MEASURECT

A Device to Non-Invasively Measure Erectile Function in the Male Spinal Cord Injury Population

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BME 474: Medical Device Design

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2 PROBLEM STATEMENT

We will design a device to noninvasively measure the degree of penile rigidity in male spinal cord injury (SCI) patients between the ages of 18 and 40 to quantify erectile function. Tests will be done over a period of approximately two hours in a sedentary state.

3 BACKGROUND

3.1 ANATOMY AND PHYSIOLOGY OF ERECTILE EVENTS

The penis consists of two chamber types, membranes, veins, and connective tissues. A cross-sectional view is provided below in Figure 1. The main chambers involved in erectile events are the two large corpora cavernosa (CC) and the corpus spongiosum (CS). Each of these chambers is surrounded by tunicae albuginea which place limits on their expansion.

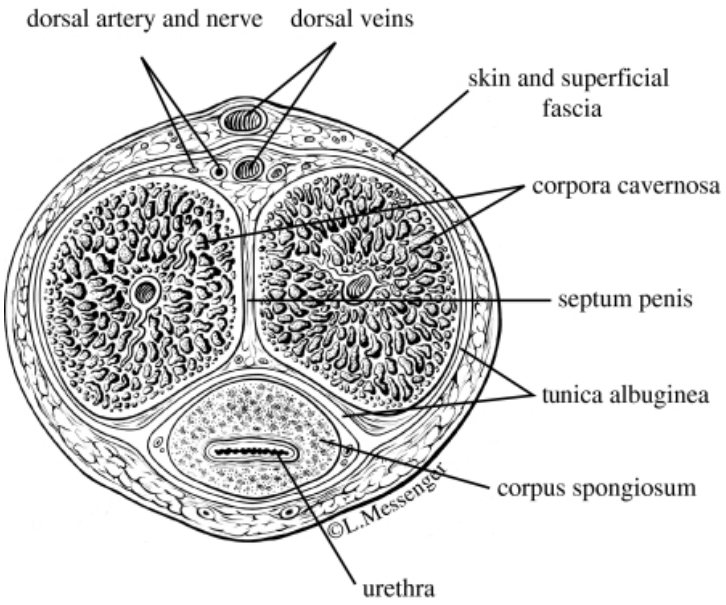


Fig. 1: Penile cross-section (Padma-Nathan, 1999)

An erection is defined by the presence of adequate rigidity to avoid the buckling of the penis during intercourse (Jannini, 2009). For an erectile event to occur, the brain must send a signal through the parasympathetic nervous system via the spinal cord to release nitric oxide (NO) (Goldstein; 1995; Saenz de Tejada, 2004). NO relaxes the smooth muscles in the CC, enabling them to expand with increased blood flow into their lacunar spaces (Goldstein, 1995; Saenz de Tejada, 2004; Udelson, 2007). The spongy erectile tissue of the CC expands significantly while the CS provides greater resistance to expansion to prevent excessive forces upon the urethra (Nout, 2007). Expansion occurs concomitantly with the constriction of venous outflow resulting in blood containment, penile enlargement, and rigidity (Udelson, 2007). The stages of erectile events are characterized by their increases in baseline intracavernosal pressure (ICP) and intraspongiosum pressure (ISP) and summarized below in Table 1. (Bernabe, 1999; Schmidt, 1995). Traditionally, monitoring of ICP has been considered the gold standard for evaluating erectile activity.

Table 1: Six Phases of Erection Response (Moncada, 1999)

Phase of Erection Response	*Characterization*
Flaccid	Baseline ICP assumed to be slightly greater than central venous pressure
Latent	O_2 partial pressures increase
Tumescence	Rapid increase in ICP to reach equilibrium mean systolic arterial pressure
Full erection	Increase in ICP to nearly systolic pressure
Rigid erection	Increase in ICP to suprasystolic level
Detumescence	Rapid fall of ICP to baseline levels

3.2 ERECTILE DYSFUNCTION

Erectile dysfunction (ED), as defined by the International Consultation on Sexual Medicine, is the consistent and recurrent inability to acquire or sustain an erection of sufficient rigidity and duration to engage in satisfactory sexual intercourse (McCabe, 2016). Prevalence of ED is positively correlated with age as multinational studies have found a fourfold increase of ED in men in their 70s compared to men in their 20s (Feldman, 1994; Rosen, 2004). Classically, the causes of ED have been clustered into two categories, psychogenic and neurogenic. Psychogenic ED involves cases where the individual may have difficulty in becoming sexually aroused, with the brain consequently failing to send a signal to the CC (Udelson, 2007). Psychogenic ED is associated with anxiety, guilt, depression, or conflict around various sexual issues (Ende, 1990). In contrast, neurogenic ED involves cases where the brain is willing but unable to send a signal as the result of physical problems (Udelson, 2007; Ende, 1990). Neurogenic ED is often the case of SCI ED (Shridharani, 2016). The exact mechanism of an erectile event that is disrupted by SCI is not known, but it is speculated to involve an inability of the spinal cord to relay signals.

3.3 RELATIONSHIP BETWEEN SPINAL CORD INJURIES AND SEXUAL FUNCTION

When surveyed, the male SCI population reported that sexual function deficits were one of their top issues affecting their quality of life post injury with their primary reason for pursuing sexual activity being for intimacy needs rather than fertility (Alexander, 2009; Anderson, 2007). These deficits included erectile and ejaculatory dysfunction as well as decreased fertility (Biering-Sorensen, 2001). Their erections are often short-lived and lack the rigidity required for penetration but are easily initiated (Kreuter, 1996). Both the diagnostic and therapeutic landscape for ED in the male SCI population are limited by the lack of quantitative measures. The current clinical landscape is primarily surveys which are weakened by issues with self-reporting and assume the patient has a sexual partner, which is not always the case with the SCI population. The most used survey is the Five-Item Version International Index of Erectile Function (IIEF-5), included in the appendix (Rosen, 1999).

3.4 EXISTING PRODUCTS AND SOLUTIONS

Sexual function research began to take off in the early 1970s with invasive sexual function measurements in animal models (Nout, 2007; Shamloul, 2008). A typical model of this type done by Steadman, et al. in 2019 involved implanting a telemetric pressure catheter in the right proximal shaft of the CC (Steadman, 2019). This methodology is not popular for use in humans given that it involves invasive surgery, so devices have been developed to attempt to quantify erectile events non-invasively.

The RigiScan device was introduced in 1985 as the first device to provide portable at home recordings of nocturnal penile tumescence and rigidity (NPTR) at the tip and base of the penis (Bradley, 1985). The functionality of the device is based on the idea that if NPTR measurements are obtained then the cause of ED is neurogenic rather than psychogenic, an idea that has never been definitively demonstrated (Meisler, 1990). The RigiScan records penile deformation to a fixed squeezing force (radial compressibility) which is then translated to an arbitrary radial rigidity value (Bradley, 1985). However, significant controversy has emerged over time over the accuracy, reliability, and usefulness of the RigiScan (Elhanbly, 2018; Udelson, 1999). The device struggles from a poor correlation between radial compressibility and axial buckling as well as cost and relatively poor reproducibility (Jannini, 2009; Chen, 1999). In one study the RigiScan was found to have 81% sensitivity and 82% specificity (Karadeniz, 1997).

To try and correct for the errors in radial measurements, the Digital Inflection Rigidometer (DIR) was patented in 1993 to measure penile axial rigidity (Barbara, 1994). To operate the device, the patient presses the device against their own penis and recordings are taken when inflection occurs, corresponding to the maximum rigidity at that time (Barbara, 2011). The DIR was found to correlate well with IIEF-5 diagnoses but did not take off or truly enter the clinical landscape due to high patient discomfort (El-Sakka, 2003). A complete erection rigidity assessment device would need a combination of axial and radial rigidity through uses of devices like the RigiScan and DIR to increased cost and inconvenience (Zheng, 2012).

Ultrasound technology has become widely used for clinical imaging of ED. Color doppler ultrasound has been used to analyze temporal changes in penile blood flow, but tumescence alone provides an incomplete picture of erectile function (Huang, 2007). In the past couple of years, promising studies have applied shear wave elastography (SWE) to ED via measurements of CC penile rigidity (Zhang, 2015; Inci, 2017; Cui, 2018; Lee, 2020).

3.5 SHEAR WAVE ELASTOGRAPHY

SWE is a safe, non-ionizing, and non-invasive technique to obtain stiffness measurements without manual compression. By emitting highly focused short-duration acoustic radiation forces, shear waves are produced which propagate perpendicular to the direction of tissue displacement (Nightingale, 2002). Shear wave velocity (SWV) values are positively correlated with major mechanical properties indicating material rigidity such as Young's modulus assuming the material is a linear, isotropic, and elastic body (Palmeri, 2005). The propagation of shear waves is determined by the stiffness of the tissue with stiffer tissues resulting in faster SWV (Nowicki, 2016). SWV can be related to Young's modulus using the following equations (Sigrist, 2017):

$$c_s = \sqrt{\frac{G}{\rho}} \quad (1)$$

$$E = 2(v + 1)G \quad (2)$$

$$E = 3G = 3\rho c_s^2 \quad (3)$$

Assumptions for the above conversion for penile rigidity include that the tissues are homogenous and that shear wave speeds are on the order of magnitude of 1-10 m/s, the standard approximation for soft tissue (Taljanovic, 2017). Because of the high water content of soft tissues, the Poisson's ratio is near 0.5 and the density of penile tissue is assumed to be 1.01-1.06 g/cm^3, the standard density for soft tissues (Sigrist, 2017; Park and Lakes, 2007).

4 SPECIFICATIONS AND CONSTRAINTS

After defining a problem statement and completing research on the relevant physiology and medical technology present in the field of male sexual dysfunction, we began to develop a list of needs we aimed to satisfy through our solution. These needs and their prioritization were based on a combination of independent research and from discussion with our client Dr. Casey Steadman. The needs are listed as follows ranked from highest priority (1) to least priority (9).

1. Device is safe to be used on human patients
2. Device is comfortable so that it does not interfere with natural erection
3. Device provides quantifiable measurements of erectile function for a minimum for the duration of the clinical test
4. Device should be noninvasive/minimally invasive
5. Device should measure changes in stiffness during erectile event
6. Device should be portable between lab rooms
7. Device's data should be accessible on a lab computer
8. Device can be used on multiple patients
9. Device can be used by a researcher in the field

To rank the user needs from highest to lowest priority each need was first ranked individually from a score of 1-5, with a score of 5 indicating the highest importance. We discussed as a team how to rank the needs with the same score. Needs receiving a higher priority were those which without the device would not be usable. Our highest priority was the safety of the device. Any device that could cause potential harm to a patient should not be used under any circumstance. We also prioritized the ability of the device to take measurements of the penile stiffness. Addressed in the second need, a device that lacks comfort and restricts the patient's natural physiology would have no use given that the application of the device is to measure the penis during an erection event. Needs like portability and administration were ranked lower. While a non-portable device could cause inconvenience, it would not prevent the required data from being collected. Similarly, while it is ideal that any researcher in the field should be able to administer this device, if due to safety concerns only select individuals could use the device this would not prevent the usability altogether.

After developing needs-based characteristics, we began mapping needs to testable constraints for our solution. As each design specification was developed, we ensured that it mapped back to one of the nine user needs addressed previously. Competitive values were taken from the Rigiscan, Digital Inflexion Rigidometer, and from invasive surgery results previously performed by Dr. Steadman. The marginal value was selected based on discussions with Dr. Steadman as to what the minimum required value necessary to still have a useful device were. The design specifications are listed along with their related competitive value, marginal value, and ideal value in Table 2.

Table 2: Design Specifications

User Need	**Design specification**	**Competitive value**	**Marginal value**	**Ideal value**
Device provides quantifiable measurements for duration of the clinical test	Battery life	8 hours (RigiScan)	2 hours (length of clinical test)	≥24 hours
Device measures changes in stiffness	Resolution (95% CI)	Scaled value(not actual reading)	100 data points over the range	1000 data points over the range
Device can be used by a researcher in the field	Ease of use	7/10	5/10	8/10
Device should be portable between lab rooms	Transportability	Can be carried without use of a cart, weighs less than 10 lbs	Can be wheeled in a cart from room to room, weighs less than 250 Ib with the cart	Can be taken home by subjects
Device should be accessible on a lab computer	Storage/Transmission	3 sessions (24 hours) of stored data that can be exported to computer (RigiScan)	1 session (2 hours) of stored data that can be exported to computer	Real-time telemetry
Device is safe to be used on human patients	Use of the device will not cause harm to the patient	Non-invasive (RigiScan) Requires surgery for use (Steadman paper)	Does not cause significant harm during length of expected use (2 hours)	Does not require surgery for use, biocompatible
Device can be used on multiple patients	Sterile use by multiple patients	Disposable plastic cover over components	Disposable components that are easy to replace	Autoclave
Device provides quantifiable measurements	Sampling	Every 15s (RigiScan) 50 measurements/s for 5s at a time (DIR)	Every 10s	Every 2s

Device is safe to be used on human patients	Patient Data Protection	Each patient assigned a number identifier	Compatible with the encrypted database that Duke stores its research on, Palmeri mentioned in class	HIPAA compliant
Device is comfortable so it does not interfere with natural physiological processes	Level of Comfort	4/10 (Rigiscan due to bulk)	5/10 (comfortable for 2 hours)	7/10 (comfortable for 5 hours)
Device measures erectile stiffness	Circumference Measurement Bounds	9 - 13 cm	10 - 12 cm	7 - 15 cm
Device provides valid measurements	Shear Wave Velocity Readings*	0.79-2.79 m/s	0.1-5 m/s	0.1-10 m/s
	Maximum Tension Sustained			

* The shear wave velocity readings specification was added after we decided to pursue a solution using ultrasound technology

Of the many device specifications developed, some of the key specifications were the level of comfort, the resolution, and the sampling rate. The level of comfort mapped back to the second highest priority need from the needs list. Because the device measured a natural physiological process of the body that may have been compromised due to spinal cord injury, it was extremely important that the device would not further compromise this process by causing discomfort. The resolution and the sampling rate were also important specifications as those were brought up specifically by the client. Resolution especially was an important specification for our client given the poor resolution of the RigiScan.

5 FINAL DESIGN TECHNICAL DOCUMENTS

Our final mechanical design is a semicircle attachment. We chose this design because of its compatibility with either a linear transducer along with longitudinal axis or a curved transducer along the axial plane, giving us the freedom to experiment with different ultrasound transducer designs. In addition, the design distributes stress well along the body, protecting the electrical components within. Finally, the semicircle attachment has a simple form factor, making it easy to 3D print or rapidly prototype, while also having a secure attaching mechanism of strapping around the penis. The semicircle attachment provides a robust, blank canvas for the later integration of the ultrasound interface.

