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April 22, 2008

Dr. Mark Gartner
CEO Ension

Dear Dr. Mark Gartner

We are submitting our business plan for a newly designed central venous catheter device. The device is intended to replace the current method and equipment for placement of a central venous catheter (CVC). Due to the numerous complications occurring from current CVC placement, it is a matter of great importance that steps are taken to reduce error and provide better treatment for patients.

Our design includes a needle, a three-way connector piece that contains a one-way valve to prevent blood loss following the removal of a support handle, a comfortable support handle, and a pressure sensor. These components will fit together to allow the clinician to enter a vessel, obtain the vessel's blood pressure, determine whether the vessel is a vein or artery, obtain visual confirmation of blood in the connector from the vessel, remove the handle without blood loss, and insert the guide wire into the patient. With the pressure sensor, comfortable support handle, and prevented blood loss, the new design will minimize error associated with accidental arterial punctures as well as reduce the amount of CVC associated infections.

We thank you for your review of our business plan and would appreciate any feedback or input you may have in our design process.

Sincerely,

Jennifer Adams, Janet Chan, Evan Hill, Matt Wolf

Engineering Equipment for a Simplified Central Venous Catheterization

Business Plan Proposed By:
Jennifer Adams
Janet Chan
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Matt Wolf

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DEVICE SUMMARY

Our design team offers a new central venous catheterization device, which provides the clinician with a more comfortable support handle and a pressure sensor in order to minimize the error associated with the current method of central venous catheter placement.

MARKET WITHIN CVC TECHNOLOGY

A catheterization is defined as the use or insertion of a tubular device into a duct, blood vessel, hollow organ, or body cavity to inject or withdraw fluids for diagnostic or therapeutic purposes. [1] Catheters are commonly placed in the veins of patients who have recently suffered from a severe decline in blood pressure due to blood loss. These patients often lack pronounced peripheral veins and must be administered a central venous catheter (CVC). CVCs allow drugs to be delivered quickly and effectively into the central blood system and provide the clinician with venous pressure information. The most common CVC is inserted into the internal jugular (IJ) vein.

The current procedure for the placement of an IJ CVC is extremely complex, resulting in a high possibility of significant error. The clinician must first insert the needle into the blood vessel. The syringe is then removed and a piece of plastic tubing is connected to the needle in order to test whether the needle has entered the vein or artery. Upon correct needle insertion into the vein, the guide wire must be thread through the needle and placed at the correct depth within the patient. Following the guide wire insertion, the clinician must still remove the needle, thread the dilator over the guide wire and into the patient, remove the dilator, thread the catheter into the patient, remove the guide wire, and secure the catheter in place. Minimizing the amount of error within this procedure is an area of great interest. Although the IJ CVC has the least occurrence of complications, there are still several common complications associated with the placement of the CVC.

One of the most common and most serious complications associated with CVC placement is infection of the catheter site. In the year 2000, there were 2.013 incidents of infection associated with central lines per every 1000 patients discharged, not including patients

with immunocompromised systems. [2] These infections can be caused by an amalgam of small errors. The use of sterile equipment is extremely important in the procedure; however sterile equipment cannot fully prevent an infection. Surfaces including the skin and rough cuts can make very inhabitable sites for bacteria. Multiple insertions and jagged incisions provide more rough surfaces for a bacterial infection. These punctures occur when the clinician is unable to place the CVC correctly, which occurs in about 25% of IJ placements. [3] In addition, blood lost from the patient can contaminate the site and provide another surface for bacteria to grow on.

An even more serious, though less common, complication is the possibility of arterial catheterization. Puncturing an artery occurs in approximately 5% of IJ attempts and can cause serious hemorrhages. [3] A patient with an already compromised blood pressure could then have further associated complications. While it is possible for the clinician to easily and quickly correct their mistake when checking the pressure, clinicians pressed for time may not use the tubing to check. If this occurs, the artery can be fully catheterized which can lead to blood or air embolisms and possible death.

While the statistics of complications may seem to be low, CVC placement is an extremely common procedure that is used in a myriad of patient conditions. Often central lines must be placed in trauma or surgical situations in which the patient is in a compromised state. These conditions increase the risk of CVC placement. It is extremely important for clinicians to have a more reliable and efficient method of placement.

In addition to clinicians, hospitals also aim to reduce risk to their patients in an effort to provide a high standard of care. Recently, Medicare stated that they will no longer pay for certain medical errors and that hospitals must bear the cost themselves. [4] In light of this statement,

hospitals will be even more concerned with minimizing complications for all procedures, including IJ CVC placement.

