July 26, 2020

Dr. Craig Scratchley
School of Engineering Science
Simon Fraser University
Burnaby, BC, V5A 1S6

Re: ENSC 405W Project Proposal for VALIS

Dear Dr. Scratchley,

The attached document outlines the project proposal for VALIS, a Vascular Acoustic Light Imaging System. VALIS is a photoacoustic imaging system specialized for imaging vasculature. Our goal is to design a photoacoustic imaging system that is available for smaller scale research labs, by reducing both the cost and size of the system compared to current similar products on the market. Furthermore, we aim to improve the versatility of imaging by implementing a handheld device to receive acoustic signals, giving more freedom for real-time imaging.

Enclosed in this document are the highlights of the design of VALIS and an overview of the project and company as a whole. It starts with the background needed to understand VALIS, the products scope and a full system overview. Next the benefits and risks are analyzed along with the market. Lastly, we go through the company’s details, the projects plan in terms of timeline as well as the cost of both product development and to the end user.

Our capable team consists of 6 talented SFU senior engineering students; Ryan Chahal, Glenn Ferguson, John Kim, Alex McGovern, Steven McLeod, and Sean Paulsen. We come from various backgrounds, with experience in optics, electronics, software, and other forms of hardware, which we will combine to make an outstanding affordable photoacoustic imaging system.

Thank you for taking the time to review our project proposal. If you have any questions or inquiries, please feel free to reach out to us through our GitLab or contact our Chief Communications Officer, Glenn Ferguson, at gferguso@sfu.ca.

Sincerely,

Sean Paulsen
Chief Executive Officer
VivoLux
Enclosed: Project Proposal for VALIS

Project Proposal
for
VALIS
Imaging the Sound of Light

Team Members	Sean Paulsen	CEO
	Glenn Ferguson	CCO
	John Kim	CIO
	Ryan Chahal	COO
	Alex McGovern	CSO
	Steven McLeod	CTO
Submitted To	Dr. Craig Scratchley	ENSC 405W
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Executive summary

Medical imaging techniques are one of the primary drivers for the improvement of modern healthcare. From the conception of x-ray imaging at the end of the 19th century to the now numerous rapidly advancing imaging modalities available, medical imaging techniques are responsible for much of our understanding of biological processes, and structures. Photoacoustic imaging (PAI) as a novel medical imaging technique that combines an optical source driving molecular excitation and an ultrasonic sensor to record.

PAI utilizes the principles discovered by Alexander Graham Bell in 1880 [1] when he first recorded the photoacoustic effect that sunlight had on materials of varying absorption levels. It was not until the 1960s and the invention of the laser, which allowed highly monochromatic light sources, that PAI began development [1]. PAI harnesses the fact that different tissues and materials absorb different wavelengths of light more efficiently. By leveraging this phenomenon, various tissues within the body can be selectively imaged. Illuminating an area with light tuned to the peak absorption wavelength of the desired tissue to be imaged causes the tissue to absorb the incoming photons. Upon absorption, the molecule will gain energy and release it in the form of heat. Through rapid heating, the illuminated tissue will undergo thermoelastic expansion and localized pressure build-up occurs. As a result, acoustic waves are generated, which can be measured outside the body using an ultrasonic transducer.

VivoLUX aims to produce a prototype Photoacoustic Imaging system that is capable of in vivo imaging of microvasculature structures, while still being affordable for small clinics and research labs. The prototype aims to be manufactured for less than $1500. VALIS is made of 3 major components. First, the imaging probe, which is comprised of a set of high-power LEDs, and an ultrasonic transducer array. Second, the LED controller which is both a power source and variable function generator. Third, the DAQ which processes the transducers data into a form readable by a PC running a custom MATLAB program.

Currently PAI competition includes major biomedical manufacturers such as the FUJIFILM VisualSonics. However, systems available today cost between $200 thousand and $1 Million dollars. At this price point, the research market is left essentially untouched. VALIS will be available for a maximum one tenth this cost, which will be more than sufficient to cover all associated production costs whilst. Our capable team of highly skilled senior SFU engineering students are designing VALIS for maximum user comfort and safety, without sacrificing quality.

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Glossary

Term	Description
ADC	Analog to Digital Converter
BOM	Bill-of-Materials
CAGR	Compound Annual Growth Rate
CT	Computed Tomography
DAQ	Data Acquisition
EM	Electromagnetic
MRI	Magnetic resonance Imaging
NIR	Near Infrared
PACT	Photoacoustic Computed Tomography
PAI	Photoacoustic Imaging
SNR	Signal to Noise Ratio

1. Introduction and Background

1.1 Introduction

Advancements in imaging systems and techniques have offered a wealth of knowledge on biological tissue. With new imaging modalities being developed and old ones being improved, both researchers and health care professionals are able to better understand what they are looking at and make better decisions. It is difficult to imagine life without the conveniences of modern-day technology. Prior to the end of the 19th century, when x-rays were first being explored as an imaging technique, any form of internal examination of an organism was only possible through dissection or other heavily invasive methods [2]. Since its inception, medical imaging has progressed immensely. However, despite the numerous modern imaging modalities and techniques, they all have their drawbacks.

X-ray imaging and computed tomography (CT) scans, a more sophisticated type of x-ray imaging, offer high contrast images of dense tissue such as bones due to their absorption characteristics. This however comes at a cost. These high frequency forms of electromagnetic (EM) radiation are ionizing rays, which have the potential to cause perturbations on an atomic scale; leading to changes in the genetic structure and material found within cells. The changes caused by ionizing radiation are directly correlated to an increased risk of the altered cells becoming carcinogenic.

