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March 26th, 2021

Dr. Craig Scratchley
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Re: ENSC405W Design Specification for livEn’s Retina Imager and Laser Beamer, RILab.

Dear Dr. Craig Scratchley,

In the attached document, please find our design specifications document for the RILab as prepared by livEn’s Puru Chaudhury, Jiung Choi, Eduard Durech, Vincent Le, Kyle Smolko, and Daria Zhevachevska.

RILab’s purpose is to safely and efficiently design a semi-automated laser eye therapy system that deals with abnormal and diseased tissue in the eye. Treatments include Pan Retinal Photocoagulation, PhotoDynamic Therapy, and more.

The design of the RILab features a fundus camera, an optical scanning mirror, and a laser where we will be viewing the image of the retina through a GUI. The processed image through the camera will become skeletonized where several zones will be set for exposure and non-exposure to a laser for treatment. We will be using motion tracking to ensure safety while the laser, positioned via a scanner, will have its power titrated from low to high to perform the laser eye treatments.

This document will outline the specifications required to accomplish the RILab’s purpose in terms of both the software and the hardware design. Comparisons and justification for the chosen designs will be extensively explored with supporting test plans to ensure the correctness of the system. The document will also include the user interface and appearance design with supporting test plans.

If you have any questions regarding the attached report, please contact our Chief Communications Officer, Vincent Le, at 778-881-6800 or at bvle@sfu.ca.

Sincerely,

Eduard Durech
Chief Executive Officer
livEn

Design Specification

Retina Imager and Laser Beamer

RILab

Company 5

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Issue Date:
March 26th, 2021

Abstract

Ophthalmologists currently perform laser eye therapies such as Pan Retinal Photocoagulation (PRP) and PhotoDynamic Therapy (PDT) manually [1]. As such, a need for a semi-automated system has been identified to streamline and ameliorate these similar procedures and advance the field. The system outlined in this document enables medical residency students and professionals in other fields that are not yet experienced ophthalmologists to perform these procedures [1]. In addition to making the procedures easier to perform, time is freed for ophthalmologists to focus on more hands-on procedures where they are most needed, as ophthalmology is experiencing a shortage of specialists [2]. livEn has taken this project and presents the design specifications in this document for RILab.

The design specifications made in this document are justified such that the RILab solves the problem of semi-automating laser eye therapies while integrating a clinician for monitoring and verification. Primary considerations include safety, ease of use, and increased speed of the procedures. The software design specifications focus on image acquisition, processing, and tracking through algorithmic control and a graphical user interface. The hardware design specifications, in terms of the proof-of-concept, focuses on the integration and interaction of a FLIR Blackfly S camera, a set of galvanometer-based mirrors, and a laser diode. Our decisions and justifications were based off of the hardware's ability to interact with each other. We are using Ubuntu server as the operating system that can control the one-dimensional movements of two optical scanning mirrors. The system further controls a camera that can take clear images of the retina and live video, as well as a laser used for the procedure. Lastly, this document further details the graphical user interface to control and view the system as well as provides a description of appropriate test plans to ensure the correctness and validity of our components and subcomponents.

Acknowledgements

livEn would like to express our gratitude to Dr. Marinko V. Sarunic and his lab, the Biomedical Optics Research Group at Simon Fraser University, for allowing us to work with the research and equipment from the lab. We would also like to thank Dr. Zaid Mammo for his medical contribution as a practicing ophthalmologist for 9 years. We would also like to thank them for helping us create the original project idea.

Version History

Version #	Implemented By	Revision Date	Approved By	Approved Date	Reason
1.0	Vincent Le	02-23-21	N/A	N/A	Initial design document drafted.
1.1	Vincent Le	03-21-21	Jiung Choi, Eduard Durech, Kyle Smolko, Daria Zhevachevska	03-21-21	Appendix B: User Interface Appearance completed and added to the document
1.2	Kyle Smolko	03-24-21	Eduard Durech	03-26-21	Added to sections 2.1, 3.2, and 3.5.
1.3	Vincent Le, Daria Zhevachevska, Puru Chaudhary	03-25-21	Eduard Durech	03-26-21	Completed the letter of transmittal, title page redesign, acknowledgements, and the product design specification approval page. Initial revisions to the glossary. Started the abstract and introduction. Added to sections 3.3. Added to sections 3.1
1.4	Kyle Smolko, Puru Chaudhary, Daria Zhevachevska, Vincent Le	03-26-21	Eduard Durech	03-26-21	Edited section 3.4. Added to section 3.5. Edited section 3.1. Edited section 3.3. Adding to Appendix C. Completed Appendix C. introduction.
2.0	Vincent Le, Eduard Durech, Kyle Smolko, Jiung Choi	03-26-21	Eduard Durech	03-26-21	Completed the glossary, abstract, and the conclusion. Completed section 2. Completed Appendix A Completed section 3. Proofread for edits.

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Glossary

Term	Definition
Clinician	A clinician is a doctor having direct responsibilities and contact with a patient. In our document, this includes ophthalmologists, their assistants, and medical resident students.
Fundus	The bottom, the base, or the inner lining of a hollow organ. In terms of our document, fundus will be referring to the inner lining of the eye opposite to the lense, also known as the retina.
Treatment Area	A region on the image that is selected by the algorithm or selected by the clinician where the laser treatment shall be applied.
Medical Residency	Postgraduate students who are training in the field of medicine.
No Treatment Area	A region on the image that is selected by the algorithm or selected by the clinician where the macula and the vessels are located. No laser is allowed to shine there.
Ophthalmologist	A specialist doctor in the field, study, and treatment of disorders and diseases in the eye.
Optical Scanning Mirror	A small rectangular mirror that is able to scan a laser in two axes.
Optical Table	A vibration control platform that absorbs shock and vibrations to minimize any movements that may misalign any lasers or optical components.
PDR	Proliferative Diabetic Retinopathy is an effect as a result of diabetes. The conditions of diabetes results in abnormal blood vessels forming in the eye which can lead to a loss of vision.
PDT	PhotoDynamic Therapy is a two-stage treatment that combines light energy with a drug (photosensitizer) designed to destroy abnormal cells and vessels after light activation.
Phantom Eye	A phantom eye is a term used to generalize the test subject for optics. A phantom eye has a wide range from a piece of tissue to a piece of paper, and a drawing of an eye to a porcine eye to a rat's eye.
PRP	Pan Retinal Photocoagulation is a laser eye therapy that can decrease the size of abnormal blood vessels which can lead to blindness.
Retinal Camera	A specialized camera that is able to photograph the retina of an eye.

Table 0.1: Glossary covering the important terms in this Design Specification Document

1.0 Introduction

1.1 Background & Purpose

Laser eye therapies can be used to treat many disorders such as Panretinal Photocoagulation (PRP) and PhotoDynamic Therapy (PDT). The PRP procedure is the most common example in which there are areas to improve with our solutions as recommended by Dr. Zaid Mammo via extensive user interviews [1]. PRP and other laser eye therapies are similar to each other to some extent and, as such, livEn is focusing on conditions which can be treated via laser exposure.

These therapies are done manually and we can see that a semi-automated system is needed, which has also been identified by Dr. Marinko V. Sarunic. Manual systems largely rely on the ophthalmologist's motor skills and take up significant time from them, while the field is experiencing a shortage of these specialists.[2] The current process is lengthy and requires each exposure be manually positioned and timed, with tens of such exposures being completed per procedure. Our system will be designed to streamline and ameliorate the amount of time ophthalmologists must invest in these laser eye therapy procedures. This will be done by semi-automating the process of laser eye therapies.

livEn's RILab is mainly an algorithmic design project used to determine where it is safe and not safe to fire a laser onto a human retina. The algorithmic general outline can be found in Figure 1.1.1. Our project also includes hardware components that we have and will be continuing to research such that livEn can put together an increasingly efficient system as compared to current systems. The implementation and automation of these hardware components is not currently available for ophthalmologists and, as such, novel control and integration will pose a challenge. Further novel processing techniques such as detecting diseased tissue and auto-populating therapy patterns while tracking the eye for movement will also be developed. These features will be integrated into a standalone and reliable system as safety is paramount.

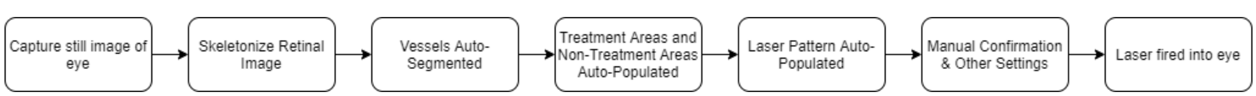


Figure 1.1.1: Block Diagram of the RILab's Procedure

1.2 Document Scope

The purpose of this document is to specify and justify the design specifications needed to fulfill the purpose as described in *Section 1.1*. These design specifications were made to fulfill the requirements from livEn's *Requirement Specification Document*. This document will also feature the user interface and appearance design attached with analytical and empirical test plans, as well as feature supporting test plans for the components and subcomponents of our system.

1.3 Proof of Concept Scope

The RILab's proof of concept stage will include the integration of a FLIR scientific camera, a Galvo optical scanning mirror, and a laser diode within our custom optical model. The hardware will be controlled by a Raspberry Pi via our graphical user interface (GUI). Our GUI will be designed to support the semi-manual aspects covering our semi-automatic algorithmic design and they will be coupled with the needed hardware components as seen in Figure 1.3.1. Detection of vasculature and auto-population of therapy patterns will also be carried out which will guide the laser in an automated fashion.

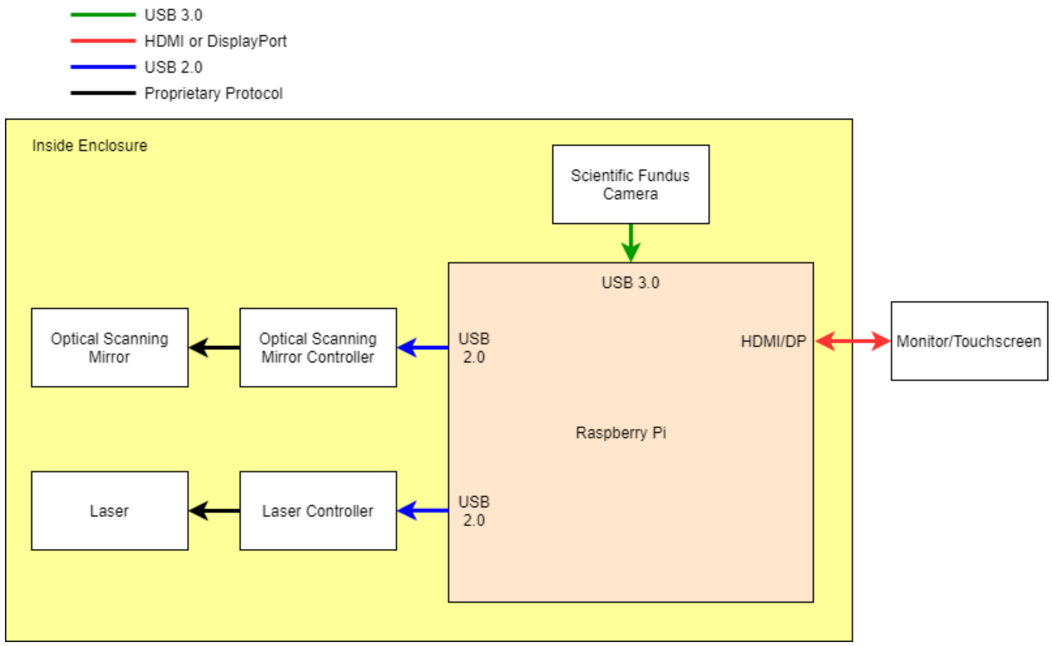


Figure 1.3.1: Block Diagram of the RILab's Hardware Components

This proof of concept will prove that a laser can be accurately, precisely, and correctly aimed by our optical scanning mirrors and be safely fired onto our phantom eye as viewed by our scientific camera. It will also prove that image processing techniques can be used to automate the tedious, manual clinical parts of the procedure by autogenerating therapy patterns. These tests will be detailed in Appendix C. The important notes to take from Appendix C is that our laser is currently a simple laser diode only able to fire at a specified duration. There are many other parameters to take into account such as the laser's spot size, the laser's power threshold and titration, the laser's repeating firing interval, and the laser's firing pattern.

