Pressure Cylinder Controlled Release Valve

Final Design Review Report

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1.0 Executive Summary

This project aims to integrate an automatic gas release system in a pre-existing scaffold fabrication process for tissue engineering applications.

To form the proper scaffold structure, the fabrication process is heavily influenced by the change in its surrounding pressure. The current production involves a pressure transducer and electric valve that is managed manually to create a suitable pressure environment for the scaffold. This method, although functional, proves to be ineffective when creating several batches; the user needs to constantly monitor the developing pressure profile and alter voltage parameters accordingly to create a linear gas release under a predetermined slope.

To alleviate this problem, this project designed and implemented a feedback loop within the present system. This would allow the user to set a time frame for the gas release, thus directing the system to produce the desired pressure profile. The negative feedback loop follows a set line equation in conjunction with a Boolean case structure that dictates how the release valve must behave to create the user-defined pressure drop.

The constructed LabVIEW code was tested in its performance in the following categories: linearity in the pressure profile produced, variability between the set point equation and the actual pressure drop, usability of the graphical interface, and electric valve response time. Applications of test protocols showed that the LabVIEW code achieved its intended function and improved upon the predecessor system currently in use in the laboratory.

This project also incorporated a design and build of a housing unit to hold the components involved in the pressurization process. The procedure requires a tube-like pressure chamber with a top-heavy electric valve attachment that causes the center of gravity of the apparatus to shift when in use.

The manufactured housing unit was tested in the following criteria: variability in angle measurements, and structural stability during use at extended periods of time. Implementation of the test procedures revealed that the manufactured housing unit was structurally sound and stable. The housing unit is now used in the laboratory.

2.0 Introduction and Background

2.1 Introduction

The stakeholder for this project is Dr. Christopher Heylman, who aims to use the resulting scaffolds in supporting osteoblast growth in his tissue engineering research. The system currently involves a pressure cylinder, transducer, and electric valve for scaffold fabrication, all of which cannot be physically altered in this project. These components are connected through a DAQ (data acquisition) device supported by LabVIEW to monitor the pressure profile.

The current issue with this design centers on the lack of automatic features in the electric valve. The release valve behavior is solely dependent on manual voltage inputs to determine how much to open/close the valve to create the sought after linear release. This approach, although repeatable, remains ineffective can lead to an inconsistent pressure profile.

The primary goal for this project is to create a coding procedure that will allow for user-defined inputs to create a desired pressure profile. Ideally, the user should be able to state the time of gas release and invoke a linear pressure profile based on those parameters.

The secondary goal involves designing a housing unit capable of withstanding the uneven geometry of the fabrication device while maintaining stability throughout the pressurization procedure.

2.2 Background

Customer Meetings

The customer highlighted several issues with the current system. The control system works appropriately but is limited in the speed that the feedback is given. Additionally, the mechanical performance of the valve releasing pressure from the cylinder remains temperamental as it does not always respond to the user-defined voltage parameters. The most crucial aspect in need of improvement, although the current process works, is the set input parameters occasionally do not achieve the desired pressure profiles, thus producing a less than viable scaffold.

Currently, the release valve has two modes of operation, an on/off mode and a constant, partial opening. Use of either method still requires a manual manipulation to create the desired linear pressure profile. There is a PID control system involved in the present system; however due to issues regarding the previous code, it is unusable and needs to be redone or removed.

Ideally, the customer would like to set a time frame for the gas release (ie. 800 psi to 0 psi in 30 seconds), and a new feedback loop system that would allow the pressure valve to auto-regulate the release to create a linear pressure drop.

Existing Designs

Unfortunately, due to the high specificity of the project, the competitors shown in Table I do not provide a comprehensive basis of comparison for this project. The automatic pressure valves selected for the competitive matrix were chosen as they were the closest in terms of mechanical behavior and end-goal design.

Most of the competitors found only generated automatic pressure (gas/liquid) releases as a fail-safe process should the mechanical systems exceed established safety parameters. The electric valves shown will only respond to a triggered gas release to protect the user and surrounding equipment, with little regard to how the pressure behaves within the chamber.

The project objective deviates from this function as how the gas is released when the valve opens is prioritized. The release must be regulated to create a proper environment for scaffold fabrication, thus requiring software integration other competitors did not implement.

Table I: Related Devices

Device	Description
Watts Relief Valve [13]	Provides automatic pressure release to protect a water heating system
Allied Electronics Pressure Valve [1]	Prevents excessive system pressure
Emerson Safety Relief Valves [7]	Used in thermal and pressure relief applications
Grainger Adjustable Relief Valve [5]	Prevents the build up of pressure in systems containing air, oil, or water
Bryan Donkin Pressure Relief Valves [8]	Protects regulators and downstream systems against overpressure conditions; suitable for creep relief

Related Patents

As with competitor products, there were no patents that easily resembled the scope of this project. Table II outlines patents that most closely encompasses the functions of the LabVIEW code either through mechanical operation or other software means. However, much like the previous section, these patents rank the gas release as a safety precaution in existing systems rather than a developed method for use in biological/biomedical applications.

Table II: Related Patents

Patent	Description
US201402617821	Sensor for both outside and inside pressures. Valve opens when inside pressure is too high
US3211174A	Maintains pressure in a controlled area
US3159176A	Pressure release occurs when back pressure exceeds a certain value
US3618627A	Pressure relief system used to regulate pressure between a pressure system and a field
US3827449A	Releases pressurized fluid using sliding piston. Non repeatable.

Technical Literature

The following articles outline scaffold behavior and environmental conditions needed for fabrication. These articles were reviewed to better understand the emphasis of the linear pressure profile required to create the scaffolds.

A. *Active growth factor delivery from poly(D, L-lactide-co-glycolide) foams prepared in supercritical CO2:*
   This article summarizes a method for producing microporous foams that contains encapsulated proteins through the use of supercritical CO2. Foams were saturated with CO2 at supercritical conditions and then supersaturated at ambient conditions to cause nucleation and precipitation of the polymer [4]. Proteins, like the basic fibroblast growth factor, were encapsulated within the foams. The release and activity of the bFGF from the foams resulted in a protein release rate greater from structures made in CO2 than those from a salt leaching technique [4].

B. *Poly(lactide-co-glycolide) porous scaffolds for tissue engineering and regenerative medicine:*
   This articles summarizes the fabrication approaches, mechanical properties, in vitro degradation and modification of PLGA scaffolds [6]. Several approaches for fabricating three-dimensional porous scaffolds includes porogen leaching, fibre bonding, phase separation, and gas foaming. Also, there are several factors that affect the mechanical properties of the porous scaffolds: porosity, pore shape, dry or wet state, and copolymer composition. These properties are very important to consider especially for tissue regeneration [6].

C. *Studies on the interactions of CO2 with biodegradable poly(dl-lactic acid) and poly(lactic acid-co-glycolic acid) copolymers using high pressure ATR-IR and high pressure rheology:*
   This article summarizes the interactions of polymers with CO2 which is essential for fabrication porous scaffolds. It is stated that biodegradable polymers can be plasticized

using high pressures of CO_2 [9]. This process is monitored by a high pressure attenuated total reflection Fourier transform infrared (ATR-IR) and rheology. The data that was acquired from the high pressure ATR-IR shows that interaction of CO_2 in PLGA copolymers relates to the glycolic acid content [9].

D. *Degradation behaviors of biodegradable macroporous scaffolds prepared by gas foaming of effervescent salts:*
This article summarizes the degradation factors of the scaffolds. Ammonium bicarbonate and citric acid were used to fabricate the biodegradable polymeric scaffolds through a gas foaming/salt leaching method [10]. The scaffold was shown to have homogenous pore structures throughout the matrix. The porosity and mechanical strength of the scaffolds were controlled by adjusting the concentration of citric acid. Three in vitro degradation studies of the scaffolds were performed and it exhibited marked swelling behaviors at different time points. The matrix swelling were due to the massive water uptake into the degrading scaffolds [10].

E. *Preparation of porous PLGA/HA/collagen scaffolds with supercritical CO2 and application in osteoblast cell culture:*
This article summarizes the use of a supercritical CO_2 saturation technique for a hybrid porous scaffold of PLGA. In order to choose the optimal composition of the scaffold, expansion factors were studied after CO_2 treatment [11]. Saturation temperature, saturation time, and saturation pressure were recorded to evaluate how it affects the pore structure. This allowed for the control of the pore size and porosity by manipulating the conditions mentioned [11].

Industry Codes

The following industry standards and regulations listed are applicable to the LabVIEW code objective.

A. *Center for Biologics Evaluation and Research: HCT/P's Regulated under 21 CFR 1271.3(d)(1) and Section 361 of the PHS Act* [2]

B. *California Code of Regulations, Title 8, Section 4650. Storage, Handling, and Use of Cylinders Subchapter 7. General Industry Safety Orders Group 9. Compressed Gas and Air Equipment Article 76. Compressed Gas and Air Cylinders* [3]

C. *CFR, Title 49, Subtitle B, Chapter I, Subchapter C, Part 173, Subpart G, Section 173.301 - General requirements for shipment of compressed gases and other hazardous materials in cylinders, UN pressure receptacles and spherical pressure vessels* [12]

3.0 Customer Requirements and Design Specifications

3.1 Indications for Use

This project will integrate an auto-regulatory pressure release system into a pre-existing mechanism involved in creating PLGA scaffolds. The current system incorporates a pressure cylinder, an electric valve, and a pressure transducer, all of which are managed manually to create a desired pressure profile for the scaffold environment.

This project will not alter any of the current components, but add a code to automate the gas release influencing the pressure profile. This project will utilize a feedback loop to provide a robust and repeatable gas release, allowing for a more effective scaffold fabrication process.

This project will also incorporate a design and build of a housing unit to hold the components involved in the pressurization process. The mechanism in use involves a tube-like pressure chamber with a top-heavy electric valve attachment. This geometry makes it difficult for a single person to perform the pressurization, thus creating a need for a more sufficient and stable housing unit.

3.2 Product Design Specifications

Successful execution of the project is defined by the quality of the scaffolds produced after fabrication. To create the “popcorn” effect (PLGA expansion), the scaffold must experience a pressure drop of 26.67 psi per second over a 30 second span. The customer emphasizes that the resulting pressure profile created by the control system using this slope must be strongly linear. The pressure profile produced must also be repeatable with little variability across the batches to ensure uniformity in the scaffolds. The customer requests for the ability to allow for user-defined parameters within the LabVIEW code while maintaining the auto-regulatory features that would eliminate the need for manual operation.

To address these needs, the following metrics shown in Table I were applied. Linearity of the pressure profiles were first examined by a minimal coefficient of determination, R^2. The repeatability of the profiles produced was then quantified by a maximum normalized sum of residuals obtained for each pressurization given a set sampling rate, Σe. The graphical user interface was then judged for usability by the success rate of the interactions between the user and the front panel design.

Table I: Code Design Specifications

Customer Requirement	Engineering Metric	Specification
Linear Pressure Profile	Linearity	Linear Regression Line: $R^2 \geq 0.70$
Repeatable	Variability	Residuals: $\Sigma e < 64{,}000$/min sampled at 10 Hz
Usability	Success Rate	Time to complete pressurization: 5 minutes Errors: less than 2
-	Feedback Response	Time for valve to open: $\tau < 6.5$ s

Successful completion of the housing unit is exemplified by its structural stability both during and off use. It must be able to withstand the weight of the full pressurization apparatus while maintaining an upright position despite its uneven geometry.

Validation of these metrics are outlined in Table II. To ensure that the housing unit remains upright, angles across the three connecting points of the base tables were measured and verified to be of little to no variation in between. The force check test procedure was also used to confirm the strength of the unit to be able to endure the weight of the apparatus.

Table II: Housing Unit Design Specifications

Customer Requirement	Engineering Metric	Specification
Stable Structure	Structure Stability (Angle)	Angle: Less than or equal to 5 degrees
Stable Structure	Structure Stability (Weight)	Withstand at least 50 lbs

3.3 House of Quality

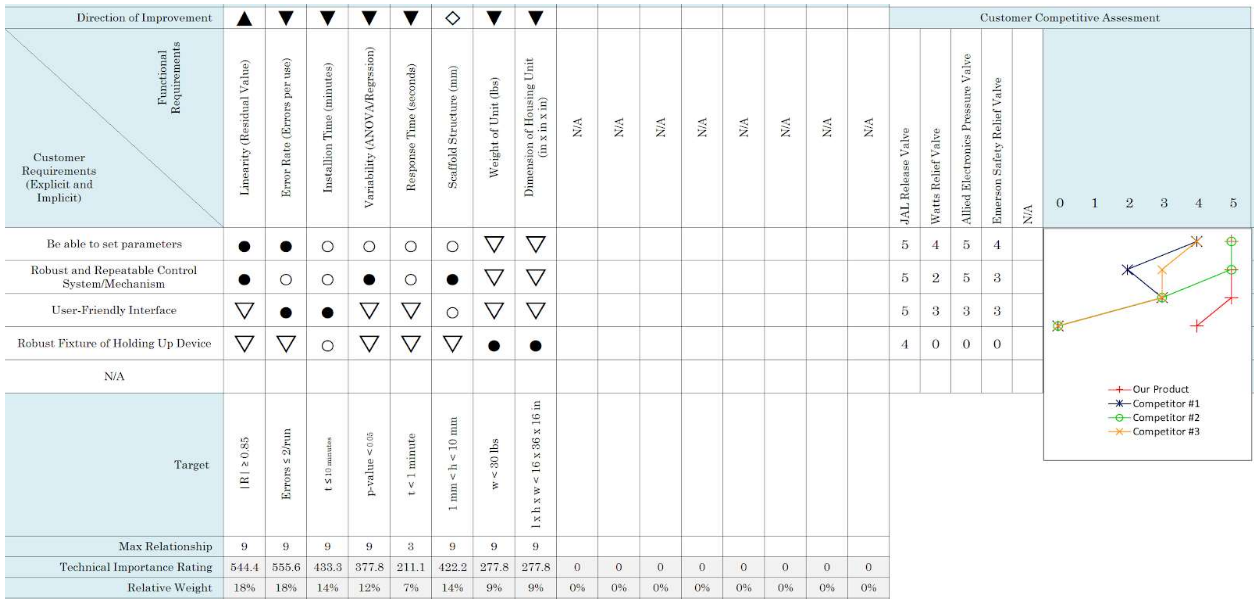


Figure 1: House of Quality

Our House of Quality consists of customer requirements, functional requirements, target values for the functional requirements, importance ratings, and comparisons between other products.

