ENSC 305W/440W Grading Rubric for Functional Specification

Criteria	Details	Marks
Introduction/Background	Introduces basic purpose of the project.	**/05%**
Content	Document explains the functionality of the proposed product without excessive design content (i.e., outlines the "what" rather than the "how").	**/10%**
Technical Correctness	Ideas presented represent valid functional specifications that must be considered for a marketed product. Specifications are presented using tables, graphs, and figures where possible (rather than over-reliance upon text).	**/15%**
Process Details	Complete analysis of problem. Justification for chosen functionalities. Sources of ideas referenced. Specification distinguishes between functions for present project version and later stages of project (i.e., proof-of-concept, prototype, and production versions). Comprehensively details current constraints.	**/20%**
Engineering Standards	Outlines specific engineering standards that apply to the device or system and lists them in the references.	**/10%**
Sustainability/Safety	Issues related to sustainability issues and safety of the device are carefully analyzed. This analysis must cover the "cradle-to-cradle" cycle for the current version of the device and should outline major considerations for a device at the production stage.	**/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, executive summary, 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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Oct 17th, 2013

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

Dear Professor Lakshman One:

The attached document is the Functional Specification for the OraLite optical system developed by IDENTEC. The goal of our 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 will serve as a guide for the system architecture and development of the OraLite system needed to resolve the current issue with imprecise differentiation between real tooth material and composite fillings in clinical practice.

Our diverse team of 4 senior biomedical and electronic engineers is dedicated to the development of the OraLite. Please feel free to forward any questions or concerns about our Functional Specification document to dkayra@sfu.ca.

Sincerely,

Damian Kayra

Chief Executive Officer
IDENTEC

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

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Issued date:

October 17th, 2013

Revision:

1.6

Executive Summary

The market for dental health is an ever expanding institution with the total dental care expenditures in both the public and private sectors of Canada increasing from $1.3 billion in 1980 to $12.6 billion in 2012 [1]. Today, the most common procedure performed by dentists are cavity restorations and replacements. In recent years, silver amalgam fillings have been gradually phased out in favor of the more modern and aesthetically pleasing composite fillings. These composite fillings are designed to mimic real tooth material in both appearance and mechanical properties. This makes it extremely difficult for the dentist to distinguish them from the real tooth during replacement procedures. Due to this difficulty, the common practice during composite filling removal is to drill a larger opening than the previous cavity to ensure complete removal of the old filling. This leads to unnecessary elimination of healthy tooth during composite removal procedures

At IDENTECH we propose to create a system, the OraLite, that will allow dentists to visually differentiate between tooth material and composite resin fillings to ensure complete removal of all expired resin materials without removing excessive amounts of healthy tooth.

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
- Suitable optical filters
- Optical adapter system to attach the optical filters onto the dental loupes

The first phase of development will consist of extensive preliminary tests to find a light source that will produce the desired fluorescence. The second phase will determine which optical filters will enhance the contrast of light to create optimal working conditions. The third and final phase will develop an adapter system that will help mount the optical filters onto the dental loupes.

The technology that we propose to develop does not exist. It will be one of a kind. The OraLite optical filters will visually separate the composite fillings from real tooth using only passive optics. It will also enhance the quality of the dentist’s work by reducing overall composite filling removal procedure time. This innovative and easy to use system will allow dentists to quickly and accurately remove and replace composite resin fillings in patients.

Table of Contents

List of Figures

Glossary of Terms

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

1. Introduction

IDENTECH 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 characteristics and visually separate the two materials. The requirements for the OraLite optical system, as proposed by IDENTECH, are described in this functional specification.

1.1 Scope

This document describes the functional requirements that must be met by a functioning OraLite optical system. This document explains all the system requirements and step by step analysis of the test procedure. It will also shed some light on the optical adapter system. Using the listed requirements, the OraLite optical system will be traceable to its roots and the design decisions can be easily followed for future use.

1.2 Intended Audience

The functional specification is intended for use by all members of IDENTECH. The chief executive officer shall refer to the functional requirements to monitor the overall progress throughout the various phases of the project. 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.

1.3 Classification

Throughout this document, the following convention will be used to describe a functional requirement:

[Rn-p]	A functional requirement

where **n** is the functional requirement number and **p** refers to its priority. The priority is described in one of the three values:

- **I** The requirement applies to the proof-of-concept system only.
- **II** The requirement applies to both the proof-of-concept system and the final production system.
- **III** Requirement is only applicable to the final production system.