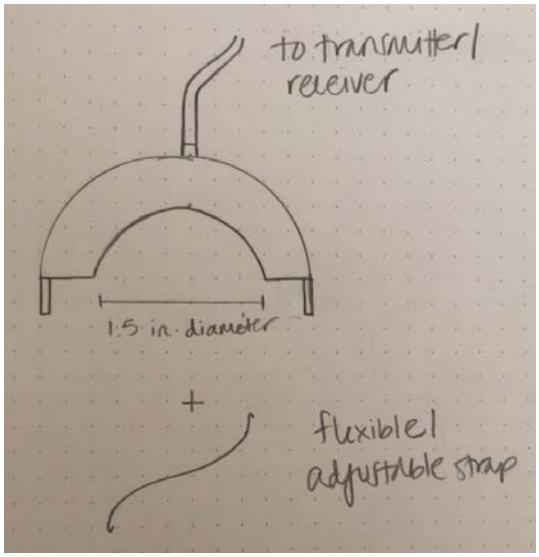


Fig. 3: Sketch of final design

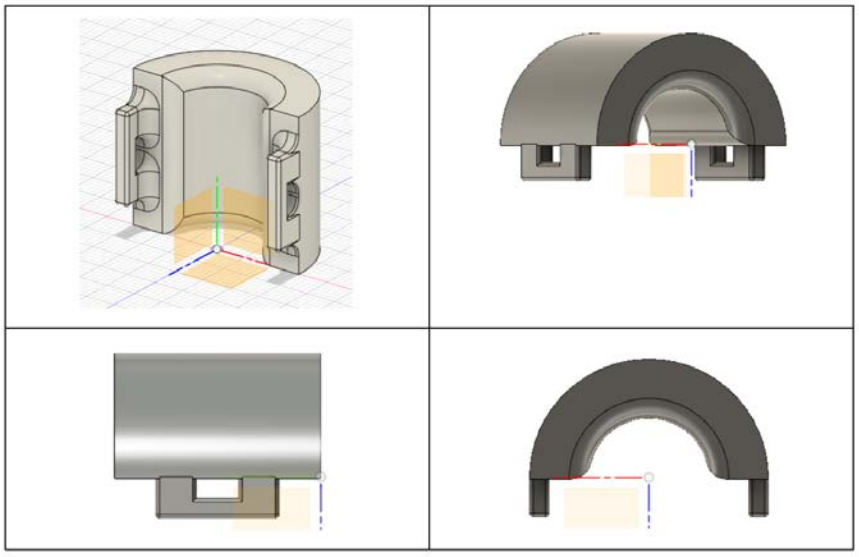


Fig. 4: CAD renderings of final design

6 LABOR & BILL OF MATERIALS (LBM)

An estimated LBM is included below in Table 3. Due to the significant amount of R&D required to develop the device being proposed in this report, most approximations are provided as their minimum estimate.

Table 3: Estimated Labor & Bill of Materials

Process Step	*Material*	*Quantity*	*Cost at Full Scale ($)*	*Number of People*	*Duration of Task (hr)*	*Cost (minimum)*
Attaching probe to patient	Gel	1	0.327	1	0.25	$0.327
	Single-use strap	1	3.33	1	0.25	$3.33
R&D and production for probe	Linear transducer	1	5000+	4	100+	$5000
	Backing	1	500+	4	75	$500
	Electronics (hardware)	1	5000+	4	100+	$5000
	Electronics (software)	1	500+	4	75	$1000
Manufacturing housing	Unknown	1	--	4	--	--
Software design and V&V	Python, text editor	1	--	4	--	--
Patient data protection	Python, text editor	1	--	4	--	--
TOTAL						TBD

7 FAILURE MODE AND EFFECT ANALYSIS (FMEA)

A preliminary FMEA was created to identify potential failure modes and their causes, effects, probability of occurrence, and consequences. Based on this analysis, plans were drafted to mitigate risks. A condensed FMEA worksheet is included below in Table 4. Hazard risk index scores of 17 to 20 are acceptable without review, 10 to 16 are acceptable upon completion of quality assurance review, 6 to 9 are undesirable with written and reviewed decision required to proceed, and 1 to 5 are unacceptable.

Table 4: Failure Mode and Effect Analysis

Potential Failure Mode	*Cause*	*Effects*	*Risk Index*	*Mitigation Plan*
Ultrasound gel dries out.	Method dependent: gel valve/probe valve is not airtight.	Decrease in signal quality. Study ceases.	11	Ensure the design for the coupling is airtight. Gel must retain moisture for at least 2 hours.
Air bubbles become trapped between the probe and skin.	Method dependent: air was not properly sucked out of pouch before gel insertion.	Decrease in signal quantity. Study ceases.	14	Develop a proper vacuuming protocol if the gel pouch method is used.
Probe movement during measurement.	Probe not secured properly prior to imaging.	Decrease in signal quantity. Study ceases.	9	Generate a method of securing the probe to the coupling interface. Possible securing methods include adhesive or mechanical.
JSON file does not transfer to desktop.	Bandwidth is too low; computer has limited storage; resolution of computer	No data transferred to desktop; cannot collect valid data	14	Include test checks on GUI that the user can perform to ensure that data is transferring the expected amount and expected type.
Device waterproofing is insufficient or there is damage to protective cover.	Inappropriate waterproofing: ultrasound gel or ejaculate contact electrical components.	Electrical shock.	10	Perform verification testing for waterproofing/sealing.
Failure to import data from MATLAB.	Failure of interface between GUI and MATLAB.	Procedure delayed or stopped until data can be imported.	11	Verification testing of interaction between GUI and MATLAB.
An unauthorized party gains access to patient data.	Failure of patient data protection.	Patient confidentiality could be compromised.	14	Implement methods for protecting patient data (i.e. passcodes, encryption).
The inappropriate patient's data is accessed,	Failure of patient data protection.	Patient confidentiality could be compromised.	14	Implement methods for protecting patient data (i.e. passcodes, encryption).

imported, or exported.				
Failure to export to LabChart.	Failure of interface between GUI and LabChart	Procedure delay or stop until data can be exported.	11	Verification testing of interaction between GUI and LabChart.
Failure to export as a CSV.	Failure of interface between GUI and local storage.	Procedure delay or stop until data can be exported.	11	Verification testing of interaction between GUI and local memory.
Device becomes contaminated and unsterile.	Insufficient sterilization or sterile barriers.	Device is not usable for multiple patients.	10	Sterilize device in between uses. Include cheap removable coverings in between uses.
Probe generates excessive heat.	Heat output is outside of acceptable ranges or cooling mechanism is insufficient.	Probe causes patient discomfort or tissue damage.	10	Verify heat generation is within acceptable standards. Verify cooling mechanism if necessary.
Device does not turn off.	Wires shorted between switch and power.	Overheating; damage of device long term	10	Ensure that wires are insulated with nonconductive coverings to prevent wire shorting.
Device does not turn on.	Switch is shorted; insufficient power; not connected to power source	Cannot take measurements: device is non usable	10	Determine power required for full machine before and provide supply necessary to handle this.
Device interferes with other medical equipment in the room.	Drawing too much current; taking up too much space on the network.	Device is unusable in a setting where other technologies will be used: limits use case and hinders usability	15	Make sure the device complies to the relevant standards when connected to wall power or the wireless network.
Body hair inhibits accurate SWV readings.	Hair on the skin traps the air underneath it, presenting an obstacle to ultrasound measurement.	Ultrasound image quality decreases: patient monitoring ceases.	9	Shave hair off from affected area. Make sure to tuck hair away from area where the probe will be applied.
Patient moves during imaging.	Penile tissue grows and curvature increases over course of erectile event.	Ultrasound image quality decreases.	7	Place probe in region least likely to move upwards during event (base).

Covering of the probe is damaged.	Could get chipped from collision with metal or dropped to floor	The device could shock the patient.	8	Test smoothness during production and before use.
Probe causes skin abrasion.	Probe covering is not smooth or is damaged.	Patient skin discomfort or injury.	10	Test smoothness during production and before use.
Probe fires continuously.	Hardware malfunction or imaging parameters inappropriately defined.	Probe overheats causing patient discomfort or injury.	8	Verification of hardware. Include user instructions or guides related to measurement parameters.
Probe falls out of alignment.	Coupling mechanism between probe and gel fails.	Measurements might be compromised. Procedure delay or stop until probe is realigned.	9	Verification testing of coupling mechanism in various sedentary and mobile states.
Sufficient contact with skin cannot be achieved.	Too much or too little gel is used.	Procedure delay until an appropriate amount of gel is applied or removed.	11	Include detailed instructions about ultrasound gel quantity and use.

8 TESTING TO SPECIFICATIONS

8.1 PLANNED TESTING TO SPECIFICATION

Due to the remote nature of the project, some of the planned testing to specifications never had a chance to happen. The planned tests are detailed below.

8.1.1 Test: Probe Can't Harm the Patient

To ensure our device will not harm the patient, several tests were planned to be performed with the ultrasound probe. The first would be to measure heat given off by the ultrasound probe while in use, the device would fail the specification if it got to a temperature outside of our specified range. The second test would be to measure the voltage on the surface of the probe while in use, the device would fail the specification if the voltage exceeded a specified threshold. Finally, the parts of the device touching the patient would be tested for biocompatibility, which would entail making sure the materials selected are compatible with human skin.

8.1.2 Test: Transportability

To ensure our device could easily be transported, our planned test was to weigh the device to ensure it is below 50% of maximum occupational lifting.

8.1.3 Test: Sterile Use by Multiple Patients

It was necessary to ensure our device would be sterile for patients to use, an important consideration for medical devices. Our devised test was to coat the device in paint that glowed under ultraviolet light, follow the sterilization protocol, apply it to a simulated patient surface, take it off after two hours, and then see if any part of the simulated patient surface had paint on it by shining an ultraviolet lamp over it.

8.2 OCCURRED TESTING TO SPECIFICATION

The testing to specification that we were able to perform are shown below.

8.2.1 Test: Maximum Tension Sustained

The system was tested to detect potential mechanical failure modes. The displacement and stress at the handles and center of the semicircle attachment was too high, so further filleting was done to reduce stress buildup. The simulation results for the first iteration of the design are shown in Figure 5 below.

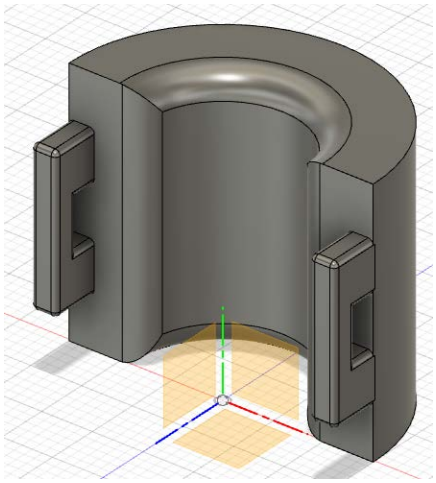
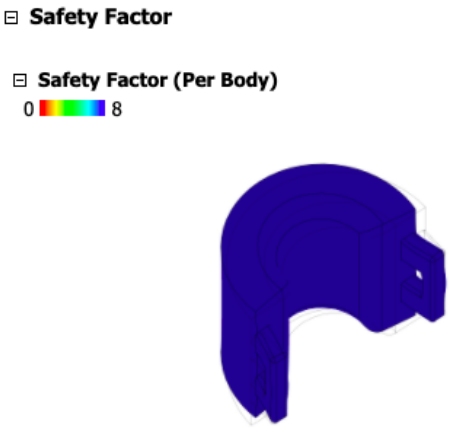
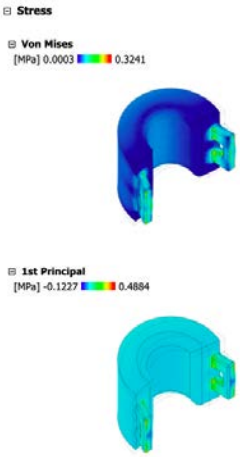
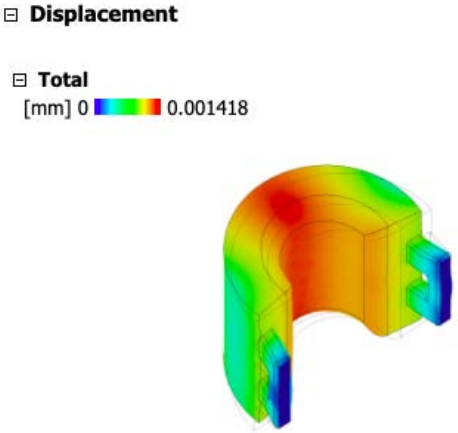
	
Revised CAD of semicircle attachment	Safety Factor Simulation
	
Heatmap A of Stresses Location on Body	Heatmap B of Stresses Location on Body

Fig. 5: Simulation results for original model

The simulation results for the revised CAD model demonstrate that these fillets improve the design because there is less stress at the handles and less displacement where the transducer would be placed, in the center of the arc. The transducers must be protected from stress, because they are not stress resistant. The revised CAD model's rendering and simulation results are shown below in Figure 6.

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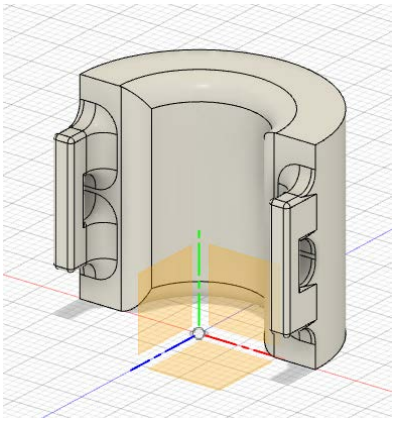
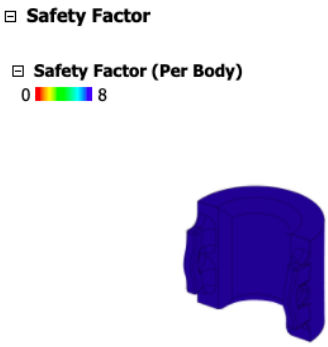
<tr><td>  </td><td> 
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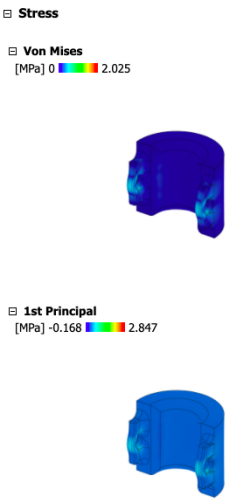
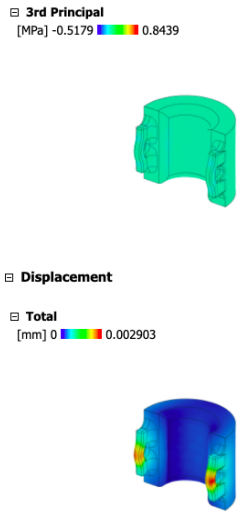
<tr><td> 
</td><td> 
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<tr><td>Heatmap A of Stresses Location on Body</td><td>Heatmap B of Stresses Location on Body</td></tr>
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Fig. 6: Simulation result for revised model

8.2.2 Test: SWV Readings, Resolution, and Sample Rate

To test the accuracy of shear wave velocity values to predict stiffness, we planned to image PVA phantoms. We would compare the predicted stiffness based on the measured SWV values to the actual stiffness of the phantom, measured with a durometer.

