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A Robotic Platform for At-Home Ultrasound Diagnostic Imaging

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Abstract

A continuation of a project where a portable teleoperated robot for ultrasound diagnostic imaging was developed. The importance of telemedicine in a post-pandemic world is emphasized through this diagnostic tool. The device remains a six degree-of-freedom teleoperated robot that utilizes a third-party portable ultrasound probe for image collection. The design of this device was remodeled to include motion mapping based control interface and six degree-of-freedom position feedback control for intuitive, easy, and accurate operation. Safety of the device was enhanced by improving the emergency stop function. A human subject testing protocol was developed and attempted.

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1. Introduction

1.1 Importance of Remote Ultrasonography

Ultrasounds are one of the most commonplace diagnostic imaging techniques utilized worldwide by clinicians, having been around for 70 years they have continued to see increased amounts of scans performed. In the US for example, ultrasound readings increased from 177 to 347 per 1000 person-years in a sixteen year span (Smith-Bindman, et al., 2019). While ultrasound readings are accurate and extremely useful, the quality of readings are operator-dependent with the probe requiring a trained sonographer to carry out a reading. In regions where trained medical professionals are limited, the availability of well-performed ultrasound examinations are reduced. The continuation of this section will pinpoint the importance of improving access to proper scans through the use of remote-scanning alongside the rise of telemedicine.

1.2 Project Background

Our project is the third iteration of a device that originated in 2020, at the height of the COVID-19 pandemic. The first iteration of this device had 6-degrees of freedom for the probe, and a sharp, rigid housing with few safety mechanisms. The final device for the first year can be seen below in Figure 1. The device consisted of a set of seven stepper motors and commercially available hardware and was built from a combination of laser cut acrylic and 3D printed polylactic acid (PLA) parts. The designed device met its desired goals of portability and teleoperation.

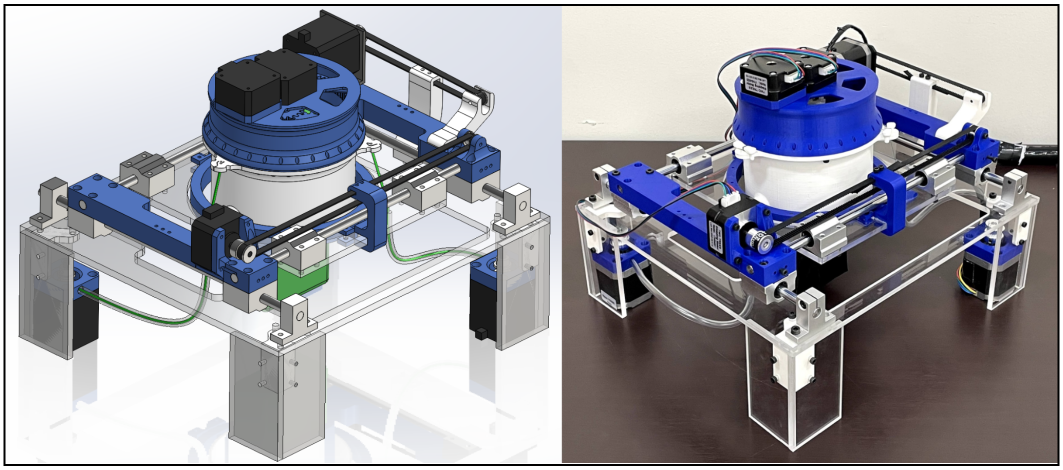


Figure 1: Initial Design of the Device

The second iteration of the device prioritized an increase in safety and comfort of the device. It incorporated an acrylic enclosure for the device to protect the user from contact with the moving parts of the device that also improved the overall support structure of the device. A vacuum sealing conforming contact was also added to provide comfort and a better fit of the device to the subject. Air is vacuumed out to provide a rigid fit to the contours of the human subject, as the device itself has a more rigid shape. Additional improvements included the redesign of the probe clamp to fit a Clarius probe, as well as some electrical and organizational additions to improve the device's design and make it more streamlined.

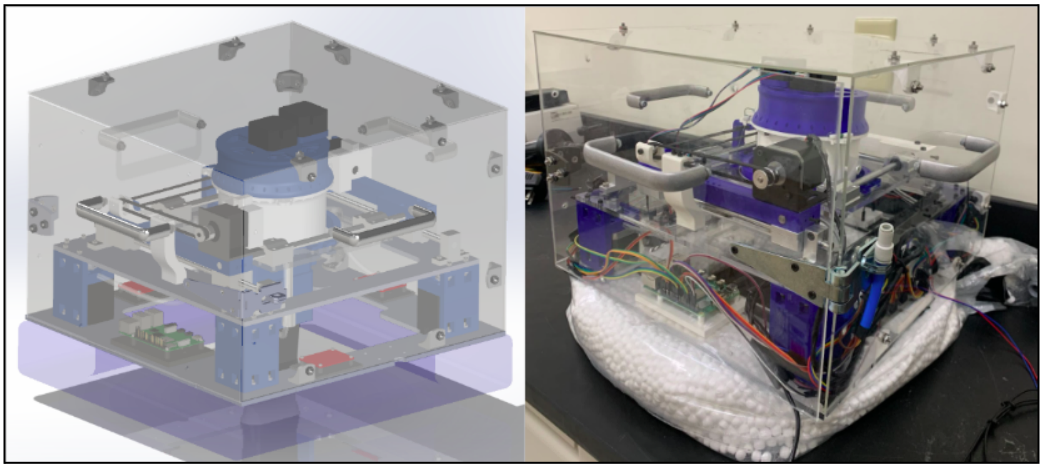


Figure 2: Second Iteration of the Device

1.3 Our Goals and Objectives

For this year’s device iteration, our team focused on updating the teleoperated ultrasound device’s software and hardware to make it more suited for clinical applications. The main goals were to improve the device's movement capabilities by replacing the preceding phone controller through the implementation of an intuitive six degree-of-freedom (DoF) handheld motion mapping controller and feedback control through the use of linear encoders and a gyroscope.

The team also aimed to improve the electrical components used within the device. This included the reorganization of the wiring and devices and integrating the encoders and a gyroscope to improve its motor functions.

2. Background

2.1 Ultrasound Imaging Systems

Previous work in the field of ultrasound imaging systems has focused on developing devices with various characteristics for different applications. Two of the more important devices we have reviewed are the SYRTECH and TERESA systems, both with 3 degrees of freedom (Das, 2023). We have analyzed the design of these devices because they were the first in the field, created in 1999 and 2003. The SYRTECH system, developed at the University of Orleans, was the first tele-operated ultrasound system using satellite transmission (Gourdon, et al, 1999). This device was streamlined in order to create a subsequent device, TERESA.

Figure 3: SYRTECH Device with Ultrasound Probe

The TERESA system was developed by many of the same scientists for the purpose of being used in even more remote applications such as the international space station (Vieyres, et al, 2003). It is a universal USG device, whereas SYRTECH was only made to use for cardiac and liver imaging.

Figure 4: TERESA Device

Other devices have larger DoFs in the six or seven range but lack remote control capabilities, which are suitable for an in-office clinical application. There have also been systems developed with wireless remote control capability. These proofs of concept show that the use of a multiple degree system allows for greater range of motion and control compared to other devices currently available, while having the capabilities to be controlled in a teleoperated fashion.

2.2 Feedback control

A former version of the device included a control system that would direct the motion of x, y, z, and k directions. However, this system lacked a way to “home” the device, as well as any idea of where the ultrasound probe was at any given moment. The team explored options for feedback control, an important aspect of the remote-controlled device.

Laser ranging has been in use since the 1960s and it can be an effective way to measure distance in rotary and linear applications (Ma, et al., 2022). Optical sensors such as the

VCNL4040 use light waves that reflect off a single surface to "utilize the reflected components to determine the pose of the object in relation to the transducer" (Saad, et al., 1999). The sensor we have selected for this project integrates a proximity sensor, ambient light sensor, and a high power IRED into a compact device. This type of sensor is used often in robotic applications because of its size and resolution in small spaces.

Gyroscopes are commonly used in robotics measuring the rate of rotation to obtain angular displacement. Accelerometers work by measuring the rate of change of acceleration. To combine them is a convenient and important step forward for our project. The MPU6050 6-DoF Accelerometer and Gyroscope is an integrated 6-axis MotionTracking device combining a 3-axis gyroscope, 3-axis accelerometer, and a digital motion processor (Siepert, n.d.). It has been used in video stabilization and control/navigation applications.

Feedback control systems using a variety of sensors operate using transfer functions between the input, in our case motion mapping from the remote operator's ultrasound probe model, and the output, in our case the movement of the device.

2.3 Motion Mapping

Motion mapping has been widely used in medical applications, from athletic performance to motor skills to movement of medical instruments. Optical and non optical sensors can provide accurate and valuable information about position and orientation of the subject of study. Of the various non-optical types of sensors, electromagnetic data acquisition was the most applicable variation for this project. Electromagnetic motion-mapping appliances "detect the orientation of wired and/or wireless sensors by assessing the interaction between an emitted electric field and flowing current" (Baribeau, et al., 2022). The VIPER sensor is a motion-tracking sensor that can accurately track the movements of the ultrasound probe in real-time, making it possible to create a more intuitive and accurate control system for a tele-ultrasound device. This new control system allows for more precise control over the position and orientation of the ultrasound probe, which can be crucial for obtaining accurate ultrasound images. The VIPER system uses a wired sensor that connects to an electromagnetic field-emitting source, tracking in 6-degree-freedom with sub-millimeter accuracy. This system can be used to accurately capture the movement of a hollow, cloned ultrasound probe for remote operation of the device in real time.

The application of motion mapping to our tele-ultrasound device has many benefits, including improved accuracy, precision, and ease of use of the system as a whole. With the use of such motion-mapping sensors, healthcare providers can potentially remotely control the ultrasound probe, making it easier to obtain high-quality images and diagnose patients more effectively, even in remote cases. This is a significant development that has the potential to revolutionize the way that ultrasound imaging is performed. As the technology continues to evolve, it is likely that we will see even more advanced applications of motion mapping in the field of healthcare.