2. System Overview

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) Loupe Optical Filters
3) Optical Adapters

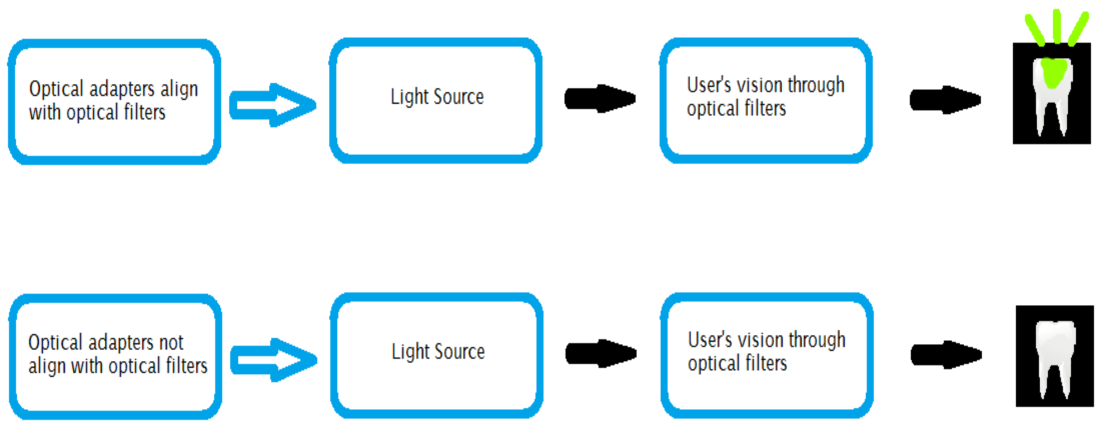

Figure 1: System Overview [2]

The individual components shown in Figure 1 will be integrated into current dental optics to be as simple and intuitive as possible, assisting dentists in composite filling removal procedures without impeding their speed. The light source is a standard dentistry 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. A protective lens with maximal transmittance will be installed along with the optical filters to prevent physical damages to the filters. The protective lens will also block sub-420nm light to shield the dentist from any UV light leaking from the light source to prevent any hindrance to the dentist during a procedure.

Optical adapters will be used to connect the optical filters onto the dental loupes. Apart from its simple attachment operation, the optical adapters will also provide dentists the luxury of alternating their vision from normal settings to enhanced settings using a straightforward swivel mechanism. With a flick of a finger, dentists will be able to revolve the optical filters away from the dental loupe and view the tooth sample normally. The rotated optical filters will remain in this position unless it is physically adjusted by the user. 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.

