Design Review III

ME450 Design and Manufacturing III - *Fall 2006*
Project 16 - *Mammography Compression Paddle*
December 13, 2006

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ABSTRACT

A mammogram is a common and effective procedure for breast cancer detection. In the event hat abnormal tissue is detected, a wire localization procedure is performed. To accomplish this, the breast must be compressed with a mammogram paddle that has an opening in it and a coordinate system etched on the paddle. However, locating the abnormal tissue with an opening in the paddle is difficult since the original X-ray was done with a solid paddle. An ideal paddle would provide compression to the entire breast and provide access for a wire localization procedure to be conducted anywhere on the compressed surface.

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INTRODUCTION

On September 10, 2006 the Radiology Department at the University of Michigan approached the mechanical engineering department with a proposal for the redesign of a mammography compression paddle. Dr. Carolyn Blane, the project's sponsor, had a desire to redesign the current paddle to make it easier to perform a procedure known as 'wire localization.' This procedure is conducted if abnormal calcified tissue is identified. To accomplish this, the breast must be compressed with a mammogram paddle that has an opening in it and a coordinate system etched on the paddle. However, locating the abnormal tissue with an opening in the paddle is difficult since the original X-ray was done with a solid paddle. An ideal paddle would provide compression to the entire breast, and provide access for a needle biopsy to be conducted anywhere on the compressed surface. If successful, the final prototype produced from this design project would allow the compression, detection, and wire localization procedures to be accomplished using one paddle, all while decreasing the total time needed and increasing patient comfort.

After meeting with Dr. Blane, a set of customer requirements were developed as a means of identifying what needs were most important. These customer requirements are shown below:

- Paddle material must provide the necessary compressive force
- Material must be durable
- Material must be radiolucent (transparent to X-ray)
- Access must be granted to entire compressed surface for wire localization procedure
- Paddle must be easily cleaned and sanitized.
- Paddle should increase the comfort of the patient undergoing the procedure

These customer requirements were used to develop a QFD chart to organize which design characteristics were most important. Once the primary design characteristics were identified, the concept generation phase began. This phase entailed developing a variety of concepts in an attempt to determine an ideal design. After several concepts were generated, a selection process commenced in order to determine the best concepts.

This report serves as the culmination of the innovative design process. The design problem has been fully solved through meeting all customer requirements and development of a working, validated prototype. The final design is an ideal solution to the breast compression problem posed. The breast compression paddle allows for universal application of a wire localization procedure while providing full compression of the patient. These two customer requirements were the core of the design needs as specified by the sponsor. The final product is directly related to the prototype generated with minor design adjustments made to improve comfort, cleanliness, usability, and effectiveness. Through validation testing the final product will serve to benefit the Radiology department at the University of Michigan in hopes of improving the accuracy and effectiveness of the wire localization procedure. This in turn will have a positive affect on the treatment and removal of detrimental breast cancer in patients.

PROBLEM DESCRIPTION

Projected grid is fixed in location with respect to paddle

Calcifications can occur anywhere in the volume of the breast. Current paddle technology is problematic because it has limited range. In current designs, paddles used for wire localization procedures have a rectangular hole on the compression surface. This hole is present to allow access to the skin to perform a wire localization procedure. If abnormal tissue is detected on the very top of the breast and near the chest, it is difficult to position the hole on the paddle so calcifications fall within the boundaries of the grid. Repositioning and recompressing the breast is time consuming and uncomfortable for the patient. A paddle that is capable of determining the coordinates of calcifications while keeping the breast in compression and requires no repositioning is desired.

Imaging is inaccurate due to hole in compression surface

Multiple paddles are used to perform imaging, some with holes and some without. Imaging accuracy is decreased in paddles with holes because breast tissue can expand through the opening. Non-uniformity of breast thickness due to paddle opening can distort imaging. A paddle that allows for complete surface compression and still allows for grid projection and wire insertion is desired.

Multiple paddles are used to compress the breast

In different stages of the detection process, two different compression paddles are used. The first paddle provides full surface compression while the second paddle has a hole for wire insertion and fails to provide full surface compression. The entire process requires changing the paddles twice. A paddle that can provide full compression, grid projection, and wire insertion is desired.

Paddle does not conform to patients shape and causes discomfort

The current paddle design is square and contains metallic parts. Square geometries are not conducive to the curvature of the body and metallic parts are cold to the touch. A more ergonomic paddle that conforms to the body and has a limited amount of metal exposed is desired.

Stress on paddle causes stress fractures and cracking

The paddle with the projected grid has a rectangular hole in it whose boundaries are susceptible to high stresses. Repetitive use and up to 30 pounds of force during each compression causes paddle fatigue. The paddle cracks in locations where stresses are concentrated. Failure of the paddle while under compression could cause serious bodily harm to the patient. A contoured paddle that distributes loading and minimizes stress concentration sites is desired.

INFORMATION SOURCES

The major sources of information used will come from paddle manufacturers and the Food and Drug Administration. The FDA is the primary organization for establishing rules and regulations regarding mammogram paddles. Other sources of information include but are not restricted to: mammography technicians, doctors, and patients. The marketing of these devices is primarily to radiology units within a hospital.

Major technical benchmarks for mammogram paddles:

1. The chest wall of the compression paddle must be straight and not provide any curvature to the chest wall.
2. The paddle must be flat relative to the table, unless designed by the manufacturer to do otherwise.
3. The device must have hands-free compression controls.
4. The paddle needs to provide uniform compression of the breast
5. Prevent material failure

The information gap that previously existed in understanding the engineering guidelines for breast compression paddles was filled by talking with Dr. Goodsitt and Dr. Chang of the University of Michigan radiology department. During this meeting, topics that were discussed included: different materials that could possibly be used, general design concepts, and patient comfort. The advantages and disadvantages of these topics were also discussed.

In the discussion with the radiology department, the idea of a wire mesh was introduced. To get a better understanding of how a mesh contact surface could be applied to the design, Cayman Sports Company of Ann Arbor was contacted. Information was shared regarding tennis string material properties and the stringing process.

To conduct a more thorough patent search, Siemens medical and AR Custom Medical were contacted to obtain patent numbers for their needle biopsy compression paddles. However, Siemens has yet to respond to inquiries and AR Custom Medical said there are no legal patents for their current products. Because of these impediments, patent information regarding needle biopsy compression paddles is lacking. It is possible that the most recent patents for these products may be expired so they are public domain. A keyword search on the USPTO's website did not turn up any results for needle biopsy compression paddles. Based on the patent search and contact with these companies, the major designs for this project will not be infringing on current intellectual property. Results for related patent searches are in Appendix A.

Once the final design is chosen for this project, the next step will be determining testing procedures and material costs. To investigate the testing of these devices; multiple doctors, engineers, and lab technicians will be contacted. On the manufacturing side, material costs will be calculated with the help of Bob Coury and any of his resources or references.

Since design review 2 more information has been obtained regarding strings which will make up the mesh contact surface. Cayman tennis shop supplied six different materials for string testing and Berkley fishing line was purchased at Dunham's sporting goods. A total of eight strings were tested for radiolucency and tensile strength.

To determine radiolucency of the different strings, testing was conducted with Dr. Goodsitt and Dr. Chan of University of Michigan hospital. Once the more promising materials were identified representatives of the different string manufactures were contacted to obtain more information. However, no response to these inquires have been received.

Information to compile the bill of materials for both the final design and prototype was obtained from the website www.mscdirect.com. This website is an industrial supply company who sells raw materials as well as other industrial materials.

CUSTOMER REQUIREMENTS AND ENGINEERING SPECIFICATIONS

Engineering targets for this project shown in Table 1 were developed based on the sponsor's requirement and FDA rules. The correlation between these targets and requirements is shown in the Quality Function Deployment (QFD) in Appendix B. The first two orientation related targets are based on FDA rules which mandate that the paddle be flat with respect to the receptor plate and that the chest wall of the paddle be at a right angle to the receptor plate. The paddle orientation has a direct influence on patient comfort and avoidance of skin irritation. Note that all dimensional targets are based on current paddles in use. Grid projection area was chosen to be equal to the compression area so a biopsy could be performed to any questionable location on the compressed surface without readjustment of the patient. The grid corresponds to radiolucency and how limited access to the compressed surface is. Force dispersion is a measure of the force that the breast applies to the paddle's surface area and was determined from the necessary compressive force customer requirement. Maximum stress is a measure of the force that the breast exerts on the paddle divided by its compression area which is also developed for the necessary compressive force. An essential target is the use of radiolucent material to ensure that X-ray images are displayed correctly. Material use is determined by the customer requirements for radiolucency, cleaning effort, and transparency. Finally, the contact surface parallel to the patient's chest wall was chosen to be curved to ensure patient comfort.

Table 1: Engineering Design Targets and Constraints

Design Targets	**Constraints**
Orientation w.r.t. chest wall	90 ± 10°
Orientation w.r.t. the receptor plate	± 10°
Paddle length	25 cm
Paddle width	24 cm
Paddle thickness	2 mm
Compression area	360 cm^2
Grid Projection area	360 cm^2
Force dispersion	150 N
Max. Stress across paddle	< 4.20 kPa
Material	Lexan or similar
Corner geometry	< 10 mm
Contact surface geometry	Curved
Skin deflection	< 1 cm
Grid cell size	~ $1cm^2$
String tension	178 – 267 N
Radiolucency rating	10

Customer requirements that were given a high normalized importance value such as radiolucency, providing necessary compression, and access to the entire compressed surface were based on paddle functionality. The other requirements were given lower values based on their lack of added value to functionality during the procedure.

Skin deflection is an engineering specification that deals with compression of the breast. Vertical skin deflection is desired to be at a minimum to ensure accuracy of imaging. The skin deflection is presumed to be a result of grid cell size and string tension. A small grid cell size will ensure a low skin deflection because it makes the opening for skin to protrude through smaller. Ensuring that skin deflection is under this maximum limit will prevent any issues with imaging inaccuracy.

Grid cell size and string tension are two parameters which have been appended to the list of engineering specifications.

Grid cell size was chosen as a new specification because it ensures the guide needle will be able to pass through the grid. The lower limit of the specification is the diameter of the guide needle, 8mm. Setting this lower limit is essential because the most desirable grid cell size is one that is extremely small. A smaller grid cell size minimizes vertical skin defection and increases accuracy for wire localization. But, setting the lower limit for grid cell size at the guide needle diameter optimizes the reduction of vertical skin deflection and provides the greatest accuracy possible.

String tension is another engineering specification that was appended to the design analysis. This specification is based on the fact that string tension affects vertical string and skin deflection. Regulating string tension is important because a lack of string tension will result in a failure of proper uniform compression and an overly tense string risks critical failure and buckling of the mounting frame. The ideal string tension would minimize the amount of vertical deflection in skin and strings (increasing tension) but also minimize the amount of stress on the mounting frame to prevent buckling (decreasing tension).

Radiolucency is another engineering specification that was considered in the design process. Specifically, the materials that must be radiolucent are the strings because they are in the path of the x-rays. Radiolucency is important because calcifications that lie below the strings must have the potential to be detected. If the strings are too radiopaque the grid becomes a distraction to mammogram reading for the technician. Selection of a radiolucent string that meets the physical demands of a tensile mesh is desired. Additionally, rating for the radiolucency of materials was based on the relative contrast present in mammography films. If the strings were too much of a contrast to artifacts in the breast (calcifications) they were deemed useless. Thus, the string chosen was the most radiolucent.

PROJECT PLAN

The design process for a new compression paddle will have several important milestones; namely the design reviews, design expo, and final report. It will take numerous amounts of individual design tasks to reach each milestone. Upon completion of brainstorming, a final design concept will be chosen to build upon. The final concept will then be modeled using CAD software. This will ensure prototype durability and provide opportunities for simulated testing to ensure design requirements are met. Constraints will be given to allow for proper manufacturing and construction of the working prototype. Manufacturing plans and drawings will start the prototype build process. By the design expo, a working prototype will be completed and tested

properly with all of the supporting documentation for presentation. The use of the Gantt chart in Appendix C will help in completing and organizing the design process by the set deadlines. This chart is organized in such a way that shows groups of smaller individual tasks placed underneath a larger task goal. The individual tasks are to be completed before their larger task goal is met.

For the third design review, the alpha design has been developed and completed. The design has been analyzed and passed all fundamental mechanics. All components have been modeled in CAD, specifically using Solid Works. These components have had materials selected for both final design and prototype manufacturing. The next step of the design process is to lay out specific manufacturing plans for the individual paddle components and obtain the materials to begin manufacturing and assembly. The $400 budget is achievable.

Progress of the design process for the breast compression paddle is at its expected level. There have been no unexpected setbacks to slow the planned progress. As long as individual and team goals set in the Gantt chart are followed closely, the major milestones will be met on time. As with all design projects, unexpected events do tend to show up and interfere with the design path. If and when these events do occur, they will be recorded and handled efficiently as to avoid any lost time.

PROBLEM ANALYSIS

Engineering Fundamentals

To analyze the top five paddle designs, several engineering fundamentals were identified as a means to judge design specifications. The fundamentals fall into two categories: solid mechanics and material properties.

Engineering fundamentals related to solid mechanics played a major role in evaluating project goals. First, the paddle must be able to handle the loading required during the mammography procedure. This entails designing a paddle that is able to handle all associated stresses and strains. Second, the paddle must be able to handle frequent iterations of loading. This necessitates designing a paddle that is able to handle not only single instance stresses, but also fatigue stress due to frequent use.

In addition to solid mechanics, material properties played a major role in evaluating the project goals. As discussed above, any material selected for evaluation must possess material properties that enable it to withstand all stresses and strains of the mammography procedure. Additionally, any material selected must be clear and radiolucent. The radiolucency of the material describes how transparent the material is to x-rays, and is a major design constraint.

Models and Testing

Once a final design has been evaluated and confirmed to meet customer requirements, a computer model will be generated. This model will allow for easy modification of design parameters, as well as provide some initial virtual testing. After the computer model is developed, a prototype will be constructed from that model. An ‘Alpha’ prototype will be used for testing engineering targets and meeting customer requirements based on the engineering fundamentals described in this report. It will be at this point that any changes to the model will

be made, and subsequent prototypes generated in an effort to meet all the targets and requirements. Stress and strain testing will be the primary means of evaluating the strength and durability of the prototype. Additionally, radiological testing will occur to ensure that all materials used meet the radiolucency design constraint.

Difficulties regarding the potential design

After meeting with the sponsor, several specifications were developed to define the goals for the initial design. After these specifications were developed, numerous potential difficulties regarding the design were identified. Chief among these identified difficulties was the need for any design to meet FDA regulations. The FDA regulates mammogram technology and procedures, so any design must meet the needs of the sponsor and comply with all regulations. Second, the design must provide access to the desired biopsy area while still providing adequate compression of the skin for an accurate X-ray reading. If adequate compression is not reached, then mammograms taken will not be of the quality needed to perform a detailed examination. Third, the design must keep skin deflection to a minimum, with the ideal case being no deflection at all. This is a challenge because a certain amount of skin area must be exposed to perform a wire localization procedure. Fourth, any new paddle must be constructed in such a way as to resist bending stresses. Previous generations of compression paddles used for biopsy procedures have been viewed with various stress cracks and other evidence of wear. Finally, the design must accomplish all the desired traits listed above while minimizing patient discomfort wherever possible. This presents a challenge because current paddle designs and biopsy procedures make little effort to address the comfort of the patient undergoing the procedure.

Design Drivers

The discussion of potential design difficulties facilitated the development of several design 'drivers,' or metrics as a means to narrow any design possibilities and insure that the specifications were achieved. The design drivers for this project are listed below:

- Must allow access for a wire localization needle to be inserted
- Must be able to be used with patients of various sizes and shapes
- Must provide adequate compression
- Must meet FDA regulations
- Must be able to be cleaned and sanitized for repeated use

The design driver regarding paddle versatility for various patients was added to insure that the design would be universally applicable. In addition, the driver regarding ease of cleaning and sanitation was added after a discussion with one of the lab technicians in the radiology department. The technician pointed out that current mammogram paddles used in this application often are hard to clean and make ready for new patients after a wire localization procedure is performed.

Major Problems Expected

As with any new design, several major problems have the potential to derail any successes. The first and most prominent potential problem is making sure our paddle design achieves our goal of providing adequate compression while preventing skin deflection. This is the primary goal of any mammogram paddle used for wire localization procedures, and is fundamentally necessary

for our design to function properly. The way in which this problem can be avoided is by going through many design iterations to make sure the specifications are met. A second potential problem is finding a material that meets all of the design requirements, as well as meeting the hospitals requirements for x-ray compatibility, cleaning ease, and safety. Materials used in paddles today meet these criteria, so any final design must also meet these criteria. One way to avoid this problem is to contact various materials specialists for input on what materials will meet these criteria. Additionally, contacting hospital staff to find out what the safety and sanitation procedures are, and design towards those guidelines will be helpful. Another problem that, while not intrinsically related to our design, is still important is finding subjects to test the paddle designs and provide feedback. Patient and doctor input will be crucial in determining if the final design functions in real world scenarios. In order to avoid this potential problem, contacting current patients and doctors in the Radiology Dept. and asking for their assistance with the design will be critically important.

Special Equipment/Technical Assistance/Logistical Assistance Needed

Invariably, there will be situations in which the problems discussed above will require additional support and assistance to solve. For issues related to mammography equipment, technical assistance from the hospital will be needed to provide access and expertise in this field. For problems related to materials selection and construction, technical assistance from professors and doctors in the field of medical technology will be needed to insure the final design meets the specifications. And finally, in an attempt to assure that the paddle design works well in a real world lab setting, logistical assistance in finding test patients and receiving input from doctors and patients will be necessary in validating the design.

CONCEPT GENERATION

Concepts for the needle biopsy compression paddle were generated first from individual effort. Once all team members thoroughly understood the problem and had developed several individual concepts, a team meeting took place and a collaboration of individual ideas solidified into formal concepts. After this “deep dive” of ideas and brainstorming, a total of 24 ideas were generated. Of the 24 ideas, four of the most promising solutions were selected. The general population of concepts was classified into the following categories: mesh, shapes, membranes, and doors/snap outs.

The first design is from the *mesh category*. This design would involve two separate parts. The first part is the frame and consists of three sides and a slot which goes around the inside perimeter of the frame. The second part is the frame which the mesh will be strung through. This second frame will slide in and out of the slot and will be able to “float” from side to side in the slot when not in compression. This movement feature will allow for removal of the paddle over the biopsy needle. This design can be seen in appendix D.6.

The second major design is a *hybrid of categories from shapes and mesh*. It consists of a rectangular shape which could fold along a 45 degree axis then changing the shape to a triangle. The rectangle will have strings in one direction along its length. When it is folded the strings will overlap each other creating a mesh and grid. This design can be seen in appendix D.5.

The third design is from the *door/snap out category*. In this design, multiple doors would be used to make up the entire surface of the paddle. These doors would be hinged and then have a latch on the chest wall side of the paddle. The doors would also be able to be opened and allow for removal of the paddle over the needle biopsy. This design can be seen in appendix D.10.

The fourth design is a *hybrid of the shapes and doors categories*. This design has a rectangular frame with multiple triangles in the frame. Each triangle will be hinged somewhere along the rectangular frame and will open and close to allow for needle biopsy. This design can be seen in appendix D.12.

CONCEPT SELECTION PROCESS

In the concept selection phase, designs were classified by category and rated by their advantages and disadvantages. To select the final design, a category will be chosen that has the most positive advantages, meets all customer requirements, and meets all deliverables. The following two design categories are the most promising for meeting all requirements. Selection of an alpha prototype will come from one of these two categories.

Door

The door concept is a solution that allows for removal of a solid portion of the compression surface so wire localization can occur. This concept is conducive to the wire localization procedure because it keeps the breast in compression and allows for needle insertion at the same time. Listed below are the advantages and disadvantages of utilizing a design with a door.

Advantages:

- Full surface compression
- Load distribution over entire contact surface
- Access for wire localization to entire contact surface
- All solid parts, durable rigid
- As comfortable as a paddle with no doors

Disadvantages:

- Hinges are complicated
- Hinge mechanism(s) must be radiolucent if in x-ray path
- Center locking difficulty
- Moving parts create pinch points
- Potentially difficult to determine which door to open

Mesh

The second major theme of the various potential designs was based on a mesh contact surface. Examples of this theme can be seen in Figures D.5, D.6, D.7, and D.11 in Appendix D. Mesh was selected as a possible alternative to the current design because it has potential to meet all customer requirements and engineering targets. Advantages and disadvantages are shown below.

Advantages:

- Allows for maximum compression while providing access for needle biopsy

- Provides a built-in grid that can be used to identify calcifications
- Calcification identification and wire localization procedure to occur simultaneously
- Potentially more comfortable to patient then current paddle designs

Disadvantages:

- Allows for a certain amount of skin deflection
- Possibility of mesh material failure occurring more than current technology
- Potentially harder to clean
- Potentially less comfortable to patient then current paddle designs

ENGINEERING DESIGN PARAMETER ANALYSIS

During the refinement of the prototype paddle design, it became necessary to use engineering principles to influence design decisions. To achieve this, three main design parameters were identified along with their associated engineering principles. These principles were used to provide engineering justifications for many of the difficult design constraints encountered. The three main design parameters were material selection, dimensions, and orientation.

Materials

The choice of construction material has been the most rigorous engineering parameter thus far in the design and validation process. Pursuit of a prototype in which the major theme centers around employing tennis racquet-like strings as the breast contact surface indicates the material selected for these strings is of paramount importance. Each string material that was examined for must meet two major engineering constraints. First, the material must be radiolucent. Any material that restricts or obstructs the view of potential calcifications cannot be used. Second, the material must be strong enough to handle the tensile forces experienced during a mammography procedure. During a procedure, a paddle can exert up to 120 Newton's of force on a breast. Therefore any material selected for the strings must be strong enough to handle peak loads. The primary means of determining if the strings used for the prototype meet engineering parameters is through validation testing. Tests to measure radiolucency and tensile strength of string materials will allow for the necessary analysis of material constraints.

In addition to the material selected for the strings, the material selected for the frame to hold these strings is also important. Current paddles are built using steel frames, so incorporating a steel frame in the prototype described in this report is a logical decision. Steel is strong enough to handle the loads involved in mammography procedures, and the size of the prototype minimizes the need to decrease the weight of the frame. In order to insure that the frame does not fail by a bending moment, a simple static loading analysis was conducted. The results of this analysis can be seen in Appendix G. During the mammography procedure, the steel framed prototype paddle will be subjected to roughly 0.44 MPa of stress. The yield stress of steel is on the order of 250 MPa, which means that the paddle is experiencing less than one percent of yield. This vast under-loading should provide a more than adequate safety factor.

Dimensions

There were several factors that guided selection of the final prototype dimensions. First among these was the total working area available for x-ray. The receptor plate on the mammography machine has a finite area for which x-rays are received, thus the paddle cannot be larger than the

working area. Another factor that influenced the final prototype is the size of the needle guide used during the wire localization procedure. When determining the spacing for the strings in the prototype, it was found that having the smallest possible spacing between strings would cause the least amount of skin deflection and successfully distribute applied pressure. However, spacing between the strings needs to be large enough to allow for the needle guide to be safely inserted, and have a small amount of extra space on the sides. Finally, thickness of the paddle surface that contacts the patient's chest wall was subject to analysis. Ideally, the thickness of the surface would be as thin as possible, permitting the largest amount of tissue to be x-rayed. The presence of strings, under tension, passing through this surface requires metal composition to minimize material stresses. In the final design, a thin lexan sheet will be added to the back of the frame. The lexan chest contact plate is to minimize patient comfort by feeling warmer.

