
ELECBME 5P06 Final Report

SpectraStream: A Urinary Multispectral Sensing Device for Point-of-Care Monitoring and Diagnosis of Chronic Kidney Disease

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SUMMARY

Chronic kidney disease (CKD) and related pathologies impair the kidney's ability to filter blood. Symptoms do not appear until the late stages of the disease when there is already irreversible kidney damage. Consequently, in the United States, CKD is a leading cause of death, and the healthcare system spends billions of dollars on treatments, such as dialysis and kidney transplants, which are burdensome to undergo.

Creatinine is a waste product generated from muscle metabolism that circulates in the blood until filtered into the urine by the kidneys for excretion. It is a biomarker for kidney health, where low concentrations in the urine indicate kidney impairment and the possible presence of CKD. There are no point-of-care methods for accurately quantifying creatinine levels in the urine or blood. The cost, complexity, and required training associated with current CKD diagnostic and monitoring procedures present significant obstacles within healthcare systems by adding strain to already burdened facilities and healthcare personnel. Thus, there is a clear need for streamlined CKD diagnostic and monitoring solutions to catch the disease in the early to middle stages and generate more autonomous treatment monitoring.

SpectraStream is intended to be a low-cost, portable, accurate and easy-to-use spectrometer leveraging recent advancements in miniaturized multispectral sensing technology to quantify urinary creatinine levels at the point-of-care (PoC). The proposed device involves a straightforward operating procedure where users collect a urine sample, mix it with a test tube prepackaged with reactant to produce a creatinine-dependent colour change, and analyze spectral differences using the sensor readings. SpectraStream measures intensity levels of incoming light across fourteen colour channels spanning the visible, near ultraviolet (UV), and near-infrared (NIR) spectra. The device features a low-complexity 3D-printed PLA chassis that houses a PCB, integrating an ams OSRAM AS7343 multispectral sensor, a high-powered LED light source, an ESP32 microcontroller, user peripherals, and a rechargeable lithium-ion battery management chip. A 3,5-dinitrobenzoic acid reaction enables the multispectral sensor to detect changes in creatinine levels, manifesting as various spectral absorbance changes within the 350 nm to 700 nm wavelength range. A simple physical button setup and OLED display permit the user to readily initiate a urine sample scan and send creatinine concentration data to a healthcare professional over the cloud for assessment. With a unit cost ranging from \$50 to \$80 and a compact form factor that fits within a 20 cm cube, SpectraStream aims to provide a streamlined means of estimating urinary creatinine concentration and kidney health.

The potential impact across the healthcare industry is significant, given CKD's high prevalence and the prohibitive costs and complexities associated with conventional lab equipment for diagnosing and monitoring CKD. The design's low cost, straightforward operation steps, and portability make it an ideal choice for at-home monitoring of urinary creatinine concentration, offering substantial value to users afflicted with CKD or those concerned about their kidney health.

DESCRIPTION

SpectraStream is an affordable, miniaturized, and easy-to-use point-of-care spectrometer for at-home monitoring of creatinine, an important biomarker for chronic kidney disease. By mixing a urine sample with chemicals to produce a colour change, creatinine concentration is analyzed through multispectral sensing.

Streamlined kidney health monitoring is required to reduce the billions of dollars annually spent on chronic kidney disease treatment. SpectraStream is an affordable, portable, and easy-to-use spectrometer for accurate at-home monitoring of kidney health through multispectral analysis of a urine sample - aiming to provide early insight into kidney complications.

DECLARATION OF ACADEMIC ACHIEVEMENT AND CONSENT

As a future member of the engineering profession, the student is responsible for honestly performing the required work without plagiarism and cheating. Submitting this work with my name and student number is a statement of understanding that this work is my own and adheres to the Academic Integrity Policy of McMaster University and the Code of Conduct of the Professional Engineers of Ontario.

Submitted by Evan Gintonis, gintonie, 400198214

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LIST OF ABBREVIATIONS AND SYMBOLS

ADC	Analog to Digital Converter
ANOVA	Analysis of Variance
AoI	Angle of Incidence
BoM	Bill of Materials
CKD	Chronic Kidney Disease
DNBA	3,5-Dinitrobenzoic acid
iBioMed	Integrated Biomedical Engineering
I2C	The Inter-Integrated Circuit I2C serial communications protocol
IC	Integrated Circuit
LDO	Low-Dropout Voltage Regulator
MLR	Multiple Linear Regression
NIR	Near-Infrared
NIRS	Near-Infrared Spectroscopy
OLS	Ordinary Least Squares
PCB	Printed Circuit Board
PoC	Point-of-Care
PoCT	Point-of-Care Test
RGB	Red, Green, Blue
SDK	Software Development Kit
SDS	Safety Data Sheet
SNR	Signal-to-noise
UART	Universal Asynchronous Receiver Transmitter serial communications protocol
UTI	Urinary Tract Infection
UV	Ultraviolet

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1. CHAPTER 1: PROJECT PROPOSAL

1.1 TEAM CHARTER

Team Charter

Team Number: 27

Please list full names and MacID's of all Team Members.

Full Name:	MacID:
Lauren Stephens	stephl4
Ernest Spahiu	spahiue
Evan Gintonis	gintonie

Roles and Responsibilities

*In this section, you can identify who will be responsible for what roles in a team. At this stage, you should focus on the high-level administrative tasks (e.g., taking meeting minutes, submitting documents to Avenue, scheduling meetings, communicating with instructors, etc.). However, as the project progress roles may expand and become more specific. As needed, you can attach an addendum to this charter and submit with future deliverables (important: the original team charter should **never** be changed once all team members have signed it).*

Roles assigned to Lauren:

- Taking meeting notes and completing stakeholder meeting documents
- Ensuring team adheres to proposed Gantt chart/WBS
- Becoming subject matter expert on clinical applications
- Completing initial hardware and optical design

Roles assigned to Ernest:

- Submitting documents/assignments to Avenue
- Communicating on behalf of the team to schedule meetings, clarify instructions, or ask questions with teaching staff/stakeholders
- Becoming subject matter expert on existing technology
- Completing initial low/high-level software design

Roles assigned to Evan:

- Maintaining the OneNote notebook with relevant rubrics, planning documents, and prototyping notes
- Organizing team members calendars and sending invites/booking room space for meetings
- Becoming subject matter expert on multispectral colour sensing
- Completing initial hardware and mechanical design

Expectations of Behaviour, Work Ethic, and Professionalism

Summarize what will be expected of all team members.

- Examples can be found in Breakout Box 2.2 of [Chapter 2 excerpt from Biomedical Engineering Design](#).

It is expected all team members:

- Meet all assigned deadlines, or communicate struggles meeting deadlines at least 2 days in advance
- Show respect when communicating with team members
- Contribute ideas and give constructive criticism where appropriate
- Attend and participate all scheduled group activities, arrive on time and prepared
- Show proper time management by giving oneself proper time needed to complete tasks

Communication and Documentation Management

This section is intended to outline the frequency of meetings, who is expected to attend each meeting, and the expected format for meetings (e.g., in-person vs. virtual). You should also describe where documents will be stored (e.g., OneDrive, Google Drive, MS Teams, etc.).

- Team meetings will be held on virtually on MS Teams when appropriate
 - Team meetings will involve all members attending
 - Team meetings will happen ~1 time per week on normal weeks, with frequency increasing when major deadlines are approaching
 - Team meetings will typically be held in the evenings, starting around 7-9pm
- Subteam meetings will be held virtually on MS Teams when appropriate
 - Subteam meetings will involve members on that subteam (ex. hardware subteam, software subteam, etc.)
 - Team meetings will happen when necessary
- Stakeholder meetings with Dr. Koven will be held on MS Teams
 - Stakeholder meetings will involve all members attending, with the addition of Dr. Koven
- Internal team notes will be stored in OneNote
- Assignment drafts will be stored in OneDrive and uploaded to the MS Teams channel for easy access

Other Commitments

List anything team members should be considerate of when scheduling meetings, assigning tasks, or working towards deadlines. Examples include, but are not limited to, midterm schedules, work schedules, availability limitations due to weekend availability (e.g., due to commuting), scheduled time out of town, religious observances, etc.).

Lauren's Commitments:

- EFRT responder

- Involves being "on-call" ~4-6 times per week and training once a month (usually last Friday of the month)
- At these times Lauren may be reachable if she is not with a patient, but may be unreachable at any point if she is responding to a call
- Midterms scheduled for October 23rd, October 30th, and November 3rd

Evan's Commitments:

- McMaster Mars Rover Team Senior Member (commitment schedule is very flexible)
- Midterms schedule for October 23rd and October 30th

Ernest's Commitments:

- Work: Involves Thursday afternoons and occasional weekends where he may be slow to respond/unavailable
- Recreation and Fitness (flexible): Usually busy from 9:30 – 11 am for classes and recreation, still reachable.
- Midterms: October 18th and October 23rd

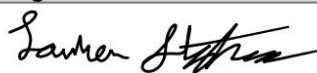
Conflict Management and Accountability

Explain how you are going to manage conflict should it arise. The focus here should be on resolution rather than punitive measures. Section 2.5 from the [Biomedical Engineering Design textbook](#) is an excellent resource that you are encouraged to review.

A major potential conflict that can arise is a team member failing to deliver on deadlines consistently, or not doing their fair share of work. The first step to managing conflict will be a verbal "first warning" to the team member, in which the team member would be expected to communicate how they intend to improve on delivering quality work on time. The others bringing forth the issue should focus on being as open and non-judgmental as possible. If the team member does not improve, the second step would be to get help from faculty and teaching staff.

In general, the team should try to manage conflict by addressing it early, listening to feedback openly, and striving for resolution within the team.

By signing below, all team members certify agreement with the team charter as outlined below.

Full Name:	Signature:	Date
Lauren Stephens		10/03/23
Ernest Spahiu		10/03/23
Evan Gintonis		10/03/23

1.2 MOTIVATION

Healthcare systems in Canada and the United States are more strained than ever with the rising population and economic pressures resulting from the COVID-19 pandemic. Healthcare professionals, such as Dr. Alex Koven from the University of Toronto, the inaugural stakeholder for the SpectraStream project, are pushing for more patient-centred and streamlined clinical diagnostic and monitoring procedures in urology. A point-of-care test (PoCT) is a diagnostic test performed outside a clinical lab, typically within the patient's home. PoCTs are an example of a growing trend toward efficiency and convenience in healthcare, as they have seen a steady increase in popularity over the past 40 years since their introduction [1]. The effective integration of PoCTs in solving clinical problems, such as diagnosing or monitoring urological conditions like chronic kidney disease, will help relieve healthcare resources, yield quicker clinical decisions, and generate more positive patient outcomes.

The fundamental motivation behind SpectraStream is the recent development of multispectral sensing technology. Unlike typical RGB colour sensors, which only possess photodiodes sensitive to red, green, and blue light, multispectral colour sensors possess an array of colour channels across the near UV, visible and NIR spectra [2]. Dr. Koven has demonstrated the application of near-infrared spectroscopy (NIRS) for evaluating bladder health [3]. Thus, multispectral sensing could open pathways for PoC methods that utilize light's interaction with biological tissues or substances to quantify a person's health.

One of the first concerns in incorporating multispectral sensing as PoCT is the challenge of portability. Commercially, a primary advantage of PoCTs is their small form factor, allowing one to operate the device themselves or a healthcare professional to perform analyses at the bedside [4]. However, multispectral sensors have historically been considerably large due to their usage in terrain and satellite imaging [5],[6]. A secondary drawback of NIRS and similar clinical techniques is the bulky connecting optic cables required for operation [3]. However, advancements in optical filter design and electronic chip manufacturing have resulted in miniaturized chip-based multispectral sensors like the AS7343 from ams OSRAM [2]. The AS7343 possesses an area of no more than 10 mm² in area and offers sufficient sensitivity to light intensity changes [2]. Another vital issue for healthcare professionals and patients is the prohibitively high cost of multispectral equipment, with commercial prices reaching around 5000 USD [6]. Given that one of the general goals of PoCT testing is to reduce relatively expensive care and encourage more patients to be assessed and treated, the relative cost of multispectral sensors in the past has been counterintuitive to implement in most of these clinical initiatives. Contemporarily, it is possible to apply recent advancements in low-cost miniaturized multispectral sensing to address the low-cost requirement of PoCTs and create a commercially feasible device, as products like the AS7343 typically cost \$10 per unit [6].

Our group aims to develop a cost-effective and portable multispectral PoCT device for the detection and management of pathologies in the field of urology, empowering clinicians and patients with convenient diagnostic insights to reduce strain on the healthcare system.

1.3 IMPACT

Developing effective PoCT devices in urology could have broad implications for healthcare systems and economic landscapes. For instance, the United States healthcare system spent \$124.5 billion on CKD treatment costs in 2019 as it is a leading cause of death [7]. Kidney impairments are some of the most common health problems seen by primary care physicians and contribute to a heavy economic burden concerning expenses relating to treatment and prescriptions - costs only expected to increase with time. CKD is one of the many pathologies, like liver disease and diabetes, with the potential for remote monitoring with a low-cost multispectral PoCT device because they are linked to urinalysis [8]. Urinalysis in PoC settings using dipsticks or some lab-based tests relies on mixing urine with chemicals or enzymes that produce a colour change indicating the state of health [8]-[11]. Therefore, the success of realizing a multispectral PoCT for urinalysis can significantly reduce the costs associated with urinary pathologies, particularly in expenses related to hospital stay, travel and associated lab testing. Cost reduction in healthcare is critical in today's political climate, where many countries are having to limit growth in healthcare spending to tame budgets [4]. Stakeholders, such as Dr. Koven, benefit from reduced patient hospital visits and durations of stay, as overburdened hospitals can allocate more resources to the most at-risk patients, thereby improving the overall congestion in a society's healthcare network. The patients themselves also see immediate benefits, such as the convenience of bedside care and a lower number of required clinic visits. Additionally, one can argue that PoCTs benefit equity in society as such devices are valuable to vulnerable populations in remote communities who may otherwise not have access to care. Furthermore, PoCTs can improve awareness in at-risk groups who may not have considered standard care a prior option [4].

1.4 BACKGROUND AND LITERATURE REVIEW

A urinalysis test is imperative for diagnosing and monitoring many disorders, including urinary tract infections (UTIs), kidney diseases, liver diseases, and diabetes [8]. The production and elimination of urine involve many body functions and can give insight into the balance of water in the body, metabolic processes, and waste elimination [8]. Urine is also rich in biomarkers, and sample collection is simple, non-invasive, and non-biohazardous, making it a critical PoCT [9].

A complete urinalysis examines the chemical, microscopic, and physical properties of urine [8]. A chemical exam involves testing the sample using a dipstick with several chemical reactants attached to it. The reaction produces a colour change, which can test for blood cell presence, sample pH, and glucose concentration [10],[11]. Furthermore, colourimetric urinalysis can detect creatinine, bilirubin, ketone bodies, or nitrites [10],[11].

For applying multispectral sensing in this project, colour changes are of interest. Urine is typically pale yellow due to urochrome, a yellow-pigmented waste product [10]. During dehydration, antidiuresis ensues, and water is reabsorbed from the collecting duct of the kidney nephron, resulting in more concentrated and darker yellow urine [12]. Other colours can suggest other pathologies, such as orange indicating liver or bile duct problems, red indicating gross hematuria (blood in the urine) or porphyria (liver disorder causing a buildup of porphyrins), and green indicating a UTI [10], [11]. Certain medications and food can also induce a change in urine colour

[10], [11]. As previously discussed, one can employ chemical reactants to produce urine sample colour changes in the presence of specific biomarkers.

Patients or clinicians use a heavily subjective 8-point colour scale to assess urine colour, but there has been some effort to quantify the value. Belasco et al. [12] used a spectrophotometer to measure urine colour and expressed it in the $L^*a^*b^*$ colour space. L^* indicates the lightness of the sample (ranging from 100 as white to 0 as black), and a^* and b^* are colour directions ($+a^*$ is the red axis, $-a^*$ is the green axis, $+b^*$ is the yellow axis, and $-b^*$ is the blue axis). The $L^*a^*b^*$ parameters were used to train a multiple regression model to predict the osmolarity of the urine, which relates to the hydration status of the participants. They found an increase in dehydration resulted in darker and more significantly yellow urine and that the $L^*a^*b^*$ model accounted for 74% of the variance in osmolarity. This study, published in 2020, claims to be one of the first to use objective colour measurements to assess hydration [12].

Symptoms of diabetes insipidus are polyuria (frequent urination) and polydipsia (excessive thirst), leading to the excess production of dilute urine [10]. In a conference paper, Fajrin et al. [13] used the TCS3200 red, green, and blue (RGB) colour sensor to diagnose diabetes, noting that diabetic samples were more transparent with less sediment. Using ten diabetic non-diabetic samples as training data, they diagnosed diabetes with 100% accuracy in ten test samples [13].

Lafuente et al. [14] developed a urinometer to measure the flow and colour of urine in catheterized patients. They employed a TCS34725 RGB sensor to automate the detection of hematuria and stated they were looking to validate their design with other urine discolouration pathologies. They showed the sensor could discern between different colours, opacities, tonalities, and brightnesses by testing liquid samples prepared by mixing water with various dyes. They also acknowledged the colour sensor's typical error range of $\pm 2\text{-}5\%$ and that these deviations from the actual colour values may pose problems when detecting small urine colour changes [14].

Devices manufactured to detect colour changes are available from several companies. One such example is Nix Sensors, which invented a portable colour sensor unit comprised of a printed circuit board (PCB), LED light source, and “true colour sensor” [15]. Readings obtained from the sensor are fed through on-board integrated circuitry and transmitted wirelessly through Bluetooth [15]. The outputs can then be converted into several usable colour spaces, making the design applicable to a number of situations, such as identifying paint colours, measuring food ripeness, or conducting quality control of raw materials. Another China-based company has filed a patent for an RGB-based urinalysis device and processing method, although no commercial device is available [16].

In all the literature reviewed, there is no device that combines urinalysis and multispectral colour sensing. Multispectral imaging has seen the most applications in the satellite and agriculture sectors, with biomedical applications slowly developing [17]. One such advancement is in burn care, as multispectral imaging techniques have shown the potential to improve the accuracy of burn extent and severity assessment [17]. Urinalysis appears to be a promising field with respect to multispectral colour sensing in a PoCT environment, as existing colour-sensing devices fail to maintain appropriate sensitivity and precision.

1.5 PRELIMINARY DESIGN CRITERIA

The primary objective of this project is to leverage low-cost, miniaturized multispectral sensor technologies to design a PoCT device that can generate meaningful spectral outputs to assist healthcare professionals in making effective clinical decisions for the detection and management of pathologies in the field of urology. The design must adhere to the criteria outlined in Table 1-1 to meet the objective and Stakeholder needs. Each item is classified as a Technical, Economic, Environmental, Ergonomic or Societal criterion.

1.6 PROJECT PLANNING AND DESIGN PROCESS

The development cycle of the proposed multispectral colour sensing PoCT device involves problem definition, concept generation, concept evaluation, preliminary design, detailed design, and communication of results. The subsequent work breakdown structure (Figure 1-1) and Gantt chart (Figure 1-2) describe subtasks, timelines, and responsibilities.

The development cycle starts with problem definition. All members will perform a literature review on relevant subjects concerning the device, such as multispectral colour sensing, urinalysis, similar technologies on the market, etc. Collaboration with the Stakeholder, Dr. Koven, will commence with the inaugural goal of identifying the needs of the end-users of the device, patients, and healthcare professionals. Given sufficient information collection, device function, objectives, requirements, and constraints can be identified to complete the problem definition. All team members are expected to contribute to problem definition, with an estimated completion date of mid-late October.

After finalizing the device's function and purpose, concept generation must occur. Concept generation entails brainstorming ideas to adhere to the previously identified design criteria through various methods, like rapid ideation. Each team member should conceive at least one concept and then prepare a sketch, flowchart, or PowerPoint presentation to communicate the idea. Concept generation is expected to take one week following the completion of the problem definition.

Concept evaluation follows concept generation. A detailed decision matrix will be formed, weighing each potential idea against the design criteria. Collaboration with the Stakeholder is required to provide feedback on the generated concepts and decision matrix. Deciding an idea the Team and Stakeholder agree with defines the end of the evaluation stage. Concept evaluation is expected to take one week following the completion of concept generation.

Fourthly, preliminary design involves forging the first draft of the design segments of the multispectral spectrophotometer. Such design segments include mechanical, optical, hardware, low-level firmware, and high-level software. Firmware entails programming a microcontroller within the device, which interfaces with the multispectral sensor and a peripheral device, like a computer, that will run high-level software for colour data analysis and presentation. In preparation for the proof-of-concept presentations commencing at the end of November, an evaluation kit of the chosen multispectral sensor will be purchased to accelerate firmware development. The proof-of-concept unit for the device will consist of an inaugural mechanical and optical design based on the evaluation kit. The PoC is expected to display shifts in colour data based on changes to urine

sample colour with low-level software. The proof-of-concept unit can subsequently be used as a basis for high-level software development. Hardware design integrating the device's electronic components in a small form factor will happen simultaneously with PoC development. Evan will primarily work on mechanical design since he is interested in honing his 3D modelling skills. Lauren will tackle optical and hardware design since she is familiar with circuit design and optics from her electrical engineering courses. Evan will mentor Lauren in this endeavour since he has printed circuit board and optical design experience from extracurriculars, and his co-op. Ernest will primarily tackle software development as he has the most experience in this field based on academic courses and co-op experience. Ideally, the preliminary design will be finished by the beginning of the Winter semester, with a week allocated to design reviews in early January.

Most of the Winter semester will be allocated to detailed design, which consists of prototyping, verifying test units against design criteria, and making design improvements where necessary. Meetings will be arranged with the Stakeholder at least once a month for design validation to ensure the end needs of the user are met.

Upon design completion, final documentation describing each design segment must be generated. Design drawings dimensioning mechanical and hardware components must also be exported. A final report and presentation summarizing all design information must be compiled for communicating the design and its performance to other engineers and researchers. Two weeks before the capstone expo and final report deadline have been allocated for communicating results, which all team members are expected to contribute to.

Table 1-1: Preliminary design criteria generated following an initial literature search and Stakeholder discussion. Each item is classified as a Technical, Economic, Environmental, Ergonomic, or Societal criterion.

Req. #	Category	Description and Reasoning
1	Economic	The device cost must lie within the price range of 25 CAD to 75 CAD – a similar price range to PoC blood pressure monitors [18].
2	Ergonomic	The device must be simple to use such that the complexity does not exceed that of a COVID-19 Rapid Antigen Test, a widely accepted PoCT [19].
3	Technical	The device must provide accurate measurements. This criterion shall be expanded upon during Design Configuration in Chapter 2 when the measured analyte has been identified.
4	Technical	SpectraStream must adhere to the rules & regulations surrounding a Class II diagnostic medical device in Canada.
5	Ergonomic	The device must fit in a 20 cm cube to ensure portability.
6	Societal	The device must be mass manufacturable. All PoCTs are widely distributed.
7	Technical	The device must operate in a room temperature range of 15-25 degrees.
8	Technical	The urine colour of interest must be in the visible light spectrum, approximately 380 to 700nm, for a multispectral colour sensor to detect it with multiple colour channels.
9	Environmental	Reagent(s) that manifest a colour change must be safe for at-home use and disposal.
10	Societal	The analyte quantified should be relevant to a condition that needs a PoCT to reduce healthcare system strain.
11	Technical	The electrical circuitry must include proper protection (e.g., a fuse) and a switch to break the electrical connection from the power source in an overcurrent event or emergency.
12	Technical	The device should be battery-powered to permit portability. The battery lifetime be expanded upon during Design Configuration in Chapter 2 when a clearer device description is outlined.
13	Ergonomic	Features, like buttons or handles, must be sized appropriately for older patients with reduced dexterity to operate the device.
14	Ergonomic	Any user interface must display instructions and results while maintaining an intuitive design for patients and healthcare professionals.