Functional Requirements and Target Values:

- Linearity: Achieve a coefficient of determination value greater than or equal to 0.70
- Error Rate: Perform less than 2 errors per use
- Installation Time: Set up system in under 10 minutes
- Variability: Achieve a sum of residuals less than 64,000/min sampled at 10 Hz
- Feedback Response Time: Valve opens in less than 6.5 seconds
- Scaffold Structure: Produce a scaffold with height between 1 and 10 mm
- Weight of Housing Unit: Must weigh less than 30 lbs
- Dimension of Housing Unit: Have dimensions of length and width less than 24 in and height less than 36 in

Based on the relationships between customer requirements and functional requirements, it is observed that Error Rate, Linearity, and Installation Time are the most important requirements to be considered the most when trying to meet our customer requirements of our product.

When comparing our product with the Watts Relief Valve, Allied Electronics Pressure Valve, and Emerson Safety Relief Valve, one major difference is that our product comes with a housing unit while the others don't. With that, we were able to give our product a rating of while the others with a rating of 0. From this, it still stands that our product will be better than current products since we meet all customer requirements.

4.0 Stage Gate Process

4.1 Concept Review

LabVIEW Code

In the initial design stages of this project, three different approaches to the code were assessed for user-defined input capability and consistency in the pressure profiles produced. The following table explores each concept and potential issues with each method.

Table III: Comparison of the initial concepts for pressurization sequence.

PID Control System	Manual Control System	Hybrid System
This method would utilize experimentally determined PID constants and apply to the current system. Using this system would allow for varying user-defined slope values for the pressure profiles. This method was already explored by the previous master student wherein they obtained the optimal PID constants.	This method would follow the currently used step-by-step procedure for partial valve opening during pressurization. This method is already proven to work empirically and provides a repeatable method to obtain the desired pressure profile. Method is only specific to one linear pressure profile: 800 to 0 psi in 30 seconds.	This method would combine the two previous systems. It would utilize the pressure transducer for the PID control portion, but also allow for user interaction in the manual controls. This method will provide an automated gas release of other pressure profiles and a manual step-by-step release if desired.

Front Runner Design - PID Control System

This concept was selected due to its feasibility and versatility in producing varying pressure profiles. It fulfilled the necessary parameters required by the sponsor and would have no need for any user-tampering during pressurization. The PID system would also utilize the components already within the system and optimize its use due to the auto-regulatory functions within the code.

The hybrid concept would also be a suitable approach for this project, however there was less of a priority in extensive customization of the pressure profiles. Further development of this design would likely branch out to the hybrid concept, but for the purposes of this project and its scope, the PID control system design is more feasible and all-encompassing.

Housing Unit

The 2 initial concept ideas for the housing unit were:

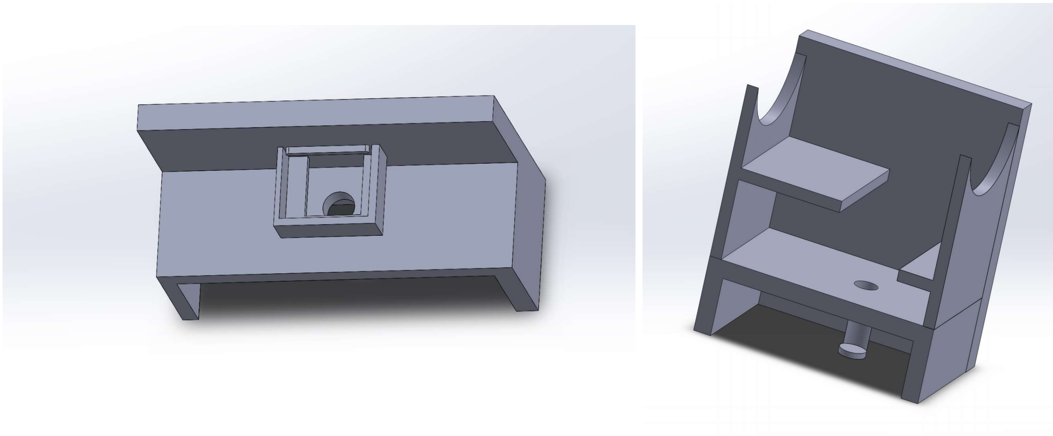


Figure 2: (Left) Concept 1; (Right) Concept 2

Housing Design 1: From the left image above, this design will have a hinge and a box-like case structure that can house the pressure cylinder system. The hinge will serve to attach a panel that can "close" the box-case structure and cover the top portion of the pressure cylinder above. The box-case structure itself will serve to "house" the unit itself with supporting panels on each side to be able to carry the left and right parts of the system.

Housing Design 2: From the right image above, this design will have left and right panels as well as an integrated cup holder. The left and right panels will include supporting boards to carry the left and right parts of the system. The curvatures on the panel will allow for wires to hang from the sides. The pressure cylinder holder will serve to hold the pressure cylinder so that it is not hanging freely when it is being used.

Front Runner - Housing Design 2

This concept was chosen because it has more components that may further support the pressure cylinder system. Although design 1 may also be able to hold up the system, it lacks more extra support since the box-casing structure will be attached to the backboard. Design 2 has more supports, especially from both sides and the integrated cylinder hold will be very useful as well. From a manufacturing standpoint, design 2 will have more complexity because of the curvatures and cylinder shape. Overall, regardless of the manufacturing processes, this design will be able to support the pressure cylinder system due to many supporting components that it has.

4.2 Design Freeze

LabVIEW Code

For the code design, the team chose to pursue a draft for a PID control system that would incorporate the pressure transducer and electric valve involved in the pressurization process. There is already a data aquisition device (DAQ) provided by the sponsor that would facilitate communication between the two components, and thus the designed feedback loop. The team also planned to use the preceding LabVIEW code from the previous student as a basis for the PID control system. The virtual instruments (VIs) used in the predecessor code for the pressure transducer and electric valve are still applicable for the PID approach and will be used in the new LabVIEW code. This design however is heavily reliant on experimentally determining the PID constants that would produce the most accurate and repeatable linear pressure profile desired. This can be done by first implementing experimental constants in a full pressurization and then using these values in MATLAB to run tests and simulations across a wider data set.

Housing Unit

As mentioned above, the housing unit will be developed from the concept 2 design. The materials that will be used are plywood and screws. The components of the housing unit includes a back board, base table, base table supports, cylinder cup holder, left panel and left panel plates, right panel and right panel plates. This design will be manufactured in Mustang 60 Machine Shop using machining tools such as table saw, band saw, and drill press.

4.3 Design Review

LabVIEW Code

Further review of the research behind the predecessor code showed that the previous student already implemented the proposed PID feedback loop. The student used MATLAB to simulate varying PID constants in a very similar process this project initially aimed to do. The team discussed other feedback system methodologies and have decided to pursue a different approach. As the previous student already tested a wide array of PID constants to optimize pressurization performance, the team instead chose to focus on its resulting performance metrics. The regression and residual values using the predecessor PID control system will be used as a basis of comparison for the new code design, further outlined in the *Description of Final Prototype Design* section of this report.

Housing Unit

The final prototype design did not end up incorporating the right panel and right panel plates because there needed to be enough space for the pressure to be vented out at the right portion of the system. Overall, the left panel, backboard, pressure cylinder cup holder, base table, and base table support components were still kept as part of the final prototype design. A displacement test simulation was going to be performed in order to check whether the design is capable of withstanding heavy forces. This was going to be done on Abaqus but after receiving feedback from the sponsor, this type of test was not required.

5.0 Description of Final Prototype Design

5.1 Overview

LabVIEW Code

The final prototype design for the code incorporates a boolean case structure which compares real time measurements of the pressure decrease to a desired pressure decrease calculated from a set line equation. Said equation is determined from the actual initial pressure, which is read at the beginning of the process, and an user-inputted drop time. If the difference between the actual and desired pressure at any given time is less than 0, the boolean case structure sets the voltage of the electric valve to 2V. Otherwise, the valve is set to close.

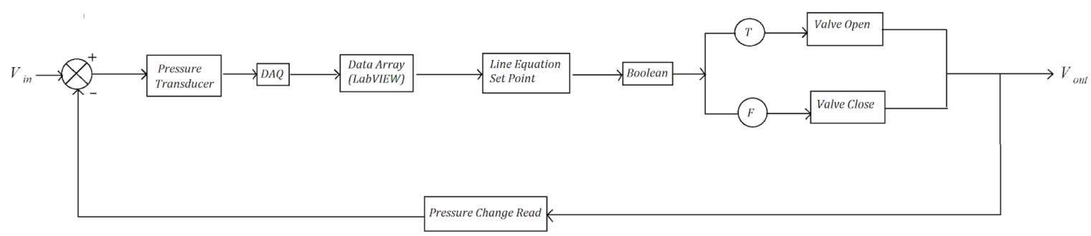


Figure 3: Circuit schematic of gas foaming feedback loop.

Housing Unit

The housing unit will support the pressure cylinder system. Currently, the lab has a table with an insertion for the pressure cylinder. However, it doesn't have any supports that can hold up the top heavy portion of the system which leads to tipping over. The design that was developed will be used as the new housing unit for the pressure cylinder system. The final prototype design includes a base table, two base table supports, left panel and left panel plates, backboard, and pressure cylinder cup holder.

5.2 Design Justification

LabVIEW Code

The most significant deviation from the predecessor LabVIEW code is the difference in approach regarding the feedback loop. The final design implements a Boolean case structure wherein there are two modes of function (T/F) as outlined in Figure 3. This code was chosen because of its increased versatility from its PID counterpart wherein the user has more leeway in regards to the pressure profile created. In this code design, there are more user-set inputs that will dictate the pressure behavior, thus increasing usability of the front interface and potential uses of the LabVIEW code. This code design also functions under an increased sampling frequency than its predecessor, ultimately increasing the accuracy of the pressure profile produced by better quantifying the variability across each time step.

Housing Unit

The prototype was designed so that the existing components are still going to be incorporated and also have similar dimensions. The overall height and width are similar, but the prototype design is shorter in length. This is because the current support takes up a lot of space of the table without the extra length serving any purposes. This way, there will be more room on the table and the pressure cylinder system will be more secured..

5.3 Analysis

LabVIEW Code

To determine whether or not the final prototype met and/or exceeded the specifications determined from the customer's metrics and the previous student's code, several statistical tests were performed. For lineratity, a linear regression was performed to determine R^2 values for five trials. These five trials were validated using a one-sided t-test, as well as a normality plot, both with confidence levels of 95%. For variability, the sums of residuals of the same five trials were calculated. They were then validated in the same way as linearity. For feedback response time, the time taken for the valve to open was found for the same five trials. They were then validated in the same way as linearity. For success rate, five subjects were informed of the project and how to use the code, then set free to attempt a pressurization. The resultant errors (questions asked or mistakes made) were tabulated, and a pass rate was calculated using a proportion of passes over total trials.

Housing Unit

For the final prototype, two protocols were performed to ensure that it meets the engineering specifications for structure stability. The first test was an angle check. This test measured the angles of the base table supports. It observed whether the base table supports are flat on the surface of the table. The angles measured was validated using a t-test. The validation results determined whether the measured angles are good enough so that the prototype can be considered as stable. The second test was a force check of the pressure cylinder system. This test allows to observe whether the prototype does in fact hold up the pressure cylinder system. A pass rate of 80% or greater for all observations will consider the prototype stable as well.

5.4 Cost Breakdown

LabVIEW Code

All of the software needed for building and testing the code was available through the school. Because of this, the code portion of this project did not add to the cost.

Housing Unit

For the first prototype built, we initially purchased two pieces of 1' x 4' plywood and a pack of #8 x 1'' screws. This added up to $23.28. After attempting to assemble the pieces of the prototype, we realized we needed longer screws, so purchased a pack of #8 x 1 ¼ " screws, which added $7.06 to the total cost. There was no cost for manufacturing because the resources needed to build the prototype are available for free at Cal Poly through the Mustang 60 Machine Shop or Aero Hangar.

The amount spent on the first prototype was $18.75. As the final prototype solely used materials already being used for the previous iteration of the housing, the total cost of the final prototype was $0, but would be around $8.71 if the materials had been unavailable. The total cost of this project was $30.34.

Table IV: Bill of Materials for Final prototype

B.O.M. per iteration		Source	Price
Plywood (458503)	1	Home Depot	$8.35
Screws (96055)	7	Home Depot	$0.36
Metal adjustable block	1	Cal Poly	N/A

5.5 Safety Considerations

There aren't many easily achievable hazards involved in this project. The most likely hazard would be bodily harm while using the table saw in the machine shop.

The pressure vessel (CO2 cylinder) itself must also be handled carefully, as it is heavy and its weight is unevenly distributed. Improper handling of the vessel may lead to residual pressurized areas within the system. If left over long periods of time, may cause damage to mechanism and cause pressure loss to the vessel.

To mitigate these risks at least two team members will be present in the ATL lab room during pressurization tests and in the machine shop for housing builds. Proper safety training will also be necessary for access to the ATL lab room. The proper protocol for pressurization of the pressure cylinder is outlined in Table V below.

