

Valve for Bodily Fluid Drainage for Paralyzed Individuals

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Client: Dan Egan

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ABSTRACT

Urine storage and drainage are problems that many individuals confined to wheelchairs face on a daily basis. Currently, systems are available that collect fluid wastes, such as urine, into a bag that can be drained through medical tubing. A valve that can be opened by the individual when the bag has reached its capacity regulates this restriction of urine flow. Often, these valves can have wire failures or sedimentation collection from the passage of urine over time restricting the open flow of fluid and causing problems for the user, including slow draining times. A fluid drainage valve must be designed to fix these problems while creating a safe and comfortable system for the individual to use without worry or embarrassment. Through the processes of brainstorming and background research, design alternatives were generated. Further research must still be done to conclude on what would be the best solution: a solenoid pinch valve, occluding the urine flow; an air-pressurized valve; and an electromagnetic cap valve are possible solutions that would improve the urine drainage system for the client.

INTRODUCTION

Many people have suffered injuries that have left them confined to wheelchairs. As a result they lose the ability to perform many typical daily activities. One of these activities is the drainage of waste fluids. Since these individuals no longer have the ability to urinate, a catheter must be fed through the abdomen to the bladder to collect the urine. The catheter drains the urine through a tube into a bag placed near the ankle. The bag must be drained periodically through another tube that is opened and closed using a mechanical valve (Figure 1).

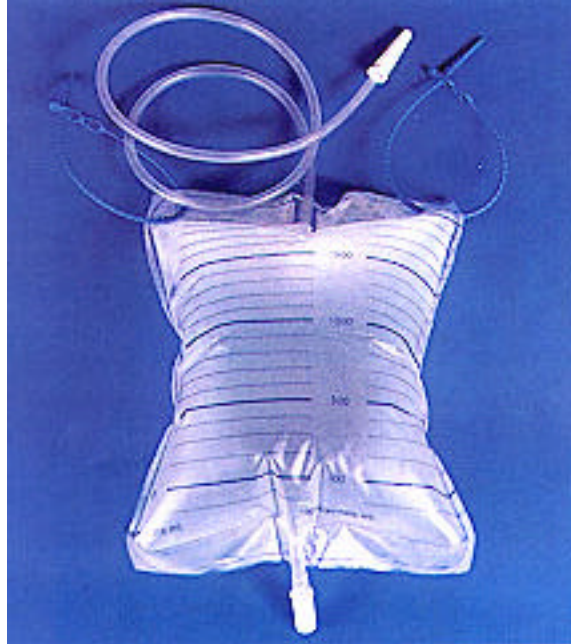


Figure 1: Urine bag and tubing used to drain bladder. Picture taken from www.narang.com/urinebag.html (11).

In many cases the individual is physically unable to manually release the valve to drain the urine and requires assistance to do so. This restriction can be limiting and embarrassing to the individual. A device must be created that allows the individual to control the drainage of the urine at his or her own discretion.

The client for this project, Dan Egan, is one such individual. A high school football injury crushed three of Dan's cervical vertebrae (C4 through C6), which left him paralyzed from the waist down, with limited motion of his arms, and unable to perform urinary function. His limited range of motion prevents him from being able to open and close the mechanical valve on the tubing coming off of the urine bag.

PROBLEM STATEMENT

In order to better suit the needs of individuals that are paralyzed, handicapped, or make use of a wheelchair on a daily basis, the goal is to design a waste-fluid drainage system for the well-controlled, accurate and dependable disposal of stored liquid wastes. The device must incorporate a secure valve system that controls the flow of urine that is stored in a one-liter bag attached to the user's leg. Typically, the bag needs to be emptied only once in an eight-hour workday. The opening and closing of the valve must operate solely at the discretion of the user, without failure in any conditions, via a switch located within accessibility of the user. The urine that passes through the tubes or the device must not sediment over time. Additionally, the device must remain unobtrusive.

The main goal of the project is to construct the valve so that a one-liter fluid bag is able to drain quickly upon opening of the valve. We hold comfort, ease of use and safety of the client as paramount aspects of the device, while offering the product at a reasonable cost.

Some of the most important specifications for the design of this project are

- (1) Low failure rate (due to urine sediment or wiring problems)
- (2) Accidental drainage prevention (operate only at user's discretion)
- (3) Drainage time (as quickly as possible)
- (4) Safety (electrical components sealed, leakage prevented, etc.)

For a complete listing of the design specifications see Appendix A (Product Design Specifications).

INFORMATION GATHERED

A significant amount of research was done to gather information for the project design. Websites, Internet searches, personal contacts and textbooks were utilized to gather the information. A reference list is contained in Appendix B. The background information is contained in detail in Appendices C - G.

Initial information was obtained from a meeting with Dan Egan, the project client, on the device that he is currently using. This device consists of a solenoid valve whose inlet is attached to the tubing from the urine bag. Additional tubing is attached to the outlet of the valve. This tubing runs near the floor where the urine drains out. The valve is wired to the battery of Dan's wheelchair, which it uses as its power supply. The valve is also wired to a normally closed, toggle switch that Dan controls. An internal spring keeps the switch closed. When the switch is held in the on position the valve is opened and the urine drains out of the bag into a drain in the floor. For more information on the current device and the meeting with Dan see Appendix C (14).

Current devices similar to the product being designed were researched to help gain an understanding of what existing products were available. Internet searches were performed and several products were found. One product found was the "Power leg-bag emptier" (1). Acro Associates is a company that specializes in making solenoid valves for the application of medical fluid drainage (2). Patent searches were also done for existing devices similar to the design ideas. Several products and companies were found (1,3,4). Towards the end of the semester a product was found that was very similar to the design of the project. This product, the "Electric Leg Bag Emptier," manufactured by

21st Century Scientific, Inc. has two models, both of which use a valve wired to a switch with wiring that connects to the batteries of the power wheelchair (15) (Appendix D).

Since having a valve is essential to the design, various kinds of valves were researched, mostly through Internet searches and company website searches. Several valve companies were found. Many of these companies had valves with options that would be very beneficial to the design specifications for this project. Several important valve characteristics were found. Some valves had the option of either a normally closed or normally open design. Some valves could be run off of a DC voltage supply. The valves were made of a variety of materials including Teflon and stainless steel. A few solenoid valve companies were found and given special attention since the valve that Dan is currently using is a solenoid valve. One specific type of solenoid valve that was looked at was the pinch valve, which would simply “pinch” off a tube, preventing the fluid drainage, while the valve was closed. A few companies that supply pinch valves are ASCO valves (5), Acro Associates (2), and Bio-Chem Valve Inc. (16). A notable advantage to using a pinch valve is that the fluid being drained never comes in contact with the internal components of the solenoid. A great deal of information was found on many types of valves, their characteristics, and the companies that supply them (2, 5-7) (Appendix E).

The valve currently being used by the client, a Red-Hat valve from ASCO Valves, is part of a large family of valves whose function is dependent upon solenoids. Also, many pinch valves and isolation valves are solenoid valves. The design and mechanisms of solenoid valves are discussed in Appendix G (2, 12, 13).

The components of urine lead to problems with the current device because of blockage from urine sedimentation. Research was done to find the components of urine that lead to crystal formation (sedimentation). It was found that the crystal formation from urine is mostly attributed to the formation of mineral crusts, which are composed of either hydroxyapatite or struvite. This information promoted research of materials that would prevent the attachment of these mineral crusts to the valve, and thus prevent blockage. Some of the materials found that would inhibit attachment were heavy metal cations, Teflon (TFE polymers) and hyaluronan. A more detailed description of the contents of urine and of the coating materials can be found in Appendix F (8-10).

DESIGN ALTERNATIVES

The two main design tasks for this project are to design a valve that controls the flow of urine through a tube and to design a system, which controls the state (on or off) of this valve. After brainstorming, the design alternatives for the valve were subdivided into three categories: improving the current device, purchasing an existing valve, and designing a new valve. Design alternatives for the control system include variations in the wiring and switch design.