To ensure our planned design meets the specifications of being able to read SWV values, have a sensitive resolution, and a sufficiently high sampling rate, we tested an ultrasound system with the help of PhD students working in the Wolf Lab. We confirmed that ultrasound systems can measure SWV in a sufficient resolution and can sample at the necessary rate (1 sample / 10s) for our application. That testing is depicted below in Figure 7.

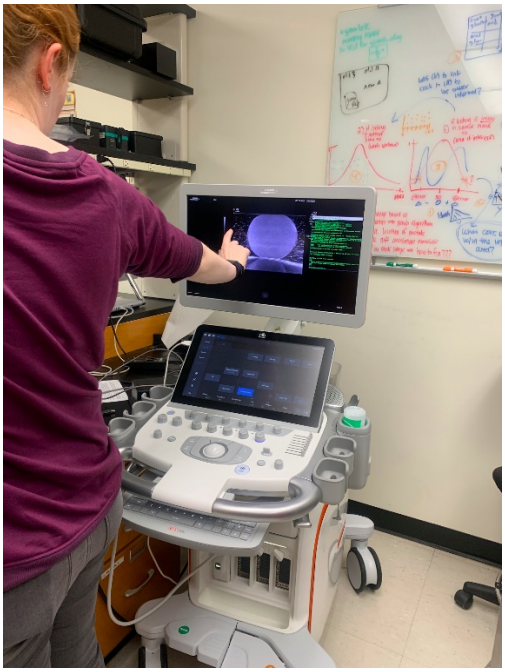
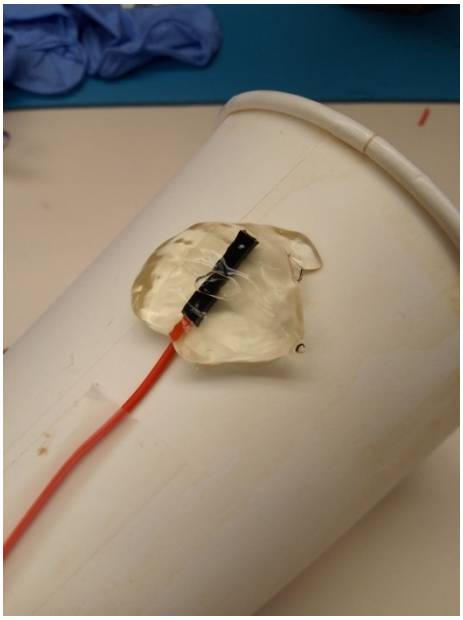
	
Live ultrasound demonstration	SWV heat map shown for square tissue regions

Fig. 7: Photographs from live ultrasound demonstration

8.2.3 Test: Device Provides Valid Measurements

For the ultrasound device to provide valid measurements, we had to meet the specifications that the coupling mechanism chosen keeps the gel moist, doesn't leak the gel, keeps the probe in place, and doesn't have air bubbles between the probe and the skin for 2 hours. Several designs were tested, and the winning design is shown below. The Tegaderm IV Patch meets all of the specifications. After 24 hours, the gel was still moist, no gel had leaked, and there continued to be no air bubbles between the probe and the skin. Photographs of the Tegaderm IV Patch testing are included below in Figure 8. The results of testing for the other coupling options are included in the appendix.



U/S gel applied to probe

No air bubbles between probe and ‘skin’

Fig. 8: Photographs from Tegaderm IV Patch testing

8.3 Software Testing to Specification

Given the lack of sample data and the lack of a chosen method for storing data, test scripts for the user interface and data processing workflow were not implemented. However, the proposed protocols and plans for unit and system testing are described below. Relevant tools for unit testing and code style are Pytest and PEP8, respectively.

8.3.1 Test: User Interface and Clinical Data Handling

Planned testing for the GUI script includes testing for button presses, menus, and user inputs. For button presses, unit testing would determine if a button press successfully directed the user to the next desired step. A list of the planned unit tests for button presses is shown below:

- Enter → does pressing the Enter button prompt the software system to receive the information in the window?
- Import Data → does pressing the Import Data button prompt the software system to move to the relevant submodules for importing data from the ultrasound system?
- Calculate Rigidity → does pressing the Calculate Rigidity button prompt the software system to move to the relevant submodules for calculating rigidity?
- Export Data → does pressing the Export Data button prompt the software system to move to the relevant submodules for exporting data?
- Refresh → does pressing the Refresh button prompt generation of a list of patient files in the session menu?
- Graph → does pressing the Graph button prompt the software system to move to relevant submodules for graphing data?
- Close → does pressing the Close button successfully terminate the GUI session?

For menu selections, unit testing would determine if a highlighted menu item successfully accepted user input. A list of the planned unit tests for menus is shown below:

- Export Options → does selecting an item in the drop-down menu save the user input and direct the user to the right exporting submodules?

For input windows, unit testing would determine if a user input is successfully recorded. A list of the planned unit tests for input windows is shown below:

- Input Window:
    - Does the window recognize and raise an error for missing input?
    - Does the window recognize and alert for new users?
    - Does the window recognize and alert for existing users?
    - Does an existing user ID with existing patient files allow the user to access these files?

A list of planned unit tests for calculations and conversions is shown below:

- Does the rigidity calculation function accurately convert shear wave velocity (SWV) to rigidity?
- File conversions:
    - Does the file conversion script successfully convert the patient's files to .csv files?
    - Does the file conversion script successfully transfer patient files to LabChart?

8.3.2 Test: Patient Privacy

At the forefront of this project's ethical considerations is ensuring patient privacy. Below is a list of proposed tests to ensure that patient privacy is protected throughout the entire clinical workflow.

- Does the system ban access to the user interface and patient files unless a valid user ID is entered?
- Does the system terminate after being idle for a prolonged amount of time to avoid allowing unauthorized access?
- Does entering a patient ID retrieve only the corresponding patient's information and files?
- Are a patient's files removed from the user interface when a new user or patient ID is entered?

8.3.3 Test: Data Processing

Planned testing for data processing included using tools such as Mockaroo to generate JSON files with the format expected from the ultrasonic workstation. This data processing workflow was developed exclusively for the research and development setting. The capability of the Raspberry Pi (a stand-in for the ultrasonic workstation) would be tested by validating that data from Mockaroo could be transferred to and stored onto the Raspberry Pi and then later transferred to a CPU to analyze and store the data. The scripts required to test this process are listed below.

1. Script for checking that there is data stored at the expected location of the Raspberry Pi after transfer
2. Script for checking that data stays stored at the correct location when the device is powered off
3. Script for checking that data is not deleted from Raspberry Pi until it has been transferred to the CPU
4. Script for that data is available on the CPU after a transfer has been initiated on the Raspberry Pi

9 DESIGN ITERATIONS

This section will illustrate all brainstormed solutions, present decision matrices for major solutions that were selected, discuss engineering drawings and schematics for prototypes, and discuss testing protocols and results for low- and mid-fidelity prototypes that directed design decisions.

9.1 MIND MAPPING

To actualize a solution to measuring penile rigidity in male SCI patients, we started by first determining physiological responses affected by penile rigidity that could be measured. After determining these responses, the team searched for existing technologies that could measure these responses. These responses are displayed in yellow text boxes in Figure 9. It was determined that the most direct measurement of rigidity was through internal pressure measurements of the ICP. However, getting internal pressure readings was only possible via invasive surgeries, failing our design specifications, and was therefore removed from consideration. For this reason, we chose to research and began iterating through designs that indirectly measured penile rigidity such as external pressure, blood flow perfusion, muscle contraction, size, and force.

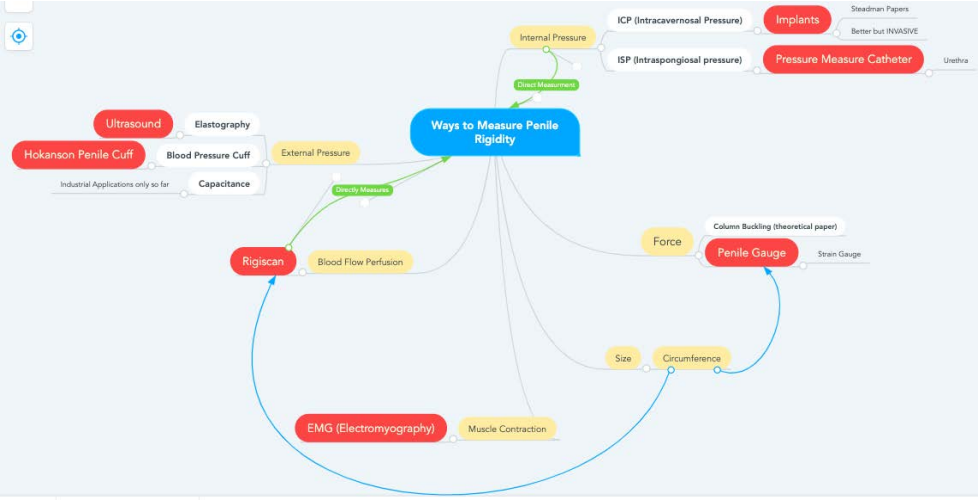


Fig. 9: Brainstorming mind map of quantifiable physiological responses that measure penile rigidity

9.2 BRAINSTORMING SOLUTIONS

9.2.1 Axial and Radial Rigidometer

When investigating possible methodologies for measurement, we determined three plausible solutions that utilized pre-existing technologies. The first solution combined the technology of the RigiScan to measure radial rigidity with the DIR which measured the axial rigidity as displayed in Figure 2. While the RigiScan claimed to directly measure penile rigidity, studies had proven that the radial measurement was not sufficient in determining true rigidity and ability to achieve intromission. For this reason, we proposed a solution that incorporated both axial and radial rigidity measurements to determine a rigidity value via a novel algorithm. The proposed design is depicted in Figure 10.

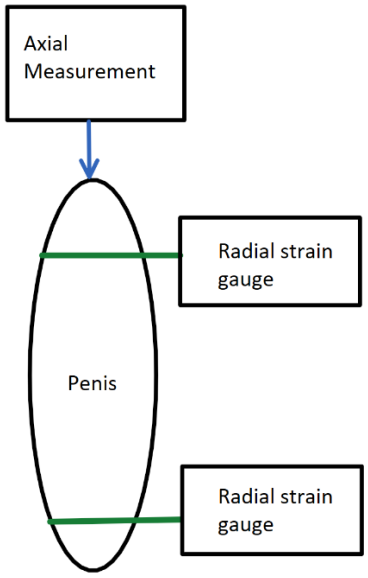


Fig. 10: Radial and axial rigidity measurement solution

To provide some context about the RigiScan and the DIR, their mechanisms will be explained. The RigiScan gathers data using two inflatable rings around the base and midshaft of the penis. In our planned device, the RigiScan is being modelled by the two green circles, marked ‘Radial Strain Gauge’. The RigiScan’s inflatable rings contract until they exert a specified force on the penis. The measured radial penis stiffness is inversely proportional to the degree of contraction of the RigiScan.

The DIR, modelled in Figure 11, also works through the exertion of physical force on the penis. The DIR operator exerts an axial force on the penis and can see the force exerted on a display. The DIR operator continues increasing the axial force until the penis buckles or they reach the DIR’s maximum force of 3500 grams. The DIR can detect the penis buckling by detecting a change in the direction of the force, this is shown in Figure 3. The DIR was an intriguing prospect to us because it directly measures penile axial rigidity, which is the best metric for assessing stiffness.

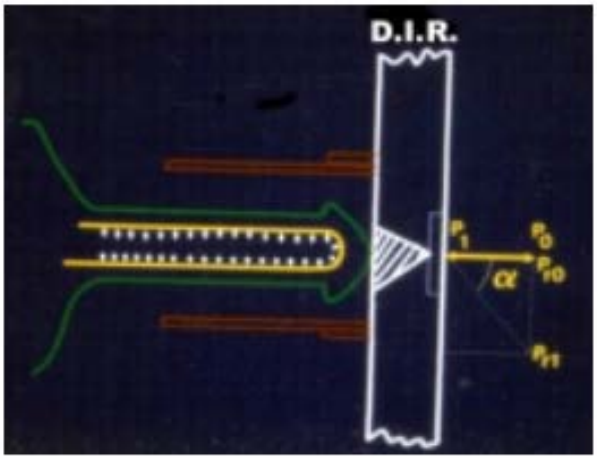


Fig. 11: DIR mechanism (Barbara, 2000)

9.2.2 EMG + Radial Strain Gauges

The second proposed solution, shown in Figure 12, takes measurements from two of the physiological responses affected by penile rigidity, blood perfusion and muscle contraction, and proposes to construct an algorithm to quantify their overall rigidity from these two readings. One huge advantage of this design is that both the strain gauge and the EMG have been validated and used before throughout sexual medicine literature. They have been confirmed to accurately measure the blood perfusion (strain gauge) and the muscle contraction (EMG). When the penis is erect it becomes engorged, it inflates due to the increased amount of blood perfusing inside. The increase in blood flow can be detected by the strain gauge. Another physiological phenomenon tied to the erection is the contraction of the muscles, which is a key component to the stiffness of the penis. The EMG detects the electrical impulses that direct muscles to contract, tracking this phenomenon. However, both measurements are indirect measurements of stiffness as they only directly track the physiological effects of muscle contraction and blood perfusion. These two physiological effects combined can be used to indicate the ability of the penis to maintain an erection, which relates to but does not directly quantify its stiffness.