3. Design and Results

3.1 Design Advancements

Throughout the year our team focused on improving the device through our goals and objectives to improve the device's movement capabilities by replacing the preceding phone app controller through the implementation of an intuitive 6-DOF handheld motion mapping controller and feedback control. The team also focused on improving the electrical components used within the device and adding encoders and a gyroscope.

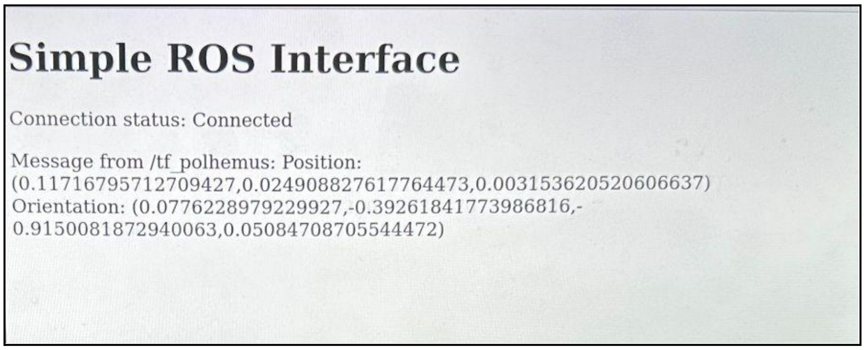
3.1.1 Motion Mapping

Previously, our device was controlled from a mobile app that was launchable on a smartphone. This approach was effective in controlling the device remotely, but it did not give the operator any sense of feedback or a way to smoothly operate the robot. The data for each axis of movement was input manually through a slide bar, which limited the intuitiveness of the controls. In this former iteration of the project, the device was operated only with visual aid (the sonographer would have to be in the room to see the probe orientation in person).

This method had numerous limitations when it came to controlling the movements of the ultrasound probe. This iteration of the device proposed the idea of being controlled by a professional sonographer remotely. These sonographers have been trained using a traditional probe for their entire careers and would not be used to a phone-app interface. To address these limitations, a new approach using a Polhemus VIPER sensor was implemented. Our new and improved design includes a 3D printed copy of an ultrasound probe for the sonographer to utilize in operation of the device. The motion and orientation of this clone probe is tracked by inserting the VIPER sensor into the bottom of the probe.

Figure 5: Polhemus Viper^{TM} Electromagnetic Motion-Tracking Sensor

The sensor is run over ROS on a host machine, where all of the information generated by the sensor is displayed and translated into a .html file. The file was then launched as a Websocket server on the local wifi where other computers could connect to the url and see the information transmitting from the VIPER sensor, seen in Figure 6.



Simple ROS Interface

```
Connection status: Connected

Message from /tf_polhemus: Position:
(0.11716795712709427,0.024908827617764473,0.0031536205206066637)
Orientation: (0.0776228979229927,-0.3926184177398681 6,-
0.9150081872940063,0.05084708705544472)
```

Figure 6: Server ROS Interface Display

Below in Figure 7 is a diagram of the workflow of the data from the Polhemus VIPER sensor to the pose controller in the Raspberry Pi on the robot.

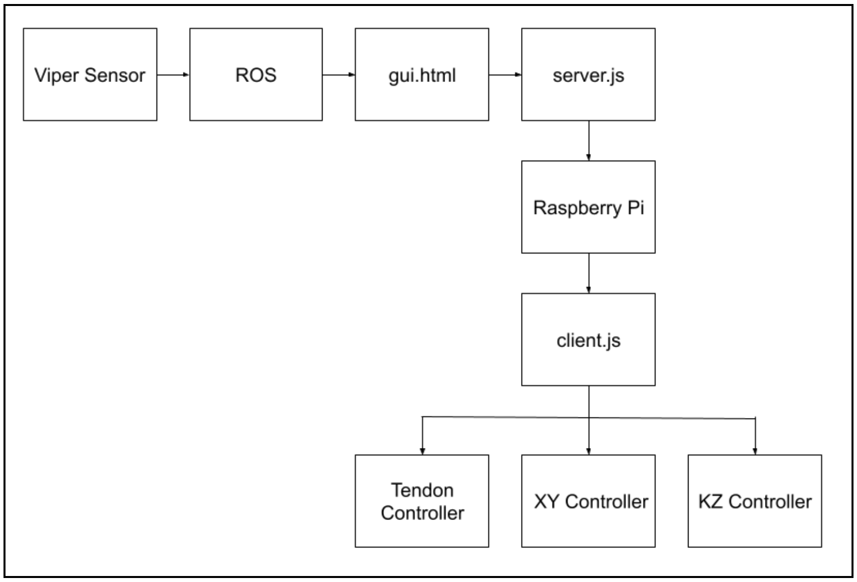


Figure 7: Motion Mapping Workflow

By connecting to the Websocket server from the Raspberry Pi using the client.js file, we are able to receive information broadcast from the server from the sensor. Any device running the client.js file can receive and access this data as long as the host machine running the VIPER sensor is running on the same wifi network as the machine requesting server data.

Once the client receives the position and orientation data from the server, those numbers are fed into the pose controller, where the numbers are processed and fed to the motors of the robot. Currently the pose controller is directly mounted on the client using an IPC connection, which allows the information the client receives to go directly into the pose controller from the server.

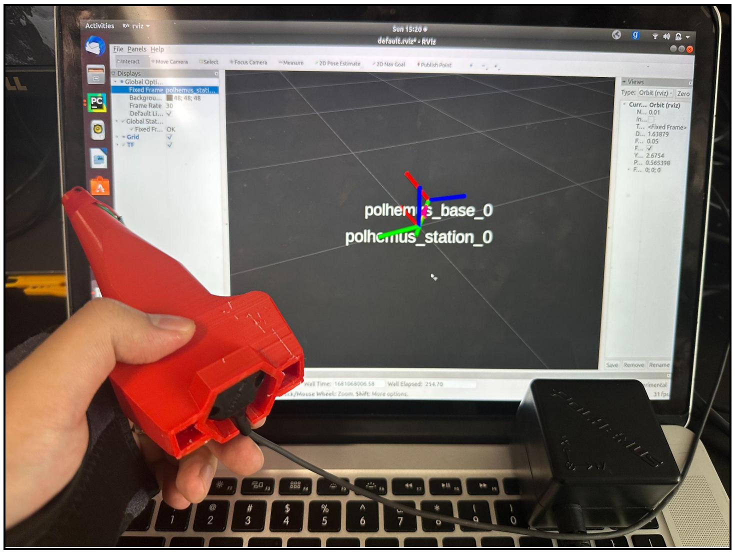
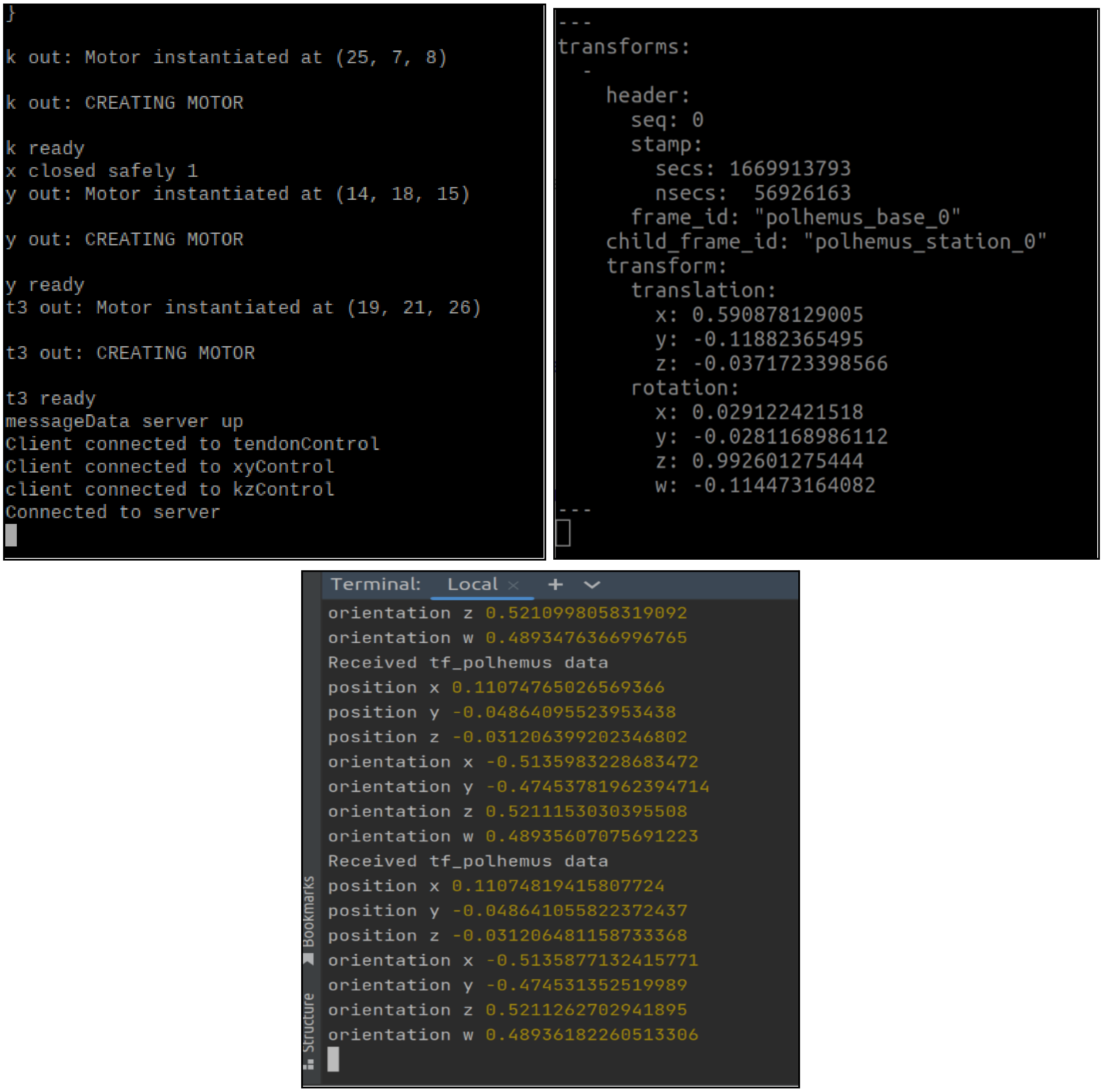


