

## Slit Lamp Ophthalmoscope Redesign

Michael Hostetler, Austin Mattmiller, Alexis Brewer

## Table of Contents

1.0	Executive Summary
2.0	Introduction and Background
3.0	Customer Requirements and Design Specifications
3.1	IFU
3.2	Product Design Specifications
3.3	House of Quality
4.0	Stage Gate Process
4.1	Concept Review
4.2	Design Freeze
4.3	Design Review
5.0	Description of Final Prototype Design
5.1	Overview
5.2	Design Justification
5.3	Analysis
5.4	Cost Breakdown
5.5	Safety Considerations
6.0	Prototype Development
6.1	Model Analyses
6.2	Evolution of Prototypes
6.3	Manufacturing Process
6.4	Divergence Between Final Design and Final Functional Prototype
7.0	IQ/OQ/PQ
7.1	DOE
7.2	Verification and Validation
8.0	Conclusions and Recommendations
8.1	Recommendations
8.2	Conclusions
9.0	Acknowledgments
10.0	Appendices
10.1	Appendix A: References
10.2	Appendix B: Project Plan (PERT Chart)
10.3	Appendix C: CAD Drawings
10.4	Appendix D: FMEA, Hazard & Risk Assessment
10.5	Appendix E: Pugh Chart
10.6	Appendix F: Vendor Information, Specifications, and Data Sheets
10.7	Appendix G: Budget
10.8	Appendix H: Raw Data

## 1.0 Executive Summary

The slit lamp ophthalmoscope is used by ophthalmologists for diagnosis of pathologies in the eye. The device is used for identifying ocular diseases or indications of other possible systemic diseases to treat them before the diseases progress. Redesign of the ergonomics and adjustment mechanisms of the slit lamp ophthalmoscope will attempt to improve the compatibility of the device across a greater variety of patients. The wider headrest tower of 12.75 inches, the wider table cutout of 12 inches, and the 12 inches of extension of the headrest tower creates a better ergonomic fit for the patient and doctor. The wider headrest tower will decrease the proximity of the doctor's hand when adjusting the device and give more space to the patient, while the wider table cutout and extension will allow the patient to sit comfortably for longer periods than the previous device. For a quality diagnosis, correct positioning of the ophthalmoscope is required. Deflection tests were done to ensure position of the headrest tower was not compromised during loading. All p-values were less than 0.001 meaning the device can withstand loading of a patient's head without a change in eye position in the microscope view. The ergonomic capability was also tested with the headrest tower to make sure sufficient space was available for the patient to measure our specification for greater comfort in the device. The patient needs to be very still without moving their head position, which is why patient comfort is essential for a quality examination by an ophthalmologist.

## 2.0 Introduction and Background

### 2.1 Introduction

The slit lamp ophthalmoscope is a device used to examine an individual's eyes to diagnose disease. Patient exams are limited by the technology used by the ophthalmologist to correctly identify specific details of the eye. The eye can reveal a large percentage of health issues, even before they are detected elsewhere in the body or by the patient. This project is about revising the current slit lamp ophthalmoscope to benefit the patient so they are comfortable during the exam which in turn benefits the ophthalmologist to give a better diagnosis from a more thorough examination. Ophthalmologists diagnose what they can see and are limited by the mobility of the current slit lamp ophthalmoscope. The background of the slit lamp ophthalmoscope will explain the shortcomings of the current device. The product specifications will guide the changes that are being made and the timeline of major due dates are shown in the project planning section in **Appendix B**.

### 2.2 Background

Technology is constantly evolving as new inventions are created and used to perform tasks to meet the needs of society. When the first ophthalmoscope was created in 1877 by von Zehender and Westien, the device was improved upon many times until finally in 1950, Littman had unveiled a new version of the device with a multitude of adjustment possibilities that was recognized for its technical progress. Since the final adjustments unveiled in 1975 of the lateral and vertical adjustability options, there has not been advancement in the ergonomics or positioning of the device (1).

While most of the current slit lamp ophthalmoscopes have very similar designs, there have been some improvements that give some variability based on what the developers believe consumers want most. There has been some improvement in making the device lighter and more

portable as well as having a device with lithium rechargeable batteries (2). This is a change from the standard slit lamp ophthalmoscopes that most optometrists own and is designed to be used ideally by pediatrics, nursing homes, etc. There are also other slit lamp ophthalmoscopes that provide “live images in real time at 10x magnification,” connect to WiFi, and have an improved rechargeable battery life of four hours (3). These devices are typically used in a rapid bedside diagnosis. In another design, a built-in integrated diffuser in the filter wheel was added to give the examiner a better view of the eye for diagnosis (4). Another feature added to the stationary slit lamp ophthalmoscopes is a higher resolution camera and speed 50% faster than previous models (6). This allows for a more accurate diagnosis and a shorter time for the patient to remain in the same position. An autofocus and image capture feature were added to a slit lamp microscope that helps in adjusting light conditions to provide a more accurate diagnosis over an extended period of time (7). While the general structure and purpose of the ophthalmoscope has remained the same, there have been various changes that target improving the diagnosis of ocular pathologies.

After completing a slit lamp ophthalmoscope patent search in the United States, the first slit lamp was patented in 1974 (5). This device model has remained relatively the same throughout the years as modern technology greatly enhanced its functionality, but left the ergonomic design as it was originally. **Table 1** conveys some of the patented changes that have been made through the years.

**Table 1. Slit Lamp Patent Search Results**

United States Patent #	Title
3,832,041	OPHTHALMOLOGICAL APPARATUS FOR USE IN AN EXAMINING ROOM
3,944,341	WIDE-ANGLE OPHTHALMOSCOPE AND FUNDUS CAMERA
4,128,317	HEAD POSITIONING MEANS FOR OPHTHALMIC EXAMINATIONS
7,347,552	DEVICE FOR EXAMINING THE ANTERIOR AND POSTERIOR SEGMENTS OF THE EYEBALL
7,708,402	GOGGLES FOR IMPROVED OCULAR VISION

Progress in retinal and ocular research has led us to be able to start to use artificial intelligence to offer insight into the condition of the retina and ocular disease (8). This is the newest form of technology still in development when diagnosing the conditions in the eye. Machine learning and deep learning can assist doctors to compile a database of known diseases and their symptoms when viewing the eye to give more accurate diagnosis and better treatment following an exam. Retinal drug delivery options are also starting to emerge in the world as treatment for retinal diseases that can lead to visual impairment and blindness (10). The slit lamp ophthalmoscope needs to be improved with modern technology to work precisely for every

patient, to provide the optimal form of treatment. If we can improve the current design of the slit lamp ophthalmoscope to have a comfortable and accurate eye examination for any individual, then we can further improve examinations for better treatment and early stage prevention.

Recent developments in imaging technologies now allow documentation, qualitative, and quantitative evaluation of peripheral retinal lesions (12). This means we can compile data for use in future diagnostic exams if we are able to correctly examine the human eye with a newly designed ophthalmoscope. Integrating a better set of tools will help streamline the exam process while making it more accurate and comfortable for the patient and doctor to use. A new device, an indirect ophthalmoscope, could provide a higher magnification (up to 15X) that would offer advantages in fundus and eye diagnosis during an eye exam (12). A higher magnification of the eye without the direct increase in brightness would provide an advantage to diagnosis and surgical uses. A better ophthalmoscope would be a breakthrough in the field. For now, adjustable brightness is a main aspect for improvement along with adjustments for compatibility with all patients.

From the FDA guidelines there are many different standards and regulations that must be followed for this device. The regulation number is 886.1850 and the standards and regulations required for this device are listed below in **Table 2** (9).

**Table 2.** FDA Standards and Regulations

Standard/Regulation	Description
ISO 10939, 15004	Specifies requirements and test methods for slit-lamp ophthalmoscopes
IEC 60601- 1	Medical electrical equipment: General requirements for safety
IEC 60601- 4	Collateral Standard: Programmable electrical medical systems
UL 544	Professional Medical and Dental Equipment
UL 2601-1	Medical electrical equipment: General requirements for safety
21 CFR 801, 21 CFR 502	Misbranded drugs and devices
21 CFR sections 1040.10 and 1040.11	Laser safety and labelling

Many lenses and pieces of the slit lamp ophthalmoscope have been updated in the last 50 years, but the functionality, compatibility, and comfortability have remained the same. The current design of the slit lamp ophthalmoscope is effective for diagnosis and complete redesign of the device is unnecessary, however a few modifications can be made to make the device more comfortable and easier to use. The discussions with Dr. Mark Sherman helped solidify what

changes and advancements need to be made to better the device including the need for precision, ergonomics, and mobility of the device.

### 3.0 Customer Requirements and Design Specifications

#### 3.1 Indications For Use

The modified slit lamp ophthalmoscope is a non-invasive device which is AC-powered and used by an ophthalmologist or optometrist to examine the media (cornea, aqueous humor, lens, and vitreous humor) and the retina of the eye. The ergonomic and adjustability modifications make the device easier to use for a wide variety of patients and doctors during an in office examination.

#### 3.2 Product Design Specifications

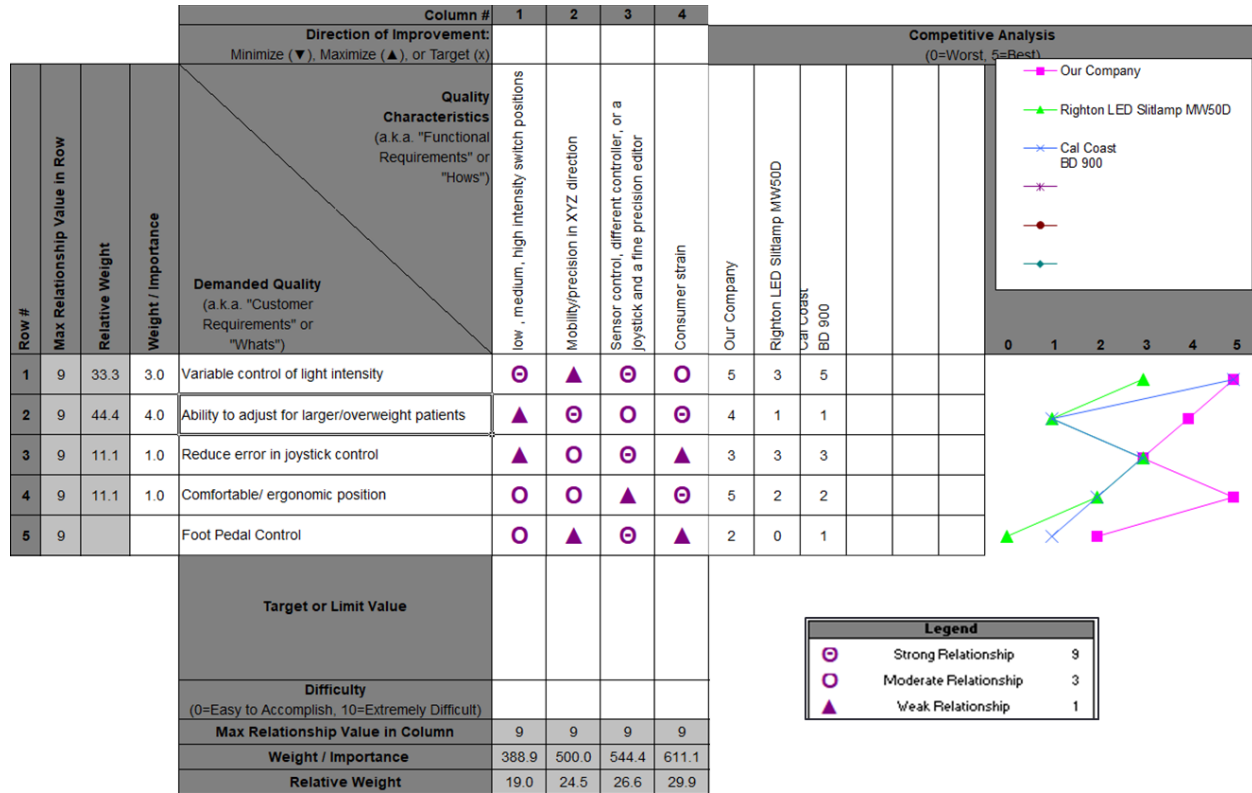
The specifications of this device were derived from the requirements of Dr. Mark Sherman and can be found in **Table 3**.