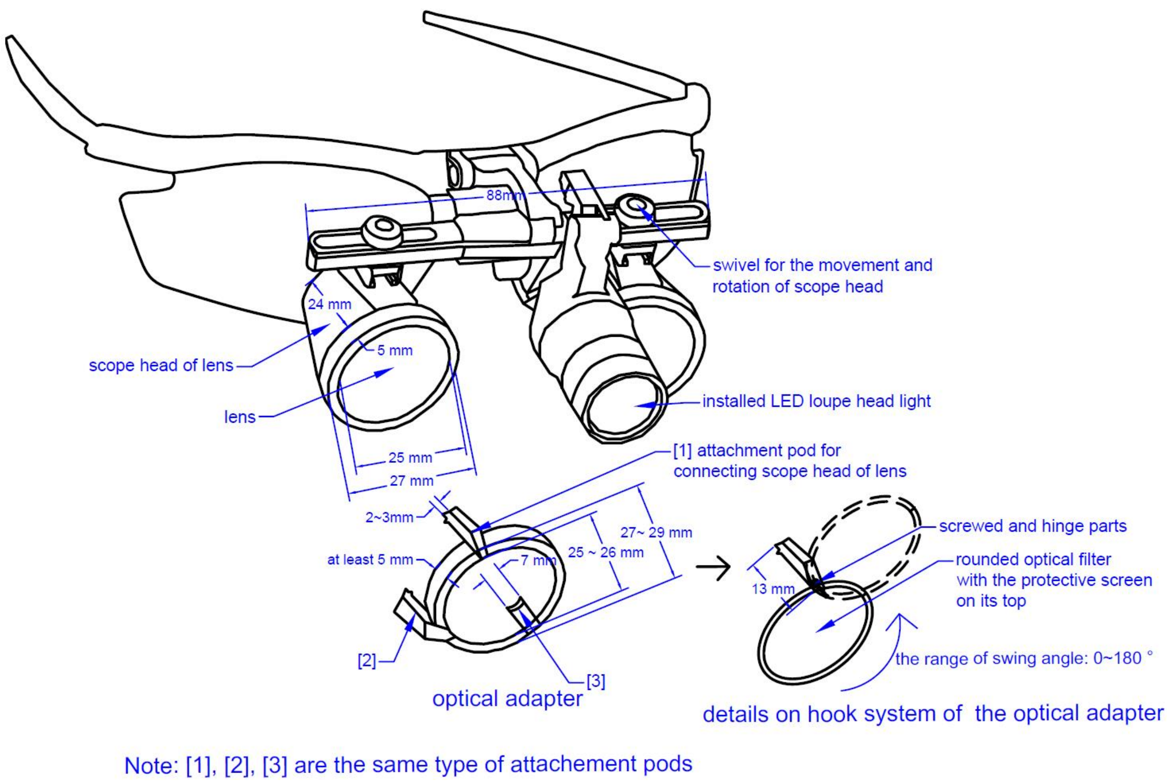

Figure 2: System Design

The proof of concept of the OraLite optical system encompasses all the basic functionality 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.

2.1 System Requirements

[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

[R4 – II] The retail price of OraLite shall be under CDN$3000

2.2 Physical Requirements

[R5 – I] The OraLite system shall be similar in appearance to a regular dental loupe

[R6 – I] The weight of the system shall not feel uncomfortable to the user when being worn for a long period of time

[R7 – I] The system will be easily packed away in the dental loupe storage case

[R8 – I] The OraLite system shall be unisex

[R9 – I] Dental loupes shall be able to flip up to remove magnification

[R10 – II] Different magnification of dental loupes shall be available to fit the user's optimal work distance from the patient

[R11 – III] The OraLite system will come in both flip-up and clip-on loupes for those who already wear glasses

[R12 – III] The dental loupes shall be adjustable horizontally and vertically to custom fit to any user's face

2.3 Electrical Requirements

[R13 – I] The OraLite system shall be safe and compliant with medical standard for electrical devices

[R14 – I] The device shall be an existing consumer grade product with a minimum battery-life of six hours

[R15 – II] Battery pack will be rechargeable using standard 110/120V at 60Hz AC

[R16 – II] Power cord shall be have a length no greater than 3m and must be detachable from the battery pack

2.4 Mechanical Requirements

[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

[R19 – II] All parts should be easily replaceable if damaged

[R20 – II] All mechanical parts can be manually adjusted to suit a user's preference

2.5 Environmental Requirements

[R21 – I] The light source, optical filter, and optical adapter shall operate normally between the temperatures of 0°C and 50°C which is well within typical dental clinic environments [3]

[R22 – I] All equipment shall be fully operational from 0% to 90% relative humidity which is well within typical dental clinic environments [3]

[R23 – I] The OraLite system shall be easily sterilized

[R24 – I] All components shall be recyclable after its lifetime

2.6 Standards

[R25 – I] The OraLite system shall conform to ISO 13485 standards [4]

[R26 – I] The OraLite system shall conform to UL 60601 standards [5]

[R27 – I] The OraLite system shall conform to ANSI standards

[R28 – I] The OraLite system shall conform to ISO 7405 standards [6]

[R29 – I] The OraLite system shall conform to FDA standards

[R30 – I] The OraLite system shall conform to IEC 60601-1 standards [7]

2.7 Reliability and Durability

[R31 – I] The OraLite system shall be able to withstand daily dental clinic usage

[R32 – II] Each component shall be easily interchanged and replaced by the user if needed

[R33 – II] The system shall be shock and water resistant

[R34 – II] The OraLite system shall have a minimum life cycle of 5 years

2.8 Safety Requirements

[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

[R38 – I] The battery pack shall be designed with failure mode and effect analysis for risk mitigation

[R39 – II] Mechanical components will have no sharp edges to injure the user

[R40 – II] Battery pack shall securely attached to the user using a clip-on system with its wires strategically organized to be unobtrusive to the user

[R41 – II] Safety glasses for the patient will be included with the system that block sub-420nm light

2.9 Performance Requirements

[R42 – I] The intensity of the light source shall respond instantaneously upon manual adjustment on the battery pack

[R43 – I] Composite fillings shall be clearly distinguishable when viewed through the OraLite system

[R44 – I] The OraLite system shall be able to distinguish multiple brands of composite fillings

[R45 – I] The OraLite system shall be able to identify 99% of the composite filling within the tooth

[R46 – II] The system will not alter the properties of any materials within its work area during operation

2.10 Usability Requirements

[R47 – I] The manual adjustments shall be intuitive and easy to use

[R48 – II] The components of the dental loupe shall be upgradeable by buying the upgraded components online

3. Light Source

The light source of the OraLite optical system will be responsible for not only illuminating the tooth sample but also emitting the required wavelength of light to generate the differentiable spectral emissions from the tooth and composite resin. This component will consists of modifying an existing dentistry light with the custom light source to match industry standards. For our prototype, the Feather Light LED headlight manufactured from Ultra Light Optics Inc. will be altered to fit the application. This custom light source will emit the specific wavelength of light best suited for the application that was chosen through detailed experiments from near infrared (IR) to UV spectrum. The power of the light source will be supplied through a battery pack which will be attached to the user using a clip-on mechanism. The intensity of the emitted light will also be adjustable through the battery pack which is the common practice in dentistry.

