In-vivo Thyroid Photoacoustic Camera
Product Requirements Document
“Beam Squad”

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Revision History

Rev	Description	Date	Authorization
A	Release	November 2 2015	All
B	Added timeline Laser delivery requirements Updated responsibility	November 15 2015	T, Z
C	Updated fitness for use, desirables Added budget/materials Added specifications Updated timeline	November 22 2015	All
D	Added group responsibilities Added proposed laser delivery systems Updated budget/materials Added recourses needed Added appendix	December 09 2015	All
E	Updated divergence spec Updated focusing lens spec and price Updated resources needed (lens design)	December 11 2015	All

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1. Introduction

The in-vivo photoacoustic camera currently being researched has the potential to be a tool used in detecting early stage thyroid cancer. The camera is being developed under the supervision and with the help of Dr. Navalgund Rao, a professor in the Imaging Sciences Department at RIT, Dr. Vikram Dogra, a doctor in the Radiology Department at the University of Rochester Medical Center (URMC), and Dr. Bhargava Chinni, a researcher in the Department of Imaging Sciences at URMC. The goal of this project is to ultimately create a laser delivery system which will deliver laser light to a handheld probe. If time permits, this probe will also be designed and fabricated.

Vision

An in-vivo photo-acoustic thyroid imaging system for use in a clinical setting, with the purpose of differentiating between normal and malignant tissue within the thyroid. This consists of a laser source, laser delivery system, an imaging probe, and a detector within the probe. The primary goal of this project is to design the laser delivery system which connects to the imaging probe placed against the patient’s neck. This delivery system must have low power loss and must produce a uniform beam, as the source of illumination for the imaging probe.

2. Environment

As a laboratory instrument, it needs to operate in the following environment:

Temperature

15-35 ℃ - safe operation/ meets specifications

Relative Humidity

Non-condensing – meets specifications and safe operation

- Acoustic lens **5** must be able to be submerged in water or a similar liquid.
- The liquid used in the setup should have matching acoustic impedance to the reflecting plate **4**.
- During normal operation, the imaging probe **3** will come into contact with human tissue **8**. Therefore any parts of the probe in contact with human tissue must be readily cleaned and sterilized. Also, the probe must be sealed from outside fluids and gases.
- Wall power is necessary for the laser that is used as the source. The laser which acts as the source for the camera, will be too large to be portable and as such, must be located on a tabletop, far enough away as not to impede the physician.
- The probe **3** itself must be handheld and easily portable.
- The images produced by the imaging probe must be displayed in real time on a computer monitor, connected to the probe.

3. Laser Safety Issues

- The laser proposed for use in this product is characterized as a class four laser.
- The laser used in this camera falls under ANSI standard Z 136.1 specifying that the peak power of the laser pulses incident upon tissue must be less than 20 mJ/cm^2.

4. Fitness for Use

4.1 Fitness for Use:

Our group is responsible for the laser delivery system that delivers the source illumination (laser light) to an imaging probe **3**, similar to that which has been created already for an in vitro application. As such, the delivery system will:

- Be able to move in three dimensions
- Produce a uniform beam (uniformity metric is still being discussed)
- Result in power loss <50%

4.2 Specifications		
Laser Source		
Wavelength	=	700-1200nm; specifically 760, 850, 930, and 970 nm
Pulse Repetition Frequency	=	1-10 Hz
Pulse Duration	=	3-5 ns
Pulse Peak Power	=	10-70 mJ/cm^2
Beam Diameter	=	8mm
Laser Delivery System		
Power Loss	<	50% over 700-1200 nm bandwidth
Divergence	<	0.5 mrad
Uniformity of output beam	>	90%
Movement	=	Able to move in x,y,z directions
Detector		
Transducer array	=	32 element, linear array
Pitch	=	0.3 mm
Element Dimensions	=	0.7 x 1 x 0.15 mm
Center Frequency	=	8 MHz