**Table 3.** Customer requirements for the improved slit lamp design.

Customer Requirement	Engineering Metric	Specification	Rationale
Variable control of light intensity	Low, medium, high intensity switch positions	Brightness in lumens % of full light brightness - 0-100%.	Light needs to be bright enough for examiner to see into a patient's eye but comfortable for extended use
Ability to adjust for larger/overweight patients	Clearance from table in inches	Minimum 1" clearance for patients who are overweight	Having a wider cut out of the table allows for the patient to sit closer to the slit lamp ophthalmoscope and to have a more accurate eye examination.
Support patient's head while maintaining proper eye position.	Pounds of force	Support 20 lbs. and deflect less than 5 degrees vertically and horizontally	A patient's eye needs to be in the proper position, this specification provides a factor of safety of 2 to ensure the device can be loaded without deflection

### 3.3 House of Quality

The house of quality matrix seen below in **Figure 1** relates customer requirements with each of the quality characteristics to determine the weight or importance of each.



**Figure 1.** House of Quality matrix ranking the importance of the features.

## 4.0 Stage Gate Process

### 4.1 Concept Review

Several concepts were considered before narrowing our design and scope of work to meet the requirements of our sponsor within the given timeframe. Our first concept of the modified slit lamp ophthalmoscope features a larger portion of the table cut out in order to provide more space for the patient comfort. A pneumatic pump will be added to adjust the headrest in a front/back and up/down direction. It also features a wider headrest support in order to allow for more range of motion of the slit lamp on the doctors end. The second concept of the modified slit lamp ophthalmoscope features a foot pedal pump that adjusts the headrest height. There also will be a wider headrest in order to accommodate the swiveling motion of the slit lamp. It will also have two small circular indents in the table to hold eye drops. The third version of the modified slit lamp has a foot pedal for moving the headrest tower up/down and forward/backward. There is a bag or holder clipped to the side of the table for holding eye drops and other supplies that may be needed during an exam. The table has a cut out for more room for the patient. The headrest also is able to move forwards and backwards when needed. The final concept, which we decided to pursue, has a larger cut out of the table, a drawer track to adjust the headrest forward and

backward with a stopping mechanism in place, a wider headrest to allow for swivel motion of the slit lamp, and a continuous variable light dimmer switch.

#### **4.2 Design Freeze**

For our final design we decided to reuse the vertical posts from the donated slit lamp. This allowed us to reuse the threaded post for the vertical chin rest adjustment. For the forward and backward motion of the headrest tower, we used a 12” drawer track. We attached this to the table by using a 12” aluminum angle and attached the drawer slide to a 12” long square aluminum tube. The vertical posts would be welded to the top of the square tube to be secured in place. We also made the headrest 22” wide to allow for less awkward vertical adjustment for the patient as well as allowing for the swivel of the slit lamp. We improved the previous light switch by adding a dimmer switch for continuous variability of light. Finally, we increased the dimensions of the cutout in the table for overweight patients.

#### **4.3 Design Review**

The final design is different in a few ways than the initial device design. First, we added a support bar across the top of the vertical posts to stabilize the head rest compared to not having a support bar in the initial design. A major change we had to make was the attachment of the vertical posts to the aluminum square tubing. Instead of welding the parts together at a 90 degree angle, we bored a hole into the top surface of the tubing to fit the post through. We then drilled a hole through the bottom side of the tubing concentric with the bored hole on top. Then we tapped the hole to size a bolt through the bottom sticking straight out of the bored hole to slide the vertical post onto to create a more rigid and supportive base. There was a small change in the cover plate over the light switch as we bought a plastic cover plate instead of using aluminum sheet metal. We made a few aesthetic changes to make the whole device look better including rounding some corners and additional sanding. Then, the table, chin rest, and support bar were lightly sanded and a clear coat of polyurethane was applied to the surfaces to create a finish that could be wiped clean if necessary.

## **5.0 Description of Final Prototype Design**

### **5.1 Overview**

The final prototype slit lamp ophthalmoscope has a larger table for more ease of use and to support a wider chin rest and headrest structure. The chinrest can be adjusted up and down on the vertical posts as on the existing slit lamp and, in addition to this, the headrest tower is mounted on drawer slides to allow for twelve inches of front to back adjustment. The table also has a larger elliptical cutout beneath the headrest and the slit lamp was wired with a variable brightness light switch.

### **5.2 Design Justification**

This design was chosen because the larger cut out in the table, an ellipse that is 18” wide and 5” deep allows for patients that have a larger midsection to sit comfortably in the table. The chinrest curves out and can be moved front to back on the drawer slides to mitigate the strain of leaning into the machine by allowing the chin rest to come to the patient. Furthermore, the wider chinrest alleviates the feeling of claustrophobia and the awkwardness of the ophthalmologist



adjusting the chin rest in close proximity to the patient's face. Lastly, the adjustable light switch allows for the ophthalmologist to dim the brightness of the light, if the light is too bright in the patient's eye and causing discomfort.

### **5.3 Analysis**

After completion of our final prototype device we believe it could be produced as a beneficial product for optometrists and ophthalmologists. There are a few things that could be streamlined in the manufacturing process by using plastics instead of wood or already made tabletops with a premade table stand on wheels. The overall design is a prototype that could be remade to be more aesthetic with more rounded corners and tighter tolerances on machining than we were capable of with our equipment. The device works as intended within the scope of work we were given. Overall we are pleased with the functionality and range of motion, however, a more compact or smaller set of drawer slides could make the device less bulky. The full extension on the drawer slides is not necessary, but if the device was made and used in a clinic it may be utilized more than we can predict.

### **5.4 Cost Breakdown**

The cost of each of the parts required to manufacture a single modified slit lamp table and head rest can be found on the next page in **Table 4**.

**Table 4.** Cost breakdown of materials required to build one slit lamp table and head rest.

Item Description	Supplier	Product Number	Unit	Quantity	Cost/ Unit	Total Cost	Amount Used in 1 Device	Cost for 1 Device
12" Full Extension Ball Bearing Drawer Slide	Home Depot	D80612C-Z P-W	2-pack	1	\$11.98	\$11.98	1	\$11.98
1.5"x 48" 1/16" Aluminum Angle	Home Depot	802597	inch	1	\$19.57	\$19.57	24" (1/2)	\$9.79
Skylark Contour C.L Dimmer Switch for Dimmable LED, Halogen and Incandescent Bulbs, Single-Pole or 3-Way, White	Home Depot	CTCL-153 PDH-WH	unit	1	\$21.97	\$21.97	1	\$21.97
23.75"x47.75"x0.75" Birch Plywood	Home Depot	813952011 723	inch	1	\$26.75	\$26.75	24"x 24" (1/2)	\$13.38
1"x1"x48" 1/16 Aluminum Square Tubing	Home Depot	801307	inch	1	\$19.54	\$19.54	24" (1/2)	\$9.77
5/32" 1.5" Machine Screws and Nuts	Miners Ace	395380-A	unit	6	\$0.55	\$3.30	6	\$3.30
#4 3/4 Cabinet Screw	Miners Ace	439202	unit	6	\$0.11	\$0.66	6	\$0.66
1/4-20" Machine Screw	Miners Ace	1787L	unit	6	\$0.27	\$1.62	6	\$1.62
1/4"-20 Nuts	Miners Ace	H180147	unit	6	\$0.14	\$0.84	6	\$0.84
Hex Bolts 1/4"	Home Depot	AFD	inch	2	\$0.20	\$0.40	2	\$0.40
Light Cover	Home Depot	CW-1-WH	unit	1	\$3.96	\$3.96	1	\$3.96
16-14 AWG Butt Splice Wire Connectors 15Pk	Home Depot	15-123	unit	1	\$2.51	\$2.51	4	\$0.63
3/4"x 30' Vinyl Carded Electrical Tape	Home Depot	30002656	unit	1	\$2.24	\$2.24	1/10	\$0.22
Tack Cloths 3Pk	Home Depot	HDTC-3PK	unit	1	\$2.97	\$2.97	1/3	\$0.99
2" Polyester/Bristle Stain Brush	Home Depot	HD 1521-2	unit	1	\$7.47	\$7.47	1	\$7.47
Clear Polyurethane	Home Depot	242175H	ounce	1	\$7.98	\$7.98	1/5	\$1.60
Total								\$88.58

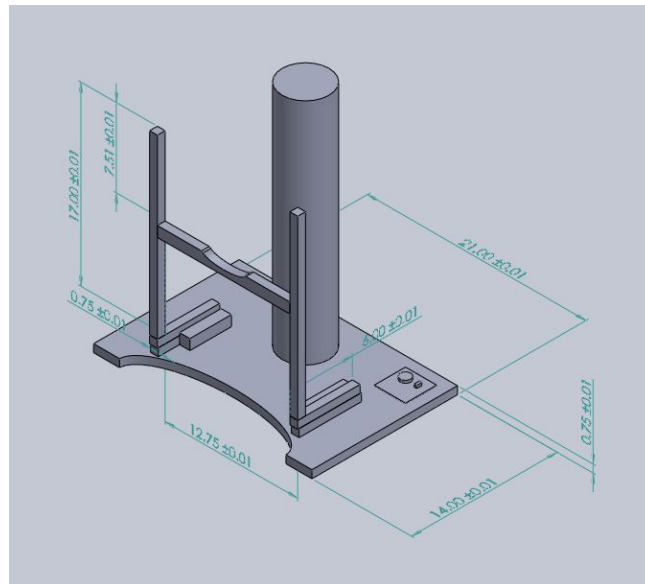
## 5.5 Safety Considerations

We have to consider a few things in regards to our safety when we manufacture our final prototype. We will be working with electrical components and must make sure we are aware of the voltages we are working with and ensure that we are maintaining the voltage levels and include a failsafe trip if there are unsafe levels of fluctuation in voltage. When manufacturing our table and chin rest, we must abide by the machine shop rules. All members will have their yellow tag certification prior to the manufacturing phase of the project. Safety glasses will also be worn during any machine shop work and load testing.