Orientation

Orientation of the paddle with respect to the patient and the x-ray receptor plate are parameters that are tightly regulated. The FDA mandates that the orientation of the paddle must be parallel with respect to the receptor plate during compression. Additionally, the portion of the paddle that contacts the patient's chest wall must be completely vertical. These two parameters have heavily influenced the design, and have governed the shape and dimensions of the entire paddle.

FINAL DESIGN DESCRIPTION

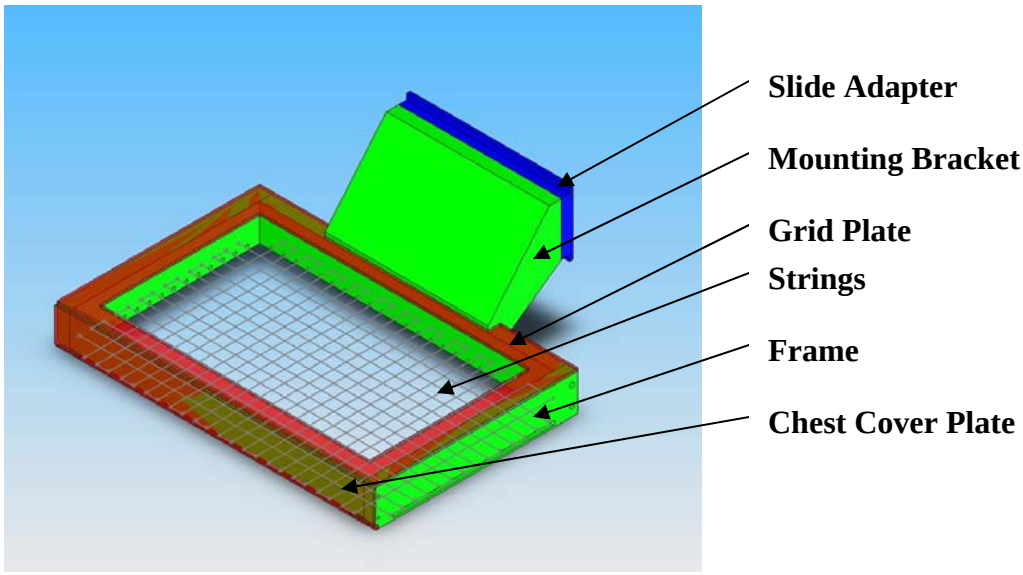
The Physical Design Solution

The final design solution has several characteristics which make it the ideal solution for a breast compression paddle conducive to wire localization. The features which set the chosen breast compression paddle apart from other considered designs include:

- Wire localization to occur anywhere in the volume of the breast without having to reposition or recompress the breast
- Compliance with all FDA breast compression paddle regulations
- Minimization of vertical skin deflection through the plane of contact
- Ease of use, cleanliness, and repair
- Solid construction and durability due to lack of moving parts

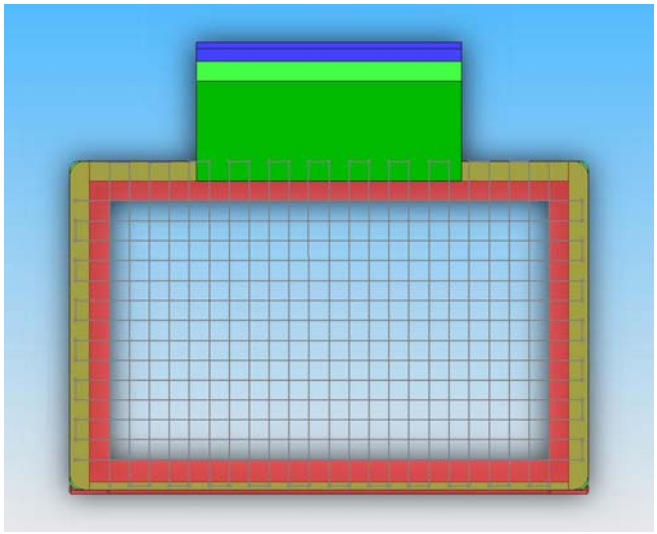
All of the beneficial features specified above are embedded in the design characteristics of the paddle. The assembly shown in Figure 1 consists of six parts: chest cover plate, frame, grid plate, mounting bracket, slide adaptor, and strings. The overall dimensions are seen in the component detail of Figure F.1 in appendix F.

Figure 1: Isometric view of final assembled design with the 6 components listed



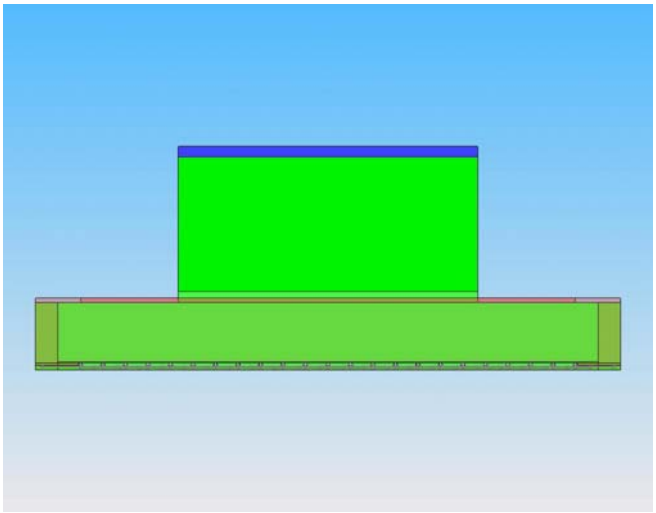
The paddles general dimensions are 44% of the x-ray receptor plate area. The reason that it does not cover the entire plate is to meet patient comfort by not being too bulky for various patient arm and chest positions.

Figure 2: Overhead view of final design assembly



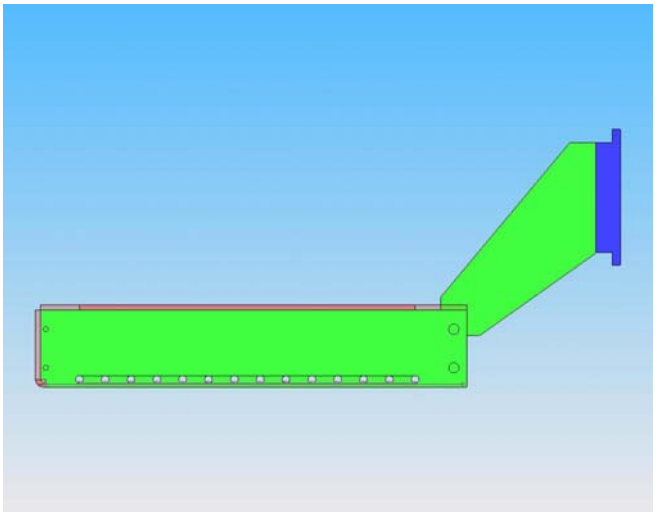
In addition, note the curvature and fillets in locations specific to patient contact. Most notably, the chest wall surface has fillets on all of its respective corners thereby increasing patient comfort and usability. This surface is produced by using a lexan cover plate. The lexan cover provides to the patient by reducing the cold feeling that a metal surface would have due to the lexan having a lower thermal conductivity. The filleted plate also covers the sharper machined edges of the metallic front plate. The front plate needs to be metal in order to provide the required strength while the strings are in tension.

Figure 3: Front view of final design assembly



Notice also the ports along each side of the mounting frame. These ports are used to string the paddle to the necessary line tension and ensure the lines are always orthogonal to one another.

Figure 4: Side view of final design assembly



Material Considerations

Having physical dimensions is not nearly enough for creating an effective physical prototype. In this design challenge, material selection is exceedingly important because it will account for the majority of patient component interaction, it places important engineering constraints on the design, and is an opportunity to enhance the manufacturability and durability of the paddle.

The design's effectiveness is largely contingent upon the strength, durability, and radiolucency of the compression strings. The final design solution utilizes FireLine fishing wire from Berkley. The reason for this material selection is as follows:

- Strength to radiolucency ratio is extremely high compared to other strings tested
- Availability of material is nationwide / easily accessible
- Easy to work with and string through mount
- Appropriate tensile strength without sacrificing over design

FireLine is the most promising material to use, but further tensile testing is needed to use the string in the paddle. When tested for radiolucency, the FireLine was invisible. It was found that this line is made from a material called Dyneema, which a synthetic fiber in the form of High Performance Polyethylene (HPPE). Dyneema is used in many high performance applications, including body armor, rock climbing, and sailing, so its strength is justified in the breast paddle application. A stronger and larger diameter line will be purchased for further testing. Because the material tested was not visible, there will be a grid cover plate that rests on top of the paddle that will appear on the x-rays to assist in locating the calcifications for a wire localization.

The other essential part that needs materials consideration is the mounting frame. This frame has several responsibilities. These include:

- Ability to keep tensile strings in uniform tension
- Must remain parallel with respect to receptor plate (cannot warp during loading)
- Must have anti-creep properties and resist stress fatigue

The basic necessities of this mounting frame make 1018 Steel (cold finished) a great fit for the design. The 1018 steel is conducive to this design component because it is inexpensive, widely available, easy to machine and manufacture, and most importantly will meet the material responsibilities of the mounting frame as specified above.

Parts and materials list

An itemized listing of parts and materials required for the construction of the breast compression paddle is provided in Figure E.1 of appendix E. The items listed in the Bill of Materials (B.O.M.) are stock materials that will require machining before they are useable components. Since the final design is intended for mass production, supplies will be bought in bulk and manufactured in a way to minimize materials and costs. The cost of materials for each saleable paddle will therefore be less than the total price given in the Final Design B.O.M.

How it works

The final design is comprised of two separate parts: compression strings and the mounting frame. In this case, the strings are run through the ports on the mounting frame creating an orthogonal mesh covering the entire plane of the compression paddle. Securing these strings to the mount to ensure there is no slippage guarantees the compressive surface will not be slack and not fail to compress the breast (assume no critical material failure). After being strung and the strings are verified to be fastened appropriately (this only occurs once in he life of the paddle), the compression paddle is mounted to the mammography unit. The technician will lower the paddle to compress the breast to the desired depth and the mammogram will be taken. If a calcification is discovered, the grid surface will indicate in which cell the calcification occurs and a wire will be inserted into the breast to physically mark the location of the abnormality. The breast will

then be decompressed and a horizontal compression of the breast will take place to determine the vertical depth at which the wire will be inserted.

In essence, the job of this paddle was to perform three main functions:

1) compress the breast to the desired thickness
2) allow for a large grid to allow universal access to any part of the breast
3) allow for wire localization to occur while the breast is in compression

The final design concept achieves all of these functions.

Why it will work

The paddle will assuredly perform the desired paddle functions. Confidence in its effectiveness will be achieved through passage of validation and verification testing. In addition to this testing, the compression paddle will also be constructed to engineering specification. Ensuring that the paddle is constructed with respect to the planned specifications ensures no limits are over stepped and engineered safeties are in place.

Benchmarking

The prototype design successfully meets the customer requirements discussed in the QFD diagram in Appendix B. Table 2 shows how the prototype paddle design compares against the current technology, and how it meets the customer requirements. The largest improvements over the current paddles come in the requirements that have the highest relative weight.

Table 2: Comparison of the current paddle and the prototype to the customer requirements

Customer Requirements	Relative Weight	Current	Prototype
Transparency	6	9	8
Lightweight	4	5	5
Comfortable	7	3	6
Radiolucent	10	7	8
Durable	9	7	8
Easy to Clean	8	7	7
Easy to interchange	3	7	9
Provides Necessary Compressive Force	10	9	9
Provides Access to Compressive Surface	9	3	10
Universal Application	7	1	10
Does Not Irritate Skin	4	7	8
Does Not have Pinch Points	5	9	8
Universal to All Brands	2	9	9

PROTOTYPE DESCRIPTION

The prototype for the wire localization breast compression paddle will be a full scale replica of the final design. The prototype will consist of eight essential components, including: sliding adaptor, mounting bracket, frame (4 separate sides), lexan chest plate, mesh contact surface, and grid cover plate. The details of these components and their assembly are shown in appendix F.

The B.O.M. for the prototype is listed in appendix E. All of the items listed are stock material that will need to be machined and manufactured into each component.

The sliding adaptor will be made of poly vinyl chloride (PVC). This is similar to ABS plastic used in the final design and has comparable material properties. Dimensions will be identical to the existing adaptor allowing for compatibility to the GE Senograph 2000D. Two holes will be drilled in the adaptor to allow for attachment to the mounting bracket.

The mounting bracket, which connects the adaptor to the frame, will be made of aluminum and the dimensions will again be the same as the final design. How the bracket attaches to the frame is extremely important to localized stress at the connection points. A working prototype of this part will show the final design durability.

The frame will consist of five parts made out of two different materials. The parts which make up the front, back, and sides will be made of aluminum while the part which will go against the chest wall will be made of lexan. The four metal sides of the frame will be connected to one another using small screws. The lexan cover plate will be attached to the chest wall side of the frame improving patient comfort by insulating the patient's skin from the metal frame. This cover plate will be connected to the frame using bolts. Small holes which will allow guidance for the mesh contact surface traverse the outside perimeter creating a virtual grid.

Characteristics of the mesh contact surface have yet to be determined. These characteristics are principally material and grid spacing. Testing on these two parameters is still taking place and is expected to be completed by November 7th, 2006. Testing to follow will include additional material testing for radiolucency and a skin deflection test to determine optimal grid spacing. See the following section, Validation Approach, to see the predicted methodology for determining optimal mesh characteristics.

A grid cover plate will be equal in size to the frame and will be made of lexan. This plate will be marked with a rectangular grid in accordance to the grid size to enable proper location of suspicious tissue. This part will simply rest of the top of the frame and will be removed once the location has been identified.

The most important functions of the design are to provide access to the entire surface area for a wire localization procedure and to minimize vertical skin deflection. A functional prototype will prove that both of these functions are achieved with the final design solution. This will be physically shown by applying the mesh contact surface to provide full access and by demonstrating the skin deflection on a synthetic breast. This prototype will show that the mesh design will be able to undergo necessary stresses associated with the breast compression and how manufacturing of the product will be feasible on a commercial scale. The issue of how to tie a sufficiently strong knot while maintaining the correct amount of tension in the line will also be identified through a working prototype.

INITIAL MANUFACTURING PLAN

There are some aspects of the prototype design that are not feasible from a large scale manufacturing perspective for the final design. The differences between the final design and prototype include: use of materials, fasteners, and frame structure. Most physical differences are due to contrasting production intents. Most notably, the difference in processes to manufacture a one time prototype is vastly different from a mass production saleable model. For example, mass production models will be built using automated machinery and assembly processes, whereas the prototype will be built from the team members' direct machining skills. If each model that was manufactured for sale was built like the prototype, the end product would be excessively expensive and would not be saleable.

The prototype will not differ from the final design by way of the mesh material selected and compression surface area. The mesh material is an important selection for the design because it must not interfere with abnormal tissue detection and provide the required strength and comfort levels. The prototype will use the aluminum material that was carefully chosen above according to the design process.

To manufacture the prototype, the final design will be broken down into individual components that will ultimately be assembled together. The components include the sliding adaptor, mounting bracket, frame, mesh contact surface, chest plate, and grid cover plate. The components are each modeled in CAD and will be accurately manufactured from detailed engineering drawings. The slide adaptor, mounting bracket, and frame will be machined from aluminum stock using a mill from planned steps. The grid cover plate will be laser cut from a lexan sheet. A three week time frame has been set to start and complete the manufacturing of the prototype.

VALIDATION APPROACH

Preliminary Test Procedures

The primary means of identifying if the prototype meets our engineering specifications is by conducting a validation procedure. This procedure consists of several tests designed to evaluate various aspects of the prototype. The first two tests are to be completes prior to the construction of our prototype, while the final test will be conducted after construction.

The first test to be conducted will be a radiolucency test of the various potential string materials. This test was conducted to establish which string materials would present the least obtrusive medium to the x-rays utilized during a mammography procedure. Several varieties of tennis racquet string were tested, as well as two types of fishing line. After the testing was completed, it was determined that FireLine was the material that was most radiolucent, and that its obstruction of calcifications was the lowest of the materials tested.

The second test to be conducted will be tensile testing of the potential string materials. This test will be conducted to determine which material has the highest yield strength, as well as to determine the strain levels associated with the yield strength. The procedures for these various tests can be seen in appendix H along with images depicting these procedures.

Preliminary Prototype Validation

Validation is the strategic process in which the final design solution will be rated for effectiveness as a whole. Specifically, the final physical prototype will undergo a series of tests/experiments to determine how well the customer requirements and engineering specifications have been met.

The main categories for effectiveness are a combination of engineering and customer specifications. The categories for investigation are as follows:

1) How well does the compression paddle allow for the universal application of a wire localization procedure?
2) What is the amount of the vertical skin deflection that occurs on a compressed breast at the maximum compression limit?
3) What is the amount of lateral string deflection that occurs along the compression surface at the maximum compression limit?
4) What is the amount of mount deflection (rotational/translational) at the maximum compression limit?

To optimize the device, testing can be performed to determine relationships between controllable engineering parameters and desired customer requirements.

Controllable engineering parameters

- Overall grid size
- Grid cell size
- String tension
- Mount design

Desired Customer requirements

- Maximization of receptor area
- Minimization of vertical skin deflection
- Minimization of lateral string deflection
- Minimization of mount deflection

Achieving desired customer requirements

Maximize reception area

Why: To make the mammogram conducive to all breast sizes. If the paddle is too small, it may fail to compress tissue that has calcifications in it.

Description of test procedure:

Calculate the area of the contact surface by multiplying the length by the width of the compression surface. Ensure that that the length and width are similar of the receptor plate are similar to that of the compression paddle.

Minimize vertical skin deflection

Why: To create a uniform thickness throughout the breast and prevent imaging inaccuracies

Description of test procedure:

It is unclear what engineering specifications influence vertical skin deflection. It is presumed that grid cell size is the primary contributing factor and string tension is the secondary factor. To determine a relationship between vertical skin deflection and the presumed engineering factors a simple test can be performed.

The relationship between skin deflection and grid cell size can be determined by varying the grid cell size linearly and approximating a quadratic function for vertical skin deflection. For this test, create square grids with sides of 1.0 cm, 1.5 cm, and 2.0 cm. Increase the grid cell size in a linear 0.5 increment and respectively obtain the vertical skin deflections for each square grid size. With three grid size/skin deflection datum, a quadratic fit can be created to model the relationship. A similar test can be performed to determine the relationship between string tension and vertical skin deflection. Simply select several different string tensions and measure the respective vertical skin deflections to create a quadratic approximation.

Minimize lateral string deflection

Why: To create uniform grid spacing so locating abnormal tissue is reproducible and accurate

Description of test procedure:

Like vertical skin deflection, the main factors which influence lateral string deflection are unclear. It is presumed that string tension is the primary contributing factor and grid cell size is the secondary factor. To determine a relationship between lateral string deflection and the presumed engineering factors a simple test can be performed.

The relationship between lateral string deflection and string tension can be determined by varying the string tension linearly and approximating a quadratic function for lateral string deflection. For this test, set string tensions ranging from the minimum tension limit to the maximum tension that change in linear increment. With each linear increment, obtain the value for lateral string deflection. With the multiple lateral deflection/string tension points, a quadratic fit can be created to model the relationship. A similar test can be performed to determine the relationship between lateral string deflection and grid cell size. Simply select different grid cell sizes and measure the respective lateral string deflections to create a quadratic approximation.

Minimize mount deflection

Why: To ensure reproducibility and durability of the mount

Description of test procedure:

There are several different mounting scenarios that can be used but the biggest influence to mounts stability and durability is a material concern and not a dimensional concern. Construction of a rigid and durable mount can be validated by testing different materials and

determining deflection occurs. In this case, deflection is defined as rotation and translation from the mounting configuration in the unloaded state.

Other engineering specifications observed

Additional engineering specifications observed that may not be tested include:

- Whole vertical grid deflection
- Depth of radiopaque material at chest wall
- Stress on the mount adapter

Whole vertical deflection is the maximum deflection of the compression surface from the virtual plane created by the holes bored in the rectangular mount. The tension in these strings will be such that the amount of deflection that occurs in the maximum loading condition is considered small compared to the length of the string. Additionally, overlapping and weaving strings increases the resistance to vertical deflection. Thus, the amount of whole vertical deflection will be small.

Depth of radiopaque material at chest wall will be minimized as much as possible. A radiopaque material is one that does not let x-ray radiation penetrate its surface. Currently, there is no test for this engineering specification, but the limit on this specification relates to strength. The design must be strong enough to support string tension but must be as thin as possible.

Ability to counteract harmful stress on the mount adapter will be mostly a material concern. Use of steel in the mount will ensure that the mount is stable and durable. The maximum load on the compression paddle is approximately 120 N and the moment arm is approximately 0.145 m. Thus, the maximum moment that can be achieved is approximately 27.24 N-m. This magnitude is relatively small for what a steel rod is capable of handling. A steel rod with square cross section of 53 mm by 133 mm produces only 437 kPa of stress given a maximum moment of 27.24 N-m. The yield stress of steel is approximately 250 MPa. The maximum applied stress is not even 0.175% of the yield strength of steel. Thus, even a very thin cross section of steel can produce a very strong, reliable, and durable mount.

Preliminary Validation Testing Findings

Radiolucency Testing

The first test performed in our validation process consisted of testing the radiolucency of potential string materials. In order to do this, each sample was placed on an object known as a phantom breast. A phantom breast is a device that is made of synthetic material, but when x-rayed, it exhibits the same characteristics (density, radiolucency, contrast) of a real breast. The samples that were tested are listed below:

1. Vanish Fluorocarbon 8 lb. fishing line
2. Wilson SG Extreme 16 gage tennis string
3. Polystyrene 16 gage tennis string
4. Polystyrene 17 gage tennis string
5. Squash SG squash string

6. Head SG 17 gage tennis string
7. Prince SG Duraflex 17 tennis string
8. Fireline Micro Ice 4 lb. fishing line

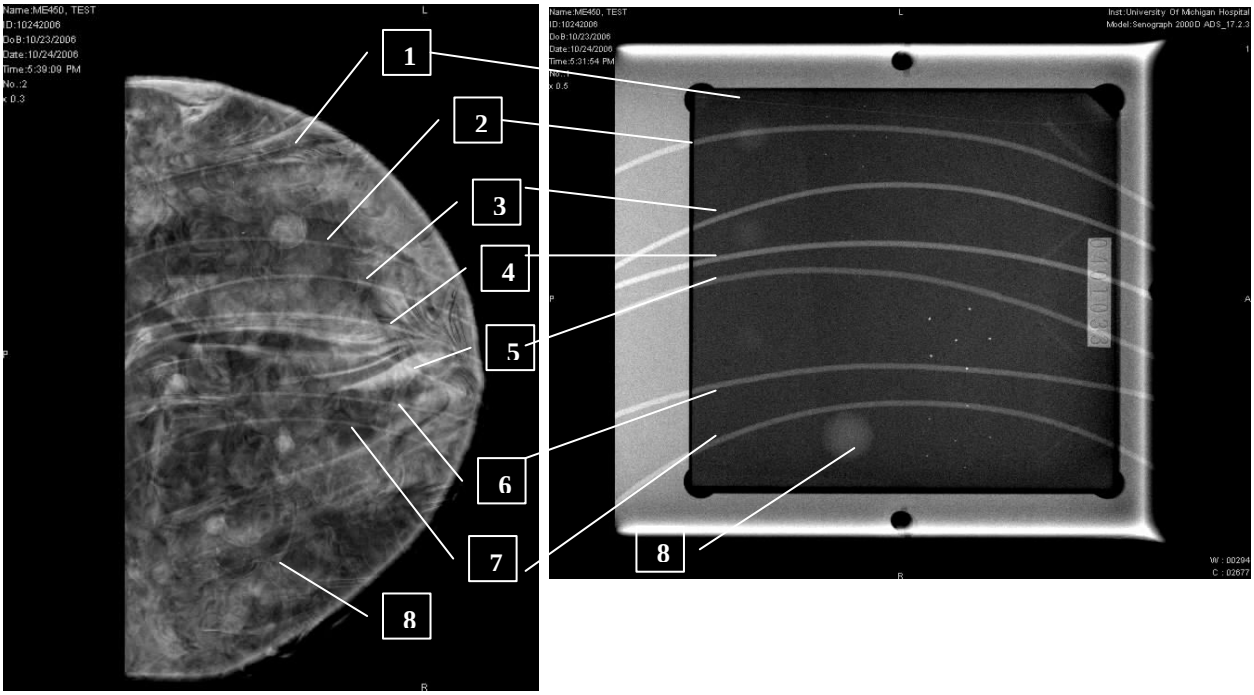
All 8 strings were taped on the phantom and an x-ray was taken. The results are listed in Table 3 and observed in Figure 5. For the scoring, a rating of 1 equates to the least radiolucent, most obstructive material. A rating of 10 equates to the most radiolucent, least obstructive material.