Figure 8: Viper Sensor Position Display with Sensor relative to Origin

The IPC connection was adapted from the code of the previous iteration of the project, which also mounted the IPC connection directly to the server they created to host their phone app.



```
}

k out: Motor instantiated at (25, 7, 8)

k out: CREATING MOTOR

k ready
x closed safely 1
y out: Motor instantiated at (14, 18, 15)

y out: CREATING MOTOR

y ready
t3 out: Motor instantiated at (19, 21, 26)

t3 out: CREATING MOTOR

t3 ready
messageData server up
Client connected to tendonControl
Client connected to xyControl
client connected to kzControl
Connected to server
```

```
---
transforms:
  -
    header:
      seq: 0
      stamp:
        secs: 1669913793
        nsecs:  56926163
      frame_id: "polhemus_base_0"
    child_frame_id: "polhemus_station_0"
    transform:
      translation:
        x: 0.590878129005
        y: -0.11882365495
        z: -0.0371723398566
      rotation:
        x: 0.029122421518
        y: -0.0281168986112
        z: 0.992601275444
        w: -0.114473164082
---
```

```
orientation z 0.5210998058319092
orientation w 0.4893476366996765
Received tf_polhemus data
position x 0.11074765026569366
position y -0.04864095523953438
position z -0.031206399202346802
orientation x -0.5135983228683472
orientation y -0.47453781962394714
orientation z 0.5211153030395508
orientation w 0.48935607075691223
Received tf_polhemus data
position x 0.11074819415807724
position y -0.048641055822372437
position z -0.031206481158733368
orientation x -0.5135877132415771
orientation y -0.474531352519989
orientation z 0.5211262702941895
orientation w 0.48936182260513306
```

Figure 9: Terminal Output for Viper^{TM} sensor operation

3.1.2 VCNL4040 Laser Encoder

As mentioned in the literature review, implementing a working feedback control is important to ensure precise control over the ultrasound probe when the device is in operation.

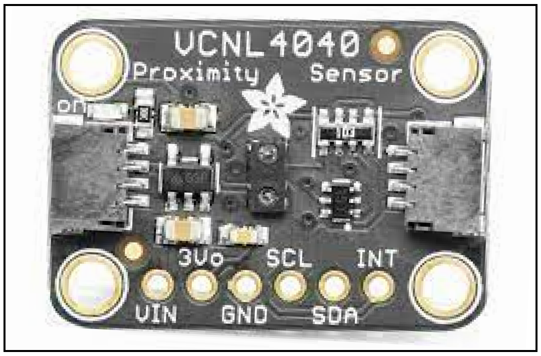


Figure 10: VCNL4040 Proximity Sensor

In order to map the robot’s x and y movement in its chassis, the team selected the VCNL4040 laser proximity sensor, shown in Figure 10, due to its small size, up-to 0.1mm ±10% accuracy, and availability of code libraries.

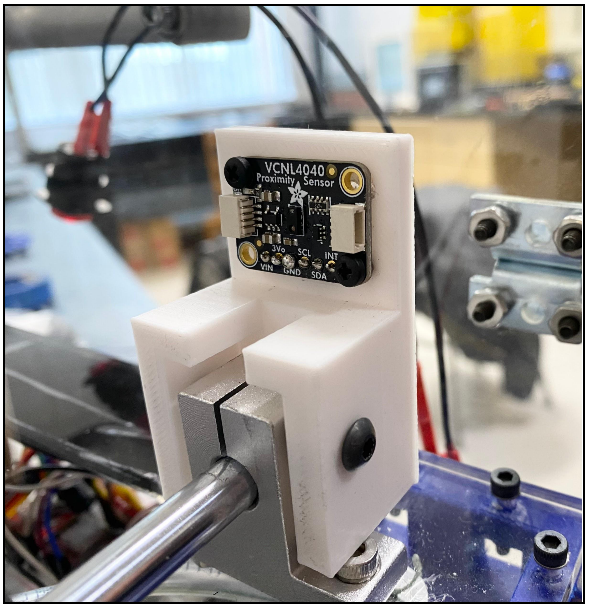


Figure 11: Installed X-Encoder

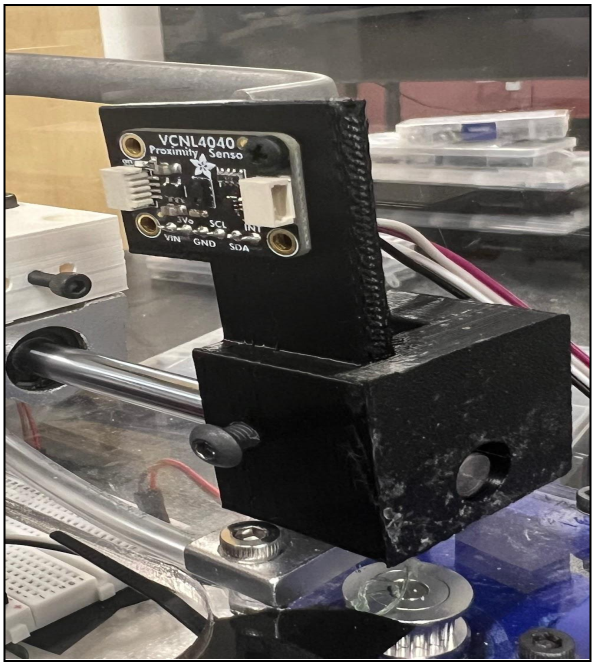


Figure 12: Installed Y-Encoder

Above in Figure 11 and Figure 12 are the locations of the encoders which will read the x and y distance(s) of the device when in motion. These sensors when run using the Adafruit VCNL4040 python library return a proximity value which is inversely proportional to the distance from the encoder the reference point is. Where the closer the reference is to the encoder, the respective proximity value increases. These proximity values are useful only when the device is able to apply the value to the respective location in the x and y axis, as such the team needed to develop a model which can take these proximity values and give them a millimeter measurement.

The device has 85mm of space on both the x and y axis which needs to be modeled. In order to develop the model, each encoder was set up to sample data every 0.1 seconds and stores these samples in an array. Starting from one end of the x and y axis the device was moved in half millimeter increments as the encoders sampled data. With each sample millimeter location and respective proximity values they can have a mathematical model made. The team chose a quadratic regression model to create an equation which best fits a set of data. Utilizing the NumPy python library to compute these models (Appendix D.A)

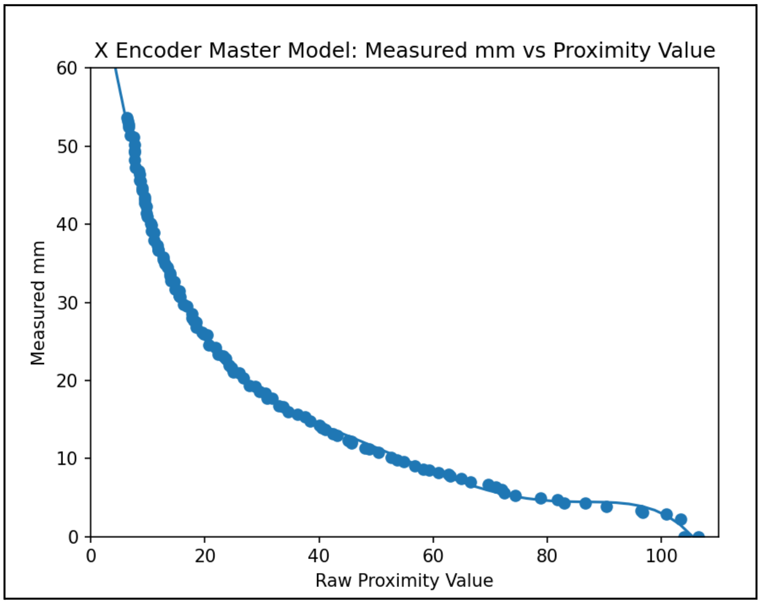


Figure 13: X-Encoder Quadratic Model

Figure 13 above shows the plot of the X-encoder quadratic model, fitting the data collected. The equation for the model is defined below as:

$$X_{dist} = (-8.945 * 10^{-8})x^5 + (2.741 * 10^{-5})x^4 - 0.003x^3 + 0.181x^2 - 5.264x + 79.69$$

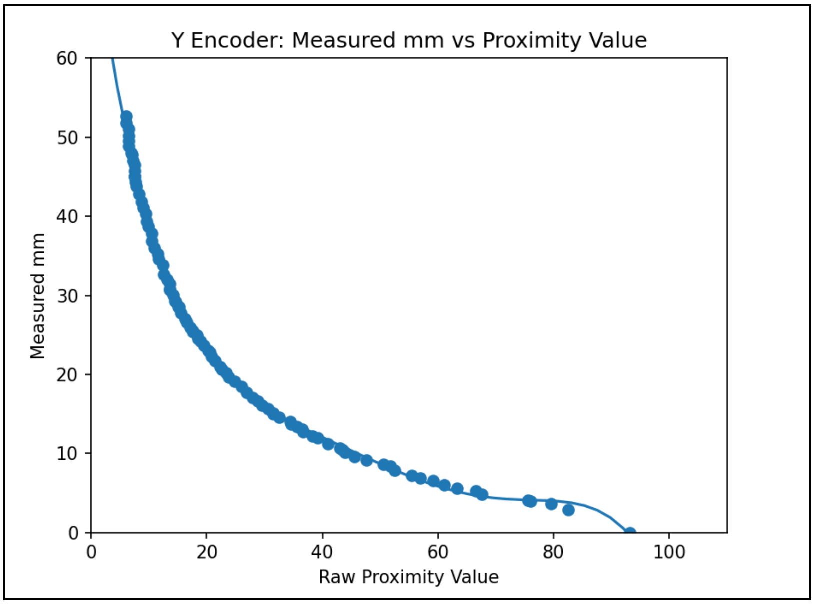


Figure 14: Y-Encoder Quadratic Model

Similar to the X-encoder, Figure 14 above shows the plot of the Y-encoder quadratic model, fitting the data collected. The equation for the model is defined below as:

$$Y_{dist} = (-1.484 * 10^{-7})x^{5} + (4.025 * 10^{5})x^{4} - 0.004x^{3} +.213x^{2} - 5.648x + 78.02$$

Using these models we can enable much more functionality in the device, being able to accurately move the device according to the Viper sensor's location through feedback control.

