CAPSTONE DESIGN COURSE

MIM 1502
Final Design Report

Ambulatory Intravenous Fluid Holder

Final Report

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May 30, 2001

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AMBULATORY INTRAVENOUS FLUID HOLDER

Wednesday, May 30 2001

Prof. Greg Kowalski
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Subject: Letter of Transmittal

Dear Prof. Kowalski,

We are sending you our report on the design and fabrication of a prototype for an Ambulatory Intravenous Fluid Holder for hospital patients. Hospital patients are encouraged to ambulate after operation to promote respiration and blood circulation for accelerated recovery. Patients with intravenous infusion currently ambulate with wheeled pole set-up, which is inconvenient and can interfere with low ceilings and carpeting.

Our report gives the steps followed in arriving upon a final prototype, based on Dr. Stephen B. Corn MD’s patent (patent number 5,776,105). The prototype meets the requirement of the patent, and has also been designed to easily incorporate standard hospital equipment. It is made of harness, an infusion device, and a standard intravenous tubing assembly. The device allows conversion from pole to harness without disconnection of any fluid line making it completely sterile. Also, the harness does not include any ferromagnetic components.

The writing of the report had taken into consideration many discussions with medical doctors from Children’s Hospital and Brigham Women, and nurses from the Nursing Department at Northeastern University to have insight, and have feedback on our design.

Our design team would like to thank Professor Kowalski, Professor Mohammad E. Taslim, and Dr. Stephen B. Corn for helping and guiding us through this project. We would also like to thank Children’s Hospital and Brigham Women’s Hospital for sponsoring this project.

Any questions or comments on our report and/or prototype may be directed to our advisor at Northeastern University, Professor Mohammad E. Taslim.

Sincerely,

Anthony Tomasi

Nazif Mohdazhar

Todd Taylor

Mark Fernandes

Stephane Wadjas
Ambulatory Intravenous Fluid Holder

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Abstract
Hospital patients who require intravenous infusions to aid in their recovery are currently encountering several physical challenges while ambulating using standard IV pole assemblies. There are several devices already designed, which alleviate these difficulties. However, many of these require electronic controls, making them too complex and expensive to be implemented as standard hospital equipment. Other designs do not incorporate existing hospital IV equipment. Due to cost and in-service training, hospitals prefer not to modify their existing IV equipment. Therefore, a need exists for a simple and inexpensive device that allows for safe and comfortable ambulation while making use of existing IV equipment. A design concept has been developed that will address these needs. Testing and analysis have shown that this design will safely and effectively provide ambulatory intravenous infusion.
The Need for the Project

Ambulating, or walking, is a beneficial activity for recovering hospital patients. Current intravenous infusion methods do not allow the patient to do so safely and conveniently. During the post-surgical recovery process, hospital patients are given an intravenous infusion in order to provide hydration and to keep their vein open (KVO), so that medication can be quickly and safely infused into the patients. While in this recovery stage, patients are encouraged to ambulate. This basically helps to prevent blood clots from forming in a patient’s extremities and to simply keep the patient in good respiratory condition. Also, exercise can result in an accelerated recovery, and faster recovery generally means an earlier discharge from the hospital.

Current ambulatory IV equipment consists of a fluid bag placed at a specific height on a vertical pole with a wheeled base. Due to the fluid bag’s weight (approx. 2.2 lbs), the base of the pole must be broad, keeping the wheels far enough apart to prevent the pole from tipping over. These requirements make the IV system cumbersome and even dangerous to push around, commonly interfering with low ceilings, uneven door thresholds, carpeting, and small hospital restrooms.

The current methods for supplying intravenous fluids to immobilized or stationary patients are entirely sufficient. Therefore, it would be redundant to invent an entirely new mechanism of fluid infusion. Given this situation, the need is introduced for a device capable of adapting existing IV technology to a mobile application, requiring no complex equipment or electronics.

The Design Project Objectives and Requirements

Requirements

Our design group was presented with four primary requirements that the design must accommodate. The first requirement compatibility with existing hospital equipment. The design must allow any health care provider to easily convert a stationary IV setup to an ambulatory one in minimal time. Therefore, the IV bag (1000, 500, or 250ml) must be transferred to its ambulatory application and pressurized without interrupting infusion. The second requirement is sterility. The process of transferring the standard IV system to its ambulatory application must not introduce any contaminants into the fluid nor put the health care provider at risk of contracting any infectious diseases from the patient. Third, the device cannot contain any ferromagnetic components. It is expected that the device will be used in close proximity to MRI equipment, and any ferromagnetic materials may cause undesired interference with this Magnetic Resonance Imaging as well as other medical electronics. Lastly, the IV system’s drip chamber must be kept in a nearly vertical position at all times. The system will primarily be used while patients are upright. However, it must also allow them to sit down and recline slightly without affecting performance or safety. Maintaining the drip chamber in a vertical orientation will prevent air from communicating with the fluid flow.
Objectives

Our design is intended to achieve five basic objectives. First, it has been designed for easy setup and use by both the patient and the health care provider. The health care provider should require minimal training or instruction on how to use the device, and the patient should have little interaction with the device once in use. It has also been ergonomically designed for comfort and versatility for a variety of users. The device is fully adjustable for a wide range of patients and can be worn differently for a wide variety of injuries. The third objective is to supply a convenient means of flow rate regulation. The flow rate can be monitored through the drip chamber, but a method for adjusting the rate is also necessary. Along the same lines, the device must be self-sufficient once it is set up and attached to the patient. It must not require any outside power source or computer programming. Rather, the necessary pressure must be created and maintained by a manual hand pump. Last but not least, the device must be cost effective. Since it is to be considered for implementation in the modern medical industry, it should be available for approximately the same price as current ambulation equipment, namely the standard IV pole.

Design Concepts Considered

Many different design concepts were considered to solve the problem of current ambulatory IV infusion. However, only 2 major styles were seriously investigated and analyzed. The first concept was the use of a soft-shell, based on safety, ergonomics, and compatibility with current equipment. It would consist of two components: a harness and a pressure infusion device. The soft-shell would accommodate standard size fluid bags, standard pressure infuser bag, and tubing assemblies. The harness would comfortably attach all of the necessary equipment to the patient. The second concept was the use of a hard plastic casing to enclose the fluid bag. It would consist of a cylindrical chamber, housing the fluid and infuser bags. It was considered to address many safety issues raised on our first concept. The hard shell would protect the fluid bag from increased pressure if the patient were to fall down or bump up against something. Also, it would have been possible to incorporate a fluid level indicator, to allow medical personnel and patients to be able to monitor fluid level in the bag. However, from testing and consultation of several health care professionals, we have determined that our initial concerns about increased pressure are less significant than we had originally thought. It was also determined that a hard casing could cause severe injury to the patient in the event of a fall. Moreover, it was learned that a larger infusion of fluid will not necessarily be harmful.
Recommended Design Concept

The recommended design concept uses a soft-shell design that includes a harness and infuser bag. The infuser bag will be used to apply the necessary pressure on the IV bag to infuse fluid to the patient.

Design Description

Our recommended design concept was chosen based on concerns of safety, ergonomics, compatibility with existing equipment, and cost. It consists of a harness, and a pressure infuser bag. The infuser bag applies pressure onto the fluid bag to induce steady fluid flow. We have chosen to make use of an infuser bag that is currently on the market, The Vital Signs IN-800, as it fulfills all of our requirements and guidelines. This 500 cc infuser bag features a mesh netting which will hold a variety of fluid bag sizes ranging from 250 to 1000 ml. The infuser bag is then pressurized with the use of an attached manual hand pump, creating pressure against the fluid bag and inducing flow. The harness, fabricated primarily of Velstretch® Brand Fabric, comfortably attaches the fluid and infuser bags onto the patient’s body. A prototype of this harness has been designed and fabricated. Our Pro/Engineer model of this harness can be seen in the figure on the left.

Analytical Investigations

Analytical research was done primarily dealing with the potential effects of air being accidentally infused in the patient’s vein. It was calculated that, under proper use, the maximum amount of air that could ever be infused into the patient would be approximately half of the volume of the drip chamber, which is 8.43 ml. Consultation of the Miller Handbook of Anesthesia yielded a safe air infusion standard of 0.50 ml per kg of body weight. For a 150-lb person, this states that around 34 ml of air can be safely infused, assuming the person is in normal physical condition. However, after consulting several health care professionals, a more conservative measure of 10 ml was taken to be a safe maximum. This volume, coupled with the fact that it is very unlikely to infuse the 8.43 ml of air, suggest that the danger of air infusion will be of clinically insignificant consequences.

Experimental Investigations

Extensive testing was performed for three major purposes. First, to gain a full understanding of the normal operation of our device and the interaction between components. From this, we determined that flow rate could be easily monitored through the drip chamber and conveniently controlled by an in-line roller clamp. Second, to experimentally test the event of accidental air infusion. From this, we saw that it would take approximately 8 minutes for the air to travel from the drip chamber to the patient. It was also discovered that this could be easily compensated for, by bleeding the air out of the system through a medication port. Lastly, we wanted to investigate how long the system could safely operate when left unattended. It was found that the system could supply acceptable rates of fluid flow (6-31 drips/min) for about 45 minutes with no user interaction. All of these tests were accomplished with the use of the test setup that can be seen to the left.