Table 3: Results from Radiolucency testing

String Sample	Radiolucency
1. Vanish Fluorocarbon 8 lb. fishing line	8
2. Wilson SG Extreme 16 gage tennis string	6
3. Polystyrene 16 gage tennis string	2
4. Polystyrene 17 gage tennis string	2
5. Squash SG squash string	3
6. Head SG 17 gage tennis string	6
7. Prince SG Duraflex 17 tennis string	6
8. Fireline Micro Ice 4 lb. fishing line	10

The results of these tests show that the Fireline Micro Ice 4 lb. fishing line was the most radiolucent material out of all the samples tested. These tests were repeated several times with the Fireline Micro Ice material doubled and quadrupled in thickness, and it continued to exhibit vastly superior radiolucency ratings. The second most radiolucent material was the Vanish Fluorocarbon 8 lb. fishing line. Of the tennis strings, the Wilson, Head, and Prince nylon strings provided the best results. The two polystyrene samples proved less than adequate due to their relatively low radiolucency. In addition, the squash string had relatively low radiolucency, and received a poor rating from Dr. Goodsitt due to its striated exterior.

Figure 5: Images of radiolucency for each string



PROTOYPE VALIDATION TESTING

The validation of the prototype is an important step in determining how well the customer requirements and engineering specifications had been accomplished. The first step in validating the prototype was to ensure that the device could fit into the mammogram machine, and that it was capable of handling the loading parameters experienced during a mammogram procedure. To determine this, the prototype was taken to the radiology department of the U of M hospital in order to simulate a mammogram procedure. After placing the prototype into the GE Senographe 2000D mammography device, it became clear that it fit and could be tested for durability. The second test was conducted to determine the prototypes durability. A phantom breast was placed on the GE device, and the prototype was lowered onto the phantom. The prototype was then loaded to 120 N, the maximum level for which the paddle was designed to experience. Upon loading of the prototype, it was determined that the prototype frame was strong enough to handle the loading.

The second validation testing procedure consisted of determining the x-ray characteristics of the prototype. The setup for this test shows our prototype fitted into the GE Senograph machine in Figure 6. To accomplish this, an x-ray was taken with the prototype placed over a different phantom breast. This particular phantom is designed, when x-rayed, to exhibit characteristics that accurately mimic a real breast. After evaluating the x-ray, it was determined that the Fireline MicroIce string material was highly radiolucent, and that it was barely visible in the x-ray. Furthermore, it was determined that the prototype would allow for accurate detection of calcifications and other noteworthy items.

Figure 6: Prototype fitted into the Senograph mammography machine

The final validation testing procedure consisted of determining skin deflection for both the current design and the prototype. To accomplish this, it was necessary to find a means of simulating a mammogram procedure without the need of a living patient. After consulting our sponsors, it was determined that placing a chicken breast in a plastic bag, while not ideal, would provide data that could be reasonably extrapolated to simulate a mammogram procedure. The first step was testing the current design and establishing a baseline level for skin deflection. After this was complete, the same test was conducted on the prototype. At that point, it became evident that the prototype limited skin deflection more than the current design.

CUSTOMER REQUIREMENT ANALYSIS

After validation testing was complete, the prototype was measure up against the customer requirements which were developed for Design Review 1. The current design and the prototype were graded using an empirical rating system, using sponsor feedback and testing results as the determining factors. Table 4 on page 25 provides an examination of how the prototype compares to the current design when meeting customer requirements. A detailed description of several key customer requirements is listed below the table.

Table 4: Customer Requirement Matrix comparing our prototype to the current design

Customer Requirements	Current Paddle	Prototype
Transparent	9	7
Lightweight	5	5
Radiolucent	7	7
Durable	7	7
Easy to Clean	7	5
Provides Necessary Compressive Force	9	9
Access to Entire Compressive Surface	3	9
Does not Irritate Skin	7	7
No Pinch Points	9	9
Minimize Skin Deflection	7	9

-*Transparency*: The prototype scored high, albeit relatively lower than the current design, when analyzing transparency. A primary reason for this discrepancy has to do with the thickness of the front chest plate. The original prototype engineering drawings called for the front chest plate of the paddle to be a thickness of 0.25 in. When the manufacturing phase of this project began, it became apparent that a thickness of 0.25 in would be very difficult to manufacture. At that point, the decision was made to change the thickness to 7/16 in for ease of manufacturing. This change in thickness meant that more breast tissue would be blocked during a mammogram, which necessitated the lower score.

-*Radiolucency*: The initial goal of the prototype was to obtain a radiolucency rating higher than that of the current design. After conducting radiolucency testing, it was determined that using Fireline fishing line would result in greater radiolucency than the material currently used, Lexan. This improvement would have necessitated a higher score than the current design, if it wasn't for the fact that the front chest plate had to be made thicker. For the issues that were raised in the

transparency section above, it was determined that a radiolucency rating equal to that of the current design was in order.

-*Easy to Clean*: One of the issues that is often overlooked during the wire localization process is how to clean the paddle after the procedure is complete. During a wire localization procedure, it is likely that material such as blood and sweat can be deposited onto the paddle. Cleaning the paddle is not only a process of tidiness, it is necessary to stop the spread of viruses and bacteria. The prototype received a lower score than the current design in the 'ease of clean' category due to the crossing nature of the stringing material. The fact that the strings cross each other at numerous locations could potentially result in a paddle that is harder to clean than the current design.

-*Necessary Compressive Force*: Providing the necessary compressive force was one of the most important customer requirements. The current design received a rating of 9 in this category, and the prototype was designed to make this requirement a top priority. After the design phase of this project was completed, it became clear that any string material that was to be used needed to be very strong and stiff. The Fireline fishing line material that was chosen exhibits high tensile strength with low strain. When incorporated into the prototype, this string material provides a level of compression comparable to that of the current design.

-*Accessibility to the Compressed Surface*: Providing access to the compressed surface was the main inspiration for the initiation of this project, so it was clear that the prototype needed to excel in this category. The major problem with the current design is that it grants access to a very limited area of the breast tissue. The prototype, with its mesh of fishing line spaced in 1 cm increments, provides access to virtually the entire compressed surface.

-*Minimize Skin Deflection*: The minimization of skin deflection was a customer requirement that was added during the concept generation phase of this project. After several conversations with our sponsors at the University of Michigan Hospital, it became clear that the minimization of skin deflection was a design criteria that they wanted incorporated into the prototype. The current design, with its single access window, allows for a level of skin deflection that our sponsors are concerned with minimizing. The current design has an access window with an area of roughly 16.5 cm^2. The prototype has 273 openings, with an average area of roughly 1 cm^2. The open nature of the prototype, the paddle allows for minimal skin deflection through each opening.

DESIGN CHANGES

Throughout the manufacturing process there were decisions made to modify the design in order to make assembly less complicated and prevent waste of material. One of the major changes was to the frame assembly. In the original design the frame would have fastened together using bolts. The design change made was to weld the frame pieces together. A reason for the change was to represent the structure of the final design by making the frame one continuous piece. Recall that the frame of the large scale production of the final design will be formed as one piece, differing from the individual frame components in the prototype.

Another design change occurred in the mounting bracket assembly. Before manufacturing began, the bracket was changed to be hollowed out to save weight. A decision had to be made to either manufacture the hollowed bracket from one piece of aluminum or individual components which would require further assembly. The decision was made to manufacture individual components to prevent the large amount of wasted material that would come from machining out of one piece of aluminum. It was then decided to weld the individual components of the bracket together as opposed to fasten them for the same reasons as the frame assembly. The mounting bracket will not be produced from welding together individual components, but instead one formed piece.

When the decision was made to weld the individual frame and mounting bracket components together, there was a possibility to either weld or fasten the two assemblies together. The prototype design was modified to fasten the two assemblies together in order to quickly disassemble and ease of stringing the Fireline through the frame.

The plexiglas chest plate on the prototype was originally designed to curve underneath the frame to cover any metal to skin contact. It was determined that the fragile nature of this material would prevent machining the cover plate into the designed shape. The thickness of the chest plate was originally designed to be as thin as the final design, but due to machining limits on the material, it was decided to not change the plate thickness from its stock form. The design was changed to cover only the front of the frame. In the late stages of the manufacturing process the cover plate was modified to fasten on to the front frame using two countersink screws.

Originally, the prototype frame was designed to have all outside corners filleted, which included the side and bottom corners. Upon further analysis it was determined that since only the front of the frame comes in contact with the patient, so only these corners should need to have smooth, comfortable edges. The prototype design was changed to save further machining time by not filleting the edges on the rest of the frame.

Some of the changes to the prototype did not reflect in any change to the final design. These changes, which included welding components and rounding fewer edges, were made to better represent the final design and to allow for less machining time for the same end result. There were other design changes to the final design that were not applied directly to the prototype, such as the grid cover plate redesign, that will be discussed in a later section.

COST ANALYSIS OF FINAL DESIGN MANUFACTURING

Manufacturing Costs

The cost of manufacturing a final product will be influenced by several factors including: materials, labor, and availability. In this cost analysis, heavy focus is placed primarily on the most significant factors (materials and labor). Analysis pertaining to availability will assess fluctuations in market price of materials and labor, but since this is such a small percentage of what the manufacturing cost is overall, the amount of discussion on this topic will be minimal.

Classification of the final product cost will be described using a single paddle as the metric. Defining the cost of one paddle will enable future cost projections and allow small alterations to be streamlined into the cost analysis if need be.

Materials

The approach for assigning a material cost to the final product is to create an itemized list of each material used, in what amount/quantity, and how much it costs. Summing the individual costs of components then determine the overall cost of materials.

The final product is composed of multiple components and materials. Table 5 is a listing of all materials used to construct the final product:

Table 5: Cost analysis of large scale final design manufacturing

Component	Material	Amount/Quantity	Unit Price	Cost / Paddle
Frame	Steel (1018)	12.13 in3	$5.14 / in3	$62.34
Mounting Bracket	Steel (1018)	6.80 in3	$5.14 / in3	$34.76
Slide Adapter	ABS Plastic	5.63 in3	$0.31 / in3	$1.74
Cover Plate	Lexan	3.04 in3	$0.27 / in3	$0.82
String	Dyneema	6.94 yards	$0.15 / yard	$1.04
Bolts	Stainless Steel	11 bolts	$0.027 / bolt	$0.297
Sealant	Silicon	1 cc	$0.015 / cc	$0.015
			TOTAL COST	**$101.01**

Labor

Calculation of a final product labor cost is estimated for the construction of just one paddle and is generalized using an hourly labor machining rate. In reality, labor cost is a function of multiple factors including: how many paddles will be made per year, the process by which the paddle is made, quality restrictions on the paddle, tolerances associated with dimensioning, where the paddle is going to be made, and what resources are available (tools, man power, stringing technology).

Generally, here is how the following factors would most likely influence labor costs:

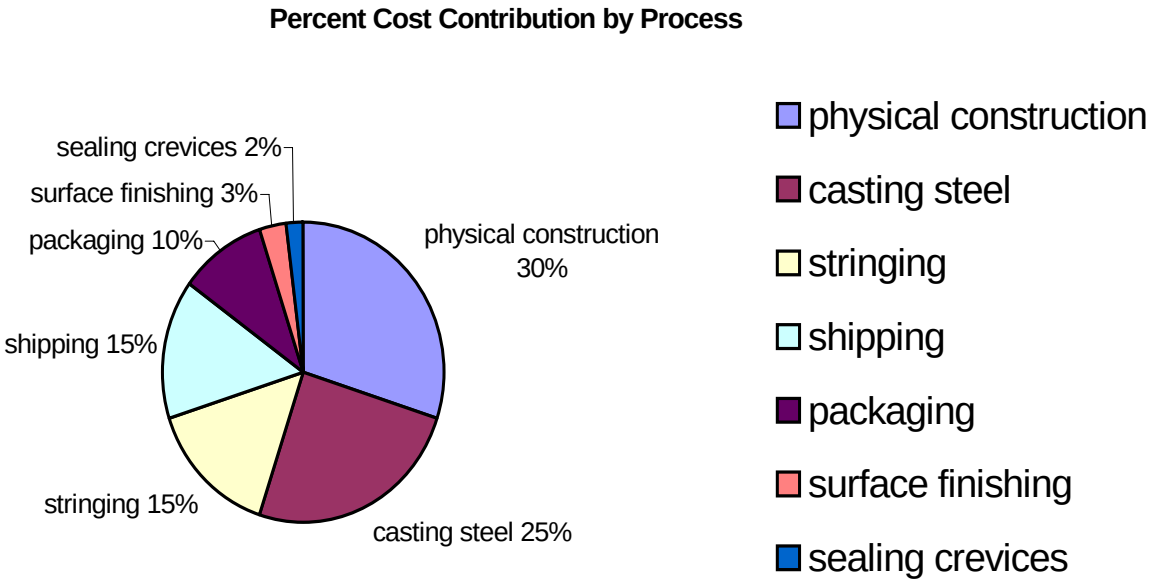
- Increase in number of paddles produced per year decreases the unit labor cost
- Increase in the quality restrictions increases the unit labor cost
- Decrease in dimensioning tolerances increases the unit labor cost

Quality restrictions are a generalized precautionary measure for how defects are sorted and managed. From a six sigma perspective, achievement of only one defect in a few million paddles would result in extensive durability, strength, and cyclic testing. Gathering this type of information requires a multitude of resources and ultimately increases labor cost.

Determination of a final labor cost per paddle is a difficult generalization to make because there are so many unknowns. But, knowing what processes are involved in constructing the final product and the amount of effort required for each process is telling of the magnitude of the labor cost. In the final product, the most expensive process would be the actual manual construction of the final product. In addition to this, the forming of the cast steel parts for the frame and

mounting bracket would be a close second. You could generalize the cost of the paddle by assigning a certain percentage contribution each process makes to the overall cost of the final product as shown in Figure 6.

Figure 7: Pie chart showing distribution of manufacturing costs



Another factor in determining labor costs that is specific to the manufacturing problem posed with the breast compression paddle is stringing technology. Ideally, the best device would be capable of stringing the paddle with uniform tension for each pass. Current technology does not exist that would serve this purpose. There are racket stringing devices that are use for racket sports but these are suited for a larger oval shaped frame, not rectangular. Discovery of a new device to perform the desired stringing operation may become a large capital cost requiring training, research, and an operator.

Availability

Materials for use in the final product are widely available on a global market. Most notably, the two most prevalent materials 1080 steel and polycarbonate do not significantly fluctuate in price and are always in heavy supply. Use of common materials ensures that drastic price changes or supply shortages will never become an issue with construction of the final product. Additionally, use of common materials increases that price stability of the final product. Use of rare or specialty materials has potential to have volatile negative affects on price stability.

RECOMMENDATIONS FOR FUTURE DESIGN WORK

The initial design of this product was considered to be very successful and was capable of addressing the major problems that were posed. However, if this design is going to be taken further with plans of commercialization, the following recommendations should be considered for future design revisions.

The grid cover plate from the alpha design was meant to be one removable piece that simply attached to the frame. While this idea seemed logical at the projects start it was determined, via the prototype, that grid markings etched directly into the frame would be a better choice. This would eliminate the extra piece and would also be more cost effective. Another option is to design a smaller grid plate and enable it so that the plate can slide over the area of interest. This will ensure that the grid markings show up on the x-ray and that the grid plate will be out of the way when not in use.

A second recommendation is in regards to the stringing method. The prototype was strung simply using a brute force method which is inadequate for a working product. It is important that the tension in each string be equal and to the recommended value. This would best be achieved through use of a locking string (such as the idea behind zip ties) along with a torque key.

The last recommendation concerns the mesh surface but deals with eliminatin the stringing process all together. It is recommended that the use of one mesh be studied. This could be done by molding the mesh directly into the frame. This would eliminate the issues concerning the stringing process and would eliminate the cleaning concerns all together.

With these recommendations in mind, further refinement to the existing prototype will be possible and with it the possibility of commercialization.

CONCLUSIONS

Work has now been completed on designing a new mammogram compression paddle to better suit the needs of the Radiology Dept. here at the University of Michigan Hospital. The initial phases of work consisted of gaining a greater understanding of the current problem, as well as current methodology for mammogram and wire localization procedures. Once this was complete, a set of customer requirements were made to help the design process. These customer requirements were then translated into engineering specifications in order to develop quantifiable targets for the design.

Once a set of engineering specifications were developed, a plan for design and construction was created. This plan illustrated the critical deadlines in the design process, as well as provide an organizational tool to streamline development. It was at this step where the analysis of the problem began. During this analysis, several potential roadblocks to success were identified, and their respective potential solutions planned. These consisted of problems related to meeting FDA regulations, achieving adequate compression, allowing easier access for a wire localization procedure, and increasing patient comfort.

The initial design development process is complete. This process required several design concept iterations, but eventually yielded two major design themes and the groundwork for a prototype solution that will meet all customer requirements and engineering specifications.

In addition, design development is finalized. This process consisted of generating computer models of the final customer approved design. These models were used for testing and prototype

development. Currently an existing prototype has been developed which is based on these computer models. Validation of the model has taken place and string testing is complete.

The redesigned breast compression paddle has addressed both of the primary issues concerning universal wire localization access and full surface compression. It has effectively minimized skin deflection and opened the entire area of compression for wire localization. These two objectives were achieved using a mesh contact surface. Overall this project was a success. However there are future refinements which must be taken into consideration if this project is to be taken further.

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"MAMMOMAT 1000 / 3000 Nova Accessories." Siemens. 1 Dec. 2005. 24 Sept. 2006
<http://www.medical.siemens.com/webapp/wcs/stores/servlet/ProductDisplay?storeId=10001&langId=11&catalogId=11&refererView=CategoryDisplay&selectView=ProductDisplay&selectName=productId&relatedCatName=MammographycatTree=100002%2C14207*4171535711&level=0&productId=17213>.

"MSC Industrial Supply Co." MSC. 23 Oct. 2006. <http://www1.mscdirect.com/cgi/nnsrhm>.

"The Mammography Quality Standards Act Final Regulations." Food and Drug Administration.
24 Sept. 2006
http://www.fda.gov/ohrms/dockets/98fr/994910gl2.pdf>.

United States Patent and Trademark Office. 7 July 2006. 24 Sept. 2006
<http://www.uspto.gov/patft/>.