Patients with many varieties of conditions require CVC placement, making it an extremely large field within healthcare. With the current procedure, there are numerous complications and risks, which should be addressed in order to enhance patient care. Hospitals are continuously concerned with increasing quality of patient care, and a device which minimizes harmful complications will be in high demand.

DESIGN FOR A NEW CVC DEVICE

Minimizing possible complications was the most important consideration when designing a new device. Discussion with anesthesiologist Dr. William McIvor provided insight into the largest areas of difficulty in placing a Central Venous Catheterization (CVC) line. The most common difficulty amongst clinicians seems to be the placement of the line in the vein. Both Dr. McIvor and studies have indicated this to be a large area needing improvement. [4,5] Many problems leading to misplacement of the CVC include complexity of the pressure measuring technique and awkward hand positioning. In order to make this process simpler for clinicians, the first consideration is to add a pressure sensor to the CVC device. The addition of a pressure sensor eliminates the cumbersome task of manually checking the pressure, a task which takes additional time and better accommodates error. To include a pressure sensor, a connector must be designed to allow the blood flow to enter the pressure sensor while also providing a port for a handle. By containing a one-way valve, the connector prevents blood loss following the removal of the handle. This eliminates the need for a clinician to awkwardly place their thumb over the port. Finally, an ergonomic handle is designed to maximize clinician comfort while performing the procedure. By maximizing clinician comfort and simplifying the procedure, the error associated with CVC placement will be minimized.

Our design for a new CVC device addresses numerous problems associated with the current procedure for placement of a CVC and will therefore be competitive in the market for CVC technology. The competition will be briefly described below. Since major changes in the new design involve a three-way connector, comfortable handle, and pressure sensor, these components will be described individually following the explanation of the competition. After the design descriptions, the specific methods of device production and testing will be described.

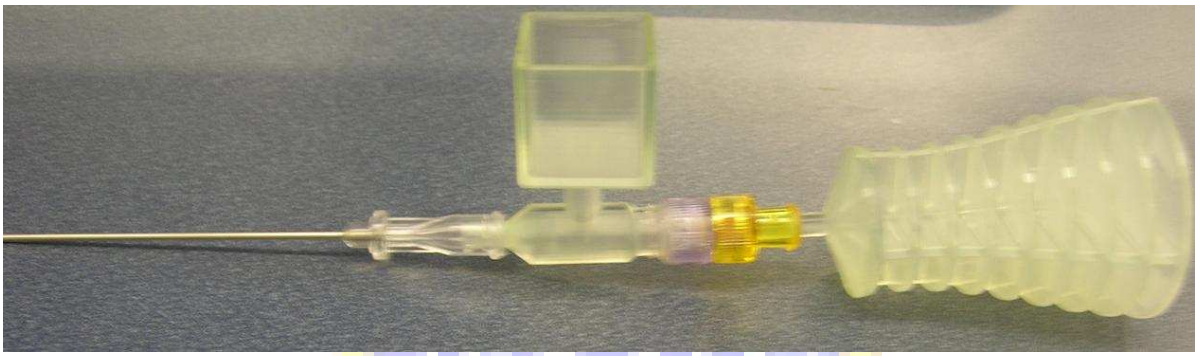

FIGURE 1: The overall design for the CVC device.

COMPETITION

The redesigned device will compete with both current CVC syringe and tubing technology. The traditional syringe used in CVCs consists of a needle and syringe with plunger. The current venous checking technology is the tubing previously described. The use of the redesigned device would eliminate the use of both the traditional syringe and tubing. This provides a competitive edge by greatly minimizing the complexity of vessel entry confirmation. Additionally, continuous confirmation of venous pressure will be available throughout the entire guide wire insertion step.

The ergonomically designed support handle provides the physician with a comfortable and easy way to insert the needle. The physician does not need to be concerned with balancing the syringe and retracting the plunger in order to confirm vessel entry. Currently, blood spills occur when the syringe is removed from the needle and attached to the tube, when the tube is filled with blood (during arterial puncture), and when the tube is removed from the needle. The redesigned CVC device eliminates each of these situations by decreasing the instances of connections and disconnections to the device. The one-way valve also prevents blood loss, allowing for a cleaner and more sterile environment.

The redesigned device cost will be approximately five dollars more than current CVC syringe technology. However, research has shown that costs resulting from CVC complications range from $6,000 to $90,000 per patient. [7] Approximately five million patients receive central venous catheterizations per year, ten thousand of which experience complications due to infection. [2] Conservatively estimating only $10,000 per complication, yearly expenses for CVC associated error total around $100 million. For approximately five million kits, total costs of the redesigned device will exceed current kit costs by $25 million. Therefore potentially $75 million could be saved per year.

