Fluid Management Injection Team

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Table of Contents

Abstract 3

Background 4
- Angiography 4
- Client Description 5

Current Devices and Designs 6

Problem Motivation 8

Design Requirements 10

Design Alternatives 12
- Saline Dispensing 12
- Manifold Mechanics 13
- Manifold Stand 15

Design Matrices 18

Final Design 27

Testing 29
- Pressure 29
- LED Spike Illumination 30
- Flow Pattern 31
- Fluid Delivery 32
- Saline Drip 33
- Efficiency 33

Cost 36

Time Management 36

Ethics 38

Future Work 39

References 41

Appendix 42
- Project Design Specifications 42

Abstract

Angiography is a medical imaging technique used to view blood vessels, specific organs, or tissues. Multiple liquids are used during angiography including contrast agents, saline solution, and medicines. A contrast agent is a substance injected to make blood vessels visible during imaging. Saline is used to prevent clots in the system and to remove any unwanted substances in the manifold or tubing. A manifold is the device that delivers these liquids into the patient. Currently, the manifold setup is cumbersome to use and the detection of air bubbles is difficult, increasing risk to the patient. A redesigned manifold and stand were developed to solve these issues. Results from several tests concluded that the prototype manifold is more efficient than the current manifold, can deliver precise amounts of fluid and withstand pressures reaching 300 mm Hg. Further testing showed that the addition of an LED light effectively aids in monitoring saline flow. Following testing, the team determined what work needs to be completed in the future to improve the devices and run clinical trials.

Background

Angiography

Angiography is the medical imaging of blood vessels in the body of a human or animal. Doctors use angiograms to visualize blood flow in order to treat blood vessel conditions. Some conditions that angiography detects are peripheral artery disease, which is blockage of the arteries outside the heart; aneurysms, which are enlargements of the arteries; and malformations of arteries. To view these vessels, angiography utilizes three imaging technologies; X-ray, Magnetic Resonance Angiography (MRA), and Computed Tomography (CT) [1]. However, the imaging technologies are not sufficient to view the vessels alone. For x-ray images, a radio-opaque chemical is injected into the vessel. Because it is radio-opaque, x-rays do not travel as well through the liquid, and these vessels are highlighted on the resulting image. For magnetic resonance angiography, paramagnetic liquids are used. These liquids used for imaging processes are called contrast or contrast agent, and are commonly administered via manifold injection.

X-ray angiography, or catheter angiography, is the imaging technology Dr. Strother utilizes in his lab. X-ray radiation is aimed at the part of the body that is being examined. The machine produces radiation waves which are passed through the body, and the body absorbs the rays. Different parts of the body respond differently to the x-rays, which allow radiologists to interpret the images. Bones appear white on x-ray images because they absorb the x-rays, whereas soft tissues show up gray. Contrast agents aid in visualizing the vessels. Common contrast substances include barium, iodide or gadolinium. The contrast is injected into the vessel. This allows for clearly defined vessels in the x-ray image [1]. To inject the contrast, a catheter is inserted into a minor vessel and is guided into the major artery of interest, where the physician

then uses a hand syringe or power injector to introduce the contrast agent. . The images are recorded on a film, or saved to a digital image recording plate [1].

The second imaging technology is Magnetic Resonance Angiography. This type of imaging does not use x-rays to view the inside of the body but instead uses a powerful magnetic field, radio waves, and computer to produce images [2]. Contrast agents are still used to view the blood vessels, because they allow for greater visibility of vessels. An electric current is passed through wire coils, producing a magnetic field [2]. Other coils placed in the machine are sending and receiving radio waves. These radio waves redirect spinning protons, which are in the nuclei of hydrogen atoms [2]. A computer processes these signals and transforms the data into an image of a slice of the body.

Computed tomography (CT) is the third imaging technology, and is similar to x-ray imaging. The process of viewing the inside of the body is the same as x-ray imaging: x-ray radiation travels through the body, enabling the physician to see bones in white and soft tissue in gray. However a CT scan consists of taking a large number of x-ray images from different angles all around the body [3]. A computer is used to process the large volume of data and as a result, the scan is able to produce multidimensional views of the body's interior. There have been improvements to the CT scans which allow for more slices to be obtained in a shorter amount of time, which allows for greater viewing possibilities [3].

Client Description

Dr. Charles Strother is the client for this project. Dr. Strother works in the Department of Radiology at the UW School of Medicine and Public Health. Currently, Dr. Strother is conducting angiographic research at the Wisconsin Institute for Medical Research He proposed this project in order to develop a more efficient and streamlined method to inject contrast in the

body, with a purpose of reducing the amount of radiation to which physicians are exposed during a procedure.

Current Devices/Designs

The devices currently used to inject contrast agents and saline solution are hand injectors and power injectors. The manifold is the preferred method of dispensing these fluids to the catheter, and is only used for hand injections at this time. The Medrad Avanta Fluid Management System is also available on the market, but is extremely expensive. Pressurized saline bags deliver a saline flush throughout the procedure, but saline level visibility is difficult due to dim lighting used during the procedure to enhance the view of images on the monitor.

Manifold

The current device Dr. Strother uses to inject contrast and saline into a patient is a manifold. This device can be categorized as a hand injector, which is a device that requires manual injection of the contrast into the patient. A manifold is an apparatus that collects contrast and saline from their respective reservoirs and directs them into the patient via a catheter. A manifold consists of a main line connecting to the catheter, and various valves that connect perpendicularly to the main line. These valves are connected to various sources, such as contrast, saline and a waste flush. Figure 1 shows a 4-valve manifold at the top with valves connecting to various tubes. The catheter is connected on the far right of the manifold and the connection on the left side of the manifold is closed. A syringe is sometimes connected to this closed port to aspirate unwanted fluid in the manifold.

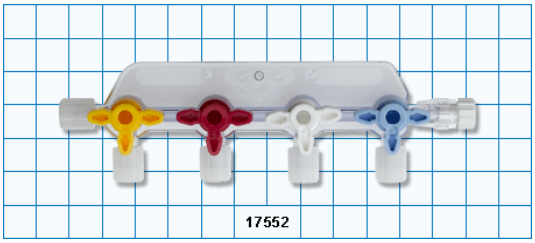

Figure 1. A 4-valve manifold shown with 3-way stopcocks [4].

There are many difficulties encountered when utilizing the manifold system, primarily due to poor ergonomics. The entire system is very disorganized, with many tubes covering the operating table and no exact location for manifold placement during the procedure. This increases the number of nonproductive interactions, or interactions not inherently necessary to perform the manifold function, that occur, which increases the procedure time. Also, it is difficult to detect air and blood presence in the main line of the manifold. However, manifolds allow for quick repetition of trials and are inexpensive.

Medrad Avanta Fluid Management Injection System

The Medrad Avanta Fluid Management Injection System is a type of power injector used for delivering contrast to a patient. It is used for a variety of cardiac imaging such as ventriculograms and aortagrams. The system can change its flow rates depending on the type of procedure being conducted. For images of smaller vessels, the system can inject contrast at low rates and low volumes, and for larger vessels or saline flushing, the system can inject at higher rates and larger volumes [5]. The increase in efficiency from this system reduces the time of procedure, which reduces exposure to radiation to the physician. The Medrad Avanta system, shown in Figure 2, is a whole unit. An LCD touch screen displays information such as flow rates and pressure gauges.

Figure 2. Medrad Avanta Fluid Management Injection System [5]

Additionally, the Medrad Avanta system features an air management system with level sensing and gross air detection [5]. This device is efficient and performs the task of injecting contrast and saline accurately, but it is very expensive and high

tech. However, our client would ideally like our final design to mimic many of the Avanta's primary functions.

Saline Dispensing

The current method Dr. Strother uses to dispense saline to the manifold is a simple setup consisting of a sterile saline bag connected to a manifold through a tube.

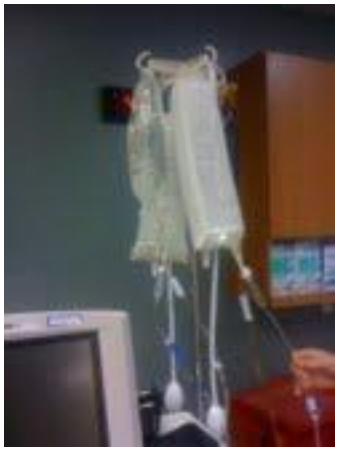

Figure 3. Saline bag in pressure sleeve

Shown in Figure 3, the saline bag is placed inside a pressurized sleeve. This sleeve keeps pressure on the saline bag to maintain a steady stream of saline exiting the bag. It is difficult to detect the level of saline with the current design, because the fluid is clear and the sleeve covers the bag. This could introduce patient risk if air is injected into the patient when the saline bag is empty. The tube that connects the saline bag to the manifold is transparent and made from polyvinyl chloride (PVC). Before the procedure, the tubing needs to be wiped to make sure no outside water drops are present. This allows easier detection of air bubbles inside the tube.