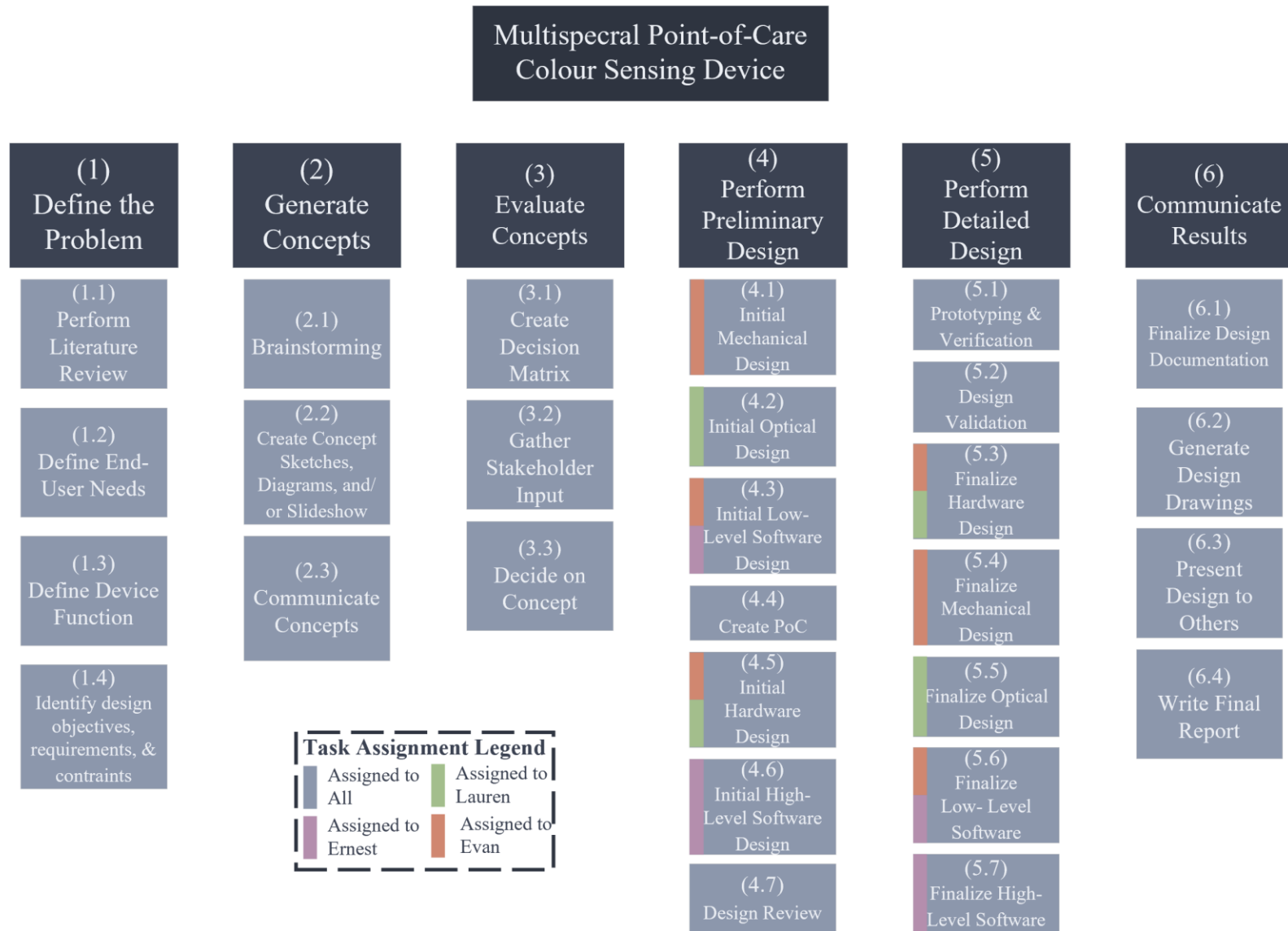


Figure 1-1: Work breakdown structure for the development cycle of the proposed multispectral colour sensing PoCT device.

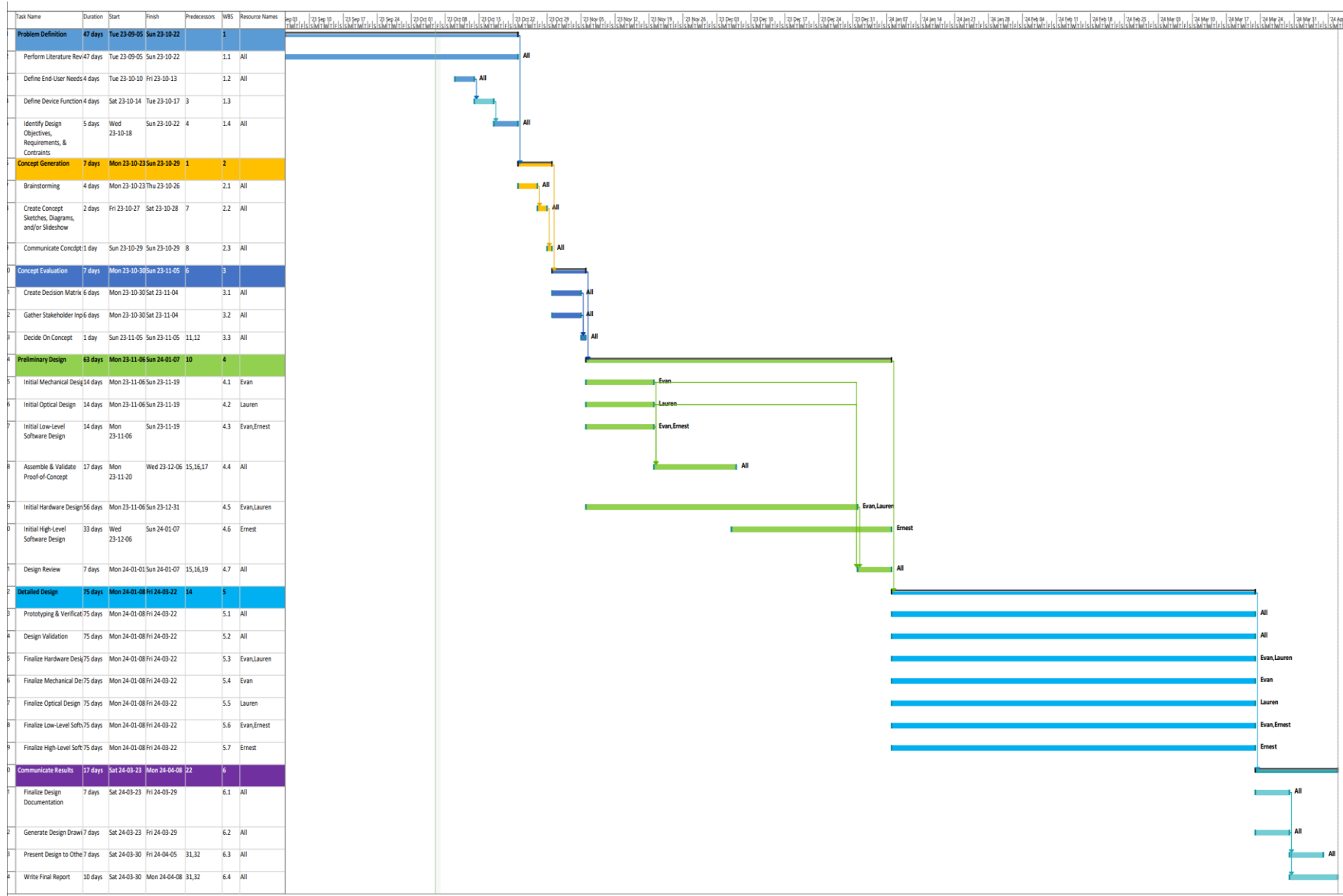


Figure 1-2: Gantt Chart for the development cycle of the proposed multispectral colour sensing PoCT device.

1.7 CHAPTER 1 REFERENCES

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2. CHAPTER 2: PROOF-OF- CONCEPT DESIGN CONFIGURATION

2.1 DESIGN INVESTIGATION

2.1.1 Chapter 1 Recap and Design Direction

As mentioned in Chapter 1, rapid population growth and economic tumbles, such as the COVID-19 pandemic, have tolled healthcare systems worldwide. There is a critical need for accessible and automated medical devices for diagnosing and monitoring common health complications, such as kidney, heart, or liver disease, in their early stages to reduce their financial and temporal impact on healthcare facilities and workers.

Urinalysis test strips are a simple and non-invasive PoCT that provides a gateway for examining the health of bodily systems [1],[2]. The user dips test strips coated with reagents into their urine, which produces visible colour changes in the presence of biomarkers like glucose, ketones, or bilirubin [3]. The user then crudely quantifies these biomarkers by comparing the test strip with a colour chart. The human eye is notoriously poor at colour matching since it only consists of cone cells sensitive to red, green, and blue light [4]. Quantifying complex colours such as yellow and purple rely on postprocessing from the brain, and colour-sensing performance differs highly from person to person [4]. Furthermore, variations in environmental lighting conditions can change the appearance of colour [4]. Consequently, most urinalysis tests accurately and precisely quantifying biomarkers involve sending a sample to a lab for analysis with a spectrophotometer or other sensing methods, which strains healthcare resources.

With developments in optical filter design and electronic chip manufacturing over the past three years, multispectral colour-sensing integrated circuits (ICs) have emerged which can quantify light intensity over many colour channels across the visible, near-UV, and NIR spectra [4],[5]. For example, the OSRAM AS7343 contains fourteen colour channels from 350 nm to 1000 nm (see Figure 2-1) [5]. Contrarily, legacy colour sensors only consist of red, green, and blue channels, like the human eye [4]. Following amplification and digitization of a colour channel's photodiode current, the multispectral sensor returns its ADC count: an integer value proportional to the intensity of the coloured light the channel detects [6]. Multispectral sensors are tremendously cheaper and smaller than lab-grade spectrophotometers. For instance, the AS7343 costs an average of 10 CAD per unit and boasts a 3.1 mm by 2 mm package size [5].

Following the project proposal and insight from new stakeholders, namely biophotonics experts Dr. Qiyin Fang and Tianqi Hong, SpectraStream, a low-cost, accurate, and portable spectrometer leveraging multispectral colour sensing, aims to bridge the gap between accurately and precisely quantifying analytes in the urine to relieve healthcare system strain.

2.1.2 Design Criteria

The following tables list updated SpectraStream design criteria, given the more specific direction of developing a PoC spectrometer to improve urinalysis accuracy. General (Table 2-1), chemical (Table 2-2), electrical (Table 2-3), opto-mechanical (Table 2-4) and firmware/software (Table 2-5) design criteria are listed. "Must" is used to indicate a mandatory requirement. "Should" is used to indicate an additional nice to have.

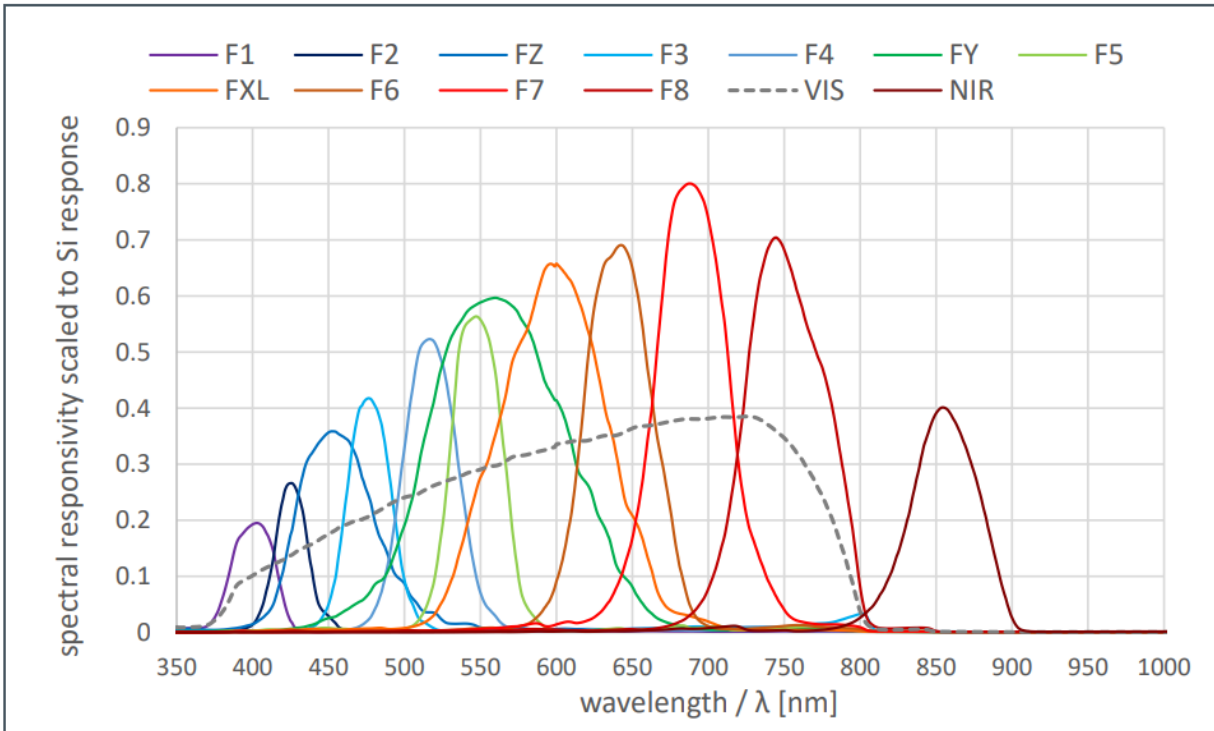


Figure 2-1: Spectral responsivities of ams OSRAM AS7343 colour channels [5].

Table 2-1: General design criteria.

Req. #	Description
1.1	The device cost must lie within the price range of 25 CAD to 75 CAD – a similar price range to PoC blood pressure monitors [7].
1.2	The device must be simple to use such that the complexity does not exceed that of a COVID-19 Rapid Antigen Test [8].
1.3	The device must provide accurate measurements of the chosen analyte, for example, within +/-2mM.
1.4	SpectraStream must adhere to the rules & regulations surrounding a Class II medical device in Canada.
1.5	The device must fit in a 20cm cube to ensure portability.
1.6	The device must be mass manufacturable. PoCTs are widely distributed.

- 1.7 The device must operate in a room temperature range of 15-25 degrees.

Table 2-2: Chemical design criteria.

Req. #	Description
2.1	The urine colour of interest must be in the visible light spectrum, approximately 380 to 700nm, for a multispectral colour sensor to detect it with multiple colour channels.
2.2	Reagent(s) that manifest a colour change must be safe for at-home use.
2.3	The analyte quantified should be relevant to a disease or condition that needs a PoCT to reduce strain on the healthcare system.

Table 2-3: Electrical design criteria.

Req. #	Description
3.1	The device must be intelligent enough to read ADC counts from the multispectral sensor and process data onboard or offload it to an external processing unit.
3.2	The electrical circuitry must include proper protection (e.g., a fuse) and a switch to break the electrical connection from the power source in an overcurrent event or emergency.
3.3	The multispectral sensor must reside in the optical area of the PCB - the space on the top of the board, inside an annular keep-out used to seal the board to the light path.
3.4	The multispectral sensor must be the only major component in the optical area. Tall chip components close to the sensor may interfere with the incident light.
3.5	The annular keep-out area sealing the board to the optics must be free of copper traces or vias, keeping the PCB area flat for a better seal.
3.6	The PCB solder mask must be black. Black solder masks absorb any additional light that misses the sensor. If not implemented, such light could reflect into the optical path and eventually reach the multispectral IC. The non-direct path taken by this light may skew the measurements slightly [9].
3.7	The light source must be powerful enough to illuminate the sensor and utilize the full-scale ADC range with an available photodiode current gain setting.
3.8	The spectral power distribution of the light source must be strong in the wavelength range used to quantify the urine analyte to ensure a sufficient signal-to-noise (SNR).
3.9	The device should be battery-powered to permit portability. The device should require charging or battery replacement after a minimum of 1000 scans.

- 3.10 The device should have Wi-Fi or Bluetooth capability for communication with external processors, such as a phone.

Table 2-4: Opto-mechanical design criteria.

Req. #	Description
4.1	The optical path between the light source and sensor must be light-tight to minimize leakage light to and from the sensor, which could skew results.
4.2	The sensor module must mount in the system such that the angle of incident light (AoI) on the sensor is $<10^\circ$. Filter shift may occur if light reaches the sensor at a large AoI, which will skew the measurements [9].
4.3	Mechanical parts concerning the optical path must be black for the same reason as Requirement 3.6.
4.4	The container which holds the urine sample must allow for transmission of the light wavelengths of interest.
4.5	Features, like buttons or handles, must be sized appropriately for older patients with reduced dexterity to operate the device.
4.6	Electrical components must be easily removable for servicing.

Table 2-5: Software and firmware design criteria.

Req. #	Description
5.1	Patient data sent to the cloud must follow the appropriate security regulations.
5.2	The user interface must display instructions and results while maintaining an intuitive design for patients and healthcare professionals.

2.1.3 Generation & Evaluation of Chemical Design Concepts

A literature review of common substances analyzed for lab-based urinalysis was conducted. Creatinine, glucose, and bilirubin were among those researched.

Creatinine is a widely accepted biomarker for the monitoring and diagnosis of CKD [10],[11]. A urinary creatinine concentration greater than 20 mM typically indicates renal impairment [10],[11]. The Jaffe reaction is the primary colourimetric method for estimating creatinine concentration reported by the literature [10]-[12]. When alkaline picrate mixes with creatinine, a red colour complex forms, resulting in changes in the solution's absorbance spectra from 350 nm to 600 nm [13]. Such absorption alterations are linear with creatinine concentration and measured using a lab-grade spectrophotometer, as shown in Figure 2-2 [13]. Despite its simplicity, cheapness and quick response time, the Jaffe reaction includes downsides [10],[11]. Picric acid is required to

create the reagent, an explosive chemical when dry [10]. The user must dilute the urine sample at least 10-fold for the reaction to behave linearly [10]. Lastly, the reaction has many interferents, such as temperature, pH, proteins, and other compounds in the urine, that generate systematic error [10]. Enzymatic and other colourimetric creatinine detection methods are present in the literature [10],[14],[15]. However, they are costly, complex, or not well-proven [10],[14],[15]. Since no PoCT for creatinine exists, CKD is a highly undiagnosed disease in the early to middle stages, making it a leading cause of death in the United States and a primary healthcare expense [16].

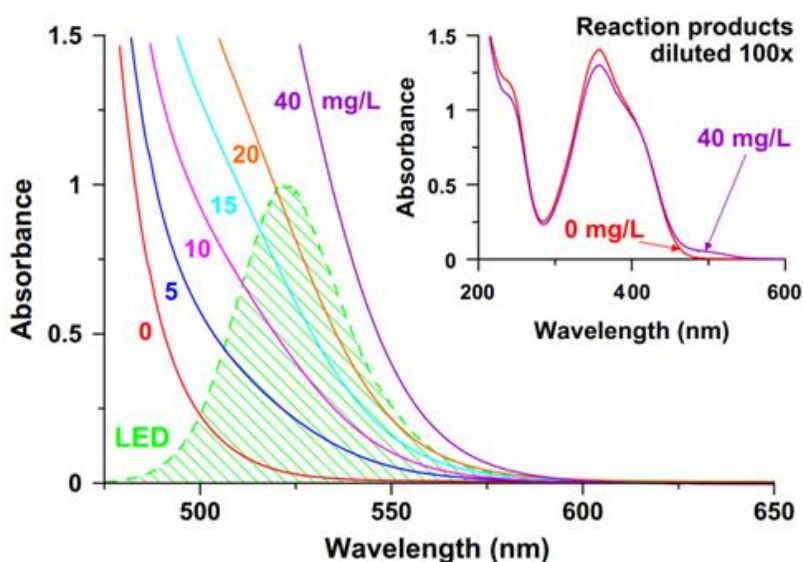


Figure 2-2: Jaffe reaction product absorption spectra with various concentrations of creatinine standards.

Glucose is the most analyzed component in the urine due to its relation to diabetes. Upon adding Benedict's reagent to a urine sample, one can observe a colour change from blue to green to red with increasing glucose concentration. Mitra et al. explored measuring such colour change with an ambient light sensor and using a blue LED as a source. However, the transmission spectra of the blue light were non-linear with glucose concentration, and Benedict's reaction required sample heating to 100°C for at least 10 minutes [17].

Excessive bilirubin in the urine indicates issues with the liver, gallbladder, or pancreas, which can lead to conditions like jaundice. Jaundice is highly prevalent in newborns, making bilirubin testing a necessity. The Diazo method and Fouchet's reagent are two methods of bilirubin detection that produce a blue colour with increasing bilirubin concentration. Both these reagents require extraction of bilirubin from the urine to a solid form through another chemical reaction or test papers. [18]

Table 2-6 shows a decision matrix based on the design criteria of cost simplicity, accuracy, safety, and impact. Scores were assigned for each criterion based on the above discussion. After analyzing the decision matrix, it was decided to pursue estimating creatinine concentration due to the cheap, simplistic nature of the Jaffe reaction and the driving need for a PoCT for CKD.

2.1.4 Generation & Evaluation of Electrical Design Concepts

The only company offering chip-based multispectral sensors is AMS OSRAM, a global leader in the optoelectronics industry. The existing spectral sensors in their catalogue include the AS7343, AS7265x, and AS7341. All sensors consume low power and rely on I2C communications to a host processor [5],[21],[22]. The primary difference between each sensor is the trade-off between cost, complexity, and number of spectral channels, summarized in Table 2-7 below. Since SpectraStream is intended for a PoC setting, the AS7343 was chosen as it was the cheapest option with a sufficient density of colour channels.

Table 2-6: SpectraStream chemical design decision matrix. Ratings are on a scale from 1-5.

Criteria	Req. #	Weight	Creatinine		Glucose		Bilirubin	
			Rating	Weighted Rating	Rating	Weighted Rating	Rating	Weighted Rating
Cost	1.1	0.15	4	0.6	3	0.45	4	0.6
Simplicity	1.2, 1.6, 2.2	0.15	3	0.45	2	0.3	1	0.15
Accuracy	1.3	0.25	3	0.75	2	0.5	3	0.75
Safety	2.3	0.2	2	0.4	5	1	5	1
Impact	2.4	0.25	5	1.25	2	0.5	3	0.75
Total		1		3.45		2.75		3.25

Table 2-7: Multispectral sensor options.

Sensor	Number of Colour Channels	Cost if Buying One Unit (CAD)
AS7343	11 channels over the visible spectrum. 1 NIR channel. One clear channel. 1 flicker channel.	\$14.12
AS7341	8 channels over the visible spectrum. 1 NIR channel. 1 clear channel. 1 flicker channel.	\$14.21
AS7265x	18 channels spaced 20 nm apart from 410 nm to 940 nm. Comes as a triad of 3 ICs.	\$47.93

2.1.5 Generation & Evaluation of Opto-Mechanical Design Concepts

The first step in the design investigation of the optical path is to choose an adequate light source. LEDs were chosen over lamp-based lighting as the light source modality due to their small form factor, reliability, low power consumption and cheapness. The light source was limited to a single white LED for the SpectraStream proof-of-concept. A white LED colour temperature of 4000 K was opted for since white LEDs of this type exhibit the most prominent power density in the 350 nm to 700 nm range detectable from the Jaffe reaction (see Requirement 3.8) [13],[23].