Valves:

Improving the Current Device

The ASCO Red-Hat valve currently in use could be re-designed to better meet the needs of our client. Proposed changes:

- Increase the diameter of the drainage hole in the valve (current diameter is ~ 2-3mm). This would allow more fluid to flow through the valve per unit time, thus decreasing the total drainage time.

- Coat surfaces of the valve with a material that would prevent the formation of mineral crusts. Possible coatings include metal cations (Fe^{3+} , Ga^{3+} , and Cd^{2+}) or hyaluronan.

Purchasing an Existing Valve

Many different types of valves currently exist on the market, many already in biomedical applications. One design alternative is to purchase an existing valve and apply it to our problem. Some types of existing valves are:

- Pinch Valves: These valves are either solenoid actuated or pneumatic. They pinch off a tube to stop the flow of fluid. These valves are available in a wide variety of sizes and are compatible for tubing of different diameters. (Figure 2).
- Isolation Valves: These valves keep the fluids separate from the solenoid, which would help to prevent crystal formation. They can also be coated with Teflon, which is chemically resistant. (Figure 3).



Figure 2: Solenoid Pinch Valve manufactured by Bio-Chem Valve Inc. Is compatible for tubing with inner diameter 5/16 in.



Figure 3: Solenoid Isolation Valve manufactured by Nresearch Inc. Picture copied from www.nresearch.com (12).

Designing a New Valve

During brainstorming, many new ideas for valve designs were suggested. These ideas can be grouped into four categories: Mechanical, Pneumatic, Electromagnetic, and Chemical.

- Mechanical:
 - “Coleman Cooler” – This idea is based upon the spigot attached to many larger drink coolers. A button would be depressed (likely through electrical control) that would open a hole through which fluid would flow. Releasing the button would close the hole and stop drainage. (Figure 4)
 - “Garden Hose” – This idea is based upon the garden hose attachment that, when twisted, opens a hole through which water flows. More twisting results in increased flow, whereas reverse twisting stops the flow. (Figure 5)
 - “Athletic Squirt Bottle”- Like typical squirt bottles, this idea involves a cap that when pulled allows fluid to exit the tubing. When the cap is pushed back to its original position, flow will cease. (Figure 6)
- Pneumatic:
 - “Air Bubble/Pressure”- This design uses varying air pressures to control when fluid is released from the tubing. A pocket of air is injected to reseal tubing after each emptying of the bag. (Figure 7)

- Electromagnetic:
 - “Electromagnetic Cap”- The electromagnetic valve concept utilizes magnetism to raise and lower a metal plunger inside rubber tubing (Figure 8). The necessary components for this design include a metal plunger with a rounded, cupped end piece that could seal off a section of latex tubing, a circular electromagnetic cuff that could fit around the tubing, and a power source, preferably the 24 Volt power supply found on most electric wheelchairs.
 - When the electromagnet is off, the weight of the plunger and the fluid will be enough force to pull the plunger down (Figure 8), creating a tight seal between it and the flexible rubber tubing and preventing any fluid from leaking out. This ensures that the valve will be in a normally closed position, and that accidental leakage is prevented even if the power supply fails. When the fluid needs to be drained, the electromagnet will be activated, creating an electric field that will attract the metal plunger, pull it up (Figure 9), and let the fluid drain around it and out the bottom of the tubing. This will allow the bodily fluids bag to be emptied at the user’s convenience, anywhere that a floor drain is available.

- Chemical:
 - All of the above ideas could utilize a chemical coating to prevent crystal formation and the adhesion of proteins and bacteria. This coating would help to prevent slow drainage and/or failure due to clogging.

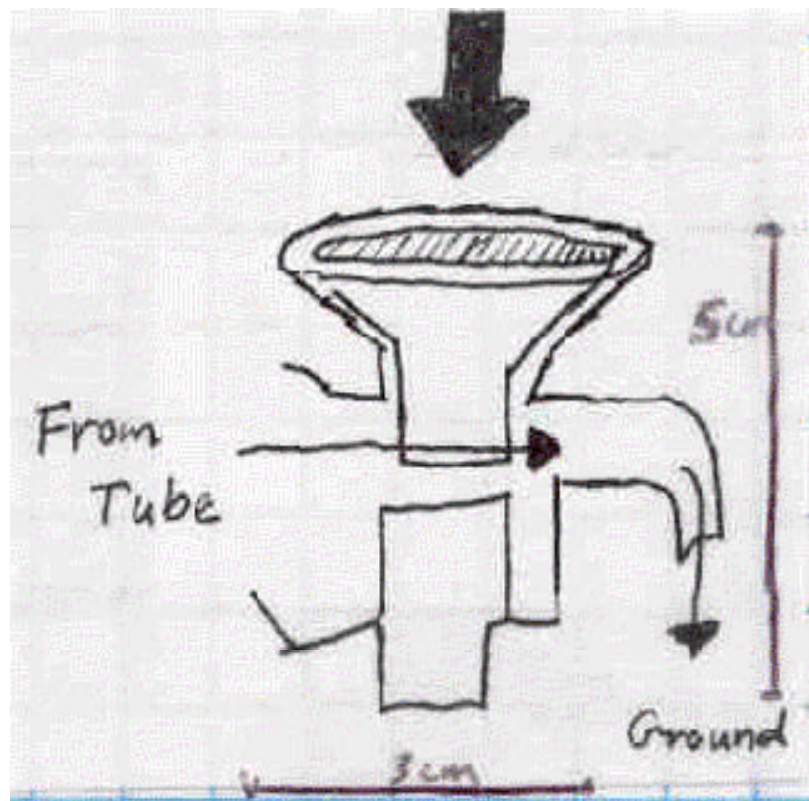


Figure 4: Sketch of “Coleman Cooler” valve design.

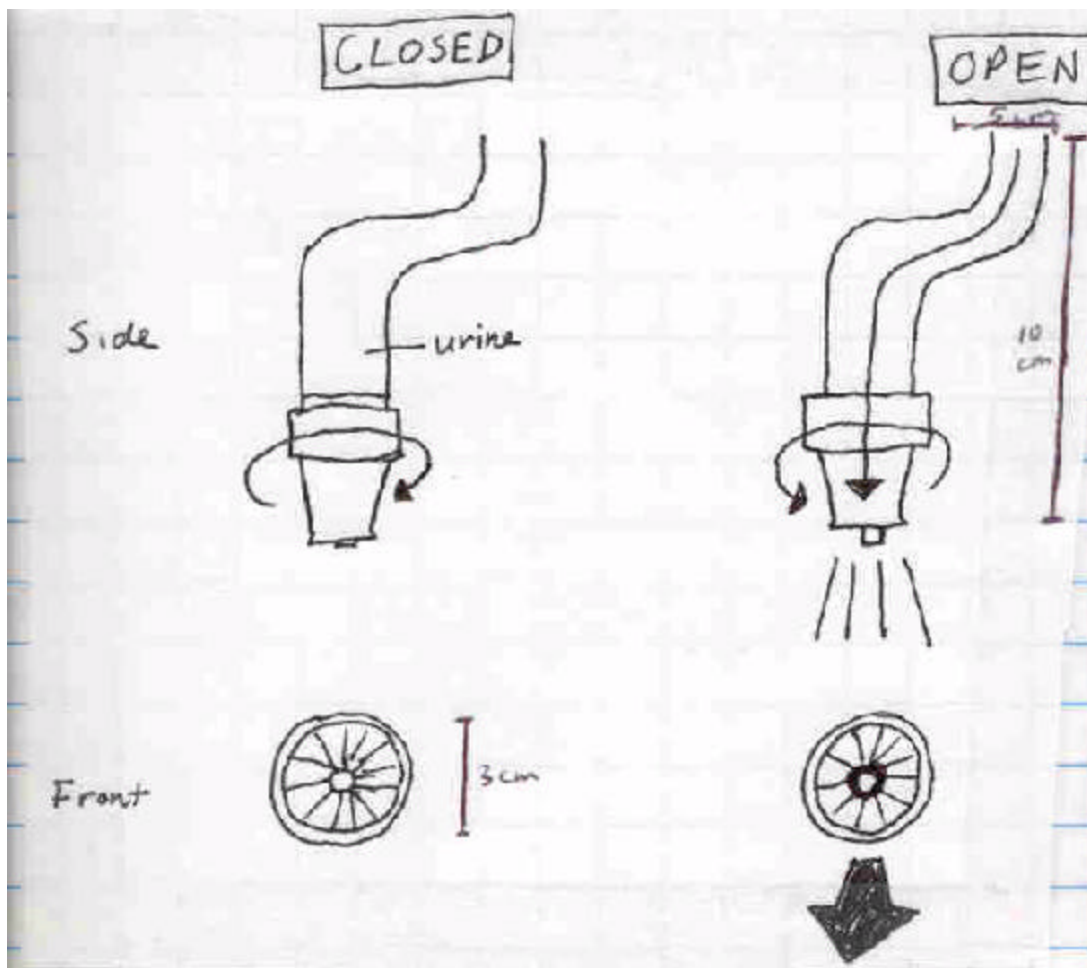


Figure 5: Sketch of "Garden Hose" valve design.