3.2.3 MPU-6050 Gyroscope

An additional step to provide feedback control for the device is utilizing the MPU-6050 gyroscope for attaining the roll, pitch, and yaw. Below in Figure 15, is an image of the MPU-6050 and Figure 16 shows an installed gyroscope on the ultrasound probe clamp.

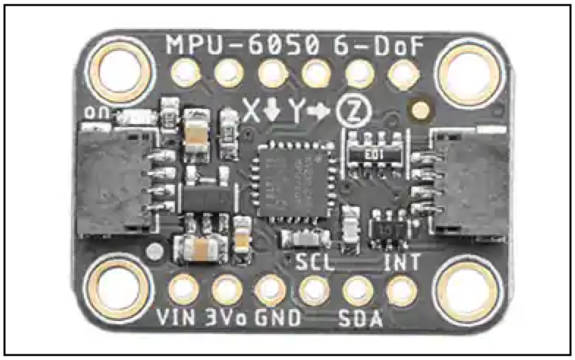


Figure 15: MPU-6050 Gyroscope

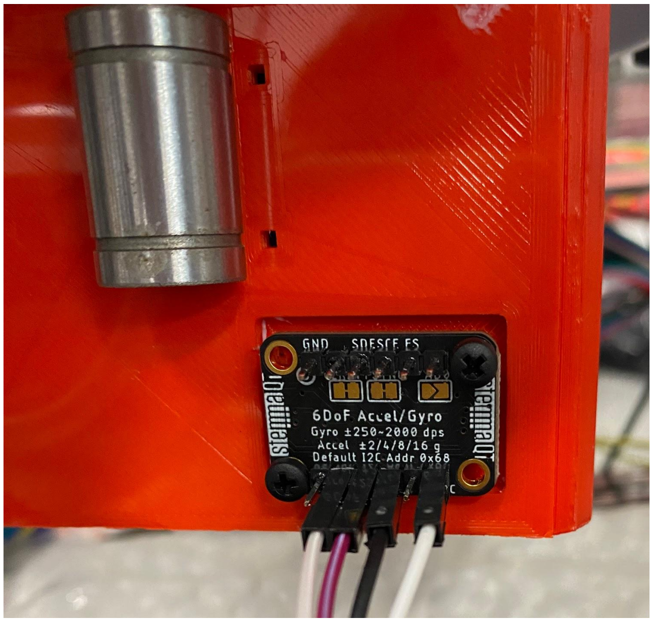


Figure 16: Installed Gyroscope

To run the sensor using python code, the Adafruit Circuit Python MPU-6050 library was used as the primary driver (Appendix D.C). In order to reduce uncertainty of the data from the gyroscope, a kalman filter or Linear Quadratic Estimation (LQE) (Appendix D.D). The code is able to output the corresponding angular measurements of the ultrasound probe when installed in the device.

3.1.4 Raspberry Pi Rewiring

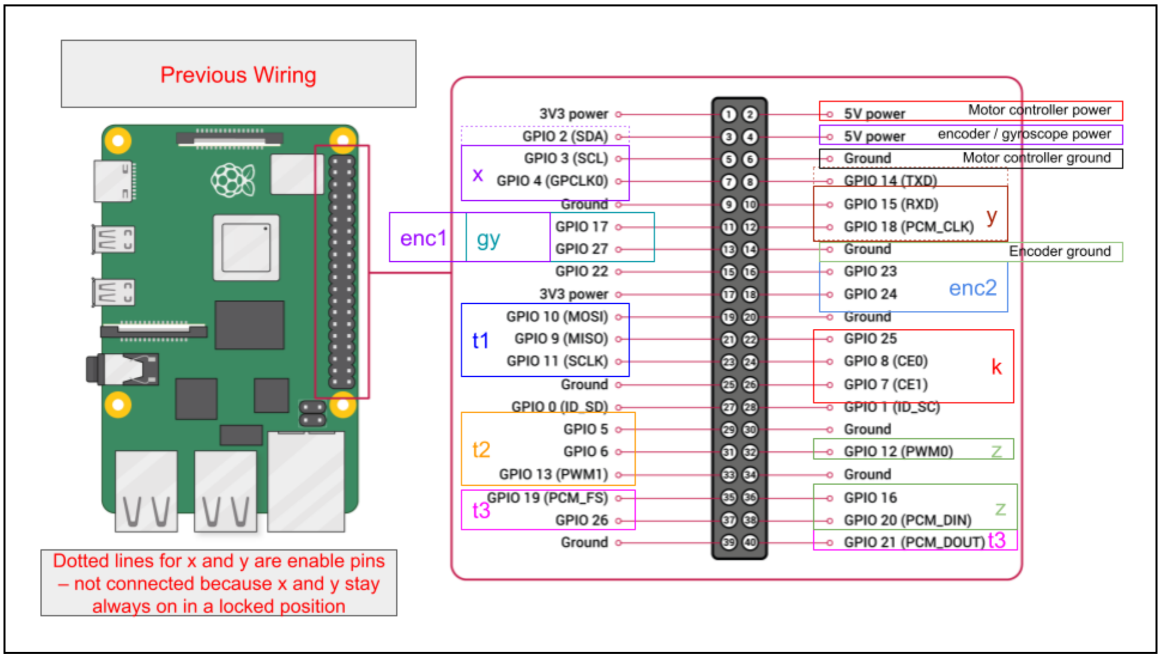
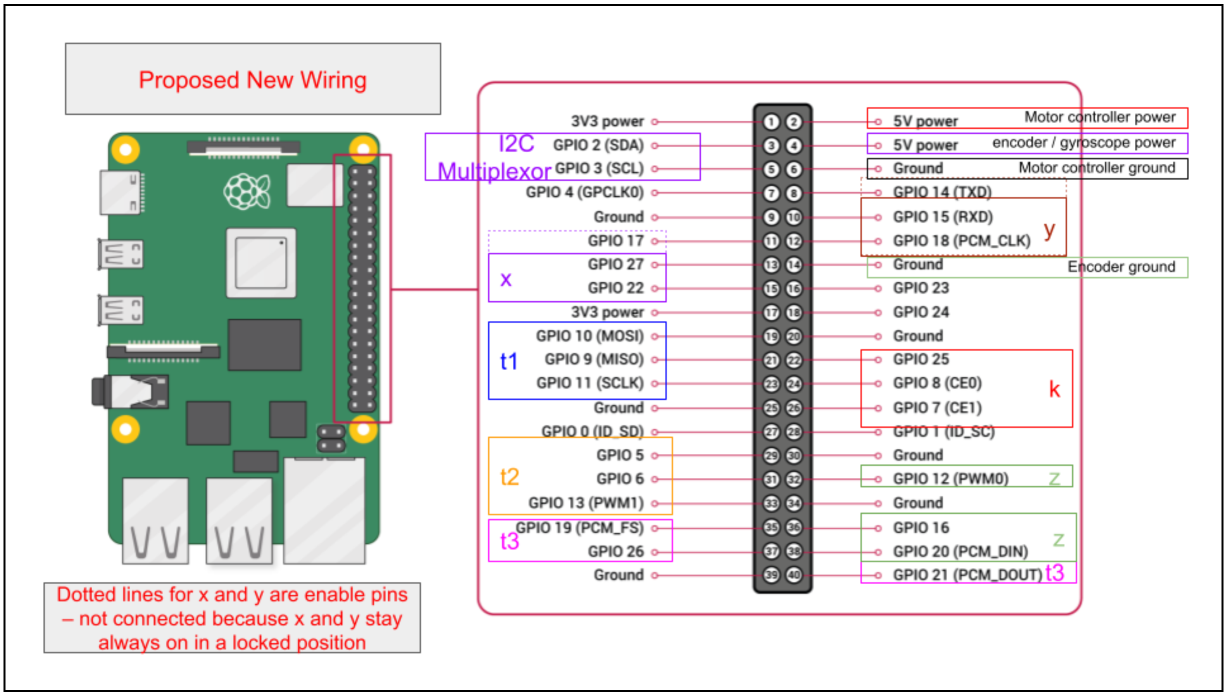


Figure 17: 2022 MQP Wiring

Figure 17 above shows the previous wiring detailed by last year's MQP team. Here the team had planned to utilize the Pi's GPIO 17 and 27 for the first encoder as well as the gyroscope. Also planning to utilize GPIO 23 and 24 for the second encoder and multiple ground pins for the sensors. While the Pi had these GPIO pins available, they had not taken into account the challenge of programming the GPIO pins to operate as a new inter-integrated circuit (i^2c) serial bus. The team had initially attempted to follow through with their previous wiring idea, however quickly found that the Pi's standard GPIO output-high does not reach 5V which these sensors require to function properly. This method would require not only additional coding, but also the addition of a logic-level shifting circuit.

In order to alleviate this problem and allow all sensors to properly operate the team decided to adjust the current wiring of the Pi. The Raspberry Pi already has dedicated pins (GPIO 2,3) which operate as SDA and SCL pins, with python libraries that utilize them. Because of these factors, it made sense to have the SDA and SCL pins transmit data.



