

Design Document

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Eisa Alyaseen - eha33@nau.edu

Alex Anderson - amt646@nau.edu

Abdulrahman Aziz - aaa797@nau.edu

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Introduction:

The Heart Bytes team is an electrical engineering capstone team working for W.L. Gore & Associates in order to create a stent crimping machine. The team is currently working alongside a mechanical engineering capstone team to create a fully functional machine. The Heart Bytes team is responsible for designing the electrical circuits and code the software necessary for the machine to function. The mechanical engineering team is designing an iris shaped crimping mechanism that will be combined with the design the Heart Bytes team created to create a functional machine. Stent crimping machines are devices used to contract medical stents to a desired diameter or until a specified radial force has been exerted on the stent. Stents are metal tubes that are surgically inserted within a person's blood vessel to ensure proper blood flow. Similar stent crimping machines to what the team is creating already exist on the market with high costs since it is a relatively niche product, but the team is trying to produce a device that is equally reliable at a lower cost.

As mentioned earlier, the client for this project is W.L. Gore & Associates which is an engineering company that specializes in the use of fluoropolymers in various different applications. One of the larger divisions within the company is the Gore Medical Products Division, which makes use of these fluoropolymers in order to create a number of various medical products. One of these products that the Gore Medical Division makes is an endovascular stent graft which requires it to be crimped before implementation, as mentioned in the previous paragraph. This required crimping process is the reason why W.L. Gore & Associates is interested in the device the mechanical engineering team and the Heart Bytes team are creating.

Before the team started work on the project, overall requirements for the project were given to the team. The first requirement includes meeting safety standards, this requirement includes standards by OSHA, ANSI, and any other relevant standards. The next requirement is that the machine must utilize an iris shaped crimping mechanism, which the mechanical engineering team is designing. Another requirement is that the team must document their iterative design process for safety and design reasons. The machine must also have a graphical user interface (GUI) to display the radial force and diameter of the stent currently. The team is also responsible for meeting specifications related to the diameter, radial force exerted, and the length of the stent that have not been set yet and will be chosen by the team.

Previous Work:

Alex's previous work:

The first piece of prior work that the team researched was the Final Report from the NAU Gore Capstone Team from 2020. W.L. Gore & Associates tasked a mechanical engineering capstone team with creating a stent crimping machine with similar requirements to the ones given to the Heart Bytes team. Since the projects are so similar, the Heart Bytes team is able to look back at this project in order to determine what worked for the project and what ultimately did not. This final report covers the entirety of the process the previous team went through including the entire engineering process and their iterative design process. Due to the global pandemic in 2020, this project was not able to be completed, but the previous research and designs are still a great reference. Since this project was undertaken by a mechanical engineering team, the electrical engineering aspects of this project were not covered in great detail so this document was used as a reference to figure out what needs to be done but not how to implement it. This document could also help figure out what went right and what went wrong with this project to not make any of the same mistakes. [1]

The next document the team researched was "System Design Approach to Medical Device Development" by Mark Wehde. This document elaborated on the various safety standards that need to be met when designing a medical product and how to approach meeting these standards. This document was broken up into two distinct sections: the author describing a process in which medical devices should be built and then a discussion regarding standards and risk management. The process that the author described is an iterative process with six steps that should be thoroughly documented. These steps include: design and development planning, design input, design output, design review, design verification, and design validation. The product should be safe by design, have all necessary protective measures and provide all safety material to the user. The second half of the paper discusses how to test a product and do a risk assessment of a product. To do this, all different types of risks that could occur should be assessed. The risks should be mitigated as much as possible. [2]

The third document the team researched was "A Comparative Reliability and Performance Study of Different Stent Designs in Terms of Mechanical Properties: Foreshortening, Recoil, Radial Force, and Flexibility" by Dong Bin Kim and Hyuk Choi from the journal Artificial Organs. The purpose of this document was to discuss current stent design and various improvements that could be made. The researchers tested four different variables that can affect the stent including both radial force and diameter of the stent. The researchers discussed their testing processes to determine the radial force exerted upon a stent and how to find the diameter of the stent, which was helpful in determining methods to test these variables in the stent crimping machine. Although not an electrical engineering article, after reading it, an

understanding of what stents were, how they worked, and how to measure variables such as radial force has been greatly increased. [3]