Table V: Protocol for Pressurizing Pressure Cylinder

Pressurization Protocol		
Programs: LabView		
Location: ATL lab room		
Pre-conditions: Ensure the pressure cylinder, CO_2 cylinder, and midpoint valves are fully closed. Have program up and ready to be used, with DAQ connected to computer.		
Step	**Protocol Step**	**Expected Results**
1	Open the CO_2 cylinder all the way	Reading on first gauge should match desired pressure
2	Open the midpoint valve all the way	Reading on the pressure cylinder gauge should match first gauge
3	Close the midpoint valve all the way once chamber is pressurized	No sound to signify any leaked gas
4	Close the CO_2 cylinder all the way	All valves are closed and ready to perform pressurization

Table VI: Design Hazards

Description of Hazard	Planned Corrective Action	Planned Date	Actual Date
Exposed screws on housing device	Covering of points with rubber	3/1/19	3/1/19

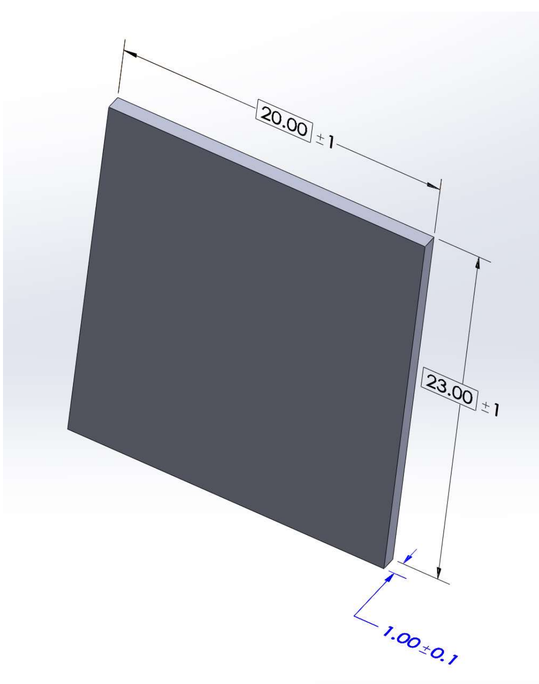
6.0 Prototype Development

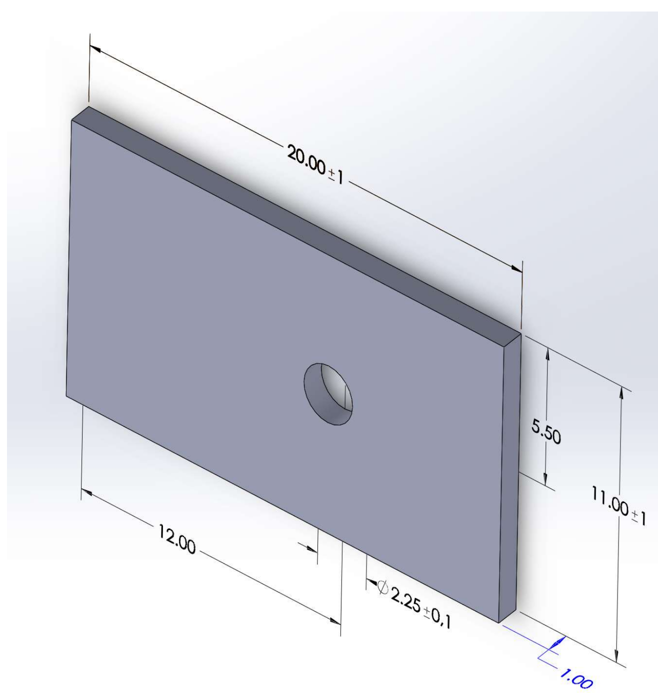
6.1 Model Analyses

As this project is code-oriented, prototypes will involve code design and drafting. As of now, members are still studying PID control systems and analyzing the previous model drafted by another student before.

However, the project also involves the design and build of a housing unit for the scaffold fabrication system. The current mechanism uses a pressure chamber and a top-heavy electric valve attachment that needs to be held upright throughout the pressurization procedure. The geometry of the device makes it difficult for a single person to perform the pressurization, thus expanding the project scope to incorporate a housing unit.

Figure 4 below shows the selected design for the housing unit as well as its dimensions for each component.. This model will be constructed in wood with a weight capacity of at least 50 lbs to account for the top-heavy geometry. There is an integrated cup-holder design to further ensure that the pressure chamber will remain stable throughout the entire pressurization process.





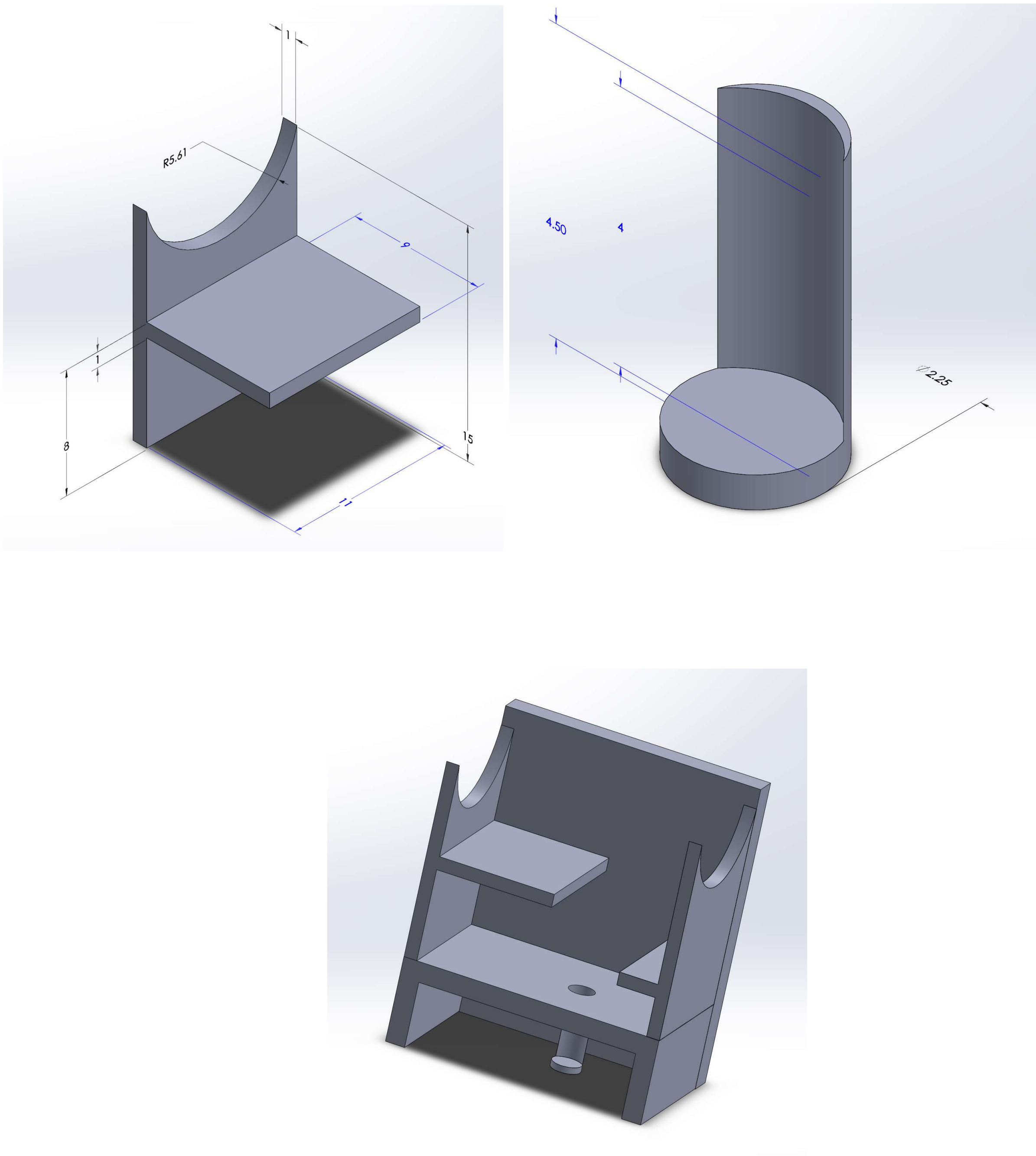


Figure 4: Solidworks Design of Housing Unit with Dimensions of Each Component

6.2 Evolution of Prototypes

LabVIEW Code

The code of a master's student, shown in Figure 5, was studied to provide background for the project. Initially, a PID controller, like the one in the previous student's code, was the frontrunner for the new design.

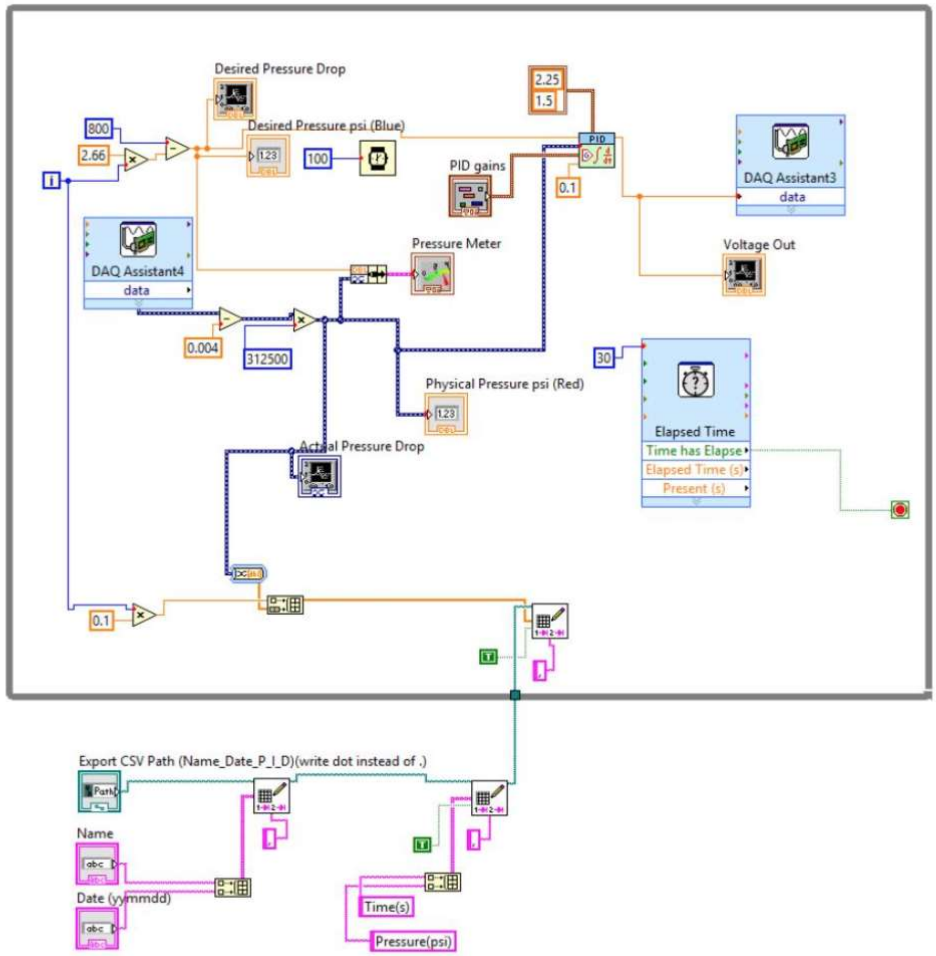


Figure 5: Master's Student's Thesis Code

The first prototype for this project, shown in Figure 6 below, involved a set line equation and a boolean case structure within a while loop. Said set line equation was not programmable from the front end of the code.

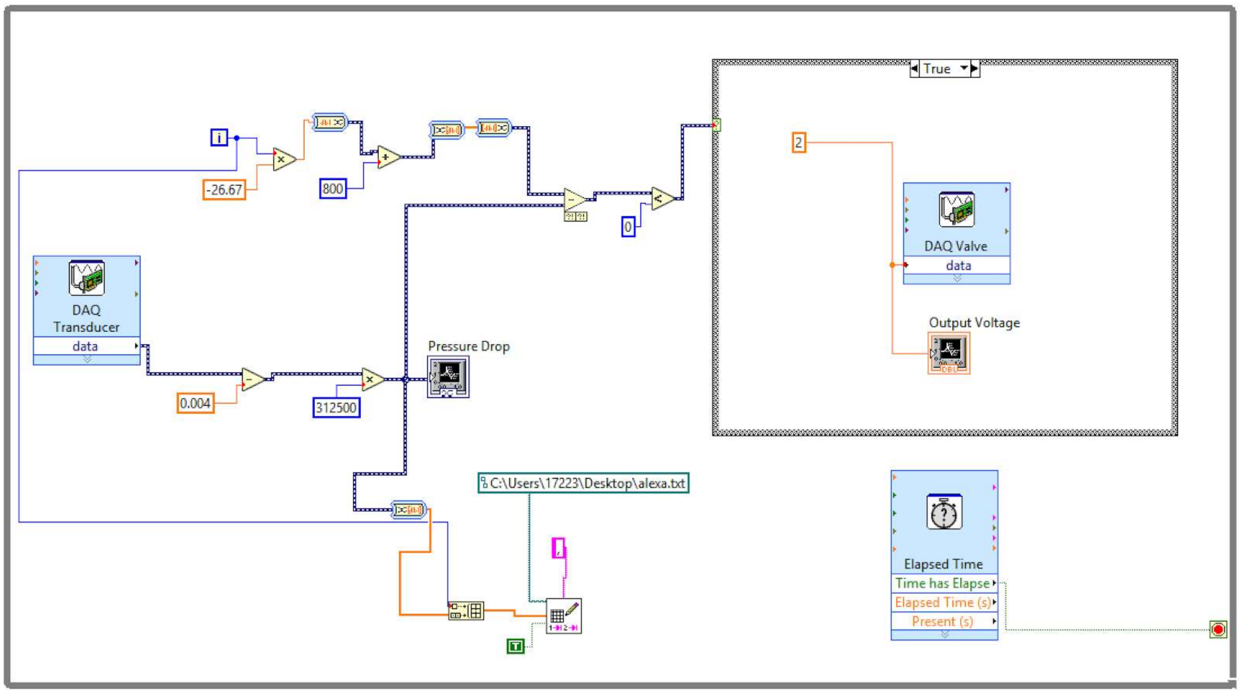


Figure 6: First Functional Prototype

The final prototype, shown in Figure 7 below, also involved a set line equation and a boolean case structure within a while loop. For this iteration, however, the set line equation was based off of a user-inputted drop time and a real time initial pressure reading done outside of the while loop. This addition allows for the user to customize a pressure drop to their specifications.

