Safe Method to Teach Fluoroscopy During Surgical Simulation

Product Requirements Document

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E	12-15-2017

Authentication Block

Rev	Description	Date	Authorization
A	Initial PRD	11-03-2017	KA
B	Second PRD	11-16-2017	KA
C	Third Revision PRD	12-1-2017	KA
D	Fourth Revision PRD	12-14-2017	KA
E	Final Revision PRD	12-15-2017	KA

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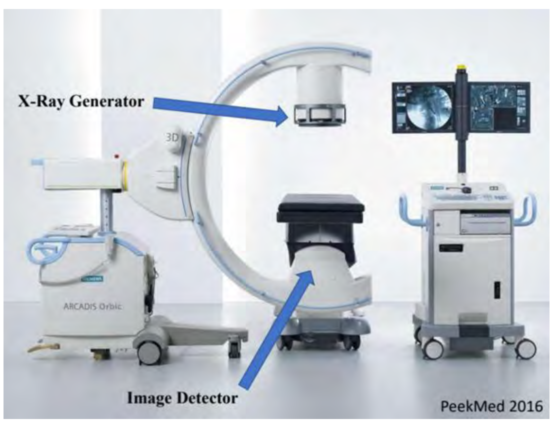
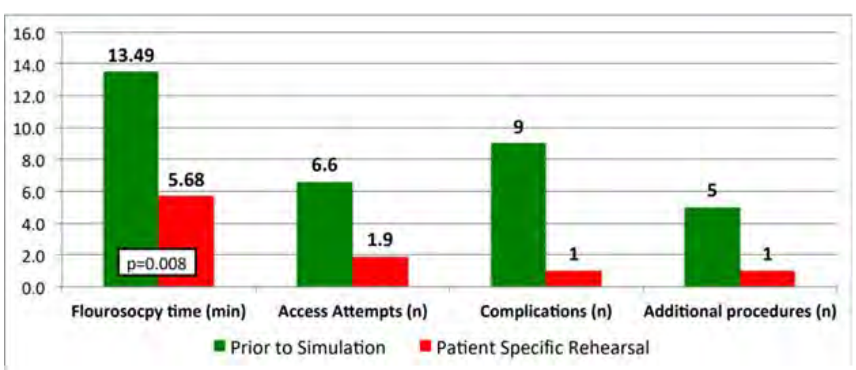
The NIR surgical simulation system is a customer driven product. As such its design inputs are derived from the direction of our customer, Dr. Ahmed Ghazi.

VISION

The product is a near infrared (NIR) imaging system prototype that can be used in simulations in surgeries to accurately replicate the current technology of fluoroscopy using the NIR light in place of X-Rays. Design includes an optical lighting and imaging system that must image through PVA (Polyvinyl Alcohol) or other customer approved material and a display to show real time results. If time and resources allow will include mechanical prototype that will rotate 30 degrees on the roll axis and 15 degrees on the pitch axis. Performing these practice surgeries gives the surgeons a much higher rate of success, and this project will allow them to perform these practice surgeries in a safe environment. This design is intended to be reproducible.





"Improved Patient Outcomes with Simulation"

PROJECT SCOPE

Our responsibilities include: designing and testing the optical system, working with our customers to select the best materials, and constructing a functioning prototype of the system.

We are not responsible for: making the sample material.

TIMELINE

By October 18th, 2017	• Recieve Team Assignments • Initial meeting with Customer and Optics Advisor
By November 17th, 2017	• Complete Product Requirements Document Reviews #1 and #2 • Secure laboratory testing room ○ Begin testing PVA samples • Apply for a Mechanical Engineering Senior Design Team to work in conjunction with ours • Additional Customer and Advisor Meetings
By December 13th, 2017	• Research and explore more sample materials • Finalize Product Requirements Document
By end of Winter Break (~January 17th, 2018)	• Learn LightTools • Research new sample materials
January	• Test new and researched materials • (Hopefully) begin working with Mechanical Engineering Senior Design Team
February	• Finalize Sample Material • Finalize Design Specifications • Finalize Bill of Materials
March	• Begin building • Begin testing • IA Presentation
April	• Finish building • Finish testing • Present at Design Day

ENVIRONMENT

No specific environment needs, not a controlled environment. Intended to be used indoors.

Temperature

Standard room temperature: 20-25°C

Relative Humidity

20% or higher

It will operate under outlet power.

REGULATORY ISSUES

Based on the final source chosen we will need to do analysis to determine the safety hazards of the final design.

Laser safety goggles may be needed while in use.