## 6.0 Prototype Development

### 6.1 Model Analyses

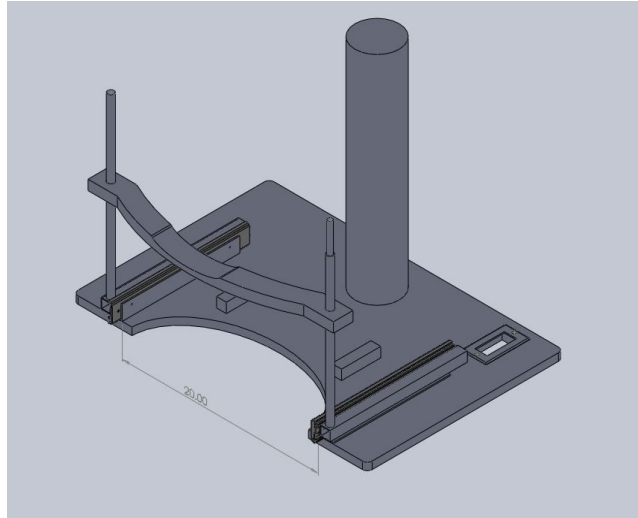
The preliminary SolidWorks model of our conceptual prototype is shown below in **Figure 2**. Our initial design ideas were based upon Dr. Sherman's input and critique of multiple slit lamps being inadequate for larger patients. The main goal of this first prototype was to widen the headrest and expand the table cut out section on the patient side



**Figure 2.** Initial solid model of proposed concept of modification to the slit lamp table and chin rest.

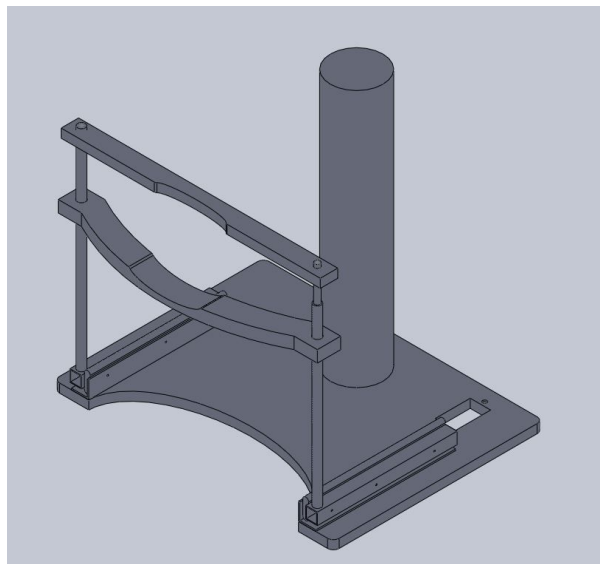
### 6.2 Evolution of Prototypes

Version 1 of the prototype, seen below in **Figure 3** saw the choice to use drawer slides to move the headrest forward and backward. The initial table was 30" x 20". There was also a convex curve added to the chinrest to reduce the need for a patient to lean into device.



**Figure 3.** First version of modified slit lamp ophthalmoscope.

Version 2 of the slit lamp ophthalmoscope, seen below in **Figure 4**, is very similar to the first version. Minor changes were made to the length of the aluminum tubing and angles from 14 inches, down to 12 inches. The table dimensions were also modified from 30" x 20" to 24" x 18" to enlarge the dimensions of the table, but retain practicality without the table being overly large. The last modification that was made was the addition of the top head rest support to produce stability to the entire vertical head/chinrest structure. See **Appendix C** for all part dimensioned drawings.



**Figure 4.** Final solid model of the slit lamp table and headrest modifications.

The final functional prototype that was manufactured based upon the final solid model design is seen in **Figure 5**. This prototype was used in testing for design verification and validation and will be delivered as the final prototype of the project.

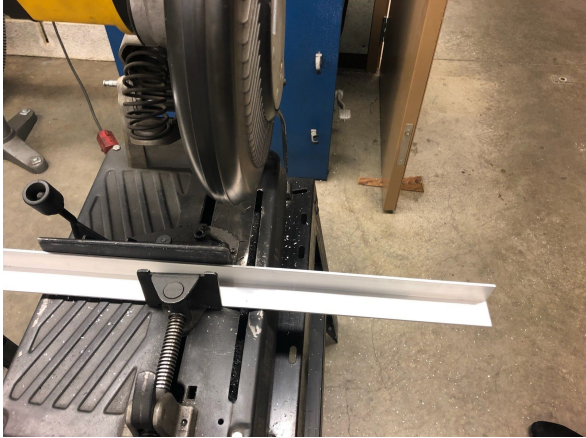

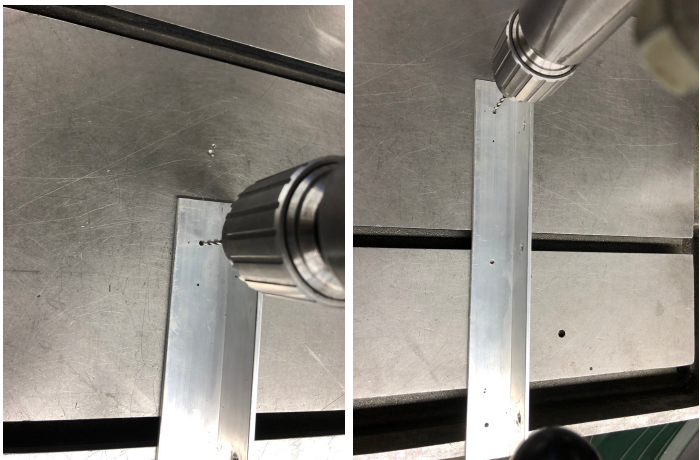


**Figure 5.** Final functional prototype of modified slit lamp.

### **6.3 Manufacturing Process**

**Tables 5-11** below list all of the manufacturing steps to make each of the parts used in the modified slit lamp. Many steps include a photo adjacent to the written instructions to provide clarity. See **Appendix C** for all dimensioned drawings.

**Table 5. MPI A: Aluminum Angle**




Step	Instructions	Photo
1	Measure and cut 1.5"x1.5" aluminum angle at length of 12" L using a fine toothed chop saw. Determine a left and right side angle.	 A photograph showing a chop saw in a workshop setting. A piece of aluminum angle is being cut by the saw. The saw is mounted on a stand, and the aluminum angle is held in place by a clamp. The background shows a concrete floor and some workshop equipment.
2	Use a belt sander to grind off excess metal.	 A photograph showing a person's hands using a belt sander to grind a piece of aluminum angle. The sander is a Wilton brand machine with a red belt. The aluminum angle is being held against the sander's table. The background shows a workshop environment.
3	On the face that will screw into the table, drill a 1/8" hole at 1", 6" and 11" along the line 5/8" from the free edge.	 Two photographs showing the drilling process. The left photo shows a close-up of a drill bit entering an aluminum angle. The right photo shows the drill bit further into the angle, creating a hole. The background is a metal workbench.

4



On the face that will mate with the drawer slide, tap a  $\frac{1}{4}$ -20 hole on a line 0.5" at increments of  $1\frac{5}{8}$ ",  $5\frac{1}{2}$ " and  $10\frac{1}{2}$ " from the back end. To tap the hole, predrill with a #7 drill bit then use the  $\frac{1}{4}$ -20 tap rotating a half turn clockwise and a  $\frac{1}{4}$  counterclockwise.






**Table 6. MPI B: Aluminum Square Tubing**





Step	Instructions	Photo
1	Cut 1" square aluminum tubing using a chop saw with fine toothed blade to a length of 12".	 A photograph showing a chop saw with a yellow handle and a large circular blade cutting through a piece of square aluminum tubing. The tubing is held in a metal vise on a workbench. The background shows a workshop environment with a blue cabinet labeled 'aldson'.
2	Use belt sander to grind off excess metal.	 A photograph showing a person's hands using a belt sander to grind a piece of metal. The sander is a large industrial machine with a red and grey body. The brand name 'WILTON' is visible on the machine's housing. The metal piece is resting on a workbench.
3	Drill a 5/8" hole 0.5 inches from one end and centered at 0.5" from the side, this will become the front and top side. Use a 1/8" bit in a drill press at low speed and increase bit size in 1/8" increments to bore the hole until at 5/8" diameter.	 A photograph showing a drill press in operation. A drill bit is positioned to drill a hole into a piece of square aluminum tubing. The tubing is held in a metal vise on the drill press table. The background shows a workshop environment with various tools and equipment.




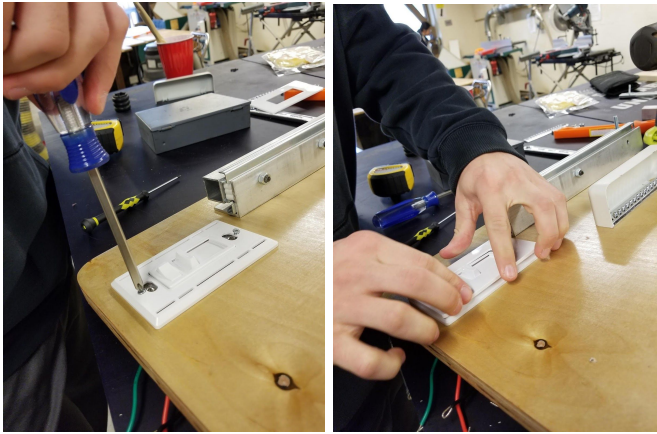
4	<p>Using a <math>5/32</math>" drill bit on a drill press, drill 3 holes straight through the side of the tube. Holes along the centerline of <math>0.5</math>" at increments of <math>1\ 15/16</math>", <math>6\ 15/16</math>" and <math>10\ 3/4</math>" from the back end.</p>	
5	<p>Tap a <math>1/4</math>-20 inch hole on the bottom of the tubing centered at <math>1/2</math> inch and 1 inch from the front end. Using a #7 predrilled hole and <math>1/4</math>-20 tap, using a half turn clockwise and a quarter turn counterclockwise.</p>	

**Table 7. MPI C: Table**




Step	Instructions	Photo
1	Use table saw to cut 24"x48"x3/4" plywood to 24" by 18" rectangle.	 A photograph showing a person's hands operating a table saw. A large sheet of light-colored plywood is being cut on the saw's table. The saw has a red blade guard and the word "SAW" is visible on the side.
2	Use jigsaw to cut out a 5" vertical radius and 9" horizontal radius ellipse centered at 12" on the long side of the table, this will become the front.	 A close-up photograph of a red jigsaw cutting into a piece of plywood. The blade is visible, and the cut is following a curved path.
3	Use jigsaw to cut out hole for dimmer switch. The hole is 3" L x 1.75" W. See Part drawing in <b>Appendix C</b> for location of light switch hole.	 A close-up photograph of a red jigsaw cutting a rectangular hole into a piece of plywood. The blade is visible, and the cut is following a straight path.