Magnetic resonance imaging (MRI) is another imaging modality specialized for soft tissue. With the addition of a contrast dye, MRIs are able to produce high-quality images at different depths in the body. Furthermore, they use a powerful magnetic field and a radiofrequency to acquire their images, which eliminates the risks associated with ionizing radiation. The primary drawback associated with MRI machines is the high cost to purchase and operate them. Moreover, due to the strong magnetic fields involved in MRIs, complications may arise for any patients with metal implants. Furthermore, neither MRIs nor x-ray imaging methods can be done in real time.

There are purely optical imaging modalities that use visible or near infrared light (NIR). Based on the absorption, transmission, and reflection of the light an image can be generated. This is heavily limited due to the heavy scattering characteristics of light, which makes purely optical imaging techniques only practical for superficial imaging.

Acoustic waves attenuation through biological tissue is far less than EM waves in the visible or NIR spectrum. This makes ultrasound, also known as sonography, a viable method for imaging deeper into the body. Sonography is a real time imaging modality that can image various types of tissue and even measure perfusion using a doppler effect in vivo. Ultrasound machines use a transducer with typically a piezoelectric material to generate and receive ultrasonic waves in the range of a few megahertz. Longer wavelengths allow for greater imaging depths at the tradeoff of lower resolutions. Higher frequency waves provide higher resolution images but have higher levels of attenuation. Ultrasounds are considered a safe non-ionizing imaging technique, however, there are limitations in image resolution and quality. Furthermore, acoustic waves do not travel well through dense tissue or gaseous mediums such as bone or air in the lungs [3].

There is a new imaging modality that implements both a light source and ultrasonic waves known as photoacoustic imaging (PAI). Different tissues and materials absorb different wavelengths of light and by leveraging this phenomenon, various tissues within the body can be selectively imaged. By illuminating an area with light tuned to the peak absorption wavelength of the desired tissue to be imaged, the tissue will absorb the incoming photons. Upon absorption, the molecule will gain energy and release it in the form of heat. Through rapid heating, the illuminated tissue will undergo thermoelastic expansion and localized pressure build-up occurs. As a result, acoustic waves are generated which can be measured outside the body using an ultrasonic transducer. Although the photoacoustic effect was observed and recorded in the 19th century [4], many modern-day inventions and technological advances were needed to make photoacoustic imaging a reality.

PAI is a safe, non-invasive imaging modality that can produce high-resolution images. PAI can offer higher spatial resolution compared to sonography since optical scattering is not a limiting factor for the spatial resolution and the acoustic waves travel half the distance compared to conventional ultrasound [5]. Furthermore, PAI can be done in real time and provide high-quality imaging without many of the caveats associated with other imaging modalities.

2. Scope

The scope of VivoLUX's VALIS imaging system is to produce a prototype Photoacoustic Imaging system that is capable of in vivo imaging of microvasculature structures, that is affordable for small clinics and research labs. This prototype will be able to image live organisms, display the image on a User Interface (UI), give important information about the image such as depth, and have customizable settings for the user to choose from. This can be accomplished by:

- Using LED's to excite the area to be imaged
- Using an Ultrasound transducer to detect acoustic waves produced by LED excitation
- Converting the Ultrasound transducer data through an Analog to Digital Converter (ADC) and a Data Acquisition Unit (DAQ)
- Processing the converted data with an image reconstruction algorithm to provide meaningful images of the subject

Producing an affordable prototype is important in order to capture our target demographic of small clinics and research labs, who are unable to purchase the expensive Photoacoustic Imaging systems currently available. Creating an affordable prototype that can be manufactured for less than $1500 can be achieved by:

- Using high powered LEDs as a more cost-effective light source compared to lasers
- Using easily accessible components for ADC and DAQ unit
- Creating a prototype that can be used with clinical or research computers, and can be integrated with existing software such as MATLAB
- Ensuring components and parts can be easily repaired or replaced to reduce need to purchase expensive new components

The prototype will consist of a transducer and light source enclosure that can be held by the user for imaging and will be easily maneuverable. In addition to this, it will include an ADC and DAQ unit that will handle the conversion of transducer data to digitized data for image processing and transfer it to a computer through USB. Finally, it will include an easy to run MATLAB script that will complete the real time image reconstruction as well as produce a UI for user interaction and viewing the images. The final step of our prototype development will be to thoroughly test the prototype to ensure it meets the requirements we have determined. This can be achieved by testing on ultrasound and photoacoustic phantoms designed to mimic real world applications.

This document will go over the system overview and the design of each component and how they interact. It will also go over a risk and benefit analysis, as well as a market analysis showing the current and forecasted size of the market and competitors. Finally, we will cover the company structure, prototype development planning, and the prototype design cost considerations.

3. System Overview

The VALIS system consists of 3 major components. First, the imaging probe, which is comprised of a set of high-power LEDs, and an ultrasonic transducer array. Second, the LED controller which is both a power source and variable function generator. Third, the DAQ which processes the transducers data into a form readable by a PC running a custom MATLAB function. Figure 3.0.1 gives a high-level overview of the systems parts.

