ENSC 305W/440W Grading Rubric for Design Specification

Criteria	Details	Marks
Introduction/Background	Introduces basic purpose of the project.	**/05%**
Content	Document explains the design specifications with proper justification for the design approach chosen. Includes descriptions of the physics (or chemistry, biology, geology, meteorology, etc.) underlying the choices.	**/20%**
Technical Correctness	Ideas presented represent valid design specifications that will be met. Specifications are presented using tables, graphs, and figures where possible (rather than over-reliance upon text). Equations and graphs are used to back up/illustrate the science.	**/20%**
Process Details	Specification distinguishes between design details for present project version and later stages of project (i.e., proof-of-concept, prototype, and production versions). Numbering of design specs matches up with numbering for functional specs.	**/15%**
Test Plan	Provides a functional test plan for the present project version. (Note that project success will be measured against this test plan.)	**/10%**
Conclusion/References	Summarizes functionality. Includes references for information from other sources.	**/05%**
Presentation/Organization	Document looks like a professional specification. Ideas follow in a logical manner.	**/05%**
Format Issues	Includes letter of transmittal, title page, abstract, table of contents, list of figures and tables, glossary, and references. Pages are numbered, figures and tables are introduced, headings are numbered, etc. References and citations are properly formatted.	**/10%**
Correctness/Style	Correct spelling, grammar, and punctuation. Style is clear concise, and coherent. Uses passive voice judiciously.	**/10%**
Comments		

IDENTEC

School of Engineering Science • Simon Fraser University
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Nov 14th, 2013

Professor Lakshman One
School of Engineering Science
Simon Fraser University
8888 University Drive
Burnaby, British Columbia
V5A 1S6

Re: Design Specification for OraLite Optical System

Dear Professor Lakshman One

The attached document is the design specification for the OraLite optical system developed by IDENTEC. The goal of this project is to implement an optical system with existing dental optics to assist dentists in visually identifying composite resin fillings from real tooth material. This system will help dentists visually differentiate between the two materials during composite filling removal procedures.

The enclosed document outlines the design specification for describing the proof of concept for the OraLite optical system. The architecture and development for the prototype system aims to resolve the current issue with imprecise differentiation between real tooth material and composite fillings in clinical practice.

Our diverse team of four senior biomedical and electronic engineers is dedicated to the development of the OraLite. Please feel free to forward any questions or concerns about our design specification document to dkayra@sfu.ca.

Sincerely,

DKayra

Damian Kayra

Chief Executive Officer
IDENTEC

Design Specification - OraLite Optical System for Visual Differentiation of Tooth Material from Composite Fillings

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Revision:

1.5

Executive Summary

The design specification for the OraLite optical system explains in length the design and development of the proof-of-concept model. The design specifications in this document are solely for the proof-of-concept model. The design for the light source and mechanical adapter has been given special importance and as such described in very minute detail.

There are three development components of the OraLite optical system:

- A light source that will produce fluorescent emissions from the tooth and composite filling materials
- Optical filters
- Optical adapter system to attach the optical filters onto the dental loupes

This document provides justification for our design choices. The OraLite optical system light source emits specific wavelength of light to generate the differentiable spectral emissions from the tooth and composite filling materials. The light source is designed to illuminate the work space at a wavelength of 405nm. Optical filters that block the 405nm incident light and enhance the contrast of the fluorescing materials to the user will be attached to the dental loupes with a mechanical adapter. The mechanical adapter design is a simple model consisting of an outer hollow circle which fits perfectly onto the dental loupes and locks into place. The optical filters will be fixed inside the adapters which then will be fixed onto the dental loupes. A small window has been kept open for future improvements in the mechanical adapter system.

A description of the system test plan has been included which lists all the testing that has been done on the optical filter in chronological order. Hardware packaging outlines the design of the outer box that will be needed to maintain the integrity of the product.

The timeline that we targeted in the Functional Specification for the OraLite optical system has been strictly followed. We haven't had major halts in the product development during the design phase. We are confident that we will be able to follow the timeline to the very end and finish this product by Nov 27, 2013.

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Terms & Acronyms

ANSL	The American National Standards Institute
DMD	Doctor of Dental Medicine
FAQ	Frequently Asked Questions
FDA	Food and Drug Administration
IEC	International Electrotechnical Commission
IR	Infrared
ISO	International Organization for Standardization
OEL	Occupational Exposure Limits
RGD	Rapid Gas Decompression
TLV	Threshold Limit Values
UV	Ultraviolet

1. Introduction

IDENTEC aims at developing the OraLite optical system which will aid dentists in visually distinguishing tooth material from composite fillings. Using the natural optical differences between tooth and composite resin, the OraLite system will enhance the distinct visual characteristics of these materials which will enable dentists to visually differentiate between them. Our aim is to develop the product as an ad-on which can be mounted on existing dental loupes. This design specification describes the technical details for the design of each part of the OraLite optical system.

1.1 Scope

This document specifies the design of the OraLite optical system and explains how the design of each part meets the functional requirements as described in Functional Specification for the OraLite optical system. It explains how each subsystem is implemented and validates design choices. The design specification includes all the requirements for the three main parts of the product:

- Light source design
- Optical filter design
- Mechanical adapter design

The hardware packaging part specifies the design for the outer box and explains how the product is to be properly secured inside this box. The appendices and the figures included in this document will help facilitate the design decisions in the production of this system in the future.

1.2 Intended Audience

The design specification is intended for use by all members of IDENTEC. The chief engineer shall refer to this document to ensure that all the requirements are met in the final product. Technical officers will refer to it to maintain synchronicity between all the designs and the design specification mentioned in this document. Chief operating officers will consult this specification report to implement the design as per the specifications described in this document.

2. Overall System Design

The OraLite optical system is a highly intricate device that works in conjunction with existing dental optics to assist dentists in visually identifying composite filling materials. This distinctive system can be broken down to three modular components:

1) Light Source
2) Optical Filters
3) Mechanical Adapters

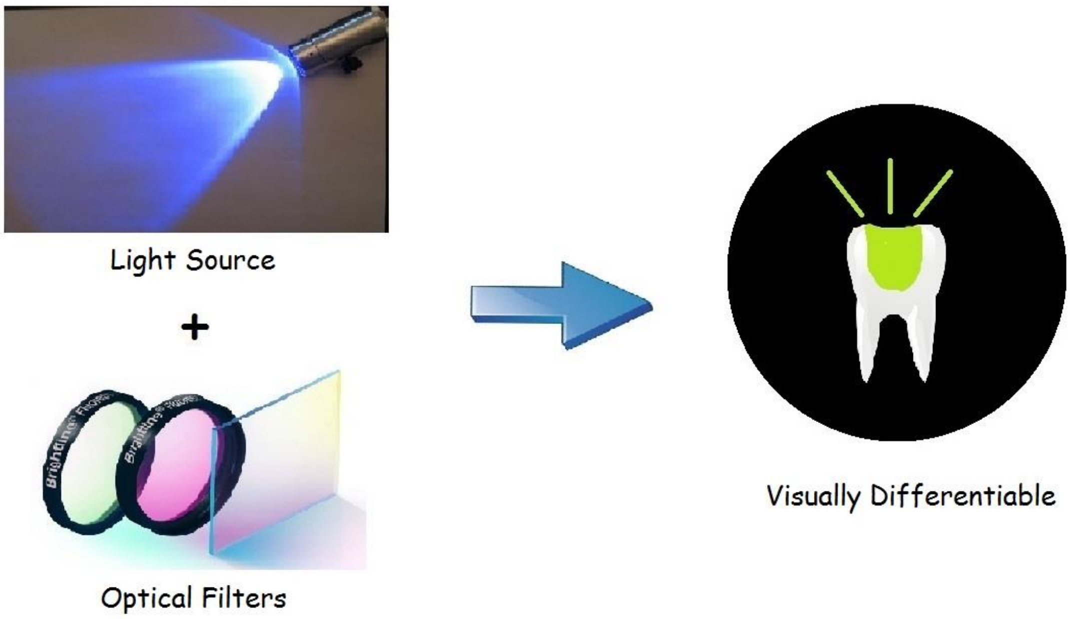


Figure 1: System overview [1], [2], [3]

Figure 1 is a high-level block diagram of the OraLite system and each individual component shown will be integrated into current dental optics to be as simple and intuitive as possible in assisting dentists in composite filling removal procedures without impeding their speed. The light source is a standard dental loupe light modified to emit near ultra-violet (UV) light to illuminate the patient’s mouth and teeth. A portable battery pack will be used to supply and vary power settings to control the brightness of the emitted light. Ideally, both white and near UV light will be interchangeable within a single light source attachment controlled through the battery pack; however, due to time and budget restraints in the first stage of development, this will be an area to be further refined prior to production and in conjunction with dental light manufacturers. The light source will be attached to typical dental loupes to comply with industry practice for reliability and usability.

When near UV light illuminates both the composite and tooth, light of different wavelengths is produced from the two materials. OraLite loupe optical filters, which are installed onto the dental loupes, will then visually separate and enhance the contrast between the emitted light to visually differentiate the two materials. The OraLite filters will also block sub-425nm light to shield the dentist from any UV light leaking from the light source to prevent any hindrance to the dentist during a procedure. A protective lens with maximal transmittance will be installed along with the optical filters to prevent physical damages to the filters.

Optical adapters will be used to connect the optical filters onto the dental loupes. Using a simple attachment method, the optical adapters will provide dentists an enhanced field of vision without them moving a finger. The adapter will combine the optical filter with the protective lens and tightly unite them with the dental loupes. Together, the light source, loupe optical filters and optical adapters make the OraLite an intuitive system to assist dentists in all cavity restoration procedures. Figure 2 as shown below demonstrates the prototype design of OraLite.