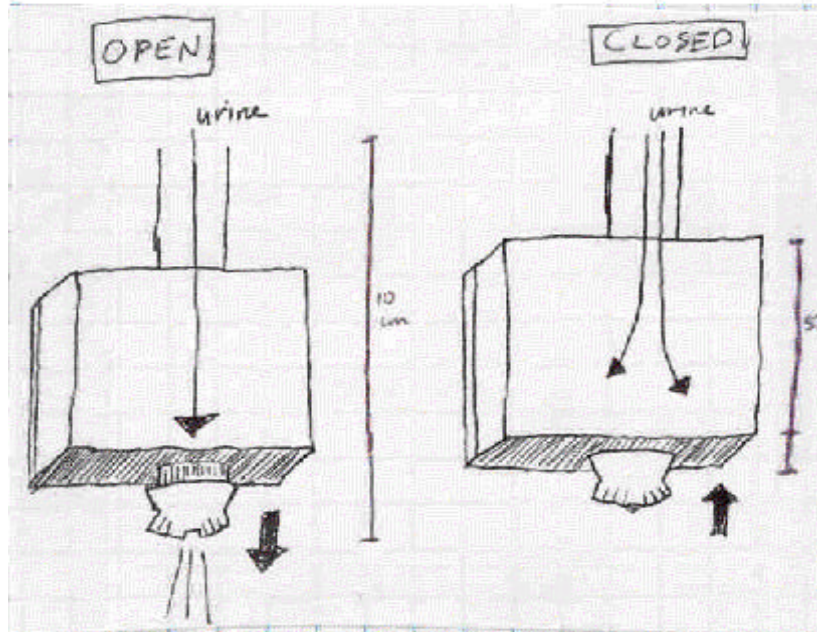


Figure 6: Sketch of "Athletic Squirt Bottle" valve design.

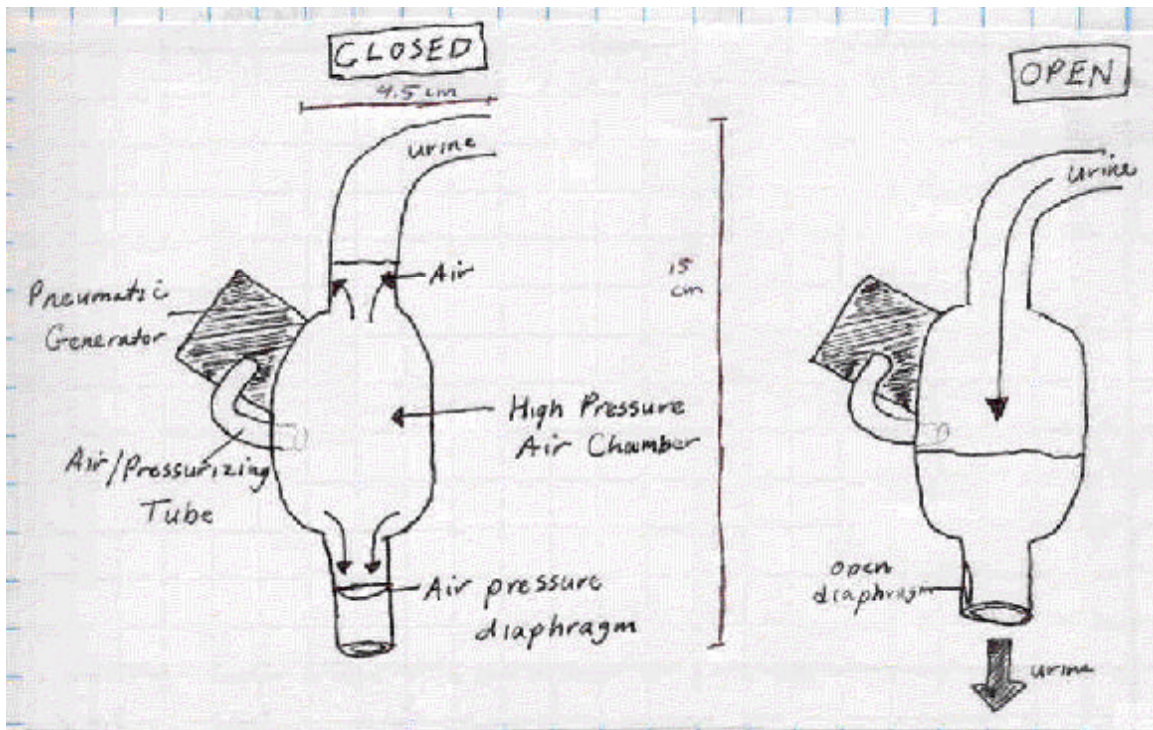


Figure 7: Sketch of "Air Bubble/Pressure" valve design.

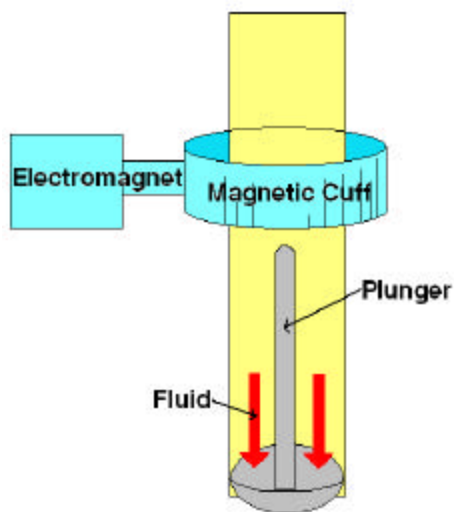


Figure 8: Diagram of “Electromagnetic Cap” valve design in closed position.

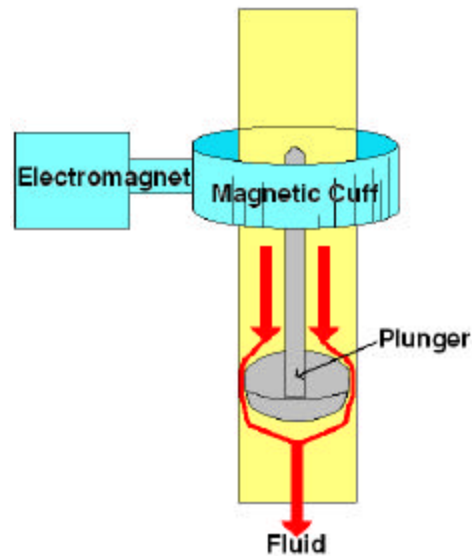


Figure 9: Diagram of “Electromagnetic Cap” valve design in open position.

Control System: Switch

The toggle switch currently being used is an adequate solution for the control system. A wireless remote control option is being considered, as well as a cover for the switch to help prevent accidental drainage (Figure 10).