This setup consisted of the infuser bag that we are using in our design, a standard tubing assembly, a variety of catheters (ranging from 12-20 gauge), and a fluid column that was constructed to simulate the body’s venous pressure of approximately 11 mmHg.
Key Advantages of Recommended Concept

As explained in the above sections, our final design concept will allow for safe and convenient ambulatory intravenous infusion. This design will be consistent with all of our design objectives and requirements. It makes use of current hospital equipment, which will make the design cost effective and familiar to health care professionals. The design will allow for sterile transformation from stationary to ambulatory application. It will contain no ferromagnetic components, and will keep the drip chamber in a vertical position. The soft-shell design will be both comfortable and versatile, and alleviate the issues that would have been created by falling on a hard shell design. The roller clamp will provide a suitable method of flow rate regulation. As the testing proved, the design will be self-sufficient once in use. Overall our design meets all of our stated goals.

Financial Issues

The two components of the design that will need to be purchased are the pressure infuser bag, and harness. The infuser bag retails at $17, and the harness prototype cost $48.

Since our design incorporates current hospital equipment, it has proven to be quite cost-effective. The pressure infuser bag has a retail value of approximately $17. Although we have not obtained a quote for the mass production of the harness, we have had prototype versions produced for only $48. The assumption is that this cost will dramatically decrease if it were put into production. These combined costs will relate competitively against a current IV pole price of $30. The costs of tubing assemblies and IV fluid bags are not relevant to the unit cost, as they are necessary, regardless of the infusion method.

Recommended Improvements

A secondary design that could be investigated would be a one-piece harness and inflatable bladder.

A secondary design that was looked into was using a harness with a built-in inflatable bladder. This design would be similar to the current design, but it would incorporate the pressure infuser bag and harness as one part. The section of the harness that is securing the fluid bag would be an inflatable bladder, similar to a standard blood-pressure cuff, which would apply pressure on the fluid bag. By combining the infuser bag and harness, it will help minimize the number of parts and steps involved in transferring the unit between stationary and ambulatory use. The current design would have the fluid bag being removed from the stationary location, placed into the infuser bag, then placed into the harness. The new design would allow the fluid bag to be placed directly into the harness, where it could be pressurized to infuse the fluid. Similar to the existing infuser bag, the device would be manually pressurized using a hand pump, and would include a relief valve to prevent over inflation.

This design was something that we had intended to pursue as a secondary venture. However, delays in the fabrication of our original harness have made the fabrication of this auxiliary design impossible. Given more time for development, this concept would serve as an excellent option to our chosen design.
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ACKNOWLEDGEMENT AND COPYRIGHT

The design team would like to thank everyone who has contributed to the completion of the “Ambulatory Intravenous Fluid Holder” project. First, we would like to thank the sponsor for the project, Children’s Hospital and Brigham and Women’s Hospital in Boston, MA, and extend special thanks to our mentor for the project, and inventor of the Ambulatory Intravenous Fluid Holder, Steven B. Corn, M.D. We would also like to thank Monique Yoakim for her assistance in legal matters pertaining to the project and James H. Phillip, M.E. (E.), M.D. for his technical insight and advice.

In addition, we thank Northeastern University for presenting the opportunity to work on the project, and for providing the necessary facilities to bring it to completion. We extend special thanks again to our faculty advisor for the project, Professor Mohammad E. Taslim and the course coordinator, Professor Greg Kowalski. Thanks to Matt Ulinski and his staff for overseeing use of the design lab and help in purchasing and fabricating equipment. Also, thanks to Robert Denn for his advice on writing this report.

“We the team members,

M. Fernandes  Naif Mohdazhar  T. Taylor

A. Tomasi  S. Wadjas

hereby assign our copyright of this report and of the corresponding Executive Summary to the Mechanical, Industrial, and Manufacturing Engineering (MIME) Department of Northeastern University.” We also hereby agree that the video of our Oral Presentation is the full property of the MIME Department.

Publication of this report does not constitute approval by Northeastern University, the MIME Department, or its faculty members of the findings or conclusions contained herein. It is published for the exchange and stimulation of ideas.
1. INTRODUCTION

Our design group has been assigned the task of designing and fabricating a working prototype of an Ambulatory Intravenous Fluid Holder. This device will be used to help patients who have begun recovery from surgery to ambulate or move safely around the hospital. Ambulation is commonly encouraged of hospital patients due to its favorable contribution toward recovery. The design will allow them a greater range of freedom, making tasks simple that were once burdensome or impossible.

Ambulatory patients currently receiving IV fluid infusions must be accompanied by a cumbersome IV fluid bag and wheeled pole set-up, which can easily interfere with door thresholds, low ceilings, carpeting, and small hospital restrooms. These frequently encountered obstacles can cause ambulation to be potentially hazardous, and may limit a patient’s mobility.

The proposed design will alleviate these difficulties and give the patient full use of both hands. It will be conveniently and comfortably worn on the patient’s body. More importantly, the device will be inexpensive and compatible with all standard IV equipment currently in use at most hospitals. This will allow any health care provider to transform a patient’s standard IV setup into a fully mobile system, in a simple and timely manner, without interrupting fluid flow or risking exposure to infectious disease. Hospitals will not consider implementing such a device if these requirements of cost and compatibility are not met.

Figure 1. Schematic of ambulatory device, as outlined in Patent Number 5,776,105.
This design is described in Patent Number 5,776,105, invented by Stephen B. Corn, M.D. and Assistant Professor of Anesthesia at Harvard Medical School in Boston, Massachusetts. Figure 1 above is a schematic representation of the device, as explained in the patent. Figure 2 below displays one of the possible positions of the device on a patient. As a result of extensive patent research, we have determined that no device is currently available to fulfill all of the claims of Patent Number 5,776,105, as listed in Appendix F. There are several existing systems that provide an alternative to the standard pole and bag, some of which can be worn on a patient’s body. However, most are either complex electronic devices or do not facilitate easy transfer of standard hospital intravenous equipment. The proposed design will be an innovation in standard medical equipment, simple in design and construction, while being cost-effective.

![Figure 2](image)

**Figure 2.** Schematic of ambulatory device in proposed orientation on patient.

1.1 PROBLEM STATEMENT

During the post-surgical recovery process, patients are given an intravenous infusion in order to provide hydration and to keep their vein open (KVO), so that medication can be quickly and safely infused into the patients. While in this recovery stage, patients are encouraged to ambulate. Advantages of such exercise
include a decrease in deep vein thrombosis, which often results in pulmonary embolus and life threatening respiratory morbidity. This basically means that exercise helps to prevent blood clots from forming in a patient’s extremities and travelling to the lungs. If this occurs, the patient may suffocate. Also, exercise can result in an accelerated recovery, and faster recovery generally means an earlier discharge from the hospital. This tends to become a primary concern with regard to health insurance companies and their willingness to cover hospital fees. Therefore, it is in the patient’s best interest to become ambulatory as early as possible, lowering health risks and leading to the shortest possible recovery time.

Current ambulatory IV equipment consists of a fluid bag placed at a specific height on a vertical pole with a wheeled base. These fluid bags, generally 1000-ml (approximately 2.2 lbs.), must be placed high enough on the pole to ensure the proper pressure gradient due to gravity, capable of overcoming the body’s venous pressure. Due to the fluid bag’s weight, the base of the pole must be broad, keeping the wheels far enough apart to prevent the pole from tipping over. These requirements make the IV system cumbersome and even dangerous to push around, commonly interfering with low ceilings, uneven door thresholds, carpeting, and small hospital restrooms.

The current methods for supplying intravenous fluids to immobilized or stationary patients are entirely sufficient. Therefore, it would be redundant to invent an entirely new mechanism of fluid infusion. Given this situation, the need is introduced for a device capable of adapting existing IV technology to a mobile application, requiring no complex equipment or electronics.

1.2 REPORT LAYOUT

The information that is conveyed in this report is a reflection of our group’s work throughout the design process. For optimal organization, this information has been broken down into six chapters. The first of these chapters is our “State of the Art Review”, which is Chapter 2 of the report. This section includes the specifications and requirements with which our design must comply. This section also displays detailed results of patent research that has been conducted, concluding that no device currently exists, capable of solving the stated problem.

Chapter 3, which is titled “Design” gives a complete and detailed description of our design process. This includes a detailed breakdown of the design concept that has been selected, along with the reasoning behind all pertinent decisions. Other concepts that have been considered are also described extensively in this section.

Chapters 4 and 5, “Analysis” and “Test Results”, include the results of extensive research and testing that have been performed. This includes experimental results and interpretation, as well as analytical work to verify these results. Chapter 6 is a summary of final prototype testing at Brigham Women’s Hospital by Steven Corn, M.D. and also includes his final approval. Finally, Chapter 7 is a brief forecast of future work.
to be performed. This includes testing of our final prototype as well as alternative design concepts that we are still considering and planning to evaluate.

In addition to these six body chapters, the report contains a set of Appendices, which are referenced several times in the text. The Appendices include sketches, test data, documentation, as well as analytical computations.
2. STATE OF THE ART

This chapter will analyze and identify the “state of the art” of ambulatory intravenous infusion, and specify guidelines that must be followed in this design. The guidelines are conveyed by a detailed itemization of the specifications and requirements that our design must meet. The current “state of the art” is documented by a summary of extensive patent research.

2.1 SPECIFICATIONS

The design must include a pressure infuser bag, which applies pressure to a standard IV bag, and a manual pump for maintaining appropriate fluid pressure to overcome venous pressure in the body. The following are the specifications of the design.

2.1.1 Compatibility with Existing Equipment

The design must incorporate existing intravenous equipment typically found in hospitals. The design must also allow any health care provider to easily convert a stationary IV setup to an ambulatory one in minimal time. Therefore, the IV bag (1000cc, 500cc, or 250cc) must be transferred to its ambulatory application and pressurized without interrupting infusion.

