# Design, Testing and Calibration of a Small Syringe for Use with a Power Injector

## Mid-Semester Report

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## **Abstract**

Our client, Dr. Charles Strother, is a specialist in angiographic imaging research. He works predominantly with small animals, where there is a lack of appropriate angiography equipment suitable for the procedures being performed. Angiography is a medical imaging technique used to visualize blood vessels in the subject under examination.  Contrast medium is injected near the point of interest, so clear pictures are depicted.  Small amounts of this contrast agent are injected quickly into the small animals, but current devices are geared towards much larger subjects.  Consequently, Dr. Strother has developed a prototype syringe, which is capable of delivering the necessary small amounts.  There are many problems associated with the new design, including difficulty in air bubble detection and removal, the absence of the preferred volume range of 0.1 to 2.0 cc, and the lack of a calibration chart between the large syringe and the smaller one.  We have designed a second prototype to address these problems, and the team will use the remainder of the semester to build, thoroughly test, and calibrate the syringe.

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## Background

### *Client Description*

The client, Dr. Charles Strother, works in the Department of Radiology at the UW School of Medicine and Public Health. He is conducting research at the Wisconsin Institutes for Medical Research which involves the use of angiographic imaging. He proposed this project in order to develop a device that can be used with the power injectors he currently uses to safely and effectively perform angiographic studies on small animals used in his research.

### *Angiography*

Angiography is a medical imaging technique used to visualize blood vessels in key areas of the body for diagnosis and treatment of medical conditions. It can be used for identification and study of multiple conditions including aneurysms, atherosclerosis disease, arteriovenous malformations in the brain, and pulmonary embolisms. Common areas of interest are the brain, kidneys, pelvis, legs, lungs, heart, neck, and abdomen. Angiography is performed using one of three imaging technologies: x-rays with catheters, computed tomography (CT), and magnetic resonance imaging (MRI). The presence of a contrast agent, a material that has a different opacity than soft tissue, is often required to produce the pictures [1]. Typically, water soluble iodide is used during x-ray procedures to make blood vessels opaque, and paramagnetic substances are used during magnetic resonance imaging [2]. A particular technique commonly employed in angiographies is digital subtraction angiography (DSA). In DSA, one image is taken before contrast agent is present and a second image is taken once contrast agent is present. The first image is then digitally subtracted from the second image to eliminate images in regions that do not contain contrast. This allows blood vessels containing contrast agent to show up very clearly in images [3].

Catheter angiography, or x-ray angiography, is very similar to regular x-ray exams. X-rays are absorbed by the body to varying degrees depending on the specific location on the body the procedure is directed at.  Dense bone absorbs a large amount of radiation while softer tissues allow larger amounts of x-rays to pass through. Consequently, bones appear white on x-rays, soft tissues appear as shades of gray, and air appears black. In catheter angiography, a catheter is inserted into an artery in the groin or arm. Contrast agent is injected via the catheter. Once the contrast agent has reached the blood vessels of interest, the area is exposed to small bursts of radiation to record an image on a film or digital image recording plate. Contrast agent is opaque to x-rays; thus blood vessels containing contrast agent appear bright white in images [1].

Computed tomography (CT) angiography also uses x-rays to form images but is able to produce three-dimensional images. In CT angiography, contrast agent is injected into a peripheral vein. Then, the subject is exposed to numerous x-ray beams and absorption is measured by a number of electronic x-ray detectors to produce a large number of two dimensional cross-sectional images. These images can then be compiled to create multidimensional views of blood vessels. CT angiography is less invasive than catheter angiography, because it does not require a catheter to inject contrast agent into a large artery or vein. CT angiography also produces more precise and detailed imaging of blood vessels than MRI angiography [4]. However, it does not eliminate the exposure to x-rays.