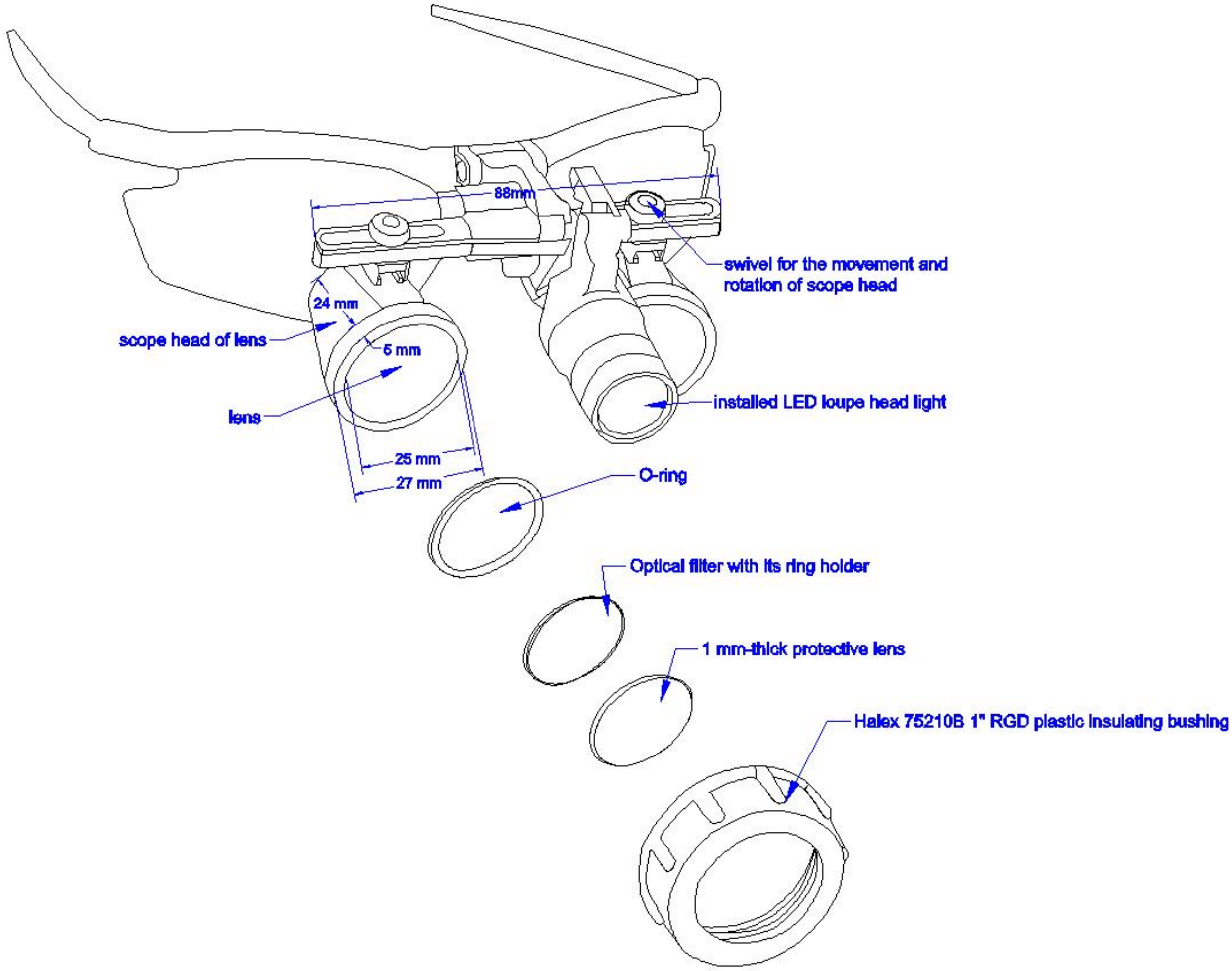


Figure 2: System design – exploded view [4]

The proof of concept of the OraLite optical system encompasses all the basic functionalities listed above to be as simple as possible for a dentist to operate. After completion, a prototype product of OraLite will be tested by Dr. Brian Bostrom, DMD. With his feedback, and using an iterative design process, we at IDENTEC will ensure a high quality product prior to market release.

The following system requirements are met in our proof-of-concept model:

[R1 – I] The OraLite system will not require any software program and computer analysis to interpret the tooth sample
[R2 – I] The optical filter and attachment shall be minimally intrusive to the dentist and patient
[R3 – I] The optical filters will utilize passive optics to differentiate composite fillings from tooth material
[R6 – I] The weight of the system shall not feel uncomfortable to the user when being worn for a long period of time
[R13 – I] The OraLite system shall be safe and compliant with medical standard for electrical devices
[R17 – I] The optical adapter components shall not be any more visually obtrusive than a regular dental loupe
[R18 – I] The OraLite system components are all detachable from the dental loupe
[R35 – I] Near UV light will be low enough power to have no potential harm to both the dentist and patient over long periods of use
[R36 – I] All electrical components shall be enclosed
[R37 – I] All OraLite system will come with a neck cord string to prevent any sudden drop during operation
[R43 – I] Composite fillings shall be clearly distinguishable when viewed through the OraLite system
[R47 – I] The manual adjustments shall be intuitive and easy to use

3. Optical Properties

It is essential to understand the optical properties of tooth and composite fillings before designing the circuitry of the OraLite system. The optical team at IDENTEC devised a rigorous set of tests to gather the necessary spectrum data of tooth and composite filling samples. A near UV LED with a peak at 405nm and a full width at half maximum of 17nm was selected as the light source for the data collection. This specific light source was selected as it was the most readily available option which provided reliable visual differentiation between tooth and composites. The spectral data between the two materials was collected in an optics laboratory at Simon Fraser University and the testing results will be detailed here.

3.1 Tooth Sample Spectrum Analysis

Using the near UV LED light source, a set of methodical testing was performed on extracted human teeth to ensure that visual separation of the materials was possible. In order to collect precise data, an extremely sensitive spectrometer is required. The apparatus was set up with the near UV light source clamped at the same height as the tooth sample and the spectrometer probe positioned as closely as possible to the fluorescent signal without contact.

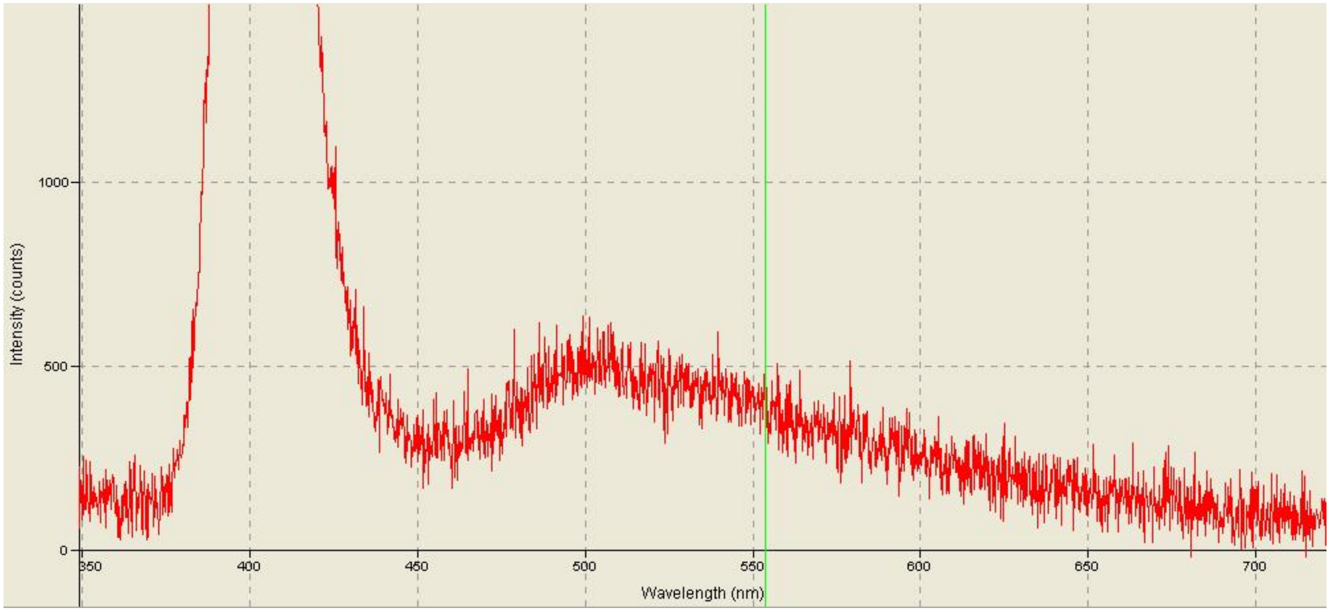


Figure 3: Spectrum of fluorescence emitted from material within tooth [5]

Enamel, the hard material that coats the outside of our teeth, does not display any fluorescence under the near UV light source. However, the materials found within a tooth, mainly dentin, do display a fluorescent signal. Figure 3 displays the emission spectrum of materials inside the tooth, with the large peak at 405nm being the light source. The spectrum remains consistent throughout samples of different teeth. The spectrum displays a peak at around 500nm with a sharp drop-off of intensity for wavelengths lower than 500nm and a long tail up to around 650nm.