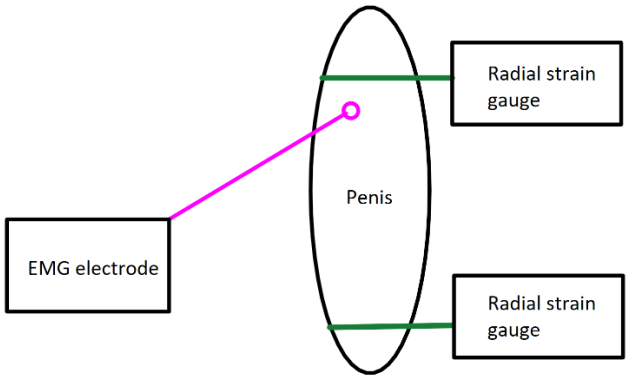


Fig. 12: EMG + radial strain gauge design

9.2.3 Ultrasound Measuring SWV

The final proposed solution utilized an ultrasound probe to measure the shear wave velocity through the penis. The ultrasound probe would utilize ARFI technology and require pre-existing image analysis technology to determine rigidity from shear wave velocity. Like the second solution, this solution utilized pre-existing technology although it required some modifications for this particular application. A coupling mechanism for holding the ultrasound and minimizing noise would need to be designed for this design.

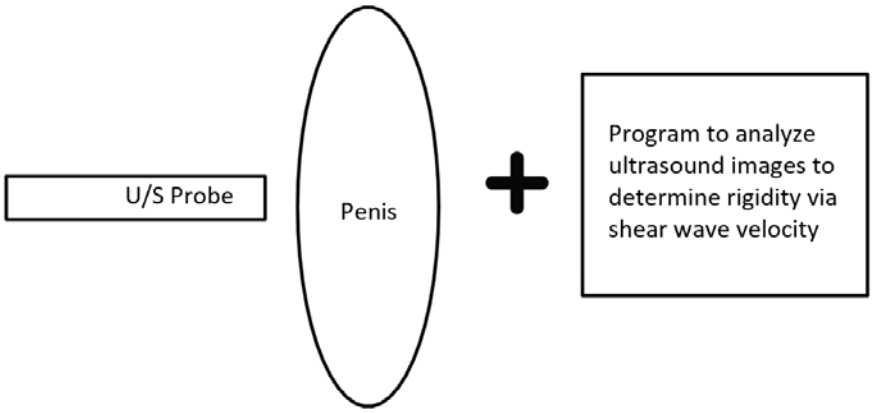


Fig 13: Ultrasound measuring SWV design

9.3 LOW-FIDELITY PROTOTYPES

9.3.1 Ultrasound Solutions: DIY SWV and Existing Ultrasound

Low fidelity-prototypes were then designed from the previously identified solutions to help in the process of selecting a final design option. The use of ultrasound technology was actualized into two different low fidelity prototype concepts. The first was similar to the originally proposed identified solution. This solution used a pre-existing probe with a high frequency linear array transducer and would require a frequency from 7.5 to 18 MHz using B-mode ultrasound. However, this prototype presented issues in terms of application specifically to the penis. A coupling mechanism needed to be developed to keep the probe at the same location during the entire study period. Furthermore, depending on the size of probes available the clinician may have needed to physically hold the probe in place which could have interfered with the natural body process. The diagram for the low-fidelity prototype for this solution is Figure 5.

The second proposal utilized ultrasound technology but simplified the technology needed by bypassing the image processing software by directly calculating the wave velocity. This could theoretically be accomplished by placing the transmitter and receiver on either side of a cap placed on the tip of the penis. The researcher would measure the cylinder diameter before and after the erection event and use the average value to assume the distance traveled. The time between wave emission and reception would be measured and stored at a constant rate over the duration of the experiment. Wave velocity values could then be calculated from diameter/time. While coupling mechanisms were still a concern, the flexibility of this design, which could use a small transmitter and receiver seemed more ideal than the bulky ultrasound probe for our application. In addition, we believe the simplicity of the measurement, as opposed to the image construction of ultrasound probes, would reduce the necessary hardware, also contributing to a smaller final form factor for the device. The low fidelity prototype for this proposal can below at Figure 14.

Fig. 14: Low-fidelity prototype for DIY SWV design

9.3.2 EMG + Strain Gauge Solution

A low-fidelity model of the EMG and Strain Gauge solution was created by drawing a more detailed schematic of the device shown in Figure 15. The model contains four measurement points. To get a full understanding of the erection, a solution requires muscle contraction and blood perfusion measurements to be taken at the tip and base of the penis. Having four measurement points increased chances of tangling and of devices pulling or falling off. Given the diameter changes and movement the penis undergoes during the erection, it seemed likely that at least one of the 4 devices could fall off. In addition, the indirectness of the measurements was not ideal. Our client wished for a measurement of the stiffness of the penis, and while blood pressure and muscle contraction are factors in penis stiffness, they do not directly measure it, which is a weakness of this design.

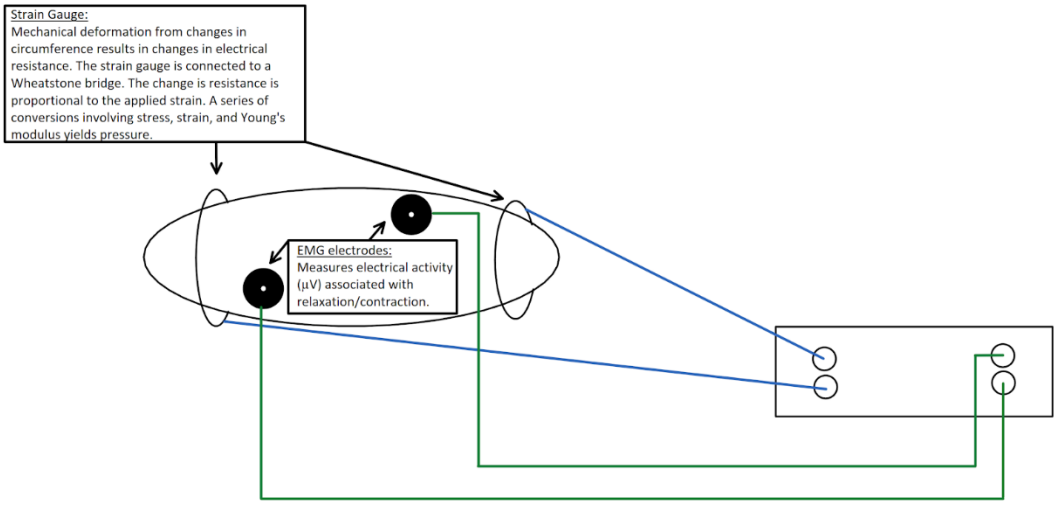


Fig. 15: Low-fidelity prototype for EMG + strain gauge solution

9.4 Evaluation of Low-Fidelity Solutions

In order to compare the low-fidelity models and select a solution that aligned closest to the design specifications a Pugh Matrix was utilized for decision-making. The RigiScan considered in a clinical setting was used as a baseline because it is an existing solution in the marketplace. An additional solution considered for device design was the application of a durometer, a device that measures the hardness of a material. However, this method was ruled out from consideration as the discomfort resulting from taking measurements would interfere with natural erectile activity. The Pugh Matrix scores were decided upon through group discussion and is displayed below in Table 5 with a scale being included in Table 6.

Table 5: Pugh Matrix for Exiting Low-Fidelity Prototyping Stage with DIY SWV decision

	Baseline (RigiScan)	*Probe U/S*	*DIY SWV*	*Rigidometer*	*Radial + EMG*
Comfort	0	2	1	-2	0
Resolution	0	1	2	0	0
Ease of Use	0	-1	1	-2	0
Directness of Measurement	0	1	2	2	0
TOTALS	0	3	**6**	-2	0

*The RigiScan is being considered in a clinical setting (does not consider application at home)

*Did not include the Durometer method in this analysis. We had concerns about its interference with natural erectile activity.

Table 6: Pugh Matrix Scale

2	Much better than baseline.
1	Better than baseline.
0	Equal to baseline.
-1	Worse than baseline.
-2	Much worse than baseline.

9.5 Mid-Fidelity Prototype: DIY SWV Solution

Based on the totals, our first-place design was the DIY SWV device. As a group, we felt that this measurement method would allow the clinician to most directly and accurately measure penile rigidity while allowing the most dimensional flexibility for differing patient penile anatomies. Our proposed solution utilized an ultrasonic transmitter. The signal would be picked up by the receiver and be taken through a signal processing circuit. The found time delay between pulse transmission and reception would be used to calculate the shear wave velocity values using a microcontroller such as an Arduino Uno. The analyzed data would then be sent to the computer for the clinician's records. We created a wiring diagram that showed a broad overview of how we were going to make this device a reality and wrote down our planned user experience. Part of our ideal user experience is that the Arduino would be programmed to provide visual cues so that the user knew when data was being received and transferred. These would be shown on an LCD Shield with the Shield's push buttons serving as the user interface for the system. The system diagram is displayed in Figure 16.

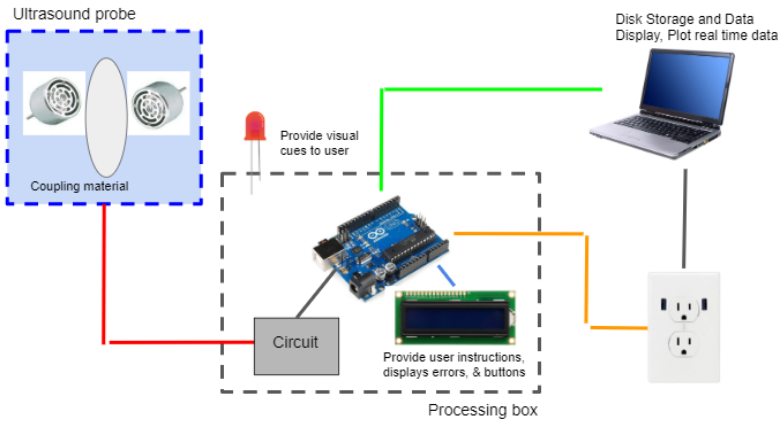


Fig. 16: Wiring diagram for original DIY SWV design

We planned to have two options for data transmission, in the first option data would be stored to an SD card attached to the Arduino and transferred later on. In the second, data could transfer live to the computer program (i.e. LabChart). The first data flow was conceptualized in order to make the device portable and independent from a personal computer for functionality. The workflow is visualized in Figure 17.

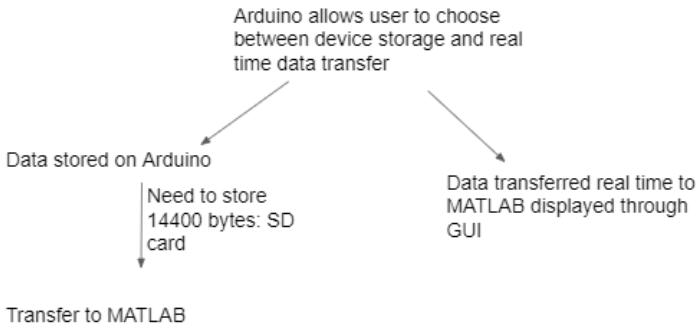


Fig. 17: Data transmission workflow for original DIY SWV design

9.5.1 Reality Check: Meeting with Petek

However, after consulting with Dr. Palmeri and Petek Sener, an alumnus working at Micro Elastic, a startup that is manufacturing ultrasound devices that measure skin elasticity, we realized there were a number of challenges and problems with our current proposal. First, the Arduino microcontroller implemented did not sample at a high enough rate for our application. Ultrasound signal is typically in the MHz range, and Arduinos sample below 10 kHz. Second, our planned system was lacking in the hardware necessary to transmit and receive ultrasound pulses.

The processing pathway is explained below. To create an ultrasound pulse alone, a PC must issue commands to an FPGA using Python code, the FPGA's gates must be coded to direct a microcontroller to set the channels within a transducer on and off in specific timing. To then receive the signal, the signals picked up by the transducer crystals must be put through a band pass filter that allows only signals between 10-20 MHz through, transfer those signals at an ADC, feed them into an FPGA, and then transfer them to the PC. The processing pathway is displayed in Figure 18.

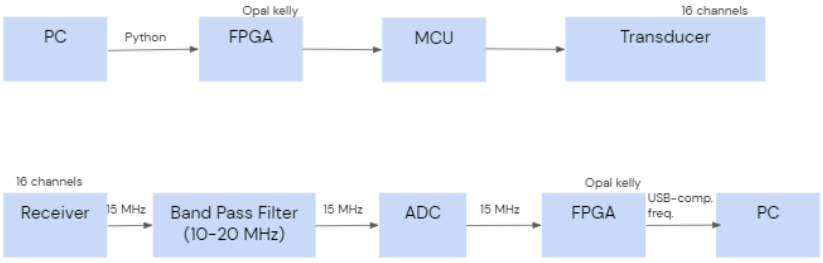


Fig. 18: Processing pathway required for DIY SWV

9.5.2 Re-Evaluation of Decision Matrix

Some of the major challenges to developing an ultrasound system included working with FPGA (including programming the FPGA and working with VHDL), identifying and attaining the appropriate number of transducer elements, the high noise associated with constructing the circuitry ourselves, and that fact that Micro Elastic has devoted years of work to develop the hardware themselves. Given our limited time frame and knowledge gap, we recognized that developing our own ultrasound based SWV solution would be impossible by the end of the semester. We reevaluated our Pugh Matrix adding in an additional specification of feasibility of development based on existing technology. From the Pugh matrix shown in Table 7, optimizing an existing ultrasound system for our application became the most feasible option.

Table 7: Pugh Matrix After Feedback with Existing U/S Decision

	RigiScan	*Existing U/S*	*DIY SWV*	*Rigidometer*	*Radial + EMG*
Comfort	0	2	1	-2	0
Resolution	0	2	2	0	0
Ease of Use	0	0	1	-2	0
Measurement Directness	0	1	2	2	0
Ease of Construction	0	1	-2	0	1
TOTALS	0	**6**	4	2	1

9.6 MID-FIDELITY PROTOTYPE: EXISTING ULTRASOUND SYSTEM ADAPTATION

9.6.1 Finding the Correct Ultrasound System

After deciding to use an existing ultrasound system for our design, the next step was to choose which to use. Since purchasing an ultrasound system would place us far outside our budget because most ultrasound systems begin around $5,000 when refurbished, Dr. Palmeri gave us access to the AcuNav. The AcuNav is an intracardiac probe and it comes in a 10F catheter form. A picture of the catheter form factor is shown in Figure 19. The small size, flexible wire, and light weight probe tip made this option a plausible solution.

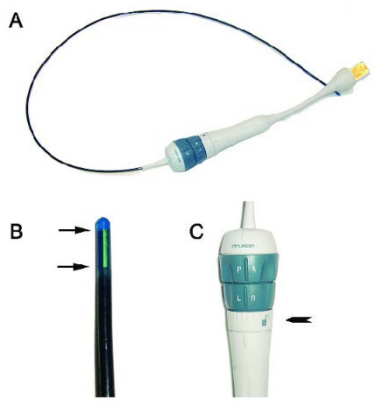


Fig. 19: A is the entire device, B is the transducer array, C is the control for the catheter (Ligthart, 2006)

9.6.2 Coupling Mechanism

For our application, the control of the catheter needed to remain fixed in place. To accomplish this, we planned to design a housing using CAD. Sketches of the planned housing can be found in the appendix. Secondly, in order to fit this probe for our application a specific coupling mechanism needed to be engineered to keep the catheter in place during the erection event while minimizing air bubbles in between the catheter and gel.

