Eduard Durech
School of Engineering Science
Simon Fraser University
8888 University Dr
Burnaby, BC V5A 1S6

February 21st, 2021

Dr. Craig Scratchley
School of Engineering Science
Simon Fraser University
8888 University Dr.
Burnaby, BC V5A 1S6

Re: ENSC405W Requirements Specification for livEn's Retina Imager and Laser Beamer, RILaB.

Dear Dr. Craig Scratchley,

The attached document is the requirement specifications for 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 automate laser eye therapy treatments that deal with abnormal and diseased tissue in the eye. These treatments include Pan Retinal Photocoagulation, PhotoDynamic Therapy, and more.

We will be working with a fundus camera, an optical scanning mirror, and a laser, and we will be viewing the eye 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.

On top of the requirements specifications organized throughout the alpha, beta, and production phases, this document also covers sustainability and safety requirements, engineering standards, and a proof-of-concept acceptance test plan for this project.

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

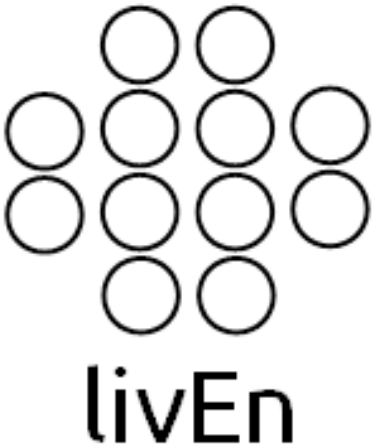
Sincerely,

Eduard Durech
Chief Executive Officer
livEn

# Requirements Specification

# Retina Imager and Laser Beamer

# RILaB




Authored by:
Jiung Choi
Vincent Le
Kyle Smolko
Eduard Durech
Puru Chaudhary
Daria Zhevachevska

Submitted February 21st, 2021 for approval to:
Shervin Jannesar
Michael Hegedus
Craig Scratchley
Chris Hynes

School of Engineering Science
Simon Fraser University

# Abstract

livEn's Retina Imager and Laser Beamer (RILaB), is a semi-automated control system that is able to have a clinician guide its operation for laser eye therapies. There are many laser eye therapies that this project can apply to, such as Pan Retinal Photocoagulation (PRP) and PhotoDynamic Therapy (PDT). These therapies are currently controlled manually by ophthalmologists and clinicians. Our product aims to aid in automating and speeding up a key part of this process. This will alleviate a portion of their workload and allow medical residency students to perform these therapies themselves. To achieve this goal, livEn is creating RILaB to integrate a fundus camera, a high-powered laser, and an optical scanning mirror with our control algorithm. Our algorithm will acquire a fundus retinal image using the camera and process it to create a high-level segmentation of regions for laser treatment and healthy tissue avoidance. The regions may then be further refined and confirmed by a clinician. The appropriate regions in the patient's retina can then be targeted by the laser using appropriate coordinates derived from our algorithm. These coordinates guide the laser beam via an optical scanning mirror. With the highest priority is on safety, we also have our algorithm decide when it is safe to fire the laser and allow the clinician to make the final call. The laser then begins titrating its firing power from low to high depending on the degree of burn needed. The control system does not consider elements such as a mounted contact lens to keep the patient's eyes open, and head/chin rests to keep the motion of their head still. This document describes the specifications that such a device must adhere to in order to allow ophthalmologists and clinicians to perform the above functions efficiently and safely while improving the speed, efficiency, and ease of use for such a system. These specifications are grouped in terms of software, hardware, safety, sustainability, and engineering standards.

# Acknowledgements

livEn would like to thank the many individuals that provided their expertise and insight to the creation of the requirements specification of RILaB.

We would first like to express our gratitude to Dr. Marinko V. Sarunic for letting us work with the research and equipment in his lab, as well as helping to create the original project idea.

We would also like to thank the individuals who helped us conceive the hardware requirements for this project, Laura Vargas and Ringo Ng.

Next, none of this would have been possible without Dr. Zaid Mammo, our ophthalmologist reference, for his expertise on Pan Retinal Photocoagulation and other laser eye surgeries in general.

Lastly, we would like to thank the instructing unit of ENSC405W for their guidance thus far. Thank you to Professors Craig Scratchley, Shervin Jannesar and Andrew Rawicz as well as our Teaching Assistants Chris Hynes and Mike Hegedus.