THE THREE WAY CONNECTOR

The three-way connector connects the needle, handle, and pressure sensor. The three-way connector also incorporates a duckbill checkvalve at the port joining to the handle. Each port's dimensions are specifically designed to ensure a firm and secure connection. This provides stability for the device as a whole by preventing the parts from falling apart during the procedure. The connector is a hollow cylinder with two ports on each of its circular faces. The third port is on the slender side of the cylinder and perpendicular to the other ports. The needle and checkvalve are placed in the parallel ports while the pressure sensor is placed into the perpendicular port. The valve is a one-way duckbill checkvalve obtained from www.Qosina.com (part number 80065, http://www.qosina.com/catalog/part.asp?partno=80065). The valve is displayed in Figure 2 below. The duckbill checkvalve (purple and yellow piece in Figure 1) allows the guide wire to be inserted through the three-way connector and needle after the handle is removed, while keeping blood from leaking out of the device.

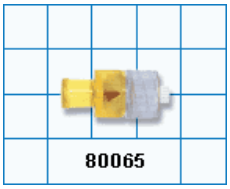

FIGURE 2: The duckbill checkvalve offered by Qosina. Each square is $1cm^2$.

The inner diameter of the needle port, pressure sensor port, and handle port are 2.49mm, 4mm, and 4.17mm respectively. The outer diameter of the needle port, pressure sensor port, and handle port are 4mm, 6mm, and 7.87mm respectively. The inner diameter of the center of the connector is 3.65mm and the outer diameter is 9.78mm. The overall length of the connector is 33.46mm. Prototypes of the three-way connector were produced by Andy Holmes of the Swanson Institute at the University of Pittsburgh. SolidWorks designs were used to produce the prototype using the stereolithography (SLA) technique. The purpose of the prototype is to verify connection between the necessary parts and ensure the chosen dimensions allow for necessary blood follow. Following stereolithography prototype verification, a second prototype will be produced using silicone rubber mold and vacuum casting. This prototype will be used for clinical testing to verify device function. Upon final prototype device verification, a production level device will be produced using plastic injection molding. The three-way connector will be constructed out of polyethylene in order to visualize blood flow. Figure 3 below provides an illustration of the three-way connector.

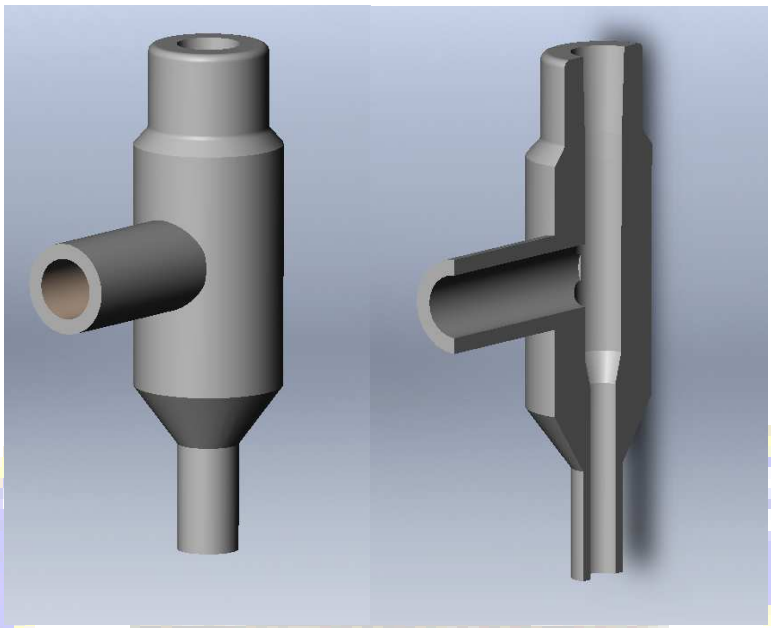

FIGURE 3: Solidworks design for the connector.

THE SUPPORT HANDLE

The support handle is ergonomically designed to rest in the curvature of the physician's hand. Through ergonomic evaluation, a design similar to that of a shortened screwdriver handle was chosen as being easiest for the clinician to manipulate during the procedure. The handle is 75mm long and approximately 25mm in diameter. However the actual diameter varies along its length due to the design of the handle. The port into the connector has a length of 10mm, an inner diameter of 4mm, and an outer diameter of 5.5mm. This port is designed with a tight connection fitting into the valve and three-way connector. The handle was prototyped by Andy Holmes of the Swanson Institute at the University of Pittsburgh. The initial prototype was made using SLA. The purpose of this prototype is to verify handle ergonomics and connection to the valve and three-way connector. A second prototype will be produced from a silicone rubber mold and vacuum cast. This prototype will be used for clinical tests to verify device function. Upon final prototype device verification, a production level device will be produced using plastic injection molding. Figure 4 below provides an illustration of the handle.