Problem Motivation

Our client's request for an improved manifold arises from a need for a more efficient, safer way to manage fluid injections for imaging procedures. The system that is currently used is oftentimes disorganized, and it is not unusual for the setup to span the entire operation room. Injections involve large amounts of tedious work, especially since a common but difficult to control problem is fluid contamination. If air gets into the system and is not removed prior to injections, serious complications can result in the patient. In current manifolds, it is difficult to see and remove air bubbles, especially if they become trapped in locations such as the stopcocks.

Another problem that can lead to time-consuming work is blood moving up the catheter into the manifold. If blood becomes stagnant in the catheter, it can clot. If clotted blood is re-injected into the patient, it can block an artery, presenting serious danger to the patient. Additionally, contamination of fluids due to blood is another general concern. The imaging technology commonly used for these procedures is x-rays. Due to the length of these procedures, which can often involve over 50 injections, exposure of operators to x-rays can be a source of concern. Current devices, which offer methods of speeding up the process or presenting safeguards against the threats posed by air and blood, are relatively high-tech and very expensive. The final improved manifold design will reduce manifold interactions which are not necessary, including re-adjusting the manifold or positioning the stopcocks. It will make air bubble prevention and detection faster and will prevent blood from moving up into the catheter and back into the system. In order to hold the manifold in place during operations, a device will be fabricated to fix the manifold in an easy to use location and position for the user.

Our client's request for a method of monitoring the level of saline reservoirs arises from the frequent and integral use of saline during procedures. It is often needed for mixing with contrast for injections or for cleaning syringes and other apparatus. However, one of the more important roles of saline is the saline flush which is run through the catheter. This flush runs at all times, even when no injection is being performed, to keep blood from flowing up into the catheter. However, since the fluid is clear and the bags are kept in pressure sleeves, which serve to keep a constant flow of saline running at all times, it is often difficult to see how much saline is left in the bag. In addition, it is common procedure to dim lights in the operating room to make it easier to see monitors in the room, making it even more difficult to keep track of the status of saline reservoirs. If the bag runs empty and is not quickly replaced, the pressure that keeps blood

from flowing up the catheter is lost and the problems previously mentioned with blood entering the system can be encountered. Therefore, our design will provide a means for indicating when the saline reservoir is empty as well as preventing air from moving into the catheter and thus the patient when the saline runs out.

Design Requirements

The design of the new manifold should ultimately streamline the angiographic process. This means it must allow for easy fluid management for injections. As part of this requirement, our client has requested that it be compatible with a power injector as well as the hand syringes that are more commonly used for these procedures. The components (i.e. stopcocks) must be simple to manage. The device should be space efficient and not cumbersome to the operator. Access to the input ports should not be obstructed in any way by the design, and it must be able to be quickly connected to the various fluid reservoirs used for procedures. The manifold must be able to deliver both contrast and saline flush to a catheter and must also have extra ports to be used as needed. The new design must offer free access to the catheter lumen at all times. As a medical device, the manifold must meet the Occupational Safety and Health Administration (OSHA) standards. Since it will be a disposable device, sterilization is not a major concern. However, the channels and fluid contents of the device must be highly visible to allow for quick and easy detection of air and blood in the system. It should also reduce the incidences of air bubble development and blood influx to the catheter. The entire device should be easily rinsed with a saline flush at any time, and a waste removal system must also be implemented into the design. As a fluid management device, it must deliver the desired volumes of saline and contrast agent at the desired flow rates to the patient consistently and accurately. It is used for lengthy operations as mentioned earlier, so it must be robust enough so it will not break and that

components will not become disconnected during operation. Since the device will be used in a setting in which x-rays and contrast agents are used frequently, it must be inert to both x-ray radiation and the fluids it is used to manage.

The manifold holder must be space efficient, so it should not occupy a large amount of space in the operating room. It must effectively make the manifold easier to use, both in the manner it supports the manifold as well as where it allows the manifold to be placed. It should reduce the number of non-essential interactions operators must perform with the manifold, leading to a faster procedure time. Since it will be close to both the subject and the fluids being injected into the subject, it must be able to be sterilized, most likely via autoclave. It must hold the manifold securely to prevent undesired movements but must not interfere with operation of the manifold. Since it will not be disposable, the holder must be durable and should be designed for long-term use. The material used to construct the device should be chemically inert and resistant to x-ray radiation

The saline monitor should allow for the saline level to be assessed during use. The device must allow operators to quickly assess whether the saline is dripping from distances typically encountered in procedures and under lighting conditions present during procedures. As with the other devices, it should be space efficient and simple to use to help streamline the procedure. It must meet aforementioned OSHA safety standards, and if it comes in contact with the saline it must be sterilized. It should be chemically inert to all liquids used in the procedure, especially saline, and should also not be affected by x-ray radiation.

Design Alternatives- Saline Dispensing

In order to solve the problems with the current methodology of saline level detection described above, the team created three potential models. Each design incorporates different means of achieving the desired result- reducing the possibility of air injection into the patient.

Hanging Alarm Design

The first design, shown in Figure 4, utilizes the same hanging saline bag, but integrates an alarm system that alerts the physician when the saline levels reach a certain volume. When the alarm sounds, the user must change out saline bags to ensure patient safety. Each saline bag has a specific weight when empty, so the alarm is triggered when the bag reaches this critical level. The weight of the bag would be measured by a hanging scale, which would be attached to the stand as well as to the top of the saline bag. A circuit accompanied by a threshold value would be connected to the digital scale, which would set off the alarm. This design would have minimal effect on the arrangement of the workspace area, as the scale would be hung on the stand already holding the saline bag.

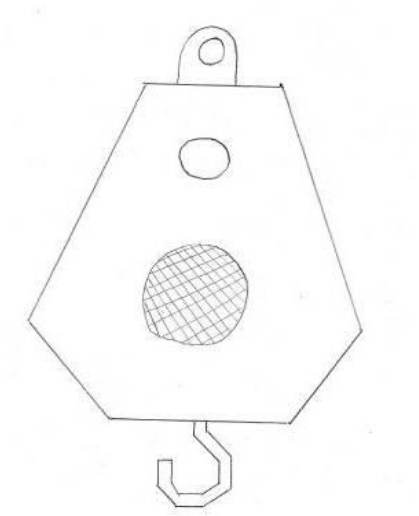

Figure 4. Hanging Alarm Design

Peristaltic Pump Design

The second design, shown in Figure 5, replaces the hanging bag of saline with a peristaltic pump. The pump would be set to dispense a consistent, reliable amount of saline per unit time, and can be turned off or on at any time in the procedure. The peristaltic pump would be positioned on

Figure 5. A peristaltic pump with variable flow [6]

the operating table, or on another table off to the side of the main one. This would aggravate the existing problem of space management present throughout the procedure. The saline is very easy to see in the design, unlike in the hanging saline bag, and can be added at any time. A disadvantage to this design is that if the saline level does reach zero, the pump will continue to push air through the tubes toward the subject.

Floating Ball Design

Figure 6. Flexible chamber with green ball at bottom [7]

The last design, shown in Figure 6, is very similar to the original set-up in that it utilizes the bag to deliver the saline in the procedure. An air embolism protection device is connected underneath the saline bag, which includes a floating ball in the saline present. The ball floats visibly while the saline drip is running, but when the level reaches zero the ball acts as a stopper to the tubing leading to the patient. Consequently, no air bubbles can be introduced to the subject, and the physicians can easily exchange bags to continue with the angiography. The device is disposable and will be connected to the saline bag before each procedure.

Design Alternative- Manifold Mechanics

Air bubble detection, stopcock management, and fluid control were all problems stressed by Dr. Strother, therefore major emphasis was placed on the mechanics of the manifold itself. Each design listed below addresses these issues and presents a way to improve time efficiency and the ergonomics of using the manifold in an angiography procedure.

Single Piece Design

The first design, shown in Figure 7, emphasizes space efficiency through its design by placing each manifold element in close proximity to each other. One-way valves will be incorporated directly on the manifold leading to each of the five ports. This addition to the original manifold will ensure that no blood from the subject moves up the lines toward the fluid reservoirs. The design is very simple, requires minimal set-up, and relies on the existing stopcocks to direct fluid flow from the manual contrast injections.