2.1.2 Sterility

The process of transferring the standard IV system to its ambulatory application must not introduce any contaminants into the fluid nor put the health care provider at risk of contracting any infectious disease. In order to ensure sterility, the fluid bag and tubing must be converted from the pole setup to the pressure bag without disconnection of the fluid line.

2.1.3 Vertical Drip Chamber

To ensure proper operation of the system, the fluid drip chamber must be maintained in a nearly vertical position at all times. The system will primarily be used while patients are upright. However, it must also allow them to sit down and recline slightly without altering performance. In a situation where the patient would by lying down, it is assumed that they would revert back to their stationary means of infusion. Please see Figure 3 for a schematic of the drip chamber.
2.1.4 Use of Ferromagnetic Components

Use of ferromagnetic components is prohibited for our application. It is expected that the device will be used in close proximity to MRI equipment. Any ferromagnetic device may cause undesired interference with Magnetic Resonance Imaging.

2.2 REQUIREMENTS

There are several issues that can be categorized as design requirements. The specific requirements of the ambulatory IV fluid holder design are as follows.

2.2.1 Cost Effectiveness

To be considered for implementation in the modern medical industry, the product must be cost effective. Therefore, this design should be available for approximately the same price as ambulation equipment used now, which is approximately thirty dollars for an IV pole. The product should be inexpensive enough so that the hospitals can consider it as a disposable. At the same time, the device could be re-used if necessary.

2.2.2 Ease of Setup and Use

Simplicity of use is a necessity for both the patient and the health care provider. The patient should be able to use the device with minimal instruction from their provider. Similarly, the health care provider should not require any specific training or instruction on how to operate the device. It must be a straightforward and timely process to transfer the IV equipment from its standard upright setup to the ambulatory holder.
The patient should be able to easily remove the IV equipment with little or no help and hang it back on a
vertical pole or hook if necessary, for purposes such as using a restroom or lying down.

2.2.3 Comfort and Versatility
The harness and all of the attached IV equipment must be arranged in such a way that the patient’s
movement is not greatly inhibited. Also, the harness must be adjustable to accommodate all sizes of
patients as well as all types of injuries. For example, a person with an abdominal incision must have the
option to attach the device to his or her shoulder or somewhere that does not interfere with his or her
incision. Likewise, a patient with an upper torso incision or injury should be able to wear the device
comfortably around his or her abdomen.

In addition to size adjustments, the body strap or harness must provide some means of holding excess
lengths of tubing, as well as a paging device. The paging device would provide a convenient and
systematic method for contacting patients when necessary, and could be used to indicate when pressure
must be added to the infuser bag.

2.2.4 Flow Rate Regulation
The ambulatory IV design must contain a means of controlling the flow rate of the fluid from the IV bag to
patient. By observing the drip chamber, flow can be monitored. However, the design will need some
method for adjusting the flow rate to keep it within an acceptable range.

2.2.5 Self Sufficiency
The device must be entirely self sufficient once it is set up and attached to the patient. It must not require
any outside power source or computer programming. The necessary pressure must be created and
maintained by a manual pump, attached to the pressure bag. This will allow patients to easily increase the
pressure if necessary.

2.3 PATENT SEARCH
In order to improve our understanding of the technology related to our design project, we have conducted
an extensive patent search. Web sites, such as IBM Patents and the United States Patent and Trademark
Office, were the primary sources used for this research. Out of twenty patents that were reviewed, eighteen
were related to the Ambulatory Intravenous Fluid Holder project in some way.

In general, the purpose of this research was to inspect what is currently available on the market. It was also
to ensure that our design would not be infringing on any other patents. Components such as a pressure
infusion device, a carrying case, and a fluid delivery system were the main focuses of this research. The
Ambulatory Intravenous Fluid Holder depends on the reliability of these systems to work properly.
No patents were found that fulfill the same claims as Patent Number 5,776,105, as outlined in Appendix F. This confirms that our design and its intended application will be unique. The summaries below discuss the reasons why the following patents do not meet the requirements of our design. These patents are grouped according to common characteristics that disqualify them from use in this application.

### 2.3.1 Electronic Devices

All of the patents listed here require the use of electronic devices for operation. This creates a number of problems when operated in the applications for which we are designing. Electronics can add to the cost of the device, produce electric signals, and can be complicated to use. Also electronic devices will contain metal components, which may have adverse effects on some hospital equipment. Patent number 5,342,313 is an infusion pump, which delivers IV fluids at predetermined rate from a standard flexible IV bag. This pump assembly contains a computer memory controlled mechanism, motor, and customized electronic circuits, which regulate the volume, pressure of the bag, and fluid output. Patent number 5,399,166 describes a portable infusion device worn as a shoulder bag, which consists of a rigid housing containing an air bag, drug bag, tubing assembly, and self-monitoring electric pumping device. Patent number 5,348,539 is an infusion pump with a controller regulating the hydraulic system that is used for standard pre-filled single dose IV bags. Patent number 5,168,892 contains an electrical control panel, needing a battery pack, through which flow and pressure can be regulated. Patent number 5,250,027 is a design that contains a microprocessor that uses several programs to control the motor to alter the flow. Patent Number 5,232,439 uses a method for mechanically pumping fluid from an IV to the patient. This design consists of a motorized rotating wall that reduces the volume in which the fluid bag resides, thus expelling the fluid into the patient. Due to the changing bag volume and surface area, the rotating wall will be moving at different rates to keep the fluid flow rate at a constant rate. Patent #5,700,257, which can be seen in Figure 4 includes an electronic IV pump with a plastic plate to provide rigidity to the pack. As can be seen, all of these designs contain electrical components that exclude them from use in the ambulatory IV bag holder design.
2.3.2 Use of Non-Standard Equipment

The devices in this section do not meet the design criteria because they do not use or are not totally compatible with standard hospital IV equipment. One of the design requirements was that this device would use all standard hospital IV equipment. The hospitals will not be willing to switch to all new equipment for an ambulatory IV fluid holder, so the design must adapt to the existing assemblies. Along with the electrical components mentioned above, patent number 5,399,166 does not use a standard IV bag. Patent number 4,507,116 introduces an apparatus for infusion from a liquid bag. This liquid bag is not a standard IV bag, nor does it connect to the standard tubing assembly. Patent Number 5,356,379 is a design that includes a collapsible fluid bag and a dual tube design. The fluid bag discharges the fluid through the tubing assembly to the patient. One tube provides a flow rate that overcomes the venous pressure exerted by the patient; the second tube provides a higher flow rate and contains a port from which a medication can be introduced. The purpose of the dual tube assembly is that after a medication is discharged into the patient, a higher pressure flow pushes it through the body quicker, administering treatment at a faster rate. This design does not incorporate the standard IV bag or tubing assembly. Patent numbers 5,492,534 and 5,318,540 are similar because they consist of a pump that expels fluid by a variety of means such as osmotic pump, electromechanical reaction, release of pressurized fluid or gas, or mechanical means. None of these designs use a standard tubing assembly or IV bag. Patent number 5,336,188 contains an assembly that houses the fluid in a thin walled base and is expelled by an internal energy source. The energy source may be an elastomeric membrane or an expandable sponge. This design does not use a standard IV bag or tubing assembly. Patent number 5,074,839 consists of a collapsible nonstandard IV fluid bag, inside a rigid...
vessel. A hand pump is manually pumped pressurizing the rigid vessel, pushing the fluid out of the bag/vessel assembly and into the patient. Patent number 4,857,055 is a device that employs a rigid vessel, flexible fluid holder, and two leak-proof pouches. A low-pressure gas inflates the pouches causing the flexible fluid holder to reduce in volume and the fluid to be discharged. This design does not use a standard IV bag or tubing assembly. None of these designs meet the requirement of using the standard IV equipment.

### 2.3.3 Non-Ambulatory Devices

All of the devices listed in this section are designed for non-ambulatory applications. These apparatus are designed to be standalone, stationary units. Patent numbers 5,348,539, 5,492,534, 5,318,540, 5,074,839, and 4,857,055, discussed in the non-standard equipment section, are stationary units. Patent number 4,090,514 consists of a bladder which wraps around the fluid bag and is secured by the use of Velcro®. Pumping an external hand pump fills the bladder, and the bladder exerts a pressure on the fluid bag causing the fluid to be expelled. This device is used on a stationary hook. None of these devices will meet the ambulatory specification.

### 2.4 CONCLUSION

Considering the issues surrounding the use of the current pole and IV bag setup, it is clear that some modifications to the ambulatory intravenous system are necessary. Basing our design on Dr. Stephen B. Corn MD’s patent, we have taken these issues into account and have attempted to design a prototype that incorporates all necessary aspects to accomplish these goals. Our design allows safe and convenient ambulation while making use of standard hospital IV equipment. It consists of a manually pumped infuser bag that applies the appropriate pressure to overcome the body’s venous pressure. This easy to use and ergonomic design allows the patient to move more freely and without the hazards encountered with the current ambulatory system.

After performing an extensive patent search to investigate other products on the market, it was concluded that no patent exists to fulfill all of the requirements stated in this report. This search also certified that our design would not be infringing upon any existing patents.

As our research supports, there is no product designed to fulfill all of the requirements outlined in this report. Therefore, a need exists for a simple and inexpensive device, which allows for safe and easy ambulation throughout the hospital.
3. DESIGN

This chapter is broken down into three major sections: Chosen Design, Design Concepts, and Intended Use. The first section is a detailed breakdown of the design concept that we have chosen. This includes component breakdown as well as reasoning behind all decisions made. The Design Concepts section outlines other design concepts that we have considered and their reasons for being eliminated. Finally, the Intended Use section states the intended purposes and procedures for using the Ambulatory Intravenous Fluid Holder.

