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A Robotic Platform for At-Home Ultrasound Diagnostic Imaging

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Abstract

The field of telemedicine has grown significantly in the last several years and the ongoing COVID-19 pandemic has specifically highlighted the need for a variety of telemedical diagnostic tools. This project developed an at-home ultrasound diagnostic imaging system in the form of a 6-degree of freedom teleoperated robot designed around existing third-party portable ultrasound probes. Via the robot, the probe can be controlled remotely by a sonographer using a mobile website. Our design focuses on safety, portability, and ease of use. We have built a prototype and demonstrated the safety and efficacy of the proposed tele-ultrasound system.

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Table of Contents

Table of Figures

Table of Tables

1. Introduction

1.1 Clinical Significance

Sonography or ultrasound imaging is one of the most used diagnostic imaging techniques. This is because of its high accuracy and wide range of diagnostic uses. However, ultrasounds are also considered highly operator dependent. Due to the need for precise probe positioning, those administering ultrasound exams must be highly trained in sonography and anatomy. Since diagnostic imaging requires trained experts in the field in order to perform an exam, ultrasound imaging is only widely available to those living in areas where there are qualified professionals. This means that those living in remote or in-need communities where there are fewer hospitals and sonographers have limited access to ultrasound technology. In this section, we will discuss how this lack of availability to sonographic imaging combined with the rise of remote medicine leads to a clinical need for a robotic platform for at-home ultrasound diagnostic imaging. We also explore the effects of the COVID-19 pandemic on this clinical need as well as research into previous attempts at tele-ultrasound devices.

1.1.1 Remote Medicine

With the rapid development of technology over the past few decades, people all across the world are now able to connect with one another at almost any given time. This technology boom has also impacted the medical community, with vast advancements in the capabilities of hospitals and doctors. This is especially prevalent in the rise of remote medicine. This type of medicine allows doctors to connect with their patients while being physically distant from them. Remote medicine has a variety of applications including being able to expand the benefits of modern medicine to desolate locations. This can allow doctors to deliver higher quality care to more patients regardless of where they live. Also, with less people needed to use a hospital's facilities, the hospitals can save costs on maintenance and prevent wear on machines due to constant use. This can bring down medical costs for the patient as well.

This relatively new version of medicine has started to become widely used in the area of ultrasounds. Ultrasound exams, which typically are performed within a clinical setting, have a unique capability to adapt to the remote aspect through the rise of portable devices. In 2013, medical device company, Siemens, came out with a fully wireless ultrasound transducer. Therefore, with the reach of ultrasound probes ranging further than before and with no need for the wires to be plugged into monitors, researchers have been able to attempt to bring these devices fully remote. However, while the devices do not require patients and doctors to be in the same physical location, a major disadvantage to current research into tele-ultrasound devices is that there still is a requirement for a trained sonographer to administer the exam and maneuver the device with respect to the patient. While this allows more freedom for ultrasounds to be performed, it prevents them from becoming fully remote.

1.1.2 The Effect of COVID-19 on Medical Imaging

This increase in the need of remote medicine in order to expand medical treatments to desolate locations is coupled with the emergence of the COVID-19 virus in 2019. With the airborne virus quickly expanding to become a global pandemic that has lasted well into 2021, the medical community has experienced a strain on its ability to provide routine examinations. This is because hospitals are having to dedicate an overwhelming amount of resources towards pandemic efforts which leaves less resources for non-emergency exams.

This can be seen especially in the areas of neonatal medical imaging. Ultrasound exams are a critical part of monitoring a pregnancy. The World Health Organization recommends at least one ultrasound performed before 24 weeks of gestation in order to detect any “fetal anomalies and multiple pregnancies.” However, ultrasounds at various points in a pregnancy can be used for determining important information about a pregnancy. At 7 weeks gestation, an ultrasound can be used to confirm pregnancy, determine a due date and see whether the pregnancy is molar or ectopic. From 13-14 weeks, an ultrasound can determine the possibility of Down Syndrome. At 18-20 weeks, an ultrasound is able to detect even more anomalies within a pregnancy. At 34 weeks, the approximate size and placental position can be determined through ultrasounds (Vora, 2017).

However, The Center for Disease Control labels pregnancy as an increased risk for COVID-19 and therefore are encouraged to stay home and away from places with increased risk for COVID infections such as a hospital (COVID-19, 2020). Meredith Rochon, MD and Chief of Maternal Fetal Medicine at Lehigh Valley Health Network, says “Remember, the safest thing you can do for you and your baby is stay at home,” (Rochon, 2020). With this advice being encouraged upon not only people who are pregnant but also upon anyone with a condition that qualifies them as high risk for COVID-19, the amount of ultrasound exams being performed in hospitals dropped significantly during the pandemic.

Within Massachusetts specifically, the following diagram outlines the daily imaging volume by modality type at Mass General main hospital along with key COVID-19 timeline milestones (Lang, 2020).

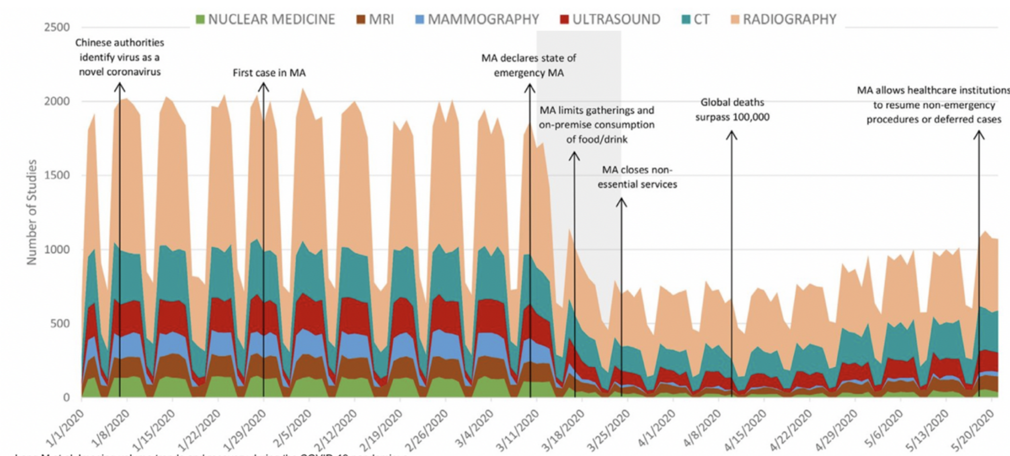


Figure 1: Medical Imaging at Mass General main hospital during COVID-19

The diagram highlights a dramatic decrease in the amount of imaging, including ultrasounds, that were performed. This is partially due to the restrictions on non-essential hospital visits Massachusetts had put in place but even after loosening the restrictions, the quantity of images performed has not returned to its pre-pandemic numbers. However, the need for ultrasound along with other medical imaging services has not lowered. This could have a negative impact on the overall health of the community as pregnancy anomalies and other diagnoses made with ultrasounds can go undetected.

With conflicting government and CDC advice to stay home and away from hospitals there exists a need to create a way to complete medically necessary ultrasound exams without having to leave home. This need provided the context for this project of creating an at-home tele-ultrasound device. This would remove the need for the trained medical professional to be with the patient and allow patients to complete exams with only a tele-robotic device.

1.2 Research into Tele-Ultrasound Devices

Throughout the past couple of decades, there have been previous research and attempts into designing a tele-ultrasound device. Based out of France, the PRISME Lab focused its efforts on compact, standalone tele-ultrasound devices. This lab created three different prototypes for a device that accomplishes this goal called OTELO, ESTELE, and PROSIT. However, the size and weight of these devices made them unsuitable for use as at-home tele-ultrasound devices. The issues with these devices largely surrounded the balance between weight and degrees of freedom. Iterations of each device went back and forth between compromising flexibility and the size and weight of the overall device. This meant that the devices within the PRISME Lab such as OTELO, ESTELE, and PROSIT, never made it past the research domain and into the market as an self-administering at-home ultrasound device. In addition to the research into standalone devices, other research has explored the option of attaching an existing robotic arm to an ultrasound probe to combat the weight to degrees of freedom ratio. However, this solution is often large in size and therefore is not transportable or applicable to at-home exams.

1.3 Design Objectives

Based on the clinical significance as well as the previous attempts for a tele-ultrasound device this project developed four main objectives: portability, ease of use, tele-operation and safety. For portability, the device must be lightweight and small enough for an average person to hold it with minimal effort involved. It also must be comfortable to sit on a person's body without causing the patient any harm. Thus, there exists a need for a lightweight device. In order to achieve the remote medicine need, the device must also be able to be shipped to the patient from the hospital. This puts another constraint on the size of the device.

Regarding ease of use, the goal for the tele-ultrasound device is that it can be operated by patients with no prior experience or knowledge of anatomy. This device aims to remove the need for the second trained medical professional to administer and guide the device as seen in the previous designs. This will require the device to have more degrees of freedom so the device can be robotically adjusted to the correct orientation for the given exam without the patient having to move it manually. This way the patient will not need to have any training on administering ultrasound or have an expansive knowledge of anatomy.

The third objective of the project is tele-operation. As mentioned previously, the device would be able to be controlled by a sonographer in a remote location. In order for the device to work, this would involve a level of manual gross movement control by the patient to place the device in the correct general position on the body. The device should have six degrees of freedom (full maneuverability) within this general area so that the sonographer can accurately place the probe using fully robotic fine movement control.

Finally, the device must be designed with safety in mind. As this device will be operated in a patient's own home rather than a controlled environment such as a clinic or a hospital, the device must be safe to use. The device should be fully enclosed and there should be no area where a patient or user could be caught or pinched by the motion of the mechanism. The safety factor must also take into account a patient's comfort levels. Specifically, the device needs to allow the patient a level of control for their comfort using the device. The device should not be tied down to the patient in any way. The force that is exerted on the body should be limited by the weight of the device and the patient should be able to remove the device easily at any time. This way the device will not exert too much force on one's body and cause harm.

2. Background

While there is a notable current need for this type of device due to the COVID-19 pandemic and a significant rise in telemedicine, this is in no way the first venture into tele-ultrasound. One of the first tele-ultrasound projects was the SYRTECH handheld telerobotic ultrasound system developed in 1998. This device spawned a series of mechanically-similar devices over the subsequent fifteen years. In addition to this line of smaller tele-ultrasound devices, many projects have investigated using existing robotic systems such as large robotic arms for tele-ultrasound applications. Finally, a series of commercial non-robotic ultrasound probes have been developed for at-home use, particularly aimed at the neonatal or "baby monitoring" market. Here, we will review the history of these devices and the mechanisms that drive them in an effort to identify possible areas of focus and innovation.

2.1 SYRTECH and PRISME Lab

The SYRTECH tele-ultrasound device was developed in 1999 at the University of Orleans in France. Motivated by the scarcity and concentration of trained sonographers as compared to the distribution of need for diagnostic ultrasound imaging, researchers created a system for the movement of an ultrasound probe using three degrees of freedom that could be controlled by a remote sonographer. The mechanism is pictured below in Figure 2 (Veieyres, 2003).

Figure 2: SYRTECH Design

The SYRTECH mechanism formed the basis for another fifteen years of tele-ultrasound research at the University of Orleans. From 2000-2003, they developed the TERESA system, which was based on a streamlined version of the SYRTECH mechanism with an additional degree of freedom allowing the probe to press into the body surface. The focus of the TERESA project was to develop the SYRTECH mechanism for space and exploration purposes. Pictured in Figure 3, it resembles a more user-friendly SYRTECH device (Vieyres, 2003).

Figure 3: TERESA Design

Following the TERESA project, the University of Orleans joined a larger coalition of research universities in France to create a multidisciplinary research institute called PRISME, which stands for Multidisciplinary Research Laboratory in Systems Engineering, Mechanics, and Energetics. This coalition would go on to iterate on the original SYRTECH/TERESA mechanism, creating a series of prototype tele-ultrasound devices for clinical use.

2.1.1 OTELO

The OTELO design was the one of the first iterations on the SYRTECH mechanism developed by PRISME. Their goal was to come up with a design that would be able to be used by an untrained professional. The two prototypes of the device that they designed, as seen in Figures 4 and 5, had 6 degrees of freedom and were small enough in size to be portable (Delgorge, 2014).