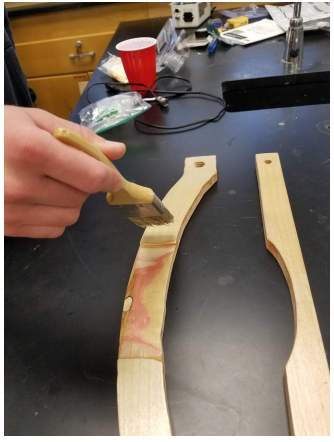
4	Use hand drill to drill out 5/16” holes to attach electrical box to the underside of the table.	
5	Use a file as needed in the light switch hole to get the switch to fit snug.	
6	Use belt sander to round corners of table.	
7	Use rotational sander to smooth the elliptical cutout.	

**Table 8. MPI D: Light Switch**




Step	Instructions	Photo
1	Make sure no power is going to the system and then detach the ground wire from the old switch.	
2	Detach the other 2 wires from the switch and make sure to keep them labeled (red, green, black).	
3	Reattach the wires to the new switch using wire connectors and electrical tape.	
4	Set switch into hole in table and screw down.	
5	Test to ensure light works.	
6	Place cover plate over switch.	
7	Test again to ensure light works.	




**Table 9. MPI E: Chin Rest**

Step	Instructions	Photo
1	Use a table saw to cut a rectangular block 22.25" L X 4" W in 1" thick wood.	 A photograph showing a person's hands guiding a piece of light-colored wood across a table saw. The saw is a Skil saw, with the brand name visible in red on the side. The person is wearing a green shirt and is focused on the task. The background shows a workshop setting with other tools and equipment.
2	Trace guidelines onto top surface for inside curve out. Circular arc with radius of 20", centered 2" on either side.	 A photograph of a piece of light-colored wood lying on a dark surface. A white string is stretched across the wood to form a circular arc, which has been traced onto the wood's surface. A yellow measuring tape is also visible on the surface next to the wood.
3	Use a scroll saw to cut the outline from step 2.	 A photograph showing a person using a scroll saw to cut a piece of wood. The scroll saw is a yellow and black machine with a curved table. The person is wearing a black shirt and is carefully guiding the wood through the saw. The background shows a workshop setting with other tools and equipment.

4	<p>Use the hand router to cut the chin rest groove 6" wide, 0.5" deep, centered on the part.</p>	
5	<p>Drill a 5/8" hole 1" from front and 1" from side, on both square ends of the chinrest. Use a 1/8" bit in a drill press at medium speed and increase bit size in 1/8" increments to bore the hole until at 5/8" diameter.</p>	
6	<p>Add a finish with a clear coat of polyurethane .</p>	




**Table 10. MPI F: Head Rest**

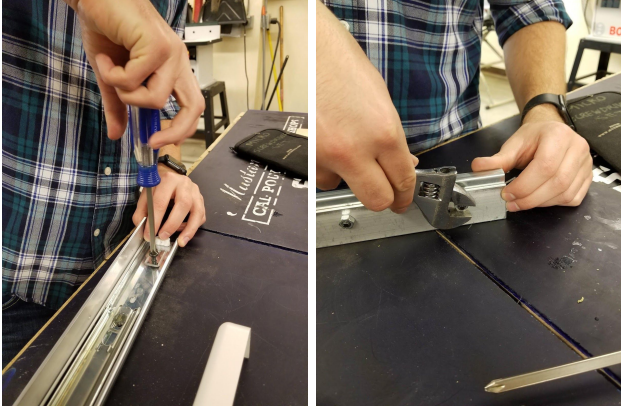
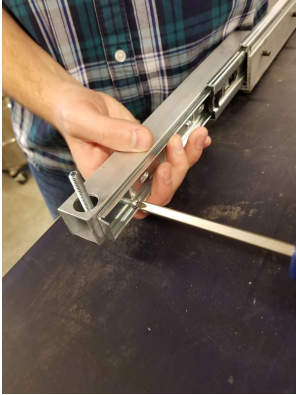

Step	Instructions	Photo
1	Measure and cut a rectangular piece of $\frac{3}{4}$ " plywood to a dimension of 22.25" by 1.5" using a scroll saw.	 A photograph showing a scroll saw in operation. The saw is positioned on a dark, flat workbench. A piece of light-colored plywood is being cut by the saw's blade. The background shows some workshop equipment and a wall.
2	Mark center of part at 11.125" and 3" on either side of the center and trace an ellipse with long radius of 3" and a short radius of $\frac{1}{2}$ ".	 A close-up photograph of a piece of light-colored plywood lying on a white surface. A black marker is placed on the surface next to the plywood. A faint, hand-drawn ellipse is visible on the plywood, centered along its length.
3	Drill a $\frac{7}{16}$ " hole on each end centered at $\frac{3}{4}$ " from the front and 1" from long end.	 A photograph showing a person's hand operating a drill press. The drill bit is positioned to drill a hole into a piece of plywood that is held in place by a red vise on the drill press table. The background shows a workshop environment with various tools and equipment.

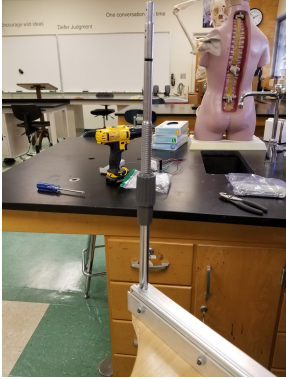
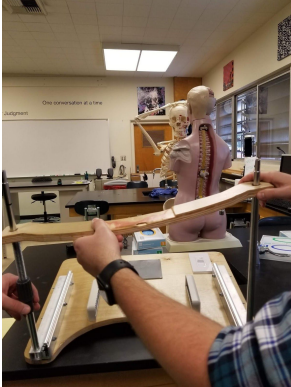
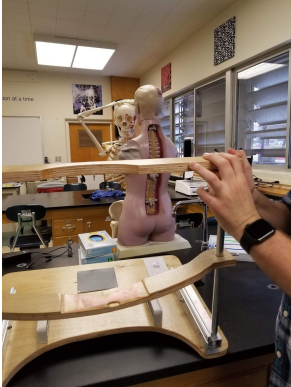
4	Using a scroll saw, cut out the traced guideline of the partial ellipse.	 A close-up photograph showing a person's hands operating a scroll saw. The saw is cutting a piece of light-colored wood on a dark, curved work surface. A thin, dark line is visible on the wood, representing the traced guideline for the partial ellipse. The background shows a workshop setting with wooden walls and other equipment.
5	Using a belt sander, sand the ends.	 A photograph of a belt sander in operation. The sander has a large, red, textured sanding belt. A piece of light-colored wood is being fed into the sander from the left. The brand name "WILSON" is visible on the top of the machine. The work surface is dark and appears to be a table.
6	Add a finish with a clear coat.	 A photograph showing a person's hand using a brush to apply a clear coat finish to a piece of wood. The wood is held vertically, and the brush is being used to apply the finish to its surface. The background is a dark, flat surface, possibly a workbench. A small white card with text is visible in the background.



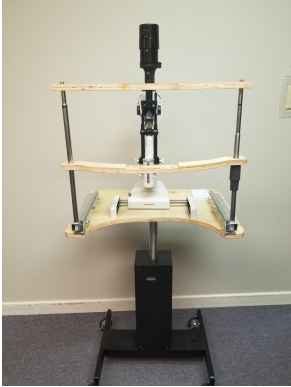


**Table 11. MPI G: Assembly**

<b>Step</b>	<b>Instructions</b>	<b>Photo</b>
1	Screw the table to the mount using the ¼” screws from the original slit lamp. The screws are arranged in a 5.5” square on the center line 4” from the back end	
2	Secure mount to stand and tighten nuts with 3/16” allen wrench.	
3	2X Insert ¼”-20 2”L screw into bottom of square tubing and tighten using a wrench.	

4	<p>Screw drawer tracks to metal angle using 6 x <math>\frac{1}{4}</math>"-20 machine screws and tighten nuts with a wrench.</p>	
5	<p>Screw square tubing to drawer slides using 6 x <math>\frac{5}{32}</math>" machine screws and nuts aligning with the circular holes on the inner slide and the <math>\frac{5}{8}</math>" bored hole oriented to the front of the table.</p>	
6	<p>Screw metal angles to table using 6 x #4 <math>\frac{3}{4}</math>" cabinet screws. The screws are linear and spaced 5" apart with the back screw 7" from the back edge. As a check the front screw should be 1" from the front edge.</p>	

7	Place chin rest posts in both $\frac{5}{8}$ " holes in the square tubing.	
8	Slide chin rest onto the vertical poles.	
9	Slide headrest onto the vertical poles.	

<p>10</p>	<p>Screw slit lamp tracks using existing <math>\frac{1}{8}</math>" screws from the original slit lamp. The screws are spaced <math>4\frac{5}{8}</math>" oriented front to back and located 5.75" from the center line with the back screw 8.25" from the back edge.</p>	
<p>11</p>	<p>Screw plastic rectangle to table using <math>\frac{1}{16}</math>" screws from the original slit lamp. The rectangle is centered on the table. The screws are 4.50" apart across the centerline, 4.125" apart front to back, with the back screws located 1.875" from the back edge.</p>	
<p>12</p>	<p>Install the Slit lamp onto slit lamp tracks.</p>	

The device history record can be found in **Table 12**. This table lists the day each of the MPI instructions were completed and each part manufactured, signed off by the person who made the part.

**Table 12.** Device history record from slit lamp table and headrest.

Device Manufacture Date: 02/10/2019    Quantity:1		
MPI Step	Sign Off and Date	Deviations from MPI
A	Austin Mattmiller 2/1/2019	None - Austin Mattmiller 2/1/2019
B	Austin Mattmiller 2/1/2019	None - Austin Mattmiller 2/1/2019
C	Michael Hostetler 2/1/2019	None - Michael Hostetler 2/1/2019
D	Austin Mattmiller 2/28/2019	None - Austin Mattmiller 2/28/2019
E	Michael Hostetler 2/6/2019	None - Michael Hostetler 2/6/2019
F	Michael Hostetler 2/18/2019	None - Michael Hostetler 2/18/2019
G	Alexis Brewer 2/28/19	None - Alexis Brewer 2/28/19

#### 6.4 Divergence Between Final Design and Final Functional Prototype

The final functional prototype diverges from the final design in the way that the vertical posts are attached to the square tubing. The design called for a weld, but in the final functional prototype, a  $\frac{5}{8}$ " hole was bored and the post was slid into this hole with a  $\frac{1}{4}$ "-20 threaded bolt coming from the bottom into the tube to secure it. The chin rest that was manufactured used  $\frac{3}{4}$ " birch plywood instead of the 1" thick wood called for in the design. Additionally a clear coat of polyurethane was added to the wood surfaces to provide an aesthetic finish and a easily sterilizable surface.