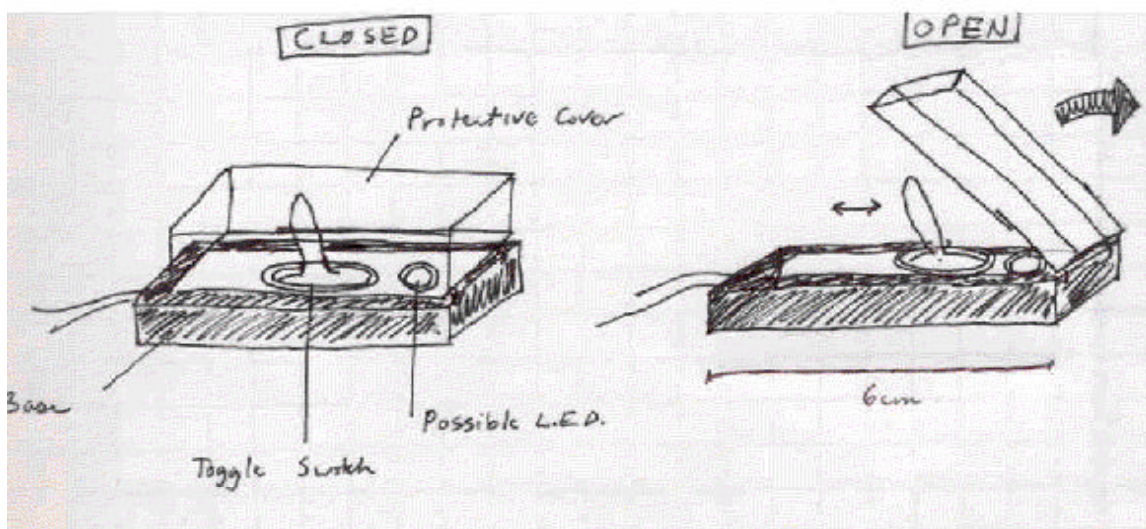


Figure 10: Sketch of protective switch cover design.

Wiring

In order to prevent wire failure we are considering the following:

- Thicker Insulating Wire – The insulation used on the wiring for the current device is the typical plastic insulation seen on most home electronic devices. Perhaps using a higher grade, thicker insulation on the wires would help to prevent the wires from breaking and causing failure.
- Mounting the Wires to the Wheelchair – The wires on the current device are only anchored with a small piece of Velcro that holds the wire coming from the valve to the connector for the power. Mounting the wires to the wheelchair with clamps or some other mechanical option could assist in reducing the amount of flexing that the wiring undergoes, thus reducing the incidence of failure.

PRELIMINARY EVALUATION

Criteria pertinent to the design specifications were evaluated for each proposed solution in the design matrix (Appendix H). The criteria most important to the client are low failure rate, accidental drainage prevention, and drainage time. For practicality, it is also important that the design be feasible.

At mid-semester it was decided to narrow the design solutions to three main alternatives including improving on the existing valve, incorporating a pre-manufactured valve, and the “Electromagnetic Cap” design alternative. As a result there is more detailed information regarding the evaluation of these three alternatives.

The design alternatives of improving the existing valve and incorporating a pre-manufactured valve scored well specifically on feasibility, drainage time, and failure rate. An ASCO Red-Hat valve (existing valve), and a Bio-Chem series P-150 pinch valve were purchased for preliminary testing. The isolation valve was not further investigated because of the clear advantage of the pinch valve's ability to be used directly on the tubing coming off of the urine bag. When tested, the pinch valve drained a full, 1-liter urine bag much faster (in approximately 20 seconds) than the Red-Hat valve (1 minute 37 seconds). Upon examination of the Red-Hat valve, it was determined that boring the ports larger would be difficult and possibly damaging to the valve. Both options scored low in the criterion of new technology, but this is not a high priority in the design.

The "Coleman Cooler" and "Athletic Squirt Bottle" design alternatives scored well on drainage time, but scored poorly on the important criteria of feasibility and accidental drainage prevention. In regards to feasibility, electrically controlling these devices would be a considerable design challenge.

The "Garden Hose" design alternative scored well on safety, but scored poorly on feasibility for the same reasons as the "Coleman Cooler" and "Athletic Squirt Bottle" design alternatives. This alternative scored only average on drainage time because it was believed that the device would not open enough to allow for fast fluid drainage.

The "Air Bubble/Pressure" design alternative scored well on accidental drainage prevention and drainage time. Drainage would occur rapidly because, when in the open position, there would be nothing blocking fluid flow in the drainage tube. Once again, feasibility was an issue because the air pressure would be difficult to control without complicated and bulky equipment.

The “Electromagnetic Cap” design alternative scored well on accidental drainage prevention, but poorly on feasibility. This alternative scored only average on drainage time for the same reasons as the “Garden Hose” alternative.

Additionally, cleaning would be minimal, since the cuff is completely outside the tubing, and would probably need little maintenance, the tubing is changed bi-weekly, and the metal plunger could be soaked in some sort of non-corrosive cleanser every time the tubing was changed. Most importantly, it appears to be a new way of applying electromagnetism that has never been attempted before, and thus scored well in the area of new technology in the design matrix.

However, mathematically trying to calculate the magnetic force required to pull the magnet up proved that the idea probably was not very feasible. The forces acting on the plunger are its own weight, the weight of the fluid, and the force of friction along the sides of the tubing to create a tight seal. The magnetic force (F_m) would have to overcome all these forces.

$$(1) F_m > m_{\text{plunger}}g + m_{\text{fluid}}g + F_{\text{friction}}$$

Since the frictional force would have to be very large to ensure a leak-proof seal, the magnetic force required to overcome it would also need to be very large. And, the cup of the plunger would rub against the tubing all the way it was pulled up, never letting the fluid escape through. This means that some sort of necked, funnel-like tubing would need to be used so that when the plunger was pulled to the up position, the tubing diameter would be larger and the cup of the plunger would not touch the tubing sides. However, this means that the client would have to use a different type of tubing.

Although it is still feasible to find a new kind of tubing, it was difficult to determine the magnetic force the electromagnet would be required to produce. Since the friction coefficient for the tubing was unknown, the frictional force could not be mathematically determined. However, if we had actually built a prototype, we could have determined the conditions necessary for the prototype to work (17), and then derived the magnetic force using the following equations:

$$(2) F_m = i s \times B$$

$$(3) F_m = B \times qV$$

$$(4) B = \mu_0 n i$$

where F_m is the magnetic force, i is the current supplied to the magnetic solenoid, s would be the distance between the plunger and magnet, B is the magnetic field strength, q is the constant value for the charge on an electron ($1.6 \times 10^{-19} \text{eV}$), V is the voltage supplied to the magnetic solenoid, μ_0 is the permeability of free space ($4\pi \times 10^{-7}$), and n is the number of turns in the wire used to make the solenoid. Thus, changing the distance (s) between the plunger and magnet or changing the number of turns in the solenoid could vary the required strength of the electromagnet.

A prototype was never built because two additional problems became apparent with the design. First, the same magnetic field that pulled the plunger up would attract ions present in the urine, either eventually causing the tubing to clog up near the electromagnet or coating the plunger, making an even stronger magnetic force necessary. Secondly, the cap of the plunger would have to be perfectly round to create a tight seal; otherwise, if even a tiny nick were present on the side that met with the tubing, fluid would be able to leak through.

After evaluating the options through the use of a design matrix (Appendix H), testing, and obtaining further information, it was proposed that the best solution at this time would be to incorporate a pre-manufactured pinch valve.

PROPOSED SOLUTION

The pre-manufactured pinch valve that was purchased was the Series 150-P solenoid pinch valve from Bio-Chem Valve Inc. The specifications for this valve (Table I-1) and a diagram of the dimensions (Figure I-1) can be found in Appendix I. A discussion of the general operation of solenoid valves is available in Appendix G. However, a detail account of the operation of the Bio-Chem valve was not available from the company.

The pinch valve came with its own silicon tubing. This tubing was removed and replaced with the latex tubing used by the client. This tubing is connected to the outlet of the urine bag. Both urine bag and tubing are manufactured by Hollister Incorporated. A momentary toggle switch (part number 900-8524 purchased from Radio Shack) is used to control the on/off status of the valve. For the purposes of design testing a Hewlett Packard power source was used to supply the 24 Volts required for the operation of the pinch valve. However, in practical application, the two 12 Volt wheelchair batteries will be used in series to power the valve. The pinch valve is mounted to an elastic strap by way of a sewn fabric cuff. The elastic strap has Velcro attached, which will be used to fix the strap around the users calf (Figures 11, 13). Appendix J offers an overall diagram of the device. Appendix K includes a table of the prices of all of the components of the final design.