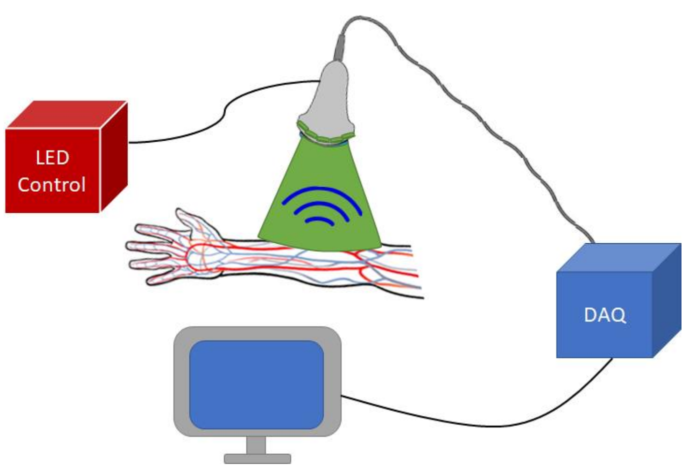


Figure 3.0.1: High level system overview of VALIS

3.1 Hardware

The main hardware components that make up VALIS are the light source and its controller, the transducer, and the data acquisition (DAQ) unit. An array of high luminous efficacy 10 W LEDs centered at 523 nm mounted around the transducer will act as the light source. Lenses will be mounted on each LED to restrict the viewing angle to ten degrees to restrict the illumination area to the region being imaged. By pulsing the LEDs at the shortest duration possible with as high power as possible, the greatest photoacoustic effect will be generated. Higher power pulses will generate acoustic waves with greater amplitude, while shorter pulse durations increase the spatial resolution of the generated image. To detect the acoustic waves, the transducer will be a linear array of piezoelectric material that has a center frequency in the range of 2 MHz to 8 MHz. A transducer array in this frequency range will allow for high quality images in real time.

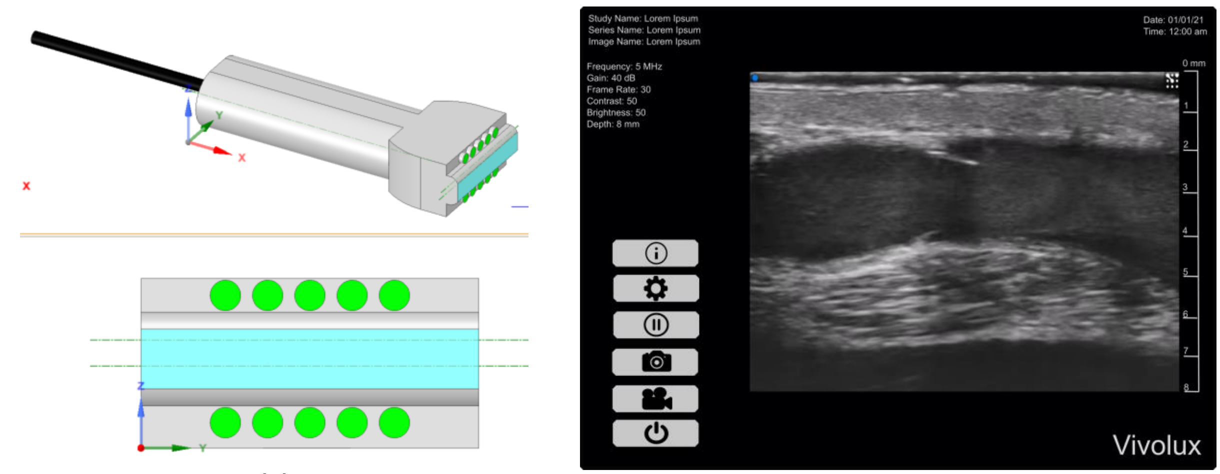
After filtering and amplifying the signal from the transducer, an ADC will create a discrete digital signal the microcontroller can store and transmit to the computer for image reconstruction. Analog multiplexers are used to create a multiplexer chain, which is used to allow multiple signals to feed into the same ADC. User safety is paramount for VivoLUX; therefore, a safety lockout that can act independently of the microcontroller will be implemented. A button on the handheld probe will enable LED activation and image acquisition after the system has been powered. There will also be a contact sensor to mitigate accidental actuation while the system is not actively imaging.

3.2 Software and User Interface

To power the device and obtain the necessary data for image reconstruction, a computer with MATLAB will be required. The system will require a connection to the computer via USB in order to have the data collected and projected into an image. With those requirements, the user for VALIS is expected to have some prior experience with running MATLAB scripts for the backprojection needed to construct the image. To eliminate any confusion, a detailed guide with images will be provided to demonstrate a user-friendly step-by-step guide on how to connect the device, use the device, and run the MATLAB script to obtain their desired image.

In addition to the hardware and software requirements, VALIS does not use a tunable light source for imaging. The wavelength for the device has been set specifically for imaging the vasculature. This fact will be clearly labelled in both the packaging and the instructions manual to notify the users of the limitation. With those clearly labelled, the users are expected to know the use case for VALIS before purchasing the device.

VALIS will consist of a handheld probe that is connected via wired communication and power line to the power supply, microcontroller, and other hardware components. The operator will be required to, with high dexterity, orient the probe on the surface of the patient or phantom being imaged. A proposed 3D CAD model of the handheld probe and the GUI of the software can be seen in Figure 3.2.1.



(a) (b)

Figure 3.2.1: User interface examples (a) A 3D CAD model of the handheld probe (b) Example GUI for the general use of the device

4. Risks and Benefits

VivoLUX has worked hard to mitigate any risks involved with our VALIS system, and to elevate the benefits associated with our system. The risk and benefit analysis that we have completed identifies possible areas of concern in safety and performance of the device, as well as possible areas of advantages such as cost, availability, usability, and environmental impact.

4.1 Risks

As with most medical devices there are some inherent safety risks that need to be mitigated in order to successfully manufacture a device. In the case of the VALIS system, the main safety concern is the light source used for excitation, as it may cause burns or damage to skin and eyes. In order to meet safety requirements and ensure the safety of the subject and the user, the light source must meet the skin MPE (Maximum Permissible Exposure) requirements. This reduces the risk of injury to the subject during imaging and can be accomplished by calculation concerning the energy of the light source, exposure time and pulse time of the light source. In addition to skin MPE it is important to protect other objects sensitive to light exposure, such as eyes. To protect eyes and other sensitive areas, the device has been designed to only begin imaging when it is touching the surface to be imaged. This is accomplished by using a proximity sensor to determine the distance the light source is away from the object.