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## List of Tables

# 1.0 Introduction

livEn is creating a semi-automated control system and graphical user interface (GUI), that is able to safely and efficiently perform laser eye therapies. We will be comparing and contrasting the advantages and disadvantages of our application against the regular method of performing this procedure as we work on the project.

## 1.1 Background & Purpose

Laser eye therapy is controlled manually by ophthalmologists. The goal of livEn is to semi-automate this process such that the ophthalmologist can have a more streamlined approach to their operation. In addition, as per comments from Dr. Zaid Mammo, a semi-automated process that is deemed to be safe may also prove to be useful to medical residency students as well as professionals in other fields that are not yet experienced ophthalmologists in terms of their practice and education [1]. This frees up time for ophthalmologists to focus on more hands-on procedures where they are most needed, as ophthalmology is experiencing a shortage of specialists [2].

Laser eye therapies can be used to treat many disorders [1]. livEn is focusing on conditions which can be treated via laser exposure. As such, our project should be able to cover many of these laser eye therapies including Pan Retinal Photocoagulation (PRP), shown in figure 1.1, and PhotoDynamic Therapy (PDT). PRP is the largest example in which we are aiming to help as recommended by Dr. Zaid Mammo [1]. It is most known for reducing the risk of vision loss by 50% to those affected with proliferative diabetic retinopathy (PDR) [3]. PDT is an older treatment dating back to the 2000s where doctors would use a laser to activate an applied photosensitizing agent which would collect in abnormal blood vessels in the eye [4].

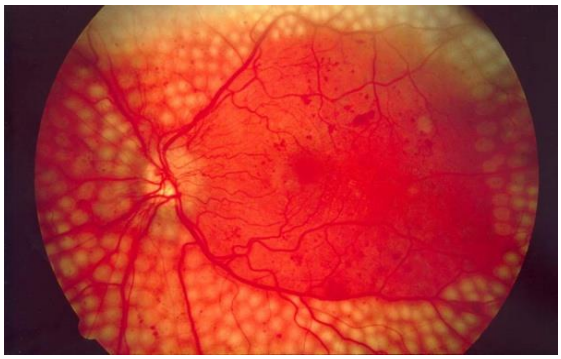

*Figure 1.1:* Example of a fundus image with PRP therapy (white dots created by laser burns) [5]

## 1.2 Document Scope

The purpose of this document is to specify the functional and non-functional requirements of our system applicable to its software and hardware. The document will also specify the stages of development in which a requirement should be met.

Lastly, this document covers the safety requirements that absolutely need to be met, sustainability requirements that our project can feature, and the Engineering Standards that must be met.

## 1.3 Project Scope

The scope of our product includes three main components for a control system and GUI to accomplish our purpose. We will be looking into fundus retinal cameras, optical scanning mirrors, and different lasers. Our system must be able to:

1. View an image of the retina through the fundus camera.
2. Process the image to our GUI and skeletonize it.
3. Have a clinician brush select the regions that need treatment as well as brush select the regions that must be avoided by the laser.
4. Set coordinates within the region that will then control an optical scanning mirror to guide the laser.
5. Incorporate motion tracking to correct for movement.
6. Have our GUI notify when it is safe to fire and wait for the clinician to initiate the procedure.
7. Titrate the laser power starting from a low power and going up to a user defined threshold.

To fulfill this project scope, our system incorporates the clinician with the use cases as described in figure 1.2 below.

