Instrument Controlled Microscopy for Neurosurgical Applications

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Abstract

Our client, Dr. Joshua Medow, is a neurosurgeon at the UW Hospital. While operating, he uses a microscope to view the inside of a surgical cavity. Although the microscope has autofocus capabilities, it tends to be more of a hindrance than aid and therefore is usually not utilized during a procedure. The goal of this project is to design a new autofocus system that is capable of refocusing to a certain depth based on the location of a surgical instrument in the opening. The system may not interfere with other instruments or impede the surgeon's ability to perform necessary maneuvers. Our team has created three potential design ideas based on these guidelines. One incorporates a linear Hall Effect sensor to detect a magnetic field, another uses infrared sensing with a light emitting diode, and the last employs a sliding mechanism. Based on the results of our design matrix, we have chosen to pursue the option that utilizes infrared sensing.

Background

Neurosurgery is a specialized division of surgery that functions to diagnose and treat disorders and injuries that occur in the central and peripheral nervous systems ¹. Dr. Joshua Medow is a neurosurgeon at the UW Hospital and an assistant professor of the Department of Neurological Surgery in the School of Medicine and Public Health. During a neurosurgical operation, Dr. Medow uses a microscope to magnify the cavity created to perform the procedure. This microscope is typically located at a distance between eight and sixteen inches (twenty to forty centimeters) from the incision opening. There currently is an autofocus system integrated

into the microscope, but because of its limitations Dr. Medow usually chooses to deactivate it and manually control the focus of the microscope. Manual focusing consumes time, as he must stop the surgery, focus until the correct depth is achieved, and then resume operating. Therefore finding a more convenient method is desirable².

Current Design

Currently, surgical microscopes have passive autofocus systems that operate similar to those of single-lens reflex cameras. Light from the subject scene is directed to a pixel strip known as a charge-coupled device, or CCD. This sensor then provides input to a microprocessor that contains algorithms capable of computing how much contrast exists between different elements within the picture. When the subject is out of focus, the intensities of neighboring pixels on the CCD will be similar. If this is the case, the microprocessor will refocus the lens and make new calculations to determine if the intensities became more alike or distinct. It will continue to move the lens until it locates the position at which there is a maximum difference between the intensities of adjacent pixels. In order for this process to function properly, the scene must provide sufficient light and contrast ³. This system is often ineffective in surgical applications because a lack of contrast frequently exists in a magnified portion of the brain or spine. Also, the system is incapable of refocusing to a different location at the surgeon's discretion.

Problem Statement and Motivation

In conducting a complex neurosurgery, a surgeon operates within a cavity up to six inches in depth. Navigation within this cavity is aided by an operating microscope, which exhibits a depth of field of approximately 6 mm. Consequently, the surgeon may only observe, and therefore operate within, a relatively small fraction of the cavity at any given time. The

auto-focus feature included in the existing microscope further complicates procedures as it rarely focuses to the desired depth, nor does it stay at the desired depth while conducting surgical maneuvers. To correct this inconvenience, the surgeon must adjust the focus depth manually. In order to do so the surgeon must halt the surgery and refocus the microscope by hand to the desired depth. This is extremely problematic because standard surgical procedure calls for frequent changes in depth and therefore the surgeon is required to frequently refocus the microscope. The refocusing process not only consumes valuable time, but also disrupts the surgeon's train of thought and interrupts any maneuvers requiring continuous movement of an instrument from one depth to another. In order to simplify and improve the use of a frameless microscope in stereoscopic neurosurgery, our client Dr. Joshua Medow has challenged us to devise an auto-focusing device that may be integrated on to his existing microscope to alter face. Our product will function to eliminate the need to manually refocus the microscope to alter its focus in response to changes in the position of the surgeon's instrument tip.

Design Requirements

The design requirements for this project are outlined in the PDS in the Appendix, and explained in more detail here. As with any surgical instrument, the design constraints of this project are strict and precise. Failure to abide by these requirements may result in extreme harm to a patient, as well as complicating standard surgical procedures. The first of these strict requirements is safety. The design of this device must, at all costs, not interfere with any surgical materials nor may it hinder the performance of the surgeon. This device must also have the capability to be easily sterilized following procedures without disrupting functionality. Any

electrical components included in the design must be housed appropriately, and materials used must not release any substances that are harmful when exposed to the human brain.

Along with strict safety guidelines, our design must be ergonomically sound. A surgeon with a limited background in electronics must be able to easily use it. Furthermore, it is necessary for the device to be integrated with other surgical instruments without difficulty.