1.4 System Overview

The RILab will be controlled via a Raspberry Pi microcontroller with our proprietary interface. It is currently designed on Qt and will interact with the camera, laser, and optical scanning mirror as seen in Figure 1.4.1.

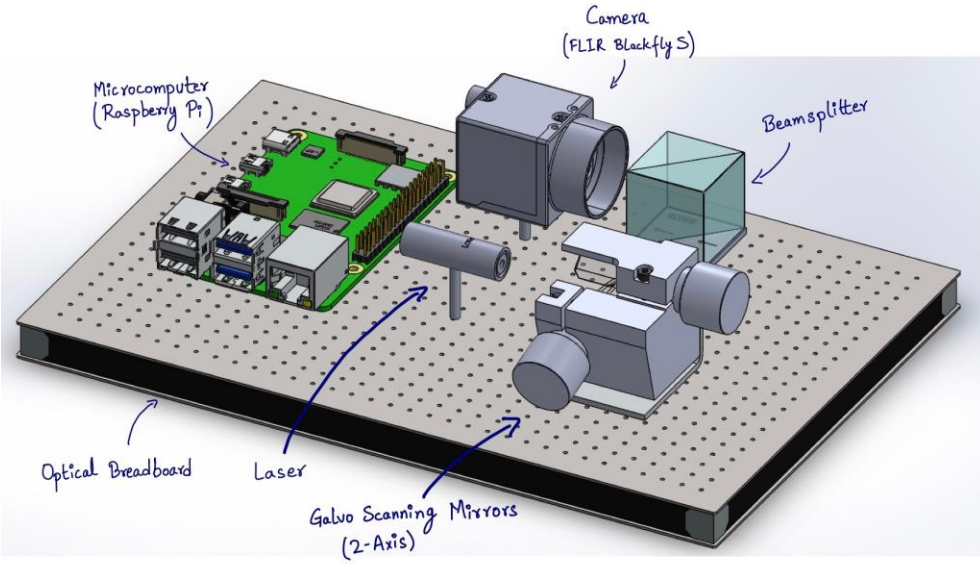


Figure 1.4.1: Proof-Of-Concept RILab SolidWorks Design V1

1.5 Design Nomenclature

The notation of our requirements are as follows:

D - {Section} . {Subsection} . {Design Number} - {Project Phase}

1. The D stands for design.
2. The section indicates the respective section of the design document.
3. The subsection indicates the respective subsection of the design document.
4. The design number indicates the number of design specifications in the section.
5. The project phase is divided as follows:
    - *a.* A - alpha phase/the proof-of-concept
    - *b.* B - beta phase
    - *c.* P - production phase

Example: D-2.1.1-A
Design - Section 2.1 . First Design Specification - Alpha Phase/Proof-of-Concept

2.0 Software Design Specifications

2.1 General Software Design Specifications

2.1.1 Alpha Stage

The software capabilities of our system were specifications requested by our ophthalmologist contact Dr. Mammo [1] and further explained in Appendix B. The abilities will allow a clinician to have the final say in the process for safety and automate parts of the procedure which are most time consuming for the clinician, namely the manual firing and control of the laser. The general algorithmic control flowchart is displayed in Figure 2.1.1.

In order to meet our UI requirements, we will be using Qt for development of the user interface as explained in detail in Appendix B. In order to interface properly with our hardware featured in Section 3, C/C++ will be our primary programming languages for interfacing and controlling the hardware.

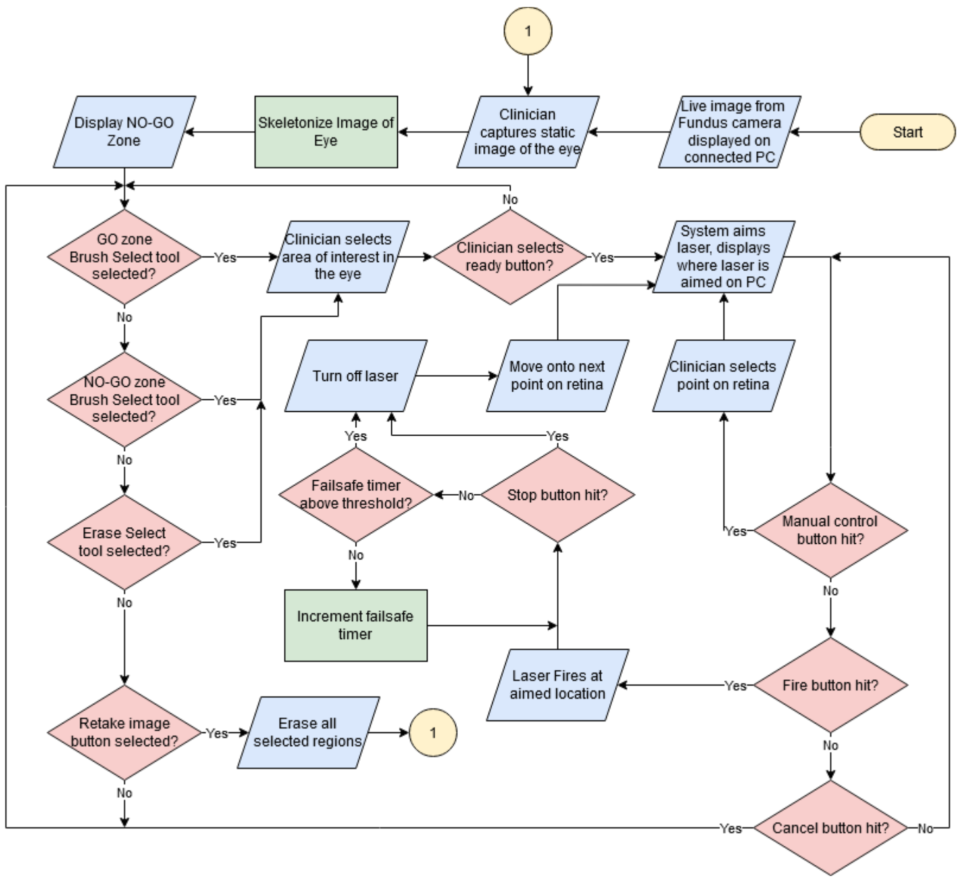


Figure 2.1.1: High-Level Algorithm Flow Chart for the RILab [1]

2.1.2 Beta Stage

The beta stage of our project will be implementing more sophisticated hardware such as variable laser powers and wavelengths. These hardware upgrades assist the clinician in carrying out their procedures and more closely simulates the behaviour of the production level system. With these upgrades, the clinician must be able to have more control over the characteristics of the hardware based on different therapies. The increased control of the system will be implemented using the requirements outlined in Table 2.1.1.

2.1.3 General Software Design Specifications Summary

Table 2.1.1 holds the design specifications needed to support our general software requirements.

Design ID	General Software Design Specifications Technical Description	Corresponding Requirements
D-2.1.1-A	The software will display a real time fundus image and capture a still image.	R-2.1.1-A, R-2.1.2-A, R-2.1.9-A
D-2.1.2-A	The software will skeletonize the vasculature of the still image.	R-2.2.1-A
D-2.1.3-A	The software will feature a brush select for a clinician to select treatment and avoidant regions for the laser.	R-2.1.3-A, R-2.1.4-A, R-2.1.5-A
D-2.1.4-A	The software will auto-populate the therapy patterns on the still image once region selections are completed.	R-2.1.6-A
D-2.1.5-A	The software will notify the clinician when the laser is firing and the procedure's progress.	R-2.1.7-A
D-2.1.6-A	Hardware control will be done in C/C++.	
D-2.1.7-B	The software will allow the clinician to input laser power threshold, duration of laser exposure, and laser wavelength.	R-2.1.10-B
D-2.1.8-B	The software will feature interrupts for the clinician to stop the process in case of mistake or restart it.	R-2.1.8-A, R-2.1.12-B
D-2.1.9-B	The software will allow the clinician to override the entire procedure and revert back to full manual control as if in a conventional system.	

Table 2.1.1: General Software Design Specifications

2.2 Image Processing Design Specifications

2.2.1 Alpha Stage

To achieve semi-automation of the procedure, image processing will be used to segment parts of the retina image. This is an initial step in limiting the amount of manual control the clinician must do to complete the procedure. Image processing will be done using a mixture of conventional image processing techniques and machine learning. Segmentation in general has known solutions in machine learning and as such will be used for the vasculature segmentation. To support this, Keras will be used as a well-supported machine learning library which supports extensive functions for implementing machine learning models, especially convolutional neural networks which are commonly used in image processing. Keras also uses a Tensorflow backend which allows for easy inferencing once our model is developed. As such, Python will be the primary language of development for prototyping machine learning and image processing pipelines before being implemented in the final system.

For the machine learning pipeline, U-Net is a common architecture known for accurate segmentations with little memory consumption [3]. The architecture is a convolutional autoencoder which will also help in gauging the decision making processes of the model. This helps alleviate concerns about the "black-box" nature of machine learning models, as convolutional networks can be easily probed to see what filters they use and visualize their decision making process using querying. The architecture is shown in Figure 2.3.1.

2.2.2 Beta Stage

Further image-processing will be implemented to further automate the laser eye therapies. Segmentation will be expanded to include segmentation of diseased tissue, which will enable the process to be streamlined and allow the clinicians to simply input laser parameters and confirm the auto-generated treatment procedure.

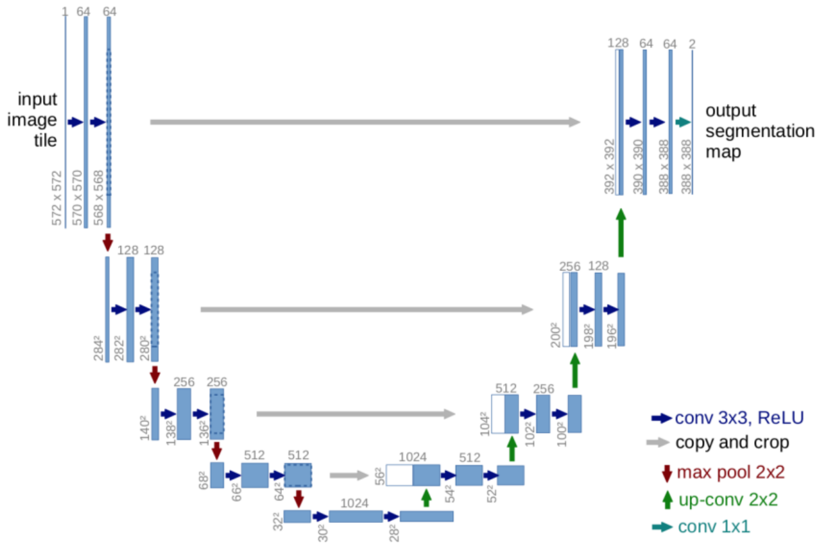


Figure 2.2.1: U-Net Architecture Used for Image Segmentation [3]

2.2.3 Image Processing Design Specifications Summary

Table 2.2.1 displays functions of the image processing pipeline.