Alongside the safety concerns of the light source, other more general risks must be mitigated. First of all, overcurrent and or overpower of the device must be protected to protect the users from electric shock, and to protect the components of the device. This can be achieved through a combination of a reliable power source, overcurrent protection circuitry and a grounding shield around the enclosure of the device to protect the user from any accidental exposure. Another possible risk is high temperatures created by the light source and other components. As the light source is very high powered, it is probable to give off large amounts of heat, which could be dangerous to the user as well as the subject. In order to mitigate this risk, a cooling system consisting of heat sinks and fans has been designed, as well as temperature sensing circuitry to provide feedback concerning the device temperature and shut the device off if it reaches temperatures too high for use.

Finally, some risk exists with the performance of the device. For the device to be successfully marketed and sold to the target demographics, it is important that the performance is sufficient to complete the tasks it was designed to do. Finding a balance of performance and cost becomes a difficult task, but through strategic component selection and a robust image reconstruction algorithm, the performance of the device should be more than sufficient for imaging in clinical and research applications.

4.2 Benefits

VivoLUX's main goal is to bring Photoacoustic Imaging to demographics that otherwise would not be able to use it due to its high costs. This goal has possible benefits to a large number of people, including the stakeholders in our company, users of the device and the healthcare system in general.

As for stakeholders, the possible benefit is quite easy to see. The VALIS system offers low manufacturing costs, relatively low cost of sale, few maintenance costs, and a large untapped market of users looking for cost effective imaging systems. With reduced costs, a high profit margin can be achieved while still keeping the device affordable. The vocal demand for Photoacoustic Imaging systems proves a market exists, but the lack of affordable systems leaves a large part of that market available for VivoLUX to take advantage of.

For researchers using the VALIS system, the benefits reside in the availability and cost of the system, as well as the performance. Photoacoustic Imaging can offer important perspectives and information regarding their research, information that would otherwise be out of reach due to cost. Reducing this cost and making such devices easier to obtain would prove to be incredibly beneficial in a laboratory environment by expediting research, offering new information, and ultimately providing opportunities to understand things in an entirely new way, all of which would contribute to improved quality of research being conducted.

The case of the VALIS system being used in small clinics or other healthcare environments offers benefits to many different factions of healthcare. First of all, the clinic who has purchased the VALIS system benefits as they are able to perform diagnostic imaging that they may not have been able to do before, and they have the ability to provide better care for patients in their care. Patients also benefit as they are able to receive a better standard of care in local clinics without the need to consult larger clinics, specialists, or hospitals. This is especially useful for clinics in secluded or rural areas, where large hospitals and specialists might not be easily accessible.

The healthcare system in general would benefit on many different fronts from the adoption of VivoLUX's VALIS system. The obvious benefit of a lower cost diagnostic imaging system would help ease strained hospital and clinic budgets and facilitate reallocation of funds. Along with the low cost, another benefit would be a further decentralization of the healthcare system, which would alleviate strain on major healthcare centers and hospitals. As VALIS is made available to smaller clinics, there is less of a need for patients to frequent hospitals and large centers, as they can receive the care they require at these clinics. This reduction of patient traffic in hospitals would decrease the overcrowding experienced by many hospitals and free up more resources for the patients of that hospital, which would be a great benefit of both the healthcare system and the patients.

Lastly, the VALIS system would benefit the environment as well, due to its reusability, long life and easy component replacement. With a 'cradle to cradle' design, each component is designed to be able to be replaced or repaired without the need to replace the entire device, thus leading to less waste and longer use of the device. This is an obvious benefit to the environment, resulting in a reduction of refuse going to landfills, less manufacturing necessary to produce replacement devices, and a lower net carbon footprint.

5. Market, Competition, Research and Rationale

VALIS is an affordable alternative to existing photoacoustic imaging systems designed to image the vasculature. VALIS, being a medical device, is mainly targeted towards physicians, patients, and researchers. However, due to the hardware and software requirements, as well as the restricted wavelength application of the system, the main target for VALIS will be researchers that possess the requisite background knowledge, hardware, and software components.

5.1 Market

The surging rate in non-transmissible diseases, such as stroke and cancer, drives the market growth of medical devices such as VALIS across the globe. Figure 5.1.1 clearly shows the expected market growth in the global photoacoustic imaging market for the years 2020 through to 2027. The global optical imaging market was anticipated to be approximately $1.9 billion by the end of 2018, with a compound annual growth rate (CAGR) of 11.37% [6]. There has been a rising number of investments in research and development in the clinical market coupled with the constant pace of technological advancements leading to the development of hybrid imaging systems such as PACT systems [6]. However, a huge obstacle for the high demand and growth is the high cost of maintenance and installation of the devices. To overcome this hurdle and occupy a share of the growth market, VALIS' main objective is to be an affordable and versatile real time imaging system. To achieve this goal, VALIS was designed with the assumption that the user has access to some requisite hardware and software components.