Magnetic resonance (MR) angiography, unlike the previously mentioned methods, does not use x-rays or radiation to form images. Instead, it uses powerful magnetic fields and radio waves. Wire coils in the magnetic resonance imaging (MRI) machine establish a magnetic field as electric current is passed through them. Then, while the subject is inside of this magnetic field, radio waves are sent and received by other coils in the machine. This redirects the axes of spinning protons, the nuclei of hydrogen atoms in the subject, which produces signals which are detected by the coils. These signals are used to generate images of thin slices of the subject, which can then be studied from different angles. Once again, contrast material is needed in this procedure to produce images of blood vessels. Contrast media is introduced intravenously into a vein in the subject's hand or arm. Benefits of this method are that MR angiographies are non-invasive, do not require exposure to ionizing radiation, and are less expensive than catheter angiographies [5].

Power injectors are used to effectively and efficiently deliver contrast agents during angiographic procedures. Power injectors are devices which can be programmed to deliver set amounts of contrast agent at set flow rates in a reproducible manner. They are able to provide a tight bolus of media, which enables maximum enhancement and visualization of images without large amounts of wasted agent. They also enable controlled and precise timing of the delivery of contrast agent so that contrast agent is in the correct location when images are taken. Since imaging technologies can take images very quickly, it is very important that the bolus of agent is in the appropriate place when images are being collected. As mentioned before, power injectors can be set to deliver consistent flow rates and volumes, making injections easy to customize for specific studies or patients. Power injectors are made of a head where syringes filled with contrast material are inserted, plungers to dispense contrast from the syringes, tubing leading from the syringes to the patient, and a computer control unit where flow rates and volumes are set. The starting and stopping of injections are also controlled from this control unit [6].

## Current Devices/Treatments

Although there is a wide availability of syringes for use with power injectors, none currently allow for injections of small (1-2 cc) volumes and thus are limited for small animal studies.

### *Hand Syringes*

Handheld syringes have been used to deliver small volumes of contrast medium for angiographic procedures. These are typically limited by a lack of adequate power. These injections require power that is often in excess of manual capabilities. It is also difficult to handle the syringe and simultaneously monitor other parts of the injection procedure. This leads to suboptimal imaging during angiographies. Cardiovascular Innovations has developed a handheld syringe that addresses many of these issues. It uses a lever system to drive the plunger into the syringe barrel, and allows use of the entire palm to grip the handle, which allows for greater degrees of pressure. [7] However, this design does not meet our client's request that the device be compatible with a commercially available power injector.

### *200 cc Syringes*

To solve the issue of injection power, one current device used for angiographies, is power injecting 200 cc syringes. They work with a battery powered injector to deliver specific volumes of contrast for larger animals, including humans. This device is efficient and offers control of multiple variables, including delayed start, volume delivered, concentration (it mixes from a syringe of contrast and a syringe of saline to change concentration), flow rate, and injection time. [8] However, this volume is too large to be precise enough to work with small animals, so it cannot be used without modifications.

***Covidien Optistar LE MR Injector***

Another large volume syringe injector has been created by Siemens. Their LE MR injector is designed to work with 60 cc syringes for MRI contrast delivery. It is an AC powered injector consisting of dual syringe power heads and a full color touch screen (Figure 1). This device allows for timed contrast single bolus and dual phase injections of contrast medium. [9] Again, the major problem with this design is that the volume is too large, so modifications would be necessary.

**Figure 1**: Siemens LE MR power injector. [3]

***Prototype***

To address the volume issues of the larger syringes, our client has designed a prototype 1 cc syringe which can be used with the current 200 cc syringe and software. This prototype has a 1 cc syringe fitted within a 200 cc syringe. The plunger arm of the 1 cc syringe attaches to the 200 cc syringe's rubber plunger, as shown in Figure 2. Preliminary testing has revealed that some modifications to this design may result in a workable device, but problems currently exist. Air bubbles commonly occur when loading the prototype, and are sometimes difficult to identify. Construction limitations result in an inability to extend the plunger arm to its maximum length. Additionally, the device is not calibrated with the software designed for a 200 cc syringe, so the amount of volume injected is not easily known. [10] These issues must be addressed before this design becomes a viable option.