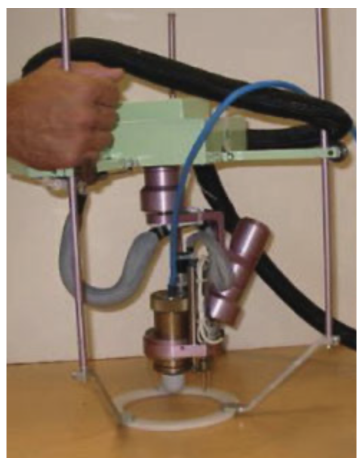


Figure 4: OTELO 1

Figure 5: OTELO 2

However for both OTELO 1 and OTELO 2, they were only able to get the weight down to 6kg which was still too heavy to be comfortable to place on a human being with their contact surface design. The idea at the time was to create a device that would first prove the concept of the portable tele-medicine device and then expand on it and develop it with the next iteration of designs. The first iteration of the OTELO device consisted of an expert station, a patient station and a communication link for the two systems. The expert station consisted of a live feed of the ultrasound on a control monitor and the sonographer could change the position and rotation of the probe as well as record what was being monitored. The patient station consisted of a robotic probe holder, video conference link and the probe itself. However, the OTELO project was unable to solve the issue of the device being too heavy to comfortably perform an exam. As a result, the project never made the transition from the research lab to market.

2.1.2 ESTELE

Following the OTELO Project came ESTELE, which was an acronym for Expert System for Tele-Echography. It shared the base goals of the OTELO project. However, ESTELE was designed with only four degrees of freedom, much like the TERESA and SYRTECH devices. The device being used on a patient can be seen in Figure 6 (P. Arbeille, 2008).

Figure 6: ESTELE

This project utilized a dummy probe to control the movements of ESTELE. This can be seen in Figure 7 (P. Arbeille, 2008).

Figure 7: Expert Using Dummy Probe for ESTELE

When testing the effectiveness of ESTELE compared to a conventional sonogram, they found that ESTELE could perform 80% of the imaging tasks that a conventional in-person ultrasound exam could. While this device allows patients in more remote locations the ability to get expert sonograms, the ESTELE device still required the use of a trained medical professional to be in the same physical location as the patient in order for the exam to be performed. This meant that the device was not suitable for at-home applications. ESTELE made significant advancements for a compact tele-ultrasound device, however its inability to transfer to an at-home setting limited its use past the research domain.

2.1.3 Optimization and the PROSIT project

The PROSIT mechanisms were designed by the PRISME lab as a result of a kinematic optimization process on the general design of the ESTELE mechanism. The goal of this optimization was to increase the maneuverability of the probe while decreasing the size of the overall mechanism and reducing the impact of singularities on probe movement.

Researchers at the PRISME lab used standard kinematic optimization techniques to improve the maneuverability of the spherical wrist design used in TERESA, OTELO, and ESTELE. This resulted in a mechanism that was easier to control and produced smoother movements. In addition to these improvements, the optimization reduced the impact of control singularities on the probe. Figure 8, below, shows the manipulability of each device (L. Nouaille, 2012).

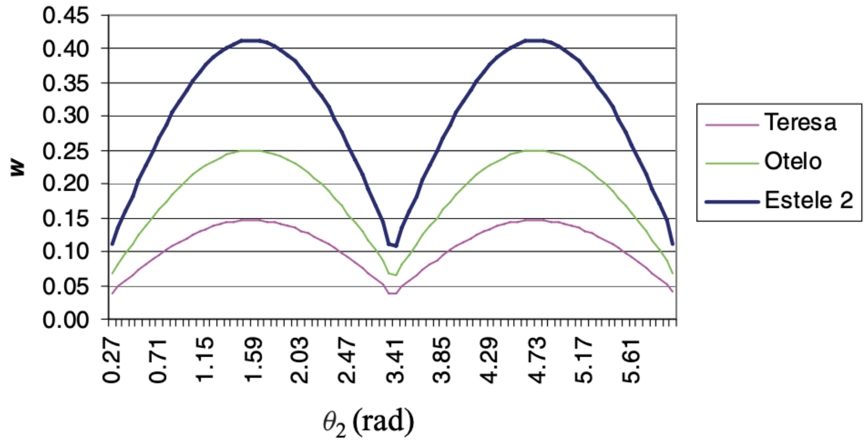


Figure 8: Manipulability Index for PRISME Lab Devices

The higher the manipulability index (w), the easier the robot is to control. The three lowest points in this graph represent positions around which the robot's movement is jerky and fast. As shown in this graph, the OTELO project resulted in a slight increase in manipulability over the original TERESA project. The ESTELE 1 robot shared the same kinematic structure as OTELO. ESTELE 2 had the newer, optimized kinematic structure, resulting in better control.

However, the improved manipulability of ESTELE 2 came at a price: size. Its improved metrics were achieved by angling the base anchor point 45° off center. In fact, the PRISME researchers determined that the overall optimal solution for the system would have the base anchor point at a 90° angle which would nonsensically require links to pass through the patient's body.

The 45° angle of ESTELE 2 reduced the impact of the central singularity but required a much larger frame to accommodate it. This increase in size, from ESTELE 1's 420mm to ESTELE 2's 520m, made it cumbersome to work with. The proposed ESTELE 2 CAD model can be seen in the Figure below (L. Nouaille, 2012).

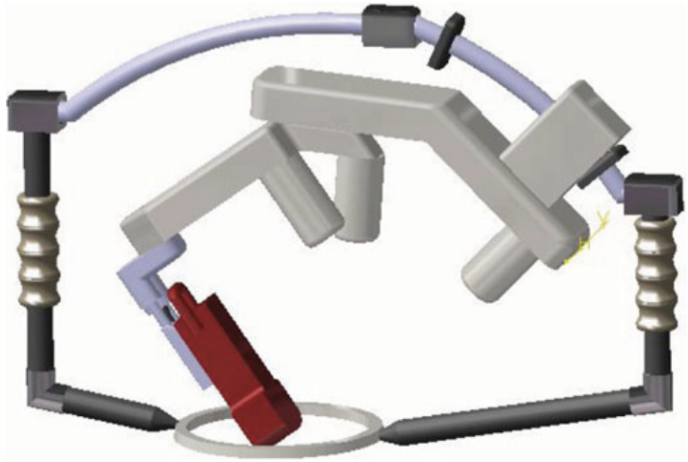


Figure 9: ESTELE 2 CAD Model

The researchers then introduced a compactness measure to their optimization, resulting in the PROSIT 1 model. This model was 420mm (the same as ESTELE 1) and shared many of the same kinematic characteristics with ESTELE 1. However, it included a 10° angle of the base anchor point. This improved the overall manipulability of the mechanism without sacrificing compactness. Even with kinematic optimizations and the resulting control improvements, this system was still limited to four degrees of freedom and required a medical professional to administer the exam in person.

2.2 Melody System

This new PROSIT design and prototypes garnered the interest of the company Advanced Echo Technologies (Ad Echo Tech). The PRISME lab licensed the PROSIT design to Ad Echo Tech, who developed it into their commercially available Melody Telerobotic Ultrasound Solution. The Melody system allows for trained sonographers to perform ultrasounds on a patient remotely through the use of a robotic arm and a “dummy probe”. The trained professional is able to control the movement of the actual probe by moving the “dummy probe” and watching a real time screen displaying the images captured. On the patient side, an ultrasound probe is mounted on a robotic arm that is safely maneuvered by a healthcare professional into place. The probe then mimics the movement of the dummy probe in order to perform the examination. The following images highlight the Melody system from the patient perspective as well as the sonographer’s side (MELODY, 2016).

Figure 10: Melody System on Patient

Figure 11: Melody System Sonographer View

The Melody system sought to create a solution to the balance of size and degrees of freedom that PROSIT and the previous devices mentioned by the addition of the robotic arm support attachment. This would allow for some of the weight and pressure to be taken off the patient and transferred to the arm. The base model of the Melody system without the robotic arm, seen below, resembles the mechanisms utilized in the PROSIT device (MELODY, 2016).

Figure 12: Melody System without Robotic Arm

With the size and anchoring system needed for the robotic arm, the Melody System is largely reserved for clinical applications as the device is not easily portable. This means that patients would still need to travel into the clinic or hospital setting for an exam. It also requires at least two medical professionals in order to complete the ultrasound exam: the sonographer as well as the trained medical staff needed to operate the robotic arm and put the device in place. This removes the ability for the exam to be self administered by the patient. Therefore, while the Melody system is commercially available, there still exists a need for a portable tele-ultrasound device that can be operated (on the patient side) by non-medical and untrained users.

2.3 Tele-Ultrasound using Existing Robotic Systems

While the line of devices from the PRISME lab were our focus due to their (intended) handheld nature, there have been many other completely different avenues of exploration for tele-robotic ultrasound systems. A common solution for research projects aiming to prove the utility of tele-robotic ultrasound is to attach an ultrasound probe to the end of a commercially available robotic arm. This solution is fast and effective but results in a device that is not portable or user-friendly and is often very overpowered. Projects like this that get through to the commercialization phase end up as clinical tele-robotic ultrasound systems that require a large amount of training and expertise to operate. A representative example of this type of device is the MGIUS-R3 developed by MGI Tech, pictured in Figure 13 (MGIUS-R3, 2019).

Figure 13: MGIUS-R3 System

The MGIUS-R3 is a telerobotic ultrasound system for clinical settings. It consists of a wheeled base station with an integrated ultrasound system and robotic arm. The 5-DOF arm is a customized Universal Robots UR5 collaborative robotic arm. The operation of the system is similar to that of the Melody system in that it requires a trained medical professional to perform the exam with the patient while a remote sonographer controls the motion of the probe. This device is very effective for its intended use and has even been used to perform cardiopulmonary assessments of COVID-19 patients with satisfactory results (Shengzheng, 2020).

The MGIUS-R3 is one of a collection of tele-ultrasound systems that use adapted, commercially-available robotic arms to control ultrasound probes. These systems are effective for clinical settings but lack the portability and ease of use required for at-home ultrasound diagnostic imaging.

2.4 At-home Tele-Ultrasound Devices

While at-home ultrasound diagnostic imaging is still an unserved market, there are simple at-home ultrasound probes available for consumers. These devices mostly focus on fetal monitoring and are not aimed at diagnostic imaging. The Baby-Watcher, Baby-Scan, and PulseNmore are the three leading affordable fetal monitoring devices. The Baby-Watcher is a handheld device which uses a USB cord to connect to a specifically provided laptop (Make, 2021). The Baby-Scan is a handheld ultrasound device which is able to pair to your smartphone via WIFI. The app stores a timeline of each time you use the device; thus, the user can watch how the baby grows and helps to share it on social media (World's, 2021). Finally, the PulseNmore is a handheld ultrasound device which docks on any android USB-C smartphone. The device displays the ultrasound image on the docked smartphone. The data is also transferred to a physician who can help in real time to assure the scan went well or if further steps should be taken (Visionary, 2021).

However, all of the devices are not replacements to going to the hospital for ultrasound exams as they do not provide the ability for diagnostic imaging. With the need for accurate and precise positioning and measurements in order to diagnose fetal health, a simple image is not enough for diagnostic purposes. Any at-home ultrasound device intended for diagnostic purposes must also contain the ability for precise positioning of the probe in order to record the correct views and small measurements that are needed to make real medical decisions. Thus, no device currently on the market achieves the goal of being a fully functional at-home tele-ultrasound device for diagnostic imaging.

3. Design

Based on our research into the history of tele-ultrasound devices, we began the brainstorming and ideation process for our own device. The following chapter discusses the specification of the design requirements for the at-home tele ultrasound device and an overview of the final prototype. This chapter also discusses in detail each mechanical module of the prototype as well as the design process of how each part came together to work in the overall design.

3.1 Design Requirements

In order to set numerical parameters on the device, the team conducted an interview with two highly trained sonographers. We consulted with Professors Jeffrey Hill and Debra Crandell of Massachusetts College of Pharmacy and Health Sciences (MCPHS) to determine the maximum angle needed for the rotation of a probe during an ultrasound exam as well as the estimated travel distance needed in each direction. In their expert opinions, the full cone angle range was 40°-60°. This means that mechanisms within the device that allowed for the probe to rotate must be able to tilt 20°-30° in each direction. The sonographers also mentioned how translational movement was less important than the rotational movement. Even with the patient having no knowledge of anatomy, Professors Hill and Crandell estimated that for translation, one to three inches would be enough. In terms of pressure, Professors Hill and Crandell emphasized how different ultrasound exams require different levels of pressure with neonatal imaging being on the lighter side while a gallbladder exam would require more pressure. They estimated that 1-2 inches of movement along the z-axis would be ideal for actuating pressure. They also highlighted the variety amongst ultrasound probes in terms of shape and size. Therefore, another design requirement for this device was to have the ultrasound probe clamp be easily exchangeable as well as accommodating multiple different types of probes. Following their advice, we created Table 1 (below), listing the specific design requirements for this project.

Table 1: Design Measurement Requirements

Category	Requirement
Translational Movement	1-3 in.
Angle of Rotation	20°-30°
Z Direction Movement	1-2 in.
Overall Size	Max: 14 in. Cube

These numerical requirements were used in addition to the design objectives of portability, ease of use, tele-operation, and safety to shape the final design of the device.

