Mirror mechanism design with Encapsulation for Ultrasound-guided PCNL access

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Major Qualifying Project by:

Srikar Nekkanti

Jieping Zhao

Advised by:

Professor Haichong Zhang (WPI)

Acknowledging:

Yichuan Tang (WPI)

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Abbreviations:

Percutaneous Nephrolithotomy – (PCNL)

Ultrasound – (US)

Computer Aided Design – (CAD)

Polylactic acid – (PLA)

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Abstract:

Kidney stones, also known as calculi, are mineral deposits that form in the renal calyces and pelvis or attach to the renal papillae. It is the most common disease of the urinary tract, with a high rate of recurrence in patients afflicted with the disease. The prevalence of this disease along with recurrence rates is increasing, affecting nearly 12% of the world's population throughout their lives[1]. Percutaneous nephrolithotomy (PCNL) is regarded as the preferred treatment for medical professionals to remove or address renal calculi[2], [3]. While the procedure is incredibly safe and observes widespread use without difficulty, it presents a range of risks to the patient and requires a high level of training, preparation, and resources due to its nature being an invasive procedure, with the procedure taking up to three hours per patient. The challenges presented to the surgeon include the perfecting the alignment of the ultrasound probe, the needle and patient's target region.

The purpose of this study is to develop a cheap, intuitive, and safe medical device that aims to easily guide the surgeon towards the needle insertion path and thus cutting the amount of time and resources required to begin the procedure itself. The proposed device utilizes a mirror-mechanism that is situated in a locally encapsulated housing, allowing for the needle to be inserted in the same plane as the probe without compromising image quality or safety. While previous work has been conducted in the same study, this project aims to address the fundamental obstacles encountered by previous contributors and provide a simplified, real alternative to current solutions offered on the medical device market.

Client Statement:

PCNL requires a needle insertion into the patient's body, usually through the back. This process is risky and requires well-trained technicians in co-ordination with the surgeon. The overall complication rate for PCNL procedures is said to be around 21.5%, which is relatively high[4], [5]. While these complications are usually minor, such as excessive bleeding, this leads to further intervention on the patient's behalf and extends long surgical procedures. Image guidance through the use of an ultrasound probe is a very intuitive, low-cost and real-time procedure that can be used by the surgical staff to visualize the needle's path and its target, simplifying the procedure and minimizing the risk.

The current state of Ultrasound imaging in PCNL however, creates difficulties for medical professionals due to its design, along with the difficult and time-consuming task of aligning the probe's field of view with the needle's path.

Revised Client Statement:

PCNL requires the insertion of a needle into the patient's body that is guided through an imaging modality such as Ultrasound. This process is risky and complicated since it requires co-ordination of the US set-up in tandem with the needle guidance and insertion. The client needs a medical device that integrates the needle insertion and imaging into a singular solution, greatly simplifying the process and reducing the time taken. This device should be intuitive,

low-cost, disposable, lightweight and sterilizable. The solution must function outside of a water tank with an encapsulation solution, enable needle insertion with a high degree of accuracy and enable guidance of the needle through real-time imaging comparable to current solutions.

1 Background:

1.1 Epidemiology: Renal Calculi

Renal calculi, commonly known as kidney stones, is the most common disease of the urinary tract. The stones can be formed at various locations of the urinary tract, including the kidney, ureter or urinary bladder and do not initially present any symptoms in the patient. In a healthy patient, urinary filtrate is created in the glomerulus of the kidney and passes into a series of tubules where the volume and the solute levels are adjusted through a series of reabsorptions and secretions[6]. This urine is then excreted at the end of the urinary tract, thus leaving the body with dissolved wastes. However, the formation of kidney stones occurs when the filtrate contains an excess of solute, meaning that it cannot be dissolved, leading to crystallization of the various minerals or salts that make up the solute. Overtime, these crystalline structures can build up and aggregate, leading to blockages, dilation of the kidney and injury in the urinary tract and major features of the kidney itself. [1], [7]

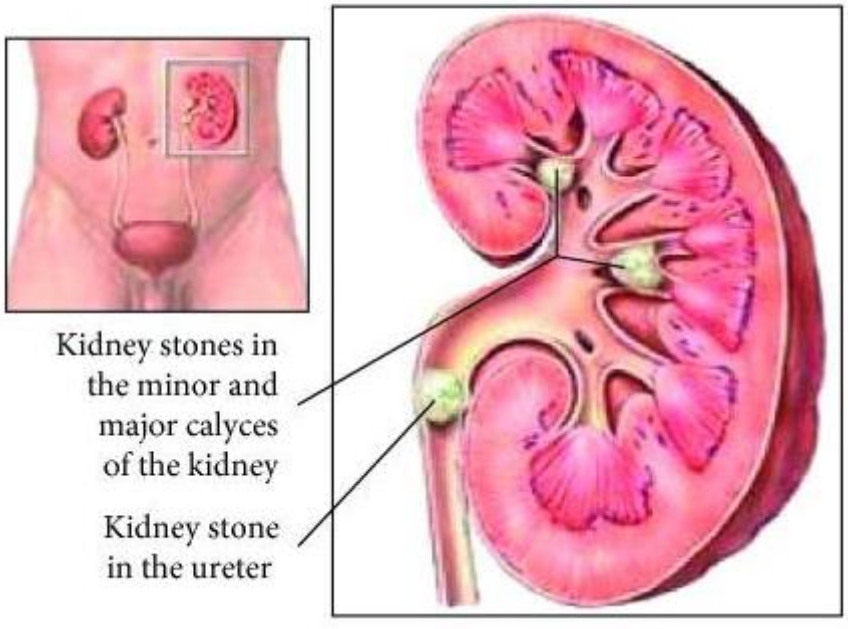

Figure 1: Kidney Stone locations within the major features of the kidney.

The kidneys are extremely important organs and are responsible for the filtration of large amounts of fluid each day from the body. Unhealthy kidneys are extremely concerning as they can further affect the normal functioning of the nervous, muscular, circular, and lymphatic systems. While the formation of renal calculi can take place over a large period of time, it is

crucial that the formations and blockages are removed or broken down so that the kidneys can continue to remain healthy.[1]

1.2 Ultrasound (US) Imaging Technology

Ultrasound Imaging technology has observed widespread clinical use for the better part of over 50 years and is a crucial tool in diagnosis of a variety of medical conditions. It is used in tandem with treatment options, surgeries, therapy, or diagnostic tools for abdominal, cardiac, neural, gynaecological, urological and in other body structures [8]. The most distinct advantages that ultrasound imaging holds over other popular imaging modalities such as x-ray is its ease of use, non-invasive nature, the lack of any radiation exposure to patients and its real time imaging capabilities using a simple handheld probe [9]. These characteristics make the modality cheap, intuitive, and safe for applications where radiation is not desired such as in gynaecological applications like pregnancy scans. The probe, also known as the transducer, is placed over the desired or target area and moved over the patient to obtain images [10].

The technology works through a series of pressure waves that are emitted by piezoelectric components in the transducer of the probe. When powered on, the electric current causes these elements to expand and contract, creating a sound wave that can be propagated in the direction the probe is facing. These waves then enter the patient and move through the tissue, organs and other structures in the body and are reflected to the transducer [8], [10], [11]. The transducer then receives these reflected waves, which in turn is converted into electric current, acting as the raw data. This raw data can then be processed to beamform and put together a typical US image. Figure 2 below shows how an ultrasound probe utilizes the piezoelectric effect to obtain images of the target region.

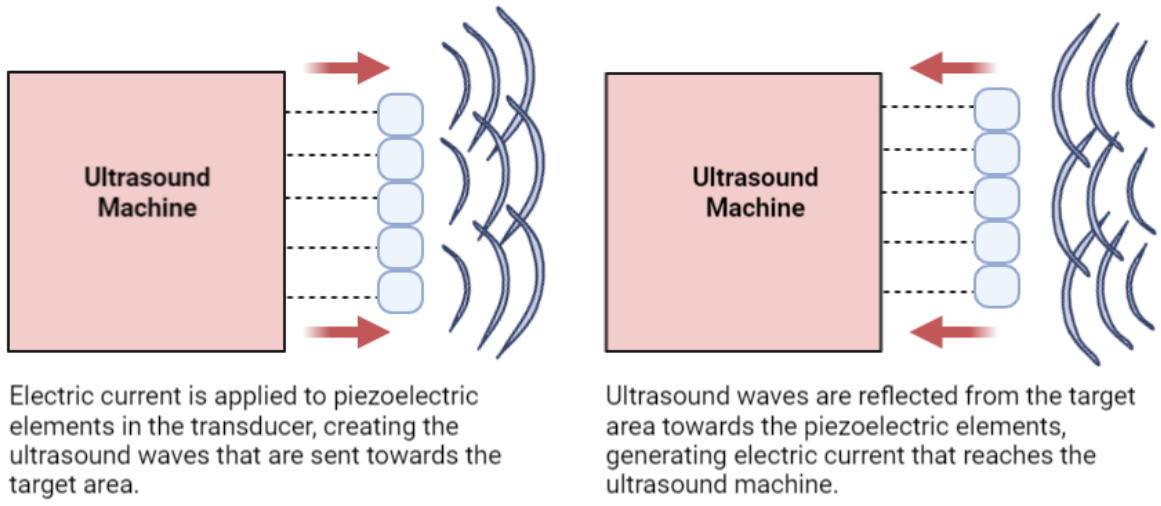

Figure 2: The usage of piezoelectric principles by the ultrasound machine to obtain images of target area.

Once the ultrasound machine has received the raw data, it can then be processed into a US image. To do this, it is important to understand the basic principle through which images are constructed and data is interpreted. US imaging uses beamforming, that assumes that sound travels at a known and constant speed. The waves that are reflected to the probe can hence be

interpreted using this principle – waves that are reflected the quickest towards the probe are bounced back from shallower structures or features close to the probe. Similarly, wave reflections that reach the probe later are structures that are deeper inside the target area, where the sound waves take longer to reach and bounce back [11]. Figure 3 below portrays this visually.

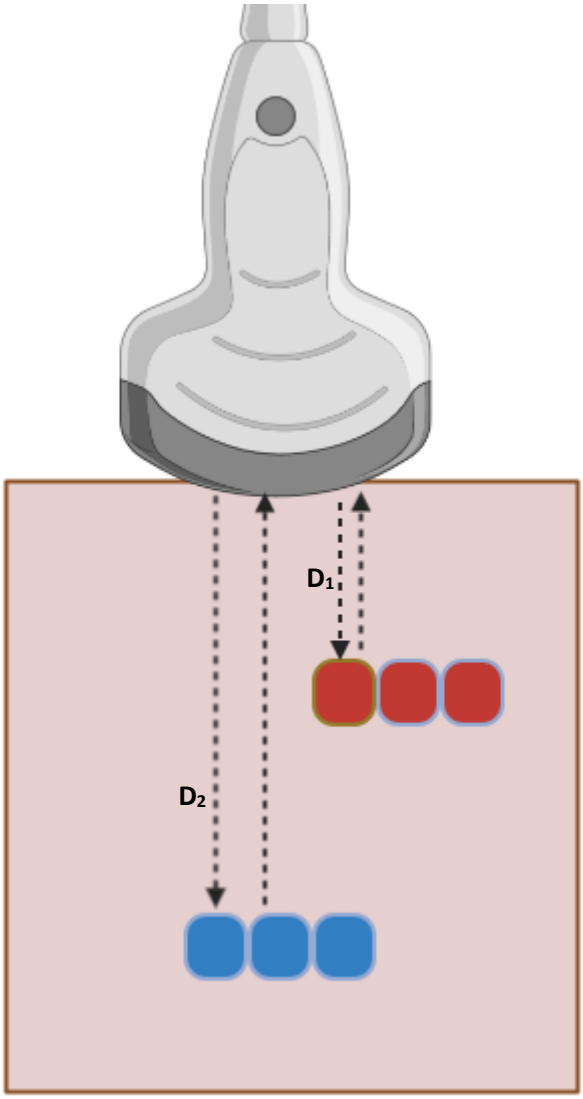

Figure 3: A demonstration of how travel distance for ultrasound waves can indicate the proximity of features in the patient's target area.

This concept can further be demonstrated using the following equation.

$$2D = v * t$$

In the above equation, the distance from the probe to the feature being image is denoted by D, while the time taken for the signal to be sent and reflected back is denoted by t. v denotes the velocity of the ultrasound in that medium. In the case of figure 3, v is fixed since both red and blue sets of structures are in the same medium. Therefore, the ultrasound machine can then calculate that the distance D_1 for the red structures is shorter than D_2 for the blue structures as it takes longer for the probe to receive the reflected signal (t).

Using this principle, the computer can use the current generated by the waves to construct an US image (most commonly in 2D). This image is usually a cross-section view of the procedural target area that is in line with the transducer's imaging plane. The speed of sound travelling through tissue is assumed to be at 1540 m/sec, requiring the ultrasound machine to interpret data rapidly, allowing for real time imaging of the patient [8], [11]. One other important aspect to consider is that of attenuation: along the path of the ultrasound waves, the interaction between the waves and tissues causes a reduction in intensity. This phenomenon is known as attenuation. In addition to this, the physical properties of the target area such as density, elasticity and viscosity can greatly affect attenuation levels of the signal. For example, the bones in the human body heavily absorb the ultrasound waves. In contrast, any gas present in the target area will near-perfectly reflect the ultrasound waves.

This process can greatly affect the ability and quality of the ultrasound image generated. Reflected waves are greatly important as they are then received by the transducer and thus provide useful information about the target area. Mediums that are characterized by near-perfect reflection such as pockets of gas will send back ultrasound waves that usually still have all the intensity, they left the transponder with – this can act as a barrier for the waves to reach beyond that medium to explore further since they are being reflected almost immediately. In contrast, mediums such as bone absorb the waves and convert it into another form of energy such as heat will reflect waves with a much weaker intensity. Strong absorptive mediums such as bone therefore cause the formation of an acoustic shadow since there is not enough intensity in the ultrasound waves to inspect further beyond it. This signifies the importance of liquid materials and mediums in ultrasound, as they do not excessively reflect or refract the ultrasound waves. These mediums can also thus serve as a taxi of sorts; through which ultrasound waves can reach greater distances to image the target area. This property of the difference in interaction and disturbance is known as the acoustic impedance of that certain medium. It is defined as follows:

$$Z = d \times v$$

In the above equation, the acoustic impedance is denoted by Z, the density of the medium is denoted by d and the velocity of the ultrasound signal within that medium is denoted by v [11]. It is extremely fundamental for this project to understand the significance of acoustic impedance due to its operational nature of passing two mediums to reach the target area, with regards to the challenges of encapsulation for the device.

In addition to this, there are various other factors that one must consider while performing ultrasound imaging. One such factor is frequency: defined as the number of vibrations per unit of time. Frequency is expressed in hertz (Hz). Ultrasound frequencies are those above 20kHz, which is at the level much higher than that human can naturally perceive. While one might believe that higher frequencies are beneficial to the imaging quality and can be used to increase the imaging plane's distance deep into the human tissue, this does not hold to be true. Higher frequencies do increase absorption of the ultrasound signal proportionately, but disproportionately increase attenuation and back-scattering even more. Therefore, most ultrasound applications for imaging usually limit the frequency to a maximum of 15 MHz Another important factor is the voltage itself. Increasing the voltage of the signal uses the amplitude of the received signal and increases it to the desired setting. While this can be used to increase visibility of signals that are harder to see at lower amplitudes, it also means that

other undesirable effects are garnered as result of the increase. An increase in voltage often also increases artifacts, blurring and can disproportionately highlight and oversize already strong signals observed in the image [8], [9], [11].

All in all, it is important to recognize the various fundamentals and principal factors in play when using an ultrasound device. To obtain the best possible image to fit the project's needs, it will be crucial to balance a wide variety of parameters. An ideal image would boast a high spatial, temporal and contrast resolution, all at the same time. However, it is up to the operator of the ultrasound machine to find the right compromise and find the right set of conditions while keeping artefacts to a minimum. For example, a higher frequency might provide a superior spatial resolution at lower depths, but severely impedes the ability to image at high depths. A lower frequency can provide greater penetration for the ultrasound signal, but compromises in spatial resolution overall. It is also up to the user to identify the correct mode of ultrasound imaging, along with the right type of ultrasound transducer.

There are various methods of utilizing the signals that the transducer receives upon being reflected from the target area. The A-mode method displays signals in the form of simple spikes along a time base, with the amplitude of the signal received on the Y-axis and the time on the X-axis. As previously discussed, the position of the spike on the Y-axis along time signifies the distance from the probe [12]. This mode is only used to display 1-D information and does not constitute an image in any conceivable manner. Figure 4 shows what a typical A-mode ultrasound reading can look like.

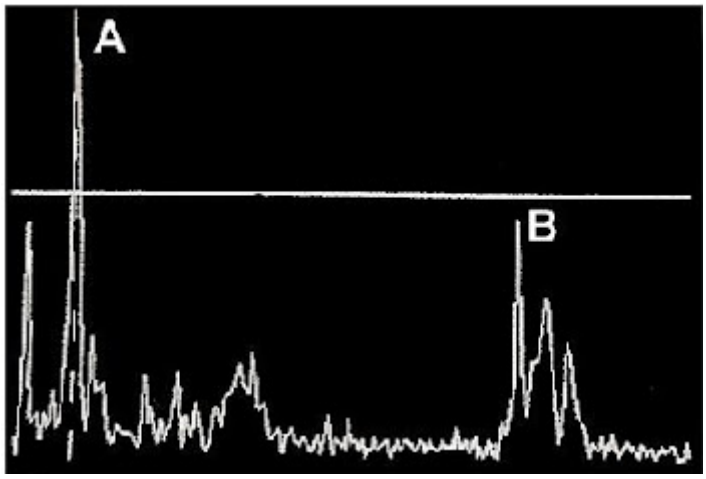

Figure 4: Example of A-mode display [8]

The Brightness mode (B-mode) uses the signals received by the probe, plots, and displays them as dots across a spectrum of intensities. The brightness of the dots is proportional to the measure of the size of the signal received by the transducer. For a given region of the ultrasound imaging plane, a line of dots is displayed, thus creating a 2D image that shows amplitude (brightness) and distance from the probe itself. Figure 5 shows a typical example of the B-mode method. The B-mode method is the most common way the ultrasound is used in a diagnostic application.

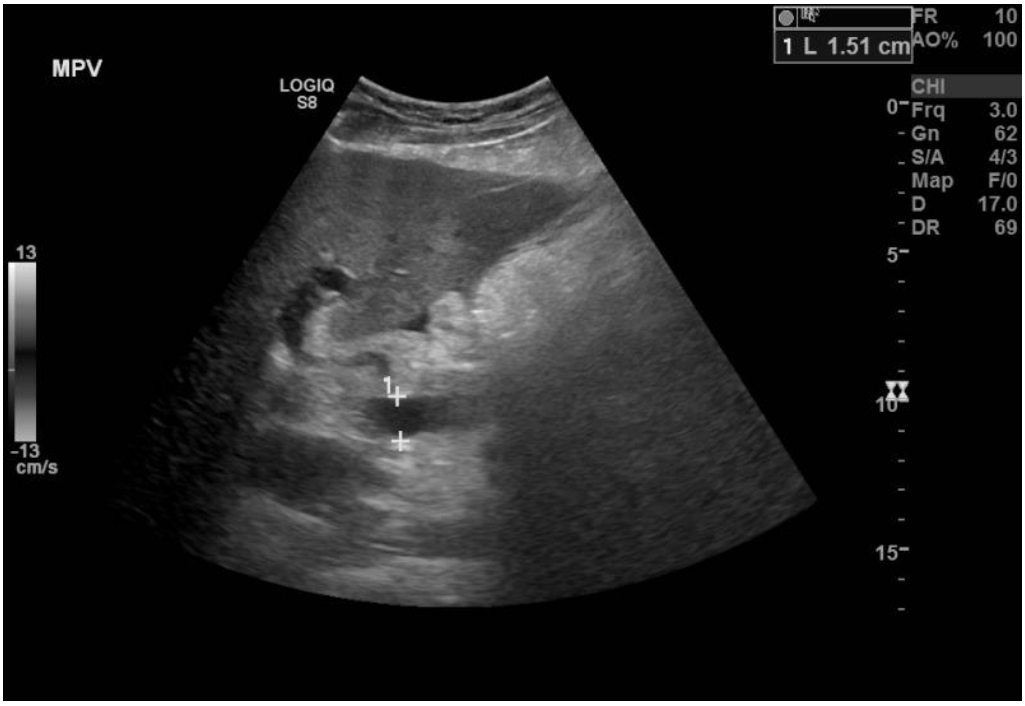

Figure 5: B-mode ultrasound image example of a vein [13].

The real time imaging method utilizes the B-mode method of scanning at a rapid successive rate. This rate is so high that it is enough to create the semblance of motion, as images are displayed as they are acquired. As mentioned above, there are also various types of US probes that have a wide variety of applications. These include linear array, phased array, convex array, and endo-array probes. For the purposes of this project, a convex array probe was used as it utilizes a higher range of frequencies for better penetration of the ultrasound signal, making it easier to reach the target area for PCNL procedures and soft tissue regions [14]. Figure 6 shows what various transducers in use in the medical diagnostics field include.

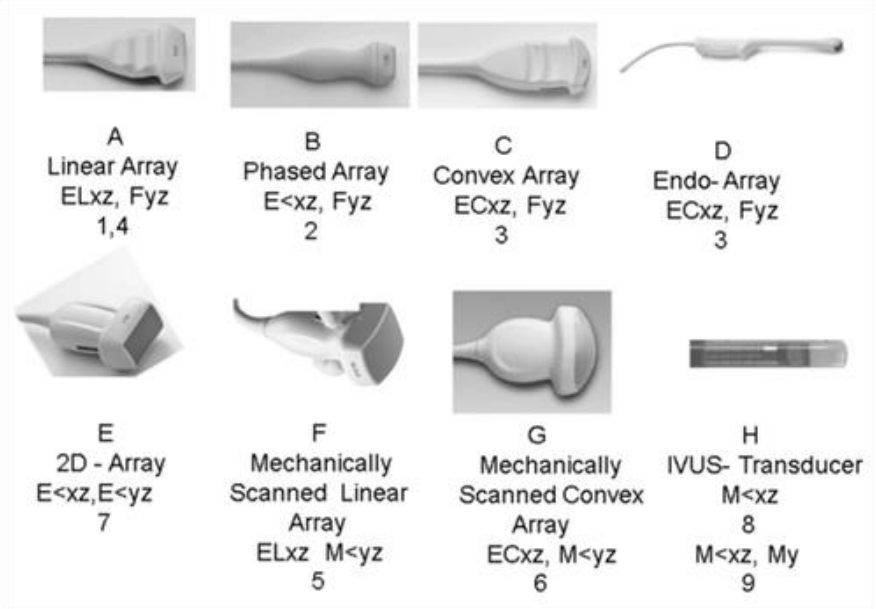

Figure 6: Transducer Type examples along with image formats and axis information [14].

1.3 Current State of needle insertion, guidance and PCNL

As discussed previously, the incidence of nephrolithiasis (formation of kidney calculi) has risen sharply, acting as a global trend. Percutaneous nephrolithotomy (PCNL) is often considered to be the gold standard procedure in tackling this increasingly prominent medical issue and can play an extremely important role in managing larger renal calculi [1], [15].

PCNL is often required when the renal calculi or stones are larger than 2 cm in size. While the surgical procedure is not considered to be immensely risky, planning and gathering adequate information on the patient's kidney in order to achieve successful renal access is extremely crucial to the success of the procedure [15]. Traditionally, this involves the use of extensive computer tomography (CT) well prior to the actual procedure. The use of multiphase CT allows the medical team to evaluate the space of the kidney in relation to the calculi, along with a possible plan to gain access to the kidney specific to that patient. The medical team also evaluates the risks possibly posed by the PCNL procedure. A patient who is also suffering from Hepatosplenomegaly (HPM), for instance, will face significant risks and complications if they are subjected to PCNL. This evaluation thus reduces the risks of complications to patients and allows for careful planning for renal access [3], [4].

During the procedure however, traditional fluoroscopy is required to follow the established plan and guide the renal access through the needle. Traditional fluoroscopy (commonly known as the X-ray) is most often utilized by the medical team. Fluoroscopy guided procedures can usually follow a variety of approaches towards needle guidance and access [4]. Figure 7 below demonstrates the various approaches taken by medical professionals during PCNL.

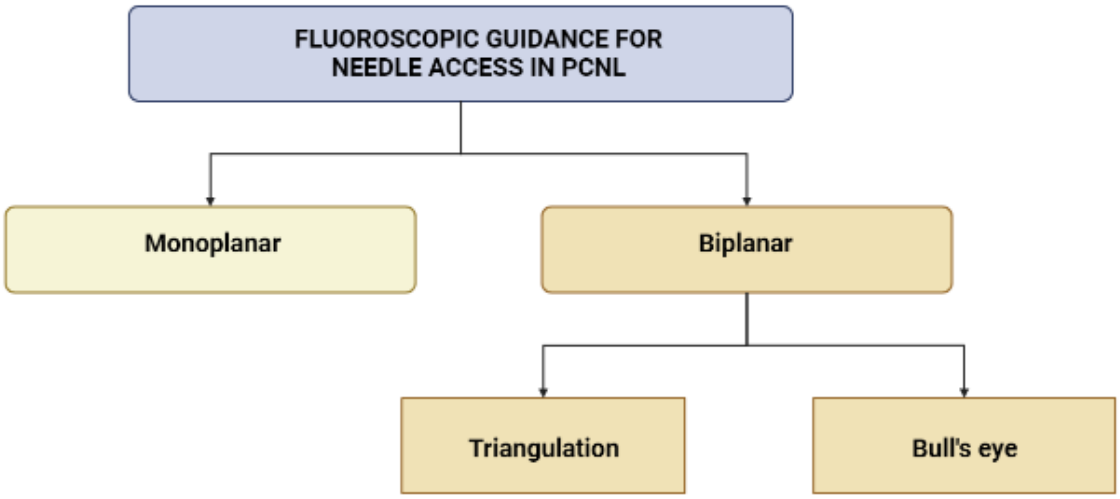

Figure 7: The various approaches considered for fluoroscopic guidance in PCNL [16].

A monoplanar approach involves using the fluoroscopy to obtain pictures or images of the patient at a chosen angle by the medical team, closely identifying the approach angles and approximate entry points, thus proceeding with needle access. Biplanar fluoroscopy, however, enables real time imaging of the patient. The bull's eye approach uses a C-arm perpendicular

to the patient, which is used to mark the targeted calyx. The needle is then seen as a dot on the images, allowing the medical team to control the trajectory of the needle and the depth of the puncture. The triangulation technique uses a different approach: the medical team identifies two or three known features on the image that can be used as points of reference. Using these points of reference, a known point is then calculated and determined as the target calyx, with the marked points used as the point of entry. This procedure follows no standard or set procedure, varying greatly depending on the patient's anatomy and the surgeon's preferences [4], [17]. While these approaches towards PCNL needle guidance and access have proven to have a good rate of efficacy and success – they hold numerous disadvantages.

Figure 8: Fluoroscopy guided PCNL procedure.

Fluoroscopy guided procedures expose the patients to radiation, are extremely cost-prohibitive, flawed in terms of their real time imaging capabilities when compared to more modern modalities and have extremely steep learning curves for medical staff – making the procedure significantly harder at the most critical point [18], [19].

1.4 Ultrasound Guided PCNL Needle Access

Ultrasound guided renal access has become an increasingly popular way to modernize the PCNL procedure while significantly reducing patient risk, cost, time taken for the procedure and the overall training for medical staff. US guided access is radiation free, can increase accuracy, provide a more accurate real-time imaging solution all while maintaining a high success rate and positive clinical outcomes [20].

While pre-operative procedures, testing and evaluations remain largely the same for US guided PCNL, the focal point of the procedure is completely revamped with the US modality guiding the medical staff instead of a fluoroscopic set-up. A curved array ultrasound transducer

is often utilized. Frequency can be adjusted to respond to patient anatomy, allowing the medical team more flexibility to manoeuvre with imaging depth, while also provided the capability to search for other obstacles and features surrounding the insertion area. In general, the US depth is often set to 8-12 cm in range, with an average operating frequency of 3.5 MHz Surgeons performing the PCNL procedure then hold the probe with one hand, while holding the needle with the other. This allows the surgeon to move the probe around if required and to find the best possible position to the insert the needle for renal access. Once inserted, the surgeon is able to monitor the depth, position and visually evaluate the angle of the needle through the US modality in real-time [16].

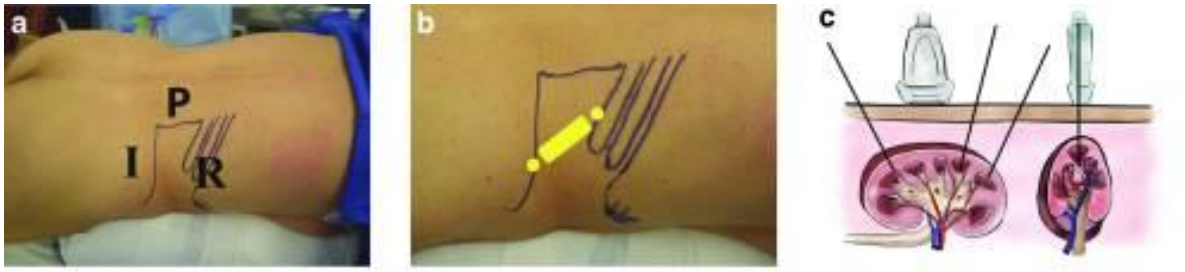

Figure 9: (a) longitudinal approach to renal access with US guidance (b) Markings for anatomical points of reference for PCNL. (c) Axial and coronal view of the US imaging plane with potential approaches for renal access by needle [16], [20].