3.1 CHOSEN DESIGN

Considering the need to develop a superior system for ambulatory intravenous infusion, our group has gone through the design process and chosen an optimal design concept. This concept was chosen based on concerns of safety, ergonomics, compatibility with existing equipment, and cost. Extensive research was performed to investigate various modes of failure and safety concerns that have been introduced throughout the design process.

The design of the fluid holder consists of two major components: a harness and a pressure infusion device. These are the two structural and functional components that must be incorporated and support all standard IV equipment found in hospitals. These include standard size fluid bags (1000cc, 500cc, 250cc) and a variety of tubing assemblies. Tubing assemblies generally include a standard sized drip chamber, medication port(s), a roller clamp to adjust flow rate, and one or more shutoff points.

The design is an intravenous infusion system that can be worn directly on a hospital patient’s body, instead of being supported by a tall vertical pole. Since the fluid bag will be located at the same or lower height as the catheter in the patient’s upper extremity, the fluid must be infused by some means other than gravity. This is accomplished by the use of a pressure infuser bag inflated by a manual hand pump. The fluid bag is held against this infuser bag by a mesh pouch and compressed. This entire assembly is then attached directly to a patient’s body with the use of an ergonomically designed harness, which is fully adjustable to fit any post-surgical patient. The major components of this design are detailed in this chapter.

3.1.1 Harness

The purpose of the harness is to comfortably attach all of the necessary IV equipment to the patient. The primary material of this harness will be female (loop side) Velcro®. Plastic buckles and male (hook side) strips of Velcro® will be placed at all connection and adjustment points. These Velcro® strips (denoted by numbers IA to ID on Figure 5 below) will allow full adjustment to accommodate virtually any user. Since
the whole skeleton of the harness will be constructed from female Velcro®, it will be convenient to attach anything with a male Velcro® strip at any location on the harness, such as pouches or accessories.

Feature 2 below represents a hook that will support the fluid bag and infuser bag in the vertical direction. Feature 1A represents two Velcro® flaps that will enclose the fluid / infuser bag. The small Velcro® strap (feature 1C) will serve as a retainer for the drip chamber, keeping it in a near-vertical position during normal operation. It will also prevent kinking of the fluid line when the patient sits down or presses against anything. Features 1B and 1D are strips of male Velcro® that allow the shoulder and waist straps to be adjusted.

Excess tubing can be conveniently placed underneath the Velcro® waist strap. The tubing contains many in-line components such as medication ports and shutoff clamps, which are susceptible to being caught on obstacles. This Velcro® strap will help to prevent snagging of the tubing as the patient is walking and keep the tubing off of the floor. A soft pouch was initially considered for this function, but there were concerns about the tubing being kinked inside of the pouch. A second pouch can be added on the waist strap to hold a beeper and/or timing device. This could be used to notify the patients at a pre-determined time interval when pressure in their infuser bag is getting low. It will also provide a means of calling the patient back to his or her room or designated area when necessary.

The plastic buckles indicated by Feature 4 allow for length adjustment of the shoulder strap and lateral adjustment along the rear portion of the waist strap. This will make it possible to mount the fluid bag to either the left or right shoulder, depending upon the location of the patient's surgical site. Finally, the areas that are indicated by number 3 are reinforced double stitching. These will be the critical stress regions and are therefore supplemented with reinforced stitching.
3.1.2 Pressure Infuser Bag

The function of the pressure infuser bag is to provide the pressure gradient necessary to infuse intravenous fluid into a patient's vein. For the average person, Central Venous Pressure (CVP) ranges from about seven to eleven mmHg (www.healthsci.utas.edu). Therefore, an appropriate IV infusion device must overcome this pressure by some means. Current ambulatory IV infusion is accomplished by the use of gravity to create this pressure gradient. Therefore, this infuser bag must be capable of providing a similar pressure gradient, without the use of gravity.

The pressure infuser bag that we have chosen to incorporate is an infuser bag that is currently on the market and already in use in hospitals for several applications. This is important to the overall design because healthcare professionals will already be familiar with such a device. This will minimize any training and learning curves associated with being introduced to a completely unfamiliar device. The particular make
and model that we have used in our testing is the Vital Signs Incorporated IN-8000, which is a 500cc infuser bag. We have also investigated the use of a 1000cc bag, the Vital Signs IN-9000. However, it was found that the 500cc bag requires less frequent manual pumping than the larger one, as described in the “Test Results” section. Both of these bags are available directly from Vital Signs for approximately $17.00 each.

A schematic of the IN-8000 is shown in Figure 6 above for reference. This bag is effective because of its ability to hold a steady pressure on the fluid bag with minimal pumping by the user. Also, the 500 cc infusion chamber and its mesh netting are somewhat shorter than a standard 1000 cc IV fluid bag. This will prevent the fluid bag from being completely drained during normal use because the air bag will not be able to force all of the fluid out of the IV bag. Figure 13 in the “Analysis” section shows how the infuser bag holds the fluid bag.

This is a simple solution to an extremely critical safety concern of air being infused into the patient’s body. A fresh IV bag contains approximately 10 cc of air before it is tapped. Although this is a relatively small volume compared to the fluid volume, it could result in undesirable consequences if it were infused into a patient’s vein. It has been determined from our research and speaking with several health care professionals that approximately 6 cc of air is commonly infused into a patient’s vein (Philip). Although this is not favorable, it is a common occurrence in hospitals when the drip chamber becomes inverted. However, there are several conditions such as various forms of Congenital Heart Disease (CHD), where if small amounts of air were to enter the circulation, serious consequences could result. If a small amount of air
air were to enter the vein of a typical patient, it would travel through the vein to the right ventricle of the heart and then be absorbed by the lung, causing no serious side effects. This would be impossible for a patient with a CHD, as the air pocket could pass through a small hole in the intra-ventricular septum, and into the left ventricle. This would cause the air to bypass the lung and be pumped back out to the body and potentially to the brain, resulting in undesirable side effects and possibly death. Although these conditions are extremely rare, they are still considerations that must be taken into account in the design of such a device. By implementing the above mentioned infusion chamber, these occurrences will be avoided by preventing air from being infused during normal operation.

Other components of the infuser bag include the manual hand pump, the three-way valve, and a loop at the top, as can be seen in Figure 6 of the IN-8000. The hand pump provides a simple, non-electronic, and fully self-sufficient means of creating the pressure in the infuser bag. The three-way-valve is required to inflate and deflate the infuser bag. Finally, the fabric loop serves as a means of holding both the fluid bag inside the infuser bag, and the infuser bag to the harness on the patient.

The pressure gauge shown on the IN-8000 has been proven to have no significant use for controlling flow rate. This is due to the fact that the flow rate will be determined by reading the drip rate in the drip chamber, and not by the pressure in the infuser bag. However, this gauge will indicate to the health care provider when the bag is being over-inflated. This useful feature, coupled with the fact that the IN-8000 is a common hospital supply led us to choose this as the infusion device for the final design.

3.2 OTHER DESIGN CONCEPTS

Throughout the design process, many considerations have been introduced and analyzed. One of these designs is the soft-shell concept as detailed above. The second concept would make use of a hard plastic casing to enclose the IV fluid bag. The hard cased device would consist of a cylindrical chamber that would completely enclose the fluid bag. The IV bag would be pressurized longitudinally from one end by an infuser bag, which would also be housed within the hard shell. A sketch of this design can be viewed in Appendix C. This type of design was considered because of many preliminary safety concerns that have arisen throughout our research.

One major concern that was being addressed with the hard shell concept was the risk of a patient falling down or bumping into things. If a patient were to fall with their weight on the fluid bag or lean against a table, the pressure on the IV bag would increase. This would increase the flow rate and possibly burst the bag. The hard shell would protect the fluid bag from any added pressure imposed by an external force. However, as a result of testing, we have determined that this is not as large of an issue as it had appeared. No matter how much pressure is applied to the fluid bag (within the physical limitations of the bag), the flow will still be constricted by the roller clamp. The flow rate will still increase slightly upon an applied force, but nowhere near as dramatically as if the line was not constricted. If the applied force was large
enough to explode the bag, then all pressure in the bag would be lost and the flow would stop. In this unlikely event, the patient would be in no physical danger from the device, as a check valve located in standard IV tubing assemblies prevents reversal of flow. This would prevent against any blood loss of the patient through the open line connected to their vein. In addition to these flow-related aspects, it was realized that a hard shell could actually worsen a patient’s injury during a fall, whereas a soft-shell device would serve as a cushion.

Another feature that we intended to incorporate into a hard shell chamber would be a fluid level indicator. We considered this to be a useful feature, as it would provide a simple display of fluid level, which could be read by medical personnel as well as the patient. This device would have been a simple flag indicator located between the fluid bag and the infuser bag. As the fluid bag drains, the indicator would move accordingly down a calibrated level scale. This can be seen more clearly in the device sketch in Appendix C.

Aside from these few advantages of a hard shell design, we have concluded that it may introduce more problems than it would solve. First of all, the mechanism of infusion would be completely altered. Instead of pressurizing the bag circumferentially, the hard shell device would be infusing it longitudinally from one end. This would result in compressing the bag in a way that is not intended. Most IV fluid bags on the market contain seams along both sides. By compressing the bag longitudinally, we would be running the risk of kinking and possibly tearing the bag at these seams. In light of this concern, a variation of longitudinal infusion was considered. Rather than pushing against one end with a flat plate, the use of a wedge was investigated, to come closer to the intended pressurization of the bag. However, it was found that such a mechanism would require complex injection molding and tracking within the shell, which would greatly increase our cost.