FIGURE 4: Solidworks design for the device handle.

THE PRESSURE SENSOR

The pressure sensor is the key component of the device design. The pressure sensor allows the physician to eliminate the cumbersome step of checking the pressure manually and also allows for the unique ergonomic design of the support handle and connector. Although the ultimate goal of this device is to develop a compact pressure sensor display, this goal was unattainable within the amount of time allotted for project completion. However, the first step, proof-of-concept, was obtained through production, verification, and validation.

The pressure sensor circuit is shown below in Figure 5.

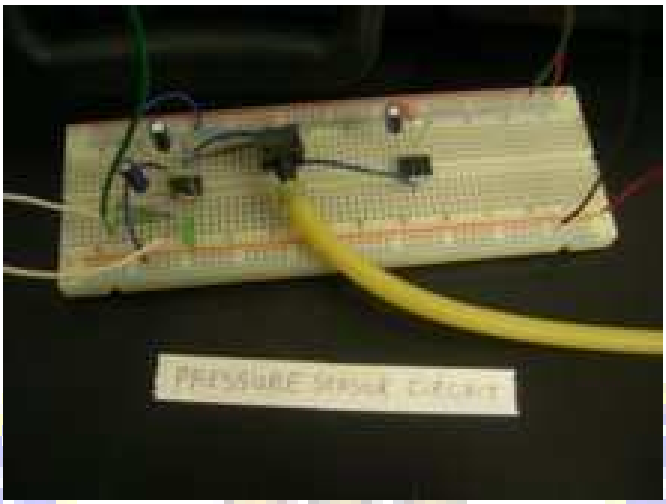

FIGURE 5: Image of the constructed pressure sensor circuit.

As a general description, fluid from the vein is channeled through the needle, into the connector and into tubing that leads from the connector to the pressure sensor, PX26-005GV, which was obtained from Omega (shown in Figure 6).

FIGURE 6: The pressure sensor from Omega.

The pressure sensor receives excitation of a regulated +10V from an integrated circuit, REF01, obtained from NewarkInOne (part # 59K9004). With the exact regulation of the excitation voltage, the strain gauge within the pressure sensor changes the voltage output of the pressure sensor proportional to the change in pressure of the tubing. The output of the pressure sensor is then amplified by an integrated circuit, AD620, obtained from NewarkInOne (part # 59K4387). Once amplified the voltage is connected to a data acquisition device, DAQ 6800, obtained from National Instruments (part # 779051-01). The DAQ 6800 converted the voltage into a digital signal that could be used in LabVIEW. The digital signal was then processed and converted into pressure through calibration equations. Finally, within LabVIEW, the signal was analyzed as

above or below 30mmHg and a LabVIEW display, shown in Figure 7, produced the final pressure readout and red or green light. (Full schematics shown in Appendices A and C)

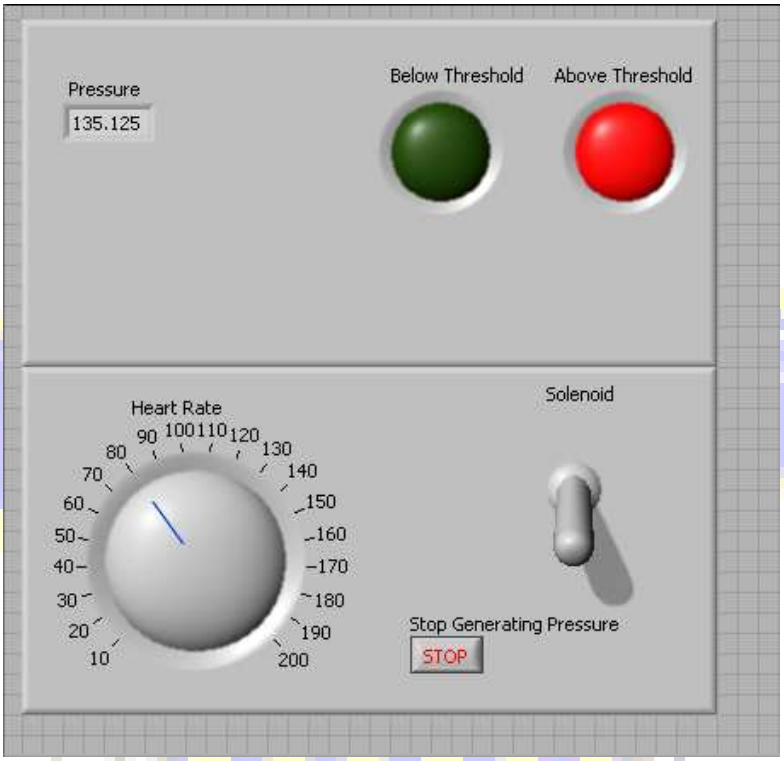

FIGURE 7: The LabVIEW output produced when a high pressure is obtained.