US guided PCNL in prone or supine position has been proven to be just as effective as conventionally guided PCNL, with the added safety of no radiation exposure and its long-time effects on the patients. In addition to this, the use of doppler flow features can also help the surgeon visualize the vascular structures in the target area.

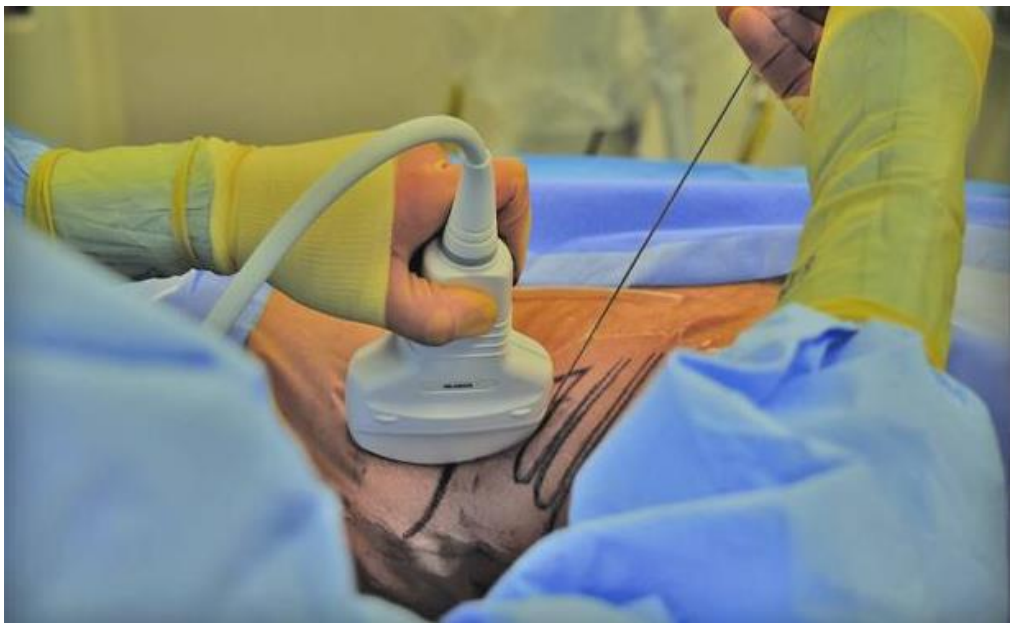

Figure 10:PCNL Needle insertion being performed while maintaining real time US imaging for guidance [16].

However, there are still disadvantages to this approach. The steepest disadvantage is the required expertise in handling the US probe while simultaneously commencing needle

insertion with the other hand. This can be proven to be a difficult task that requires US expertise, along with a high level of co-ordination and even additional help in the operating room. In addition to this, surgeons who are mostly acclimatized to conventional PCNL might have difficulties understanding the optimal point of entry in geometrical relation to that of the probe's imaging plane. Thus, there is room of improvement or optimization in terms of simplifying the procedure further, while allowing for greater flexibility on the surgeon's part and reducing the time taken to gain renal access [16], [20].

This project therefore proposes a low-cost, simplified, intuitive medical device that can integrate the needle guidance and imaging into a singular disposable solution –while maintaining encapsulation required for probe operation and image quality.

1.5 Current Market Alternatives

The need for simpler and more intuitive US guidance for needle insertion is not restricted to PCNL and can apply to a variety of clinical applications. As such, there have been several products available on the market that are hoping to improve the accuracy, simplicity, and efficiency of US guided procedures by attempting to integrate needle guidance and alignment into the imaging plane. Figure 11 below shows a few of these products that have been publicly announced.

Figure 11: In order (left to right): Civco needle guide,Ethos Iris Needle Guidance system and EDM Medical solutions needle guide [21].

In general, these systems all share several characteristics in terms of their design. The device comes in the shape of an attachment that can be secured onto the probe of choice, with a needle guide on one end of the marked transducer. The needle guides allow the user to lock in place so that any needle deviation from the imaging plane or desired position is avoided. In essence, the solution simplifies the needle insertion procedure and reduces the level of experience and training required with conventional needle insertion. The trajectory the needle, while at the start is out of the imaging plane, is inserted at an angle through the puncture point so that it eventually enters the trajectory of the US beam upon insertion. Figure 12 below showcases this concept with an example of how the out-of-plane image insertion works.

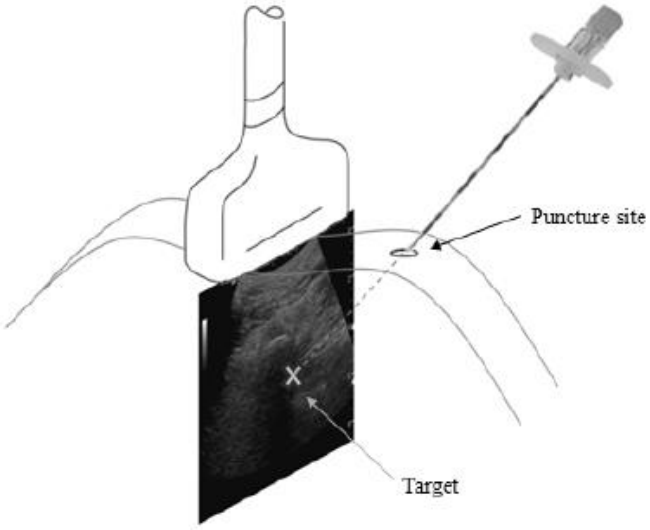

Figure 12: Trajectory of needle that is out of imaging plane during needle insertion procedure. Through angle of insertion, the needle will reach the target and intersect with imaging plane axially [22].

Some of the current products on the market are also extremely modern. The Ethos Iris, for instance, is equipped with needle tracking system using cameras to track the needle's location during the procedure. This allows for increased visibility and visualization for the user, reduces risk of deviation from the planned trajectory and allows for real-time tracking. However, this does not necessarily reduce the requirement of extensive training and co-ordination, as the users will have to train to take advantage of the camera and it's required positioning, along with increases expenses [21].

Another disadvantage with this method of needle insertion is that it is not practical for certain applications – such as PCNL. For PCNL, the forward-view of the needle is required to be in the same plane with good alignment. Using this method would also increase the amount of distance travelled by the needle, increasing risks of deviation and re-insertion. While products such as the Iris are extremely competitive for procedures such as Spinal taps, it cannot be used in the context of this project.

1.6 Previous MQP Project

Project team from last year has started a design of a needle-mirror synchronized mechanism. Their design provided an intuitive needle insertion method that consisted of a needle insertion mechanism and an imaging visualization software.

The principle of their design is very similar to the current device of this paper. The ultrasound waves emitted by the probe will go over one reflection by the mirrors before reaching the target. The probe is put in a container horizontally, while the mirror reflects the ultrasound waves vertically down. The needle will align with the reflected ultrasound waves by going through a hole at the center of the acrylic mirror [23].

The difference between the two designs is that the project team from last year added one degree of freedom to both the needle and the mirror so the two can both rotate for a small angle. The needle-mirror synchronized mechanism contains two sets of timings belts and pully wheels. These parts give a 2:1 ratio between the needle and the mirror. For every two degrees the needle has moved, the mirror will rotate along with it for one degree [23].

Different from the design of this paper, the device from last year's project team integrated electronic components into the device. Their design contains a display for menu navigation and an encoder to output the current orientation of the needle. The display screen is fixed on the top of the probe container for monitoring.

Despite the elegancy of their design, they did not create a fully functional product. The device they created does not have an encapsulation mechanism which means that their design could only work in a water tank environment. Additionally, their design lacks a needle release mechanism. The needle must be pulled out from the hole in the mirror for extractions.

2 Methodology

2.1 Project Overview

The project's various aspects were tackled by rank of importance, with the more fundamental aspects of the project taking priority earlier in the year.

2.1.1 Research and Developmental Phase

The project began with the research and developmental phase, which lasted seven to nine weeks in total. In this phase, the team conducted a literature review. This stage was extremely important since it enabled the team to understand a wide range of concepts. This included the fundamental principles of the ultrasound imaging modality, the advantages and disadvantages of ultrasound as opposed to other imaging techniques, current standards and technology, the epidemiology behind nephrolithotomy and the PCNL procedure and it's increasing importance in society. It was important for the team to gain a deeper understanding of the scope and potential impact of the project. Using this understanding, the team was able to form a plan for the direction of the project, along with the desired deliverables. This included studying what approaches previous teams have taken to tackle the project, along with the implementation of feedback and desired improvements that could be made on top of the progress already achieved. Key aspects of the project were outlined using this approach, followed by further research and a proposal for a design of the new system. A rough prototype concept was thus established, and the team set to prepare implementation of the project plan.

2.1.2 Design Development and Experimental Planning Phase

The first part of the phase involved the purchase of materials required for testing and prototyping. This included extremely crucial components, such as the mirrors that needed to be cut to dimension as specified. In addition to this, the team also trained to develop CAD modelling skills on both Fusion 360 and SolidWorks since a good handle of modelling was required for the prototype. The team also prepared and outlined key resources available such as 3D printers, an ultrasound machine and a research workspace that would be required for any testing of the medical device. It was also important for the team members to learn how to use an ultrasound probe and understand safety and other good practices that need to be observed during its use. Testing plans were also outlined so that the team would be prepared to test basic imaging functionality, alignment, encapsulation, and structural integrity.

2.1.3 Testing and Experimental Phase

The team used SolidWorks to develop a prototype CAD model of the proposed medical device with detail and 3D print it. Once printed, the team set out to begin basic testing of structural and functional properties for the project. This included drop testing, basic encapsulation, and leak testing along with laser alignment testing to check mirror alignment and imaging functionality. This process involved an extremely large learning curve, with constant improvements being made based on feedback from the testing performed along with further research and comments from the advisor. After nearly five iterations of this initial prototype, a deeper, imaging test was conducted with a well-improved design iteration. This test was conducted in a water tank on an ultrasound phantom and provided the team with valuable feedback that included fundamental flaws that needed to be addressed to achieve the set project targets.

2.1.4 Major Redesign Phase

The major flaws identified in the previous phase included the large, so called "blind spot" in the imaging plane, along with image noise, artefacts, and design implementation difficulties with regards to 3D printing the various prototypes. Minor issues such as mirror placement and slot design were also outlined as requiring vast improvement in this phase. Based on this feedback, the team strongly believed that there was a need for a complete revamp and redesign of the largest and most important part of the device – the rigid "case". The team incorporated the feedback, changing major aspects of the design such as the number of mirrors, encapsulation planning and even developed plans and parameters for aimed improvements and testing. The team moved from a top-probe access with dual mirror system to a side-access, single mirror system, allowing for a more accurate and rigid design.

2.1.5 Iterative Improvements and Experimental Phase

Once the redesigned prototype was 3D printed in the third part of this phase, further testing and iterative improvements were made. The team was able to make crucial progress with regards to the functionality of the design. The blind spot in the imaging plane was drastically reduced to the point where it no longer negatively affected the applicability of the device in PCNL procedures. In addition to this, the mirror slots and securement were improved upon and perfected, along with the notch component and other surfaces becoming more streamlined and simplified. The team also identified further issues during the testing, such as the securement of the US transducer itself during testing and how it was negatively impacting image testing. This was an important aspect to the project that was not previously explored, as any movement of the probe due to it not being secured in the device rendered image testing ineffective and unreliable. This meant that the team could not differentiate between other fundamental issues with regards to the design in the results of imaging tests. This led the team to develop a "mould" for the probe to be seated in so that it could be secure – allowing the team to conduct reliable, valid image testing to improve other design flaws. As The team developed three separate components to secure the mirrors and prevent movement while testing, a "top" part for the probe mould to prevent upwards movement and a bottom part where the US transducer would be seated. Through iterative improvements, the team also then changed the position of the notch in the design to be slightly to the left. It was at this point that another round of testing, this time with a needle – was performed in a water tank along with a phantom.

The team was then able to successfully show the needle in the imaging plane, along with a minimally present blind spot and improved image quality.

2.1.6 Encapsulation and Material Testing Phase

The next phase of the project focused exclusively on one objective: encapsulation and imaging functionality of the device outside of a water tank. To do this, the team first evaluated the various components of the device model and took time to simplify and combine where possible. This reduced the number of printed components for the device from four to two – a top "lid", along with a bottom "case". The components were combined, and the final design was intended to closely support and facilitate the total encapsulation of the mirror mechanism of the device. Once this was done, a variety of materials were purchased that the team believed through research could serve as potential encapsulation material. Image testing was performed with ultrasound gel encapsulation outside of the water tank using these various materials. This helped the team evaluate image quality and encapsulation to determine the best possible material for the medical device. Through testing, the team was able to identify two materials that allowed for the encapsulated device to function – which were then further evaluated and analysed to determine the final encapsulation material.

2.1.7 Conclusion Phase

To conclude, the team wished to complete the final round of experimental testing to address the overarching deliverable: the applicability of a simplified, rigid-body device that integrated needle guidance directly into the imaging plane to US-guided PCNL procedures. To do this, a gelatine phantom was designed with a target for the needle to reach through the device and US guidance.

This description includes the entirety of the "Mirror Mechanism Design with Encapsulation for Ultrasound guided PCNL access" project. This included a total of seven phases: The Research and Developmental Phase, Design Development and Experimental Planning Phase, Testing and Experimental Phase, Major Redesign Phase, Iterative Improvements and Experimental Phase, Encapsulation and Material Testing Phase and the Conclusion Phase. The project underwent a systematic, iterative design process that incorporated testing and feedback consistently over the course of the twenty-five weeks.

2.2 Design Development

During the initial design developmental phase, the team was able to propose three different concepts. The first design encompassed a five-component set up that included a U-shaped case. This case would include a singular slot at a 45-degree angle for a continuous mirror slab to sit in. A singular hole punch in the centre of the lid of the case and the mirror would allow for the needle to pass through the device, piercing the material lining the bottom of the case. The material used to encapsulate the bottom of the case would have to be a self-healing material that could potentially be resealed once insertion was complete. It would also have to be acoustically transparent to allow the reflected ultrasound signal to reach the target area. In addition to the case, two additional components would be attached via "arms" that would enable a secure positioning of the probe through a side access into the case. To enable encapsulation and functioning outside of a water tank, the case would also house a valve

through which water could be poured in, covering the probe and the mirror mechanism – thus conceptually enabling US imaging.

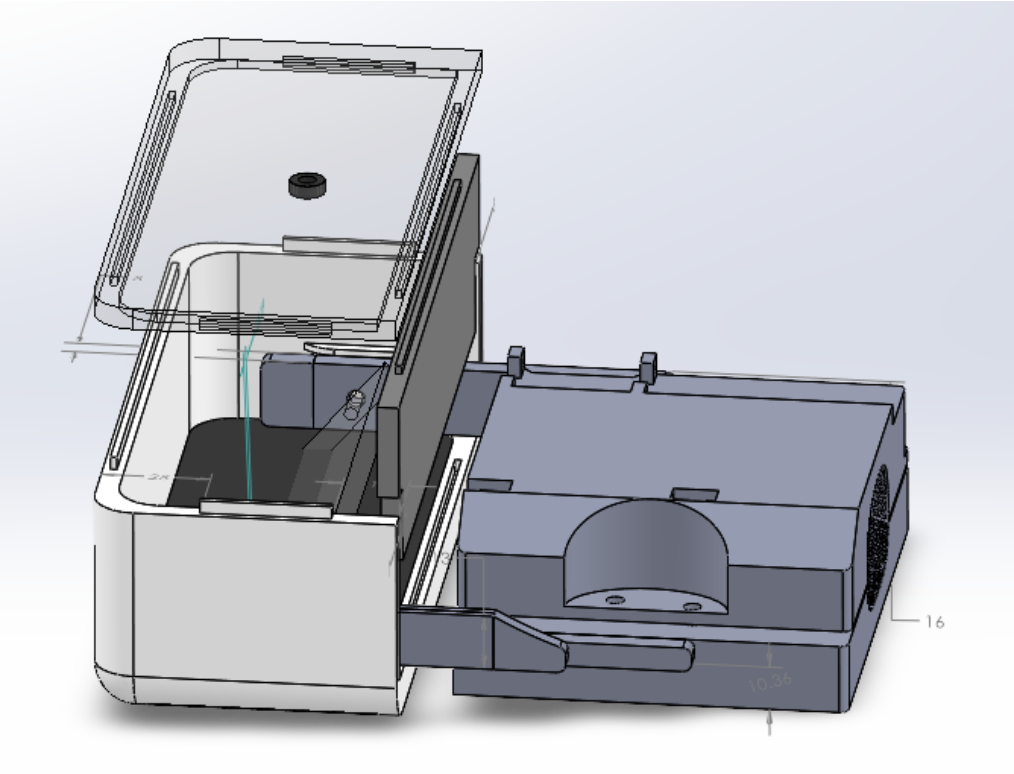

Figure 13: Concept A proposed during Design Development. Pictured is the fully assembled device with a U-shaped case, along with the connect probe securement and lid components.

Concept two, however, proposed a solution where the bottom part of the U-shaped case in question would not have to be sealed at all. Instead, the concept proposed the use of air-suction to adhere to the patient's skin, essentially sealing the bottom without an intermediary layer. To enable this, the walls of the case were made 2.4 times thicker, with a redesigned valve that could be fashioned to work with a suction-mechanism based device. This same valve, once suction was achieved, could then theoretically be used to fill the case with water, solving the encapsulation issue at hand.

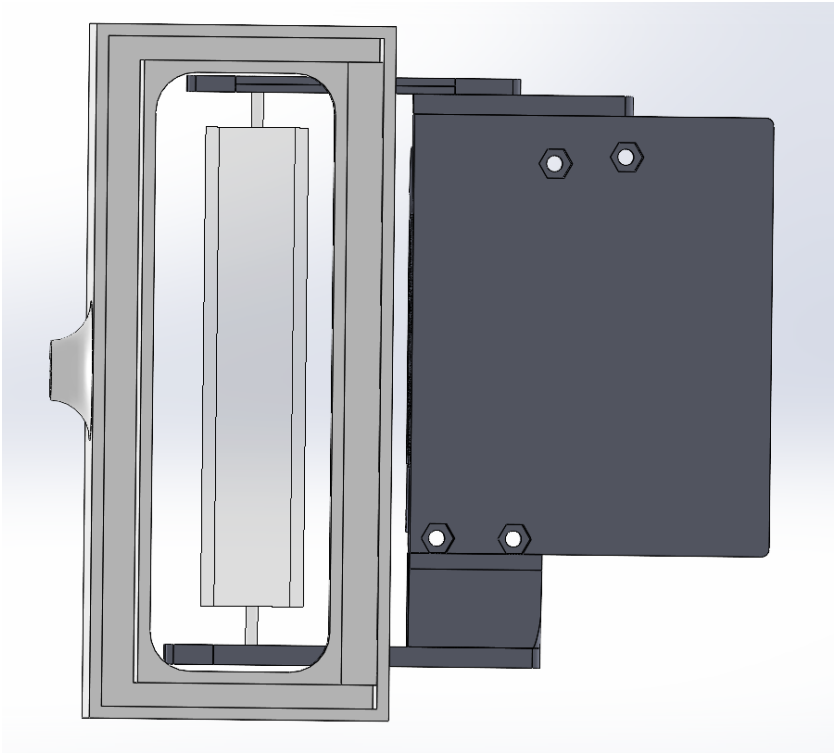

Figure 14: Proposed Concept B during design development. This concept is extremely like the previous design pictured in

Concept three was radically different from the other two. While the previous concepts were appealing in nature, the team questioned the viability of these designs with regard to the project's over-arching goals. Concept one would require the team to find a self-healing and acoustically transparent material that would enable needle insertion with guidance, drastically increasing the costs of production and potential risks of complications during assembly of the device. Concept two, while removing the intermediary self-healing material required the use of air suction on the patient's skin so that the device could seal itself. The use of air-suction would not only increase costs, but also increase setup time, resources required for surgeons and potentially affect the overall PCNL procedure. The use of suction on the patient's skin could cause minor harm and risks, along with possible complications during needle insertion and guidance. This led the team to develop a concept that utilized a more rectangular shaped case that could house two mirrors in parallel, both seated at a 45-degree angle. Instead of a side access via arms and additional components for the transducer, the probe would be seated directly into the case at the very top, with a customized slot that could enable a snug and secure fit. Theoretically, the ultrasound signal could then be reflected twice via the dual mirror mechanism before reaching the target area. The second mirror would also have a "notch" built into the centre of the slab. This notch would serve the same purpose as the pin hole design from concept A, allowing the needle to pass through the mirror while showing on the imaging plane in real-time. An advantage of this proposal was that due to the notch, the needle could then be left in place even if the rest of the case had to be removed. This separation of the insertion and the guidance component of the device thus also removed the need for a self-healing material to seal the bottom of the case – greatly simplifying the task and reducing costs as long as it was acoustically transparent and capable of supporting encapsulation. To better visualize this, Figure 15 below shows how US transducer can be seated on top and still maintain functionality through the dual-mirror mechanism (left), along with a concept CAD depiction of the proposed

design (right) that depicts how the notch design enables needle insertion without harm to encapsulation.

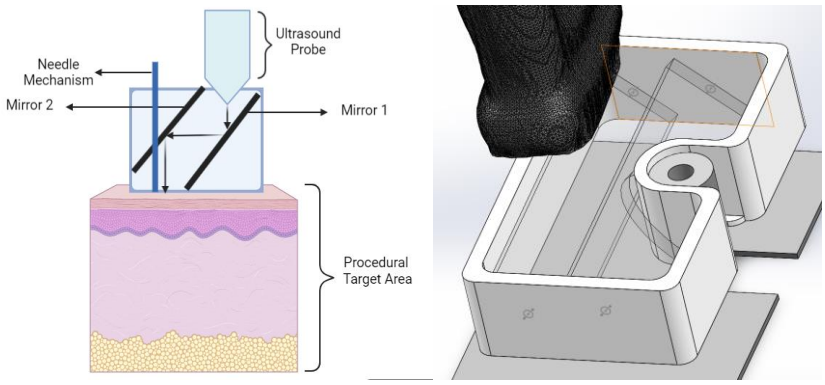

Figure 15: Proposed Concept C during design development. This concept utilizes a dual mirror system with an external notch and top-probe access. Pictured on the left is the theoretical path for US beam originating from the probe along with needle mechanism.

While concept C seemed to align with the project's goals and targets the most, the team identified a wide range of flaws and potential areas of improvement during the testing and experimental phase, leading to the redesign and creation of Concept D. This design combined aspects of concept A and C. It simplified the device by switching to a single mirror mechanism and reverting to probe access through the side but still choosing to implement the notch feature from concept C. The notch also underwent a series of iterative changes to enable needle guidance without compromising on imaging functionality.

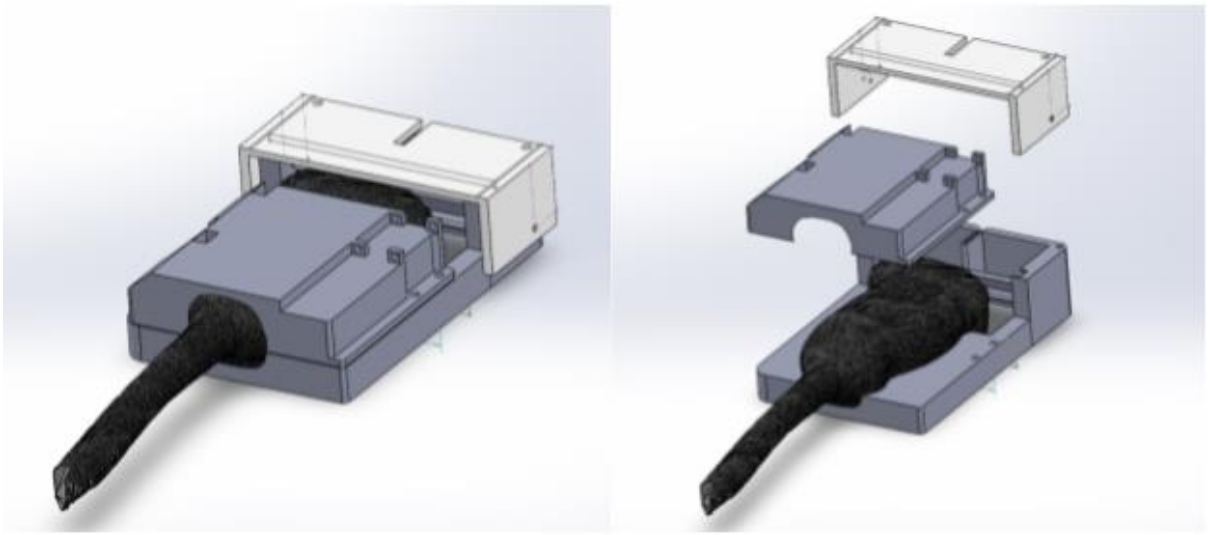

Figure 16: Full-assembly concept for Concept D design that demonstrates full encapsulation along with combined elements of Concept A and C.

2.3 Design Selection

To select a design, the team had to revisit the client statement and the additional requirements outlined for the applicability of the device during PCNL. The client statement outlines the following requirements:

1. Device must function without encapsulation in a water tank.

   When submerged in a water tank without water encapsulation mechanism, the medical device should output images with relatively good quality. The target object should be clearly visible with minimal noise. The image quality with the device installed to the ultrasound probe should be at approximately the same level as when the probe is working alone without the device reflecting the ultrasound waves.

2. Device must enable needle insertion with a high degree of accuracy comparable to current solutions.

   The medical device must include mechanisms that guides for needle insertion. The guiding mechanism must be steady to ensure safe insertion into human body. Moreover, different from the needle insertion mechanism provided by the current market products, the path of the needle guidance must perfectly align with the ultrasound waves so the position of the needle can be caught precisely. The needle tip needs to be accurately observed by the probe to better aid surgeons.

3. Device must enable needle guidance in real-time using US comparable to current solutions.

   While the needle is installed into the needle insertion mechanism, the ultrasound probe should be consistently output image of the needle. This feature will provide surgeons with the instant position of the needle, and so doctors can decide on how to proceed next based on the current needle tip position.

4. Device must be intuitive and easy to use.

   The layout of the medical device must be straight forward. The product should have minimal training time before using. The structure of the design should be simple to reduce mistakes because of the misunderstanding of the device.

5. Device must be sterilizable.

   To ensure a clean surgical environment, the medical device must be made sterilizable. This product will have direct contact with human bodies constantly, so sterilization must be accomplished to avoid risks of possible infections.

6. Device must be low-cost.

   The cost of this medical device should be relatively cheap so that when leakages or other types of damages occur, surgeons can easily dispose it and replace with a new one. Other solutions in the market are not expensive, so this medical device needs to be low-cost to be selected by surgeons.

7. Device must be light weight.

The total weight of this product needs to be low enough to allow easy manipulation for surgeons. As a result, the materials used to produce the medical case need to have low density, but at the same time, ensuring enough structural strength.

8. Device must be disposable.

   The materials used to make the medical case need to be environmentally friendly, and it must not be toxic to enable safe and fast disposal. Disposing such medical device should be convenient.

In this list above, requirements one, two and three are ranked equally as the most important requirements for the client and the project. Solutions four to eight are ranked by importance, with four being most important after one to three, and eight being the least important. Using this ranking, a Pugh Concept selection matrix can be created and utilized. The highest ranked requirements will be given the highest weight in terms of points (six), while other requirements are weighted by numerical rank. The baseline used for the comparison in this Pugh Concept selection matrix was current US standard insertion and guidance procedure. This is to compare the proposed solutions to the current standard, so that the team is aware if a design is better or worse for the various categories. If the design is considered better than the current standard, it will be scored a one. If it is comparable, it will be assigned a 0. If the proposed design is worse, it will be assigned a -1. The scores for each category are then multiplied by the ranked weight assigned to that requirement, which can then be tallied up and compared to decide on the final design. Table 1 below shows the Pugh Concept Selection Matrix.

Requirement	Rank (Weight)	Standard US guided PCNL procedure (Baseline)	Concept A	Concept B	Concept C	Concept D
Independent and viable encapsulation solution	6	0	-1	-1	0	1
High degree of accuracy for needle insertion	6	0	0	-1	0	0
Real-time guidance of needle using US	6	0	0	-1	1	1
Ease of Use	5	0	1	-1	1	1
Sterilizability	4	0	0	0	0	1
Low-cost	3	0	0	-1	1	1
Light-Weight	2	0	-1	0	0	-1
Disposability	1	0	0	0	0	-1
TALLIED SCORE		**0**	**-1**	**-26**	**14**	**21**

Table 1: Pugh Concept selection matrix based on four concepts developed by the team.

Based on the Pugh Concept selection matrix above, the concept with the highest tallied points is concept D, with a total of 21 points. While concept A is almost comparable to the baseline, Concept B is clearly worse with a score of -26 points in total. Concept C does score well as it sports slight improvements in real-time guidance, ease of use and low-cost, Concept D integrates the positive design features of both concepts A and C, thus leading to a high score.