Considering the issues of safety, cost, and convenience as indicated above, the soft-shell concept was chosen as the final design. In addition to the specific issues addressed above, the soft-shell device is much more favorable because of its simplicity and familiarity to health care personnel. The type of infuser bag and pumping mechanism employed in the soft-shell device is currently used for several hospital applications. Knowing this, the soft-shell device will be much more accepted by health care professionals, as they are already familiar with its operation. A hard-shell device would operate differently, making people reluctant to accept its implementation.

### 3.3 INTENDED USE

The design of this ambulatory intravenous fluid holder is intended to allow safe and convenient IV infusion while ambulating in a hospital setting. The primary user of this device would be a patient recovering from surgery, who is otherwise in good health. This means that the patient is not physically dependent upon the nutrients and hydration of the IV fluid itself. However, it is still desirable to keep the line open into their
vein for infusion of medication and other fluids. Therefore, the main intent of the design is to keep the patient's vein open while ambulating, which means supplying some flow of fluid into the vein. This minimum flow is around 25 cc/hr, but varies from person to person.

This device has been designed with many intentions and assumptions regarding its proper use. Although our goal is to design the device as fail-safe and as simple to use as possible, a certain level of understanding and competency is still expected of the user. This includes both the health care professional administering the device, as well as the patients themselves. However, the patients can only be expected to know what is told to them by the health care professional. Therefore, some level of introduction and/or training should be required of anyone before using the device.

Prior to implementing the device, it is assumed that the patient will already have an intravenous infusion in place. It is also assumed that this infusion was administered properly, which includes but is not limited to, removing all air from the IV bag initially. This infusion would most likely be set up with an electronic IV pump or bedside stand. Upon the need to use the ambulatory device for the first time, the patient should do so with the assistance of a qualified health care provider. This use should be supervised until the patient is comfortable with the basic operation of the device.

Regardless of who is setting up the device, one must first attach the harness and adjust it to a comfortable fit. At this time, the roller clamp in the IV tubing assembly should be turned off to avoid any rapid changes in flow rate, as well as preventing air from being induced into the system. Once the harness is carefully adjusted and the fluid flow is stopped, the IV bag can be removed from its current infusion device, with all tubing still attached. This should be done in such a way that the bag or drip chamber is never inverted. This is to safeguard against any air being introduced into the line, even though the air in the bag should have been removed when the IV infusion was initially placed. The fluid bag must then be inserted in the pressure infuser bag and held in place by threading the loop from the infuser bag through the hole in the top of the fluid bag. This fluid bag and infuser bag combination can now be placed onto a hook on the harness by the same loop on the infuser bag. This will support the IV bag in the vertical direction. Next, the two wide Velcro® flaps on the harness can be wrapped around the bag, securing it to the patient's body. The small Velcro® strap on the harness below the bag should be used to constrain the drip chamber to a vertical orientation.

The infuser bag can now be pressurized with the use of the attached hand pump. This should be pumped until the infuser bag is firmly pressing against the fluid bag. At this time, the roller clamp can be slowly opened to resume flow. The proper flow rate can now be obtained by either increasing the pressure in the infuser bag or adjusting the roller clamp. It is recommended to produce a flow rate of approximately 30–32 drips per minute. This is the maximum flow rate desirable for typical patients. This will minimize the interaction required of the patient, as the flow rate will slowly decrease with time. Test results have shown
that the device can remain pressurized for up to 40 minutes before reaching the minimum pressure required to keep the patient's vein open (KVO). Therefore, any ambulation of 40 minutes or less should require no interaction by the patient.

If it is expected that the patient will be ambulating for longer than 40 minutes, he or she should be equipped with a beeper or timing device indicating the need to re-pump the bag occasionally. Information on the behavior of the flow rate can be seen clearly in the Testing Results section.
4. TEST RESULTS

There were some concerns about the use of the ambulatory intravenous fluid holder after the final design concept was decided upon. There were three main issues that we intended to address by conducting the following experiments. The first issue was the basic operation of the device. We needed to know how the different parts of the system interacted, and we needed to know how we could affect its operation. Without a working model, we were having trouble understanding how to relate the IV fluid flow rate to the pressure in the infuser bag. Another concern was the possibility of air being introduced into the fluid flow if the drip chamber were to become inverted. Tests were conducted to determine how long it would take for the air to reach the patient's body in this situation. The final issue explored was to see what would happen if the system was left unattended. These tests were conducted to see how long a patient could ambulate without adding pressure to the device as fluid left the IV bag.

4.1 BASIC OPERATION AND FLOW RATE REGULATION

Our initial intention was to use the pressure gauge on the infuser bag to indicate how the system was operating. This pressure gauge measures the air pressure inside the infuser bag. Our assumption was that a low pressure in the infuser bag would indicate that the flow rate was too low and that the bag needed to be pumped to increase the flow rate. A high-pressure reading would mean the opposite; the flow rate was too high and the bag should be depressurized to an appropriate level.

More consideration of these ideas brought up a number of questions. Most of the answers that we were able to arrive at taught us a great deal about the dynamic nature of the system. The initial notion of using the gauge on the infuser bag to monitor flow would rely on the volume of the fluid bag remaining constant. This would mean that the interaction between the infuser bag and the fluid bag would only depend upon the amount of air in the infuser bag. In reality, this is not the case because the IV bag loses volume as the infuser bag applies pressure to it. As fluid leaves the IV bag, the pressure that it applies to the infuser bag will decrease. The gauge will show a lower pressure in this case, because of the lower pressure caused by the fluid bag pushing back against the infuser bag. So the pressure interaction between the two bags is constantly changing as fluid leaves the IV bag.

To illustrate these ideas, consider two extreme cases. In the first, the IV bag is full, and the pressure infuser bag is pumped to a high-pressure level. Some of this pressure will come from the IV bag pressing against the infuser bag. Assuming that the roller clamp and other features on the tubing assembly are set to allow unrestricted fluid flow, the flow rate will be high. Now consider a second case, where the infuser bag is pumped to the same pressure level again. The fluid bag, however, is empty. The infuser bag still reads the
same pressure as in the first case, even though there is no flow. Therefore, it cannot be relied upon to provide all of the information needed for effective operation.

It was decided that we would run tests at normal operating conditions to collect data and try to draw some conclusions about the relationships between flow rate, infuser bag pressure, roller clamp setting, and volume of fluid flow. Our hope was to gain some basic understanding of how the system variables interact and also use this information to develop some operating guidelines.

4.1.1 Testing Setup

In order to simulate the fluid flow correctly, the venous pressure of a patient's body had to be taken into account in the experiment. The flow must work against this pressure in actual operation, so this pressure had to be modeled in the experiment. A column of saline fluid of a height measured to duplicate intravenous pressure was used to simulate the body's intravenous pressure. The fluid was poured into a hollow metal tube with an inlet at the bottom and outlet near the top exactly 19.3 cm higher than the inlet (See Appendix D and Figure 8 below). The IV fluid line was connected to the bottom inlet, making the system pressure work against the fluid column in order for flow to occur. Tubing was connected to the outlet and then run downhill, off the table, to a graduated cylinder where the fluid was collected and measured (See Figure 9). Please refer to Figure 7 above for a complete understanding of the test setup.
4.1.2 Basic Operation - Test 1
The first test run was intended to measure the IV fluid volume output over time, the drip rate at determined time intervals, and the number of pumps required to keep the drip rate in a desired range. We believed these to be the most important variables governing the device’s operation. The goal of the ambulatory intravenous fluid holder is to keep the vein open by supplying a continuous flow of IV fluid at a rate
between 25 and 125 cc/hr. This experiment was run to get a general impression of how the variables interact and to see the system work in this range.

The experiment was set up using the larger sized infuser bag (Vital Signs IN-9000) and a full IV bag. The catheter at the end of the line was the smallest size used in normal IV fluid administration, 20 gauge. There are other sizes, but it was decided to start the experiment with the smallest gauge and to try other catheter sizes in future experiments. The infuser bag was pumped to supply pressure to the system with the roller clamp closed initially. Once the clamp was opened, we let the system run for a few minutes to allow fluid to flow throughout. The roller clamp was then adjusted so that the drip rate was at the high end of the acceptable range, about 125 cc/hr, which we calculated to be about 30 drips per minute (see Appendix E). Once this was achieved, a baseline measurement for fluid volume was taken from the graduated cylinder, the time and drip rate were noted, and the experiment was started. New measurements were taken at five-minute increments including the volume change in the graduated cylinder as well as the drip rate. As fluid left the IV bag, the infuser bag needed to be pumped to maintain pressure to maintain the desired drip rate for the experiment (between 20 and 30 drips per minute). When the measurements were taken, the number of pumps needed to bring the pressure back up to the top of the acceptable range was estimated and applied. This is done so that the drip rate did not fall below the lower end of the range used in this experiment. Eventually it was discovered that with the large infuser bag used in this experiment, one pump given to the bag would increase the drip rate by approximately four drips per minute. Using this as a guideline, the pressure could be accurately maintained in the range throughout the experiment.

After a sufficient amount of data was collected in this range, the drip rate was allowed to decrease more to investigate the behavior of the system. The same relationships between drip rate and pumps were found at any level tested. From this we concluded that the relationship between time, drip rate, and pumps in the infuser bag could be predicted for all acceptable flow rates.
The chart above (Figure 10) represents the total volume of fluid flow over time for this test. The relationship is linear because we maintained a nearly constant range of flow rates throughout. These are the results we expect to find during normal use by a patient. The lower values seen after 3500 seconds resulted from letting the drip rate decrease, but the relationship still remains linear.