To ensure reliability and accuracy, it was decided to measure the transmission spectra of white light through the urine sample in a cuvette as this is the method colourimetric lab-based creatinine concentration tests employ with spectrophotometers [10],[11] (see Requirement 1.3). Since most glass cuvettes on the market are tinted to optimize the transmission of light through the side of the cuvette, the light source and multispectral sensor are oriented adjacent to each long edge of the cuvette (see Requirement 4.4).

2.1.6 Proposed Proof-of Concept Design Summary

In summary, SpectraStream estimates urinary creatinine concentration by measuring the transmittance spectra of the Jaffe reactant mixed with a diluted urine sample using a multispectral sensor. The user shall extract a urine sample, mix it with the Jaffe reactant and place the cuvette in the portable spectrometer. The device will compute creatinine concentration from the multispectral data through a statistical model and then display the results on the user's phone or an on-device screen.

2.2 MODELLING AND ANALYSIS

2.2.1 Proof-of-Concept User Flow

Having evaluated several possible candidate design ideas and choosing creatinine monitoring using the Jaffe reaction, the SpectraStream operating procedure is clear. With the design criteria in mind, a high-level user flow for SpectraStream has been developed.

1. First, the user will urinate into a cup for sample collection. This is consistent with traditional a urinalysis procedure.
2. Next, the user will extract a small volume of their urine using a disposable transfer pipette or syringe and place it inside the cuvette.
 - a. Volumetric analysis will be performed to develop a feasible protocol for the user to perform, which is described in Sections 2.2.2 and 2.2.3.
3. The user will then empty the preloaded vial of reagent solution into the cuvette.
 - a. This will contain alkaline picrate, which is used to form the colour-changing complex, along with the water needed for the dilution.
 - b. The user will cap the cuvette and shake, fully incorporating the urine, water, and reagent.
4. Finally, the user will place the cuvette into the device and begin the measurement process.
 - a. The colour change will take 15 minutes [12]. The user is free to leave the device and return later.
5. Behind the scenes, the device will wait for the reaction to finish, then measure the transmittance light colour using the multispectral sensor.
 - a. The device may send the sensor channel information to the user's phone/laptop through a secure means for processing.
 - b. An algorithm will be developed for predicting creatinine concentration from the channel values. This algorithm is described in Section 2.4.
6. This user will be notified when the reading is complete.
 - a. They can dispose of the solution and clean out the cuvette.
 - b. The measurement will be available for viewing on the user's phone/laptop. It will show whether that reading is within normal ranges, as well as a trend of creatinine concentration over time.

Overall, the final decision concept aims to provide an accurate creatinine concentration reading, informing the user on whether they fall within a normal range and allowing them to track it over time.

2.2.2 Urine Dilution Characterization

As discussed, the primary con of the Jaffe reaction for PoCT applications is the requirement for the urine sample to be diluted, with the literature showing dilution factors ranging from 20-fold to as high as 100-fold [12],[22]. The lower the urine dilution factor, the more feasible the procedure and the higher reduction in sample collection error. As such, this procedure will be used to characterize the Jaffe reaction, model the response of our multispectral colour sensor to the reaction, and determine the lowest possible dilution factor to ensure accuracy and ease-of-use for the user.

1. Dilute HCl with water to create 1000 mL of 0.1 M HCl.
2. Add 1 g of creatinine powder to the HCl solution.
 - a. This is our master creatinine stock solution with a concentration of 1g/100mL.

$$\frac{1 \text{ g}}{1000 \text{ mL}} \left(\frac{1000 \text{ mg}}{1 \text{ g}} \right) \left(\frac{1 \text{ mL}}{0.01 \text{ dL}} \right) = \frac{100 \text{ mg}}{\text{dL}} \quad (2.1)$$

- b. The final solution of 100 mg/dL emulates a typical urine creatinine concentration.
 - c. This stock solution can be diluted further to create various concentrations for testing. The dilutions tested can be found in Table 2-8.
3. Dissolve 1 g of crystalline picric acid in 100 mL of water to make a 1% solution of picric acid.
4. Add 1mL of the picric acid solution, 1 mL of 1 M NaOH, and 1.5 mL of water to a vial.
 - a. This is the Jaffe reagent with a total volume of 3.5 mL.
5. Add the vial of Jaffe reagent to 2.5 mL of the diluted stock solution.
 - a. This results in a 6 mL total sample volume.
 - b. Shake the solution and wait 15 minutes to observe the colour change.

Three different creatinine concentrations will be made to test our sensor with the full range of possible colour changes at each dilution. For normal, the 100 mg/dL stock solution will be used. For low, 20 mg/dL of creatinine will be created, and for high, 300 mg/dL will be created [23]. Below is a sample calculation for the first row, which is a low concentration diluted by a factor of five.

$$C_1 V_1 = C_2 V_2 \quad (2.2)$$

where C_1 is the concentration of the original stock solution, V_1 is the volume of the original stock solution, C_2 is the concentration of the desired solution, and V_2 is the volume of the desired solution.

$$C_2 = \frac{\frac{20 \text{ mg}}{\text{dL}}}{5} = \frac{4 \text{ mg}}{\text{dL}} \quad (2.3)$$

A low concentration (20 mg/dL) diluted by a factor of five means the desired solution has a concentration of 4 mg/dL.

$$\left(\frac{100 \text{ mg}}{\text{dL}}\right)(V_1) = \left(\frac{4 \text{ mg}}{\text{dL}}\right)(2.5 \text{ mL})$$

$$V_1 = 0.1 \text{ mL}$$

The volume of stock solution should be 0.1 mL.

$$V_{\text{water}} = V_2 - V_1 \quad (2.4)$$

$$V_{\text{water}} = 2.5 \text{ mL} - 0.1 \text{ mL} \quad (2.5)$$

$$V_{\text{water}} = 2.4 \text{ mL} \quad (2.6)$$

By subtracting the volume of stock solution from the total volume, we find the volume of water added should be 2.4 mL. These calculations are repeated for the rest of the dilution factors and creatinine concentrations in Table 2-8.

Table 2-8: Stock solution and water volumes needed to make test samples.

Dilution Factor	Creatinine Concentration	Stock Solution Added (mL)	Water Added (mL)
5x	Low (20mg/dL)	0.1	2.4
	Normal (100mg/dL)	0.5	2
	High (300mg/dL)	1.5	1
10x	Low	0.05	2.45
	Normal	0.25	2.25
	High	0.75	1.75
20x	Low	0.025	2.475
	Normal	0.125	2.375
	High	0.375	2.125
50x	Low	0.01	2.49
	Normal	0.05	2.45
	High	0.15	2.35

The goal of this procedure would be to find the lowest dilution factor that produces a detectable colour change that relates to creatinine concentration. Having too low a dilution will cause mass overload, where the Jaffe reagent will be the limiting factor instead of the creatinine in the sample. As such, the maximum colour change will be observed for every creatinine colour concentration, instead of a range we can measure with our device. The results of this analysis will help characterize sensor behaviour and influence the steps the user must take to prepare their sample.

2.2.3 Proof-of-Concept Creatinine Concentration Prediction

The AS7343 features a photodiode array with different optical bandpass filters placed atop to make the photodiodes sensitive to specific light wavelengths [5]. Each colour channel (deemed F1, F2, etc.) outputs a current proportional to the intensity of the wavelength of light it detects [5]. Such current enters an integration analog-to-digital converter (ADC), which outputs an ADC count: an integer value proportional to the photodiode current and light intensity for a given colour channel [5]. ADC counts are the data used to predict creatinine concentration. In theory, since the Jaffe reaction produces a red colour change, as the creatinine concentration increases, the ADC counts for red channels will increase, and ADC counts for other channels will decrease. Therefore, channels at higher wavelengths of light are positively correlated to creatinine, and channels at lower wavelengths are negatively correlated.

A procedure is developed to model this correlation. Data is collected using the proof-of-concept SpectraStream device, further explained in Section 2.4. Python is used to import, clean, and model the data (Appendix 7.1)

1. Test samples are made to model the sensor's characteristics. Six samples are prepared using water and food colouring.
 - a. The first sample is a translucent blank sample.
 - b. The next sample emulates normal urine, without a colour change. These would model what the urine would look like if it had a dangerously low creatinine concentration after adding the Jaffe reactant.
 - c. The last 4 samples are various stages of the Jaffe reaction, modelling various creatinine concentrations.
2. After obtaining channel ADC values from the device for all samples, the data is imported into Python.
3. The data is cleaned.
 - a. Rows and columns that do not contain information about ADC counts in the six samples are dropped.
 - b. A column is added that holds the creatinine concentration that the sample is trying to emulate.
 - Since the food colouring added was done linearly, we assume a linear scale for the creatinine concentration.

After this step, we obtain the following dataframe (Table 2-9):

Table 2-9: Result after data from proof-of-concept device is cleaned.

Creatinine Concentration	F1 (400nm)	F2 (424nm)	...	F8 (745nm)	NIR
0	836	3819	...	3808	2238
40	807	3096	...	4197	2487
80	748	2215	...	4357	2593
120	712	2020	...	4351	2583
160	627	1570	...	4325	2545
200	627	1449	...	5106	2837

To analyze which channels are potentially relevant to SpectraStream, a correlation matrix is employed (Figure 2-3).

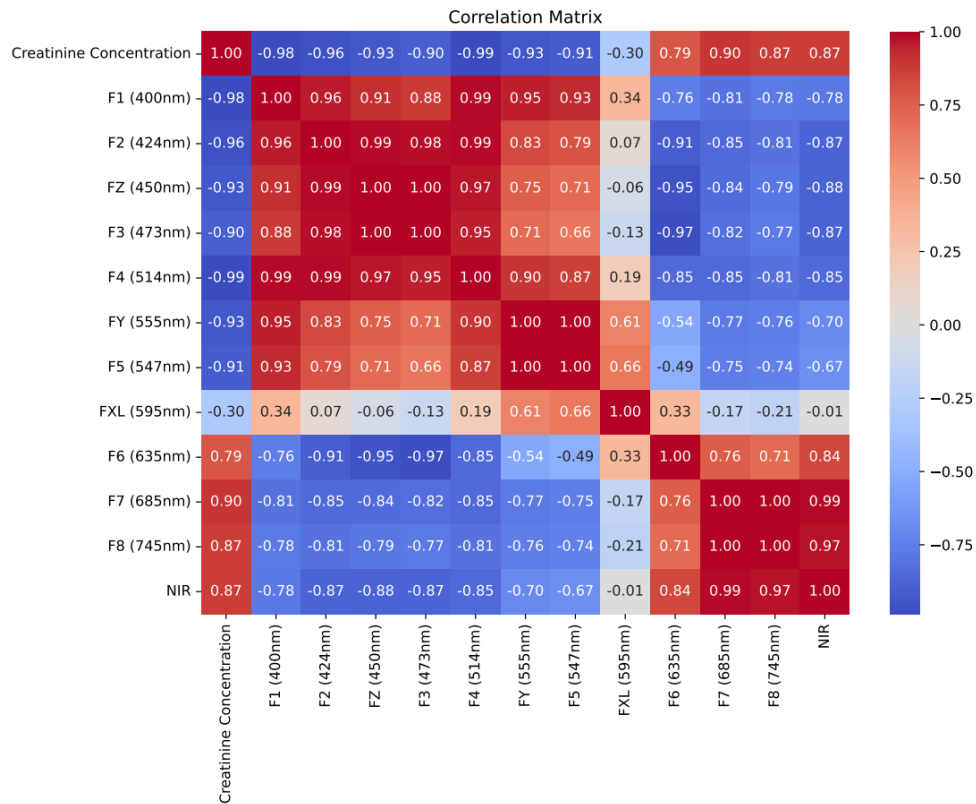


Figure 2-3: Correlation matrix between creatinine concentrations and channel ADC values following proof-of-concept testing.

From the correlation matrix, there is a high level of association for most channels with creatinine. Furthermore, the channels corresponding to small wavelengths of light are strongly negatively correlated, whereas channels corresponding to large wavelengths of light are strongly positively correlated, which matches the expected behaviour. This demonstrates that SpectraStream can detect colour changes in the sample and that the Jaffe reaction likely provides a suitable colour change.

From this analysis, multicollinearity exists, where several independent variables are highly correlated. In fact, some channels are perfectly collinear, such as F5 (547nm peak) and FY (555nm peak). Based on the theory of the multispectral sensor, this is to be expected, due to the channels having a range of wavelengths that generate a current in the transducer. The behaviour of the channel can be described through the spectral responsivity graph provided by the manufacturer (Figure 2-1). This graph shows that several channels overlap, and the F5 channel is completely inside the FY channel. As such, it makes sense they are perfectly collinear.

Further analysis was conducted on this data to model creatinine concentration and simulate how our concept would work. Since there is a high number of channels and a low number of test samples, only three channels were chosen to serve as variables in the model. They were chosen to be representative of the whole visible colour spectrum, which reduces multicollinearity and strengthens the model. As such, channel F2 (424nm peak), channel F5, and channel F7 (685 nm peak) were used as independent variables in an ordinary least squares (OLS) regression (Figure 2-4). OLS is chosen due to its simplicity and interpretability. During this investigative stage, being able to note which channels are significant and how the channels affect the concentration output is invaluable. Additionally, OLS is well suited for simple linear relationships, which makes it highly applicable to this setting.

	coef	std err	t	P> t	[0.025	0.975]
F2 (424nm)	-0.0344	0.007	-4.661	0.019	-0.058	-0.011
F5 (547nm)	-0.0071	0.002	-3.583	0.037	-0.013	-0.001
F7 (685nm)	0.0068	0.000	24.789	0.000	0.006	0.008

Figure 2-4: Results of OLS regression using F2 (424 nm), F5 (547 nm), and F7 (685 nm) channels

The results of the regression show that creatinine can be modelled using the formula:

$$C_{\text{creatinine}} = -0.0344 \times F2 - 0.0071 \times F5 + 0.0068 \times F7 \quad (2.7)$$

The resulting R^2 statistic is 0.997, showing that the variance in the creatinine concentration can near perfectly be described by the three channels used. The p-values of all three channels are less than 0.05, indicating that these channels are significant in predicting creatinine. Overall, this model shows that predicting creatinine concentration from the colour change produced by the Jaffe reaction could be viable.

2.3 LIMITATIONS OF ANALYSIS

In this section, two methods for analysing the feasibility of the proposed concept are discussed. The first describes and calculates the tests needed to characterize the urine dilution requirements, and the second model's creatinine concentration as a function of the sensor outputs.

The first method assumes that the appropriate dilution constant will fall somewhere between 5x and 50x and does not consider any additional testing if these values do not work. It also assumes

that dilutions present in the literature can be extrapolated for SpectraStream's needs. This imposes a constraint on the scope of the testing. The procedure proposed is limited in its usefulness, as knowing the appropriate dilution constant does not ensure that it can be implemented by the user during sample preparations. Only after finding the correct constant through chemical testing will the feasibility be known, and Requirement 1.2 for ease-of-use can be evaluated. The calculations are also limited by the ability to create these samples accurately, which is constrained by the tolerance of the equipment used.

For the second method, it is assumed that the colour gradient represents a linear scale of creatinine concentrations, and that food colour and water can accurately reproduce the colour change seen during the Jaffe reaction. Another assumption made is that the values obtained from the multicolour spectral sensor are accurate, which is supported by the fact that the channels' behaviour was as expected. By using an OLS model, it is assumed the data is linear, independent of errors, exhibits homoscedasticity, and has no endogeneity. The model is limited by the small amount of test data and high number of channels, which leads to data overfitting. To remedy this, only three channels were used, and more rigorous data collection is needed to use all available channels. The model is also limited by the multicollinearity, which may lead to unstable coefficients, loss of statistical significance, or difficulty in identifying variable importance when using an OLS regression approach. Other more complex modelling tools, such as principal component analysis or regularization techniques could be used to mitigate this limitation, which may be investigated in model iterations.

2.4 FINAL DECISION CONCEPT: PROOF-OF-CONCEPT

2.4.1 Proof-of-Concept Overview

Figure 2-5 shows the proof-of-concept SpectraStream device. The design was realized after the bulk of the investigative work and obtaining a substantial grasp of the underlying theory behind the sensor analyzing preliminary model results. The objective behind the proof-of-concept - to characterize the unique spectral signatures of fake urine-coloured solutions - was achieved. This milestone advances the SpectraStream project towards creating a low-cost, easy-to-use, accurate spectrometer for estimating urinary concentration for CKD monitoring.

The proof-of-concept device is a 3D-printed PLA chassis containing a 4000 K white LED module and an AS7343 sensor mounted onto an OSRAM evaluation board. The left side of the device secures the LED light source in place using two bolts, while the right side firmly holds the evaluation board. During operation, the light source and sensor are connected to an ESP32 microcontroller development kit, which powers the LED and collects readings from the sensor through I2C.

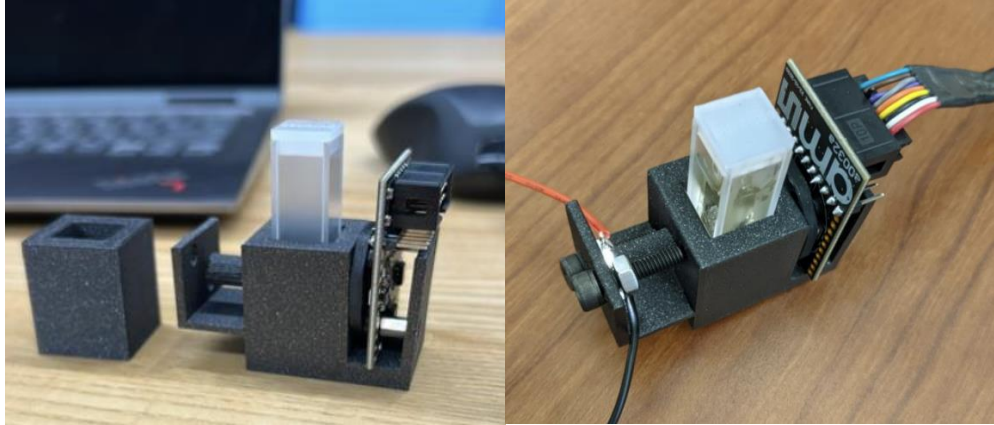


Figure 2-5: Proof-of-concept device, bare (left) and wired (right).

The device consists of two main chassis components: 1) the body and 2) the cap. The main body measures 53.3 mm in length, 23.5 mm in width, and has a height of 30 mm. The cap is placed over the cuvette sample, emulating the operation of a standard spectrophotometer, and increasing the device's total height to 57.7 mm. An initial sketch was created using calliper measurements of the board, as shown in Figure 2-6, and served as the starting point for the mechanical design. A simplified CAD model with the LED fixture was subsequently developed in Autodesk Inventor, as illustrated in Figure 2-7. The black filament absorbs light, reducing unwanted reflections that could be detected by the sensor and introduce errors. In Figure 2-8, the dimensioned engineering drawing of the base can be viewed, and in Figure 2-9, the dimensioned engineering drawing of the cap can be viewed.

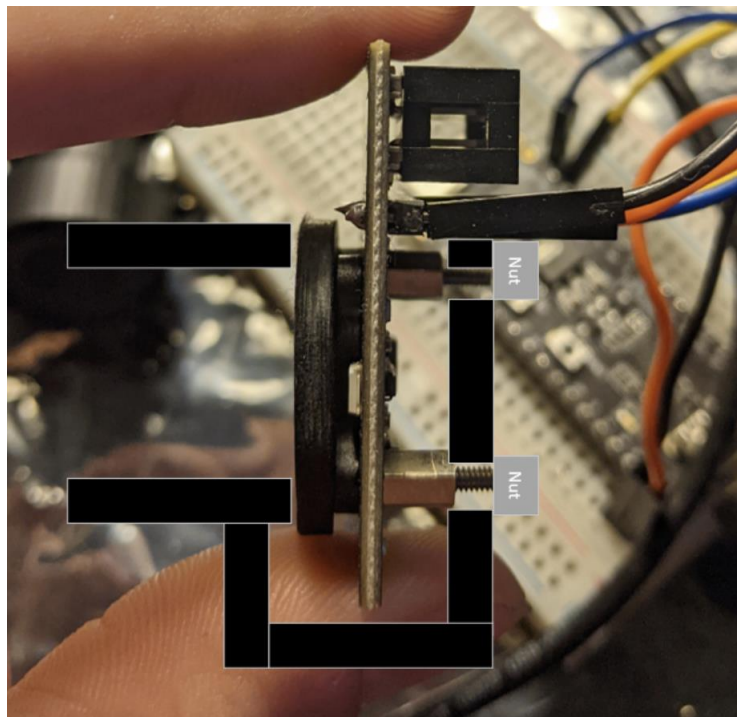


Figure 2-6: Initial sketch of board mounting.

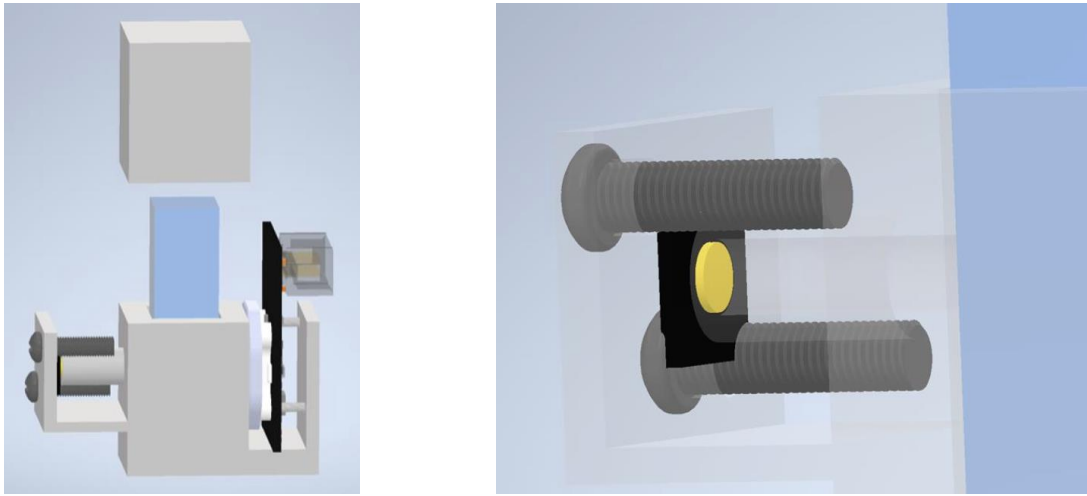


Figure 2-7: CAD model of device (left) with close-up of LED mounting (right).