ANSI/IEC 62471- Photobiological Safety of Lamps and Lamp Systems [1]

Classification - 4 Risk Groups (RGs) based on potential acute hazard:

• RG 0 (or Exempt) – no risk for up to 10,000 s

• RG 1 (low risk) – no risk under normal conditions of use (up to 100 s)

• RG 2 (moderate risk) – no risk due to aversion response to bright light sources (up to 0.25 s)

• RG 3 (high risk) – potential risk even from momentary exposure

Hazard	Wavelength range (nm)	Max. reported risk group
Actinic UV	200-400	RG3
Near UV	315-400	RG3
Blue light	300-700	RG2
Retinal thermal	380-1400	Exempt/ RG1
IR eye	780-3000	RG3

[2]

FITNESS FOR USE

The system will:

Consist of an NIR illumination source, camera, and a fold mirror to shorten the path length, as well as optics after the illumination source and before the camera as needed.

Need to image through 10 cm of PVA (minimum).

Illumination aperture should be 10 cm (diameter).

700-1000 nm wavelength, Specific single wavelength will be tested and the optimal chosen.

-Currently using NIR LED Flashlight as source of approximately 850nm

-May evaluate the the mid and long wave infrared

It is desirable that:

The cost of the scanning system is <5000$ USD, though ultimately the cost is dependent on how reproducible the product can be.

If there is time and/or team resources available:

-Software and pedal system to turn the light source (and camera) on and off

-A mechanical mount that is portable and will rotate 45 degrees (C-arm), as well as a surface for the sample to rest on.

→Will need support from a mechanical engineering senior design team.

Required Specifications	
Parameter	**Requirement**
Minimum Diameter of Sample (cm)	10
Minimum Depth (cm)	10
Maximum Depth (cm)	$\geq$ 25
Source	

Wavelength (nm)	700-1000 (NIR range)
Camera	
Frame Rate	≥ 30 fps
Minimum Feature Size	~ 1 mm

BUDGET

What We Need		
Item	**Price**	**Source**
940-nm flashlight	$ 20.00	Amazon
10 cm square mirror	$ 10.00	Amazon
Safety Goggles	$ 200.00	ThorLabs
PVA, 100 g	$ 15.00	Amazon
LED (850nm) Floodlight	$ 30.00	Amazon
Fresnel Lens	$ 90.00	Edmund Optics
LightTools Software	N/A	Through the school

PROPOSED SYSTEM DESIGN

Specifications of the System design including wavelength, imaging and illumination distances will need to be determined after the material is determined. Based on the material, we are open to changing design to better deliver project.