Design ID	Image Processing Design Specifications Technical Description	Corresponding Requirements
D-2.2.1-A	A U-Net derivative will be used for segmentation of vasculature and diseased tissue.	R-2.2.1-A, D-2.1.2-A
D-2.2.2-A	Machine Learning implementations will be developed using a Tensorflow backend.	D-2.2.1-A
D-2.2.3-A	Image processing techniques will be developed in Python.	D-2.2.2-A
D-2.2.4-A	Physical distances must be algorithmically derived from the retina image.	D-2.1.4-A
D-2.2.5-B	Diseased tissue will be automatically segmented.	R-2.2.2-B

Table 2.2.1: Image Processing Design Specifications

2.3 Tracking Design Specifications

Tracking will only be implemented in the beta stage of this project and will seek to minimize the use of equipment to keep the eye stable such as a mounted contact lens. As the eye involuntarily moves during fixation on a target due to tremors, slow drifts, and microsaccades, tracking must be able to correct for these to avoid damaging healthy eye tissue due to movement. Normal microsaccadic movement during fixation can occur at a frequency of 3Hz [4] and, as such, the tracking algorithm must be able to update at least as fast.

As pupil tracking would require another camera, increasing the complexity and size of our system, tracking will be done using the retinal images. This can be completed in many ways such as by feature tracking. A reference, or target, image will need to be used and registered by each consecutive image taken. The requirements to achieve tracking are given in Table 2.3.1.

Design ID	Tracking Design Specifications Technical Description	Corresponding Requirements
D-2.3.1-B	The software will track movement using retinal images.	R-2.3.1-B
D-2.3.2-B	The software will register a target image to consecutive images at a rate of at least 3Hz.	R-2.3.2-B, D-2.3.1-B
D-2.3.3-B	Image processing techniques will be developed in Python.	R-2.3.3-B

Table 2.3.1: Tracking Design Specifications

2.4 Operating System Design Specifications

The operating system to be used for the alpha stage and beta stage are roughly the same. For the alpha stage, the group has chosen to use Ubuntu server as the operating system to be run on the main processing unit for the system. For the beta stage, the group will be using a custom derivative of Ubuntu provided by NVidia which contains the binaries required to use the integrated graphics processing unit (GPU) on the board for machine learning inference. As we are developing a standalone system, the operating system must be lightweight and support our algorithmic pipelines. The design requirements of the operating system are given in Table 2.4.1.

Design ID	Operating System Design Specifications Technical Description	Corresponding Requirements
D-2.4.1-A	The operating system will be able to run a Python interpreter for simpler machine learning inference.	D-2.2.3-A
D-2.4.2-A	The operating system will be lightweight.	
D-2.4.3-A	Linux will be used as the primary operating system.	D-2.4.1-A, D-2.4.2-A

Table 2.4.1: Operating System Design Specifications

3.0 Hardware Design Specifications

3.1 Structural Design Specifications

3.1.1 Alpha Stage

At the proof-of-concept stage, our focus is going to be on getting the camera optics aligned for imaging a phantom eye and aligning the laser guidance mechanism, i.e. the Galvo scanning mirrors and lenses required to focus the laser-beam at the target. We have a preliminary estimation of the distances between each component and the focal lengths needed for the lenses based on the optical modelling data from the Zemax optical design software, discussed in Section 3.6. First, we will create a proof-of-concept design on an optical breadboard. As optical systems are highly prone to alignment problems, we will use this breadboarding phase to extract and finalize the exact dimensions and tolerances needed to build the structural design of our engineering prototype (beta stage). [5]

The justifications for choosing an MB18 - Optical Aluminum Breadboard [6] are as follows:

- Shock absorption as outlined in [D-3.1.1-A]
- A large enough size as outlined in [D-3.1.2-A] & [D-3.1.3-A]
- And an appropriate material and finish as outlined in [D-3.1.4-A]

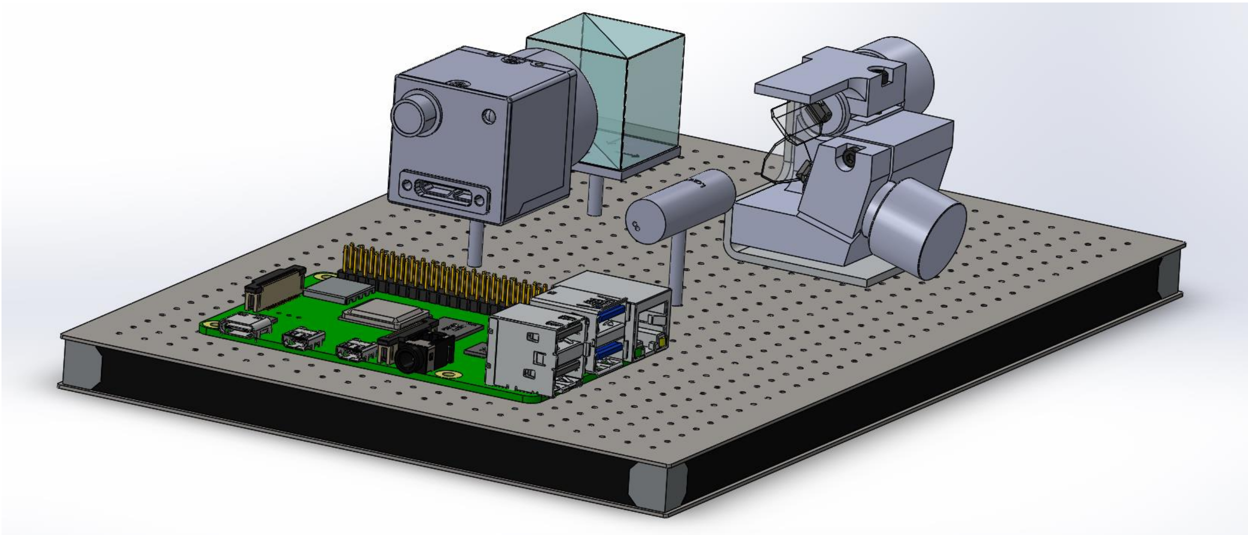


Figure 3.1.1: Proof-Of-Concept SolidWorks Design V2

3.1.2 Beta Stage

For the engineering prototype, RILab will have a 3D printed custom casing to house all the components of the optical unit. This casing will isolate the components from environmental factors such as dust, lens smudges, glaring artefacts, et cetera. Based on the size and complexity of the casing, we may also opt to include some rubber bushings/pegs and foam paddings to isolate the individual components and the complete housing from vibrations. [5]

The justifications for choosing 3D printing as the encapsulation are mainly that 3D printing is a cheap option that can encapsulate our system outlined in [D-3.1.5-B]. This needs to be further researched to complete before the beta deadline.

3.1.3 Structural Design Specification Summary

Table 3.1.1 holds the design specifications needed for our structural base.

Design ID	Design Specifications Technical Description	Corresponding Requirements
D-3.1.1-A	The optical breadboard can handle 120 N of force applied at the center to eliminate any tremors.	R-3.1.3-B, R-3.1.4-B
D.3.1.2-A	The optical breadboard is 18 inches by 18 inches by 0.5 inches which is large and thick enough to fit our other components.	
D-3.1.3-A	The optical breadboard has 0.25 inches -20 taps which are just large enough to attach our components onto the breadboard.	
D-3.1.4-A	The optical breadboard is an aluminum plate with matte black anodized finish to not cause any electrical and optical interference.	
D-3.1.5-B	The encapsulation will be done by 3D printing to isolate our components from hazardous environmental factors explained in 3.1.2. Material TBD	R-3.1.6-B

Table 3.1.1: Structural Base Design Specifications

3.2 Processing Unit Design Specifications

3.2.1 Alpha Stage

For the proof-of-concept, the team is constrained by the compatibility of the processing unit with the other components, but it is not constrained by the performance requirements of the system. As such, the group has chosen to use a Raspberry Pi 4 [7] running Ubuntu server as the main computer and operating system for the engineering prototype.

The justifications for choosing this unit are that is has the following features:

- USB 3.0 Ports for interfacing with Camera outlined in [D-3.4-A].
- GPIO Pins for controlling Laser outlined in [D-3.3-A].
- Pulse-width modulated general purpose input/output (GPIO) pins for analog signal to driver for optical scanning mirror outlined in [D-3.5-A].
- Uses the same architecture as the processing unit to be used in the beta stage outlined in [D-3.2-B].

3.2.2 Beta Stage

For the engineering prototype, the team must take the performance requirements of the system into account as well. As such, the group has chosen to use an NVidia Jetson Xavier NX [8] running NVidia's custom derivative of Ubuntu as the main computer and operating system for the engineering prototype.

The justifications for choosing this unit are as follows:

- USB 3.1 ports for interfacing with Camera outlined in [D-3.4-B].
- USB 3.1 port for controlling Laser outlined in [D-3.3-B].
- Pulse-width modulated GPIO pins for analog signal to driver for optical scanning mirror outlined in [D-3.5-B].

3.2.3 Processing Unit Design Specifications Summary

Table 3.2.1 below summarizes the design specifications and their corresponding requirements for the processing unit.

Design ID	Design Specifications Technical Description	Corresponding Requirements
D-3.2.1-A	The processing unit will have USB 3.0 ports.	D-3.4-A
D-3.2.2-A	The processing unit will have GPIO pins.	D-3.3-A

D-3.2.3-A/B	The processing unit will have GPIO pins capable of pulse-width modulation.	D-3.5-A D-3.5-B
D-3.2.4-A	The processing unit will use the same architecture as the processing unit in the beta stage.	D-3.2-B
D-3.2.5-A	The processing unit will have USB 3.1 ports.	D-3.4-B D-3.3-B

Table 3.2.1: Processing Unit Design Specifications

3.3 Laser Design Specifications

Before selecting the laser design specifications, the laser physics and the biological interactions were first understood. The PRP treatment aims to destroy new vascularization in the retina, which leads to restricted blood supply to the tissues. The light from the laser shined on the retina is absorbed by the retinal pigment epithelium (RPE) and is then converted to heat, which denatures the protein of the vessel and causes the vessel to burn and leave grey coloured scars on the retina [9]. When selecting the range of the laser wavelength, the absorption peaks of hemoglobin and deoxyhemoglobin were considered. Figure 3.3.1 shows the absorption coefficients of different types of molecules. The two main molecules which are present in the vessels at RPE are hemoglobin and oxyhemoglobin, the light absorption coefficient of these two molecules are the highest at around 560nm. In addition, the standard wavelengths used in PRP to destroy the vessels are yellow (561nm), green (532nm), and red (670nm) wavelengths with laser power 200-250mW.[10]

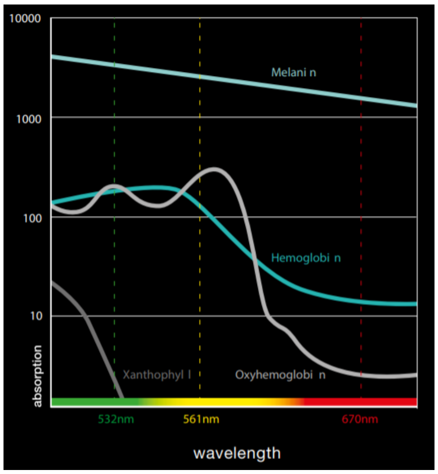


Figure 3.3.1: Wavelength Clinical Characteristics [10]

The retinal lesion size depends on many factors such as laser power, pulse duration, and beamwidth. Figure 3.3.2 shows size of the retinal lesion plotted as a function of laser pulse duration for different laser power settings.