4.3 Desirables

Our group is responsible for designing the laser delivery system that will deliver laser light to an imaging probe. If time permits, we will also proceed with creating said imaging probe according to our customer. It is desirable that the entire system:

- Be able to image one lobe of the thyroid using a handheld, portable probe **3**
- Have a resolution of 0.7x1.0x0.15 mm, based on the size of the detector elements **6**.
- Produce images through the use of inexpensive real time focusing with C-scan image display on the detector.
- Contain a beam shaping diffuser **7** that can convert a circularly or linearly shaped beam to a linear distribution **8** such that the beam matches the dimensions of the linear array transducer **6**.
- Contain either a thin glass plate **4**, which acts as an acoustic reflector, or a plate composed of an acoustically transmissible material, coated with an optically reflective coating.

Using proposed delivering system with beam arm, the system may also:

- Include a coupling system **1** from laser source to the delivery system, as well as from the delivery system to the probe.

5. Group Responsibilities

5.1 We Are Responsible For:

- Designing a laser delivery system for a multi-mode infrared laser that will be the most efficient at minimizing power loss
- Design the laser delivery system such that it delivers pulses at or under 20 mJ/cm^2 in order to meet ANSI standards
- Building and testing a prototype with the customer’s laser system to make sure the delivery system is up to the customer’s expectations

5.2 We Are Not Responsible For:

- Designing and creating a prototype of the imaging probe
- Finding a method in which to couple the imaging probe to our laser delivery system
- Integrating the software that will be used to analyze images of thyroid tissue with the entire system
- Any finite element analysis involving the transmission rate of ultrasound through the imaging probe