3.1 Light Source Requirements

[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

[R53 – I] A minimum power of 2W LED will be used to ensure sufficient brightness

[R54 – I] Thermal resistance material will surround the electrical circuits inside of the housing to prevent overheating of the LED electrical components

[R55 – I] The light source shall operate at a safe temperature even after long hours of use

[R56 – III] The lens attached to the enclosed housing will focus the light to operate at the user's working distance

[R57 – III] The headlight will have dimensions of 1.65cm in diameter and 1.93cm in length and weigh approximately 3g

[R58 – III] The battery pack will have dimensions of 5.59cmx2.54cmx9.91cm and weigh approximately 141.7g

[R59 – III] The battery pack will have a maximum charging time of 3.5 hours

4. Loupe Optical Filters

The loupe optical filters are the most essential component of the OraLite optical system. When the light source illuminates the tooth sample, the filters will visually separate composite from tooth material by enhancing the emission wavelength differences from the two materials. From the user's point of view, the composite filling will fluoresce in a bright green colour whereas the tooth will appear as a dim purple colour. The two optical filters will fit over the magnifying loupes dentists use to view their working space. It is extremely important for the optical filters to have a high transmittance of light because of the inherent light losses in loupe magnification. The optical filters will be attached onto the dental loupe using the custom designed optical adapters.

4.1 Loupe Optical Filter Requirements

[R60 – I] The optical filters shall be bandpass filters with a maximum range from 430nm to 490nm

[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

[R64 – I] The protective lens shall not greatly obstruct the transmittance of the filters

[R65 – II] The optical filters and protective lens shall be fog resistant

[R66 – II] Filters and protective lens will be scratch resistant

[R67 – III] Dimensions of the optical filters shall be 25mm in diameter to completely cover the magnifying loupes

5. Optical Adapters

Optical Adapters serve several important functions, including:

- To provide protection to the dental lens
- To provide the socket for supporting the installation of standard optical filters over loupe lenses
- To swing upwards at a specific maximal angle and be angled downwards.
- To be fixed firmly at a certain position when in operation or idle status.
- To avoid blocking the vision area of lens or LED loupe light.

To prevent unnecessary over-swinging of the optical adapters, it is important that optical adapters are installed and screwed correctly to fit the dental loupes by adding tiny accessories that are light-weight. The requirements listed in the following subsections refer to terms that will now be defined.

- ➢ Optical Adapters' dimensions are determined according to the size of lens and lens' cover.
- ➢ Optical Adapters' materials and the methods of fixing should be consistent with the whole design of the dental loupe.

Optical Adapters' dimensions are a vital factor for 2 reasons:

1. To ensure the optical adapters can be easily installed and disassembled from the top of the lens.
2. To ensure a snug connection when optical adapters (female) are mounted onto the lens (male).

The following requirements for the optical adapters reflect the guidelines prescribed by a standard dental loupe setup (HEINE HR Binocular Loupes) which is being adapted for the OraLite prototype.

5.1 Optical Adapter Requirements

[R68-I] The hinge parts between optical adapters and scope head of lens should be as small as possible and not impede the user's vision

[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

[R71-I] The angle of swing of optical adapters should be no more than 180 degrees

[R72-I] The optical adapters should be lockable at the lowest position and at the maximal angle

[R73-I] The hinge parts should not affect the smooth movement of optical adapters when switching into operation or idle status

[R74-I] The outer surface of optical adapters should adhere to installed optical filters

[R75-II] The length of the hinge component between optical adapters and scope head of lens should be at least 2mm longer than the thickness of the optical filters

[R76-III] The inner diameter of optical adapters will be 25mm-26mm and the outer diameter should be 27mm-29mm

[R77-III] The thickness of optical adapters should be at the least 5mm but no more than 10 mm

6. User Documentation

User documentation shall be provided by means of a website. The website will be dedicated to providing technical support as well as a user manual. There will be a choice to navigate the website in English, Spanish, French, Chinese and Hindi keeping in view of the major international markets. The website will include the following:

- User manual
- Video tutorials
- Technical support
- Frequently Asked Questions (FAQs)
- Purchasing information

The user manual will provide the basic knowledge for operating the OraLite optical system. Video tutorials will cover the in-depth working mechanism of the system. There will be a 3-D model of the product, developed using AutoCAD, to give the users an overall working view of the product. Technical support will help the end users if they have any questions about the performance of any part, or if they have any trouble regarding the use of the OraLite optical system. The FAQs will cover the potential questions that the end users will have in their mind regarding the product.