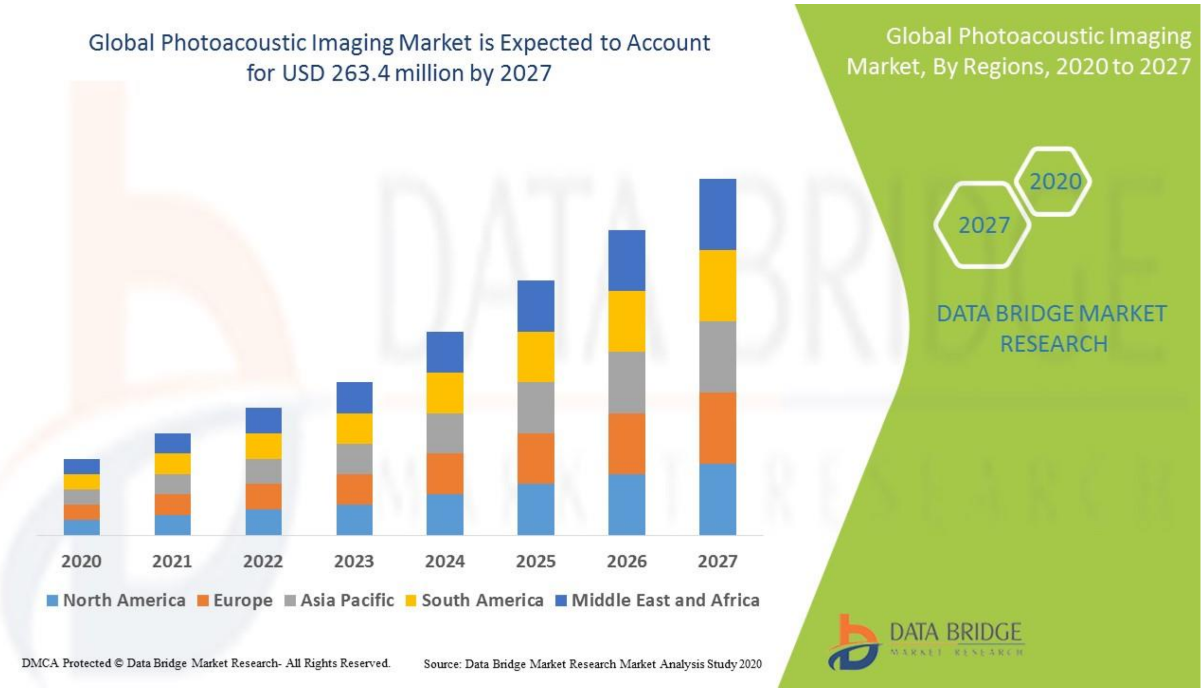


Figure 5.1.1: Global Photoacoustic Imaging Market Growth Graph from 2020 to 2027 [7]

Naturally, the most expensive components in a PACT system are the three core components: the optical illumination source, the transducer, and the DAQ unit. Commercially available solutions for PACT utilize prohibitively expensive laser sources, often tunable, that can be used to image various different tissues at their associated wavelengths. A typical Q-switched Nd:YAG pulsed laser that is often applied to these PACT systems can cost between $15 and $100K USD depending on the energy and width of the pulse [6]. In addition, an application specific ultrasound transducer probe for the PACT system can cost anywhere between $1K and $200K USD which adds to the already high cost of the system [6]. The sizable unit cost of a traditional PACT system is a direct result of substantial Bill-of-Material (BOM) costs; Observing Figure 5.1.2, it can be seen that a commercial PACT system can range from $100K to $950K.

PACT system	Vevo LAZR X	Vevo LAZR	PAFT	MSOT inVision 128	Nexus 128+	LOUISA 3D
Company	Fujifilm VISUALSONICS Inc. ON, Canada	Fujifilm VISUALSONICS Inc. ON, Canada	PST Inc. TX, USA	iTheraMedical GmbH, Germany	Endra Life Sciences, MI, USA	TomoWave, Inc. TX, USA
Approximate Cost	~950K	~750K	~315K	~470K	~375K	~215K
Image						
Application	Oncology, cardiology, molecular and neuro biology	Same as LAZR-X	Small animal imaging	Real-time whole body imaging	Molecular, Tumor hypoxia etc.	Breast cancer research

Figure 5.1.2: Typical Price List of Commercially Available PACT Systems [6]

5.2 Competition

One of the biggest manufacturers of photoacoustic imaging systems is FUJIFILM VisualSonics Inc. with their Vevo LAZR and LAZR-X. Their LAZR-X system is an advanced, multi-modal preclinical imaging platform that provides rich feature sets. Their system provides a wide range of wavelengths (680 - 970nm and 1200-2000nm) with high resolution for multiple applications including oncology, molecular biology, neurobiology, and cardiology [8]. Other competitors include PST Inc. and TomoWave Inc., amongst others, all of whom provide their own unique application of photoacoustic imaging systems.

In comparison with the established commercial PACT systems, VALIS' design encompasses several crucial improvements that make it more usable in a wide array of applications. One key difference is that VALIS was not designed as one single hardware unit; rather, VALIS takes advantage of an external computer, a monitor, and a widely accessible software, MATLAB. With this arrangement, the cost of maintenance is very low as the system does not require as much attention to the software or the hardware components that come as proprietary, integrated whole. This application of the PACT methodology makes VALIS more portable and less cumbersome than others, and contributes to the significantly lessened cost when compared to other systems. All of the aforementioned systems cost significantly more than what VALIS is projected to cost, which will prove to be a huge obstacle for market growth as previously mentioned. In short, our PACT system will be accessible to a larger audience with manageable installation and maintenance costs.

6. Company Details

VivoLUX was founded in May 2020 by a group of highly talented senior engineering students passionate about developing medical imaging devices that are not only rich in information but break the convention of unattainable medical devices. The company's brand name was born out of necessity to emphasize our goal of creating in-vivo, within the living, imaging solutions that harness the power of light. By combining these two simple and powerful features the company brand “VivoLUX” was created.

Figure 6.0.1: VivoLUX company logo

Our introductory product is the Vascular Acoustic Light Imaging System, or VALIS for short, rooted by the abundant need for an easily accessible and ultra-high contrast imaging system for vasculature. VALIS will allow researchers to study the complex and rapidly advancing field of vasculature systems that are responsible for oxygen exchange and transport, indicating cancerous growths, and much more.

6.1 Meeting the team

Sean Paulsen - Chief Executive Officer (CEO)

Sean is a fifth-year biomedical engineering student with great interest in medical imaging, neurotechnology, cardiovascular medical technology, and lasers and optics. He has experience working with the BC cancer agency to design compact wireless ECGs for use in radiation therapy, performed research and published a paper in the field of laser imaging, and has worked in R&D in the industry. He also has experience with molecular identification and spectroscopy. As the CEO of VIVOLUX, Sean is responsible for managing the resources and operations of the company.