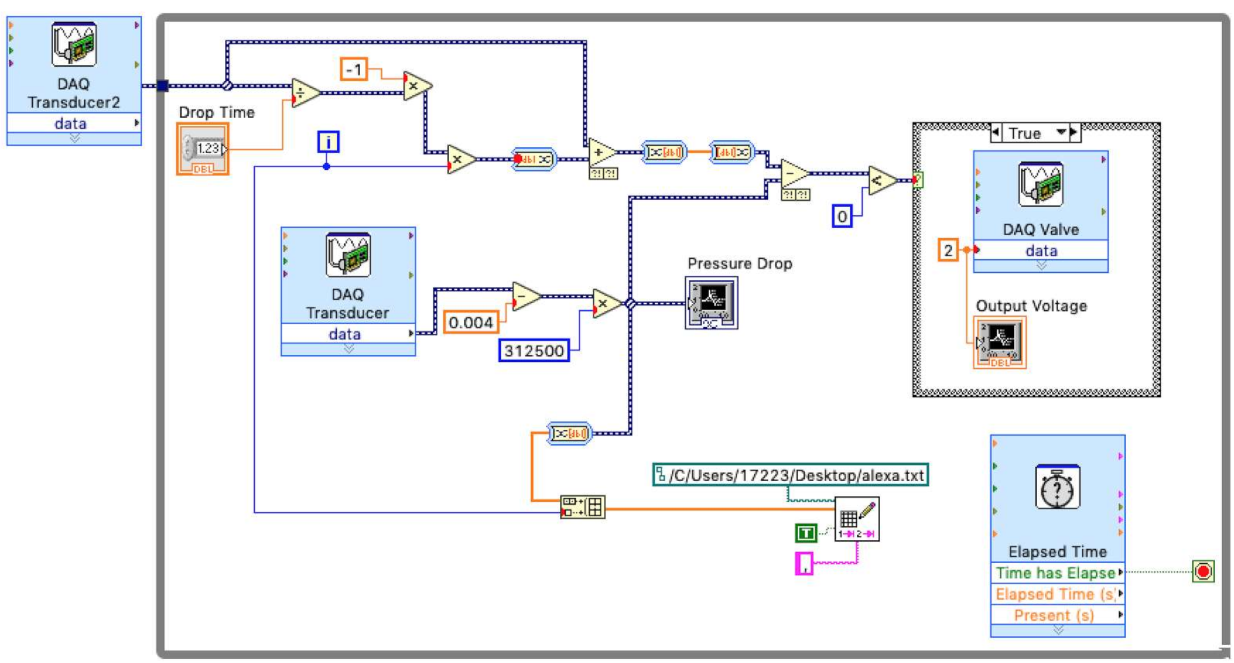


Figure 7: Final Function Prototype

Housing Unit

Evolution 1:

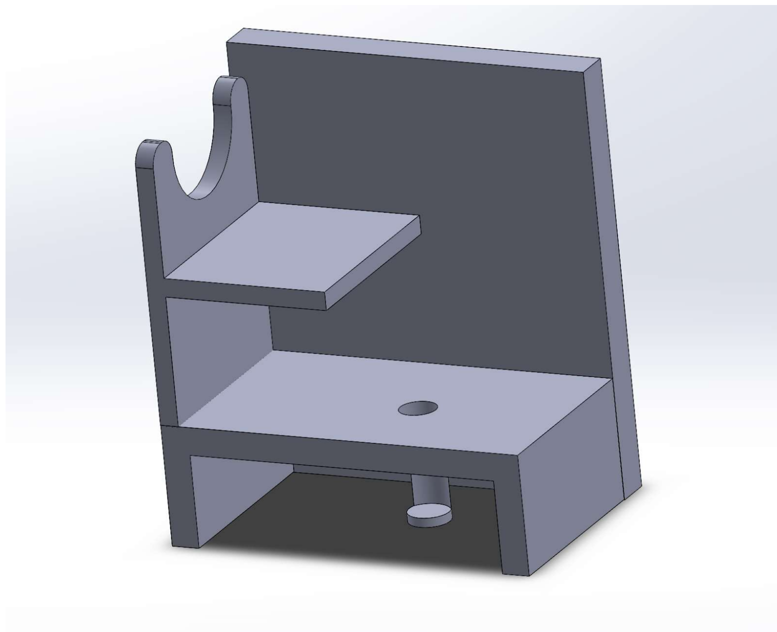


Figure 8: Prototype Evolution 1

Figure 8 above shows the changes that were made for the housing unit. Firstly, the right panel was removed in order to allow for adequate space for the pressure to be vented out during the pressurization. Also, the sharp edges of the left panel were rounded due to safety considerations. Overall, one component of the housing unit was removed and the sharp edges were rounded.

Evolution 2:

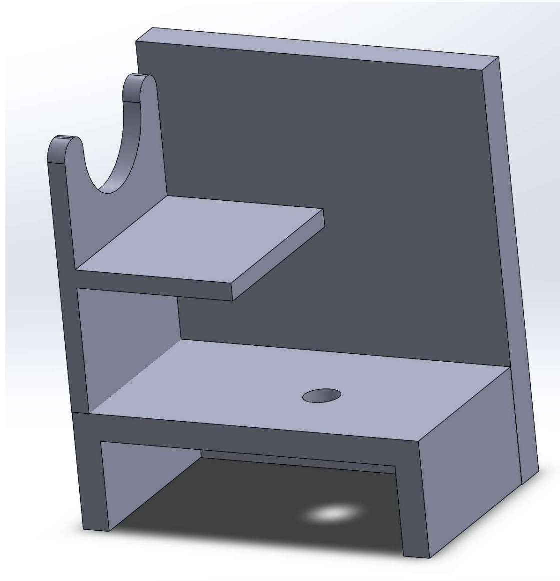


Figure 9: Prototype Evolution 2

Figure 9 above shows a change that was made for the housing unit. The pressure cylinder cup holder was removed due to the complexity of manufacturing. Overall, one component of the housing unit was removed and everything else remained the same.

Evolution 3:

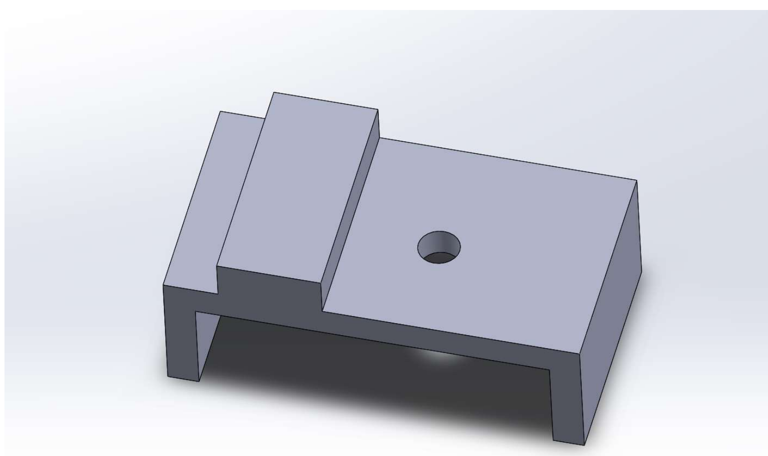


Figure 9: Prototype Evolution 3

Figure 9 above shows the final changes that were made for the housing unit. The backboard was removed, as well as the left panel. Instead, a block piece of wood was added as a component that will serve as the main support of the pressure cylinder system. Overall, two components were removed and a new one was added.

6.3 Manufacturing Process

Table VII: MPI for Code

Step	Procedure
1	Download LabView software and NI-DAQmx driver via: http://www.ni.com/en-us/support/downloads/drivers/download.ni-daqmx.html#291872
2	Open LabView file: *Gas_Foaming_Pressurization.vi* to initialize software
3	Create a blank *.txt* file and save as *Pressure_Values.txt* on the desktop folder
4	Open Block Diagram Window on LabVIEW software and add file path to *Write Delimited Spreadsheet vi*
5	Once pressurization system is prepped and connected, click *Run*.

Table VIII: DHR for Code

MPI Step	Deviations from MPI	Completed By	Date
1	N/A	Alexa Balbuena	10/01/2018
2	N/A	Alexa Balbuena	01/24/2019
3	N/A	Larkin Ingram	01/24/2019
4	N/A	John Reyes	01/27/2019
5	A control variable was created within code design - allows user to set initial pressure value in psi.	Larkin Ingram	01/31/2019

Table IX: MPI for Housing Unit

Step	Instructions	Image
1	<u>Dimensioning of Plywoods</u> Trace five separate dimensions on piece of 48’’x12’’ plywood: 1. Base Table (24’’x12’’) 2. Base Table Support 1 (5.5’’x12’’) 3. Base Table Support 2 (5.5’’x12’’) 4. Wood Piece 1 (5”x12”) 5. Wood Piece 2 (5”x12”)	
2	Before using compound miter saw to cut out the pieces, place plywood onto flat surface and use clamp to secure it *Notes on Compound Miter Saw ● Make a cut by pushing saw away from you ● Laser shows where blade will cut ● 12 inch minimum part size	

3	<u>Base Table</u> Properly align saw onto the base table traces then cut it *Should get 24’’x12’’ piece of wood for base table *Picture is after the base table has been cut out	
4	<u>Base Table Supports</u> Properly align saw onto the base table support trace then cut it repeat for the other base table support trace *Should get two 5.5’’x12’’ pieces of wood for base table supports *Picture provided is after the base table supports have been cut out	
5	<u>Base Table Hole</u> Using Drill Press with a 2 ⅛ ‘’ drill bit, drill a hole onto base table that is 3’’ away from the Top Edge and 5’’ away from the Left Edge *Picture provided is before the hole is drilled	

6	<u>Base Table Supports Screw Holes</u> Before drilling, adjust the height of the flat surface to give enough space to drill the holes. After adjusting, use clamps to secure the wood. Using Drill Press with a ⅛ '' drill bit, drill two holes onto the 1'' thick long side (first picture) and short side (second picture) that are an inch away from the edges of the base table supports *Screws will be coming through the holes of the base table surface into the holes of the long side of base table support *Base table supports are screwed together with the base table *Pictures provided are after the holes have been drilled	
7	<u>Base Table Screw Holes</u> Before drilling, adjust the height of the flat surface to give enough space to drill the holes. After adjusting, use clamps to secure the wood. Using Drill Press with a ⅛ '' drill bit, drill four holes that are one inch away from all edges of base table Drill three holes that are 11 ½ '' away from left edge and 6 11/16'', 5 4/16'', and 3 12/16'' away from top edge of base table *Screws will be coming through the base table surface into the long side of both base table support holes *Base table is screwed together with the base table supports *Metal block is screwed together with the base table *Pictures provided are after the holes have been drilled	

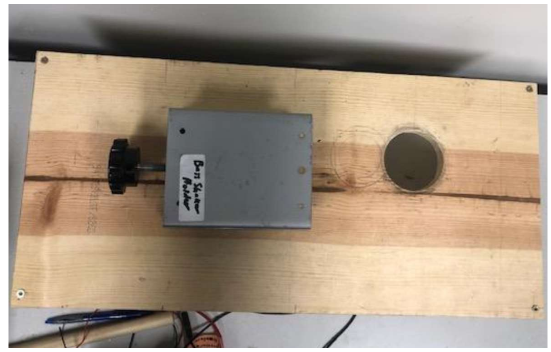
8	<u>Prepare for Assembly</u> Once all components have been cut, place on table and pre-assemble them to visualize how it is going to be attached before screwing them all together After assembling the base table itself, proceed with the metal block attachment Place metal block 6 5/16'' away from left edge, 3 and 12/16'' away from top edge as shown on the right then screw block onto base table for the final touch *Pictures provided are after assembling all the components	 

Table X: DHR for Housing Unit

MPI Step	Deviations from MPI	Completed By	Date
1	N/A	Alexa Balbuena	02/01/2019
2	N/A	John Reyes	02/01/2019
3	N/A	John Reyes	02/01/2019
4	N/A	John Reyes	02/01/2019
5	N/A	John Reyes	02/01/2019
6	N/A	John Reyes	02/01/2019
7	N/A	John Reyes	02/01/2019
8	N/A	Larkin Ingram	02/28/2019

6.4 Divergence Between Final Design and Final Functional Prototype

LabVIEW Code

The final design of the code involved a boolean case structure within a while loop. For the final functional prototype, some cosmetic changes were implemented to the set line equation. The customer is now able to customize the pressure drop on the front end of the program by inputting a desired drop time. The actual initial pressure is measured by the pressure transducer from outside of the while loop at the time of initialization.

Housing Unit

In the end, the final prototype did not end up incorporating the additional components that was originally designed. The left panel, right panel, backboard, pressure cylinder cup holder, were all removed. The base table with a cylinder hole and the base table supports were still used. Also, the final design did not include a metal block. This was screwed on the base table to serve as a main support of the pressure cylinder system. From our last evolution of prototype, a wooden block was the main support for the system but it was learned that the height of the pressure cylinder system may be adjusted. The block of wood that was going to be implemented was not able to accomodate any height changes since it was supposed to be fixed onto the base table. Replacing it with the metal adjustable block covers this problem and is able to be adjusted to the pressure cylinder system's height as desired. This final prototype ended up just as effective as our original design but it was easier to manufacture. Figure 10 below displays the final functional prototype.

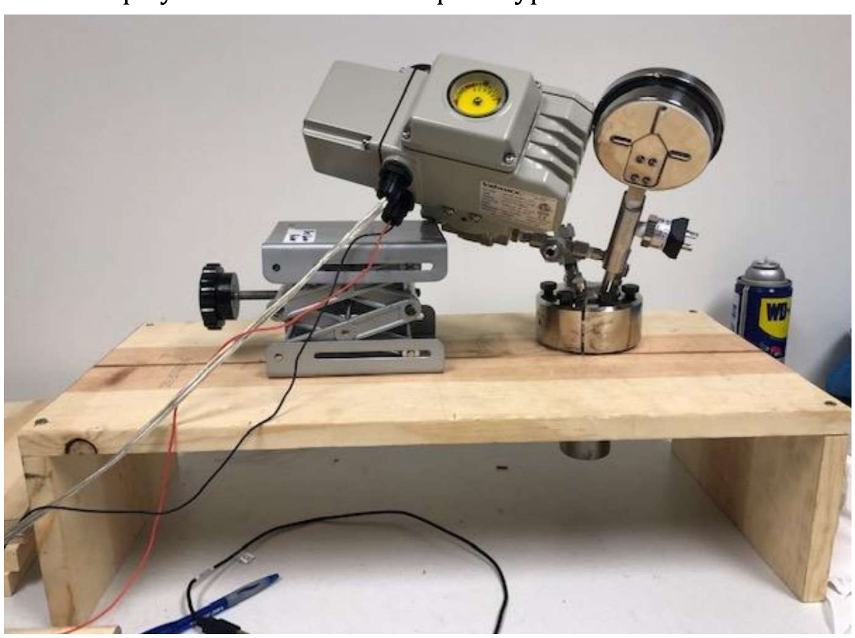


Figure 10: Final Functional Prototype

7.0 IQ/OQ/PQ

7.1 DOE

Note: Power calculations for the following test protocols are in the Verification and Validation sections of this report.