APPENDIX A – Patent Search Results

Figure A.1: Example of contoured surface geometry

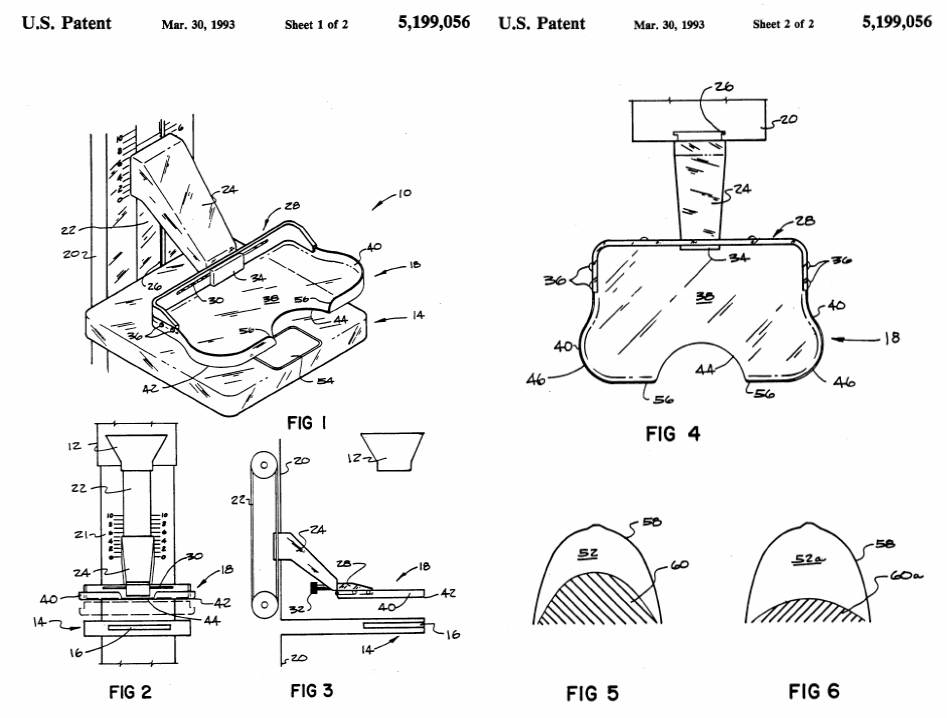
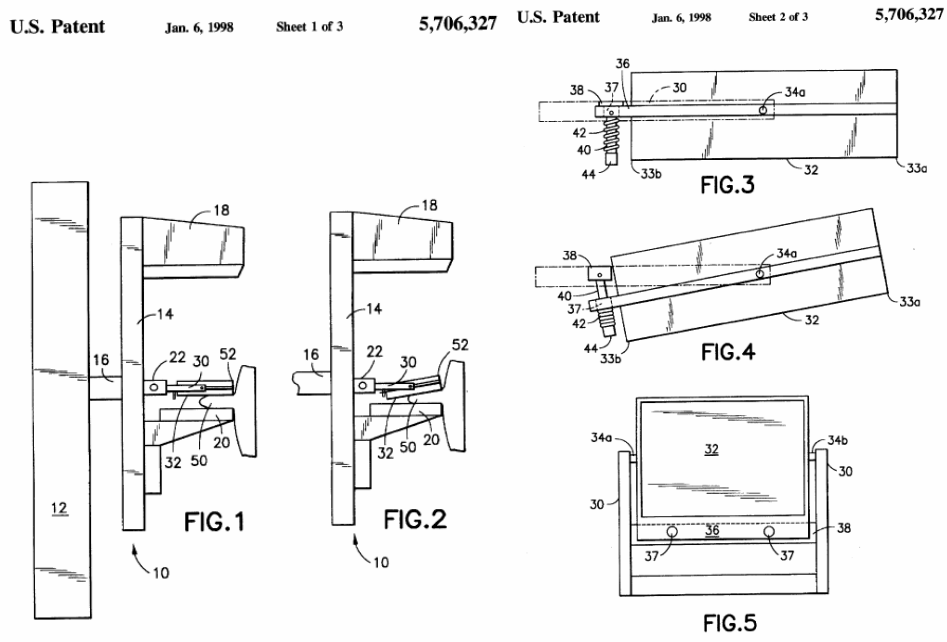
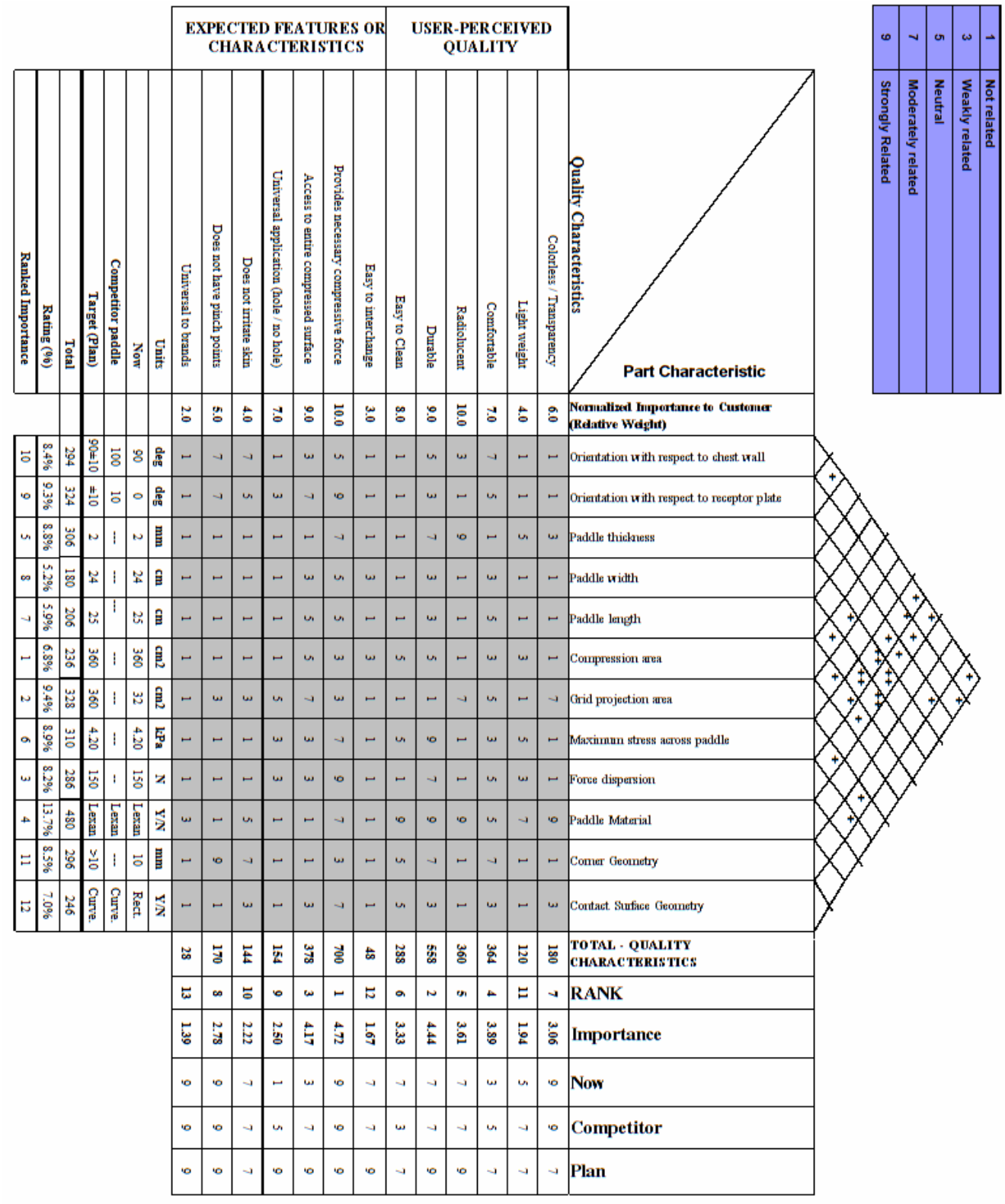


Figure A.1: Example of variable orientation paddle



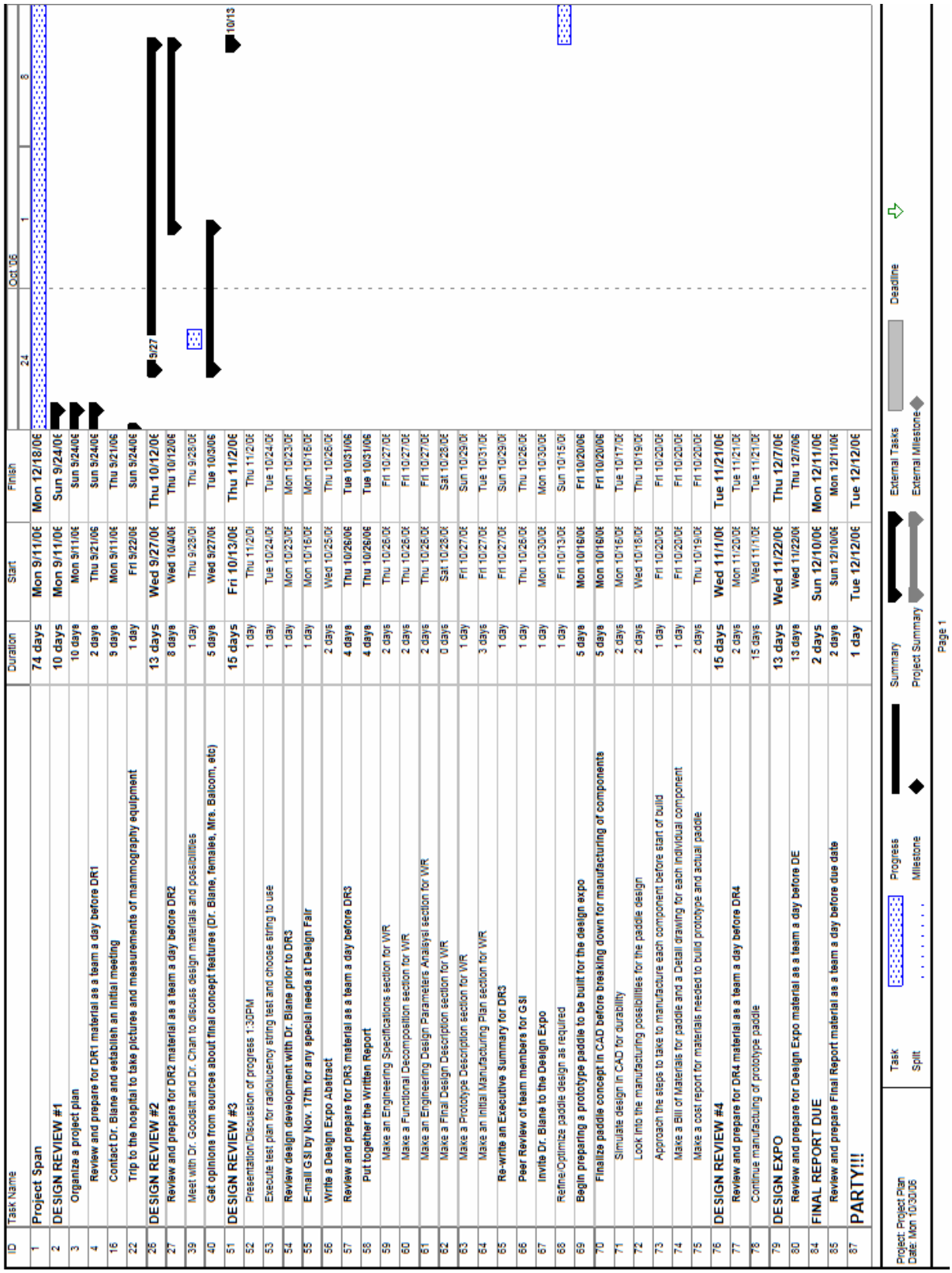
APPENDIX B – QFD Diagram

Figure B.1: QFD diagram that the new paddle design will be based upon



APPENDIX C – Project Plan

Figure C.1: Gantt chart to assist in initial Project Plan



ID	Task Name	Duration	Start	Finish
1	**Project Span**	**74 days**	**Mon 9/11/06**	**Mon 12/18/06**
2	**DESIGN REVIEW #1**	**10 days**	**Mon 9/11/06**	**Sun 9/24/06**
3	Organize a project plan	10 days	Mon 9/11/06	Sun 9/24/06
4	Review and prepare for DR1 material as a team a day before DR1	2 days	Thu 9/21/06	Sun 9/24/06
16	Contact Dr. Blane and establish an initial meeting	9 days	Mon 9/11/06	Thu 9/21/06
22	Trip to the hospital to take pictures and measurements of mammography equipment	1 day	Fri 9/22/06	Sun 9/24/06
26	**DESIGN REVIEW #2**	**13 days**	**Wed 9/27/06**	**Thu 10/12/06**
27	Review and prepare for DR2 material as a team a day before DR2	8 days	Wed 10/4/06	Thu 10/12/06
39	Meet with Dr. Goodsitt and Dr. Chan to discuss design materials and possibilities	1 day	Thu 9/28/06	Thu 9/28/06
40	Get opinions from sources about final concept features (Dr. Blane, females, Mrs. Balcom, etc)	5 days	Wed 9/27/06	Tue 10/3/06
51	**DESIGN REVIEW #3**	**15 days**	**Fri 10/13/06**	**Thu 11/2/06**
52	Presentation/Discussion of progress 1:30PM	1 day	Thu 11/2/06	Thu 11/2/06
53	Execute test plan for radiolucency string test and choose string to use	1 day	Tue 10/24/06	Tue 10/24/06
54	Review design development with Dr. Blane prior to DR3	1 day	Mon 10/23/06	Mon 10/23/06
55	E-mail GSI by Nov. 17th for any special needs at Design Fair	1 day	Mon 10/16/06	Mon 10/16/06
56	Write a Design Expo Abstract	2 days	Wed 10/25/06	Thu 10/26/06
57	Review and prepare for DR3 material as a team a day before DR3	4 days	Thu 10/26/06	Tue 10/31/06
58	Put together the Written Report	4 days	Thu 10/26/06	Tue 10/31/06
59	Make an Engineering Specifications section for WR	2 days	Thu 10/26/06	Fri 10/27/06
60	Make a Functional Decomposition section for WR	2 days	Thu 10/26/06	Fri 10/27/06
61	Make an Engineering Design Parameters Analysis section for WR	2 days	Thu 10/26/06	Fri 10/27/06
62	Make a Final Design Description section for WR	0 days	Sat 10/28/06	Sat 10/28/06
63	Make a Prototype Description section for WR	1 day	Fri 10/27/06	Sun 10/29/06
64	Make an Initial Manufacturing Plan section for WR	3 days	Fri 10/27/06	Tue 10/31/06
65	Re-write an Executive Summary for DR3	1 day	Fri 10/27/06	Sun 10/29/06
66	Peer Review of team members for GSI	1 day	Thu 10/26/06	Thu 10/26/06
67	Invite Dr. Blane to the Design Expo	1 day	Mon 10/30/06	Mon 10/30/06
68	Refine/Optimize paddle design as required	1 day	Fri 10/13/06	Sun 10/15/06
69	Begin preparing a prototype paddle to be built for the design expo	5 days	Mon 10/16/06	Fri 10/20/06
70	Finalize paddle concept in CAD before breaking down for manufacturing of components	5 days	Mon 10/16/06	Fri 10/20/06
71	Simulate design in CAD for durability	2 days	Mon 10/16/06	Tue 10/17/06
72	Look into the manufacturing possibilities for the paddle design	2 days	Wed 10/18/06	Thu 10/19/06
73	Approach the steps to take to manufacture each component before start of build	1 day	Fri 10/20/06	Fri 10/20/06
74	Make a Bill of Materials for paddle and a Detail drawing for each individual component	1 day	Fri 10/20/06	Fri 10/20/06
75	Make a cost report for materials needed to build prototype and actual paddle	2 days	Thu 10/19/06	Fri 10/20/06
76	**DESIGN REVIEW #4**	**15 days**	**Wed 11/1/06**	**Tue 11/21/06**
77	Review and prepare for DR4 material as a team a day before DR4	2 days	Mon 11/20/06	Tue 11/21/06
78	Continue manufacturing of prototype paddle	15 days	Wed 11/1/06	Tue 11/21/06
79	**DESIGN EXPO**	**13 days**	**Wed 11/22/06**	**Thu 12/7/06**
80	Review and prepare for Design Expo material as a team a day before DE	13 days	Wed 11/22/06	Thu 12/7/06
84	**FINAL REPORT DUE**	**2 days**	**Sun 12/10/06**	**Mon 12/11/06**
85	Review and prepare Final Report material as a team a day before due date	2 days	Sun 12/10/06	Mon 12/11/06
87	**PARTY!!!**	**1 day**	**Tue 12/12/06**	**Tue 12/12/06**

APPENDIX D – Concept Generation

Concept sketches for new compression paddle designs

Figure D.1: A metal frame holds a removable membrane that compresses and provides access to all areas of the compressed surface

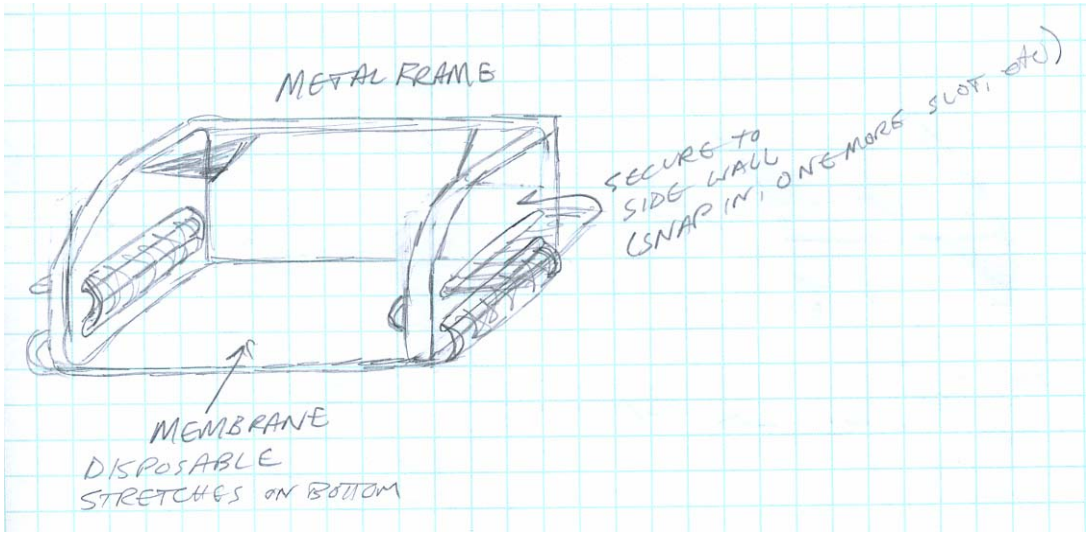


Figure D.2: A 2 layer Lexan paddle. The bottom layer slides out of either side to give access to template holes on top layer

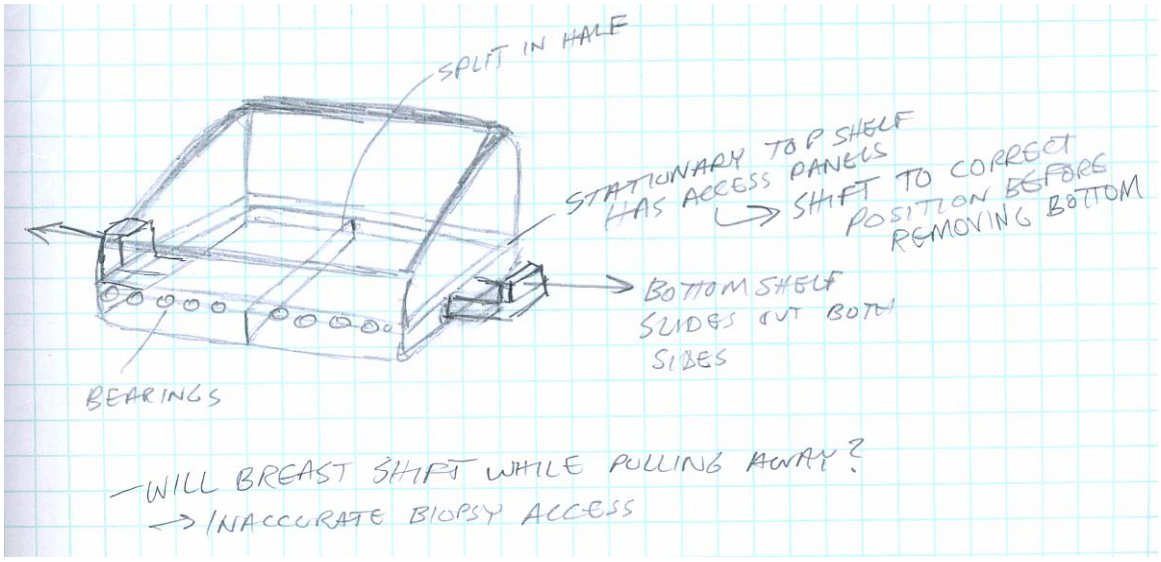


Figure D.3: Rotating disc with cutout pattern to insert wire

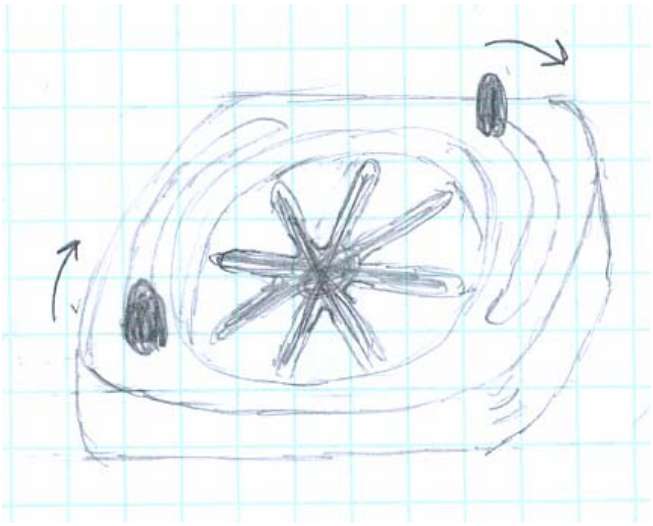


Figure D.4: Interchangeable solid template designs

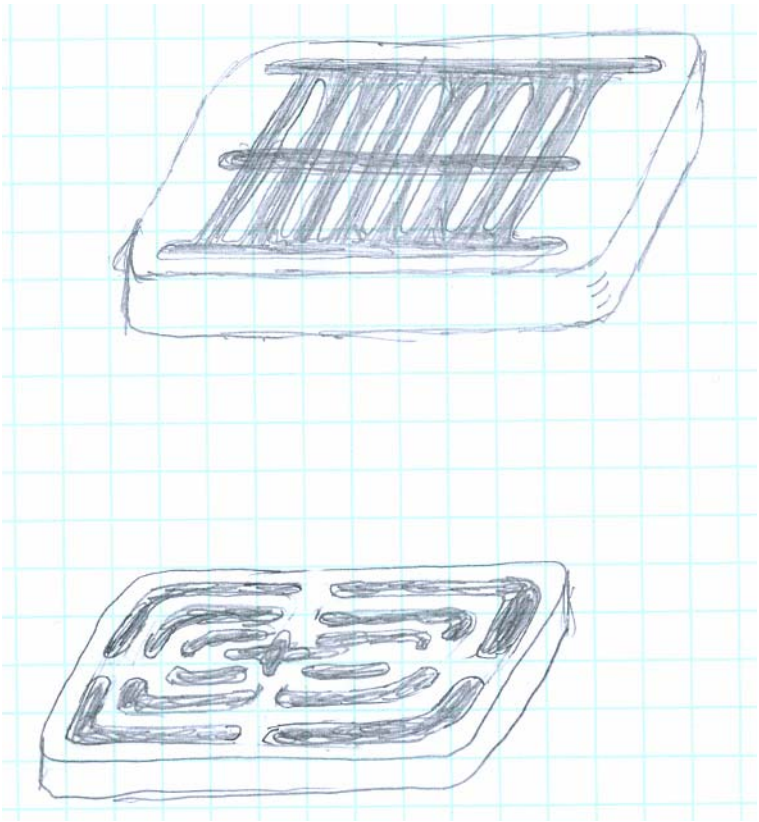


Figure D.5: Triangular mesh with self aligning grid

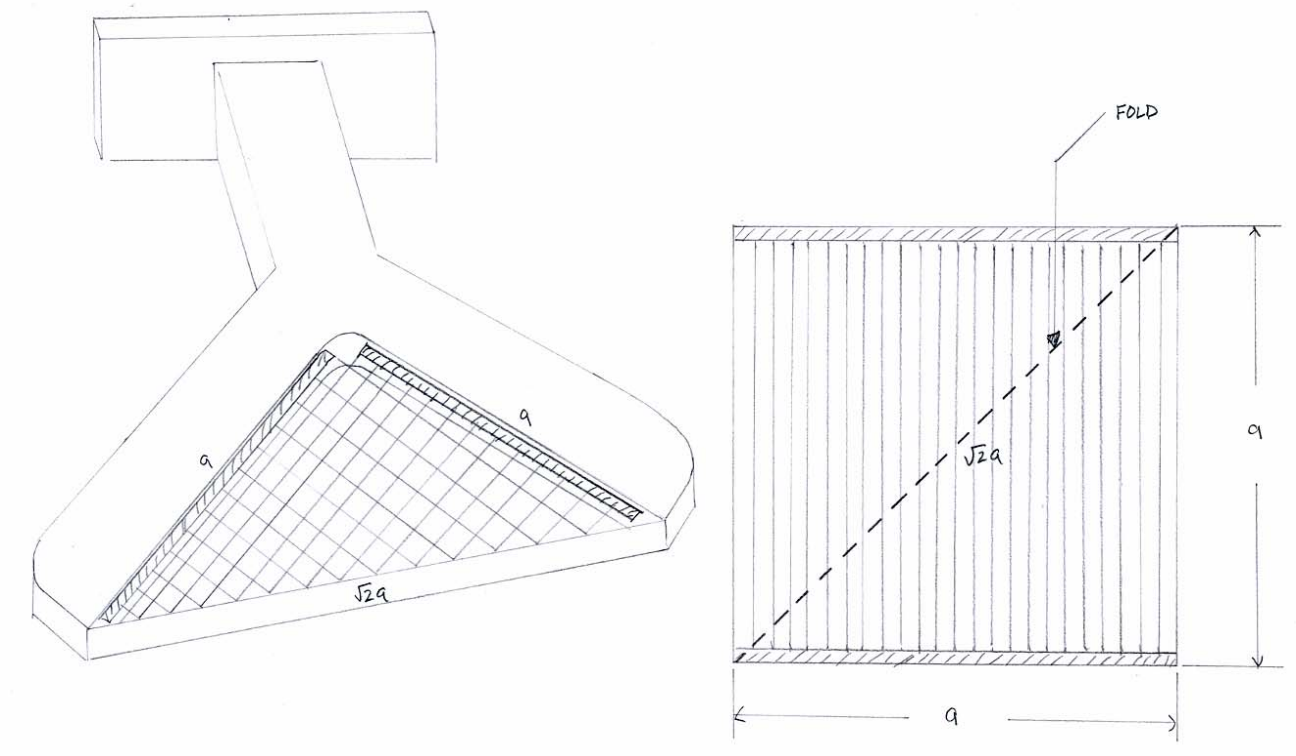


Figure D.6: Rectangular mesh with contoured contact surface geometry

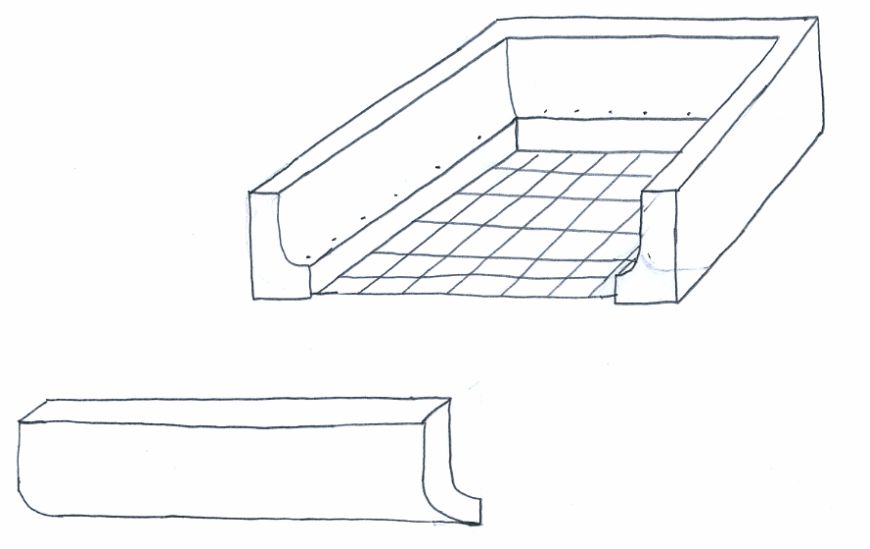


Figure D.7: Self tightening mechanism for tension management on rectangular mesh grid