6. Proposed Laser Delivery Systems

6.1 Articulated Beam Arm Method

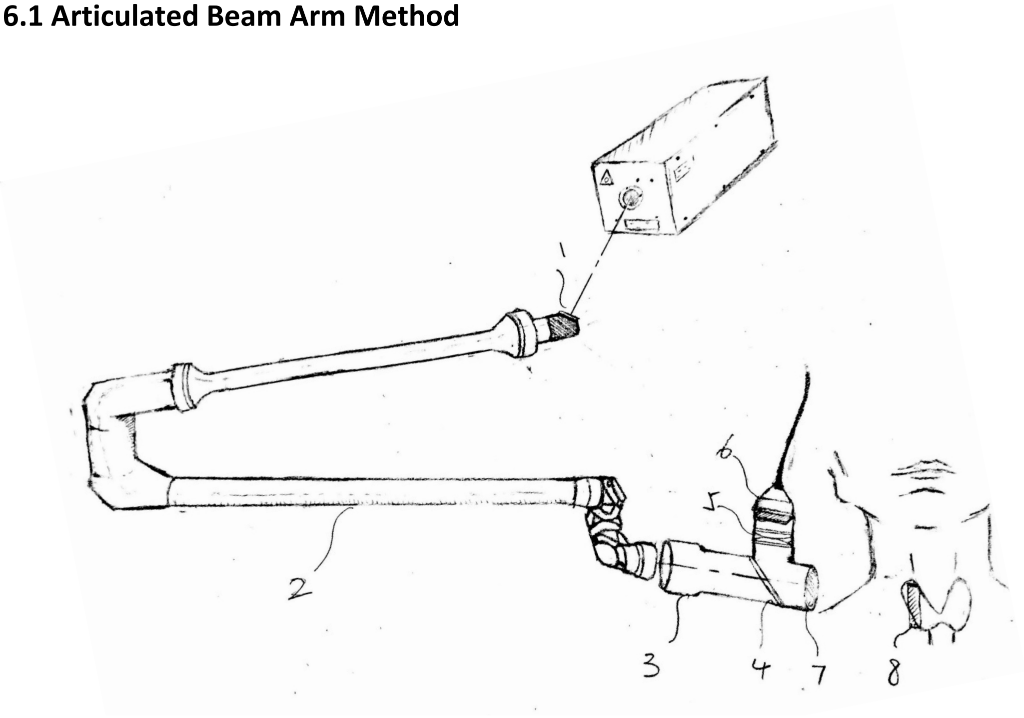


Fig.1 Articulated beam arm layout of in-vivo photoacoustic camera

<table>
<tr><th colspan="2">Main Requirements and Specifications</th></tr>
<tr><td colspan="2">• Piping that can withstand high power laser
• AR coated prisms or mirrors coated to be ~99% reflective
• Translational system for movement in three dimensions</td></tr>
<tr><th>Advantages</th><th>Disadvantages</th></tr>
<tr><td>• Low power loss
• Performance related to wavelength and power of incident laser beam related to the prisms or mirrors located inside of the beam arm
• (These prisms and mirrors can be easily selected to match our specifications)</td><td>• A simple mechanical design may be clunky and unwieldy, while a more complex mechanical design, allowing for fluid movement in three dimensions, would be time consuming
• Difficult to ensure proper alignment of mirrors</td></tr>
</table>

6.2 Lightguide Method

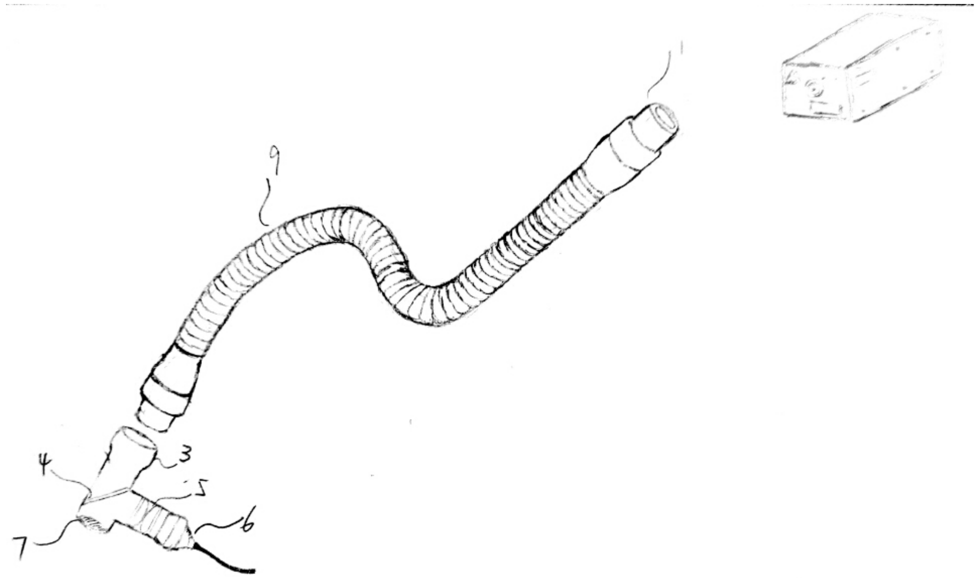


Fig.2 Lightguide layout of in-vivo photoacoustic camera

<table>
<tr><th colspan="2">Main Requirements and Specifications</th></tr>
<tr><td colspan="2">• Lightguide, usable in the Visible-IR spectrum (see Appendix.C)
• (Currently exploring the possibility of using a 6.35 mm diameter, 1.22 m long lightguide provided by Dr. Rao)</td></tr>
<tr><th>Advantages</th><th>Disadvantages</th></tr>
<tr><td>• Flexible and easy to use
• Readily Usable
• Will allow us time to design the imaging probe that will be connected to the laser delivery system</td><td>• Power loss increases with length of the light guide- must keep the lightguide short
(the lightguide is comprised of many smaller optical fibers, whose core sizes are small. Therefore power will be lost upon entering the lightguide as well)
• Produces a diffuse laser, rather than the desired, high uniformity laser beam
• May not be able to handle high powered pulses- TBD</td></tr>
</table>