Figure 2: **Client's Prototype**

***Digital Subtraction Angiography Micro-injector***

Digital subtraction angiographies offer an appealing approach to imaging in small animals because of high spatial and temporal resolution and the ability to visualize and measure blood flow. In a design by De Lin et. al., a micro-injector for use with this imaging technique was developed. It uses $N_2$ triggered by computer software to push contrast through a zero dead volume direct lift solenoid valve. The contrast is stored in a heated reservoir to reduce viscosity. This system is designed to inject precise amounts of contrast at high flow rates into specific areas. [10] Although testing has shown that this design is capable of delivering repeatable small volumes, it does not meet the client's vision of a product compatible with a commercially available power injector.

## Problem Motivation

Our client's request for the design, construction, and calibration of a small volume power injecting syringe arises from the need to be able to inject contrast medium into small animals for angiographies. Devices currently exist for use with large animals, including humans, but there is nothing effective for small animals, such as rats. Larger syringes cannot be used to deliver small volumes of contrast with the precision necessary for angiographies. Hand syringes have been previously used, but they lack the precision of a machine controlled injector and the pressure needed to deliver the contrast to the final location. Our client's prototype, designed to rectify these problems, introduces new problems with air bubbles which can clot blood vessels, potentially leading to death. Also, the software designed for use with a 200 cc syringe does not display the volume of contrast held in the one cc syringe. As a result, our client would like us to develop a prototype which accounts for these issues. The final design will solve the previously mentioned problems. It will include a calibration between the reading displayed by the 200 cc software and the actual volume in the one cc syringe. As a final requirement, it will either be disposable or easily cleaned.

## Design Requirements

Our client's work requires precise injection of contrast fluids into lab rats in order to perform effective angiograms. The current power injector used in his lab, the Accutron HP-D, does not meet his needs for small animal injection. It lacks certain qualities relating to accuracy, utility, and safety that our design will need to fix.

Because the syringe will be used to inject small amounts of fluid, as small as 0.2 cc, it will need a level of accuracy that is not found in larger syringes. To address this problem, the design will have a margin of error no larger than 3 percent. Furthermore, there must be a comprehensive interface that would allow an operator to determine the actual volume of contrast fluid injected based on the displayed readout on the power injector's interface.

The design itself must be user-friendly, simple to implement, and cost-effective. By following the appropriate design requirements, the prototype will be marketable, practical, and more able to satisfy the client's need. First, the design must be retro-fit to the Accutron HP-D. In accomplishing this goal, the power-injector's software cannot be altered, and the machinery of the pistons themselves must remain unchanged. To improve on the current prototype, the design needs to withdraw the plunger of the smaller syringe fully when the piston is entirely pulled back. Second, the components of the design that come in contact with the fluid should be disposable and should be able to withstand the temperature and pressure of an autoclaving machine. Another necessary trait in the design is visibility. The current design obscures the view of the smaller syringe. This design flaw gives rise to two problems: the measurements on the syringe are difficult to see, and air bubble detection and removal is extremely difficult and many precautionary steps must be taken to ensure the safety of the subject. These air bubbles, if not removed, can cause serious complications in the injected organisms. While incorporating these requirements, the mechanism should not cost more than ten to twenty dollars, which is the average cost of a power injector syringe on the current market.

In addition to these specifications, the product must also meet certain safety requirements. One concern raised is that the design should be latex-free so as not to exasperate allergies in the test subjects or staff. In addition to a latex free composition, the design must also include a safety lock, so that the piston does not accidentally overdrive and cause complications in the Accutron HP-D or cause injury to the operator.

## **Design alternatives**

In order to solve the problems with the current methodology of small-animal angiography illustrated above, the design team devised three potential models. Each of these three ideas is original in nature and has advantages and disadvantages over each other.