Eisa Alyaseen's previous work:

The first source Eisa used talks about the standards that need to be met when designing a vascular stent, more specifically a geometrical stent used in surgical operations. There are many design standards and parameters that need to be met when designing a vascular stent. The source mentions these parameters as the dimensions of the source, the medical requirements such as sterilization of the whole graft tube of the vascular stent, and a minimal flexible quotient to the vascular stent. This source further talks about the need for using special types of precautions, such AS making sure the spring system won't jam once inside a blood vessel as it can be extremely detrimental. In conclusion, this source lists all necessary aspects that need to be met when designing a gore stent, and will largely help our capstone team when designing the vascular stent according to global standards [4].

The second source Eisa used includes mostly research aspects of the various types of gore stents that can be used given the specific situation. There are gore stents of various sizes depending on the vascular tract of the patient. Furthermore, there are various gore stents with different spring systems for expansion and contraction. These gore systems allow the control of blood pressure and blood flow. The second source goes into detail about the various types of designs and about the basic spring system designs used in a vascular stent. There are three different spring types which are lineal, semi torsional, and torsional types of springs. These spring designs have various expansion rates when within the blood vessel. Furthermore, the source also talks about the various aspects of the design and the blood flows that these designs can support. This source concludes that the most frequently used and the most optimal spring type for vascular stents is the semi-torsional spring system, as it provides easy expansions and contraction while also providing good mobility [5].

The third source talks about the various antennas that can be used to control the stents while inside the blood vessels. A remotely controlled stent is more useful during an operation as it provides less work with wires and provides more space for surgical operation. Recently, smart stents attract lots of attention by integrating different sensors with cardiovascular stents for detecting vascular restenosis or measuring the blood flow condition including blood pressures and blood velocity. Then, the measured medial signals can be transferred to the external monitoring systems via wireless communications including the RF front ends and antennas. Different antenna designs have been studied including magnetic-field-coupled resonant antennas, miniaturized embedded antennas, and stents acting as antennas. In this research, we proposed a helix-like stent antenna by considering the whole stent as an antenna for better radiation performances. The stent antenna was designed at 2.4 GHz for the minimum loss when

transmitting through the body and human tissues. Meanwhile, the stent antenna had an omnidirectional radiation pattern which would be beneficial for arbitrary receiving angles [6].

Abdulrahman Aziz's previous work

The first source talks about the various spring systems that can be used in a gore stent and also about the comparison methods of virtual stenting. This source compares various designs of a gore stent and decides through various tests which design of the gore stent is optimal. This source talks about how endovascular repair using the gore stent leads to better treatment outcomes. The aspects of using a gore stent during an operation include fewer complications such as less blood loss during surgery as the gore stent can also be used to control blood pressure and flow one inserted within the blood vessels. The gore stent also results in shorter surgery times. There has been a large amount of research work that has been carried out in order to analyze the mechanical behavior of stents with various designs and spring systems and to test each of these designs under certain conditions as well as simulating their implantation within an artery or a blood vessel. As mentioned in this source, the tests that were carried out test each gore stent design in order to determine the optimal design configuration for a gore stent. These test assets include studies on the expansion mechanisms that are used by the gore stent when within blood vessels. Furthermore, tests were carried out on the interactions of the gore stent with the vessel wall in order to make sure of the safety of the blood vessel. As mentioned in this source, the authors of the source concluded that the best design configuration for the gore stent was the load-free partially expanded configuration. Any design of a gore stent that is similar to this configuration was included to have superior mobility and flexibility while within the blood vessels [7].

The second source includes a study about the geometrical stents along with a practical application of mapping of commercial coronary stents in Indonesia. This source also talks about the practical obstructions and complications that are faced when applying a gore stent. One of the most frequent complications during the operation of a geometrical stent is restenosis which correlates with geometric aspects of the stent. Interventional cardiologists who are operating with these stents have the authority to select the geometrical stent design that is optimal for their patients. This source studies and looks at the stent design mapping of the currently existing geometrical stents in Indonesia, from the eyes of a cardiologist. According to the collected data on geometrical stent operations, there were ten different types of geometric stent designs that were almost identical to the stents used in hospitals. According to the work carried out by the authors of this source, it can be concluded that geometric stent design is not yet the main reason for interventional cardiologists in determining the choice of coronary stents used for patients with coronary heart disease [8].