Some important conclusions were drawn from this first experiment. First, and most importantly, we found that it is simple to maintain the appropriate flow rate levels to keep a patient’s vein open. By knowing the initial drip rate, how much the drip rate decreases over time, and how the number of pumps added to the infuser bag increases drip rate, we know that the behavior of the device is predictable over time. With this information, it should be easy to define operating procedures for any setup (i.e., catheter gauge, infuser bag size).

Another important conclusion was that while the volumetric flow rate defines the amount of fluid that the patient receives, the drip rate is what determines the flow rate directly. By measuring both parameters in our experiment, we were able to verify some of the information we had relating drip rate to volumetric flow rate (See Appendix E). This is an important conclusion because it means that the drip rate is the important variable in operation of the device, much like traditional IV setups. Health care providers using our device in ambulatory patients will measure flow rate just as they do with traditional IV setups, by counting the number of drips per minute. This will give an accurate flow rate estimate. The roller clamp can then be
adjusted to give the appropriate drip rate, and pumps given to the infuser bag will maintain this rate as fluid leaves the IV bag.

4.1.3 Basic Operation – Test 2

This test was conducted using the same procedure as the first test. A smaller infuser bag and an 18-gauge catheter were substituted for the original equipment. The results of this test can be seen in the graph of Figure 11 below. The behavior of the system was found to be the same with this setup as in the first test with one exception. The smaller infuser bag required fewer pumps to provide pressure than the large bag required. One pump in the smaller infuser bag will increase its volume by a greater percentage than one pump in the larger bag. This means that the smaller infuser bag will require fewer interactions from the user during operation to keep the infuser bag pressure high enough to supply IV fluid to the patient at an appropriate flow rate. Also, the smaller IV bag is more comfortable to wear because of its size. These were the important conclusions taken from this test, which led us toward the decision to use the smaller infuser bag moving forward with the design.

![Volume vs. Time Graph](image)

**Figure 11.** Volume vs. Time for Small Infuser Bag and 18 Gauge Catheter.

4.2 AIR IN THE LINE

One of the other concerns with the device was the possibility of air being introduced into the fluid flow by the drip chamber being moved to an orientation where the fluid no longer creates a seal at its exit. If the drip chamber is rotated past a horizontal position, or in a worst case scenario, tipped upside down, air can
be introduced into the flow and through the tubing assembly to the patient’s body. While these situations
are unlikely to occur, we conducted tests to see what happens when the drip chamber does allow air into the
tubing en route to the patient’s body with the infuser bag pressurized. In this situation, air would be pushed
through the line toward the patient’s body.

4.2.1 Test 3

We conducted several tests to investigate what happens when air gets into the fluid flow. First, the drip rate
was adjusted to 30 drips per minute, simulating a worst case scenario, as this is the highest potential
operating flow rate. The drip chamber was then tipped up so that air communicated with the tubing at the
exit of the drip chamber as the system continued to flow. The air began to flow very slowly through the
tubing assembly. The drip rate was continually monitored as the air moved through the line, and the
infuser bag was pumped when necessary to maintain this high flow rate. The column of air took an average
of eight minutes to reach the catheter at the end of the tubing at the highest normal operating flow rate of
the device. This meant that a patient would have plenty of time to contact help if the air in the line was
noticed.

Since tubing assemblies vary in length, the velocity of the air in the line is more meaningful than the time
measured for our specific setup. These measurements and calculations can be seen in Appendix A. The
time measured for our case was approximately 8 minutes, which corresponded to approximately 1 foot per
minute.

4.2.2 Procedure to Remove Air from the IV Tubing

After finding the length of time that it takes for the air to get through the tubing and to the patient, we
developed a method to bleed air out of the tubing before it reaches the patient’s body. If air in the line is
noticed early enough, the flow can be stopped using one of the clamps on the tubing assembly. The air can
then be bled out through one of the valves located on the tubing assembly before the clamp restricting flow.
In this situation, pressure is maintained between the patient and the clamp so that no flow or back-flow
occurs, and the infuser bag pressure is acting against atmospheric pressure at the open valve allowing the
air and some fluid to escape from the system. After the air is released, the valve can be closed and the
clamp reopened to resume flow to the patient’s body. This procedure allows the healthcare provider to
release air from the line without taking the catheter out of the patient’s body. Restarting an IV is not
desirable, and this procedure avoids having to do so.

4.3 UNATTENDED OPERATION

Another concern about use of the ambulatory intravenous fluid holder was the amount of time that the
device would remain effective if left unattended by the user. During normal operation, the patient or health
care provider should pump the infuser bag to add pressure to the fluid system as the IV bag loses fluid and
the pressure gradient decreases. If this is not done, the pressure difference between the patient’s body and the pressurized fluid will eventually be zero. At this equilibrium state, flow will no longer occur.

4.3.1 Test 4

A test was conducted to find the amount of time that the ambulatory intravenous fluid holder could maintain adequate fluid flow without interaction from the user. The test was conducted similarly to Test 1 and Test 3. The infuser bag was pumped and fluid flow was started so that the drip rate was at the maximum of the acceptable range to keep the patient’s vein open, about 30 drips per minute. The drip rate was monitored just as in the other tests, but no pumps were given to increase the infuser bag’s pressure. The test was run until the flow rate slowed to 6 drips per minute, the lowest acceptable level. This test was run twice, and on both occasions, the time elapsed was over 40 minutes. This means that a patient who ambulates for 40 minutes or less will not be required to interact with the device at all. A patient ambulating for longer than 40 minutes will be required to pump the infuser bag occasionally as described previously.

![Drip Rate vs. Time](image)

*Figure 12. Drip Rate vs. Time with Small Infuser Bag.*

4.4 CONCLUSION

From these tests, we were able to gather some valuable information about the behavior of the ambulatory intravenous fluid holder. The most important discovery was that under normal operating conditions, regardless of the equipment setup, the roller clamp was the most effective way to adjust drip rate. This is ideal since healthcare personnel use the roller clamp for adjustments in current IV setups.
Another observation was how easily the system can be controlled. Supplying adequate fluid flow over a long period of time requires minimal user input. If the ambulating period is less than 40 minutes, the patient will not be required to interact with the device at all. If the patient ambulates for longer than 40 minutes, some input will be required. The bag should be pumped four times every ten minutes to maintain a high enough pressure gradient for adequate IV fluid flow.
5. ANALYSIS

To address concern about the potential of a patient falling down while using the ambulatory intravenous fluid holder, research was done to determine the likelihood of this occurring. Several healthcare professionals were consulted for input on this issue. None of these professionals found the issue to be a clinically significant concern. Given the condition of the patients that will be using the device, falling down would be an extremely rare occurrence. Also, the remote chance of a patient falling down would not be increased by the use of the ambulatory IV device.

To ensure that all potential hazards of the device have been explored, research was done on the potential effects of air in the fluid line. Results in the “Testing Results” section show the amount of time that a patient would have to get help if this situation did occur. While the chance that air would actually reach the patient’s body in such an improbable sequence of events is so remote, the effects of the air on the human body were researched to see what might happen in this worst case scenario.

5.1 CALCULATION METHODS

Below are the methods used for calculating the results of air being introduced into the fluid line. Although rare, air could be accidentally infused into a patient’s body during ambulation. Varying from person to person, an amount of 10 milliliters or more of air could be harmful to patients (Philip). Analysis was done to further investigate the maximum amount of air that can get into a patient while using our system. There are two possible ways for air to enter the patient from the IV system: if the fluid is totally pumped out of the IV bag, or if the drip chamber was tipped over and air was allowed in the tubing system. For both cases, the volume of air was measured and the mass under atmospheric conditions was determined using the ideal gas equation:

\[ PV = nRT \]  \hspace{1cm} \text{Equation (1)}

where \( P \) is the pressure, \( V \) is the volume, \( n \) is the number of moles, \( R \) is the universal gas constant, and \( T \) is the temperature. The mass, \( m \), can be obtained by multiplying the number of moles (\( n \)) with the molecular mass (\( M \)) of the substance, which is air. This relationship is given by the following equation:

\[ m = n \times M \]  \hspace{1cm} \text{Equation (2)}

Using mass conservation, the volume of air was once again calculated under body conditions (absolute pressure of 103325 Pa and temperature of 310 K). The results obtained were compared to the maximum
The percentage of error for this volume measurement was also calculated to make sure that the data acquired was valid.

5.2 RESULTS AND DISCUSSION

The calculations discussed below were based on the worst possible case that could occur while ambulating with our device. Assumptions were made about the amount of air that could be infused into the patient’s body from the IV bag and drip chamber. The assumptions are:

- The empty space in a new IV bag is filled with air (i.e. bag was not properly bled at setup).
- Air occupies half of the drip chamber during operation.