3.3.1 Alpha Stage

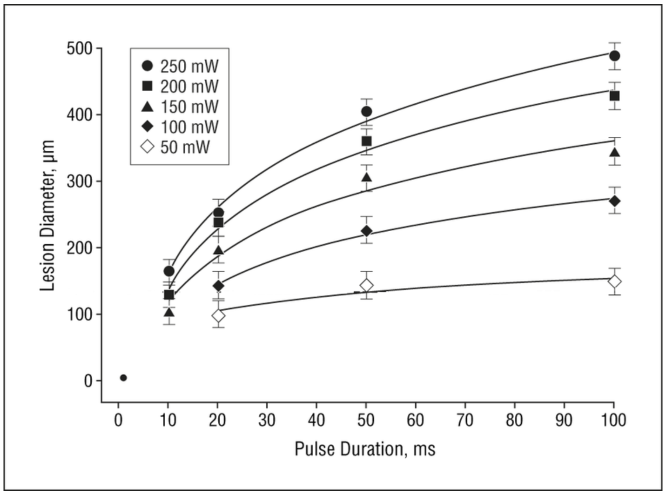


Figure 3.3.2: Clinical Size of the Lesion vs. Laser Pulse Duration for Different Laser Power [11]

The group has decided to use a simple Class IIIR laser diode with power of 5mW and a red wavelength of 650nm to use in the alpha stage. This laser pointer will be operated only for initial testing purposes. The main objectives of alpha stage development is to test the galvo mirror steering and the software performance.

The justifications for choosing a simple laser pointer:

- The laser beam can be expanded with expanding and collimating lenses to a desired diameter, as outlined in [R-3.2.1-A].
- The laser beam can be steered by the galvo mirror fast, accurate and precise, as required in [R-3.2.2-A].
- The laser is driven from 2.8V to 5.2V input voltage.
- The laser can be controlled by an ARM microcontroller.
- No special training is required to use Class IIIR lasers.

3.3.2 Beta Stage

Research on the market prices of medical lasers with high power, tunable wavelength and with very short pulse duration has shown that such devices have a very high cost. Furthermore, operating such lasers is not safe and requires special training.

For the reasons mentioned above, the group has decided to acquire OBIS 488-20 LS [12], which is a Class IIIB laser. These lasers meet design requirements for beta phase listed in Table 3.3. In addition, particular attention was given to the operational environment and required laser safety training.

The justifications for choosing the OBIS 488-20 LS:

- The laser beam can be expanded with expanding and collimating lenses to a desired diameter, as outlined in [R-3.2.1-A].
- The laser beam can be steered by the galvo mirror fast, accurate and precise, as required in [R-3.2.2-A].
- The laser is driven from a 12 V input voltage.
- The laser can be controlled by an ARM microcontroller.
- When applied for longer duration, the laser has the wavelength and the power to destroy the vessels.
- The laser is cheaper than the medical laser used in PRP.
- The laser is safer to use than the medical laser used in PRP.

3.3.3 Laser Design Specifications Summary

The design specifications in Table 3.3.1 are the standard laser specifications for the PRP treatment; they were collected from Dr. Mammo, Dr. Sarunic and Ellex Integre Pro Scan Brochure [1].

Design ID	**Design Specifications Technical Description**	**Corresponding Requirements**
D-3.3.1-A	The laser will have a light ray with a visible red wavelength (650nm).	
D-3.3.2-B	The laser will make burns with approximately half a spot size separation.	R-3.2.2-A
D-3.3.3-B	The laser will have a light ray with a wavelength of 488nm.	R-3.2.3-B (modification made)
D-3.3.4-B	The laser will deliver power of 20mW.	R-3.2.4-B (modification made)
D-3.3.5-B	The laser will be able to fire every 50 – 1000ms.	R-3.2.5-B (modification made)
D-3.3.6-P	The laser will make approximately 50-1000μm (diameter) sized burns on the retina.	R-3.2.1-A (modification made)
D-3.3.7-P	The laser will have a light ray with a tunable wavelength of 530-670nm.	

D-3.3.8-P	The laser will deliver titrating power (200-250mW) limited by a threshold.	

Table 3.3.1: Laser Design Specifications

3.4 Camera Design Specifications

For the alpha stage, the team is not constrained by the camera's ability to take photos of a real retina. This is a requirement for the beta stage. The team has decided to use the FLIR Blackfly S USB3 camera [13] for the alpha and beta stages, as the same camera can be used to achieve all of the alpha and beta stage requirements, provided that the modifications to the optical system outlined in [D-3.6-B] are made in the beta stage.

The justifications for choosing this camera are that the camera has the following properties:

- Captures images, as outlined in [R-3.3.1-A].
- Streams real-time video at 226 frames per second, satisfying [R-3.3.2-A].
- Dimensions are 29 mm × 29 mm × 30 mm, which satisfies [R-3.3.3-A] provided that the structural design outlined in [D-3.1-A] and [D-3.1-B] accommodates this.
- Can take images of the retina, satisfying [R-3.3.4-B] provided that the modifications to the optical system outlined in [D-3.6-B] are made in the beta stage
- Has a resolution of 1440 × 1080, satisfying [R-3.3.5-B]

Table 3.4.1 below summarizes the design specifications and their corresponding requirements for the camera.

Design ID	**Design Specifications Technical Description**	**Corresponding Requirements**
D-3.4.1-A	The camera will be able to capture images.	R-3.3.1-A
D-3.4.2-A	The camera will stream real-time video at 226 frames per second.	R-3.3.2-A
D-3.4.3-A	The camera's dimensions will be of size 29 mm × 29 mm × 30 mm.	R-3.3.3-A D-3.1-A D-3.1-B
D-3.4.4-B	The camera will be able to image the retina.	R-3.3.4-B D-3.6-B
D-3.4.5-B	The camera will have a resolution of 1440 × 1080.	R-3.3.5-B

Table 3.4.1: Camera Design Specifications

3.5 Optical Scanning Mirrors Design Specifications

For both the alpha and the beta stage, the team will be using galvanometer-based scanning mirrors to guide the laser beam to its intended destination. The team has decided to use two of the 6210H single-axis galvanometer scanners from Cambridge Technology [14] for this purpose. The reason why two of these scanning mirrors are needed is because these mirrors rotate on a single-axis, so in order to project any part of a 2-dimensional plane, two of these mirrors will be needed.

The justifications for choosing these mirrors are the following:

- Two of these mirrors will be able to point the beam at any region of interest in the eye, satisfying [R-3.4.1-A].
- The mirror can make small angle step movements at a speed of 1000°/sec, satisfying [R-3.4.2-A].
- The team already has access to two of these mirrors free of charge, courtesy of Prof. Sarunic.

Design ID	**Design Specifications Technical Description**	**Corresponding Requirements**
D-3.5.1-A	Two mirrors will be able to tilt along 2 axes (x-y) to span all regions of interest in the eye.	R-3.4.1-A
D-3.5.2-A	The mirror actuation speed will be 1000°/sec.	R-3.4.2-A
D-3.5.3-A	The mirror will support continuous full-speed operation of the tilting actuators at all times.	R-3.4.3-A
D-3.5.4-A	The mirror's size will be 12.7mm.	R-3.4.5-A (modification made)
D-3.5.5-P	The mirror's actuator will be 29mm.	R-3.4.6-P (modification made)

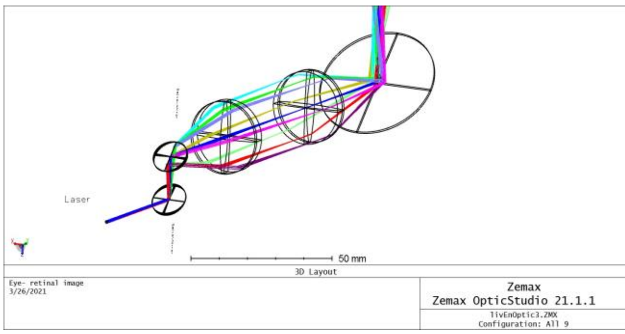
Table 3.5.1: Optical Scanning Mirror Design Specifications

3.6 Optical System Layout Design Specifications

3.6.1 Alpha Stage

For the alpha stage, a simple laser pointer is used as it is justified in section 3.3. The two single-axis galvanometer-based scanning mirrors are placed at 45 degrees angle and these mirrors will only be able to tilt in one direction, with the first mirror tilting about the x-axis and the second mirror tilting about the y-axis. We have chosen the maximum tilt angle to be 5 degrees in both the x and y directions for two reasons:

- For higher maximum tilt angles, the laser beam will go outside the scope of the lens and never reach the retina (Figure 3.6.1).
- For lower maximum tilt angles, all the laser beams will have no problem reaching the retina, however the target area covered on the retina would be too small for it to be used for treatment (Figure 3.6.2).



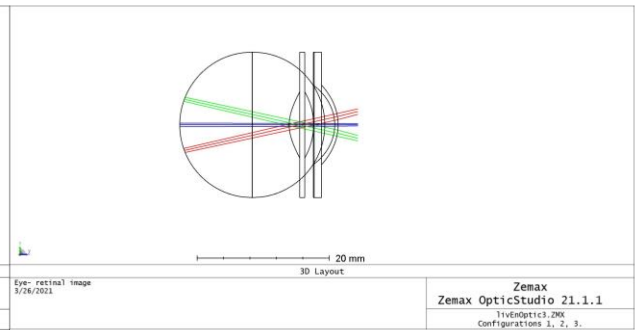


Figure 3.6.1: Angled View of Galvo Mirrors

Figure 3.6.2: Side View of the Eye

The beam will travel through the achromatic doublet lens in series so that all the beam converges onto the surface of the beam splitter regardless of their angle. Mirror movements will be synchronized by microcontroller and the eye movements will be tracked by the FLIR blackfly S USB3 camera in realtime. Figure 3.6.3 displays the overview of our optical system.

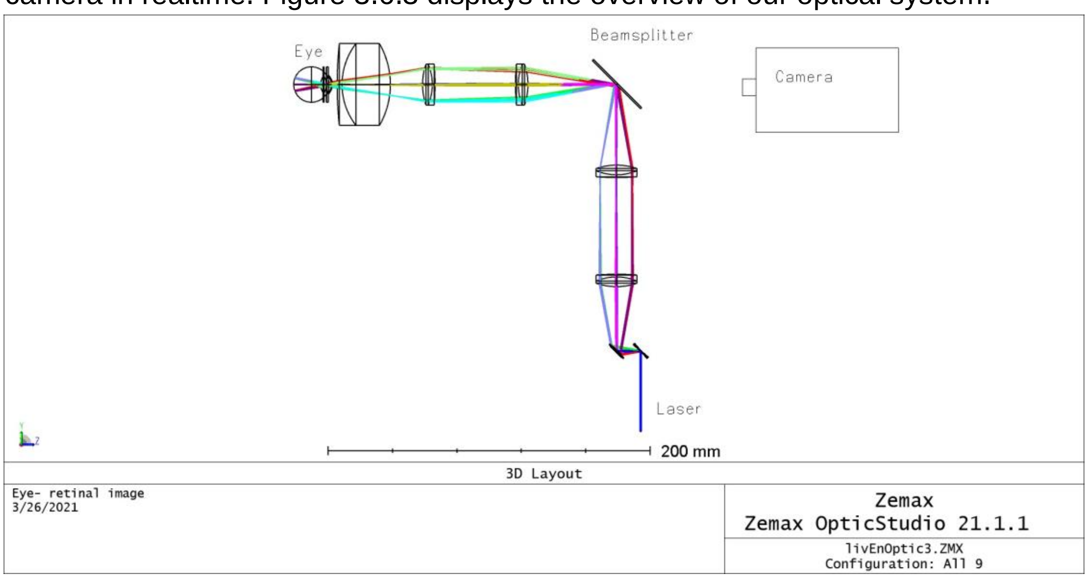


Figure 3.6.3: Optical System Design

3.6.2 Beta Stage

For the beta stage, the optical system design will stay relatively the same. The PRP laser will be used instead of a simple laser, and the lenses and beam splitter used in the beta stage will change depending on the aperture size of the camera and wavelength of the PRP laser.