## 7.0 IQ/OQ/PQ

### 7.1 DOE

#### Test Protocols

1. Load Testing:

Materials:

Finished Prototype, Plastic Bucket, weights up to 20 pounds, spring scale, tape measure, safety glasses, protractor, 12" string, washer

1. Make sure everyone is wearing safety glasses.
2. Tie the string around the washer and attach the opposite end of the string to the center of the protractor.
3. Attach the protractor to one side of the head rest, parallel to the drawer slide. 90 degrees should be pointing straight down. See **Figure 6A**.
4. Place the spring scale handle around on the center of the chinrest, making sure the chinrest is secured in place for the test.

5. Measure the initial angle on the protractor.
6. While the headrest is not extended (0"), add the bucket with 20 lb weight to the hook scale. See **Figure 6B**.
7. Measure the loaded angle using the protractor. The difference between the initial and the load is the angle of deflection.
8. Repeat steps 5-7 for a total of 10 trials
9. Using the tape measure, extend the headrest to 6" and repeat step 5-8. See **Figure 6C**.
10. Repeat steps 5-8 for 12" extension.



**A.**

**B.**

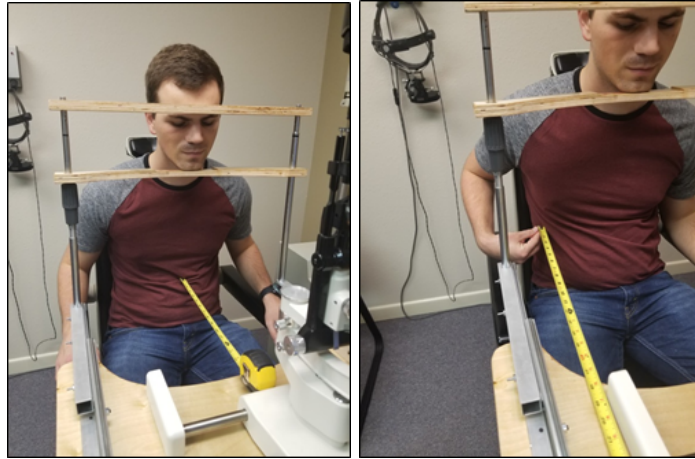
**C.**

**Figure 6.** **A)** Image of how the string is attached to the protractor and then attached to the horizontal tubing as mentioned in Step 2-3. **B)** Image of the 20 lb bucket applied to the center of the chinrest as described in Step 6. **C)** Image of measuring the extension of the slide described in Step 9.

## 2. Range of Motion Testing:

Materials: Completed prototype, Tape measure, 10 volunteers, chair/stool

1. Have volunteer sit up straight with their back against the chair in front of the slit lamp.
2. Measure distance from the center of the table cut out to the volunteer's rib cage: anteriorly and laterally, keeping the tape measure parallel to the floor.  
**See Figure 7.**
3. Extend the headrest until the patient's head is resting in the device
4. Record the distance extended
5. Repeat with 10 volunteers.



**A.**

**B.**

**Figure 7.** **A)** Image of the anterior rib cage clearance measurements described in Step 2. **B)** Image of lateral rib cage clearance measurement described in Step 2.

### 3. Light Switch Functionality Test

1. Make sure the power cord is unplugged, the switch is off, and dimmer is set at the lowest setting
2. Plug in power cord and verify switch is still off.
3. Turn on switch and slowly move switch up to 100% and verify the switch continually gets brighter to maximum brightness.
4. Have a volunteer sit in chair in front of slit lamp.
5. Have Dr. Sherman verify he can see into volunteer's eye.

## 7.2 Verification and Validation

Our verification and validation data was collected using the above protocols and were compared to the engineering specifications using a single sample t-test with a significance level of 0.05. The averages, standard errors, and p-values from the t-tests of the vertical and horizontal deflection tests are shown below in **Table 13** and **Table 14**, respectively. The data shows that the prototype meets and passes the required loading and deflection specification for supporting 20 lbs and deflecting less than 5 degrees vertically and horizontally.

**Table 13.** T-test results for chin rest vertical deflection with 20 lb load at different extensions

Extension (inches)	Mean Deflection From Vertical (degrees)	Standard Error	P-Value
0	2.95	0.117	<0.001
6	2.25	0.154	<0.001
12	2.55	0.117	<0.001

**Table 14.** T-test results for drawer slide horizontal deflection with 20 lb load at different extensions

Extension (inches)	Mean Deflection From Horizontal (degrees)	Standard Error	P-Value
2	0.5	0	*
6	0.5	0	*
12	1.1	0.1	<0.001

\*All values were identical giving standard deviation = 0, however the mean was below the specification of 5° meaning the device is passes specification tests.

The data for the clearance tests both lateral and anterior can be found below **Table 15**. A BMI of 25 is considered overweight. The average BMI of our subjects was 27. Our device meets and passes the specification for a 1” clearance for both the anterior and lateral measurements taken with overweight patients.

**Table 15 .** T-test results for clearance of ribcage for test subjects: anteriorly and laterally

	Mean Clearance (inches)	P-value
Lateral Clearance	9.304	<0.001
Anterior Clearance	13.363	<0.001

## 8.0 Conclusions and Recommendations

### 8.1 Recommendations

Our device could be improved upon in several ways even after our modifications. A large change would be to make the slit lamp vertical posts attach straight to a track in or on the table that would slide in and out. The posts could be welded on or threaded on to a bolt to make them rigid, at a 90 degree angle with the table, and more stable. Another recommendation is to completely redo the wiring system to work with just a switch and a plug in. It would be beneficial to remove the electrical box that initially came with the table because it seems to be unnecessary. A simpler system could be devised. Lastly, an aesthetic makeover using plastic for the headrest and chinrest instead of plywood would make the device visually appealing for the market

### 8.2 Conclusions

The device is successful in meeting the objectives outlined in our indications for use, design specification matrix, and the design of experiments. The device was mostly reverse-engineered to improve the existing design by using old parts with new additions. The headrest tower passed the engineering specifications for load bearing, range of motion, and clearance. The chin rest and the drawer slides surpassed the specifications for angle of deflection



testing. Overall, this redesign of the traditional slit lamp ophthalmoscope greatly improves the accessibility and ergonomics for a wider variety of patients.

## 9.0 Acknowledgments

We would like to acknowledge Dr. Sheman for sponsoring this project and providing guidance on the use of the slit lamp as well as the staff of the Pacific Eye office in Lompoc, CA . We would also like to thank Dr. Heylman and Dr. Whitt for their support and guidance. We would also like to thank Jacob Smart for assistance with the solid modeling and dimensioned drawings.

## 10.0 Appendices

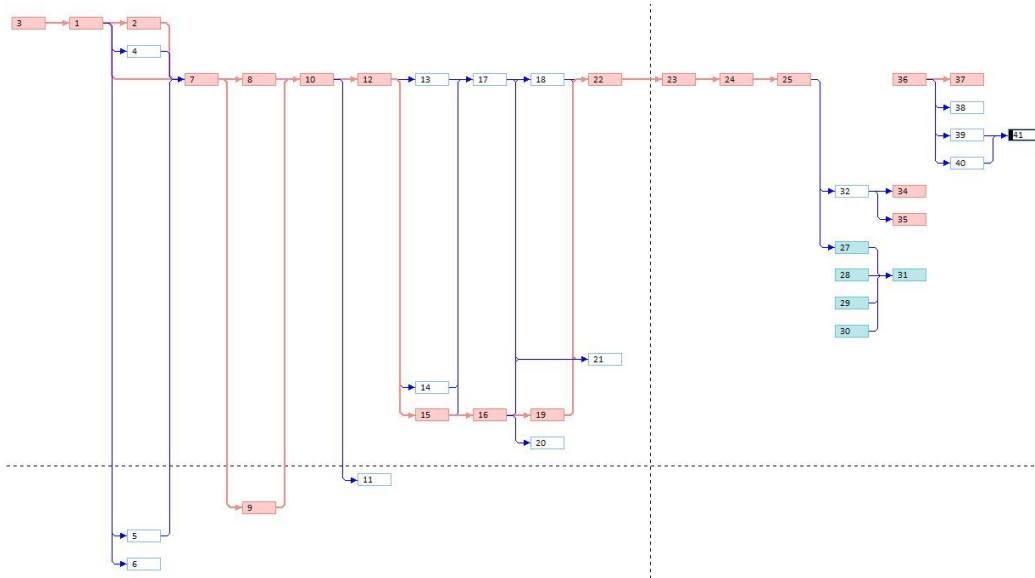
### 10.1 Appendix A: References

- (1) Artes, Paul H. "History of the Slit Lamp (Dieter Schmidt, in Gellrich MM 'The Slitlamp')." *Academia.edu*,  
[www.academia.edu/12334561/History\\_of\\_the\\_Slit\\_Lamp\\_Dieter\\_Schmidt\\_in\\_Gellrich\\_MM\\_The\\_Slitlamp\\_](http://www.academia.edu/12334561/History_of_the_Slit_Lamp_Dieter_Schmidt_in_Gellrich_MM_The_Slitlamp_).
- (2) "Portable Slit Lamp, Handheld Slit Lamp." *Digital Eye Center*,  
[www.digitaleyecenter.com/product/portable-slit-lamp/?gclid=EAIaIQobChMIzd7Wy5iH3gIVmNlkCh3WhQuyEAYYASABEgKZHfD\\_BwE](http://www.digitaleyecenter.com/product/portable-slit-lamp/?gclid=EAIaIQobChMIzd7Wy5iH3gIVmNlkCh3WhQuyEAYYASABEgKZHfD_BwE).
- (3) "Digital Portable Slit Lamp HSL-600." *Digital Eye Center*,  
<https://www.digitaleyecenter.com/product/digital-portable-slit-lamp-hsl-100/>
- (4) "Keeler Symphony K Series Slit Lamp." *Brawn Medical*,  
<https://www.brawnmedical.com/products/slit-lamps/table/keeler-symphony-k-series>
- (5) US PATENT SEARCH  
<http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&p=1&u=%2Fnethtml%2FPTO%2Fsearch-bool.html&r=0&f=S&l=50&TERM1=slit+lamp+ophthalmoscope&FIELD1=&co1=AND&TERM2=&FIELD2=&d=PTXT>
- (6) "CSO SL9900 Digital LED Slit Lamp." *Hanson*,  
<https://www.hansoninstruments.co.uk/optometric/slit-lamps/cso-sl9900-digital-led-slit-lamp>
- (7) "SL5H/SL5H LED SLIT LAMP MICROSCOPE." *Medi Needs*,  
<http://medineeds.com/product-slitlamp-sl5hsl5hLED.php>
- (8) "Artificial intelligence in retina." *Progress in Retinal and Eye Research*, 1 August 2018,  
<https://www.sciencedirect.com/science/article/pii/S1350946218300119>
- (9) Center for Devices and Radiological Health. "Search for FDA Guidance Documents - Slit Lamp Guidance - Guidance for Industry." *U S Food and Drug Administration Home*

Page, Center for Devices and Radiological Health,  
[www.fda.gov/RegulatoryInformation/Guidances/ucm080174.htm](http://www.fda.gov/RegulatoryInformation/Guidances/ucm080174.htm).