This device must also satisfy strict performance requirements, as it is used in highly technical surgical procedures. Mainly, it must possess the ability to track the position of the tip of a surgical instrument in an efficient manner. In doing so, our device should refocus with a lag time of less than one second, and should be compatible with any surgical implements. The device must also have a small margin of error, and high reliability. Due to the 6 mm depth of field of the microscope, and the necessity for extreme precision during surgery, our device should accurately track the tip on an instrument to within 1 cm of its actual position, and refocus the microscope with the same degree of accuracy. This degree of accuracy must be maintained throughout the lifetime of the device, to ensure its reliability meets the standards of the other instruments in the operating room.

Another important design constraint is the durability of the device. This device must have a life in service (provided it is well maintained and serviced) of three to five years. Along with this life of service, the device must have a long shelf life; meaning long periods of inactivity would not affect the usage and performance of the device.

This device will function in a meticulous operating environment. It will not be exposed to extreme high or low temperatures, as most procedures are conducted at or near room temperature. The operating room is also held to a high standard of cleanliness, which implies the

device will be operated in a dust-free environment. This device must also withstand exposure to UV light, as it is prevalent during neurosurgical procedures.

Finally, the physical specifications of the device must not obstruct the surgical procedure in any manner. As a result, the entire device must be less than 2.25 kg (5 pounds). The weight of components mounted on the surgical device, however must have minimal weight (no more than 15-20 grams), as it may not disrupt the balance of the instrument. The maximum size of the device should be 6" X 6", however the size of the device should also be minimized, as space is limited in the operating room. Provided that they are safe for the operating room and surgical procedures, any materials may be used in this device.

Hall Effect Sensor

When moving charges, also known as current, encounter a magnetic field, they experience a force perpendicular to both the field's direction and the direction of the charges' velocity. When current passing through a metal plate encounters a magnetic field, the force experienced by the individual moving charged particles causes these particles to deflect toward one end of the plate. The degree of deflection depends on the magnitude and direction of the applied magnetic field with larger deflections corresponding to greater magnitudes in directions

more perpendicular to the plane of the plate. As deflection occurs, a buildup of charged particles on one end of the plate establishes a potential difference across the plate proportional to the degree of deflection. This potential difference is known as the Hall Potential and the phenomenon to which it leads is known as the Hall Effect. Hall Effect magnetic sensors, like the one shown in Figure 1, measure the Hall Potential across



Fig. 1: Phidget 1108 Magnetic Sensor³ The figure shows the Phidget Hall Effect sensor, which uses angle and intensity of magnetic field to determine position.

an internal plate and, from that, calculate the magnitude of the perpendicular component of an applied magnetic field.

Our design incorporating a Hall Effect sensor consists of two components, an emitter mounted on a surgical utensil and a detector mounted on the microscope. A simple rare earth magnet serves as the emitter. It mounts on the utensil within a removable cap, which is interchangeable among as many utensils as is feasible via a screw clamp system. Specialized caps for more eccentrically shaped utensils will be designed if time allows. To detect the magnetic field emitted by the magnet, a Phidget - 1108 Hall Effect based magnetic sensor mounts above the surgeon's workspace and reads the magnitude of the perpendicular component of the emitted magnetic field. Because this data alone is insufficient to calculate the position of the emitter, let alone that of the utensil's tip, we must constrain the configuration of the utensil while the system focuses. In other words, while the focusing system is engaged, the surgeon must hold the utensil parallel to the vertical axis with the tip at the desired depth. With a known utensil configuration, and therefore a known magnet configuration, the data from the detector is transformed, via microprocessor, to the distance between the detector and the emitter. From this distance, the known length of the utensil and information about the utensil's configuration, the position of the utensil's tip is calculated and the microscope is focused accordingly.

While this design's wireless aspect makes it attractive at first glance, the practical considerations of its implementation limit its applicability as a solution to our problem. For instance, the Phidget – 1108 exhibits a maximum range of detection of a sizeable rare earth magnet of approximately four inches and a range of approximately two inches in which fourth inch variations in the magnet's position are differentiable. Furthermore, the 1108 only detects magnets in these ranges provided the magnets are positioned directly below the sensor. This

alone makes our design unviable as surgeons typically hold their utensils around nine inches from the microscope during an operation. However, even in the event that we modified our design to accommodate the short range of the detector, the weight of a rare earth magnet of strength sufficient to reach the detector would tend to disrupt the precise balance of most neurosurgical utensils.