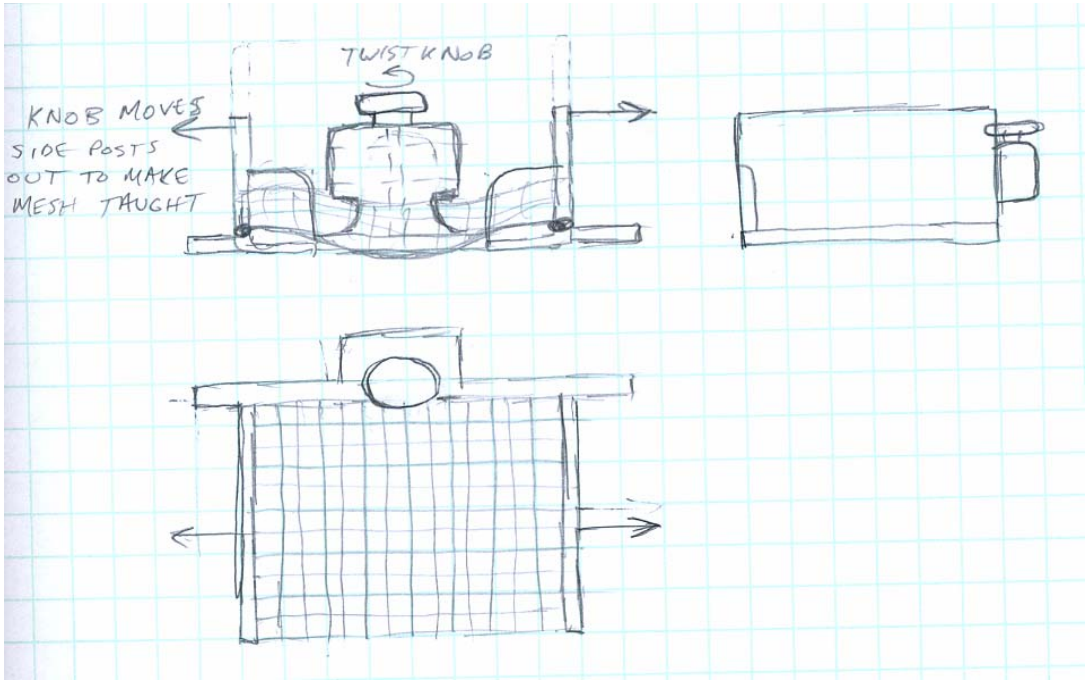


Figure D.8: Interchangeable/removable rubber inlay for solid full compress paddle

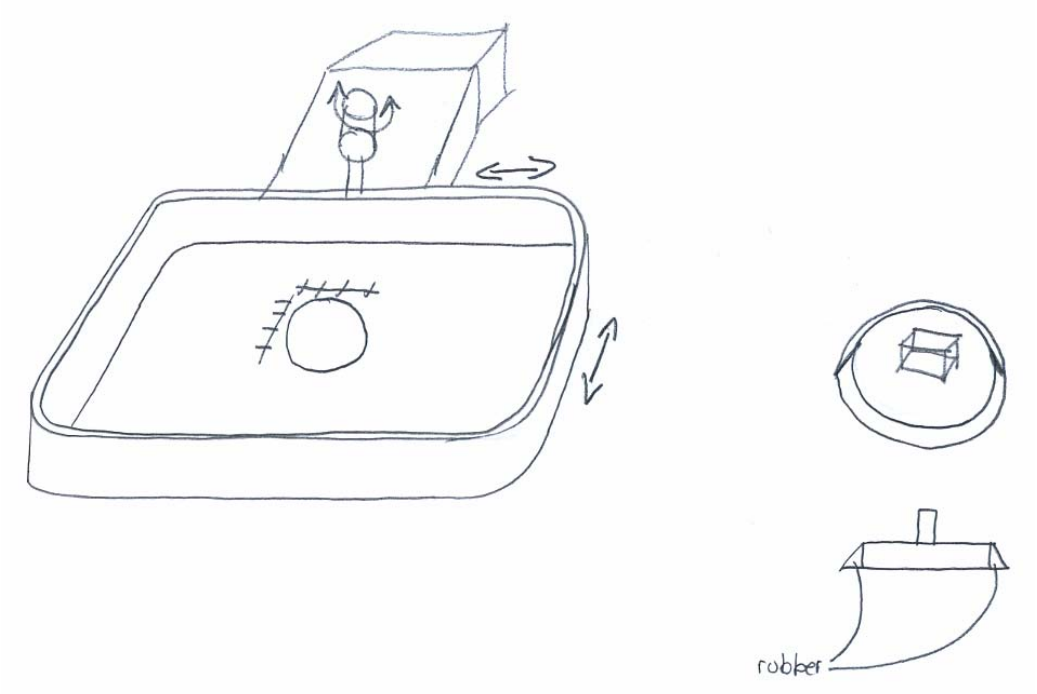


Figure D.9: Interchangeable/removable threaded disc inlay for solid full compress paddle

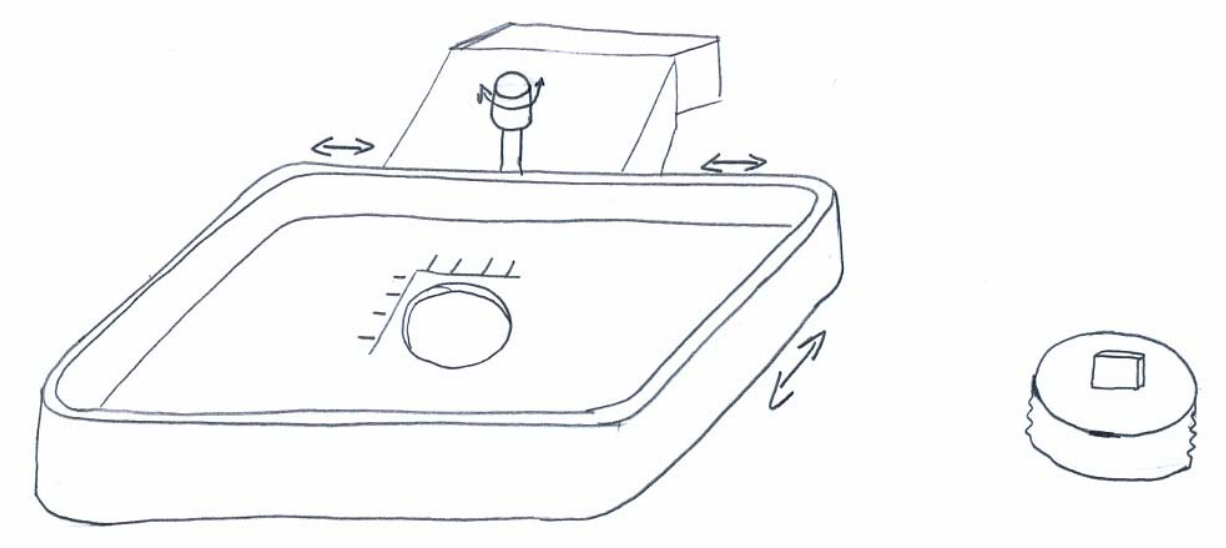


Figure D.10: Single axis hinge with multi door configuration allows for full compression and mobility

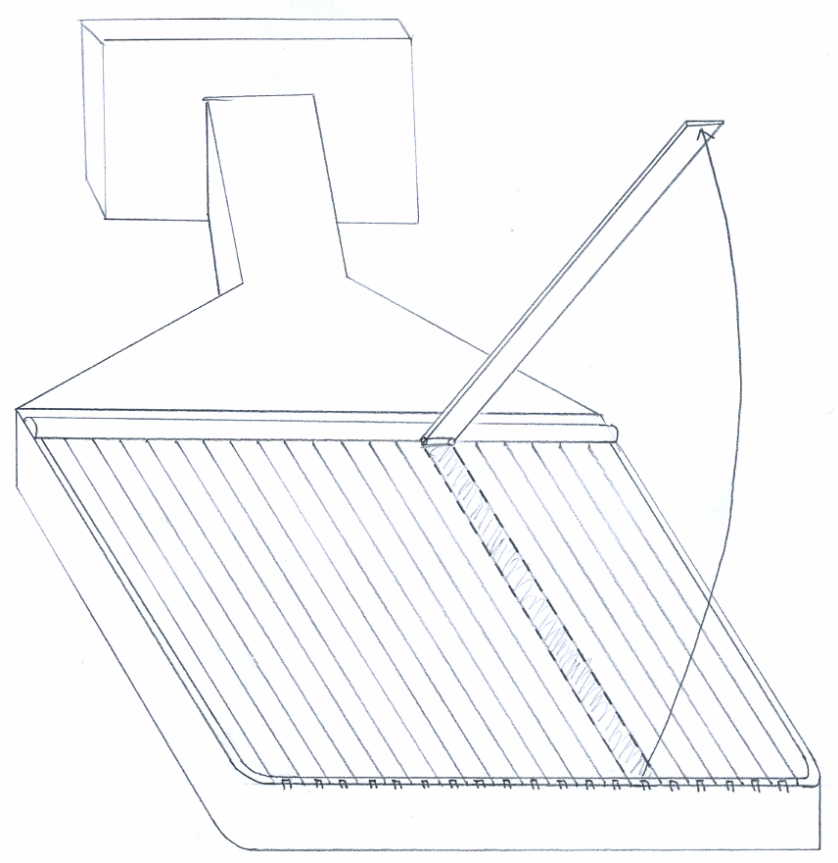


Figure D.11: Single slot rectangular frame for insertion of interchangeable mesh grid

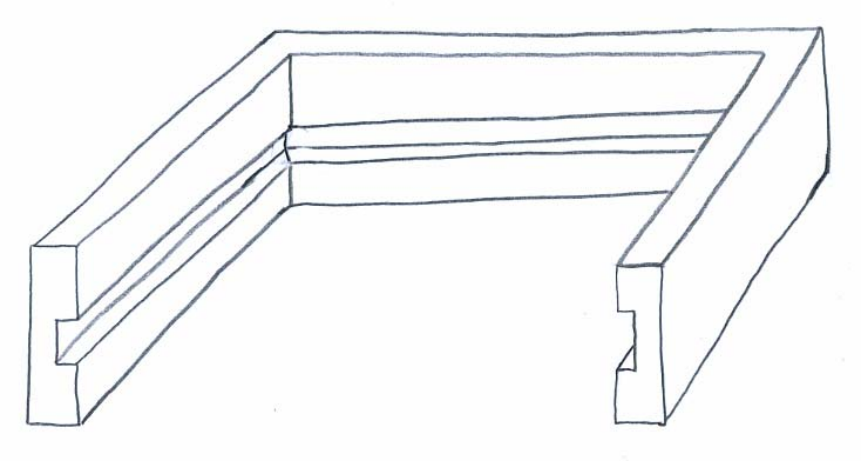


Figure D.12: Multi hinge / Multi shape full compression paddle with movable door system

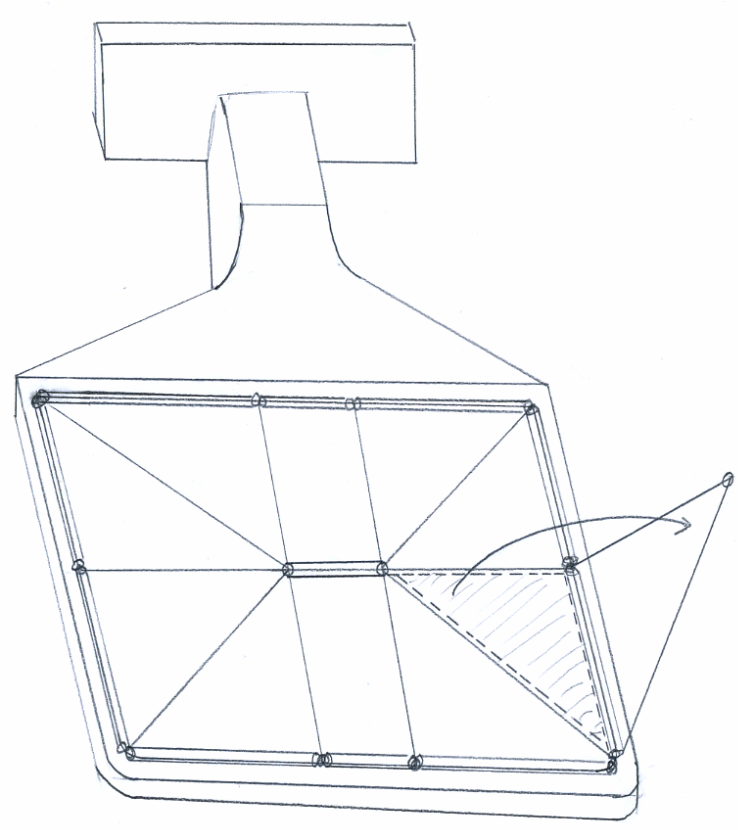
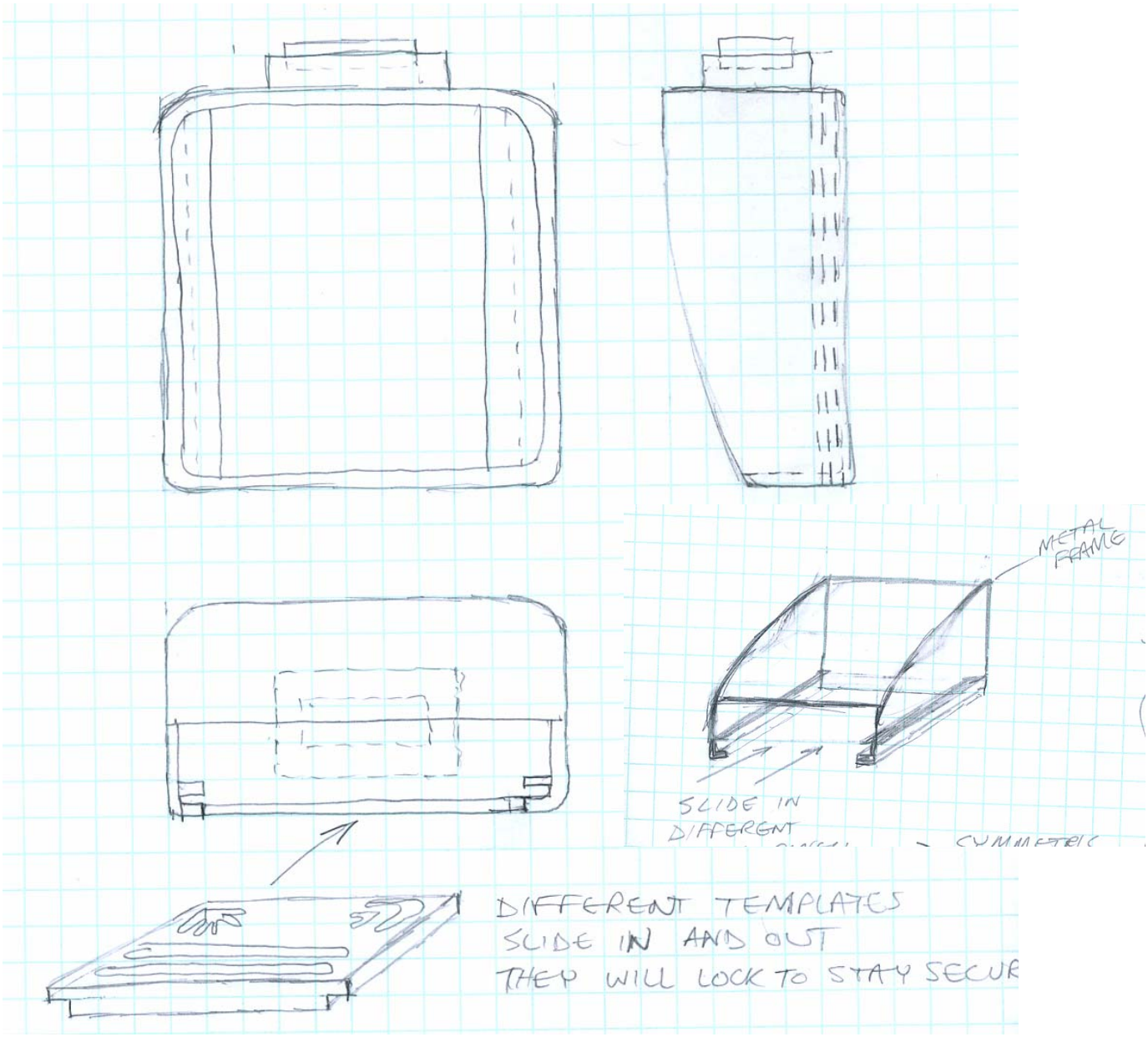


Figure D.13: A 2 layer Lexan paddle. The bottom layer slides out of either side to give access to template holes on top layer



APPENDIX E – Materials Listing

Figure E.1: Final design B.O.M.

FINAL DESIGN - PARTS AND MATERIALS

	Component	Material	Specification	Manufacturer	Part Number	Cost
Final Design	Adapter	Acrylonitrile butadiene styrene (ABS)	Sheets - Plastic Material Material: ABS Thickness: 3/8 Length: 12 Width: 12 Color: Beige	MSC Direct Inc.	52419785	$ 27.60
	Mount	1018 Steel Cold Finished	1018 Steel Cold Finished Squares Material: Steel - 1018 Length: 12 Length: 1 Width: 3 Height: 3	MSC Direct Inc.	3917473	$ 128.06
	Frame Left Frame Right Frame Back Frame Front	1019 Steel Cold Finished	1018 Steel Cold Finished Rectangles Material: Steel - 1018 Length: 36 Length: 3 Thickness: 1/2 Width: 1-1/2	Made in USA	3897436	$ 21.37
	Chest Wall Cover	Polycarbonate	Polycarbonate - Clear Material: Polycarbonate Thickness: 3/16 Length: 12 Width: 12	MSC Direct Inc.	63405377	$ 9.67
	Grid Cover Plate	Polycarbonate	Polycarbonate - Clear Material: Polycarbonate Thickness: 3/32 Length: 12 Width: 12	MSC Direct Inc.	63405252	$ 5.72
	String	FireLine Micro Ice with Dyneema	50 yards - Smoke 10/4 Lb. Test/Line Diam.	Berkley Inc.	FLIPS10-42	$ 5.89

TOTAL COST **$ 198.31**

Figure E.2: Prototype design B.O.M.