- (10) "Pharmacokinetic Aspects of Retinal Drug Delivery." *Progress in Retinal and Eye Research*, Pergamon, 24 Dec. 2016,  
[www.sciencedirect.com/science/article/pii/S1350946216300635](http://www.sciencedirect.com/science/article/pii/S1350946216300635).
- (11) "Progress on Retinal Image Analysis for Age Related Macular Degeneration." *Progress in Retinal and Eye Research*, Pergamon, 7 Nov. 2013,  
[www.sciencedirect.com/science/article/pii/S1350946213000694](http://www.sciencedirect.com/science/article/pii/S1350946213000694).
- (12) "The Clinical Relevance of Visualising the Peripheral Retina." *Progress in Retinal and Eye Research*, Pergamon, 10 Oct. 2018,  
[www.sciencedirect.com/science/article/pii/S1350946218300399](http://www.sciencedirect.com/science/article/pii/S1350946218300399).
- (13) "An Optimized Zoom Ophthalmoscope." *Ophthalmology*, Elsevier, 31 Oct. 2013,  
[www.sciencedirect.com/science/article/pii/S016164208434310X](http://www.sciencedirect.com/science/article/pii/S016164208434310X).

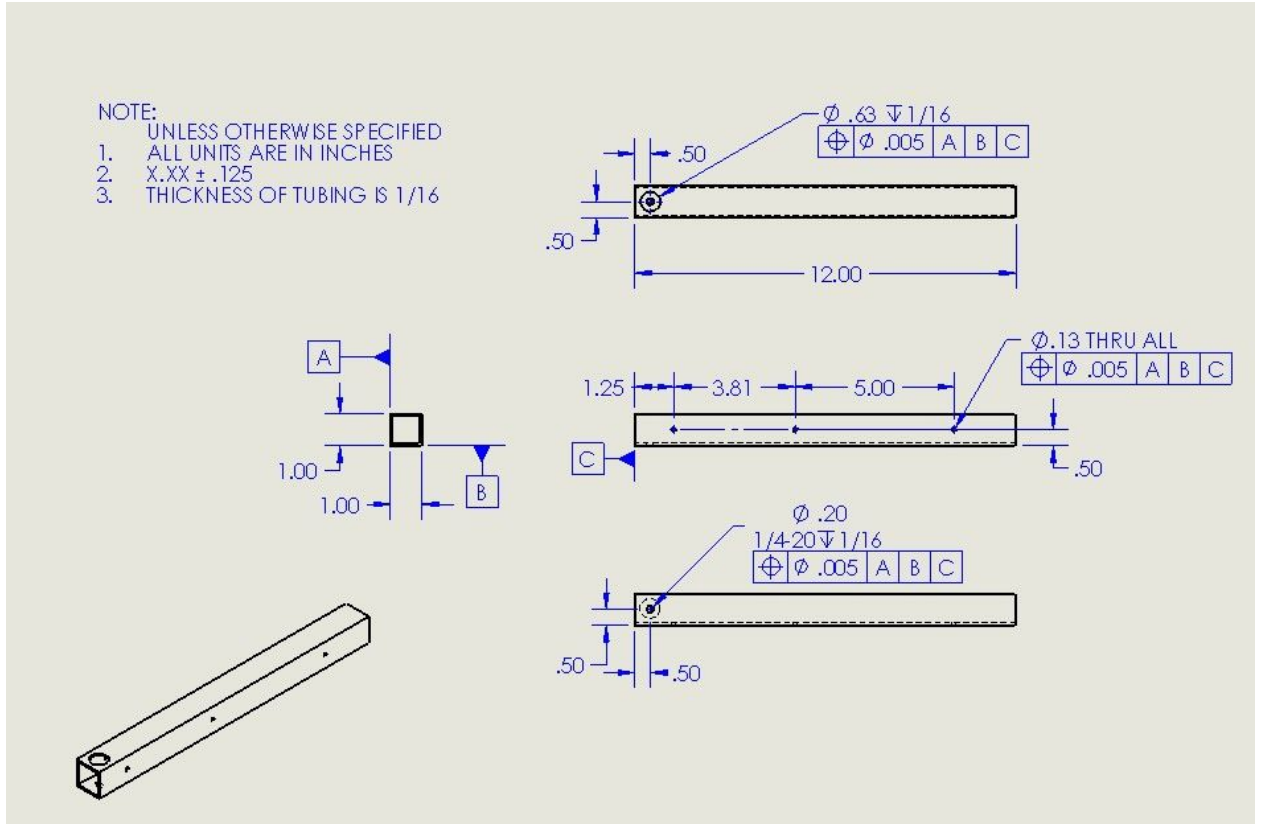
## 10.2 Appendix B: Project Plan (PERT Chart)



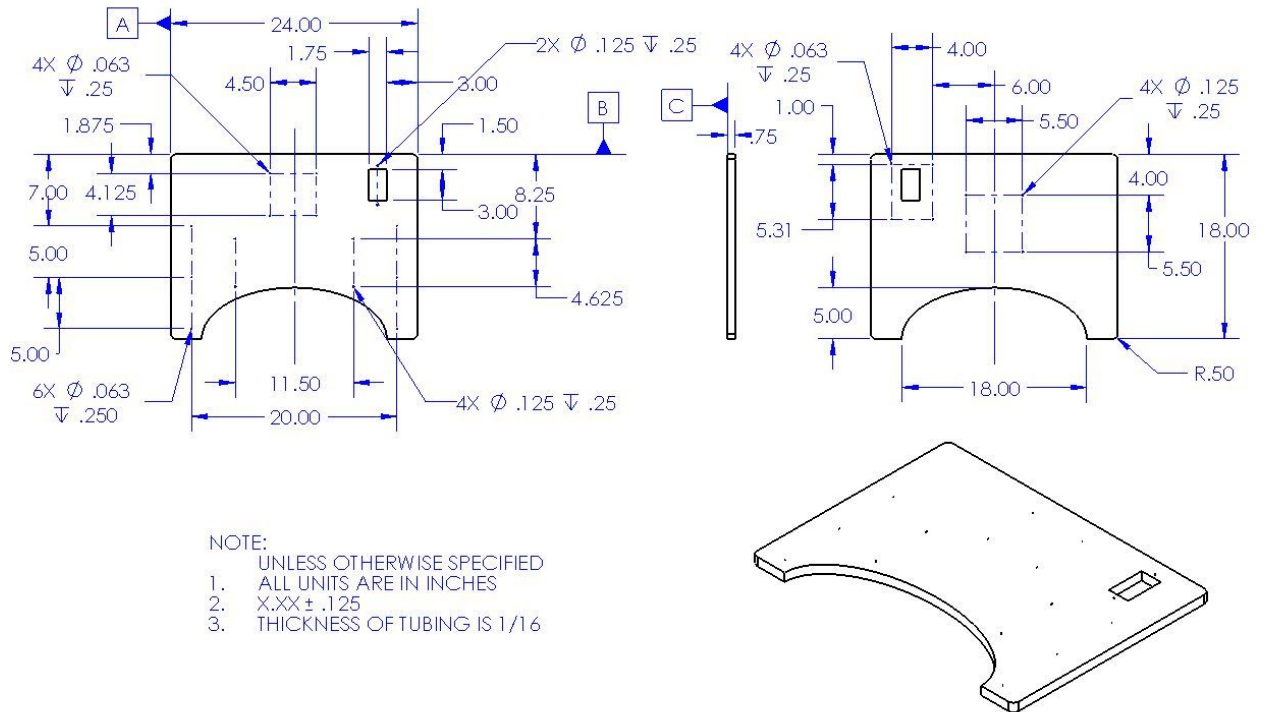
	Task Name	Duration	Start	Finish	Predecessors
1	Product Specification Matrix	1 day	Tue 10/2/18	Tue 10/2/18	3
2	Hazard and Risk Assessment	3 days	Wed 10/3/18	Fri 10/5/18	1
3	Introduction to Sponsor	1 day	Mon 10/1/18	Mon 10/1/18	
4	DOE and Conjoint Forms	1 day	Wed 10/3/18	Wed 10/3/18	1
5	Conjoint Presentation and ANOVA Analysis	1 day	Wed 10/3/18	Wed 10/3/18	1
6	Total Available Market	1 day	Wed 10/3/18	Wed 10/3/18	1
7	Project Planning Presentation/ Analysis Report	1 day	Mon 10/8/18	Mon 10/8/18	1,2,4,5
8	House of Quality	1 day	Tue 10/9/18	Tue 10/9/18	7
9	Pugh Chart	1 day	Tue 10/9/18	Tue 10/9/18	7
10	Preliminary Design	14 days	Wed 10/10/18	Mon 10/29/18	8,9
11	Status Update Memo	1 day	Tue 10/30/18	Tue 10/30/18	10
12	Concept Review Presentation	1 day	Tue 10/30/18	Tue 10/30/18	10
13	Midpoint Project Report	14 days	Wed 10/31/18	Mon 11/19/18	12
14	Status Update Memo	1 day	Wed 10/31/18	Wed 10/31/18	12
15	Develop Preliminary Design	14 days	Wed 10/31/18	Mon 11/19/18	12
16	Develop Prototype construction Plan	2 days	Tue 11/20/18	Wed 11/21/18	15
17	Preliminary Design Presentation	1 day	Tue 11/20/18	Tue 11/20/18	15,13,14
18	Preliminary Prototype Plan Presentation	1 day	Thu 11/22/18	Thu 11/22/18	16,17
19	Update MS Project with concerns	2 days	Thu 11/22/18	Fri 11/23/18	16
20	Eco Indicator 99 LCA Quantitative Method	1 day	Thu 11/22/18	Thu 11/22/18	16
21	First Draft of final Report	14 days	Fri 11/23/18	Wed 12/12/18	16,17,18
22	Final Test and Manufacturing Plan Presentation	14 days	Mon 11/26/18	Thu 12/13/18	19,18
23	Break	21 days	Fri 12/14/18	Fri 1/11/19	22
24	Buy Materials	1 day	Mon 1/14/19	Mon 1/14/19	23
25	Create Manufacturing Instructions	2 days	Tue 1/15/19	Wed 1/16/19	24
26	▲ <b>Build Prototype</b>	<b>13 days</b>	<b>Thu 1/17/19</b>	<b>Mon 2/4/19</b>	<b>25</b>
27	Manufacture Part A and B	1 day	Thu 1/17/19	Thu 1/17/19	25
28	Manufacture Part C	1 day	Sat 1/26/19	Sat 1/26/19	
29	Manufacture Part E	1 day	Tue 1/29/19	Tue 1/29/19	
30	Install Light Switch (D)	1 day	Fri 2/1/19	Fri 2/1/19	
31	Assemble Parts	1 day	Mon 2/4/19	Mon 2/4/19	30,27,28,29
32	Develop Testing Plan	1 day	Thu 1/17/19	Thu 1/17/19	25
33	▲ <b>Test Prototype</b>	<b>1 day</b>	<b>Sun 2/24/19</b>	<b>Sun 2/24/19</b>	<b>26,32</b>
34	Loading Test	1 day	Sun 2/24/19	Sun 2/24/19	32
35	Range of Motion Test	1 day	Fri 3/1/19	Fri 3/1/19	32
36	Preliminary Functional Prototype Presentation	9 days	Mon 2/25/19	Thu 3/7/19	33
37	Status Update Memo	9 days	Fri 3/8/19	Wed 3/20/19	36
38	Status Update Memo	2 days	Fri 3/8/19	Mon 3/11/19	36
39	Final Poster Presentation	4 days	Fri 3/8/19	Wed 3/13/19	36
40	Final Report and Presentation	6 days	Fri 3/8/19	Fri 3/15/19	36
41	Case Study and Debrief	1 day	Mon 3/18/19	Mon 3/18/19	39,40