6.3 Optical Fiber Bundle with Beamsplitters Method

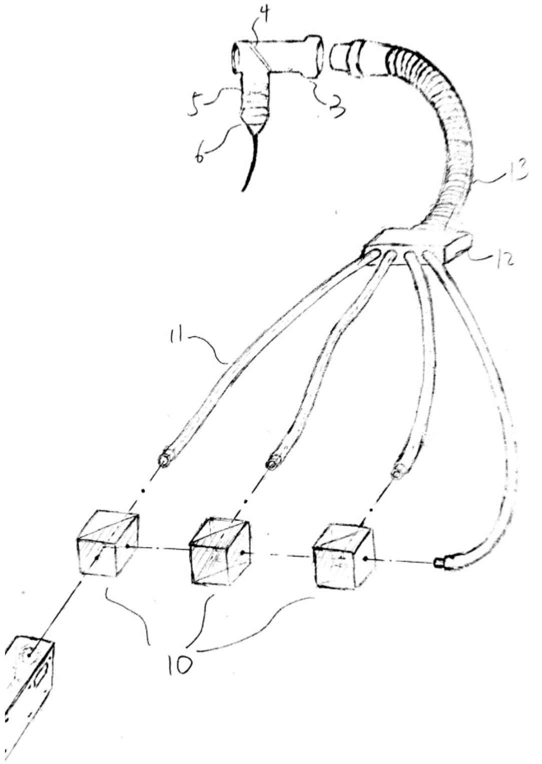


Fig.3 Optical Fiber Bundle with beamsplitters layout of in-vivo photoacoustic camera

<table>
<tr><th colspan="2">Main Requirements and Specifications</th></tr>
<tr><td colspan="2">Multiple beamsplitters; this number will vary based on our final design of the system
Multiple lightguides or optical fibers; again, this number will vary depending on the final design of the system and the damage threshold of each fiber or lightguide
Focusing Lenses; depends on the number of fibers or lightguides we plan to use
Box with black coating or paint around the inside, in order to ensure that no laser light reflects off the inside of the box; minimizes stray light escaping from the delivery system</td></tr>
<tr><th>Advantages</th><th>Disadvantages</th></tr>
<tr><td>By splitting the laser beam into multiple fibers or lightguides, we are able to avoid destroying the fibers or lightguides with pulses ≥ 10 mJ/cm2
Allows for flexibility of lightguide or fiber optic cable</td><td>Each fiber or lightguide produces power loss; therefore if too many fibers or lightguides are used, the system will approach >50% power loss
Requires multiple beamsplitters, optical fibers or lightguides; may inflate cost
Efficient coupling of fibers or lightguides to the beamsplitters must be ensured in order to reduce power loss; this makes the system more difficult to design</td></tr>
</table>

7. Materials

Our budget has been loosely set at anything less than $1000. The materials necessary for testing and construction of the laser delivery system are listed below:

Proposed delivery system	Items for construction/testing	Price
Articulated Beam Arm Method (Fig.1)	Piping	May already be available through WHK lab
	Thor Labs 15 mm right angle prism-mirror, with protective silver coating	Each prism is about $69
	Edmund Optics broadband dielectric coated λ/10 15 mm mirror	Each mirror is about $85
Lightguide Method (Fig.2)	Edmund Optics ¼” diameter, 48” long lightguide	Provided
Optical Fiber Bundle with Beamsplitters Method (Fig.3)	Thor Labs 2 m, 550 µm core diameter high power multimode fiber optic cable	Each cable is about $191
	Edmund Optics ¼” diameter, 48” long lightguide	Provided
	Multiple Thor Labs 20 mm, 50:50 cube beamsplitters	Each beamsplitter is about $190
	Multiple Edmund Optics plano-convex, high damage threshold, focusing lenses; 12 mm diameter, 12 mm focal length	Each lens is about $37

8. Resources Needed

The following individuals will be used as advisors for our team:

- Graduate student (provided by WHK) for advising on possible lens designs for our delivery system
- Jim Zavislan for advice on the radiometry of our system
- Dr. Navalgund Rao for general system help

The following software will be used in the design process:

- CODE V for optical design
- CAD for modeling prototypes of the delivery system

9. Timeline

By 11/23/15 (PRD Review 2)	• Test beam arm setup with HeNe 623.8nm laser and infrared laser (1520nm) ○ Done in order to test overall power loss through the system • Begin creation of a Bill of Materials • Research other medical uses of PA imaging to gain additional insight • Obtain beam diffuser from Per to begin testing possible ways to shape our laser beam in the imaging probe
By 12/4/15	• Run tests on possible laser delivery systems ○ Find spec sheet on Per's lightguide (make sure less than 50% power loss) ○ Use customer's laser to test power loss in beam arm system • Double check specifications of laser theoretically work for this application • Identify areas of confusion in PRD to ask customer before final presentation
By 12/9/15	• Present final Project Review Document in class • Finalize our Bill of Materials • Meet with last year's photo-acoustic team for advice • Create schedule for spring semester in order to test/examine all realistic laser delivery possibilities
By 12/15/15	• Order parts/gather borrowed parts for future assembly • Finalize list of possible/realistic ideas for laser delivery systems
January	• Month of testing possible laser delivery systems on customer's laser ○ Need to find system most effective at minimizing power loss • Investigate possible geometries of imaging probe ○ Draft imaging probe CAD model ○ Think of materials to be used for reflector
February	• Finalize general design of laser delivery system • Draft CAD model of delivery system • Investigate methods of coupling laser to delivery system • Begin building first working prototype of delivery system
March	• Testing of delivery system prototype with customer's laser • Working towards building finalized delivery system • Construct final CAD model of delivery system If time permits, • Construct the imaging probe and test laser delivery through probe • Investigate ways of coupling the imaging probe to the laser delivery system • Construct CAD model for imaging probe
April	• Couple laser to deliver system; if we are able to create the imaging probe, we will try to couple the delivery system to the probe to create final design • Final testing of laser delivery system ○ Making sure correct alignment is in place ○ Power loss effectively minimized If we can design and create the imaging probe, • Final testing of delivery system coupled with image probe and error checking

Appendix

Appendix A:

This appendix section contains a list of all properties that the overall photo-acoustic thyroid imaging microscope must have that are not directly related to our project. They are very important to keep in mind.

- During normal operation, the imaging probe will come into contact with human tissue and/ or liquids. Therefore any parts of the probe in contact with human tissue must be readily cleaned and sterilized. Also, the probe must be sealed from outside fluids and gases.
- The probe itself must be handheld and easily portable. The laser which acts as the source for the camera, will be too large to be portable and as such, must be located on a tabletop, far enough away as not to impede the physician.
- Wall power is necessary for the laser which is used as the source for the probe. The images produced by the imaging probe must be displayed in real time on a computer monitor, connected to the probe.
- The system be capable of taking a series of sequential images where the transducer automatically increments the axial position of the tissue and stores an image for each of these axial positions.
- For a 20 x 20 mm section of thyroid tissue, have a typical acquisition time of of 2 minutes.
- Produce four consecutive images of the thyroid tissue at wavelengths 760, 850, 930, and 970 nm in order to examine the concentration of oxy-hemoglobin, deoxy-hemoglobin, lipids, and water in thyroid tissue.
- Be able to use these four images to identify areas of oxygenated and deoxygenated hemoglobin using chromophore analysis.
- Contain an inexpensive acoustic lens system, optimized for use in a liquid environment.
- Be able to be moved and operated with a minimum of adjustments.