Several coupling mechanisms were considered. Some of the designs considered include using latex gloves filled with ultrasound gel, Tegaderm IV patches, and self-sealing injection ports. Of these designs, the Tegaderm IV patches performed the best under testing, so we chose them to serve as our coupling mechanism moving forward. The coupling mechanism designs and the testing results are summarized in Table 8 below, providing evidence for our choice of the Tegaderm. The full coupling mechanism designs and testing results are available in the appendix.

Table 8: Summary of coupling testing

Design	**Failure Mode Observed**	**Useful?**
Tegaderm/IV Patch	U/S gel can have bubbles Gel can be squeezed out	Yes, best solution
Stopcock Valve with latex	Latex sucked into valve, blocking air Leaky bond between latex and nozzle	No
Self Sealing Silicone Cap w/ needle syringe	Patient can be injured by needle	No, dangerous
Custom U/S Gel Pouch with Ziploc bag	Plastic bag doesn't work	No

9.6.3 Wiring Diagrams and Data Workflow

However, while the AcuNav was capable of ARFI imaging and theoretically could be used to calculate SWV, there were no existing ultrasound workstations available through Duke to perform SWV imaging using the AcuNav. The available transducer models were much larger and heavier than the AcuNav, and we have likely needed to reevaluate the coupling mechanism for their usage.

Therefore, instead of presenting a fully functional, self-contained device, we proposed developing a solution that achieved functionality for data processing, probe/gel coupling, and shear wave velocity measurements using ultrasound individually, but did not create an overall functionality between these three components. The fully functioning system that could connect all three components is visualized in Figure 20.

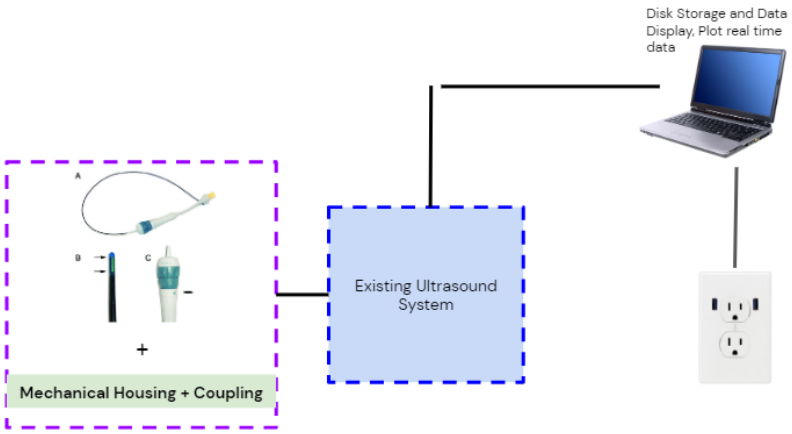


Fig. 20: Wiring diagram for full system design

For our solution, we planned to prove each functionality separately. First, using the aforementioned Tegaderm/IV Patch coupling mechanism, we would use the AcuNav in B-mode imaging (workstations for this type of imaging were available at Duke) to validate the use of the coupling method. Secondly, we would utilize the transducers that were compatible with ultrasound workstations capable of performing shear wave velocity imaging on known PVA gel stiffnesses we planned to self-manufacture (recipe in the appendix) to show that ultrasound technology could be used to determine material stiffness. Lastly, to prove the functionality of data processing, a Raspberry Pi used to represent the ultrasound work stations would take in simulated ultrasound data from the Field II program and transfer it to a CPU using a Python GUI to store and process the data as seen in Figure 21. More details about the GUI system can be found in the Measurect Graphic User Interface Manual section of the appendix.

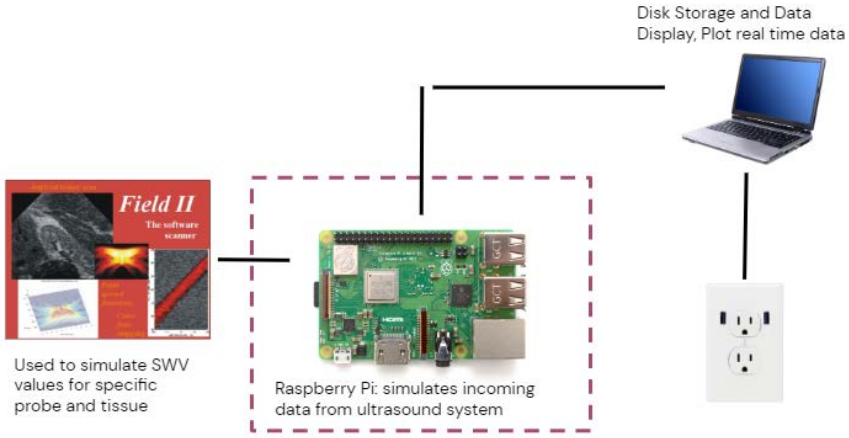


Fig. 21: Wiring diagram for simulation workflow

9.7 Mid-Fidelity Prototype: Work Done Post COVID-19 Disruptions

However, our solution and goals had to shift significantly once the project became remote. Lack of physical access to ultrasound equipment as well as other technology resources, forced us to shift our efforts from physical development, construction and testing to more theoretical diagrams and protocols. Instead of developing testing and coupling mechanisms using an existing ultrasound probe, we began sketching and generating CAD models for our own idealistic probes. Using these probes, we developed a protocol for running ultrasound simulations using Field II, an ultrasound simulation software used by Dr. Palmeri, to determine design details for a functional probe. We also developed a workflow and user manual for user interface that mediates data handling between the ultrasound system and the clinician.

9.7.1 Choosing Our Probe

We included the sketching and brainstorming pages of our design work in the appendix so that readers can follow along with our design ideation. We designed four probe models and chose the semicircle model due to its ease of construction and compatibility with different transducer types: curved axial transducers as well as longitudinal linear transducers. A rendering of the model is included in the technical documents section of the report.

9.7.2 Simulation Plan to Test Design Feasibility via Field-II

To determine the shape of the transducer we wished to put into the transducer, we turned to Field-II, a MATLAB-based ultrasound simulation software. We put together two simulation plans for determining how effective different transducer shapes are at finding SWV after conversations with Felix Jin. This simulation plan would be used to find the correct transducer shape for our design. However, knowing our design constraint of measuring a penis, which has changing dimensions, we can make an informed decision and say the transducer will likely have to be linear and resting on the longitudinal axis so it is not affected by the change in penis diameter over the course of an erection. These simulation plans are summarized in the appendix.

9.7.3 Simulation Plan to Test Design Feasibility via Field-II

To ensure our design would operate without mechanical failure modes present simulations were run in Fusion360 to test its structural integrity. Based on the tests, the handles and the arc where the transducer would lie had high stresses on them. To ease the stresses, fillets were added to the final design. The simulation results can be seen in the testing to specifications section.

9.8 Summary Of Design Iterations

Our group looked at three different solutions to measuring penis stiffness, and initially decided to move forward with a DIY SWV solution. After doing more research, we saw that the DIY SWV solution would require more resources and knowhow than we have. We then moved to an approach that utilized existing ultrasound technology, specifically the AcuNav system. We built and tested a coupling mechanism, verified that ultrasound technology is capable of gauging tissue stiffness, and created a software pipeline to process the collected data. Post COVID-19, we shifted our attention to designing the ideal transducer for our design, which included creating CAD models, making simulation plans in Field II, and improving the design's mechanical integrity through Fusion360 simulations.

10 REGULATORY

10.1 FDA 510(K) SUBMISSION

To gain a better understanding of the regulatory procedures for medical device innovations, we began developing some of the sections for an FDA 510(k) submission to gain marketing clearance of diagnostic ultrasound systems and transducers. These regulatory procedures were based on the FDA's marketing clearance of ultrasound systems and transducers.

10.1.1 Section 5.2.1: Indications for Use

The diagnostic ultrasound system is intended to measure shear wave velocity of the penis using ARFI ultrasound imaging. The device must be operated by a healthcare clinician or researcher appropriately trained in performing ARFI imaging mode and specifically trained on using the device on the penis. The device use settings are in a hospital or clinical space, where testing of up to two hours can be performed. Given that this device is specifically for a research study, it will likely only be used in clinical spaces carrying out the experimental studies. Given this system's unique application and novel quantitative information on a sexual organ of the body, this device will require a Premarket Approval application submission as set forth in Section 515 of the FD&C Act and part 814 (21 CFR part 814) of the regulations or a De Novo request for classification under Section 513(f)(2) of the FD&C Act.

10.1.2 Section 5.2.2: Device Description

While the final subject device was not fully developed under the time constraints, in this portion of the submission model designation, design, patient contact materials, and control panel and system operation of the device would be discussed. Following the general description an in depth description of each transducer along with its operation in each mode and mode combination would be listed. The necessary transducer parameters are listed as follows: (1) the transducer model designation and type (e.g., mechanical sector, rectangular phased array, curved linear array, annular phased array), (2) the size and spacing of element(s), (3) geometrical configuration, (4) total number of elements in the array, (5) array dimensions, (6) the maximum number of active elements for a single pulse, if applicable, and (7) the nominal ultrasonic frequency or frequencies of the transducer assembly. Secondly, the operating controls that could cause a change in the radiated field (e.g., output, pulse repetition frequency, transmit focal length, sector angle, image rate, pulse duration, depth, and sample volume) should be fully explained. Features unique to the particular technological characteristics, which for our application could have been the coupling mechanism and patient contact material would also be described in this section. Lastly, the specific track of the device which is dependent on the maximum global acoustic output must be identified and addressed.

10.1.3 Section 5.2.3: Predicate Device Comparison

A 510(k) submission summary must also identify comparable predicate device(s) to which the subject device is being claimed to be substantially equivalent Whenever possible, the related 510(k) numbers for the predicate device(s) should be included. The subject device should be compared to the predicate device(s) in terms of key technological features such as indication(s) for use, general device description (i.e., design, patient contact materials, operational characteristics, specifications), acoustic output and device settings used, general safety and effectiveness information; and proposed and/or final

labels, labeling and promotional materials. The accessories or kits intended for use with the predicate device(s) should be identified as well.

10.2 IEC 60601 Worksheet

A worksheet for the IEC 60601 standard was completed. Pertinent parts of the standard include how hardware must be assembled so that it is safe for the end user from electrical and physical standpoints. The standard also informs us on how to properly label our device and how to structure the user interface in a manner that is standard with the rest of medical devices. Another interesting aspect of the standard is that it details how to create a comprehensive risk management plan for the physical, electrical, and software components of the device. The IEC 60601 standard is useful for understanding what it takes to push a product into the medical device marketplace and reading through it while completing this worksheet was a beneficial experience for our team. The worksheet itself is included in the appendix.

10.3 IEC 62304 Worksheet: Software Class A

The main purpose of the software system in this full device system is to mediate communication between the ultrasound system and the clinician. The user interface accepts user input, initiates the collection of recorded data from the ultrasound system, and processes and exports data. This functionality is further outlined in the GUI Instruction Manual in the appendix. This software system cannot contribute to a hazardous situation. It cannot initiate nor terminate measurements or start nor stop hardware function. Therefore, the system falls under software safety class A. A table containing the considerations for testing, development, and maintenance in accordance with IEC 62304 is included in the appendix.

11 DISCUSSION OF ETHICS

When developing a medical device, especially one intended for use in a population of individuals recovering from injuries or illnesses, a discussion of ethical consideration and possible societal impacts is necessary. The ultrasound-based system discussed in this report holds great promise in promoting research and care for the male SCI community; however, without proper considerations and precautions, it has the potential to harm individuals, impede research and healthcare advancements for the male SCI community, and exacerbate existing inequalities present in healthcare systems. After thorough consideration, three major potential ethical ramifications were identified as well as plans for preventing adverse outcomes.

11.1 PREVENTING PATIENT HARM

If proper considerations of patient harm are not performed, the device could cause temporary or permanent physical harm to the patient.

In order to prevent patient harm, the device should follow all relevant safety guidelines outlined by relevant regulatory organizations (i.e. FDA or EU). The device should also undergo safety testing guided by documents including FMEAs and testing protocols. With regards to this device specifically, rounded, rather than sharp edges should be implemented in mechanical designs, design and protocols should be created such that the device does not impede blood flow, the device should be non-invasive, material should be selected to avoid irritation and abrasion and include consideration of allergies, and the ultrasound should be used with pulsatile rather than continual transmission to avoid heating or burning tissue. In addition, IEC 60601 was reviewed and is addressed in the Regulatory section of this report.

11.2 PROTECTION OF PATIENT INFORMATION

If safeguards are not implemented to protect confidential patient information and data, patient privacy could be compromised.

To mitigate the risk of compromising patient privacy, the use of security measures including patient IDs rather than explicit names, limited access to the confidential information, passwords, and direct connections rather than Bluetooth should be exercised. In addition, any software systems should be developed, used, and maintained in accordance with IEC 62304.

11.3 PREVENTING IMPROPER INFORMATION AND ADVERTISING

If information spread and advertising of the device is not properly controlled, the device could be mistaken for a therapeutic or diagnostic device by the patient and/or the clinician. While iterations of this device could utilize the data to diagnose the severity of erectile dysfunction in male SCI patients, in its current form this is solely a measurement device used for research purposes and produces no explicit diagnoses. Confusion regarding the application, abilities, and purpose of the device could cause psychological harm in the involved parties and possibly result in legal action.

In order to prevent infiltration of misleading information and advertising, the device should be paired with a user manual including instructions for use such as a description of the recommended patient population, description of appropriate use (i.e. study duration, duration of direct application, recommended environment for use, etc.), the scope of the device, and clear statements clarifying that the device is neither diagnostic or therapeutic. In addition to a user manual for the clinician, the device should

also come with a guide created specifically for patients that describes appropriate uses of the device and statements clarifying that the device's only intended purpose is only to measure and not to diagnose or treat patients suffering from erectile dysfunction.