***Center-Mounted Syringe***

The first design, shown in figure 3, was created to mimic the current syringe prototype in style, with a few alterations. The small, inner syringe will be larger than that in the prototype to ensure the necessary dispensable volume range is met. This range is 0.1 cc to 2.0 cc, so the design incorporates a 2 cc syringe into the sketches. The smaller syringe is mounted permanently into the larger syringe in the prototype, which poses loading problems. Consequently, in this design, the 2 cc syringe will be mounted in a twist-and-lock mechanism that allows syringe removal for loading. Loading outside the larger syringe saves considerable time and energy and is much less cumbersome. The 2 cc syringe will be positioned directly in the center of the larger syringe, which allows the plunger to apply a force directly in the center of the syringe. The change in syringe size will not require an alteration of the larger, 200 cc syringe, because the entire inner syringe will be encompassed by the outer

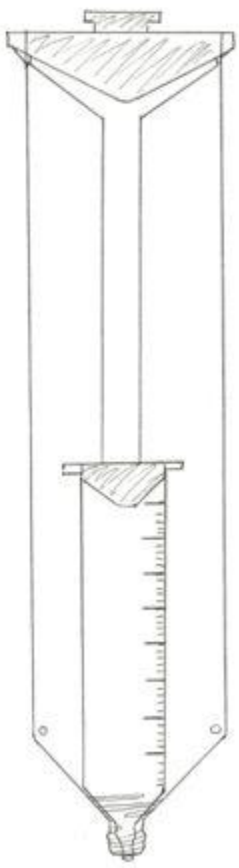

**Figure 3**: Center-Mounted Syringe

syringe. The plunger of the smaller syringe will be attached to the larger plunger mechanized by the machine itself the same way as the prototype. The plunger will slide into a slit that is designed to provide stabilization, but also easy removal.

### ***Side-Mounted Syringe***

The second model incorporates the inner syringe being attached to the outer syringe and a tube drawing the contrast medium out of the larger syringe. The 2 cc syringe will be fastened to the outer syringe with a collar-type mechanism. This system ensures that it is easy to see into the inner syringe to detect air bubbles. Because the inner syringe is positioned off-center in the larger syringe, the 200 cc plunger will have to apply force near the edge of its circumference. A different method of plunger attachment is therefore necessary. The slot method will work, but will need to be positioned near the edge of the larger plunger with similar stabilization support and assembly. The tubing connecting the 2 cc syringe and the catheter tubing must be flexible enough to maneuver from the side of the larger syringe out the tip.

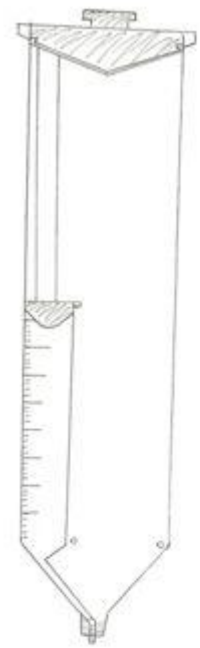

**Figure 4**: Side-Mounted Syringe

*Protruding Syringe*

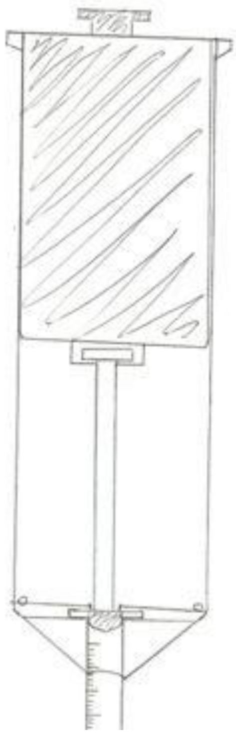

**Figure 5**: Protruding Syringe

This design features the 2 cc inner syringe protruding from the mouth of the larger, 200 cc syringe. In order for this design to work, it will be necessary to cut off the tip of the larger syringe, so the 2 cc syringe can fit through the mouth of the larger syringe. The smaller syringe will be fastened into the larger syringe with the same method as the center-mounted syringe: a twist-and-lock mechanism. The syringe will be able to be removed easily because of this method of attachment. The plunger will need to be lengthened to fit the new position of the smaller syringes thumb press, because the small syringe plunger does not reach the same length as with the other two designs. The same slotting mechanism as the current prototype will be used to attach the 2 cc syringe plunger into place.