3.2 Composite Filling Sample Spectrum Analysis

Using the same apparatus as the tooth sample spectrum analysis, spectral data of composite filling material (Grandio, colour A3) was obtained. The composite filling has been previously cured using a typical dental curing light and analyzed by itself along with the OraLite light source under the spectrometer. There are many different types of composite materials manufactured by numerous companies; however, this specific composite was chosen because it is one of the most commonly used in Canada, manufactured by VOCO for the 3M Corporation.

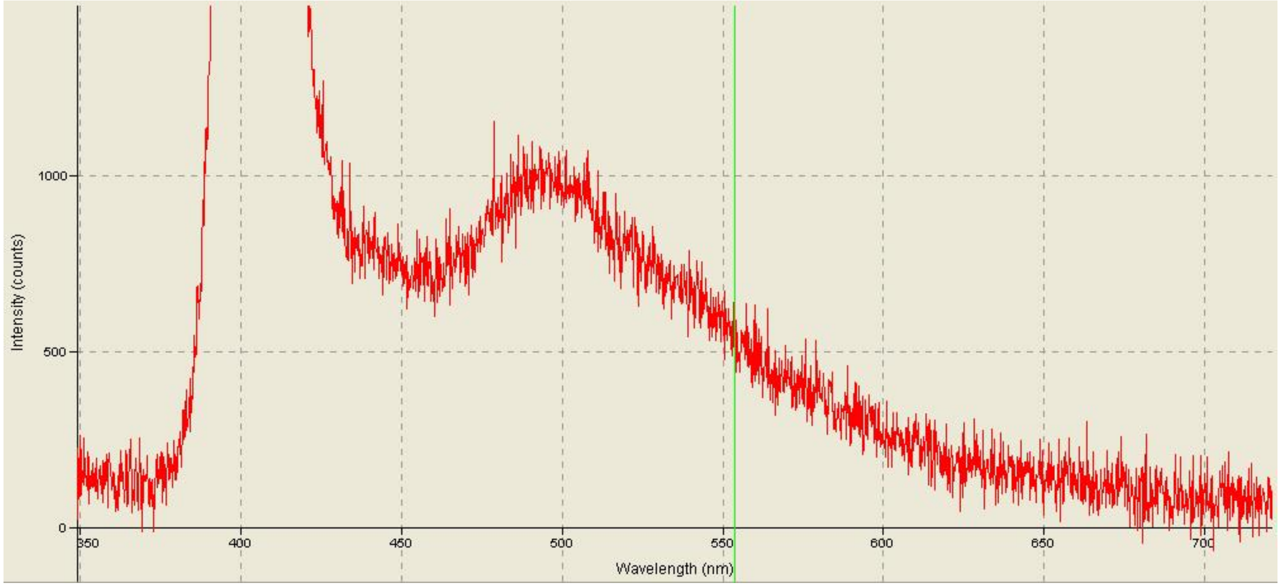


Figure 4: Spectrum of fluorescence emitted from composite filling material [6]

Figure 4 displays the emission spectrum of the Grandio composite filling material, with the large peak at 405nm being the light source. The spectrum remains consistent throughout samples from the same manufacturer. The spectrum displays a peak at around 490nm with a sharp drop-off of intensity for wavelengths lower than 490nm and a long tail up to around 650nm.

3.3 Spectrum Comparison Analysis

From Figure 3 and Figure 4, the spectral data showed the peak fluorescence between tooth and composite filling to be 500nm and 490nm respectively. This particular wavelength difference would have been difficult to separate even with an optical filter; however, the spectrum also displays the composite filling to fluoresce significantly stronger in intensity than the signal emitted by the material from inside the tooth. From the spectral data and visually examining multiple tooth samples and composite fillings, the testing staffs at IDENTEC have concluded the tight fluorescence wavelength difference between the two materials to be an insignificant factor to the functionality of the OraLite system. The composite filling fluoresces at a much stronger intensity than the material inside the tooth and can be visually differentiable to the user. Furthermore, dentin appears to fluoresce in a vein-like pattern whereas composite fillings would fluoresce as a cluster.

4. Light Source Design

Dental loupes are effectively magnifying glasses used by clinicians to perform their tasks and they are quickly becoming popular with both dentists and dental students in modern dental practice. There are three principle reasons for adopting magnifying loupes for dentistry: to enhance visualization of fine detail, to compensate for loss of near vision, and to ensure maintenance of correct posture [7]. Foreseeing the change in current dental practices, the optical team at IDENTEC decided to incorporate the OraLite light source as a dental loupe light instead of the traditional dentistry lamp. This custom-made dental loupe light will be a cost-effective alternative compared to dentistry lamps without sacrificing any illumination to the patient’s mouth or discomfort to the dentist.

Figure 5: Dental loupes benefits [8]

The OraLite system light source will be responsible for emitting the specific wavelength of light to generate the differentiable spectral emissions from the tooth and composite filling materials. Our team at IDENTEC designed the light source to illuminate the light at a wavelength above 400nm to stay away from the UV spectrum for safety concerns. This prototype system will consist of light emitting components that are designed to operate using the Ultra Light Optics^{TM} Feather Light LED loupe battery pack source. This section will highlight the specifications of the OraLite light source.

The following light source requirements are met in our proof-of-concept model:

[R49 – I] The light source shall fit snuggly in the middle of the dental loupe without obstructing the user’s field of vision
[R50 – I] The light source shall be easily attached to the dental loupe through a clip-on mechanism
[R51 – I] The peak emitted wavelength of light will be 405nm to be in the near UV spectrum
[R52 – I] The light source shall be bright enough to operate in a brightly lit dental clinic with both fluorescent and clinical lighting on
[R54 – I] Thermal resistance material will surround the electrical circuits inside of the housing to prevent overheating of the LED electrical components
[R56 – III] The lens attached to the enclosed housing will focus the light to operate at the user’s working distance

4.1 Ultra Light Optics^{TM} Feather Light LED Specification

Figure 6: Ultra Light Optics^{TM} Feather Light LED system [9]

The Feather Light LED loupe light developed by Ultra Light Optics^{TM} is one of the most popular choices for LED headlights for dentists in the market. The headlight of the Feather Light LED is smaller than a dime and weigh lighter than a nickel to be one of the lightest and smallest LED loupe light. The specifications of the Feather Light LED are shown in Table 1.

Headlight Specifications		**Battery Specifications**	
Diameter	0.65”	Dimension	2.2”x1”x3.9”
Length of Module	0.76”	Weight	5oz
Weight	0.13oz (3g)	Battery Type	Advanced High Capacity Regulated Lithium Ion Power
		Charging Time	3.5 hr
		Duration	8 hr

Table 1: Feather Light LED specifications [9]

Due to the popularity of Feather Light LED loupe light, our optical team decided to modify the internal circuitry of the loupe light to match the OraLite system application. Special thanks to Dr. Bostrom for donating his Feather Light LED to IDENTEC. This custom modification would not have been possible without his generosity.

4.2 Emitted Light

The emitted light will be the key to illuminating the mouth and producing a spectral emission from the tooth and composite that is visually differentiable to the dentist. From the user’s point of view, the composite resin will fluoresce in a bright green colour whereas enamel will not fluoresce. The intensity of the composite fluorescence will be dependent upon the wavelength and brightness of the emitting light.

A variety of light wavelengths were tested on composite and tooth material, ranging from near IR to long wave UV. Upon review of the data, it was found the optimal excitation wavelength was 385-395nm which corresponded with the literature research [10]. For safety concerns, our optical team decided that a near UV light source at 405nm provided the best visible contrast while complying with Health Canada safety standards for a light source. It was also found light sources above 410nm wavelength decreased in fluorescence intensity of the composite exponentially.

Apart from having a correct wavelength to produce the fluorescent emission from the composite, the light source also have to be bright enough to illuminate the patient's mouth and tooth. The working distance of a dentist is the distance measured from the point between the dentist's eyes and the patient's mouth. In the sitting position, the typical working distance will range from 14 inches to 20 inches [11]. To ensure the practical use of the OraLite system, it is imperative for IDENTEC to select a light source that is powerful enough to clearly illuminate the patient's mouth from the dentist's working distance.

Figure 7: Dentist's working distance [12]

With the wavelength and brightness requirements in mind, the optical team selected USLASERS Inc D405-20 laser diode as the emitting light source. This light source is a 20mW 405nm laser diode. A laser diode was selected over a typical LED because laser diodes were found to emit light at a much more precise wavelength while also providing a stronger luminescence at further distances. From testing, the team determined a 20mW laser diode to be capable of producing adequate brightness for the OraLite system application. The functional specification datasheet of USLASERS D405-20 can be found in Appendix A.