Infrared Light Sensor

The GP2D12 is manufactured by Sharp as an infrared (IR) range finder. Behind one of its lenses is positioned an 850(+/- 70)nm light emitting diode (LED)⁴. Under normal operating circumstances the GP2D12 focuses light from this LED into a concentrated beam, which travels in a straight line until it encounters an



Figure 2: Sharp GP2D12 IR Range Finder⁵ The Sharp infrared sensor would detect a infrared LED mounted on the surgeon's tool.

object. Upon striking most objects' microscopically erratic surfaces, the beam scatters in all directions. Some of the reflected rays strike the GP2D12's second, infrared filtered lens and refract onto a charge coupled device (CCD). CCD's transform incident light into a voltage which depends on the portion of the CCD's surface the light strikes. The surface of the CCD in the GP2D12 exhibits raised portions that allow the voltage produced by the CCD to correspond to the angles of the incident light relative to an axis perpendicular to the CCD. From the angle at which reflected light strikes the CCD and the known angle at which the light originally leaves the GP2D12, the distance between the GP2D12 and the object from which the light reflected can be calculated through triangulation.

Like our design based on the Hall Effect sensor, the infrared sensor design employs an independent emitter and sensor system. In this case, two components comprise the emitter

portion of the system, a utensil mounted 850nm infrared Light Emitting Diode (LED), and a wristband mounted power supply. The IR LED mounts on the utensil through a cap very similar to that used to mount the magnet of the Hall Effect sensor design. However, the size of the cap may require adjustment to accommodate any circuitry necessary to power the LED. Slack, insulated wiring runs from the LED in the cap to a wristband, on which mounts a power cell and, as much as possible, the circuitry required to power the LED.

The detector portion of this design incorporates two, GP2D12 IR range finders, modified such that they do not emit their own infrared light. This modification allows the GP2D12 to detect IR light from other sources, namely our utensil mounted LED, without interference from its own emissions. The 850nm LED used as the emitter in this design approximates a point source of light. Therefore, it emits rays in all directions from a small area of origin just as would the reflected beam of the GP2D12's own source. Furthermore, since the wavelength of our LED matches that of the GP2D12's filter, the GP2D12 should allow light originating from the LED to reach its CCD just as it would allow light from its own source. Therefore, the modified GP2D12s no longer detect the incident angle of light reflected from a distant object but rather the incident angle of light emitted by our LED. The angles detected by the two GP2D12s along with the known, fixed distance between the detectors, provide enough information to triangulate the position of the utensil mounted LED. However, this position does not allow for calculation of the position of the utensil's tip since many utensil configurations are possible for a single LED position. Consequently, we must limit the configuration of the utensil during focusing just as we did in the Hall Effect sensor based model. A vertical utensil configuration provides the vertical distance between the LED and the utensil tip and allows the position of the tip to be calculated from the position of the LED. The triangulation of the position of the LED, the subsequent

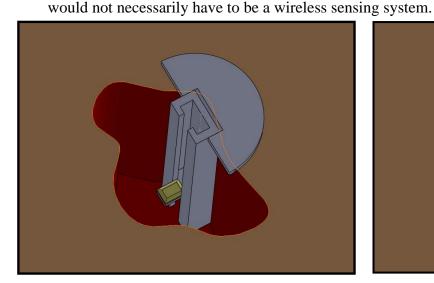
calculation of the position of the utensil tip and finally, the focusing of the microscope based on tip position is all handled by a single microprocessor mounted on the scope with the detectors.

Despite this design's inclusion of wires, it remains a viable option. Due to the amount of slack in the wires linking the utensil to the wristband, significant rotation of the utensil with respect to the wrist should remain possible. Beyond such rotation we assume that the wrist will translate and rotate along with the utensil, so the wires will not factor into the utensil's motion. Consequently, appreciable restriction of the utensil's range of motion should not occur. In addition to preserving the utensil's range of motion, powering the LED with a wristband-based source reduces the weight of the component mounted on the utensil. This becomes important when a procedure requires a precisely balanced utensil. Finally, the factor which distinguishes this design most from the Hall Effect sensor design is the ability of light to travel long distances with minimal attenuation. Whereas the range of the Hall Effect sensor literally fell short of our requirements, the 10 to 80 centimeter normal operational range of the IR detector-emitter combination meets and exceeds our specifications.