Figure 11: Attachment of urine bag and pinch valve to leg.

Product Testing

After products for two design alternatives were purchased, testing of these products was performed. The two alternatives that were tested were the existing valve and the pre-manufactured pinch valve. Both valves were tested to determine the amount of time each would take to drain approximately 1 liter of water from a urine bag. Each valve was wired to a momentary toggle switch and to a 24 Volt power supply. When the switch was held in the “on” position, the valve opened and the urine drained out of the bag.

The existing valve (ASCO Red-Hat valve) was connected to the drainage tubing coming off of the urine bag via a barb fitting that was screwed into the inlet of the valve (Figure 12). Another barb fitting was screwed into the outlet of the valve and this was where the fluid drained out of the system. The pinch valve was placed directly onto the latex drainage tubing from the urine bag so the fluid drained directly from that tubing (Figure 13). The pinch valve was also tested using the original silicon tubing that the valve was designed for. The pinch valve was placed on the silicon tubing and the latex drainage tubing from the urine bag was connected to the silicon tubing via a 2-way hose barb fitting. The fluid flowed through the drainage tubing into the silicon tubing where (when the pinch valve was opened) the fluid would drain to the ground. The results of the time testing can be seen in Table 1; the pinch valve obviously had a much faster drainage than the Red-Hat valve, even when the pinch valve was used with the silicon tubing attached to the drainage tubing.

The latex urine bag drainage tubing was left in the pinch valve (with the pinch valve in the closed position) to test for breakage of the latex tubing over time. The tubing showed no signs of wearing after being left in the pinch valve for approximately one week. Finally the entire final design system (pinch valve placed directly on latex drainage tubing from the urine bag) was tested. The system (disconnected from the power source) was worn by an individual (Figure 11) for approximately two days with no signs of leakage from the pinch valve. However, the urine bag had leakage problems.



Figure 12: ASCO Red-Hat valve attached to urine bag drainage tubing via barb fitting.

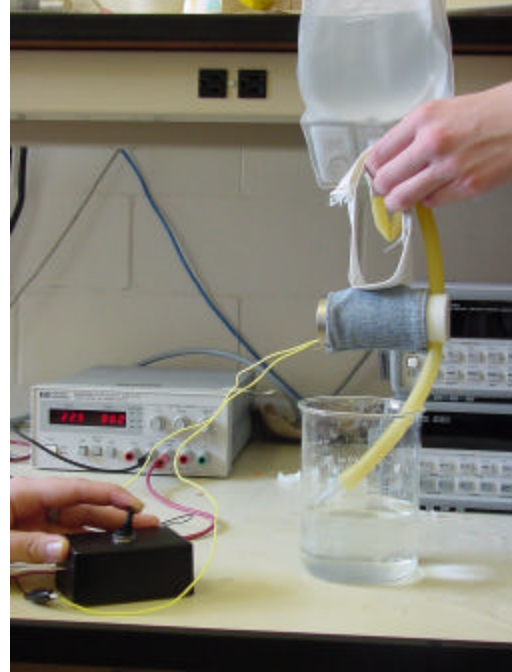


Figure 13: Pinch valve attached directly to urine bag drainage tubing. Pinch valve and switch are wired to power supply.

Testing system	Volume Drained	Time to drain
Pinch valve attached directly to latex drainage tubing coming from urine bag	1125 mL	20 seconds
Pinch valve attached to silicon tubing, which is connected to drainage tubing from urine bag via 2-way hose barb fitting	1025 mL	18 seconds
Existing (Red-Hat) valve attached to urine bag drainage tubing via barb fitting screwed into inlet of valve.	1050 mL	1 min, 37 seconds

Table 1: Results of timed tests of drainage of approximately 1Liter of water from urine bag via tubing connecting to pinch valve and Red-Hat valve.

DIFFICULTIES

Various difficulties were encountered over the course of the semester. Scheduling meeting times between the four group members was always a challenge. Another difficulty was deciding on one design solution. Since several good design solutions were formulated, it was challenging to decide which one design alternative to pursue as the

final design. Evaluation of several pertinent design criteria with respect to each design alternative was helpful with this challenge.

As mentioned, toward the end of the semester, a product was found on the market that was very similar to the proposed solution. The Electric Leg Bag Emptier 2 (15) uses a pinch valve and momentary toggle switch wired to the batteries of a power wheelchair. Although there are a few differences between this product and the proposed solution, the “Electric Leg Bag Emptier 2” would be a significant competitor for the proposed solution. There are two problems that the “Electric Leg Bag Emptier 2” has that could be capitalized on. First this product has a prohibitively high price of \$550, not including shipping costs. If the proposed solution could be made available for significantly less than this amount, it would have an advantage over the product. Secondly, the “Electric Leg Bag Emptier 2” has a warranty of only six months. If the proposed solution could be guaranteed for a longer period of time it would be a more appealing option.

Finally, the proposed solution does not meet the criteria of affordability very well. It was hoped that the purchase price of the proposed solution would not exceed \$200. However, the components of the proposed solution alone have a total price of more than \$200, not even taking into consideration assembly costs. The pinch valve alone costs more than \$200 (with shipping). A possible solution would be to redesign the pinch valve so that it could be manufactured or purchased at a lower price.

CONCLUSION

Ethical Considerations

When discussing the medical ethical issues of the design, a few questions were considered that involved the safety, moral, and personal aspects that concern the client, potential future customers that would consider purchasing the product, and the environment. These questions were as follows:

1. Is there something wrong personally, interpersonally, or socially with the current design solution, that would affect the life of the client in anyway?
2. Is there conflict that could be damaging to people, animals, the environment, other institutions, or to society?
3. What might potential problems/issues with the current solution upon use of the project do to people as persons-- who have dignity, rights, and hopes—in an everyday lifestyle?

Safety and dignity issues are the main considerations in regards to the project. The operation of the device, which requires the continuous force on a switch, considers only customers who have at least minimal movement in their upper limbs. Although the switch may easily be moved to the foot position to accustom paraplegics who have lost motor ability in their upper body, the current design does not suit quadriplegics. A sip and puff operation system might include these individuals as well. Electrical safety in the wiring and general failure of the device might result in hurting the patient rather than helping them, making life more problematic than before the device was purchased.

Costs and insurance issues are always factors when regarding new technology in medicine. The cost of this device might not be affordable for low income or underprivileged persons. Although these people may be the individuals that truly need the device, they would not be able to afford something that would make life easier. In this way, the cost of the device is a discriminatory factor that should be considered.

In regards to the environment, the solution does involve the use of materials that may leach after long-term exposure to a variety of substances. The bag and tubing are made of polymers that may release unknown toxins into the environment upon drainage of the valve. Possible allergies to the latex tubing are a concern to both the customer and anyone who comes in contact with the device. Disposal of the product after use might also cause environmental problems.

Most importantly, the successful operation of the device over its entire use is a paramount issue. If the valve works, the customer's life is improved. If the valve fails, the dignity of the customer is jeopardized, as failure in the drainage of the device may lead to embarrassing and harmful situations that might otherwise have been avoided.

Future Directions and Technologies

There are still a variety of steps to be taken in order to further develop the project. These new technologies aim at making the device safer, more user-friendly, and more able to accommodate a wider variety of customers.

Looking into material that can be used for the safe insulation of wires and connections of the device to the battery and the switch is a primary goal for the future. All exposed wires should be protected from a variety of substances and environments, including climate changes and fluid contact (i.e. rain). Mounting the switch in a

convenient, protected location is also an issue that needs to be considered. An optional and removable switch cover can be designed for customers who are concerned about the accidental bumping of the switch.

The installation and fastening of the product to many wheelchair models needs to be designed and tested so that it is durable and can withstand shocks and weather. The tubing can be tested in many positions, so that kinking and bending can be prevented. A secure adhesive or Velcro strap will be designed to secure the valve to the customer's leg. Overall testing of the device and evaluation needs to be performed before any of these ideas will be considered.