It is, however, important to note that Concept D was entirely designed during Re-design phase of the project. While the team initially chose concept C, testing and experimentation showed the need for improvement in various area – thus leading to the conceptualization of concept D. Once concept D was chosen after its conceptualization – the team began a process of finalizing it. This process included iterative design improvements, testing, throughout the final four phases of the project. The sections that follow detail the finalized design that the team arrived at, along with the design specifications and testing.

2.4 Risk Management

Risk	Chance of occurrence Low/Med/High	Influence if occurs Low/Med/High	Mitigation
Materials for encapsulation are above budget, difficult to achieve, or unhealthy for human skin	Med	High	Ensure that a wide variety of materials can be tested – look into biocompatibility thoroughly. Ensure that 3D prototyping is taken advantage of to minimize prototyping costs.
Prototype of encapsulation model does not work/cause leaking	Low	High	Use a water tank to submerge the device. Engage and iterate using CAD to improve encapsulation. Try a wide variety of materials that may be applicable for imaging.
The quality of parts is not durable/lacks dimensional accuracy	Low	Med	Try different manufacturing methods, or choose parts that do not require might precision
Device is over-complicated and difficult to engage with for the user.	Low	Low	Ensure that a rigid-body design is implemented with minimal to none moving components, focus on one handed use for handling of device.
Ultrasound signal is not clear/heavily polluted by noise and artefacts.	Med	High	Ensure and retrace steps towards mirror mechanism design. Ensure through alignment and mirror securement. Use of water tank/suitable mediums for imaging.

Table 2: Risk Management Plan for Potential Obstacles regarding research and iterative design development.

2.5 Design Process: Component Background

2.5.1 Ultrasound Probe

Our team hopes that in the future, any feasible device that aims to play a role in ORs across the world will have to be compatible with nearly any kind of probe that observes use for PCNL procedures. However, for the purposes of this project, the team chose to use a C5-2 curved array transducer that is produced by Phillips, then repurposed by Verasonics. Figure 17 below showcases this specific probe.

Figure 17:Philips C5-2 Convex curved array Probe.

As discussed previously in this report, a wide variety of probes are available from multiple companies that can be used for different applications. For the purpose of this project, the medical device's intended purpose is to facilitate soft-tissue organ needle insertions, specifically through the back to access the kidney in order to remove renal calculi. Therefore, the transducer that is best suited for this situation would require a large elevation focus, with a wide range of applicable frequencies to be able to tune the focal depth of the probe. The C5-2 probe utilizes 128 elements to generate its signals, with a pitch of 0.506-0.510 mm and an elevation focus of 50-70mm. The curved convex design enables the user to have a wide imaging plane, providing valuable information regarding the target area and its features. This also helps minimize the risk of complications to the patient, as the operating surgeon has more detailed information that can be used for the guidance and insertion of the needle [24].

2.5.2 Materials:

For this project, the device components will be exclusively 3D printed using PLA plastic for rapid-prototyping and testing. This served as a two-fold advantage to the team: the first advantage being that 3D printing enables rapid prototyping with low-lead times and the second advantage being that it directly helps meet the requirements of the project: maintaining a low-cost production. The finalized design for concept D utilizes two 3D printed components that are required to assemble the device. This includes a "lid" component that sits above the probe, and a "case" component that sits in front of and below the US probe. This design is incredibly simplistic when compared to earlier concepts, as the four to five components in early iterations were combined and simplified to leave only two printed components. Once finalized however,

the medical device was 3D printed to specifications using polylactide (PLA). This was done to provide a high degree of dimensional accuracy with the printed parts for the final iteration, along with providing other benefits such as a smooth finish, high strength, durability. The team found this important to do so that the final round of testing with the resin-printed prototype serves as a good representation of the close-to-finish production quality design.

2.5.3 Mirror Mechanism

The mirror mechanism is one of the most crucial elements of this device. It is extremely important to ensure that needle itself is aligned correctly with the ultrasound probe, so that it reflects the US beam at the right angle towards the target area. This device is entirely rigid, with no moving parts or adjustability for the mirror mechanism itself. The mirror is installed by sliding it into the slots which are angled at 45 degrees with respect to the incoming ultrasound beam from the side. Figure 18 below visualizes the mechanism and how it behaves in the implemented design.

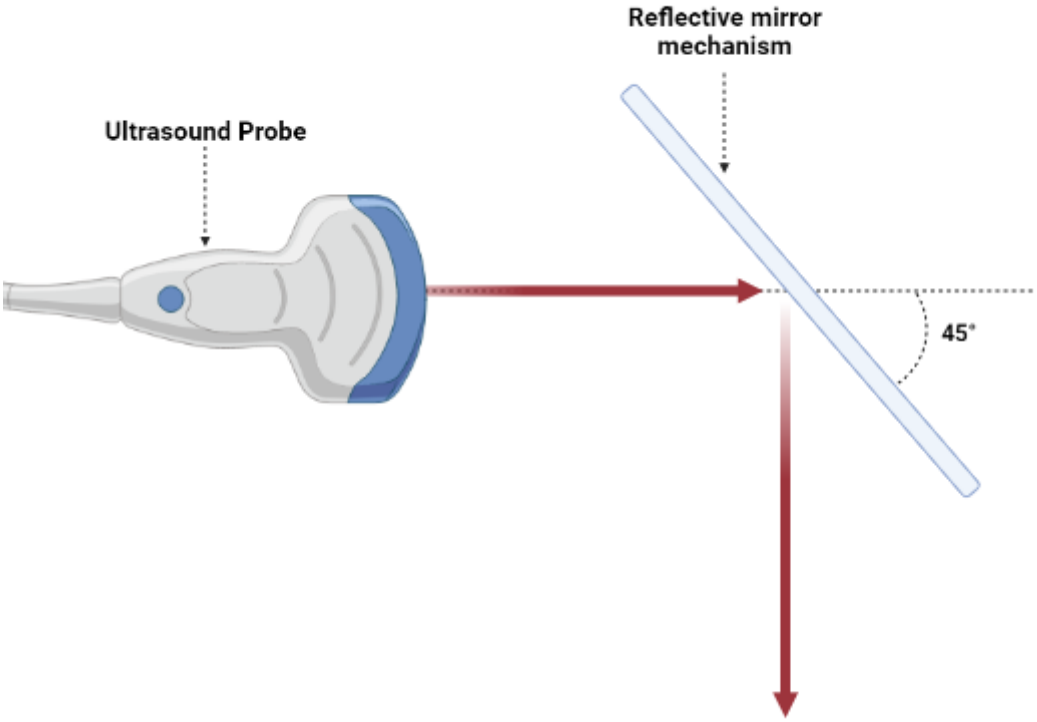

Figure 18: How the mirror mechanism reflects the ultrasound beam in the current design.

To meet the requirements one and three outlined in the design process section, it is important that once placed into the slot, the mirrors remain fixed and secure so as to not affect the angle of reflection and thus the overall imaging functionality. While figure 18 depicts the concept that the fourth design put forward, the team went through an extensive iterative process with one major re-design and multiple adjustments to ensure that the imaging functionality of this device is comparable to current solutions offered on the market.

2.5.4 Notch Needle-Pathway Mechanism

The needle pathway and guidance work in tandem with the integrated mirror mechanism, placing just as high in terms of importance for the success of this project and its applicability to PCNL procedures. For the medical device to prove successful for usage in PCNL, it is crucial that the needle presents itself in the imaging plane and can therefore be guided by the user in real-time using the US capabilities. In order for this to be possible, the needle must be inserted at the very same angle and align with the angle of reflected beam itself. Figure 19 below demonstrates this concept, presenting the needle approach and required pathway so that it presents in the imaging plane of the medical device.

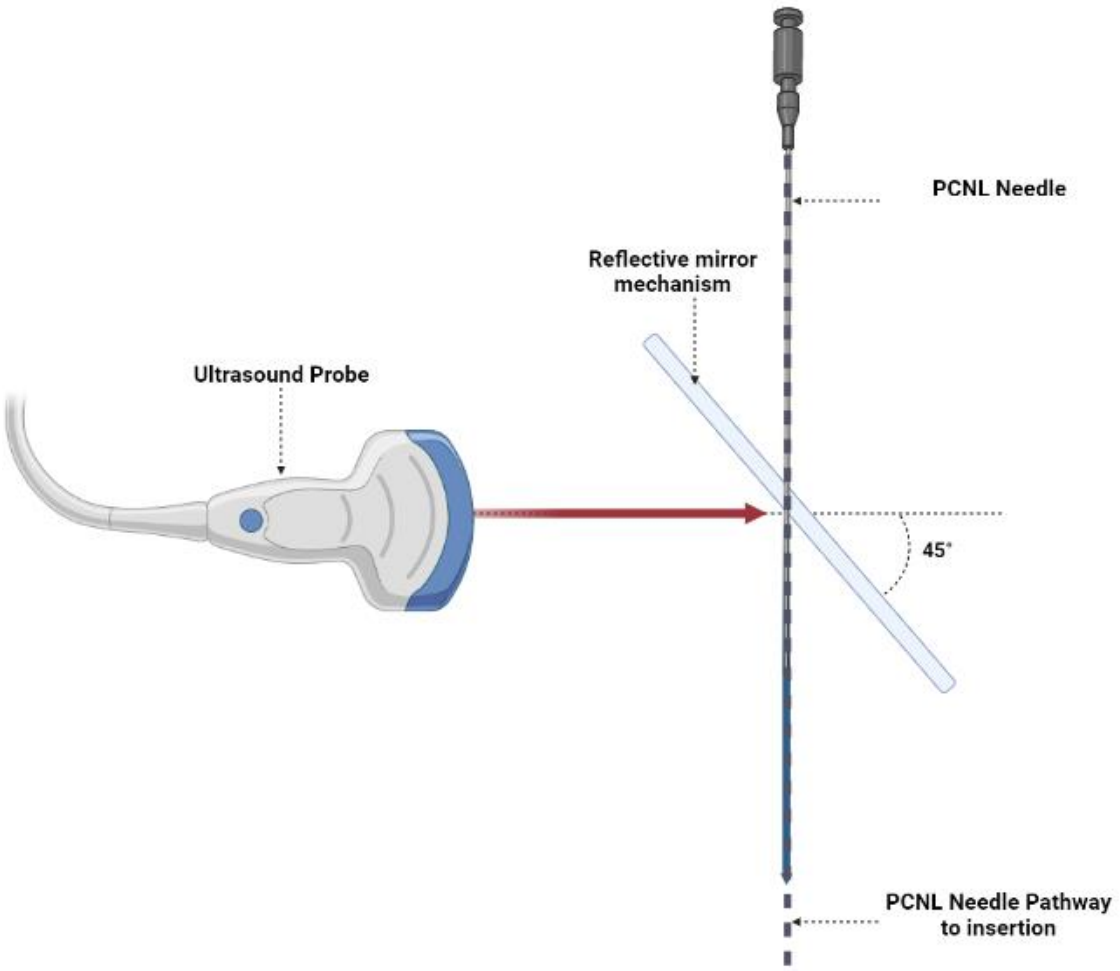

Figure 19: Needle alignment requirements with respect to the mirror and reflected ultrasound beam.

In the figure above, the blue arrow depicting the reflected ultrasound beam overlaps the dotted line that depicts the PCNL needle pathway itself. Without this overlap, while US imaging would still be possible, the needle would not be visible to the medical device's user to guide and reach the targeted renal calculi in a patient. This concept also applies to a dual-mirror mechanism, where the same requirements would apply to the second mirror that reflects the beam prior to it reaching the patient's target area.

This design requirement poses a risk and a unique challenge to the functionality of the device itself. The needle's pathway would mean that it would have to pierce any material that lines the bottom of the medical device, interfering with encapsulation and possibly affecting imaging capability once insertion into the patient's skin begins. However, this also presents a second challenge – if the needle was to be guided accurately to the target, the device itself needs to be removed from the patient's skin so that the surgeon or operating staff can proceed with the nephrolithotomy procedures. This would not be possible if the needle passed through the device – in essence, acting as a fixed component.

To address these unique design requirements and ensure functionality, the team came up with a way for the needle to pass through the mirror while remaining completely independent of the device itself – therefore not affecting the encapsulation or the ability to remove it after insertion was complete. This solution is presented as the "notch" – a protruded surface within the device itself that passes through the mirror, encompassing the needle pathway. This design would, in theory, place the needle "outside" of the encapsulated components of the device, allowing the team to meet the design requirements. Figure 20 portrays this design concept below.

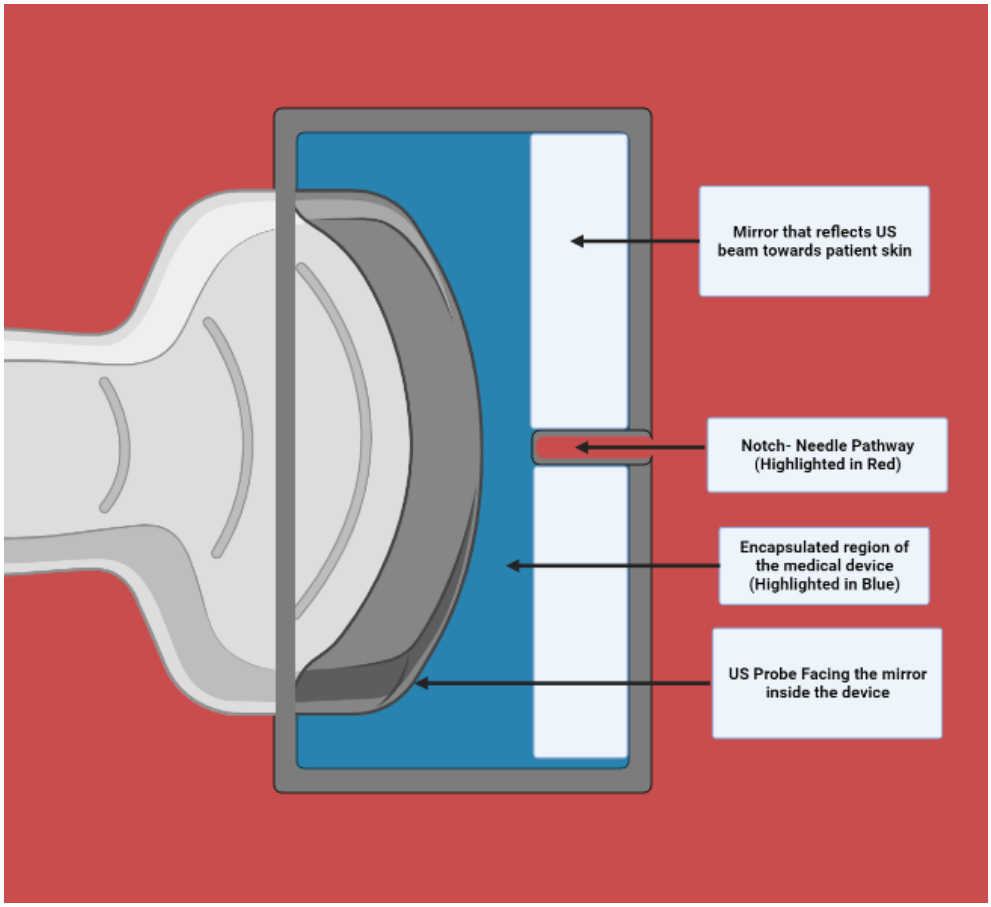

Figure 20: Needle Notch Pathway Mechanism Concept within the context of a single mirror encapsulated medical device for PCNL.

In the figure above, the region highlighted in red represents the "outside" of the device which does not require any encapsulation, while the region highlighted in blue represents the "inside" of the device. The needle notch mechanism essentially extends the "outside" region into the device itself – integrating itself into the design, but not requiring any encapsulation

since its sole purpose is to provide the needle pathway so that inserts in alignment with the reflected ultrasound signal. This design essentially splits the mirror into two – presenting its own set of risks towards imaging capability and providing the team with difficulties during the iterative process. However, its implementation allows for the team to simplify the encapsulation process and allows for the device itself to be safely removed once insertion is complete.

2.5.5 Encapsulation and material selection

As discussed in the preceding background sections, the importance of acoustic mediums and so called "taxis" for the ultrasound beam cannot be understated. For the proposed design of this device to work, it is essential that the probe and the mirror mechanism are thoroughly encapsulated in a medium that enables US imaging with a high resolution while ensuring that scattering, excessive attenuation, and acoustic impedance are all kept in check. In the conventional context of US guided PCNL, the user simply applies a portion of US gel to the patient's skin, placing the probe on it and proceeding to use the imaging functionality. However, the nature of this design requires the probe to utilize the mirror mechanism to direct the US beam towards the patient – thus requiring the entire setup to be encapsulated or submerged for it to function as intended. Therefore, the team is required to carefully consider the acoustic properties so that the US images obtained are representative of the patient's actual structures, preventing major distortion and artefacts. Without the appropriate US medium, the US waves would simply reflect off the air instead of the mirror. Therefore, the use of something such as US gel provides a material that allows for US beam propagation while avoiding a drastic "acoustic mismatch".

Ensuring thorough encapsulation for the device requires the design of the rigid-body components itself to minimize leakage of any US medium such as gel. In addition to this, the bottom of the case itself also requires a material that can not only be capable of encapsulation, but also be acoustically compatible with the US imaging modality so that it does not completely block or significantly impede the US beam from reaching the patient's skin.

Other design considerations include the fact that even with a medium such as US gel – artefacts and other undesirable traits such as distortion can occur through air bubbles present within the setup. It is therefore important that the user has easy access to the medium within the device to remove, refill or address issues such as visible air-bubbles.

Materials were hypothesized to replace the role that the water tank plays and ensure independent encapsulation using mediums such as the US gel. These materials should be acoustically compatible with the US modality of imaging and imitate the impedance of the tissue itself. During the research and development phase, the team narrowed down the potential materials to dry, rubber-like, elastic materials such as latex and silicone. The team also chose to proceed with the consideration of transparent polycarbonate as one of the encapsulation candidates, as it could be acoustically transparent and allowing for the US beam to pass – while providing better encapsulation and easier assembly due to its more rigid properties.

Material	Natural Rubber Latex Sheets	Silicone	Clear Polycarbonate
Source	Amazon	Amazon	Amazon
Manufacturer	Theraband	Sotica	XCEL
Size/Quantity	0.015 inches (Thickness) 5 Ft * 5 inches sheets	0.047 inches (Thickness) 8*8 inches sheets.	0.02 inches (Thickness), 12 by 12 inches sheets

Table 3: Materials purchased for encapsulation component of the project.

2.6 Design Process: Iterative prototyping and design finalization

2.6.1 Iteration 1:

To begin with, the team designed a case that would be capable of holding the more detailed, individually designed components. The case was designed to be 12.3 cm (length), 6 cm (width) and 3cm (depth) with a total volume of 221 cm^3. Once the main case was designed, focus was shifted towards the fundamental components of the medical device that would work in tandem to achieve the outlined requirements.

In the first iteration, the team focused on creating a simple solution that could hold the dual-mirror setup in parallel at an angle of 45 degrees for the mirror-mechanism component. To do this, the team extruded parts of the case to form an L-shaped extension where the second mirror could be seated. Meanwhile, the first mirror would utilize the backend of the case itself as support, with a simple tab protruding from the side of the case providing support so that it can sit at 45 degrees. In this design, the mirror which reflects the ultrasound signal first sits slightly higher than the second mirror, closer to the probe. The second mirror, while parallel to the first, is recessed further into the case. Since the mirror angles are fixed, it is important to seat the mirrors at an appropriate angle and distance (from the probe to the mirrors, distance between the mirrors, and distance the signal travels in total before reaching the patient). The signal originating from the probe must reflect off the first mirror at a ninety-degree angle onto the second mirror, which is then redirected again towards the patient's skin. Two single slab mirrors which were 11.2 cm in length and 3 cm in width, with a 6 mm thickness were used for this design. Figure 21 provides a depiction of the mirror support mechanism in 2D layout (right) and a view of the mirrors when seated as portrayed in CAD (left). The mirrors are seated 8.012 millimetres apart, and the distance between the first mirror and the probe was designed to 14 millimetres. The ultrasound would be positioned perpendicular to the ground and the signal will be directed straight down onto the first mirror.

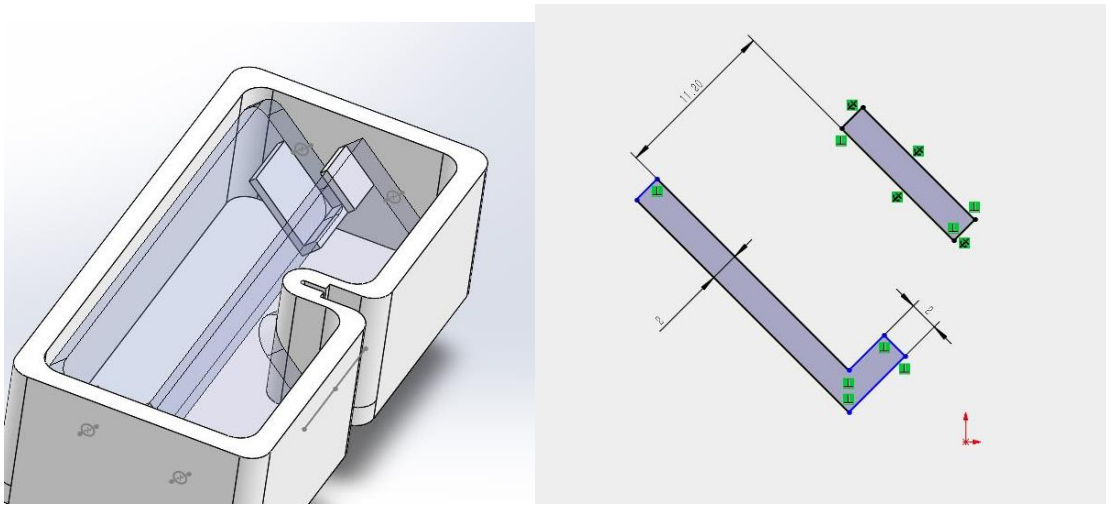

Figure 21: 3D model of first iteration prototype with mirrors seated into the device (left). 2D Layout of needle support tabs that extrude from the side walls of device.

In addition to the mirror support mechanism, the team also designed the first iteration of the notch component itself. As explained in the previous section, the notch was designed to intrude into the case itself, allowing for the needle pathway to be aligned with the case. The shape of the notch itself was designed to be a curved surface, with a peculiar inner wall so that it would work with a smaller componenet designed to hold the needle in place. This smaller component is pictured below, along with a visualization of how the component would slot into the notch to hold the needle.

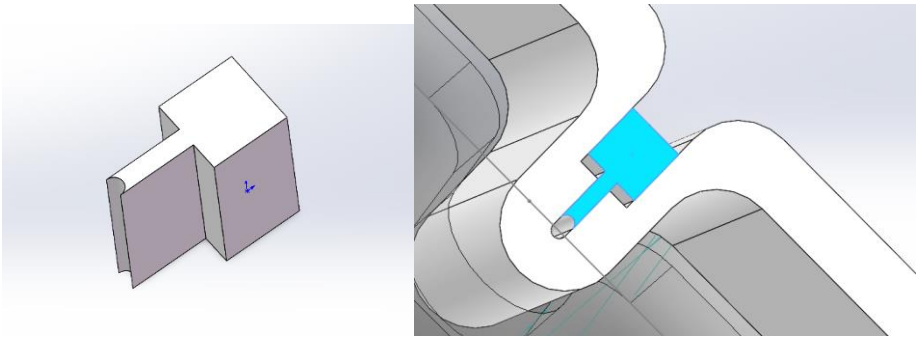

Figure 22: Needle holder/basic release mechanism pictured by itself (left) and slotting into the notch of the medical device (right).

As pictured in figure 22 above, the needle holder/release mechanism once slotted in creates a hole that is wide enough for the needle to be inserted through the notch itself towards the target area. Figure 23 depicts two of the initial 3D printed components – the prototype in gray (left) focused on the case and the notch design itself, while the green prototype was printed so that team could assess the mirror support tabs itself (right).

Figure 23: First iteration prototype with an enclosed bottom used to visualize the case and needle notch-pathway (left) and the first iteration prototype used to visualize and assess the mirror support tabs (right).

2.6.1.1

2.6.2 Iteration 2:

In the second iteration, the team implemented a number of changes to the CAD model for various components – with a focus on the mirror support mechanism and a goal to simplify the needle-notch pathway to better align with the team's goals of focusing on mirror-integrated encapsulation. The team initially recognized the need to better accommodate the chosen C5-2 probe at the time, therefore requiring a change in dimensions for the largest component – the case. Our team therefore increased the width and the depth of the case itself from 12.3 cm (length), 6 cm (width) and 3cm (depth) to 12.3 cm (length), 6.5 cm(width) and 3.2 cm (depth). In addition to this, the distance between the two mirrors in the case was increased from 13.2 mm to 14.97 mm.

The mirror slot system was also reworked, removing the support tabs present inside the case and instead implementing a recessed slot system with a wide entry that narrows down to secure the mirror in place once inserted into the device from the top. Figure 24 depicts the 3D CAD model visualization of the larger case with the recessed mirror mechanism support implemented (left) along with a 2D layout design of the slotted design (right).

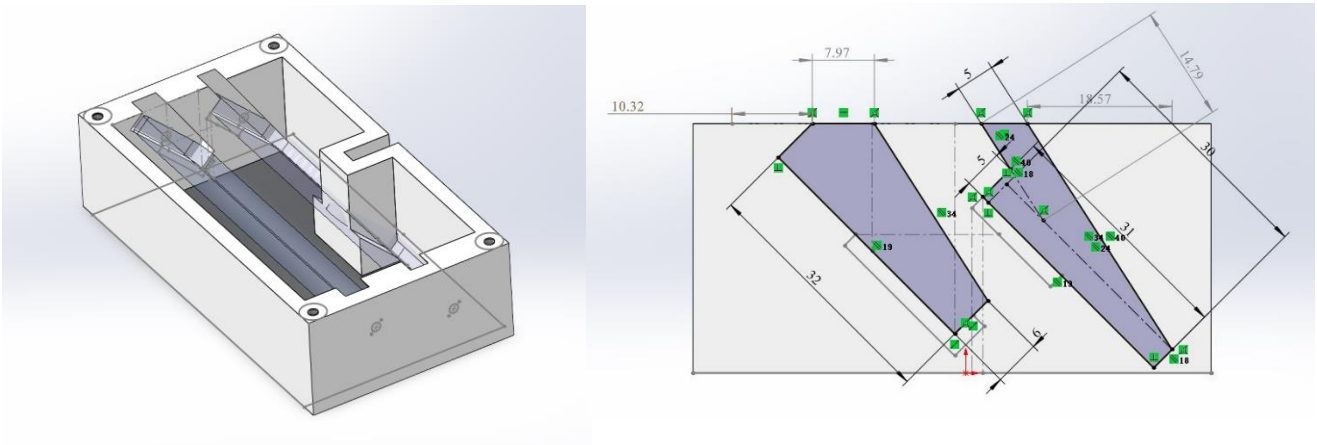

Figure 24:3D CAD model depiction of larger case along with implemented recessed mirror support mechanism (left), 2D layout and dimensions of recessed slot system with wide entry points at the top.

Another major change with regards to iteration two is the simplification of the needle-notch pathway itself. In order to align with the interests of the team and the outlined deliverables of providing an mirror-integrated encapsulation solution, the team decided to refocus and further place more importance to those aspects of the project rather than that of the needle-notch pathway at that point of the project. With this in mind, the team set out to first fully confirm the mirror-reflection and case design, planning to focus on the notch at a later stage. Figure 25 provides a depiction of a 3D printed prototype to visualize and assess the recessed mirror slot system.

Figure 25: Printed prototype with newly implemented recessed slot solution to mirror support and securement.

In addition to implementing changes to existing components of the design, the team also set out to design a "lid" component for the device where the probe could be seated, in addition to closing the top of the medical device itself. The team therefore took advantage of the recessed slot system and decided to take advantage of this design, creating "teeth" that could slide into the mirror slots – in effect, this would allow for the lid to be attached, while sealing the wide-entry of the mirror slots, minimizing any risks of the mirrors moving out of place once the device was assembled. Figure 26 depicts the implemented design for the lid in 3D CAD modelling software.

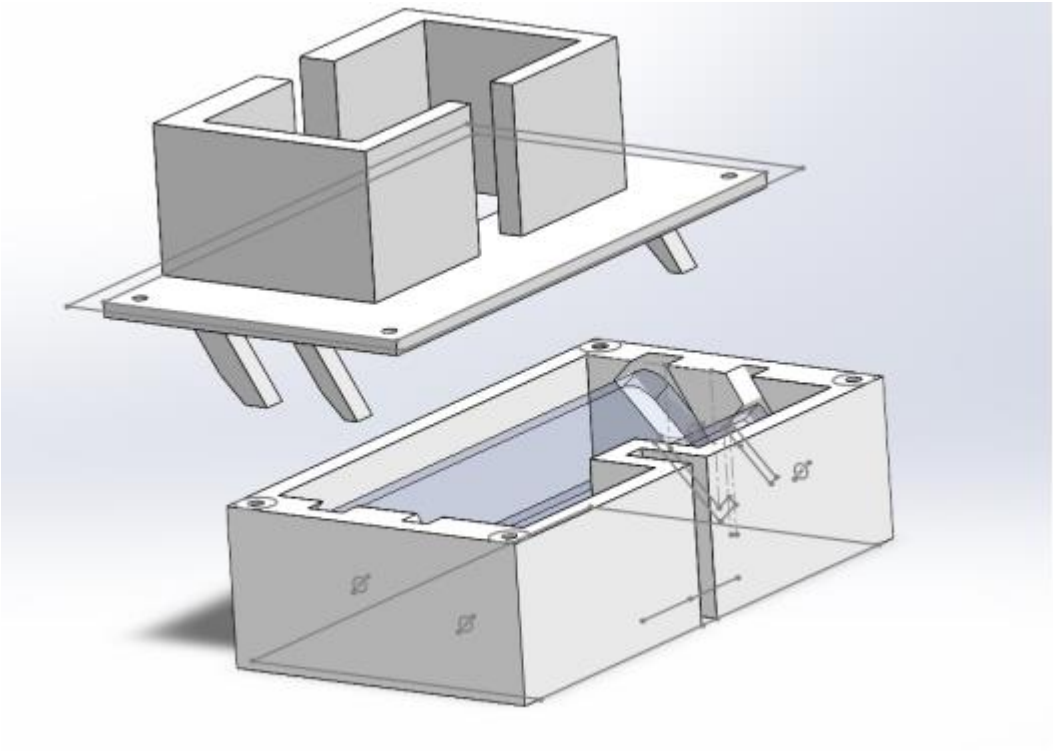

Figure 26:: Finalized second iteration CAD design with both lid and case components.