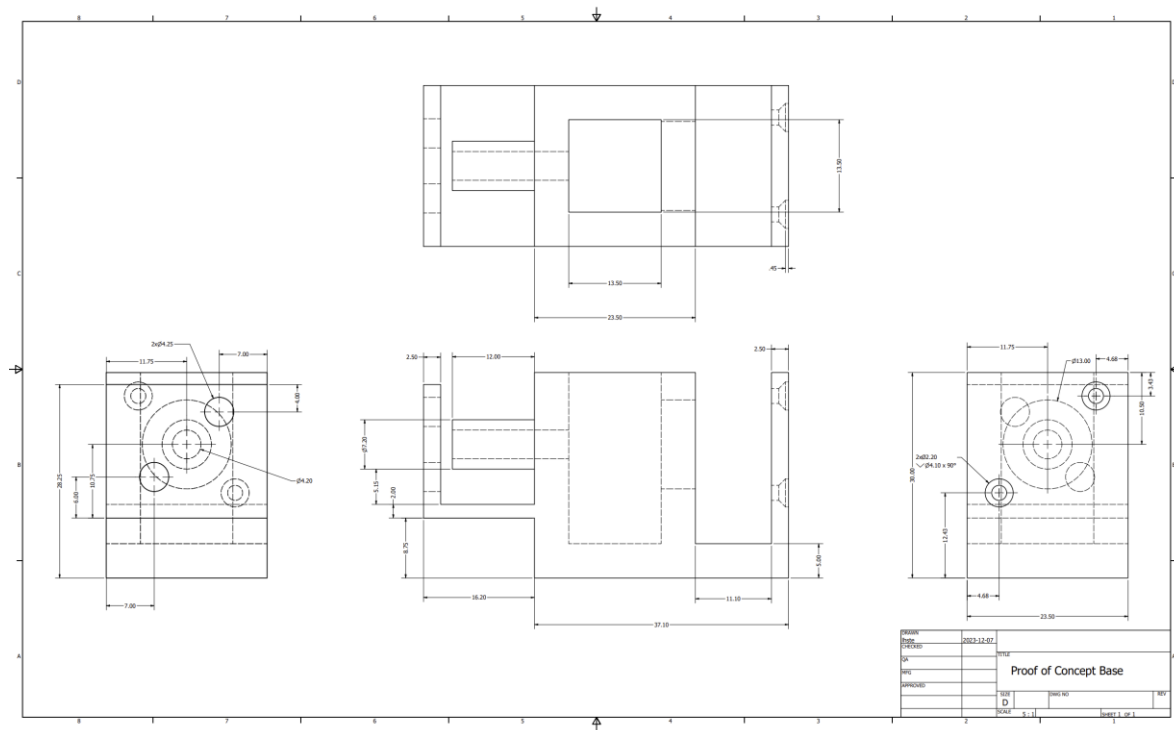


Figure 2-8: Engineering drawing of base.

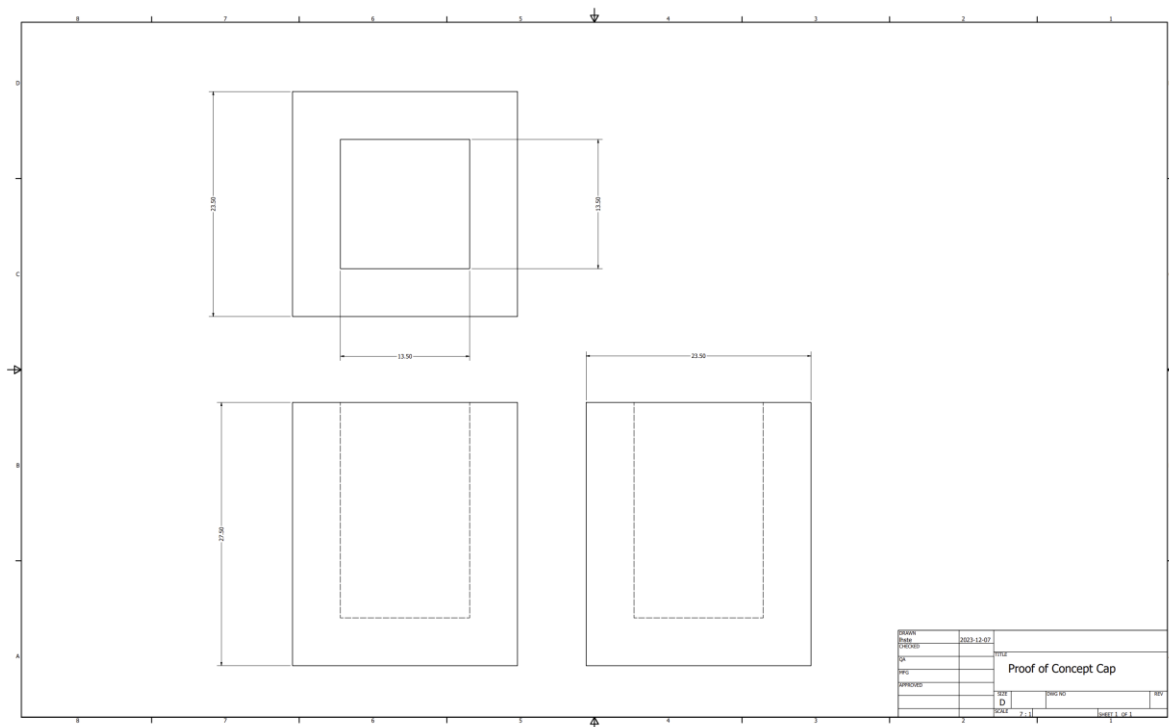


Figure 2-9: Engineering drawing of cap.

2.4.2 Proof-of-Concept Methodology

In preparation for the testing phase, various chemical, electronic, and general parts were purchased and are detailed in bills of materials (BOMs) found in Table 2-10 to Table 2-12. Food colouring solutions, ranging from light yellow to red, were prepared as mock urine solutions and placed into rectangular quartz glass cuvettes for readings. The lid was placed over the cuvette to seal out environmental light during each measurement, and a clear solution was used as the preliminary blank. The ams OSRAM AS7343 Software Development Kit (SDK) was then utilized to generate spectral graphs from the sensor readings. Demonstration videos are available below:

- 1) Demonstration #1: <https://www.youtube.com/watch?v=aE-YKJGUeL0>
- 2) Demonstration #2: <https://www.youtube.com/watch?v=CP6rJOVq7F0>

Table 2-10: Chemical Bill of Materials.

Material	Quantity	Cost (CAD)	Vendor	Link	Notes
Creatinine	10g	\$ 42.60	Sigma	HERE	Comes as a powder.
Ultra-pure water	500mL	\$-	Sigma	HERE	Can source from iBioMed wet lab.
HCL	100mL	\$ 15.00	Sigma	HERE	0.1N solution. Purchase from Mac Lab stores.

NaOH	100mL	\$ 15.00	Sigma	HERE	1N solution. Purchase from Mac Lab stores
Picric Acid	100g	\$ 90.50	Sigma	HERE	Comes as a power moistened with water
Transfer Pipettes	100 pcs	\$ 11.00	Amazon	HERE	1 mL volume for urine dilution
Uric Acid	25g	\$ 61.00	Sigma	HERE	Optional
UriSub	250mL	\$ 45.00	CST	HERE	Optional, synthetic urine
Subtotal	\$ 280.10				
Tax (13%)	\$ 36.41				
Shipping	\$ 32.00				
Total	\$ 348.51				

Table 2-11: Electronic Bill of Materials.

Part Number	Quantity	Cost (CAD)	Manufacturer	Link	Notes
AS7343-DLGM	3	\$ 45.69	AMS OSRAM	HERE	Sensor
1528-4698-ND	1	\$ 23.37	Adafruit	HERE	Sensor breakout board
1642-CLU7L3-0104C4-403H7X5-ND	1	\$ 4.92	Citizen	HERE	Chip-on-board LED
90-CMB1304-0000-000C0H0A40G-ND	1	\$ 3.03	Cree	HERE	Chip-on-board LED backup
Subtotal	\$ 77.01				
Tax (13%)	\$ 10.01				
Shipping	\$ 8.00				
Total	\$ 95.02				

Table 2-12: General Purchases.

Item	Quantity	Cost (CAD)	Source	Link	Notes
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Quartz glass cuvette	2	\$ 28.48	Amazon	HERE	
RCH-MIKROE	1	\$ 65.62	MIKROE	HERE	Backup evaluation board.
M2 screw kit	1	\$ 12.38	Amazon	HERE	Used for mounting sensor.
Subtotal		\$ 106.48			
Tax (13%)		\$ 13.84			
Shipping		\$ 0.00			
Total		\$ 120.32			

A separate test was performed using the backup board which has no SDK or existing libraries to work with. Given this, a custom firmware guide was created to interface with and collect values from the board, depicted in Figure 2-10. The board was connected to an ESP8266+ display kit and hooked up via I2C connections, as shown in Figure 2-11. The RGB light source was oriented towards the sensor, and an output graph of several core colour channels was plotted as the light colour changed, as visible in Figure 2-12. This preliminary setup lays the foundation for future board design work and further device refinement.

Capstone Firmware

Current Steps:

1) Using <Wire> library from arduino:

- a. Need to import
- b. `Wire.begin()` in setup

WRITING

- c. Need `Wire.beginTransmission(DEVICE_ID)` followed by
X2 `Wire.write(TARGET_REGISTER)`, first is to set register, second is to
actually write in data
- d. Need `Wire.endTransmission(TARGET_REGISTER)`, after every REG access

READING

- e. Need `Wire.beginTransmission(DEVICE_ID)` followed by X1
`Wire.write(TARGET_REGISTER)`, **just** to set register
- f. Need `Wire.endTransmission(TARGET_REGISTER)`, after every REG access
- g. Need a `Wire.requestFrom (TARGET_REGISTER, # of bytes to read)`
- h. Need a condition [if `Wire.available()`]
- i. Need to set value = `Wire.read()` to store the data from the register

2) Setting up the AS343 sensor:

- a. Make sure to read REG_BANK, if you are planning to access 0x58 to 0x66
the value needs to be set to 1, and the opposite is true for the other
registers.
- b. To turn the sensor **ON**, set bit 0 of the REG_ENABLE to 1. This will not
enable measurements but is meant to be the configurable state where the
sensor parameters should ideally be set. Writing configuration options
during the sensing stage can result in bad readings.
- c. Set bit 7 of REG_LED to 1 to turn on the LED (assuming the wiring for it is
already setup), bits 0 – 6 control the current going to the LED. **256 mA is
the max** recommended safe operating current for the onboard LED unit.
- d. Set the ATIME using REG_ETIME (default is 100).
- e. Set ASTEP using REG_ATEP_LSB (default is 999).
- f. Set gain using REG_AS7343_CFG1, there are current multiple of these CFG
registers, but it's unclear now if they all must be set.

Figure 2-10: Proof-of-concept pseudocode firmware for AS7343 sensor.

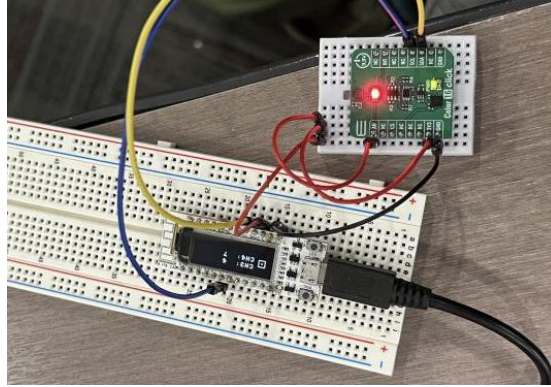


Figure 2-11: Proof-of-concept experimental setup with backup spectral sensing board.



Figure 2-12: Proof-of-concept backup board output results.

2.4.3 Proof-of-Concept Results

Testing was conducted on nine different solutions, the majority of which exhibited visibly distinct distributions. Figure 2-13 displays the results of the channels plotted as a spectral density for each sample, while Figure 2-14 presents plots comparing channel values for the solutions as they transition from clear to dark red. It is evident that there are spectral differences in all the solutions, as both the shape of the distributions and the intensity of the channels change with each measurement.

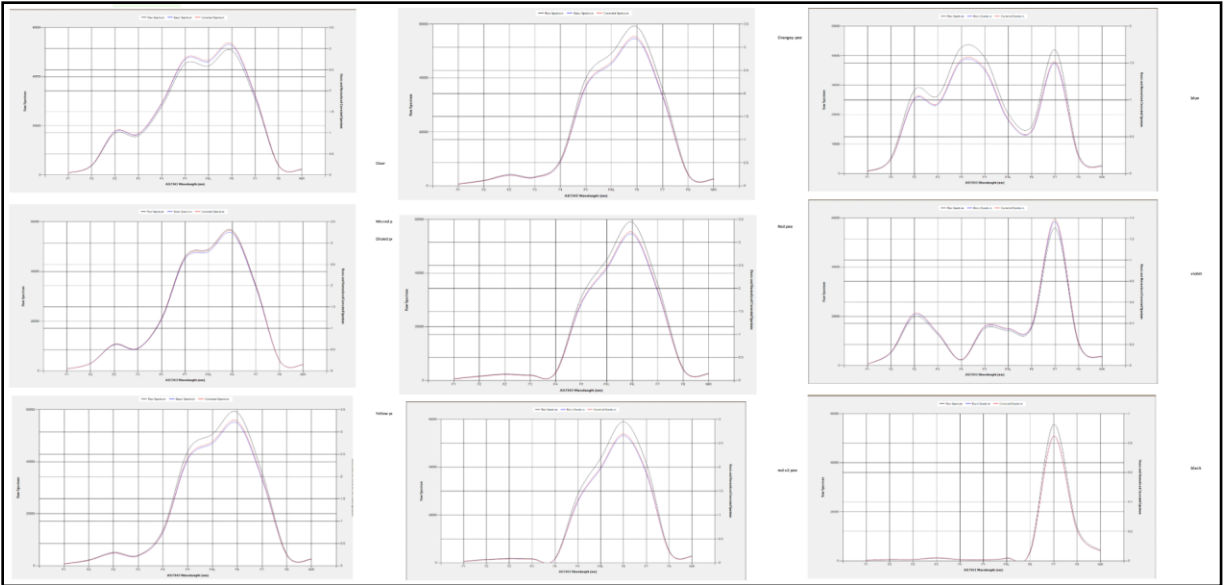


Figure 2-13: AS7343 SDK spectral outputs of different solutions.

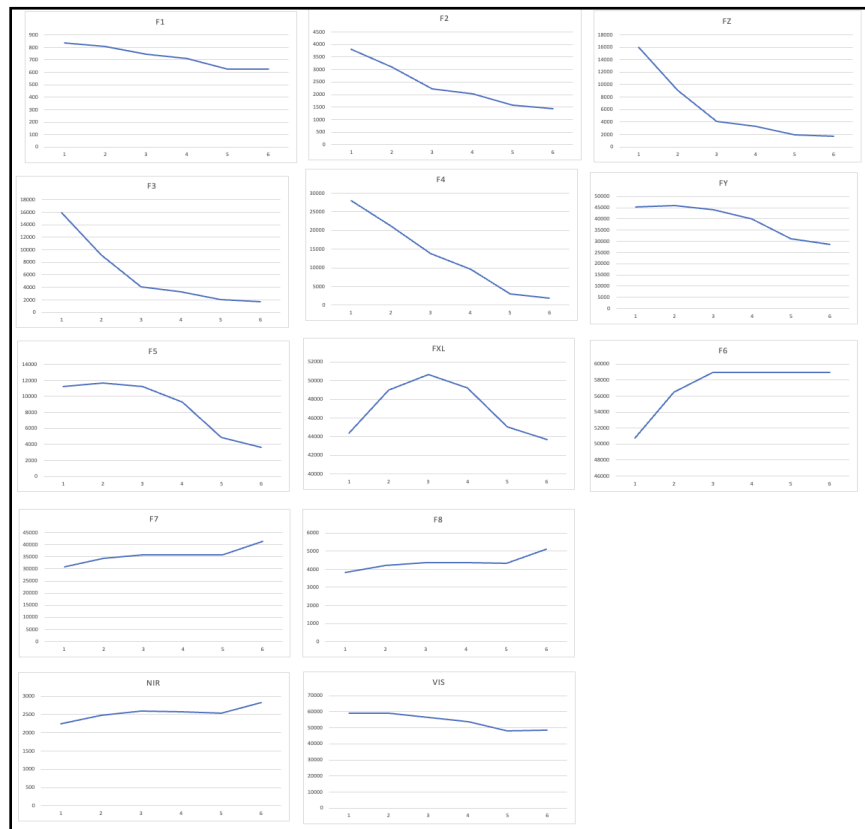


Figure 2-14: AS7343 evaluation kit colour channel data plotted for urine-coloured samples.

Figure 2-15 presents an overlapping plot of all channel intensities and their corresponding solutions, offering a clear representation of these trends.

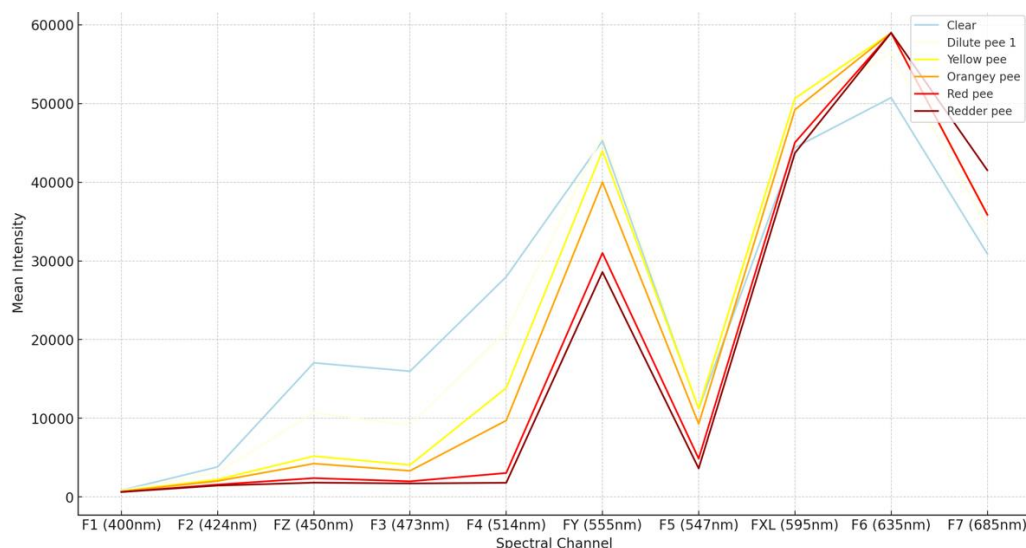


Figure 2-15: Channel intensity values of differing solutions.

2.4.4 Comparison to Modelling and Analysis Results

The prototype testing demonstrates that the device can generate unique spectral fingerprints for varying urine-coloured samples. As mentioned in Section 2.2.2, the device will undergo testing with different creatinine concentrations, covering the full spectrum of possible colour changes at each dilution. The obtained results do not yet prove that the device is capable of accurately detecting creatinine concentrations in urine. However, the colour channel data demonstrates that the device can reliably categorize colour shifts in urine-like environments by measuring spectral changes within the wavelength range of 350 nm to 600 nm – corresponding to the absorbance-varying range of the Jaffe reaction.

The correlation matrix in Figure 2-3 predicts that lower wavelength channel intensities would decrease, and higher wavelength channel intensity would increase with rising creatinine concentrations. The results shown exhibit the same pattern, with the difference being that the cause is food colouring produces the colour shift, not the Jaffe reaction. The results of the correlation matrix are explained due to the overlapping channels, as shown in Figure 2-1, meaning that nearby channels are highly correlated. This aspect is again confirmed by the results, which demonstrate that nearby channels share similar intensities and trends. In the proof-of-concept results, all channels are considered, and several have a clear association with the colour shift. This contrasts the model, which only used three channels to avoid overfitting. Future work will involve repeating measurements of the same samples to obtain an idea of distribution and variance. Analysis of variance (ANOVA) testing will be employed to determine statistical significance between measurement intensities for samples, and regression will be used to model any patterns observed between measurements.

2.5. UPDATED PROJECT PLAN (NOVEMBER 2023)

Since the inaugural project plan described in Section 1.6, the problem definition, concept generation, and concept evaluation phases of the SpectraStream project have been completed. Furthermore, the preliminary design for most aspects of SpectraStream were successfully finished. Although the project is on schedule, many challenges await in the Winter Semester.

The preliminary electrical design has not commenced due to unexpectedly allocating more time to other project elements, such as the mechanical and chemical proof-of-concept development. It involves consolidating what electronic components we wish to include in the SpectraStream design following proof-of-concept validation, such as an OLED display or rechargeable battery. Additionally, a schematic and PCB to house the multispectral sensor and other electronics must be created. At the beginning of the Fall, the deadline for this task was deliberately set for the middle of Winter break to provide buffer time for development of an initial CAD model of the SpectraStream electronics module. This permits time for revision of the preliminary opto-mechanical design in preparation for prototyping during the Winter semester. Ideally, the first revision of the PCB will be tested at the beginning of the Winter semester during initial prototyping.

Other tasks planned for completion over the Winter break are developing an initial high-level software configuration to process ADC counts from the multispectral sensor to estimate creatinine concentration and to perform an inaugural design review.

The schedule has not been altered for the remainder of the Winter semester, which primarily consists of the prototyping phase. The biggest challenge will be to optimize the Jaffe reaction by performing experiments to determine each reagent's optimal concentrations and volumes to balance performance and ease of use. The form factor of the mechanical design will be enhanced to make it easier to use for those who lack dexterity and minimize leakage light introduced in the optical path. The ADC count data gathered during the considerable testing phase will also be used to evaluate numerous models, such as regression, T-tests, or ratiometric measures, to determine the optimal approach for estimating creatinine concentration. The last hurdle involves testing the device with human urine to evaluate how other compounds, such as bilirubin and proteins, affect our device's chemical and optical performance. It will then be decided how to mitigate errors caused by such interferents.

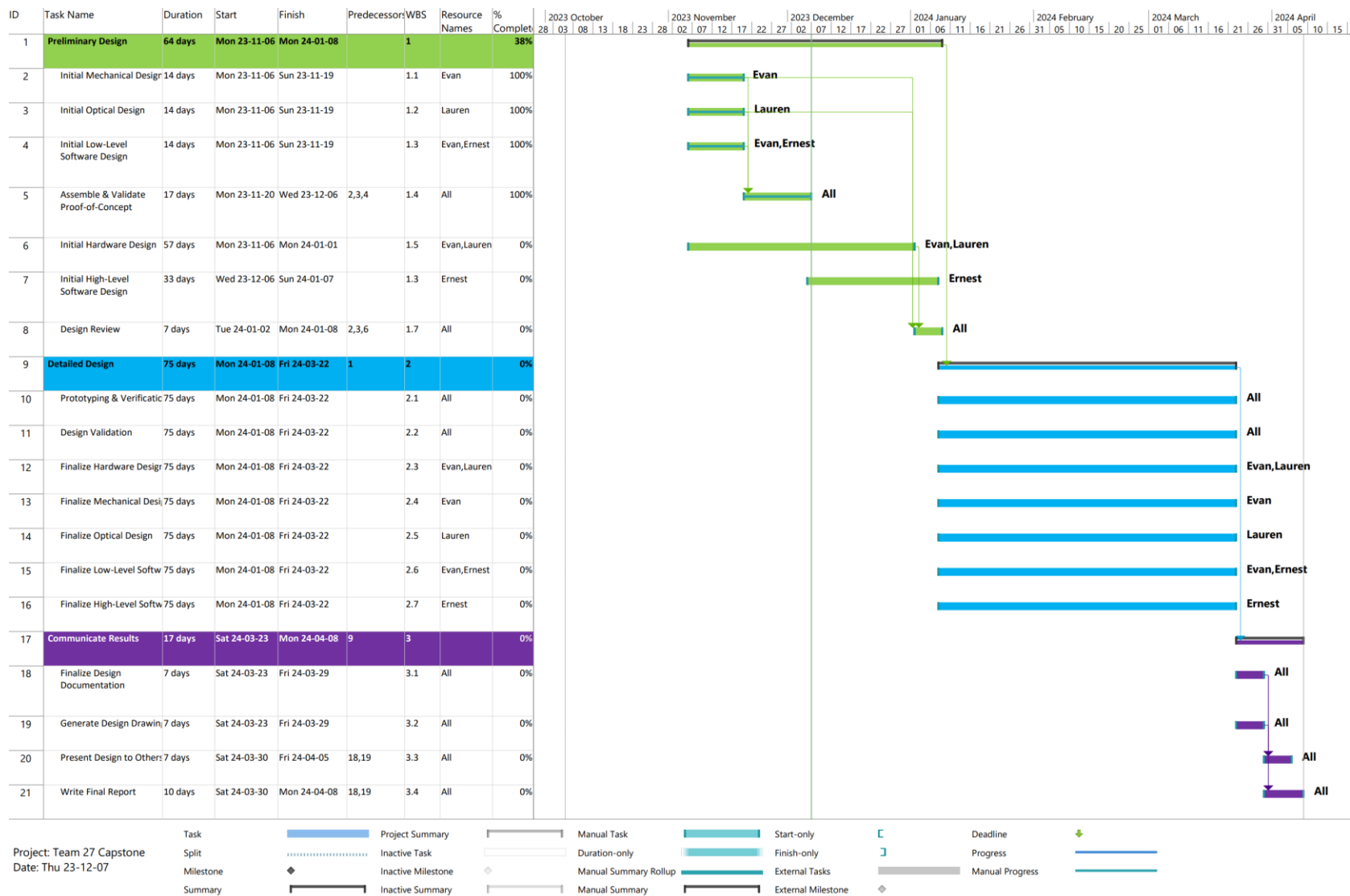


Figure 2-16: Updated Gantt chart as of November 2023.