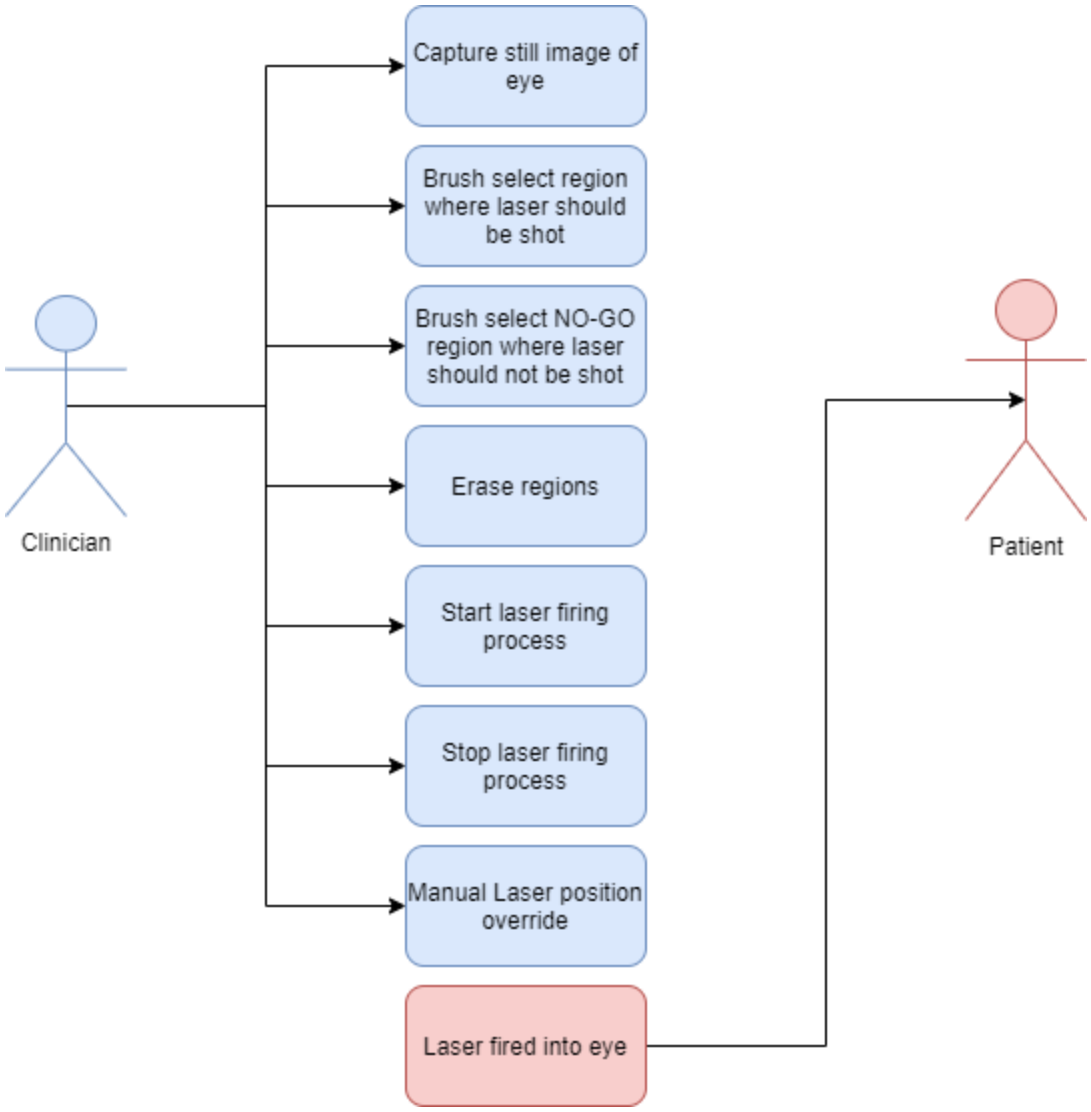


*Figure 1.2:* Use Case Diagram of the RILaB

## 1.4 System Overview

The clinician will be able to do the tasks in 1.3 using our GUI. The commands that they input will then communicate with our hardware through a microcontroller to perform the laser eye therapy. More details will be provided in the design specification document. As for the requirements specification document, livEn will be working with the hardware listed in table 1.1 to meet the requirements described in below sections, 2, 3, 4, & 5.

| System Parts | Part Description |
|---|---|
| Fundus Camera | Images the patient's retina. |
| Laser | Low to high powered laser that will be able to accurately and safely shine in the desired regions. |
| Optical Scanning Mirror | Scanner used to position the laser's beam. |
| Beam Splitter | Aids in coupling the camera and the laser. |
| Microcontroller | Synchronization and operation of components will be controlled by a microcontroller. |
| Linear Stage | The above will be mounted on a linear stage for movement in the xz-plane. |
| Optical Table | The entire unit will be mounted onto an optical table in order to prevent vibrations from interrupting any ongoing procedures. |

*Table 1.1:* Hardware parts and descriptions

Our system will consider using mounted contact lenses to prevent the patient from blinking as well as head and chin rests to minimize movement.

## 1.5 Requirements Nomenclature

The notation of our requirements are as follows:

R - {Section & Subsection} . {Requirement Number} - {Project Phase}

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

**Example:** R-2.1-A
Requirements - Section 2.1 . First Requirement - Alpha Phase/Proof-of-Concept

A - alpha phase requirements are requirements which aim to be presented as a proof-of-concept by the end of ENSC405W.
B - beta phase requirements are requirements which aim to be presented as a proof-of-concept by the end of ENSC440.