In regards the future technologies of the device, a "sip and puff" system can be designed for quadriplegic individuals instead of a switch operation. The valve could be activated with the design of a remote control or voice-activation system, to make operation more accustomed to a variety of people.

As always, however, seeking ways to reduce the cost of the product while keeping the quality, operational and safety standards high is also a goal.

Concluding Remarks

A great deal of progress was made over the course of this semester in addressing the problem of disabled individuals not being able to control the drainage of their own waste fluids. Several design alternatives were generated and a final design solution was decided upon that best fit the criteria of the project. A working system was built and tested and performed as expected, meeting the expected criteria. However future development is still a possibility (if not a necessity). Perfecting of the existing components of the device is necessary. Also, more components could be added.

Appendix A:**Product Design Specifications****Team Members:** Angela Heppner, Shannon Kane, Jeff Phillips, Sarah Schram**Title:** Valve for bodily fluid drainage for paralyzed individuals**Last updated:** February 20, 2001

Function: This valve will be designed to drain the urine bags of individuals with catheters at the discretion of the individual. The valve should be able to drain a 1000 cc bag in less than 5 minutes without the incidence of failure due to blockage from urine sediment or wiring failure. The valve must be durable, affordable, and as discrete as possible

Client Requirements:

- Fast drainage time (as quickly as possible, from testing this was determined to be approximately 20 seconds)
- Less failure due to blockage from urine sediment
- Less failure due to wiring problems
- Valve should not be attached to the wheelchair
- Operation controlled by a switch that requires continuous pressure.
- Device control with a switch that electrically activates it
- Device able to be powered by wheelchair batteries (12 to 24 volt energy requirement)
- Accidental drainage should not be possible

Design Requirements:**1. Physical and Operational Characteristics**

- a. *Performance requirements:*
 - Valve should be usable any time during the day
 - Only used on average once a day
 - Should drain as quickly as possible
- b. *Safety:*
 - Electrical safety concerns: avoid exposed wires
 - Waterproofing of all electrical components to avoid shocks
- c. *Accuracy and Reliability:*
 - Functions repeated daily without failure
 - No accidental drainage
- d. *Life in Service:*
 - Functions 24 hours a day, 7 days a week
 - Should perform for at least 2 years without failure
- e. *Operating Environment:*
 - Should not be damaged when exposed to extreme hot and cold
 - Waterproof: resistant to snow and rain
 - Resistant to changes in humidity

- Could be exposed to any environment
- f. *Ergonomics:*
 - Switch needs to be in reach, likely near one of the arms of the chair
 - Device should not interfere with daily routine of the client
- g. *Size:*
 - Small enough so that it is not in the way
 - Approximately 8 cm x 8 cm x 8 cm or less
- h. *Weight:*
 - Cannot be so heavy such that it detaches from bag
 - Approximately 500 gm or less
- i. *Materials:*
 - Noncorrosive materials
 - Able to operate within pH range of 5.0-7.0 (average pH of urine)
 - Able to operate within extreme temperature conditions (-20°F - +100°F)
- j. *Aesthetics:*
 - Preferably small enough so that it cannot be easily seen
 - If visible, the device should be of a color and style such that it is inconspicuous

2. Production Characteristics

- a. *Quantity:*
 - Just a prototype for the time being
- b. *Target Product Cost:*
 - Less than \$200
 - Cost depends greatly on the estimated life span

3. Miscellaneous

- a. *Competition:*
 - The solenoid valve currently produced by Automatic Switch Company (this valve is not produced for biomedical purposes, it was adapted by Dan and his brother)
- b. *Standards:*
 - It will have to meet FDA requirements if multiple units are produced.
 - If clinical trials were begun, NIH human subjects approval would be required

Appendix B: References

- (1) RD Equipment, Inc. www.rdequipment.com. Website for disability care products.
- (2) Acro Associates, Inc. www.acroassociates.com. Website for pinch valves and fluid control systems.
- (3) Delphion Intellectual Property Network. www.delphion.com. Website for patent searching on products.
- (4) Cleveland Medical Devices Inc. www.clevemed.com. Website for Cleveland Medical Devices Inc., a developer, manufacturer, and distributor of rehabilitation and physiological monitoring equipment.
- (5) ASCO Valves. www.ascovalves.com. Website for Asco Valves, a solenoid valve manufacturer.
- (6) GC Valves. www.gcvalves.com. Website for GC Valves, a valve manufacturing company.
- (7) AllValves. www.allvalves.com. Website for AllValves, a valve manufacturing company.
- (8) Ratner, B. D., et al., eds. *Biomaterials Science, An Introduction to Materials in Medicine*. Academic Press, 1996.
- (9) Biocoat. www.biocoat.com. Website for coating products for bio materials.
- (10) Berne, R. M., and M. N. Levy. *Principles of Physiology*. St. Louis: Mosby, 2000.
- (11) Narang Enterprises. www.narang.com. Website for surgical, medical, and hospital goods.
- (12) NResearch Inc. www.nresearch.com. Website for NResearch, a valve manufacturer.
- (13) Orion Valves. www.orionvalves.com.co.uk. Website for Orion Valves, a valve manufacturing company.
- (14) Egan, Dan. Personal interview. 5 Feb. 2001.
- (15) 21st Century Scientific, Inc. www.wheelchairs.com/accessories.htm#top. Website for wheelchair accessories including the “Electric Leg Bag Emptier” and the “Electric Leg Bag Emptier 2.”
- (16) Bio-Chem Valve Inc. www.bio-chemvalve.com. Website for Bio-Chem Valve Inc., a company that produces pinch valves.
- (17) Ching, Emily. Personal interview. 11 April 2002.

Appendix C: Information from meeting with Dan Egan 2/5/01

Information concerning Current Device:

- It uses a solenoid actuated valve manufactured by ASCO (Automatic Switch Company)
- Valve called a RedHat Valve
- Valve made of brass or steel
- Stainless Steel Valve:
 - Serial #38405 1
 - Catalog #U 8225 B8U
- The valve requires a 24V DC power source, which is provided by two 12V batteries, connected in series on Dan's wheel chair
- Valves cost \$30-\$40
- A wire spring and heat shrink tubing have been added to keep the wires on the valve from moving
- The valve is turned on (the plunger moves allowing drainage) by a switch on the wheelchair. The switch must be continuously depressed during drainage.
- The valve is attached to a plastic tube coming from a one-liter plastic bag, used to collect urine from the bladder, on the leg
- The bag is drained, on average, once a day
- Once the drainage system (bag, tubing, valve, connection to battery) is set up, no further assistance is required unless failure occurs
- Valve needs to be replaced every 1-2 years

Problems with the Current Device:

- Failure
 - The small hole in the valve becomes blocked due to sediments in the urine. This inhibits drainage.
 - The wires fail
 - The device has failed twice in the last 6 months
- It takes over 5 minutes for the bag to drain, this is undesirable
- The valve needs to be cleaned at least once a month.

Other Available Devices:

- A mechanical sip and puff device
- Craig Rehab makes a device similar to the one currently in use. However, it costs \$350 and is enclosed in a large steel box

Money Issues:

- Cost is not covered by insurance
- If the device is a very good solution and is long lasting, ~\$200 would still be considered reasonable.

Other Important Design Issues:

- The device cannot be too heavy.

Appendix D: Current Devices and Patent Search Information

A US patent search revealed many products specifically designed to empty the urine bag of someone who is disabled. Sketches and descriptions of these products can be found on-line at www.delphion.com (3). The motivations for inventing four of these products closely matched the problem statement of this project, and were very similar to some of the ideas proposed.

The oldest device found, called the “Disposal device for wheelchairs”, was issued patent no. US3931650 on January 13, 1976. A valve mounted on the person’s wheelchair is connected to the drain tube of a urine bag. This valve can either be opened manually, if the person can reach it, or by a solenoid and low current switch, allowing the bag contents to empty into a floor drain. Additionally, a timing circuit integrated into the solenoid closes the valve after a predetermined time, preventing the valve from being accidentally left open, and allowing the handicapped user to both open and close the valve with a single switch operation (3).