2.6. CHAPTER 2 REFERENCES

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3. CHAPTER 3: IMPACT AND RISK

3.1 ETHICAL CONSIDERATIONS

3.1.1 Storing Patient Data

Advancements in internet communications, cloud technologies, and IoT devices have transformed how healthcare data is stored and handled. Many organizations have replaced paper-based services in favour of cloud services and online portals. SpectraStream follows this trend and aims to store patient recordings on local storage and transmit readings over Wi-Fi to a web application portal. This approach offers significant benefits to convenience and accessibility but also opens attack vectors for bad actors looking to use sensitive data for their gain. It has been reported that a complete patient record can be worth hundreds of dollars on the dark web [1]. From 2005 to 2019, about 249 million individuals were affected by healthcare data breaches [2]. This number has grown in recent years. The unsecured web application that the SpectraStream prototype hosts is the most substantial security risk, as anyone can access it by holding the specific IP address of the site. Attackers can also intercept unencrypted traffic as the device transmits or uses hardware exploits to access the data inside physical storage.

Although it is difficult to entirely remove all potential vulnerabilities from the device, several mitigation strategies exist. Introducing a credential-secured web application and database is a feasible improvement that significantly increases the security of patient records. Our group implemented this strategy by modifying the current database software to require a username and password. Another strategy would be considering hardware modifications to reduce physical attack vectors but ultimately found that most modifications would involve disabling communication paths, such as removing the USB port on the microcontroller. These modifications significantly reduce the effectiveness and purpose of the microcontroller as a prototyping tool to develop features and debug existing problems. They also require significant hardware changes and future work to maintain the existing power and communication dependencies that rely on such ports.

3.1.2 Accessibility

Aside from patient confidentiality and data security, digitizing healthcare data can present an ethical accessibility issue. Socioeconomic or health-related issues may limit patient access to technology. Some patients cannot use smartphones effectively for tasks due to the small screen sizes and limited dexterity, or patients may not be able to afford a device with a larger screen. Multi-device access to records has been implemented to address these potential inequalities. The design decision influenced the judgment to use a hosted web application accessible via an IP address on any device that supports internet browsing.

Physical and mental accessibility is also a key consideration. Researchers believe that more than 50% of seniors over the age of 75 have kidney disease [3]. As this group would be part of our target population, care has been taken to streamline the user experience and provide an accessible

device. These individuals may have limited mobility, hearing or vision loss, or difficulty interpreting complex instructions. A large LCD screen, tactile buttons, and a simple web application interface have been chosen to reduce the effects of disability or impairments. Since the inaugural prototype, device size has been increased significantly, reducing the need for precise hand-eye coordination, and simplifying patient-device interaction.

3.1.3 Ethical Sourcing

As with any engineering design, ethically sourced components should compose SpectraStream. Many electronic components, like lead, contain hazardous substances if not sourced from ethical and reputable suppliers. The Restriction of Hazardous Substances (RoHS) is an electronics manufacturing standard that restricts levels of unsafe materials in electronic components [4]. Suppliers that violate the RoHS standard may immorally sell unsafe products to consumers. RoHS-verified components from reputable electronics manufacturers (such as Texas Instruments or AMS) were used for SpectraStream to ensure ethical sourcing and safe distribution of the product.

Additionally, there has been global concern regarding conflict minerals, characterized by harvesting through child labour and environmental degradation at the bottom of the supply chain [5],[6]. SpectraStream features a lithium-ion battery for portability purposes, although these batteries contain conflict minerals such as lithium and cobalt. Implementing a rechargeable battery in SpectraStream significantly reduces the number of conflict minerals required to sustain device operation over its lifetime compared to a non-rechargeable battery. To further influence the impact of unethical sourcing, we have performed current consumption testing on our prototype to select the minimum battery size and, consequently, the number of conflict minerals used. Our SpectraStream draws a maximum current of 350mA during a 5-second spectrum acquisition scan, enabling us to use a low-power 1Ah to 3Ah lithium-ion battery cell while providing sufficient battery life to the user.

3.2 HEALTH AND SAFETY

3.2.1 Electrical Safety

Safety is always a dominant characteristic of electrical design. The primary safety concern with SpectraStream is the lithium-ion cell or external USB power sources. Lithium-ion batteries store high amounts of energy in a small package. Therefore, sudden impacts, over-temperature, over-discharge, or improper charging procedures can result in battery fire or explosion [7]. Luckily, lithium-ion batteries are remarkably safe if engineers follow proper design procedures. The SpectraStream prototype employs a standardized 18650 lithium-ion battery cell. Using a standardized lithium-ion battery size permits the use of an appropriate holder to ensure the battery does not dislodge from the device when dropped. Moving on, battery charging ICs are widely available on the market and provide enhanced protection for lithium-ion cells. SpectraStream shall use the Texas Instruments BQ24259 battery charging IC, which features battery over-voltage, under-voltage, over-current and over-temperature features to prevent electrical hazards [8]. It also features a dedicated charging cycle for lithium-ion cells and protection against power adapters

with voltage or current ratings incompatible with lithium-ion charging [8]. The BQ24259 can be placed in a "shipping mode," so the battery can be securely installed in the device during shipping to the customer, drastically improving safety during manufacturing and distribution. Furthermore, appropriate fusing is placed in series with the battery as a redundant circuit protection method in case the BQ24259 fails.

3.2.2 Chemical Safety

A SpectraStream user is expected to mix a urine sample extract with a small volume of chemical reactants in a pre-packaged plastic cuvette. The original reactant proposed in Section 2.1.3 was alkaline picrate, created by dissolving picric acid in NaOH. As noted, picric acid is caustic, toxic, and explosive when dry [9]. After discussion following proof-of-concept testing, it was deemed picric acid was unsafe for at-home use, and the hazard must be eliminated from the chemical procedure to ensure device feasibility.

Lewińska et al. showed that one can substitute a safer compound, 3,5-dinitrobenzoic acid (DNBA), in the Jaffe reaction to produce the same red-coloured complex detectable with a colour sensor. The updated reactants include 0.3 M of DNBA dissolved in 0.25 M NaOH and water. The colour change is linear for a wider range of creatinine concentrations than the Jaffe reaction, as shown below, permitting lower sample dilution factors. Unlike the Jaffe reaction, DNBA is more robust to interferents present in the urine, such as albumin and glucose, increasing the device's accuracy when testing with actual urine. [10]

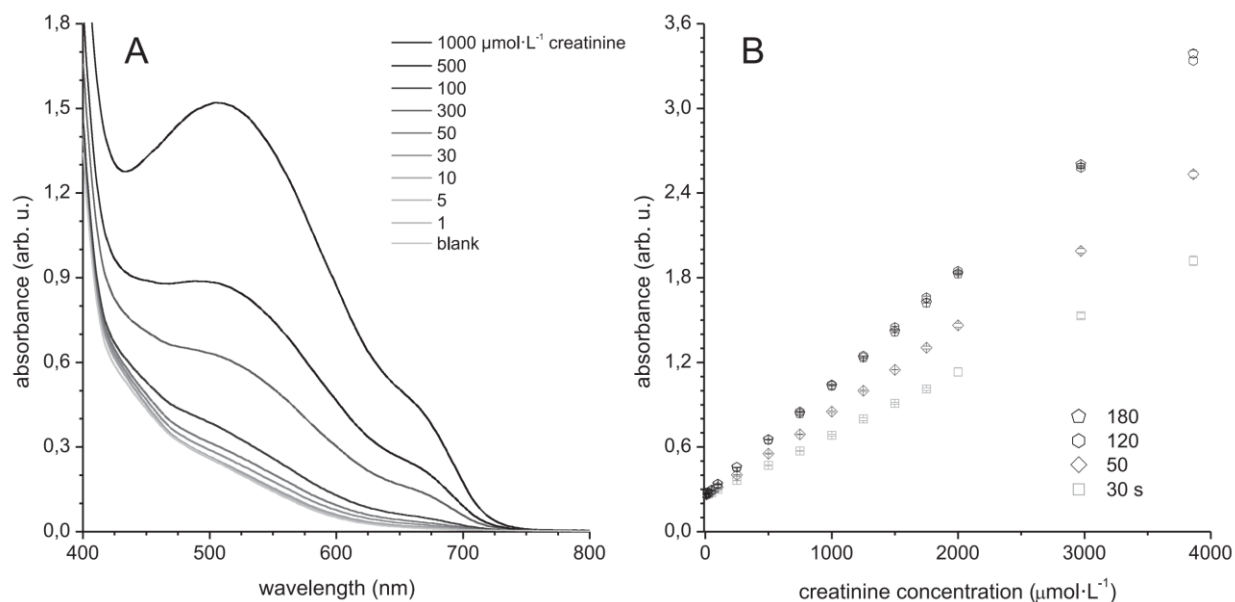


Figure 3-1: DNBA reaction product absorption spectra with various concentrations of creatinine standards (left) and generated standard curves for specific times after initiating the reaction (right) [10].

DNBA and NaOH still possess safety concerns, such as skin and eye irritation, in the proposed concentrations [11],[12]. DNBA is also acutely toxic if inhaled. Since these reactants are required for SpectraStream operation, one cannot readily eliminate their associated hazards. However, the

risk and severity of the chemical safety concerns can be reduced by taking the following steps. All SpectraStream cuvettes shall be packaged with secure child-proof lids to decrease the chance of chemical spillage or ingestion. Secondly, the number of chemicals employed in a test will be minimized as much as possible without degrading ease of use to limit the severity of any spillage or ingestion. Lastly, hazard labels shall be placed in appropriate package locations to alert the user of the risks associated with SpectraStream and what to do in the event of chemical exposure.

Current literature has been exploring metal nanoparticles to produce creatinine-dependent colour changes [9],[13],[14]. Such nanoparticles are associated with none to minimal safety hazards. However, their reliability and performance are inferior to DNBA due to their novelty, hence the use of DNBA as a replacement for picric acid. Research regarding nanoparticles for creatinine colour change reactions will be monitored moving forward. SpectraStream will be recharacterized for this reactant if developments look promising to eliminate remaining chemical safety concerns.

3.3 ENVIRONMENTAL CONCERNS

The regular use of SpectraStream involves various chemical reagents, some of which have environmental hazards. As previously mentioned, the reactants are DNBA and NaOH. HCl is used to create fake urine samples for prototyping that the user will not interact with. The first step to mitigating any harmful environmental impacts arising from reagents is to study the SDS of all materials. All reagents, except for HCl, contained environmental warnings prohibiting drainage into drains, and DNBA was found to be a long-term aquatic hazard [11]. Strong acids and bases can also damage piping or leach into the environment, producing toxic vapours that harm wildlife. It is necessary to dispose of waste only at safe disposal plants.

The first strategy employed by the team to reduce risk was to research safer alternatives to the reagents involved in the original reaction. Originally, picric acid was planned for use in place of DNBA due to its prevalence in literature but was eventually replaced with DNBA due to safety and environmental concerns. The second strategy was to prepackage all reagents into kits and leave only the mixing steps to the user. The risk of ecological damage is substantially reduced, as only the necessary amounts of each reagent are included. This strategy also enables the team to dilute the NaOH before usage, which is one of the most effective ways to reduce their hazardous properties for users and the environment.

Unfortunately, improper disposal of reagents remains the primary risk for environmental damage, and it is expected that at least some users will attempt disposal via household drains. The most effective mitigation strategies involve controlling disposal at a lab or disposal site – but this defeats the primary goal of the prototype, which is to be an at-home PoCT device. Alternatively, the team could provide disposal containers and pick up waste at periodic, scheduled times. This strategy might be logistically possible for a large corporation but is not feasible for a capstone group with limited resources. Instead, SpectraStream labelling shall include disposal instructions. The labelling will contain safety data sheet (SDS) warnings, and further research regarding nearby safe disposal sites will be conducted. For instance, chemical disposal will occur at the iBioMed wet lab during prototyping. Although the responsibility of safe disposal will still fall on the end-user, they can still ensure they are presented with the correct information and steps.

Aside from the reagents, the device includes a recyclable PLA chassis, internal circuitry, and batteries. Most Canadians do not return dead batteries to a supplier or retailer and instead throw batteries in the garbage or send them to a depot, presenting a critical environmental problem [15]. As batteries enter landfills, they eventually corrode and leak harmful chemicals into the earth, contaminating ecosystems and groundwater. To avoid contributing to this issue, rechargeable and recyclable batteries were incorporated into the design, which the user may reuse for many years.

3.4 STANDARDS AND CODES

SpectraStream is from Ontario, Canada. Thus, the standards, codes, legal, and regulatory factors governing that jurisdiction must be followed. In Canada, the medical device industry is regulated by Health Canada under the Food and Drug Act [16]. The accompanying Medical Device Regulations outline requirements for different classes of medical devices, with Class I (posing virtually no risk to a user) to Class IV being high risk, where failure means substantial harm to the operator [16]. Based on the rules in this regulation, SpectraStream would be Class II since it is “an active diagnostic device [...] that supplies energy for imaging or monitoring physiological processes” [17]. SpectraStream must be licensed as a Canadian medical device and follow the associated regulations for deployment. Such regulations include ISO 13485, which specifies requirements for quality management of medical devices across the entire life-cycle of the device, including design and development, production, and storage [18]. We would also have to adhere to IEC 60601, a multi-part series of technical standards specifically for medical electrical equipment [19]. Although many of these regulations are not possible for the stage our device is in, such as obtaining a medical license or safety attestations from the manufacturer, our group is aware that our device is a Class II, which means compliance with regulations will be more extensive.

Another facet of our design to consider is the electrical design, which was designed to limit device current draw and high voltages. A 3D-printed chassis was also manufactured for the electrical equipment, which could be modified to adhere to IEC 60529, a regulation about enclosures for electrical equipment [20]. Another consideration was the battery since batteries are considered medical devices when designed, manufactured, and labelled for use with medical devices [21]. General-use rechargeable batteries were used, so they would not be considered a separate medical device.

SpectraStream contains chemical reagents. It must follow the standards and codes for selling chemical products. The user will be introduced to chemicals that may be corrosive, are not safe to ingest, and should not come into contact with the eyes when referring to the relevant chemical safety data sheets [11],[12]. Consequently, hazard symbols and first aid treatment on all packaging that informs users of these hazards must be included to follow the Consumer Chemicals and Containers Regulations as part of the Canada Consumer Product Safety Act [22].

The risk of non-compliance with these standards and codes could result in misinformed consumers, leading to injury. For the electrical standards, having unenclosed, high-current systems could lead to electrocution, and having unlabelled chemicals could lead to chemical burns. For the Medical Device Regulations, non-compliance could lead to inadequate quality control or issues deploying

the product without a license. Failing to adhere to these regulations, especially if someone were injured as a result, could lead to legal ramifications.

3.5 UPDATED PROJECT PLAN (FEBRUARY 2024)

Design of the second SpectraStream prototype iteration that integrates our device's electrical, chemical, mechanical, and software components into a refined and integrated package has commenced since the successful proof-of-concept presentation and initial prototype development in the Fall.

Concerning the SpectraStream electrical design, imperative electronic components such as the battery, battery charging IC, buttons, OLED display, and microcontroller have been selected. Finalization of the printed circuit board design by the end of February is planned, which integrates the above electrical components in a compact and manufacturable package. Completing the prototype PCB earlier in the month would have been ideal to permit more time for testing. However, the aforementioned electronic components have been purchased to test them individually to de-risk the electrical testing phase of the second prototype.

Completing the updated mechanical design for the next prototype by the end of February is intended. The updated mechanical design involves adding a proper enclosure for the updated PCB and improving ergonomic usage by enlarging its size so those with hand dexterity issues can easily use it. Reaching the end-February deadline is currently feasible.

Additionally, the switch from picric acid to DNBA to produce the colour change reaction with creatinine caused chemical ordering and testing delays. With chemicals on order and expected to arrive by the end of February, commencing the chemical testing with the updated reagent will happen in early March. Like the electrical design, offering testing delays by using food colouring to emulate colour change reactions to flush out other project elements is underway.

Lower priority tasks include improving the user interface and data visualization for our high-level software, which must be completed by the end of March in preparation for the final capstone deliverables.

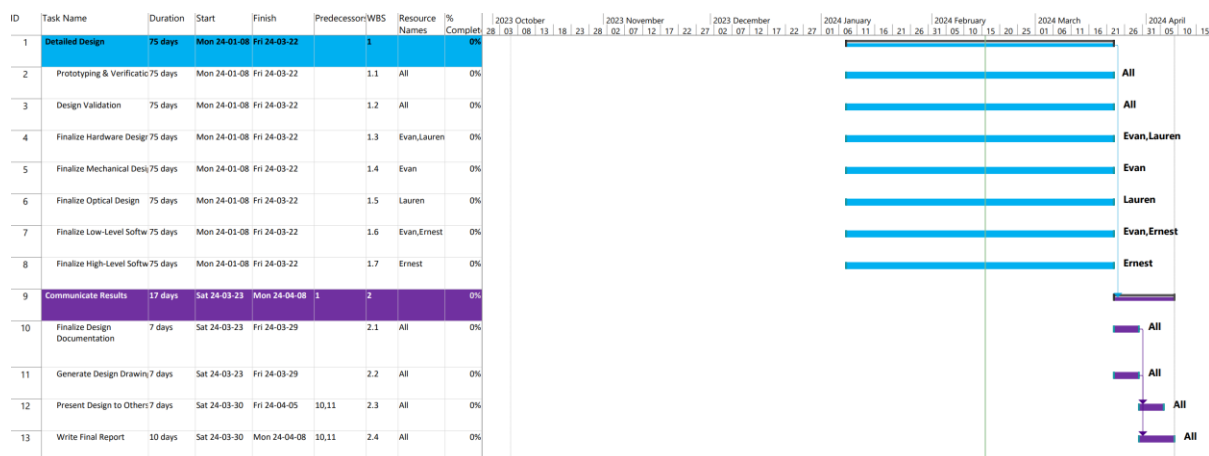


Figure 3-2: Updated Gantt chart as of February 2024.

3.6 CHAPTER 3 REFERENCES

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4. CHAPTER 4: RESULTS AND DISCUSSION

4.1 DESIGN DEVELOPMENT, ANALYSIS, AND OPTIMIZATION OF THE FINAL DESIGN

4.1.1 Chemical Procedure Development

As discussed in Section 2.2.2, extensive chemical testing must be performed to develop the procedure for the user to perform. This involves initial characterizations of the DNBA reaction, determining the lowest possible dilution factor, developing a standard curve to equate sensor measurements with creatinine concentration. The detailed laboratory procedure and methods to create samples for these tests can be found in Appendix 7.2. Here, the relevant theory and analysis will be discussed.

Initial DNBA Reaction Test

This initial test is aimed to imitate the DNBA reaction performed by Lewińska et al. [1] and ensure reproducibility of results for the proposed application. This paper, introduced in Section 3.2.2, provides a comprehensive study into the necessary conditions for this reaction and sufficient validation of its accuracy with human urine samples.

To replicate this study, six different creatinine concentration test samples ranging from 0-200 μ M were created. To determine the time necessary for the reaction to reach steady state, the sample was measured with the benchtop spectrophotometer at 465 nm. Once the absorbance maintained stability for several minutes, the sample was measured using the SpectraStream prototype.

This test identified that absorbance steady state was reached after 12 minutes and began to decay after 16 minutes (red portion of Figure 4-1). As such, moving forward, spectrophotometer and sensor data were measured after 12 minutes.

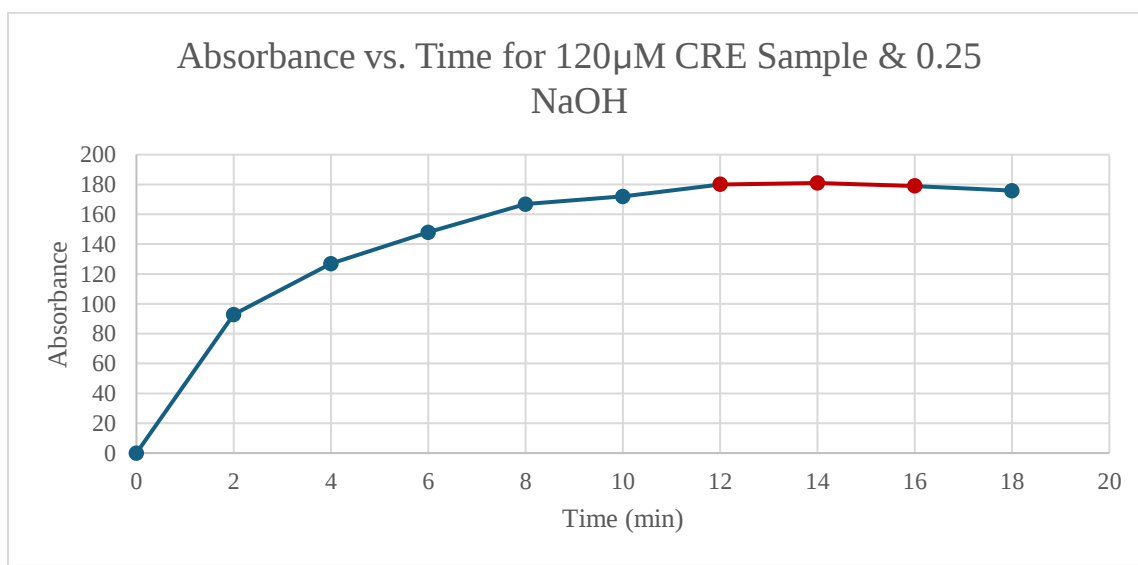


Figure 4-1: Plot showing the time for the DNBA reaction to reach steady state.

Visually, the blank solution was slightly orange due to the reagent, and a red colour developed when the creatinine samples were combined with DNBA. This was consistent with the colour profiles reported by Lewińska et al. [1].

The spectral data from the sensors showed some differences in channel values at different creatinine concentrations, with the left spectra corresponding to 80µM and the right spectra corresponding to 160µM (Figure 4-2). Three distinct peaks are evident, with the two main ones centered at colour channels FY (555 nm) and F6 (635 nm). Differences can be seen in the maximum ADC count reached and the gap between peaks.

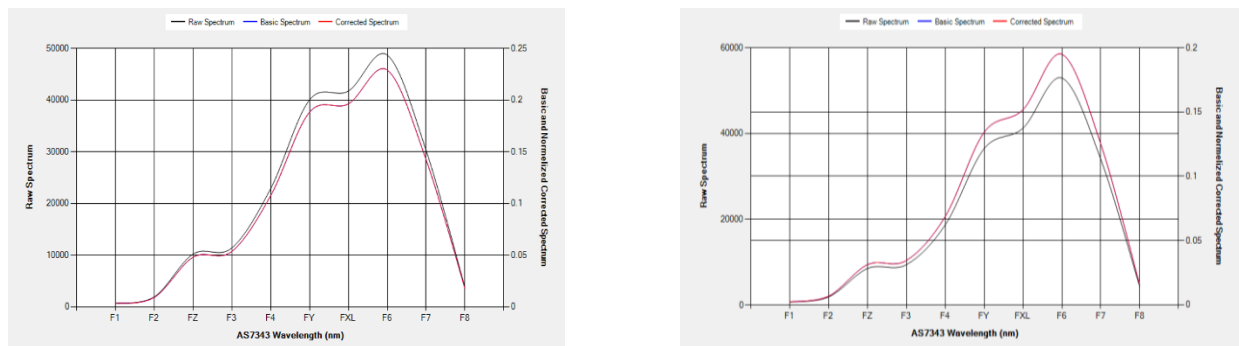


Figure 4-2: Spectrum graphs showing differences between creatinine concentration colour changes. Samples contained 80 µM (left) and 160 µM of creatinine (right).