# 2.0 Software Requirements

## 2.1 General Software Requirements

In order to support semi-manual operation, acquisition and algorithmic control will be done by the software whereas the clinician should set a small number of parameters that will ensure the safety of the operation. Table 2.1 describes the software capabilities required by our project and also the requirements that our algorithm must consider when deciding when it is safe for a laser to be fired as seen in figure 2.1. Requirements for the GUI must also ensure ease-of-use for the operator in order to maintain safety and increase the speed efficiency of the procedure.

| Requirements ID | Requirements Description |
|---|---|
| **R-2.1.1-A** | The software application must display the real time fundus image of the eye in a graphical user interface. |
| **R-2.1.2-A** | The software application must be able to capture a still image of the fundus image of the eye and display it. |
| **R-2.1.3-A** | The software application must have a “GO Zone Brush Select” tool so that a clinician can select the region of treatment. |
| **R-2.1.4-A** | The software application must have a “NO-GO Zone Brush Select” tool so that a clinician can select the region of no treatment. |
| **R-2.1.5-A** | The software application must have an “Erase Selection” tool to deselect a GO region or NO-GO region. |
| **R-2.1.6-A** | The software must auto-populate the therapy’s treatment pattern where the laser must shine. |
| **R-2.1.7-A** | The software application must notify the clinician when the laser shining process has started and ended. |
| **R-2.1.8-A** | The software must enable the clinician to start and stop firing a single laser with the “Fire” and “Stop” buttons. |

| | |
|---|---|
| **R-2.1.9-A** | The software application should have a “Retake Image” tool to erase all selected regions and retake the still retinal image. |
| **R-2.1.10-B** | The software application must allow the clinician to enter the laser power threshold. |
| **R-2.1.11-B** | The software application must have a user friendly and intuitive graphical user interface that can be used easily from a medical residency student to an experienced ophthalmologist. |
| **R-2.1.12-B** | The software must enable the clinician to start and stop the firing process of all points with “Ready” and “Cancel” buttons. |
| **R-2.1.13-P** | The software application should automatically detect the threshold power value for each individual shining laser. |

*Table 2.1:* Software and GUI Requirements

## 2.2 Image Processing Requirements

Image processing serves as a pre-processing step in order to alleviate the amount of work a clinician must do during the procedure. Table 2.2 includes varying levels of automated selection of tissue types which a clinician would normally do manually. The goals of these requirements is to serve as an extra level of safety and reduce possible human error.

| Requirements ID | Requirements Description |
|---|---|
| **R-2.2.1-A** | The software application should use an algorithm to skeletonise the vascular network in the fundus image. |
| **R-2.2.2-B** | The software application should automatically detect and highlight the NO-GO vessels region. |
| **R-2.2.3-P** | The software application should automatically detect and highlight the NO-GO macula region. |
| **R-2.2.4-P** | The software application should automatically detect and highlight the GO treatment region. |

*Table 2.2:* Image Processing Requirements

## 2.3 Tracking Requirements

Tracking ensures movement of the patient is corrected so as to not shine the laser on unwanted regions. It also ensures the clinician does not have to continuously re-align the system. Table 2.3 covers what tracking must do in order to effectively track regions of the eye and guide other equipment.

| Requirements ID | Requirements Description |
|---|---|
| **R-2.3.1-B** | The software must be able to track the selected region. |
| **R-2.3.2-B** | The software should be able to register retinal images. |
| **R-2.3.3-B** | The software must be able to continuously output updated positions of grid points. |

*Table 2.3:* Tracking Requirements

Figure 2.1 features a high-level algorithm that describes the general procedure of laser eye therapy done manually with minor modifications on how a semi-automated procedure may work. The software requirements in table 2.1 will reflect the procedure here in the figure below.