4.3 Electrical Circuitry

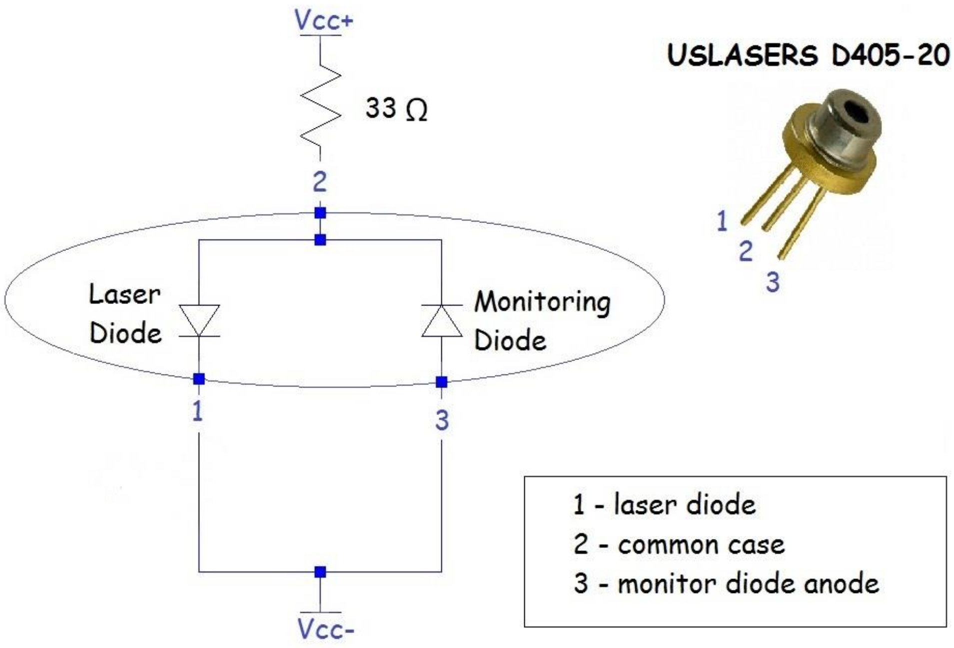


Figure 8: OraLite light source component circuitry [13]

The OraLite light source electronic component circuitry is represented in Figure 8. The light source circuitry of the OraLite system requires the integration of the USLASERS D405-20 laser diode and the Ultra Light Optics^{TM} battery pack. The battery source uses an advanced high capacity regulated lithium ion power and operates at 7.4V. From the functional specifications in Appendix A, the D405-20 laser diode operating limits are well documented. The internal resistance of the laser diode was found to be 68 ohms. Using ohms law and voltage divider calculations, the optical team found a simple resistor of 33 ohms in series with the power supply and diode had the best brightness intensity and wavelength performance.

Calculations:

$$operating\ voltage = 7.4\ \times \frac{68}{68 + 33}$$

$$operating\ voltage = 4.98V$$

$$operating\ current = \frac{7.4}{68 + 33}$$

$$operating\ current = 0.0733A = 73.3mA$$

Using a limiting current resistor of 33 ohms in series with the laser diode, the operating conditions of 4.98V and 73.3mA can be achieved. Both of these parameters are well within the operating specifications of the laser diode and provide adequate fluorescence of the composite filling during testing. The positive and negative power source will be soldered onto the laser diode leads in the final product.

4.4 Passive Thermal Heat Sink

The light source circuitry is designed to operate the laser diode in its ideal condition; however, laser diodes are extremely sensitive to temperature changes. The centre wavelength of the laser diode will shift by changing the temperature and the driving current [14]. With the laser diode operating in the small outer housing, the temperature surrounding the laser diode will increase dramatically which in turn cause the output wavelength to shift. To minimize this wavelength shift phenomenon, a passive thermal heat sink was designed to be incorporated with the light source. Figure 8 represents the dimensions of the USLASERS D405-20 laser diode.

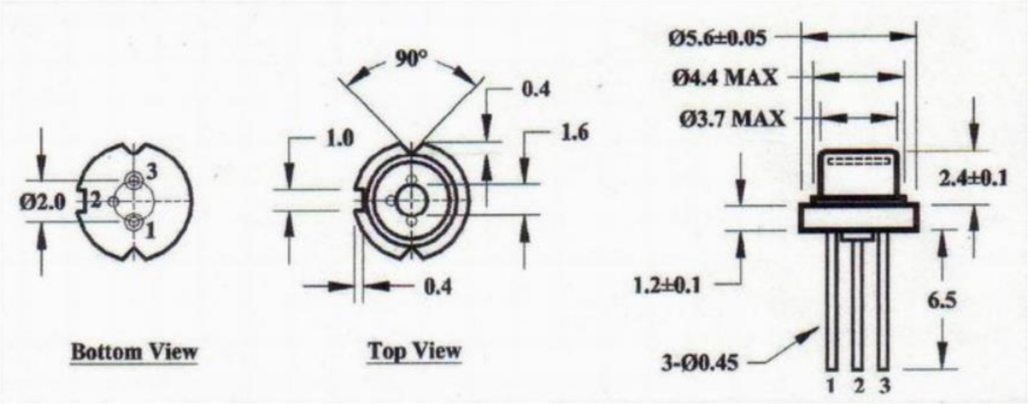


Figure 9: USLASERS D405-20 dimensions [15]

The USLASERS D405-20 laser diode is a very small laser diode with only 5.6mm in diameter. This is ideal for the OraLite system because the laser diode will be small enough to fit inside the outer housing from Ultra Light Optics^{TM} enclosing all the circuitry. Copper is typically the industry standard for manufacturing heat sinks; however, weight is an important factor in the OraLite system and thus aluminum was chosen as the preferred material. Using a block of aluminum metal, the heat sink was milled and refined to have an opening in the middle for the laser diode to be positioned with maximum surface area contact between the heat sink and laser diode. The aluminum heat sink will fit tightly within the outer casing of the light source. Figure 10 and Figure 11 represent the dimensions of the custom-made passive thermal heat sink.

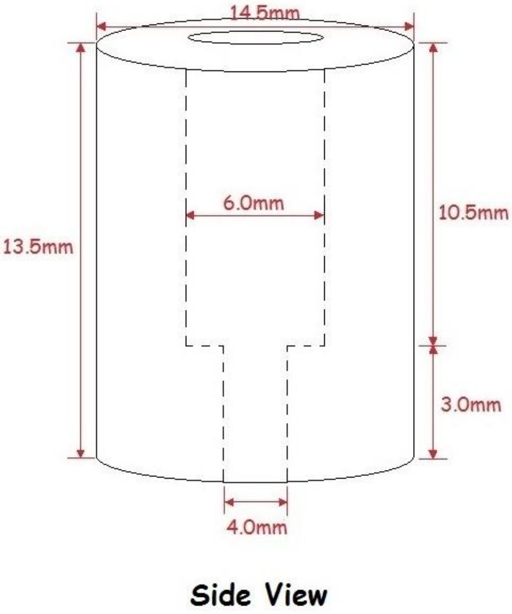


Figure 10: Passive thermal heat sink side dimensions [16]

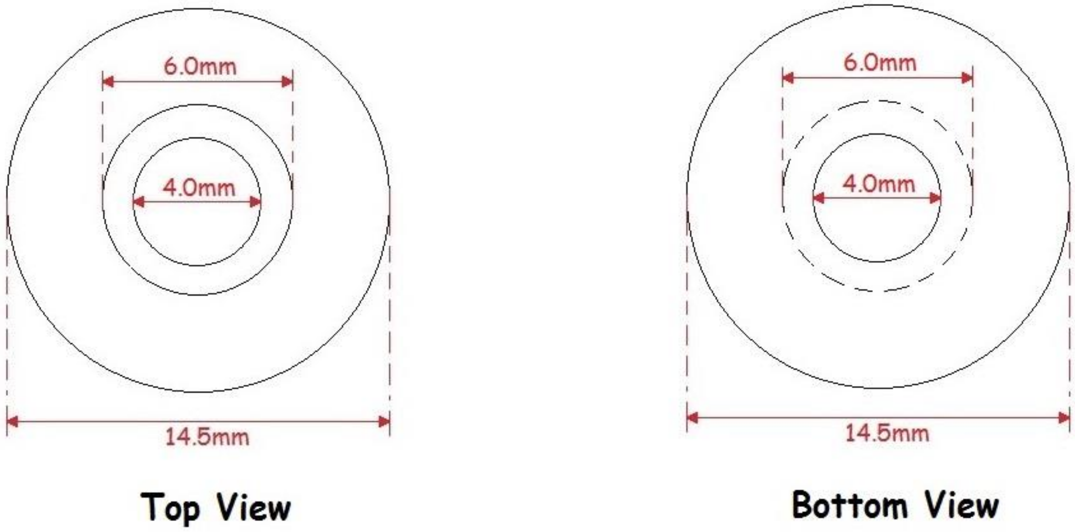


Figure 11: Passive thermal heat sink top and bottom dimensions [17]

The laser diode will be placed in the middle of the aluminum heat sink using a non-electrical conductive thermal paste for efficient heat transfer. Artic MX-2 carbon-based thermal compound was the selected bonding agent. The laser diode leads are protected with wire covers to prevent short circuiting with the lead ends exposed at the bottom of the heat sink for power source connection. Within the bottom 4.0mm diameter cavity, 3M Fire Barrier Water Tight Sealant 3000 was packed into the heat sink to hold all the components in place. The figure below displays the final product of the heat sink that will be integrated into the OraLite optical system.

Figure 12: Final product of the heat sink [18]

4.5 Optical Lens

The laser manufacturer specifies a beam divergence of 20 degrees and 9 degrees (Appendix A), which produces an oval shaped output which is adequate for illuminating the mouth. However, the beam diverges much too quickly upon exiting the headpiece, and a lens must be employed to slow the rate of divergence. A minimum beam diameter of 6 centimeters is required for illuminating the mouth during dental procedures and the working distance of dentists ranges from 35cm to 51 cm [11]. At the minimum working distance of 35cm the un-modified laser beam is 40cm across at its widest point. To slow the beam divergence to provide a 6cm beam diameter at the minimum working distance of 35cm, a planoconvex lens with a 20mm forward focal length from Edmund Optics was selected (Appendix B). The lens is fitted onto the end of the light assembly housing (Figure 12).