A newer valve, called the “Power Bag Emptier”, operates in much the same way. It additionally offers a “support means” to mount the valve on the wheelchair, which allows it to be away from the user’s skin and clothing. The valve turns on by activation of at least two electrical switching means, but no timing circuit is mentioned. This patent US5397315 was issued March 4, 1995, and is maintained by R.D. Equipment, a company started and operated by an individual in a wheelchair. The standard switch model can be purchased on-line at www.RDequipment.com at a cost of \$250.00 (1).

Another device was issued patent no. US5092856 on March 3, 1992. The “Valve for a catheter reservoir bag” also has a drain valve designed to attach to the frame of a

wheelchair, bed, or other object. It makes use of an electrical, spring-loaded plunger pinch valve. In the normally off position, the plunger pinches shut the drain tube of the reservoir bag, so that no liquid can pass through. It can be activated remotely by a hand lever mechanism connected to a cable on the valve, or by a solenoid on the cable. Activation retracts the plunger, so the bag can be drained into a floor drain (1).

The newest device uses a pump mounted on a wheelchair, to empty the leg bag contents into a waste receptacle. The “System for draining a urinary drainage container” was recently issued US patent no. 6012181 on January 11, 2000 (3). The drain tube of the urine bag is connected to the inlet port of the pump, while another tube is connected to a discharge port of the pump. A valve controls substance flow through the pump, and can be selectively positioned at “open” or “closed” without the help of an attendant.

Cleveland Medical Devices manufactures another electrical solenoid pump called the “Liberty Valve.” Like the other valves, it uses a dual switch to ensure the urine bag contents won’t be emptied accidentally. It easily connects to currently manufactured leg bags, and runs off a 24 volt battery found on most power wheelchairs. It can be ordered on-line at www.clevemed.com (4).

21st Century Scientific, Inc. manufactures two variations of a “Electric Leg Bag Emptier.” Both models use a momentary toggle switch wired to a valve. The models have wiring connections to be attached to the batteries of the wheelchair itself. The original “Electric Leg Bag Emptier” uses a 24-volt electrical valve that connects to the bottom of the leg bag drain tube. The “Electric Leg Bag Emptier 2” uses a 24-volt electric pinch valve through which the leg bag drain tube easily threads. These products can be viewed on-line at www.wheelchairs.com/accessories.htm#top (15).

Appendix E: Valve Information

A general Internet search on valves provided endless information on valve companies and their products. A company called GC valves was found (6). Their valves are of particular interest because they are solenoid valves (which is the same kind of valve that Dan Egan is currently using). One important characteristic about the valves that they produce is that they are available in both normally open and normally closed forms, which would allow the user to have constant control over the flow of urine. Another attribute to the valves is that they can be powered by a DC power supply (like the wheelchair battery). A special feature of the GC Valves website is that it contained a specifications form that could be filled out by the customer stating the desired specifications and purpose of the valve needed.

All Valves was another valve company found on the Internet, whose valves had characteristics of specific interest for this design (7). They sell both high and low-pressure valves made of various materials. One of the materials used is Teflon, which might help with preventing valve blockage from urine sediment.

ASCO Valves is the company that produces the valve currently being used by Dan Egan. ASCO Valves produces various solenoid valves (5). They sell several lines of valves including a Medical and Analytical line. This line consists of three main families of valves. The first family contains the general service valves, which are available with conventional and latch solenoids, a variety of orifice sizes and mounting configurations, and various seal materials. The second family of valves are the isolation valves, which keep the draining fluid from coming in contact with the internal components of the solenoid. One class of isolation valves are the Teflon (TFE) isolation

valves, which have parts made of chemically resistant TFE polymers. The third family of valves are the pinch valves. A pinch valve controls fluid flow by squeezing soft tubing to block flow and releasing it to allow flow. The valves are available in the two-way, normally closed configuration and have a variety of DC voltage requirements. The largest tubing available for use with the pinch valve has an inner diameter of 0.250 inches and an outer diameter of 0.375 inches. The tubing coming off of the urine bag has an inner diameter of 0.3125 inches and an outer diameter of 0.50 inches.

Bio-Chem Valve Inc. is a valve company that produces various solenoid valves including several varieties of pinch valves. The largest pinch valve that they manufacture allows for tubing with an inner diameter of 5/16" which is the same as the inner diameter of the urine bag tubing (16).

Appendix F: Urine Content and Coating Materials

Mineral crusts formed on Biomaterials due to Urine:

Mineral crusts often form on polymeric prostheses used to alleviate urinary obstructions. These mineral crusts consist of hydroxapatite or struvite, an ammonium and magnesium containing phosphate mineral. These mineral crusts may be prevented by the use of specific metal ions such as Fe^{3+} , Ga^{3+} , or Cd^{2+} . These cations have been shown to inhibit hydroxyapatite crystallization (8).

Hyaluronan, a polysaccharide of the glycosaminoglycans class, is found in all tissues and body fluids of mammals. It is a lubricous and hydrophilic molecule, which has been shown to prevent the adsorption of platelets, proteins, and bacteria. The molecule lends it self to cross-linking and immobilization, therefore the body perceives it as inert. Medical grade hyaluronan is produced on a commercial scale. Due to its prevention of adhesion, hyaluronan may prove useful to this project by preventing crystallization, which leads to valve clogging (9).

Composition of Urine:

Substance	Level present in Urine
Na^+	50-130 mEq/L
K^+	20-70 mEq/L
Ammonium	30-50 mEq/L
Ca^{++}	5-12 mEq/L
Mg^{++}	2-18 mEq/L
Cl	50-130 mEq/L
Inorganic Phosphate	20-40 mEq/L
Urea	200-400 mM
Creatinine	6-20 mM
PH	5.0-7.0
Osmolality	500-800 3Osm/kg H_2O

* Normal urine contains no glucose, amino acids, protein, blood, ketones, leukocytes, or bilirubin. (10).

Appendix G: Solenoid Valve Research

Solenoid valves tend to be the most popular mechanism on the market for the operation of valves for medical purposes. A variety of companies focus their efforts on simple two-way and three way solenoid valves or pneumatic valves that may pinch off tubing and hold a particular force against the tubing in place for a long period of time.

One particular company, Arco Associates specializes in pinch valves that are operated by a variety of solenoids ranging in power and sizes.

A solenoid valve operates, or actuates, when current flows through hundreds of coiled wires that create a magnetic field inside the solenoid. The device uses this strong magnetic field to force a block or pinching apparatus down against the plastic tubing. The magnitude of the power stroke or pinching force is proportional to the strength of the magnetic field. Usually, 10 to 70 Watts of power is required to maintain force against the tube (Figure10).

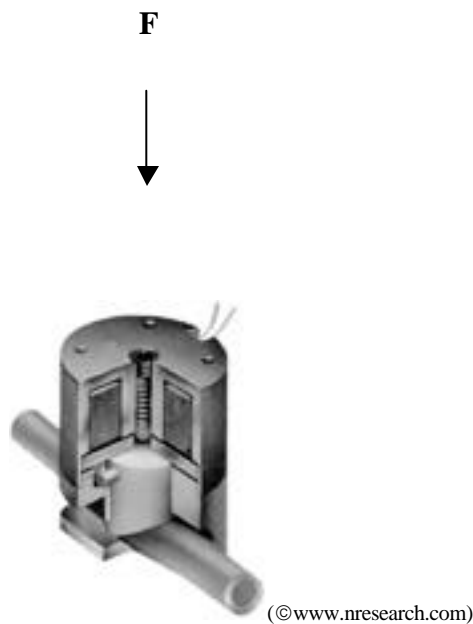


Figure 10: The solenoid pinch valve applies a magnetic field to a solid block, occluding the tubing underneath. Solenoids are typically cylindrical in shape and are operated electronically. Picture taken from www.nresearch.com (12).

Most solenoid valves operate on DC power, often using 12V or 24V systems, though solenoid wires can be wound to supply voltages from 10-100V. The resistance within the coils may also vary on the voltage and tubing sizes that are used. Maintaining the temperature of a solenoid valve during operation is critical, because of the large amount of resistive heat radiated by the coils. As current passes through the wires, resistive heat is dissipated to the external surface of the valve. The generation and dissipation of heat must equalize in order for the coils to not become overheated; the temperature of the valve must be no more than 190 degrees Fahrenheit during valve operation (2).