3.2 Design Overview

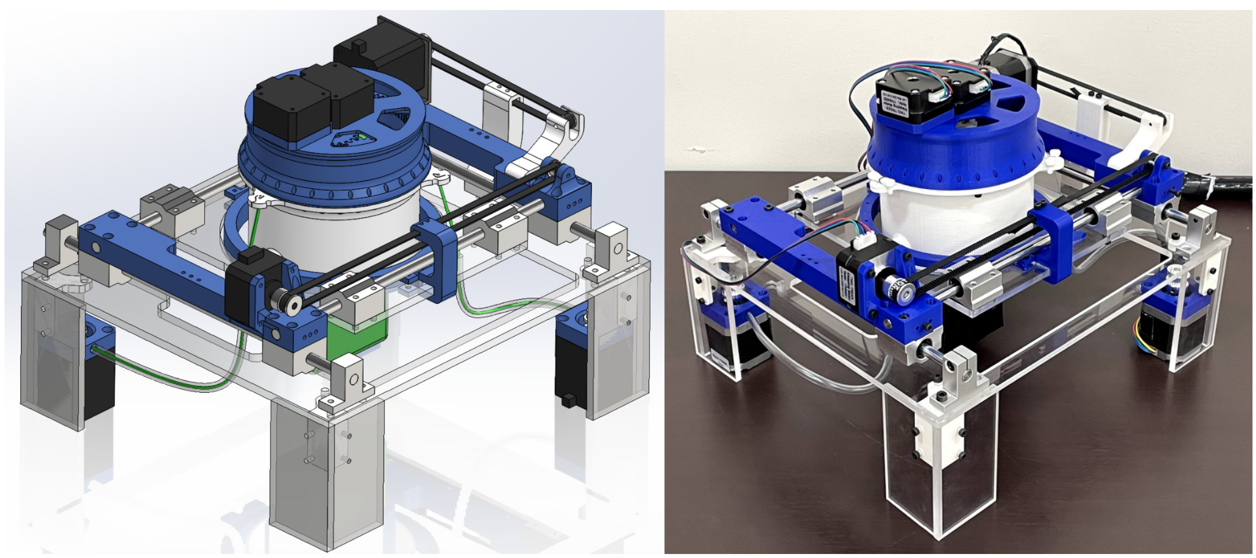


Figure 14: Final Design CAD and Real Life

Our final design is a 6-DOF benchtop prototype manipulator built around a Clarius C3 wireless probe. Pictured above in Figure 14 is the final Solidworks CAD assembly of the design alongside the physical prototype. Further images of the device can be seen in Appendices A and B. Driven through a set of seven stepper motors and built from a combination of laser cut acrylic, 3D printed PLA plastic parts, and commercially available hardware, it meets or exceeds the design requirements laid out by our clinical consultants. Its overall design specifications are listed below in Table 2.

Table 2: Design Specifications

Category	Requirement	Measurement
Translational Movement	1-3 in.	2.3 in.
Angle of Rotation	20°-30°	23°
Z Direction Movement	1-2 in.	3.1 in.
Overall Size	Max: 14 in. Cube	12 x 13 x 12 in.

The prototype serves as a proof of concept for our mechanism's compact nature, full 6-DOF maneuverability, and consistent control over probe location and orientation. The device includes an onboard Raspberry Pi B+ V1.2 to run its seven motors and connect to the internet. It requires only a connection to a wall outlet for power and is teleoperated over the web via a smartphone web application.

As a benchtop prototype, this device provides a proof of concept that our design objectives of portability, ease of use, teleoperation, and safety can be met. With regards to **portability**, the mechanism and support structure is handheld and small enough to be easily shipped. As a 6-DOF manipulator, it places very little onus on the patient to maneuver the probe, giving fine robotic control to the sonographer and making the device **easy to use** for patients. We have prototyped a **teleoperation** solution via a mobile web application that proves the remote capabilities of the device. Finally, the device can be fully enclosed with no exposed moving parts except for the probe and is light enough to easily be lifted from the patient's body if needed, making it **safe** to use. However, for each of these objectives to be fully met, future work needs to be done to enclose all motors, wiring, and control circuitry as well as reduce the weight of the device through more customized material selection.

In the following sections, we will go over the design of the device and its control systems. While prototyping this device, we split up the mechanical design into "modules" that each control two degrees of freedom. This module based design allowed for concurrent development of various components of the device. It also provided a way to improve upon mechanisms without redesigning the entire device. In Figure 15 below, each of the three mechanical modules can be seen color coded along with labeled degrees of freedom.

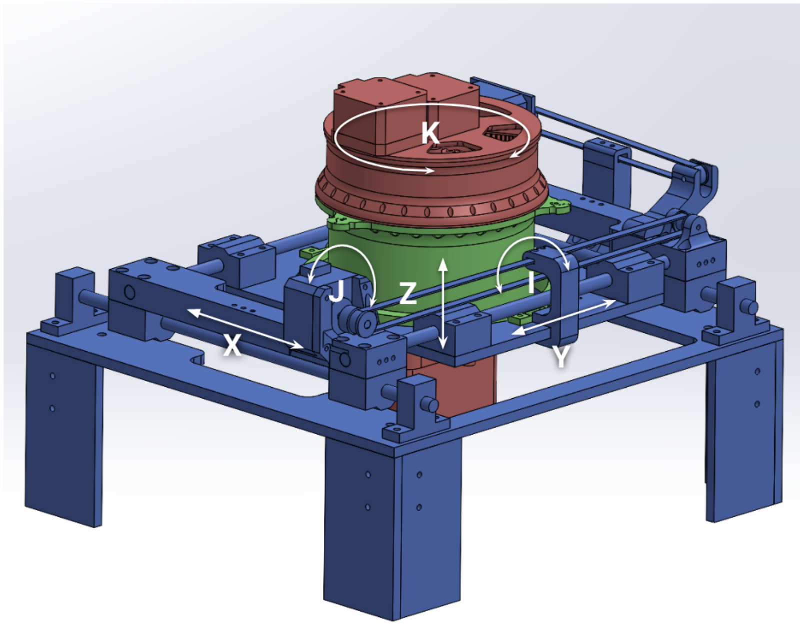


Figure 15: Module Based Design

The XY Module, in blue, provides the device's translation of the probe across the contact surface on the patient's body. The IJ Module, in green, allows the device to tilt with respect to the body contact surface. Finally, the KZ Module, in red, controls the rotation of the probe as well as the pressing of the probe onto the body contact surface.

3.3 XY Module

3.3.1 Ideation of XY Module

The XY Module was the first mechanism we developed. This is because this motion required the largest distance and therefore would set parameters on the size and shape of our device. We came up with two main ideas for this module's design, which can be seen in Figure 16 below.

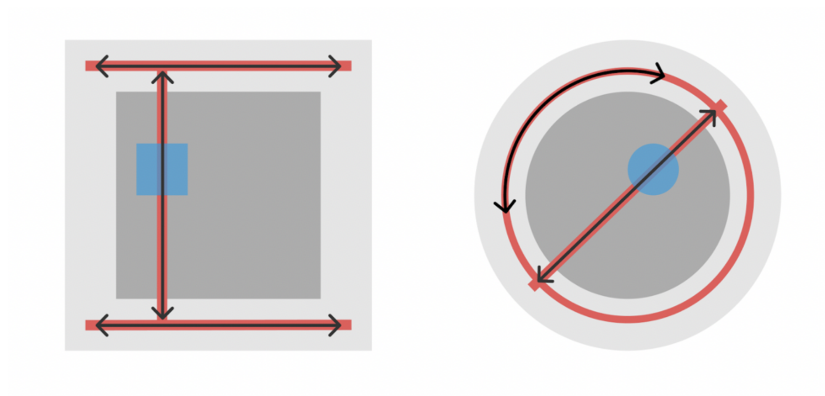


Figure 16: Design Comparison for XY Table

The rectangular system on the left, was based on a classic Cartesian XY mechanism. This option was simplistic however had enough proven applications to prove it would work for our design requirements. However, we wanted to fully explore alternatives to the commonly used coordinate system so in an attempt to reduce the overall size of the device as well as reduce any sharp corners which could impact the safety of the device, we explored changing the XY system to circular coordinates. This would allow us to have roughly the same range of motion for the probe. However, we discovered that because of the circular nature of the second system, there was a control singularity at the center. This creates an inability to accurately control the position of the probe. We also determined that the amount of weight and space saved by the circular system was insignificant as a large amount of the space on both options was open. Therefore, this ideation process led us back to the linear XY system.

This system was largely based off of a 3D printer's linear rail system. This was because of the readily available parts for the linear system, which would streamline the manufacturing process and reduce the amount of parts we would have to custom make. Also, this system is proven to be effective through its extensive use in 3D printers. 3D printers require a precise level of control, similarly to an ultrasound exam, in which small, accurate movements are needed in order to diagnose patients. This system also does not suffer from the singularity at the center of the circular coordinate system. Also, with the XY system being completely linear it allows for the motors which will pull the system to have consistent control and therefore be more precise in location. Ultimately, with the XY motion, we found simplicity was the best. It provided no additional benefits to change the system to the circular and only would require more special made parts.

3.3.2 Final Design of XY Module

Following the decision to utilize the linear system in our final design, we implemented it into our overall design. Figure 17 (below), shows our CAD model of the base of the device with the entirety of the XY system on top.

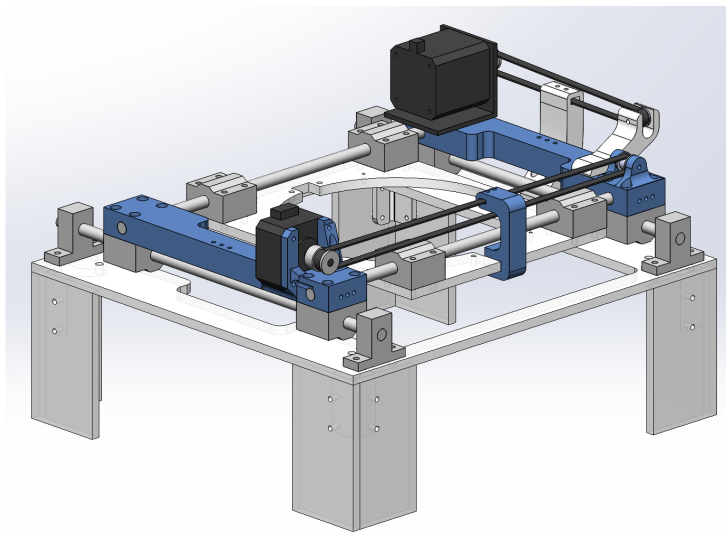


Figure 17: CAD Model of XY System

As can be seen in the model, the XY system is connected via screws directly to the base of the device, which currently is laser-cut acrylic. The screws hold the mounting brackets which hold the four rods that allow for the motion across the X and Y axes. In the middle, there is a large plate with a hole in it which houses both the KZ and IJ Modules. This plate is connected via linear bearings to the Y rods which allows the entire plate to move with the probe along the Y axis. Each axis movement is controlled by a motor and belt system. The belts are connected to the motors as well as held on the opposite end via custom made holders. The motors are mounted on top of custom 3D printed x-axis sliders that rest on top of the x-axis rods. This customization allowed us to specially design the mounts needed for the motors as well as for the belt system. Each belt pulls against a 3D printed clamp that also serves to join either end of the belt. Overall, the XY Module allows the probe to be moved 2.5 inches in both the X and Y axes as well as having consistent control over its location as designed.

3.4 IJ Module

3.4.1 Ideation of IJ Module

The IJ Module controls the angle of the probe with respect to the patient's body. This angle of the ultrasound beam relative to the tissue or organ of interest is known as the "angle of insonation." These movements are some of the most important in an ultrasound exam as fine adjustments here result in a large change in the imaging plane of the probe. As a result, while few tele-ultrasound systems include six degrees of freedom, almost all include robotic control over the angle of insonation. This gave us a larger bank of previous designs to pull from while brainstorming our solution for these degrees of freedom.