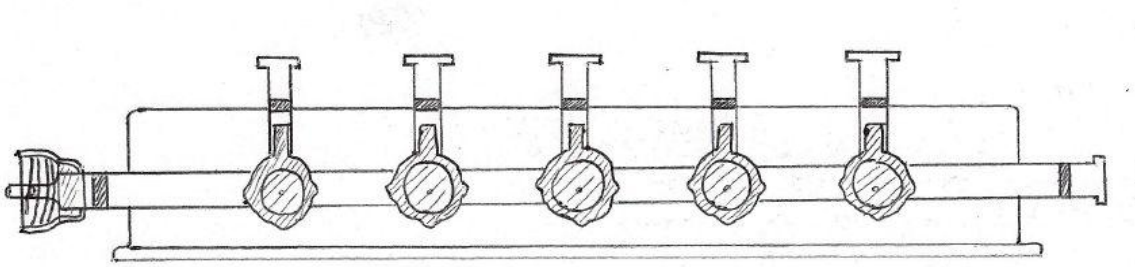

Figure 7. Single piece manifold with 5 valves

Screw Clamp Design

The second design, shown in Figure 8, utilizes a manifold shell without stopcocks incorporated into the manifold itself. One-way valves and screw clamps are integrated into the

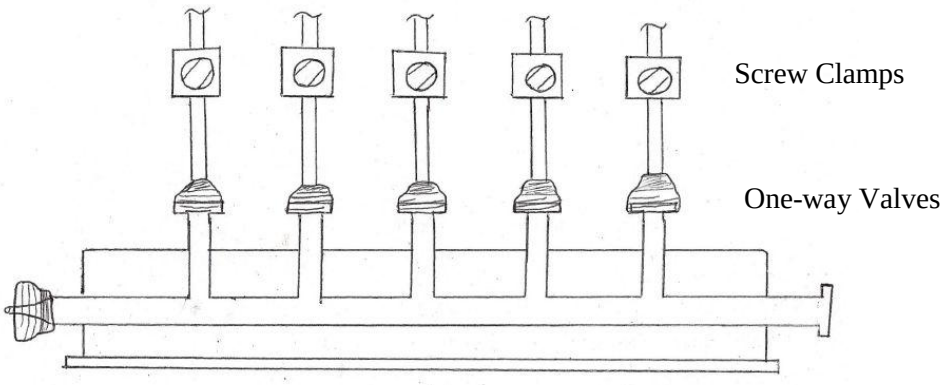

Figure 8: Manifold with square screw clamps

system on each of the five port lines themselves. An advantage of this design is that air bubble detection in the manifold is enhanced, because it has an open line with few pieces hindering its view. Additionally, air bubble formation is decreased with this design, because there are no places for the air to become trapped, as was the case with the stopcocks. The one-way valves offer the same protection from blood contamination as mentioned in the single piece design.

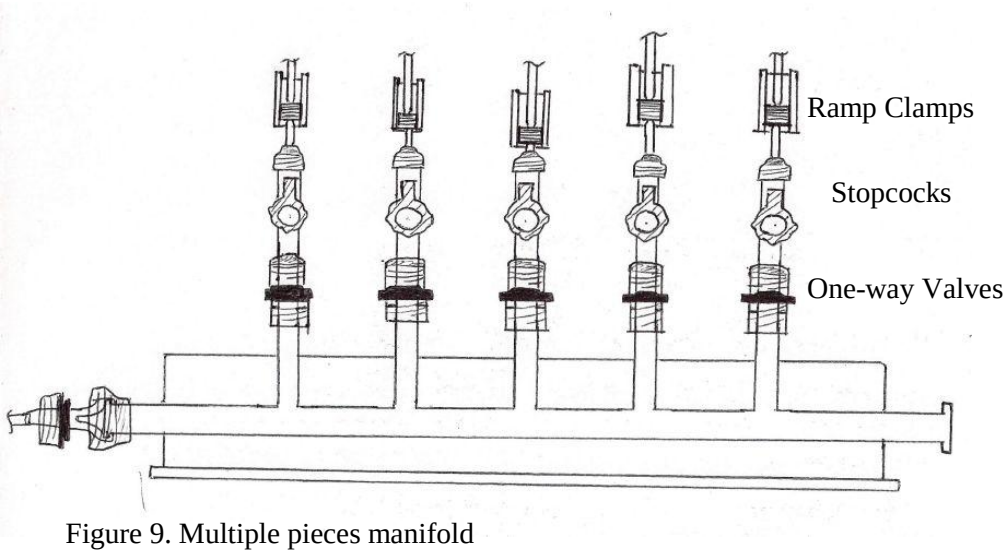

Figure 9. Multiple pieces manifold

Multiple Piece Design

The third design, shown in Figure 9, integrates aspects of the two previous designs, but also adds ramp clamps upstream of the manifold. These components offer graduated control of fluid flow, which is important for allowing saline and contrast through the manifold at various flow rates. Again, the manifold shell is clear of stopcocks, making the main line visible.

Design Alternative- Manifold Stand

Faced with the problem of work space inefficiencies and disorder, the team devised three ways to improve the functionality of the manifold device as well as decrease the expected procedure time by eliminating nonproductive interactions with the device. This will be measured

by comparing the number of non-productive interactions and procedure with the current manifold and the prototype by performing mock injections.

Weighted Block Design

The first design, shown in Figure 10, incorporates a weighted mount for the manifold. Dr. Strother expressed concern over the large number of manifold readjustments during a procedure, so a holder presenting more stability was designed. The manifold is attached to the block through a sliding mechanism that inhibits manifold movement during use. Additionally, rubber pads will be affixed to the bottom, offering yet more motion inhibition. The block will be set on the table, which will require slightly more work space than the original manifold.

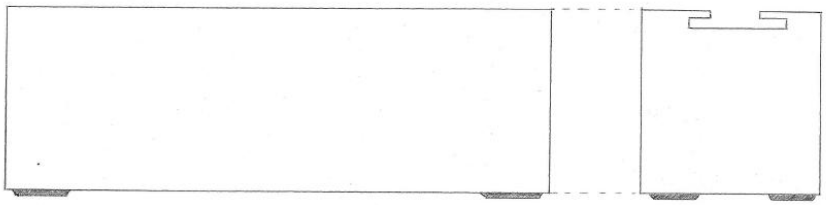

Figure 10. Weighted Box

Moveable Arm Design

The second design, shown in Figure 11, utilizes an arm similar to that of a desk lamp. The device will be made out of metal, so it is easily sterilized. This offers full range of motion for the manifold, as well as location fixation (locking mechanism) once the desired position is achieved. The arm will be mounted on a floor stand, so the manifold will not be on the operating table, offering more workspace for the physicians. The manifold will be held in place by a clamp at the end of the arm. This design has the advantage of having adjustable height for the device, because of the lack of fixation to the table.

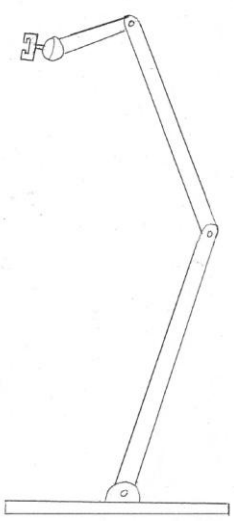

Figure 11. Movable Arm

Clamp Design

The last design, shown in Figure 12, features a moveable clamp that attaches to the edge of the operating table. The clamp will be fabricated out of metal, so it can be autoclaved and

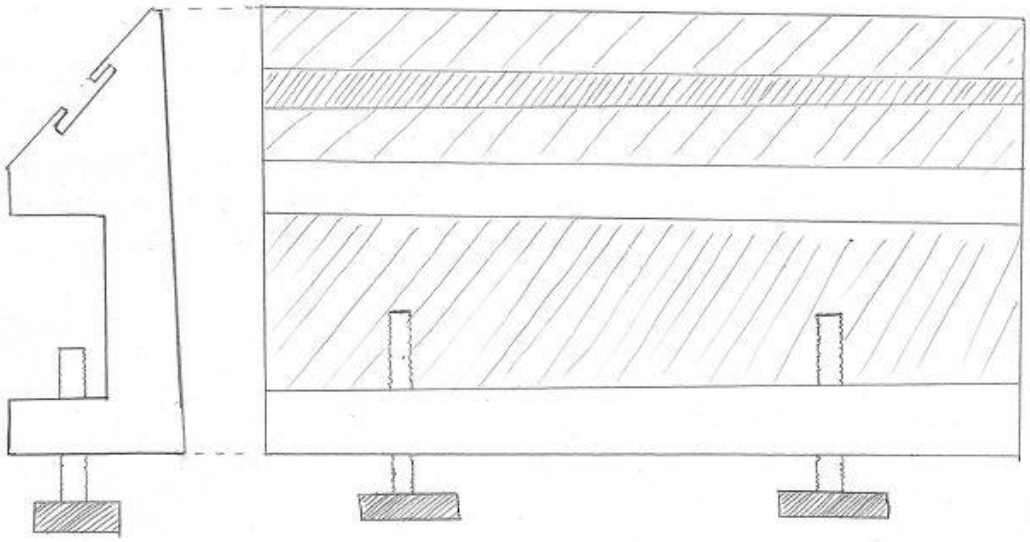

Figure 12 Clamp manifold holder

used in clinical applications. The device can be placed in any location and can be moved during the procedure. The manifold will be mounted to the clamp in the same way as the weighted block, through a sliding mechanism that ensures no manifold motion once clamped down. This method offers complete stability of the manifold, unlike the previously discussed designs, and saves table space by extending the manifold off the table. The design also positions the manifold at an angle, making it easy for a person standing near the manifold to look down on it and have a clear view.