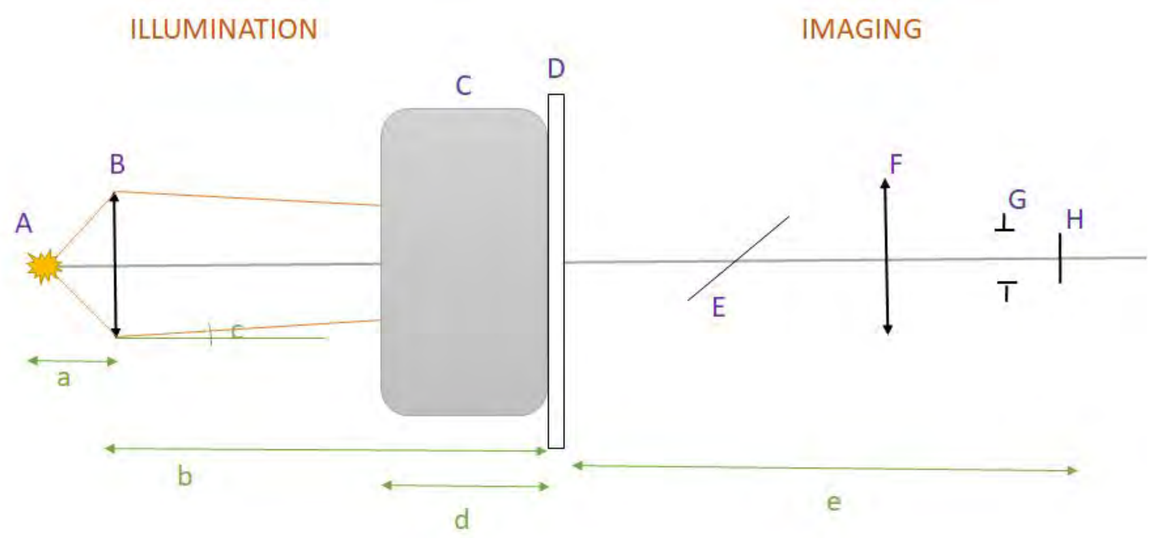


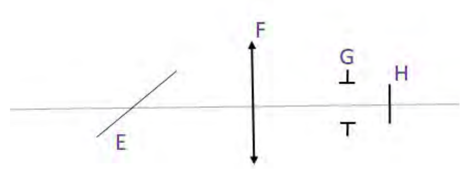
Figure 2: System design. Not to scale

A	Source: 700nm-1000nm; currently using 850nm
B	Positive Fresnel lens: Focal Length TBD
C	Sample: Material to be analyzed
D	Sample Table
E	Fold Mirrors: Will be added as necessary Note: figure does not show the bending of light at mirror
F	Condensing optics Note: only one lens is shown, but will add more as needed
G	Aperture Stop of Camera
H	Sensor

a	Distance between source and lens -will need to optimize
b	Lens to table -60cm minimum
c	Angle of light from illumination design -5° or less estimate
d	Height of sample that will need to be imaged through -10-25cm
e	Path length from the table to the sensor -30-70cm

Imaging Design:

Imaging design will be dependent on material chosen and therefore may change. Major components will be fold mirrors, condensing optics, and a camera with given sensor and aperture.

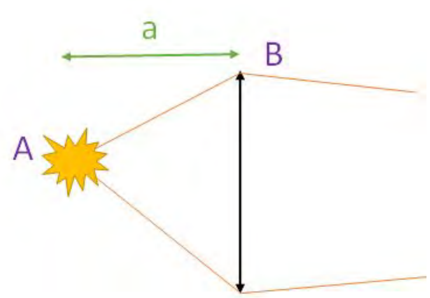


Imaging Design limited by existing camera.

Illumination Design:

Illumination design will be dependent on material chosen and therefore may change.

Option 1:



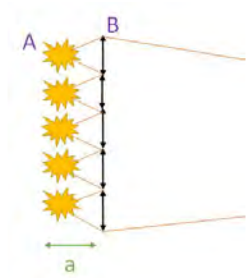
A: Source- LED, NIR

B: Positive Fresnel Lens

Pros: Cheaper

Can use commercial optics

Option 2:



A: LED Array

B:Lens Array

Pros:Thinner form factor

More customizable

MATERIALS

Materials will need to be explored and an analysis on key optical properties, including the scattering, transmission, absorption, and index will need to be done on all proposed sample materials.

Material to explore include but are not limited to:

Agar, Gelatin, additives to PVA

PVA

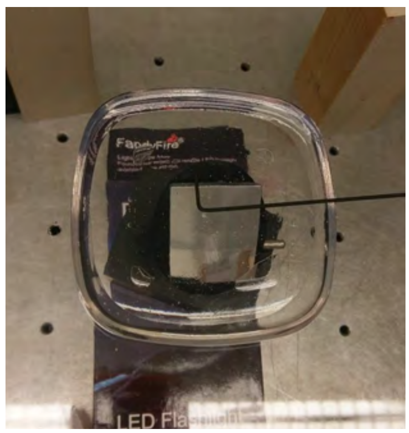
Refractive Index (10% PVA, 90% water)	~1.3515 (measured) *Varies with water % and polymerization
Refractive Index (100% PVA)	1.46916

Currently the PVA we got from our customer has a marbled pattern that is difficult for us to image through with good quality. We tested two samples of 10% PVA and 7% PVA and was able to resolve 1mm with a thickness of 2.5 cm.

7% PVA

10% PVA

DMSO



DMSO Sample

REFERENCES:

1. Miller, Sharon, and William Calhoun. "Non-Coherent Light Sources." Fda.gov, www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Radiation-EmittingProducts/TechnicalElectronicProductRadiationSafetyStandardsCommittee/UCM526259.pdf.
2. Lidplussdesign. "El Rey Salvador, The Art of Lighting, Photobiological Safety Standards." *El Rey Salvador*, 2014, www.erslighting.com/useful-information/photobiological-safety-standard/.