7. Test Procedures

IDENTEC has devised a rigorous set of testing procedures to ensure proper device functionality and safety. Preliminary testing has already been completed with the materials the IDENTEC team is currently working with, and will be detailed here.

7.1 Light Source Spectrum Analysis

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 decided that a near UV light source provided the best visible contrast while complying with Health Canada safety standards for a light source.

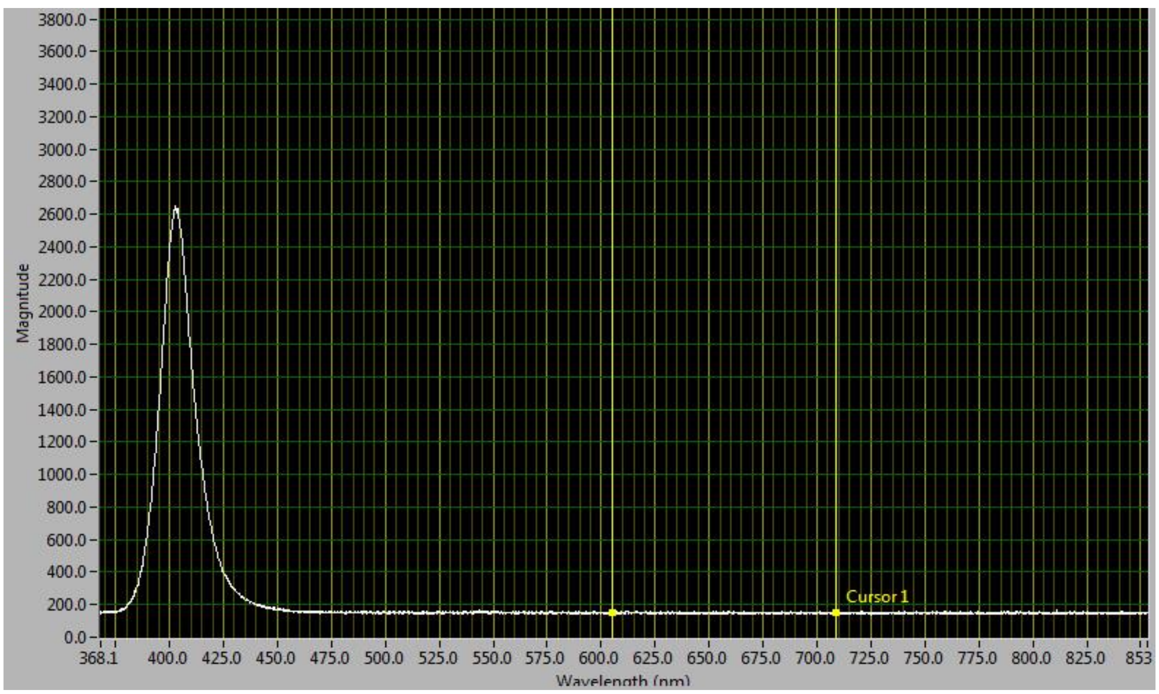

Figure 3: Light source output spectrum

Figure 3 displays the output of the OraLite light source as measured by a spectrometer. The source has a peak of 405nm and a full width at half maximum of 17nm. The source provides a narrow spectrum of light that stays well within the safety guidelines for a light source. Nonetheless, when the system is completed a rigorous series of tests will be conducted to measure the luminosity of the source and determine safe operational procedures in accordance with guidelines set by Health Canada.