The upper part of the lid component also had two U-shaped extrusions, which were designed to match the US transducer's dimensions and to allow for the transducer's securement in any fully assembled version of the prototype. The team also added four screw-holes to both the lid and the case itself, so that an additional method of attachment other than the "teeth" could be implemented, increasing the rigidity of the device when assembled.

2.6.3 Iteration 3:

Previous work and progress conducted by the mirror mechanism team resulted in a dual mirror setup that reflected the ultrasound waves emitted by the probe towards the desired procedure target area. This mirror setup was contained in a rigid-body case that was made up for two parts: the upper portion or 'lid' where the probe is seated, and the 'case' which held slots for the mirrors and was placed in contact with the patient's skin. Upon realization of this design, the team proceeded to test the device with regards to imaging quality, depth, device build quality and laser alignment. While the team was successful in obtaining ultrasound images using this design, it found several shortcomings that could be improved upon. For instance, the distance between the probe and the target area was too huge, and the mirror alignment could be slightly different every time since the mirrors were not rigidly constrained. This led the team to implement a complete redesign of the entire medical device, with the largest change being that the team no longer utilized a dual-mirror setup but moved to a design that utilized only one mirror. While in principle, the fundamental imaging techniques did not change, this shift of mechanical structure resulted in a variety of changes to the design. Figure 27 represents the shift in design of the mirror mechanism, with the previously implemented dual mirror system on the left, along with the current design using the single mirror setup.

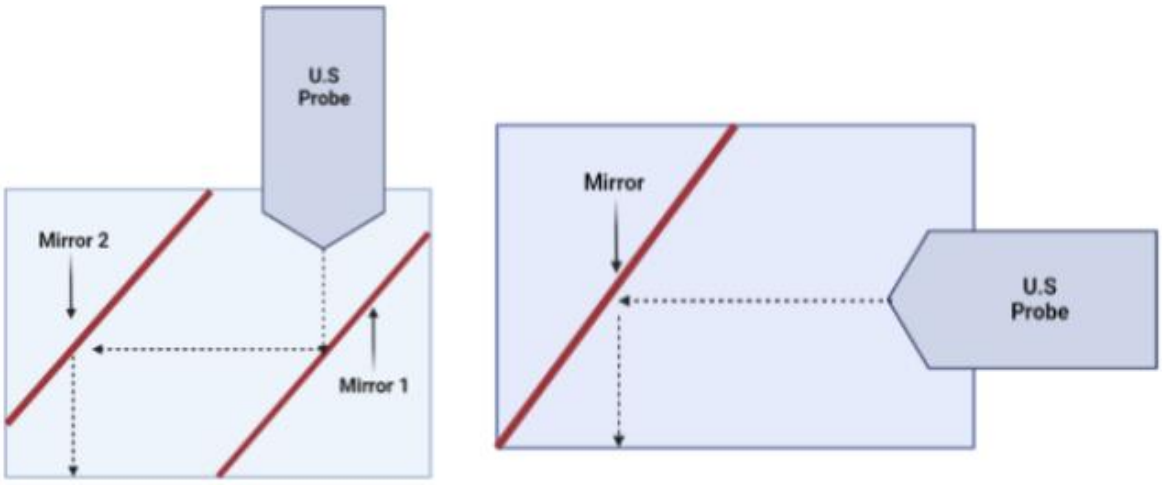

Figure 27: Visualization of probe position, ultrasound beam path in: dual mirror system (left), and single mirror setup (right).

As seen above, the newer design cuts the distance that the ultrasound waves would need to travel by removing one of the two mirrors. In addition to this, the removal of the mirror also changes the orientation of the probe, as it is seated in the side of the rigid body case instead of the top. The dimensions of the mirror, however, did not change at 11.2 cm in total length, 3 cm in width and a 6 mm thickness.

For the first implementation of this newly implemented mirror mechanism for the medical device, the primary focus was to ensure that the single-mirror design was functional and still allowed the team to meet the outlined deliverables. In addition to the removal of the dual mirror, the case was now "W"-shaped along with the needle-notch pathway. The recessed slot system was still implemented, but with a more uniform width throughout, removing the wide entry as it was found to be largely unnecessary. The "slot" on the left was removed to be completely left open, so that the mirror could now be inserted from the side. The newer, more uniform dimensions of this component are depicted in the 2D layout in the figure below.

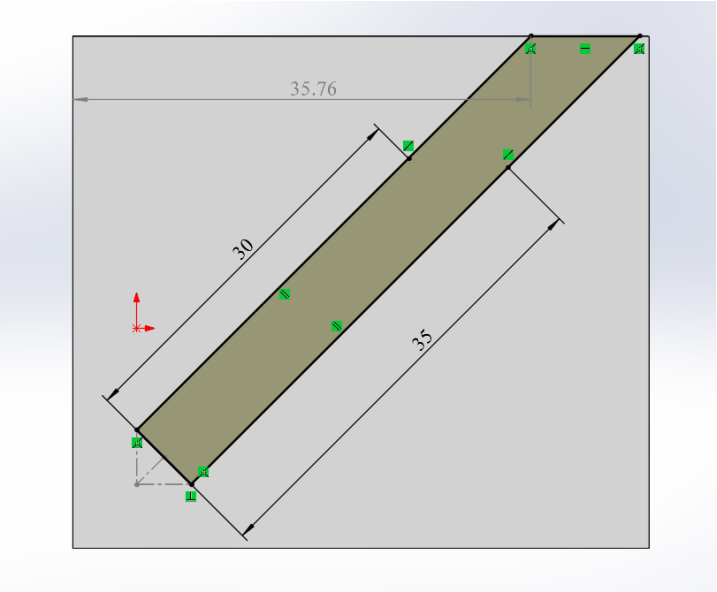

Figure 28: 2D layout of slot dimensions for the redesigned case and mirror-integrated mechanism.

The change in the position of the probe itself (moving away from seating the probe on top of the device to implementing a side-entry for it to direct the beam towards the mirror) led to the team to leave the area in front of the mirror completely open. The notch-needle pathway was however left unchanged for this iteration of the device. The CAD design for this iteration can be found below in figure 29 below along with the 3D printed prototype.

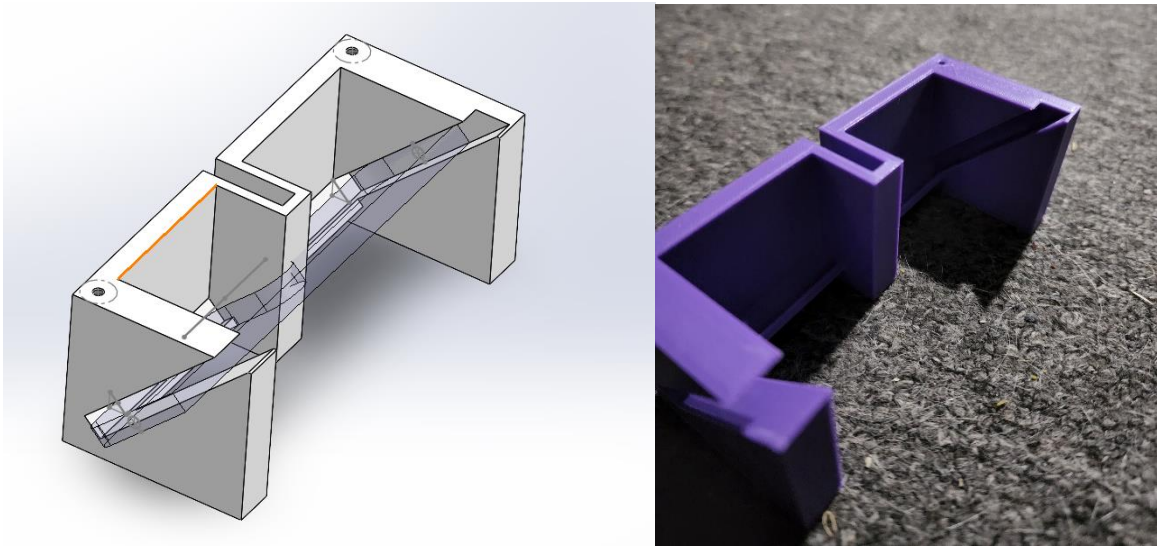

Figure 29: Redesigned single-mirror system visualized in CAD (left) and as a 3D printed prototype (right).

2.6.4 Iteration 4:

Iteration three provided the team with important information and validated that the principal design can be applied to image for the purposes of the surgical procedure, while it also revealed some drawbacks of the design. For instance, the notch for needle guide mechanism was too wide that there was an obvious blind spot in the imaging process. The mirrors were not stable in their slot, either. The lack of mirror holding design also led to images with poor qualities. To address the issues observed with the previous iteration, the team made several changes. First, the notch itself was redesigned completely to further reduce the size of the blind spot occurred when the target was right beneath the notch. The component was further narrowed down to 3.1 mm from 10 mm. This was done by narrowing both the inner and outer sections of the notch, as seen below in figure 30. In addition to narrowing the notch itself, it was also moved slightly off centre towards the left of the device. The edges of the notch were also smoothed out to become a curved outer surface. The team made these changes to minimize the effects of the notch's intrusion into the medical device on the imaging capabilities of the device. By doing so, the mirrors themselves could be longer, enabling a larger reflective surface and reducing any blind spot caused by the interruption in the mirror-design.

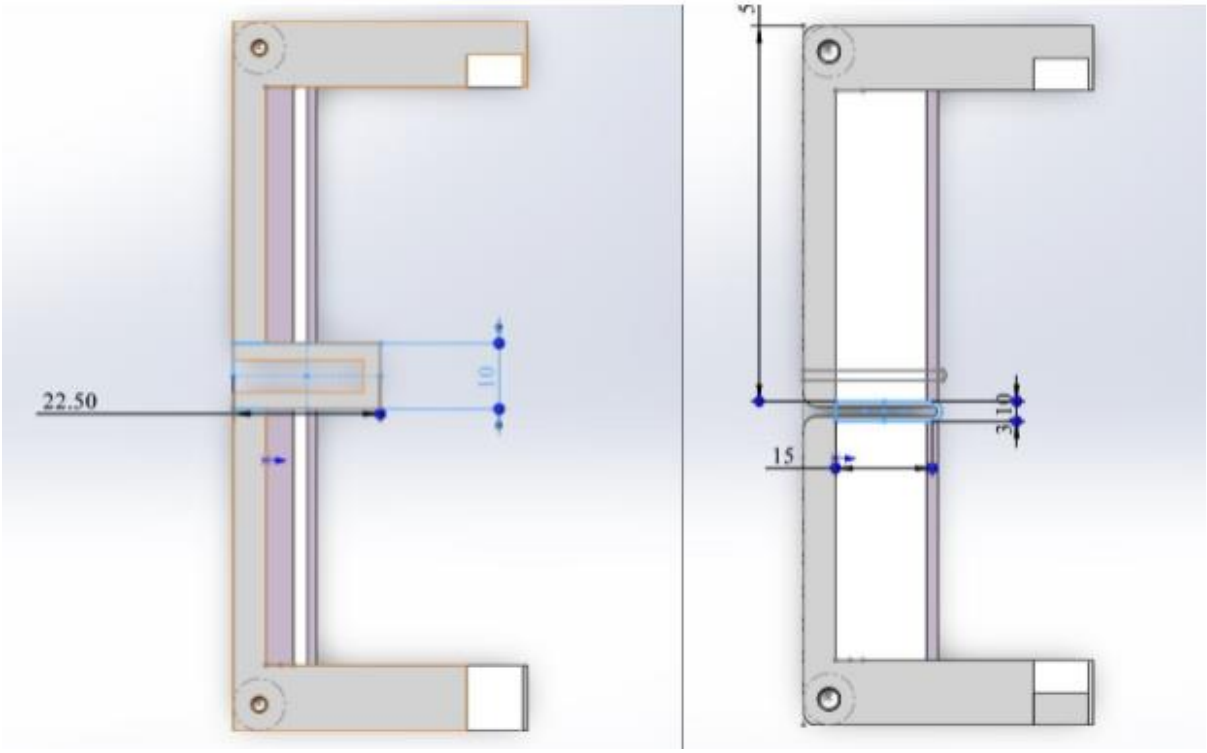

Figure 30: Comparison of older notch design from previous iterations (left) to most recent iteration (right).

The team also made additions to the overall setup with the rigid body case itself receiving an additional extended area where the ultrasound probe could be seated securely. This area was moulded based on a 3D model of the probe itself provided to the team by Yichuan Tang. Figure 31 depicts the newly implemented design with the extended moulded piece combined with W-shaped case from the previous iteration.

Another feature added to the medical device was that the team added a layer of mirror holding mechanism in the mirror slots. Before this iteration, the mirror slots were way wider than the actual width of the mirrors to ensure successful insertions of the mirrors. In iteration four, as the team had become more familiar with the extent of accuracy of the 3D printer, the width of the mirror slots was narrower. However, the opening of the mirrors slot at the top of the medical device was left wide open to allow fluent insertion of the mirrors until the bottom of the slots.

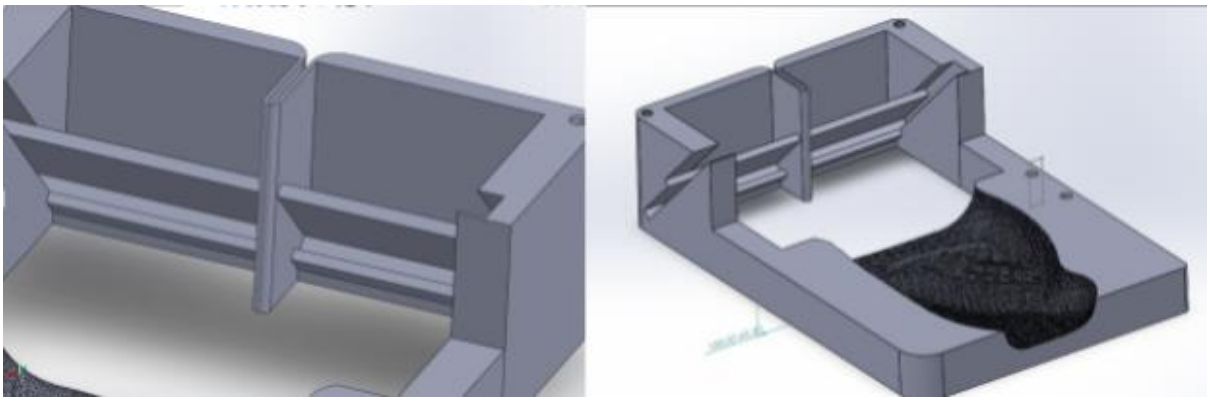

Figure 31: A 3D CAD visualization of Iteration 4's notch changes and extended moulded component designed to hold the US transducer.

The team also recognized the importance of encapsulation. Previous tests of this medical device have all been in an acrylic water tank with a submerged setup. However, a practical real-life application would require some method of encapsulation such that the device can operate without being submerged entirely. To begin addressing this, two new components were designed that would begin to move the design towards a more sealed setup. The first component was designed to act as the "lid" for the W-shaped case component itself, while the second component was designed to secure the probe from the top, with a mould like that of the lower piece that was newly added. To prevent the probe from moving out of place, both moulded parts were given screw mounts so that they could be securely attached to act as a singular piece. Similarly, the top component for the W-shaped case was also given screw mounts like that of previous iterations to prevent unnecessary movement and move towards a more encapsulation friendly design. Figure 32 depicts a fully assembled prototype with the newly designed top components along with a 3D visualization of the probe.

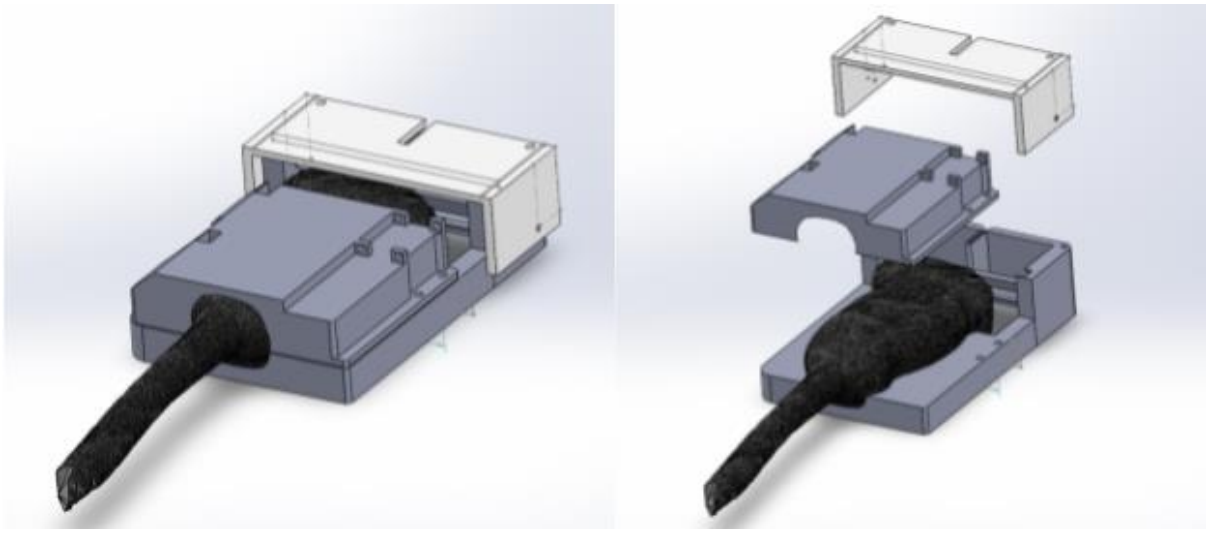

Figure 32: A 3D CAD visualization of the fully assembled prototype of iteration 4 (left) and the newly designed top components and their respective placements – Gray top: to secure probe from above, White: to move towards an encapsulation friendly design and close W-shaped case from above (right).

Aside from the changes of the top design to enable encapsulation, the needle release mechanism was also renewed. As shown in Figure 31, the primary principle of the needle guide stayed unchanged: the needle guide would have a half circle at its end, and it would form a whole circle together with the round end of the notch path. Because the width of the notch was greatly narrowed, the needle guide was made longer so the thin front part stays completely in the notch, while the thick rectangular part sits outside of a bucket-shape container specially designed on the back of the W-shape mirror case.

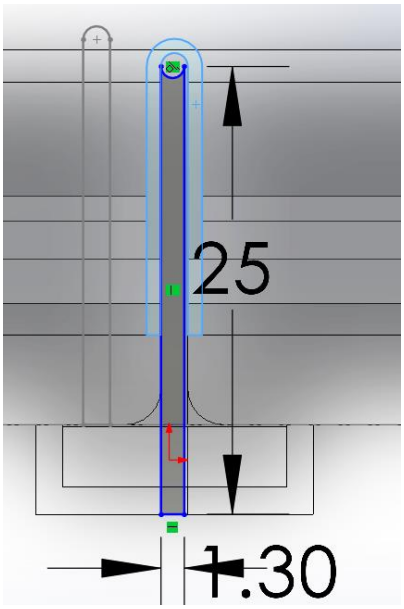

Figure 33: Redesigned needle notch pathway for iteration 4.

This needle guide was held still by the black needle lock shown in Figure 34. As the medical device is at work, the blue needle guide will sit on the bucket-like which prevents the needle guide from sliding downward. The bucket-shape container in Figure 34 was made on the outside of the notch. Once the blue needle guide is at position, the black lock should be dropped into the bucket to secure the needle guide so it will not slide out from the notch. If the needle needs to be released from the medical device, the needle guide can be easily pulled out after the needle lock is picked up from the bucket.

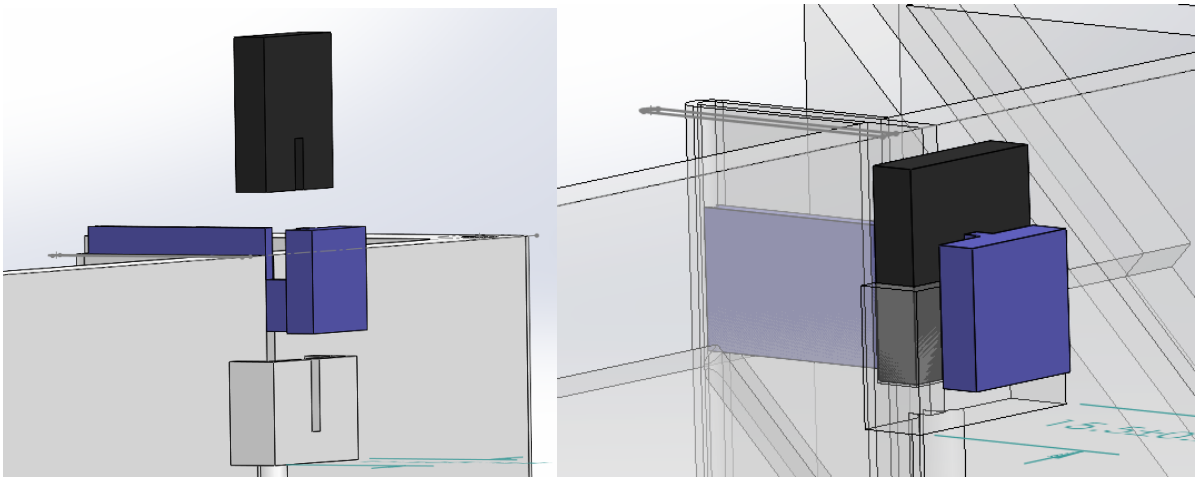

Figure 34: Redesigned locking and release system for needle notch pathway in iteration 4.

2.6.5 Iteration 5:

Iteration 4 integrated the moulded probe container and the W-shaped single-mirror case together as a first step to accomplish the encapsulation of the device while maintaining its imaging capabilities. In that iteration, the team succeeded in ensuring the stability of image quality since both the probe and the mirrors constrained tightly whereas the encapsulation of the device was not secured as there was still a long gap between the top design, the 'lid', and the top moulded part to hold the probe. In iteration five, the team integrated the two top parts together as marked blue in Figure 35. The side and top surfaces of the moulded upper design of the probe holder was made flat to match with the W-shape mirror box. Despite being flat on its surfaces, the top part of the probe holder needs to be coherent with the height and width of the W-shape mirror box. To achieve this, this top design was made thicker both vertically and horizontally. The team also extended the length of the top part so it can reach the W-shape mirror container. Once the integration was finished, with the blue top design screwed to the main bottom half of the medical device, the general encapsulation should be accomplished.

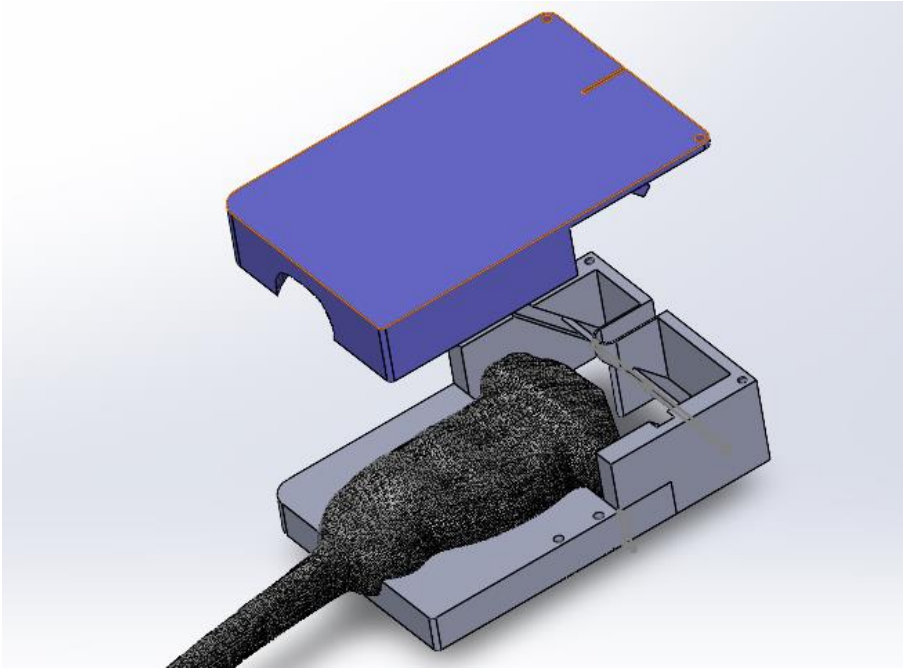

Figure 35: Encapsulation design for top "lid" component that seals the device and prevents leakage of US gel around probe and the top of the device.

There was also a major update on the needle guiding system. The team redesigned the needle path so the position of where the needle will be inserted can be controlled every time. The notch path for the needle was changed significantly as shown in Figure 36.

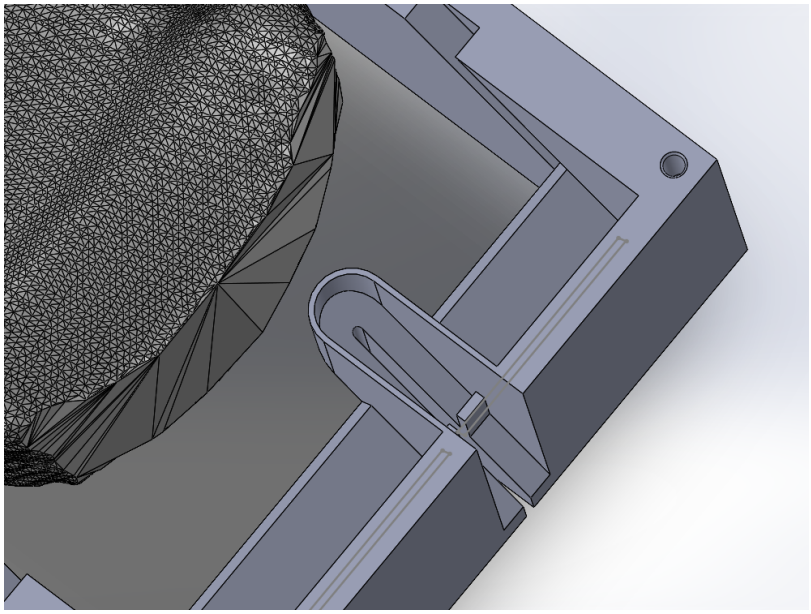

Figure 36: Redesigned notch that has been widened towards the top to allow for easier insertion and narrowed near the integrated mirror mechanism.

The upper half of the notch was widened to 11.1 millimetres for its outer diameter. To avoid any negative influence on the imaging quality, the lower half of the needle notch stayed unchanged. The increased room on the upper half makes it possible for a larger design of needle guidance mechanism while the expansion in width stops at the top surface of the plane that is used to hold the mirrors.

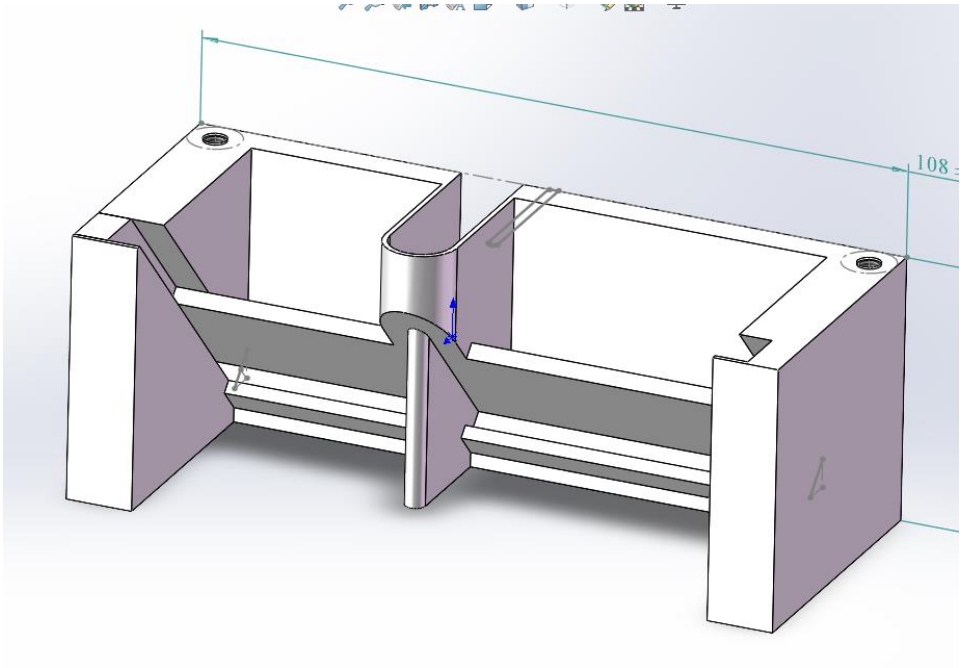

Figure 37: Case component without the extended moulding for the US probe depicting the notch-needle pathway redesign to allow for more space with the integrated mirror mechanism.