Appendix B:

If we are able to design the accompanying imaging probe that is to be attached to the laser delivery system, we will need to purchase or find separate materials. These are listed below:

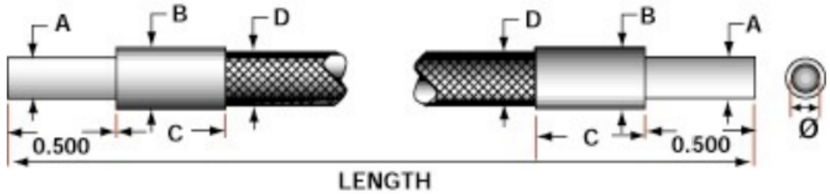
System Component	**Purposes**	**Price**
Imaging Probe Part **3**	Items necessary for construction/testing	3D printed; printing plastic ~$5 per cubic inch
Engineered Diffuser (Beam shaper) **7**	Engineered Diffuser from RPC Photonics	Each diffuser, according to the RPC website ranges from $160 – 250
Ultrasound Reflector **4**	Edmund Optics high efficiency, AR coated window	Each window is about $15
Acoustic Lens **5**	3D printing material, possibly PZT	Again, plastic material is ~$5 per cubic inch

Appendix C:

The following tables are contain the specifications of the lightguide we are planning to use in the lightguide method (see **Fig.2**) as well as the adapters Edmund suggests to use when coupling to the laser source:

Flexible Fiber Optic Light Guide, Stock No. #39-367

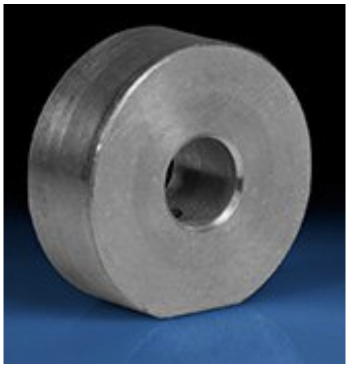
Acceptance Angle (°)	68
Diameter (mm)	6.35
Length (cm)	121.92
Fiber Diameter (µm)	50



Fiber Bundle Dimensions (mm)	A: 7.92 B: 10.72 C: 14.22 D: 10.41
Numerical Aperture NA	0.55
Index of Refraction n_d - Core	1.581
Index of Refraction n_d - Cladding	1.487
Packing Fraction (%)	82% nominal
Operating Temperature (°C)	-40 to +107
Compatible Light Guide Adapter	SX: #38-944 MX: #66-905
Minimum Bend Radius (mm)	38.1
Type of Illumination	Fiber Optic Light Guide
Geometry	Spot Light
RoHS	Not Compliant

0.316" ID, Fiber Optic Adapter SX-6, Stock No. #38-944

Model Number	SX-6
Inner Diameter (inches)	0.316
Inner Diameter (mm)	8.03
Outer Diameter (mm)	25
Thickness (mm)	9.5
Construction	6061-T6 Aluminum
Type of Illumination	Accessory
RoHS	Not Compliant



0.316" ID Fiber Optic Adapter MX-6, Stock No. #66-905

Model Number	MX-6
Inner Diameter (inches)	0.316
Inner Diameter (mm)	8.03
Outer Diameter (mm)	25
Thickness (mm)	32
Construction	6061-T6 Aluminum
Type of Illumination	Accessory
RoHS	Compliant

Appendix D:

The following table contains the specifications of the multimode fiber we are planning to use in the beamsplitter method (see. **Fig.3**)

0.10 NA Multimode Step Index Optical Fiber, Stock No. #HPSC25

Wavelength	=	400 - 500 nm and 700 - 1400 nm
Numerical Aperture	=	0.100 ± 0.015
Core index	=	Proprietary[1]
Cladding index	=	Proprietary[1]
Core Diameter	=	25 ± 3.0 µm
Cladding Diameter	=	125 ± 2.0 µm
Coating Diameter	=	245 ± 10 µm
Core/Clad Concentricity	<	1.0 µm
Coating	=	Two-layer Acrylate
Operating Temperature	=	-60 to 85 °C
Wavelength	=	400 - 500 nm and 700 - 1400 nm
Numerical Aperture	=	0.100 ± 0.015
Core Diameter	=	25 ± 3.0 µm
Cladding Diameter	=	125 ± 2.0 µm
Coating Diameter	=	245 ± 10 µm
Operating Temperature	=	-60 to 85 °C

1. This proprietary information is not provided.