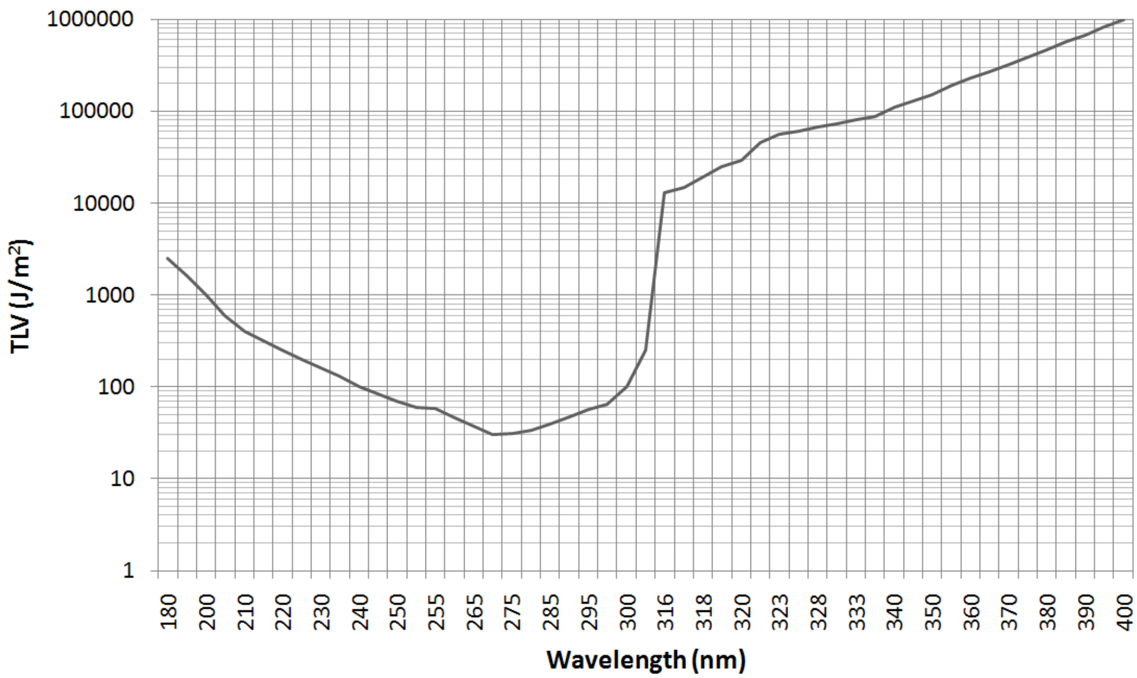

Figure 4: Occupational Exposure Limits (OEL) for light wavelengths [8]

Figure 4 details the Threshold Limit Values (TLV's) for skin exposure to UV light. Shorter wavelengths have a very low exposure limit while longer wavelengths have much longer exposure limits. Additionally, the total irradiance of UV-A Spectral Region (315 to 400 nm) on the unprotected eye is limited to 1.0 milliwatt per square centimetre for periods greater than 16.7 minutes and to 1.0 joule per square centimetre for shorter periods [9].

Since the OraLite system has minimal power in the sub-400nm range, and will not be shining directly into the eye for extended periods of time, IDENTEC does not expect to have any major safety concerns with the light source.

7.2 Tooth Sample Spectrum Analysis

Using the light source detailed above, preliminary testing was performed on extracted human teeth to ensure that visual separation of the materials was possible. In order to collect precise data, a more sensitive spectrometer was required than that used for the light source. IDENTEC would like to thank Derek Sahota for the use of his optics lab, spectrometer and expertise in spectral analysis. The results in the following sections would not have been possible without his help.