The needle guide itself also had a complete overhaul. Instead of cooperating with the wall of the notch to form a full circle, this new needle guide has a whole circle with a diameter

of 1.5 millimetres, which will work well with the 18-gauge needle (1.27 mm) the team is currently using.

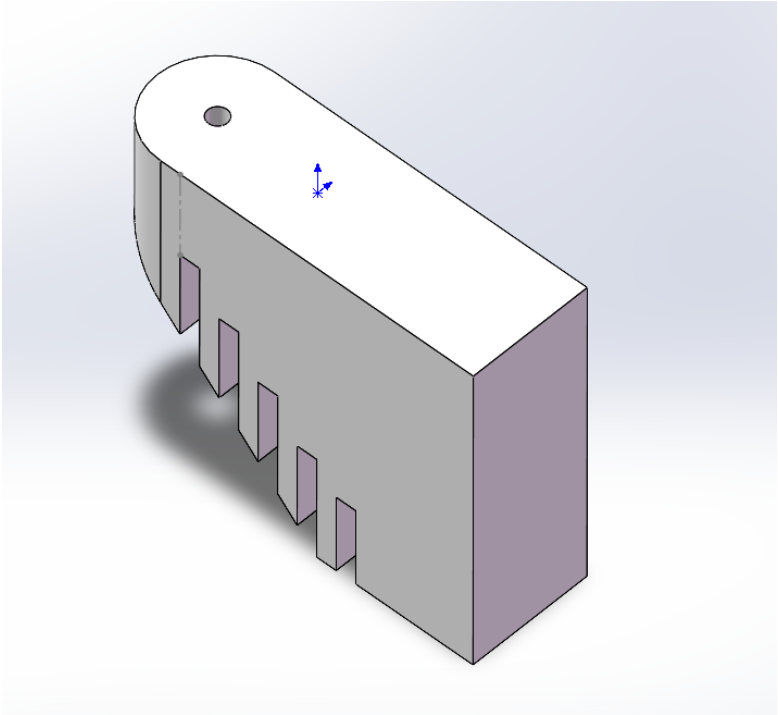

Figure 38: Newly implemented component that slots into the needle-notch pathway, allowing for release, accurate guidance at a straight angle into the imaging plane.

There are five clearances at the bottom of this needle guide design with of interval of 1.5 millimetres from each other. These clearances will constrain the needle guide to the slope of the notch and stop it from sliding once the needle guide is inserted to the panel on the notch.

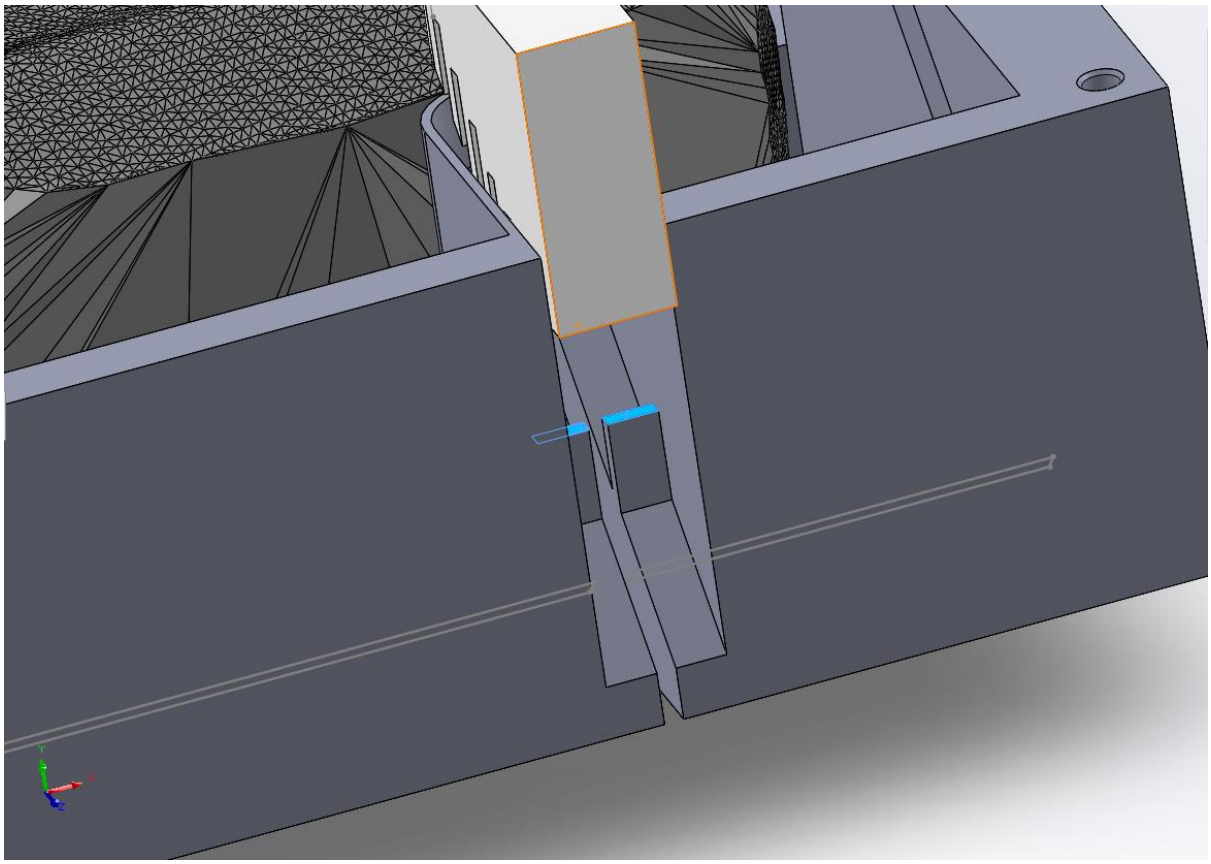

Figure 39: Image depicting the insertion of the needle guidance component into the needle notch pathway of the medical device.

2.6.6 Encapsulation

Once the device design was close to being finalized at Iterations 4 and 5, the team also started more focused work on encapsulation. This included the work done for iterations 4 and 5 where the team included moulded components for the probe. The team also simplified the numerous components from iterations 3 and 4, where the design components were grouped into either "top" or "bottom" oriented components, and then integrated into a singular piece for each group. These pieces were then designed to slot in and be further secured by screws, so that the preferred medium of US gel does not leak out from the top or the sides of the medical device, including the point of entry for the probe itself. Once these design changes were implemented, it was important to address the main component of concern for the encapsulation solution – the open bottom section of the case itself, where the device contacts the patients' skin or target area.

As discussed in previous sections, the team acquired three different materials – latex-rubber, silicone, and clear polycarbonate plastic to fulfil this role. Once the materials arrived, they were measured and cut to the size of the opening on the bottom of the medical device. Each material was then attached to the device, effectively sealing, and separating the device itself from the target area. The team then conducted a series of imaging tests using the US transducer and gel

medium on a phantom, the results, and details of which are expanded upon below in the testing section.

3 Experimentation Methodology & Results

3.1 Testing – Phase 1: Initial Prototyping Tests

3.1.1 Test Setup and Description – Drop test

To testify the overall structural strength of the designed medical device, the chosen 3D printing material (PLA plastic) and the integrated mirror mechanism, a drop test was designed. In this test, the team released the medical device from certain heights and let free fall to the ground.

The team used a measuring tape to mark different heights against a wall adjacent to a hard tiled surface that was clear of any objects or interferences. Heights were measured and marked on the wall from 1 ft to 5 ft above the ground, with a 1 ft interval between each mark. The area below the marks was then made clear so there would be no additional factors damaging the medical device. The fully assembled 3D printed prototype was first raised to the 1 ft mark before being dropped onto the ground. Once the prototype had reached the floor and stopped moving; qualitative data would be collected by visually looking for cracks or damages on the medical device. The device would also then be disassembled so that the team could assess if the drop caused any damage to the mirror mechanism on the inside of the device. The same procedures would then be repeated for three times from each marked position on the wall, with the team using a different 3D printed prototype for each set of heights to avoid any cumulative damage from affecting the test results. The extremely simple setup for this test is depicted in the figure below.

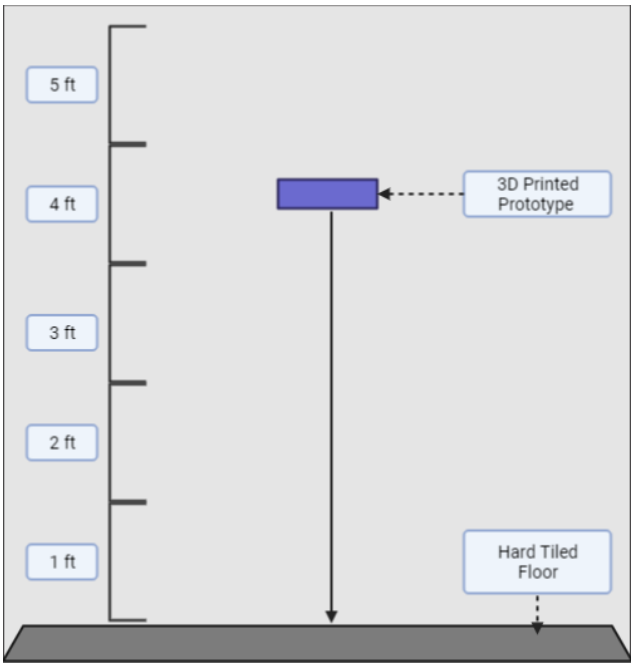

Figure 40:Drop Test Setup showing the marked wall and how the medical device prototype was dropped vertically.

3.1.1.1 Test Results

The drop test performance of the medical device was evaluated based on any visible cracks, broken tabs, bent parts or any other types of damages on the 3D printed prototype itself. The prototyped passed this test at every marked height, and there were no visible damages of any sort on the prototype. This allowed the team to assume that the 3D printing process and the material together contributed towards a prototype that was structurally sound and could most likely avoid damage in any real life-high stress workplace. In addition to this, the team was able to also evaluate that the mirror mechanism on the inside of the device would also likely avoid any damage, also validating the quality of the mirror support slot system.

3.1.2 Test Setup and Description – Laser Alignment Test (Dual-Mirror Design)

The laser alignment test was designed to evaluate the integrated mirror mechanism component of the medical device. This test is important as before any imaging itself is performed with a fully assembled device, the team needs to ensure that the current design of the device allows for accurate reflection of the US beam onto the target area as intended. While the US modality does not emit the same signal as the laser's beam of light, it will still allow the team to visualize the reflection of any signal via the mirrors and thus identify the point of intersection at which the needle must be inserted through the notch (As described in figure 19). The laser level used for this test emits a vertical and a horizontal beam of light, allowing the team to find and align the centre of the signal to the centre of the US transducer itself.

The laser alignment test was first performed to the medical device from iteration 2, which was the case that utilized a dual-mirror reflection. The team first fully assembled the medical device to imitate a working situation. Then, the team put the probe into the top design component, also known as the 'lid', so that the centre of the probe (as measured and denoted by felt tip pin) would ideally match with the laser level mark. An optical imaging table was used in combination with the gyroscope-equipped laser level in order to ensure that the beam emitted by the laser tool is always straight and balanced correctly. The usage of the table also allowed the team to test the functionality with the probe at various

The test was performed at different positions on the table to check if the laser beam always aligned at the same location. This was done by using the grid of screw mounts on the table, where the probe was placed 6,12 and 18 rows away from the case.

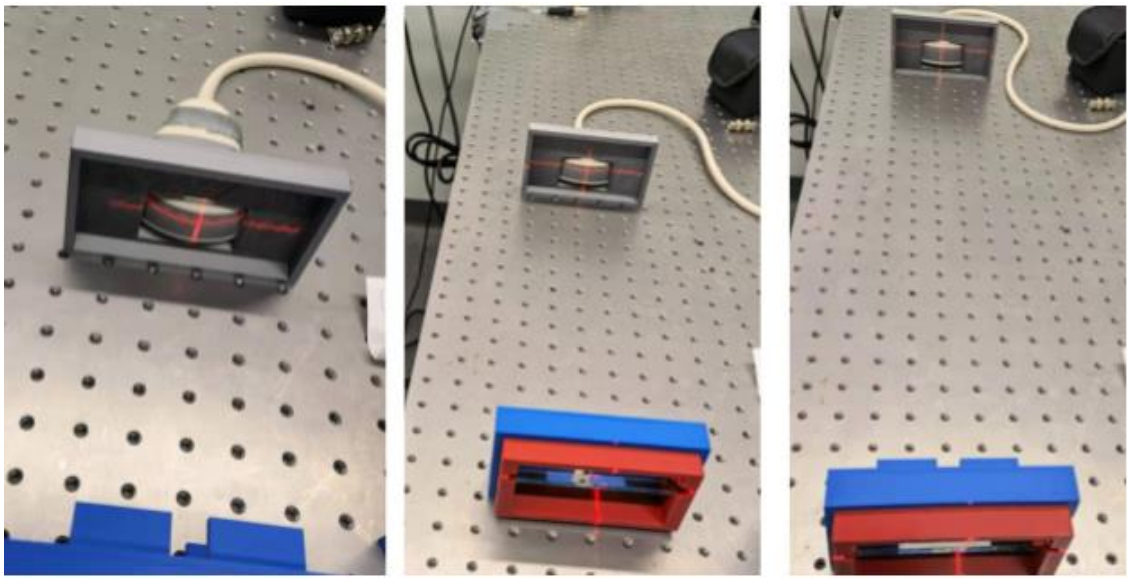

Figure 41: Laser Alignment testing showing the laser crosshair signal with successful alignment at short and intermediate distances, and slightly out of alignment at the longest distance.

3.1.2.1 Test Results

The improvements made between the first two iterations of the medical device allowed for proper alignment of the laser being reflected from the mirror system, indicating that the device itself is capable of imaging using the ultrasound probe (See figure above). Though the laser landed at the absolute centre of the probe when it was in the blue lid, the landing location was not stable as the distance between the medical device and its top design increases, which suggested that potential structural flaw existed in either the design principle or the 3D printing process. In theory, the distance between the components on the optical table should not affect the alignment between the signal and the device - this became one of the several reasons that caused the team to choose single-mirror reflection.

3.1.3 Test Setup and Description – Imaging Test in water tank

Through the previous test, the team gained confidence in the medical device's capability to relay the US signal to the target area effectively through the integrated mirror mechanism. To further establish and qualitatively evaluate the prototype, a full-scale imaging test was required. Since the team had not established a means of encapsulation, the entire testing setup had to be submerged in a large acrylic tank filled with distilled water. A phantom constructed out of a series of string was then dropped into the tank. This series of string and two metal corners would, when imaged at a cross-sectional plane, provide a series of dots on the imaging plane along with two larger triangular like structures as the imaging targets. The medical device was then fully assembled with the US probe and submerged into the water tank and placed above the phantom.

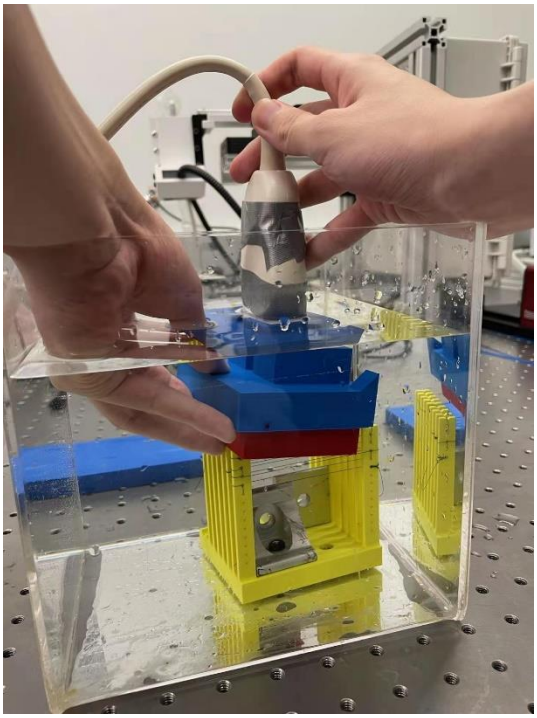

Figure 42: Testing setup with phantom (in yellow) and submerged device in acrylic water.

3.1.3.1 Test Results

The results are depicted below.

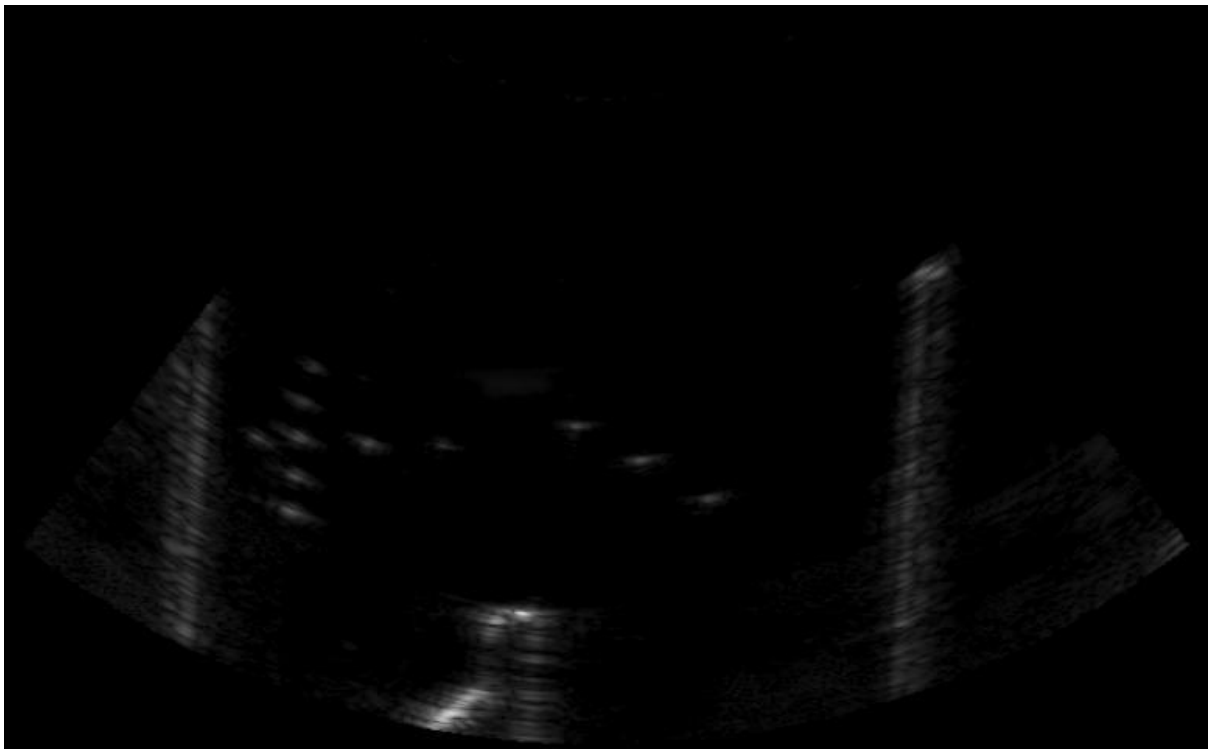

Figure 43: Cross section image collected from phantom test with only the probe. The dots are the known markers in the phantom.

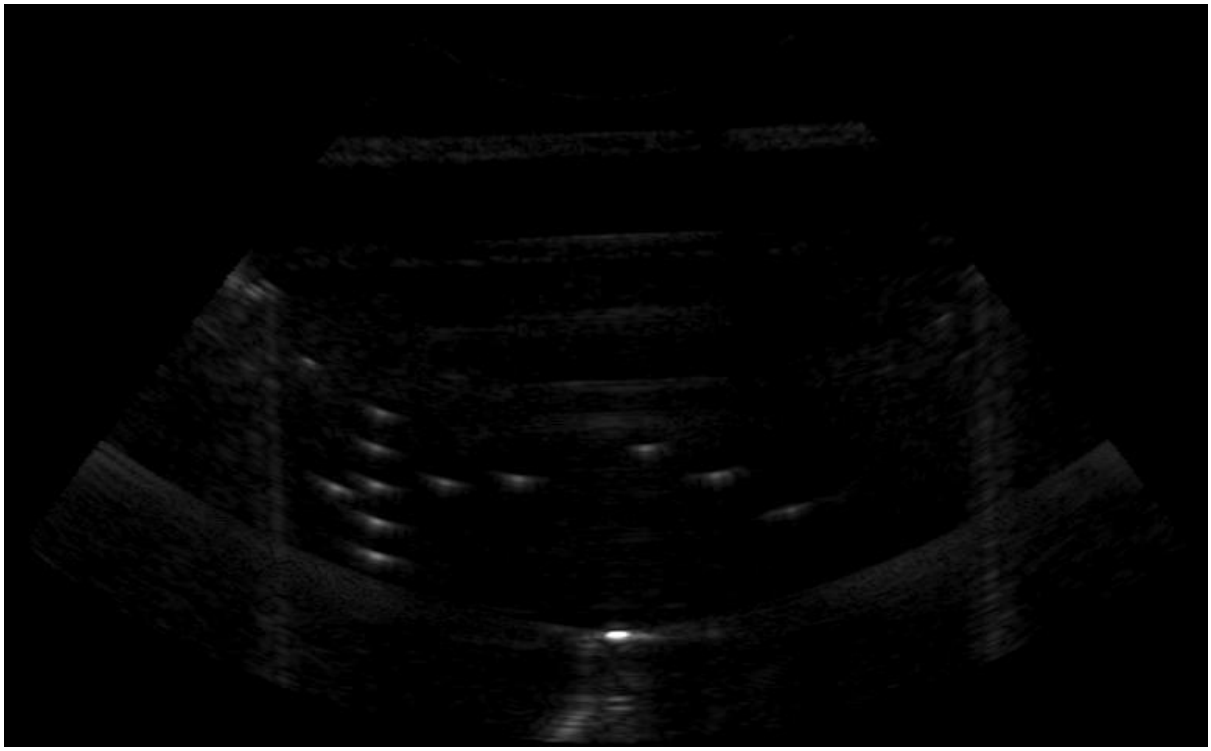

Figure 44: Cross section image collected from phantom test with fully assembled device.

Figures 43 and 44 show that the continuous dual mirror setup is very capable of collecting images in the same target area. The dot pattern that is visible in figure 43 is like the one found in image 44. The amount of noise is slightly more prominent in the image taken using the medical device, but it does not impede any of the target area or phantom markers for the purpose of this test. However, it is important to note that this initial round of image-testing did not implement the then designed needle notch pathway. Upon confirming the imaging capabilities in the first round of testing, the team sought to then evaluate the effectiveness of the design further with all its components implemented in the prototype.

The results of this test can be found below:

Figure 45: Cross section image collected from phantom test with only the probe. The dots are the known markers in the phantom.

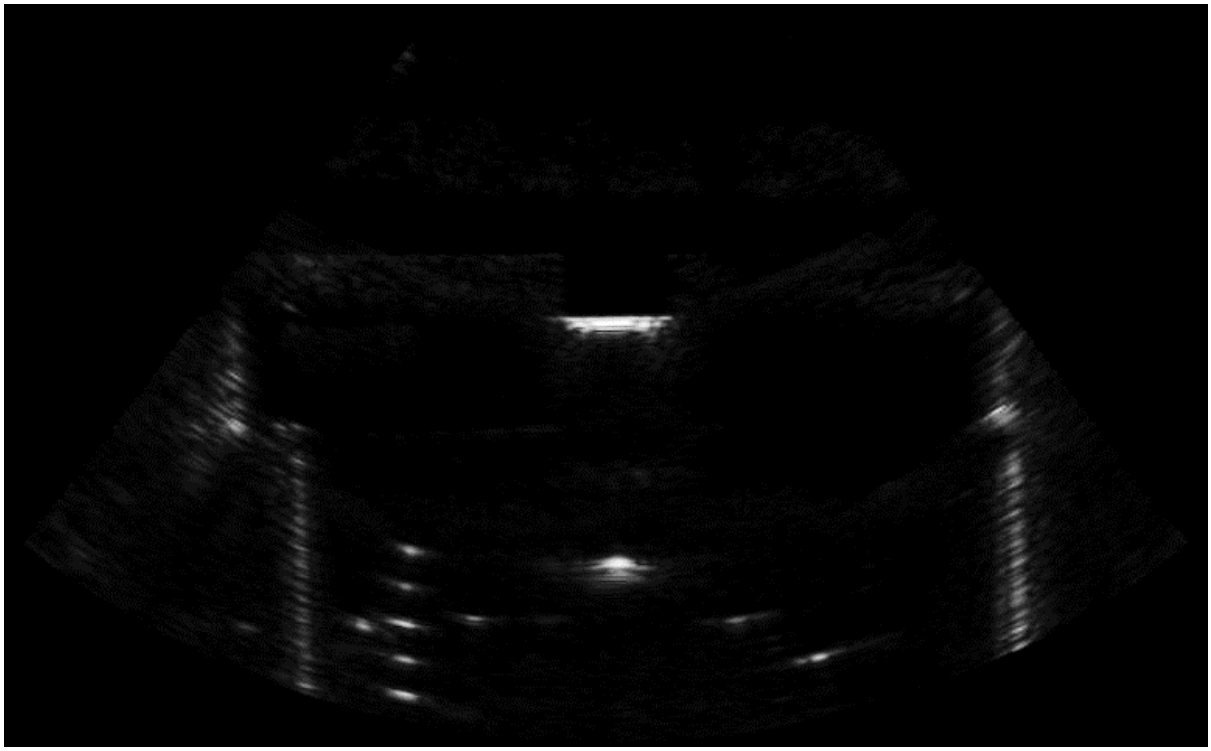

Figure 46:Cross section image collected from phantom test with fully assembled device (with needle-notch pathway).

Through comparison of figure 45 and 46, it is evident that the needle notch pathway negatively affects the quality of the image to some extent. In figure 46, the amount of noise present is significantly larger than that in figure 38, along with a discontinuous image halfway between the imaging plane. It is likely that the "break" in the image is caused by the gap itself

in the device's case, causing the ultrasound signal to be reflected within the device in undesirable ways. To further explore and document the effects of the changes made in this iteration, our team also sought to identify if there is a break in the imaging plane along the middle due to the gap created by the needle notch pathway component.

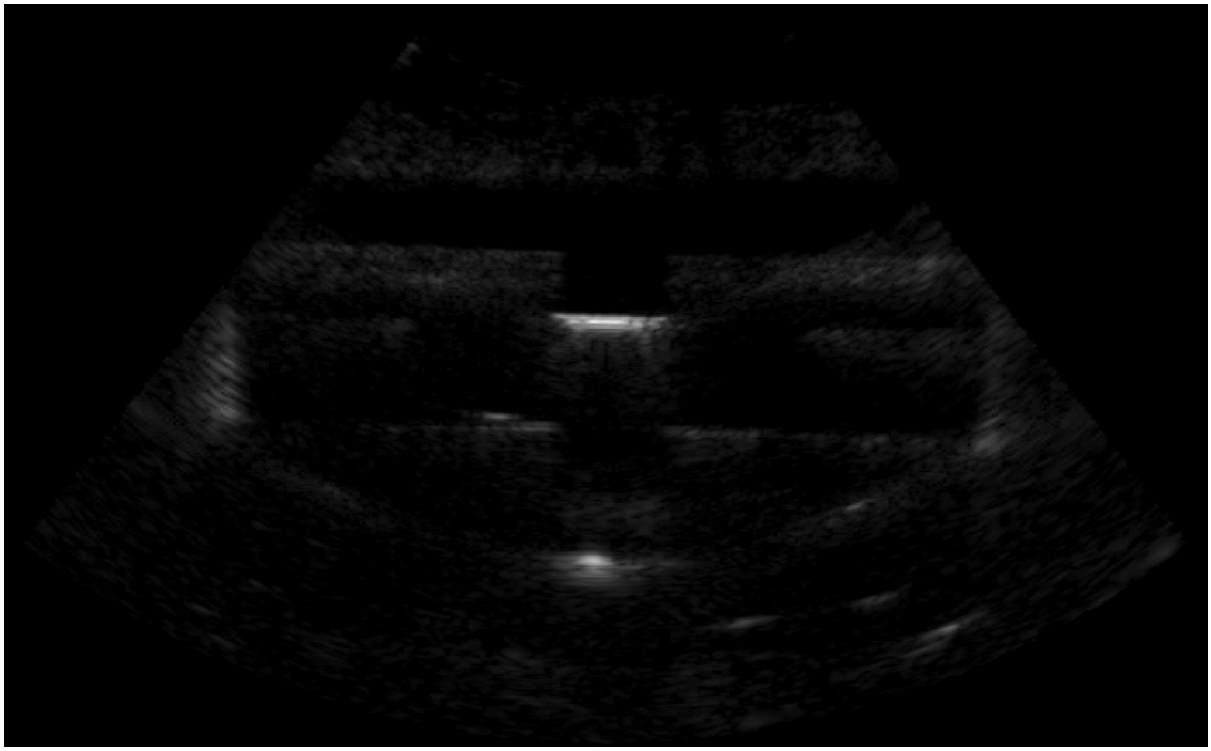

Figure 47: Cross section image collected from phantom test with fully assembled device (split-mirror setup) and phantom markers placed in the middle section of the imaging plane.