Future optimizations to this test were averaging several measurements to reduce error, increasing LED current to improve SNR, and taking measurements over a more comprehensive creatinine concentration range that represents clinically relevant values.

Dilution Factor Test

The next experiment built upon the initial testing, but aimed to find the minimum possible dilution factor that produced a linear colour change with respect to creatinine concentration. Relevant literature indicates this factor could range from 10-fold to as high as 100-fold [1]-[3]. Iterating upon the procedure outlined in Section 2.2.2, four different dilution factors (5x, 10x, 20x, and 40x) were proposed, with the optimal dilution being only 5x. As such, the 5x dilution was completed first and fully analyzed statistically for linearity, with further tests being necessary if the 5x dilution became too quickly saturated or showed significant nonlinear behaviour.

Creatinine concentrations of 0 mM to 4 mM were made, which corresponded to the normal range of 0 mM to 20 mM when accounting for the 5x dilution. These visually produced a substantial variation in colour after the DNBA reaction occurred (Figure 4-3).



Figure 4-3: Visually distinguishable colour changes following the DNBA reaction with samples containing differing creatinine concentrations.

The data was fit with a linear regression and assessed using the R^2 value, which measures the proportionate amount of variation in the creatinine concentration that can be explained by the given channel [4]. The larger the R^2 , the more variability is explained by the linear regression model, with a perfect fit having an R^2 of 1. For a single channel, the model had an R^2 value of 0.83 (Figure 4-4), which rose to 0.98 when only predicting concentrations from 0 to 2mM (Figure 4-5).

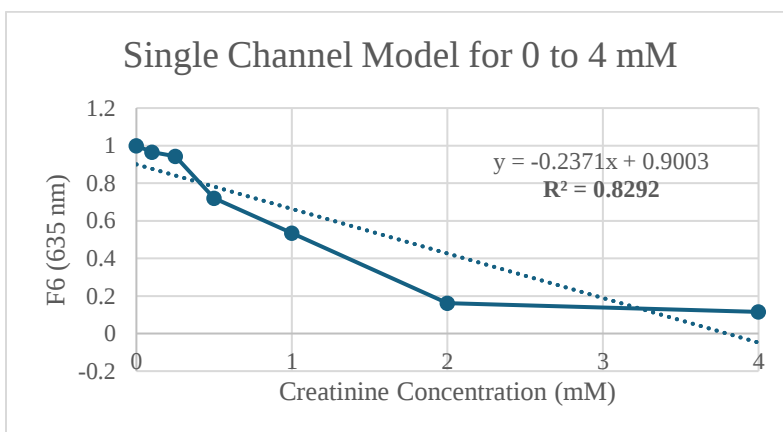


Figure 4-4: Linear regression of F6 channel data for whole range following DNBA testing with a 5x sample dilution.

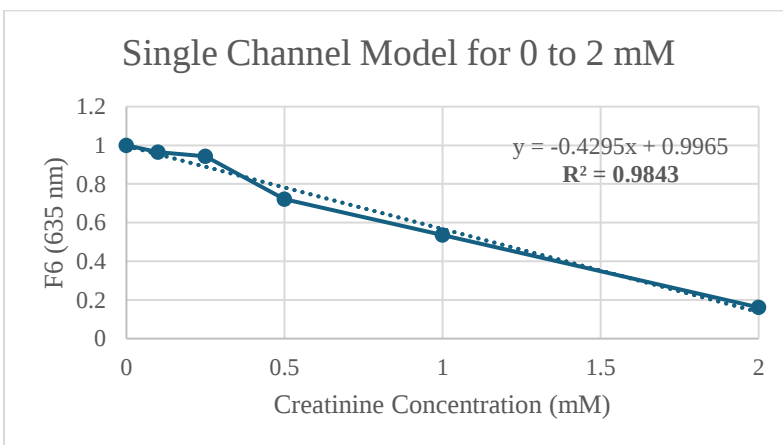


Figure 4-5: Linear regression of F6 channel data for creatinine sample concentrations between 0mM and 2mM with a 5x sample dilution.

More advanced models were also investigated. Since the gap between the FY (555 nm) and F6 (635 nm) peaks grew with increasing creatinine concentration, the ratio between these values was used as the input for a linear regression. This resulted in an R^2 value of 0.98 across the entire 0 to 4mM range (Figure 4-6).

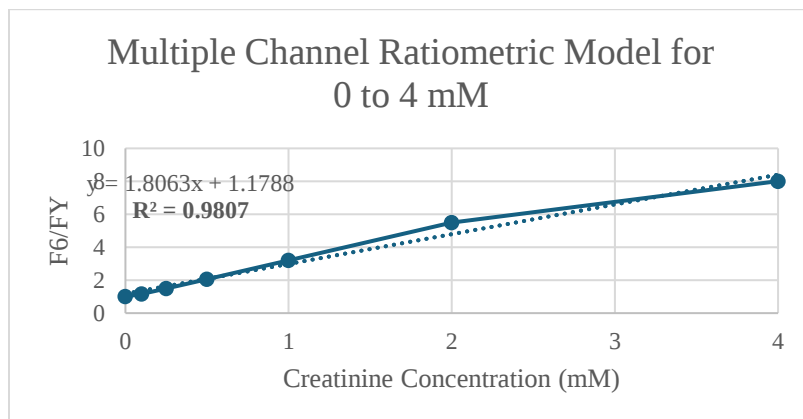


Figure 4-6: Linear regression of F6/FY ratio for whole range

This model showed that a 5x dilution factor was feasible to use, which was our optimal outcome. As such, no further optimizations were needed. It also validated the need for multispectral sensing, since it showed predictive accuracy increased with the use of multiple channels.

Standard Curve Test

The final experiment aimed to create a standard curve using the final SpectraStream device. Absorbance spectrophotometry relates the absolute absorbance, also called the extinction coefficient, to the sample concentration through the Beer-Lambert Law [5]. It states that the optical absorbance of a coloured molecule in a transparent solvent varies linearly with both the sample pathlength and the molecule concentration [5]. This can be mathematically expressed as:

$$A_{\lambda} = \epsilon cl \quad (4.1)$$

where A_{λ} is the absorbance, ϵ is the extinction coefficient, c is the concentration of the coloured molecule, and l is the pathlength. In an ideal experiment, this law could be used to calculate the concentration of creatinine by knowing the absorbance and pathlength alone. In reality, a series of solutions with known concentrations are made and a graph of concentration versus measured absorbance is created, called the standard curve. This standard curve may not exhibit perfectly linear behaviour, which allows for better correspondence between absorbance and concentration [5].

The reactant quantities, dilution factor, and overall procedure were determined from previous experiments. The standard curve involved making 20 different samples across the testing range to fully characterize the spectral properties of the reaction (Figure 4-7).



Figure 4-7: Sample preparation for standard curve creation.

Standard curves were made for each channel, where the normalized ADC counts were used as a proxy for absorbance (see Figure 4-8 for an example). This data was used to train our final model, which is discussed in Section 4.1.2 below.

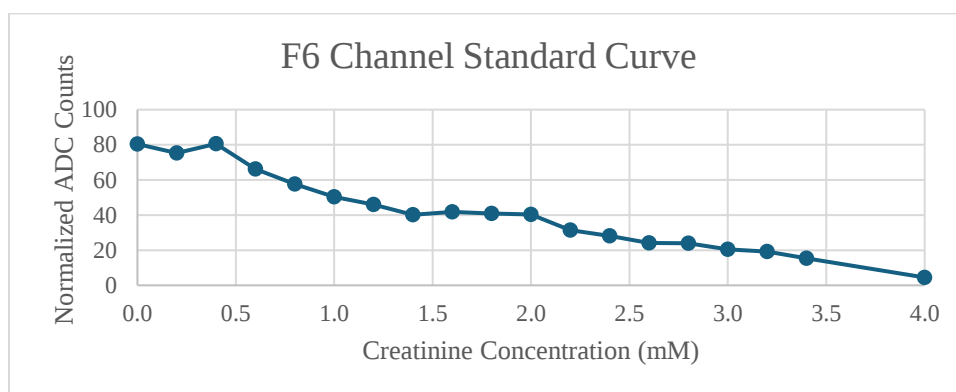


Figure 4-8: Standard curve creation for F6 (635 nm) channel.

4.1.2 Development of Creatinine Prediction Model

Multiple linear regression (MLR) is a mathematical technique used to model the relationship between multiple independent predictor variables and a single dependent outcome variable [4]. It takes the form:

$$y = a_1x_1 + a_2x_2 + \dots + a_nx_n \quad (4.2)$$

where y is the dependent outcome variable, x_i are the predictor variables, a_i are the linear regression coefficients, and n is the number of predictor variables. Due to the linearity of the Beer-Lambert Law, MLR is proposed as an effective modelling technique for the SpectraStream. Linear regression has also been used to estimate chemical components through spectrophotometric measurements in the literature with success [1], [6], [7].

The data from the standard curve chemical test was imported into Python as a Pandas dataframe to clean, model, and visualize the data (Appendix 7.3). The following procedure was followed, which is adapted from Section 2.2.3.

1. The data is cleaned. Rows and columns that do not contain information about relevant ADC counts or creatinine concentration are dropped. The ADC counts are normalized to the blank sample. This produces the following dataframe:

Table 4-1: Result after data from standard curve creation is cleaned.

Creatinine Concentration (mM)	F3 Normalized	F4 Normalized	...	F7 Normalized	F8 Normalized
0.0	1.00	1.00	...	1.00	1.00
0.2	0.70	0.64	...	0.97	0.90
⋮	⋮	⋮	...	⋮	⋮
3.8	0.08	0.04	...	0.44	0.40
4.0	0.02	0.01	...	0.17	0.18

2. The data is split into dependent and independent variables and passed into scikit-learn's LinearRegression model.
3. The coefficients, intercept, and R^2 value are returned.
4. A plot of actual vs. predicted values is created and assessed for goodness of fit.

After the procedure is followed, the R^2 is determined to be 0.99 and the plot shows a high agreement with the predicted creatinine concentrations and the actual concentrations (Figure 4-9). This indicates the variance in the creatinine concentration can be near perfectly described using this model.

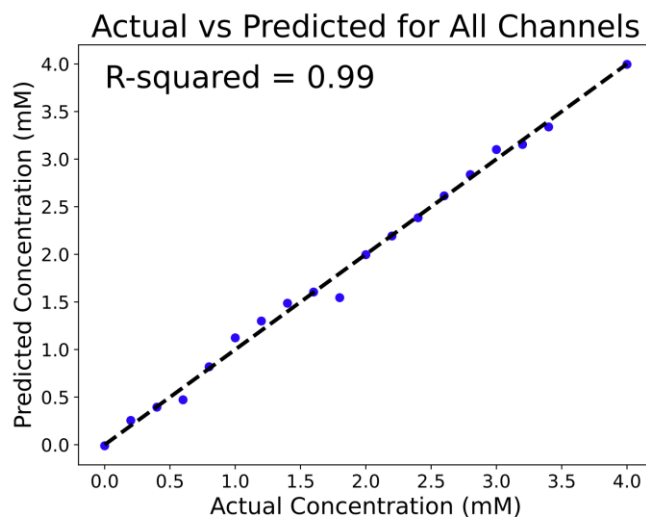


Figure 4-9: Result from MLR model.

This model shows optimizations as compared to our initial proof-of-concept prediction model. By creating samples with creatinine and the DNBA reaction, the assumption that food colouring and water can accurately reproduce the colour change is removed. By using our final device to obtain the measurements, we ensure the model is more representative of measurements that would be

obtained by the user. Finally, by obtaining a much larger sample of test data, we reduce the risk of overfitting and have more confidence in the model.

More complex modelling tools, such as principal component analysis or regularization techniques were also considered. Ultimately, the MLR model was chosen as the preferred technique due to its relative simplicity and superb goodness of fit. Other models would not be able to significantly outperform MLR but would reduce the interpretability of the results and needlessly complicate the data modelling procedure.

4.1.3 Development of Electrical Architecture

Following analysis of design criteria, proof-of-concept testing, and discussion with Stakeholders and Co-Instructors, the following electrical architecture was devised for the final SpectraStream prototype (Figure 4-10). All electronic tasks occur on a custom PCB - categorized into logic and power components. See the schematic in Figure 7-3 of Appendix B.

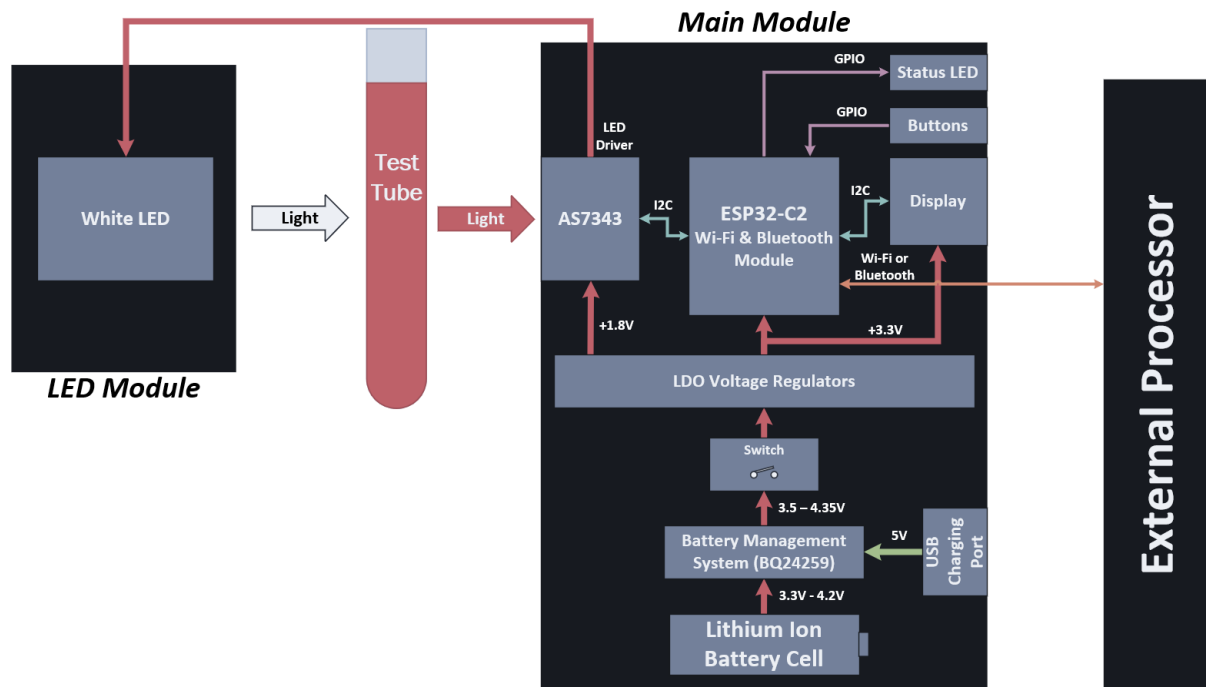


Figure 4-10: SpectraStream electrical architecture diagram.

The logic components consist of the AS7343 multispectral sensor. An ESP8684-MINI-1-H2 (in the ESP32-C2 family of microcontrollers) communicates to the AS7343 through I2C, and processes retrieved spectral data. It may relay spectral data and computed creatinine concentration to an external OLED through I2C, a web server using Wi-Fi, or a host PC through USB for observation. The user may initiate creatinine measurement with the device through buttons connected to GPIO pins on the MCU. The flexibility with communication protocols and low cost

of the ESP8684-MINI-1-H2 satisfied the appropriate design criteria in Table 2-3, explaining its use in the final SpectraStream design. The AS7343 contains a built-in LED driver that sinks current up to 250mA. Its connection was broken out to header pins on the PCB to power the white LED. An extra set of header pins for an ESP32 PICO development kit was included as a backup if the ESP8684-MINI-1-H2 becomes non-operational.

To determine the appropriate battery for SpectraStream, electrical current consumption tests on the prototype from Figure 2-11 were performed by placing a multimeter in series with the USB connection powering the ESP8266, AS7343 development kit, and OLED screen (a part of the ESP8266 breakout board). See Figure 4-11. It was found the OLED and MCU consume a standby current of 31 mA and a maximum current of 130 mA when communicating with the AS7343 and transmitting spectral data over Wi-Fi. The LED module meant to illuminate the urine sample was omitted from this setup, but its current was assumed to be the worst-case value of 250mA [8]. Table 4-2 lists the results from the current consumption test.

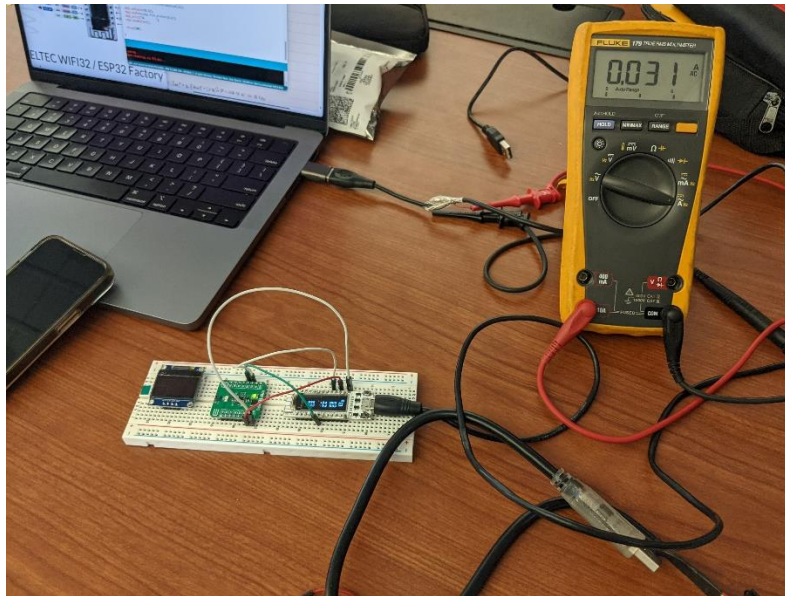


Figure 4-11: Prototype battery lifetime testing.

Table 4-2: Prototype current consumption test results.

Metric	Current (mA)
Sensor & MCU standby current (<i>not used in battery lifetime calculation</i>)	31
Sensor & MCU maximum current	130
LED module maximum current	250
Total current	380

Assuming a worst-case measurement time of 10 seconds, which includes retrieving spectral data and transmitting data wirelessly to a web server, the necessary battery capacity to satisfy Requirement 4.1 in Table 2-3 is,

$$1000 \text{ measurements} \times \frac{10 \text{ s}}{\text{measurement}} \times \frac{1 \text{ hr}}{3600 \text{ s}} \times 0.380 \text{ A} \approx 1 \text{ Ah} \quad (4.3)$$

A 3 Ah 18650 lithium-ion battery cell was chosen to maximize simplicity, minimize cost, and provide adequate safety factor. A TI BQ24259 battery charging IC was implemented in the PCB design as it permits the powering charging and powering of SpectraStream through a USB-C connection [9]. Additionally, the BQ24259 provides numerous battery protection mechanisms, such as overvoltage and overcurrent latching circuitry. The considerable integrated features for battery management and the affordable price of the BQ24259 made it an ideal choice for SpectraStream to minimize design complexity and preserve timelines. The output battery voltage from the BQ24259 is fed to an on-off switch in series with numerous low-dropout (LDO) voltage regulators to maintain stable system voltages despite fluctuations in battery voltage due to charge status. System stable voltages are crucial to ensure consistent white LED intensity, which affects spectral measurements.

Schematic capture and PCB layout occurred in Altium Designer. Proper PCB layout considerations were followed. For instance, filtering capacitors of datasheet-recommended value were placed close to IC power inputs and outputs. Fast-switching voltage signals on the top PCB copper layer were referenced to a continuous ground plane on the bottom copper layer to prevent crosstalk. The final PCB design is shown in Figure 4-12.

Custom cables with locking connectors were created to connect the main PCB to peripherals such as the OLED instead of breadboard wires to prevent loose connections.

The BOM for the SpectraStream electronics, which compose most of the device cost, are reported in Figure 7-4 of Appendix B. It costs approximately 70 CAD to produce one unit and 45 CAD to produce 500 units of mass manufacturing. Therefore, the cost of SpectraStream is within the intended price range of 25 CAD to 75 CAD (see Requirement 1.1 of Table 2-1).

4.2 IMPLEMENTATION

4.2.1 Electrical Implementation

The electrical design of SpectraStream progressed through three different iterations from the start of the course to the final exposition. The first prototype initially consisted of an ESP8266 wired to a breakout board containing the AS7343 (see Figure 2-12). The proof-of-concept focused only on ensuring the team was able to power on, communicate with, and read values from the sensor. A handheld RGB LED was used to simulate shifting colour wavelengths, and initial validation tests were done to confirm the functionality of the sensor in terms of displaying the correct colour shifts (Figure 7-1 in Appendix B). Current consumption testing was also performed on this prototype as discussed in Section 4.1.3.

Progression to the second prototype removed the older ESP8266 in favour of an updated ESP32 PICO for the faster processor and updated libraries. The breakout board was replaced with an AS7343 development kit from the manufacturer, which enabled the use of sophisticated software for more extensive spectral testing. The handheld RGB LED was replaced with a much brighter built-in 4000 K white LED module fixed into a 3D-printed chassis. Validation and testing for the second prototype were performed using the manufacturer development kit software package, which interpolated spectral readings. To mimic the usage of lab spectrometers, glass cuvettes filled with differing-coloured solutions were placed in the center of the device, with the LED fixed to one end and the sensor fixed to the other. Once the lid was placed over the sample to reduce light interference from the environment, spectral measurements were taken and formatted in Excel (Figure 7-2). Validation of the testing data was performed by checking that each solution channel output shifted accordingly to what was provided in the datasheet.

Significant updates to all electrical components were made to arrive at the last device iteration. The team opted to leave behind both the breakout board and development kit, replacing the functionality of both with a custom-built PCB. Through the three prototypes, the electrical implementation shows progression to increase customizability and system integration.

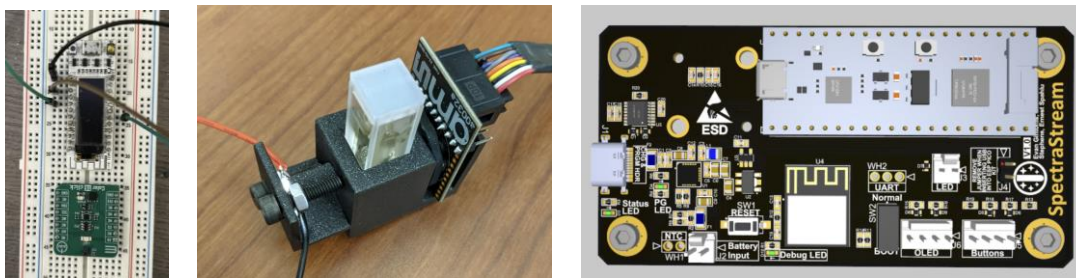


Figure 4-12: Electrical design progression.