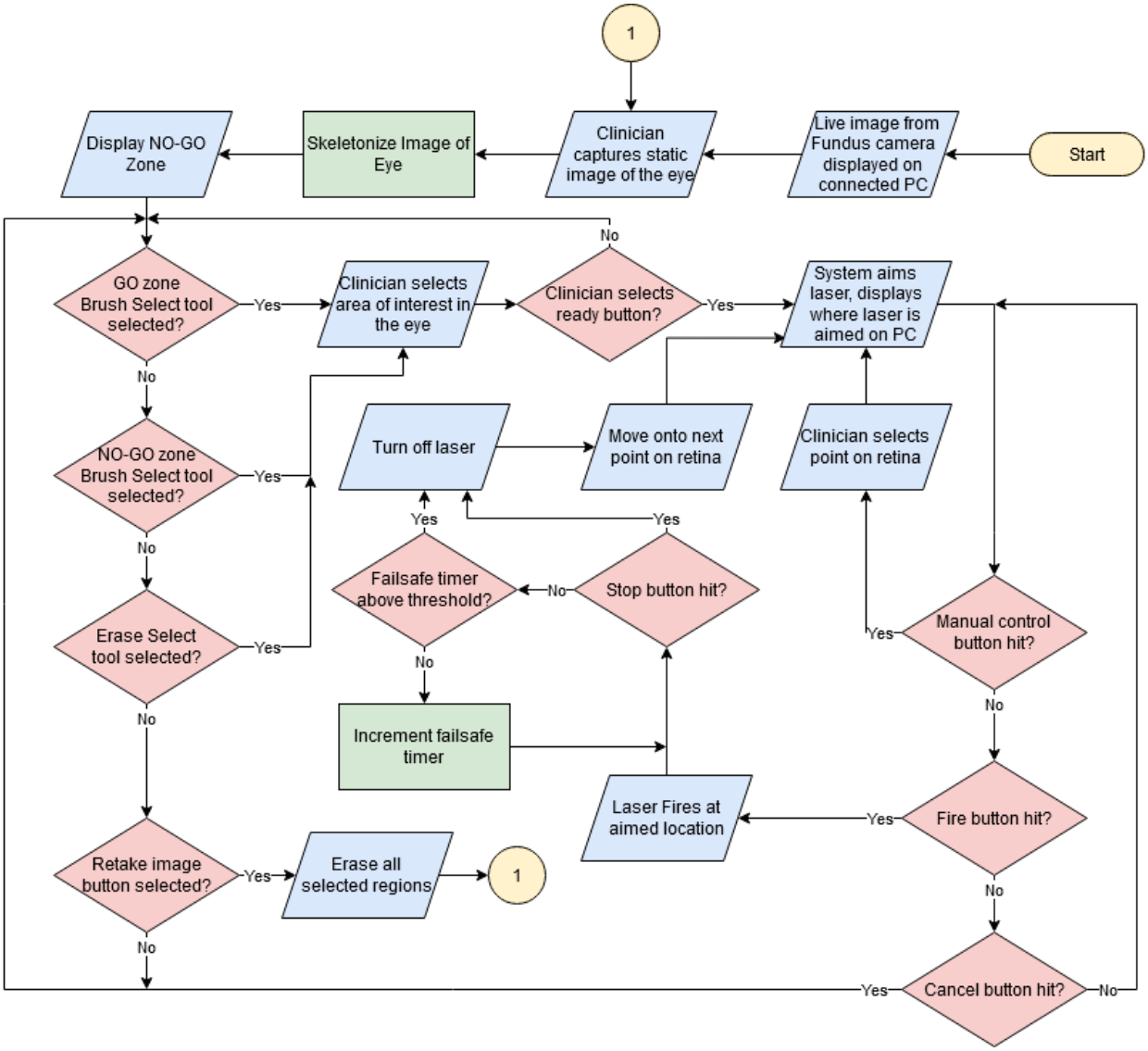


*Figure 2.1:* High-Level Algorithm Flow Chart for the RILaB [1]

# 3.0 Hardware Requirements

## 3.1 General Requirements

This section includes the hardware requirements for each of our three major components of the product that will be working closely together: the laser, the retinal camera, and the optical scanning mirror. Table 3.1 introduces general hardware requirements to hold and encapsulate our system.

| Requirements ID | Requirements Description |
|---|---|
| **R-3.1.1-A** | All hardware must interact and synchronize control. |
| **R-3.1.2-A** | The optical beam for the camera and laser must be coaxial. |
| **R-3.1.3-B** | The optical units of the hardware must be able to deal with small vibrations to keep the laser in focus. |
| **R-3.1.4-B** | The optical table must provide a rigid base and absorb vibrations caused by motorized parts. |
| **R-3.1.5-B** | The system should precisely position an object along a viewing screen for the eye to focus on. |
| **R-3.1.6-B** | The system should be encapsulated into one enclosure. |