The third source contains mostly talks about the standards of a general vascular stent which will be very useful to our project, as we intend to design the gore stent for the capstone project to the standard conditions and dimensions. This source talks about how safety parameters should be met. With regard to safety, this source gives requirements for the intended use of a vascular stent. The standards include design attributes, materials, and design evaluation. Furthermore, manufacturing and sterilization packaging of the vascular stent should also be met as the vascular stent should be sterile before use on a patient. In addition, this source talks about how it should be considered as a supplement to ISO 14630. In addition, it specifies the general requirements for theative operation of non-active surgical implants. Various ISO requirements need to be met during the design of a vascular stent. These requirements include ISO 25539-2:2008 which includes vascular stents that are used to treat vascular abnormalities. ISO 25539-1:2003 defines the permeability of an uncovered stent while both ISO 25539-1:2003 and ISO 25539-2:2008 define the functional requirements of a vascular stent. In conclusion, this source finalizes that when these standards are met during the design of vascular stents, it is within a standard design [9].

Prototypes:

Sensor system prototype by Abdulrahman Aziz:

The prototype he worked on mostly includes using a force sensor and a distance sensor inorder to measure diameter readings and reel force readings. What this means is that it is respectively used to measure the reel force of the stepper motor that was used in the prototype. The distance sensor is planned to be used to measure the diameter of the stent aperture. This prototype does not have functioning mechanical parts yet. However, this prototype is only meant to demonstrate how the sensor values will be used to measure and display diameter and reel force values of the stent stepper motor. This prototype that was made fits within the system architecture as the distance sensor is planned to be placed on the wall of the stent aperture. This is done to measure the stent diameter, while the load sensor is to be placed on the breadboard for now. Furthermore, the diameter sensor was also used to measure values while displaying measured distance data on the serial monitor. The main purpose of this is to prototype and showcase the functionality of the sensors in the aim of including them in the final stages of the project design. The demonstration of the project had a few problems. One was that there was a compatibility issue of the arduino with the force sensor. This is because an hz111 chip was not available at the time. Other than this issue, the prototype worked as expected. For the final design, the sensor compatibility issues will be fixed, or replaced with a better functioning sensor. This prototype needs to be tested many times in order to see how the prototype can be improved when including it in the final design.

Figure 1: Force sensor prototype

Figure 2: Diameter sensor prototype

Eisa Alyaseen prototype description:

This prototype mainly contains the demonstration of a single motor even though the original prototype had the concept of two different motors. In this prototype, the single motor, which is a stepper motor will be used to control the two different aspects of the gore stent. The single stepper motor used increases or decreases the reel force and the diameter of the gore stent. The stepper motor will be used to control the reel force. A main reason for this choice is that the stepper motor is good at speed control and precision. The stepper motor will also be used to control the aperture radius of the stent even though originally, it was planned to be controlled using a servo motor.. The stepper motor will be controlled using four buttons for each control. For the stepper motor control of reel force, one button will be used to increase speed of the reel, thus the force. The other button will be used to decrease the force of the reel of the stent, thus decreasing the speed. For the stepper motor control of stent aperture diameter, one button will be used to rotate the servo motor clockwise, while the other will be used to rotate it counter clockwise. Rotation of the servo clockwise will cause the decrease of the aperture radius of the stent, while rotation of servo in anticlockwise direction will cause the increase in the aperture radius of the stent.This prototype fits within the system architecture. As we discussed, our plan was to have control over the reel force of the stent while also being able to control the aperture radius of the stent. For the demonstration, there was a compatibility issue with the stepper motor and the motor controller that was available at that moment. Furthermore, there are various improvements that need to be made to the motor control final design. It is planned to make sure that the motor controller is fully compatible with the motor, while also adding a stop button to stop the motor control.

Figure 3: Eisa Alyaseen's prototype

Alex Anderson's prototype description:

For this prototype, an Arduino Mega microcontroller board was programmed with some of the basic features of the stent crimping machine along with code stubs to implement future features. The purpose of this prototype was to relearn the Arduino coding language as well as learning how to best implement future features onto the device. The Arduino Mega board was chosen for this prototype because it is planned for use in future iterations of the project. The features implemented in this prototype include: working user inputs to control the diameter and radial force of the stent, control of the stepper motor to actually change the diameter and radial force, and an emergency stop button. Future support for sensors and a GUI were added through various code stubs. The user inputs worked by having four push buttons, one corresponding to increasing the radial force, one to decrease the radial force, one to increase the diameter, and one to decrease the diameter. When either of the increase buttons are pressed, the stepper motor would turn clockwise and when the decrease buttons were pressed, the motor would turn counterclockwise.