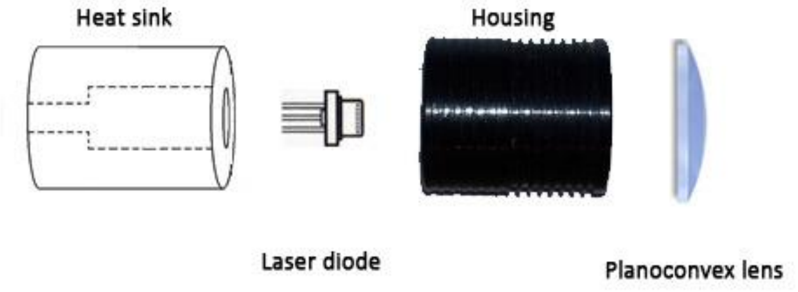


Figure 13: Exploded view of lens assembly housing [19]

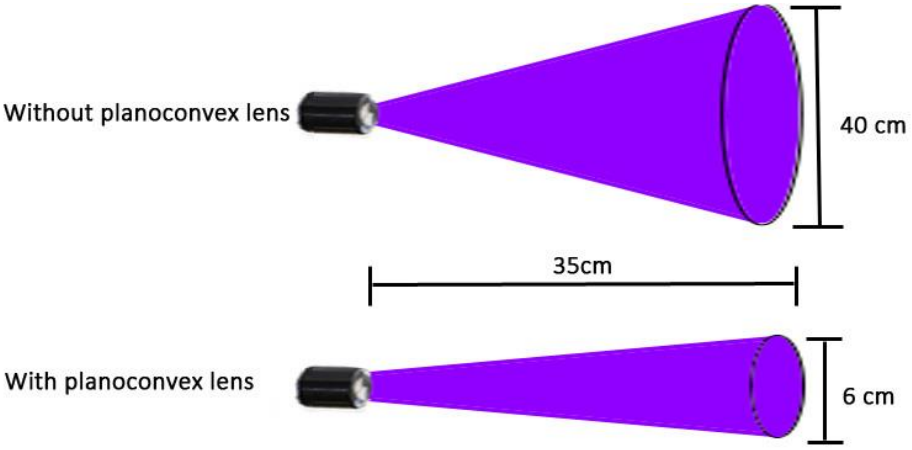


Figure 14: Beam Divergence [20]

4.6 Safety

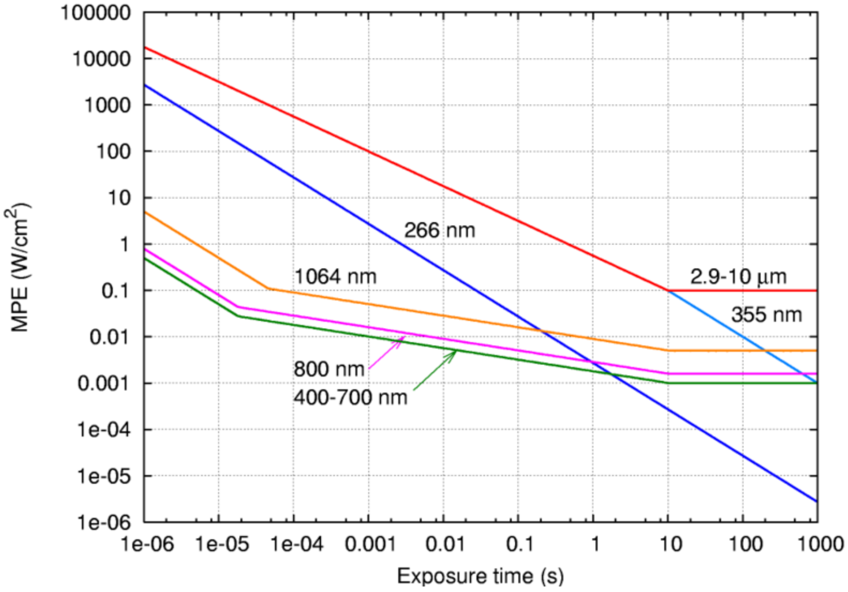


Figure 15: MPE at the cornea for various laser wavelengths [21]

The green line in Figure 14 corresponds to the maximum permissible exposure (MPE) limits at the eye for lasers within the visible spectrum. For a 1000 second exposure time the MPE is 1 mW/cm^2. The OraLite laser diode has a maximum optical power output of 20mW, however there is substantial loss expected due to the laser spreading and striking the inside of the heat sink before exiting the housing. Ignoring losses to the optical output of the laser, the expected power density at the minimum working distance is 0.7mW/cm^2 which falls below the MPE for the 1000 second time point. Actual optical power output testing will be performed to determine whether or not the laser needs to be attenuated further to meet a class 2M safety rating by the IEC (Appendix C). Regardless of the safety rating of the light source, patients will wear a simple set of goggles designed to block the laser output of the OraLite.

As a consequence of meeting the 2M laser safety rating, which specifies that the laser is safe unless viewed through magnifying optics, the optical filters that block the laser light must be fixed directly in front of the dental loupes to prevent any accidental injury to the dentist.

5. Optical Filter Design

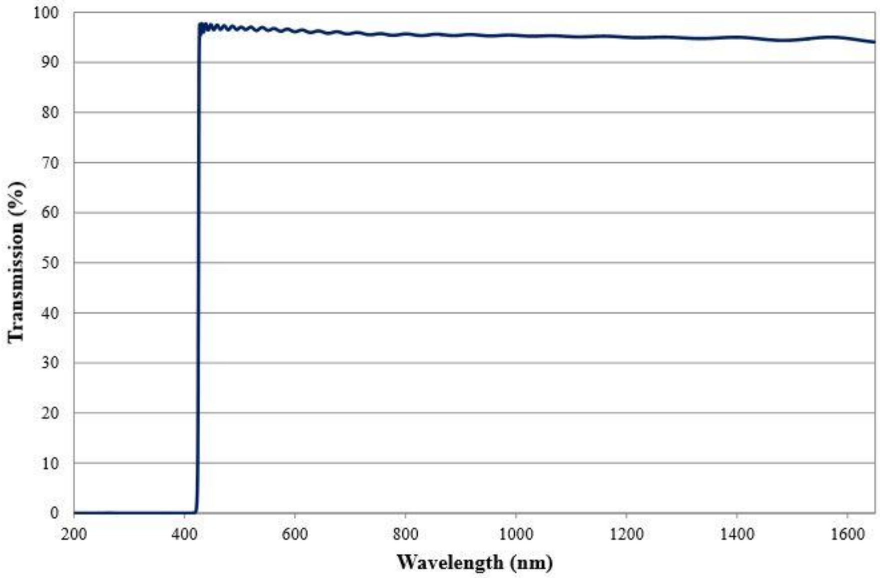


Figure 16: Edmund Optics 425nm longpass filter optical curve [22]

The optical filters of the Oralite system are designed to block the laser light from being visible to the user, leaving just the fluorescence generated by the composite material visible. A high performance 425nm longpass filter from Edmund Optics was selected. The filter has a high transmittance above 425nm which allows the filters to be permanently attached to the loupes without distorting the vision of the user during normal procedures.

The following light source requirements are met in our proof-of-concept model:

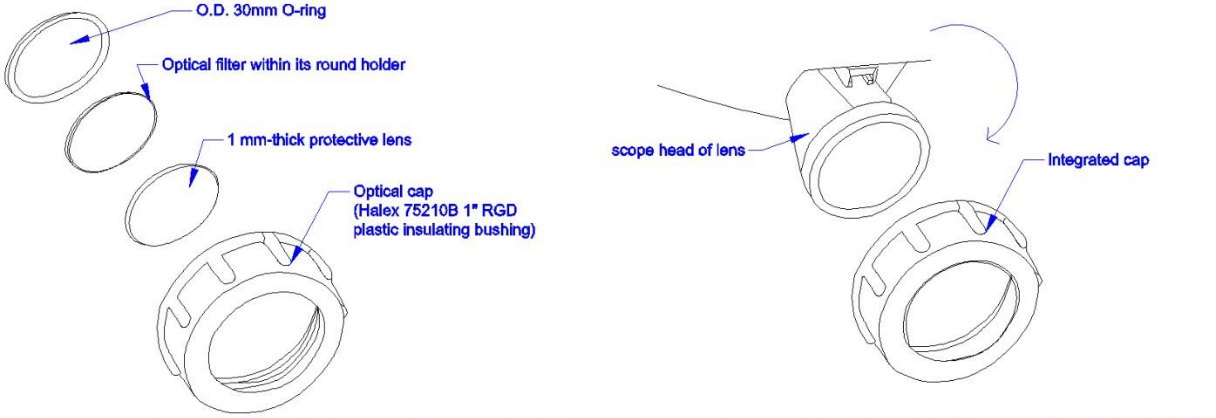
[R61 – I] Transmittance of the optical filters shall be at least 80%
[R62 – I] The optical filters shall have a protective lens to prevent any physical damage during operation
[R63 – I] The protective lens will block near UV light from the light source directly entering the user's eyes
[R67 – III] Dimensions of the optical filters shall be 25mm in diameter to completely cover the magnifying loupes

6. Mechanical Adapter

The mechanical adapter is designed to hold the optical filter in front of the magnifying loupes while protecting the filter and loupe lenses from damage. All materials are made from hardened plastic for easy cleaning and sterilization, while remaining lightweight.

As detailed earlier, one of the design considerations of using a laser diode for a light source is that the optical filters must be fixed in front of the magnifying loupes to prevent accidental magnification of the laser source causing damage to the user's eyes. To implement this, a cap containing the optical filters and protective covers that attaches directly to the loupe heads was designed.