3.6.3 Optical Layout Design Summary

Table 3.6 below summarizes the design specifications for the optical layout.

Design ID	Design Specifications Technical Description	Corresponding Requirements
D-3.6.1-A	The optical beam for the camera and laser will be coaxial.	R-3.1.2-A

Table 3.6.1: Optical System Layout Design Specifications

3.7 Hardware Design Specifications Summary

3.7.1 Alpha Stage

Table 3.7.1 features the summarized design choices for the proof of concept.

Design ID	Component	Design Choice
D-3.1-A	Structure/Base	MB18 - Optical Aluminum Breadboard
D-3.2-A	Processing Unit	Raspberry Pi 4
D-3.3-A	Laser	Class IIIR Laser Diode
D-3.4-A	Camera	FLIR Blackfly S USB3 Camera
D-3.5-A	Optical Scanning Mirror	Two 6210H single-axis Galvanometer Optical Scanning Mirrors
D-3.6-A	Optical System Layout	Dual-Galvanometer Laser Design

Table 3.7.1: Design Choice Summary - Alpha

3.7.2 Beta Stage

Table 3.7.2 features the summarized design choices for the engineering prototype.

Design ID	Component	Design Choice
D-3.1-B	Structure/Base	MB18 - Optical Aluminum Breadboard
D-3.2-B	Processing Unit	NVidia Jetson Xavier
D-3.3-B	Laser	OBIS 488-20 LS
D-3.4-B	Camera	FLIR Blackfly S USB3 Camera
D-3.5-B	Optical Scanning Mirror	Two 6210H single-axis Galvanometer Optical Scanning Mirrors
D-3.6-B	Optical System Layout	Dual-Galvanometer Laser Design

Table 3.7.2: Design Choice Summary - Beta

4.0 Conclusion

A semi-automated laser eye therapy system is needed to improve on the current procedures A semi-automated laser eye therapy system is needed to improve ease of use and time efficiency of the current procedures that are done by ophthalmologists. livEn will be creating this system to alleviate expert ophthalmologists of the time investment and to increase safety and consistency of laser eye therapies. Safety protocols and checks will remain the most important consideration while developing this product. Our intuitive graphical user interface will also ensure that error is minimized and that the laser eye therapy procedures become increasingly efficient while allowing less experienced clinicians to perform the procedures. This document has outlined the design specifications in terms of the software and the hardware that must be met to fulfill the needs as described in Section 1.

A summary of our design choices for the proof of concept:

1. Optical breadboarding is needed and will be used for the proof of concept. This is to keep the components of our system stable as optical breadboarding minimizes any tremors.
2. A Raspberry Pi 4 microcontroller has been chosen to run Linux for a lightweight environment, simple machine learning interface, and for simple development.
3. A laser diode has been chosen as the laser for the proof of concept. This is a cheap option perfect for testing movement and aim, that it can be powered on and off, and that it can burn the right spots on our phantom eye at a single wavelength.
4. The FLIR Blackfy S USB3 camera was chosen based on price, size, and ability to view a live feed and capture the image of the retina at an appropriate resolution.
5. The Galvo optical scanning mirror, 6210H single-axis galvanometer scanners from Cambridge Technology, was chosen primarily for its ability to integrate with our other components. These mirrors can individually aim our laser across 2 axes and move at the appropriate speeds.
6. U-Net will be used for the segmentation of vasculature via Keras in Python.

These design specifications were developed to fulfill the requirements outlined in the requirements specification document which detail that our proof of concept will be able to use our algorithm to safely and accurately fire our laser diode at the desired and chosen locations.

5.0 Product Design Specification Approval
5.0 Product Design Specification Approval

Signature:		Date:	03-26-2021
Name:	Eduard Durech		
Title:	CEO		
Role:	Biomedical Engineer		

Signature:		Date:	
Name:			
Title:			
Role:			

6.0 References

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Appendix A: Supporting Design Options

A.3.1 Structural Design Options

The design options for the structural base of the RILab was quite simple. RILab opted to go forth on a budget conscious route choosing breadboarding over the optical table. Optical tables provide a greater degree of shock absorption that is not yet needed in the scope of our projects in the alpha and beta phases.

The taps on optical breadboards allow us to easily align our components as compared to creating our own stages and mounts. And to conclude our immediate decision, the standard series offers the cheapest options.

A.3.2 Processing Unit Design Options

For the processing unit, the team had three options to choose from: An NVidia Jetson Xavier NX [1], the UDOO Bolt [2], or the user's own computer. The team has decided to go with the NVidia Jetson Xavier NX, with the justifications provided in section 3.2 above. Some more details on the other options are covered below.

A.3.2.1 UDOO Bolt

The UDOO Bolt is an X86-based single board computer, with an embedded Radeon Vega graphics unit. Some pros and cons of this option compared to the NVidia Jetson are shown below:

Pros:

- CPU has an X86-based architecture. This means the team would have an easier time finding compatible drivers for the components that require pre-compiled libraries. In contrast, the NVidia Jetson is based on ARM.

Cons:

- The team could not verify how well the UDOO Bolt would perform for the application's machine learning needs, and this concern was further amplified by the Bolt's use of a Radeon Vega graphics unit rather than an NVidia graphics unit, which is known to not perform as well for machine-learning applications. On the other side, the NVidia Jetson had readily available benchmarks in machine-learning applications that gave the team confidence in its ability to perform for this application. A poor performing processing unit would have made it difficult to fulfill [R-2.2.1-A] and [R-2.2.2-B].

The team decided that while it may be more difficult to find components that ship with libraries compatible with ARM, that the other components the team ultimately ended up using did provide platform-agnostic ways of controlling them, which meant this was not as much of a concern, and lead to choosing a platform that was more verifiable on performance.

A.3.2.2 User's Computer

This option would see the user connect their own computer to the system, and this computer would then act as the main processing unit. Some pros and cons of this option compared to the NVidia Jetson are shown below:

Pros:

- Cheaper, as a processing unit would not need to be purchased for the production of the system.
- Can have better performance for machine-learning inference, depending on the setup of the computer.

Cons:

- Would have to assume that the user has a computer that is powerful enough to perform the machine-learning inferences at the speed needed.
- The user, who is likely not an engineer, would need the technical know-how to understand the system's minimum requirements for a processing unit, and whether or not their system meets these requirements.
- The user would also need the technical know-how to install any dependencies needed for the software, such as Python.

Since the team understood that users of this system will not always be technical people, and that the performance of the system is critical to the safety and usability of the device, that it would be best not to continue with this option. A poor-performing host machine would make it hard to fulfill [R-2.2.1-A] and [R-2.2.2-B], and therefore by proxy, [R-4.0.6-B] and [R-4.0.9-B].

A.3.3 Laser Design Options

When choosing a laser for the RILaB system the team has considered two devices: OBIS 488-20 LS [3] and OBIS 786 LS [3]. Both devices are Class 3B lasers, which have sufficient power and wavelength to penetrate into the eye and cause damage to the retina. OBIS 488-20 LS has an output power of 20mW and a wavelength of 488nm, whereas OBIS 786 LS produces a laser beam with much higher power of 50/130mW and wavelength of 786nm. To minimize the risk of injury when designing the system, the team has decided to acquire OBIS 488-20 LS, which is in the visible range and has a much lower power.

A.3.4 Camera Design Options

For the camera, the team had two similar options to choose from: The FLIR Blackfly S USB3 model [4], or the FLIR Blackfly S GigE [5] model. The only difference between the USB3 model and the GigE model is that the USB3 model uses USB 3.1 to communicate with the host machine, while the GigE model uses gigabit ethernet to communicate with the host machine.

The team has ultimately decided to use the USB3 model. With the advent of USB 3.1, transfer rates between USB and Ethernet have equalized (both are capable of transfer rates up to 10Gbps). Since the team would not have noticed a performance hit either way, the team decided to use the USB 3.1 model as USB is an interface the team is more familiar with, and therefore would make the development process earlier.

A.3.5 Optical Scanning Mirror Design Options

For the optical scanning mirror, the team had two options to choose from: The MEMS mirrors offered by Mirrorcle Technologies [6], or the 6210H galvanometer-based scanning mirrors [7]. The team has decided to use the galvanometer-based scanning mirrors, with the justifications listed in section 3.5 above. Some more details on the other option, the MEMS mirrors, are covered below.

3.5.1 MEMS Mirrors

The MEMS mirrors offered by mirrorcle are tiny mirrors designed for high speed and high precision movements. The pros and cons of using these mirrors are listed below:

Pros:

- Requires significantly less power than galvanometer-based scanners
- Much smaller than galvanometer-based scanners
- Ease-of-use as inputs to the driver are digital rather than analog
- The team already has access to these mirrors free-of-charge courtesy of Prof. Sarunic's lab.

Cons:

- Driver requires proprietary libraries that are only distributed for X86-based systems on Windows.
- Linux libraries cost an extra $2000.
- Platform-agnostic OEM drivers which use SPI to communicate cost an extra $800.

The team would have really liked to use the MEMS mirrors, as they are a novel technology and would have been easier to use due to their digital inputs. However, the fact that the libraries were only distributed as Windows libraries compiled for X86-based systems was a blocker for using these mirrors. The team considered using QEMU's user-space X86 emulator to run an X86 executable on the processing unit, but this would not have been feasible as the shared libraries provided required the use of a Linux application called "Wine" to translate windows system calls to Linux system calls, and it would have been an extremely finicky and unreliable process to use

QEMU’s X86 user-space emulator to run a Wine process that then runs the main process. Due to these difficulties, the team decided to use the galvanometer-based mirrors instead, whose platform-agnostic driver uses a simple analog electrical signal to control the mirrors.

A.3.6 References

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Appendix B: User Interface & Appearance

B.1 Introduction

RILab's User Interface (UI) and appearance design aims to provide an intuitive, familiar, and easy method of control for clinicians integrated in the semi-automatic laser eye therapy system. RILab automates the control of the laser, camera, and novel scanning mirrors while the clinician selects regions of interest for the procedure and confirms automated clinical actions. The project, initially conceived by Dr. Marinko V. Sarunic, seeks to improve the usability and safety of laser eye therapies by meeting the goals described in Table B.1.

Usability Goals	Description
1. Learnability	Easy to learn. Can be used by medical resident students to learn.
2. Efficiency	Efficient to use. Features improvements compared to the current processes in place.
3. Memorability	The design will be memorable such that the user can easily come back to the interface and remember everything—even after an extended period of time.
4. Errors	The design will be as error-free as possible. Errors that do occur will feature detailed error messages to describe the issues and a fix. Error preventative measures will be in place to minimize user error.
5. Satisfaction	The user will not have any frustrations with the design.

Table B.1.1: livEn's Usability Goals

The novel system will be interfaced by a clinician using our Graphical User Interface (GUI), where a therapeutic laser can be guided into a patient's retina. The laser will fire at a desired wavelength, duration, power, size, and pattern which will be displayed and confirmed by the clinician. Our UI must prioritize usability goals 2 and 4 in order to be a successful and marketable medical system. These priorities serve as the basis for our design and test procedures which will be analyzed by livEn and expert users. livEn will further be following Don Norman's design principles: visibility, feedback, mapping, constraints, consistency, and affordance to meet Don Norman's Seven Elements of UI Interaction [1] and Nielsen's Heuristics [2], ensuring a safe and efficient system.