Dotted lines for x and y are enable pins – not connected because x and y stay always on in a locked position

Figure 18: Updated Raspberry Pi Wiring

Figure 18 reflects this update, the x-axis motor controller moved from GPIO Pins 2,3,4 to GPIO Pins 17,27,22. In place of the x-axis controller is a new i^{2}C Multiplexor which enables all of the sensors to work on the SDA, SCL Pins (i^{2}C Bus). The team chose the Adafruit PCA9548 8 Channel STEMMA QT / Qwiic I2C Multiplexer as it was inexpensive and easy to acquire. The Figure 19 below shows the multiplexor in the device with the sensors and Pi interfacing.

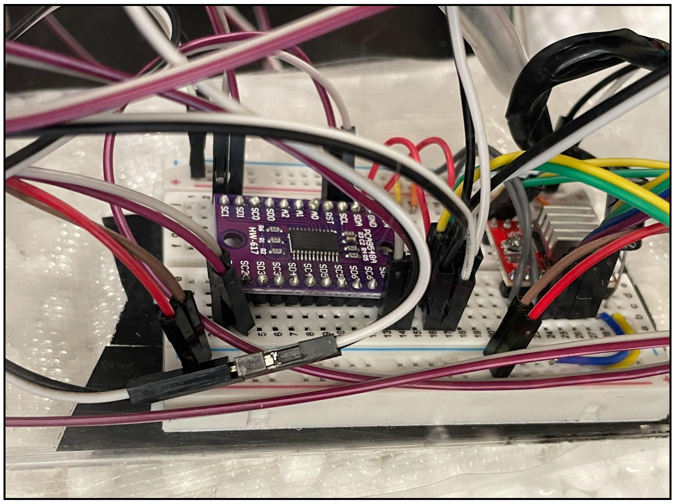


Figure 19: PCA9584 i^{2}C 8-Channel Multiplexor

3.1.5 Overall Design Adjustments

In addition to the major design advancements previously touched on in this section. There were some other design adjustments that were made in this iteration of the ultrasound device. To simulate the use of an actual ultrasound probe, a probe model was 3D printed to act as a controller for the sonographer, which can be seen below in Figure 20. It was designed to contain the Viper Sensor in the bottom hexagonal holder and has a button that can be used to start and stop data transfer from the sensor through the workflow to the device for movement.

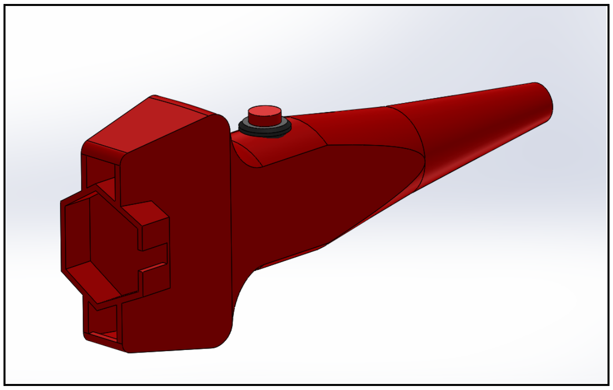


Figure 20: CAD model of motion-mapping probe controller

Additionally, design adjustments were needed to allow space for and to secure the new electronic implementation of the gyroscope and linear encoders. The probe clamp holder was redesigned to include an indented spot for the gyroscope to sit in to detect rotational motion of the probe. Housings were also designed and 3D printed to hold the encoders in place to detect motion in the x- and y-directions. These also included creating reference points which were also installed in the device to serve as a baseline distance for the encoders. Both of these mechanical design updates can be seen below notated on the full assembly in Figure 21.

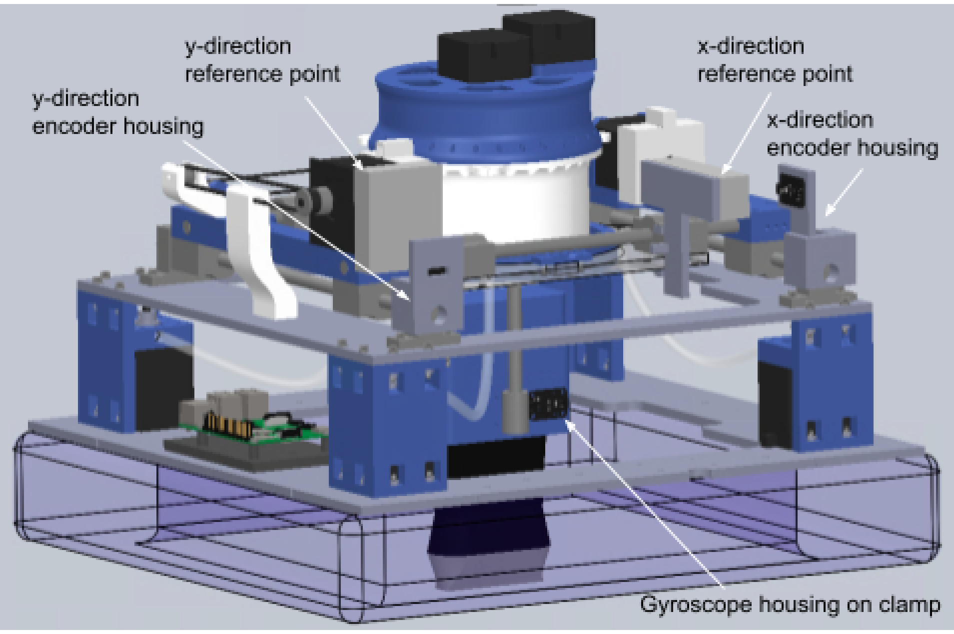


Figure 21: CAD model of final device with integrated sensors

4. Human Testing

This chapter discusses the human subject study that was planned by the team to test the designed device and its features and functionality. This aimed to serve as a proof of concept for both the design of this device and of the concept of a tele-operated ultrasound device.

4.1 Study Goals

The declared main goal of the study was to test the device and to confirm its usability and the device's ability to capture ultrasound imaging. The team also aimed to test the functionality of the innovative technology for ultrasound imaging conducted in a tele-operated way.

A protocol for testing the device was developed by the team following human subject study standards. All necessary restrictions were taken into account and the protocol was approved for use by the WPI Institutional Review Board (IRB).

4.2 Study Protocol

The study protocol was developed by the team to gather both sonographer and user experience data, as we aimed to test the device's ability to function using the new software capabilities. The study protocol was thoroughly developed to ensure that every safety precaution was taken while both effectively and equitably collecting data. A runthrough of the protocol is as follows below.

Prior to taking part in the study, the subject will be prepped by getting briefed on the device and how the study will take place then signing a consent form. The subject will then be asked to lay down and have either the ultrasound transmission pad or ultrasound gel put on their torso area.

The study will be conducted by placing the device on the subject's torso with the conforming contact supporting the device. The conforming contact is a vacuum sealing bag with plastic beads that conforms to the subject's torso. The device will then be calibrated in the z-axis to the point where the Clarius ultrasound probe is touching the subject's skin. Once the probe has made desired contact with the subject's skin, the device's operations will be tested through the use of the controller and the sonographer. The testing of the device will be done using the motion mapping control and the Viper Sensor, which will allow the sonographer to provide feedback on the controls and usability of the device's software during different movements that would be performed during a traditional ultrasound scan. These movements include different angles, a wide x-y range, and some different pressure values, not exceeding a 10 N force. At any point the subject is allowed to discontinue the scan if discomfort is felt, but steps have been taken to ensure that would not be the case.

Following the scan, the subject will be asked to provide feedback through the use of a Visual Analog Scale (VAS) that associates facial expressions to a 1-to-10 scale for several factors of the process. This participant survey can be found in Appendix G. The sonographer will also be given a survey to provide their feedback on the device and how the process went from their perspective. This sonographer survey can be found in Appendix H. Any feedback gathered can be used in further iterations of the device to make it more user-friendly for the sonographer, and also more comfortable for the subject, or patient in a real world application.

5. Discussion

The original end goal of this project was to test and calibrate the device with the help of a sonographer on a human person, allowing the sonographer to inform us on the new control system’s ease of use and to verify that the machine still worked as intended. Unfortunately, we were unable to get to the point in the project where we felt it would be beneficial to put the device on a human subject.

Our team ran into a series of problems on the software side that required more in depth code development and thus did not allow us to re-use as much code from the previous iterations as we had initially anticipated. By changing from a slide bar on a phone app to the VIPER sensor, we were required to start from the ground up again on creating a server to host all this new information. We were also hindered by the learning curve that came with understanding ROS enough to transfer data published on the /map topic into an html file that was able to live-update, and was also launchable as a server.

While we did have difficulties getting the machine ready to be used by a trained sonographer, we were able to successfully connect the VIPER sensor to a client on the Raspberry Pi. If this project is to continue, the next team would begin by testing out the connection between the IPC controller and the server to make sure the VIPER data was being transmitted correctly to the pose controller. From there, they could further calibrate everything to run smoothly and move on to human testing.

While we have set up all the sensors necessary for feedback control, there is still a need to thoroughly test it. As a consequence of running out of time on the controller, we were not able to fully integrate the feedback control with the pose controller. The current iteration of code successfully collects data from the laser encoders and gyroscope and sends it to the server. In conjunction with the VIPER data, feedback control is able to be implemented by comparing the expected location of the device with real-time data from the sensors.

6. Broader Impacts

This section of the paper will address the broader impacts of the project and its application in terms of engineering ethics, the societal impact of the device, and the economic factors considered in the larger distribution of the device that could occur at a later date.

6.1 Engineering Ethics

In every phase and aspect of this project we aimed to follow the code of engineering ethics set forth by the American Society of Mechanical Engineers. Upholding the fundamental principles of using gained knowledge for the advancement of human welfare, and striving to increase the competence and prestige of the engineering profession was paramount in the process and completion of this project. The team considered and honored the work done previously on the project by past teams, and worked to improve the functionality and design of the robot for its application as a teleoperated device.

6.2 Societal and Global Impact

In a large-scale application of the device, the potential societal and global impact can be massive for remote applications of ultrasound technology. A refined version of the prototyped device would have the ability to be deployed in any location around the world given there is access to electricity and internet access. A trained sonographer that has experience with this device would be able to provide important ultrasound screenings to communities and individuals who would be unable to access healthcare in person. This can be applied both in situations where the need is based on reducing accidental exposure to illness during pandemics, such as Covid-19 the original goal for this device, as well as to communities with reduced access to trained sonographers.