The demonstration of the prototype to the graduate teaching assistant, Alex Dahlmann, worked without issues. All of the implemented features worked on their first attempt without having to be troubleshooted. During this demonstration, the user inputs, the stepper motor and the emergency stop button were all shown. Code stubs for the sensors were tested using the analog pins on the arduino board connected to a potentiometer and were demonstrated. The code stub for the GUI was also shown, using the serial monitor on the Arduino IDE to display values.

Due to the implementation of such a high number of the requirements for the project, this prototype will definitely reduce the risk for the project moving forward. The baseline feature set that was added into this prototype will be expanded upon in order to fulfill the requirements for the project.

Figure 4: Alex Anderson's prototype

In figure 4, the prototype can be seen with all of the aforementioned parts in their places. The top four push buttons on the breadboard are the user inputs; the fifth button down is the emergency stop button, which is plugged into the reset pin of the Arduino. The stepper motor can be seen attached to its driver board which itself is then attached to the Arduino board on the digital 8, 10, 9, 11 pins. The potentiometers used for testing the sensor code stubs can be seen at the bottom of the breadboard.

Design:

While designing the stent crimping machine, there are various features that need to be implemented in order to create a fully functional design. The most important part of the device for functionality is the ability to control a motor that will be attached to the iris crimping mechanism in order to contract and expand the mechanism. In order to control the motor, there will be four user inputs, a button to increase the radial force, a button to decrease the radial force, a button to increase the diameter, and a button to decrease the diameter. If either of the increase buttons are pressed, the motor should turn clockwise and if either of the decrease buttons are pressed, the motor should turn counterclockwise. Another feature of the device is that it should be able to read data values from an ultrasonic length and radial force sensors. The final important component is a GUI that will be handled by a touchscreen display. The aforementioned inputs will also be handled by this touchscreen. In order to fulfill all of these requirements, an Arduino Mega microcontroller board will be used to form connections to all of the aforementioned parts.

Figure 5: Level 0 System Architecture

Figure 5 shows the level 0 system architecture, which gives a very simplified overview of what will be implemented in the project. In the figure, the thicker black arrows denote the flow of data between the different components while the thinner gray line shows the flow of power. The general connections that will have to be made in order for the device to run can be seen in this figure. Since this system architecture was designed, the overall design of the project has been changed to utilize a touchscreen display that will act as both the user inputs as well as the graphical user interface. This figure shows how the motor, the sensors, the inputs and outputs are all connected to the microcontroller board, which will stay true for all future designs. A more indepth level 1 system architecture can be seen in figure 6 on the following page.

Figure 6 follows a lot of the general ideas from figure 5 while elaborating on the design significantly as well as including small design tweaks in order to be more representative of the current design. The main feature added was the touchscreen display which will handle both the user inputs and the GUI. Another feature added in this system architecture is the emergency stop button, which will be implemented on the hardware level, therefore it can not be activated by the touchscreen, an additional push button will need to be added. The various different ways that the user inputs will be implemented can be seen by looking at the figure. In this figure, the red lines connecting the various components show the flow of power through the device, while the arrows indicate data and in which direction it is flowing. In this figure, the implementations of sensors were neglected due to a user error and the original file has been lost, so it could not be edited for use in this document.

Figure 6: Level 1 System Architecture

Now that the general design elements have been discussed, it is time to go more in depth on the individual elements that will be in the project. The project can be divided into two separate parts, the hardware and the software. First this document will describe the hardware that will be used and how it is planned to be used in the project. Following this, the software that is currently being used will be discussed as well as the planned changes for the code.