As seen in figure 47, the markers of the phantom are no longer visible in the image. This is because in the experimental setup, the markers are directly aligned with the gap created for the needle notch pathway, where the ultrasound signal is not reflected correctly, creating a "blind spot" in the middle of the imaging plane. To demonstrate this further, the markers in the phantom were moved slightly more to the right of the gap in the setup, where another image was taken.

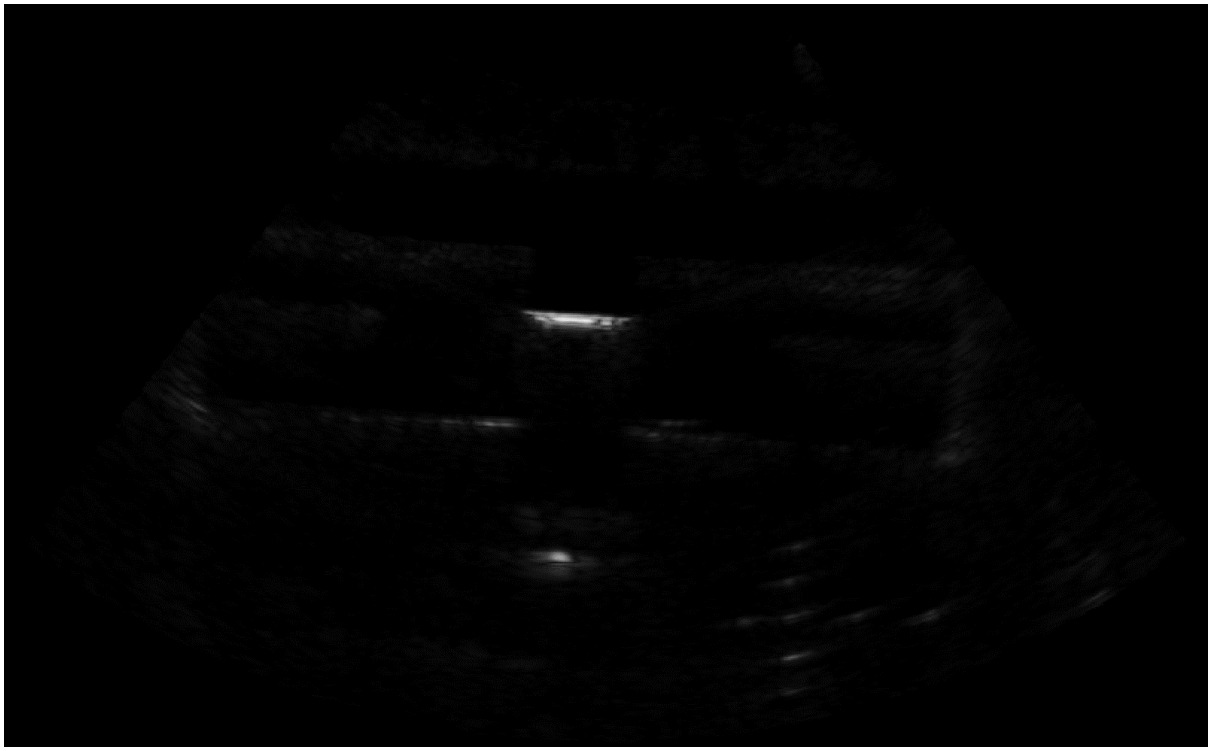

Figure 48: Cross section image collected from phantom test with fully assembled device (with needle notch pathway) and phantom markers placed in the right section of the imaging plane.

As seen in figure 48, when the markers are moved to the right of the "blind spot" they are once again visible in the image - further confirming that there is a central, vertical "blind-spot" column present in the imaging plane. Aside from the limited imaging distance, increased artefacts and noise, the prominence of the blind spot when the target was under the needle-notch pathway meant it might cover the entire region of the imaging plane. These factors led the team to heavily re-evaluate the design at this stage, thus making the pivot to a single mirror system with a heavily modified needle-notch pathway that was tested in the second phase of experiments.

3.2 Testing – Phase 2: Design Shift and Iterative Improvements

3.2.1 Test Setup and Description – Imaging test in water tank

Upon making the relevant design changes to the integrated mirror mechanism and medical device, the team sought to return and perform the same imaging test performed on the device for prior iterations as described in the first phase of the testing. This test was repeated for iterations three to five, with qualitative and quantitative improvements being made note of.

3.2.1.1 Test Results: Iteration 3

The results are depicted below. The team wanted to investigate and confirm if a "blind" spot like one observed in the previous phase of testing persisted with this design change. To do this, the device was moved from left to right such that the "plus" shaped pattern of dots in the phantom would move from the right side of the image to the centre of the image.

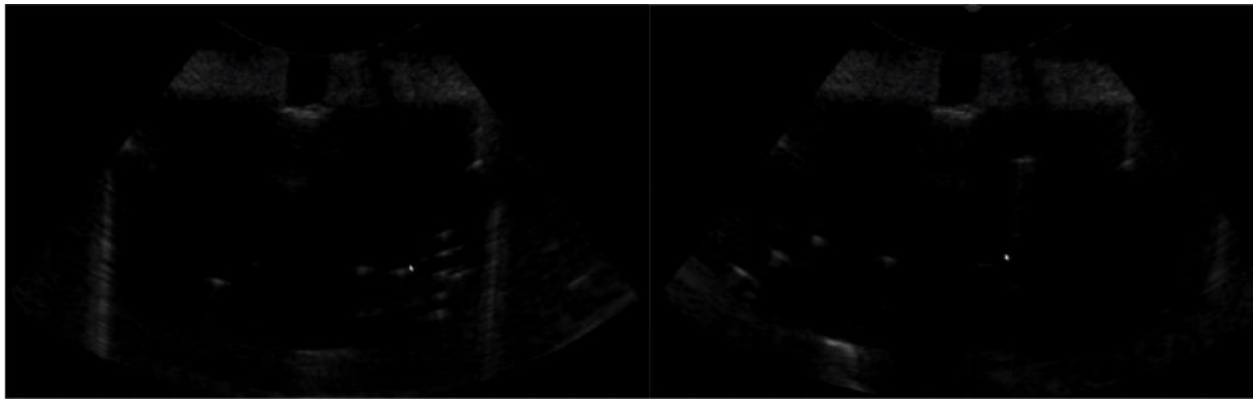

Figure 49: Phantom plus shaped pattern on the right side of the imaging plane. Right: The same pattern moved towards the centre of the imaging plane.

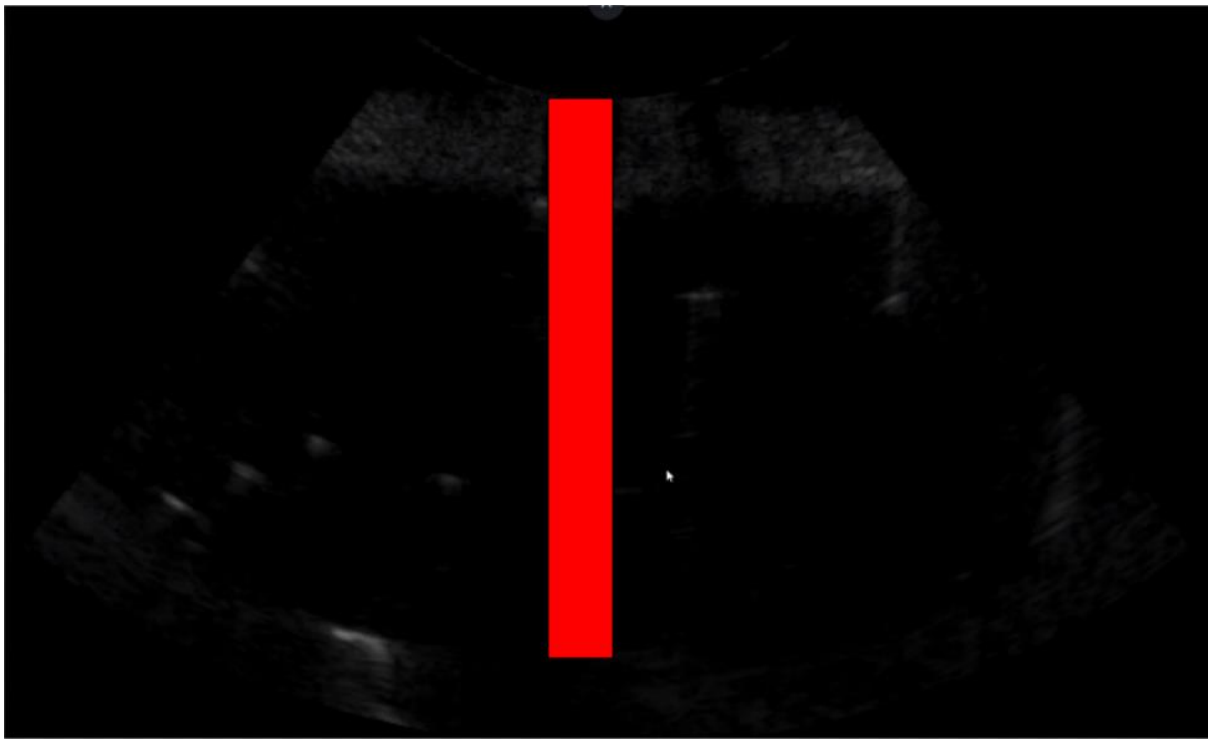

Figure 50: Image that highlights the blind spot vertical column in red where nothing is visible on the imaging plane.

Figure 50 highlights the blind spot that extends where the needle notch pathway that splits the mirrors is present on the device in red. The blind spot in the image is measured at approximately 15 mm in width as per the MATLAB gui that the ultrasound probe uses for image acquisition. To validate the design further, the team inserted a needle through the needle-notch pathway while the test setup was submerged in order to collect data and evaluate the needle visibility. However, the needle was not visible in the imaging plane itself.

The test was once again repeated for the changes made in Iteration 4 and 5, but the needle insertion was skipped for these tests until further confirmation on the mirror-alignment. The results are depicted below.

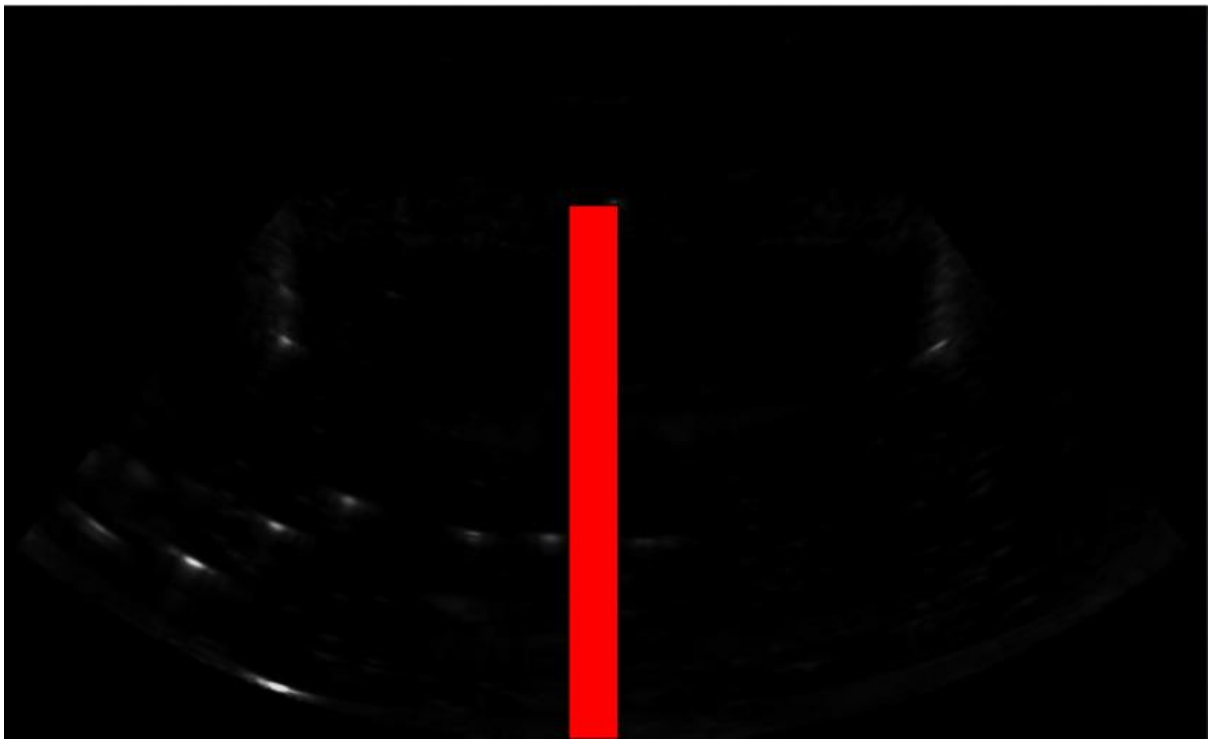

Figure 51: Image that highlights the blind spot vertical column in red where nothing is visible for iteration 4 on the imaging plane.

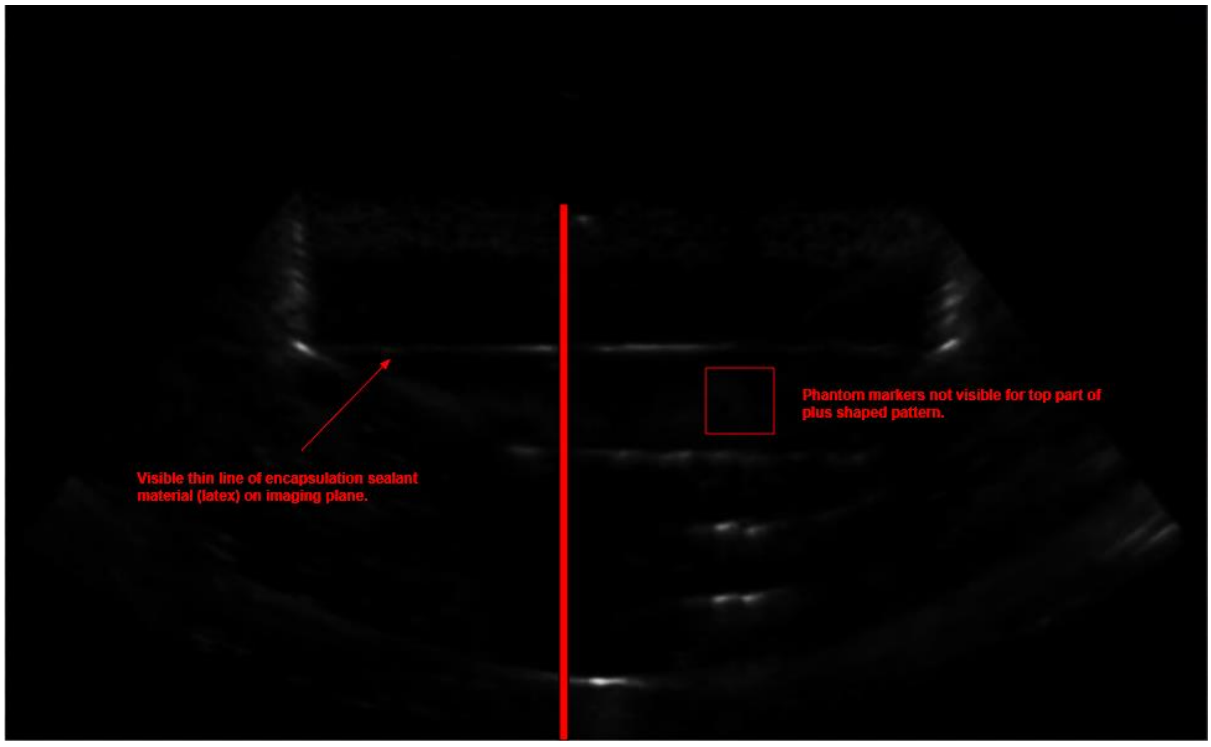

Figure 52: Annotated ultrasound image that depicts the thin latex visible in the imaging plane, the "blind spot" vertical column and the region of the imaging plane where markers are not showing from the phantom for iteration 5.

In the above images, it is visible upon initial observation that while the quality of the image itself has not changed significantly, the blind spot vertical column has been significantly reduced. In images obtained from testing iteration 3, the "plus" marker on the phantom is completely hidden by the blind spot. However, in this round of testing, the "plus" marker's

leftmost and rightmost marker dots are now visible in the image. To confirm this, the blind spot was measured by the MATLAB gui and confirmed to have been reduced from 15mm to just 3mm in width.

3.2.2 Test Setup and Description – Laser Alignment Test

Because in the earlier water tank test, the needle could not be imaged by the probe, the team decided to run another laser alignment test to check if the needle perfectly aligns with the ultrasound waves after one mirror reflection. The team used a laser level to imitate the traveling path of the ultrasound waves from the probe. The laser level was deployed on a horizontal table while the medical device was put vertically against the side of the table. At this position, the laser emitted by the laser lever was perpendicular to the probe before it reached the mirror for reflection. The team moved the medical device up or down in the vertical direction so that the laser would align with the needle guiding notch. Once the laser was shooting at the exact position where the needle would be inserted, the team would check visually if the laser would land at the centre of the ultrasound probe after reflected by the mirrors. The figures below depict the test being conducted with the use of the optical table similar to that in phase 1, but with a changed test-setup to fit the re-designed prototype with a single-mirror mechanism.

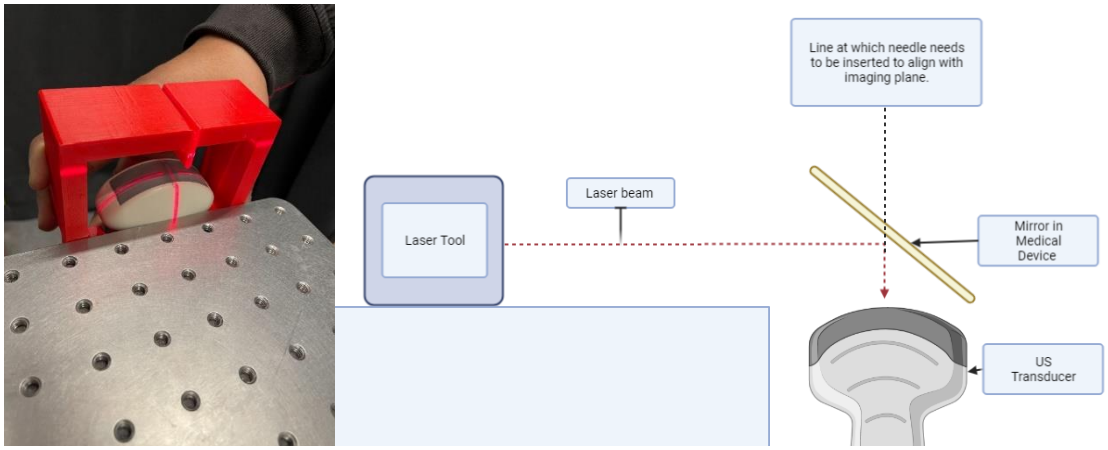

Figure 53:: Laser Alignment testing showing the laser crosshair signal with successful alignment (left) and changed test setup to fit redesigned prototype (right).

3.2.2.1 Test Results

After the team align the laser to the needle guiding notch, the laser mark appeared at the centre at the front of the ultrasound probe. This indicates that the structure of the medical device aligns

the needle correctly with the ultrasound waves, and that the probe cannot output a clear image of the needle because of other unknown reasons.

3.2.3 Test Setup and Description – Imaging Test in water tank

The team's next step was to test if the needle would show up on the imaging plane if inserted through the needle-notch pathway. This would help the team evaluate how the changes to the centering and the size of the notch affected or improved the image capability. The results of this test can be seen in the figure below. The setup for this test is the same as previous tests in the water tank in this phase.

3.2.3.1 Test Results

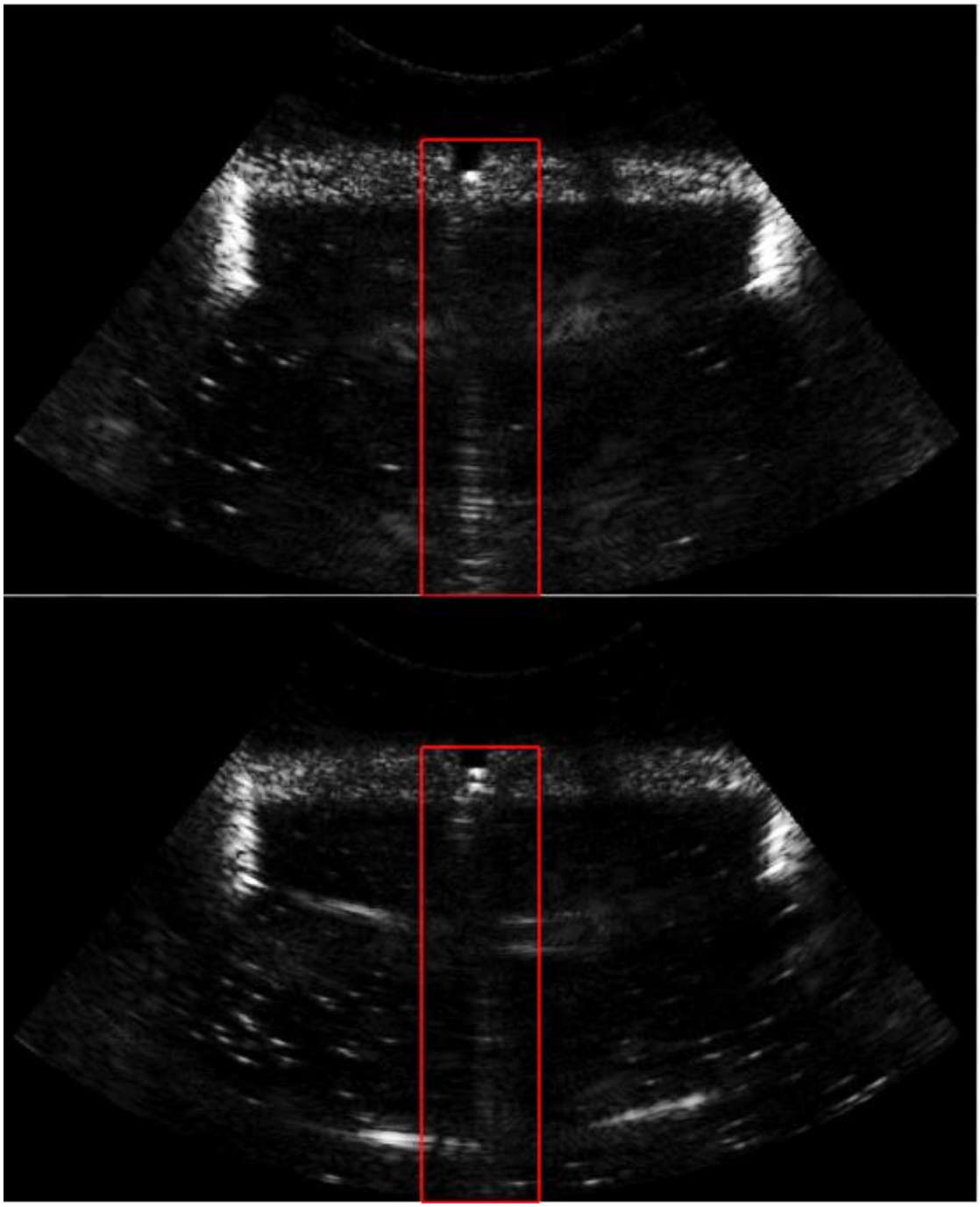

Figure 54: Ultrasound image showing the needles (highlighted in red boxes) on the imaging plane.

Upon increasing the voltage and gain of the US transducer to increase signal strength, the resultant imaging plane with the same setup is pictured below:

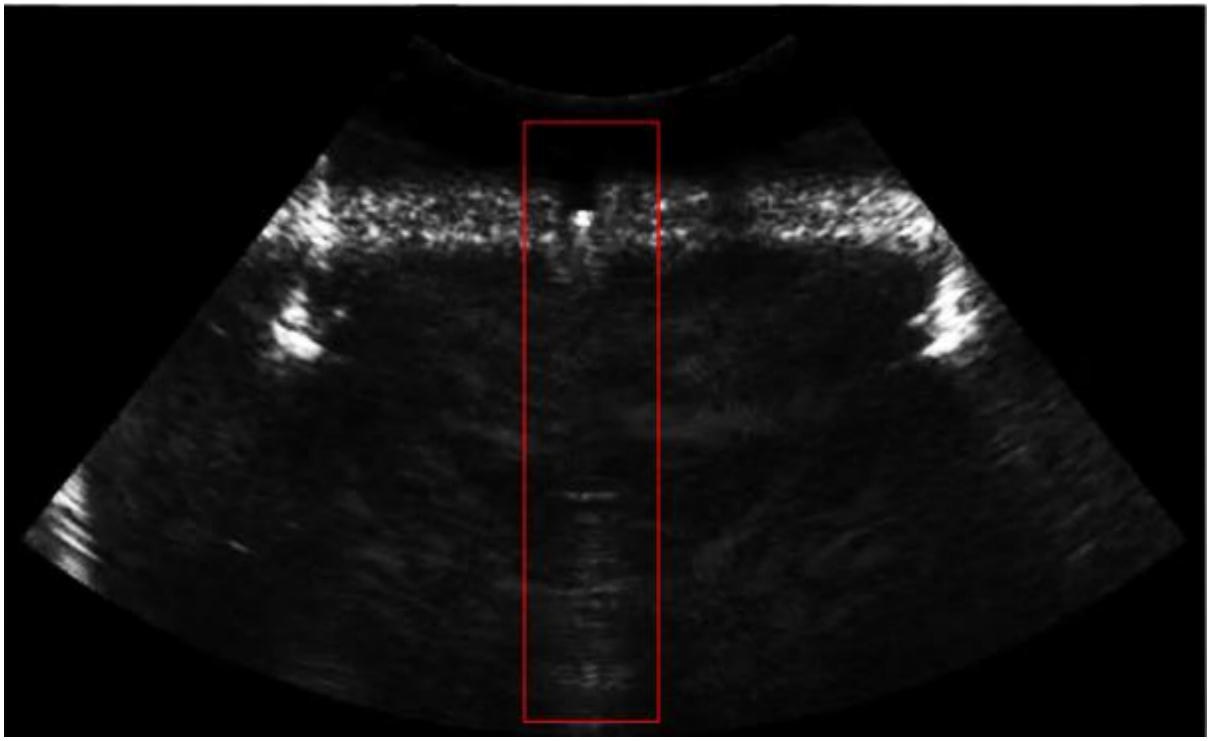

Figure 55: Ultrasound image showing the needles (highlighted in red boxes) on the imaging plane with increased gain and voltage settings.

In the above images, there is a clear improvement in the ability to see the needle on the imaging plane. One notable improvement when compared to the previous iteration is that the needle can be seen continuously, rather than just at the entry point of the notch and the tip. With this test, the team was confident in its assessment of the capabilities of the device with regards to its various components and set out to do a final validation with quantitative measures for the prototype device. These tests are detailed below.

3.3 Testing – Phase 3: Final Design Validation

3.3.1 Test Setup and Description: Design validation (Encapsulation)

As discussed in the previous sections, the final design for the mirror-integrated design with encapsulation for US guided PCNL contains a variety of crucial elements that must work in tandem for the project to meet its outlined requirements. One of these crucial elements is encapsulation itself – without the ability to work outside of a water tank, any device that is developed is simply not practical or applicable for the end user in a surgical environment. To evaluate the best possible material between the chosen three, and to evaluate the impact of the finalized method of encapsulation on the image quality, this test was performed.

To evaluate the imaging capabilities and respective quality for each material used to encapsulate the medical device, the team decided to set up and record images and image data. The setup for this test is relatively simple – the team chose to use a General purpose CIRS phantom to evaluate the US images. The CIRS general purpose phantom has a variety of targets across the axial and lateral lines, along with targets of varying sizes from dots to larger cysts in the phantom that can be identified via US. For this experiment, the team chose to make use of the first set of targets on the phantom, closest to the surface. This included a dot pattern

along with the presence of two cysts at the deeper levels of the proposed imaging plane. A small amount of water was poured on top of the phantom, allowing for good contact with the target area and reducing risks of any possible acoustic mismatches. The CIRS general purpose phantom is pictured below, along with the chosen near field axial and lateral targets.:

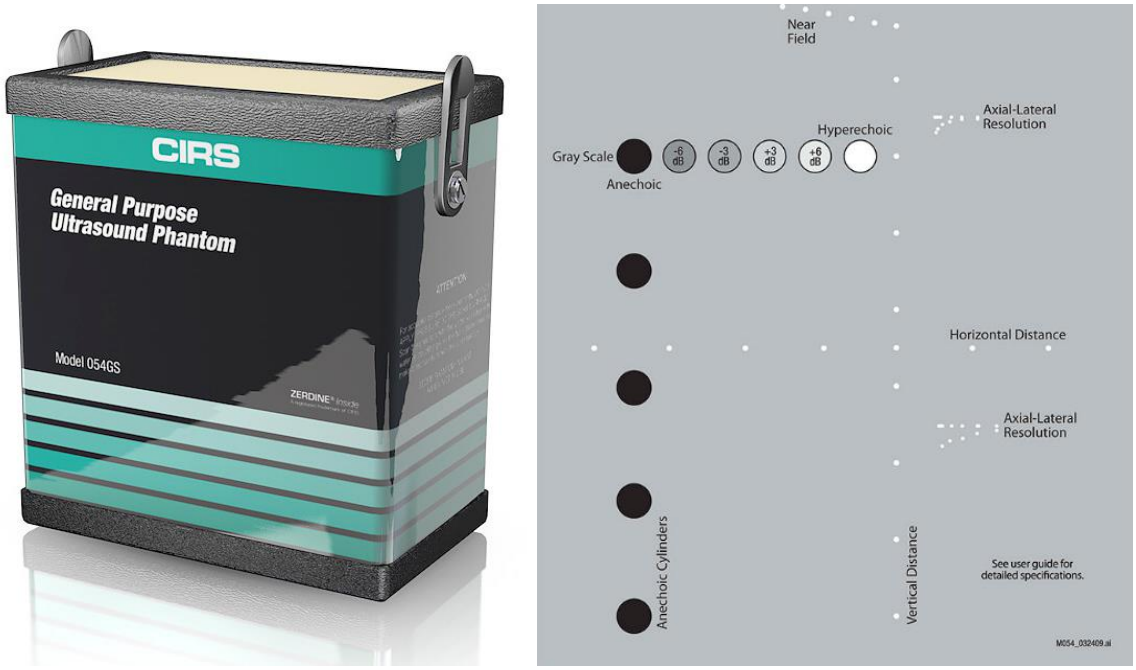

Figure 56: CIRS General Purpose Ultrasound Phantom (left) and it's denoted targets (right).