6.3 Economic Factors

In the development of this device economic factors need to be considered for the potential market of the product. The device itself is composed of various inexpensive and easily accessible components and constructed using 3D printed PLA and acrylic designed supports. In addition the device has low power consumption, with only the Raspberry Pi and AC power adapter requiring direct power where the device is located.

The original components and designs for the device are relatively inexpensive. However, the change of the controlling mechanism from a phone application to the Polhemus Viper sensor drives up the cost by a significant amount, costing upwards of $8,000 for the unit alone. Due to this, accessibility of the device can be limited by the number of sensors that are able to be acquired. In theory, however, a single viper sensor can be used to control an unlimited number of devices worldwide with proper pairing.

7. Conclusion

Ultrasonography is one of the most commonly used diagnostic imaging techniques worldwide, and some patients may not have the resources or abilities to attend a conventional appointment. This device was initialized in light of the COVID-19 pandemic in 2020 where its applications were undeniably strong. However, the development of a teleoperated ultrasound system with feedback control and motion mapping has the potential to improve access to proper scans in regions where medical resources are limited, in applications with bedridden or immobilized patients, and much more. Ultrasound examinations are highly dependent on trained operators, and this device reduces the need for so many of these sonographers. We have reviewed and highlighted previous similar efforts in this field, though these devices have varying degrees of freedom and will produce an ultrasound image of the patient, our device is groundbreaking due to its portability, compact size, 6 degrees of freedom, and exact position control by a trained sonographer. This remote range of motion and control can be useful to healthcare providers for important diagnostic tests.

Our team designed a new process for position awareness and alignment of the device. This iteration of the device is designed to be more easily operated and utilized by all parties. The device also performs more accurate motion tracking by calculating exact position coordinates and sending live feedback via position sensors.Technology such as this has been more widely used in medical applications, and our implementation of it into the device has propelled it to a new ability. The encoders track the position of the probe along the x and y axes, while the gyroscope monitors the device's rotational position and depth (z axis position). The VIPER sensor makes the control of our system much more accurate and intuitive than the previous iteration of this tele-ultrasound system. Our motion mapping and feedback control system uses these sensors and transfer functions between the input of the device (motion mapping coordinates from the remote operator) and its output (movement and position of the device). The system can then calculate the necessary adjustments to the probe's position and orientation.

7.1 Future Work

Many improvements were made to the device’s hardware and software components, but there is still room for further improvement in device functionality and aesthetics. The team realized that it is necessary that the sonographer be able to have feedback from the probe of the pressure being applied to a patient. An idea for implementing this would be through a pressure sensor on the device’s installed ultrasound probe which can both prevent the device from harming a patient by telling the motors to disengage in the direction the probe is pressing. This feedback would additionally help the sonographer ensure they are making adequate contact with the probe to produce a readable ultrasound scan.

Another potential improvement would be creating a resting place for the sonographer’s comfort in using the ultrasound probe controller to promote more intuitive positioning and orientation from the sonographer. This can be solved by using a surface with a pillow or foam where the sonographer can rest their elbow or body in order to maintain stability when performing an ultrasound scan.

Something that was not a focus in this project is the actual design of the device in relation to the human body. While the device was initially designed with sternum and stomach ultrasounds in mind, the inability for the device to perform scans comfortably on other parts of the body reduces the possible uses of the device. Last year’s team implemented the conforming body pillow which conforms to the subjects body, but additional improvements to the rigid construction of the device by increasing the range of motion can enable better chassis to be designed that allows for more diagnostic scans to be performed.

A problem that was frequently run into when booting up the server was that the IP address of the device hosting the server would change, and then the new IP address would need to be manually entered into all variable instances for the new IP. Creating a way to read and automatically fill in the IP of the device hosting the server would prevent future errors when the IP address of the computer changes. It would also make it easier to change the computer that is hosting the server, as the IP address would not be written directly into the code.

Another recommendation for future improvement is streamlining the startup process for each device. Currently there are multiple steps for each component of the startup procedure. Combining everything into a ROS launch file that can be run instead of typing in a series of individual commands would increase the speed and ease of turning the on the device.

One of the final improvements for the future of the device is streamlining the setup process for starting the device and having it run.

While the pose controller was successfully mounted to the server through an IPC connection, due to time constraints that connection was never thoroughly tested and calibrated to the robot. Currently, we are sending a ROS /tf message from the VIPER sensor, and calling those values in the pose controller. While the robot also did initially move, it now doesn't. Part of that issue could be that the numbers being sent are very small with a lot of significant figures. Adjusting the size of the values being fed into the pose controller could alleviate the small, jerky movements we experienced.

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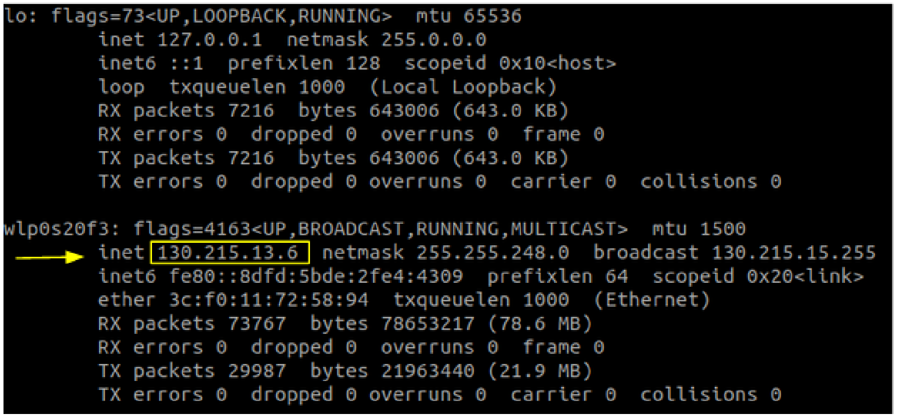
Appendix A: VIPER Sensor Startup Instructions

1. Make sure ROS Noetic is downloaded on your Linux Operating System
2. Configure the bashrc in every terminal you will be running ROS on using the
    a. **$ source ~/workspace_name/devel/setup.bash** command.
3. In the first terminal, run the command
    a. $ roslaunch polhemus_ros_driver start.launch
4. In the second terminal, run the command for Rviz visualization
    a. $ rosrun rviz rviz
5. In Rviz, click on the Fixed Frame dropdown and select polhemus_base_0
6. Choose to add a new Topic by clicking on the “Add” button and add the “TF” extension. This should allow you to visualize through Rviz the sensor node and the sensor home.
7. In a third terminal, you can run commands like **$rostopic echo /tf** to see the information coming from the sensor
    a. You can also use commands like **$ rostopic list** to see all the published topics.

Appendix B: Server Launch Instructions

1. On the same device that is going to run the VIPER Sensor, make sure that Node.js is installed. This is needed to launch the websocket server.
2. In a terminal, navigate in the Viper repo to where the "server.js" file is located and run the command **$ node server.js.** Where node is the command to run the server located in a file and "server.js" is the file name**.**
    a. If any file names are changed, you will need to go through the files and make sure that programs that call on each other (like "gui.html" and "server.js") are configured to the new names.
    b. If there are problems launching the server, make sure you have the correct IP address declared in the code files. To check your IP address, open a terminal window and type the command **$ ifconfig**.



```
lo: flags=73<UP,LOOPBACK,RUNNING>  mtu 65536
        inet 127.0.0.1  netmask 255.0.0.0
        inet6 ::1  prefixlen 128  scopeid 0x10<host>
        loop  txqueuelen 1000  (Local Loopback)
        RX packets 7216  bytes 643006 (643.0 KB)
        RX errors 0  dropped 0  overruns 0  frame 0
        TX packets 7216  bytes 643006 (643.0 KB)
        TX errors 0  dropped 0 overruns 0  carrier 0  collisions 0

wlp0s20f3: flags=4163<UP,BROADCAST,RUNNING,MULTICAST>  mtu 1500
        inet 130.215.13.6  netmask 255.255.248.0  broadcast 130.215.15.255
        inet6 fe80::8dfd:5bde:2fe4:4309  prefixlen 64  scopeid 0x20<link>
        ether 3c:f0:11:72:58:94  txqueuelen 1000  (Ethernet)
        RX packets 73767  bytes 78653217 (78.6 MB)
        RX errors 0  dropped 0  overruns 0  frame 0
        TX packets 29987  bytes 21963440 (21.9 MB)
        TX errors 0  dropped 0 overruns 0  carrier 0  collisions 0
```

Figure A-1: ifconfig IP Address Location Example

    c. If the server still does not work, it might be a problem with the WPI wifi, and you should try a hotspot to verify it is not a code issue.

Appendix C: Running the Client Instructions

1. On the Raspberry Pi, open a terminal and navigate into the tele-ultrasound repository.
2. run the “client.js” file.
    a. **$ node client.js**
    b. This should launch the pose controller and client together directly. Using commands, you can then view different elements of the data coming through.

Appendix D: Sensor Code Libraries

A. Linear Encoder Quadratic Regression Python Code

   https://github.com/nicklesscs/tele-ultrasound-2022/blob/main/encoder/EncoderTest/QuadraticRegression.py

B. Adafruit VCNL4040 Code Library

   https://github.com/adafruit/Adafruit_CircuitPython_VCNL4040

C. Adafruit MPU6050 Code Library

   https://github.com/adafruit/Adafruit_CircuitPython_MPU6050

D. Kalman Filter Library Code

   https://github.com/nicklesscs/tele-ultrasound-2022/blob/main/encoder/EncoderTest/Kalman.py

E. TCA9548 Multiplexor Code Library

   https://github.com/adafruit/Adafruit_CircuitPython_TCA9548A

Appendix E: Code Releases

1. Tele-ultrasound Repo
    a. https://github.com/nicklesscs/tele-ultrasound-2022/releases/tag/V3
    b. This repo contains the code to run the client side on the Raspberry Pi
2. Viper Sensor Repo
    a. https://github.com/nicklesscs/viper_sensor/releases/tag/V3.1
    b. This repo contains the code to run the VIPER sensor and the server

Appendix F: Informed Consent Form and Screening Questions

Informed Consent Agreement for Participation in a Research Study

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Institutional Sponsor:
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Worcester, MA | 01609-2280

Title of Research Study:
Tele-operated Ultrasound Machine

Introduction

You are being asked to participate in a research study. Before you agree, however, you must be fully informed about the purpose of the study, the procedures to be followed, and any benefits, risks, or discomfort that you may experience as a result of your participation. This form presents information about the study so that you may make a fully informed decision regarding your participation.