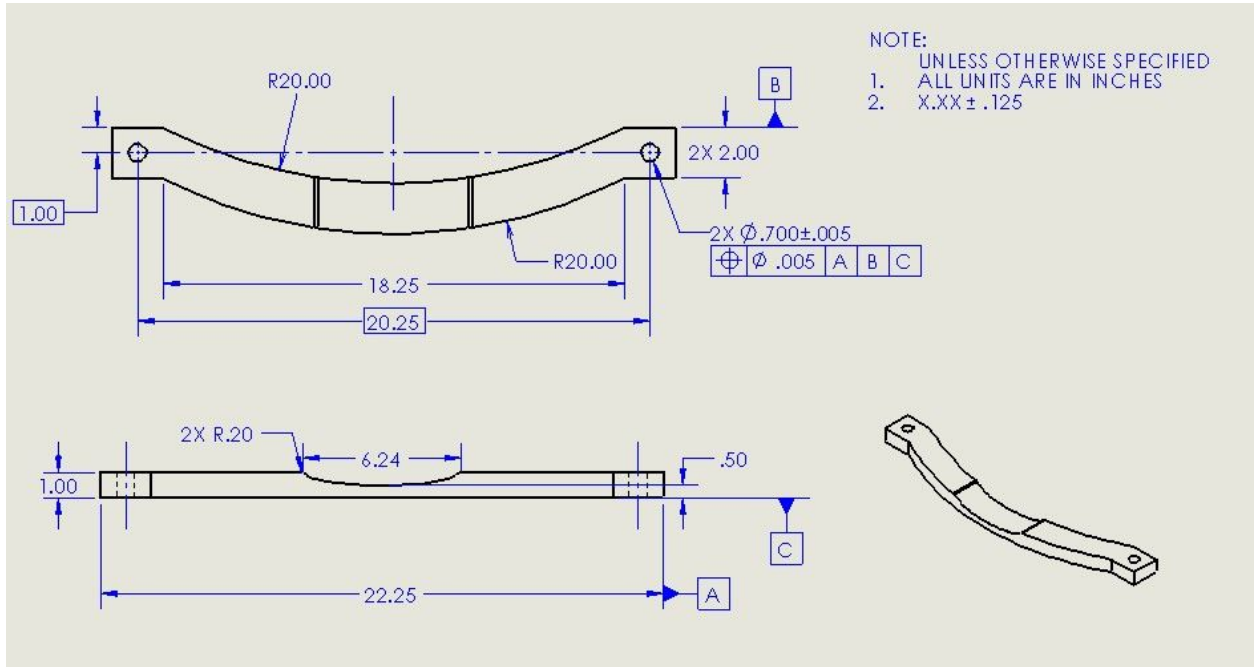
## Part B. Square Tubing



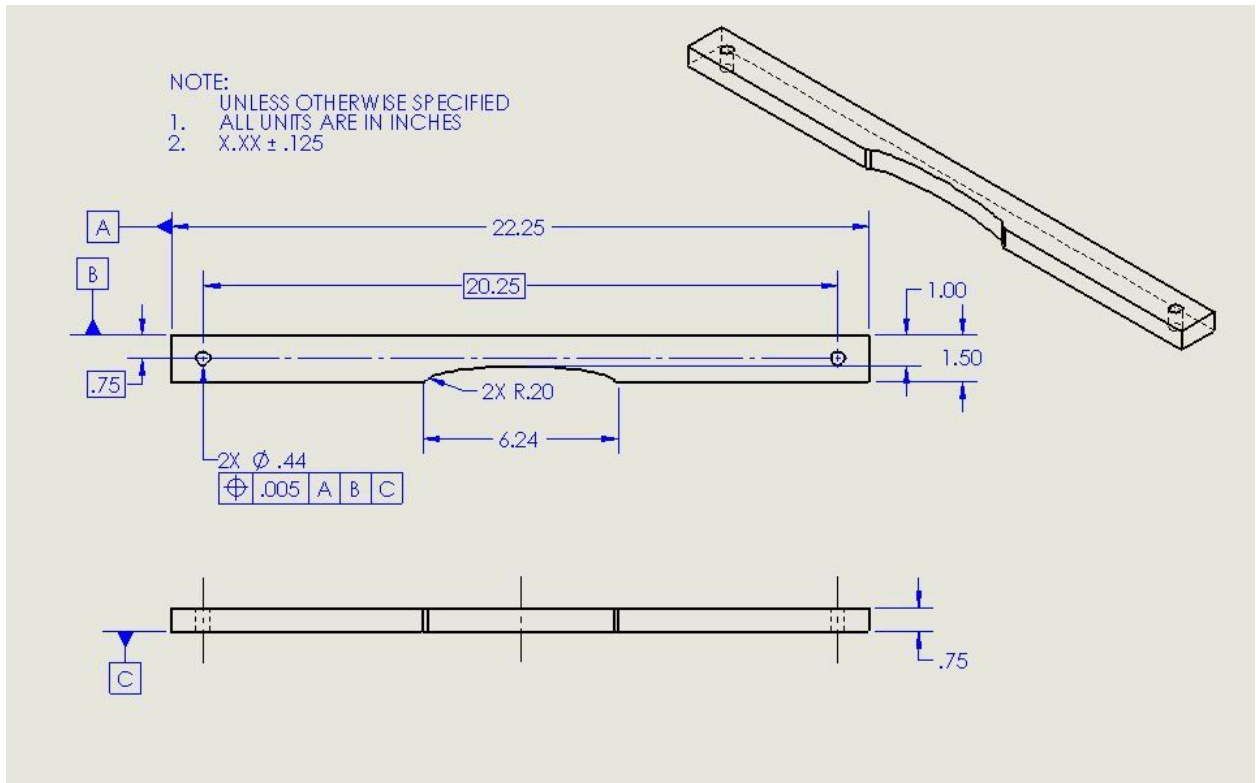
## Part C. Table



### Part E. Chinrest



### Part F. Headrest



### 10.4 Appendix D: FMEA, Hazard & Risk Assessment

Component Name	Possible Mode of Failure	Type	Causes of Failure	OCC (1-5)	DET (1-5)	SEV (1-5)	RPN	Effect of Failure on a System	Failure Improvement Alternative Actions
Eye Piece	Cracked lens	Mechanical	Movement or shipment of device to customer causes lens to crack	2	5	5	50	Eyepiece cannot be used reliably by customer, view obstructed and distorted by crack in lens	Design shipping and handling instructions to prevent excessive vibration of device
Joystick/ positioning controls	Joystick and positioning controls become stuck in position or unresponsive	Wear, mechanical	Collection of dust and debris in control housing or due to aggressive use and positioning of the device	2	5	4	40	device cannot be positioned to scan/view patient's eyes	Design housing or storage cover to minimize dust interaction
Headrest, chinrest	Breaking off or separating from arm posts	Customer use	Patient's placing head in headrest/chinrest over time causing fatigue failure	2	4	4	32	Patient unable to rest head while being examined	Design device to withstand loading of head weight or more and repeated cycling of loading and unloading
Light source	Light source fails to illuminate	Electrical, mechanical	Light source burns out, loss of power to light source	2	5	5	50	light field not projected onto eye reducing clarity of view	Select light source with lifespan of several years, indicate replacement of source before it is likely to expire
Instruction error	Misspelling or instructional error in written instructions for use	Clerical	Misspelling in the instructions from a typing error	2	2	1	4	Instructions for use unclear for customer	Establish proofreading and spell checking protocol
Power source	Loss of power to light source	Electrical	Electrical short, incomplete circuit due to wire wear or damage	1	5	5	25	Light source not activated and device cannot be used by customer	Ensure wires are well insulated and protected from damage
Base lock mechanism,	Movement not smooth or becoming stuck	Mechanical Wear	Overtime the siding base of the ophthalmoscope can become unlubricated making adjusting movements jerky or difficult	2	2	2	8	System is not able to be adjusted for patients	Determine rate of lubrication failure and provide customer with instructions on how to maintain and lubricate device



Optical components	Fungus growing on components	Wear	Inadequate cleaning and storage for period of time on the order of days to weeks. Humidity above 60% without desiccating agents	1	4	4	16	Cannot view eye through blocked components and prevents use of the device and diagnosis by user	Clearly state in instructions proper cleaning and storage of device to prevent fungus from growing.
Table wheel	Wheel becomes detached from table mount of device	Mechanical	Vibration from moving device over time or large force applied to wheel of device	1	5	2	10	Device cannot be positioned easily around room	Ensure wheels are secured to table base and that there are fail safes involved should a screw become loose
Optical refraction prisms	Misalignment of refractory prisms	Mechanical	Frequent adjustment of lenses and optical beams can cause refractor prisms to fall out of alignment	1	3	4	12	Magnification and illumination of patient eye is reduced preventing an accurate diagnosis	Determine rate of misalignment and issue calibration information to customer or provide customer with regular calibration
Lamp filament	Filament break	Electrical	Movement while lamp is on can cause filament to break	2	5	5	50	Lamp will not work and system can not illuminate patient eye	Select lamps that can handle movement and have filaments with higher yield strength
Cooling fan	Fan stops running and cooling system	Electrical	Electrical failure to the fan due to shorting or wire damage eliminates cooling system	2	1	5	10	Cooling system is compromised and device is at risk of overheating	Establish wiring protocol and spot check each device to ensure properly working fan
Cooling fan	Fan stops or runs in opposite direction	Electrical	Electrical wiring mistake cause fan to suck air into device instead of out	2	1	5	10	Device will be exposed to higher levels of dust compromising lens clarity and device accuracy	Establish wiring protocol and spot check each device to ensure properly working fan
Light source/filament	Light source fails to illuminate	Electrical, mechanical	Voltage fluctuations can cause filament to break	1	5	5	25	Light field not projected onto eye reducing clarity of view	Include voltage stabilizer in device or convert to a DC power source to minimize voltage fluctuations

Power source	Spontaneous combustion	Electrical	Intense voltage fluctuations can cause device to overheat and delicate components to ignite at flash point	1	5	5	25	System is not safe to be used due to flames	Maintain voltage levels and include a failsafe to trip if voltage levels are extreme
--------------	------------------------	------------	--	---	---	---	----	---	--

Description of Hazard	Planned Corrective Action	Planned Date	Actual
Device can be used in an unsafe manner	Clear instructions for how to use device	January 2019	N/A
Electrical Voltage	Move Power supply where connected to device from wall	January 2019	3/1/2019
Eye Damage from Bright Light	Instruction on light brightness control and	January 2019	N/A

To mitigate risks and failures identified in the failure mode effect analysis, our design remained focused on the table and chin rest modifications while leaving the actual ophthalmoscope intact. To ensure our modifications can withstand the load of a patient's head we tested the device with a factor of safety of 2 (20 pounds). Additionally, when manufacturing all components, all team members were yellow tag certified in the machine shop and worked closely with shop technicians to ensure safety and minimize risk of manufacturing.