## Design Matrix

In order to assess the viability of each of these three designs for use in small-animal angiography, a comparative examination of the three proposed models was conducted with a design matrix, shown in Figure 1 below. The design matrix provided a quantitative analysis of which idea would transition best to clinical use. The five categories used in the design matrix were accuracy, ease of manufacturing, air bubble detection and removal, compatibility with the machine, and ease of sterilization. Based on the point breakdown listed below, the protruding syringe design received the largest allotment of points, so we have chosen to move forward in the design process with this model.

**Table 1: Design Matrix**
The maximum point values are indicated in the parentheses in the row headings. The protruding syringe will be used as the primary design in the coming weeks of the project.

| | Center-Mounted | Side-Mounted | Protruding Syringe |
|---|---|---|---|
| Accuracy (30) | 22 | 25 | 29 |
| Air Bubble Detection and Removal (25) | 8 | 5 | 5 |
| Ease of Manufacturing (10) | 16 | 22 | 21 |
| Ease of Sterilization (20) | 14 | 10 | 12 |
| Compatibility with Machine (15) | 17 | 10 | 17 |
| Total (100) | 77 | 72 | 84 |

***Accuracy***

Accuracy was allotted nearly one third of the total points available, because of its importance in the application of this device. When working with such small volumes of contrast medium, it is especially important to deliver an exact amount. Too little medium will result in blurry pictures, while too much medium can result in death of the subject. The first method, the center mounted syringe, received the fewest points of the three, because as the diameter of the syringe is increased, the results become less accurate. The protruding syringe did the best in this category, with almost perfect marks, because the design allows for a slim syringe which is conducive to accurate measurement. The side-mounted syringe scored between the other two designs, because it has the same length syringe as the protruding design, but the extra tubing connecting the syringe with the catheter tubing results in more error.

### ***Ease of Manufacturing***

Ease of manufacturing was given 10% of the points available, because all of the designs would be relatively easy to manufacture. However, the protruding syringe design and the side-mounted syringe model received about half the available points, because they involve incorporating different aspects into the finished product. The protruding syringe will require the tip of the 200 cc syringe to be cut off, while the side-mounted syringe will entail the insertion of tubing connecting the syringe to the catheter tubing. The center-mounted syringe received nearly all of the points, because no major changes will be made from the original prototype.

### ***Air Bubble Detection and Removal***

One quarter of the total points was given to the detection and removal of air bubbles, because it is a vital step in the angiographic process. When bubbles are injected with the contrast medium, there is a much higher likelihood of subject death. The easiest way to prevent this from happening is to find the air bubbles and remove them before injection. The center-mounted syringe received the lowest amount of points in this category, because the syringe is placed in the center of the larger, 200 cc syringe, making it harder to see. The protruding design received 21 points, because the syringe is positioned mostly out of the larger syringe, making bubble detection relatively easy. The part of the syringe that is still contained by the large syringe will be harder to see, however, and still poses some problems in this category. The side-mounted syringe is pressed against the wall of the larger syringe, which will allow the user to see the air bubbles formed much easier than if the syringe was placed at the center. However, the user is still required to see through two layers of material, which could make it difficult to detect all the bubbles. Air bubble removal of all three designs is easy, because the syringe is removable.

### *Compatibility with the Machine*

This category received 15% of the total possible points, because it is important for the design chosen to work with the machine.  Each machine cannot be altered in any way, because the device must work with all current procedures being performed.  The center-mounted syringe received the most points, because the outer design is no different than the prototype that works well with the current machine.  The side-mounted syringe got the lowest amount of points, because the tubing connecting the syringe to the catheter may not be compatible with the machine.  The protruding syringe must be altered, because the tip of the 200 cc syringe must be removed, which could pose some problems, so it received 12 points.