Sliding Sensor

With the two previously mentioned design alternatives, there is a lot of difficulty associated with the three degrees of freedom that the user is allowed with their surgical tool. Using a sliding sensor like the one in Figure 3, the degrees of freedom of the system are reduced to one. The device would simply consist of a simple mechanical sliding mechanism to allow the sensor, either infrared or magnetic field, to move only in the vertical direction. As the surgeon moves to different locations in the cavity, they can simply slide the sensor to the depth they are working at. Shown if Figure 3a, the system with the sensor set at a depth nearly to the bottom of the cavity. Figure 3b shows the same setup with the sensor moved to a shallower depth in the

surgical cavity. This method would work with other types of electromechanical systems that allow an object to vary the output voltage depending on its location on the slider assembly and



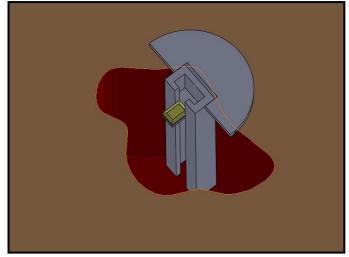


Figure 3: Sliding Sensor Figure 6a (left) shows the sliding sensor at nearly maximum depth. The depth of the sensor is much shallower in Figure 6b (right), after the sensor was slid up by an external force (user).

This system would also allow for exceptions to the size and wireless power problems that plagued the other devices. The hard mounting of the sensor would allow wires (not shown) to be run into the housing and power the sensor without limiting motion of the surgeon's tool. However, it is important to note that the sliding sensor system would be placed directly into the patient's surgical cavity, and would require the movement of the system, and recalibration of some sort (if using a sensor), if the surgeon were to require access to a portion of the cavity blocked by the sliding sensor assembly. This would be the most expensive design, as it would require the purchase of the not only the sensor components like the other devices, but also materials for the fabrication of the slider assembly.

Design Matrix

The different design alternatives all had individual strengths and weaknesses for the application at hand, and in order to efficiently compare them, a design matrix was used. This allowed for a quantitative comparison based on the relative importance of different design criteria specified by our client. Cost, Accuracy, Ease of Use, Feasibility and Appropriate Size were considered in the design matrix, with different weights depending on the importance to the client specified design criterion.

Cost

The cost was the smallest of all the design matrix criteria, allocated only five percent of the total points. This was because the cost of the device was not a major factor in the decision making for the device being designed. Cost, was considered, but not nearly as much as other design criteria because our client allowed us to go over the preliminary budget of \$500, as long as the design was not a significant risk. The infrared and Hall Effect sensors and had the highest marks for cost because they would require an infrared or magnetic source marker, and an infrared or magnetic field sensor, both of which are in similar price ranges. The sliding sensor would use an infrared or magnetic field sensor, but it would also require the fabrication of a housing device, which would increase the cost of the design.

Accuracy

The accuracy of the different designs is directly related to the way they are used in surgery. The sensors themselves are all suspect to error, but they are insignificant in the scope of the system being implemented, as the microscope has a range of depth that is viewed in focus that is much larger than the error in the sensors. The infrared and Hall Effect sensors would both be used in a wide variety of positions, and would be aligned under the sensor by the user for

depth measurement. This method is more susceptible to user errors because any horizontal distance that the marker is from the sensor is converted into a longer vertical distance. The sliding sensor would allow for the sensor to mount directly to a fixed slide system, so there is no room for error in the positioning of the sensor. For this reason, the slide system was given the highest accuracy rating followed by the two sensors.

Ease of Use

Ease of Use is a measure of the design alternative's simplicity while being used by our client and other surgeons alike. Ease of use was allocated 25 percent of our total design matrix points because making the life of the surgeon easier is the first priority with this device. If the surgeon decides that the cumbersome device requires more work to use than simply manually focusing the microscope, than the design will have failed its primary objective. The sliding sensor scored the lowest in this category because it requires the user to constantly slide the sensor up and down to the desired depth. This may be easy in some situations but more difficult if the surgical opening is particularly small, allowing for limited access to the sliding sensor. The Hall Effect and Infrared sensors would not be influenced by varying workspace sizes, as they are mounted directly to the surgical tool itself. This means that the microscope could easily be refocused whenever the user decides it is necessary. It is for this reason that the Hall Effect and infrared sensors.