Design Matrices

In order to assess the viability of each set of three designs for use in angiography procedures, a comparative examination of the three proposed models was conducted in a design matrix, shown below. The design matrices provide a quantitative analysis of which idea would transition best to clinical use.

Manifold Mechanics

In this subset of designs, the five categories used in the matrix are ease of manufacturing, cost, contamination detection, fluid control, and set-up time. Based on the point breakdown listed below, the multiple piece design received the largest allocation of points, so the team has chosen to move forward in the design process with this model.

	‘Single piece' Design	‘Multiple pieces' Design	Screw Clamp Design
Ease of Manufacturing (25)	15	20	24
Cost (5)	4	4	5
Contamination Detection (15)	10	12	14
Fluid Control (30)	24	29	18
Set-up Time (25)	20	16	18
Total (100)	73	81	79

Ease of Manufacturing

The device must be assembled pre-procedure, so it must be able to be fabricated by the nurses quickly and efficiently. Consequently, it received one fourth of the total points available. Any alteration of the manifold itself would be difficult to achieve, and the future manufacturing would be nearly impossible. The 'single piece' manifold received the fewest point in this category, as it involves direct modification. The stopcock handles are shortened, which requires machining, and the one-way valves are integrated into manifold itself. The screw clamp design scored the best in this category, because it entails no change in the manifold or alteration of stopcocks like in the first design. Screw clamps are attached down the lines off each port on the manifold, the easiest modification to the original device. The 'multiple pieces' design scored between the other two designs, because it does not involve any direct alterations of the manifold but does incorporate three other components to each port, including the one-way valve, the two-way stopcock, and the ramp clamp to control flow rate. The manifold itself will be a shell, without any stopcocks, which can be ordered pre-made.

Fluid Control

The management of the various fluids during a procedure is the most important aspect of the manifold design, because the physician needs complete control over the contrast agents and saline in order to attain sharp images in a timely manner. During the procedure, the physician is exposed to x-ray radiation, which is a concern expressed by Dr. Strother. Consequently, the amount of fluid control one has during the operation greatly reduces the time they are exposed. The screw clamp manifold displays the most precise amount of command over the various fluids but would offer the slowest operation in terms of opening or closing the lines completely, because the design only incorporates screw clamps on the port lines with a manifold shell. The

single piece design received the next largest allotment of points, because it prevents blood from reaching the fluid reservoirs with the one-way valves and also contains the stopcocks in the main line, which allow for quick opening and closing of ports. The multiple pieces manifold received near perfect scores in this category, because it allows for regulation of flow rate, along with all the other control methods stated previously including absolute stoppage from the stopcocks and blood contamination prevention through the use of one-way valves.

Set-up Time

The set-up time required to prepare the manifold for the pending procedure is also very important to the overall design and makes up 25% of the total points available. The more complex the design is, the more time is needed for the physician to ready the operating table. The multiple pieces manifold scored the lowest allotment of points in this section, because it contains the most components which will all have to be assembled before the procedure. The screw clamp design received the next highest number of points, because it's assembly only involves placing a screw clamp over the tube protruding from each port on the manifold. The single-piece manifold scored the highest because being one piece, it requires minimal set-up.

Contamination Detection

Air bubble and blood detection is imperative to the overall success of the procedure and health of the patient. Air bubbles that are injected into the subject can lead to harmful complications and blood flowing back up into the manifold can clot and reinjection can cause major problems. Therefore, the design must be conducive to locating these air bubbles and blood, therefore this category consists of 15% of the total amount of points available. The single piece design received the lowest amount of points, because it has stopcocks in the main line of the manifold which can obstruct the view of the user, making contamination detection difficult.

The multiple pieces design was awarded the next largest portion of points, because its manifold line is clear, but it also incorporates three different components that the physician must inspect to ensure patient safety. The screw clamp scored the highest amount of points in this category, because it also uses a manifold shell but only has one component (screw clamps) to hinder air bubble and blood detection.

Cost

Cost played the smallest role in the design selection process, because the main focus is on the design's functionality. Additionally, none of the parts included in any of the designs were very expensive. A package of 3 screw clamps could be bought for $20 and ramp clamps are $63 for a package of 12. Also, a package of 10 one-way valves cost $6.75 and stopcocks with one-way Luer connections are $28 for 12 pieces (Cole-Parmer) The single piece and multiple pieces designs scored 4 of the possible 5 points, because they involve multiple components or alteration of the manifold. The screw clamp received all the points, because it involves placing only one screw clamp on each port tube.

Manifold Stand

The manifold stand design matrix is comprised of ease of manufacturing, cost, versatility, stability, and space efficiency. Based on the point breakdown shown below, the clamp design received the largest amount of points and is the design that will be pursued in the future.

	Clamp	Weighted Box	Moveable Arm
Ease of Manufacturing (20)	18	19	10
Cost (5)	4	5	2
Versatility (25)	20	22	23
Stability(30)	29	20	18
Space Efficiency (20)	18	16	12
Total (100)	89	82	65

Ease of Manufacturing

As noted in the first section, the design must be within the team's abilities to fabricate successfully. Therefore, this section was allotted 20% of the total points for the design. The moveable arm design scored by far the lowest in this category, because it involves creating a stand with three segments attached via various joints. The ability to move the manifold but also maintain stability would be very hard to achieve. The weighted box manifold stand would be the easiest to construct, because it entails a box weighted down by a high density material. A slotted mechanism would be incorporated as well as rubber pads to increase the stability of the stand. Both of those additions are relatively easy to assemble. The clamp is also very easy to make, scoring only slightly lower than the weighted box design. The design involves a screw clamp which affixes to the table and the aforementioned slotted mechanism.

Versatility

The ability of the manifold stand to be placed in multiple locations is very important during a procedure; consequently, this section received 25% of the total. The physician may want the manifold to change locations during an operation or vary the location from procedure to procedure. All of the different designs scored well, because they fulfill the requirements listed above. The moveable arm received the most points, however, because it can move in the z direction, which is beneficial for physicians of differing heights. The clamp manifold stand received the lowest allotment of points, because it must be fixed to the edge of the operating table to be secure. The moveable box design scored between the previous two designs in this category, because it can move anywhere on the table, but cannot be elevated.

Stability

During a procedure, when the manifold is placed in its permanent position, there must not be any slipping or moving due to other forces placed on the tubing connected to the manifold. If this happens, nonproductive interactions with the manifold take place, leading to time inefficiency. As stated previously, procedure time must be reduced as much as possible, so the stability of the manifold stand is very important. Stability was allocated the largest portion of the total points available with 30%. Because of its nearly flawless securing application to the operating table, the clamp design scored the most points in this section. The only way the manifold could be moved is to unscrew the clamping mechanism, which cannot happen with typical manifold operation. The weighted block scored the next largest portion of points, because its rubber pads limit the amount of unnecessary sliding that the block might perform. The moveable arm has the most difficulty keeping the manifold in place, because the joints must be moveable, but cannot move because of a non-purposeful force on the manifold.

Space Efficiency

Disorganization and clutter are major problems during angiography procedures, as Dr. Strother has informed the team, therefore the manifold stand must not occupy operating table space or surrounding environment in an inefficient manner. The moveable arm includes a stand for the actual arm to attach to, which must be positioned next to the table. This requires the physicians to walk around the moveable arm when they wish to move to the other side of the operating table. Also, the stand's platform consists of a solid block, making the device difficult to stow away after procedures. Consequently, this design was allotted the lowest score. The weighted block is positioned in various locations on the table itself, which takes up space that could otherwise be used in the procedure. This design received the second largest amount of

points. The clamp manifold design scored the best, because it positions the manifold off the table, therefore reducing the space needed to set-up the necessary equipment.

Cost

The manifold stand will not be a recurring cost, so this criterion is not as important as the others, but still plays a small role in the design ultimately chosen. The moveable arm received the lowest number of points, because it involves many joints and a stand for the arm to set on, which will cost more than the simple clamp and block of the other two designs. The clamp received slightly less points than the weighted block because it is more difficult to make and requires more parts made of different materials than the simple weighted block.

Saline Bag

The design matrix shown below was used to assess the feasibility of each of the three designs for a saline bag alternative. Each design was compared and assigned values based on the categories listed in the matrix, including consistency, cost, space efficiency, safety, ease of manufacturing, and fluid level detection. Based on the point breakdown the team will be moving forward with the ball stopper design which received the largest allotment of points in the table.