### *Ease of Sterilization*

The syringes used in angiography must be sterilized every time before their use to prevent the spread of infections to the subject.  Consequently, the ease of sterilization was allotted 20% of the total points.  The side-mounted syringe received the lowest amount of points, because it will be most difficult to sterilize both the syringe and the tubing connecting the syringe to the catheter tubing.  Both the center-mounted syringe and the protruding syringe received the same amount of points, because the removal of the syringes to sterilize them is easy, and there are no other parts that need to be sterilized as well.

## Future Work

Although alternative designs have been proposed, there is still work to be done. The next step in the completion of this project is to order materials that will be required to assemble our design. The 2 cc syringes are the main item that will be needed, and are special order. Also needed is polypropylene, which is the material making up the 200 cc syringe, to make the twistlock mechanism that was discussed. Finally, the design will need a plastic material that can be molded to replace the original plunger in the 200cc syringe that will attach both to the pistons themselves and the thumb-press of the smaller syringe. Once these resources are acquired, the team will need to build a prototype that will be used for extensive testing and calibration with the power injector.

Keeping in mind the sensitive nature of the injections being done, the testing phase will require measurement of the output of the fabricated syringe versus the reading on the Accutron HP-D's display. Through this testing, it will be possible to determine the relationship between the extension of the piston and the fluid ejected from the end of the catheter, with a small degree of error that will fall in the three percent range.

Once the testing phase is satisfactorily completed, work will begin on an operation and instruction manual to accompany the design. This manual will include step by step instructions for the filling the syringe, loading the syringe into the adapted housing, and cleaning the necessary parts of the design. In addition to the instructions and operations manual, our team will design an interface that will allow calculation of the piston compression from the volume of fluid injected, and vice versa. This interface will ideally be a simple program that will use an equation found to accurately model the relationship between the piston's compression and the volume of fluid expelled. When an operator inputs either the volume injected, or the piston's compression, the unknown value will be calculated and displayed. Alternatively, another acceptable solution is to make a calibration chart describing the same relationship between piston compression and fluid expulsion.

## References

[1] Radiological Society of North America, Inc. 2011. Catheter Angiography. Retrieved 2/28/11, from http://radiologyinfo.org/en/info.cfm?pg=angiocath.

[2] Radiological Society of North America, Inc. 2011. Contrast Material. Retrieved 2/28/11 from http://radiologyinfo.org/en/glossary/glossary1.cfm?gid=80.

[3] Webster, John G. 2004. *Bioinstrumentation*. Hoboken, NJ: John Wiley and Sons, Inc.

[4] Radiological Society of North America, Inc. 2011. CT Angiography (CTA) Retrieved 2/28/11 from http://radiologyinfo.org/en/info.cfm?pg=angioct.

[5] Radiological Society of North America, Inc. 2011. MR Angiography (MRA) Retrieved 2/28/11, from http://radiologyinfo.org/en/info.cfm?pg=angiomr.

[6] MEDRAD, Inc. 2010. What is Power Injection? Retrieved 2/28/11, from http://www.medrad.com/en-us/resources/KnowledgeCenter/Pages/WhatisPowerInjection.aspx.

[7] Akhtar, S, Johnson, K, Vallabhan, R, Shutze, W, & Rees, C, Anwar, A. A new type of handheld power syringe for cardiovascular angiography. (1999, October). Retrieved 2/19/11, from http://www.baylorhealth.edu/proceedings/11_4/11_4_akhtar.html

[8] Strother, C. (2011, January 28). Personal Interview

[9] Covidien optistar LE MR Injector. (2011). Retrieved 2/19/11, from http://www.medical.siemens.com/

[10] De Lin, M, et al. (2008). A High-precision contrast injector for small animal x-ray digital subtraction angiography. *IEEE Trans. Biomed. Eng.*, 55(3), 1082-1091.