Table XI: Test Protocol for Code

Linearity Test Case		
Programs: LabView, Excel, Minitab		
Location: ATL lab room		
Sample Size: N = 5		
Pre-conditions: A pressurization must be completed prior to following test steps and pressure data is recorded on a text file.		
Step	**Test Step**	**Expected Results**
1	Open *.txt* file produced containing the pressure values	
2	Copy and paste data set into an empty Excel sheet. Label by trial number	2 comma-separated data sets
3	Separate data columns: *Data >> Data Tools >> Text to Columns >> Next* >> check *Comma >> Next >> Finish*	2 excel columns
4	Label first column as “Index” and second column as “Actual Pressure (psi)”	
5	Insert new column between the two data sets, label as “Time (sec)”. Use defining eq: **.02*Index**	
6	Create new column, label as “Predicted Pressure (psi)”. Use defining eq: **Time_(sec)*(-26.67) + 800**	
7	Truncate data to only observe time between 5 - 30 seconds only	
8	On top menu bar, select *Insert >> Scatter Plot*. Under *Chart Design >> Select Data*	
9	Place cursor under *Chart data range:* dialog box and select the rows containing “Time (sec)”, “Actual Pressure (psi)”, and “Predicted Pressure (psi)”. Create chart/axis labels as needed	Graphical overlay of actual pressure drop and set point line equation
10	Select + icon on the chart and check *Trendline >> Actual Pressure (psi).* Check *Display R-squared value on chart*	$R^2 \geq .70$

11	Record all R^2 values for N = 5 trials in Minitab	
12	Once all values are in Minitab, select *Graph >> Probability Plot >> Single >>* R^2 *>> OK*	Probability Plot normality test with a 95% Confidence Interval. Linear; P-value > .05
13	Select *Stat >> Basic Statistics >> 1-Sample t… >> "One or more samples, each in a column"* on the drop down. Select R^2 .	
14	Check *Perform hypothesis test* and input **.70** under *Hypothesized mean*	
15	*Options >> Confidence level:* **95.0**, *Alternative hypothesis: Mean > hypothesized mean >> OK >> OK*	P-value < .05 (reject null hypothesis) to pass linearity test case
Test Rationale: Quantify and maximize linearity of pressure profile produced by pressurization. The normality test was first applied to the R^2 data to fulfill the normality requirements to use a 1-Sample t-test. The hypothesized mean ($\mu = .70$) was selected through prior discussion between team members and project advisors. Although typically manufacturing tests require at least an $R^2 \geq .85$, the test statistic selected was significantly more feasible given the scope and time frame of the project.		

Variability Test Case		
Programs: LabView, Excel, Minitab		
Location: ATL lab room		
Sample Size: N = 5		
Pre-conditions: Complete steps 1-8 from the Linearity Test Case procedure.		
Step	**Test Step**	**Expected Results**
1	On Excel sheet containing trial data, create a new column labelled "Residuals (e)". Use defining eq: **Predicted_Pressure(psi) - Actual_Pressure_(psi)**	Column of values of equal length as in previous test case
2	Create a new column labelled, "Sum Residuals". Use defining eq: **2*SUM(Residuals_(e))** (units are: Residuals/min/50 Hz)	Σe > 320,000/min sampled at 50 Hz
3	Record all Σe values for N = 5 trials on Minitab	
4	Once all values are on Minitab, select *Graph >> Probability Plot >> Single >>* Σe *>> OK*	Probability Plot normality test with a 95% Confidence Interval. Linear; P-value > .05
5	Select *Stat >> Basic Statistics >> 1-Sample t… >> "One or more samples, each in a column"* on the drop down. Select Σe .	

6	Check *Perform hypothesis test* and input **320,000** under *Hypothesized mean*	
7	*Options >> Confidence level:* **95.0**, *Alternative hypothesis: Mean < hypothesized mean >> OK >> OK*	P-value < .05 (reject null hypothesis) to pass linearity test case

Test Rationale: Quantify and minimize normalized residuals during pressurization procedures.

The normality test was first applied to the Σe data to fulfill the normality requirements to use a 1-Sample t-test. The hypothesized mean selected ($\mu = 320{,}000$) was chosen based on the previous master's student's pressurization data. The preceding LabView code utilized a PID feedback loop with a sampling frequency of 10 Hz. Initial runs of this code resulted in a normalized residual value of $\Sigma e = 64{,}034$ (residuals/minute at 10 Hz). However, the code for this project reads the pressure transducer data at a sampling rate of 50 Hz. To account for this, the hypothesized mean was selected to be a scaled value of the previous student's normalized residual performance such that $\Sigma e = 320{,}000$ (residuals/minute at 50 Hz).

Success Rate Test Case

Programs: LabView, Minitab

Location: ATL lab room

Sample Size: N = 5

Pre-conditions: Test subjects must be safety trained and supervised while performing test steps.

Step	Test Step	Expected Results
1	Bring a non-team member test subject to ATL lab room	
2	Introduce subject to the user interface - highlight which portions of the front panel are relevant to the subject	
3	Have subject perform pressurization	
4	Record any errors performed while observing test subject. Errors include: Questions on how to maneuver the front panel after instruction Misunderstanding the pressure data produced Taking more than 10 minutes to produce data	Tallied number of errors
5	Sum the total the errors (E) for each subject, N = 5, and input to Minitab	Integer E values
6	Once all E values are recorded on Minitab, select *Graph >> Probability Plot >> Single >>* E *>> OK*	Probability Plot normality test with a 95% CI. Linear; P-value > .05
7	Select *Stat >> Basic Statistics >> 1-Sample t… >> "One or more samples, each in a column"* on the drop down. Select *E*.	

8	Check *Perform hypothesis test* and input **2** under *hypothesized mean*	
9	*Options >> Confidence level:* **95.0**, *Alternative hypothesis: Mean < hypothesized mean >> OK >> OK*	P-value < .05 (reject null hypothesis) to pass linearity test case
Test Rationale: Quantify and mitigate user errors that may arise from the user interface. This test case aims to determine which areas of the UI needs improvement both during real-time pressurization and data analysis.		

Feedback Response Time Test Case		
Programs: LabView, Minitab		
Location: ATL lab room		
Sample Size: N = 5		
Pre-conditions: Complete steps 1-8 from the Linearity Test Case procedure.		
Step	**Test Step**	**Expected Results**
1	On Excel sheet containing trial data, create a new column labelled "dy/dt". Use defining eq: ($\mathbf{Actual\_Pressure_{t}}$- $\mathbf{Actual\_Pressure_{t-0.5}}$)/($\mathbf{Time_{t}}$- $\mathbf{Time_{t-0.5}}$). Start at 0.5 s.	
2	Create a new column labelled, "Slope". Use defining eq: **AVERAGE**($\mathbf{dy/dt_{t-0.2}}$:$\mathbf{dy/dt_{t+0.2}}$)	
3	Observe when slope becomes constantly negative. Record initial value as τ.	Choose the instance where it remains negative indefinitely. τ < 6.5 s ideally
8	Record all τ values for N = 5 trials in Minitab	
9	Once all values are in Minitab, select *Graph >> Probability Plot >> Single >>* τ *>> OK*	Probability Plot normality test with a 95% CI. Linear; P-value > .05
10	Select *Stat >> Basic Statistics >> 1-Sample t… >> "One or more samples, each in a column"* on the drop down. Select τ.	
11	Check *Perform hypothesis test* and input **6.5** under *Hypothesized mean*	
12	*Options >> Confidence level:* **95.0**, *Alternative hypothesis: Mean < hypothesized mean >> OK >> OK*	P-value < .05 (reject null hypothesis) to pass linearity test case
Test Rationale: Quantify response time taken for valve to open during pressurization procedures.		

This test case aims to determine whether the data needs to be normalized to account for the feedback response time

Table XII: DOE for Housing Device

Angle Check Test Protocol		
Equipment: Flat Table, Protractor		
Location: ATL Lab Room/Machine Shop		
Sample Size: N = 5		
Pre-conditions: Prototype must be completely assembled.		
Step	**Test Step**	**Expected Results**
1	Place prototype on flat table	
2	Look at bottom surface of table and observe any elevations of the base table supports	
3	Use protractor to measure angles of base table supports off the surface at a corner	Less than 5 Degrees
4	Record measurements and repeat four other times at different corners to get a total of five different set of angle measurements	
5	Validate measured angles by performing a t-test; 95% confidence; $\mu < \mu_0 = 5°$	
6	Once all values are in Minitab, select *Graph >> Probability Plot >> Single >>* R^2 *>> OK*	Probability Plot normality test with a 95% Confidence Interval. Linear; P-value > .05
7	Select *Stat >> Basic Statistics >> 1-Sample t… >> "One or more samples, each in a column"* on the drop down. Select R^2 .	
8	Check *Perform hypothesis test* and input **5** under *Hypothesized mean*	
9	*Options >> Confidence level:* **95.0**, *Alternative hypothesis: Mean < hypothesized mean >> OK >> OK*	P-value < .05 (reject null hypothesis) to pass angle check test case
Test Rationale: To observe if the angles measured are efficient enough to keep the structure stable. This test protocol aims to check whether the prototype may rock back and forth. If the prototype was manufactured and assembled properly, it should be able to stay still (no rocking/tilting). This checks for structure stability and an angle that measures less than 5 degrees should still be able to show that it is		

stable.

Force Check Test Protocol		
Equipment: Flat Table, Pressure Cylinder System		
Location: ATL Lab Room		
Sample Size: N = 5		
Pre-conditions: Prototype must be completely assembled and be safety trained to perform test protocol in ATL Lab Room.		
Step	**Test Step**	**Expected Results**
1	Place prototype on flat table	
2	Place pressure cylinder system on housing unit (cylinder in the slot, top heavy portion on the left panel plate, etc.)	It can hold up the pressure cylinder system
3	Observe for at least 30 minutes to make sure it holds up (Can perform normal pressurizations while observing)	It can hold up the pressure cylinder system while it is being used
4	Record observations and repeat four other times for a total of five different observations	It can hold up the pressure cylinder system while it is being used
Test Rationale: To observe if the prototype may able to withstand at least 50 pounds. This test protocol aims to check whether the prototype can hold up the actual pressure cylinder system. This checks for structure stability and this is important since the pressurizations will be performed and it requires to be used for long periods of time.		

7.2 Verification and Validation

Table XIII: Summary of Test Results

Test	Metric	P-value	Mean	SD	Power	Result
Linearity	$R^2 \geq .70$	0.009	0.7318	0.02226	0.9857	PASS
Variability	$\Sigma e < 320,000$ (at 50 Hz)	< 0.001	73,586.2	49,342	~1	PASS
Success Rate	E < 2	PASS RATE: 100%				PASS

Feedback Response Time	$\tau < 6.5$ sec	0.0148	6.336	0.1108	~1	PASS
Angle	$\Theta = 0°$	< 0.001	0.02	0.0447	~1	PASS
Force	-	PASS RATE: 100%				PASS

Code:

<u>Linearity</u>

The linearity of the pressure profile was defined by the R^2 value obtained through a linear regression. A one sample t-test was then implemented to verify that the R^2 values were greater than or equal to 0.70. To use the 95% confident t-test, however, required a normal distribution of the R^2 values.

Table XIV: Results of Linearity Testing

Trial	R^2
1	0.7568
2	0.7437
3	0.7523
4	0.7007
5	0.7372

To address the normality requirements needed to perform the t-test, a normal probability plot was created for the R^2 values listed in Table XX. The following figure shows the 95% confidence interval (alpha = 0.05) window for a normal distribution. The p-value for the normal probability plot was greater than alpha, 0.161. This signifies that the data followed a normal distribution and the linearity can be accurately described by the proposed t-test.

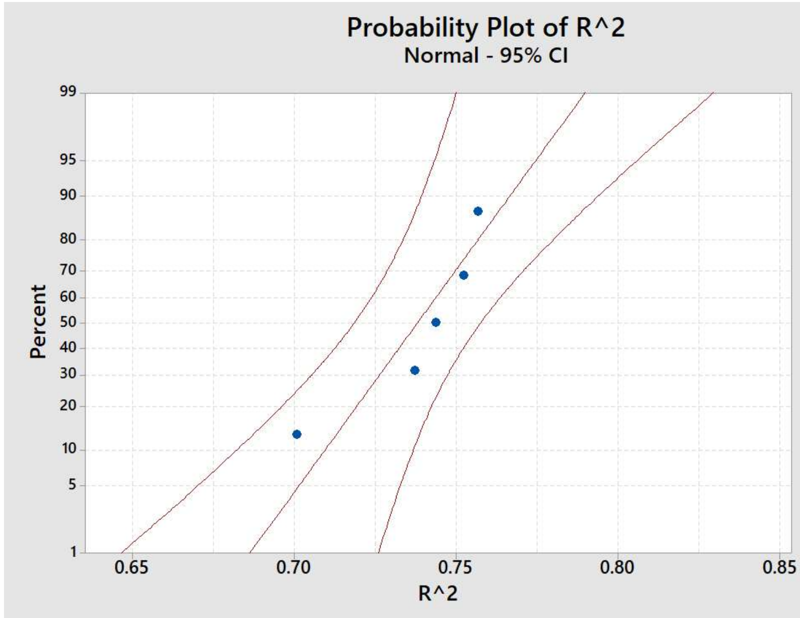


Figure 11: Normality Plot of Linearity

After a normal distribution was confirmed for the R^2 values, a one-tailed t-test with a 95% confidence level was applied (alpha = 0.05). In this test, the null hypothesis used was a hypothesized mean of 0.7 and an alternative hypothesized mean greater than 0.7 for R^2 . The test yielded a p-value of 0.009 which is less than alpha. This showed that the data produced for the linear regression was statistically significant and gave evidence that the specifications required for the R^2 value was passed.

Given a sample size of N = 5, a sample mean of 0.73814, and a sample standard deviation of 0.02226, the statistical power of this test ($1-\beta$) was 0.9857. This signifies that there is little likelihood of a Type II error occurring for the t-test.

Variability

The variability of the pressure profile was defined by the normalized sum of residuals, Σe. The decided specification for this metric was a Σe value less than 320,000 residuals/minute when sampled at a rate of 50 Hz. This metric was assessed using a 95% confidence t-test after confirming a normalized distribution of the data.