The objective of this test is twofold in nature – to firstly evaluate the difference between the three chosen materials, but also to evaluate the difference in image quality between the chosen material and the baseline itself – a simple US probe with US gel. Therefore, the team first recorded image and image data with the aid of just the US transducer and a quantity of US gel added onto the surface of the phantom, as pictured below. A roll of tape was used to prevent the gel from leaking onto the surgical table. This data would be used as the basis of the comparison between the medical device with the encapsulation and the conventional method.

Figure 57: Base line data collection using just the US transducer and the gel medium. The roll of tape was used to prevent US gel from spilling in the test area.

The next steps for this test were to fully assemble the device with silicone, clear polycarbonate, and rubber-latex, and repeating the image and data acquisition process on the same phantom while ensuring the probe marker is aligned the same on it. Like the baseline, a small amount of US gel was added on top of the phantom. The figures below depict the assembled devices being tested with each material:

Figure 58: (Left to right): Fully assembled Medical device with Polycarbonate plastic and US gel fully encapsulated along with the probe and mirror. CIRS phantom testing using the silicone material and rubber-latex material.

Once the data and image acquisition were complete, the team proceeded to perform signal processing and quantitative measures to evaluate each material. The quantitative analysis of the results is explained in the sections below.

3.3.1.1 Test Results: Encapsulation

3.3.1.1.1 Signal Processing

This section provides the details on the image processing techniques used to objectively quantify the image quality between various groups for the final validation testing for encapsulation. The log-compressed images collected during these tests using the chosen materials on the CIRS phantom are depicted below.

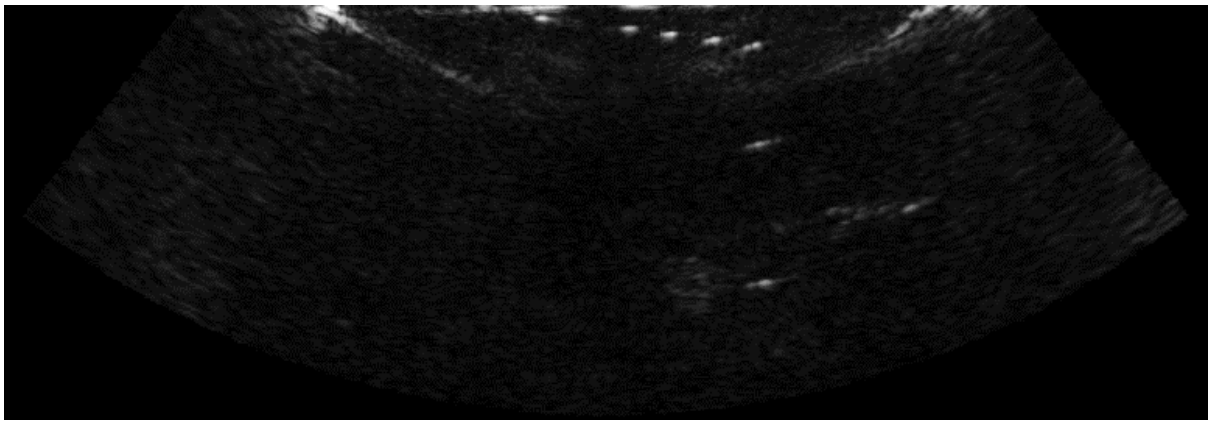

Figure 59: Encapsulation Testing Image of CIRS Phantom without encapsulation (Positive Control Group)

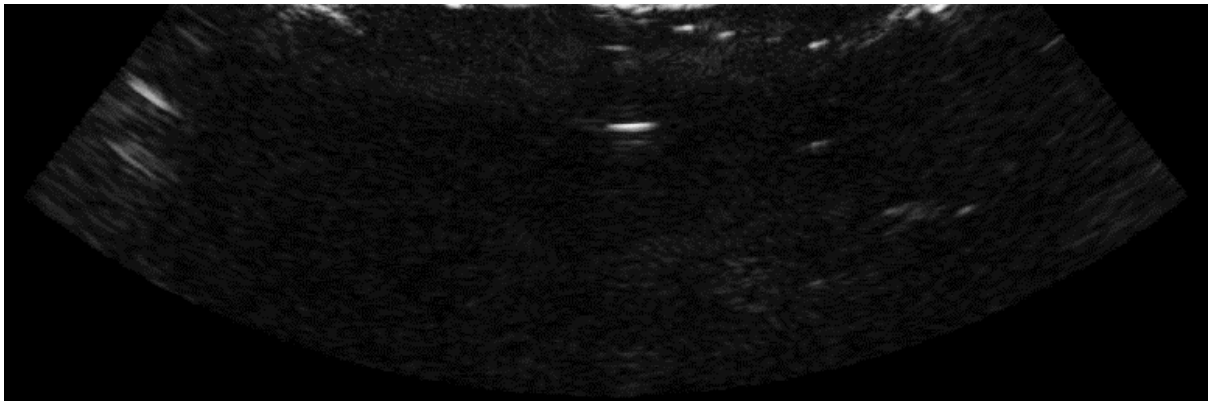

Figure 60: Encapsulation Testing Image of CIRS Phantom with Latex Rubber Material

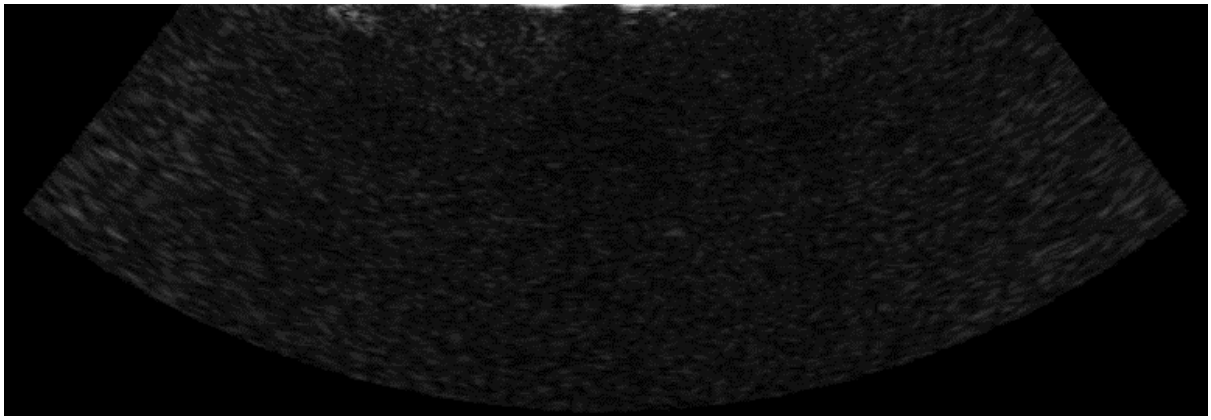

Figure 61: Encapsulation Testing Image of CIRS Phantom with Plastic Polycarbonate Material

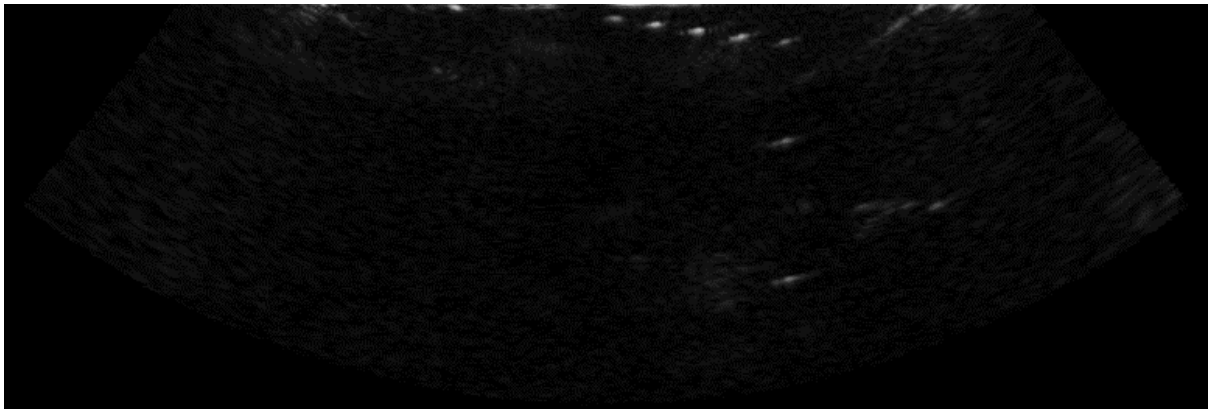

Figure 62: Encapsulation Testing Image of CIRS Phantom with Silicon Material

Through the various validation experiments, the team was able to simultaneously also collect B-mode image data (figures 59-62) via the MATLAB gui that works with the US transducer by Verasonics. Performance evaluation of the US setup and various groups is necessary to meet quality assurance guidelines and expectations that are already in practice across the medical industry. The team ran three separate quantitative analysis tests using this data which are detailed below.

3.3.1.1.2 Contrast to Noise Ratio Analysis

The contrast to noise ratio analysis is incredibly important when it comes to evaluating and estimating the contrast and target detectability in US images. For instance, a cyst is allocated as a target in a specific area of the imaging plane. The region containing the cyst is then then compared with an adjacent region outside of the target area, allowing the metric to evaluate the prominence of noise as compared to the signal itself. This is done through the collected image data. The image data is firstly organized as a matrix through MATLAB, where portions of the matrix can then be selected for the target region and the background region. The means and standard deviation of the signals within the regions are then calculated, allowing for the team to use this formula to compute CNR to obtain a singular scalar value.

$$CNR = \frac{|E_T - E_B|}{\sqrt{\sigma_{ET}^2} + \sigma_{EB}^2}$$

In the formula above, E_T and E_B are the weighted average of the target area and background area respectively, whereas σ_{ET}^2 and σ_{EB}^2 are the standard deviation values of the target area and the background area respectively. In principle, a higher CNR scalar value represents a higher ratio between the target area and the background noise, demonstrating good image quality and resolution with acceptable levels of noise [25]. The team chose two cysts as the target areas through image testing conducted using the various encapsulation materials and the positive control group with only the US probe on the general purpose CIRS ultrasound phantom (as described in Design validation test: Encapsulation).

The results for the CNR analysis are as follows:

Method of encapsulation	Identified target region: Cyst 1	Identified target region: Cyst 2
U.S probe only	0.95	0.78
Polycarbonate Plastic	0.22	0.35
Silicon	0.63	0.43
Latex rubber	0.76	0.49

Table 4: CNR scalar values for each method of encapsulation used in testing on the two identified target regions on imaging plane.

Through the analysis above, it is firstly important to note that the positive control group, where the conventional setup of using an US probe with a medium such as gel performs exceedingly well in comparison to any of the other test groups. However, when a closer comparison is done, it is quite clear that silicon and latex rubber have the capability to produce a US image that is close to the quality of the control groups, with the latex rubber showing higher CNR values for both target regions amongst the tested materials. In addition to this, it is important to note that during the test, the team had a difficult time removing small bubbles of air within the US gel once it was in the prototype device – this leads to increased acoustic mismatch, resulting in an increased level of noise in the image as well. While undesirable, the team is optimistic regarding the CNR scores and considers that there is room for improvement in the score that can be achieved through specialized tools such as vacuum chambers that can eliminate any air bubbles from the setup.

3.3.1.1.3 Full Width at Half Maximum Analysis

Spatial resolution is defined to be the axial or lateral, full-width at half maximum of the image of the target at its installed location on the imaging plane. For this test, the same image data collected for CNR was utilized, but three separate point targets belonging to the axial or lateral target groups were chosen. The image data was then converted into a matrix representative of the imaging plane, which was firstly plotted as a B-mode US image. Upon plotting the image, the targets were identified for their locations on the image using which the team was allowed to locate the relevant row in the matrix corresponding to the point target. This row can then be plotted as a 2D-plot, with the x-axis representing the number of pixels that make up the matrix, and the y-axis representing the intensity of the pixels in terms of their visibility. An example of these 2D-graphs can be found in the figure below:

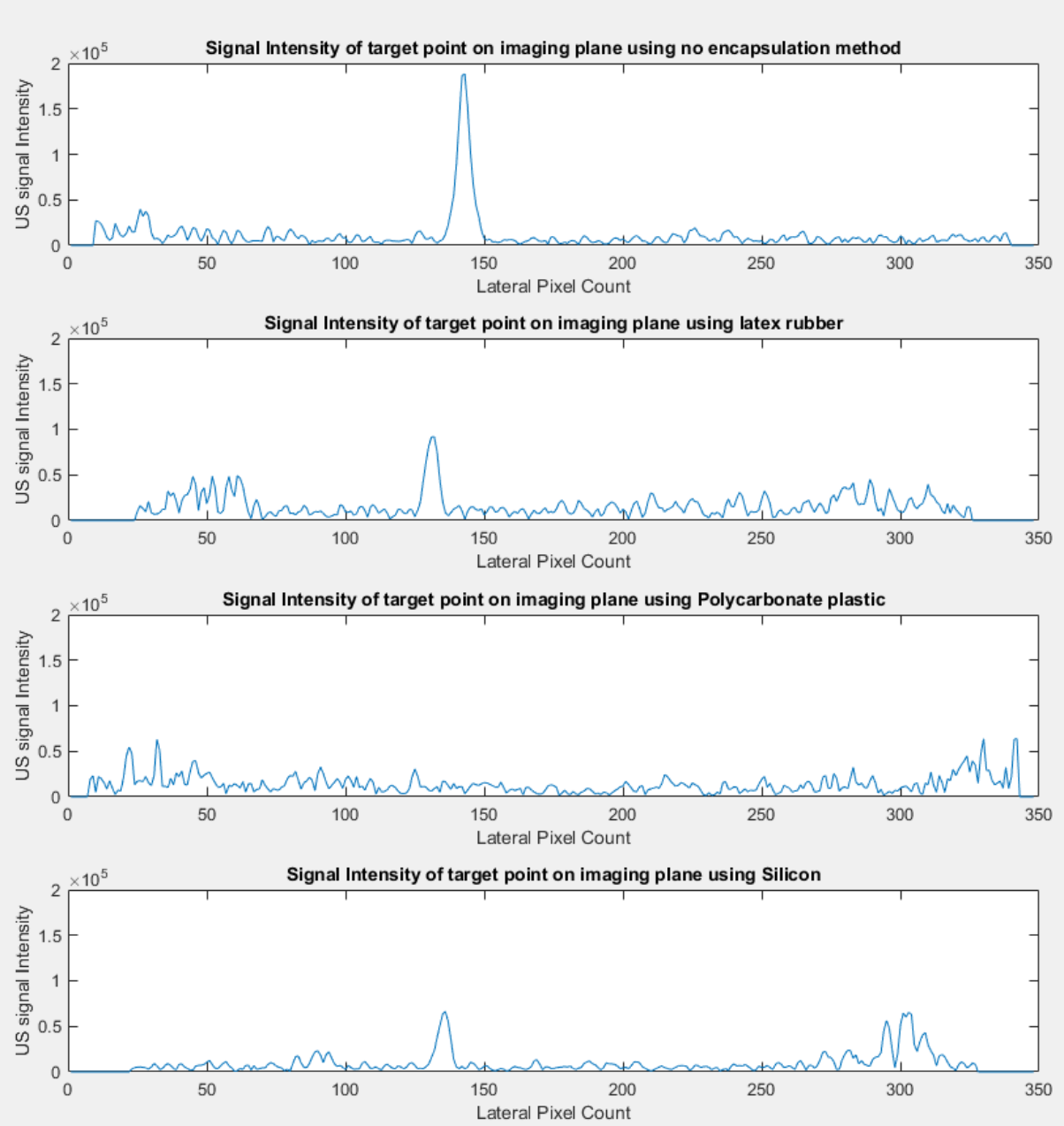

Figure 63: 2D line plots of FWHM analysis data for control and different methods of encapsulation used in testing.

Using the line plots and the known location on the x-axis of the point target, the corresponding signal peak can be identified. Once the peak is identified, the amplitude is measured. Using the amplitude, the half-width of the signal peak is then measured subsequently [25], [26]. The table below demonstrates the results of this analysis. It is important to note that each set of image data was obtained using a sample rate of 10 samples per data set, with the raw data recorded as an average of all the samples.

Method of encapsulation	Identified target signal width: Axial group (mm)	Identified target signal width: Lateral Group (mm)	Identified target signal width: Lateral Group (mm)
U.S probe only	4.60	5.88	7.22
Polycarbonate Plastic	0	3.28	4.00
Silicon	2.40	5.39	4.53
Latex rubber	4.30	5.43	6.96

Table 5: FWHM Signal Intensities for the chosen three point targets.

Using the results from the analysis above, it is once again quite clear that the positive control group still outperforms the various methods of encapsulation tested during experimentation. For the first identified target in the axial group, the FWHM width for the positive control group differs only by .3 mm when compared to that of the latex rubber. This trend is continued in the other two identified targets, with the latex rubber differing by .45 mm and 0.28 mm subsequently. Silicon rubber then outperforms the polycarbonate plastic for all tests but fails to come close to the control group or the latex rubber FWHM widths for the test. The polycarbonate plastic material performed the worst out of all the materials, as it completely failed to record a signal for the axial target used in the first test.

Using this data, it can be inferred that latex rubber is the best possible material out of the three materials in terms of imaging capabilities when compared to data collected without any encapsulation method at all. Using this result, the team chose to use latex rubber for the encapsulation method in all subsequent data collection. Latex rubber was also used for the final validation test for needle guidance.

3.3.1.1.4 Signal to Noise Ratio Analysis

The signal to noise ratio (SNR) is a test that used to measure the difference between the true signal (i.e reflecting actualy designated targets) to that of the surrounding noise. A lower signal to noise ratio is undesirable, as the images obtained using the US can be grainy or contain a very high level of artefacts and noise. This test is extremely important when evaluating any US images, as a high true signal amplitude or a low noise amplitude does not necessarily reflect upon the true quality of the image. For an image to be considered good quality, it is therefore important to use the SNR that incorporates both values. This test works in tandem with the FWHM test, as the same process is used to obtain the data used for SNR analysis [25], [26]. The image data obtained was then converted into a matrix representative of the imaging plane, which was firstly plotted as a B-mode US image. Upon plotting the image, the targets were identified for their locations on the image using which the team was allowed to locate the relevant row in the matrix corresponding to the point target. This row can then be plotted as a 2D-plot, with the x-axis representing the number of pixels that make up the matrix, and the y-axis representing the intensity of the pixels in terms of their visibility. This data is then further analysed, where the maximum point of the true signal peak is measured. Next, one-eight of the 2D beam profile is used as a representation of the noise signal to calculate the standard deviation of the noise on the image. These values are then used in the following formula below:

$$SNR = 20 \times log\ log\ 10(\frac{t}{n})$$

The formula calculates the SNR value using t, which represents the true signal peak value, and n, which represents the calculated standard deviation of one-eighth of the beam profile.

The same targets utilized for the FWHM analysis were also used for the SNR test. The results obtained from this test are depicted in the table below.

Method of encapsulation	Identified target: Axial group SNR value	Identified target: Lateral Group SNR value	Identified target: Lateral Group SNR value
U.S probe only	24.83	58.42	42.20
Polycarbonate Plastic	N/A	40.48	15.29
Silicon	18.49	47.31	22.58
Latex rubber	23.28	48.52	35.47

Table 6: SNR Values of sampled B-mode data across the chosen encapsulation materials.

The image data collected using Polycarbonate Plastic garnered mixed results. During the first test, the ultrasound probe was unable to identify the axial group target, thus resulting in a N/A value for the first test's SNR value. Even when the target was successfully identified using the Polycarbonate plastic, the SNR values for both lateral group targets were lower than other materials. The image data collected with Silicon when compared to that of the Latex rubber generated significantly smaller SNR values for the first and third targets and a showed close performance to the latex for the second target. The data collected using latex rubber showed the highest SNR values across all three targets, exhibiting the closest possible behaviour when compared to the positive control data collected using only the probe.

These results, along with the CNR and FWHM solidified our groups choice for the encapsulation material used to seal the bottom of the device. Our team made use of latex rubber for all other tests, including the final validation for the needle guidance test on the medical device.

3.3.2 Test Setup and Description – Design validation test (Needle Guidance with Gelatine Phantom)

The ability to guide the needle through the notch pathway towards a designated target is in some sense, the final validation for the device and it's intended usage. This test is incredibly important as it evaluates the entire device as opposed to certain aspects for fine tuning. Through this test, the team can evaluate the needle notch pathway, the mirror mechanism and the encapsulation working in combination all at once in order to help the user guide the needle to its target.

For this test, the team constructed a gelatine phantom of 17 mm in length, 13 mm in breadth and 6 mm in width. Sigma-Aldrich Gelatine from porcine skin was utilized for this phantom. The product has a gel strength of 300 and is soluble in water at 50mg/ml, prepared using a lab stove and a large beaker. This phantom made use of ceramic balls placed at various depths in three rows, which would serve as the intended target for the guided needle to reach or strike. These ceramic balls would show on the imaging plane as a row of four circular targets next to

each other at the same depth. Figure 59 depicts the gelatine phantom below along with the ceramic balls lodged in it.

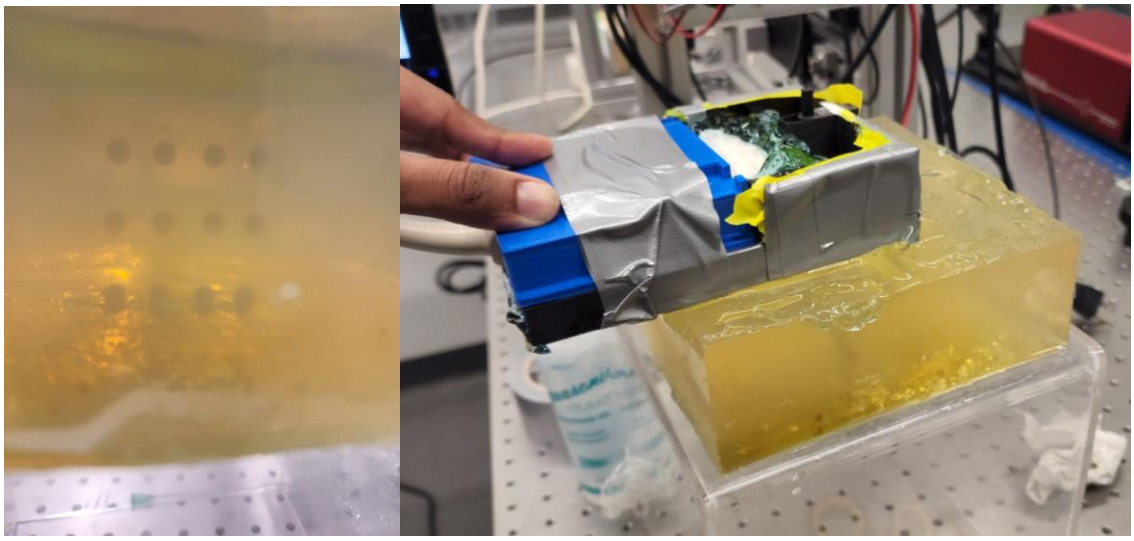

Figure 64: Ceramic ball targets embedded within the gelatin phantom (left) Prototype device being used for final validation test on needle guidance using the gelatin phantom.

The device would then be fully assembled and encapsulated using US gel and latex rubber, allowing for imaging. Once the device can locate the targets in the imaging plane, a needle is guided towards the ceramic balls using only the US feedback. This is repeated with three targets, with the user attempting to strike each target three times using the inserted needle. The fourth target is used in case one of the ceramic balls is incorrectly lodged within the gelatine or an unsuccessful attempt at needle guidance.

Once the data and image acquisition were complete, the team proceeded to perform signal processing and qualitative measures were developed to evaluate the needle guidance of the medical device.

To pass the validation for this test, the design team proposed three measures of qualitative success:

1. Successfully identify the needle tip on the imaging plane.
2. Successfully identify the point targets on the imaging plane.
3. Successfully guide the needle tip and strike the point targets on the imaging plane.

Each measure of qualitative success was evaluated using repeatability to ensure that the results obtained were representative of the device's capabilities. The results of the qualitative analysis are explained in the sections below.

3.3.2.1 Test Results: Needle Guidance

3.3.2.1.1 Identify the needle tip on the imaging plane

The team was able to successfully identify the needle tip on the imaging plane during insertion and guidance. The team was able to identify the tip three times per point target, identifying the needle tip all nine times during the test. The images below depict two of the successful needle tip visualization attempts in the gelatine phantom.

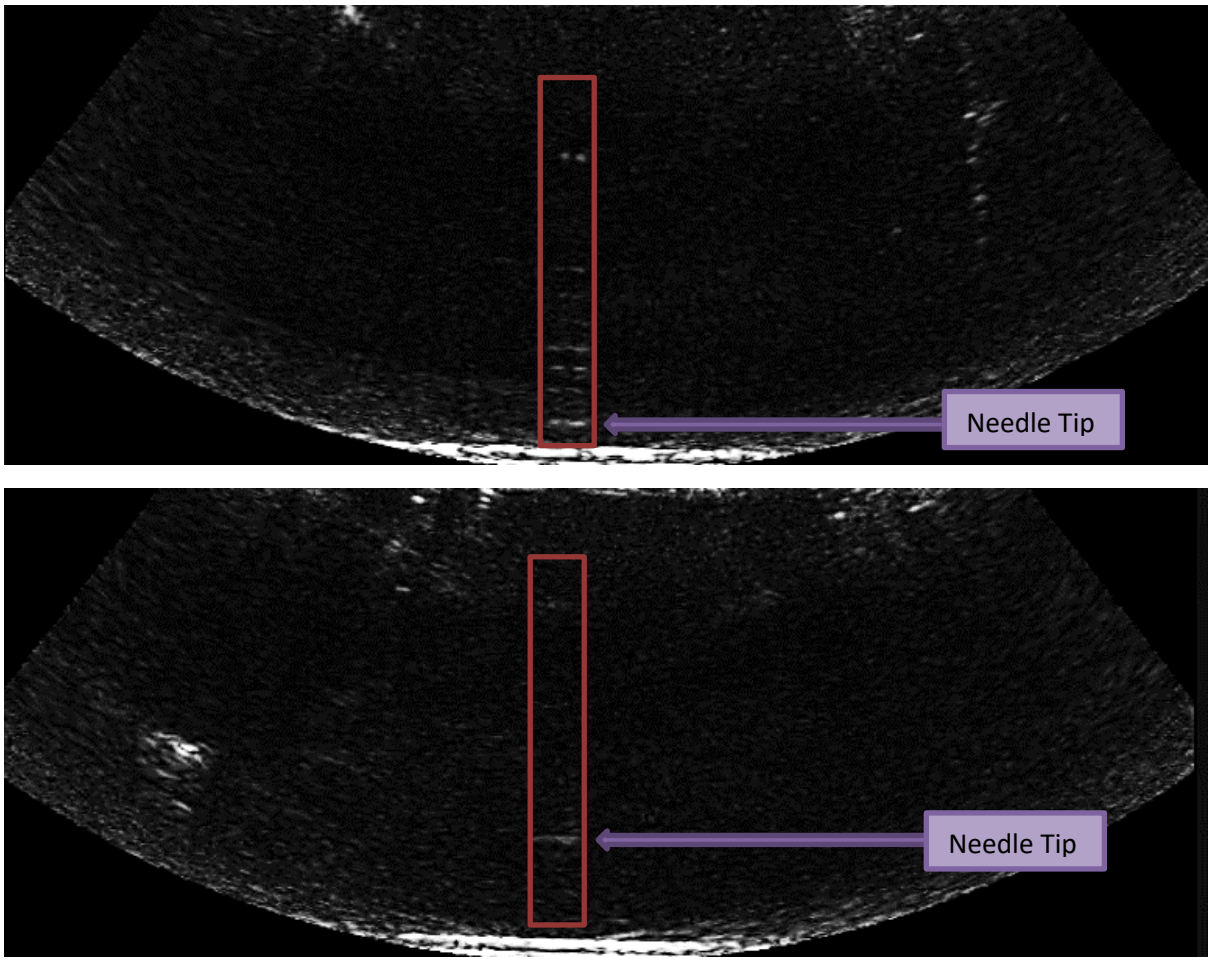

Figure 65: Final Validation Test with needle tip highlighted using yellow arrow, and needle pathway visualized using orange box.