	Peristaltic Pump	Hanging Alarm	Ball Stopper
Consistency (20)	20	16	16
Cost (5)	2	3	4
Space Efficiency (15)	10	14	15
Safety (25)	15	18	23
Ease of Manufacturing (15)	15	8	13
Fluid Level Detection (20)	19	14	14
Total (100)	81	73	85

Consistency

During an angiography procedure, there is a constant flow of saline running to the patient to ensure no blood travels back up the catheter. The flow of saline cannot vary to the extent that

it affects this prevention technique. A consistent flow rate throughout the procedure is preferred. This category received 20% of the total points available, because of its importance in maintaining patient safety. The peristaltic pump received perfect marks, because it uses rollers to provide a consistent flow rate throughout the procedure. Both of the other designs received 16 points, because they rely on the pressure jacket to maintain the consistent flow rate. Additionally, it is difficult to pump up the jacket to consistent pressures each time it is used.

Cost

As stated before, cost is not the determining factor of which design was chosen, but plays a minor role in the selection process. The peristaltic pump requires a higher initial cost, but does not involve any recurring costs. The hanging alarm system also requires the initial cost of the scale and alarm setup, but no recurring costs as well. The floating ball design costs virtually nothing up front, and only has minor recurring costs, because it is disposable, so it received the highest marks in this category.

Space Efficiency

The importance of this category is described in the manifold stand section, and is similarly applied to the saline bag alternative and was portioned 15% of the total. The peristaltic pump will be placed on the operating table close to the manifold, so it was allotted 10 points. The hanging alarm incorporates an additional scale to the saline bag hanger as well as a speaker and light, so it received the second largest score. The floating ball design entails a small attachment under the saline bag with no major space inefficiencies and scored the best in this category.

Safety

The safety of the patient is an extremely important aspect of the saline bag alternative design, so it received 25% of the total points available. If air bubbles are injected into the patient, as stated before, major complications can ensue. The peristaltic pump did the worst in this category, because there is no direct mechanism to shut down the pump when the saline solution runs out. It is much easier to see the levels, but it is up to the physician to monitor the saline. The hanging alarm features a system which alerts the physician when it is time to change out the saline bags, which eliminates the need for constant monitoring of the system. The hanging alarm system thus was allotted the second largest portion of points. The floating ball design did the best in terms of patient safety, because the ball obstructs air flow after the saline levels reach zero.

Ease of Manufacturing

As stated before, the ability of the team to construct the design must be taken into consideration, so ease of manufacturing was given 15% of the total points. The peristaltic pump comes manufactured, so it received perfect scores. The hanging alarm system would require the most amount of time and effort to fabricate, because it involves creating a circuit to produce an alarm to alert the physician of low saline levels. The floating ball also comes pre-made, but must be integrated into the saline bag flow route, so it was given the second most points.

Fluid Level Detection

Although air bubble prevention is the most important aspect of the design, the ability of the physician to monitor the saline levels before they reach critical values is also important. The fluid level detection ability received 20% of the total allotment of points. Both the hanging alarm and the floating ball designs do not improve over the current apparatus, but fluid level detection is still possible by looking through the pressure jacket. The peristaltic pump offers the easiest visualization of the saline levels, so it received the largest allotment of points.

Final Design

The final design consists of three separate pieces: the manifold, the manifold stand, and the saline drip chamber illumination LED light. The manifold, shown in Figure 13, is built from an altered five port manifold with stopcocks. Each stopcock was opened in all directions by using a small diameter drill bit and drilling the piece through to the open center. Epoxy resin was used to seal both the top and bottom of each stopcock to ensure no fluid could escape the system, as well as fix the stopcocks in place. Since rotating the stopcocks would no longer be necessary, the handles of the stopcocks were cut off to increase visibility of the fluid pathway. One-way valves were attached to the front, end and three main ports on the manifold to prevent blood and other fluid from moving up into the manifold and attached fluid reservoirs. The remaining main port is the site of waste removal, and must allow fluid to flow out of it. Each port also contains a flow switch, which

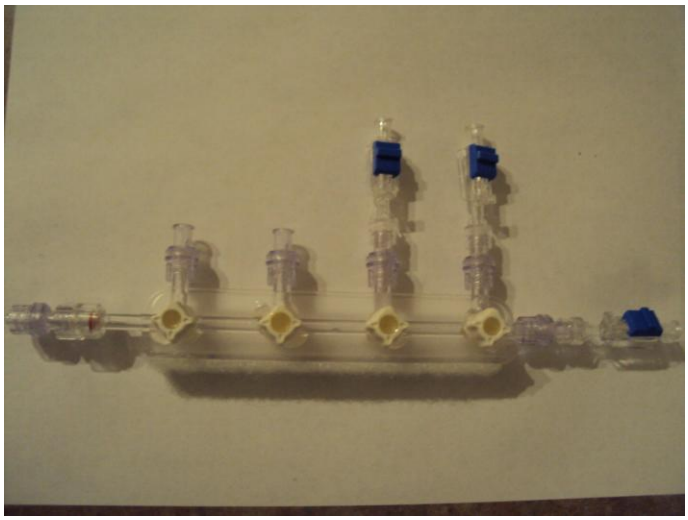

Figure 13: Manifold Prototype

controls fluid delivery to the manifold. The flow switches are easily positioned “ON” to allow fluid flow or “OFF” to stop fluid flow, with an audible click when switching between positions.

The manifold stand, shown in Figure 14 fastens to the operating table with the spring clamp of a bed lamp. The lamp head was removed from the clamp, leaving just one inch of the arm itself as an attachment point. To adjust for varying table sizes, shims are used to guarantee firm attachment and manifold orientation to the user. Three straight pieces of PVC piping and two elbow joints were assembled to create an arm to hold the manifold table above the operating table. Each connection point between these pieces was sanded down and epoxy resin was added to fix the stand in place. The PVC pipe was then placed around the metal lamp arm, and epoxy resin was applied to secure the connection. The manifold table was constructed out of clear plexiglass and was cut to the dimensions of 8 inches by 4.75 inches. The table was fastened to the PVC arm stand with epoxy resin. On the top surface of the center of the table, a Velcro strip was placed, and the opposing Velcro was attached the manifold itself on two faces for adjustable placement. The PVC piping was then spray painted blue to match the spring clamp color was aesthetic reasons.

Figure 14: Manifold Stand

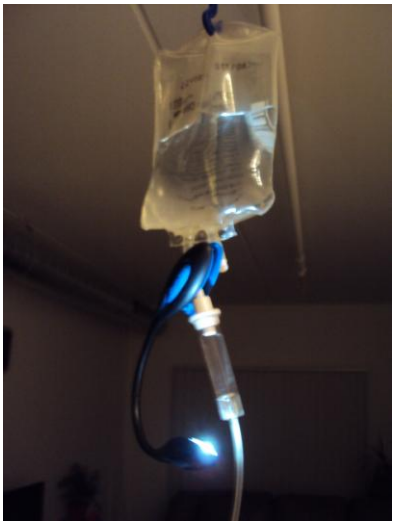

Figure 15: Saline Drip Detection Device

The saline level detection device, shown in Figure 15, consists of a book light which clamps to the saline carousel present in the operating room. Once properly positioned and

turned on, the LED light allows the operator to correctly identify if saline is dripping into the chamber, even from a distance. The light has an adjustable neck, which allows for easy modification of the illumination direction. The LED light should be placed under the saline drip chamber facing up, which allows for the easiest visualization of the saline.

Testing

Pressure Testing

In order to test the effectiveness of the one-way valves in preventing the influx of blood and other fluid into the manifold, the valves were subjected to pressurized fluid testing. A line with a spike was hooked up to a saline bag, and at the end of the line opposite the saline bag a two-way stopcock was attached. A one way valve was also attached to a second port on the two-way stopcock, and the stopcock was turned so that fluid flowed from the saline bag "backwards" into the one-way valve. That is, the system was arranged so that saline would flow through the one-way valve in the direction that the valve was designed to prevent. A cuff connected to a pressure gauge was then placed around the saline bag, and the cuff was slowly inflated to increase pressure in the system. The whole arrangement was arranged horizontally on a flat surface so that the only source of pressure in the system was due to the pressure cuff and not gravity. The one-way valve was checked for leakage at intervals of 40 mmHg, up to 300 mmHg. The upper limit of 300 mmHg was chosen because it is the upper limit of the pressure that can be generated in the human cardiovascular system, and the main cause of back flux of blood into the manifold would be due to blood pressure [8]. As can be seen in the table in Figure 13, the one-way valve did not leak at any pressure. Thus the one-way valves will effectively prevent the influx of blood into the manifold and connected systems.