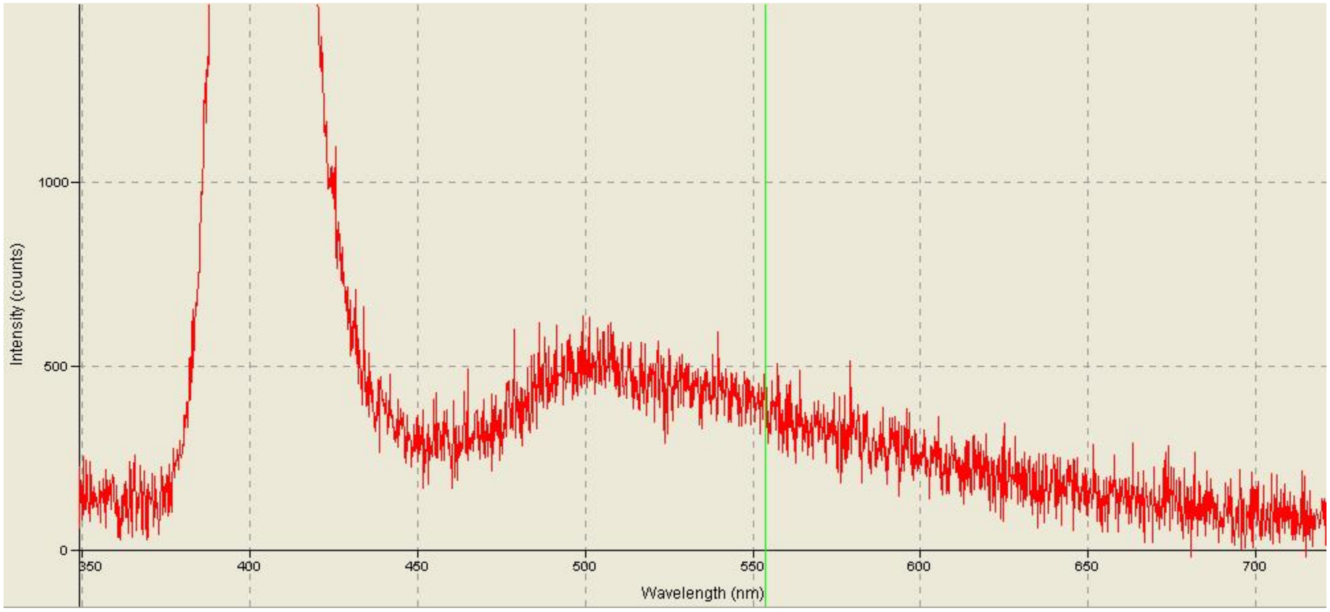

Figure 5: Spectrum of fluorescence emitted from material within tooth

Enamel, the hard material that coats the outside of our teeth, does not display any fluorescence under the OraLite light source. However, the materials found within a tooth, mainly dentin, do display a fluorescent signal. Figure 5 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.

7.3 Composite Filling Sample Spectrum Analysis

Using the same apparatus as the tooth sample spectrum analysis, preliminary 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.

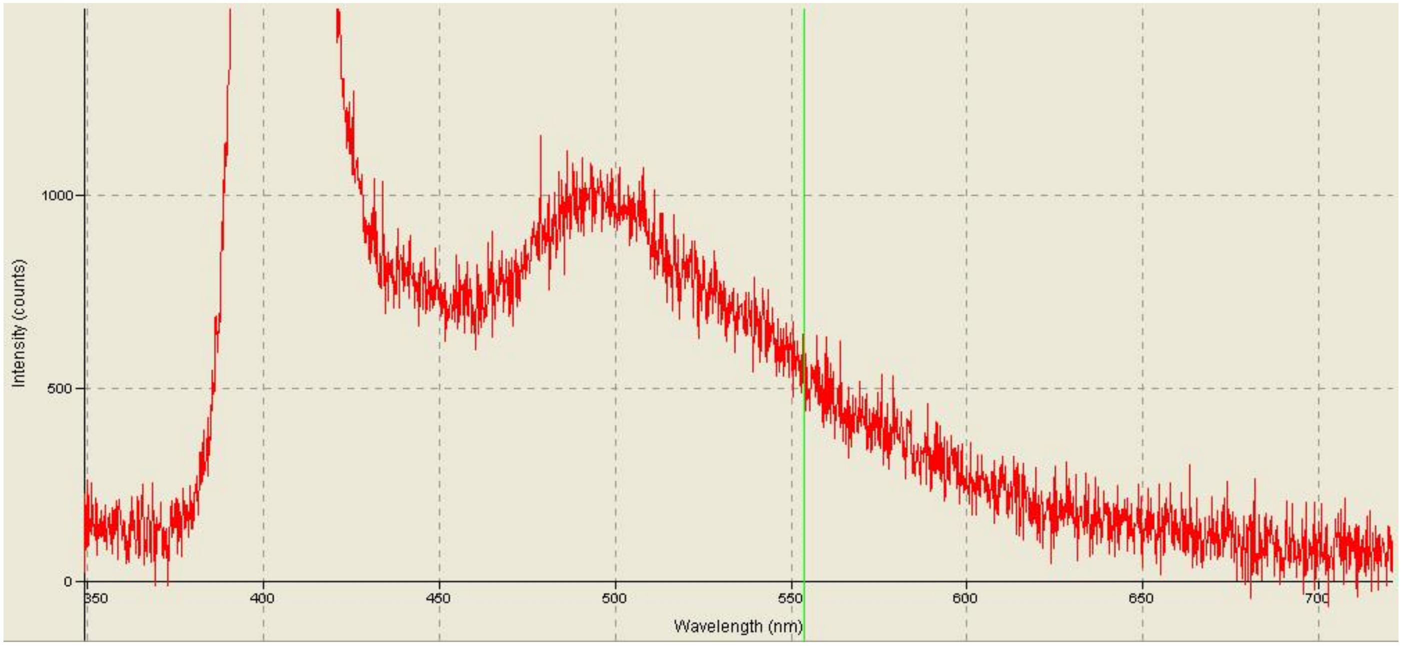

Figure 6: Spectrum of fluorescence emitted from composite filling material

Figure 6 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. Furthermore, the spectrum displays a considerably stronger intensity than the signal emitted by material from inside the tooth.