The assembly details of the proposed cap model for the optical adapter are shown in the following figures.



1. install protective lens, optical filter and O-ring into the optical cap

2. screw the integrated cap onto the scope head clockwisely

Figure 17: Assembly details of an optical adapter [23]

Figure 18: Dental loupes with optical adapters [24]

Figure 17 illustrates the profile of an optical adapter and how it connects optical filters onto the dental loupes, while the finished prototype is displayed in Figure 18. The outer cap is a threaded Halex 75210B 1-Inch RGD Plastic Insulating Bushing (Figure 19). The cap screws directly onto the dental loupes, completely covering them and preventing any light from entering the loupe without first passing through the optical filter.

Figure 19: Halex 75210B 1-Inch RGD Plastic Insulating Bushing [25]

The inner diameter on the face of the cap is 26mm, which is theoretically perfect to hold the 25mm optical filter with a 26mm round holder (Figure 20).

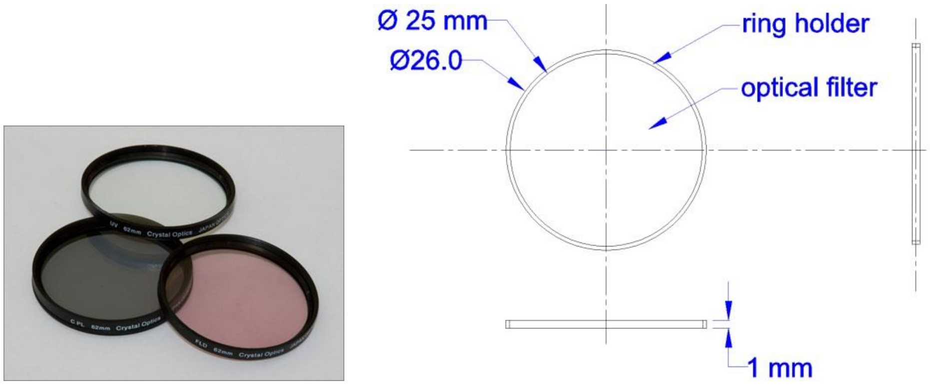


Figure 20. Optical filter with its holder [26]

In practice the assembly process has a tolerance of 0.5mm -1mm, indicating that the optical filter may detach from the face of the cap when it is installed. To avoid this, we add a 1mm-thick protective lens (26mm diameter) into the cap first.

During installation, when the plastic cap is screwed onto the scope head, the internal plastic screw thread and the optical filter may scratch the surface of the precision dental loupe due to friction. To prevent this damage, a rubber O-ring with a 25mm inner diameter (Figure 21) is placed between the filter and the loupe to protect the dental loupes from wear and tear as well as improve damage resistance.

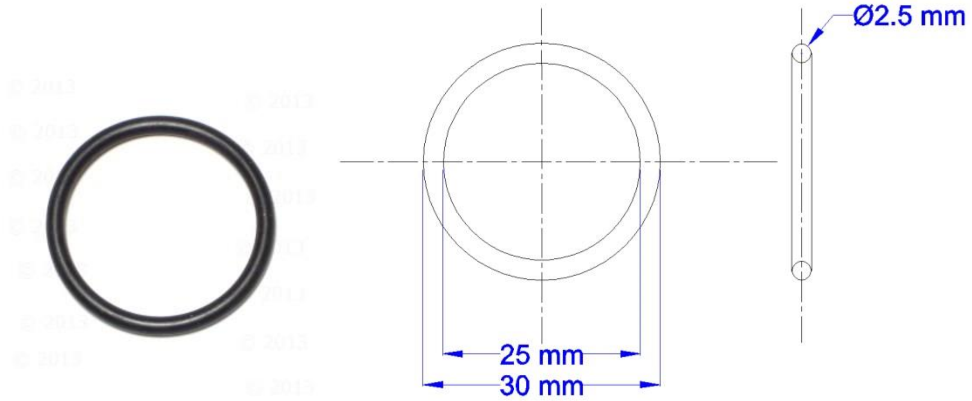


Figure 21. O-rings [27]

The summarized materials to build optical adapters are provided in the table below:

Table 2: Materials for building optical adapters

Items	Quantity	Main Specifications
Halex 75210B 1-Inch RGD Plastic Insulating Bushing	2	Face: inner diameter: 26mm, outer diameter:36mm; Height: 12mm; Back: inner diameter: 34mm, outer diameter:40mm;
O-ring	2	Inner diameter: 25mm, outer diameter:30mm; Thickness: 2.5 mm
Protective lens	2	Diameter: 26mm, thickness:1mm

The following optical adapter requirements are met in our proof-of-concept model:

[R69-I] The optical adapters should be as light as possible to provide a comfortable operational experience
[R70-I] The optical filters should be removable in a few simple steps
[R72-I] The optical adapters should be lockable at the lowest position and at the maximal angle
[R74-I] The outer surface of optical adapters should adhere to installed optical filters
[R76-III] The inner diameter of optical adapters will be 25mm-26mm

7. Hardware Packaging

The packaging of the OraLite optical system is vital to maintain the integrity of the finished product. As our product consists of expensive lenses and as such even a minor scratch on the lens can render it useless. It is of utmost importance to prevent damage to the lenses. Our packaging box has been designed keeping the aforesaid points in mind.

The finished product will be kept inside a box. The dimensions of the box are as follows:

Table 3: Hardware packaging dimensions

Length (cm)	Breadth (cm)	Height (cm)
27	22.5	8

The box consists of a handle with a hard outer shell to withstand general abuse from the user. The box will be strong yet lightweight to secure the product. The inner casing will be soft and will properly secure the dental loupe. There are four different sections inside. Figure 21 displays the inside of the box. As the optical adapter consists of two parts, the box has two sections to secure it. The middle section is where we will keep the dental loupe. It has an additional section which we can use to keep extra lens cover as back-up.

Figure 22. Hardware packaging interior [28]

The design of the box is such that once it is closed the product inside will not be loose. There is no possibility of the products inside rubbing against each other. As such, we can rely on this design of the outer box to keep our finished product intact.

8. System Test Plan

The test plan for the OraLite system will consist of two components: hardware and functionality.

8.1 Hardware Test Plan

These simple procedures are designed to ensure that the hardware is working within the desired parameters. While performing these procedures, the testing staff should refer to the Hardware Test Checklist (Appendix D).

1. Connect the light source to the portable power supply.
2. Point the light source in a safe direction.
3. Slowly increase the current to the light source by twisting the knob clockwise on the power supply.
4. Using a spectrometer, check the wavelength of the emitted light.
5. Using an optical power meter, check the optical power output of the light source at these distances from the lens: 1cm, 35cm and 56cm.
6. Allow the light source to run for 5 minutes and recheck the output spectrum.
7. Using an optical power meter, check the optical power output of the light source at these distances from the lens: 1cm, 35cm and 56cm.
8. Power down the source by turning the knob on the power supply counter-clockwise.
9. Check the temperature of the light source housing.

8.2 Functionality Test Plan

These procedures are designed to test whether or not the system is performing well and providing the user with the desired results. While performing these procedures, the testing staff should refer to the Functionality Test Checklist (Appendix E).

1. Attach the light source to the dental loupes using the provided adapter.
2. Attach the power supply to a comfortable position on the testers clothing.
3. Have the tester put on the dental loupes and adjust them until they are comfortable and able to clearly see through the magnifying lenses.
4. Connect the light source to the portable power supply.
5. Have the tester focus on an extracted sample tooth between 35cm and 56cm from the loupes.
6. The tester should try and identify where the composite filling (if any) is present on the sample tooth.

7. Slowly increase the current to the light source by twisting the knob clockwise on the power supply.
8. The tester should ensure that the light source beam is focused on the sample tooth.
6. The tester should try again to identify where the composite filling (if any) is present on the sample tooth.
10. Power down the source by turning the knob on the power supply counter-clockwise and check the temperature of the light source housing.

9. Conclusion

This document has outlined all of the major design considerations that will be implemented for the production of the OraLite system. The functional specifications from the previous document have been implemented where possible and helped shape the outcome of our final product design. Some portions of the hardware testing remain to be completed and certain aspects of the product design may be adjusted to address unforeseen complications that may arise. However, the vast majority of the design process is complete and the team is confident in their ability to assemble a working prototype in the very near future.