DEVICE MANUFACTURING

Solidworks was used to provide models for each of the handle and connector as well as an assembly for the intended final device. Also required for use of the device are a needle and a guide wire which are obtained from the current kit. The Swanson Center was utilized for all handle and connector SLA prototyping. The University of Pittsburgh Department of Bioengineering labs were used for all LabVIEW and circuit designs. In order to complete design fabrication and testing in a timely manner, the following deadlines were adhered to. Finalized SolidWorks designs were completed by January 14, 2007. An initial prototype was developed by February 8, 2008. The final prototype was produced by April 1, 2008. Evan Hill was responsible for the handle and connector design, assembly, and verification; Jennifer Adams was responsible

for the pressure sensor circuit, LabVIEW program design, and pressure sensor verification; Matthew Wolf was responsible for the design and assembly of a pressure simulator and simulator verification; Janet Chan was responsible for the documentation.

DEVICE TESTING

Adequate device performance and favorable reception by clinical professionals was required for device verification. A model simulating variable pressures was constructed to show that the new CVC device reliably distinguishes between arterial and venous pressure.

The model generated pressures from water filled IV bags through the use of water columns of variable heights, shown in Figure 8 below.

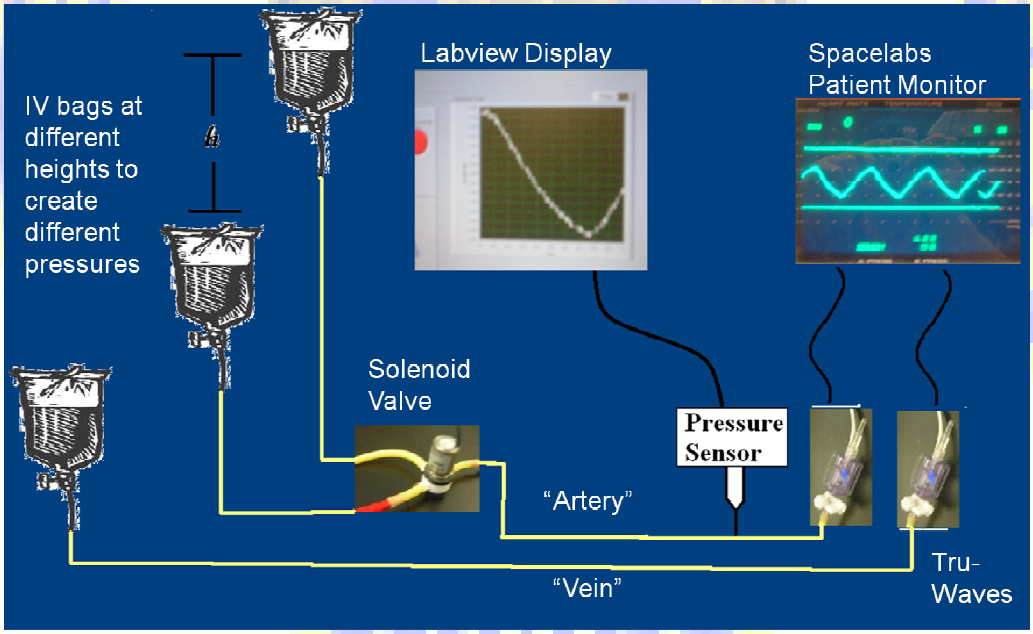

FIGURE 8: Simulator schematic.

As shown in the above schematic, the simulator utilized hydrostatic pressure in order to create varying pressures according to the equation $P = \rho gh$. The tubing from the venous IV bag was fed directly into a TruWave pressure transducer that verified the pressure through connection to a SpaceLabs patient monitor (model 514). The height of the IV bag was adjusted to produce the