B.1.1 Purpose

The purpose of this document is to provide an overview of the software user interface of livEn's RILab to control the hardware that livEn has put together. The hardware, as researched and put together by livEn, does not directly interface with the user. The design choices made in terms of the interface will be analyzed and tested with analytical and empirical tests as shown below in sections B.5 and B.6 to improve the interface.

B.1.2 Scope

This document covers the prototype user interfaces of RILab which were designed with respect to the required user knowledge and restrictions that they may have. As aforementioned, this document goes through technical analyses with analytical and empirical tests to meet Don Norman's design principles and satisfy the user's needs. The User Interface and Design Appendix will also cover the relevant Engineering Standards that apply to the proposed user interfaces for RILab.

B.2 User Analysis

Users will have to be practicing or studying ophthalmologists, with a minimum knowledge and experience of a medical resident student. These users will have most likely used similar ophthalmology systems such as Ellex, Meridian, Zeiss, or Topcon.

These ophthalmology systems are all used on PC. As such, our system will require users to physically perform point and click PC interactions with a mouse as well as textual inputs by keyboard.

Safety is of utmost importance and the user will have to know the following with their expertise and study to be able to use the system. This list considers the user's knowledge on the patient and the therapy that they are performing.

1. Laser power threshold
2. Laser colour (wavelength)
3. Laser duration
4. Laser repeat (firing interval)
5. Laser pattern
6. Characteristics of diseased tissue
7. Regions of the retina to avoid

These settings are common across ophthalmology systems such as Ellex and as such, will have affordances and signifiers to consider for consistency and ease of use.

B.3 Technical Analysis

Any technical analyses will be performed to cover the 7 Elements of UI Interaction by Don Norman.

1. Discoverability
2. Feedback
3. Conceptual Models
4. Affordances
5. Signifiers
6. Mappings
7. Constraints

B.3.1 Discoverability

Good discoverability will allow users to easily determine which actions are possible and view the current state of the system and easily interpret it.

1. The layout will follow the natural flow of the standardised laser treatment protocol.
2. The software will have familiar design features which are common with other similar eye therapy systems.
3. The buttons will be colour coded based on the button actions.
4. The buttons will have intuitive icons and clear labelling.
5. The buttons which control the health threatening actions will be more prominent.

B.3.2 Feedback

Good feedback is when the user interface clearly communicates the results of our actions such that the user is not wondering if anything has happened.

1. The interface will display a real-time retinal image during the entire treatment procedure, this will help the clinician to follow the laser firing progress.
2. The interface will display a retinal snapshot image which will be used to select the locations of the laser firing spots.
3. A progress bar with the number of spots fired on out of total spots to be fired upon will display how much of the process has been completed.
4. During the laser firing process, the identification light on the “Fire” button will turn from red to green.
5. The disabled buttons will keep the user from clicking on the button until some other condition has been met. The disabled buttons will be greyed out.
6. Selected buttons will increase in colour intensity while active.

B.3.3 Conceptual Models

Conceptual models are simple instructions of how our system will work from the user interface.

1. RILab’s software interface will closely follow the Ellex laser/slit lamp software interface which is used by the ophthalmologists at Vancouver Eye Care Center for manual laser eye therapies. This will eliminate confusion when switching from an old to a new system.
2. To assist the user with carrying out the desired task, each button of the software interface will have a mouseover instruction tooltip. This guidance element will be activated when the user hovers over a button and will display a brief helper text about the button’s function.
3. A detailed manual with step-by-step instructions will be provided as well as video tutorials.

B.3.4 Affordance

Affordance is the relationship between an object and a user. The perceived action of the object will dictate how the user attempts to perform an operation.

1. Our intention is to create an interface layout that will follow the PRP therapy protocol. This design will create a workflow which is well known by the users.
2. To guide the user throughout the treatment session, RILab will have some buttons disabled during each of the stages and will enable them only when a certain condition is met.

B.3.5 Signifiers

Signifiers provide clarity on where to perform an action. They can be communicated through text, sound, size, and colour.

1. There will be a progress bar with numeric progress which will indicate the laser firing process completion.
2. When the firing process is stopped, the progress bar will switch to a red colour to indicate that the process is not finished.
3. There will be a flashing red/green light on the “Fire” button that will indicate if the laser firing is off/on.
4. The treatment and no treatment selected regions will have a colour mask overlaid with text labels identifying the region type.
5. The interface will have an indicator which will inform the user in which mode (manual/automatic) they currently are.
6. The fire button will have a green tint and the stop button a red tint to signify their relation to the procedure (on/off)

B.3.6 Mapping

Mapping is the placement of controls and how they logically flow to be intuitive for users.

1. The layout of the software interface will follow the natural process of the eye laser treatment protocol.
2. The live and still retinal images will take most of the space on the screen as those are the working regions for the user. The still retinal image will be closest to the controls that will be used on it.
3. The buttons will be grouped based on their functionalities: laser settings, selection tools, laser control.
4. Region selections of the retinal image will appear under the mouse when clicked and continuously follow the mouse if it remains clicked.
5. A faded version of the select brush size/shape will appear under the mouse while not being applied.

B.3.7 Constraints

Constraints will restrict actions or restrict the views of some actions as to not clutter the user interface and overwhelm the user. It limits the information that the user processes in a positive manner.

1. The software will require the user to set a group of laser settings that indicate maximum power, wavelength configuration, lens type and a pulse duration before the automation process can start.
2. The interface will prevent the user from clicking the wrong buttons during certain states by disabling them until some other condition has been met.

Furthermore, livEn has decided that Nielsen's Heuristics will be of excellent use when it comes to the analytical analysis - the heuristic evaluation. Nielsen's Heuristics are broad rules of thumb that encompasses Don Norman's Seven Elements of UI Interaction [1] to meet the goals of usability. They are as simply put below:

1. Visibility of system status
2. Match between system and the real world
3. User control and freedom
4. Consistency and standards
5. Error prevention
6. Recognition rather than recall
7. Flexibility and efficiency of use
8. Aesthetic and minimalist design
9. Help users recognize, diagnose, and recover from errors
10. Help and documentation

B.4 Engineering Standards

During the graphical user interface design process we have chosen to follow International Organizations for Standardization (ISO) and the International Electrotechnical Commission (IEC) standards, which are listed below in Table B.4.

Engineering Standard	Description
ISO/IEC 11581-5:2004	Information technology — User system interfaces and symbols — Icon symbols and functions — Part 5: Tool icons [3]
ISO 9241-210:2019	Ergonomics of human-system interaction — Part 210: Human-centred design for interactive systems. [4]
IEC/TR 80002-1:2009	Medical device software — Part 1: Guidance on the application of ISO 14971 to medical device software [5]
IEC 62366-1:2015	Medical devices — Part 1: Application of usability engineering to medical devices [6]
IEC 62366:2007/AMD 1:2014	Medical devices — Application of usability engineering to medical devices — Amendment 1 [7]
ISO/TR 17791:2013	Health informatics — Guidance on standards for enabling safety in health software [8]

Table B.4.1: Engineering Standards related to UI Design

B.5 Analytical Testing: Heuristic Evaluation

The table below is based on the Usability Aspect Report (UAR) Template from Brad A. Myers and Bonnie John [9]. livEn has gone through thorough analytical testing to further improve our user interface. This design uses Nielsen's Heuristics to meet the design parameters of Don Norman's Seven Elements of UI Interaction [1], both as described in section B.3.

The scale used when indicating the severity/benefit of the issue is

1 = cosmetic
2 = minor, low priority to fix
3 = major problem
4 = catastrophic, must be fixed before product is released

Our designers have and will continue to test the user interface throughout all phases of development part-by-part and as a whole to best match heuristics and design principles.

Step-by-step testing for the system as a whole is as follows:

1. Input the upper limit for the power e.g. 200mW
2. Select a wavelength configuration.
3. Take the image of the patient's retina.
4. Select the "Go" regions of interest where the therapy is needed.
5. Select the "No-Go" regions of non-interest where the therapy is not needed and must not go.
6. Erase all regions that were selected.
7. Switch the control settings from automated to manual.
8. Select the points where the therapy must be done with point select.
9. Confirm the selected regions denoting that you are ready to go.
10. Start the laser.
11. Reset the application to its initial state.
12. Repeat steps 1 to 10.
13. Stop the laser.
14. Cancel the current process.

Table B.5.1 is an example of one of our tests where we tested the individual feedback of the buttons on our user interface.

B.5.1 Heuristic Evaluation #: 1	**Problem/Good:** Problem
Name: Button Feedback	
Relevant heuristic: Visibility of System Status (Nielsen's Heuristic) - Feedback (Seven Elements of UI Interaction [1])	
Evidence of issue: This issue is in each button as seen in section B.7. Buttons are located on the top and right side of the interface.	
Detailed explanation: The buttons, when clicked, do not provide a deep enough hue or indicator to show that it is currently selected nor provides feedback when its respective action is done.	

Severity or Benefit (low, medium, high): 2.5 **Justification:** Lack in solid feedback and visibility of system status can cause the user to miss an important action. This can lead to actions being performed more than needed, unnecessarily leading to improper use of the system.
Possible solution and/or Trade-offs: Solution is to increase the intensity of the hue. Another solution is to add a visual indicator such as a symbol as this helps with accessibility. These solutions should have no trade-offs.

Table B.5.1: Heuristic Evaluation #1

B.6 Empirical Testing

Empirical testing done by livEn is in partnership with Dr. Zaid Mammo and his eye care clinic at the Vancouver General Hospital. We will be performing the following two methods in partnership with each other:

1) Thinking Out Loud
2) Cognitive Walkthrough

The steps to go through the cognitive walkthrough are:

1. Identify & document typical users, sample tasks exposing aspects of designs to be evaluated, and prototypes.
2. Gather users.
3. Greet the gathered users.
4. Obtain consent to use the information gathered on our documents.
5. Perform an entry survey to gather more detailed information about our users and their experience.
6. The users walk through the action sequences for each task, placing themselves in the context/scenario, where we will answer the following 4 questions:
    a. Will the correct action be evident to the user?
    b. Will the user notice the correct action is available in good time?
    c. Will the user associate the correct action with the outcome they expect?
    d. Will the user interpret the response correctly and see progress from the correct action?
7. Debrief the user and perform an exit survey to gather clear feedback.
8. Compile results including problems identified and suggestions for improvement.
9. Revise design to fix problems or improve. Users may be contacted to verify insights.

livEn has gone through a single test with Dr. Zaid Mammo. We have obtained proper consent to use the information obtained from the test as shown below. This test is displayed in the appendix as an example of future tests; the format as seen in sections B.6.1 to B.6.5 can be used as such.

B.6.1 Cognitive Walkthrough: Entry Survey

1. Name
    a. Dr. Zaid Mammo [10]
2. Occupation
    a. Ophthalmologist
3. How many years have you been in the field?
    a. Retina Ophthalmologist since 2012 (9 years)
    b. Eye therapies are done daily
    c. PRP once/twice a week
4. What experience do you have with systems currently in place?
    a. Ellex, Meridian, Zeiss, & Topcon
    b. Binocular view of fundus w/ lens and laser using joystick

B.6.2 Cognitive Walkthrough: Scenario

“You’re an ophthalmologist and you need to perform panretinal photocoagulation therapy. Your patient is ready to go, eye drops, contact lenses, and all. This is your first session with this patient. All of your equipment and everything else you need is ready to go. You can now start the process on your computer.”

B.6.3 Cognitive Walkthrough: Representative Tasks/Actions

Table B.3.1 runs through the representative tasks and actions that Dr. Zaid Mammo performed on our user interface. This version of the interface can be seen in section B.7.