Glenn Ferguson - Chief Communications Officer (CCO)

Glenn is a fifth-year biomedical engineering student who has a strong passion for advancing the medical imaging field in hopes of finding solutions for brain injury. He has experience working with imaging, lasers and optics through work experience with FLIR machine vision imaging solutions and has applied those skills with various spectroscopy methods and other molecular identification techniques. He also has experience with biomedical image processing techniques and medical circuit design and safety. Glenn is the company's CCO and is responsible for all company communication.

John Kim - Chief Information Officer (CIO)

John is a fifth-year systems engineering student with strong interest in multimedia communications and signal processing. From his co-op experience with TELUS, he has gained background knowledge in data communications and has familiarized himself with optical engineering and laser applications through his courses. John is the company’s CIO, and is tasked with researching the necessary technology and data as well as keeping a consistent log of the process and progress required for development of VALIS.

Ryan Chahal - Chief Operating Officer (COO)

Ryan is a fifth year Systems Engineering student with a keen interest in image processing and intelligent system development. Through experience as a Manufacturing Engineer with Deere-Hitachi Specialty Products, he has garnered an aptitude in component design and process optimization. He also has experience employing image processing methodologies in differing contexts, including biomedical. Ryan is the company’s COO, and is tasked with strategically managing daily operations throughout the development of *VALIS*.

Alex McGovern - Chief Safety Officer (CSO)

Alex is a fifth year Biomedical Engineering student who is interested in medical imaging and providing diagnostic aids for health practitioners. He has a strong background in medical image processing, and extensive knowledge of medical device circuit design including safety circuitry. He has considerable experience working with photo optical medical devices, focusing on pulse oximetry using LED light sources. Alex is the company’s CSO and is responsible for upholding safety through all levels of development, as well as meeting safety requirements for the final device.

Steven McLeod - Chief Technical Officer (CTO)

Steven McLeod is a fifth year Computer Engineering student with an interest in computer system architectures, microcontrollers, and computer history. He has gained practical knowledge in these fields working at Intel on hardware system validation in SystemVerilog, through hobby projects such as a self-made single board microcomputer, and from debugging and repairing arcade game circuit boards. Steven is the company's CTO, which manages choosing viable hardware products that can be used throughout the project throughout its lifetime, as well as planning hardware architecture.

7. Project Planning

VALIS has a three-phase development plan that ranges from a proof of concept to the final, marketable product. The three major phases of development are shown below in table 7.1.

Phase Number	Designation	Design phase
I	C	Proof of Concept
II	P	Prototype
III	F	Final Product

Table 7.0.1: Design phases of VALIS

Phase I is to be completed as a partial fulfilment of ENSC 405W and therefore will be operational by no later than August 21st, 2020. The proof of concept prototype aims to demonstrate the physical principles behind the device's operation including:

- Produce an acquirable ultrasound signal generated by a pulsed monochromatic light source
- Successfully acquire and record the produced ultrasonic waves using a high frequency transducer
- Store a raw data set that when mapped to a 2-Dimensional matrix, shows regions of high and low intensities that relate to a phantom made of high and low absorbance materials
- Demonstrate the ability to transform raw data sets into a distinguishable image that represent cross sections of the phantom being imaged using MATLAB

The proof of concept phase of development spanned from May through to August 2020. The details of the development schedule for this phase is shown in Figure 7.0.1 below.

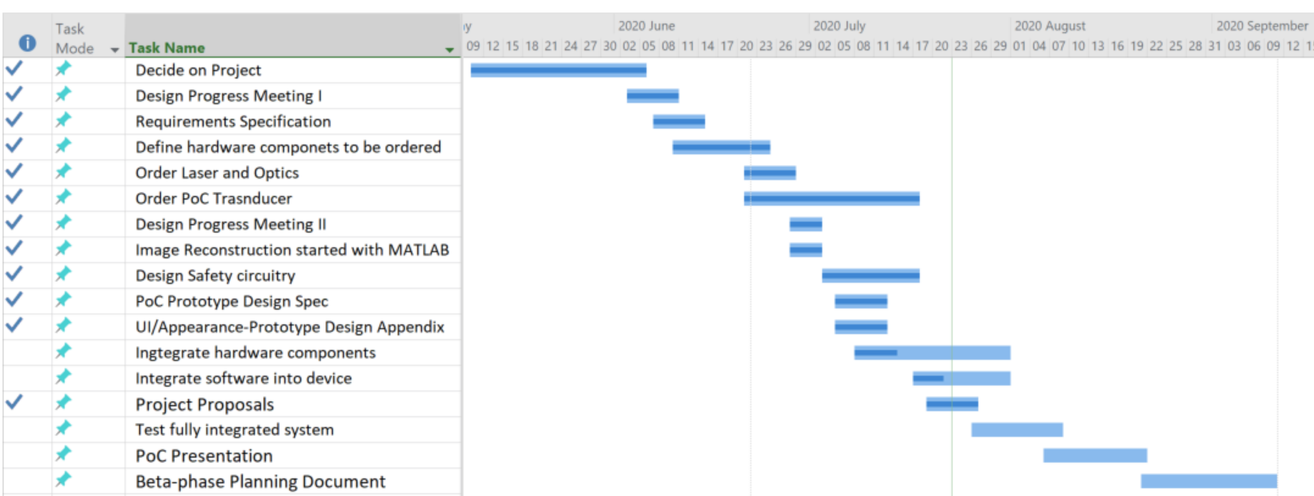


Figure 7.0.1: Gantt Chart for phase I, Proof of Concept Development

Phase II is to be completed as a partial fulfilment of ENSC 440, and will therefore be operational by no later than the end of December 2020. The proof of concept prototype at this stage aims to demonstrate the marketability behind the device's operation including:

- An increase in the systems optical power to drastically improve signal to noise ratio (SNR)
- The utilization of a transducer array in replacement of the single element to drastically improve image acquisition rates and resolution
- A custom PCB designed to for the LEDs and their control circuitry
- Optimization of image processing software to produce a real time image
- A consumer-friendly probe housing
- Fully integrated safety features including leakage current protection, proximity sensors for LED illumination control and temperature monitoring
- A user-friendly MATLAB GUI that both controls and displays what is being imaged
- Cooling added for the electronics to increase possible operating time

The prototype phase of development spans from September through to December 2020. The details of the development schedule for this phase are shown in Figure 7.0.2 below.