desired pressure (8-12mmHg). In order to simulate arterial pressure, two fluid filled IV bags were maintained at different heights to produce two different pressures that represent diastolic and systolic arterial pressures (approximately 60mmHg and 120mmHg). The IV bags were then connected to the inputs of a three-way solenoid valve from Parker (part #5116K198), and the output of the solenoid valve entered a latex tube that was fed directly into another TruWave pressure transducer. The solenoid valve operated as a switch between the two IV bags. The solenoid valve switching was controlled through a LabVIEW program that generated a square wave output. The output signal was then sent through the DAQ 6008 and then to an amplification circuit, DS2003CN, obtained from NewarkInOne (part # 41K1821). Once amplified, the circuit acted as an on/off switch to operate the solenoid valve. The switching frequency was controlled by the frequency of the square wave generated by LabVIEW. Thus this modified model gave pulsatile pressure which could be modified to physiologic pressures by adjusting IV bag height. Heart rate was simulated by adjusting the square wave input frequency. In order to provide a more life-like simulator, the two lines (artery simulator and vein simulator) were run through a Laerdal simulation neck piece currently used at the Peter M. Winter Institute for Simulation, Education, and Research (WISER) center.

Verification of the device consisted of numerous trials in which the needle punctured the simulated vein or artery and the LabVIEW output was obtained. The output from the patient monitor was also obtained and recorded for comparison. The following table provides the results obtained from these trials. Incorrect pressures were those that were greater than 4mmHg from the patient monitor output.

TABLE 1: The results from device verification.

	Correct Pressures	Incorrect Pressures	Correct Light	Incorrect Light
Arterial	9	1	10	0
Venous	12	0	12	0

Approval of this device was also to be determined using clinician participation in trial uses of the device. Due to the time constraints placed on the project as well as on physicians full schedules, full validation was unable to be performed. However, the method for validation is as follows. A seasoned clinician who has followed the course of the device development will perform a CVC placement at the WISER center on the provided training mannequins which will be installed with the new pressure generating simulator. The success rate of the procedure, the time taken for the procedure, and the number of needle sticks it takes clinicians to hit the vein will be recorded. The procedure would then be performed using the current CVC placement technology. A comparison of trial data will analyze whether a decrease in procedure time and an increase in success rate with the use of the new device occurred. Statistical inferences on the effectiveness will be computed.

Following the trials, questionnaires will be handed out in order to obtain qualitative feedback on ease of use, accuracy, comfort, pressure sensor reliability, and any additional comments regarding his experience with the new device. The questionnaire would also require the participant to choose his preferred method.

FUTURE WORKS

Additional work may be required for increased function and display options, as well as an improved simulation unit. All of the LabVIEW components may be reduced to a single compact chip. Field Programmable Gate Array (FPGA) chips are available for this purpose. This chip,

along with all other necessary circuitry and a lithium battery, may fit into the display case. An OLED display would then show the status, in which numerical pressure readings along with a waveform are displayed with the algorithm's outcome of arterial, venous, or unknown.

The simulator may also be improved to give a wider range of pressures, more accurate pressure waveforms, and to be more compact. The size may be reduced by using "pressure bags" around the IV bags. These bags act like blood pressure cuffs, inflating with air and applying pressure to the IV bag. Using this system, the height requirement of the bags is negated giving a more compact model and possibly access to pressures not possible previously due to height limitations. The accuracy of the waveform may be adjusted by lowering the fluidic impedance of the system. The use of stiffer and wider conducting tubing would reduce the compliance and resistance, respectively. The wave would then reach peak pressure values more quickly allowing for a greater response that is less affected by the heart rate.

According to the project design specification produced in the beginning stages of this project, the device was required to: differentiate between high and low pressures using thresholding, recognize pulsatility, have a compact LED display, display a waveform, incorporate an ergonomic handle, and provide an economically viable alternative to current CVC technologies. The specifications which have not yet been met are: recognition of pulsatility, a compact LED display, and waveform display. These aspects of the device design are extremely important to the eventual market of this device and are therefore high priorities in the development of future work.