Table XV: Results of Variability Testing

Trial	Σe @50 Hz
1	2,169
2	133,831
3	79,172

4	54,449
5	98,310

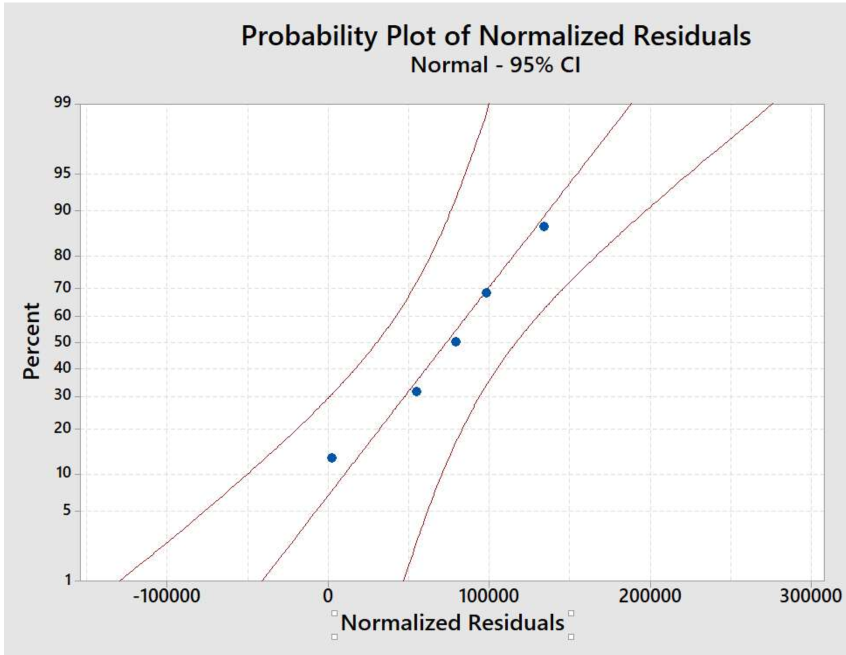


Figure 12: Normality Plot of Variability

After a normal distribution was confirmed for the Σe values, a one-tailed t-test with a 95% confidence level was applied (alpha = 0.05). In this test, the null hypothesis used was a hypothesized mean of 320,000 and an alternative hypothesized mean less than 320,000 for Σe. The test yielded a p-value << 0.05. This showed that the data produced for the normalized sum of residuals was statistically significant and gave evidence that the specifications required for the variability in the pressure profiles was passed.

Given a sample size of N = 5, a sample mean of 73,586.2 , and a sample standard deviation of 49,342, the statistical power of this test $(1-\beta)$ approached 1. This signifies that there is little likelihood of a Type II error occurring for the t-test.

<u>Success Rate</u>

The success rate of the user interface was defined by the number of errors that occurred during a full pressurization process. These errors revolved solely on the interactions with the front panel of the LabVIEW code as the other physical components involved in the procedure were not within the scope of this project.

For this test, an 80% pass rate among the subject trials were needed to demonstrate the usability of the front panel interface. A passing trial for this test consisted of a full pressurization within five minutes and two or less errors performed by the subject. As outlined in the following table, all of the test subjects passed the trial and gave evidence that the usability specifications required of the user interface was passed.

Table XVI: Results of Success Rate Testing

Trial	# Errors	Time	Pass/Fail
1	0	1 min 3 sec	Pass
2	1	1 min 17 sec	Pass
3	0	1 min 6 sec	Pass
4	2	1 min 28 sec	Pass
5	1	1 min 12 sec	Pass

<u>Feedback Response Time</u>

The feedback response time was defined by the variable τ, which signified the time for the electric valve takes to open. For this test, the response time needed to be under 6.5 seconds. A one sample t-test was then implemented to verify that the τ values were less than 6.5. To use the 95% confident t-test, however, required a normal distribution of the τ values.

Table XVII: Results of Feedback Response Time Testing

Trial	Tau (sec)
1	6.28
2	6.24
3	6.50
4	6.26
5	6.40

To address the normality requirements needed to perform the t-test, a normal probability plot was created for the R^2 values listed in Table XX. The following figure shows the 95% confidence interval (alpha = 0.05) window for a normal distribution. The p-value for the normal probability plot was greater than alpha, 0.235. This signifies that the data followed a normal distribution and the feedback response time can be accurately described by the proposed t-test.

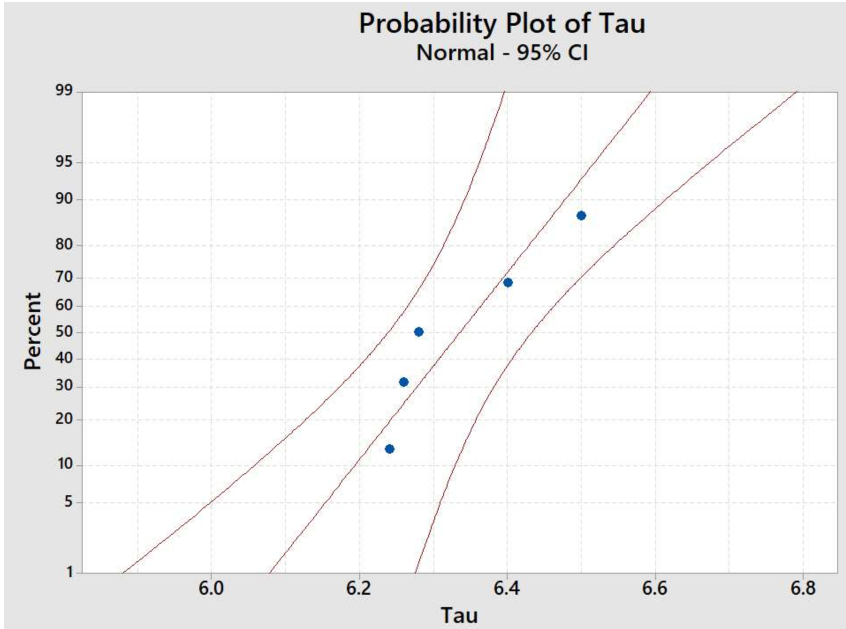


Figure 13: Normality Plot of Feedback Response Time

After a normal distribution was confirmed for the R^2 values, a one-tailed t-test with a 95% confidence level was applied (alpha = 0.05). In this test, the null hypothesis used was a hypothesized mean of 6.5 and an alternative hypothesized mean less than 6.5 for R^2 . The test yielded a p-value of 0.0148 which is less than alpha. This showed that the data produced for the linear regression was statistically significant and gave evidence that the specifications required for the R^2 value was passed.

Housing Unit:

Structure Stability (Angle)

The angles of the housing unit were measured using a protractor as shown in Figure 14 below. The angles recorded were measured from four different corners of the housing unit. An extra angle measurement was taken at a corner that seemed like it was not flat on the surface.

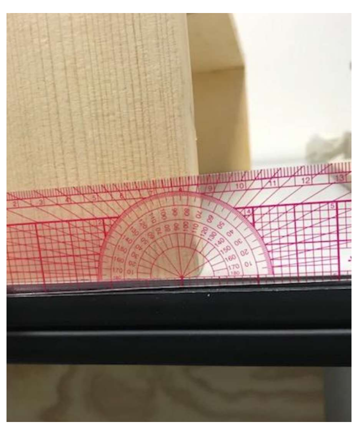


Figure 14. Measuring Angle of a Corner of Housing Unit

For this test, the desired angle should be less than or equal to 5°. After performing a one sided t-test with a 95% confidence, the p-value was found to be less than 0.001. As this p-value is under 0.05, this test is a success.

Table XVIII. Recorded Angles for Housing Unit

Angles	Θ (Degrees)
Angle 1	0°
Angle 2	0.1°
Angle 3	0°
Angle 4	0°
Angle 5	0°

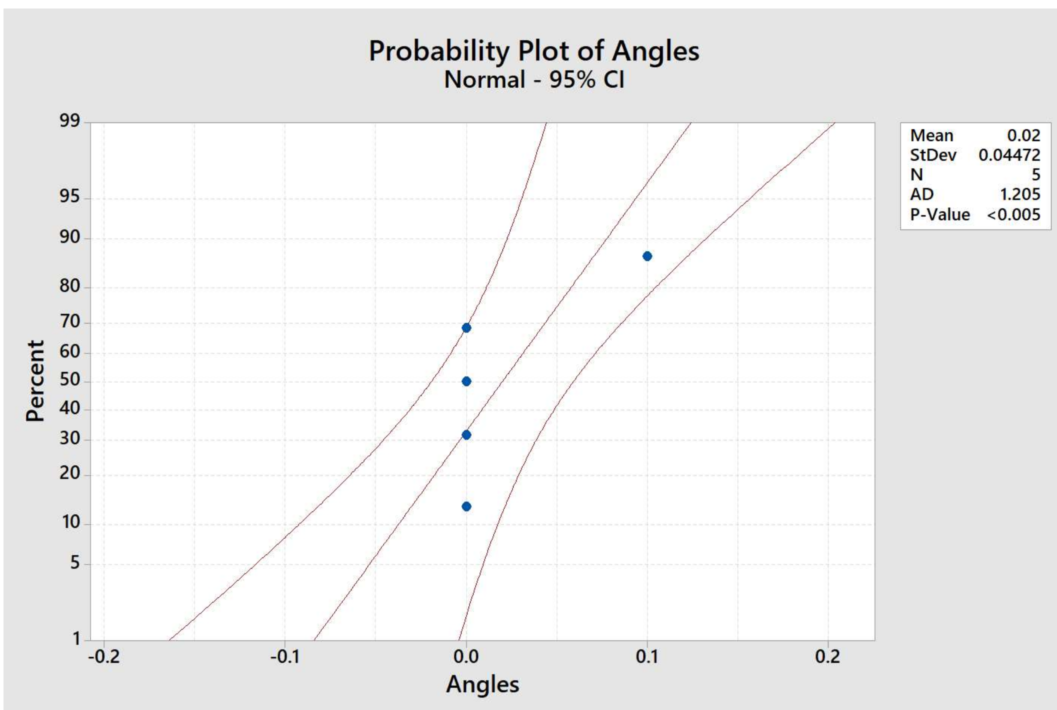


Figure 15. Normal Probability Plot of Angle Checks

From Figure 15 above, this showed a normal probability plot to check for its normality. Since the p-value was less than alpha, this signified that the data does not follow a normal distribution. However, a one-sided t-test was still performed to confirm its stability although this may not portray an accurate validation since the angle data did not follow a normal distribution.

The mean of the angles was calculated to be 0.02 and the standard deviation was found to be 0.0447. These values were then used to calculate the Power which was found to be 1 with a given sample size, N = 5. This signifies that there is little likelihood of a Type II error occurring.

Aside from the statistical tests, it can be observed that the prototype does look stable. The base table supports were completely flat on the surface of the table which means that there won't be any rocking motion. This suggested that the angles of the base table supports are close to 0 even if it wasn't measured.

Structure Stability (Weight)
For this test, the prototype should be able to withstand the forces of the pressure cylinder system (it is at least 50 pounds) for at least 30 minutes at a time for at least 80% of the trials. After testing, the pass rate was found to be 100%. As the pass rate is greater than 80%, this test was a success.

Table XIX. Observations for Force Check for Housing Unit

Observation	Time	Pass/Fail	Notes	Date
Observation 1	30 minutes	Pass (able to hold for at least 30 minutes)	Performed pressurizations while observing	02/28/2019
Observation 2	30 minutes	Pass (able to hold for at least 30 minutes)	Worked on other assignments while observing	02/28/2019
Observation 3	30 minutes	Pass (able to hold for at least 30 minutes)	Worked on other assignments while observing	02/28/2019
Observation 4	30 minutes	Pass (able to hold for at least 30 minutes)	Performed pressurizations while observing	03/01/2019
Observation 5	30 minutes	Pass (able to hold for at least 30 minutes)	Worked on other assignments while observing	03/01/2019

8.0 Conclusions and Recommendations

8.1 Recommendations

Code:
As shown in the *Validation and Verification* section above, the code performed better than its predecessor. Because of this, any recommendations made would be relatively cosmetic. A

smoothing filter could be applied to the data to minimize the sum of residuals. This could make the pressure drop more repeatable. The code which exports the data gathered during the pressurization could be altered so data is put directly into an excel file, rather than a .txt file. This would not improve the ability of the code to create scaffolds, but would improve usability of the code and the later analysis of the data.

Housing Unit:
Some recommendations that can be made for the housing unit is having a surface finish. This will make the housing unit more visually appealing. Also, adding components that allows for storage would be very helpful. After using the pressure cylinder system, it needs to be taken apart. Once that has been done, the components are just left on the table. Having components which could act as storage containers on the housing unit will allow for organization of the pressure cylinder system. The components of the system will be stored properly and safely and it is organized so that they are not scattered around on the table.

8.2 Conclusions

Code:
In conclusion, the final code prototype is a success in terms of the metrics provided by the customer. There was significant improvement over the previous code being used. Initially, the project seemed daunting, as the team had no prior LabVIEW experience. As the project progressed, however, any concerns about the learning curve of the program were mitigated.

Housing Unit:
In conclusion, the final housing unit prototype functions as intended. Although there have been changes to the housing unit designs throughout the quarter, the final design was still able to support the pressure cylinder system. The manufacturing process instructions were also updated to in order to manufacture the final evolution of the prototype design. At first, the manufacturing process seemed difficult because of the different components but the last evolution of the design involves easier and less steps to manufacture the housing unit. The final functional prototype have been validated through different test methods: Angle Check and Force Check. From those tests, they were able to show that the housing unit is very stable and can hold up the pressure cylinder system. Overall, the housing unit portion of the project improved the designer's SolidWorks skills as well as become more familiar with how to use different machining tools.

9.0 Acknowledgments

Acknowledgments for this project goes to those that had a significant impact with data collection, coming up with designs, etc. First acknowledgement goes to Matt Thomas for providing his master's thesis. His thesis provided the information needed to produce the code. Second goes to Cindy Holton for providing the key needed to access the ATL Lab Rooms. Without this, test protocols wouldn't have been performed for the pressure cylinder system. Theo Anastos and Conor Vache also assisted in familiarizing the team with the pressure cylinder system. A test protocol was developed that involved using test subjects. Megan Bell, Madeleine Hummel, Jeremy Lake, Elizabeth Peterson, and Kristin Schmidt assisted in performing the test protocol in order to collect data. Lastly, professors Dr. Heylman and Dr. Whitt provided feedback and suggestions that further helped with the progress of the project.