APPENDIX A

Mechanical Requirements

Maximum Weight	25 kg
Distance between light source and table	60-90 cm
Size	Tabletop
Arm Rotation	30 degrees roll ± 15 degrees pitch
Power Source	Outlet Power

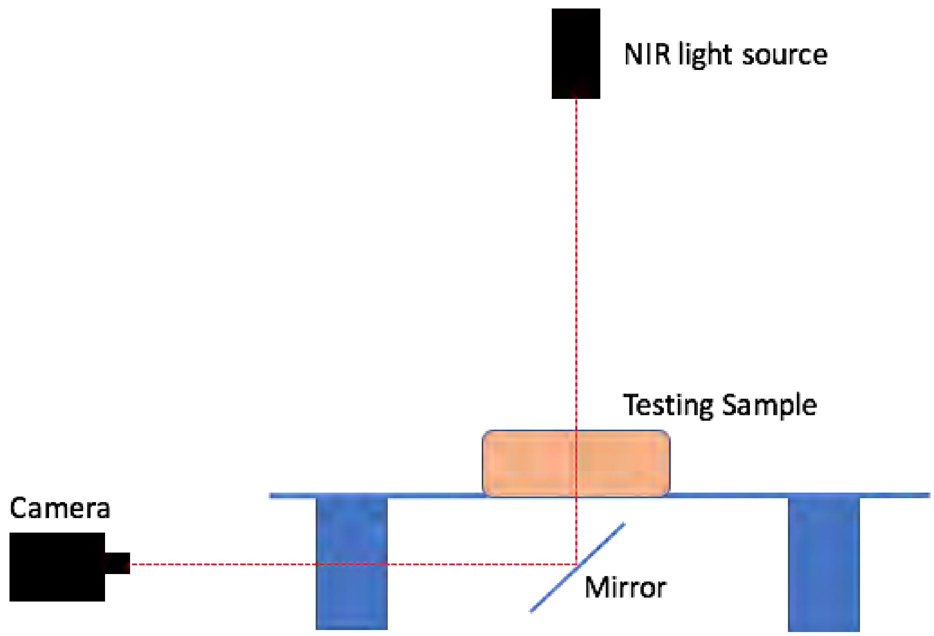
APPENDIX B

PRELIMINARY TESTING

Current System specifications

Parameter	Requirement
Source	
Wavelength (nm)-Flashlight	850
Maximum Power (mW)-Flashlight	4.8
Wavelength (nm)-Array	940
Maximum Power (W/cm^2)-Array	0.9
Camera (DMK 31BF03 Monochrome Camera)	
Maximum Frame Rate	30 fps
Pixel Size (microns)	H: 4.65, V: 4.65
Maximum Resolution (pixels)	H: 1,024, V: 768
Camera FFOV (degrees)	13.5
Lens	
Focal Length (mm)	25
F/#	1:1.4

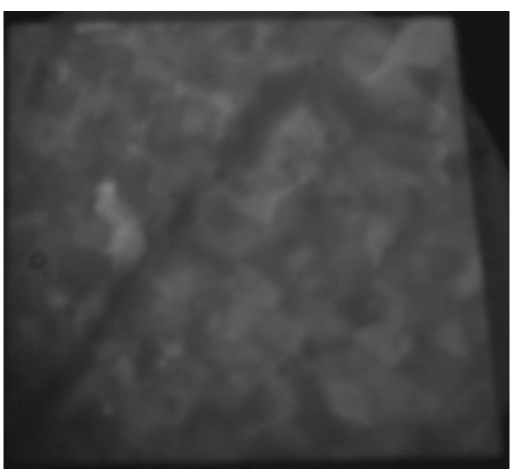
Current Testing Set-Up



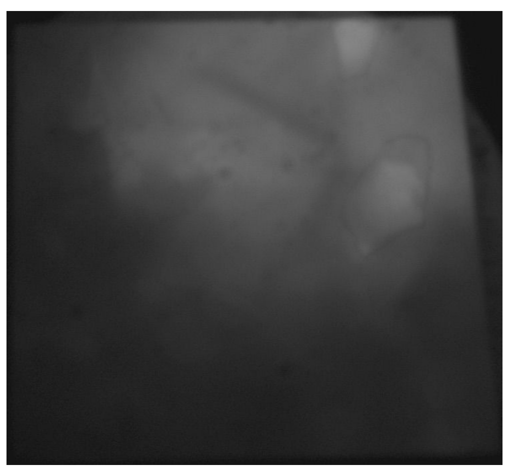
Preliminary Results

All samples are 1.5 cm thick and the object is 1 mm thick.