Using the data collected from these preliminary tests, a 460/60 nm BrightLine® single-band bandpass filter from Semrock Inc. was selected for the prototype. The filter will allow the user to see light from 430nm to 490nm, while blocking other visible wavelengths. This should highlight the composite material, while still allowing the user to see the tooth and surrounding tissues.

Further spectral testing will be performed upon completion of the prototype to ensure that the filters provide optimal performance.

7.4 System Functionality

Significant testing is to be performed on the completed prototype of the OraLite system to ensure good visual differentiation and ease of use. Testing staff will ensure that the system is able to clearly differentiate between composite filling material and material both on the exterior and interior of the tooth. Furthermore, functionality testing will be performed on all available types of composite material from manufacturers.

Once the prototype is deemed to be working, Dr. Brian Bostrom will perform a composite filling removal while using the OraLite. His feedback will be used to fine tune the final product.

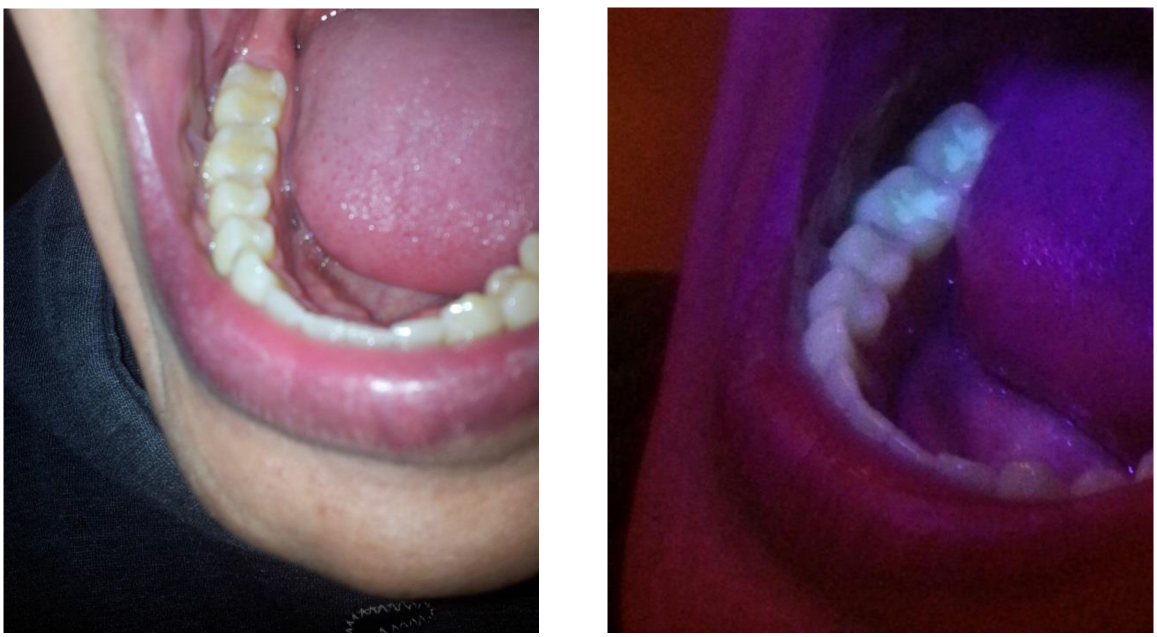

Figure 7: Preliminary OraLite Test

Figure 7 displays the results of a preliminary test of the OraLite system conducted using a simple 410nm longpass optical filter. The left image is the view of a mouth under normal light conditions, while the right image is viewed using the OraLite system. Visual differentiation of tooth and composite material is clearly visible in the OraLite image. Further contrast enhancement should be possible using the 460/60 nm BrightLine® single-band bandpass filter described above.

8. Conclusion

This functional specification document clearly describes the capabilities and requirements of the OraLite optical system. We have presented our ideas in a consistent and systematic way leading to the development of the final product which contains three major components: the adapter, light source and filter systems. Each component has been assigned requirements of various priorities. High priority requirements, denoted in this document by “I”, pertain to the prototype system and are essential to the functionality of the OraLite system. Medium priority requirements, denoted in this document by “II”, represent prerequisites that need to be met to move from a prototype to a marketable product. Low priority requirements, denoted in this document by “III”, indicate final concerns that need to be addressed in the final product. All three components of the OraLite are being developed simultaneously and we are confident in our ability to achieve all functional requirements outlined above by the target date of November 28, 2013.

9. Sources and References

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