ECE 445: Senior Design

Specialized Camera for Medical Applications

Team 6

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1. Introduction

1.1 Problem

What humans can see is subjective, inconsistent, and, most importantly, limited. In several fields, we rely solely on human vision to determine problems and solutions; however, some areas require higher resolution, wider spectral ranges, and consistent data. In a medical context, the ability to capture a variety of spectra, including those invisible to the naked eye, at a consistently accurate level can improve the assessment abilities of a medical professional, especially in surgical tasks. According to SpectralMD, limited tools are currently available to determine tissue health[1]. Multispectral imaging (MSI) can help alleviate this issue as doctors will be able to use light emitted in UV/NIR spectrums to speed up tissue diagnosis'. Additionally, combining color imaging with NIR bands can help to locate and distinguish between tumors and surrounding tissues.

Existing endoscope technology typically uses RGB endoscopes, which are confined to the visible spectrum, thus limiting the number of tissue layers it can show as visible light cannot "penetrate through the surface of the skin" [2]. A multispectral camera will allow "the physician to extract intrinsic properties and structures of specific tissues which are not visible to a human eye"[2]. MSI will allow for improved real-time diagnosis rather than invasive, time-consuming procedures. As a direct result, patient care will be expedited, and diagnoses will occur faster. MSI enhances inspection capabilities for various applications and fields but has the potential to be a very beneficial tool in the medical field.

1.2 Solution

Our solution will be a handheld device with an integrated camera sensor capable of multispectral imaging across the UV, visible, and NIR spectra with real-time visualization. NIR wavelengths go much further into tissue, so the ability to capture that data is crucial. A user will be able to hold the sensor above any object for which light can pass through and see the three different spectra displayed on a monitor. The device will be wired for power and contain an image sensor and microcontroller that is USB compatible so that it may be connected directly to a display. The image will be processed to show the three spectra (UV, NIR, and visible) on separate windows instead of as one direct image on the display. Our solution is novel compared to other medical handheld imaging devices, such as endoscopy cameras, due to the ability to capture multiple spectra in such a small device.

1.3 Visual Aid



1.4 Goals and Benefits

Through this project, our goal is to create a device that can capture multiple spectra so that it may be used in tandem with existing medical protocols to make solving medical issues and diagnoses easier. A successful project would enable physicians to see much further into the tissue to diagnose faster and less invasively. The device may also be used in other capacities, such as during surgery, to make tumor detection and removal easier.

1.5 High-level requirements list

- The device is able to display real-time video at a rate above 20 frames per second. - The device has the ability to capture signals within a spectrum of 200 - 1000nm (UV, visible, NIR).

- The device has the maximum dimensions of 2" by 2" by \sim 7" handheld enclosure.

2. Design

2.1 Block Diagram



2.2 Subsystem Overview and Requirements

Image Sensor Subsystem

- An image sensor, chosen to be an OnSemi AR0522, captures image data across the UV, VIS, and NIR spectra. This data is sent to the microcontroller over MIPI (Mobile Industry Processor Interface) CSI2 (Camera Serial Interface 2) to the controller.
 - Requirement 1: The imager must be MIPI CSI2-compatible.
 - Requirement 2: Must have a monochrome sensor with quantum efficiency levels of at least 10% at 380 nm and 10% at 700 nm.

Control Subsystem

- A microcontroller, chosen to be an Infineon CYUSB306X, processes the image data from the imaging system and prepares the video data to be sent to the monitor over the USB (Universal Serial Bus) 3.0 interface.

- Requirement 1: The microcontroller must be MIPI CSI2 and USB 3.0 compatible -Requirement 2: Image data must cover the UV, VIS, and NIR segment spectra and must be processed at a rate of 40MB of image data per second

Power Subsystem

- Power is provided over USB PD (USB Power Delivery) and distributed to the rest of the system through individual voltage regulators per power pin.
 - Requirement 1: The power subsystem must be able to supply at least 300 mA to the image sensor subsystem continuously at 1.8 V for I/O operations, 2.8 V for analog power, and 1.15 V and 3.3 V for digital power, +/- 0.1 V.

Requirement 2: The power subsystem must be able to supply at least 140mA to the control subsystem continuously at 1.2 V for core operations and 1.8 to 3.3 V for I/O operations, +/- 0.1 V.

Enclosure

- The system will be enclosed in a pen-like structure, with the camera on one end and a wire coming out of the other, connected to an external monitor for power input and video output.
 - Requirement 1: The size will be a maximum of 2in x 2in x 7in.

2.4 Tolerance Analysis

One of the constraints for our project from Professor Gruev is for the device to detect *no more* than 3 cm in any direction from a distance of 2 cm away; as a result, the "field of view angle" for the image sensor has to be 74 degrees. Anything less than or greater than this field of view angle would provide a larger/smaller field of view, which, in turn, would go against the goals of this project. Below is the mathematical analysis that supports the angle chosen.

Additionally, the image sensor must be able to process X pixels * 20 frames per second = Y Bytes per second.

3. Ethics and Safety

Development: Faulty development can lead to complications in the operating room. (e.g., misdiagnosis or incorrect incisions) which will be a detriment to patient health and safety. To avoid harm, before a potential clinical usage, a well-documented and thorough review of the fidelity and technical quality of the project by various experts within the field will be performed. Areas where the team's developers are not competent will seek consultancy from appropriate experts.

We envision accidental misuse as the result of not knowing the product's limitations when used in a clinical setting. This is an imperative factor to consider when we are concerned about patient safety. Aspects such as the device's longevity and where it can be used in a patient setting will need to be standardized to avoid any potential complications. Additionally, the attributes necessary to determine diagnosis must be tested with the device so patients are not misdiagnosed.

Safety and Regulatory Standards Industry Standards: Within the medical device industry, regulations will be determined by the intended use case of the technology. For instance, if the desire is to use it as a preliminary tool for a patient diagnosis of skin cancer, it could potentially qualify as a Class II device and follow the FDA's guidelines for further development in a clinical

setting. However, if there were a demand to use such a product as a small surgical tool, the product would undergo a stringent regulatory review known as Premarket Approval as it likely qualifies as a class III device.

4. Sources

[1]

https://www.spectralmd.com/wound-healing-technologies/multispectral-imaging/#:~:text=Multispectral%20Imaging%20in%20Diagnostic%20Medicine,visible%20to%20the%20human%20eye.

[2]

https://news.jai.com/blog/multispectral-imaging-in-healthcare-a-convolution-of-machine-vision and-spectroscopy

[3]

https://www.ethics.uillinois.edu/compliance/university_code_of_conduct

[4] <u>https://www.acm.org/code-of-ethics</u>