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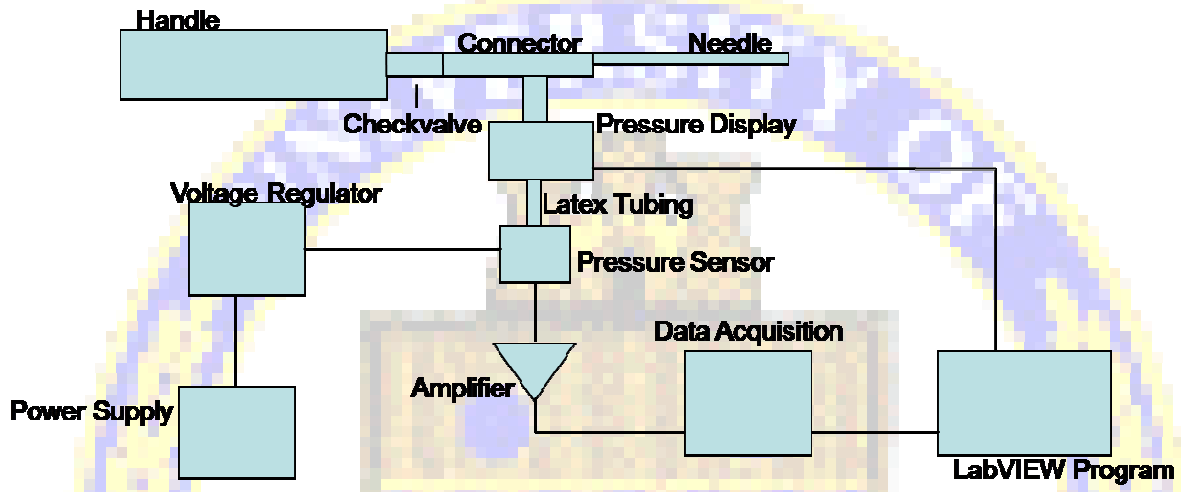
[7] Moretti E.W. et al. "Impact of central venous catheter type and methods on catheter-related colonization and bacteremia." *Journal of Hospital Infection*. 2005. 61:139-145.