PROTOTYPE - PARTS AND MATERIALS

	Component	Material	Specification	Manufacturer	Part Number	Cost
Prototype	Adapter	Poly Vinyl Chloride (PVC)	Sheets - Plastic Material Material: PVC Thickness: 3/8 Length: 12 Width: 12 Color: Gray	MSC Direct Inc.	52418696	$ 11.95
	Mount	6061 Aluminum	Alloy 6061 Aluminum Material: Aluminum - 6061-T6 Length: 12 Length: 1 Width: 3 Height: 3	Import	8663908	$ 76.34
	Frame Left Frame Right Frame Back Frame Front	6061 Aluminum	Alloy 6061 Aluminum Material: Aluminum - Alloy 6061 Length: 72 Length: 6 Thickness: 1/2 Width: 1-1/2	MSC Direct Inc.	32012403	$ 37.89
	Chest Wall Cover	Polycarbonate	Polycarbonate - Clear Material: Polycarbonate Thickness: 3/16 Length: 12 Width: 12	MSC Direct Inc.	63405377	$ 9.67
	Grid Cover Plate	Polycarbonate	Polycarbonate - Clear Material: Polycarbonate Thickness: 3/32 Length: 12 Width: 12	MSC Direct Inc.	63405252	$ 5.72
	String	FireLine Micro Ice with Dyneema	50 yards - Smoke 10/4 Lb. Test/Line Diam.	Berkley Inc.	FLIPS10-42	$ 5.89

TOTAL COST **$ 147.46**

APPENDIX F – CAD representation of the paddle design

Details of the 8 required components for the prototype design: Chest Plate, Front Frame, Front Frame, Grid Plate, Left Frame, Mounting Bracket, Rear Frame, Right Frame, and Slide Adapter