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13 APPENDIX

13.1 FIVE-ITEM VERSION INTERNATIONAL INDEX OF ERECTILE FUNCTION (ROSEN, 1999)

Questions	Scores				
	1	2	3	4	5
Over the past six months:					
1. How do you rate your confidence that you could get and keep an erection?	Very low	Low	Moderate	High	Very high
2. When you had erections with sexual stimulation, how often were your erections hard enough for penetration?	Almost never or never	A few times	Sometimes	Most times	Almost always or always
3. During sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner?	Almost never or never	A few times	Sometimes	Most times	Almost always or always
4. During sexual intercourse, how difficult was it to maintain your erection to completion of intercourse?	Extremely difficult	Very difficult	Difficult	Slightly difficult	Not difficult
5. When you attempted sexual intercourse, how often was it satisfactory to you?	Almost never or never	A few times	Sometimes	Most times	Almost always or always
The score is the sum of the above five question responses. Erectile dysfunction is classified based on these scores: 17 to 21 = mild; 12-16 = mild to moderate; 8 to 11 = moderate; 5 to 7 = severe					

13.2 IEC 62304 CONSIDERATIONS

	Development	Maintenance
Performance/Purpose	• Develop a software system for data collection, processing, and storage using a user interface	• Perform continuous V&V for the software system
Physical	• Python	• Python • Additional program or application for V&V?
Establishing traceability	• Practice design documentation (documented design inputs, product specification, failure modes, and effects analysis, etc.)	• Audit
Verification	• Data collection • Data processing • Data storage • Accessing stored data	
Validation	• Internal feedback • External feedback • Gap analysis	
Upgrades/ updates	• Document design developments	• Upgrades/updates should be administered by the clinician
Interfaces	• Verify communication between the ultrasound system and software system (data collection)	
Security	• Patient data protection • Authentication • Authorization • Audit trail • Communication integrity • System security/malware protection	• Patient data protection • Authentication • Authorization • Audit trail • Communication integrity • System security/malware protection
Data form, fit, and function	• Numerical	• Numerical (test data)
Installation	• Clinician installs software using user manual	

13.3 IEC 60601 WORKSHEET

Standard Number	*Title*	*How Applicable (if none, state why)*	*Test Method or Implementation Plan*	*Test Results*
4.1	Conditions for Application	Applicable	Patient skin must be prepared with alcohol swab before application: dry and clean. Compare device accuracy across prepared/unprepared patients.	TBD
4.2	Risk Management Process	Applicable	Failure Modes for the device must be established and accounted for	TBD
4.3	Essential Performance	Applicable	The device must meet an accuracy of 90% at all times while it is in use	TBD
4.4	Expected Service Life	Applicable	95% confidence interval that 90% of devices will not need maintenance until 5 years after first use	TBD
4.5	Equivalent Safety	Applicable	Can address the risk of overheating by adding a temperature-controlled switch that shuts the device off	TBD
4.6	Parts that Contact Patient	Applicable	Parts that contact the patient must not be able to be used in a way that physically harms the patient	TBD
4.7	Single Fault Condition	Applicable	We can make the device single fault safe by reducing risk with a negligible probability of failure, we can use insulation to prevent the ultrasound transducer from shocking the patient.	TBD
4.8	Components of ME Equipment	Applicable	Our device design includes ultrasound, which will be tested under the standards applicable to ultrasound devices	
4.9	High-Integrity Characteristics	None, our device is not expected to undergo significant stresses while in use		
4.10	Power Supply	Applicable	Our device will be connected to wall power, compliance will be checked by inspection of the accompanying documents. We will make sure in our design that the power supply will be less than 250 V.	TBD

4.11	Power Input	Applicable	We will measure the input voltage, and use the device at the upper and lower limits of its power input range, and measure the steady state current	TBD
5.1	Type Tests	None, I'm unsure what this test means		
5.2	Number of Samples	Applicable	I'm unsure of how many samples will be necessary to test each standard	TBD
5.3	Ambient temp, humidity, pressure	Applicable	I'm unsure of what the ambient conditions requirements will have to be, I can say with some certainty our device ideally will operate between room 10 degrees Celsius and 50 degrees Celsius at up to 100% humidity, and at atmospheric pressures ranging from sea level to Denver	
5.4	Other conditions	Applicable	This could be applicable	
5.5	Supply voltages, current	Applicable	This will depend on the hardware that the system will end up implementing	
5.6	Repairs and modifications	Applicable	Our device will undergo damages and it will need to be repaired. We will need to come up with a repair protocol for all foreseeable failure modes.	
5.9	Determination of Applied parts and Accessible parts	Applicable	Any openings and parts should be tested using the standard test finger and test hook shown.	TBD
6.2	Protection against electric shock	Applicable	Our device will use electricity so it will be classified as Class I or II ME Equipment. No test necessary.	
6.3	Protection against ingress of water or particulate matter	Applicable	Water cannot enter the hardware, will need to be tested by showing waterproof nature	
6.4	Methods of sterilization	Applicable	Intending on sterilizing device using autoclave, will need to perform test to show device still works after autoclave.	
6.5	Suitability for use in Oxygen rich environment	Applicable	See 11.2.2	
6.6	Mode of operation	Applicable	Non-Continuous operation, 7.2.11	
7.2	Marking on outside	Applicable	Follow standard for markings on device, from identification to accompanying documents, to me	

			equipment intended to receive power from other equipment	
7.3	Marking on the inside	Applicable	We should follow the standards for all markings on the inside	
7.4	Marking controls and instruments	Applicable	Mark power switch and units of measurement in SI	
7.5	Safety signs	Applicable	Appropriate safety sign for use of U/S	
7.6	Symbols	Applicable	Explain the symbols used for marking in the instructions	
7.8	Indicator lights and controls	Applicable	Use appropriate colored lights to communicate information to the operator: red, yellow, green have given meanings	
7.9	Accompanying documents	Applicable	Follow standards for all accompanying documents, many necessary sections	
8.1	Fundamental rule of protection against electric shock	Applicable	Follow rules outlined in how to make device safe from electrically shocking the patient	
8.2	Requirements related to power sources	Applicable	The power infrastructure of the device will be designed to standard, our device will be AC powered	
8.3	Classification of applied parts	Applicable	Wil be a Type B, BF, or CF applied part	
8.4	Limitation of voltage, current, energy	Applicable	Will be under parameters safe for the patient to use	
8.5	Separation of parts	Applicable	Where necessary, will separate parts. Materials that are in contact with the hardware must be appropriate insulators.	
8.6	Protective earthing	Applicable	Need to connect to a protective earth terminal due to high voltage of device	
8.8	Insulation	Applicable	Appropriate thickness and type of insulation will be used where necessary	
8.9	Creepage distances and air clearances	None, this is not applicable		
8.10	Components and wiring	Applicable	All wire and hardware will be mounted as the standard instructs to fix it in place	
8.11	Mains parts, components and layouts	Applicable	All of the safety features described will be implemented	
9.2	Hazards associated with moving parts	None, our device will likely not have any moving parts		

9.3	Hazards associated with surfaces, corners and edges	Applicable	We will have no edges. All edges will be smoothed to protect the patient.	
9.4	Instability hazards	None, our equipment is not intended to be placed on a floor or table		
9.5	Expelled parts hazards	None, our device will not expel parts during normal operation		
9.8	Hazards associated with support systems	None, our device will not support patients		
9.3	Leakage	Did not see this in the standard		
9.4	Ingress of liquids test	Did not see this in the standard		
10.4	Lasers and light emitting diodes	None, no lasers/LEDs used in design		
10.5	Other visible electromagnetic radiation	None, this is not used		
10.7	Ultraviolet radiation	None, our device does not use this		
11.1	Excessive temperatures	Applicable	The U/S transducer may overheat, there will be safety measures put in place to make sure it does not exceed the maximum temperature	
11.2	Fire prevention	Applicable	The U/S transducer may overheat, there will be safety measures put in place to make sure it does not exceed the maximum temperature and cause fire	
11.3	Constructional requirements for fire enclosures	Applicable	Hazardous, flammable materials will not be used.	
11.4	Intended for use with flammable anesthetics	None, our device will not use these		
11.5	Intended for use in conjunction with flammable agents	None, our device will only use ultrasound gel		

11.6	Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances	Applicable	Care will be taken to avoid the ultrasound gel leaking	
11.7	Biocompatibility	Applicable	ISO 10993 will be used to ensure we are following standards on biocompatibility. Our device will touch the skin.	
11.8	Interruption of the power supply	Applicable	This can be tested by interruption and restoration of the power supply	
12.1	Accuracy of controls and instruments	Applicable	Results must be accurate within a 95% confidence interval	
12.2	Usability	Applicable	See IEC 60601-1-6 for ensuring good usability	
12.3	Alarm systems	Applicable	See IEC 60601-1-6 for proper alarm system testing protocol	
12.4	Protection against hazardous output	Applicable	Will be tested by risk management file	
13.1	Specific hazardous situations	Applicable	None of the single fault conditions can be applied to the overheating of the U/S transducer, too great of a failure	
13.2	Single fault conditions	Applicable	Only can be used for mild failures, such as overheating of transformers or failure of thermostats	
14	Programmable Electrical Medical Systems	Applicable	Tested by compliance with standards 14.2 to 14.13	
14.3	Risk Management Plan	Applicable	Risk management plan will include a PEMS validation plan	
14.4	PEMS development life-cycle	Applicable	The development life-cycle will be documented	
14.5	Problem resolution	Applicable	A system for problem resolution must be documented	
14.6	Risk Management Process	Applicable	The software and hardware failure modes of our system will be part of the risk management process	
14.7	Requirement specification	Applicable	All of the subsystems will be documented	
14.8	Architecture	Applicable	The appropriate safety measures will be present in the architecture	
14.9	Design and Implementation	Applicable	The subsystems will all have a design and test specification	

14.10	Verification	Applicable	A verification plan will be created and used to test all essential functions	
14.11	PEMS Validation	Applicable	A PEMS validation test will be created	
14.12	Modification	Applicable	Any modification will result in new tests being written for all parts affected	
14.13	Connection by Network/Data	None, not applicable for current design		
15.1	Arrangements of controls and indicators	Applicable	Compliance will be checked by inspection of the risk management file	
15.2	Serviceability	Applicable	Regular maintenance will be required on the device, this will be mentioned in a subclause	
15.3	Mechanical strength	Applicable	Push, drop, rough handling, and molding stress relief tests will be done because this is a mobile device	
15.4	Equipment components and indicators	Applicable	Compliance will be checked by inspection of the risk management file	
15.5	Mains supply transformers	Applicable	The transformer will be subjected to the relevant short-circuit test	
16.1	General requirements for the ME systems	Applicable	The device must satisfy the tests	
16.2	Accompanying docs	Applicable	All of the relevant sections and information must be included	
16.3	Power Supply	Applicable	Compliance is checked by inspection	
16.4	Enclosures	Applicable	Compliance is checked by inspection	
16.5	Separation devices	Applicable	Compliance is checked by the tests in 8.8 and 8.9	
16.6	Leakage currents	Applicable	The touch current from or between parts of the ME system within the patient environment will not exceed 100 uA, also need to pass test in 8.7.4.4	
16.7	Protection against mechanical hazards	Applicable	Compliance checked by inspection or applicable tests.	
16.8	Interruption of the power supply	Applicable	Compliance is checked by interruption and restoration of relevant power connections one at a time and all connections simultaneously	

16.9	ME system connections and wiring	Applicable	Compliance is checked by inspection and, if possible, by interchanging connectors	
17	Electromagnetic compatibility of ME equipment and ME systems	Applicable	Compliance is checked by inspection of the risk management file	

13.4 AGAR PHANTOM FABRICATION (FROM THE DUKE ULTRASOUND WIKI)

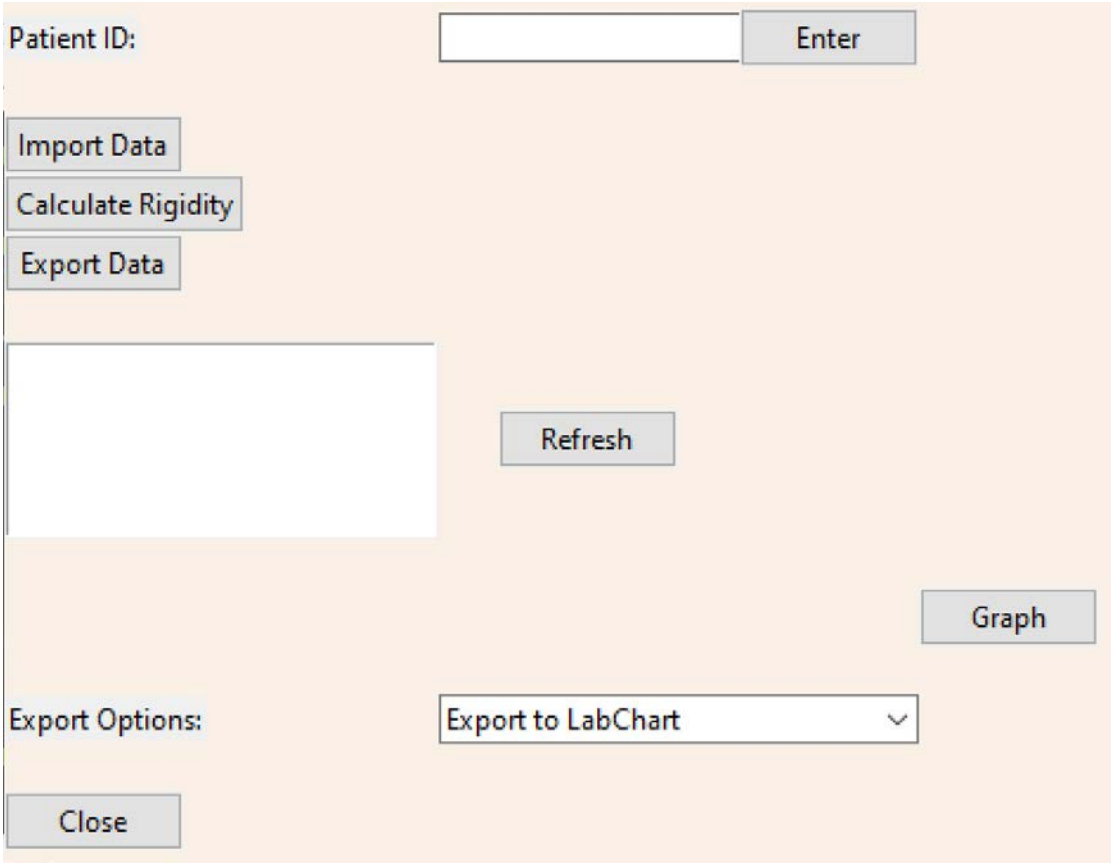
13.4.1 Materials

- 500mL of de-ionized/distilled water
- 60.8mL of N-propanol (also called 1-propanol)
- 17g of agar
    - This concentration varies to create phantoms of different stiffnesses
- Equipment
- A reasonable size of beaker
- Saran wrap
- Magnetic stir bar
- Thermometer
- Hot plate
- Spoon/spatula