Acro Associates (2), Orion Valves (13), and NResearch Inc. (12) are three of several corporations that focus specifically on the applications of solenoid valves. Medical solenoid valves have typically been used for a wide range of purposes including the regulation of bodily fluid drainage, angioplasty fluid delivery, liquid nutrients delivery and plastic surgery applications.

Appendix H: Decision Matrix

Evaluation of Preliminary Design Ideas

<i>Product Design Specifications</i>	A	B	C1	C2	C3	C4	C5
Low failure rate (due to urine sediment or wiring problems)	+	+	=	=	=	?	=
Accidental drainage prevented (operate at user's discretion)	=	=	-	=	-	+	+
Drainage time (as quickly as possible)	+	++	+	=	+	+	=
Safety (electrical components sealed, leakage prevented, etc.)	=	=	+	+	+	=	?
Size and weight will not interfere with user's daily routine	=	=	=	?	=	=	?
Easy Operation	=	=	?	?	?	?	=
Ease of Cleaning	=	+	=	-	=	+	+
Target Product Cost: \$200 or less	+	=	+	+	+	-	?
Able to operate in wide range of environments	=	=	=	=	=	=	=
Aesthetics: minimally visible	=	=	=	=	=	?	=
Feasibility	++	++	-	-	-	-	-
New Technology	-	-	=	=	=	+	++
Overall +/- (?)	5/1	6/1	3/2 (1)	2/2 (2)	3/2 (1)	4/2 (3)	4/1 (3)

A. Improve Existing Valve

B. Incorporate a Pre-Manufactured Valve

C. Design New Valve

1. Coleman Cooler

4. Air Bubble/Pressure

2. Garden Hose

5. Electromagnetic Cap

3. Athletic Squirt Bottle

Appendix I: Pinch Valve Information

SPECIFICATIONS	
Series	150 P
Voltage	24 Volts
Power Watts @ 70° F (21° C)	8.0 Watts
Current Amps @ 70° F (21° C)	0.16 Amps
Weight	16 oz
Lead Wires	15" (381 mm) 22 Gauge Teflon® Coated

Table I-1: Specifications for series 150-P Bio-Chem pinch valve (16).

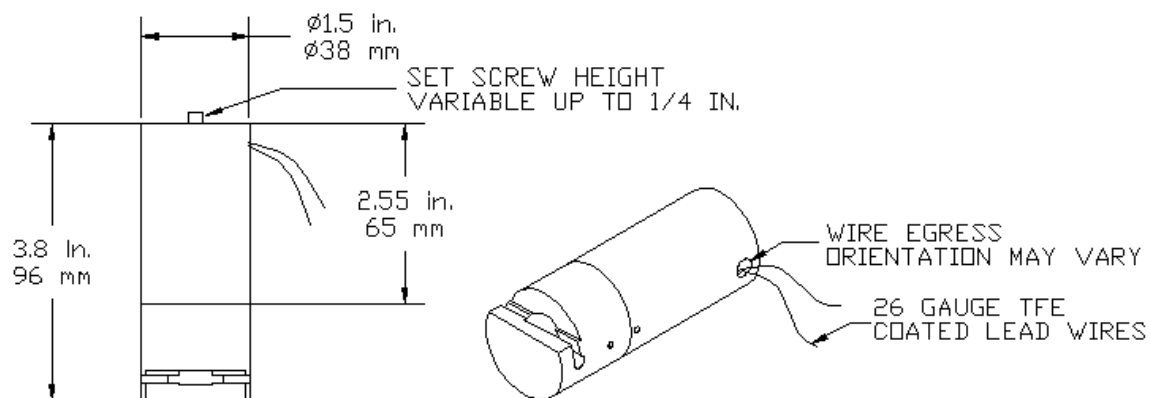
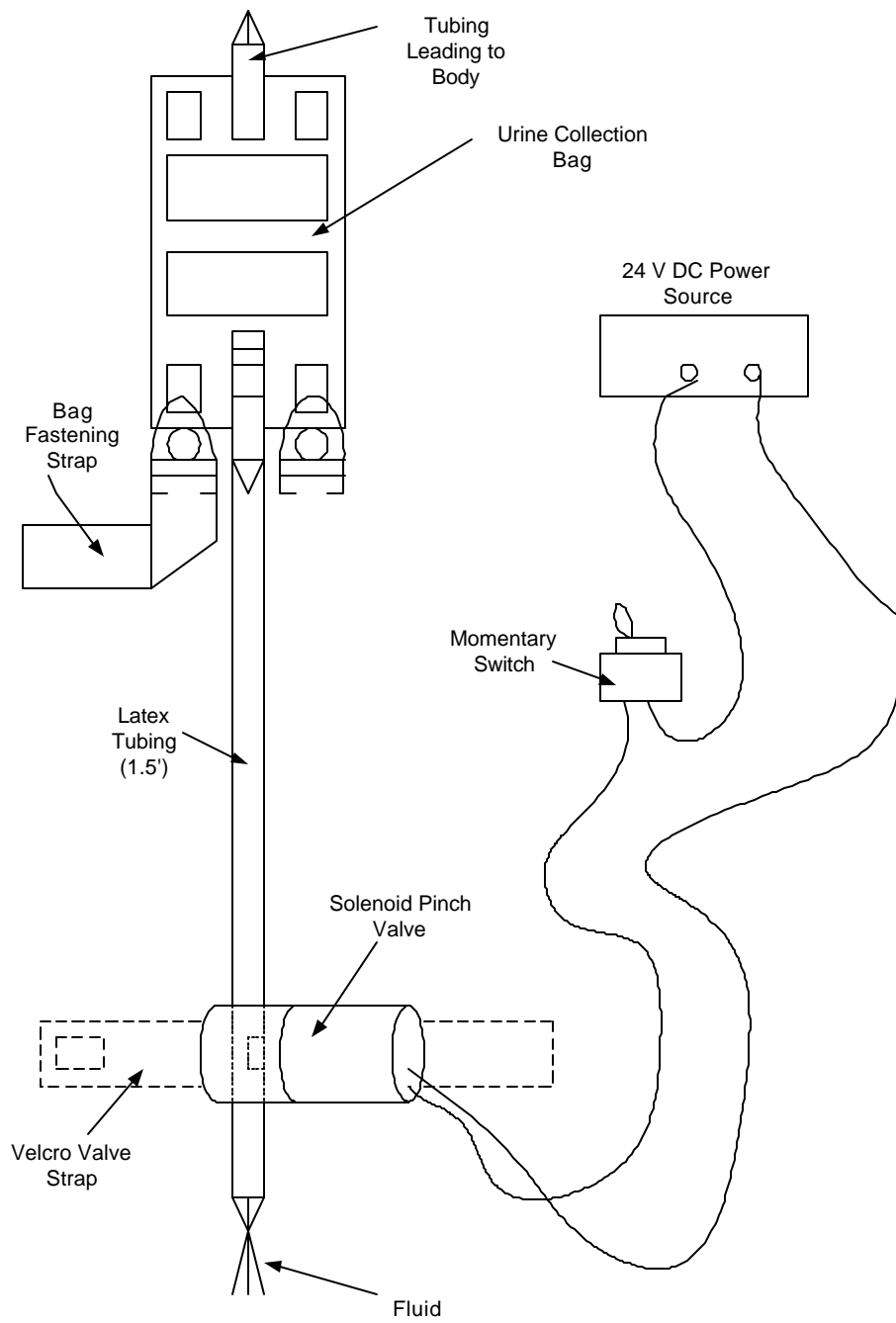


Figure I-1: 150P Pinch Valve (16).

Appendix J: Schematic of Final Design

Appendix K: Cost Analysis of Final Design

Prices of Components of Final Design

Component	Approximate Cost
Pinch Valve	\$200
Momentary Toggle Switch	\$2.50
Switch Box	\$3.99
Materials for mounting pinch valve on leg (elastic, Velcro, sewing materials, fabric)	\$3.00
Wiring materials	\$2.00
Estimated Total Cost (w/o shipping)	\$210