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Appendix A: Laser Diode Specifications

USLASERS

D405–20

● 405nm 20mW laser diode●

Features

• Device:	405nm laser diode
• Power:	20mW
• Package Type:	5.6mm TO
• PIN configuration	Style B

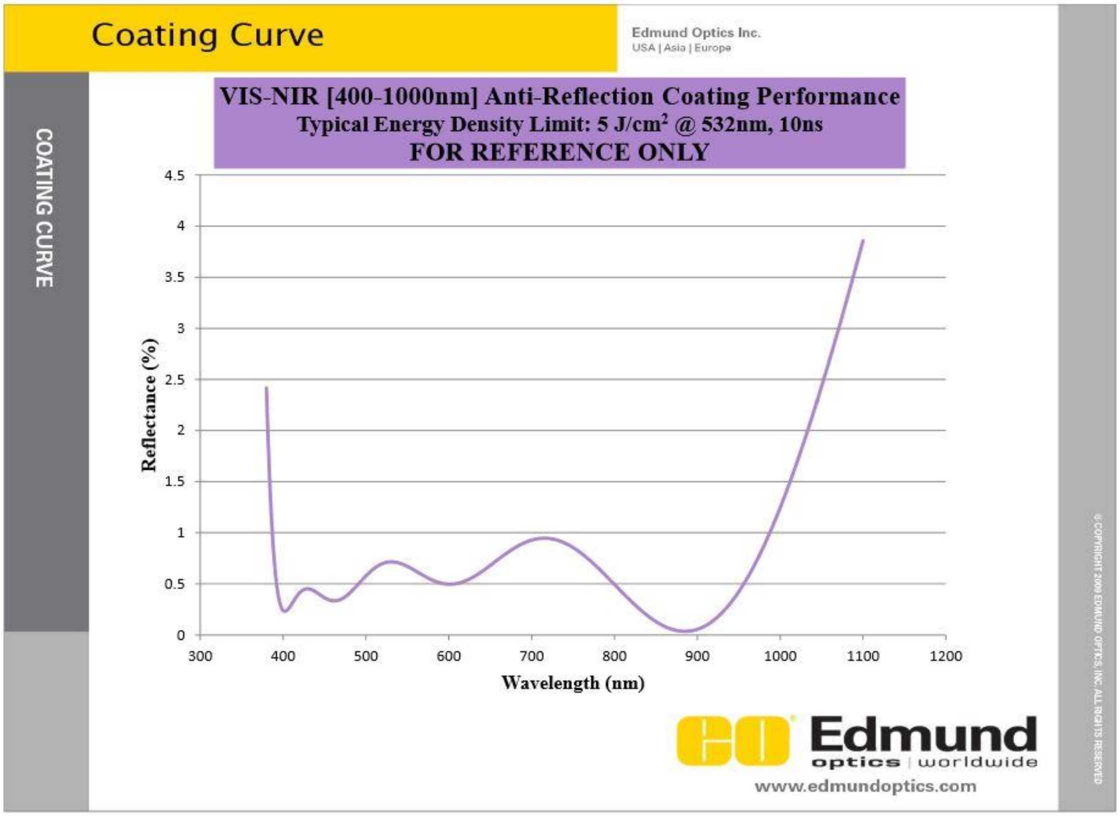
▪ Absolute Maximum Rating (Tc=25°C)

Characteristics	Symbols	Rating	Unit
Optical power	Po	20	mW
Reverse Voltage (Laser)	V	2	V
Reverse Voltage (PIN)	V	30	V
Operating Temperature	Top	-10 to +70	°C
Storage Temperature	Tstg	-40 to +85	°C

▪ Electrical and Optical Characteristics (Tc=25°C)

Characteristics	Symbols	Min	Typ	Max.	Unit	Condition
Optical Power	Po	-	20	-	mW	-
Threshold Current	Ith	-	25	50	mA	Po=20mW
Operating Current	Iop	-	50	75	mA	Po=20mW
Operating Voltage	Vop	-	5.0	6.5	Volts	Po=20mW
Slope Efficiency	η	-	1.3	-	mW/mA	-
Lasing Wavelength	λ	395	405	415	nm	Po=20mW
Beam Divergence	$\theta_{\parallel}$	6.0	9.0	12	deg	Po=20mW
	$\theta_{\perp}$	16	20	25	deg	Po=20mW
Beam Angle Deviation	$\theta_{\parallel}$	-3		3	deg	Po=20mW
	$\theta_{\perp}$	-3		3	deg	Po=20mW
Monitor Current	Im	-	0.20	0.50	mA	Po=20mW
Emission Point Accuracy	ΔX	-80	-	80	μm	
	ΔY	-80	-	80	μm	
	ΔZ	-80	-	80	μm	
Astigmatism	As	-	-	15	μm	

Appendix B: Lens Reflectance Specifications



Appendix C: Laser Safety Classes

Class	Type of lasers	Meaning	Relationship to MPE	Hazard Area	Typical AEL for CW Lasers
Class 1	Very low power lasers or encapsulated lasers	Safe	MPEs are not exceeded, even for long exposure duration (either 100 seconds or 30000 seconds), even with the use of optical instruments	No hazard area (NOHA)	40 µW for blue
Class 1M	Very low power lasers; either collimated with large beam diameter or highly divergent	Safe for the naked eye, potentially hazardous when optical instruments** are used	MPEs are not exceeded for the naked eye, even for long exposure durations, but maybe exceeded with the use of optical instruments**	No hazard area for the naked eye, but hazard area for the use of optical instruments** (extended NOHA)	Same as Class 1, distinction with measurement requirements
Class 2	Visible low power lasers	Safe for unintended exposure, prolonged staring should be avoided	Blink reflex limits exposure duration to nominally 0.25 seconds. MPE for 0.25 seconds not exceeded, even with the use of optical instruments.	No hazard area when based on unintended exposure (0.25 seconds exposure duration)	1 mW
Class 2M	Visible low power lasers; either collimated with large beam diameter or highly divergent	Same as Class 2, but potentially hazardous when optical instruments** are used	MPE for 0.25 seconds not exceeded for the naked eye, but maybe exceeded with the use of optical instruments**	No hazard area for the naked eye when based on accidental exposure (0.25 seconds exposure duration), but hazard area for the use of optical instruments** (extended NOHA)	Same as Class 2, distinction with measurement requirements
Class 3R	Low power lasers	Safe when handled carefully. Only small hazard potential for accidental exposure	MPE with naked eye and optical instruments may be exceeded up to 5 times	5 times the limit of Class 1 in UV and IR, and 5 times the limit for Class 2 in visible, i.e. 5 mW	5 times the limit of Class 1 in UV and IR, and 5 times the limit for Class 2 in visible, i.e. 5 mW

Class 3B	Medium power lasers	Hazardous when eye is exposed. Wear Eye Protection within NOHA. Usually no hazard to the skin. Diffuse reflections usually safe	Ocular MPE with naked eye and optical instruments may be exceeded more than 5 times. Skin MPE usually not exceeded.	Hazard area for the eye (NOHA), no hazard area for the skin	500 mW
Class 4	High power lasers	Hazardous to eye and skin, also diffuse reflection may be hazardous. Protect Eye and skin. Fire hazard.	Ocular and skin MPE exceeded, diffuse reflections exceed ocular MPE	Hazard area for the eye and skin, hazard area for diffuse reflections	No limit

Source: IEC Laser classfications [29]

Appendix D: Hardware Test Checklist

Condition Tested:		**Comments:**
Power cord connection to power supply is stable	Yes ____ No ____	
Light source produces visible purple light	Yes ____ No ____	
Laser wavelength is between 405nm and 410nm	Upon Startup: Yes ____ No ____ After 5 minutes: Yes ____ No ____	
Optical power output is less than 20mW/cm^2 at 1cm	Upon Startup: Yes ____ No ____ After 5 minutes: Yes ____ No ____	
Optical power output is less than 1mW/cm^2 at 35cm	Upon Startup: Yes ____ No ____ After 5 minutes: Yes ____ No ____	
Optical power output is less than 1mW/cm^2 at 55cm	Upon Startup: Yes ____ No ____ After 5 minutes: Yes ____ No ____	
Light source housing is hot to the touch	Yes ____ No ____	

Appendix E: Functionality Test Checklist

Condition Tested:		**Comments:**
Power supply attaches comfortably to testers clothing	Yes ____ No ____	
Loupes are comfortable to wear	Yes ____ No ____	
Light source produces visible purple light	Yes ____ No ____	
Tester is able to see where laser is directed	Yes ____ No ____	
Testers vision is noticeably impeded by optical filters	Yes ____ No ____	
Tester can readily identify composite filling in tooth sample	Without OraLite Yes ____ No ____ With OraLite Yes ____ No ____	

Design Spec Addendum: Laser Modulation Circuit to Reduce Optical Output Power for Eye Safety Requirements

1. Laser Modulation

The main purpose of the laser diode in our design is to excite fluorescence in the composite filling material, causing it to emit light that is visible to the OraLite User. This fluorescent emission has a certain lifetime associated with it in which it will fluoresce even if not under direct stimulation from a light source (Figure A1). In theory this should allow us to modulate the laser to emit light in square wave pulses such that the fluorescence emitted from the composite material does not decrease linearly with decreasing optical power. By modulating the laser we hope to reduce the optical output power to increase the safety of the system, without drastically decreasing its effectiveness.

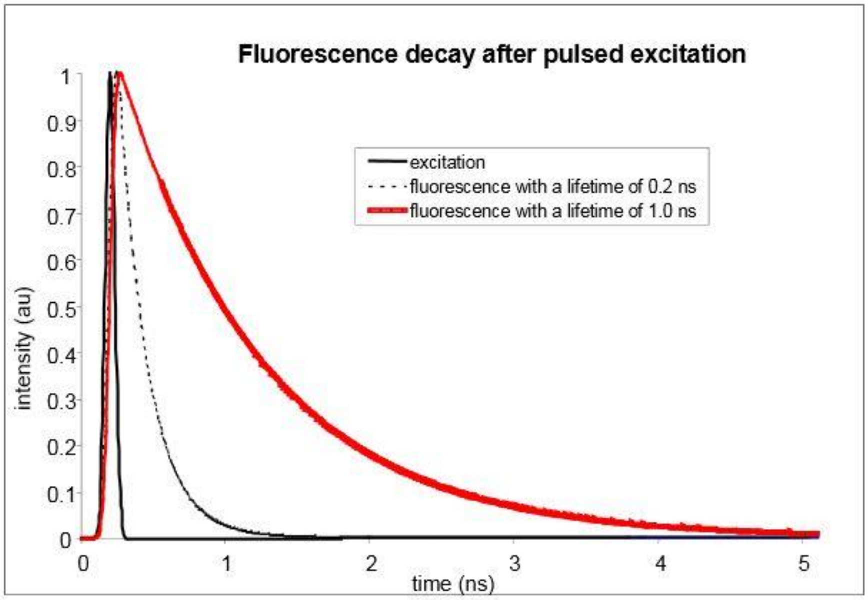


Figure A1: Fluorescent lifetime of two fluorescent dyes [A1]

Typical fluorescence lifetime varies by material, and can range from less than a nanosecond to several microseconds [A2]. The plot in Figure A1 is for fluorophores used in fluorescence microscopy, which typically have a short fluorescence lifetime on the scale of nanoseconds. Unfortunately the fluorescence lifetime of composite filling materials has not been measured, so we would need to perform the measurements ourselves at a facility with a fluorescence-lifetime imaging microscope (FLIM).