The flow switches are another element in the design that could be subjected to high pressures when closed, so they were also subjected to the pressurized fluid testing. The one-way valve from the previously mentioned set-up was replaced with a closed flow switch, and the same procedure was followed to test the leakage of the flow switch under increasing pressure. Once again, as seen in the table in Figure 16, the flow switches did not exhibit any leakage under any of the pressures to which they were subjected. Therefore, they are suitable replacements to the previously used stopcocks.

Pressure (mmHg)	Valve Leakage?	Flow Switch Leakage?
40	No	No
80	No	No
120	No	No
160	No	No
200	No	No
240	No	No
280	No	No
300	No	No

Figure 16. Pressure Testing Results

LED Spike Illumination Testing

In order to investigate the effectiveness of the LED light in monitoring the saline reservoirs, an illumination test was performed. Three conditions were tested: lights in the room on, lights dimmed with no LED illumination (to imitate dimming the lights during a procedure), and lights dimmed with the LED on. For each condition, subjects were tested at 3 different distances from the saline bag: 5 ft, 10 ft, and 15 ft. For each distance, 5 trials were conducted in which the saline was set to either flow or not flow, and the subject was asked to identify whether the saline was

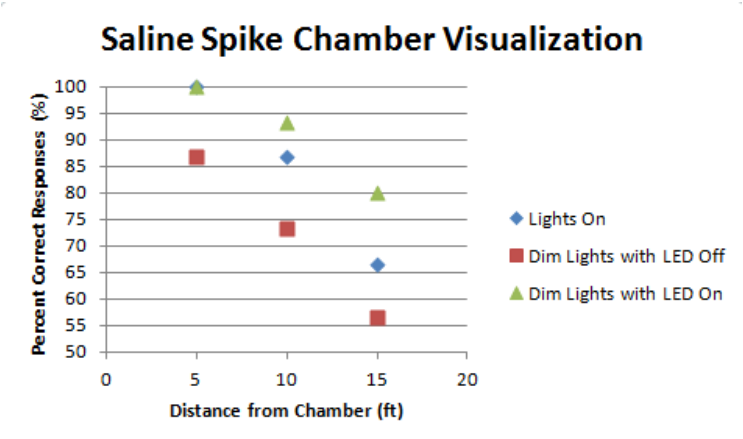

Figure 17. LED illumination testing results

flowing or not, or to identify that he could not tell one way or another. Thus, a total of 45 trials were conducted per subject, and 3 subjects were tested. The graph in Figure 17 shows the overall percent of correct answers for each set of conditions. As was expected, the accuracy of responses decreased when the lights were dimmed and no additional illumination was provided. Accuracy also decreased with distance, as expected. However, once the LED light was turned on, the accuracy of responses surpassed not only those obtained under dim lighting with no LED illumination but also the accuracy of responses under normal lighting. Thus, the LED significantly improves an operator's ability to monitor whether saline is running.

Flow Pattern Testing

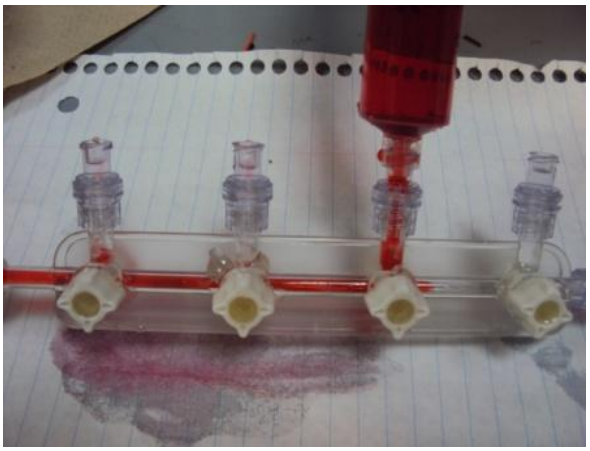

Figure 18. Example picture from flow pattern testing

Since the junctions of the manifold where the stopcocks are positioned in the prototype allow fluid flow in three directions instead of two as they did previously, it was important to confirm that fluid would still flow in the correct direction out of the manifold to the catheter during use. To test this, the system was set up such that one way valves were attached on all ports, a line from a saline bag was attached to the far back end port of the manifold, and a line leading to a collecting reservoir was attached to the front output port of the manifold. The saline was then allowed to run, so that the system filled with fluid (eliminating dead space). Then, the saline flush was turned off. A syringe was used to inject dyed water into each port one by one, allowing the path of the fluid as it entered and left the manifold to be easily seen. Pictures were taken to record results, an example of which can be seen in Figure 18. Between each injection, dyed water was

flushed from the system using saline. After all ports had been tested, the saline flush was allowed to flow and the entire process was repeated, to see if flow path of the injected fluid changed at all. For the most part, fluid flowed effectively out of the manifold. However, during the injections, fluid had a tendency to flow backwards slightly in the manifold towards the end to which the saline bag was attached. However, the volume moving backwards was a very small fraction of the total injections, and typically did not move backwards farther than a few millimeters, as the one way valves prevented any flow backwards into any of the manifold ports. For injections closer to the back of the manifold for which injected fluid had to pass several other ports on its way out of the manifold, some of the time small amounts of fluid would move up into the "necks" of the ports, but never past the one-way valves. This fluid, which was usually only a very small fraction of the total fluid injected, was easily removed from the manifold by running fluid through the affected ports.

Fluid Delivery Test

In order to confirm that the prototype still performed the primary function of the manifold, which is accurate delivery of fluid to the catheter, a fluid delivery test was performed. The manifold was set up so that one way valves were on all ports and a bag filled with water was attached to the back port. The manifold fed into a line which dispensed fluid into a beaker. The water from the bag was used to fill the system and eliminate dead space. Subsequently,

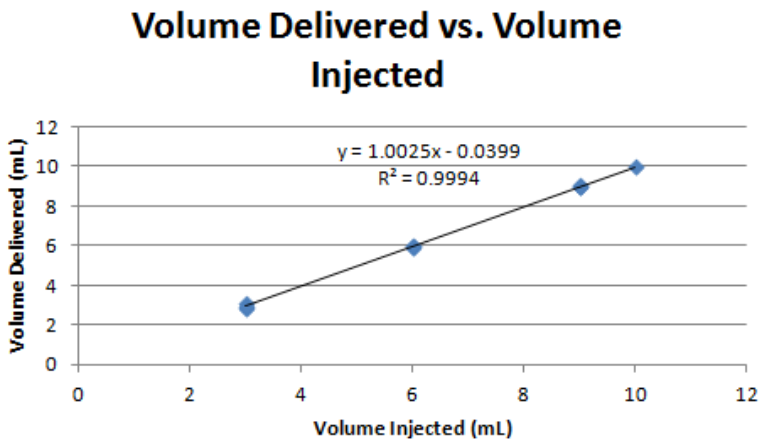

Figure 19. Fluid delivery test results

injections of known volumes of water into a dry beaker were used to gravimetrically obtain a value for the density of water, which was determined to be 1.0183 g/mL. Once this was accomplished, water injections of varying amounts from a syringe were made into one of the ports of the manifold, and the resulting fluid outputs of the manifold were collected in a dry beaker. The volume of water delivered was then determined gravimetrically using the value of the density of water obtained previously. The experimentally determined relationship between the volume injected and the volume delivered is shown in Figure 19. As the equation on the graph shows, the manifold delivers the desired volume very effectively. In conclusion, the changes made to the manifold did not interfere with the effective performance of the manifold in delivering fluids to the patient.

Saline Drip Testing

A primary concern expressed by Dr. Strother was when the saline reservoirs run dry, air bubble can flow down the tubing, into the manifold, and subsequently into the patient. In order to test whether this actually happens, a saline bag was punctured and allowed to flow through the drip chamber into a waste bucket. When the bag was nearly empty, the line was watched closely for any air bubbles that would descend from the bag to the waste fluid. In the trial, the saline bag proved to be a vacuum, and no air bubbles were sent down the system. We performed this test two more times to prove this was the case. From these results, the group was able to eliminate an air bubble prevention design from the final design described earlier. The LED light was then denoted as the main saline level detection design for the project.

Efficiency Testing

In order to assess the improvement to the procedure brought about by implementing a manifold stand, an efficiency test was performed. For this test, each subject completed two trials,

one using the previously existing manifold and no stand, and another using the new manifold and its accompanying stand. The first half of the trial involved setting up the manifold in a mock preparation for a procedure. The manifold was connected to all necessary components (saline bags, waste bag, catheter) and cleared of air bubbles. The second half of the trial consisted of 5 mock injections using a hand syringe connected to a a port on the manifold. During both portions of the test, the subject was timed and the number of nonproductive interactions the subject had with the system were counted. Nonproductive interactions were defined as any manipulation that did not perform a function inherently necessary to performing the procedure, such as readjusting the manifold or fixing the alignment of a valve. The time results of this test are displayed in Figure 20 and the nonproductive interaction results are shown in Figure 21. Both the set up time and the mock injection time, and thus the overall procedure time, were reduced when the prototype set up was used. In additon, the number of nonproductive interactions were greatly reduced by the use of the prototype set up. Therefore, the manifold prototype and stand significantly improve the efficiency of procedures it is used in.