10.0 Appendices

10.1 Appendix A: References

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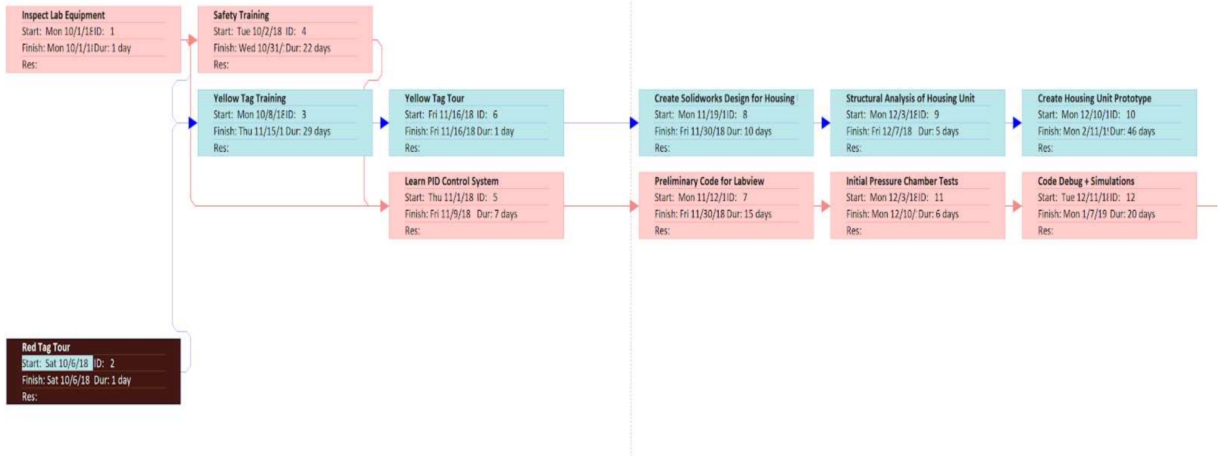
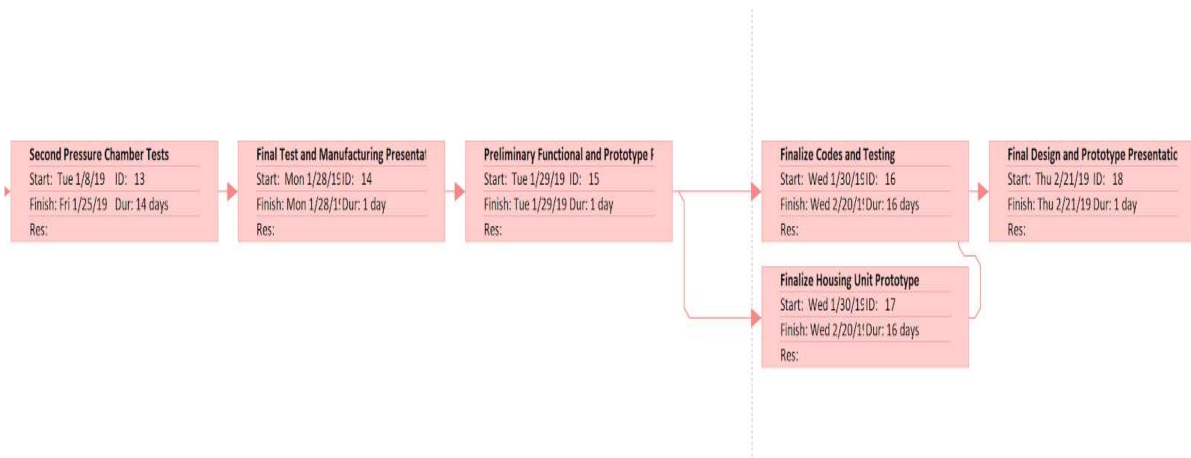
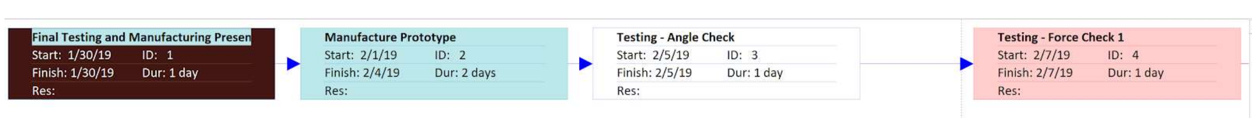
10.2 Appendix B: Project Plan (PERT Chart)

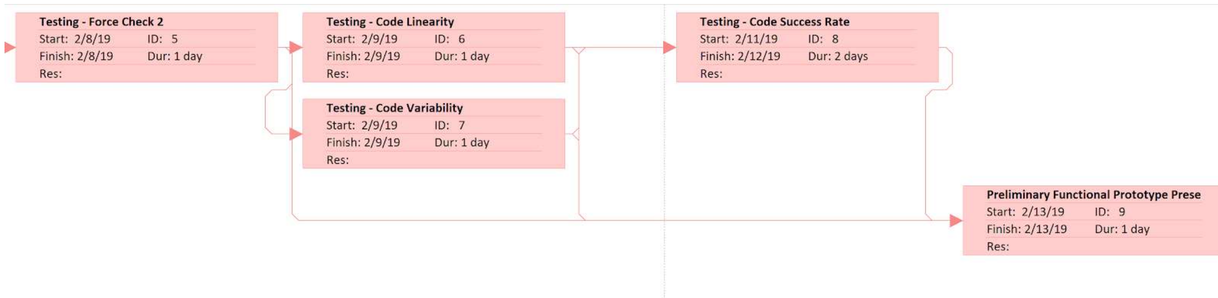




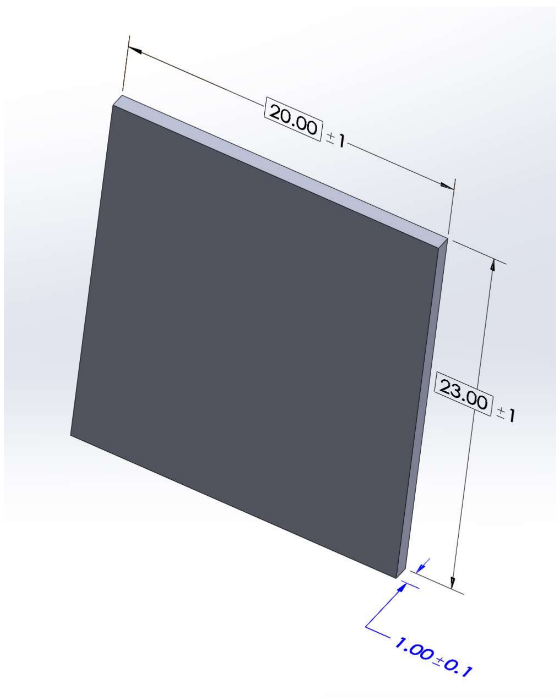
The PERT chart covers the plans for the rest of Fall quarter as well as plans for Winter Quarter. Our PERT chart mostly consists of our plans for the project and includes the presentations for Winter Quarter. This plan is not final and may subject to change if any problems occur or there are more tasks that might be added.

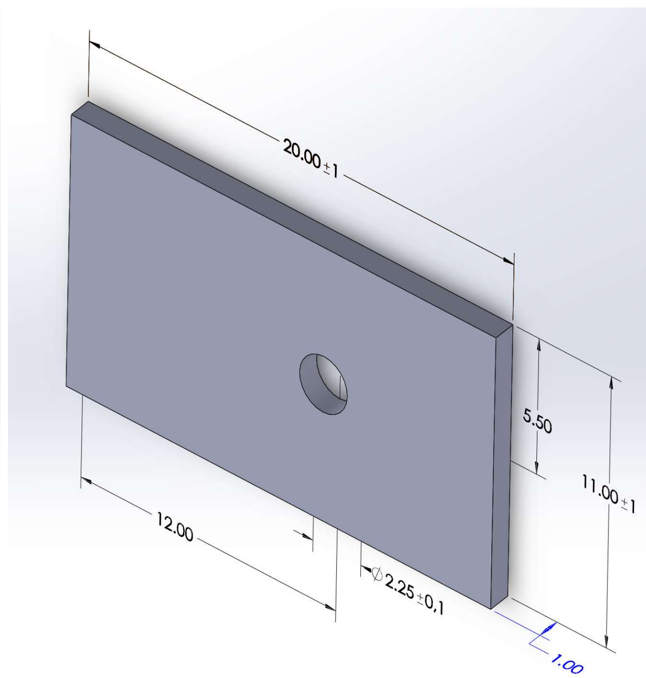
Updated PERT Chart for Winter 2019

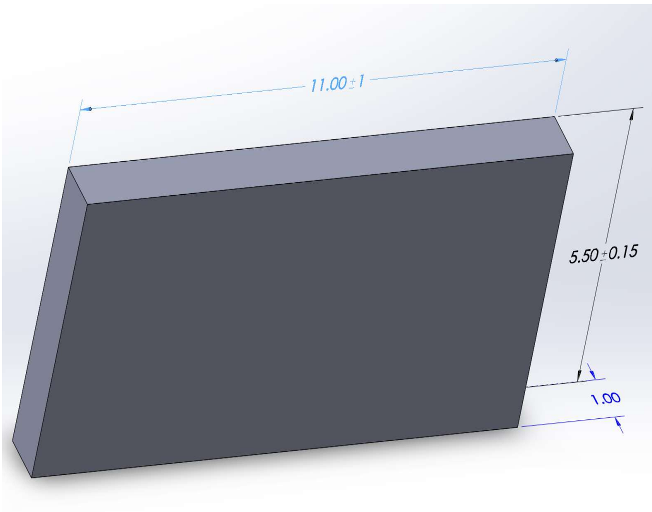




10.3 Appendix C: CAD Drawings



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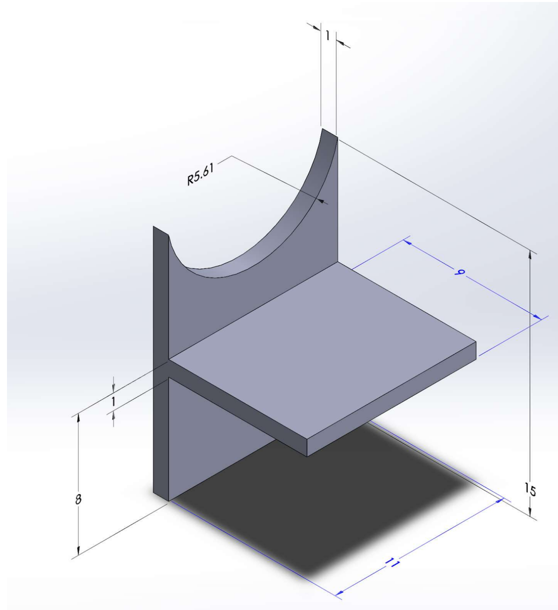
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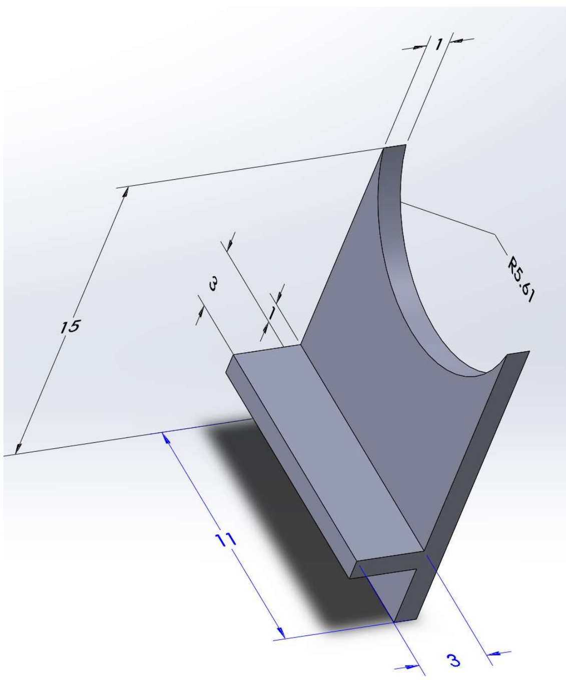
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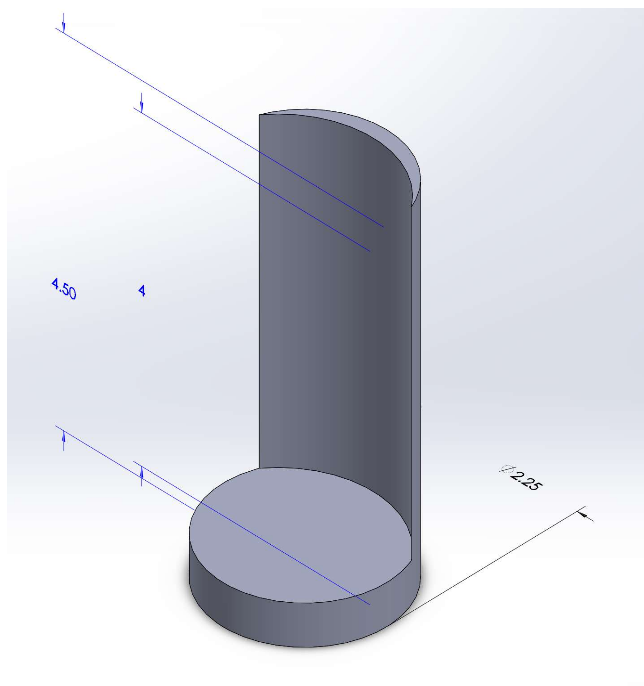
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4
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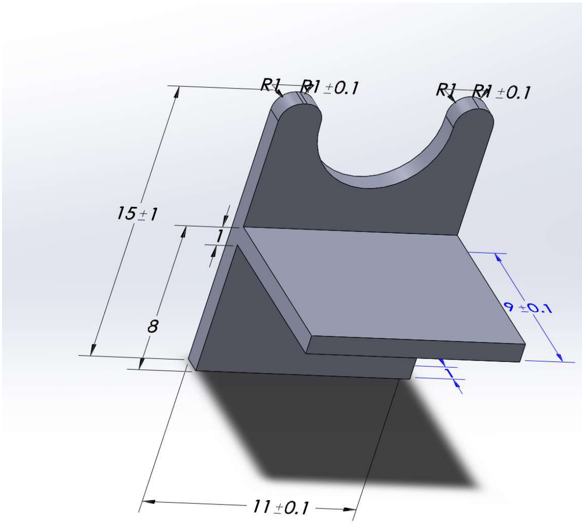
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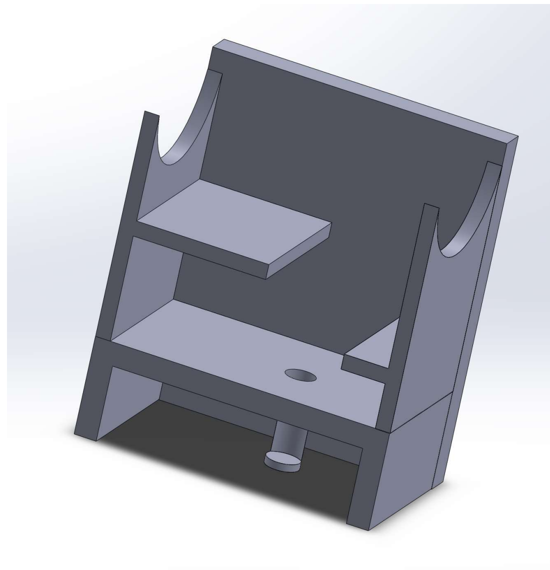
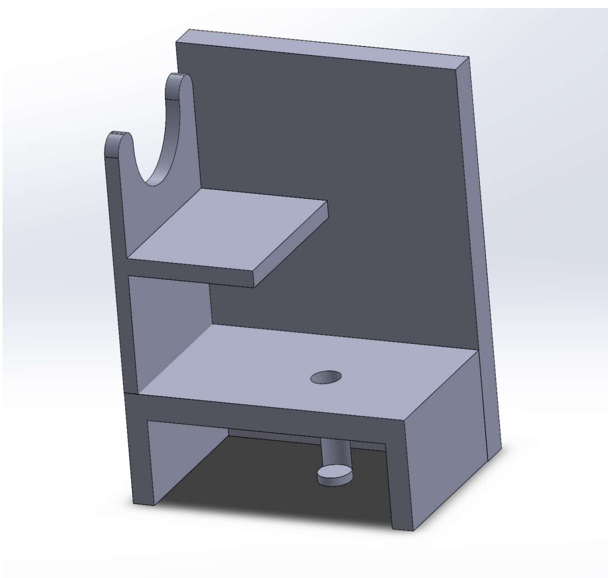
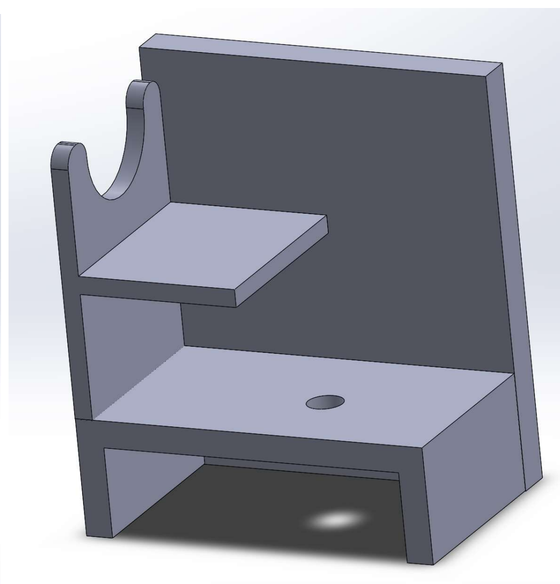
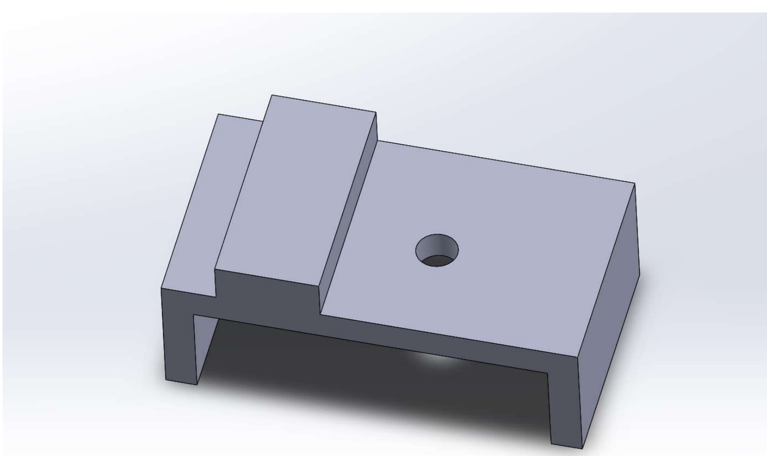