Figure 4-13 shows the implementation of the electrical components discussed in Section 4.1.3. The built-in ESP32-C2 microcontroller, backup headers for a secondary ESP32 PICO development kit, LED connections, OLED connections, voltage regulators, battery, and custom cables can be seen. The auxiliary OLED display was later embedded into the front of the chassis.

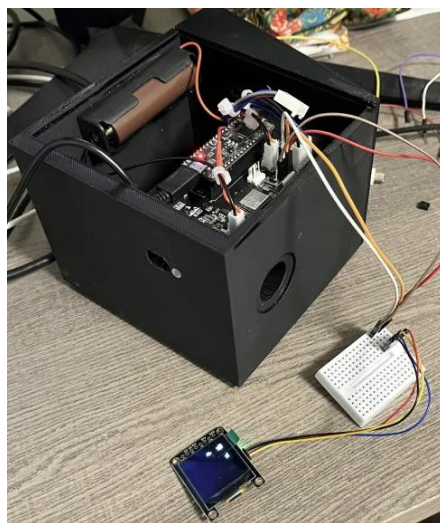


Figure 4-13: Electrical Components in Final Iteration

The PCB was first tested on the bench. When first powering the board with a benchtop supply, the supply's current limit was slowly raised in case of shorts. Once the PCB current draw stabilized at an appropriate value, all voltage rails were probed with a multimeter to confirm the voltage regulators were operating properly. The BQ24259 battery charger IC was tested by powering the PCB from the lithium-ion cell and USB-C port separately, and then together. The battery was then discharged and recharged with the PCB successfully.

Following benchtop electrical testing, SpectraStream was extensively tested in the iBioMed wet lab as described in Section 4.1.1. Each channel value was read through the website or serial interface for data measurements (Figure 7-5). Validation was performed by checking the predicted creatinine concentration values calculated from spectral measurements against the known chemical concentrations that were administered through pipetting. From running the device continuously in the lab (i.e., consecutive scans with no standby time), the 3 Ah battery lasted approximately 4 hours following a full charge.

A strong recommendation for future iterations is the inclusion of a larger, multicoloured OLED display, as the current unit is under an inch long and includes only two usable colours. Small displays reduce accessibility, as users with vision problems may not necessarily be able to read crucial data during operation. A larger display would allow for larger font sizes and many more of the essential channel readings to be displayed, and standard RGB display colours could help users easily distinguish the channels, as they correspond to differing wavelengths of light.

4.2.2 Mechanical Implementation

Progression of the mechanical design occurred similarly to the electrical design, although there were only two major iterations, as the first prototype was solely fixed on breadboards and was not contained inside a mechanical enclosure. The primary goal in both cases was to model the operation and current design of a usual lab spectrometer, which usually consists of a cuvette enclosure, with a light source on one end and a photodetector on the other end. To mimic this functionality, an initial Inventor schematic was developed around the AS7343 development board

(Figure 4-14). A rectangular chamber was placed in the center to accommodate a rectangular glass cuvette, and a cap was built to block out environmental light. The Citizen LED was affixed to the end opposing the sensor with Philips screws, and a tunnel was designed to create a fixed optical path to the cuvette sample. The chassis was built using 3D-printed black PLA filament to reduce light interference.

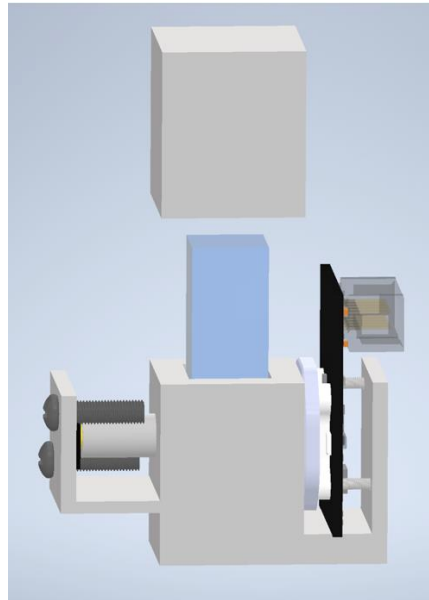


Figure 4-14: Initial Mechanical Prototype

The final design aimed to improve on all the elements considered in the first chassis prototype, while also accommodating new electrical components like the PCB, OLED, buttons, and battery pack. To begin the brainstorming process, an initial hand-drawn sketch of the final device chassis was made (Figure 7-6). This completed Inventor model design mimics the usual slanted cover of conventional mass scales, with a switch for powering the device, a black button to blank, and a red button to retrieve spectral measurements (Figure 4-15). There is also an OLED cavity with screw holes for each corner and additional internal screw holes to mount the PCB and battery pack. The backside features an opening for the USB-C port and a small hole for the status LED. The chamber features a circular redesign to accommodate larger and curved test tubes, with a cap that clicks into place. A sliding cover allows for easy access to internal components.



Figure 4-15: Final Mechanical Design

The chassis was printed in a similar fashion to the initial prototype, using black 3D PLA filament (Figure 4-16). The overall size was increased not only to accommodate the larger PCB footprint and additional components but also to allow for increased accessibility, as the older design was small enough to cause difficulties during operation, especially for users with impaired motor functions. The newer chassis is still much smaller than conventional lab spectrometers but now has a footprint that is large enough for easy interaction when placed on a flat surface and includes physical buttons for operation. Testing and validation data for the first and final chassis designs match the data for the second and final prototypes in the electrical section.



Figure 4-16: Final 3D Printed Chassis

Although some of the accessibility concerns mentioned in Chapter 3 were addressed with the larger size and addition of physical button controls, the device now contains many sharp edges and jagged components, which could potentially introduce user harm. A strong recommendation for the next iteration is to build the chassis using injection-molded plastic or similar techniques to print the chassis as one whole piece. This strategy not only provides smoother edges but also improves the overall reliability and rigidity of the device by reducing the number of independent pieces that must be adhered together.

4.2.3 Software Implementation

Similar to the electrical section, the software design progressed through three different stages. The first stage corresponded to the first prototype and revolved around setting up the initial firmware code to interface with the sensor breakout board. Since the sensor is relatively new, there were no existing libraries to interface with it, so all the register mappings and initialization steps had to be developed from scratch. A GitHub repository containing all register mappings is included in Appendix B, Section 7.6 for reproducibility. The primary functionality included in this iteration is the `ReadChannel()` function, which collects the high and low bits of spectral channels, which are then appended together to output an array of interpretable spectral values. Testing and validation results for this iteration are referenced earlier in the electrical section for the first prototype.

The second iteration focused on adjusting sensor gain and sampling time values, as well as migrating to the ESP32 and setting up the board as a Wi-Fi station to host a primitive website. The development kit software was also used during the second iteration to provide interpolated output values.

The third and final software iteration made substantial updates to the interface and overall operation of the device, in part to accommodate the new electrical components. New functions were added to output formatted data to both the OLED display and USB serial connections (Figure 4-17).

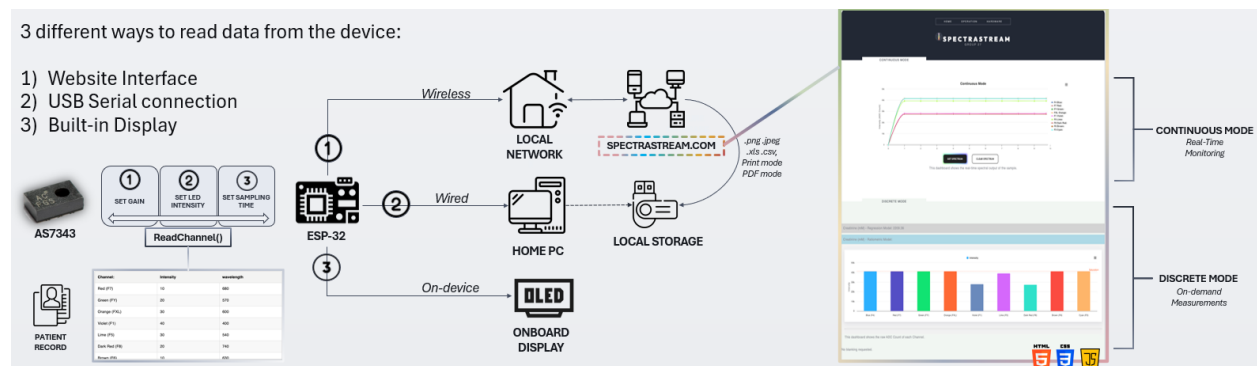


Figure 4-17: Data flow from sensor acquisition to user

The Wi-Fi server was loaded with HTML, CSS, JavaScript, and jQuery elements to create a complete web application. The ESP32 in station mode connects to local Wi-Fi connections and responds to HTTP client connections to serve GET requests, which come from clients connecting to the hosted website and performing actions. A typical server-client interaction example, where the server sends the formatted channel spectrum values as a string to the client, is shown in Appendix B, Section 7.6.

The web interface was programmed to include two modes: a continuous mode for real-time monitoring of all channel values and a discrete mode that outputs a bar chart and database table of readings upon button press (Figure 7-7). When the device is on, the continuous mode is controlled by the two buttons on the screen. Clicking “Get Spectrum” will start graphing channel spectrum values at 250ms intervals, hitting “Clear Spectrum” once will clear the graph, and hitting it twice will pause the data stream. The discrete mode can be controlled by pressing the red physical button on the device, which will update both the OLED and the bar graph and chart on the web application with the new spectral values. The discrete mode is meant for more precise measurements, due to the lower sampling time, and also outputs a creatinine concentration based on the regression model developed from chemical testing, mentioned in Section 4.2.1.

Pressing the black button will place the device in a “blanking mode,” which will adjust the AS7343 gain depending on the values read from the blank. Both the discrete and continuous modes provide easy data export methods for further analysis in the form of Excel (XLS), CSV, PDF, print, or PNG formats. Clicking the three dashes on the right-hand corners of either mode will pull up the options (Figure 4-18). The full C code for the ESP32 server can be found in Appendix B, Section 7.6.3, while the entire software package, including the web application code and asset files, can be found on the GitHub page.

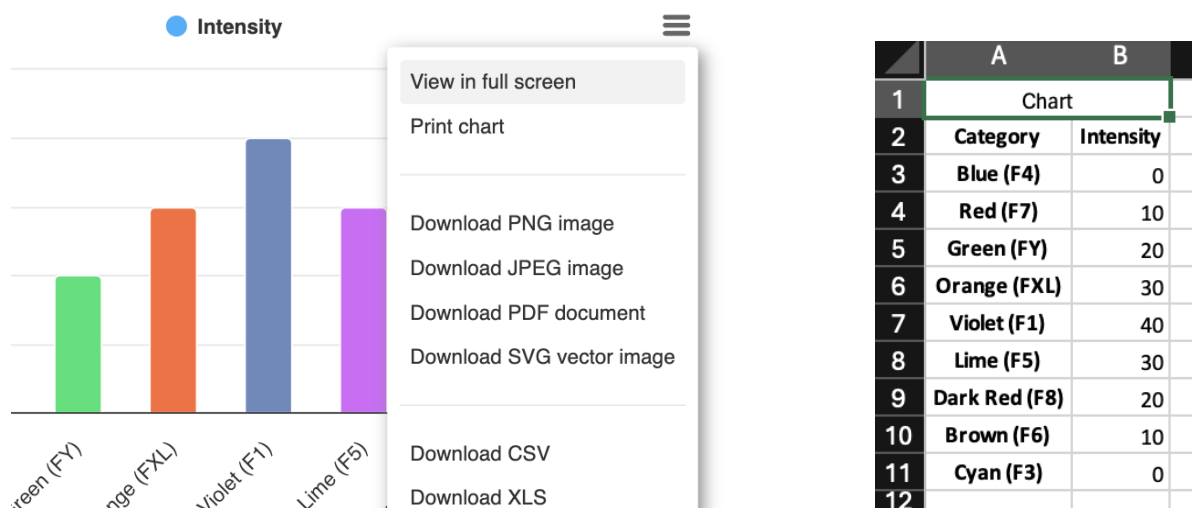


Figure 4-18: Exporting data from the web application

The web application met the accessibility goals set in Chapter 3, as it was developed with any device in mind, having basic browser functionality and included simple but comprehensive

dashboards for extracting data in an organized manner. A major security flaw that went unnoticed in Chapter 3 was uncovered and corrected. Local Wi-Fi credentials and details were included in the main server code, potentially exposing the user's private information to anyone with access to the source code. This data was removed and replaced with hidden variables set in a secrets.h file, which is unique to every user. Additionally, WPA2-specific code was added to allow connections to Mac Wi-Fi and eduroam, enabling connection to secure enterprise connections, and allowing students anywhere on campus to access the website. To address concerns discussed in Chapter 3, HTTP authenticate requests (which check for specific credentials) were added to the server code but ultimately removed due to simplicity, time constraints, and limited flash space on the ESP32 onboard memory. A temporary setup with just one user profile and credential setup was implemented to combat the limited memory space but proved to be unreliable and was removed to ensure the final demonstration and exposition were seamless. There is, therefore, a strong recommendation to tighten up security with a trusted secure database provider like Microsoft Azure or DigitalOcean, which rely on more secure SQL server authentication rather than primitive HTTP authenticate requests. Additionally, the web application does not include any auditory accessibility options or keyboard navigation alternatives, which may be essential for users with visual or motor impairments. Lastly, the current web application does not make use of newer HTML5 or React technologies, which are considered industry standards in web application development and allow for improved functionality and performance.

4.3 FUTURE WORK

The final SpectraStream prototype successfully demonstrated a strong ability to accurately quantify creatinine concentrations in urine in place of conventional methods requiring expensive lab-grade equipment, complex procedures, and trained operators, for CKD screening. It particularly excelled at providing on-demand spectral values and creatine concentration estimates at high sampling rates, in a package that costs about \$50-\$80 CAD, compared to a conventional lab spectrometer like an \$800 ThermoFisher Spectronic 20D+ [10]. The device accomplishes these feats while maintaining a modern, intuitive interface and boasting simple operation modes. However, there is significant work to be done before the SpectraStream can be considered a mature, multi-use, spectral point-of-care device.

Despite the many considerations and updates to the chemical procedure, requiring users to perform chemical mixture and dilution procedures involving hazardous ingredients remains a significant challenge. Similar examples like COVID-19 antigen rapid tests, which also include chemical mixture steps with arguably safer materials, often suffer from incorrect diagnoses due to user error [11]. The first and most essential next major step for future SpectraStream iterations, therefore, must aim to remove these procedural burdens from users. This can be accomplished in two ways: 1) determining the full linear range of the SpectraStream device to find the lowest urine dilution factor and chemical volume needed for correct readings, and 2) developing an auto-dispensing feature that is capable of intelligently diluting urine samples provided by users. The first option may remove the dilution requirement from the procedure altogether, reducing both the burden on the user and the overall possibility of user error. An additional advantage of finding a lower dilution factor is that less overall chemical volume is required for the mixture steps, which

minimizes the environmental footprint of the device. The second option removes both steps altogether, by handing the entire chemical procedure responsibility over to the device. Miniaturized versions of automated dilution systems like the Titrosampler from Metrohm and C30S from Mettler can be incorporated into the existing device to automatically dilute and mix urine samples [12]. This option may not necessarily reduce the amount of chemical volume needed and introduces further costs and complexity to the device but greatly improves the PoC capability of the device by removing user error and reducing preparation time. A secondary objective of future work in this area should develop an extensive chemical disposal procedure through collaboration with Health Canada.

Although the SpectraStream has demonstrated effectiveness as a spectral PoC device for creatinine detection, its effectiveness as a broad-use spectral fingerprint PoC device has yet to be proven. There is significant work to be done in all aspects of the implementation to achieve this goal. Firstly, extensive chemical testing should be undertaken for other common preventative care biomarkers. An example could be uric acid levels in urine, which have been measured through UV spectrophotometry as a biomarker for gout and kidney disease in previous work [13]. Although this example is similar to the current urine creatinine measurement work done for the SpectraStream, a wide variety of spectral analysis cases for different types of solutions should be used to prove the flexibility of the device. Another example involving a completely different use case is the spectral analysis of drinking water, which has been found to be able to determine water quality [14]. This also leverages the 14-channel count and broad 370nm – 900nm wavelength range of the AS7343, which is a huge advantage the device has over traditional lab spectrometers. Additional work would involve incorporating different light source options, since differing solutions may require light sources across different wavelengths. The web application would also have to be updated to include a customizable model tuning feature that trains models specific to the problem and solution being measured, since the current implementation includes hardcoded regression models that are only specific to creatinine. The development of this feature would require enough work to be a separate project on its own but is essential to extending the predictive capabilities of spectral PoC measurements to a variety of different situations.

Lastly, approval of the SpectraStream as a Class II active-diagnostic medical device in Canada is a rigorous and time-consuming process that would likely require significant updates in all aspects of the current implementation to meet the required ISO 13485 and IEC 60601 technical standards for medical electrical devices. Many of the previously mentioned drawbacks, such as unsecured patient database entries, sharp chassis edges and corners, untested lithium-ion battery safety ratings, etc., would likely need to be either entirely solved/removed or adjusted to meet an appropriate safety level. Class II devices also usually undergo a 510(k) review, which determines whether or not the new device is equivalent to existing devices in the space [15]. Given the relatively recent introduction of miniaturized spectral sensors into the general market and the lack of similar solutions in the market today, each component of the device will undergo significant scrutiny during the approval process. Future steps would involve various current leakage tests, voltage shock tests, reliability tests of the chassis, sensor, and other auxiliary components. A thermal management system will also have to be developed and tested, since the ESP32 module and battery pack have been known to generate significant heat during extended usage.

4.4 REFLECTIONS AND RECOMMENDATIONS

4.4.1 Reflections

Throughout the 8 months of capstone, there have been many successes, failures, and setbacks encountered along the way. Our group has celebrated our successes, learned from our failures, and adapted to setbacks, resulting in a final product we are proud of.

As a self-developed capstone, the details of our project were not flushed out when we began working, which made our initial project proposal an important first step in the process. Our group was successful at proposing a project that was relevant to both biomedical and electrical engineering, while also aligning with our group's interests and skill sets. We garnered interest from Dr. Shirani and several potential stakeholders, including a urology resident at the University of Toronto with an interest in biomedical engineering, medical device development, and entrepreneurship. This seemed like the perfect fit for our project, but we faced our first setback when we were unable to find a time to meet with them before our first report deadline. Without any guidance from a stakeholder, we struggled to identify design criteria in our report. This setback continued when our potential stakeholder stopped replying to emails around the end of September. We were forced to find another stakeholder, but this was difficult with a project already underway. Reflecting on this setback, it would have been beneficial to have a confirmed stakeholder as one of our first steps in the process. A relevant and engaged stakeholder could have provided our group with valuable input and feedback on our design. We could have also tried to find a variety of different stakeholders, including those living with CKD. We were focused on finding a stakeholder who could provide technical feedback, but someone living with the disease we were targeting may have been more valuable.

From a technical perspective, we had many successes. From the electrical side, two of our group members had no experience with PCB design, whereas one group member was very familiar with it. We had great success challenging everyone and adapting the project to fit everyone's level of expertise. The two inexperienced members focused mostly on creating schematics and footprints for simple components, whereas the experienced individual oversaw more complex tasks like battery management and design validation. We also had success incorporating interdisciplinary elements, like chemical, mechanical, and software design. These successes made the design configuration aspect of our project quite smooth, and we were able to present a very polished and high-fidelity initial prototype.

Although we made several overall design iterations, one failure of our group was to iterate specific design elements in our device. One example would be the OLED, which all members of the group were comfortable with using. As such, we did not feel any pressure to do rigorous testing with this element of the design. This ended up being a mistake since the OLED screen ended up malfunctioning right before our final demo. Reflecting on this failure, we believe it was our familiarity with the component that made us careless with it, since we thought we could implement it easily. With elements we were less comfortable with, we added redundancies and "prepared for the worst" when designing, but this was overlooked with the OLED. Ordering extra screens,

reading the online reviews for our chosen components, or involving them earlier in the prototyping phase could have avoided this major setback.

4.4.2 Gantt Chart Comparison

Figure 4-19 shows a Gantt chart representing actual project timelines. For the first half of the SpectraStream project, timelines met as a proof-of-concept device was created, and spectral data was obtained and related to colour changes from food colouring solutions. Thus, there is an agreement between the final Gantt chart and the Fall portion of the inaugural Gantt from Figure 1-2.

Most project delays occurred during the prototyping stage. Firstly, the Jaffe reaction was deemed unsafe due to the explosive properties of picric acid. Finding a safer alternative and waiting for the chemicals to ship meant chemical testing, listed under Design Validation, did not occur until early March and finish until early April. Chemical testing was originally scheduled to begin in early January. Although preliminary chemical testing occurred promptly and was successful, the resources put into realigning chemical timelines meant sacrificing the schedule for hardware design. PCB design, also scheduled to begin in early January, did not commence until February. PCB manufacturing and testing occurred in mid-March. Luckily, the first board revision functioned. Otherwise, a cohesive final SpectraStream prototype would not have transpired. Academic and extracurricular commitments were also more intense than in the Fall. Thus, the detailed mechanical and optical design did not commence until early March, and the final prototype was 3D printed at the beginning of April. The hardware and mechanical delays impacted the completion of firmware and software integration, which was not finished until a day before the final demo. Breadboard test setups permitted firmware and software design throughout the Winter. All Detailed Design timeline delays are visualized as shifts between the final Gantt chart and the ones presented in Figure 2-16 and Figure 3-2. Despite delays, a remarkable effort from all members resulted in a strong finish!

4.4.3 Recommendations

Going into Capstone I wish I knew:

- 1) *"How quickly the scope of a project can change - be prepared to undertake work outside your skillset and stay flexible, keep learning."* - Ernest
- 2) *"The 5P06 teaching and technical staff can provide advice on more optimized ways to make your designs come to life. Don't be afraid to get out of your comfort zone and learn a new skill with their support."* - Lauren
- 3) *"How fast time flies! Everything in Engineering always takes twice as long as it should. Always put significant effort into the Capstone to ensure enough time to prototype. Doing so will relieve much stress towards the end of the project."* - Evan

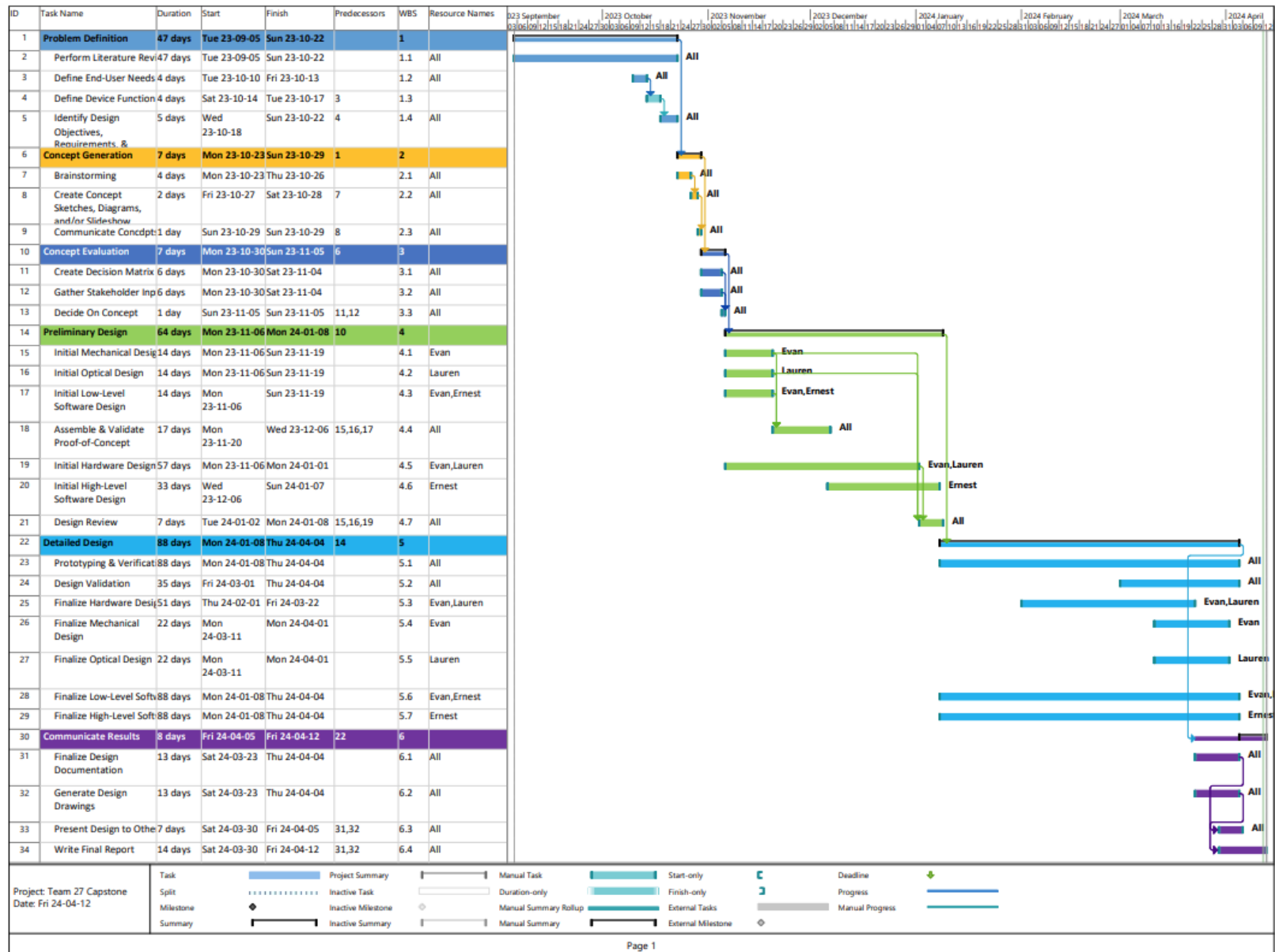


Figure 4-19: Final Gantt Chart.