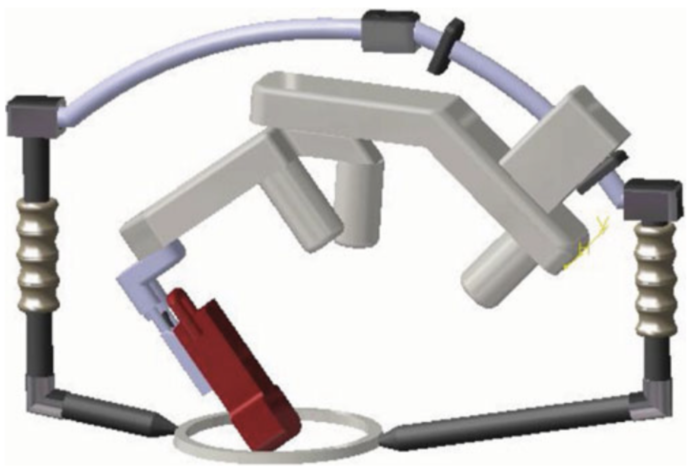


Figure 18: PRISME Lab Robotic Arm Mechanism

The PRISME lab devoted a large amount of research in the 2003-2012 period to developing kinematically-optimized, serial-manipulator arms (see Figure 18 above) for controlling the angle of insonation for their tele-ultrasound devices (L. Nouaille, 2012). One challenge of creating these manipulators was controlling what point the probe rotates around. In order to perform an effective ultrasound exam, the probe should pitch, yaw, and roll around the point of contact with the body surface. When performing this motion with a 4-DOF manipulator like those developed at PRISME lab, this requires a remote center of motion (RCM). Under these constraints (4-DOF + RCM), a serial manipulator (robotic arm) is the only solution that makes sense. These constraints also drive up the overall system size since all motors need to be arranged in such a way that their rotational axis intersects with the RCM.

As we started developing our solution, we realized that since our device had six degrees of freedom, the RCM constraint did not necessarily apply. Our center of rotation for the probe could be separate from the point of contact with the body and we could offset any unwanted translation via the XY and KZ systems. This opened our exploration of rotational mechanisms to include a wider range of potential solutions than were possible with the 4-DOF mechanisms developed by PRISME.

In order to significantly reduce the side of the IJ Module, we turned to tendon-driven robotics. A strength of tendon-driven designs is that the actuator can be moved away from the point of actuation. Using tendons, we could move the motors for the IJ Module away from the probe, making the mechanism more compact. We developed multiple tendon-driven designs, varying the support structure and tendon arrangement in each.

The first tendon-driven mechanism we developed was a dual-motor, four-tendon manipulator based around a ball joint. Pictured below in Figure 19, it utilizes two perpendicular loops of tendons, each mounted to one motor.

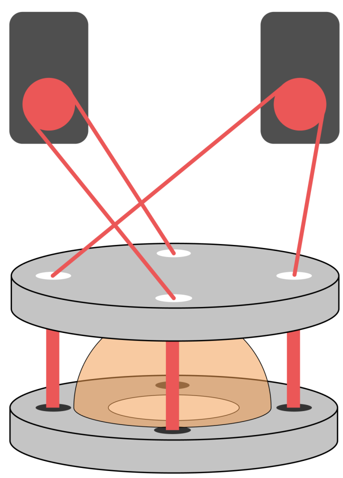


Figure 19: Tendon Driven Mechanism

In this design, one motor controls rotation about the I-axis, and one controls rotation about the J-axis. However, through a simple simulation program we developed, we learned that the "loop-based" design of this structure did not hold up as each loop's length was dependent on the position of the other loop. As a result, this system would be locked into rotating about only one axis at a time. While this specific solution was kinematically impractical, we realized that by cutting the loops and making each tendon independently controlled by increasing the motor count to four, a tendon-driven design could work. Additionally, one of the four tendons could be made redundant and removed by changing the tendon layout.

A three-tendon system was developed by arranging three independently-controlled tendons equally around the center of rotation. This solution was analyzed with the same custom simulation program and determined to be feasible and controllable. However, without perfectly rigid components, there would be some unwanted rotational flexibility around the long axis of the probe (K-axis). To combat this, we replaced the ball joint with a universal joint (often used in drivetrains to transfer rotational torque between off-axis components). This universal joint allowed for the same I and J axis rotation while preventing any K-axis rotation. This version of the device is pictured below in Figure 20.

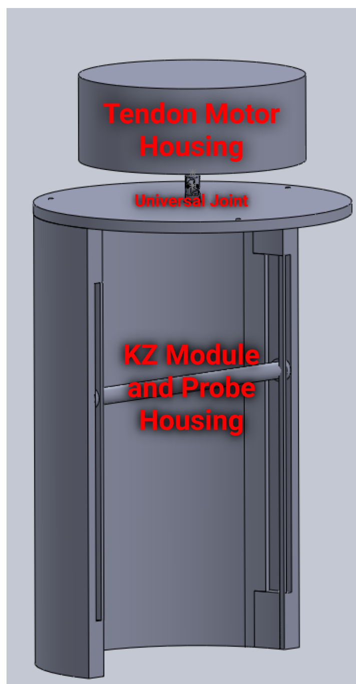


Figure 20: Three Tendon System

The biggest issue with this design was its height. As shown in Figure 20 above, the universal joint and tendon system would have to be stacked on top of the probe. In addition to height, this moved the center of rotation even farther away from the contact point between the probe and the body. This added length would have to be accounted for in an increase in the XY range of motion in order to simulate a center of rotation at the contact point. If the center of rotation was somehow placed within the probe itself, it would be closer to the contact point and would reduce the amount of XY motion needed to simulate rotation around the contact point. To move the center of rotation down, we developed a two-axis gimbal system that placed the center of rotation within the probe itself.

3.4.2 Final Design of IJ Module

Our final design for the IJ Module combines this two-axis gimbal system with the three-tendon design to create a compact, controllable, and sturdy system for angle of insonation control. Figure 21 below shows the final IJ Module as connected to the center XY plate in CAD.

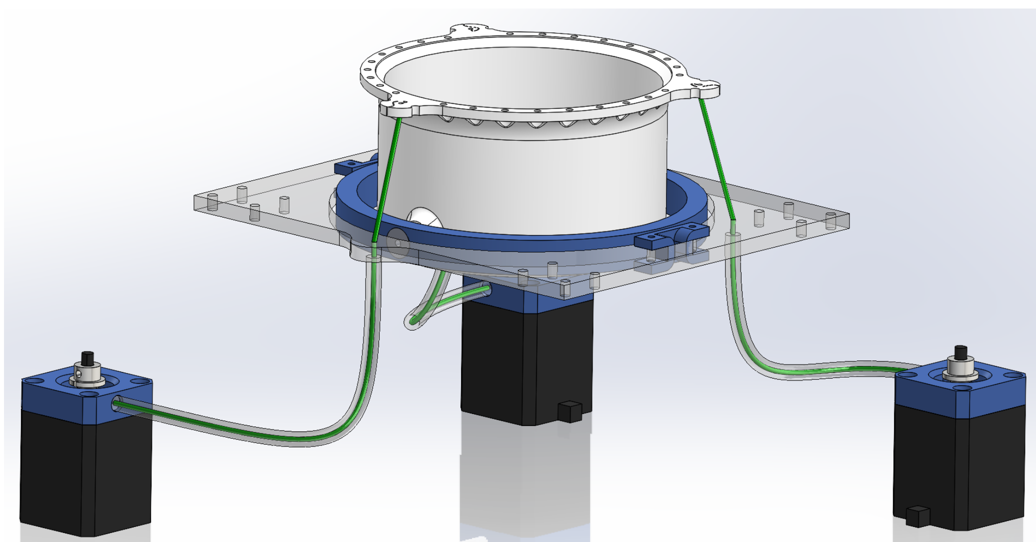


Figure 21: Final IJ CAD Model

This design allows for 23° of rotation in any direction. Additionally, within this working space, the manipulator has no singularities, allowing for consistent control of the orientation of the probe at all times. This is an especially large improvement over the Melody and PRISME devices which all feature a partial singularity when the probe is normal to the body surface that can result in inconsistent control.

3.5 KZ Module

3.5.1 Ideation of KZ Module

Following the IJ Module, the last module to develop was the KZ Module. This mechanism would involve the movement of the probe in the Z direction which allows for the pressure needed for an ultrasound exam as well as rotation about the K axis that the probe would need to properly orient its imaging. This module had very strict design constraints as it had to be small enough to fit within the other two modules but had to be large enough to fit the probe. As seen Figure 22 below, the overall shape of the KZ Module was largely predetermined.

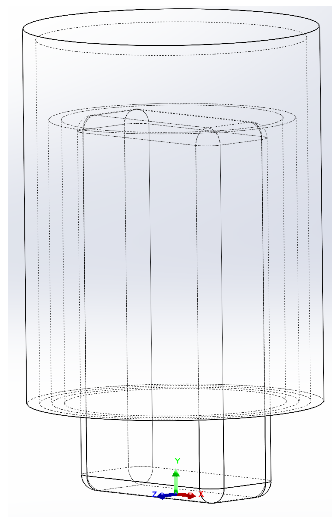


Figure 22: KZ Module Design Constraints

In Figure 22, the outermost cylinder was the size of the smallest part IJ Module that the KZ Module had to fit within. Also depicted is the model of the ultrasound probe that the KZ Module must hold. This led to us having a cylinder based design for this mechanism that would fit in between the outer shell and the probe. The idea then developed to create submodules for which the innermost cylinder would be responsible for Z movement and that entire Z-cylinder would be rotated about its axis to provide K rotation. However, there were a few drawbacks to this design. First, the motor that would control the Z movement would have to be mounted inside of its cylinder. Therefore, the K rotation would not only be rotating the probe, but also the Z motor. This would require a larger force needed from the K motor due to the weight of the Z motor. Also, because the K motor would be spinning the entire Z mechanism, it would also twist the wires connected to the Z motor. This caused us to have to consider both the K and Z movement together.

For both the K and Z mechanisms to work together we thought of adding a lead screw for the Z motion. The lead screw would be connected to the probe-holding mechanism and the outer shell of the overall KZ Module. This way the probe can be released downward incrementally. We also determined that the best way to connect the motor to the lead screw would be through a series of custom made gears. This would also allow for the motor to sit on top of the cylinder and therefore avoid the twisting of the wires. This design would also allow for the gear system to also perform the K rotation.

In addition to the K and Z movements, the KZ Module was responsible for holding the probe. This meant the design needed to incorporate an interchangeable aspect that would allow for an easy transition between different probes. Some ideas the team brainstormed included using compression springs or hinge joints. However since accessibility and interchangeability were our main goal with creating the clamp, these options would provide less flexibility with different probes. This led us to a clamp style design to hold the probe in. A 3D printed clamp fitted with a clasping mechanism locks the probe in place. This clamp is also connected to a lead screw nut that threads onto the KZ lead screw.

3.5.2 Final Design of KZ Module

After the lead screw design was determined to be the most beneficial way of controlling the probe’s movement in the K and Z directions, the final mechanism was designed. This design is more compact and able to store both the K and Z axis movement within the shell of the mechanism. This allows for more space around the outside of the device which will decrease the overall weight of the device and increase its portability. The CAD model of our final KZ design can be seen in Figure 23 below.

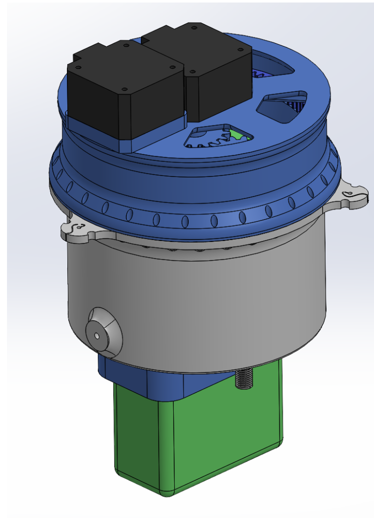


Figure 23: CAD Model of KZ Module

In addition to the lead screw, the probe needed to be stabilized to move vertically. This was accomplished by adding a stainless steel guide rod on the opposing side of the lead screw. Internally, both of the K and Z movements are controlled by two separate motors that are housed on top of the device and are connected to respective gear trains. In Figure 24 below, the Z gear train is highlighted in red.

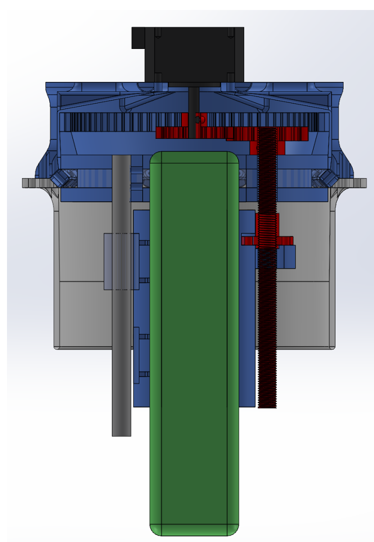


Figure 24: Z Axis Gear Train

This gear system is composed of a gear on the lead screw as well as a gear attached directly to the motor. The motor itself is attached directly to the gear system which rotates the lead screw and allows the probe to move up and down along the Z axis. This gives the sonographer control over the pressure being exerted on the patient. The range of motion the probe is able to move in the Z direction is 3.1 inches which is in line with the estimates provided in our design requirements.