# Appendix

**Design, testing and calibration of a small syringe for use with a power injector** (Power Injector Syringe)
**Project Design Specifications**

February 10th, 2011

**Group Members:** Chris Besaw, Steve Young, Donald Weier, Joe Benert

**Advisor:** Professor Paul Thompson

**Client:** Dr. Charles Strother

**Function:**

Angiography is a technique to produce x-rays of the inside of blood vessels, and over 1.6 million procedures are conducted yearly on humans alone. A small amount of contrast medium is injected through a syringe at the point of interest, which allows the image to show up clearly. Power injector syringes are the preferred delivery method, because they allow accurate amounts of medium to be dispensed at a constant rate. Currently, no small volume (0.2- 3 cc) syringes are available for small animal studies. Our goal is to design, construct, test, and calibrate a small syringe compatible with commercially available power injector.

**Client Requirements:**

- Design should deliver appropriate amount of contrast medium (0.2-3 cc) into the small animal
- Syringe must meet all medical device standards
- The device should be latex-free, clear material designed with a calibration system to prevent over-injection
- Syringe should be easy to load with contrast medium

1. **Physical and Operational Characteristics**

   a. **Performance Requirements**: The device must be compatible with current power injectors. It must successfully deliver 0.2-3 cc of contrast medium. It must be easy to use and robust enough to ensure performance during loading or while the power injector is operating. The syringe must be able to load contrast medium easily as well.

b. **Safety**: The syringe must be properly calibrated and volumes must be properly labeled. The syringe must be clear enough for identification of bubbles present in the contrast medium or any that develop during contrast loading. Prevention of air bubble development must be included in the design. The device must not break during operation in the power injector. There can be no latex in the design due to allergy concern. The syringe must be able to be cleaned and sterilized. A safety lock to prevent overdriving the piston should be incorporated into the design as well.
c. **Accuracy and Reliability**: The syringe must deliver volumes consistently for each injection sequence. The accuracy of volume delivered should be ±2-3%.
d. **Life in Service**: The syringes should be disposable and used only one time.
e. **Shelf Life**: The devices will likely be stored in a cabinet or similar space in or near the room the procedure (i.e. angiography) takes place. Components should not degrade easily over time. Typically, this is not a problem for rubbers, plastics, or glass.
f. **Operating Environment**: Environment will typically be at room temperature. The syringe will be subjected to high pressure from the power injector. Other power injector syringes are rated to 1200 psi, so the syringe must be developed to withstand high pressures as well. The device will be filled with contrast medium used for angiographies, so it should not interact chemically with such substances.
g. **Ergonomics**: The syringe will have to be easy to install and replace from the mechanism hardware. Ease-of-use is also important in the syringe design, so over-injection of contrast medium is impossible.
h. **Size**: The design must fit the current machine, which holds 200 cc syringes. No alteration to this device can be done. The actual syringe must be capable of dispensing 0.2-3 cc measurements of contrast medium into the connector tubing to the catheter.
i. **Weight**: The device has no true restrictions on weight.
j. **Materials**: The syringe must be made of clear, latex-free material to ensure that no air bubbles are developing.
k. **Aesthetics, Appearance, and Finish**: The syringe must appear professional and clean. Additionally, the device must have clear measurement markings to facilitate its use.

## 2. Product Characteristics

a. **Quantity**: We will produce one working 0.2-3 cc syringe compatible with 200 cc power injecting equipment.

b. **Target Product Cost**: Typical power injector syringes used in angiography procedures cost around $10-$20 per syringe, so this design will be similar to those values.

## 3. Miscellaneous

a. **Standards and Specifications**: The final product must meet medical device standards.
b. **Customer**: The intended user of this device will be researchers who are conducting angiographies of small animals and doctors working with patients who need angiographies done with small amounts of contrast medium.
c. **Patient Related Concerns**: The designed syringe must not over-inject the rats with contrast medium, and must prevent air bubbles from developing in the syringe from loading. The device must be ergonomic, so inexperienced administrators may be able to correctly use the syringe.
d. **Competition:** Many companies sell large syringes, but very few have developed small capacity syringes like the one being devised in this project. Therefore, there would be very little competition to this design.