medical-dictionary.thefreedictionary.com/Y-connector. [Accessed: 26-Sept-2015]

[5] Janssen-Cilag Ltd. Sporanox I.V. *10 mg/ml concentrate and solvent for solution for infusion*. 2015 [Online]. Available: https://www.medicines.org.uk/emc/medicine/2489. [Accessed: 26-Sept-2015]

[6] FDA. (October 31, 2014). *What is an Infusion Pump?*. Available: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/InfusionPumps/ucm202495.htm.

[7] C. Quinn. "Intravenous flow control and infusion devices," in *Intravenous Therapy in Nursing Practice* (2nd ed.), L. Dougherty and J. Lamb, Eds. 2009.

[8] E-Store. *Syringe Infusion Pump (SP H001).* 2015 [Online]. Available: http://www.p-wholesale.com/cn-pro/10/455to1/syringe-infusion-pump-sp-h001-435544.html. [Accessed: 26-Sept-2015]

[9] Poxon, Ian. (July 1, 2004). *Infusion Pumps- How to pick the best pump for delivery of fluids*. Available: http://www.nursingtimes.net/infusion-pumps-how-to-pick-the-best-pump-for-the-delivery-of-fluids/200125.article.

[10] Njmcca, *Peristaltic pump in motion*. 21 June 2013 [Online]. Available: https://commons.wikimedia.org/wiki/File:Peristaltic_pump.gif. [Accessed 26-Sept-2015]

[11] Government of Canada, "Medical Device Regulatioins," *Food and Drug Act,* vol. SOR/98-282, 1998.

[12] Infusionnurse. (March 25, 2011). *Calculating and counting drops...* Available: http://infusionnurse.org/2011/03/25/calculating-and-counting-drops/. [Accessed: 27-Sept-2015]

[13] Carefusion, *Alaris Pump Module.* 2015 [Online]. Available: http://www.carefusion.com/medical-products/infusion/infusion-system-devices/alaris-pump-module.aspx. [Accessed: 27-Sept-2015]