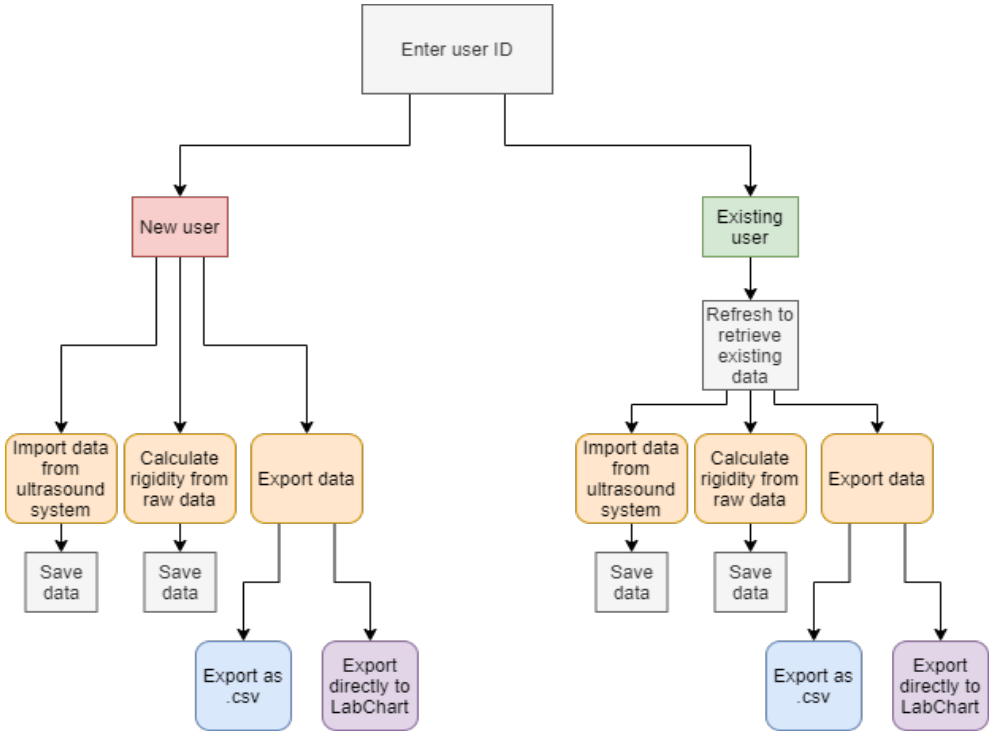
13.4.2 Procedure

1. Combine water and N-Propanol in a beaker.
2. Place the beaker on the hotplate and turn the stir knob to a speed of 6-7.
3. Slowly pour the agar powder into the solution while stirring and turn the heat knob on.
4. Cover the top of the beaker with saran wrap, pierce a hole, and place the thermometer in the beaker.
5. Heat the mixture on medium heat while stirring on high speed until a temperature of 90 deg C is reached and a clean solution is obtained.
    5.1. Note: it may take a while to get a clear solution (about 1 hour or more). Make sure that the heat setting is not turned high. In that case, the temperature will rise quickly, and the solution will start boiling before it can turn clear.
6. After the solution becomes clear, reduce the stirring speed and allow the liquid to cool to about 55 deg C.
    6.1. Note: It might be possible that the solution will start clumping as it starts cooling below 50 deg C. If the solution is supposed to be poured in a container, it can possibly be done at 60 deg C as well.
7. Slowly pour the liquid into the container to be used for gelling to avoid creating air bubbles.

13.5 MEASURECT GRAPHICAL USER INTERFACE (GUI) INSTRUCTION MANUAL



Purpose: The graphical user interface (GUI) mediates communication between the ultrasound system and the clinician.



Launching the GUI:

1. Windows/Linux
    a. Open Git Bash in the folder titled “Measurect”. This folder should contain the GUI.py, file_conv.py, patient_data.py, and SWV_calc.py files.
    b. In the Git Bash window, type “python GUI.py” and press enter to launch the GUI.
2. Mac (Python3)

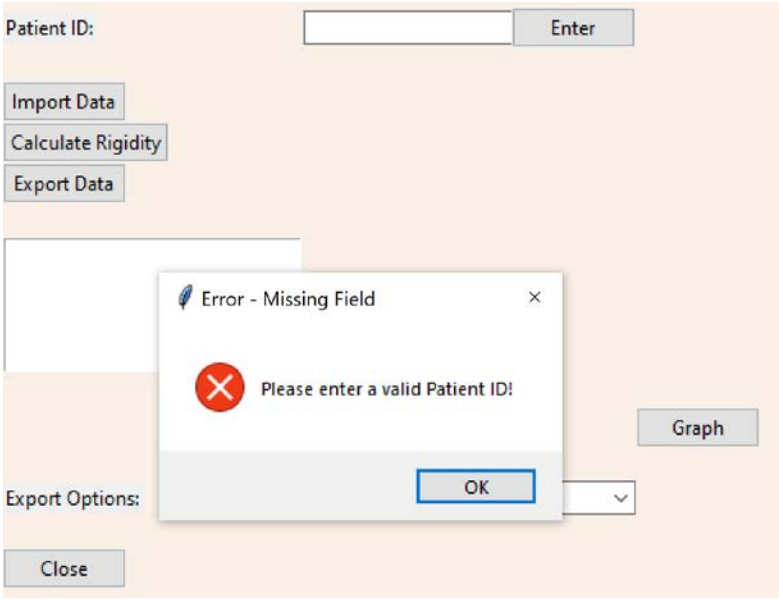
. Open Terminal in the folder titled “Measurect”. This folder should contain the GUI.py, file_conv.py, patient_data.py, and SWV_calc.py files.

a. In the Terminal window, type “python3 GUI.py” and press enter to launch the GUI.

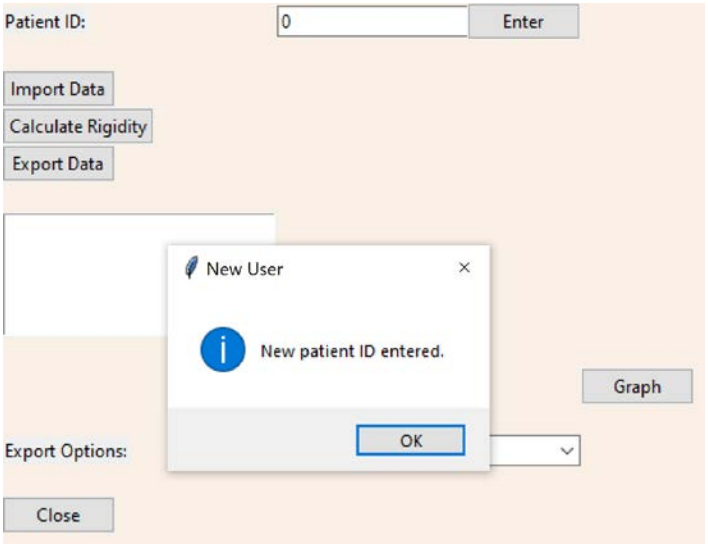
Entering Patient ID:

After launching the GUI, the clinician should enter a patient ID number.

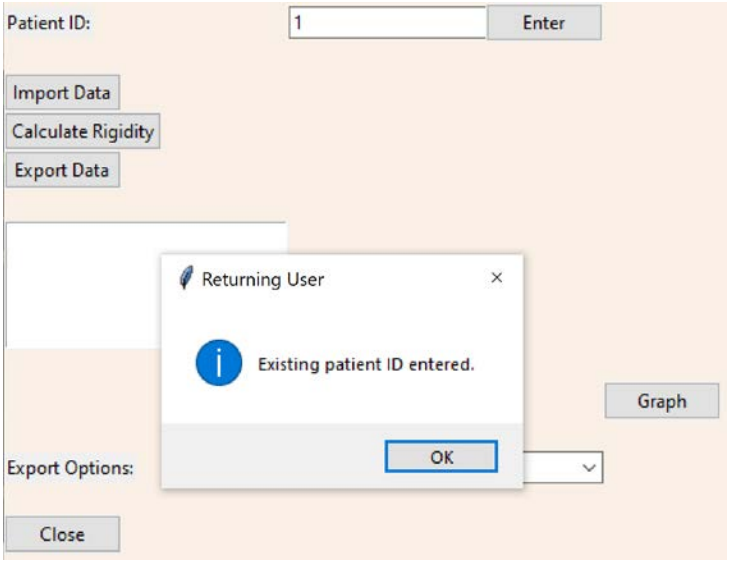
An ID number is used in place of the patient’s name to supplement patient privacy. If the clinician does not enter a valid ID, the GUI will prompt the user with an error prompting the user to enter a valid patient ID.



If the clinician enters a patient ID for a new patient, the GUI will alert the user that a new ID has been entered.

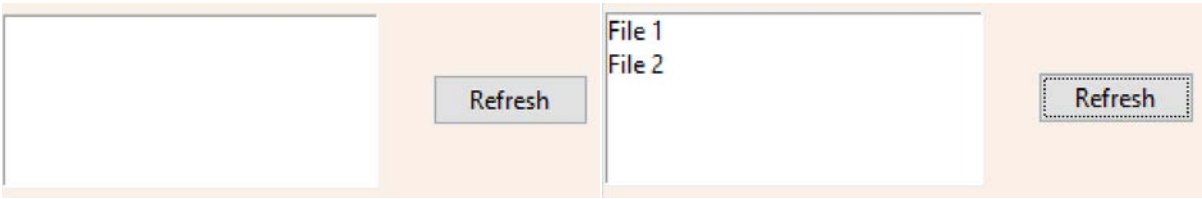


If the clinician enters a patient ID for an existing patient, the GUI will alert the user that an existing patient has been identified.



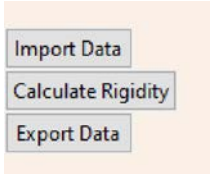
Refresh:

For existing patients, the Refresh button can be used to retrieve existing patient files.

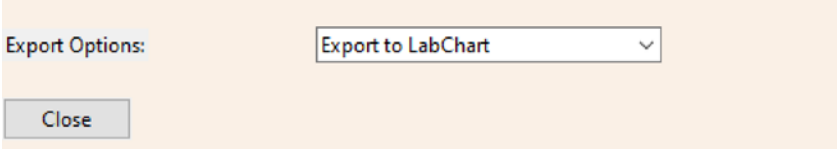


Options for Data Handling (Import, Calculations, and Export):

After the patient ID has been entered, the clinician can select from three options: Import Data, Calculate Rigidity, and Export Data.

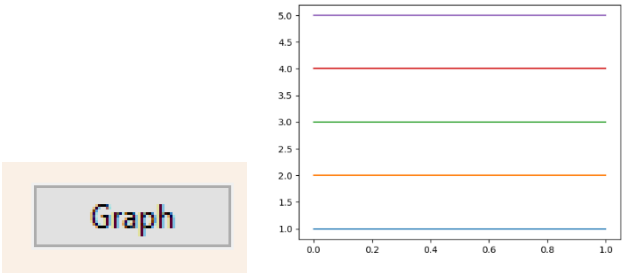


Import Data will import measurements from the ultrasound system onto the local computer. Calculate Rigidity can be used to calculate penile rigidity from either pre-existing data or recently imported data. Export Data is used to export any patient data. The clinician has the option to export the data as a .csv file (i.e. onto an external storage device) or to export the data directly to LabChart for additional processing, analysis, and visualization. The clinician can select their preferred method of exporting from the drop-down menu.



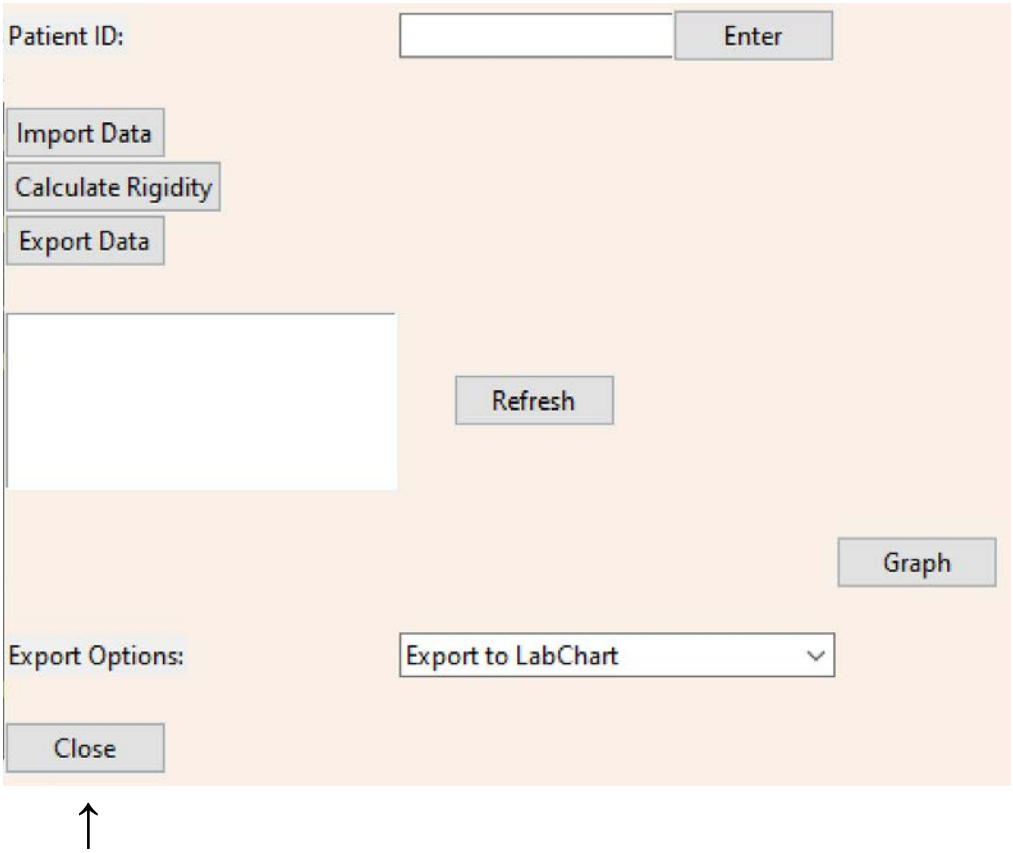
Graphing Data:

If the patient has data available, the clinician also has the option to graph the patient data within the GUI.



Closing the GUI:

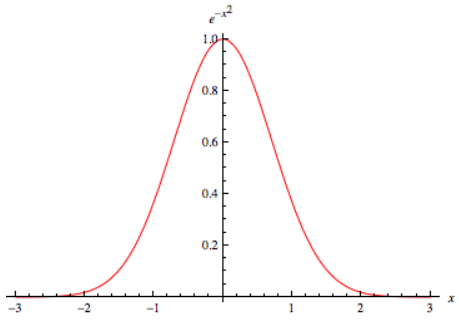
When the clinician is finished using the GUI, the window can be closed using the close button.