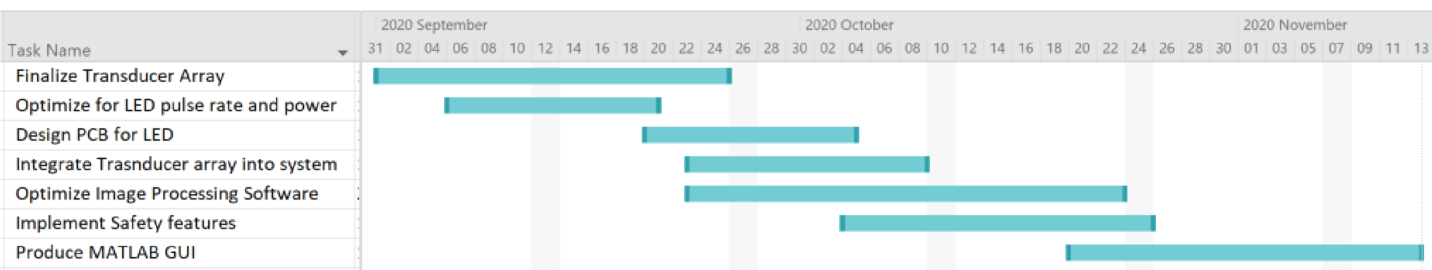


Figure 7.0.2: Gantt Chart for phase II, Prototype Development

Phase III is to be completed after the completion of ENSc 440. In this phase, a final manufacturable and saleable prototype will be produced. With VALIS, this would mean adhering to all required FDA regulations for Class 2 medical devices, as well as clinical testing before going to market.

8. Cost Considerations

8.1 Project Cost Estimates

As noted under project planning, development of VALIS has been segmented into three distinct phases: Proof-of-Concept, Prototype, and the Final Product. Each phase entails its own unique cost considerations to achieve our goal in the most cost-effective manner.

The Proof-of-Concept stage serves to quite simply prove the validity of the proposed product by distilling its core functionality into a rudimentary, though robust, prototype. Initial investment was kept to a bare minimum to preserve project capital for further development. Sourced components were primarily generic, specified such that they will work in later development stages to further minimize project costs. Current expenditures for the PoC phase are outlined in Table 8.1.1.

Component	Category	Description	Cost/Unit ($, CAD)	Total Cost ($, CAD)
LED Engin LZ4-00G108-0000	Optics	High Power LEDs - Single Color Green, 523 nm 600 lm, 700mA	19.83	198.30
DBM Optix O-005s	Optics	LED Lighting Lenses OSRAM Golden Dragon Very Narrow 14.5mm	3.39	33.90
Atmel AT89S8253-24PU	DAQ	8-bit Microcontrollers - MCU 12kB Flash 256B RAM 2.7V-5.5V	3.99	7.98
Atmel AT89S8253-24JU	DAQ	8-bit Microcontrollers - MCU 12kB Flash 256B RAM 2.7V-5.5V	3.42	6.84
Preci-dip 540-88-044-17-400	DAQ	IC & Component Sockets	1.68	3.36
Maxim Integrated MAX3223CPP+	DAQ	RS-232 Interface IC 1 uA Supply-Current, True +3V to +5.5V RS-232 Transceivers with AutoShutdown	6.74	6.74
Silicon Labs CP2102N-A02-GQFN20R	DAQ	USB Interface IC USB to UART bridge - QFN20	2.00	2.00
Texas Instruments	DAQ	Multiplexer Switch ICs Hi-Spd CMOS 16Ch Anl	0.932	9.32

CD74HC4067M96		Mltplxr/Demltplxr		
Texas Instruments MAX3221CDB	DAQ	RS-232 Interface IC 3-5.5V Single-Ch Line Drvr/Rcvr	1.88	1.88
TM130D Ultrasonic Thickness Gauge	Transducer	10mm, 5Mhz frequency probe ultrasonic transducer (comes with the gel)	89.99	89.99
SKYTOPPOWER STPH3005H Regulated DC Power Supply	Other	30 Volt 10 Amp DC Power Supply	113.04	113.04
Gikfun GK1007C Solderable breadboard	Other	5 Pieces of proto board	3.996	19.98
Diodes Incorporated DMN6040 SK3-13	Other	N MOSFET 60V 20A for switching light source	0.82	4.10
On Semiconductor 2N3904BU	Other	TRANS NPN 40V 0.2A TO-92 for current sensing	0.21	1.05
Silicon Labs SI1142-M01-GMR	Other	SENSOR OPT 850NM IR	5.54	5.54
Lumileds L1I0-0850060000000	Other	LED INFRARED SMD	3.97	3.97
Texas Instruments LMT84LP	Other	TEMPERATURE SENSOR ANALOG -50C-150C TO92-3	1.11	1.11
			TOTAL COST ($, CAD) ->	509.10

Table 8.1.1: Total Proof-of-Concept Expenditures

The goal for the Prototype stage is to refine the fundamentals demonstrated in the Proof-of-Concept into a polished device fit for production. Proposed implements include a device enclosure, a higher resolution transducer, full safety interlock integration, and an intuitive UI. Acquiring these specialized components will require a larger investment than the PoC prototype, and project capital has been allocated accordingly. Some of the costs associated with this development stage are detailed in Table 8.1.2, though these are mere estimates and are subject to change.