Hardware:

The stent crimping machine's hardware will consist of an Arduino microcontroller, a stepper motor with very fine control, the sensors, the touchscreen display and a pushbutton. The stepper motor will be connected to a stepper motor driver board. This board will be attached to the Arduino board's digital input pins 8, 10, 9, 11. The driver board will also be fed a 5V power connection and a ground in order to achieve full functionality. The stepper motor will be attached to a gear that will connect with the mechanical engineering team's iris crusher in order to adjust the diameter of the stent. The emergency stop button on the device will be a pushbutton that when pressed, connects the reset pin on the Arduino board low in order to reset the board and stop operations. The radial force sensor that is currently planned for use will be a digital sensor that requires the hx711 chip to work. The hx711 chip will be connected to two of the digital input pins on the Arduino board and will need to be fed a 5V connection as well as ground.The ultrasonic length sensor, that will be used to find diameter of the stent, that is currently planned for use is an analog sensor that requires 2 analog input pins on the arduino board and a 5V power connection and ground. The device will also be able to accept power directly from a wall socket using a 9V power supply.

Figure 7: Level 2 System Architecture

In figure 7, all of the hardware connections discussed in the previous paragraph can be seen. In this figure, the red lines connecting components show the transfer of 5V power, while the orange line shows the transfer of 9V power from the wall. The exact implementation of the touchscreen display has not been researched yet, as it was a recent change in the project requirements.

Software:

The software for the project is all written in the Arduino programming language within the Arduino IDE. The software of this project will play an important role in the success of the project since the center part of the project is a microcontroller board.

Figure 8: Flow chart of the code of the system

The processes that the code will need to follow, start with the initialization of required libraries and constants for the project. Then the stepper motor should be initialized to the aforementioned pins 8, 10, 9, and 11. The sensor pins will then be initialized as well as variables to store values of radial force and diameter. State variables for the various inputs should be defined to allow for easy detection of when an input has been pressed. Following this the setup function begins where the speed of the stepper motor will be set. Following this, the arduino starts its loop. The loop begins by detecting the radial force exerted on the stent and the diameter of the stent by reading the sensor's measured values and these values are stored in corresponding variables. Following this, the radial force and diameter will be printed on the GUI. After this, there is an if statement to determine if a user input button is pressed. If the diameter or radial force up button is pressed the code will enter a while loop to check if the button is pressed, the motor will spin clockwise, and the button will be tested to see if it is still pressed. Similar actions occur if the diameter or radial force down button is pressed with the key difference of the motor will turn counter clockwise. This process that was just described can be seen as a flowchart in figure 8. The current software being used can be seen in Appendix B.

Plan moving forward:

As the first semester of the capstone project is nearing its end, the Heart Bytes team is starting to make plans for progress over the summer break. Before the end of this semester, the Heart Bytes team and the mechanical engineering team are planning to meet in order to test the compatibility of the different stent crimping machine's parts. If all parts are compatible, the teams will combine parts in order to create a functional prototype of the machine. Although not all features are implemented at the current time, creating a working model will allow the team to determine the best way to integrate the sensors into the current design and to fine tune the motor controls. Integrating the sensor into the design has been difficult for the team to conceptualize, so once a full model of the device has been created, the team can test what locations for the sensors make the most sense. With the motor attached to the crimping mechanism, the team can test how many steps the motor will need to activate in order to contract the iris and determine what the optimal turning speed of the motor is.

Following the creation of the first iteration of the stent crimping machine, the mechanical engineering team and the Heart Bytes team should start discussing the enclosure for the stent crimping machine. The shape, dimensions, and material of the casing will all determine how aspects of the project will be designed, so determining thes as soon as possible will allow the team to make more final decisions about how to develop the machine. The process to determine the casing will be a collaborative effort between both of the teams assigned to this project, so no timeline for the completion of the casing can be provided at the moment.

The next plan the Heart Bytes team has currently, is to research how to use a touchscreen display on an Arduino board. The touchscreen will be used as both the GUI and the user inputs for the machine, so research will have to be done on both how to print to this display as well as take inputs from the display. The team is planning on spending a significant amount of time over the summer in order to properly learn how to implement the touchscreen display. Prototypes of the touchscreen display will be made over summer break and designs for a stent crimping machine utilizing the touchscreen is planned for late summer or early fall of 2022. In addition, the team also plans to test how the GUI will display sensor read values from the force sensor and the radial sensor during the summer. We also plan to improve the programming that used to read values from the force sensor and the radial sensor, so that these readings will be displayed in the GUI in the best possible manner. Furthermore, we also plan to improve the functionality of the stepper motor by improving the arduino control code that controls the motor during summer. The team plans to add a stop button to the design over the summer so that the stepper motor can be stopped at a required position.