5.2.1 Results

The mass of air in the IV bag was 0.0118 grams at atmospheric pressure and room temperature. Under normal body conditions, the equivalent volume of air was 9.92 mL. On the other hand, the amount of air that occupies the drip chamber was equal to 8.43 mL under body conditions. The percentage error for the volume measurements was 5.76%. Equation 3 below is used to obtain the uncertainty of the volume measurements.

\[
U_Y = \sqrt{\left(\frac{\partial f(\theta_1, \theta_2, \ldots, \theta_n)}{\partial \theta_1} u_{\theta_1}\right)^2 + \left(\frac{\partial f(\theta_1, \theta_2, \ldots, \theta_n)}{\partial \theta_2} u_{\theta_2}\right)^2 + \cdots + \left(\frac{\partial f(\theta_1, \theta_2, \ldots, \theta_n)}{\partial \theta_n} u_{\theta_n}\right)^2}
\]

Equation (3)

where \(U_Y\) is the uncertainty, \(f\) is the volume function, and \(U_\theta\) is the accuracy of the device. The error percentage is defined as the ratio of the uncertainty to the volume measured as given by Equation 4.

\[
R = \frac{U_Y}{V} \cdot 100
\]

Equation (4)

where \(R\) is the error percentage, \(U_Y\) is the uncertainty, and \(V\) is the volume measured. The results obtained are shown in table Table 1. The actual calculations for the volumes and error percentage are included in Appendix B.

<table>
<thead>
<tr>
<th>Table 1: Results of Calculations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Atmospheric Volume</strong></td>
</tr>
<tr>
<td>(mL)</td>
</tr>
<tr>
<td>IV bag</td>
</tr>
<tr>
<td>Drip chamber</td>
</tr>
</tbody>
</table>

30
Based on these results, it is clear that the amount of air that could be infused into the patient is far less than the limit of 0.50 mL per kg of body weight (Miller, 2008). However, most medical experts agree that an amount of 1 mL would be the reasonable limit. Therefore, the air contained in the bag and the drip chamber could be very harmful if it gets into ambulating patients.

**5.2.2 Discussion**

Air infusion could cause a great risk to patients with congenital heart disease (CHD). Among CHD patients, blood from the vein could bypass the right side of the heart to the left side of the heart due to high-pressure gradient. There is concern that the infused air would travel from the venous to arterial system and then ultimately to the brain.

Yet CHD only occurs in three out of one million people in the world (Perloff, 396). It is a very small percentage compared to the number of people who receive ambulation. Furthermore, patients with CHD have obvious symptoms that can be recognized physically by nurses and doctors. Our device will not affect this small percentage of patients since it is only intended for recovering post-surgery patients, meaning they are stable and have the abilities to do their daily activities without help from other people.

However, the amount of air contained in the bag and the drip chamber could possibly cause dangerous effects to patients without significant risk to CHD related problems. As a solution, the bag is placed in a position at which only about three quarters of its volume is underneath the mesh of the pressure infuser bag. With this setting, there would be some amount of fluid left in the bag at the end of each ambulation period, thus avoiding any air trapped in the IV bag from getting into the line. As a standard procedure, medical staff should also drain air out of the IV bag before it is used for ambulation (Richardson, 135. Otto, 9). Figure 13 below shows clearly the position of the IV bag around the pressure infuser bag.
Figure 13: Position of IV Bag in the Pressure Infuser Bag.

Based on the experiments done, it is found that a column of air would take about eight minutes to get from the drip chamber to the end of the tube at a flow rate of 30 drips/minute. The average velocity of the column of air inside the tube is 11.37 inches per minute. This means that if air ever gets into the line, the patient would have enough time to stop the flow and drain the air out through the release valve. Therefore, there would be plenty of time for assistance before air gets into the body of a falling (unconscious) patient.

From the analysis and discussions above, there is a very slim chance of air infusion while ambulating using our device. Infusing air into the body could be dangerous but it is proven that the rate at which such infusion would happen is very low. Safety measures such as preventing the fluid bag from completely emptying is taken to prevent air infusion while ambulating. Figure 13 above shows the fluid bag arrangement that prevents this. Standard procedures for medical staff on using IV equipment will also reduce the risk of air infusion.
6. HOSPITAL ACCEPTANCE

Upon completion of our final design prototype, we brought our device to Brigham and Women's Hospital for final testing and approval. Our project mentor, Stephen B. Corn, M.D. of Brigham and Women's Hospital and Children's Hospital in Boston, was able to test the device on participating health care professionals and actual hospital patients. It was found that the device performed to the full satisfaction of all medical personnel present. The device performed all critical functions as intended, namely effective infusion of IV fluid in a safe and comfortable manner. Moreover, the materials that make up the harness were found to be an optimal balance of comfort, cost, and support. Similarly, the ergonomic design of the harness was complimented for its simplicity and ease of use. Figure 14 illustrates the intended use of the final prototype.

The only suggested modifications were the inclusion of a color coding scheme and labeling of the Velstretch® straps. Dr. Corn felt that the design would benefit from color coding to signify the sides of the straps that would be in contact with the person's body. This would make it much easier for an unfamiliar user to put the harness on, without twisting the soft straps. Similarly, strap labels would allow a user to immediately distinguish between the waist and shoulder straps, which look somewhat similar. These changes would be easily incorporated into a production version of our prototype.

Finally, Dr. Corn has proposed the possibility of publishing portions of our research and testing. This work would be conducted after the completion of this course in a joint effort between Stephen Corn, M.D. and our design group. Such publication could aid in the advancement of our design into production, thus improving the standards of ambulatory intravenous infusion in hospitals.

Figure 14. Final Prototype
7. FUTURE WORK

At this stage of the project, we have developed a design concept that will address the need for a safe and convenient ambulatory IV infusion device. However, some minor design modifications, or introduction of secondary models could make the device available for a wider range of users. Our final design has been found to be optimal for the hospital environment, where secondary designs could be marketed more toward home use of every-day IV users.

7.1 ONE PIECE HARNESS AND BLADDER

A secondary design that has been looked into incorporates a harness with a built in inflatable bladder. This design would be similar to the current design, but it would incorporate the pressure infuser bag and harness as one part. The section of the harness that is securing the fluid bag would be an inflatable bladder, similar to a standard blood-pressure cuff, which would apply pressure on the fluid bag. By combining the infuser bag and harness, this design will help minimize the number of parts and steps involved in transferring the unit between stationary and ambulatory use. The current design would have the fluid bag being removed from the stationary location, placed into the infuser bag, then placed into the harness. The new design would allow the fluid bag to be placed directly into the harness, where it could be pressurized to infuse the fluid. Similar to the existing infuser bag, the device would be manually pressurized using a hand pump, and would include a relief valve to prevent over inflation.

Although this one-piece design appears to be simpler than our final design concept, it would take away some of the versatility attained by our design. The ability to remove the fluid bag from the harness during use is critical. If the patient has to use the restroom, change clothes, or lie down temporarily, it would be desirable to remove the fluid bag while still keeping it pressurized. This one-piece design would make this extremely difficult, as the entire harness would have to be removed in order to keep pressure on the fluid bag. Therefore, this design was thought of as unfavorable for hospital use. However, it would be ideal for someone who requires frequent IV or medication infusion at home. This design would allow the person to simply put their fluid bag in the one-piece harness, without worrying about the intermediate step of using the separate infuser bag.
8. CONCLUSION

Considering the issues surrounding the use of the current pole and IV bag setup, it is clear that some modifications to the ambulatory intravenous system are necessary. Basing our design on Stephen B. Corn MD’s patent (#5,776,105), we have attempted to build a prototype based on safety, cost, and convenience issues. Our design allows for the safe and convenient ambulation while making use of standard hospital IV equipment. This easy to use and ergonomic design allows the patient to move more freely and without the hazards encountered with the current ambulatory system.

After performing an extensive patent search to investigate other products on the market, it was concluded that no patent exists to fulfill all of the requirements stated in this report. This search also certified that our design would not be infringing upon any existing patents.

As a result of balancing concerns of safety, cost, and convenience, a final design concept was developed. The type of infuser bag and pumping mechanism employed in this device are currently used for several hospital applications. Knowing this, the device will be much more accepted by health care professionals, as they are already familiar with its operation.

From extensive testing, we were able to gather valuable information about the behavior of the ambulatory intravenous fluid holder. The most important discovery was that under normal operating conditions, regardless of the equipment setup, the roller clamp was the most effective way to adjust drip rate. This is ideal since healthcare personnel use the roller clamp for adjustments in current IV setups.

Another observation was how easily the system can be controlled. Supplying adequate fluid flow over a long period of time requires minimal user input. If the ambulating period is less than 40 minutes, the patient will not be required to interact with the device at all. If the patient ambulates for longer than 40 minutes, some input will be required. The bag should be pumped four times every ten minutes to maintain a high enough pressure gradient for adequate IV fluid flow.

At our commencement of this project, we have developed a design concept that will address the need for a safe and convenient ambulatory IV infusion device. Our final design prototype has been satisfactorily tested and approved at Brigham and Womens Hospital in Boston.
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Heart Point. *Atrial Septal Defect.* [www.heartpoint.com/congasd.html](http://www.heartpoint.com/congasd.html)


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Philip J.H, M.E.(E.), M.D. Director of Technology Assessment Brigham and Women's Hospital. Anesthesiologist and Director of Clinical Technology and Bioengineering Department of Anesthesiology, Perioperative and Pain Medicine Brigham and Women's Hospital, Associate Professor of Anesthesia Harvard Medical School.