13.6 Simple Field-II Plan

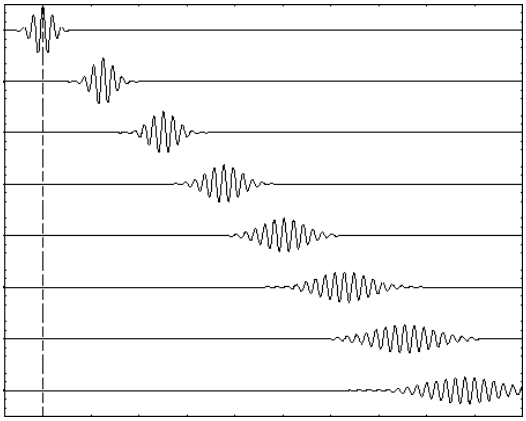
13.6.1 Model a Wave

1. Create a Gaussian wave in Fourier Space.

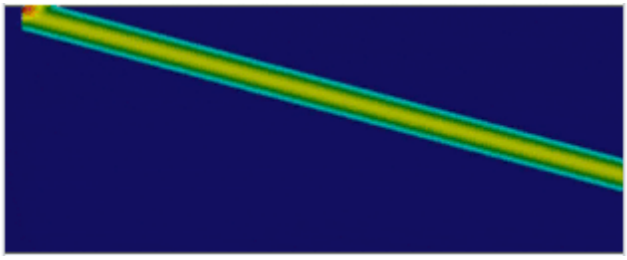


Gaussian wave (WolframAlpha)

2. Take the Fourier transform of the Gaussian to get the Gaussian in time.
    1. Traveling Gaussian wave will decrease in amplitude and delocalize over time.



3. Multiply the Fourier transform by e^{iw} to get a function of the Gaussian wave over time and space.
    1. The time and space plot shows how the wave travels through the material over time: the y-axis shows displacement, x-axis displays time, and the color gradient of the plot shows the amplitude of the wave in that location at the given time.



(Wikipedia, Wave Propagation)

4. We can estimate the SWV by taking the slope of the sound wave (distance over time).
    1. SWV is typically between 1-10 m/s.

13.6.2 Model the Wave Traveling Through an Infinite Body of Homogenous Stiffness

1. Generate scatterers using Field-II.
    a. Use a low count such as 5/cell.
2. Use the calc_kesai code to calculate angle.
3. Calculate the SWV of the wave in the tissue using Field-II boilerplate code provided by Felix Jin.

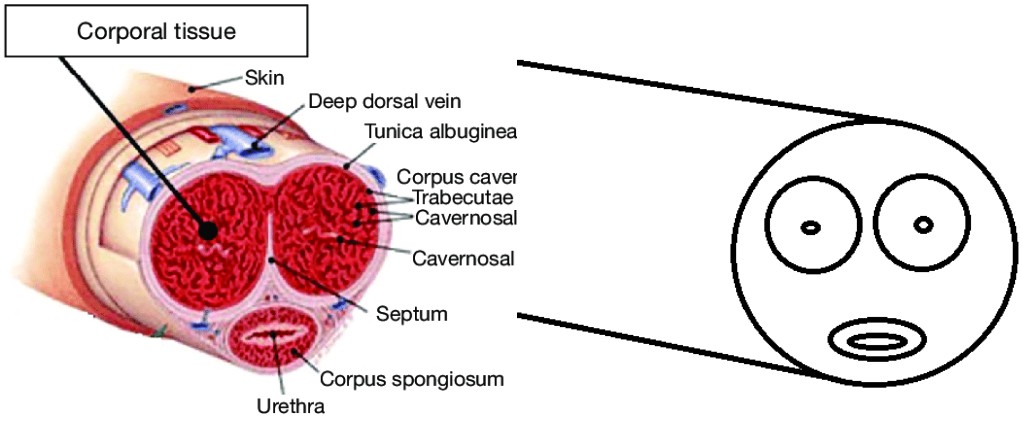
13.7 IDEAL FIELD-II PLAN

13.7.1 Model a Wave

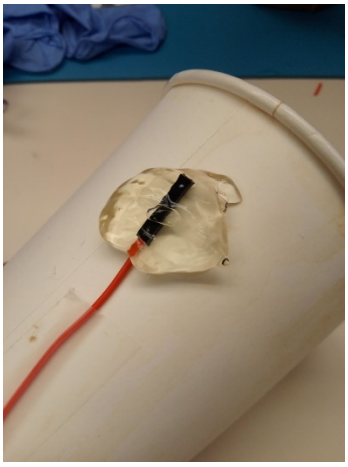
1. Model the wave similarly as above but add more realism such as a wave front by making the wave decay more slowly than it grows.

13.7.2 Model the Wave Traveling Through a Cylindrical Body with Varying Stiffnesses

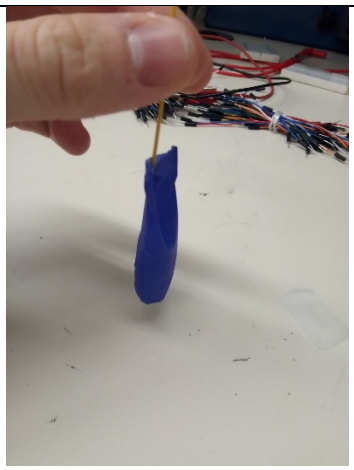
1. Create a realistic model for the human penis by creating a cylinder with cylinders of different stiffnesses inside.
2. Increase scatter density to create a more accurate model using increased computational power.



13.8 Design Iterations Components and Testing Results

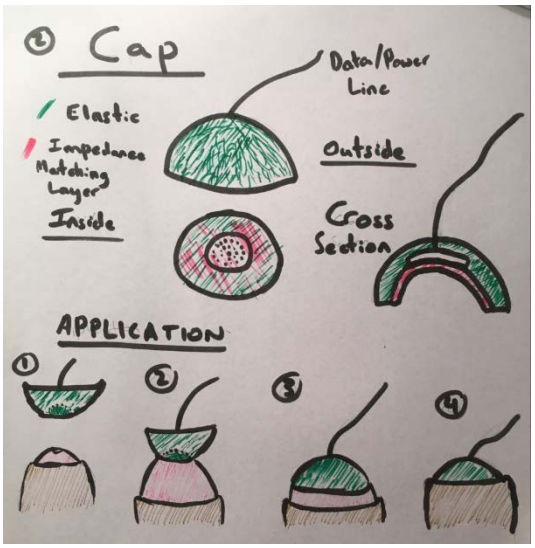
Material	*Concept*	*Pictures*	*Verdict*
Tegaderm/IV Patch	1. Ultrasound gel placed on skin 2. Ultrasound probe placed on as well 3. Sample images taken to ensure image quality is good 4. Tape down the U/S probe onto the skin (or use mastix spirit gum) 5. Ultrasound gel secured onto penis with Tegaderm 6. Make contact between the U/S gel and Tegaderm first 7. Start applying from center, making sure to squeeze out the air using the U/S gel (similar to coverslipping a slide) 8. At Tegaderm edges, press down onto skin to attach 9. Image!	 	This is the best solution yet. The Tegaderm adheres nicely to the skin and keeps the ultrasound gel around the probe. The setup is delicate, however. The gel can easily be pushed out of the dressing if force is applied to the center, and air bubbles can inadvertently be introduced when the Tegaderm is applied if done incorrectly. Finally, if there are air bubbles present in the U/S gel they will remain present even after the Tegaderm is applied.
IV Valve	1. Ultrasound gel placed on skin 2. Ultrasound probe placed on as well 3. Sample images taken to ensure image quality is good 4. Clean off the U/S gel		Because the valve's connection to the latex glove wasn't airtight, this setup couldn't really be tested. If the connection between the valve and the glove is secure, the next pain point would be the

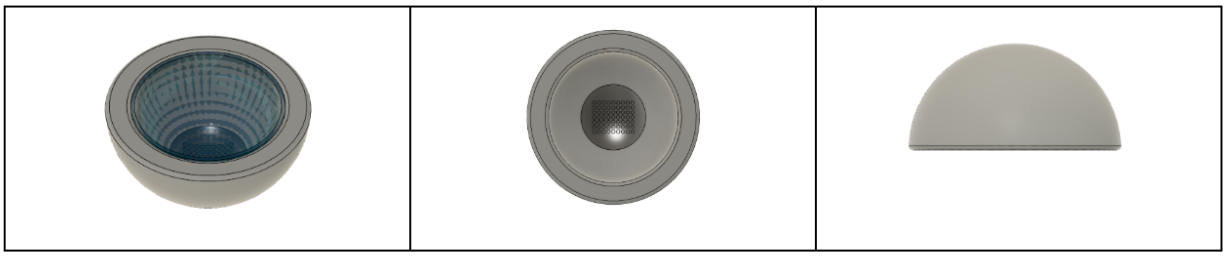
	5. Tape down the U/S probe onto the skin (or use mastix spirit gum) 6. Attach material of choice (single-wall latex) to the IV valve 7. Attach the single-wall latex to the skin using mastix spirit gum 8. Using the pump, vacuum out all of the air inside 9. Using the pump, push the U/S gel inside 10. Image!		securing of the latex to the skin, which could potentially be done with mastix spirit gum. After doing the testing, I believe this solution's chance for success is low.
Self-Sealing Silicone Cap for IV	1. Ultrasound gel placed on skin 2. Ultrasound probe placed on as well 3. Sample images taken to ensure image quality is good 4. Clean off the U/S gel 5. Tape down the U/S probe onto the skin (or use mastix spirit gum) 6. Attach self-sealing rubber injection port to single-wall latex 7. Attach edges of single-walled latex to perimeter of area on which		Conclusions not finalized prior to COVID-19 disruption.

	there will be U/S gel 8. Using hypodermic needle, pull air out 9. Using hypodermic needle, push U/S gel in		

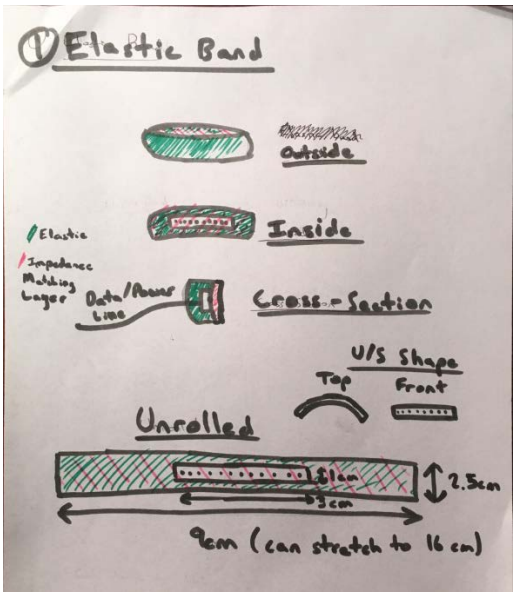
13.9 Post-COVID Design Sketches and CAD Renderings

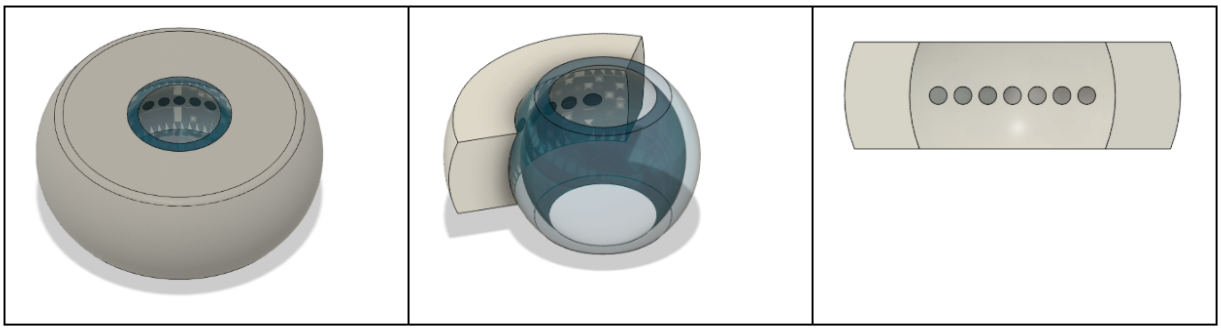
13.9.1 Cap Attachment





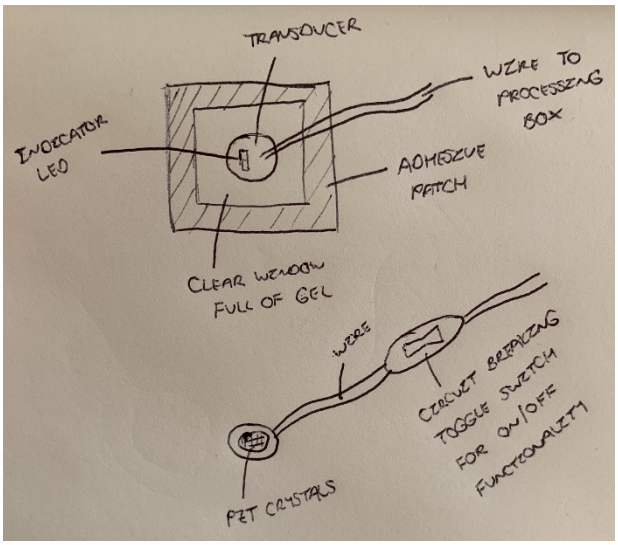
13.9.2 Ring Attachment

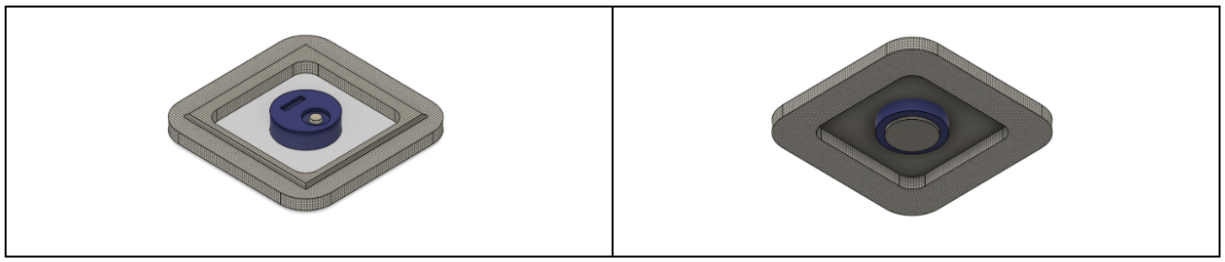




Elastic band (dark grey); impedance matching layer (blue); curved transducer element (dotted)

13.9.3 Electrode Pad





13.9.4 Elastic Band Based on Smart Watch