Figure F.1: Detailed assembly of Prototype Assembly design

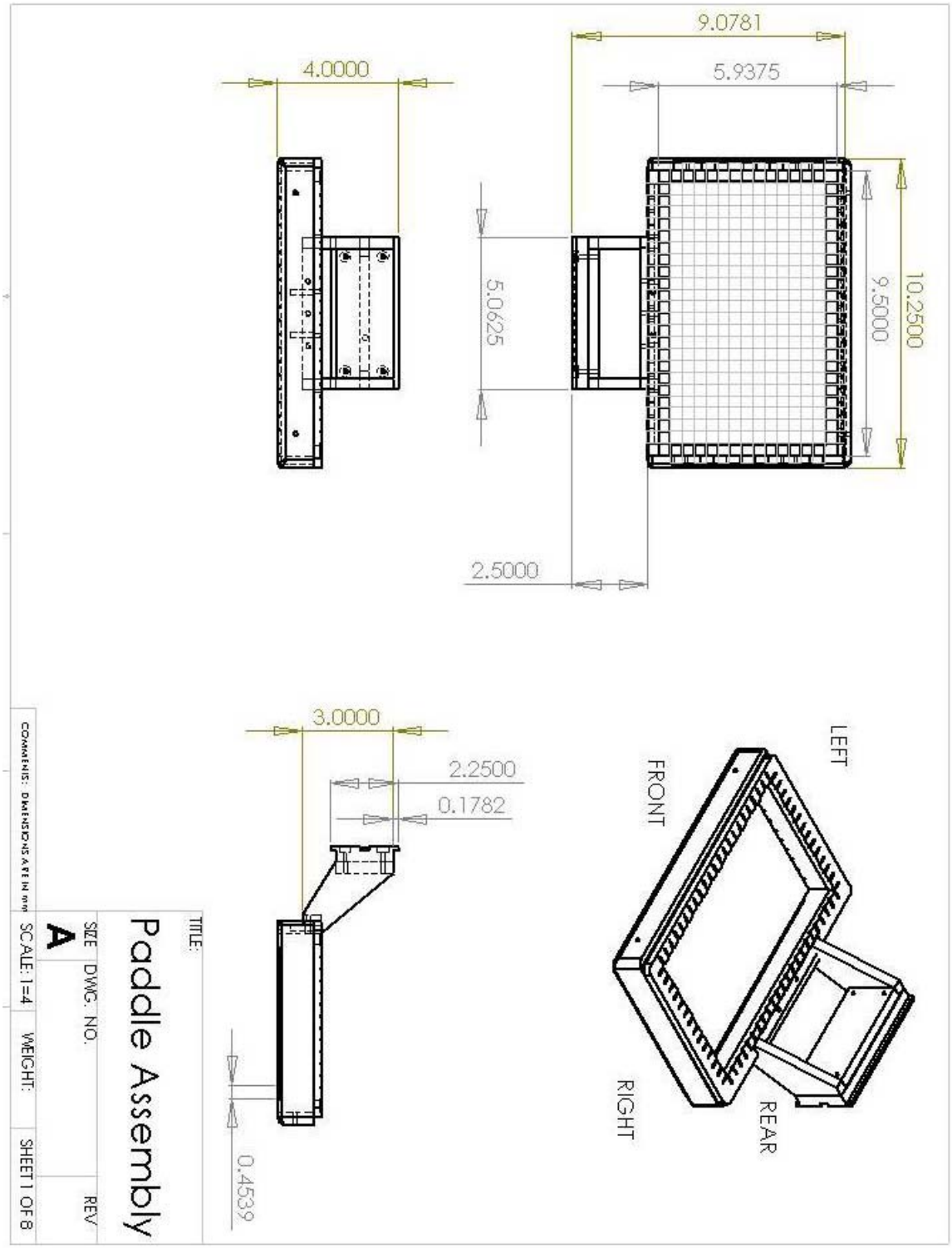


Figure F.2: Detail of Chest Plate prototype

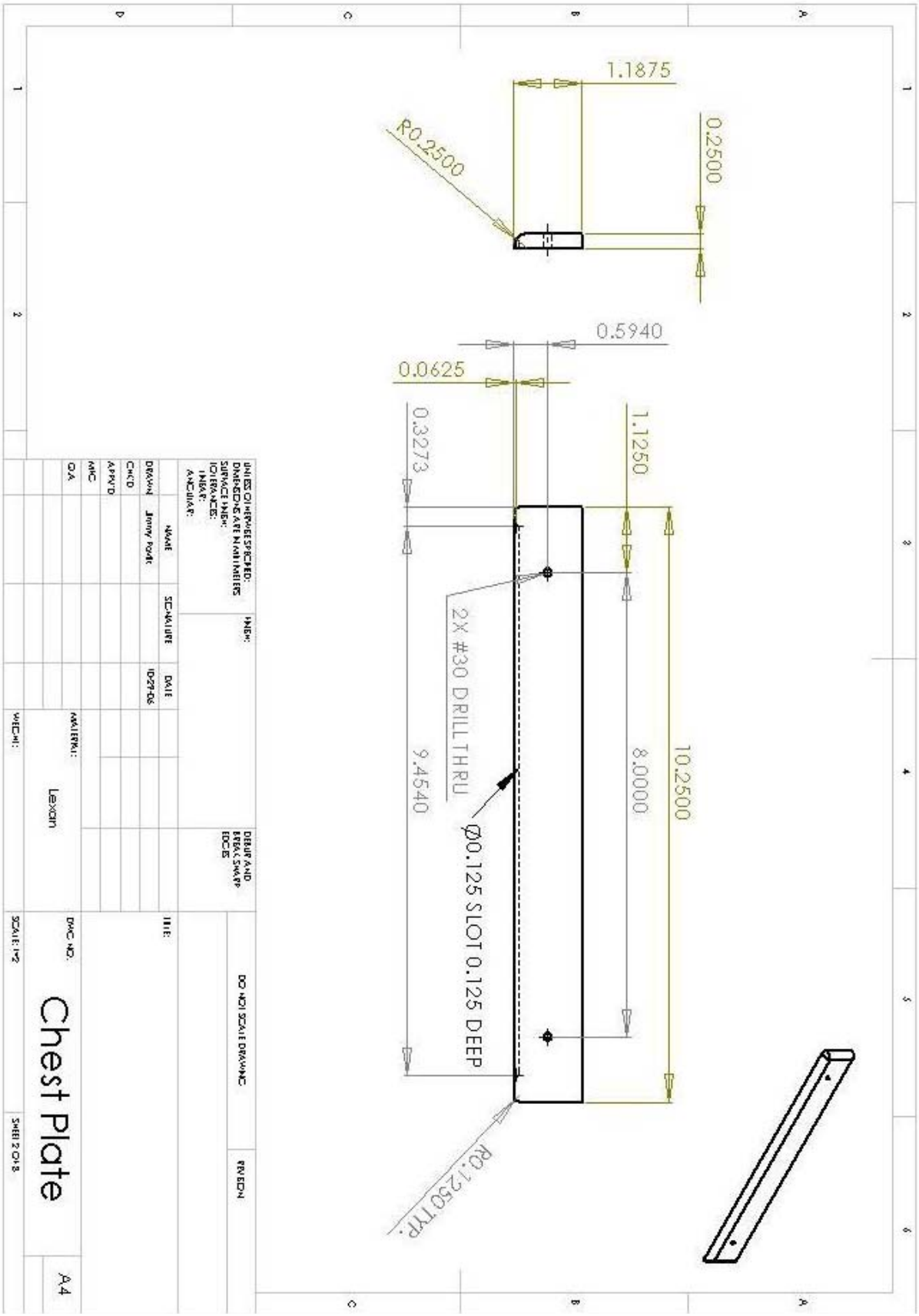


Figure F.3: Detail of Front Frame prototype

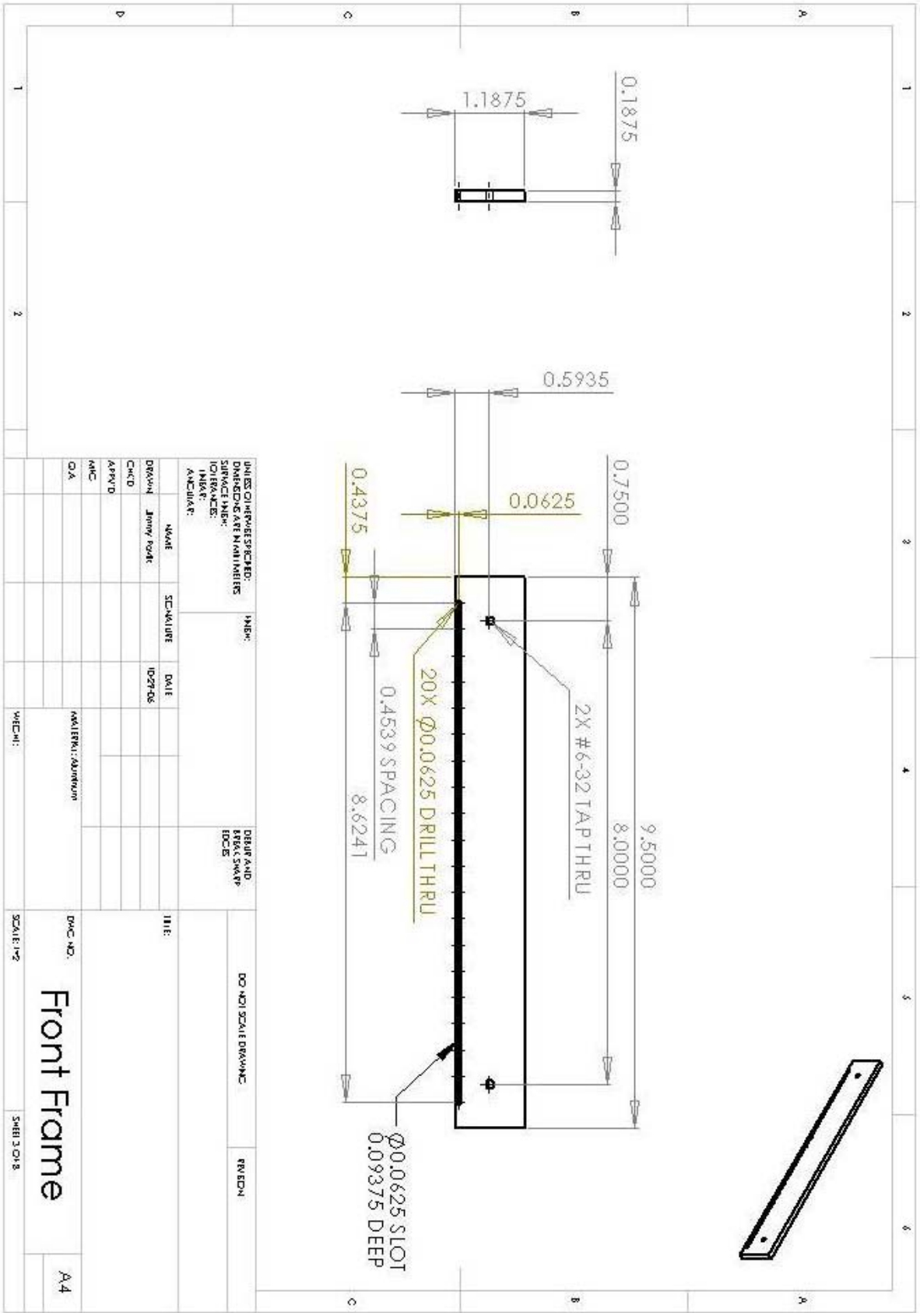


Figure F.4: Detail of Grid Plate prototype

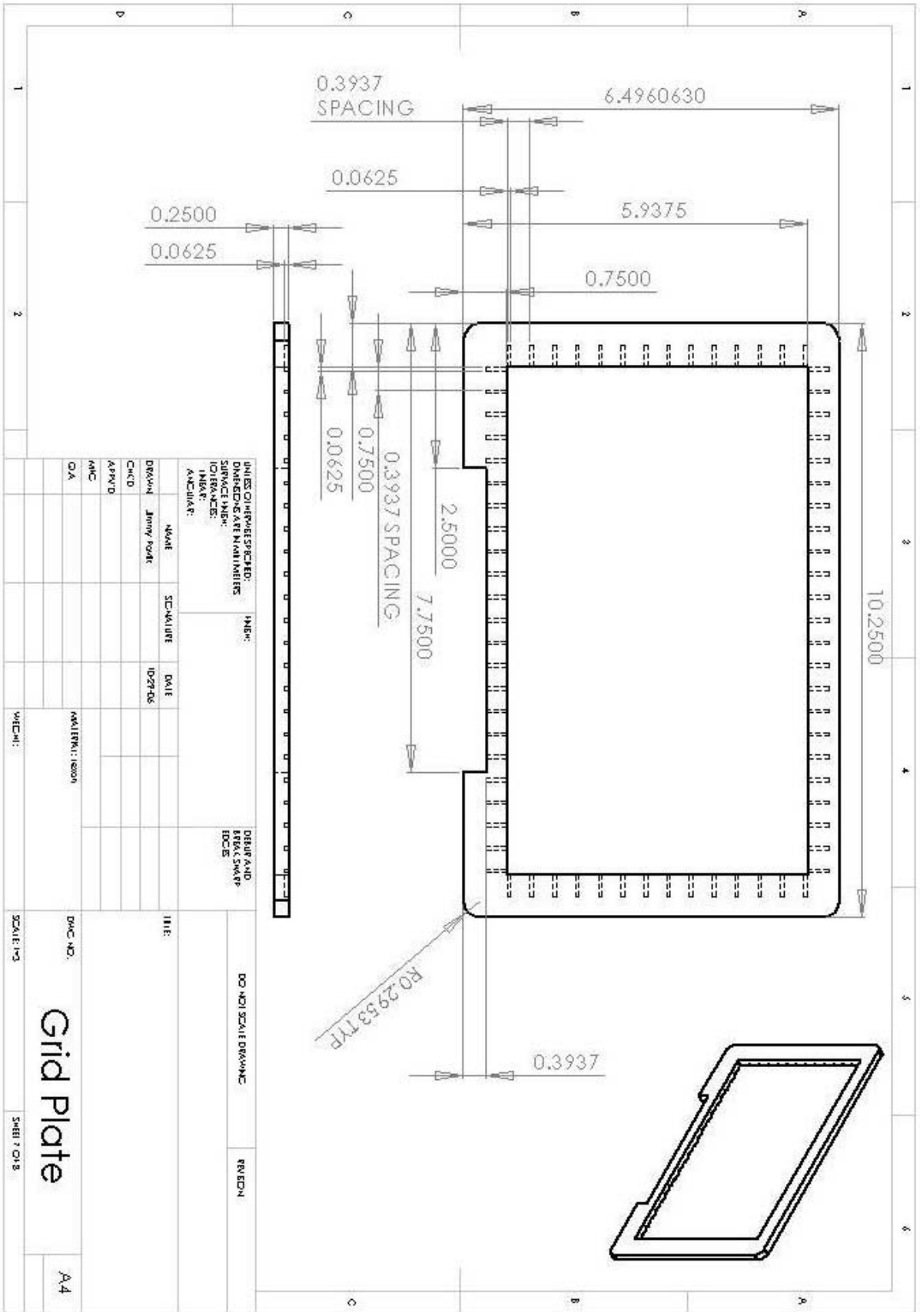


Figure F.5: Detail of Left Frame prototype

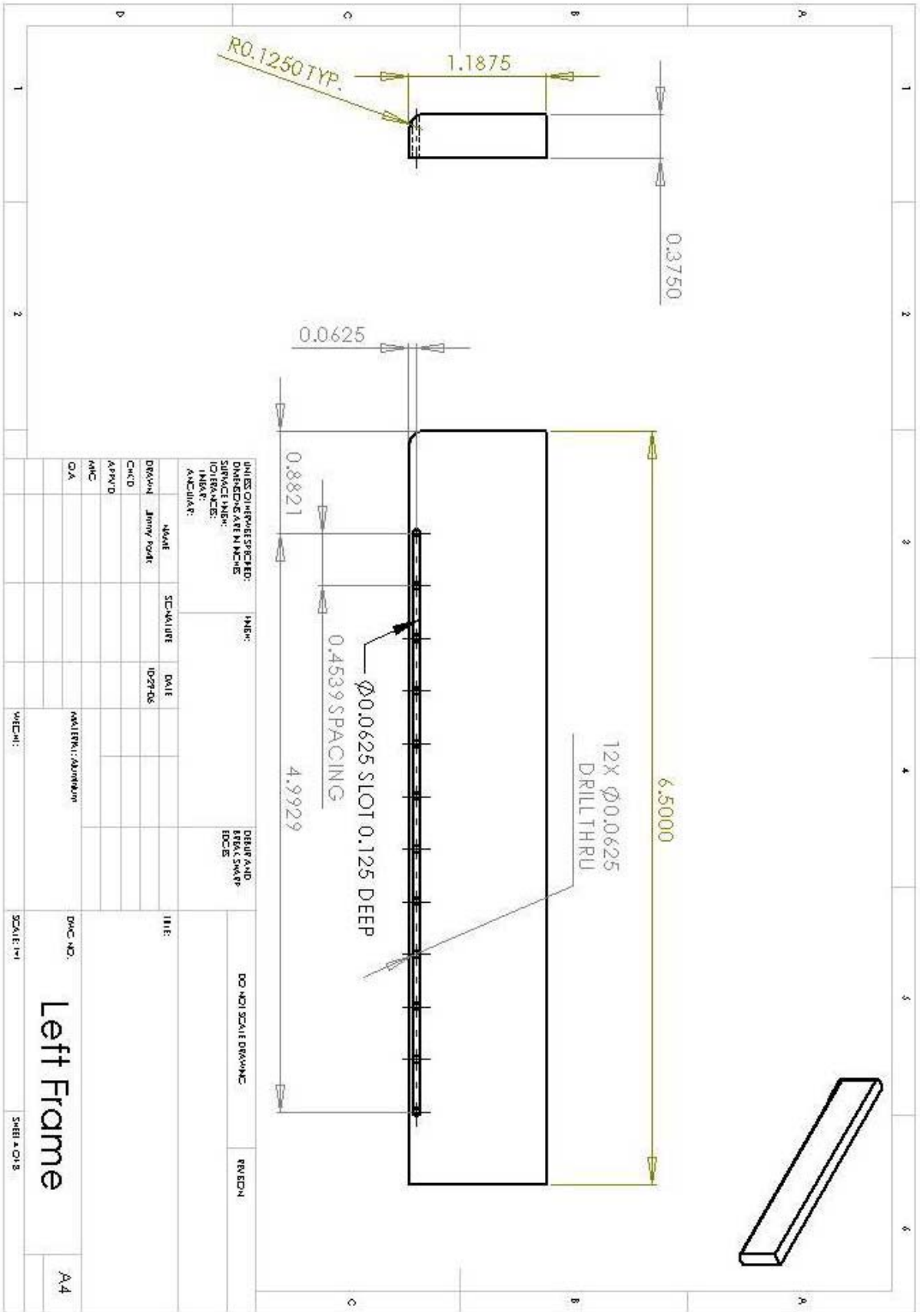


Figure F.6: Detail of Mounting Bracket Assembly prototype

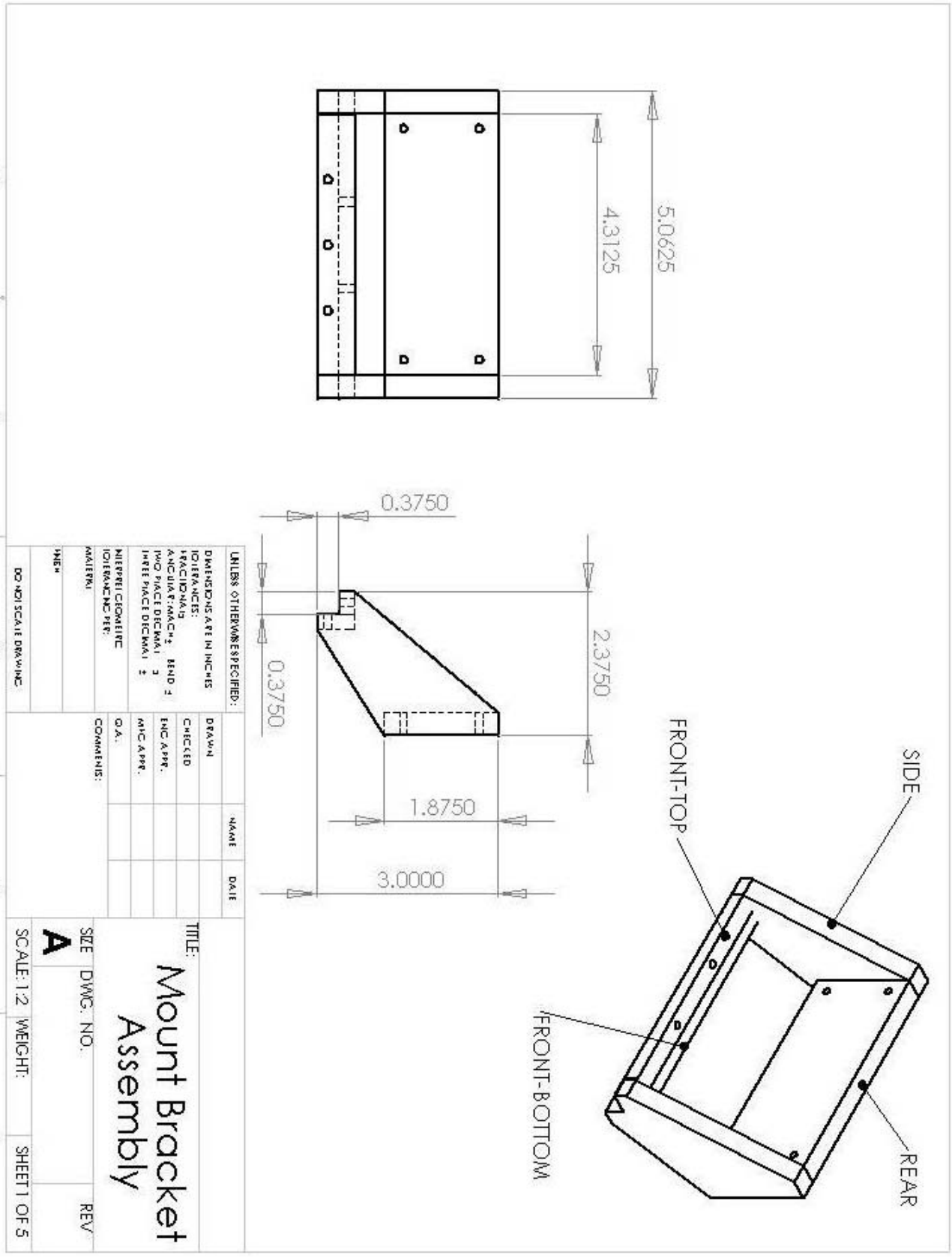


Figure F.7: Detail of Rear Frame prototype

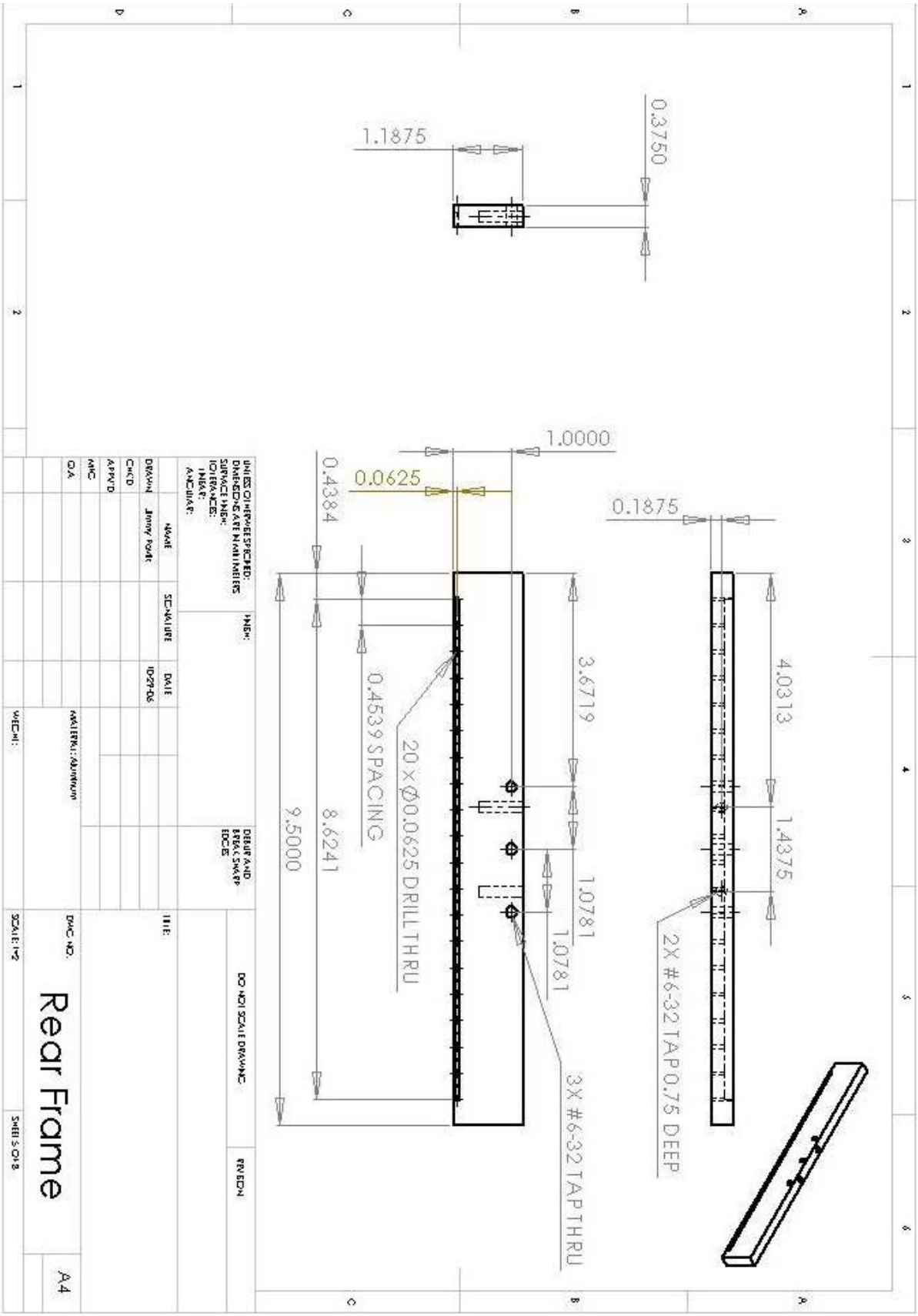


Figure F.8: Detail of Right Frame prototype

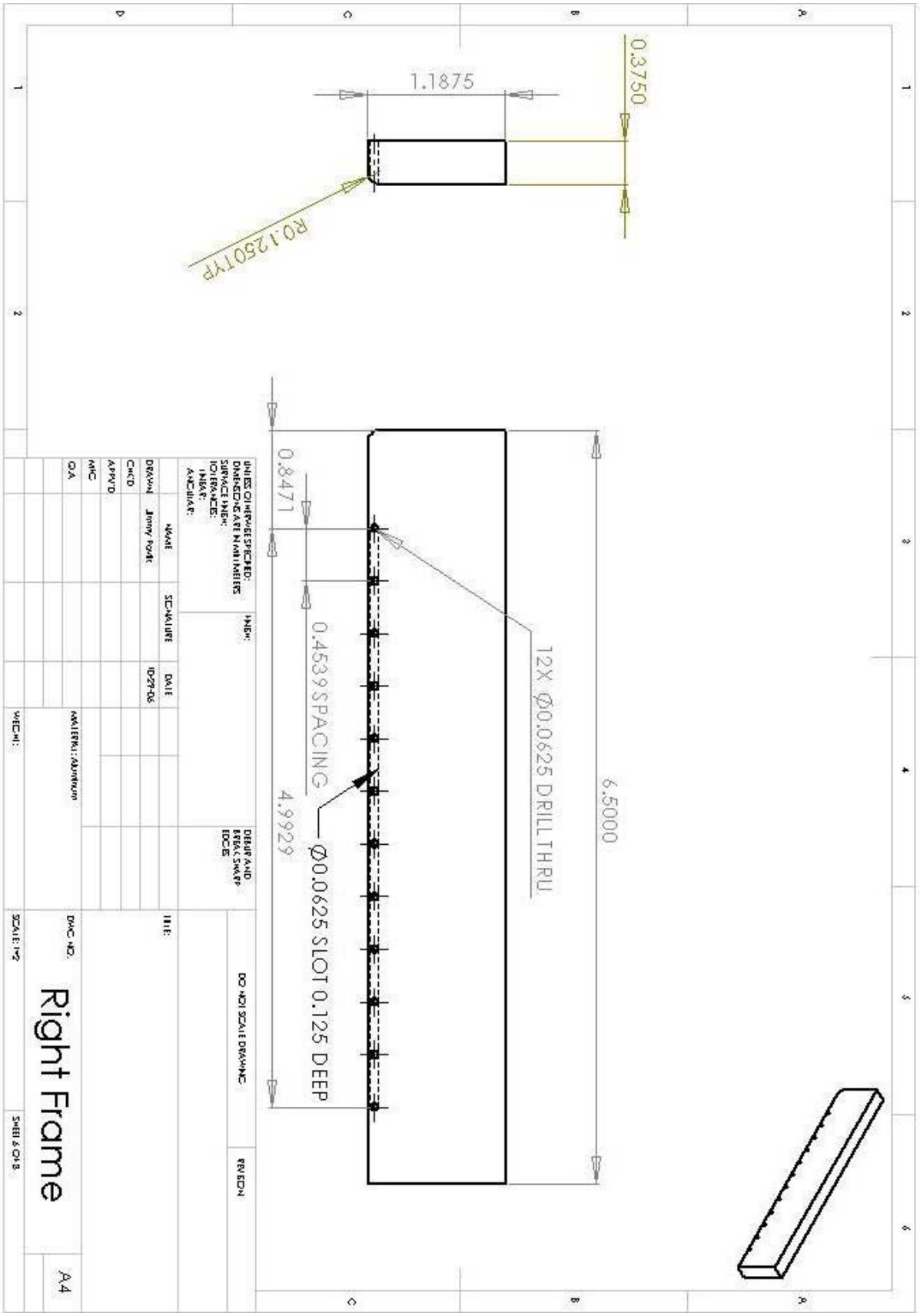


Figure F.9: Detail of Slide Adapter prototype

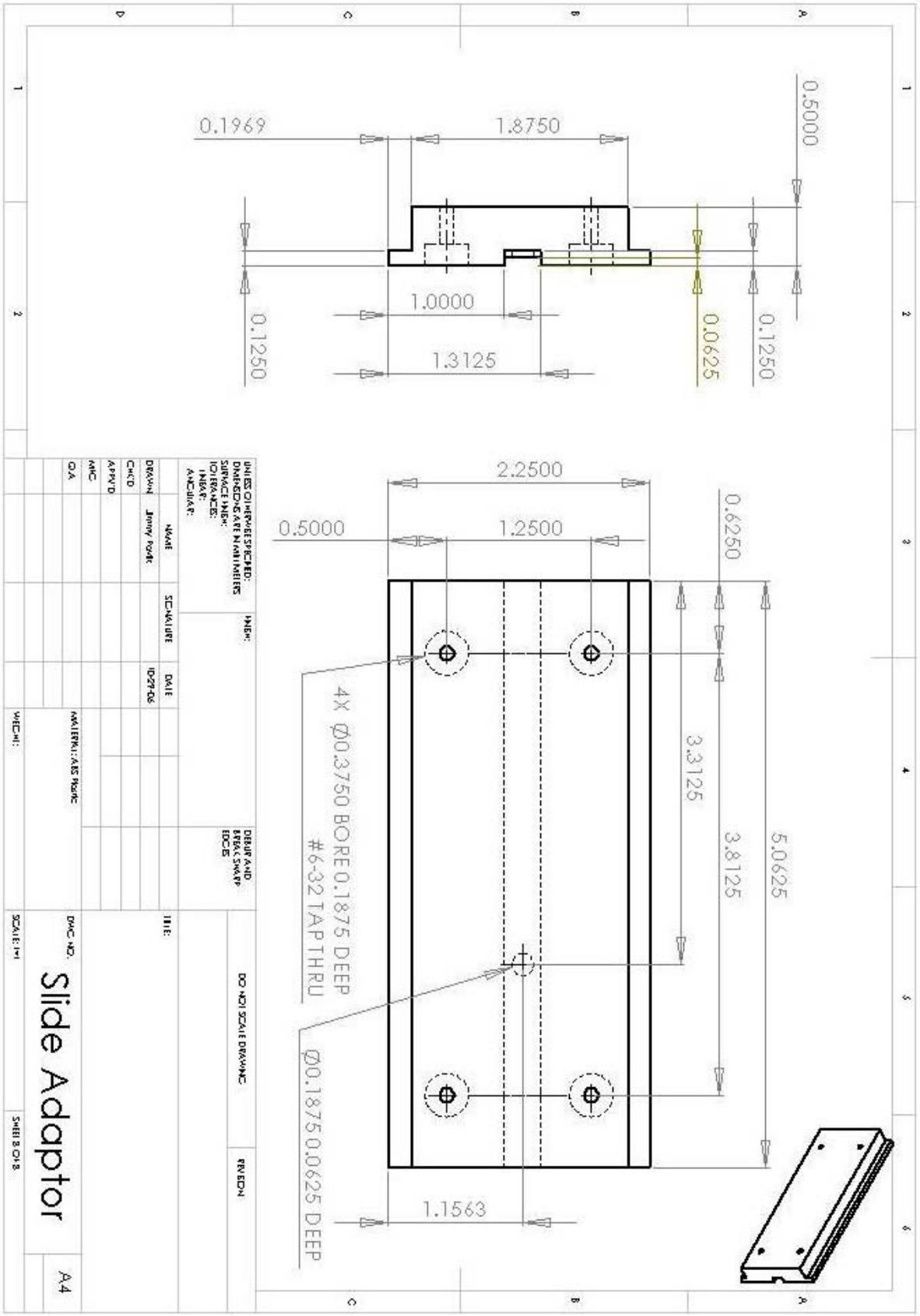


Figure F.10: Detail of Mount Bracket Front Bottom prototype

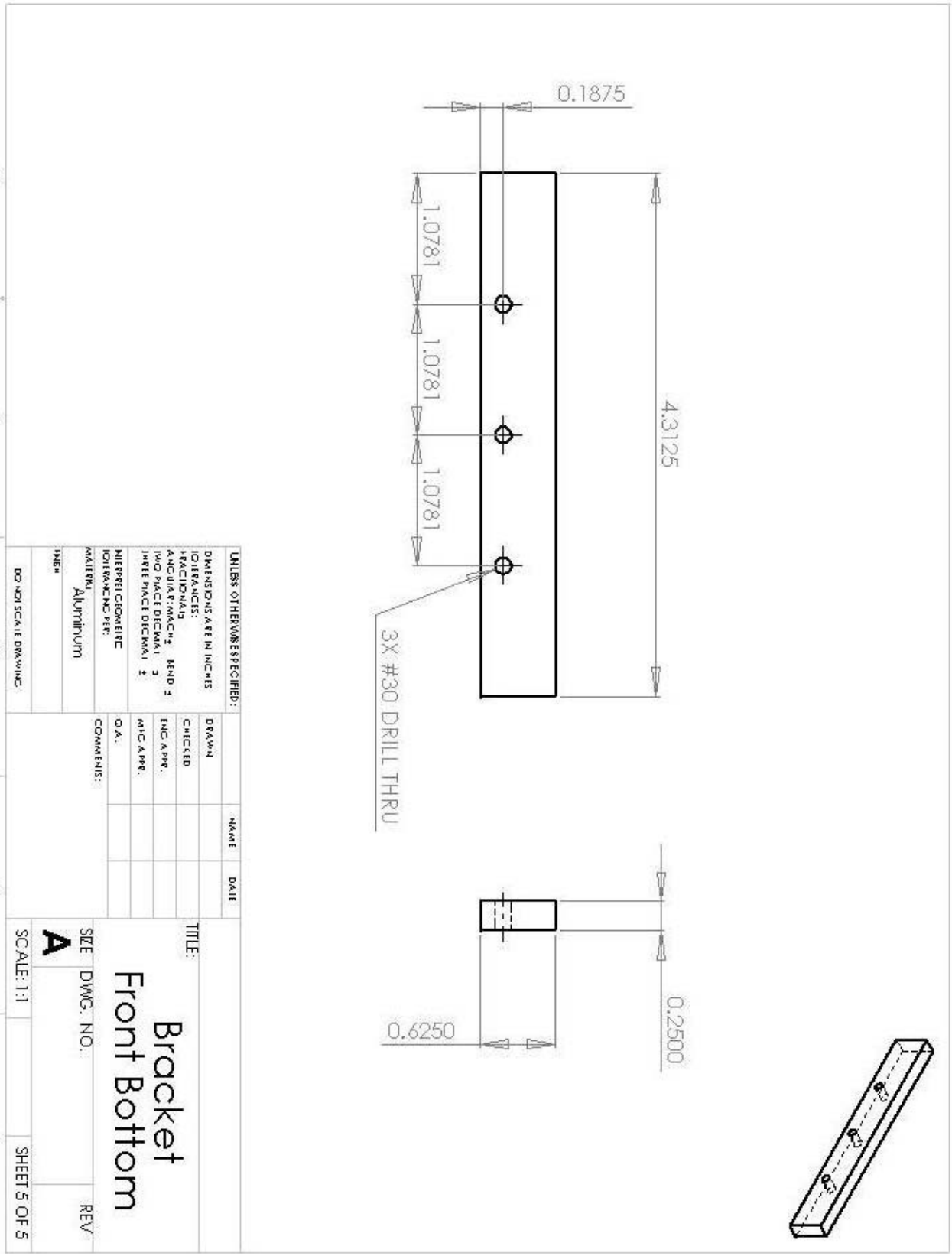


Figure F.11: Detail of Mount Bracket Front Top prototype

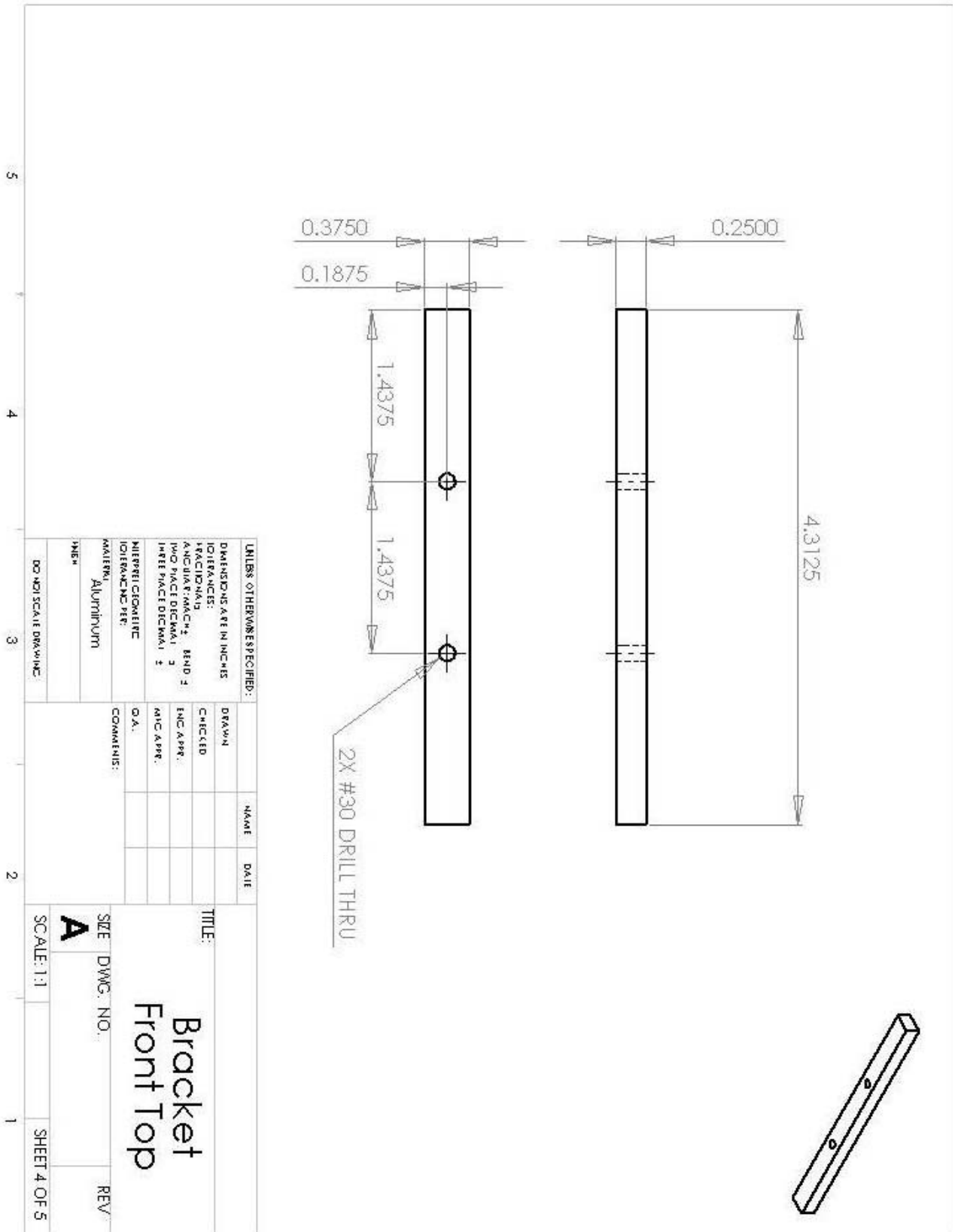


Figure F.12: Detail of Mount Bracket Rear prototype

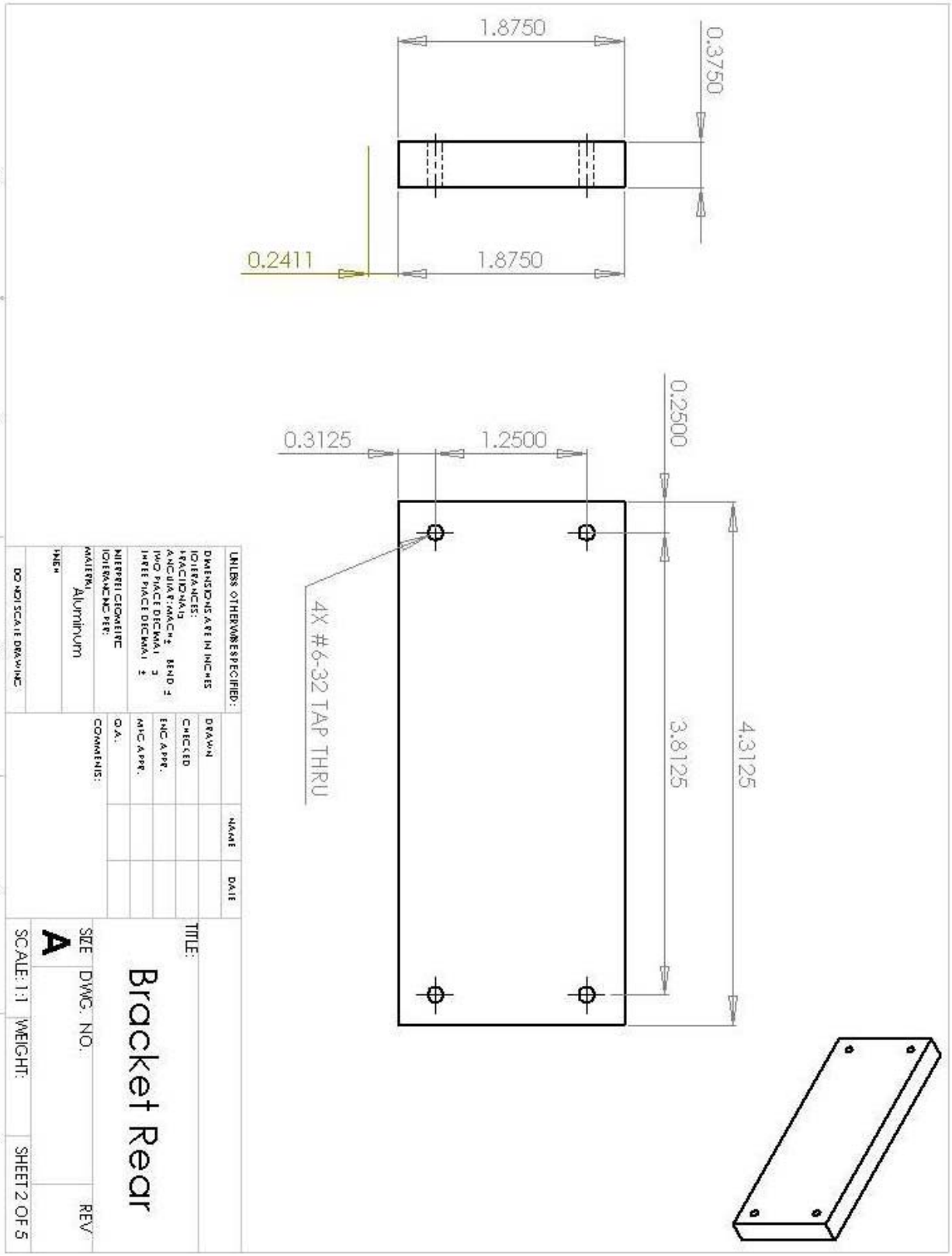


Figure F.13: Detail of Mount Bracket Side prototype

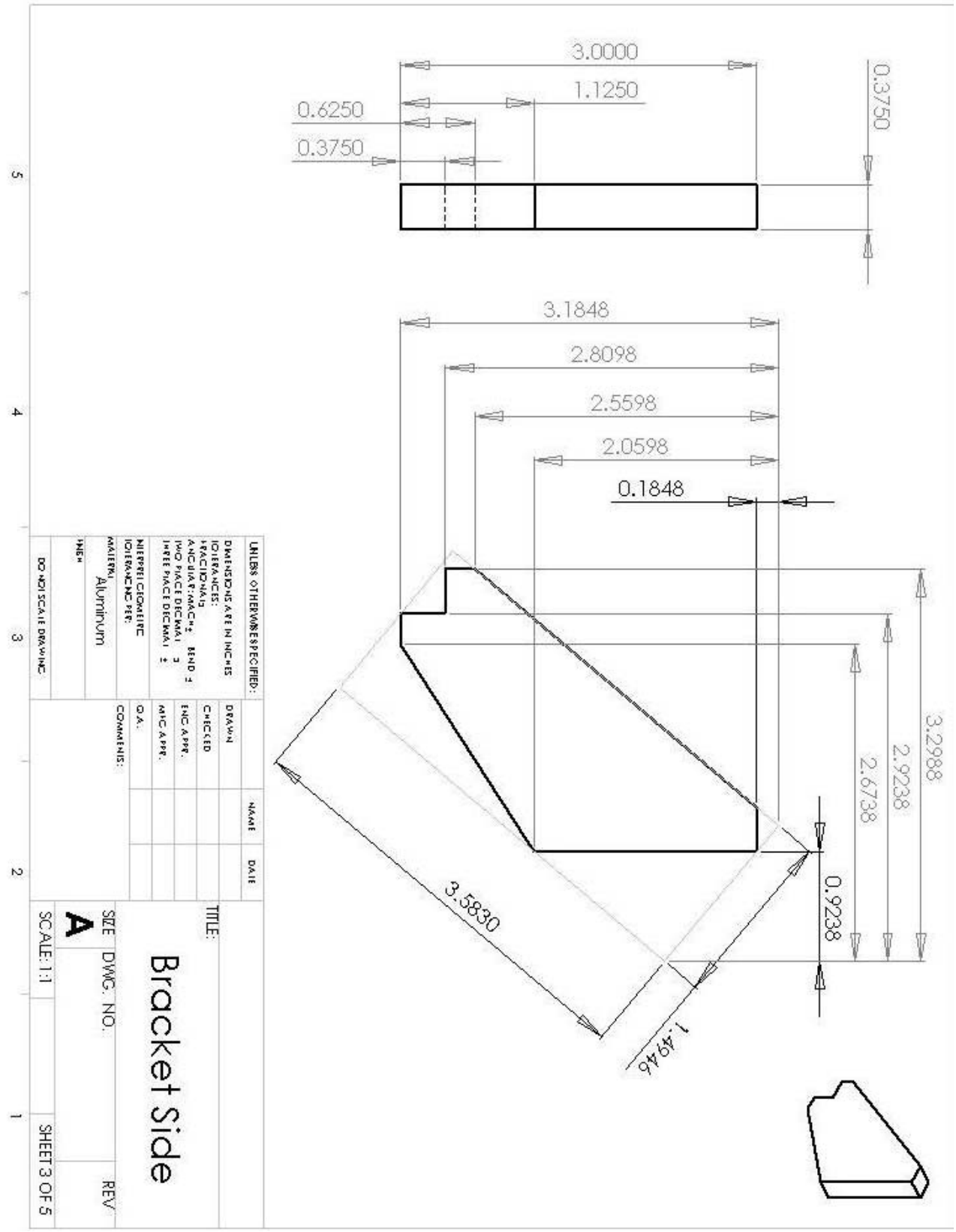
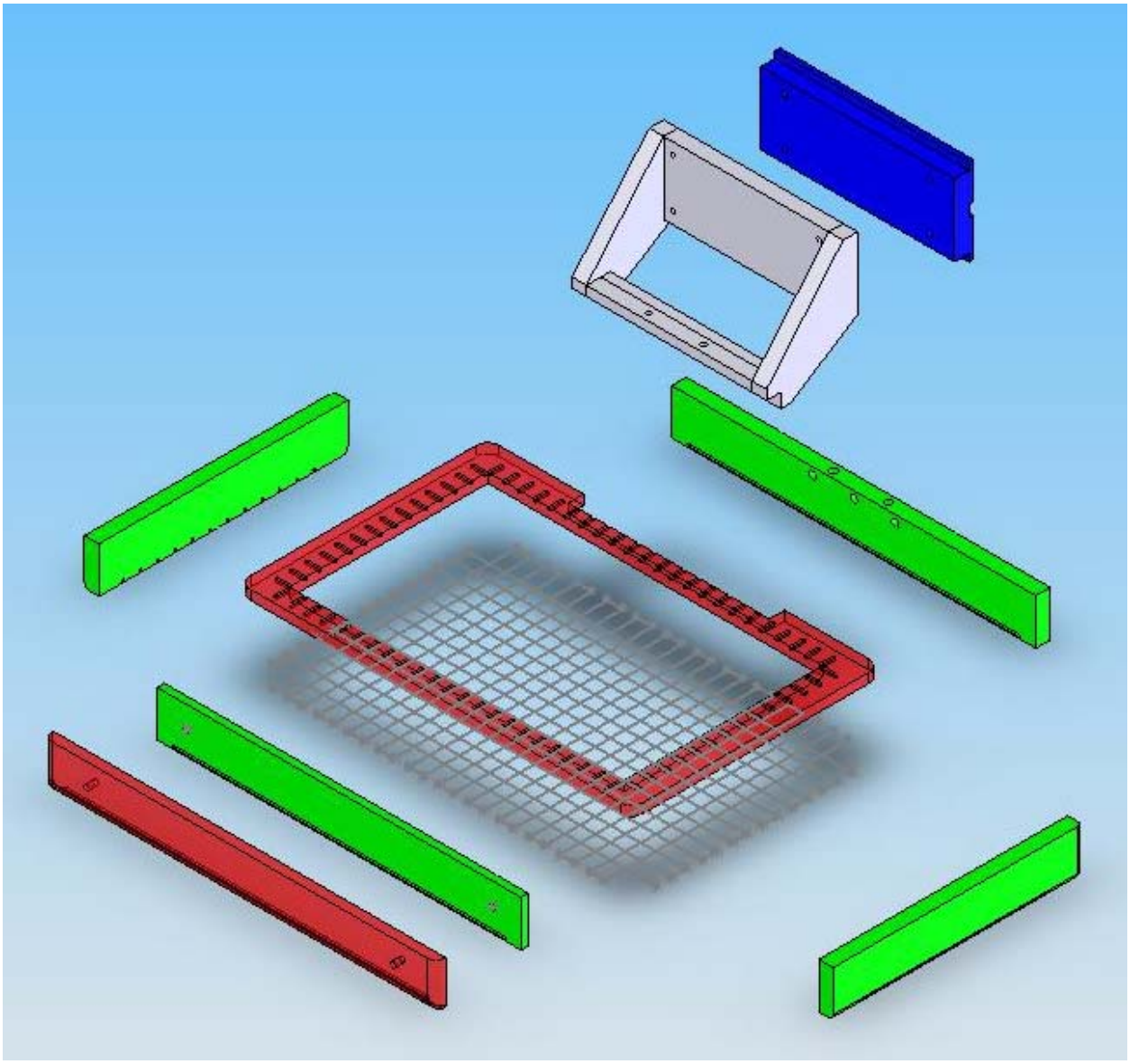
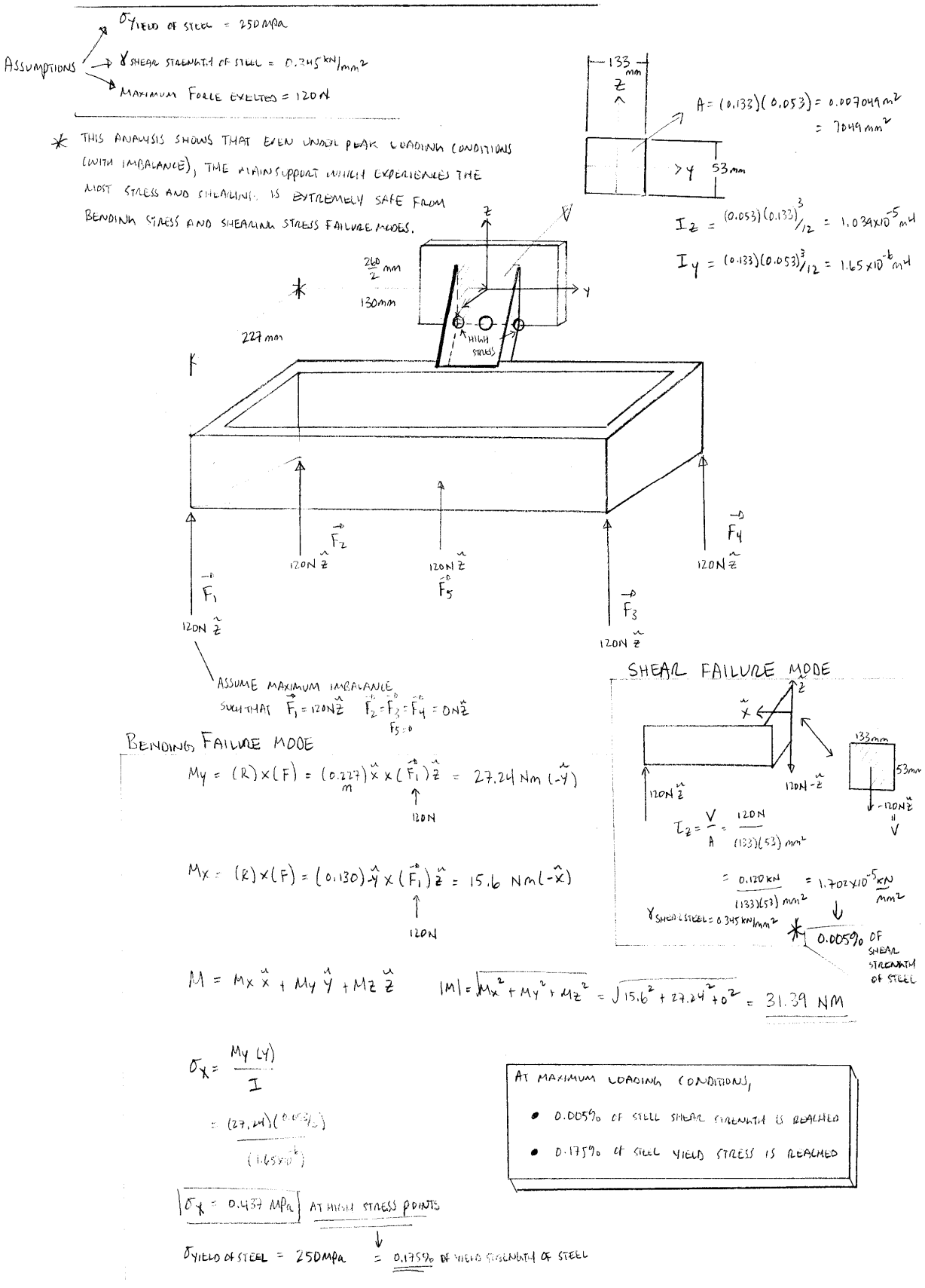


Figure F.14: Exploded view of the prototype component assembly



APPENDIX G – Free Body Diagram and statics calculations of compression paddle



APPENDIX H – Validation Testing Procedures

I. Radiolucency Testing

1. Each string will be catalogued and labeled accordingly.
2. Measurements of diameter will be taken.
3. Each string will be placed on the drone breast and an x-ray will be taken. It will then be determined how radiolucent the material is. This rating will be generated using a 1-10 scale, with 10 being the most radiolucent.