## 10.5 Appendix E: Pugh Chart

\*For all charts, the datum is bolded.

	Concepts			
Criteria	<b>Previous 455 Design</b>	Concept 1	Concept 2	Concept 3
Cost		-	+	-
Smoothness		+	+	+
Stability		0	0	0
Ergonomics		+	+	0
Size		0	0	-
Ease of Use		+	+	+
Time to Adjust		-	+	+
Total Plus		3	5	3
Total Minus		2	0	2

	Concepts			
Criteria	<b>Concept 1</b>	Previous 455 Design	Concept 2	Concept 3
Cost		-	+	+
Smoothness		-	-	+
Stability		0	0	+
Ergonomics		0	-	0
Size		0	-	0
Ease of Use		-	+	+
Time to Adjust		-	+	+
Total Plus		0	3	5
Total Minus		4	3	0

	Concepts			
Criteria	<b>Concept 2</b>	Concept 1	Previous 455 Design	Concept 3
Cost		+	-	0
Smoothness		+	-	0
Stability		0	0	-
Ergonomics		0	-	0
Size		0	0	-
Ease of Use		+	-	+
Time to Adjust		0	-	0
Total Plus		3	0	1
Total Minus		1	4	1

	Concepts			
Criteria	<b>Concept 3</b>	Concept 1	Concept 2	Previous 455 Design
Cost		+	0	-
Smoothness		+	0	-
Stability		0	-	-
Ergonomics		0	0	-
Size		0	0	0
Ease of Use		+	+	0
Time to Adjust		0	0	0
Total Plus		3	1	0
Total Minus		0	1	4

## 10.6 Appendix F: Vendor Information, Specifications, and Data Sheets

Supplier	Item	Product Number	Specification	Quantity
Home Depot  1551 Froom Ranch Rd San Luis Obispo, CA 93405	Drawer Slide	D80612C-ZP-W	12 in. Full Extension Ball Bearing	1
	Aluminum Angle	802597	1.5"x 48" 1/16" thickness	1
	Dimmer Switch	CTCL-153PDH-WH	Skylark Contour C.Lfor Dimmable LED, Halogen and Incandescent Bulbs, Single-Pole or 3-Way, White 4" L x 2" W x 1.75" D	1
	Plywood	813952011723	23.75" W x 47.75" L x 0.75" D birch	1
	Aluminum square tubing	801307	1" W x 48" L 1/16" thickness	1
	Hex Bolts	AFD	1/4-20", 2" L	2
	Light Cover	CW-1-WH		1
	Wire Connectors	15-123	16-14 AWG Butt Splice, 15Pk	6
	Electrical Tape	30002656	3/4"x 30' Vinyl Carded	
	Tack Cloths	HDTC-3PK	3Pk	1
	Stain Brush	HD 1521-2	2" Polyester/Bristle	1
	Clear Polyurethane	242175H		1
	Miner's Ace Hardware  2034 Santa Barbara Ave, San Luis Obispo, CA 93401	Machine screws and nuts	395380-A	5/32", 1.5" length
Cabinet screws		439202	#4, 3/4" length	6
Machine screw		1787L	1/4-20", 1/2" length	6
Nuts		H180147	1/4-20"	6

## 10.7 Appendix G: Budget

Planned									
Item Description	Supplier	Product Number	Purpose	Planned					
				Unit	Quantity	Cost/Unit	Total Cost	Notes	
Fish Hook/Stress Test Puller	Leftover from previous group	NA	Load Testing	lb	1	0.00	0.00	Provided	
12 in. Full Extension Ball Bearing Drawer Slide (Quantity 2)	Home Depot	D80612C-ZP-W	Headrest Adjustment	inch	1	11.48	11.48	Account for 2 for testing initial build	
1.5"x96" 1/16" Aluminum Angle	Home Depot	802597	Headrest Adjustment	inch	1	18.57	18.57	2 needed, 1 for each side of tower	
Skylark Contour C.L Dimmer Switch for Dimmable LED, Halogen and Incandescent Bulbs, Single-Pole or 3-Way, White	Home Depot	CTCL-153P DH-WH	Adjustable light	EA	1	21.97	21.97	Dimmer switch upgrade on top of table	
Screws	Home Depot	114CDWS1	Attaching parts	lb	1	6.47	6.47	Holds all the parts together	
Wood for Prototype/Table	Home Depot		New Larger Table for Device	inch	1	45.04	45.04	New Table Top	
1"x48" Aluminum square tubing	Home Depot	801307	Headrest Tower, mount	inch	1	19.54	19.54	Headrest Build	
							Total	123.07	

Actual								
Item Description	Supplier	Product Number	Purpose	Unit	Quantity	Cost/Unit	Total Cost	Notes
Fish Hook/Stress Test Puller	Leftover from previous group	NA	Load Testing	lb	1	\$0.00	\$0.00	Provided
12 in. Full Extension Ball Bearing Drawer Slide (Quantity 2)	Home Depot	D80612C-ZP-W	Headrest Adjustment	2-pack	1	\$11.98	\$11.98	Account for 2 for testing initial build
1.5"x48" 1/16" Aluminum Angle	Home Depot	802597	Headrest Adjustment	inches	1	\$19.57	\$19.57	2 needed, 1 for each side of tower
Skylark Contour C.L Dimmer Switch for Dimmable LED, Halogen and Incandescent Bulbs, Single-Pole or 3-Way, White	Home Depot	CTCL-153P DH-WH	Adjustable light	EA	1	\$21.97	\$21.97	Dimmer switch upgrade on top of table
23.75" x 47.75" x 0.75" birch plywood for Prototype/Table	Home Depot	8139520117 23	New Larger Table for Device	inches	1	\$26.75	\$26.75	New Table Top
1"x1"x48" 1/16 Aluminum square tubing	Home Depot	801307	Headrest Tower, mount	inches	1	\$19.54	\$19.54	Headrest Build
5/32" 1.5" machine screws and nuts	Miners Ace	395380-A	fastening aluminum tubing to drawer slide	unit	6	\$0.55	\$3.30	
#4 3/4 cabinet screws	Miners Ace	439202	Fastening angle to table	unit	6	\$0.11	\$0.66	
1/4-20" machine screw	Miners Ace	1787L	Fastening drawer slide to angle	unit	6	\$0.27	\$1.62	
1/4-20" nuts	Miners Ace	H180147	Securing 1/4-20" machine screws	unit	6	\$0.14	\$0.84	
Hex Bolts 1/4"	Home Depot	AFD		unit	2	\$0.20	\$0.40	
Light Cover	Home Depot	CW-1-WH	covering the dimmer switch	unit	1	\$3.96	\$3.96	

16-14 AWG Butt Splice Wire Connectors 15Pk	Home Depot	15-123	connecting the wires to the electrical box	unit	1	\$2.51	\$2.51	
3/4"x 30' Vinyl Carded Electrical Tape	Home Depot	30002656	securing wire connections in the electrical box	unit	1	\$2.24	\$2.24	
Tack Cloths 3Pk	Home Depot	HDTC-3PK	applying polyurethane	unit	1	\$2.97	\$2.97	
2" Polyester/Bristle Stain Brush	Home Depot	HD 1521-2	applying polyurethane	inch	1	\$7.47	\$7.47	
Clear Polyurethane	Home Depot	242175H	clear coat to seal the wood and simplify sterilization with a wipe	ounce	1	\$7.98	\$7.98	
						Total	\$133.76	



## 10.8 Appendix H: Raw Data

### Vertical Deflection Angle Measurements

Drawer Slide Extension					
0"		6"		12"	
Initial	20lb Load	Initial Angle	20lb Load	Initial	20lb Load
89	86	88.5	85.5	87.5	85
88.5	86	88	85	87.5	84.5
89.5	86.5	87.5	85.5	87.5	84.5
89.5	86	88	85.5	87.5	85
88.5	86	87.5	85.5	87	85
88.5	85.5	87.5	85.5	87	85
88.5	85.5	87.5	85	87	84.5
88.5	85.5	87.5	85.5	87	84
88.5	86	87	85	87.5	85
88.5	85	87.5	86	87	84.5

### Horizontal deflection angle measurements

Drawer Slide Extension					
2"		6"		12"	
Initial	20lb Load	Initial	20lb Load	Initial	20lb Load
90.5	90	90.5	90	90.5	89.5
90.5	90	90.5	90	90.5	89
90.5	90	90.5	90	90	89
90.5	90	90.5	90	90.5	89.5
90.5	90	90.5	90	90.5	89
90.5	90	90.5	90	90.5	89.5
90.5	90	90.5	90	90.5	89
90.5	90	90.5	90	90.5	89.5
90.5	90	90.5	90	90.5	89.5
90.5	90	90.5	90	90	89.5

Difference between initial and loaded angles (deflection) for horizontal and vertical angle deflection tests.

Vertical Chin Rest Deflection			Horizontal Drawer Slide Deflection		
0" deflection (degrees)	6" deflection (degrees)	12" Deflection (degrees)	2" deflection (degrees)	6" deflection (degrees)	12" deflection (degrees)
3	3	2.5	0.5	0.5	1
2.5	3	3	0.5	0.5	1.5
3	2	3	0.5	0.5	1
3.5	2.5	2.5	0.5	0.5	1
2.5	2	2	0.5	0.5	1.5
3	2	2	0.5	0.5	1
3	2.5	2.5	0.5	0.5	1.5
3	2	3	0.5	0.5	1
2.5	2	2.5	0.5	0.5	1
3.5	1.5	2.5	0.5	0.5	0.5

Patient and clearance measurements from clearance testing in Dr. Sherman's office.

Patient Data			Clearance (in)	
Height (in)	Weight (lbs)	Headrest Extension (in)	Anterior	Lateral
60	127	1	9.5	11
74	230	4	13	16
64	132	7	16	18
61	114	7	15	16
63	150	6.5	12	14.5
65	145	7	14.75	17
72	250	6.5	11.5	14
62	180	7.5	11.75	14
64	140	7.5	14.25	16
65	190	7.25	14	17
71	174	6.5	15.25	16.5