Figure 9: Gantt chart up until fall semester

A Gantt chart of the team's planned progress over the next few months can be seen in figure 7. The team will work with the prototype that is created with the mechanical engineering team until the middle of June. During this time, the team plans to create the prototype. Then the team will attempt to integrate the sensors into the design of the machine. Following this the team will spend a bunch of time testing how many steps the stepper motor will need to turn in order to make a functional machine. Finally the team will thoroughly test all of the implemented features to ensure that the device is fully operational.

After working on the prototype, the team will turn its attention towards touchscreen displays. The team will spend the remainder of June researching these displays and how to put them on an Arduino board. Following this, the next two weeks will be spent attaching a touchscreen display onto the Arduino board and learning how to properly code for it. After this, the rest of the summer will be spent adding a touchscreen to the team's current design for the stent crimping machine.

Conclusion:

As the first semester of the capstone project comes to an end, the Heart Bytes team has made significant progress in the development of the stent crimping machine. Through the prototyping process, a complete design for the machine is starting to take shape. The Arduino board, the sensors, and the motors were all thoroughly tested, which allowed the team to draft up a more final design for the project. Currently, the basic electrical components have been chosen and have been implemented into the design as well as significant parts of the software has already been coded. Since significant parts of the design have already been implemented the risk of significant parts of the project have decreased.

The general design of the project has been planned and has been laid out in this document. The team will expand upon the design until the final machine has been produced. Currently, the main change that will be implemented in our design will be the addition of a touchscreen display, which the team has not researched enough yet to add into the design at the moment. The other major change that may change the design of the project is once the team has a functional prototype with the mechanical engineering team because the team may have to alter design decisions in order to make the device work as intended. Moving into the second semester of this capstone project, the team will have a lot of work ahead of them, but with all of the progress made thus far, it should be a reasonable challenge.

Appendices:

Appendix A: Bibliography

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Appendix B: Code used

// Setup for stepper motor

#include <Stepper.h>

#define STEPS 512

Stepper stepper(STEPS, 8, 10, 9, 11);

// Define button pins

const int radForceUp = 23 ;

const int radForceDown = 25;

const int diameterUp = 27 ;

const int diameterDown = 29;

// Define sensor pins

const int radForceSensor = A0;

const int diameterSensor = A1;

// Initialize variables

int radForce $= 0$;

int diameter $= 0$;

// Initialize state variables

int RFUState $= 0$;

int RFDState $= 0$;

int DUState $= 0$;

int DDState $= 0$;

void setup() { Serial.begin(9600);

// Set default speed of motor stepper.setSpeed(50);

// Set up input pins pinMode(radForceUp, INPUT); pinMode(radForceDown, INPUT); pinMode(diameterUp, INPUT); pinMode(diameterDown, INPUT); } void loop() { // put your main code here, to run repeatedly: // Detect inputs and store current states $RFUState = digitalRead(radForceUp);$ RFDState = digitalRead(radForceDown); DUState = digitalRead(diameterUp); DDState = digitalRead(diameterDown); // Sensor Block radForce = analogRead(radForceSensor); diameter = analogRead(diameterSensor); Serial.print("Radial Force = "); Serial.println(radForce); Serial.print("Diameter = "); Serial.println(diameter); // Slow down serial monitor for testing reasons // delay(1000); // Motor Block

```
if (RFUState == 1||RFDState == 1||DUState == 1||DDState == 1) {
// Detect if radial force up button has been pressed
while (RFUState == HIGH) {
//Serial.println("RFU");
stepper.step(STEPS);
RFUState = digitalRead(radForceUp);
//delay(1000);
}
// Detect if radial force down button has been pressed
while (RFDState = HIGH){
//Serial.println("RFd");
stepper.step(-STEPS);
RFDState = digitalRead(radForceDown);
//delay(1000);
}
// Detect if diameter up button has been pressed
while (DUState == HIGH){
//Serial.println("dU");
stepper.step(STEPS);
DUState = digitalRead(diameterUp);
//delay(1000);
```
}

// Detect if diameter down button has been pressed

```
while (DDState = HIGH)
```
{

```
//Serial.println("dd");
```

```
stepper.step(-STEPS);
```

```
DDState = digitalRead(diameterDown);
```
//delay(1000);

} }

}