4. Each string will then be placed over a simulated calcification in the drone, and a similar test as (3) will be conducted. A rating from 1-10 will be generated based on how visible the calcification is beneath the string. A grade of 10 will correspond to a highly visible calcification, and a grade of 1 will correspond to a completely hidden calcification.

II. Tensile Testing

1. Each sample will be loaded into the Instron Tensile Testing Machine.
2. Each sample will then be loaded to 10 pounds of force to establish a baseline of loading.
3. Testing will continue, with loads rising by increments of 2 lbs. of force. At each level, measurements of material deflection will be taken.
4. Upon failure of the material, final force and deflection data will be collected.
5. All of the samples will then be ranked in order of yielding force.

III. Displacement Testing

1. Each sample will be loaded into the prototype frame, which will be secured in the Instron Tensile Testing Machine.
2. Initial loading of X lbs. of force will be applied to each sample.
3. After loading has been completed, a force of 10 lbs of force will be applied orthogonally to the sample.
4. Deflection of the sample from the reference frame will be measured, as well as the deflection of the skin through the grid mesh.
5. This procedure will be conducted for initial loading forces consistent with the procedure for tensile testing. (start with 10 lbs, move up in increments of 2 lbs until failure)

Figure H.1: Radiolucency contrast test rig of 8 strings

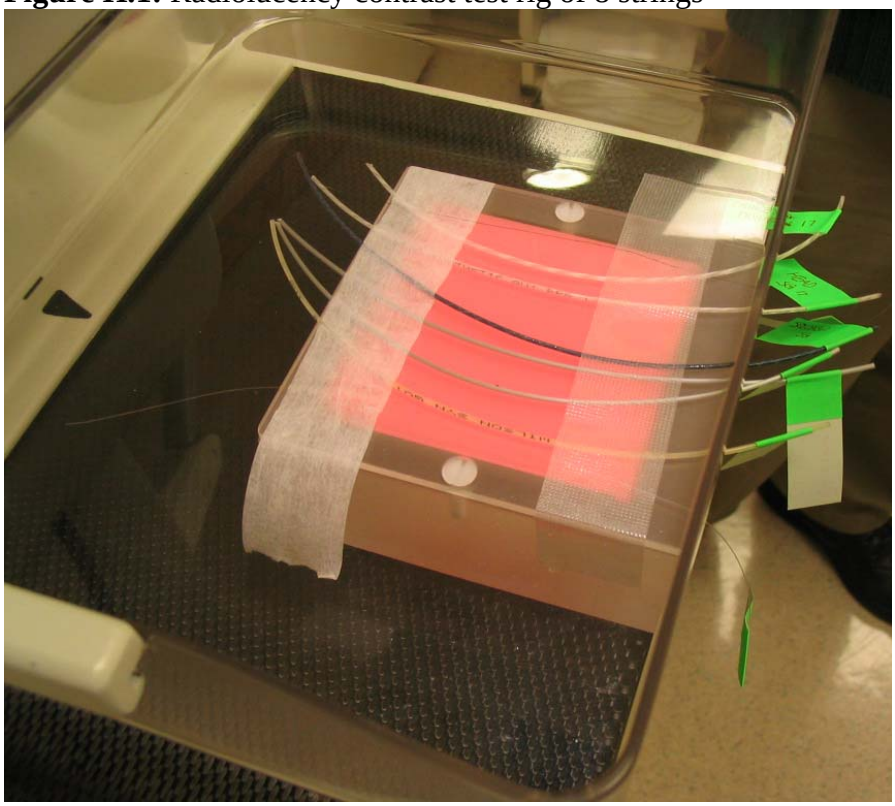


Figure H.2: Mock breast tissue and calcification radiolucency test rig

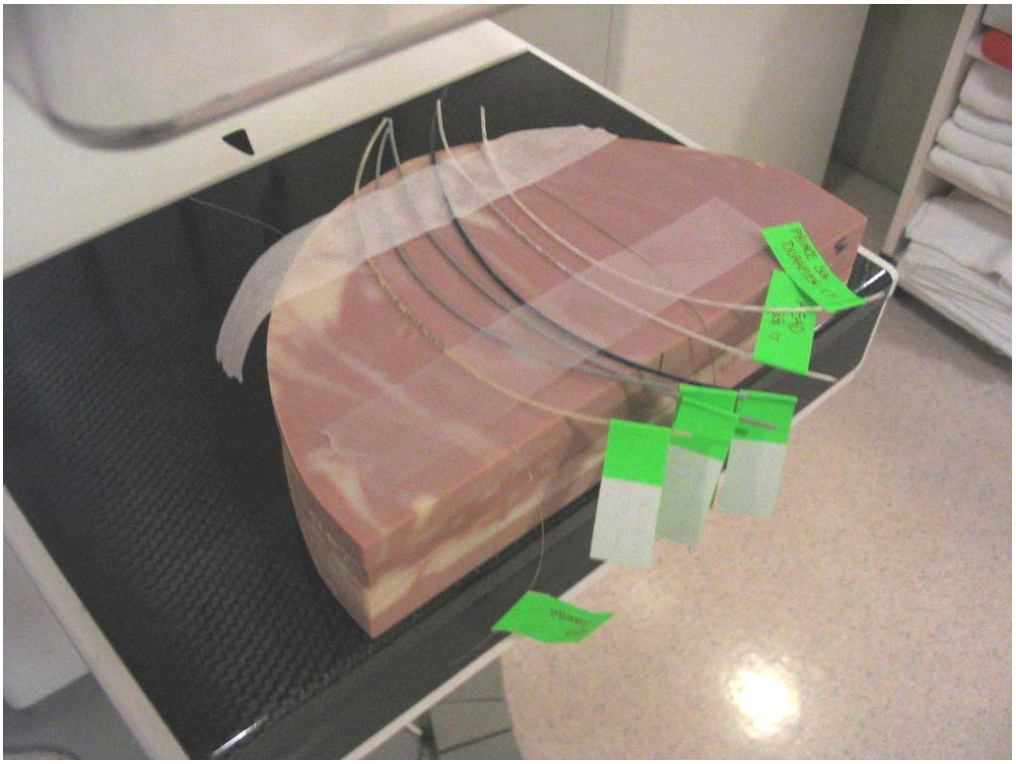


Figure H.3: FireLine is undetectable when thickened by three-fold

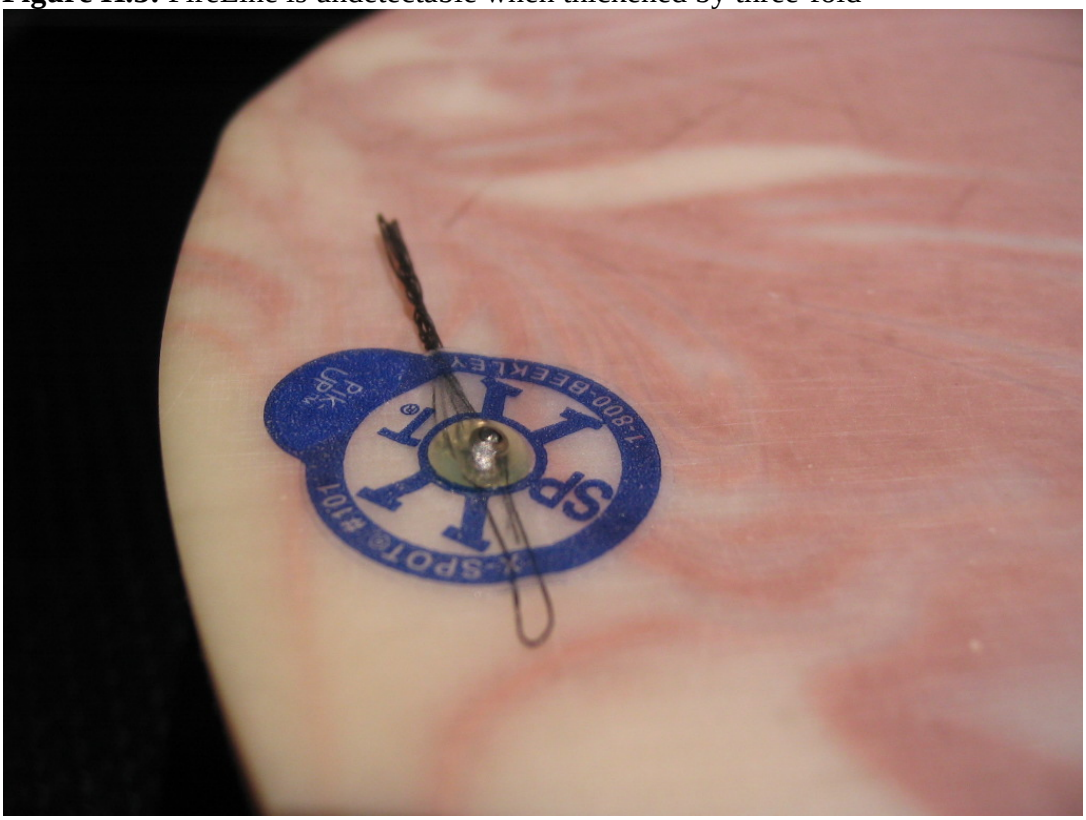
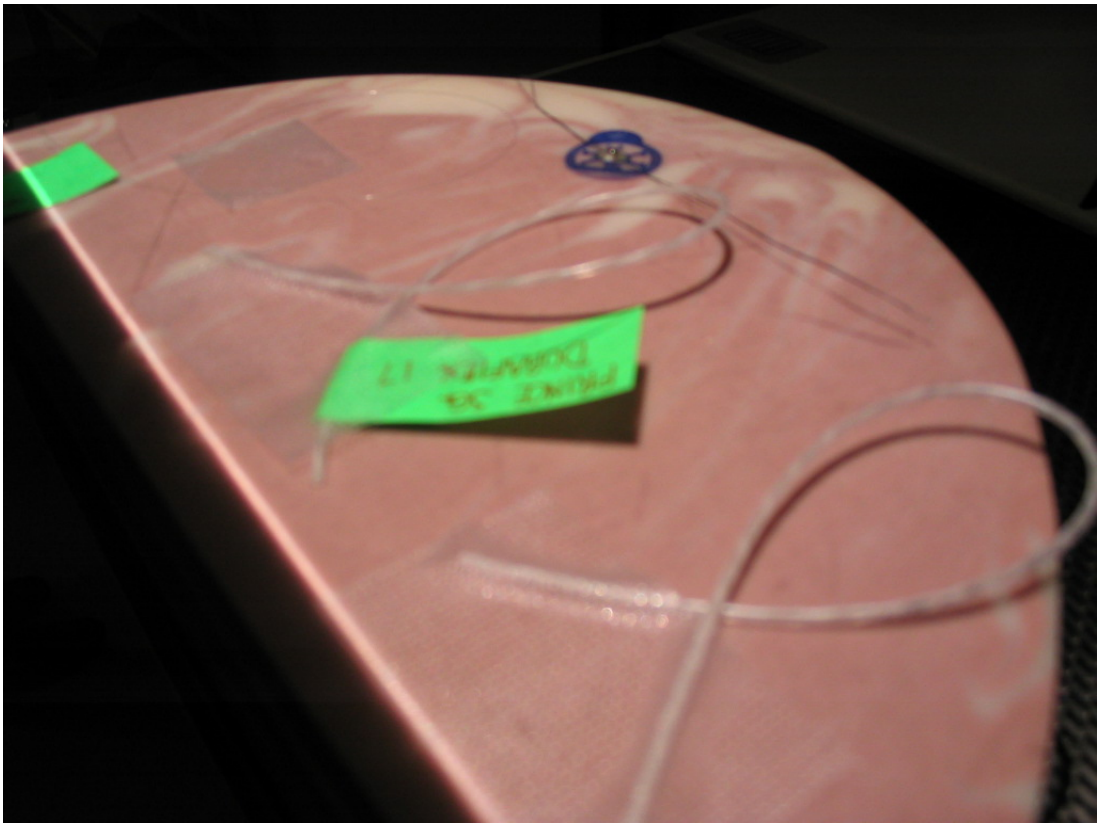


Figure H.4: String crossings does not present contrast issues in image detection



APPENDIX I – Assembled Prototype Pictures

Figure I.1: Front view of completed prototype assembly

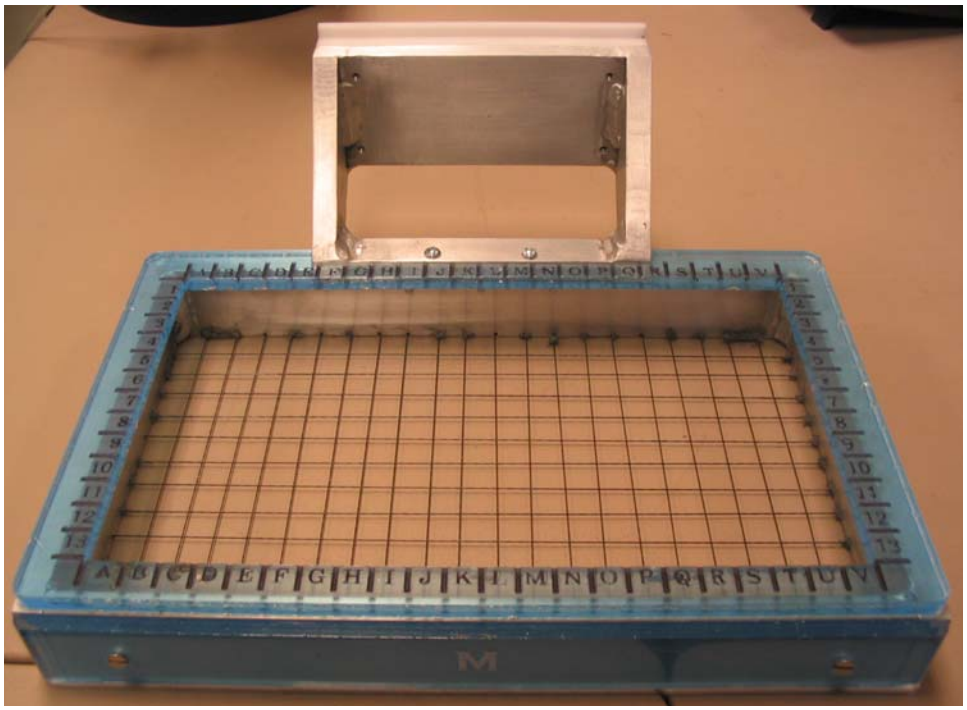


Figure I.2: Isotropic view of completed prototype assembly