Purpose of the study:

The purpose of this study is to validate the safety and efficacy of a remotely operated ultrasound device that enables the positioning of an ultrasound probe on the torso of human patients for a torso ultrasound. It should be comfortable and safe for usage. The device is to be used for ultrasound diagnostics for patients who cannot undergo scans in a hospital setting. The device allows for at-home tests, improving COVID-19 safety. The device is shown in Figure A-2 and consists of a series of mechanisms enclosed in a safety encasing and with a cushion on the bottom of the device where the device will contact your torso while performing an ultrasound scan in the torso region.

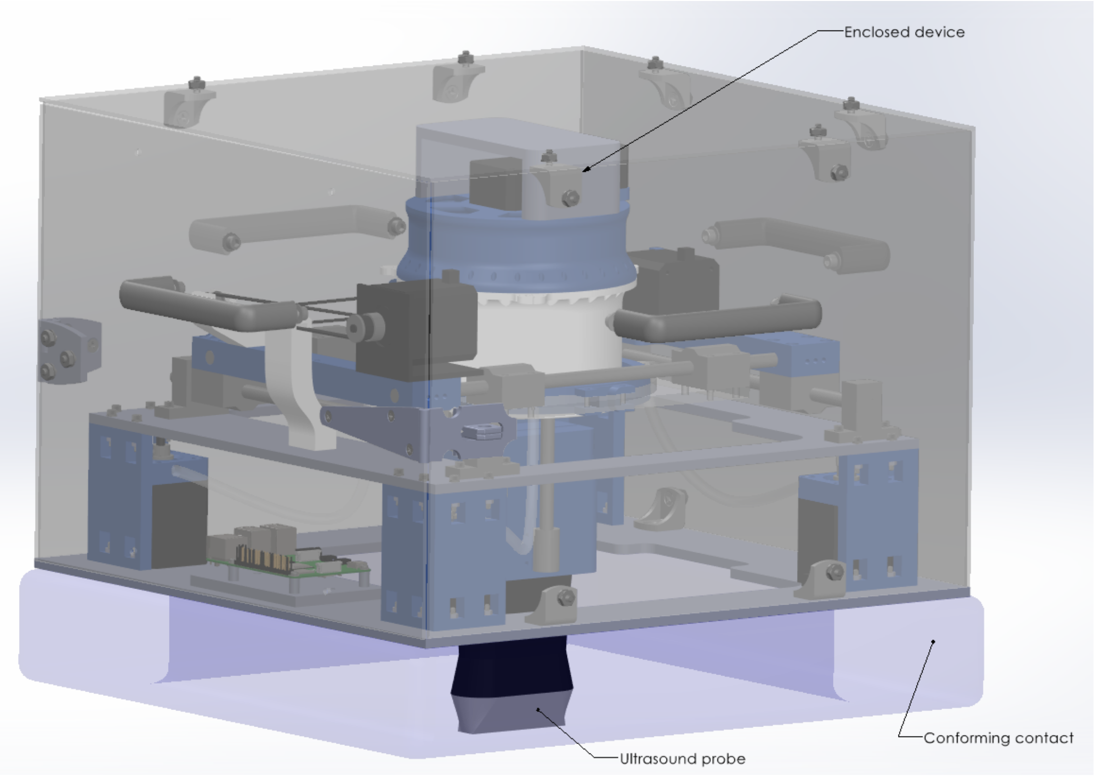

Figure A-2: Teleoperated Ultrasound Device

Why is this important?

An Ultrasound is an imaging method that uses sound waves to produce images of structures within your body. Ultrasounds are performed to help diagnose pain, swelling and infection of internal organs. The idea is to develop ultrasound technology that will decrease or eliminate the transmission of highly infectious viruses such as COVID-19. This technology will also help give access to ultrasound tests in remote areas. This study is being conducted to further evaluate the safety and validate imaging in normal subjects as a precursor to future research studies. The overall time commitment to the research study by you is about 30 minutes.

Duration of Trial

Preparation for the subjects (including consent form), preparation for the teleoperated device, ultrasound image acquisition, a participant survey, and a sonographer survey. Setup to insert the device probe inside the device, place the device on a subject's torso with the conforming contact, and start the controlling smart device takes around 5 minutes, and removing the device takes an additional 3 minutes. Including an average 6 minute ultrasound screening time leads to a under 15 minute total testing duration for a subject.

Procedures to be followed:

Upon entering the room, you will be asked to use hand sanitizer and cover your face with a mask provided. You will also be asked to sign this consent form. The device and procedure will be presented and explained to ensure there is no confusion during testing. Safety procedures and measures will be discussed including the use of the emergency stop button and proper testing behaviors by the subject.

You will begin the study by lying flat on a bed with your shirt rolled up or removed to the extent of the subject's comfortability, in order to allow access to the torso. A standard hospital-grade towel will be given to you to be draped over your chest, if needed, during the entire procedure to assure privacy and modesty. Ultrasound gel may be applied to the first area on the torso surface, but it is likely that the scan will be performed with an ultrasound transmission pad directly attached to the probe that will not lead to any material deposited on the skin. You will be given verbal instructions throughout the study. As mentioned above, the sonographer will repeat the same protocol without the assistance of the robot.

The device will be placed onto your torso by you with the help of the investigators. The conforming contact will be activated by vacuuming out the air and closing a valve. The device will be turned on, it will be calibrated and motor processes will be run. The device will be tested via ultrasound scan on the torso by the sonographer. It will be teleoperated by an experienced and certified sonographer to generate ultrasound images. The image captured will be displayed on a nearby phone screen. This image will be reviewed to ensure that the device is capable of capturing a correct ultrasound image and any incidental findings will be shared with the participant.

There is generally little or no discomfort that occurs during a regular torso ultrasound scan. The discomfort, if any, is usually from the ultrasound probe moving over the ribs. The study team will be by your side evaluating and recording this information. Both you and the sonographer can immediately stop the robot at any time using the emergency stop button.

Periodically you will be asked the level of discomfort as you would if you went to the doctors to describe pain on a scale from 0-10. This scale is called a Visual Analog Scale or "VAS" for short. For example, the number 0 would indicate no pressure or pain, the number 1 would indicate very little pressure or pain, and the number two would indicate slight pressure or pain, the number 3 would indicate mild pressure or pain, and so forth up to the number 10, which is unbearable pain. We would never want anyone to experience more than an acceptable amount of discomfort that would occur during a routine ultrasound study, so the imaging in that region will be terminated if we reach a VAS > the number 4, which "hurts a little." This level of pain is the maximum you would experience during a routine ultrasound study. As mentioned above, the study team will be by your side, closely monitoring you and the device. You may terminate the study at any time.

Following the conclusion of all testing, you will be presented with a questionnaire that asks you about your experience.

Procedure for the collected results:
Given that the study is indeed performing medical imaging, it is possible that incidental abnormal findings may be found, even in healthy test subjects. If this occurs with your ultrasound scan, the certified sonographers will present you with the details of the ultrasound and recommend steps to follow-up with a certified physician/medical expert.

Risks to study participants:

- You will have the ultrasound device placed on your body restricting your movement for the duration of the test. It weighs around the same as a heavy textbook. During the test, the ultrasound probe will apply no more than 10 Newtons to the torso area. The pressure applied by the ultrasound probe may potentially be uncomfortable, however the device is incapable of applying dangerous levels of pressure.
- The device may become unstable and move around during testing. This can result in the device falling off your body, falling forwards or backwards, or distributing weight uncomfortably on certain parts of the body.
- The device has moving components that may be a pinch hazard if dangerous behavior (putting one’s hand inside the device during operation) occurs.

- The device uses 7 motors enclosed in a small box. This can potentially result in the device becoming hot and overheated. In the event that this occurs, the device will be shut down and allowed to cool down.

COVID Risks & Minimization

- If possible, we will limit the number of times you have to come to a research site. Ideally, you will only visit the research site one time unless more information must be collected. In this case, you will be contacted and asked if they would like to participate.
- We ask every research participant if they have the symptoms of COVID-19 or have been in close contact with anyone who has or had COVID-19.
- We will email you the day before and ask you if you have symptoms; we will also ask you at the beginning of the study visit and we'll take your temperature using a no-touch thermometer.
- We will clean and disinfect the area and device using disinfectant wipes for each participant.
- Due to the nature of the study, study staff will be within 6 feet of the participant multiple times throughout the duration of the study to ensure the safety and proper function of the device.
- You will wear a face mask during the visit, and study personnel will be using appropriate PPE, including a face mask, gloves, face shield, and eye protection, as appropriate.
- All areas where you visit will have hospital-approved hand sanitizer available in the area.
- We are following the current clinical guidelines for cleaning rooms and equipment. The device contact area and the device will be cleaned after each study. The mat cover will be disposed of and replaced after each use.

Benefits to research participants and others:

The participant will be able to experience a new robotic ultrasound diagnostic platform. The participant will also see ultrasound images of their torso.

Patent Disclosure:

Patent protection may be requested for this device. The results of this study would be used as proof of concept for the device in this capacity. No identifying information would be used for this purpose.