For the K axis rotation, the gear train can be seen in Figure 25 below, in red. The motor that controls the motion is highlighted in black.

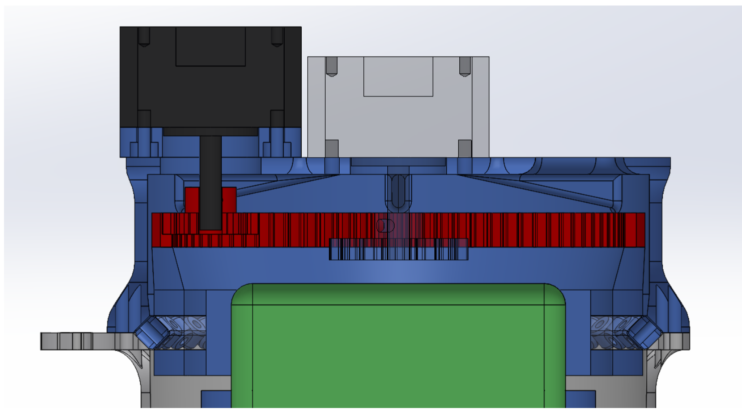


Figure 25: K Axis Gear Train

This gear system allows for the probe to have continuous rotation. All gears were 3D printed to mount directly into the housing system via setscrews. The device is able to rotate through the use of a custom 3D printed bearing built into the inner rotating component and external mounting shell. The bearing is a slew bearing using 3D printed rollers. This bearing is shown below in Figure 26 with the top section of the KZ Module removed for visibility.

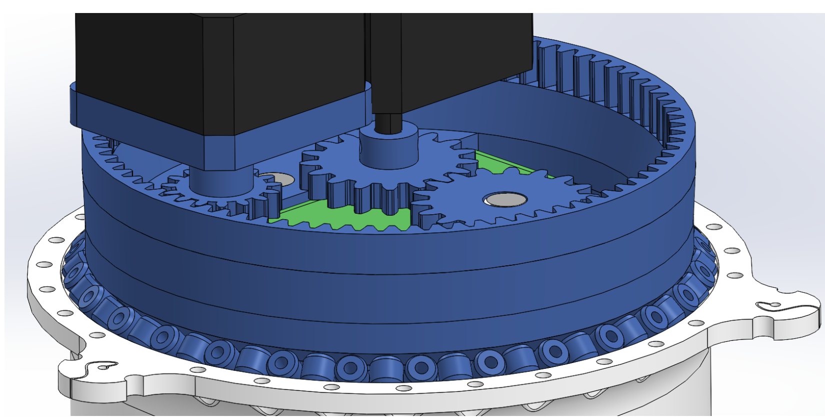


Figure 26: K Axis Bearing

The probe holder is a clamp made from two 3D printed pieces that snapped together around the probe and is supported by the lead screw and the guide rail. This style of clamp, which was fitted for the Clarius C3, allowed for the easiest interchangeability while still providing the structure needed to hold the probe. The gear system in combination with the probe clamp allowed for the device to have the proper motion along the Z axis and around the K axis while still remaining compact and portable.

3.6 Software Development

3.6.1 Smartphone Control

Figure 27: Smartphone UI

We developed a mobile web application (Figure 27) as one way for a sonographer to control the device remotely. The sonographer would be able to use this application as a remote control while viewing the ultrasound images through a separate display. It gives a sonographer direct control over the position and orientation of the probe across all six degrees of freedom.

To keep naming consistent, we utilized the set of probe movement names laid out in Bahner et al and shown in Figure 28. These names are used in the control UI and will be used throughout this section to describe probe movements.

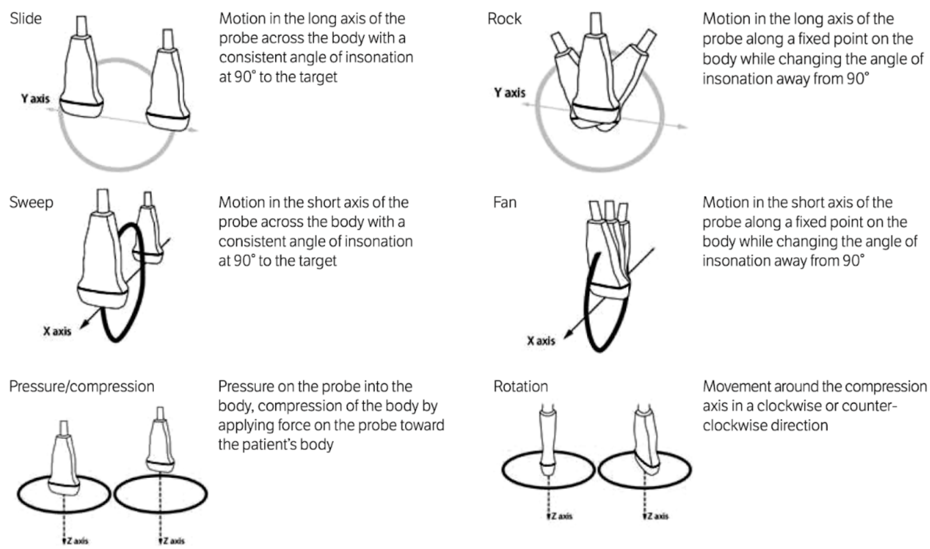


Figure 28: Probe Movement

Basic slide and sweep movements across the body surface are controlled via a dual-axis on screen joystick in the bottom left corner of the UI. This joystick controls the velocity of movement across these axes, allowing the sonographer to quickly move the probe using larger movements or fine tune the probe position by nudging the joystick.

The pressure or compression (translation along the long axis of the probe) is controlled using a vertical single-axis velocity joystick on the right side of the UI. Pulling this joystick "down" presses the probe into the body surface and pulling it "up" pulls the probe away from the body. The rotation of the probe (around the long axis of the probe) is controlled via a horizontal single-axis velocity joystick in the middle of the UI. Pulling the rotation joystick right rotates the probe clockwise and pulling it left rotates the probe counterclockwise. These single-axis joysticks are also velocity based, allowing for quick large movements or tight fine tuning.

All joystick-based controls are implemented as draggable handles that snap back to their zero-position (also zero velocity, stopping movement in that direction) when released by the user.

The last two axes of movement, rock and fan, are controlled through tilting the phone. The current angle of the probe with respect to the patient's body is shown using the display in the top half of the UI. When the sonographer presses and holds this display, the system enters an "orientation-mirroring" mode where any rotation of the smartphone is echoed by the probe on the device. Each time the system enters this mode, the initial orientation of the phone is captured and orientation changes are measured relative to this initial orientation. As a result, the smartphone can be held in any comfortable hand position and at any angle and the sonographer still has full range of rock and fan motion. When the sonographer removes their finger, the orientation-mirroring is paused and the probe orientation freezes.

The "Connect" button on the top left of the screen initiates the connection to the device. The "Reset" button on the top right resets the device to its "home" position.

The smartphone web application is deployed as a single web page that is hosted by a Raspberry Pi B+ v1.2 onboard the tele-ultrasound device. Once loaded using a smartphone web browser, the page can be bookmarked using the device's respective "homescreen bookmark" feature. Once opened from the homescreen bookmark, it will display as a fullscreen application and act similarly to a native smartphone application.

3.6.2 On-Board Software

The software architecture for this iteration of the device prioritized speed of development and modularity. Separate operations and areas of focus were kept as completely separate Linux processes that communicate over interprocess communication. Each process could theoretically be written in a different language that best matches the needs of its operations. However, in this iteration, the entire software stack is written in Javascript running in the Node.js runtime. By keeping all of the software in the same language, we were able to quickly prototype and iterate on software design and the overall component based architecture. The resulting architecture is laid out below in Figure 29.

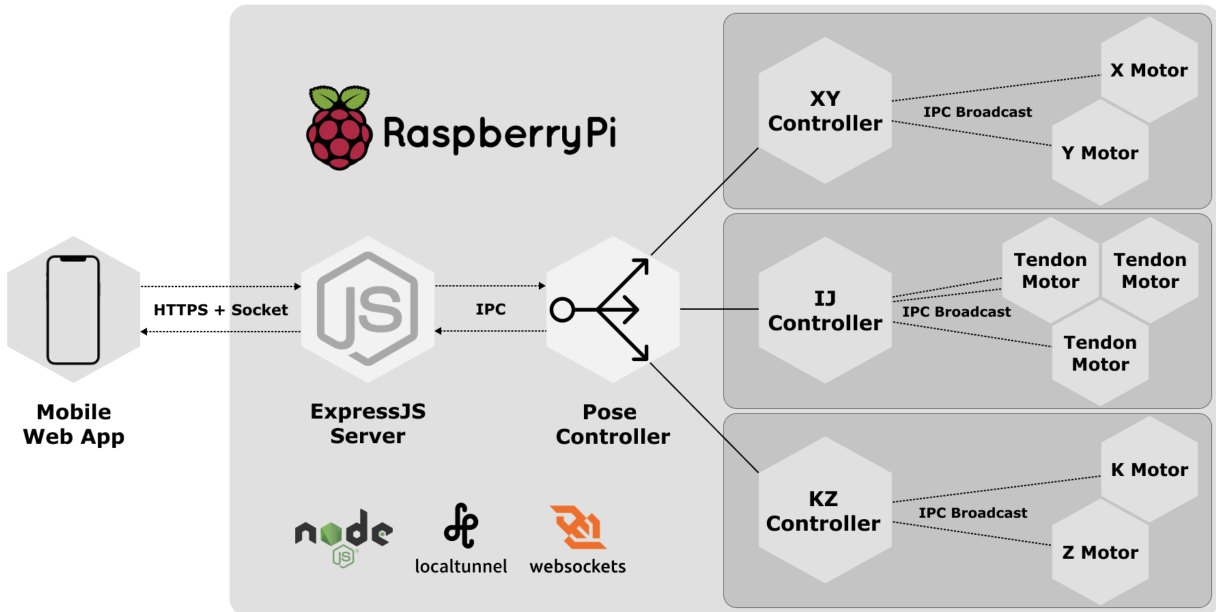


Figure 29: Raspberry PI Software Architecture

Each module of the software running on the Raspberry Pi owns a specific operation in the pipeline from control signal to motor movement. First, the **ExpressJS Server** accepts control instructions from the **Mobile Web App**. It simply passes these control instructions to the **Pose Controller** which keeps track of the intended position of the probe. When it receives new control instructions, it translates these to a "goal pose" (a description of the position of the probe across its 6 degrees of freedom). It then acts as a router, passing the relevant goal pose attributes to each **Module Controller**. For example, the X and Y goal values of the probe are sent to the **XY Controller**. The **Module Controllers** convert these position and orientation values to motor positions and send the goal motor positions to the motor drivers. The **Motor Drivers** each control the power state and position of their respective motor. This completes the translation from control signal on the web app to motor movement on the device. Now we will discuss each module in more detail.

The **ExpressJS Server** manages the device's connection to the internet. It hosts the web application for access by a sonographer and controls the web socket connection to the smartphone. This server was built with the popular Express.js library. It exposes a port on the Raspberry Pi that when accessed over https, offers an HTML file with all of the user interface graphics and logic. That same port is then used to create a websocket connection between the server (on the Pi) and the client (the smartphone). This websocket connection allows for two-way streaming of message data. It is through this websocket that the client sends all probe control commands to the Raspberry Pi. When a command is received, the server component simply passes it on to the pose controller.

The **Pose Controller** is the central heart of the robotic control of the device. It keeps track of the position and orientation of the probe using six parameters (X, Y, Z, $\hat{\imath}$, $\hat{\jmath}$, $\hat{k}$). It receives commands from the smartphone (via the server module) in the form of either raw value updates or velocities based on the control setup on the smartphone. With the current control UX, the smartphone generates exact value updates for the $\hat{\imath}$ and $\hat{\jmath}$ values (mirroring the orientation of the phone) and generates velocities for X, Y, Z, and $\hat{k}$ (due to joystick control). For the exact value updates, the Pose Controller can simply change the current value to the new value. For velocity updates, the Pose Controller contains an event loop that increments or decrements parameters based on the velocity sent from the smartphone.

When the Pose Controller receives new commands from the web server, it can either update its probe position parameters based purely on the control signal, or it can perform a more complex calculation to convert all updates to be in the probe's frame of reference. Mechanically, the center of rotation for $\hat{\imath}$ and $\hat{\jmath}$ rotation is in the center of the gimbal. However, when performing an ultrasound exam, sonographers rock and fan ($\hat{\imath}$, $\hat{\jmath}$) the probe around the tip of the probe (where it is touching the patient's body). These two centers of rotation are shown in Figure 30, with the mechanical center of rotation shown as Point A, and the sonographer-prefered center of rotation shown as Point B.