Tasks List	Gaps Filled from Prototype	Notes
1. Please input the upper limit for the power that you will be using. Let’s use 200mW		Dr. Zaid Mammo explained what he would do with expertise; however, he did not use the GUI. The cognitive walkthrough should be better introduced in the future.
2. Select the wavelength configuration to be green-red next.		Dr. Zaid Mammo appropriately chose the right colour but again without using the GUI.

3. Take the image of the patient's retina.	*Clicked Take/Retake Image button*	Take/Retake ~3s to find. Dr. Zaid Mammo did not show too much confusion.
4. Select the "Go" regions of interest where the therapy is needed. *This will bring up a brush for you to brush select over*	You will now see a shade & shape of the area that you selected where the therapy must happen.	Select – a few seconds to find; would be good to increase/change size. Dr. Zaid Mammo showed a bit of confusion when trying to find the button but did intuitively find it appropriately.
5. Select the "No-Go" regions of non-interest where the therapy is not needed and must not go. *This will bring up a brush for you to brush select over*	You will now see a shade & shape of the area that you selected for the laser not to fire at ever.	No-Go was easier as the task before set-up appropriate expectations for this task.
6. Confirm the selected regions denoting you are ready to go.	The algorithm will then show you the points on the screen. Let's assume that the laser points are displayed.	Confirm – 2 seconds. The task was intuitive.
7. Start the laser	The laser eye therapy process is ongoing. Now let's assume everything was done successfully. The progress bar at the top will be filled.	Starting the laser had no issues at all.
Additional Tasks		
1. Please erase the region that you selected.	Now your region has been erased. Now you want the process to be manual instead.	Dr. Zaid Mammo showed confusion about the erase button initially. But when the task was explained, Dr. Zaid Mammo found it in quick time.
2. Switch the control settings from automated to manual.		Automatic to manual control switch – quick and worked well.
3. Select the points where the therapy must be done	*The points will be placed as crosshair cursors*	Selected points were done in quick time and done well.

4. Cancel the current process.	This will reset the UI to it's original start state.	Dr. Zaid Mammo described how he would restart but did not include the cancel button. The cancel button may need further explanation.

Table B.6.1: Scenario 1

B.6.4 Cognitive Walkthrough: Exit Survey Notes

Note on this survey:

- This survey was completed by Dr. Zaid Mammo [10]
- These questions are more specific and high-level as the users are experts in their field.
- This was the first time we performed this test so we included questions on functions, features, and the laser eye therapy process.

1. Did the system feel good to use? Were there any frustrations? And how would you improve it?
    a. Laser/Therapy settings close to each other (wavelength, pattern, power, et cetera for laser; single spot, pattern for therapy; reference currently used GUI's).
    b. Take/Retake - towards top-left as initiates therapy, flow based on progress of procedure.
    c. Colour code fire, stop (green, red).
2. Did you see the correct terminology being used when it comes to laser eye therapy?
    a. Rename Go, No-Go to Treat, No Treatment or something more intuitive (e.g. avoid tool); erase not directly intuitive.
3. How can we improve our system so that we eliminate or minimize potential error and enable error recovery?
    a. Mark still retina image with region mask (e.g. green fire mask, mask for no fire).
    b. When fire selected have "Please confirm" popup
4. Were there any essential features or functions that were missing?
    a. Laser options - repeat time, treatment pattern (spot size, width, shape), usually 2-3 options for wavelength. Note that spot size is set by the lens being used.
    b. Lens changes the magnification factor. Having a function to select this would be pertinent.
    c. Report on the number of spots applied would be useful.
    d. Tools for increasing size and changing location of regions.
    e. Tools for increasing size and changing location of therapy dots.
    f. Lock for laser settings which applies them to the hardware, deselecting lock inactivates hardware.
5. Were there any essential steps that we are missing from the flow and process?
    a. Power not always known, maybe another setting/interface for firing power (e.g. test spot to try).

B.6.5 Cognitive Walkthrough: Compiled Results

Below is the compiled output generated from the empirical testing which we performed with Dr. Mammo. It is important to point out that not all modifications are to be implemented at the Proof of Concept stage but are anticipated to be present in the Production Phase.

1. Setting Tools
    a. Add Laser Pulse Duration input box
    b. Add a drop down box with Treatment Spot Pattern
    c. Add a drop down box with Lens Type
    d. Have Laser Settings displayed on an additional window with a still retinal image. On this page the user can test out the configured laser settings by firing a test shot on the retina
2. Button Labelling
    a. The “GO” button should be renamed as “Treatment Area”
    b. The “NO-GO” button should be renamed as “No Treatment Area”
    c. The “Erase” button should be renamed as “Modify Area”
3. Button Mouseover Tooltip
    a. Add a tooltip with button action description when hovering over the button
4. Manual Control
    a. Return complete manual control to the user and disable the automation. The interface should only display the binocular view of the retina, the laser should be controlled via joystick
5. Colour Coding
    a. Make “Fire” button green and “Stop” button red
    b. Add a coloured mask over the selected areas with additional label that will indicate the region type (Treatment/No Treatment)
6. Layout
    a. Create a layout that will follow the flow of the treatment protocol. Laser Settings -> Take/Retake Image -> Select Tools -> Confirm/Cancel -> Fire/Stop
    b. Include number of spots fired on and total number of spots to be fired upon
7. Additional Layer of Security
    a. When “Fire” button is pressed have a popup dialog box saying “Confirm the firing process” with two options “Confirm” and “Cancel”
8. Report Generation
    a. Create a pdf report with retinal images, # of spots, laser settings and date

B.7 Graphical Representation

The main focus of the RILab graphical user interface (GUI) is the live and still retinal images. The Select Tools and Take/Retake Image buttons with respective icons are displayed to the right of the retinal images. In addition, laser control is located above the retinal images, these include the larger Fire/Stop buttons which initiate and stop the laser firing, the Confirm button which confirms the treatment and no-treatment regions, and the Cancel button which cancels the whole procedure and allows the user to restart the treatment session. In addition, the Manual Control switch is located at the right top corner and when selected enables the Point Select button underneath while disabling the automation and returning full control to the clinician.

Figures B.7.1-B.7.4 display some states of the RILab prototype GUI.

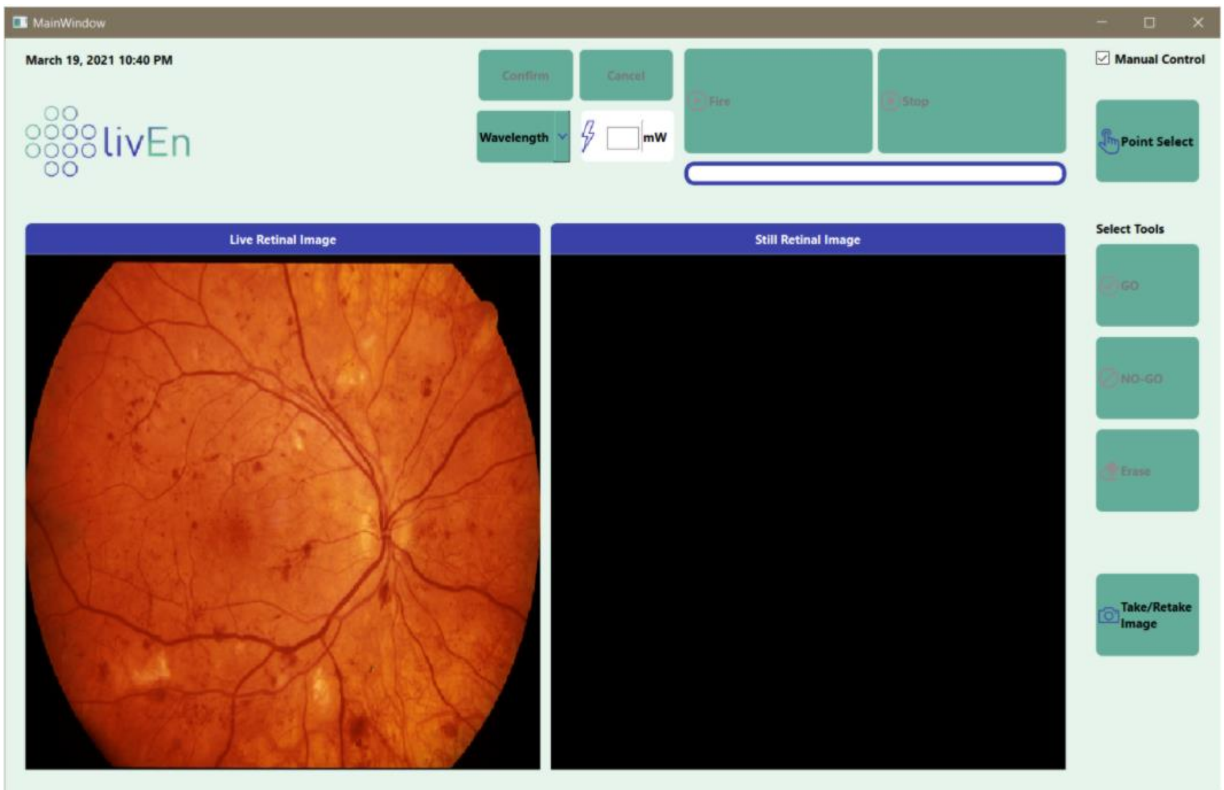

Figure B.7.1: Screen showing RILab in Manual Mode

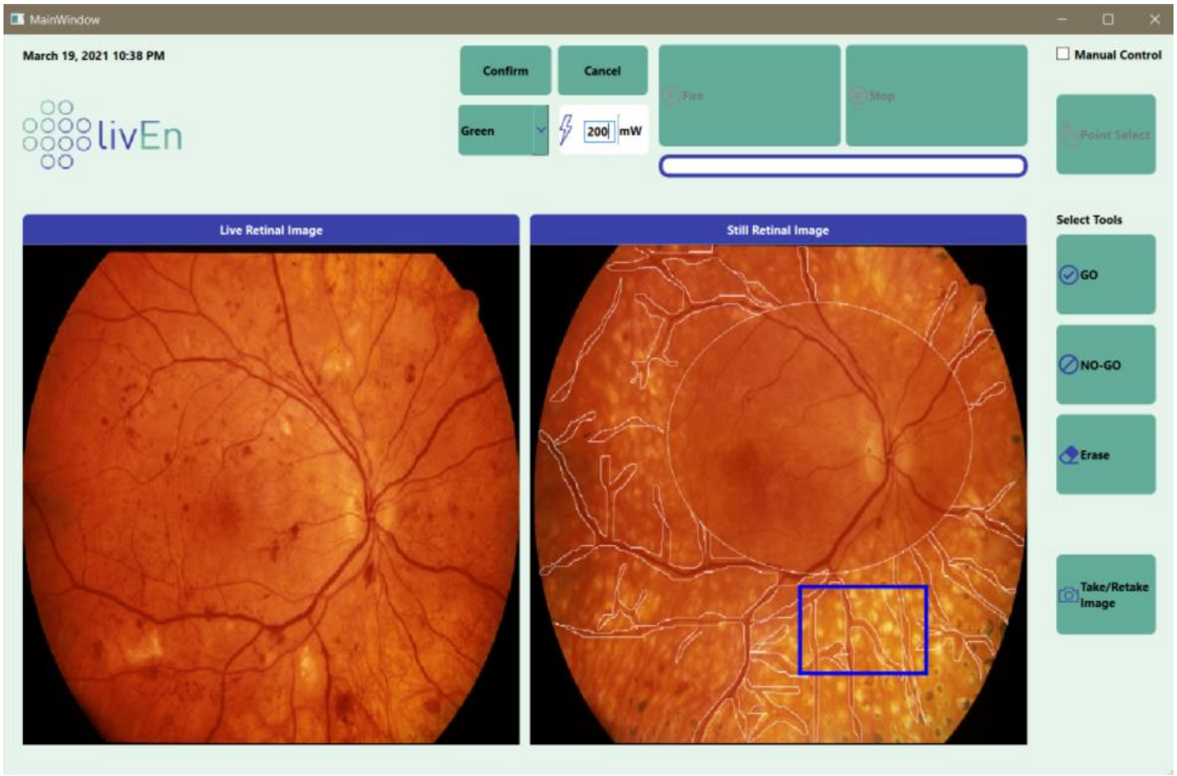

Figure B.7.2: Screen showing automatically segmented no treatment regions (white) and user-selected treatment region (blue)