Record keeping and confidentiality:

This study will capture and analyze ultrasound images along with recording answers to the provided survey. A video camera will be used to stream position of the ultrasound probe to the sonographer, and the video will not be stored, unless the participant consents to the recording of the stream. Identifying marks and internal incidental findings will be securely kept for our patients, however, this information will not be used for participant identification or in our reports/publications. All participant information will be stored on a password-protected database to which only the study investigators will have access. All data will be shared and discussed between participating investigators after the tests are complete. Your identity will remain confidential. Records of your participation in this study will be held confidential so far as permitted by law. However, the study investigators, the sponsor or its designee, and, under certain circumstances, the Worcester Polytechnic Institute Institutional Review Board (WPI IRB) will be able to inspect and have access to confidential data that identify you by name. Any publication or presentation of the data will not identify you.

Please indicate by checking this box if you consent to the probe positioning video stream being recorded and stored securely by the team: ☐

Compensation or treatment in the event of injury:
In the event of injury, you are expected to provide your own medical treatment.

Cost/Payment:
There is no cost to participate in this study. You will not be paid or otherwise compensated for your participation.

For more information about this research or about the rights of research participants, or in case of research-related injury, contact:

Principal Investigator: **Yihao Zheng**
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Human Protection Administrator: Gabriel Johnson
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- Email: gjohnson@wpi.edu

Your participation in this research is voluntary. Your refusal to participate will not result in any penalty to you or any loss of benefits to which you may otherwise be entitled. You may decide to stop participating in the research at any time without penalty or loss of other benefits. The project investigators retain the right to cancel or postpone the experimental procedures at any time they see fit.

By signing below, you acknowledge that you have been informed about and consent to be a participant in the study described above. Make sure that your questions are answered to your satisfaction before signing. You are entitled to retain a copy of this consent agreement.

You do not give up any of your legal rights by signing this statement.

(To be signed on the day of the study)

_____________________________________ Date: ___________________
Study Participant Signature

____
Study Participant Name (Please print)

_____________________________________ Date: ___________________
Signature of Person who explained this study

Robotic Tele-Ultrasound Pre-Health Screening Questions

Please circle the answer that applies to you.

1. Are you pregnant? **Yes** **No**
2. Have you tested positive for COVID in the past 7 days? **Yes** **No**
3. Do you have any of the following:
    a. Chest Pain? **Yes** **No**
    b. Abdominal Pain? **Yes** **No**
    c. Breathing problems? **Yes** **No**
    d. Chronic cough? **Yes** **No**

Name:_________________________

Signature:___________________________

Date: ______________________

Appendix G: Participant Survey

WPI Tele-operated Ultrasound Machine MQP Project

Participant Survey

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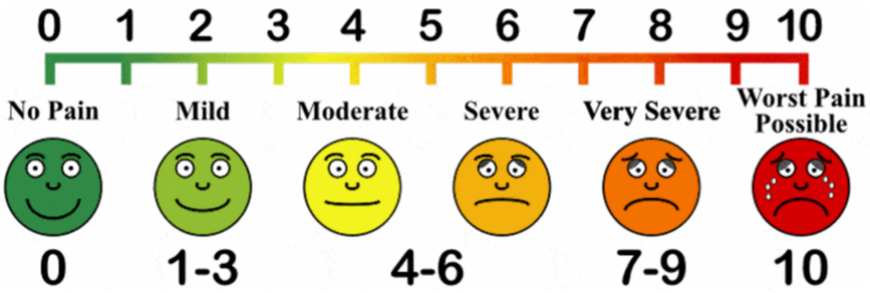
Investigator: Madeline Brady (mabrady@wpi.edu)
Investigator: Tianyang Gao (tgao2@wpi.edu)

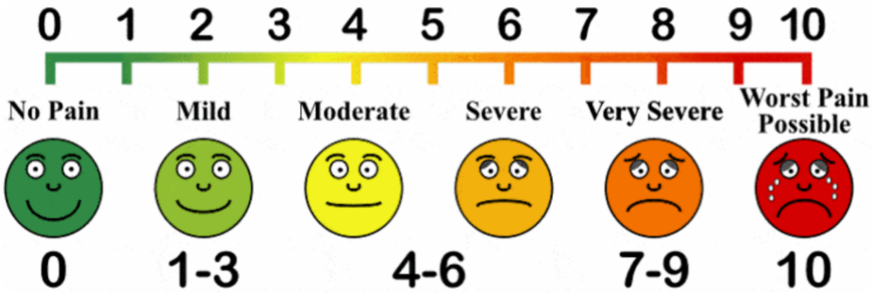
Post-trial Participant Survey

For questions with the Visual Analog Scale (VAS) of pain (questions 1-5), please circle the number that is closest to the pain experienced during the trial.

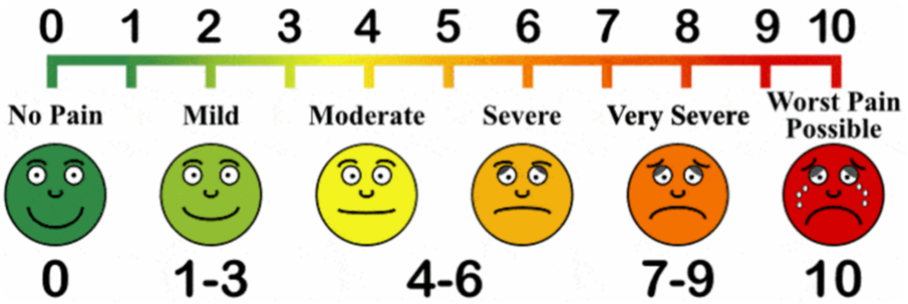
1. How would you rate your comfort level **overall** while the test was being operated?



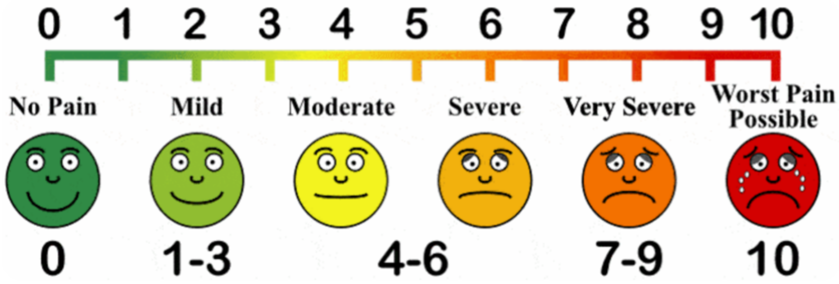
2. How would you rate your comfort level from the **weight of the device** while the test was being operated?



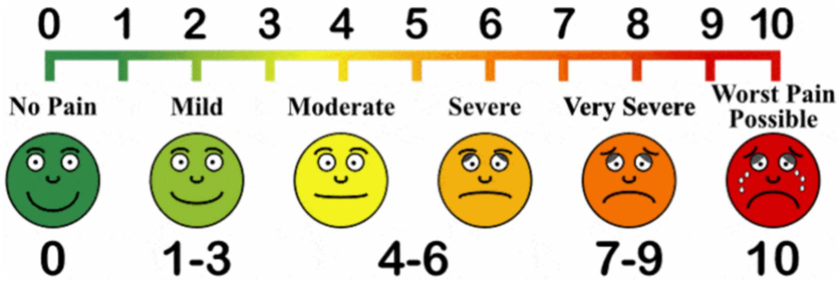
3. How would you rate your comfort level from the **contact pressure applied to the skin** of the ultrasound probe while the test was being operated?



4. How would you rate your comfort level from the **conformity** (how well the device fits to your torso) while the test was being operated?



5. How comfortable were you in **maintaining the position** and orientation of the device?



6. Did you at any point feel like you could not continue with the test?

   Yes No

   a. If the answer is yes, explain why in a few sentences or bullet points.

7. Do you feel comfortable placing and using this device on a close family member who may be old or pregnant?

   Yes No

   a. If the answer is no, explain why in a few sentences or bullet points.

8. Have you ever had an ultrasound test before?

   Yes No

   a. If the answer is yes, how does this device compare to a test done by a human?

9. With no knowledge of the effectiveness of this device, how confident are you of the device to do an equal or better job than a hand-operated ultrasound probe?

1	2	3	4	5
Not confident at all	Not confident	Neutral	Confident	Very Confident

Why?

Appendix H: Sonographer Survey

WPI Tele-Operated Ultrasound Machine MQP Project

Sonographer Operator Post Scanning Survey

Project Advisor: Professor Yihao Zheng (yzheng8@wpi.edu)

Investigator: Abbey Blauser (ablauser@wpi.edu)
Investigator: Christopher Thomas (chthomas@wpi.edu)
Investigator: Elizabeth Viveiros (eeviveiros@wpi.edu)
Investigator: Madeline Brady (mabrady@wpi.edu)
Investigator: Tianyang Gao (tgao2@wpi.edu)

Please rate the following sections comparing the tele-operated robotic scan and hand-held scan. Provide comments to support your ratings (up to two can be circled, (i.e., fair-to-good)

1. Maneuvering the probe

1	2	3	4	5
Bad	Poor	Fair	Good	Excellent

Comments:

2. Two dimensional image quality

1	2	3	4	5
Bad	Poor	Fair	Good	Excellent

Comments:

3. Diagnostic accuracy

1	2	3	4	5
Bad	Poor	Fair	Good	Excellent

Comments:

Please rate the following sections for the tele-operated scan ONLY (up to two can be circled, (i.e., fair-to-good)

1. Maneuvering the probe

1	2	3	4	5
Bad	Poor	Fair	Good	Excellent

Comments:

2. Two dimensional image quality

1	2	3	4	5
Bad	Poor	Fair	Good	Excellent

Comments:

3. Diagnostic accuracy

1	2	3	4	5
Bad	Poor	Fair	Good	Excellent

Comments:

Additional Questions

1. What was it about the device that worked well?

2. What did you like most about the device?

3. What was it about the device that DID NOT work well?

4. What did you dislike most about the device?

5. How widely accepted would a tele-operative device of this design be in the medical community?

6. Would you use the tele-operative device on the pregnant or older person in its current design?

7. What areas of the tele-operative device need to be most improved to be more functional?

8. Overall, did the tele-operative device work well, acceptable, or did it not work well?