3.3.2.1.2 Identify the point targets on the imaging plane

The team was able to successfully identify the point targets on the imaging plane during the final validation testing. As per the setup, the US probe must be able to identify four distinct point targets in a row across the imaging plane at once. The results are depicted below in the figure.

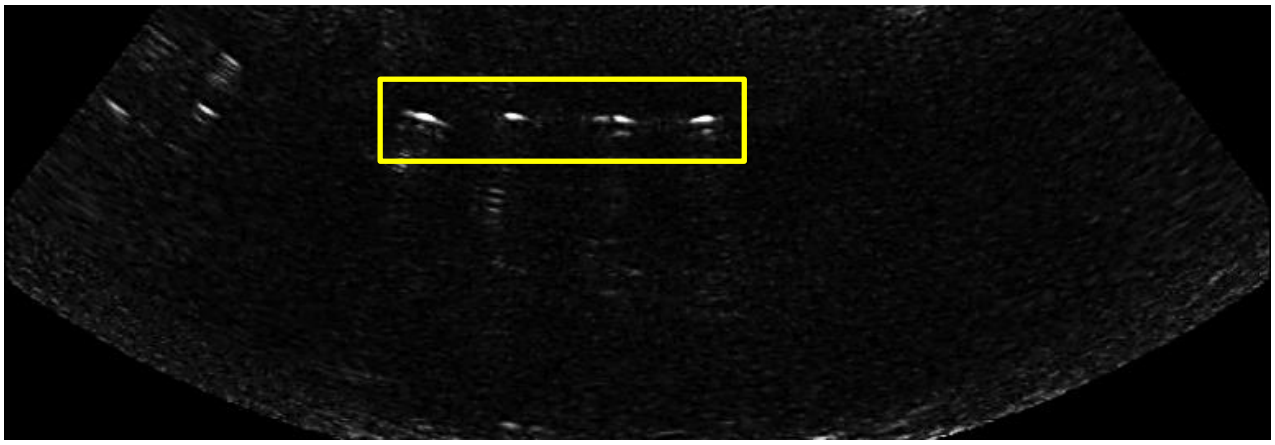

Figure 66: Captured Ultrasound Image depicting ceramic ball point targets (highlighted in yellow box) using fully assembled and encapsulated device.

3.3.2.1.3 Guide the needle tip and strike the point targets on the imaging plane

Once the team was able to successfully identify both the point targets and the needle tip individually on the imaging plane, the team proceeded to the final phase of the test and the last qualitative success measure: to be able to guide the needle tip and strike the point target. Each of the three primary point targets were attempted to be reached with the needle three times: resulting in nine total attempts. In total, the team was able to successfully reach the point target using the identified needle tip on the imaging plane all nine times. A sequence of this insertion process for two of the point targets is depicted in the figures below.

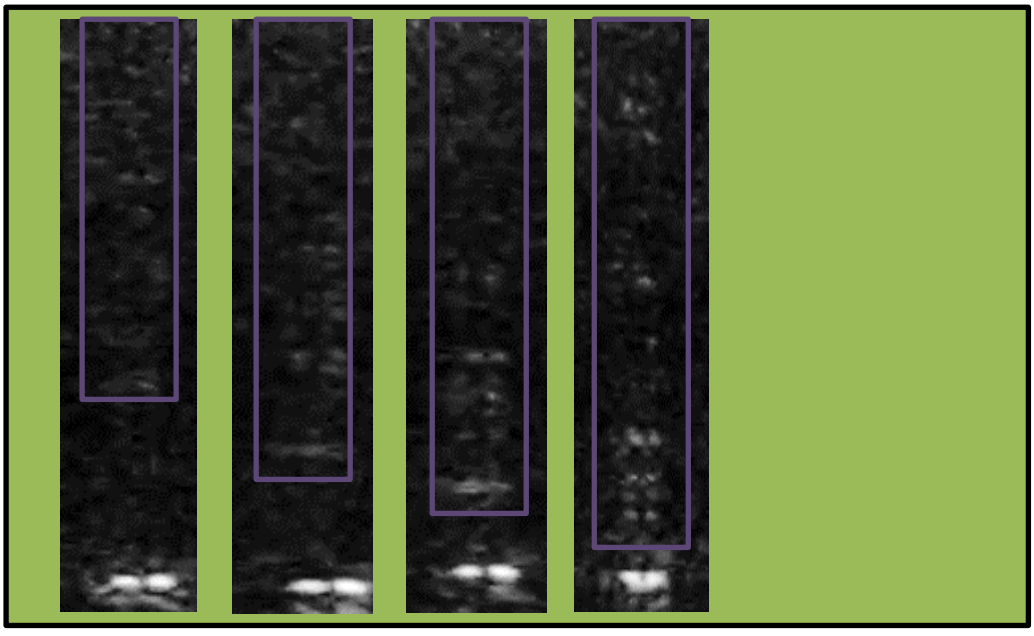

Figure 67: Sequence of images depicting how the needle (highlighted in yellow boxes) reaches the point target 1 on the imaging plane.

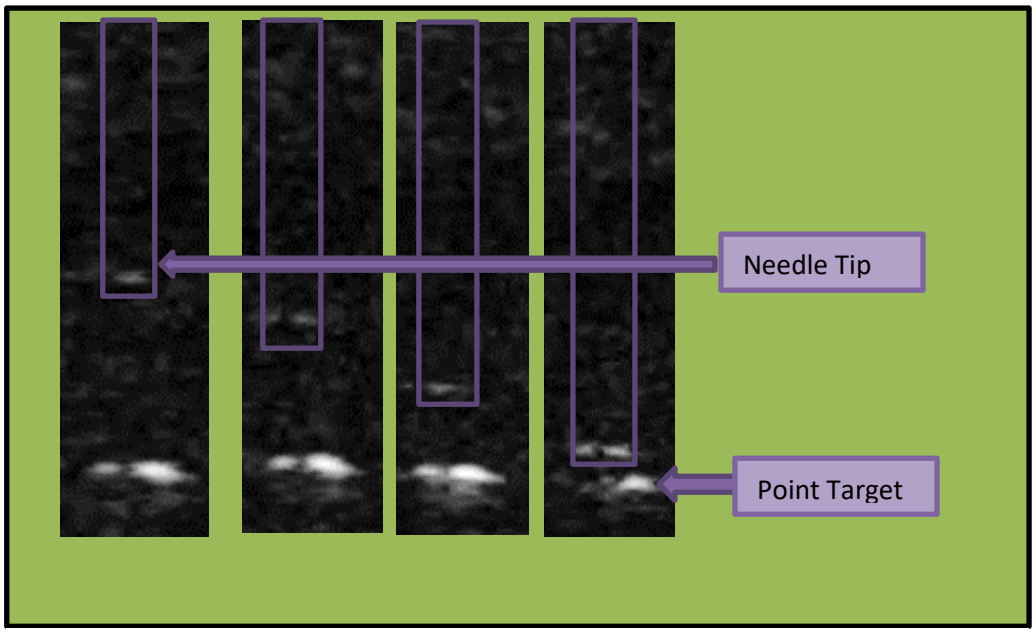

Figure 68: Sequence of images depicting how the needle (highlighted in yellow boxes) reaches the point target 2 on the imaging plane.

Based on these findings, the team was able to establish that all qualitative success measures to pass the final validation were effectively met in a reliable and repeatable manner. It is important to note that while needle visibility is restricted to the very tip of the needle when compared to that in earlier experiments conducted in the water tank, the testers were still able to visualize the needle tip clearly and use the US device to effectively guide it towards the point targets.

4 Discussion

4.1 Limitations & Future Improvement: Design Components

4.1.1 Mirror Mechanism

The mirror mechanism proved to be a successful design and setup, enabling the team to use US imaging accurately for even prolonged use. The team was able to successfully meet all validation requirements for the mirror mechanism as it allowed us to accurately identify targets on the water tank, CIRS general phantom and Gelatine phantom. However, one key improvement that could be made for future work is the independent ability to adjust the mirrors during imaging. Currently, the setup is rigid and permanently set to 45 degrees, restricting the imaging capabilities without moving the device itself. If a system or design can be implemented without compromising other key facets of the project such as encapsulation, the device would be able to adjust the mirrors to conveniently find any target or needle tip that is outside of the imaging plane.

4.1.2 Notch Needle Pathway

The notch needle pathway is one of the most important and unique components of this project. This component's implementation allowed the team to successfully insert a needle directly in line with the reflected US signal without compromising the encapsulation capability.

It also enables an easy removal of the device once needle insertion was complete by acting as an independent component to the rest of the device. Our team believes that in the future, the notch's design can be further improved to minimize any effects on the image through the usage of higher quality printing and minor design changes such as further narrowing the notch and using thinner walls for it's exterior, thus minimizing the "blind spot" it creates even further.

4.1.3 Encapsulation

The ability of the device to function outside of a submerged setup without any major sacrifices is one of the team's biggest advancements when compared to previous work conducted by other teams. Latex rubber proved to be extremely capable of enabling good quality imaging when compared to the positive control group in all quantitative analysis testing and is extremely cheap and easy to work with. The team however believes that more marginal improvements can be made through experimenting further with various densities, thickness and elasticities that can be attributed to this material. Fine-tuning the desired properties of the encapsulation material in depth can allow any future teams to minimize the effects of encapsulation to a degree where it is no longer noticeable when compared to current conventional methods of PCNL needle guidance.

4.1.4 Needle Visualization

The ability to visualize the needle with a fully assembled device has proven to be one of the team's biggest challenges. While the team was able to successfully do so during all validation and testing, it is imperative that future work continues to improve upon and build the design plan so that users can visualize the needle even more clearly so that it may be guided with a very high degree of accuracy. This can be possibly achieved in a variety of ways. One such technique could be the implementation of other modern technologies such as software aids working in tandem with small cameras that are already observing use in the medical field to help the user guide the needle using real-time pathway predictions and guidance. Another way to increase needle visualization could consider an in-depth study into the usage of echogenic needles that are specifically designed to increase needle visibility with US technology. Lastly, more design changes to the mirror mechanism and further iterative improvements could improve the needle visibility in the imaging plane for its users.

4.1.5 Limitations: Surgical Application

While the device was rigorously tested in laboratory conditions, there is often an inherent difference between the actual intended application and the controlled conditions the medical device is tested in. The team would likely face several unique challenges with regards to preparing a device or a prototype that can be used in PCNL to its full extent.

One such issue would be the wide variability of anatomical structures that patients have. While all patients undergoing PCNL would be in a prone position, each patient's body can vary in terms of risk factors, insertion points and even the level of obesity, significantly affecting the procedure itself. The level of obesity, age and patient size can affect the depth at which the needle requires to be inserted. To account for this, the device would likely have to be adjusted to be compatible with needles of varying lengths.

In addition to this, placing the device on a patient in a prone position will likely prove to be a slight challenge in some locations. The flat bottom of the device perfectly suits the gelatine phantoms with a smooth surface in laboratory testing conditions. However, a patient's back is often curved along with ridges around the spinal structures, making it difficult to place the device flush against the target imaging area.

4.1.6 Limitations: Mass Commercialization

There are several factors that need to be considered before the device can be submitted and considered 'ready' for mass commercialization. The FDA defines a medical device as "An instrument, apparatus, machine, or other similar or related article for use in mitigation, treatment, or prevention of diseases"[27]. Since the product can be identified as a medical device, it would need to go through multiple steps of regulatory approval, the first of which would be device classification. In addition to this, the team would be required to meet good manufacturing practice requirements and quality system regulations. Steps must be taken to also meet packaging, labelling, and training requirements.

While the device currently utilizes 3D printing techniques for rapid prototyping, the finished commercial product would have to be much more durable and robust in its production methods and finish. The current prototype is also only currently compatible with the C5-2 type curved transducer. A finished product would likely have to allow for design variations and components that can prove to be compatible with the wide variety of ultrasound transducers that observe use across each hospital.

4.1.7 Next Steps: Validation

Future additions to validation tests can be broadly grouped into immediate suggestions that our team was constrained with, and tests that can be implemented when the medical device is considered 'close to production'. The team can make several improvements to existing tests. This includes testing with realistic kidney phantoms, the usage of echogenic needles and a full Ultrasound setup that would typically observe usage in a real surgical context. Currently, the team makes use of a research ultrasound setup, which may not be entirely representative of the device's performance in its intended usage.

The device, upon further development, would require a rigorous series of validation tests that meet the FDA's regulatory requirements and the ability to prove its functionality outside of in-vitro tests. Some examples of In-vivo testing that could be possibly implemented soon include animal testing on a porcine subject. This could prove to be a very valuable test as the porcine kidneys are incredibly similar in structure and size to human kidneys. Kidney targets can be identified and compared to conventional US guided PCNL and even bi-planar fluoroscopy guided PCNL techniques for accuracy, time-taken, surgical risks, and efficacy.

Finally, a close-to-production prototype could also be used in a closed clinical trial, with human volunteers and close collaboration with surgeons at partner institutions. This would also likely prove to be valuable data as it would not only test the functionality and accuracy of the device, but also allow the team to gather feedback from the end-user group.

5 Conclusion

In conclusion, this project aimed to design a medical device that integrates the needle insertion and imaging for PCNL into a singular solution, greatly simplifying the process and reducing the time taken. The completed device is extremely intuitive, low-cost, disposable, lightweight and sterilizable. The device can function outside of a water tank with an encapsulation solution, enable needle insertion and enable guidance of the needle through real-time imaging. This project serves as a blueprint for future work that could be done to improve guidance, visualization, and overall ease-of-use. We hope that the final result of this project could eventually come to help cut-down PCNL surgery times and improve clinical outcomes of similar guided-needle intervention procedures.

6 Identifying Responsibilities and Impacts of the Finalized Medical Device (ABET)

Throughout the course of this project and its various phases that included research and development, design iterative changes, testing and final validation, our team worked to ensure that the relevant engineering standards and responsibilities were incorporated into the very fabric of the project. It is important to understand and make decisions or outline specific design requirements based on the professional responsibilities that an engineer must follow, along with the desire to address the specific and outlined goal.

As previously mentioned, our team recognizes the various impacts that this device could have on a variety of factors outside of engineering. This includes the environmental factors that must be considered when designing a product intended for wide-spread, global use aimed at addressing an increasingly prominent medical condition. To ensure that the designed device was environmentally responsible, the decisions made in the choice of materials for the device were made not only based on quantitative and qualitative analysis, but also with the intention of minimizing any negative impact to the environment at large. PLA plastic, which is used to create the casing for the device is fully recyclable. Other materials in the device include glass and latex rubber, which are also fully recyclable with relative ease, not requiring a high degree of breakdown or complex processes. The device is also designed to be sterilizable and intended to be re-used as required by the customer, minimizing the materials used and allowing for an eco-friendlier footprint.

The engineering team also took considerable efforts to ensure that the product would be low-cost, easy to produce and easy to transport to any medical facility that requires it. The process of 3D printing has significantly changed the current manufacturing market, allowing for large scale production of market-ready products at a very low cost. The materials chosen are also extremely easy to obtain and cheap for purchase. This low-cost design requirement ensures that a device intended to address a globally prominent medical condition is truly affordable for a global audience that experience varying societal and economic factors. Introducing a capable US guided device intended for PCNL could also directly reduce the costs for patients around the world, as it would drastically simplify the current conventional process and reduce surgery times while consuming less resources at the hospital.

Finally, the device aims to improve the clinical outcomes of PCNL surgery, reducing the chances of arterial or organ damage during needle insertion and entirely removing the risk of radiation that conventional fluoroscopy exposes to patients. The engineering team understands the potential importance of these aspects and has directly incorporated these wider goals into specific requirements during the various phases of the product development. While the project's potential is large in terms of it's applicability towards the variety of needle guided intervention procedures currently observed in medicine, the team does not consider it to pose

any large ethical risk since it is currently specifically designed for a singular purpose that applies to only PCNL surgery. The team performed extensive literature review and research into current conventional methods and product markets to ensure that the device does not pose any risks with regards to its interaction with the patient if used as intended.

7 Engineering Standards

Engineering standards consist of codes and standards. A code is a set of rules and specifications or systematic procedures for the correct methods and materials used in a certain product, while a technical standard is an established norm or requirement. For a product to have good quality and to be successfully adopted by the legal jurisdiction, certain engineering standards must be performed.

The project team chose the ISO standards as guidance. ISO stands for the International Organization for Standardization. It is a worldwide federation of national standards bodies. During the design process of the current product, the project team has been mainly focusing on ISO 13485:2016, the quality management systems for medical devices about the requirements for regulatory purposes. In the meantime, the project team also took in consideration of ISO 9001 about the general quality management principles to create a product with higher customer satisfaction.

According to the document of ISO 13458:2016, the product introduced by this paper falls into the definition of a medical device as it, in combination with an ultrasound probe, is intended to be used for the purpose of diagnosis, monitoring, and treatment, given its ability to guide a needle with clear image showing the status of insertion during a surgical process. Among the quality management principles regarding ISO 9001, the project team paid special attention to the steps of process approach, continuous improvement, and evidence-based decision making.

Process approach requires the team to collect consistent and predictable results as a coherent system. The team managed to do so by arranging testing previews during the weekly meetings. The team always check the CAD and testing environments before proceeding with the experiments to ensure the results will be meaningful and logical. A strictly controlled lab environment is also essential to meet the requirements of process approach as the team tries to keep the testing environment unchanged through the trials to eliminate influences of outside factors. The step of continuous improvement requires the team to have a constant focus on the enhancement of the product so that a consistent increase on the testing performance can be achieved. This was fulfilled by the project team that the members in the team were always trying to implement new features or new adaptations of the product to improve its performance each week. The project team collects data on the product's performance at least once a week, and then the team discuss about the result and plan for the next step accordingly. In addition to this, the table below details how the needs and constraints of the project relate to specific ISO or ASTM guidelines.

Needs	Description	Guideline
Safety	Cleanable with common disinfectants	ASTM E1837-96[28]

	Biocompatible	ISO 10993-1[29] ISO 10993-5[30] ISO 10993-10[31]
	Material Properties	ISO 4892-3:2016[32]
Product Life	Devices are reusable and can withstand sufficient cycles of use without failure	ASTM E1837-96[33]
Durability	Devices are durable and will not deform with regular use	ASTM F963-17[34]
Limited Potential for Misuse	Device design should serve only it's intended purpose and should not lend itself to outside or inappropriate uses	ISO 14971:2019[35]

Table 7: Device design needs, description and relevant ASTM/ISO guidelines.

8 References

[1] S. R. Khan *et al.*, "Kidney stones HHS Public Access", doi: 10.1038/nrdp.2016.8.

[2] C. D. Scales, A. C. Smith, J. M. Hanley, and C. S. Saigal, "Prevalence of kidney stones in the United States," *European Urology*, vol. 62, no. 1, pp. 160–165, Jul. 2012, doi: 10.1016/J.EURURO.2012.03.052.

[3] J. Bjazevic *et al.*, "The evolution of percutaneous nephrolithotomy: Analysis of a single institution experience over 25 years," *Canadian Urological Association Journal*, vol. 13, no. 10, p. E317, 2019, doi: 10.5489/CUAJ.5725.

[4] G. R. Sharma and B. Luitel, "Techniques for fluoroscopy-guided percutaneous renal access: An analytical review," *Indian Journal of Urology : IJU : Journal of the Urological Society of India*, vol. 35, no. 4, p. 259, 2019, doi: 10.4103/IJU.IJU_149_19.

[5] A. P. Ganpule, M. Vijayakumar, A. Malpani, and M. R. Desai, "Percutaneous nephrolithotomy (PCNL) a critical review," *Int J Surg*, vol. 36, no. Pt D, pp. 660–664, Dec. 2016, doi: 10.1016/J.IJSU.2016.11.028.

[6] T. Alelign and B. Petros, "Kidney Stone Disease: An Update on Current Concepts," *Advances in Urology*, vol. 2018, 2018, doi: 10.1155/2018/3068365.

[7] S. R. Khan *et al.*, "Kidney stones," *Nat Rev Dis Primers*, vol. 2, p. 16008, Feb. 2016, doi: 10.1038/NRDP.2016.8.

[8] J. A. Jensen, "Medical ultrasound imaging," *Progress in Biophysics and Molecular Biology*, vol. 93, no. 1–3, pp. 153–165, Jan. 2007, doi: 10.1016/J.PBIOMOLBIO.2006.07.025.

[9] T. A. Whittingham, "Medical diagnostic applications and sources," *Progress in Biophysics and Molecular Biology*, vol. 93, no. 1–3, pp. 84–110, Jan. 2007, doi: 10.1016/J.PBIOMOLBIO.2006.07.004.

[10] P. N. T. Wells, "Ultrasound imaging," *Physics in Medicine & Biology*, vol. 51, no. 13, p. R83, Jun. 2006, doi: 10.1088/0031-9155/51/13/R06.

[11] Ph. D. Nimrod M. Tole and Harald Ostensen, "BASIC PHYSICS OF ULTRASONOGRAPHIC IMAGING".

[12] B. J. Ostrum, B. B. Goldberg, and H. J. Isard, “A-Mode Ultrasound Differentiation of Soft-Tissue Masses,” *https://doi.org/10.1148/88.4.745*, vol. 88, no. 4, pp. 745–749, Apr. 1967, doi: 10.1148/88.4.745.

[13] “[Figure, B-Mode ultrasound showing main portal...] - StatPearls - NCBI Bookshelf.” https://www.ncbi.nlm.nih.gov/books/NBK567746/figure/article-128653.image.f4/ (accessed Apr. 05, 2022).

[14] T. L. Szabo and P. A. Lewin, “Ultrasound Transducer Selection in Clinical Imaging Practice,” *Journal of Ultrasound in Medicine*, vol. 32, no. 4, pp. 573–582, Apr. 2013, doi: 10.7863/JUM.2013.32.4.573.

[15] A. P. Ganpule, M. Vijayakumar, A. Malpani, and M. R. Desai, “Percutaneous nephrolithotomy (PCNL) a critical review,” *International Journal of Surgery*, vol. 36, no. PD, pp. 660–664, Dec. 2016, doi: 10.1016/J.IJSU.2016.11.028.

[16] C. Chu *et al.*, “Ultrasound-Guided Renal Access for Percutaneous Nephrolithotomy: A Description of Three Novel Ultrasound-Guided Needle Techniques,” *Journal of Endourology*, vol. 30, no. 2, p. 153, Feb. 2016, doi: 10.1089/END.2015.0185.

[17] J. A. Antonelli and M. S. Pearle, “Advances in Percutaneous Nephrolithotomy,” *Urologic Clinics of North America*, vol. 40, no. 1, pp. 99–113, Feb. 2013, doi: 10.1016/j.ucl.2012.09.012.

[18] K. R. Ghani *et al.*, “Percutaneous Nephrolithotomy: Update, Trends, and Future Directions,” *European Urology*, vol. 70, no. 2, pp. 382–396, Aug. 2016, doi: 10.1016/J.EURURO.2016.01.047.

[19] R. Ko, F. Soucy, J. D. Denstedt, and H. Razvi, “Percutaneous nephrolithotomy made easier: a practical guide, tips and tricks,” *BJU International*, vol. 101, no. 5, pp. 535–539, Mar. 2008, doi: 10.1111/J.1464-410X.2007.07259.X.

[20] “Ultrasound guided PCNL as good as conventional PCNL for nephrolithiasis | Latest news for Doctors, Nurses and Pharmacists | Urology.” https://specialty.mims.com/topic/ultrasound-guided-pcnl-as-good-as-conventional-pcnl-for-nephrolithiasis (accessed Apr. 05, 2022).

[21] “Solution | Ethos Medical.” https://www.ethos-medical.com/solution (accessed Apr. 05, 2022).

[22] “Trajectory planning in an ultrasound guided needle insertion procedure.... | Download Scientific Diagram.” https://www.researchgate.net/figure/Trajectory-planning-in-an-ultrasound-guided-needle-insertion-procedure-The-needle-should_fig1_253088042 (accessed Apr. 15, 2022).

[23] “Student Work | Needle Intervention System with Mirror Ultrasound Imaging | ID: 6395w9991 | Digital WPI.” https://digital.wpi.edu/concern/student_works/6395w9991?locale=en (accessed Apr. 15, 2022).

[24] Verasonics, “Verasonics Transducer Specifications.” Accessed: Apr. 05, 2022. [Online]. Available: https://verasonics.com/wp-content/uploads/2017/11/Transducer_specifications_sheet_2017.pdf

[25] J. M. Thijssen, G. Weijers, and C. L. de Korte, “Objective Performance Testing and Quality Assurance of Medical Ultrasound Equipment,” *Ultrasound in Medicine & Biology*, vol. 33, no. 3, pp. 460–471, Mar. 2007, doi: 10.1016/J.ULTRASMEDBIO.2006.09.006.

[26] E. Sassaroli, C. Crake, A. Scorza, D. S. Kim, and M. A. Park, “Image quality evaluation of ultrasound imaging systems: advanced B-modes,” *Journal of Applied Clinical Medical Physics*, vol. 20, no. 3, p. 115, Mar. 2019, doi: 10.1002/ACM2.12544.

[27] “Medical Device Overview | FDA.” https://www.fda.gov/industry/regulated-products/medical-device-overview (accessed Apr. 24, 2022).

[28] “Standard Test Method to Determine Efficacy of Disinfection Processes for Reusable Medical Devices (Simulated Use Test).” https://www.astm.org/e1837-96r14.html (accessed Apr. 16, 2022).

[29] “ISO - ISO 10993-1:2018 - Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process.” https://www.iso.org/standard/68936.html (accessed Apr. 16, 2022).

[30] “ISO - ISO 10993-5:2009 - Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity.” https://www.iso.org/standard/36406.html (accessed Apr. 16, 2022).

[31] “ISO - ISO 10993-10:2021 - Biological evaluation of medical devices — Part 10: Tests for skin sensitization.” https://www.iso.org/standard/75279.html (accessed Apr. 16, 2022).

[32] “ISO - ISO 4892-3:2016 - Plastics — Methods of exposure to laboratory light sources — Part 3: Fluorescent UV lamps.” https://www.iso.org/standard/67793.html (accessed Apr. 16, 2022).

[33] “Standard Test Method to Determine Efficacy of Disinfection Processes for Reusable Medical Devices (Simulated Use Test).” https://www.astm.org/e1837-96r14.html (accessed Apr. 16, 2022).

[34] “ASTM F 963-17 Requirements | CPSC.gov.” https://www.cpsc.gov/Business--Manufacturing/Business-Education/Toy-Safety/ASTM-F-963-Chart (accessed Apr. 16, 2022).

[35] “ISO - ISO 14971:2019 - Medical devices — Application of risk management to medical devices.” https://www.iso.org/standard/72704.html (accessed Apr. 16, 2022).

9 Appendix

9.1 ABET Requirements

The approach towards research, design process and iteration, testing and other aspects of this project were all completed by incorporating the outlined capstone and ABET professional guidelines in mind. The following section seeks to guide the reader towards parts of the report that meet the relevant criteria, and further expand on some of the criteria not directly explored in the report.

ABET OUTCOME	Relevant Sections (See TOC for page numbers)
An ability to identify, formulate, and solve complex engineering problems at the interface of engineering and biology by applying principles of engineering, science, and mathematics.	● Client Statement ● Revised Client Statement ● Background ● Methodology – Design development and selection.
An ability to apply engineering design to produce solutions that meet specified needs with consideration of public health, safety, and welfare, as well as global, cultural, social, environmental, and economic factors	● Identifying Responsibilities and Impacts of the Finalized Medical Device. ● Revised Client Statement ● Abstract
An ability to communicate effectively with a range of audiences	This entire report was written so that a wide range of audiences can easily understand the need for this project, and the design solutions implemented during the various phases. Various concept art and figures were customized and constructed specifically for ease of understanding.
An ability to recognize ethical and professional responsibilities in engineering situations and make informed judgments, which must consider the impact of engineering solutions in global, economic, environmental, and societal contexts	● Identifying Responsibilities and Impacts of the Finalized Medical Device.
An ability to develop and conduct appropriate experimentation, analyze and interpret data from living and non-living systems, and use engineering judgment to draw conclusions	● Design Process ● Signal Processing
An ability to acquire and apply new knowledge as needed, using appropriate learning strategies	● Design Process ● Extensive literature research was performed by the team at the early phases of the project to understand US technology, epidemiology and the importance of PCNL surgery.
An understanding of biology and physiology	● Background
An ability to address the problems associated with the interaction between living and non-	● Design Process

living materials and systems	

Table 8: ABET Requirements and Outcomes with relevant report sections for reader guidance.

9.2 Capstone Requirements

Capstone Rating Requirement	Relevant Sections (See TOC for page numbers)
Show that an open-ended need exists for a device, system, process, or experiment	● Client Statement ● Revised Client Statement ● Background
Show that the problem was defined, and the design criteria was clearly stated	● Methodology – Design development and selection.
Incorporate appropriate Engineering Standards in the design	● Engineering Standards ● Identifying Responsibilities and Impacts of the Finalized Medical Device. ● Revised Client Statement
Show that alternative designs were created and reviewed	● Design Process: Iterative prototyping and design finalization
Show that at least one design was tested and analyzed	● Design Process: Experimentation ● Signal Processing ● Discussion
Show that the final design was discussed or refined in terms of meeting the design criteria	● Design Process: Experimentation ● Signal Processing ● Discussion

Table 9: Capstone Rating Requirements and Outcomes with relevant report sections for reader guidance.