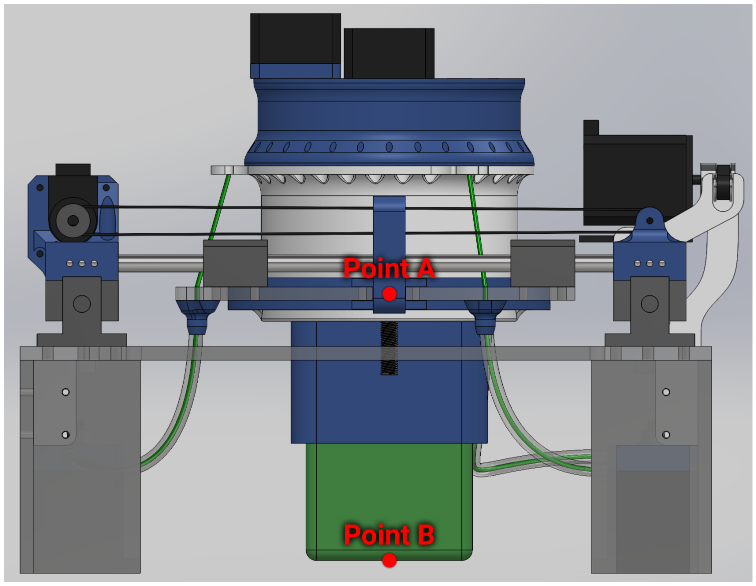


Figure 30: Rotation Control Points

In order to rock and fan around this contact point, the device must update the X, Y, Z, î, and ĵ parameters anytime there are rock and fan control updates. The Pose Controller uses a geometric model of the device to calculate the parameter updates needed for this complex rotation.

When using the "simple" mode, the Pose Controller will only change probe parameters that directly correspond to the control signals (ex: îĵ controls only impact îĵ parameters). When using the "complex" mode, the Pose Controller will update any and all parameters depending on the movement proposed by the control signal. When a parameter is updated, the Pose Controller sends the updated values to the relevant Module Controller.

Each **Module Controller** is responsible for two pose parameters. Its job is to convert the pose parameter values to motor positions and send these motor positions to motor drivers. For the **XY Controller**, this is a simple task. The XY Module is a belt-drive system where rotation of a motor is converted directly to translational motion. The XY Controller does this calculation in reverse, converting a translational position to rotational position of the motor based on the radius of the driven sprocket of the belt.

The **KZ Controller** is slightly more complicated. For $\hat{k}$ rotation, the $\hat{k}$ value of the probe is directly coupled to the motor through a gear pair. However, the Z translation via the leadscrew is loosely coupled to the $\hat{k}$ rotation due to the concentric nature of the gearing system. As the probe rotates for $\hat{k}$ changes, the Z motor must rotate at the same rate in order to offset the leadscrew's movement around the central Z drive gear. The KZ controller manages this movement so that anytime there is $\hat{k}$ rotation, both KZ motors run. The $\hat{k}$ parameter is converted to a K motor position using the (15:81) ratio of the internal gear and K motor gear. When the Z parameter changes, the KZ Controller can simply convert this Z parameter to a motor position using the leadscrew pitch and Z gear ratio (17:18).

The **IJ Controller** is the most complex of the three Module Controllers. It receives the $\hat{\imath}$ and $\hat{\jmath}$ parameters from the Pose Controller and must convert these to positions for the three motors that drive the IJ Module tendons. Using a geometric model of the gimbal system and tendon mounting points for the IJ Module, the IJ Controller converts the $\hat{\imath}$ and $\hat{\jmath}$ parameters to the tendon lengths necessary to achieve those angles. It then converts the tendon lengths to motor positions using the radius of the tendon spool mounted to each motor.

Each Module Controller has a set of software **Motor Drivers** that it runs. Each Motor Driver is a separate Linux process that controls a single motor via the Raspberry Pi IO ports. These IO ports are wired to a series of Pololu A4988 Stepper Motor Driver integrated circuits that power the motors and convert the low voltage control signals to high voltage motor signals. Any further mentions of "Motor Driver" refer to the software component that sends signals to this external hardware. Each software Motor Driver receives motor position commands from its respective Module Controller. If the position command is different from the current position of the motor, the driver starts a driving loop. Each pulse of this loop sets the stepper motor direction to point towards the goal position as received from the Module Controller and sends a pulse that "steps" the motor in that direction. This is repeated until the goal position is reached at which point the driver disables the driving loop and waits for another position command. If multiple position commands are sent in quick succession the motor driver can accept the new goal position and continue the driving loop without interruption.

Once the Motor Driver has stepped the motor to the correct position, the process of handling a control command from the sonographer is complete. The pipeline for handling control commands is modular and flexible to changes in sonographer control system, device mechanical changes, programming language, and motor choice.

In conclusion, the software developed for the device includes a mobile web application, a sonography control communication protocol and web server running said protocol, and a robotic control system for the device's unique 6-DOF mechanism.

Operation of the software and testing instructions are detailed in Appendix C.

4. Discussion and Conclusions

4.1 Future Work

At this stage in the development of this device, we have proven the mechanical and control design of the device through benchtop prototyping. Moving forward, the next step is to prepare the device for human testing with patients and sonographers. To get to the human testing stage, the device needs to be fully enclosed, material changes should be made for weight and stability improvements, and a pliable contact surface should be added to the base for patient comfort. For sonographer control tests, new control methods could be developed that give sonographers a more natural exam experience. Finally, there are various smaller software and electrical engineering features to complete to make the device user friendly and operable.

To start, the device should be fully enclosed to ensure the safety of the patient. This will guarantee that nothing will get caught within the device's moving parts that could potentially harm the patient. The enclosure would also serve to confine loose wires and the tendon motors. This enclosure could also feature handles that allow for the patient to more easily remove the device at any time during an exam.

Next, most of the hardware and rods used in the prototype were made of stainless steel. While the rigidity and sturdiness of the stainless steel helped to ensure the proper motion of the probe, it made the overall device heavier than desired. Thus, a future project could look into a lighter material for both the rods and hardware that would provide the same level of sturdiness but at a lighter weight. This would increase the device's overall portability and safety.

Another area within the design that would prepare the device for human testing is to create a pliable contact surface for the bottom of the device. This would serve as the part that contacts the body in order to improve patient comfort. Having a softer contact surface would also enhance the safety of the device and remove any sharp corners that could potentially hurt the patient.

Following the contact surface, another area of focus needed would be to enhance the sonographer control system. This could be done by creating a faux-probe, similar to the Melody system, that would allow the sonographer to control the probe's movement by moving the faux-probe. This would be another addition to the current mobile app that would give sonographers a more conventional ultrasound exam experience.

Once the device is ready to run in human trials, it will need to be evaluated by sonographers for various exam types. While the device matches maneuverability specifications confirmed both by previous device designs and our conversations with clinical consultants, it is not until real test exams are performed that these specifications can be confirmed.

Finally, various smaller software features would be developed to make the device intuitive and easy to use. For instance, a small screen could be added to the outside of the enclosure to display status and remote control connection information for the user. Additionally, a boot up system should be developed to start all necessary control programs when the device is powered on. Together with the ergonomic enclosure and comfortable contact surface, these features would make the device intuitive and natural to use with little to no technical support.

4.2 Project Impact

While there are many avenues for future work, there is a significant socio-economic impact of creating an at-home tele-ultrasound device that can be used for diagnostic imaging. The areas of impact largely surround the flexibility, resiliency and equity that an at-home ultrasound can provide. With the device not requiring a patient to be in the same physical location as the medical professional, it allows for patients to have more flexibility in where they are taking their exam as well as who is administering the exam. This can allow people who may not have a means of transportation to a clinic to have access to ultrasound technology. This level of flexibility will also increase the timing availability for exams as travel times will not be a factor. Patients will also have more opportunity to choose where they are taking an exam from as the device is able to travel with them. Additionally, there will be a greater flexibility in the provider that is administering their exam as exams would no longer be directly tied to a single location.

An at-home ultrasound device is also more resilient against any disrupting factors that may limit a patient's ability to receive an ultrasound exam. An example of this would be a large scale disaster such as the COVID-19 pandemic that significantly slowed hospital visits and diagnostic imaging. This caused a significant strain on hospital resources. There was no system in place to prepare for diagnostic imaging in a pandemic. With the creation of a device that is portable and only requires one medical professional to diagnose, in any future pandemics or similar national crisis, diagnostic imaging could still be provided. Also, on a smaller scale, an at-home system would prevent patient overload at hospitals. If patients are not required to come in person to a hospital, then sonographers are able to see more patients quicker and save room in the hospital or clinic for those who need emergency services. A shippable device would also be resilient against any traveling situations that would cause a sonographer to be out of their normal clinic or a patient to not be able to come into the clinic.

Finally, a large benefit to an at-home diagnostic imaging device is the equity it can provide. Because the device is shippable and portable, it is not required to have a clinic or hospital in the area with ultrasound equipment. This means that the access to an ultrasound can be expanded beyond just communities with a hospital or clinic in it. For at-need communities, who may not have the resources to afford a clinic or have limited medical equipment, an at-home device would mean residents could receive important diagnoses. Also, it can allow professional sonographers to diagnose in desolate or rural communities where there might not be a working professional. All of this increases the world's access to better healthcare and diagnostic imaging.

4.3 Conclusion

In review, the goal of this project was to create a robotic platform for at home diagnostic ultrasound imaging. The design surrounded the four main objectives of portability, ease of use, teleoperation and safety. The device has full maneuverability with six degrees of freedom. The XY Module can translate 2.5 inches in both the X and Y directions. The IJ Module is able to angle the probe 23 degrees off vertical in any direction. The KZ Module is able to rotate the probe continuously about its long axis and extend 3.1 inches. The device fits within a 12x13 inch box, meaning that it is handheld and easy for a patient to position for an exam. The device is controlled remotely through the use of a mobile device. It is proved to be safe for the patient to use as it is small and light enough to be easily lifted off the patient at any time. The development of this at-home ultrasound diagnostic ultrasound imaging platform expands the reach of ultrasound imaging. It offers a more flexible and resilient diagnostic ultrasound imaging system and ultimately expands global healthcare equity.

References

COVID-19 and Your Health. (2020, February 11). Centers for Disease Control and Prevention. https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/pregnancy-breastfeeding.html

Delgorge, C & Al Bassit, Lama & Novales, Cyril & Smith-Guerin, Natalie & Poisson, Gérard & Vieyres, Pierre & Urbain, L & Merigeaux, O & Aversa, F & Strintzis, M & Triantafyllidis, George & Arbeille, Ph & Comino, R & Istepanian, R.s.H. & Owens, Thomas & Bove, A & Nicolai, Giovanni & Bru, Concepció & aquila, A & Fruscione, Maria. (2014). OTELO project: mObile Tele-Echography using an ultra-Light rObot.

Lang, M., Yeung, T., Mendoza, D. P., Flores, E. J., Som, A., Lang, A. L., Pianykh, O. S., Lee, S. I., Saini, S., Little, B. P., & Succi, M. D. (2020). Imaging Volume Trends and Recovery During the COVID-19 Pandemic: A Comparative Analysis Between a Large Urban Academic Hospital and Its Affiliated Imaging Centers. Academic radiology, 27(10), 1353–1362. https://doi.org/10.1016/j.acra.2020.08.008

L. Nouaille, P. Vieyres and G. Poisson (2012). Process of optimisation for a 4 DOF tele-echography robot. Robotica, 30, pp 1131-1145 doi:10.1017/S0263574711001305

Make your own pregnancy scans at home with your partner and family. (2021, April 16). MyBabywatcher. https://mybabywatcher.com/en/

MELODY, a remote, robotic ultrasound solution. (2016). AdEchoTech. https://www.adechotech.com/products/

MGIUS-R3 robotic ultrasound system-MGI. (2019). MGI Tech. https://en.mgi-tech.com/products/instruments_info/11/

P. Arbeille et al., "Realtime Tele-Operated Abdominal and Fetal Echography in 4 Medical Centres, from one Expert Center, using a Robotic Arm & ISDN or Satellite Link," 2008 IEEE International Conference on Automation, Quality and Testing, Robotics, 2008, pp. 45-46, doi: 10.1109/AQTR.2008.4588703.

Rochon, M. (2020, April 14). FAQ for Pregnant Women during COVID-19. LHVN News. https://news.lvhn.org/faq-for-pregnant-women-during-covid-19/

Shengzheng Wu, MD, Keyan Li, MD, Ruizhong Ye, MD, Yuehua Lu, MD, Jufen Xu, MD, Linfei Xiong, MD, Ailin Cui, MD, Yaqing Li, MD, Chengzhong Peng, MD, Faqin Lv, MD. Robot-assisted Teleultrasound Assessment of Cardiopulmonary Function on a Patient with Confirmed COVID-19 in a Cabin Hospital. Advanced Ultrasound in Diagnosis and Therapy, 2020, 4(2): 128-130.