Feasibility

All of the proposed designs work well in theory, but in order to compare the different designs for use in neurosurgery, Feasibility was compared. This was the most important criteria compared in the design matrix simply because it was the biggest limiting factor when deciding on different designs. Feasibility was given 35 percent of the total points, reflecting its large

importance in the decision-making process. The infrared sensor was the clear winner, as it allows for the relatively smooth application to neurosurgery. The only difficulty with the infrared sensor is powering the infrared markers, which is easily accomplished with a wristband containing a battery for power. The Hall Effect sensor works wonderfully, even better than the infrared sensor in fact, as it does not require power to the marker (magnet). However, the Hall Effect sensor is only effective for monitoring position for extremely small distances, typically less than one inch. For use in neurosurgery, the marker would be required to travel around six inches, explaining the why the Hall Effect sensor received the lowest score (12) in the Feasibility category.

The sliding sensor did not fare much better, only receiving a slightly higher score (17) than the Hall Effect sensor. The sliding sensor design shown in Figure 3 would require limitations on the type of environment it is placed in to work efficiently. For example, if the surgical opening in the patient was not a perfectly perpendicular opening like shown in the example, this would require intrusive positioning of the slider, or a hinged system which would remove the simplicity and accuracy for which the design was initially considered. The sliding sensor would also be introduced directly into the patient's body, and would cause significant health risks unless completely sterilized after every use.

Appropriate Size

Appropriate Size is a measure of the size of the complete system relative to the constraints of the surgical setup. Our client specified that any device that affected the balance point of the surgical tools could not be used in surgery. For this reason, 20 percent of the design matrix points were allocated to Appropriate Size in an effort to minimize the size marker and minimize the adverse effects of the system on the surgeon's ability to perform demanding fine motor tasks. The sliding sensor design is actually the largest of the design alternatives but it has

the smallest effective size because it does not mount anything at all on the surgeon's tool. The system still encumbers free motion inside the cavity because of its size and location. The position of the sliding sensor would limit the amount of area the surgeon has to work on without moving the sliding sensor assembly. This explains the higher, but not perfect score of the sliding sensor. The Hall Effect sensor would require a small magnet to be mounted to the surgeon's tool, but would be relatively small and have minimal effects performance. The infrared sensor design would require a battery pack to be worn on the wrist of the user to power the infrared markers. This would also require wires to be attached to the marker on the tool, further decreasing the freedom and performance of the tool in surgery. This explains why the Hall Effect sensor had a lower score than the sliding sensor but still higher than the infrared sensor.

Design	Cost (5)	Accuracy (15)	Ease of Use (25)	Feasibility (35)	Appropriate Size (20)	Total (100)
Infrared Sensor	5	10	25	35	10	75
Hall effect Sensor	5	10	25	12	12	62
Sliding Sensor	3	13	20	17	15	70

Table 1: Design Matrix

The design matrix shows that the biggest difference in the three designs came in Feasibility, which is a measure of how easily or feasibly the design can be applied to the neurosurgical environment and limitations

Projected Costs

The budget for this project is around \$300, with flexibility depending on our ability to show a working prototype for a higher cost design. For this reason, we focused on designing a

relatively low cost prototype which will allow for proof of design before funds are exhausted on a design that doesn't end up working as well as expected. Table 2 shows the costs so far, as well as the costs expected throughout the rest of the design and fabrication process. The values for the infrared sensor and markers were estimated as we have not decided on exactly which infrared system best suits our needs for this project.

Item	Cost	
Infrared Sensor*	\$ 50.00	
Infrared Marker*	\$ 25.00	
Batteries for Marker	\$ 10.00	
Magnetic Sensor	\$ 8.97	
Miscellaneous Supplies	\$ 50.00	
Rare Earth Magnet	\$ 2.00	
Shipping/Tax	\$ 10.00	
TOTAL	\$155.97	
*Depends on particular one chose	en	

Table 2: Projected Costs

The table shows the estimated costs for the completion of the project, as well as costs already accumulated for preliminary testing

Ergonomics

The final design has to be able to be easily and efficiently used regardless of the electronics or sensor background knowledge of the user. In order to ensure the design could be

used by all neurosurgeons, not just our client, the design is intended to have minimal if any

training involved before use. The device will obviously require some instruction before use, but it will be such that anyone can follow simple instructions and easily use it. This will help reduce the learning curve with the device and allow a broad spectrum of surgeons use our device. In order to facilitate the desire to employ the device, it will be engineered in a manner that makes it easy for the surgeon or assistant to set up the device before surgery, and remove after surgery.