Component	**Category**	**Description**	**Cost/Unit ($, CAD)**	**Estimated Total Cost ($, CAD)**
PoC purchased components	-	All components carried over from PoC prototype	-	509.10
Transducer array	Transducer	Linear array transducer	May be borrowed from SFU / Otherwise estimated around $300	300
PCB	DAQ	Circuit boards required for DAQ and safety circuitry	20	60
Circuit enclosures	DAQ	Generic black box electronics enclosures	15	30
Microcontroller	DAQ	Higher specification microcontroller with more features (ADC)	50	50
Cooling Components	Other	Heatsink, fans, etc. for probe thermal management	50	50
3D printed housing	Other	Custom enclosure for handheld probe	50	50
			TOTAL COST ($, CAD) ->	1049.10

Table 8.1.2: Anticipated Prototype Expenditures

Beyond the scope of ENSC 405W/440, the Final Product stage of development will facilitate the introduction of VALIS to the mass market. This is a massively costly undertaking, fraught with marketing and certification requirements to ensure the product is safe to use, and is well received within the realm of biomedical imaging devices. The certification process is by no means trivial, and will prove to be the biggest challenge in producing VALIS on a commercial level. Production and distribution costs also feature prominently in the final push to market once certification has been completed. It is difficult to accurately ascertain the costing requirements at this stage without specialist consultation, as these expenses are largely unique to each given product. With that said, a reasonable high-level estimation has been provided in Table 8.1.3, corresponding to a Class 2 medical device FDA certification via 510k form [9].

Category	Description	Cost
Certification -510k Premarket Notification [10]	Comparison of proposed device to pre-existing devices, thereby demonstrating efficacy and conformance with safety regulations	$11,594 USD [11] One-time cost
Production	Production cost per *VALIS* unit; sum of anticipated BOM	~$1000 USD/unit Varies greatly with scale
Marketing	Costs associated with product promotion. Largely dependent on business model, revenue, and whether it is completed in-house.	6.3%+ of revenue for Business-2-Business product businesses [12]
Distribution	Shipping and handling, tariffs, and installation costs associated with sale of *VALIS* . Marketing may fall under this category.	Varies greatly depending on scale, locale, contractual obligations [13,14]

Table 8.1.3: Anticipated Final Product Expenditures

In summation, cost considerations for bringing VALIS to market are not trivial, and it is difficult to discern a tangible dollar figure at the current stage of development as unforeseen expenses are inevitable along this trajectory. Thorough consultation with market specialists will be required to develop a feasible business plan prior to introducing this product to the market. With that being said, VALIS was designed from inception to undercut the nearest competitor by a factor of ten; The TomoWave LOUISA 3D retails for $215k, so we would expect to be able to market VALIS for no more than $20k. At this price point, we are confident that production costs will be manageable, and that our product will prove to be lucrative.

8.2 Funding

8.2.1 Engineering Science Student Endowment Fund

The Engineering Science Student Endowment Fund (ESSEF) strives to provide financial assistance and facilitate development in projects proposed by Undergraduate Engineering students. Distributed by the Engineering Science Student Society (ESSS), the ESSEF is available for projects falling under one or more of the following categories:

- Category A: Competition
- Category B: Entrepreneurial
- Category C: Class
- Category D: Miscellaneous

Eligibility is ensured for funding under categories B and C, as VALIS will be completed for ENSC 405W/440, with potential for further development and eventual marketability down the road.

8.2.2 Wighton Development Fund

Named in honor of its benefactor, the late Dr. J. L. Wighton, the Wighton Development Fund's mission statement is to promote development and marketing of projects undertaken by Canadian Undergraduate Engineering students. Projects which provide tangible social benefit are of particular interest to the fund, which has enlisted Dr. Andrew Rawicz as its chair at Simon Fraser University. Designed in Canada to provide cost effective, non-invasive vasculature imaging solutions, VALIS fulfills the application criteria for The Wighton Development Fund, should the need for additional project funding arise.

9. Conclusion

There are numerous different imaging modalities and techniques ranging from ionizing methods such as x-rays to techniques involving powerful magnetic fields like MRIs. However, there are drawbacks to many of these modern imaging techniques, including but not limited to exposure to harmful radiation, cost, reduced image quality, and availability. In contrast, photoacoustic imaging aims to combat many of these drawbacks by being a safe versatile high-quality imaging modality that has the potential to be a fraction of the cost of many other imaging methods.

There are some PAI systems currently available on the market, however they are extremely costly and impractical to purchase for any smaller or private research labs. VALIS is an affordable PAI system specialised for imaging vasculature. We will bring PAI to the untouched market of researchers looking for high-quality affordable vascular imaging systems. By bringing this technology to researchers, PAI can mature into an imaging modality that is well understood, utilized to its full potential, and commonplace in clinics as ultrasound.

Our capable team of highly skilled senior SFU engineering students are designing VALIS for maximum user comfort and safety, without sacrificing quality. Our product will be a compact system with the transducer and light source mounted on an ergonomically designed handheld device. This will provide increased versatility in real time imaging, allowing the user to image various areas of the subject or patient in a single imaging session.

An infrared sensor will be used to monitor the distance between the patient or subject being imaged and the handheld housing for the transducer and LEDs. Once it is within a safe distance, the LEDs will be able to turn on. This prevents the LEDs from accidentally turning on and shining in someone’s eyes while not in use. Furthermore, there will be extra housing around the LEDs to ensure only the area being imaged is illuminated and to contain any light reflecting off the imaging surface.

Once development on VALIS has been completed, it will be made available to research labs and clinics at a cost of no more than $20k. At this price point, we anticipate that all costs associated with certification, marketing, production, and distribution will be covered, and that the product will break even after 10 units have been sold.

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