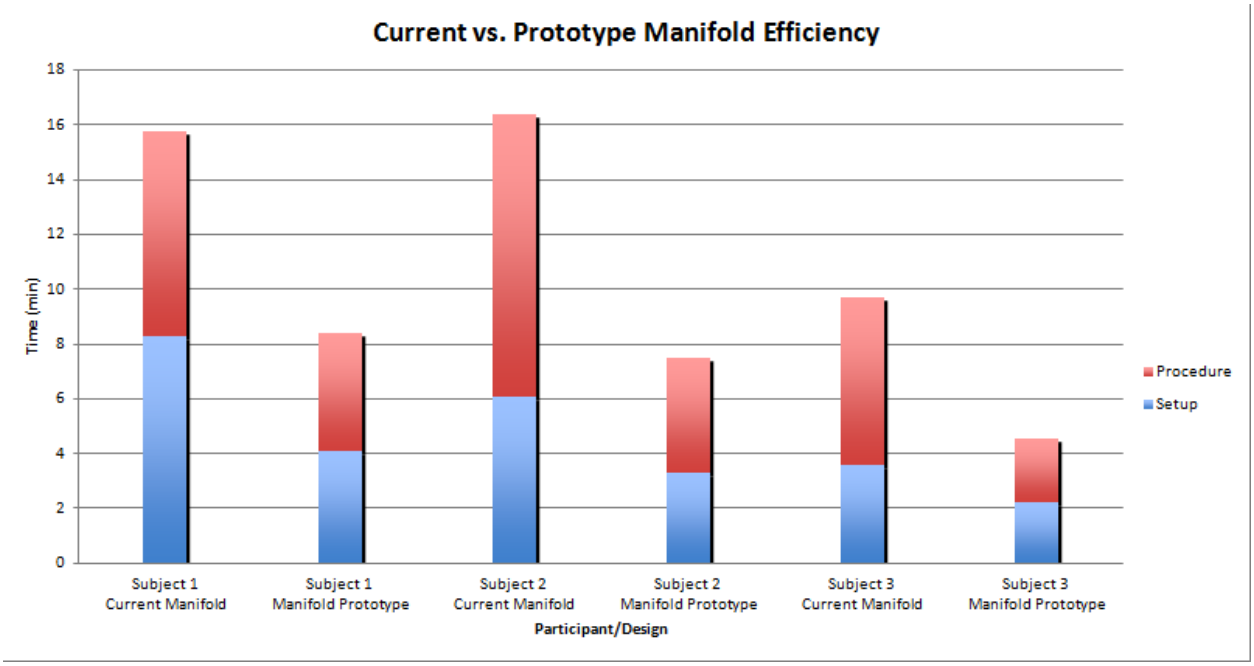

Figure 20: Efficiency testing procedure and set-up duration results

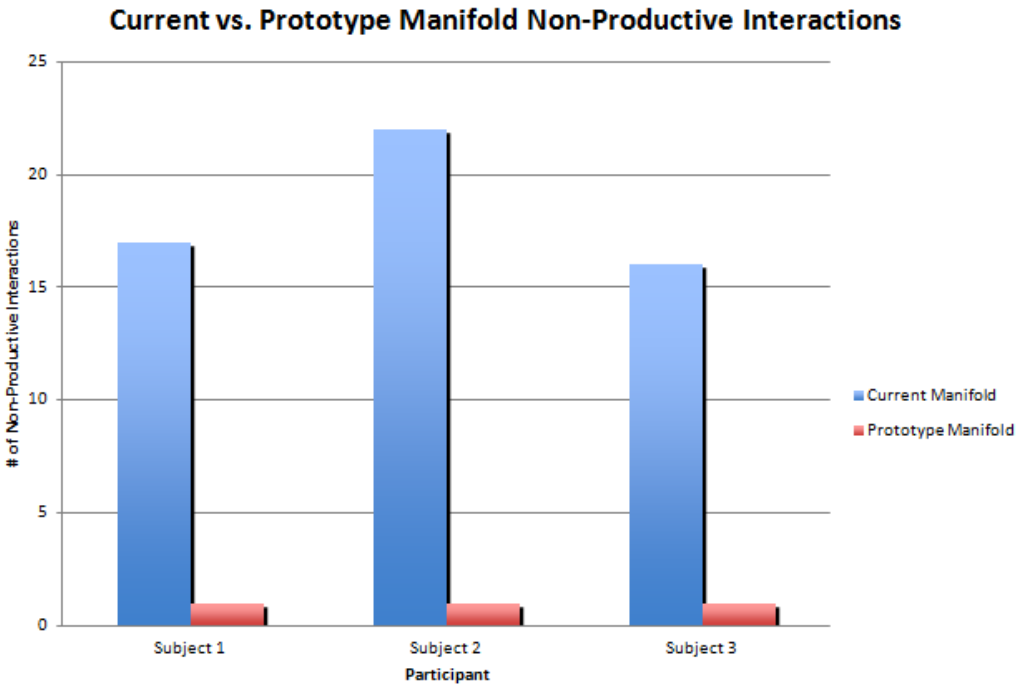

Figure 21: Efficiency testing non-productive interaction results

Cost

The entire cost of producing the prototype manifold, stand, and LED light was $60.11. Most of the cost was due to purchasing parts, as most of the fabrication was done by the team. For the manifold, the manifold piece itself which was altered to be the central piece cost $8.00. The flow switches cost $9.25 total, and the one-way luer check valves cost $6.75 in total. The Velcro used to attach the manifold to the stand was $5.99. The PVC piping and joints used to construct the stand cost $1.12 and $0.56 respectively. The plexiglass used for the table portion of the stand was $3.99. The epoxy plastics glue that was used for making the stand and for fixing the stopcocks in the manifold cost $3.97. The table clamp used in the stand came as part of a table lamp which cost $8.99. Finally, the LED light cost $10.99. If the designs proposed in this paper were used regularly in practice, the costs of the manifold would be recurring but the costs of the stand and LED light would not. In addition, the money spent on the fabrication of the prototype pieces is more than needed, because many of the materials were not used entirely. For example, only some of the Velcro, PVC piping, and plexiglass were actually needed for prototype fabrication, since there was leftover material after the prototype was made, and in order to acquire the clamp a larger more expensive piece, the lamp, had to be purchased. Thus, fabrication could be made more efficient to reduce the cost of producing the design that has been presented.

Time Management

The majority of our time on this project was devoted to identifying specific problems with the angiographic process. Many of the professionals familiar with the procedure had a vast array of critiques and suggestions, and it was difficult to narrow down the scope of the project to one that fit the allotted time of one semester. A complete summary of the team's activities over

the course of this semester can be found in Figure 22. Since two of the members of the group were very familiar with angiographies already, only minor research was necessary to gain the necessary knowledge to successfully complete the project. Early in the semester, the focus of the group was to identify these problems. People familiar with angiographies were interviewed and procedure videos were analyzed to complete this portion of the project. Subsequently, the team was able to devise solutions to the problems at hand and develop three design concepts for each separate section of the project. After doing more background research to determine the most important aspects of the separate design sections, the manifold stand, the multiple-pieces manifold, and the floating ball design were selected, and the team moved forward with these design concepts in mind. The necessary supplies and parts were gradually acquired over the next few weeks, and prototypes of each design were created. The saline floating ball design was shown to be unnecessary, so it was eliminated from the final design scope of the project and replaced with the LED light. Following the fabrication of the manifold stand and manifold itself, extensive testing was performed to ensure the semester's goals were solved.