*Table 3.1:* General Hardware Requirements

## 3.2 Laser Requirements

Table 3.2's requirement specifications were obtained from Dr. Zaid Mammo [1]. The laser's size, titrating power, wavelength, and time duration all take into account general laser eye therapies - hence the ranges. These values are chosen for effective treatments while going from a low to higher power to ensure safety.

| Requirements ID | Requirements Description |
|---|---|
| **R-3.2.1-A** | The laser must make approximately 400µm (diameter) sized burns on the retina. |
| **R-3.2.2-A** | The laser must make burns with approximately half a spot size (200µm) separation. |
| **R-3.2.3-B** | The laser must have a light ray with a wavelength of 400-500nm. |
| **R-3.2.4-B** | The laser must deliver titrating power (200-250mW) limited by a threshold. |
| **R-3.2.5-B** | The laser must shine the light for 100ms. |

*Table 3.2:* Laser Requirements

## 3.3 Camera Requirements

The camera's requirements cover the general fundus camera specifications that are required to effectively view the image of a retina and display it onto our PC as referenced in [6]. This enables the clinician to see and select which parts of the retina should receive treatment as well as display continuous progress of the therapy so the clinician can intervene in case of safety concerns.

| Requirements ID | Requirements Description |
|---|---|
| **R-3.3.1-A** | The camera must be able to take images. |
| **R-3.3.2-A** | The camera must be able to stream real-time video at a minimum of 10 frames per second. |
| **R-3.3.2-A** | The camera must be able to interface with an external PC. |
| **R-3.3.3-A** | The camera must be able to fit within the structural apparatus. |
| **R-3.3.4-B** | The camera must image the retina (fundus camera). |
| **R-3.3.5-B** | The camera should have a minimum of 512x512 resolution. |
| **R-3.3.6-B** | The camera should have a minimum Field of View of 45 degrees. |
| **R-3.3.7-B** | The camera should support a minimum pupil size of 3.5mm. |

| | |
|---|---|
| **R-3.3.8-P** | The camera should be able to automatically focus. |
| **R-3.3.9-P** | The camera should correct for blinking and eye movement. |

*Table 3.3:* Retina Camera Requirements

## 3.4 Optical Scanning Mirror Requirements

Optical scanning mirrors provide high speed optical beam steering across two axes. They contain mirrors that are able to deflect laser beams or images to optical scanning angles on each axis and can switch modes to provide an additional range of angles. The requirements below describe the need for a small mirror that can support faster speeds and a wider range of angles so that it is able to deflect lasers and scan appropriately.

| Requirements ID | Requirements Description |
|---|---|
| **R-3.4.1-A** | The mirror must be able to tilt along 2 axes (x-y) to span all regions of interest in the eye. |
| **R-3.4.2-A** | The mirror actuation speed must be able to keep up with the fast micro-movements of the eye (900°/sec maximum) [7]. |
| **R-3.4.3-A** | The mirror must support continuous full-speed operation of the tilting actuators at all times. |
| **R-3.4.4-A** | The mirror should dissipate a power less than 1mW. |
| **R-3.4.5-A** | The mirror's size should fall between 0.8mm to 2.4mm. |
| **R-3.4.6-P** | The mirror's actuator should fall between 4.23mm to 7.25mm. |

*Table 3.4:* Optical Scanning Mirror Requirements [8]

# 4.0 Safety Requirements

livEn intends to ensure that the product will be safe for clinicians and patients. The safety requirements listed below in table 4.1, label the requirements which ensure potential risks for the user and the patient are avoided.

| Requirements ID | Requirements Description |
|---|---|
| **R-4.0.1-A** | The laser power must be limited, as input by the clinician. |
| **R-4.0.2-A** | The laser pulse duration must be limited, as input by the clinician. |
| **R-4.0.3-A** | The laser control must be allowed to be overwritten by the clinician. |
| **R-4.0.4-A** | The laser must not be applied in the NO-GO region. |
| **R-4.0.5-B** | The laser must not burn vessels. |
| **R-4.0.6-B** | The laser must not burn healthy tissue. |
| **R-4.0.7-B** | The laser must always be in focus. |
| **R-4.0.8-B** | The construction must be stable and not be sensitive to vibration. |
| **R-4.0.9-B** | The entire system should be safer than a manual procedure. |
| **R-4.0.10-B** | The system construction must not have any sharp edges to eliminate the risk of injury during the medical procedure. |