Future Work

Over the course of the second half of the semester, we will seek to prove the feasibility of our infrared light based concept. As of yet we have not done any concrete testing of the GP2D12. As we move forward this will be our first step. Testing will involve wiring the GP2D12s to an Arduino Duemilanove processor which interfaces with a CPU through a USB cable. This computer interface will allow us to read and plot the outputs of the GP2D12s. Once we are able to correlate LED positions with the GP2D12's output, we will write a program that visually displays, on a computer monitor, the direction in which the microscope must be focused according to the position of the LED. If time allows, we will modify this program to run a motor in a direction dependent on the position of the LED. Finally, we will fabricate the interchangeable cap which mounts the LED on the surgical utensil and assemble the circuitry to be mounted on the wristband.

In future semesters we will seek to expand our concept to allow the microscope to focus on the utensil's tip dynamically throughout the surgical procedure. We will accomplish this by integrating a second LED into the interchangeable cap. Through a significant amount of testing we will gain the ability to correlate the GP2D12s' output with the positions of both LEDs. Using these positions and the fixed length of the utensil we will program our processor to create a line segment from the first LED, passing through the second LED and extending to the tip of the

utensil. We will then instruct our processor to track the position of the tip end of this line segment. From this position we will create a visual representation of the direction in which the microscope must focus. Finally, we will integrate our entire system into an existing microscope such that, instead of visually displaying the direction in which the microscope must focus, the processor controls a motor that physically focuses the microscope.

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Appendix

Product Design Specifications Autofocus Microscopy Group Members: John Byce, Justin Gearing, Mason Jellings, Sarah Reichert Advisor: Prof. Yen **Function:**

During a neurosurgery, a surgeon operates in a cavity which may measure up to six inches in depth. Navigation within this cavity is aided by an operating microscope which exhibits a depth of field of approximately half an inch. Consequently, the surgeon may only observe, and therefore operate within, a relatively small fraction of the cavity at any given time. In order to change the depth of operation, a task which most surgeries require be carried out frequently, the surgeon must halt the surgery and refocus the microscope by hand to the desired depth. The refocusing process not only consumes valuable time but also disrupts the surgeon's train of thought and any maneuvers which require continuous movement of an instrument from one depth to another. Our product will function to eliminate the need to refocus the microscope as the surgeon transitions from one depth of field to the next by allowing the microscope to alter its focus in response to changes in the position of the surgeon's instrument tip.

Client Requirements:

- The device must not interfere with any surgical maneuvers
- Must be lightweight
- Must be compatible with current microscopes and other surgical equipment
- Must hold up to sterilization
- Must keep instrument in depth of field at all times
- Must not interfere with other instrumentation
- Must not harm patient or medical personnel

1. Physical and Operational Characteristics

a.) Performance Requirements: The device must track the position of the tip of a surgical implement and refocus accordingly. It should refocus without any significant lag time (<1sec.) and should work with any surgical implements.

b.) Safety Requirements: The device must not interfere with the surgeon's ability to perform to his or her best abilities. It must not release any harmful substances during surgery. All electronics must be housed appropriately. Any components which will come in contact with the patient during surgery must be easily sterilized.

c.) Accuracy and Reliability: The device must track the position of the implement tip to within one centimeter (initially) of its actual position and refocus the microscope to the same degree of accuracy. It must retain this degree of accuracy throughout its lifetime.

d.) Life in Service: Provided it is regularly serviced along with the microscope and does not undergo unnecessary abuse, the device should last three to five years.

e.) **Shelf Life:** Long periods of inactivity should have no effect on the performance of the device.

f.) Operating Environment: The device will function in an operating environment. This suggests it will not encounter extreme temperatures or humidity. The device is intended to be used in a clean, dust-free environment in order to optimize the performance of electronics. It will also be designed to withstand continuous UV light exposure.

g.) **Ergonomics:** The device should be easy to use for any surgeon with minimal electronics background. It will be user friendly such that someone skilled in the art of surgery could use it without problems.

h.) Size: The device will be used in an operating room, where space is at a premium. For this reason, the footprint of the entire device should be minimized, with a maximum of 6" X 6".

i.) Weight: The component mounted on the surgical instrument should not inhibit fine adjustments by the surgeon. The entire device must not exceed 5 pounds.

j.) **Materials:** Any materials are welcome, provided they are safe for use in an operating room.

k.) Aesthetics: Aesthetics should not affect any aspect of our design as our client prefers function over appearance.

2. Production Characteristics

a.) **Quantity:** One complete prototype will be fabricated.

b.) Target Cost: Firm guidelines for cost have yet to be established, but there will be refinance allowance of \$500.00.