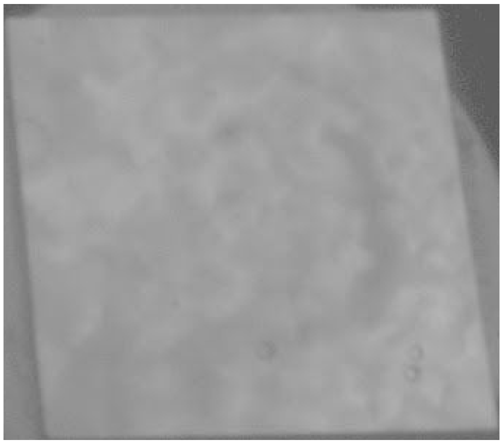
PVA



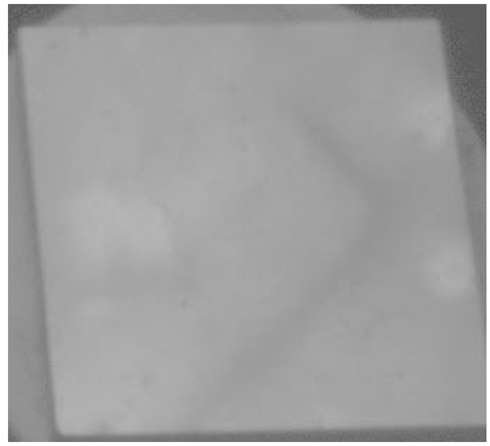
7% PVA 850-nm



10% PVA 850-nm



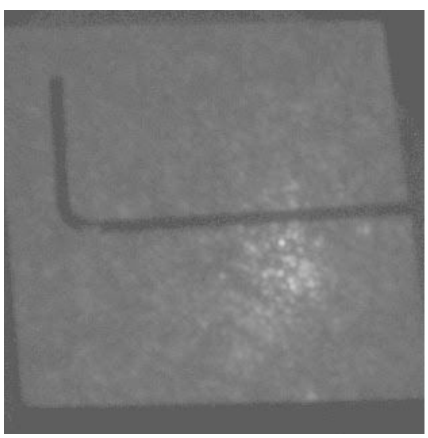
7% PVA 940-nm



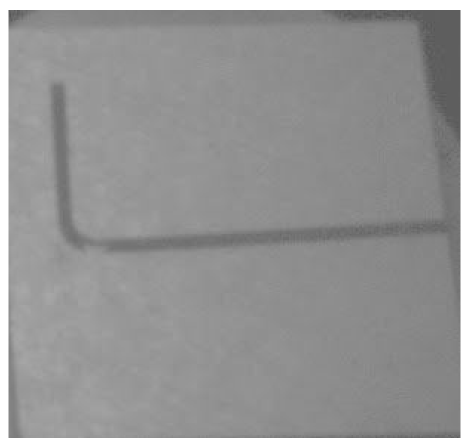
10% PVA 940-nm

After testing, we can see that both samples have a large scattering effect on both light sources. The reason for this, and the marbled patterns on the samples, is due to cross-linking during the freezing process that solidifies the sample. It creates crystals in the material that form areas of differing refractive index, contributing to the large amount of scattering. In order to solve this problem, we may have to find a new method for solidifying the PVA, or even finding a new material entirely.

DSMO



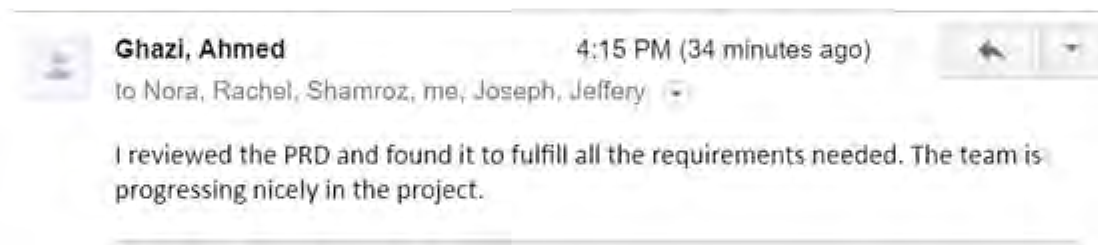
DMSO 850nm



DMSO 940nm

With the DMSO material, we get a very clear image, but the surgeon will be able to see through the sample with naked eye. To prevent this, we will consider adding an opaque layer to the top of the sample, or possibly adding food coloring or dye to the mixture: anything that NIR wavelengths can still penetrate but not for visible wavelengths. DMSO is not as stable as PVA and will shrink if left out.

This has been approved by our customer, Dr. Ahmed Ghazi (ahmed_ghazi@urmc.rochester.edu) on 12/15/17.


Ghazi, Ahmed 4:15 PM (34 minutes ago)
to Nora, Rachel, Shamroz, me, Joseph, Jeffery

I reviewed the PRD and found it to fulfill all the requirements needed. The team is progressing nicely in the project.