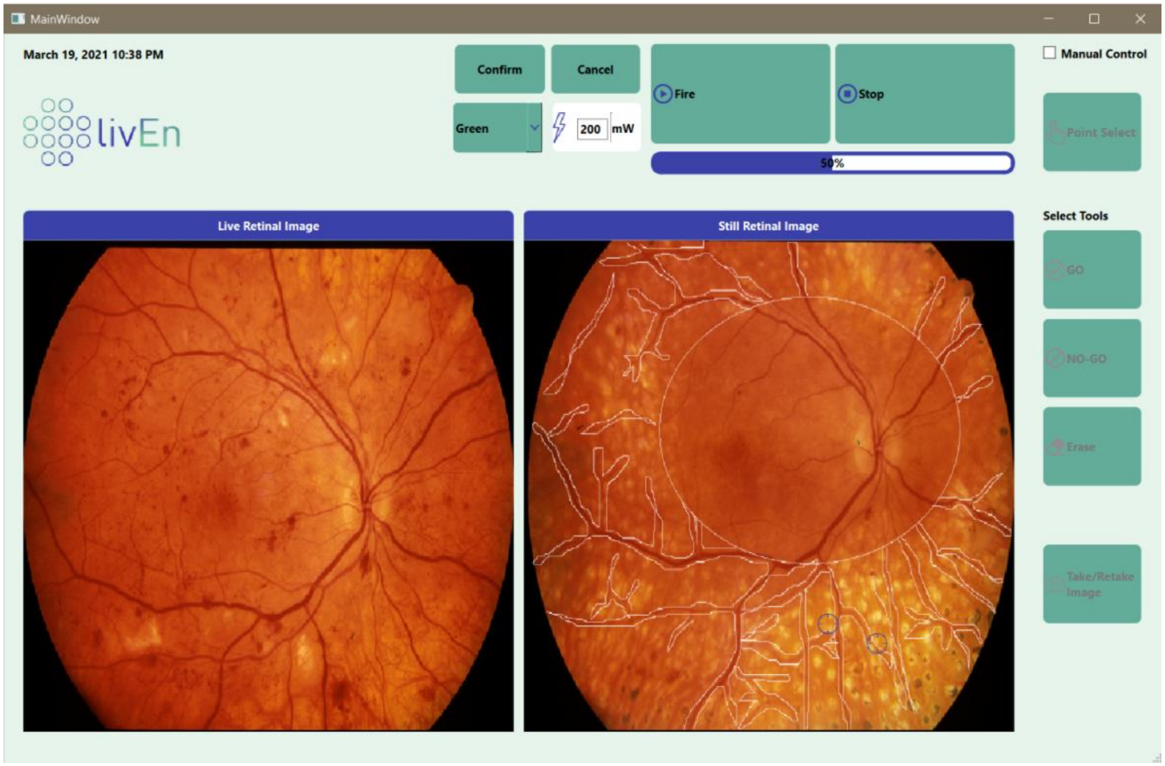

Figure B.7.3: Screen showing ongoing firing process

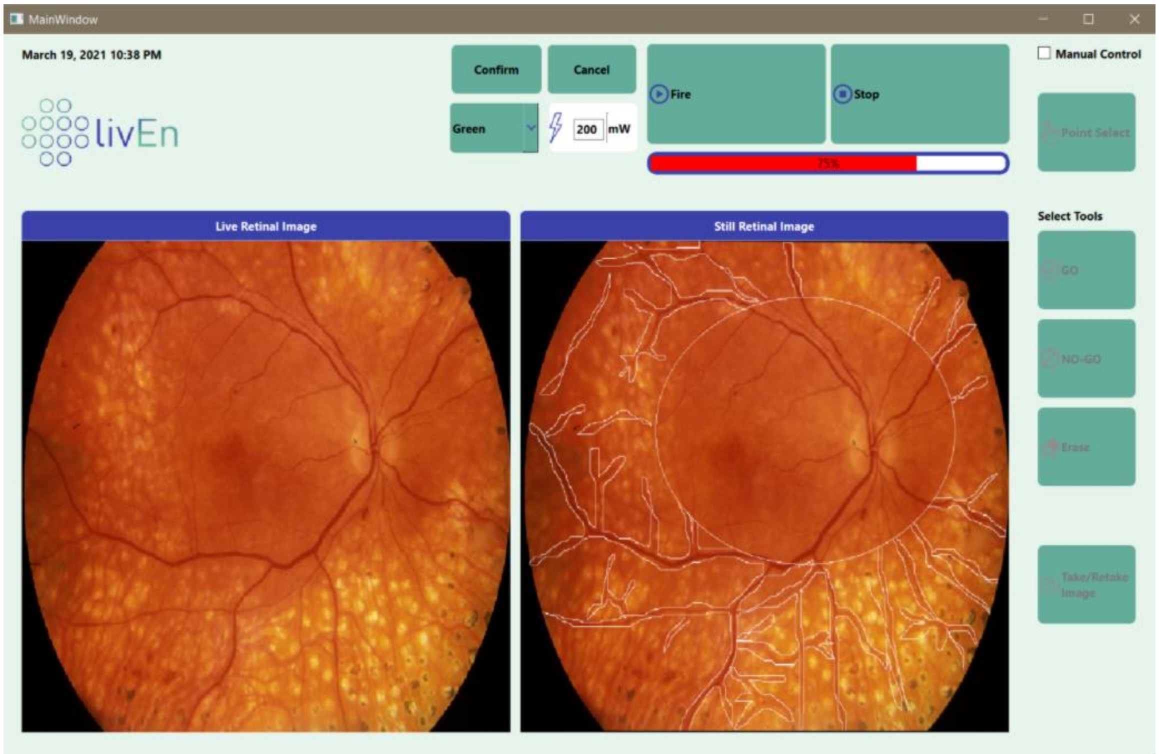

Figure B.7.4: Screen showing the firing process stopped

B.8 Conclusion

The RILab's graphical user interface covers the features needed to assist ophthalmologists and medical resident students in performing laser eye therapies. The current state of our user interface is at a phase where users can input a power threshold, highlight the appropriate regions to fire and avoid, and fire the laser. Section B.7 features the current iteration.

Our main goal is to design a controlling software for clinicians to speedup and alleviate a portion of their workload via semi-automation of laser eye therapies. This interface places an emphasis on efficiency and safety to be a usable product by safeguarding patients through error prevention and error recovery during the semi-automated treatment. We can prevent or minimize any harm that can be caused through human error by reducing the complexity of our interface design and by adding extra safety steps to initiate the laser firing.

Further work needs to be taken to meet the statements in the previous paragraph. For the proof-of-concept and appearance prototypes, our user interface must add necessary features that ensures that the laser fires correctly. These features include functions for the laser duration, laser repeat, and the laser pattern. We need an option to set the lens that is in use. And lastly, we need to add an additional process which can fire test spots before going into the full process. These items to implement are a result of our timeline and are a result of our empirical test with Dr. Zaid Mammo.

Testing is done on the interface and design using Don Norman's Seven Elements of UI Interaction and Nielsen's Heuristics to ensure that our design goals are met. livEn has and will continue to perform analytical testing through heuristic evaluations and improve our interface. We will also continue to perform empirical testing with our expert users using the test methods and templates provided in sections B.5 and B.6.

B.9 References

[1] D. Norman, The design of everyday things: Revised and expanded edition. London, England: Basic Books, 2013.

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[3] “ISO/IEC 11581-5:2004,” Iso.org, 2017. [Online]. Available: https://www.iso.org/standard/40060.html. [Accessed: 19-Mar-2021].

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[9] Cmu.edu. [Online]. Available: http://www.cs.cmu.edu/~bam/uicourse/UARTemplate.doc. [Accessed: 21-Mar-2021].

[10] Zaid Mammo, MD, FRCSC, Retina Specialist at Vancouver General Hospital

Appendix C: Supporting Test Plans

Test Purpose: The attached test plan ensures that basic functionality of our algorithm and devices is met as well as satisfying constraints of our system which will be displayed during the ENSC405W demo. These supporting test plans will ensure that each component and subcomponent of our system works as detailed.

Test Condition: For the alpha phase a phantom eye will be used for testing purposes whereas for the beta phase acquiring a biological porcine eye will be attempted for testing. The phantom eye ensures basic functionality of the software and hardware works and that they are able to communicate whereas the biological porcine eye ensures the efficacy of the medical procedure. The chosen phantom eye for livEn's proof of concept will be an image of a retina printed on a piece of paper.

Our tests are split into these components and subcomponents:

1. General
2. Software
    a. General
    b. Image Processing
    c. Selection
3. Hardware
    a. Laser
    b. Camera
    c. Optical Scanning Mirror

Table C.1 is our designed test sheet to cover our test purpose.

Test Sheet	Date:
General Requirements	
The optical beam for the camera and laser must be coaxial *Pass/Fail* The optical lenses must focus the laser on the mock retina *Pass/Fail* The algorithm outputs correct coordinates for laser positioning *Pass/Fail*	Comments:
Software Requirements	
1. General	Comments:

Mock retinal image displayed *Pass/Fail* Captures still of retinal image upon capture select *Pass/Fail* Fire button starts laser *Pass/Fail* Stop button stops laser *Pass/Fail* Confirm button confirms the image segmentation and sets the laser settings for fire *Pass/Fail* Cancel button clears all the laser settings and cancels the session *Pass/Fail* Manual Control disables automation, returns full control to the user; live retinal image is displayed *Pass/Fail*	
2. Image Processing	Comments:
Retinal image skeletonized *Pass/Fail* Vessels auto-segmented *Pass/Fail* Laser pattern auto-populated *Pass/Fail*	
3. Selection	Comments:
Vessels automatically added to avoidant area *Pass/Fail* Brush tool creates binarized treatment and avoidant areas *Pass/Fail* Erase tool discards selected region’s type *Pass/Fail* Brush and erase tool overrides automatic area generation *Pass/Fail*	

Retake Image tool erases all selected regions and retakes the still retinal image *Pass/Fail*	
Hardware Requirements	
4. Laser	Comment:
Laser shines for the duration of time, which was input *Pass/Fail* Laser aims at correct location of mock retina *Pass/Fail* Laser fires at the correct wavelength it was purchased at *Pass/Fail* Laser makes a lesion on the mock retina *Pass/Fail*	
5. Camera	Comments:
Camera takes images *Pass/Fail* Camera streams real-time video of the retina to a PC *Pass/Fail* Video feed latency on PC is adequate *Pass/Fail* Camera takes clear images and video of a mock retina *Pass/Fail*	
6. Scanner	Comments:
Mirror can be aimed in two directions, x and y *Pass/Fail* Mirror can focus the laser along all regions of the retina *Pass/Fail* Mirror speed keeps up with the speed of micro-movements of the eye *Pass/Fail* Mirror supports continuous full-speed operation of the tilting actuators at all times	

Pass/Fail	

Table C.1: Supporting Test Plans detailed to test each component and subcomponent of our system.