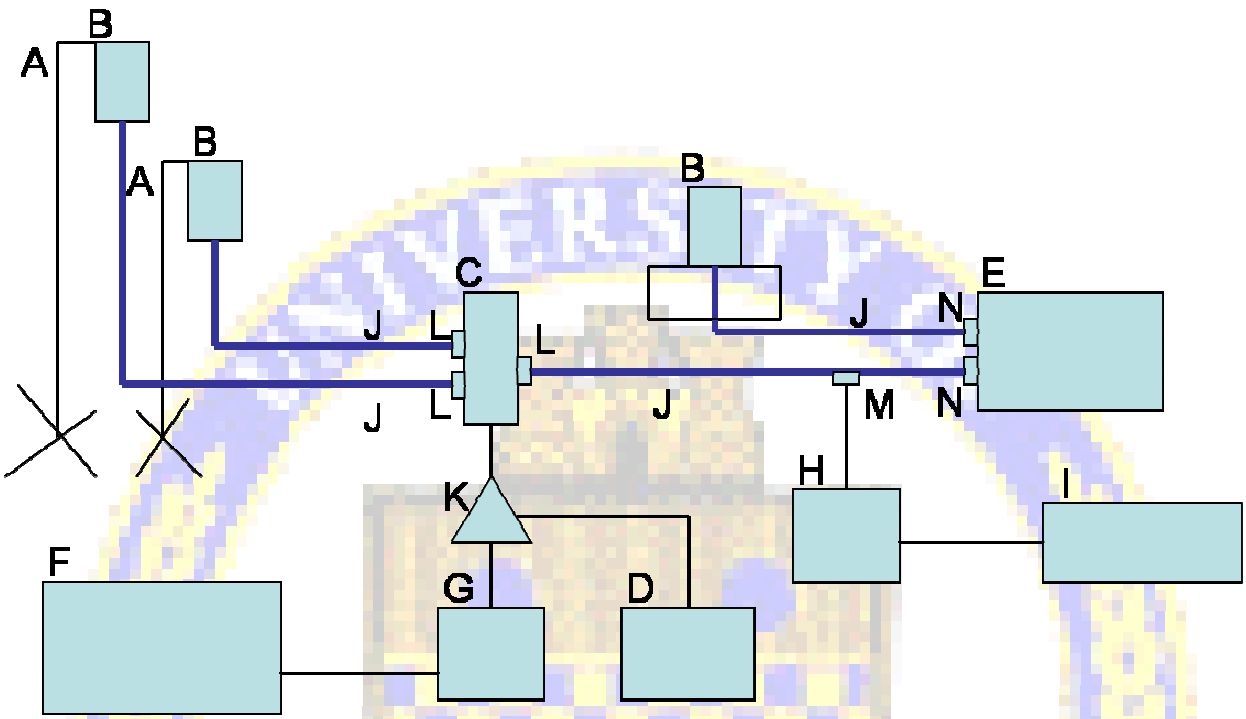
APPENDICES

APPENDIX A: GENERAL DEVICE SCHEMATIC



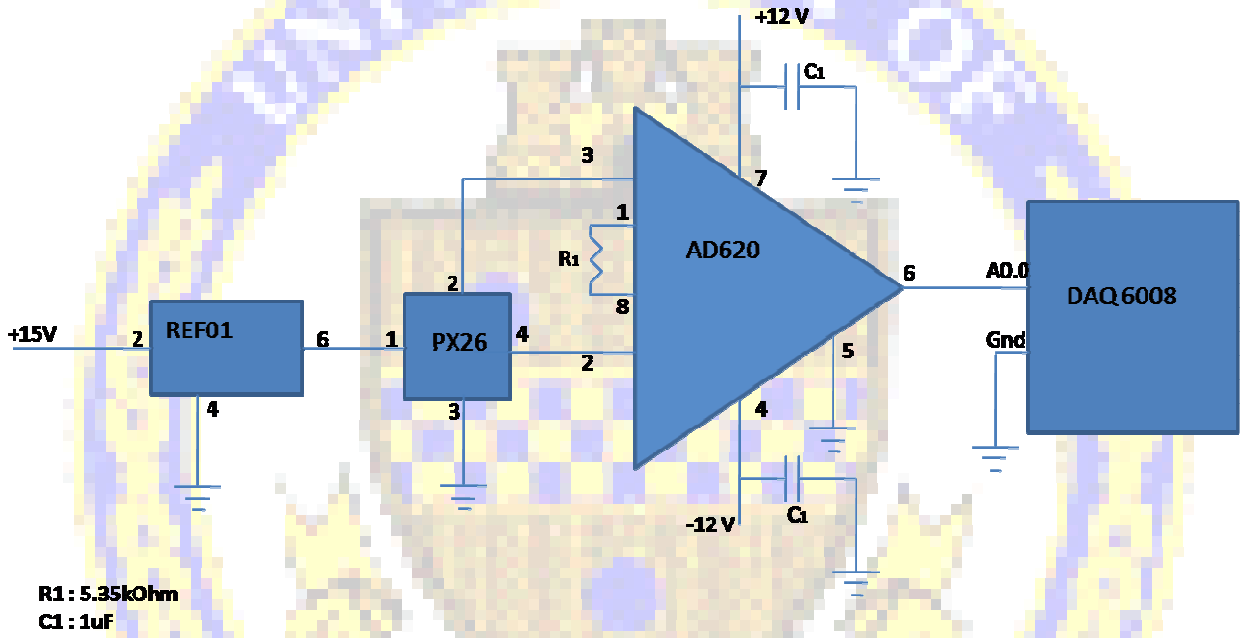
A	HANDLE	G	DIFFERENTIAL PRESSURE SENSOR (OMEGA - MODEL # PX26-005GV)
B	DUCKBILL CHECKVALVE (QOSINA - PART # 80065)	H	AD620 AMP CIRCUIT (NEWARKINONE - PART # 59K4387)
C	THREE-WAY CONNECTOR	I	USB 6008 DAQ (NATIONAL INSTRUMENTS - PART # 779051-01)
D	18 GAUGE NEEDLE	J	LABVIEW (ACADEMIC SUPPLIERS - PRODUCT ID # 858997)
E	BENCH POWER SUPPLY (SUPPLIER - PART # XK-550)	K	PRESSURE DISPLAY
F	IV TUBING (TRUWAVE PRESSURE SENSOR EXCESS)	L	REF01 VOLTAGE REGULATOR CIRCUIT (NEWARKINONE – PART # 59K9004)

APPENDIX B: GENERAL SIMULATOR SCHEMATIC



A	4 LEG IV POLE (MEDICAL SUPPLY GROUP - MODEL # ISG10170)	H	TRUWAVE PRESSURE TRANSDUCER (EDWARDS LIFE SCIENCE - PART # 9906)
B	GRAVITY SET 1000ML VINYL BAGS (MEDICAL SUPPLY GROUP - MODEL #SND199216)	I	PATIENT MONITOR (SPACELABS – MODEL # 514)
C	THREE-WAY SOLENOID VALVE (PARKER - PART # 001-0017-900)	J	LATEX TUBING (MCMASTER CARR - PART # 5234K31)
D	BENCH POWER SUPPLY (SUPPLIER - PART # XK-550)	K	DS2003CN AMP CIRCUIT (NEWARKINONE - PART # 41K1821)
E	LAERDAL NECK REPLACEMENT	L	1/4-1/8 FITTING (MCMASTER CARR – PART # 5116K198)
F	LABVIEW (ACADEMIC SUPPLIERS - PRODUCT ID # 858997)	M	1/8-1/4-1/8 T-CONNECTOR (MCMASTER CARR - PART # 5117K26)
G	USB 6008 DAQ (NATIONAL INSTRUMENTS - PART # 779051-01)		

APPENDIX C: PRESSURE SENSOR CIRCUIT SCHEMATIC



APPENDIX D: SOLENOID CIRCUIT SCHEMATIC