Vieyres, P., Poisson, G., Courrèges, F., Mérigeaux, O., & Arbeille, P. (2003). The TERESA project : from space research to ground tele‐echography. Industrial Robot: An International Journal, 30(1), 77–82. https://doi.org/10.1108/01439910310457742

Visionary Ultrasound. (2021, April 8). Pulsenmore. https://pulsenmore.com/

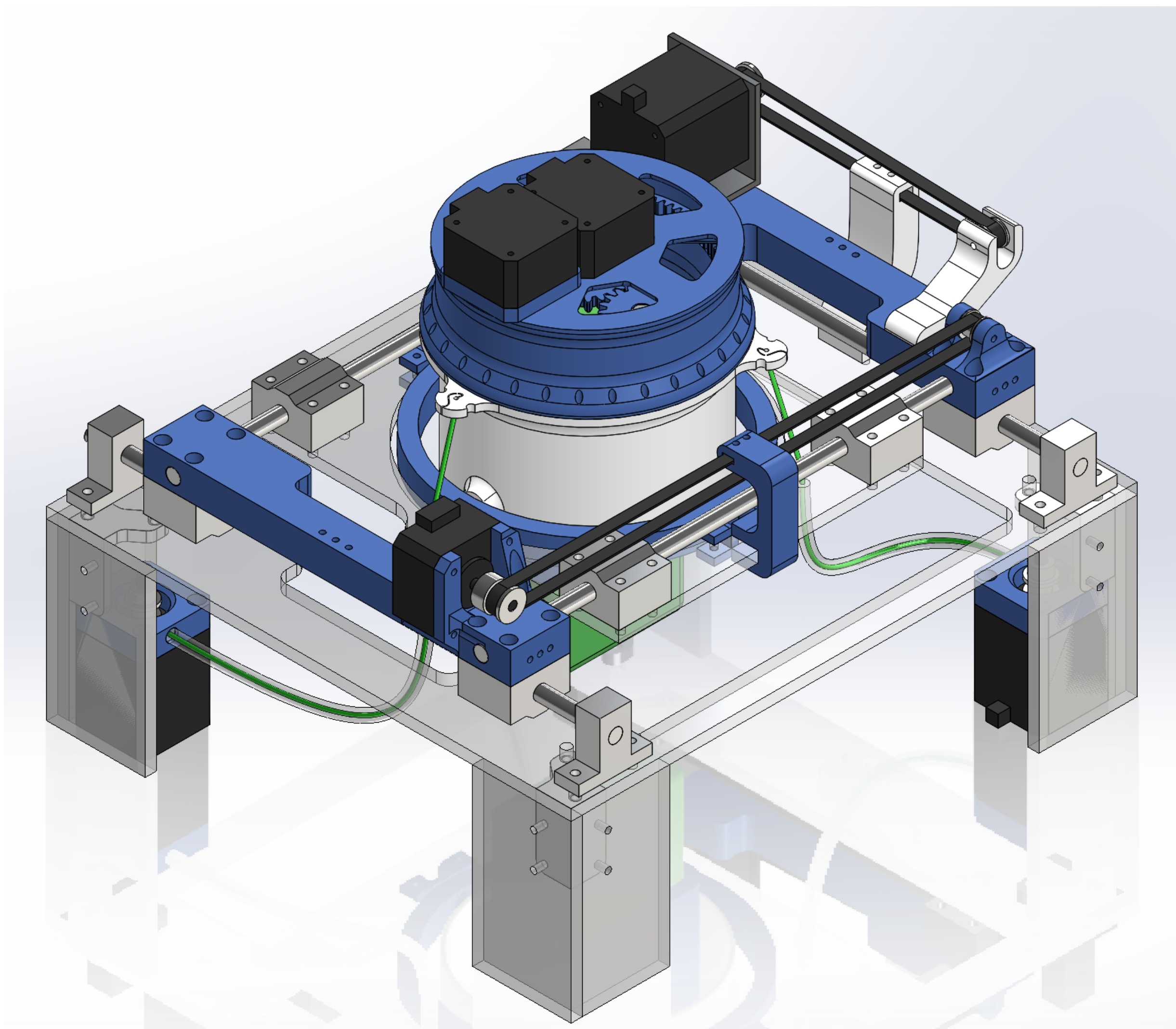
Vora, P. (2017, June 28). The government promises free ultrasounds but pregnant women are still paying large sums for the test. Scroll.In. https://scroll.in/pulse/841941/the-government-promises-free-ultrasounds-but-pregnant-women-are-still-paying-large-sums-for-the-test

World's first 2D/3D Home Ultrasound Scanner for mobile devices. (2021). Baby-Scan. https://www.baby-scan.com/

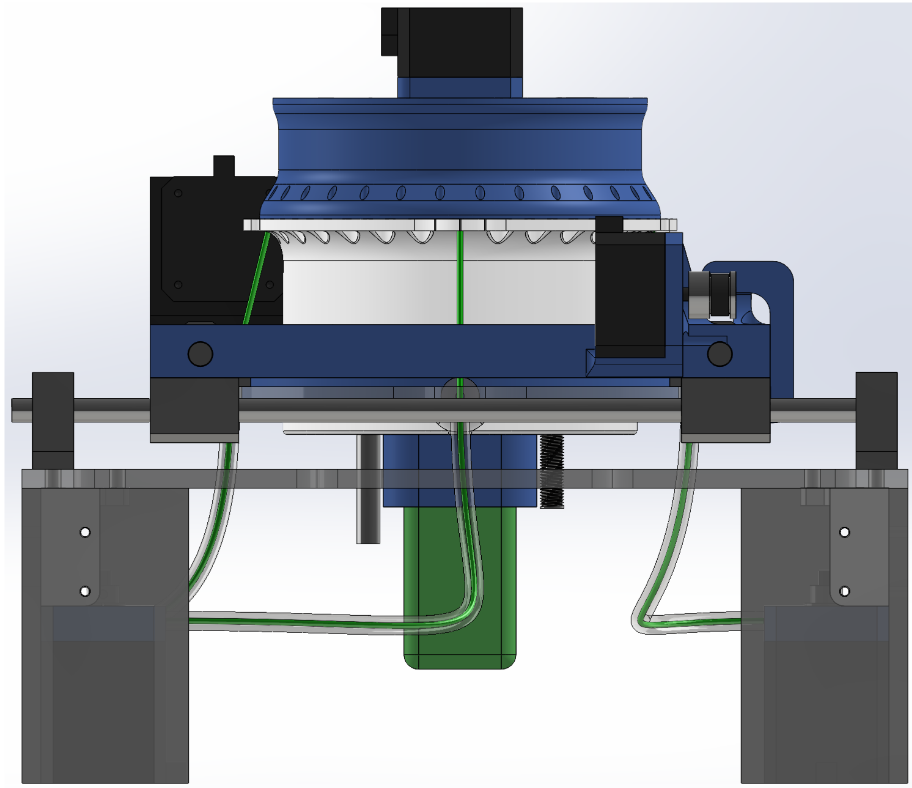
Appendices

Appendix A: Final Device Images

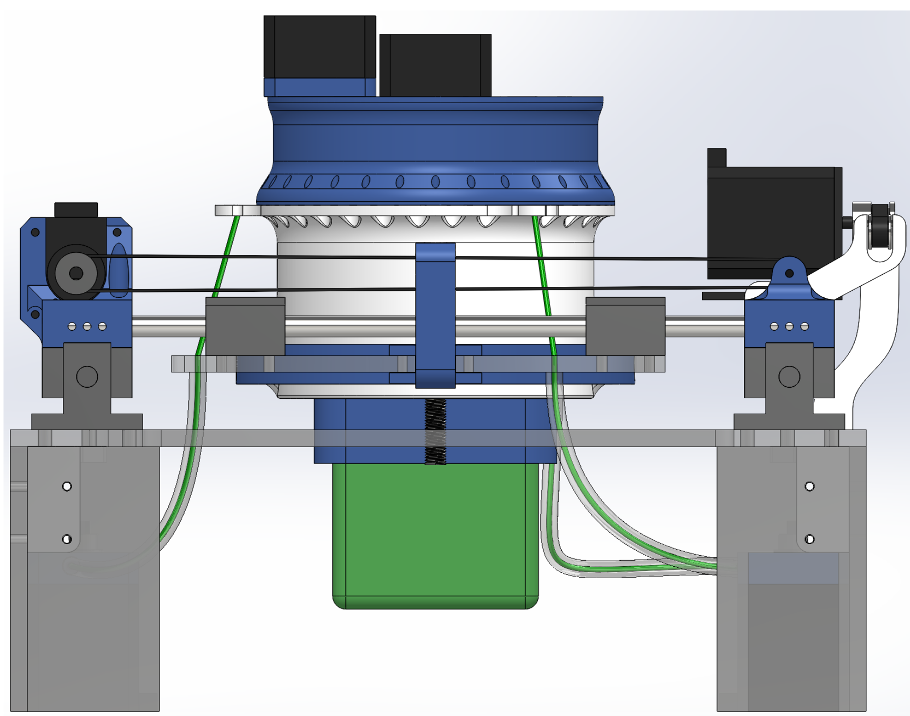
Following are the final CAD model images of the full device assembly. Partially transparent parts are laser cut from 0.25 inch acrylic sheets. White and blue parts are 3D printed in PLA using an Ultimaker S3. Nema 17 Stepper Motors are colored black. Gray metallic parts are purchased hardware. The tendons for the IJ Module are pictured in green, as is the ultrasound probe at the center. Not pictured are the various M3 and M4 screws used throughout the device.