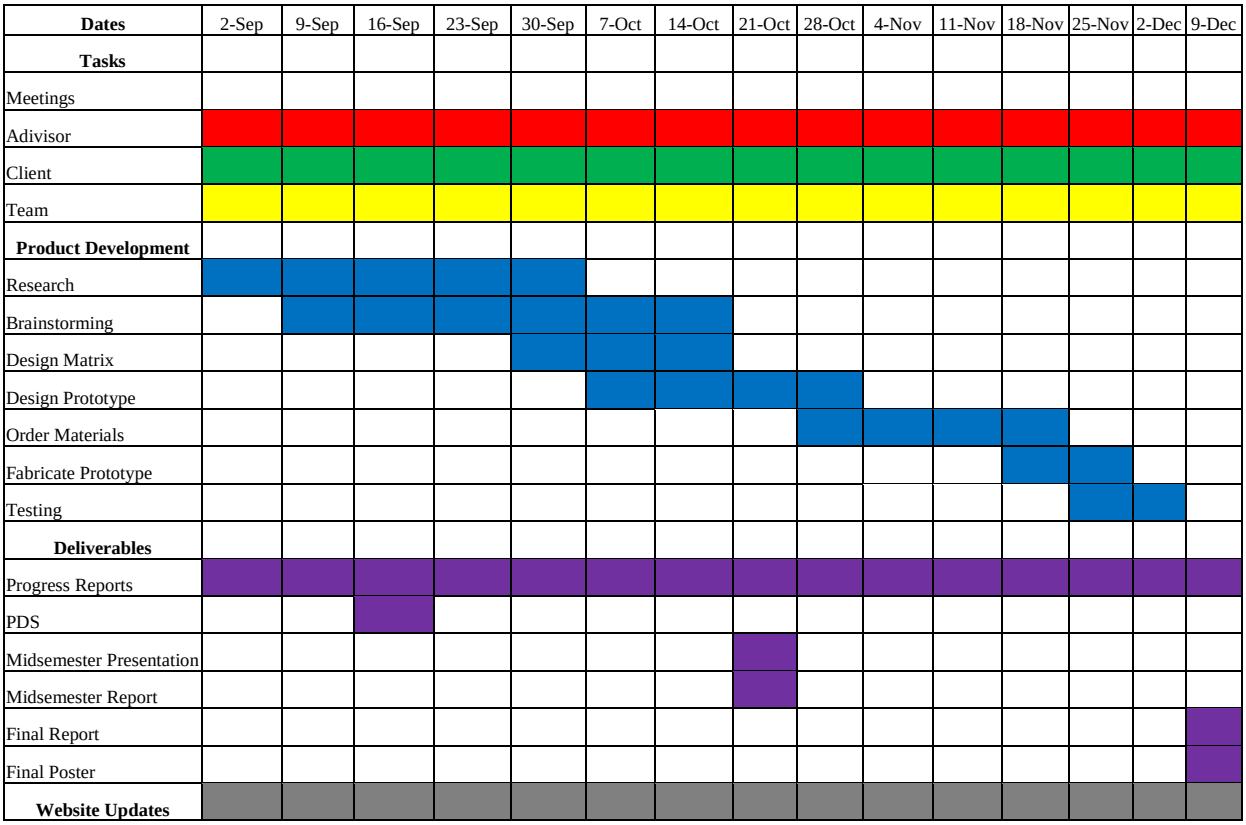

Figure 22: Project Timeline

Ethics

In the construction and implementation of the device, some ethical considerations need to be taken into account. Since the device is to be used in procedures on humans, unnecessary harm or pain should not be caused to any person the device is used on. Because of this, a priority in the design process was ensuring that air bubbles were either prevented or easily identified and removed in order to limit the risk of air entering the patient. The prevention of blood clot development was also an important consideration in the design process, since those too can pose a serious risk to patients. The safety of operators was also taken into account in the design process. The device was designed to decrease procedure time to reduce the exposure of operators

to x-rays due to long procedures. In addition, the device was designed so that it would present as little risk of injury to the operators during use, such as by sanding down corners and sharp edges.

Future Work

Although the final prototype is functional, there is still work that would need to be done to take it to clinical or professional use. With regards to the manifold piece itself, replacing the currently used modified manifold with a simple 5-port connection piece would be needed. This replacement would be a plastic piece with 5 incoming ports and one outgoing port and no stopcocks. Thus, all channels would be completely visible, and the piece itself could be made smaller and with less material than the currently used modified manifold. Aside from improving manifold channel visibility, removing the stopcocks also decreases the number of locations bubbles could get trapped in the device. Additionally, manufacturing the connection piece with the flow switches built into the ports would make the device easier to use and reduce set-up time. Built-in flow switches would also reduce the number of connection junctions, therefore reducing the number of places air can enter the system. Connector pieces that would allow the one-way valve for the waste port to be put on backwards should be added, so that fluid could only flow out to the waste reservoir. This would prevent waste from flowing out of the bag and into the manifold. The current prototype only has three flow switches implemented into the design due to the fact that only three could be acquired, but an improved design would have all ports regulated by flow switches. Designing an air embolism prevention device to place on the manifold between the outgoing port and the catheter to trap or prevent any air bubbles from reaching the patient would also be an important addition to this design in the future.

In order to take the stand to clinical use, the device would have to be made so that it could be easily sterilized. This would entail changing the material from PVC to metal, so it can

be autoclaved for sterilization. To make the device more user-friendly and versatile, the device would be altered so that it could swivel around the base for easy positioning. In addition, a mechanism allowing the table portion of the manifold stand to be set at different angles of inclination would be implemented in the design. The mechanism of securing the manifold to the stand would also be improved, since it is not always desirable to have to put Velcro on the piece before use. This alteration should also make the connection sturdier.

The clamp on the LED light would be replaced with a piece that allows it to more securely be fastened to the carousel or structure used to hold the saline bags. One possibility would be a screw clamp, which would be fastened to the carousel. Also, it was noticed that at certain positions the light could produce small glare on the spike chamber, and when viewed directly, the light was very bright. Therefore, either the light would be replaced or a covering placed on the light to make the light softer and reduce the glare produced by the light. In addition, since there are a number of different saline reservoirs that require monitoring during the procedure, using differently colored lights for different saline bags would make it easier for the physicians to distinguish between the various fluid bags. Another change that would make it easier to monitor multiple bags would be to replace the round carousel with a straight bar with hooks so that bags could be hung next to each other, so that no bag is hanging in front of any other bag and blocking the view of the saline drip chamber

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Appendix

Contrast Injection
Project Design Specifications
September 15, 2011
Group Members: Chris Besaw, Steve Young, Rafi Sufi
Advisor: Dr. Naomi Chesler
Client: Dr. Charles Strother

Function:

Client Requirements:

1. **Physical and Operational Characteristics**
    a. **Performance Requirements:** The main component of the device will be a manifold which will allow for easy fluid management for injections. It must be compatible with hand injectors as well as power injectors, which will be used for contrast agent delivery. It must be able to deliver both contrast and saline flush to a catheter. However, the manifold must also have extra ports to allow for injections of other fluids. The device must allow for constant access to the catheter during use.
    b. **Safety:** The device must make detection of air and blood in the fluid faster. This can be done via sensors such as ultrasound or by making the presence of air and blood easy to see visually. Prevention of air bubble development and blood influx must also be included in the design. The device must be able to be rinsed with a saline flush at any time with a minimal number of interactions with the manifold. A waste removal system must also be implemented in the design.
    c. **Accuracy and Reliability:** The device must be able to accurately and consistently deliver the desired volumes of saline and contrast agent at the desired flow rates. The device must be robust enough that it will not break and that components will not become disconnected during operation.
    d. **Life in Service:** The device is intended for one time use, so sterilization via autoclaving or chemical sterilization is not an issue. The device must be disposable.
    e. **Shelf Life:** The device should be able to remain in operating condition for long periods of time. Since the device is to be made mainly of plastics, this should not be an issue.
    f. **Operating Environment:** The device will be used in a surgical setting for x-ray procedures. It must be inert to x-ray radiation and any substance it is used to inject, which is primarily saline and contrast agent but could include other fluids.
    g. **Ergonomics:** Fluid flow control must be easily manageable. Detection of air and blood must be easy to perform quickly. The device should be space efficient and not cumbersome to the operator. Input ports should be easily accessible. Connection to fluid reservoirs should be quick and efficient to perform.
    h. **Size:** The manifold portion of the device should be about 6 inches long and 2 inches wide. In essence, the device should not become cumbersome to the operator during use. The entire device, including manifold, tubing, y-connectors, etc., must be as space efficient as possible.
    i. **Weight:** The manifold, tubing, and y-connectors should be lightweight.
    j. **Materials:** Plastic commonly used in medical tubing and manifolds, must be chemically inert, nonreactive to x-ray radiation, and robust.
    k. **Aesthetics, Appearance, and Finish:** Must look professional. Pieces must be clear for the most part to maintain visibility of fluid contents.

2. **Product Characteristics**
    a. **Quantity:** Our client requests one unit to be built.
    b. **Target Product Cost:** The device should be competitive with current manifolds on the market, in the range of $6.00 - $25.00.
3. **Miscellaneous**
    a. **Standards and Specifications:** The final product must meet medical device standards.
    b. **Customer:** The intended user of this device will be used by doctors and researchers who are performing diagnostic and interventional angiographers.
    c. **Patient Related Concerns:** The design must allow for controlled injections to patients, prevent air bubbles from being injected, prevent blood from flowing back up into the manifold and contaminating fluid, and must be ergonomic so that inexperienced operators may be able to correctly use the device.
    d. **Competition:** The Avanta Fluid Management Injection System made by Medrad performs many of the functions intended for this device, but is expensive and not widely used. There are very few other devices that combine the use of the manifold fluid management system and the ease of use of the power injector in the manner this device is intended for.