10.4 Appendix D: FMEA, Hazard & Risk Assessment

Component Name	Possible Failure Mode	Type	Cause of Failure	OCC	DET	SEV	RPN	Effect of Failure on System	Failure Improvement Alternative Actions
Pressure profile	Wrong pressure profile; Damaged biomaterial	Mecahnical, Coding	Gas release occured for either too long or too short of a time frame	5	10	8	400	Scaffold will not form if the pressure profile does not behave as needed. Will cause damage to the material	Use a feedback loop that outlines the ongoing pressure profile. If graph detracts from linear shape, pressure release should respond in real time to maintain it
Electric valve	Defective reaction vessel	Mecahnical, Electrical	Too much gas release - sudden spike of pressure through valve and tubing	3	7	8	168	Sudden spike of pressure to the scaffold housing unit; May damage system connectors (tubing), the housing itself, and the biomaterial	Keep a continuous monitor of how much gas is actually being released by the valve, irregardless of what the code aims to do
User Interface	Incorrect user inputs leading to harmful environment to PLGA scaffolds	Human Error	Interface may not be intuitive and lead to confusion in inputing system parameters	5	7	7	245	Incorrect/detrimental parameter inputs would still be carried out by the code, regardless of its effects on the biomaterial - may cause irreversible harm to housing unit and biomatieral	Create a user-friendly interface, create upper and lower bounds on parameter inputs to protect the system - system will not run if not within range
Pressure Cylinder	Damaged Pressure Cylinder	Mechanical	Uneven weight of the pressure cylider may fall onto scaffold	2	8	9	144	Damaged cylinder will harm the scaffold and may possibly release dangerous gas into the environment	Create a user-friendly interface, create upper and lower bounds on parameter inputs to protect the system - system will not run if not within range; This will prevent damaging the cylinder and scaffold
Gas Release	Incorrect time frame for gas release; Incorrect/inaccurate pressure profile produced	Coding, Electrical	Graphical outputs not properly represented in the code (ie. what defines a linear graph vs an exponential drop is not clearly expressed)	3	9	7	189	User inputs defining desired pressure profiles are not followed correctly; May create detrimental environment to the biomaterial and damage it irreversibly	Create the desired graphical output separately to serve as a control and compare to the actual pressure profile produced by the system - perform statistical analysis on the accuracy of the profile created

Outside of the mechanical components involved in the pressurization process, the largest risk involves the pressure profile generated by the LabVIEW code. Depending on the steepness of the curve defined by the user, pressure may be released far too quickly and damage the scaffolds currently in the chamber. To address this risk, a hard set of a 20% opening on the electric valve was applied. This forces the valve to only open to this extent, regardless of the slope defined by the user. For usability in future applications, the valve opening can still be changed in the back-end (block diagram) interface of the LabVIEW code if needed.

The next risk involves the behavior of the electric valve during the pressurization process. To ensure that a sudden spike in pressure does not occur, the following steps were taken both in the lab and the code design: members read the physical gauge attached to the pressure chamber for a more definitive value of the pressure environment and the code starts with an initial read using the pressure transducer rather than a set value of 800 psi (ideal). These two methods solidify the established values used in the feedback loop to ensure safety of the user and the manufactured scaffolds.

10.5 Appendix E: Pugh Chart

		CONCEPTS		
Selection for Criteria	DATUM	1	2	3
repeatable pressure profile	CONCEPT 1	N/A	-	+
linear pressure profile		N/A	S	S
ease of use: intuitive interface		N/A	-	S
automatic gas release		N/A	-	S
# of pluses		0	0	1
# of minuses		0	3	0

		CONCEPTS		
Selection for Criteria	DATUM	1	2	3
repeatable pressure profile	CONCEPT 2	+	N/A	+
linear pressure profile		S	N/A	S
ease of use: intuitive interface		+	N/A	+
automatic gas release		+	N/A	+
# of pluses		3	0	3
# of minuses		0	0	0

		CONCEPTS		
Selection for Criteria	DATUM	1	2	3
repeatable pressure profile	CONCEPT 3	-	-	N/A
linear pressure profile		S	S	N/A
ease of use: intuitive interface		S	-	N/A
automatic gas release		S	-	N/A
# of pluses		0	0	0
# of minuses		1	3	0

10.6 Appendix F: Vendor Information, Specifications, and Data Sheets

Items required for the use of the code to set and measure gas release is heavily reliant on its application. LabView software is necessary for the PID control system as well as an in-house pressure transducer and Data Acquisition Device (DAQ). The specifications of these components vary depending on the application of the code. The wider range of pressure drops involved, the greater need for higher specifications for the transducer and DAQ. For the purposes of this lab, the product information of the DAQ is outlined in Appendix G.

10.7 Appendix G: Budget

Item Description	Product Number	Purpose	Associated Task	Source	Planned			
					Unit	Quantity	Cost/ Unit	Total Cost
Plywood	458503	Housing for device	Housing device	Home Depot	1	2	$8.55	$16.70
#8 x 1” Screws	20992	Attach parts	Housing Device	Home Depot	1	1	$4.67	$4.67
#8 x 1 ¼“ Screws	801832	Attach parts	Housing Device	Home Depot	1	1	$5.58	$5.58
					TOTAL COST			$26.95

10.8 Appendix H: Code Development Instructions (MPI Supporting)

Step	Description
1	**Download LabView** http://www.ni.com/en-us/shop/labview/select-edition.html **Download NI-DAQmx driver** http://www.ni.com/en-us/support/downloads/drivers/download.ni-daqmx.html#291872
2	**Create Project and Virtual Instrument** a. Open software and under *Create Project* select *Blank Project* b. On top menu bar select *File* >> *New VI* c. In the new file on the top menu bar, select *Window* >> *Show Block Diagram*

3	**Create Pressure Transducer DAQ Assistant** a. Right-click *Block Diagram Window* to open Functions palette and select *Express >> Input* b. Drag and *drop DAQ Assist* into *Block Diagram Window* c. Once DAQ Assistant launches, select *Acquire Signals >> Analog Input >> Current* d. Under *Physical Channel Window*, select *cDAQ1Mod1* e. Select *Finish* **Configure Pressure Transducer DAQ Assistant** Set current input limits as shown in the diagram **To allow global use of task created:** a. Right-click *DAQ Assistant Express VI >> Convert to NI-DAQmx Task* b. Once DAQ Assistant launches, click *OK*
4	**Create Electric Valve DAQ Assistant** *a.* Right-click *Block Diagram Window* to open Functions palette and select *Express >> Input* *b.* Drag and *drop DAQ Assist* into *Block Diagram Window* *c.* Once DAQ Assistant launches, select *Acquire Signals >> Analog Output >> Voltage* **Configure Electric Valve DAQ Assistant** Set current input limits as shown in the diagram **To allow global use of task created** *a.* Right-click *DAQ Assistant Express VI >> Convert to NI-DAQmx Task* *b.* Once DAQ Assistant launches, click *OK*
5	**Create Customizable Setpoint Line Equation (y = -26.67t + 800)** a. Right-click *Block Diagram Window* to access *Functions* palette. Under *Programming* select *Numeric >> Multiply*. Drag and drop *Multiply* function in to *Block Diagram*. b. Select *Numeric >> Constant*. Drag and drop into *Block Diagram*. Input the value **-26.67** and connect to lower input terminal of the *Multiply* function. c. Within the *Functions* palette, select *Express >> Sig Manip* and drag *To DDT* to *Block Diagram*. Connect output terminal of *Multiply* to input of *To DDT*. d. Select *Numeric >> Add* and drag to *Block Diagram*. Connect output of *To DDT* to the upper input terminal of *Add* function. e. Select *Numeric >> Constant* and input the value **800**. Connect to lower input terminal of *Add* function. f. Under *Sig Manip*, drag and drop *From DDT* and *To DDT*. Place functions adjacent to each other. Connect output terminal of *Add* function to input of *From DDT,* then connect output array data type to *To DDT* input terminal. g. Create a *Subtraction* function and connect output of *To DDT* to the upper input terminal of *Subtraction*.

6	**Read and Display Pressure Transducer Data:** a. Use *DAQ Assistant* created for the Pressure Transducer. Connect data output terminal to the upper input terminal of a new *Subtraction* function. b. Create a new *Numeric >> Constant* with a value of **.004** and connect to the lower input terminal. c. Connect the output of the *Subtraction* function to the upper input terminal of a new *Multiplication* function. Create a *Constant* with the value **312500** for the lower input terminal. d. Switch to the *Front Panel Window*. Right-click to access *Controls* palette. e. Under *Modern*, click *Graph >> Waveform Chart* Change the chart title to "Pressure Drop" and y-axis to **"Pressure (psi)"** f. Switch to *Block Diagram Window* and connect the output of the *Multiplication* function to the input of the Pressure Drop waveform chart
7	**Create Boolean Case Structure** a. Connect the output of the *Multiply* function of the *Transducer DAQ* to the open input terminal of the *Subtraction* from the Setpoint Equation. b. In the *Functions* palette, select *Comparison >> Less?* and drag to the block diagram. Connect the output of the *Subtraction* function to the upper input terminal. c. Create a new *Numeric Constant* with a value of **0** and connect to the lower input terminal of the *Less? Function*. d. In the *Functions* palette under *Programming,* select *Structures >> Case Structure*. Draw the box adjacent to the *Less? Function*. e. Connect output of *Less?* to the *Case Selector* of the *Case Function*. Select *True* in the case drop down. f. Drag the *DAQ Assistant* created for the *Electric Valve* into the *True* window. g. Create a *Numeric Constant* with a value **2** and connect to the data input terminal. h. Switch to the *Front Panel window* and create another *Waveform Chart*. Label the chart **"Output Voltage"** with a y-axis titled **"Voltage (V)"** i. Attach this new icon to the data input node in the *Block Diagram window*. Leave False case structure window blank.
8	**Create Feedback System** a. In the *Functions* palette under *Programming*, select *Structures >> While Loop*. b. Draw a box encompassing all of the components created thus far. c. Drag the loop iteration, *i*, to be adjacent to the open input terminal of the *Multiply* function in the Setpoint Equation. Connect *i* to the open terminal. d. In the *Functions* palette under *Programming*, select *Timing >> Elapsed Time*. e. Place *Elapsed Time* icon near the loop condition. Set time value to be **45 seconds** and to *Automatically reset after time target*. f. Connect *Time has Elapsed* output terminal to loop condition input.
9	**Create Export Data Path** a. Create a new *From DDT* function from the *Sig Manip* option in the *Functions* palette. Connect the output node of the Multiply function of the *Transducer DAQ* to the input terminal of the *From DDT* function. b. In the *Functions* palette under *Programming,* select *Array >> Build Array*.

	c. Connect the loop iteration (created previously with the While Loop) to the upper input terminal of the *Build Array* function. Connect the output of the *From DDT* function to the lower input terminal. d. Under *Programming*, select *File I/O >> Write Delimited Spreadsheet.vi* Connect the output of the *Build Array* to the *1D Data* input terminal of the new function. e. Under *Programming*, select *Boolean >> True Constant* and attach to *append to new file?* input terminal on the *Write Delimited Spreadsheet.vi* function. f. Under *File I/O*, select *File Constants >> Path Constants* and connect to file path input terminal on the *Write Delimited Spreadsheet.vi function*. Input an existing txt/csv file to export data after pressurization. g. Under *Programming,* select *String >> String Constant* and connect to format input terminal on the *Write Delimited Spreadsheet.vi* function.