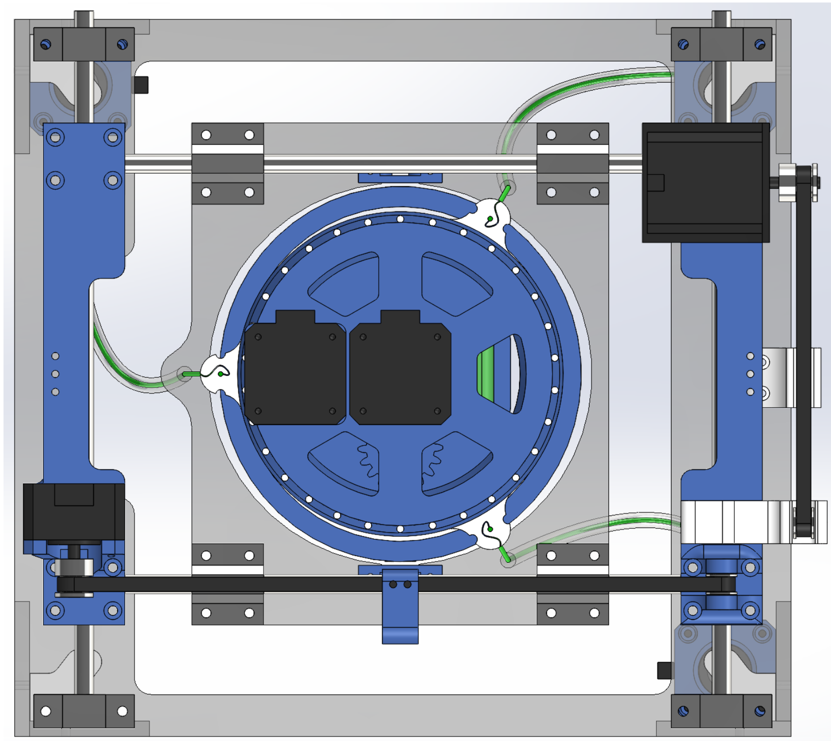
Isometric View of Final CAD Model



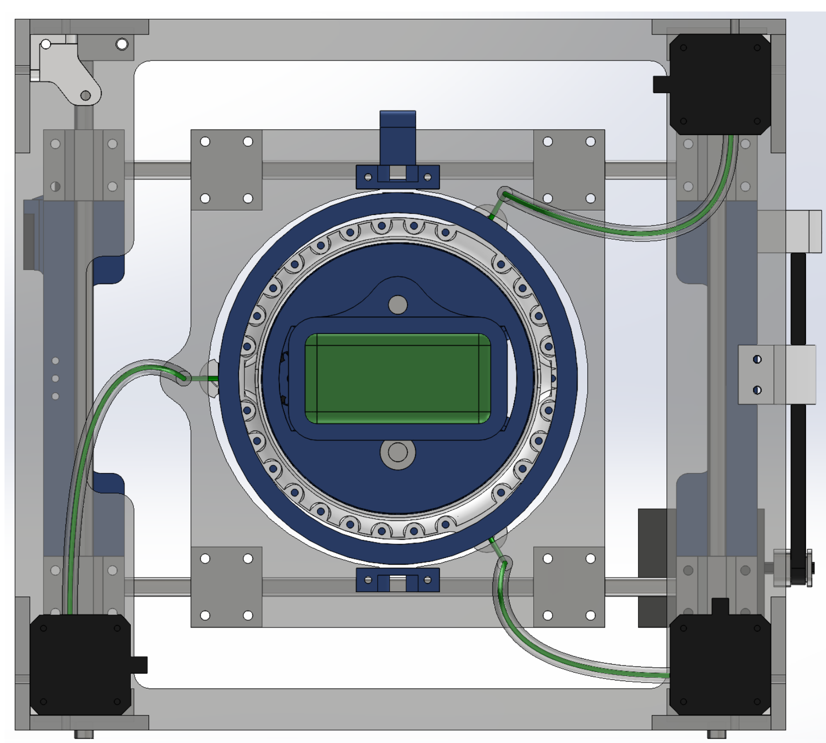
Front View of Final CAD Model



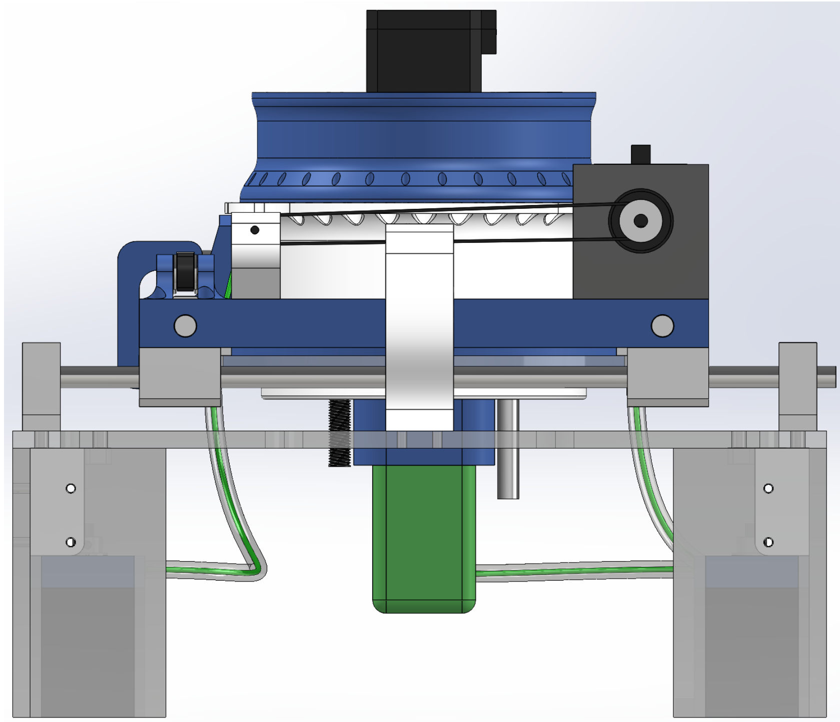
Right View of Final CAD Model



Top View of Final CAD Model

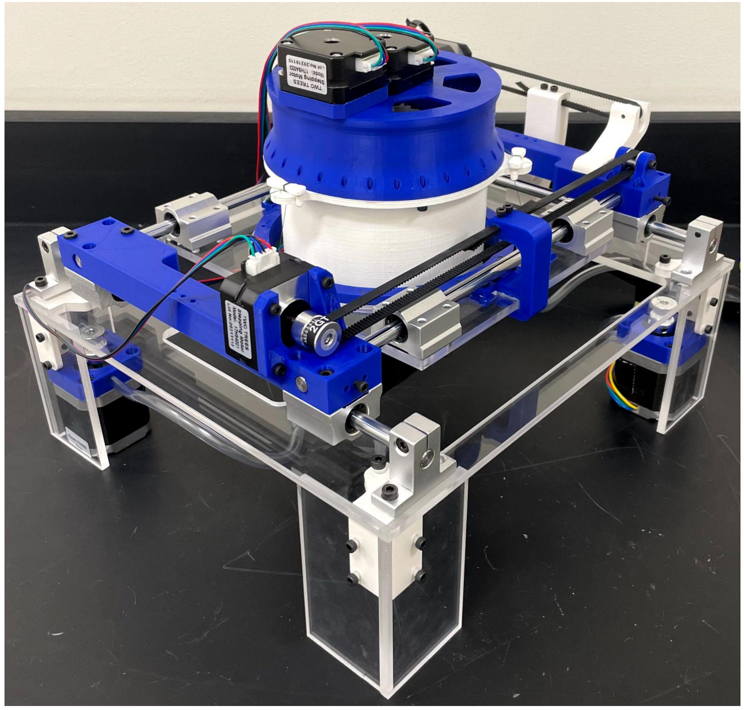


Bottom View of Final CAD Model

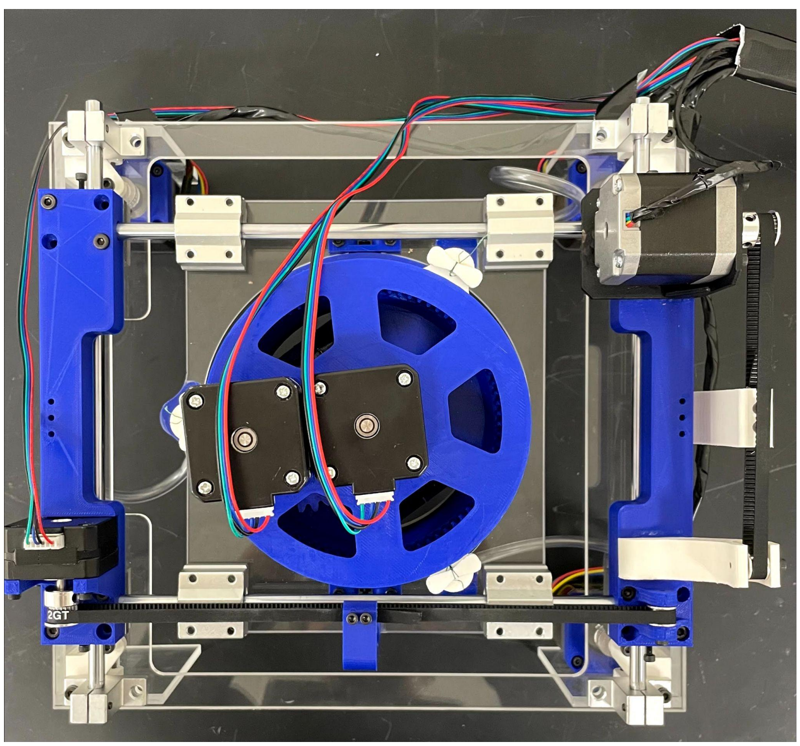


Back View of Final CAD Model

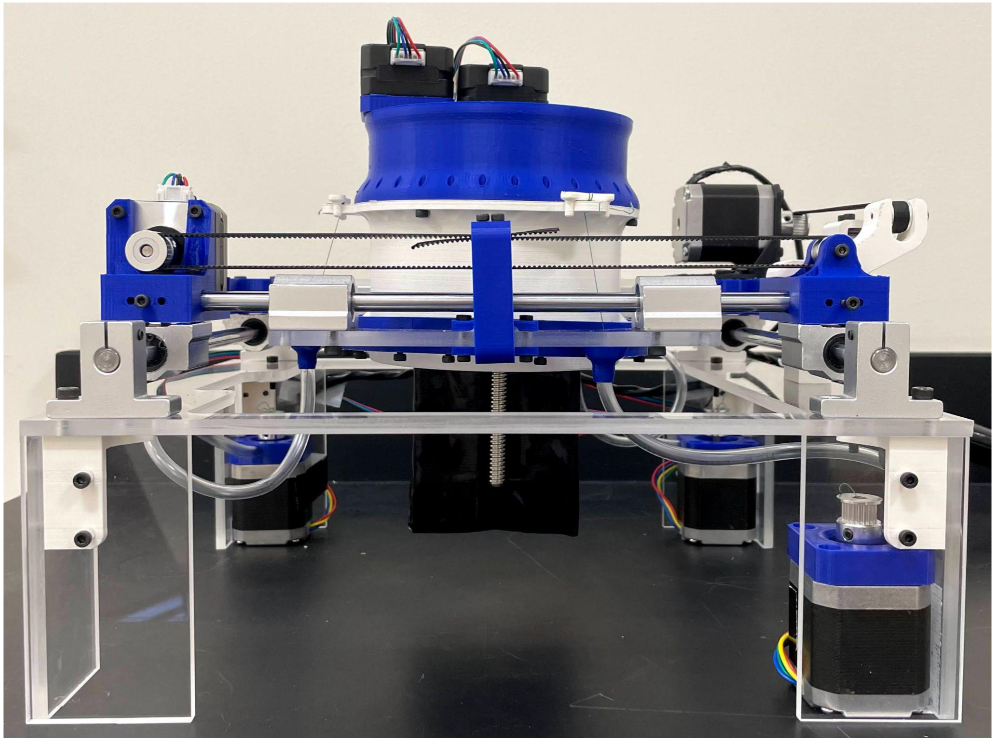
Appendix B: Physical Prototype Photos



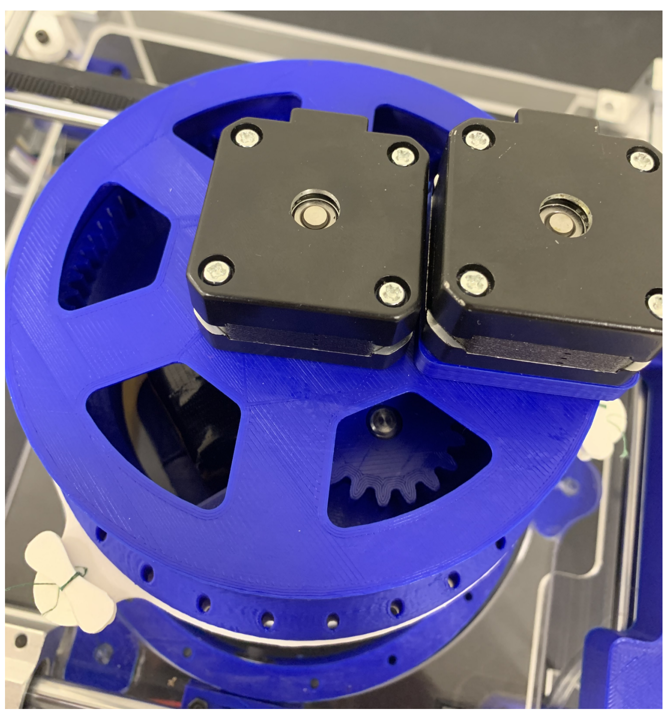
Isometric View of Prototype



Top View of Prototype



Side View of Prototype



Top View looking into KZ Module

Appendix C: Device Operation and Testing

This appendix will review the instructions for booting up the device, running the control programs, and controlling the device from a smartphone.

Booting Up:

The device currently requires two standard 15A 120V wall plugs. First, power on the Raspberry Pi using a 5V USB power supply and micro USB cable. Then, prepare the 12V power supply for the motors. Do not connect the DC power plug to the motor control circuit until the Raspberry Pi has booted and all control programs are running.

Before starting the control programs, you must "home" the device. This must be done before any control program is started or restarted. Using the top view image from Appendix A as a reference for your point of view, move the XY system as far as possible up and to the left. It should be sitting in the top left corner. Next, hold the KZ Module level (probe vertical), and tighten each tendon motor by hand so that they balance the KZ Module. This is the "home" position.

Running Control Programs:

The Raspberry Pi should automatically connect to the WPI wireless network. If it does not, it may need to be reregistered with IT. Contact WPI IT for information on registering Raspberry Pi devices for wireless connectivity.

1. Once the Pi is connected to the network, you should be able to SSH into the device using its IP address. Navigate to the `/control` folder. Once in the `/control` folder, you will need to start several programs. In one shell window, run this command to start the web server that serves the smartphone web application:

   ```
   node server/server.js
   ```

2. In another shell window (again from the `/control`) folder, run this command to start the control systems that run each of the modules and all of the motors:

   ```
   cd controller; node xyController.js && node ijController.js
       && node kzController.js
   ```

3. Finally, in order to connect to the device from a smartphone, run this command in a separate shell window:

```
lt --port 8080
```

This will output a URL pointing to the server we started in Step 1. Navigate to this URL using a smartphone to control the device.

Shutting Down:

Upon completion of testing, stop all running processes by pressing CMD+C or CTRL+C in each shell window. This will close the web server and disconnect all motors. Unplug the motor power supply. Finally, run the `sudo shutdown now` command before unplugging the Raspberry Pi power supply.