*Table 4.1:* Safety Requirements

# 5.0 Sustainability Requirements

Although it is difficult to keep sustainability a top priority when building a specialized biomedical device such as RILaB, our project will be following a cradle-to-cradle design style instead of a cradle-to-grave implementation. Several major components of our product such as the laser, optical component, scanners, and the optical table will be reused components from other devices in the Biomedical Optics Research Group at Simon Fraser University. Furthermore, the modular design of our product makes it possible so that the major components can be reused towards other projects and devices after the device is no longer in use. Table 5.1 will further explain the sustainability features that we will follow.

| Requirements ID | Requirements Description |
|---|---|
| **R-5.0.1-A** | The device should approach cradle-to-cradle design and primarily select environmentally friendly components when applicable. |
| **R-5.0.2-A** | The device should be composed of reused components from previous projects. |
| **R-5.0.3-A** | After the device's life cycle is complete, the majority of its components should be reused in other devices. |
| **R-5.0.4-P** | The system, consisting of the camera, laser, optical components, and scanner, should be encapsulated in a Polyactic Acid (PLA) encasing which is biodegradable [9]. |
| **R-5.0.5-P** | The device should operate with minimal power consumption. |

*Table 5.1:* Sustainability Requirements

# 6.0 Engineering Standards

We have selected engineering standards from engineering standard organizations such as International Organizations for Standardization (ISO), The International Electrotechnical Commission (IEC) and Canadian Standards Association (CSA) for our product. As our device will be used in clinical settings, specific standards relating to medical devices are included. Table 6.1 lists Engineering Standards pertaining to the software application, table 6.2 for the laser system, table 6.3 for the camera system, and table 6.4 for general standards of an ophthalmic instrument.

| Engineering Standard | Description |
|---|---|
| **IEC/TR 80002-1:2009** | Medical device software - Part 1: Guidance on the application of ISO 14971 to medical device software [10] |
| **CAN/CSA-CEI/IEC 62304:14** | Medical device software - Software life cycle processes [11] |
| **ISO 9241-125:2017** | Ergonomics of human-system interaction - Part 125: Guidance on visual presentation of information [12] |

*Table 6.1:* Software Application Engineering Standards

| Engineering Standard | Description |
|---|---|
| **ISO 22248:2020** | Lasers and laser-related equipment — Test methods for laser-induced damage threshold — Classification of medical beam delivery systems [13] |

| | |
|---|---|
| **IEC 60601-2-22:2019 RLV** | Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment [14] |
| **IEC 60825-1:2014** | Safety of laser products - Part 1: Equipment classification and requirements [15] |

*Table 6.2:* Laser Engineering Standards

| Engineering Standard | Description |
|---|---|
| **ISO 10940:2009** | Ophthalmic instruments - Fundus cameras [16] |

*Table 6.3:* Camera Engineering Standards

| Engineering Standard | Description |
|---|---|
| **ISO 15004-1:2020** | Ophthalmic instruments - Fundamental requirements and test methods - Part 1: General requirements applicable to all ophthalmic instruments [17] |
| **ISO 15004-2:2007** | Ophthalmic instruments - Fundamental requirements and test methods - Part 2: Light hazard protection [18] |

*Table 6.4:* Optics Engineering Standards

# 7.0 Conclusion

This document outlines the requirement specifications in terms of software, hardware, safety, and sustainability that must be met in order to fulfill the purpose and project scope that is described in Section 1 of the document. Furthermore, this document highlights the engineering standards that have to be met. Below is a summary of the functional and non-functional requirements that need to be met through each design phase.

## 1. Alpha Phase (Proof-of-Concept for the end of ENSC405W)

- Software
  - Skeletonization and display of a mock retina image.
  - Basic pre-processing and segmentation of the image.
  - GO, NO-GO and Erase select tools for region selection.
  - Retake Image tool for retaking the still retinal image.
  - Clinician-selected firing and stopping of laser.
- Hardware
  - Have the proper camera, laser, and optical scanning mirror interact and synchronize control together.
- Safety
  - Safe power and time threshold for laser firing
  - No sharp edges.
- Sustainability
  - Choose reusable hardware.

## 2. Beta Phase (Projected product for the end of ENSC440)

- Software
  - Simple and easy-to-use interface.
  - Fully fleshed out features that allow for a clinician to use.
  - Implement tracking requirements.
- Hardware
  - Consider shock absorption bases to prevent vibrations from occurring.
  - Encapsulate the product.
  - The laser will no longer be static in terms of power and will have fail safes.
  - Replace the cheaper camera used in the alpha phase with a real

fundus camera.