In order to correctly determine the modulation rate and duty cycle of the laser pulse, we also need to know the rise time (t_d) of the laser (Figure A2).

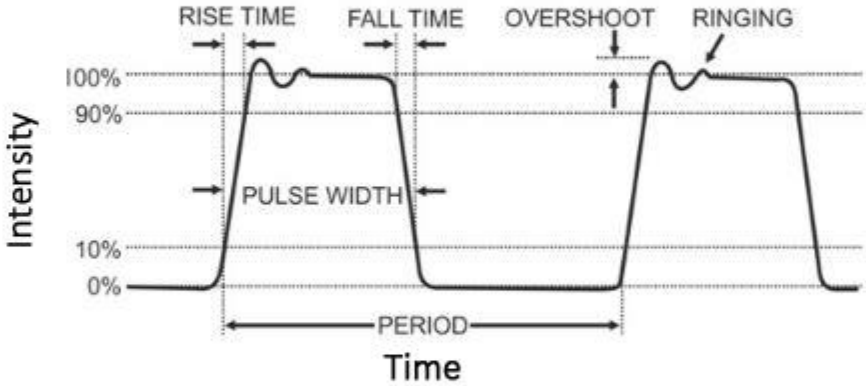


Figure A2: Modulated laser emission [A3].

This can be calculated from [A4]:

$$t_d = t_n \ln \frac{J - J_b}{J - J_{th}}$$

Where:

t_n *is the time constant for the laser diode*

J *is the current driven to the diode*

J_b *is the bias current*

J_{th} *is the threshold current to achieve lasing*

For our system, the bias current is 0, but could be raised to facilitate a faster response time (lower t_d). Unfortunately, we do not know the time constant t_n for our laser diode, and would again need to measure it a capable optics facility. However, these diodes typically have time constants in the nanosecond range and we do not anticipate this affecting our results unless we attempt to drive the laser in the MHz range.

2. Timing Circuit and Current Regulator

To modulate the laser output while maintaining a reliable current flow through the diode, a 555 timer chip in series with a current regulator circuit is used (Figure A3).

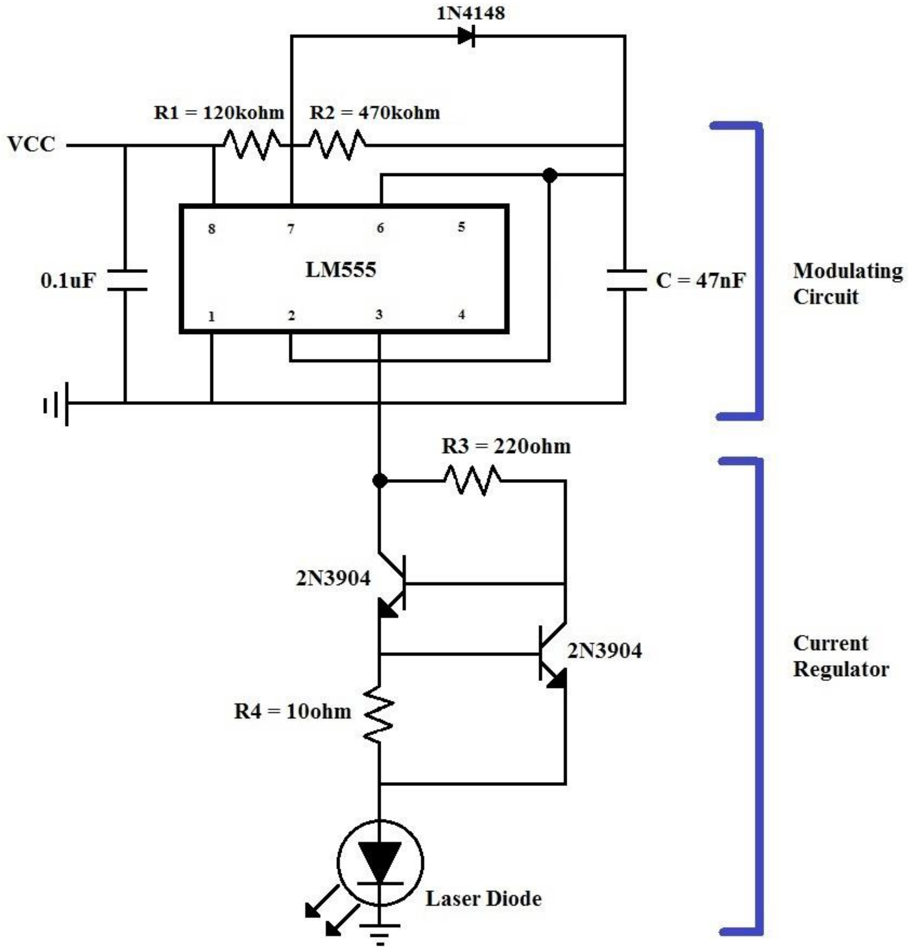


Figure A3: Proposed timing circuit and current regulator setup.

The main purpose of the above circuit is to lower the intensity rating of the OraLite light source to be at a level that will be eye safe to be used in the clinic. This is extremely important because the emitted light can potentially be dangerous if it is positioned directly to the patient's eyes at an unsafe distance. An intensity rating of $1mW/cm^2$ is considered eye safe for a continuous wave laser diode (Appendix C).

To design the modulation circuit, the intensity rating measurement of the continuous light source from the OraLite system is needed. With the help of a digital irradiance meter, the OraLite light source was measured and had an intensity rating of 17.4mW/cm^2 as shown in Table A1. This light source will be considered eye safe at a distance of 30cm away.

Table A1: Power Ratings of various elements and eye safety standard for laser light

Light Source	Intensity Ratings
Eye Safe	1mW/cm2
OraLite System	17.4mW/cm2
Cellphone Camera light	11mW/cm2

The power intensity of the light is directly proportional to the duty cycle of the modulation. As a starting point, a duty cycle of 20% was chosen and the calculations are shown below.

$$P_{avg} = P_{peak} \times DutyCycle$$
$$P_{avg} = 17.4mW / cm^2 \times 20\%$$
$$P_{avg} = 3.48mW / cm^2$$

Even though, the average power intensity is not quite eye safe, the modulation circuit will significantly lower the light source's intensity and allow the OraLite light source to be eye safe at a much closer distance. To achieve a 20% duty cycle circuit at 55Hz, a basic LM555 astable oscillator circuit was designed. Using the following equations associated with the 555 timer circuit, resistor and capacitance values were calculated and selected.

$$Frequency = \frac{1}{0.695 \times (R_1 + R_2) \times C}$$
$$OnTime = 0.695 \times R_1 \times C$$
$$OffTime = 0.695 \times R_2 \times C$$
$$DutyCycle = \frac{R_1}{R_1 + R_2} \times 100\%$$

After a rigorous set of testing, the resistor values of R_1= 120kΩ and of R_2= 470kΩ as well as a capacitance value of C = 47nF was found to best fit the modulation circuit design. The circuit accurately generated an oscillation with 25% duty cycle at a frequency of 52Hz which are close to the specified values. The new average power intensity of the light source is corrected to be 4.35mW/cm^2, which is still significantly below the original continuous wave power intensity.

The current regulator is designed in series with the modulating circuit to ensure the typical working conditions of the laser diode. Because the OraLite system is powered from a battery source, this is an important circuit for our design specification to ensure the operating current of the circuit when the battery is low on power. In Appendix A, it was found the laser diode requires a DC forward current of 50mA with a 5V potential drop to properly emit light at 405nm. Using a combination of two 2N3904 transistors, the following formulas were used to help design the circuit.

$$I_{Constant} = \frac{V_{BE}}{R_4} + I_{R_3}$$

$$R_3 >> R_4$$

$$I_{Constant} \approx \frac{V_{BE}}{R_4}$$

$$\Rightarrow R_4 \approx \frac{0.5V}{50mA} \approx 10\Omega$$

Having the resistor R_4 chosen, extensive testing found R_3 with a value of 220Ω, which is significantly larger than R_4, to best coincide with the circuit for current regulation.

Prior to mass production of the OraLite system, both the modulation circuit and current regulator circuit will need to be further optimized. Even though the 555 timer is the current industry standard for oscillators, the LM555 chip is not ideal to be implemented with a battery power source. There are less power consuming oscillator chips in the market which would be more ideal for the modulation circuit design. The power intensity of the OraLite system modulating circuit will also need to be measured and iterated for optimization. In the current regulator circuit, oversaturation of the NPN transistors may occur due to the resistor component of R_3. A single JFET transistor may have been a better choice for design for the current regulator.

Although further optimization is required for future work, the proposed circuit described in Figure A3 meets the design specifications for the OraLite system project. For a prototype design, these design specifications proved to be a great foundation to the OraLite system project.

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