**APPENDIX A: TEST DATA AND RESULTS**

Test 1: 20 Gauge Catheter; Large Infuser Bag

<table>
<thead>
<tr>
<th>Time (sec)</th>
<th>Volume (cc)</th>
<th>Drips per min</th>
<th>Pumps</th>
</tr>
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<td>0</td>
<td>60</td>
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</tr>
<tr>
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<td>28</td>
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<td>3</td>
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<td>20</td>
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<td>5462</td>
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</tr>
</tbody>
</table>

**Time vs Fluid Volume**

*20 Gauge Catheter and Large Infuser Bag*
Test 3: 18 Gauge Catheter; Small Infuser Bag

<table>
<thead>
<tr>
<th>Time (sec)</th>
<th>Volume (cc)</th>
<th>Drips per min</th>
<th>Pumps</th>
</tr>
</thead>
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<tr>
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<td>24</td>
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</tr>
</tbody>
</table>

**Time vs Volume**

18 Gauge Catheter and Small Infuser Bag

\[
y = 0.0243x + 2.0004 \\
R^2 = 0.998
\]
Test 4: Drip rate vs. time

<table>
<thead>
<tr>
<th>Time (min)</th>
<th>Drip Rate (1)</th>
<th>Drip Rate (2)</th>
<th>Delta 1</th>
<th>Delta 2</th>
</tr>
</thead>
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<td>-</td>
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<td></td>
</tr>
</tbody>
</table>

**Drip Rate vs. Time**

- Drip Rate (Trial 1)
- Drip Rate (Trial 2)
Velocity of Column of Air at Maximum Flow Rate of 30 drips/min

<table>
<thead>
<tr>
<th>Run #</th>
<th>Time (min:sec)</th>
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<tbody>
<tr>
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</tr>
<tr>
<td>2</td>
<td>7:30</td>
</tr>
<tr>
<td>3</td>
<td>8:45</td>
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<tr>
<td>4</td>
<td>7:40</td>
</tr>
<tr>
<td>5</td>
<td>8:13</td>
</tr>
</tbody>
</table>

**Average Time** 8:01

\[ Velocity = \frac{L_{\text{tube}}}{t_{\text{average}}} \]

\[
= \frac{9 \text{ in}}{8.0167 \text{ min}} \\
= 11.37 \text{ in/min}
\]
Appendix B: Analysis

Air in bag:

Volume of air, \( V = (4.5 \times 13 \times 0.2) - (A_{\text{curvature}} \times 2) \)

\[ A_{\text{curvature}} = \frac{V}{2} \left( \frac{S}{V} - \sin \left( \frac{\theta}{2} \right) \right) \]

\( S \): arc length
\( V \): volume

\[ = \frac{4.25 \times \left( \frac{9.5}{4.25} - \sin \left( \frac{9.5}{4.25} \right) \right)}{2} \]

\( = 9.85 \text{ cm}^3 \)

\[ V = 0.2 \left[ (4.5 \times 13) - 9.85 \right] \]

\( = 9.73 \text{ cm}^3 \)

- At atmospheric conditions:

\[ PV = nRT \]

\[ n = \frac{PV}{RT} = \frac{(101325 \text{ Pa})(9.73 \times 10^{-6} \text{ m}^3)}{(8.314 \frac{\text{ J}}{\text{ mol} \cdot \text{ K}})(298 \text{ K})} \]

\( = 2.98 \times 10^{-4} \)

\[ \text{mass} = nM = (3.98 \times 10^{-9})(28.97) = 0.01153 \text{ g} \]

- At body conditions:

\[ V = \frac{nRT}{P} = \frac{(2.98 \times 10^{-9})(8.314)(209.82)}{(101325 + 2000)} \]

\( = 9.92 \times 10^{-6} \text{ m}^3 \)

\( = 9.92 \text{ cm}^3 \)
Air in Drap Chamber:

Volume of air: \( V = \frac{\pi}{4} d^2 h \) 
\[ \frac{\pi}{4} \times (1.8)^2 \times (3.25) \]
\[ = 8.27 \text{ cm}^3 \]
\[ = 8.27 \times 10^{-6} \text{ m}^3 \]

- At atmospheric conditions:

\[ n = \frac{101325 \times (8.27 \times 10^{-4})}{(8.314 \times 298)} = 3.382 \times 10^{-4} \]

\[ \text{mass} = 3.382 \times 10^{-4} \times (28.97) \]
\[ = 0.00978 \text{ g} \]

- At body conditions:

\[ V = \frac{nRT}{P} = \frac{(3.382 \times 10^{-4}) \times (8.314) \times (305.82)}{(101325 + 2000)} \]
\[ = 8.43 \times 10^{-6} \text{ m}^3 \]
\[ = 8.43 \text{ cm}^3 \]
\section*{ERROR PERCENTAGE:}

\textbf{IN BAG:}

\[ V = \text{width} \times \text{length} \times \text{height} = w \times l \times h. \]

\[ \frac{dV}{dw} = lh \quad \frac{dV}{dl} = wh \quad \frac{dV}{dh} = wl. \]

\[ u_w = u_l = u_h = \pm 0.5 \text{ mm} = \pm 0.05 \text{ cm} \]

Uncertainty, \[ u_V = \sqrt{\left( \frac{dV}{dw} u_w \right)^2 + \left( \frac{dV}{dl} u_l \right)^2 + \left( \frac{dV}{dh} u_h \right)^2} \]

\[ = \sqrt{\left[ \left(4.5\times 0.05\right)^2 + \left(4.5\times 0.05\right)^2 + \left(45\times 0.05\right)^2 \right]} \]

\[ = \pm 2.93 \text{ cm}^3 \]

\[ \%\text{ error} = \frac{2.93}{11.7} = 2.5\% \]

\textbf{IN DRY CHAMBER:}

\[ V = \frac{\pi}{4} d^2 h. \]

\[ \frac{dV}{dd} = \frac{\pi}{2} dh \quad \frac{dV}{dh} = \frac{\pi}{4} d^2 \]

\[ u_d = u_h = 0.05 \text{ cm}. \]

Uncertainty, \[ u_V = \sqrt{\left( \frac{dV}{dd} u_d \right)^2 + \left( \frac{dV}{dh} u_h \right)^2} \]

\[ = \sqrt{\left[ \frac{\pi}{2} (18)(0.05)^2 \right]^2 + \left[ \frac{\pi}{4} (18)^2 (0.05)^2 \right]} \]

\[ = \pm 0.9767 \text{ cm}^3 \]

\[ \%\text{ error} = \frac{0.9767}{8.27} = 5.76\% \]
APPENDIX C: PLASTIC HARD-SHELL WITH LONGITUDINAL PRESSURIZATION
APPENDIX D: CALCULATIONS OF THE HEIGHT OF WATER COLUMN FOR BODY PRESSURE SIMULATIONS.

For testing fixture:

Pressure, \( p = \text{SG} \cdot \rho_{\text{H}_2\text{O}} \cdot h \cdot g \),

where \( \text{SG} \) is specific gravity
\( \rho_{\text{H}_2\text{O}} \) is density of water
\( h \) is height of column of water
\( g \) is gravitational acceleration.

at 15 mm Hg or 2000 Pa,

\[ h = \frac{p}{8.3 \cdot \rho_{\text{H}_2\text{O}} \cdot g} \]
\[ = \frac{2000}{(1014 \times 1000 \frac{kg}{m^3})(9.81 \frac{m}{s^2})} \]
\[ = 19.3 \text{ cm} \]

Therefore, to simulate body pressure, height of column should be 19.3 cm.

\[ \text{Diagram:} \]

\[ 19.3 \text{ cm} \]
APPENDIX E: VOLUME FLOW RATE CONVERSION METHOD

Maximum flow:

\[
125 \text{ cc} \times \frac{1 \text{ hour}}{60 \text{ min}} \times \frac{15 \text{ drops}}{\text{ cc}} = 31.25 \text{ drops/min}
\]

Minimum flow:

\[
25 \text{ cc} \times \frac{1 \text{ hour}}{60 \text{ min}} \times \frac{15 \text{ drops}}{\text{ cc}} = 6.25 \text{ drops/min}
\]
APPENDIX F: CLAIMS OF PATENT NUMBER 5,776,105

1. An ambulatory intravenous fluid delivery system comprising: a holder for securing a source of
intravenous fluid to a patient's body; pressurization means for applying pressure to the intravenous
fluid to induce infusion; an infusion line adopted to delivery fluid from the source to a patient; a drip
chamber disposed between the source of intravenous fluid and the infusion line through which the fluid
can flow in a controlled manner; and a drip chamber mounting element for mounting the drip chamber
to the holder, the mounting element serving to maintain the drip chamber in a substantially vertical
orientation in use.

2. The system of claim 1 wherein the holder further comprises at least one belt for encircling a patient's
body.

3. The system of claim 1 wherein the holder further comprises at least one shoulder strap.

4. The system of claim 1 wherein the holder further comprises at least one pouch-forming element for
holding an intravenous fluid source.

5. The system of claim 1 wherein the pressurization means further comprises a mechanical pressure
infuser.

6. The system of claim 1 wherein the pressurization means further comprises an pressurizable infuser bag
having an inflatable chamber.

7. The system of claim 6 wherein the pressurization means further comprises a manual pump for inflating
the infuser bag.

8. The system of claim 6 wherein the pressurization means further comprises a valve to prevent over
inflation of the infuser bag.

9. The system of claim 6 wherein the pressurization means further comprises a pressure gauge for
measuring the pressure within the infuser bag.

10. The system of claim 1 wherein the system further comprises a conduit for conveying intravenous fluid
between the infusion source and a drip chamber.

11. A method of delivering intravenous fluid to an ambulatory patient comprising: securing a source of
intravenous fluid to a patient's body via a holder; connecting an infusion line having a vertically-
oriented drip chamber and a stop valve to the source; mounting the drip chamber to the holder via a
mounting element that ensures that the drip chamber is maintained in a vertically orientation so that
fluid can flow through the drip chamber from the source of intravenous fluid to the infusion line in a
controlled manner; applying pressure to said source; and opening said stop valve so that the fluid can
be delivered to the patient.

12. A system of claim 1 wherein the mounting element further comprises a swivel mechanism to maintain
the vertical orientation of the drip chamber.