- Safety
  - The high powered laser must not damage any healthy tissue.
- Sustainability
  - 3D print encasing using appropriate and sustainable material.

## 3. Production Phase

- Software
  - Ease-of-use and quality of life features will be done here requiring less manual functions by a clinician.
  - Finer automatic segmentation of treatment and avoidant tissue.
  - Automated firing and stopping of laser.
- Hardware
  - Camera and system will be able to detect blinking, motion, and other factors that cause refocusing to consider safety and no more need to use the mounted contact lens.
- Safety
  - No automation injuries should occur.
  - Automated system must be safer to use than a fully-manual one.
- Sustainability
  - Ensure all components can be used following the cradle-to-cradle design approach.

These requirements were defined assuming our market and users are ophthalmologists and their eye clinic team including medical residency students. The requirements aim to create a system that will alleviate current procedures, ensure a higher degree of safety, and allow resident ophthalmologists to conduct the procedure.

# 8.0 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. |
| GO Region | A region on the image where the laser treatment shall be applied. |
| Medical Residency | Postgraduate students who are training in the field of medicine. |
| NO-GO Region | A region on the image 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. |
| PRP | Pan Retinal Photocoagulation is a laser eye therapy that can decrease the size of abnormal blood vessels. These abnormal blood vessels can lead to blindness. |
| Retinal Camera | A specialized camera that is able to photograph the retina of an eye. |

# 9.0 References

[1] Vincent Le, Dasha Zhevachevska, Kyle Smolko, Eduard Durech, Jiung Choi, Puru Chaudhary, and Dr. Zaid Mammo, “Meeting Minutes February 18,” 18-Feb-2021.

[2] "Current Trends and Challenges in Glaucoma Care: Supply of Ophthalmologists", *Aao.org*, 2021. [Online]. Available: https://www.aao.org/focalpointssnippetdetail.aspx?id=3df1324e-8154-4cd3-b1d5-721e0c941ab9. [Accessed: 18- Feb- 2021].

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# Appendix A: Acceptance 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.

**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.

| **Test Sheet** | Date: |
|---|---|
| **General Requirements** | |
| The optical beam for the camera and laser must be coaxial<br>*Pass/Fail*<br><br>The algorithm outputs correct coordinates for laser positioning<br>*Pass/Fail* | Comments: |
| **Software Requirements** | |
| 1. General | Comments: |
| Mock retinal image displayed<br>*Pass/Fail*<br><br>Captures still of retinal image upon capture select<br>*Pass/Fail*<br><br>Fire button starts laser<br>*Pass/Fail*<br><br>Cancel button stops laser<br>*Pass/Fail* | |
| 2. Image Processing | Comments: |

| | |
|---|---|
| Retinal image skeletonized<br>*Pass/Fail*<br><br>Vessels auto-segmented<br>*Pass/Fail*<br><br>Laser pattern auto-populated<br>*Pass/Fail* | |
| 3. Selection | Comments: |
| Vessels automatically added to avoidant area<br>*Pass/Fail*<br><br>Brush tool creates binarized treatment and avoidant areas<br>*Pass/Fail*<br><br>Erase tool discards selected region's type<br>*Pass/Fail*<br><br>Brush and erase tool overrides automatic area generation<br>*Pass/Fail*<br><br>Retake Image tool erases all selected regions and retakes the still retinal image<br>*Pass/Fail* | |
| **Hardware Requirements** | |
| 4. Laser | Comment: |
| Laser shines for 100ms<br>*Pass/Fail*<br><br>Laser aims at correct location of mock retina<br>*Pass/Fail* | |
| 5. Camera | Comments: |
| Camera takes images<br>*Pass/Fail*<br><br>Camera streams real-time video to a PC<br>*Pass/Fail* | |

| | |
|---|---|
| Video feed latency on PC is adequate<br>*Pass/Fail*<br><br>Camera takes clear images and video of a mock retina<br>*Pass/Fail* | |
| 6. Scanner | Comments: |
| Mirror can focus the laser along all regions of the retina<br>*Pass/Fail*<br><br>Mirror speed keeps up with the speed of micro-movements of the eye<br>*Pass/Fail*<br><br>Mirror supports continuous full-speed operation of the tilting actuators at all times<br>*Pass/Fail* | |