4.5 CHAPTER 4 REFERENCES

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5 CONCLUSION

Chronic kidney disease (CKD) impairs the kidney's ability to filter blood, posing critical and often fatal challenges for patients worldwide. Urinary creatinine, a widely accepted CKD biomarker, is filtered by the kidneys, and elevated levels indicate renal impairment. The cost, complexity, and required training needed for CKD monitoring add strain to already burdened healthcare facilities and personnel. To address these challenges, we present SpectraStream, a point-of-care test (PoCT) spectrometer that leverages multispectral sensing to quantify urinary creatinine levels through the DNBA reaction. The proposed device measures spectral intensity levels of incoming light across fourteen channels spanning the visible, UV, and NIR spectra. The design features a 3D-printed chassis housing a custom PCB, complete with an AS7343 sensor, high-powered LED light source, and microcontroller processing unit. SpectraStream involves a straightforward operating procedure where users collect urine samples, introduce appropriate reagents, and track sensor outputs through a web application. The potential impact across the healthcare industry is significant, given the high prevalence of CKD and the prohibitive costs and complexities associated with modern multispectral equipment. The design's low cost (~\$50 CAD), straightforward operation steps, and portability make it an ideal choice for at-home monitoring of creatinine levels, offering substantial value to users afflicted with CKD or those concerned about their kidney health.

The implementation of SpectraStream involved three principal areas: electrical, mechanical, and software. In the electrical domain, the device underwent three iterations. Initially, the prototype featured an ESP8266 wired to a breakout board with the AS7343 sensor, focusing on basic functionality. The second iteration transitioned to an ESP32 PICO and an AS7343 development kit, enabling more sophisticated spectral testing. The final iteration saw significant updates, including a custom-built printed circuit board (PCB) integrating the sensor, ESP32 microcontroller, user peripherals, LED board, and battery management. Mechanically, the design evolved through two iterations to mimic the functionality of traditional lab spectrometers. The initial prototype featured a rectangular chamber for a glass cuvette and a fixed optical path. The final design was updated to include a larger chassis, which accommodated additional electrical components and improved accessibility. Suggestions for future iterations include using injection-molded plastic for smoother edges and increased reliability. Software development also progressed through three stages, focusing on firmware code, Wi-Fi connectivity, and web application design. The final iteration included a comprehensive web interface with two modes: continuous for real-time monitoring and discrete for precise measurements. Security enhancements, such as removing local Wi-Fi credentials from the source code, were implemented. Future improvements could include auditory and keyboard accessibility options and leveraging newer web technologies for enhanced functionality.

While the SpectraStream prototype demonstrates promise for CKD screening with its cost-effective creatinine quantification capabilities, significant refinement is essential to evolve it into a versatile, user-friendly, and widely applicable point-of-care diagnostic tool. The device's reliance on user-performed chemical procedures presents a hurdle in ensuring accurate diagnostic capabilities. We propose future chemical work to either eliminate the need for dilution or

developing an auto-dispensing feature that would handle sample preparation independently. Another potential project involving the SpectraStream would be expanding its capabilities beyond just creatinine monitoring. By completing further chemical testing and updating the web application to include more modelling capabilities, SpectraStream can expand its predictive capabilities. To bring SpectraStream to the market, a rigorous regulatory approval process would need to be adhered to to recognize it as a Class II active-diagnostic medical device. This involves meeting stringent technical standards, including ISO 13485 and IEC 60601, and undergoing a 510(k) review to assess equivalence with existing devices. Addressing issues such as unsecured patient data, safety concerns related to chassis design and battery usage, and implementing robust reliability and thermal management systems are critical for successful regulatory clearance. The proposed future work encompasses a comprehensive overhaul aimed at enhancing the SpectraStream's functionality, usability, and regulatory compliance. By addressing these challenges and implementing the suggested improvements, the SpectraStream has the potential to emerge as a transformative tool in PoC diagnostics, benefiting healthcare providers and patients alike.

6 APPENDIX A: PROJECT MANAGEMENT

Date	Meeting With	Meeting Notes
09/15/23	Dr. Shirani	Received approval for self-developed project
09/22/23	Dr. Fang	- Discussed possibilities of Dr. Fang becoming project stakeholder - He recruited his PhD. student Tianqi who does research on PoCT
10/05/23	Dr. Fang and Tianqi	- Discussed design concept and general questions - Discussed potential pathologies that could be targeted with the device - Action items: develop a block diagram and compile literature review
11/11/23	Dr. Fang	Presented idea to measure urinary creatinine, no issues evident
11/14/23	Dr. Shirani	Presented idea of measuring urinary creatinine concentration, no issues evident
11/20/23	Mr. Rusin	- Lab orientation meeting - Discussed wet lab safety form
11/21/23	Dr. Selvaganapathy	- Presented project updates, feedback: - More concise motivation section - Make a better case for the use of multispectral sensing - Technical design criteria should be quantitative - Human factor: outline how the end-user will interface with the device
11/21/23	Mr. Bola	Met to get initial prototype mechanical chassis approved for 3D printing
12/02/23	Dr. Fang and Tianqi	- Presented project updates, comments left: - Set goal price for device consistent with other medical devices - Measuring relative change may be easier than absolute value - Look into person-to-person and sample-to-sample variation to measure error - Design a sampling procedure for the user - Actionable items: source chemical materials, upgrade design of device
01/26/24	Dr. Fang	- Discussed how to measure samples (blanking, stability of measurements, auto-calibrating test tube possibilities) - Discussed how to choose an LED to optimize SNR - Discussed data transfer options
01/30/24	Dr. Shirani	Presented project updates, no issues evident
02/02/24	Dr. Selvaganapathy	- Presented project updates, feedback - Research into interferents - Ensure design is robust to user error - Reduce number of chemicals the user must dispose of - Need prototype test data ASAP
03/06/24	Mr. Rusin	Met to perform Initial DNBA Reaction Test
03/11/24	Dr. Fang	Presented project updates, feedback

		○ Use data to look in depth on how sensor works ○ Review concepts of blue wavelength filter shift and cone half angle
03/18/24	Mr. Rusin	• Met to perform Dilution Factor Test
03/19/24	Dr. Shirani	• Presented project updates, no issues evident
03/29/24	Mr. Bola	• Final device peripheral prints were approved for 3D printing
04/01/24	Mr. Bola and Mr. Pilli	• Discussed ways to optimize large print to adhere to Design Studio print requirements ○ Considerations to laser cut walls or divide part into two separate prints • Final device mechanical chassis was approved for 3D printing
04/02/24	Dr. Shirani	• Presented project updates, no issues evident • Discussed final project demo and what we should be showcasing
04/02/24	Dr. Selvaganapathy	• Presented project updates, feedback: ○ Consider what information is necessary for a presentation
04/04/24	Mr. Rusin	• Met to perform Standard Curve Test and record demo video

7 APPENDIX B: SUPPLEMENTARY INFORMATION

7.1 PROOF-OF-CONCEPT DEVICE PYTHON MODELLING CODE

```
import pandas as pd
import statsmodels.api as sm
import seaborn as sns
import matplotlib.pyplot as plt

# Import dataset
df = pd.read_csv('AS7343_Log.csv', sep = ';')

# Drop rows with data from other tests
df = df.drop(index=range(6, 10))

# Insert row with creatinine concentrations
df.insert(15, 'Creatinine Concentration', [0, 40, 80, 120, 160, 200])

# Get column names
column_labels_list = df.columns.tolist()

# Choose relevant columns with ADC counts
sublist_of_columns = column_labels_list[15:28]
df = df[sublist_of_columns]

# Calculate correlation matrix
correlation_matrix = df.corr()

# Plot a heatmap to visualize the correlation matrix
plt.figure(figsize=(10, 8))
sns.heatmap(correlation_matrix, annot=True, cmap='coolwarm', fmt=".2f")
plt.title("Correlation Matrix")
plt.tight_layout()
plt.show()

# Get dependent and independent variables
X = df[['F2 (424nm)', 'F5 (547nm)', 'F7 (685nm)']]
y = df['Creatinine Concentration']

# Perform ols regression
model = sm.OLS(y, X).fit()
print(model.summary())
```

7.2 CHEMICAL TESTING FULL PROCEDURES

7.2.1 Initial DNBA Reaction Test

Creatinine Standard Creation

1. Using the balance scale obtain as close to 226.24 mg of CRE powder as possible. Add the CRE powder to 100mL of 0.1N HCl solution in a test tube to create a 20 mM CRE stock standard. Label the test tube.
2. Pipette 1 mL of the CRE stock standard into a test tube and dilute it with 99 mL of distilled water to create a 0.2 mM CRE working standard. Label the test tube.

DNBA Reactant Creation

3. Add 55 mL of water to a test tube. Add 45 mL of 1N NaOH to create a 0.45N NaOH solution with a final volume of 100 mL. Add the water to the test tube before the 1N NaOH for safety purposes.
4. Use the balance scale obtain as close to 6.37 g of DNBA powder as possible. Dissolve the DNBA powder in the 0.45N NaOH solution to create the 0.3M DNBA reactant. Label the test tube.
5. Add 75 mL of water to a test tube. Add 25 mL of 1N NaOH to create a 0.25N NaOH solution with a final volume of 100 mL. Add the water to the test tube before the 1N NaOH for safety purposes.

DNBA Reaction

6. Extract the volumes of creatinine working standard into separate test tubes according to Table 7-1. Add distilled water to create a final volume of 4mL in each test tube. Ensure to label the test tubes with designators. Each sample emulates a urine sample with different CRE concentration that was diluted 100-fold.

Table 7-1: Constituents for sample solutions for initial DNBA test

Sample #	0.2mM Creatinine Standard (mL)	Distilled Water (mL)	Creatinine Concentration (μ M)
0 (Blank)	0	4	0
1	0.8	3.2	40
2	1.6	2.4	80
3	2.4	1.6	120
4	3.2	0.8	160
5	4	0	200

7. Pipette 2mL of DNBA reactant and 2mL 0.25N NaOH into each test tube. Shake gently and let the reaction incubate at room temperature.
8. During the reaction, extract the required amount of one sample and measure its absorbance at 465 nm against the blank sample every two minutes. Once the absorbance reaches steady

state, measure the 465 nm absorbance of the rest of the samples using the spectrophotometer. Measure the absorbance of each sample against the blank in the SpectraStream prototype.

9. After entering the results, dispose leftover chemical into the appropriate waste containers. Ensure to keep the CRE standards and diluted NaOH solutions for subsequent experiments. Clean the workbench and equipment as needed.

Results

10. Obtain the following:
 - a. The time it took for the reaction to reach steady state. If the reaction time was excessive (>30 minutes), it may be worth repeating the experiment using 0.5N NaOH instead of 0.25N NaOH to shorten reaction time.
 - b. A graph of absorbance vs. time of the sample chosen to evaluate the reaction time.
 - c. A picture of each sample following the DNBA reaction.
 - d. Absorbance data of each sample at 465 nm measured from the laboratory spectrophotometer.
 - e. ADC counts from each channel from the SpectraStream prototype.

7.2.2 Dilution Factor Test

Reactant Preparation

1. Repeat steps 1 and 3 to 5 from Experiment 6.1.1. Do not repeat step 2 because the point of this experiment is to alter the dilution factor of the creatinine solution (i.e., manipulate step 2 of Experiment 6.1.1).

Testing Formulation 5x Dilution

2. Add the following reactants to separate test tubes (Table 7-2). Ensure the test tubes are large enough to support the 10mL final volume of each solution. **ADD THE DNBA LAST.** Otherwise, the colour change may begin prematurely. Measure each sample with a spectrometer and SpectraStream prototype 12 minutes after adding the DNBA. Record the results.

Table 7-2: Constituents for sample solutions for dilution factor test

Sample #	Creatinine Concentration (mM)	20mM Creatinine Stock (μL)	Distilled Water (mL)	0.25 NaOH (mL)	0.3M DNBA + 0.45M NaOH (mL)
0 (Blank)	0	0	5	2.5	2.5
1	0.01	25	4.975	2.5	2.5
2	0.25	62.5	4.938	2.5	2.5
3	0.5	125	4.875	2.5	2.5
4	1	250	4.75	2.5	2.5
5	2	500	4.5	2.5	2.5
6	4	1000	4	2.5	2.5

Results

3. Obtain the following:
 - a. A picture of each sample following the DNBA reaction.
 - b. Absorbance vs. creatinine concentration graphs for each formulation. Show data from each SpectraStream channel and the lab spectrophotometer.
 - c. Absorbance data of each sample at 465 nm measured from the laboratory spectrophotometer.

7.2.3 Standard Curve Test

Reactant Preparation

1. Repeat steps 1 and 3 to 5 from Experiment 1. Do not repeat step 2 since the dilution factor has changed and is addressed below.
2. Add the following reactants to separate test tubes (Table 7-3). Ensure the test tubes are large enough to support the 10mL final volume of each solution. **ADD THE DNBA LAST.** Otherwise, the colour change may begin prematurely. Measure each sample with a spectrometer and SpectraStream prototype 12 minutes after adding the DNBA. Record the results.

Table 7-3: Constituents for sample solutions for standard curve test

Sample #	Creatinine Concentration (mM)	20mM Creatinine Stock (mL)	Distilled Water (mL)	0.25 NaOH (mL)	DNBA + 0.45M NaOH (mL)
0	0	0	5	5	5
1	0.2	0.05	4.95	5	5
2	0.4	0.1	4.9	5	5
3	0.6	0.15	4.85	5	5
4	0.8	0.2	4.8	5	5
5	1	0.25	4.75	5	5
6	1.2	0.3	4.7	5	5
7	1.4	0.35	4.65	5	5
8	1.6	0.4	4.6	5	5
9	1.8	0.45	4.55	5	5
10	2	0.5	4.5	5	5
11	2.2	0.55	4.45	5	5
12	2.4	0.6	4.4	5	5
13	2.6	0.65	4.35	5	5
14	2.8	0.7	4.3	5	5
15	3	0.75	4.25	5	5
16	3.2	0.8	4.2	5	5
17	3.4	0.85	4.15	5	5
18	3.6	0.9	4.1	5	5
19	3.8	0.95	4.05	5	5
20	4	1	4	5	5

Results

3. Obtain the following:
 - a. A picture of each sample following the DNBA reaction.
 - b. Absorbance vs. creatinine concentration graphs for each formulation. Show data from each SpectraStream channel and the lab spectrophotometer.
 - c. Absorbance data of each sample at 465 nm measured from the laboratory spectrophotometer.

7.3 FINAL DEVICE PYTHON MODELLING CODE

```
import pandas as pd
from sklearn.linear_model import LinearRegression
import matplotlib.pyplot as plt

# Import dataset
file_path = '2024-04-04 Chemical Testing.xlsx'
df = pd.read_excel(file_path)

# Drop rows and columns with data from other tests
df = df.drop(df.columns[2:22], axis=1)
df = df.drop(df.columns[[0, 11]], axis=1)
df = df.drop(index=[19, 20, 21, 22])

# Get dependent and independent variables
y = df.iloc[:, 0] # Dependent variable (first column)
X = df.iloc[:, 1:] # Independent variables (rest of the columns)

# Perform multivariate linear regression
regressor = LinearRegression()
regressor.fit(X, y)

# Get coefficients, intercept, and goodness of fit measures
predicted_y = regressor.predict(X)
r_squared = regressor.score(X, y)
coefficients = regressor.coef_
intercept = regressor.intercept_

# Plot actual vs. predicted values
plt.figure(figsize=(8, 6))
plt.scatter(y, predicted_y, color='blue')
plt.plot([y.min(), y.max()], [y.min(), y.max()], 'k--', lw=3)
plt.xlabel('Actual Concentration (mM)', fontsize=18)
plt.ylabel('Predicted Concentration (mM)', fontsize=18)
plt.title('Actual vs Predicted for All Channels', fontsize=24)
plt.text(y.min(), predicted_y.max(), f'R-squared = {r_squared:.2f}',
         fontsize=24, verticalalignment='top')
plt.gca().tick_params(axis='both', which='major', labelsize=14)
plt.savefig('plot.pdf')
```

7.4 SUPPLEMENTARY FIGURES FOR ELECTRICAL IMPLEMENTATION

Demo of Functionality: <https://youtu.be/CP6rJOVq7F0>



Figure 7-1: Initial validation tests for sensor functionality using first prototype

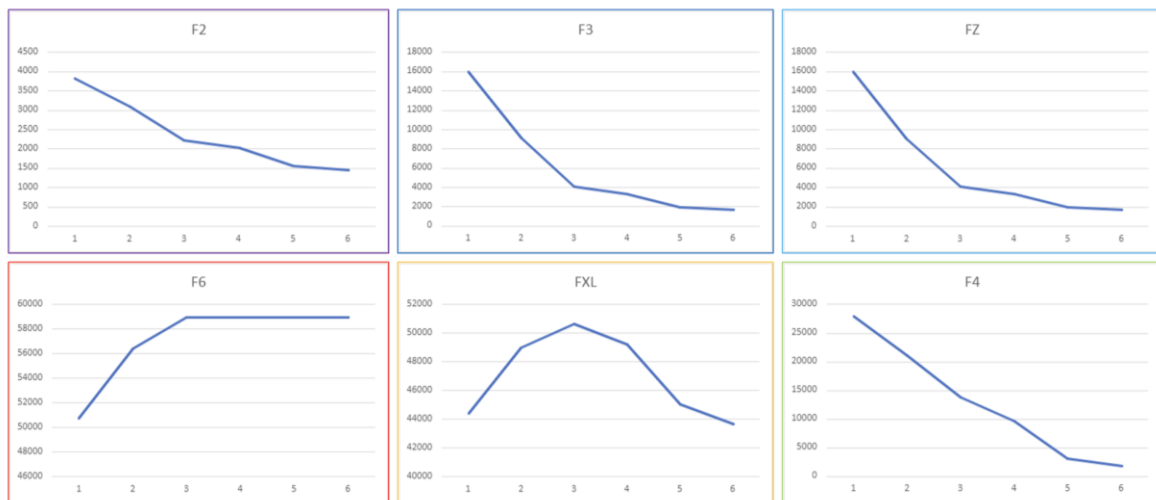
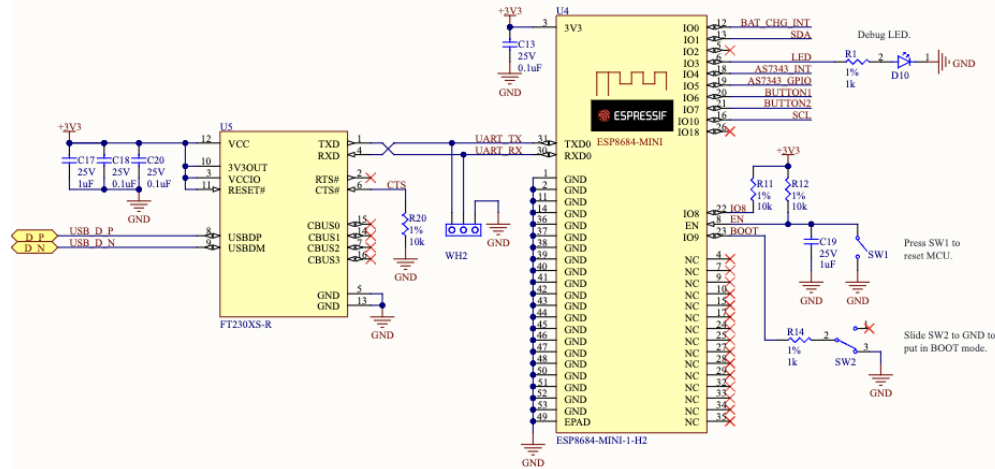
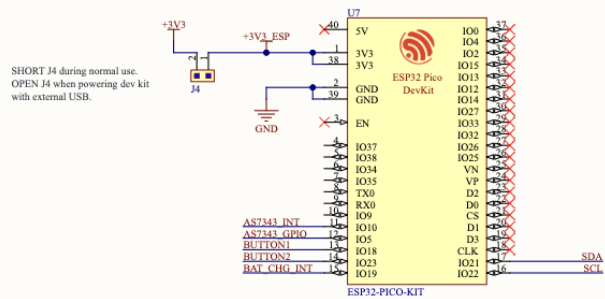


Figure 7-2: Summary of sensor ADC values from second prototype

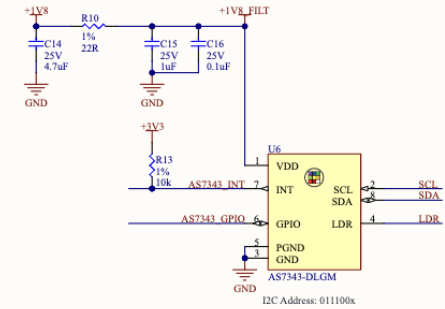
ESP8684 MCU



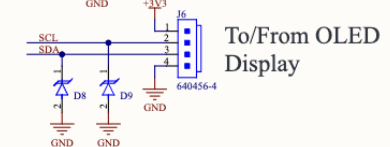
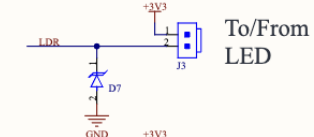
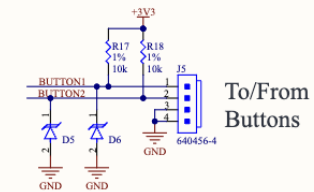
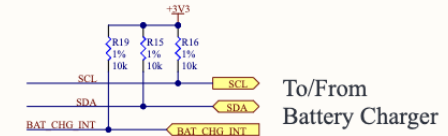
Spare ESP32 Dev Kit Connection



AS7343 Colour Sensor



Connections



POWER

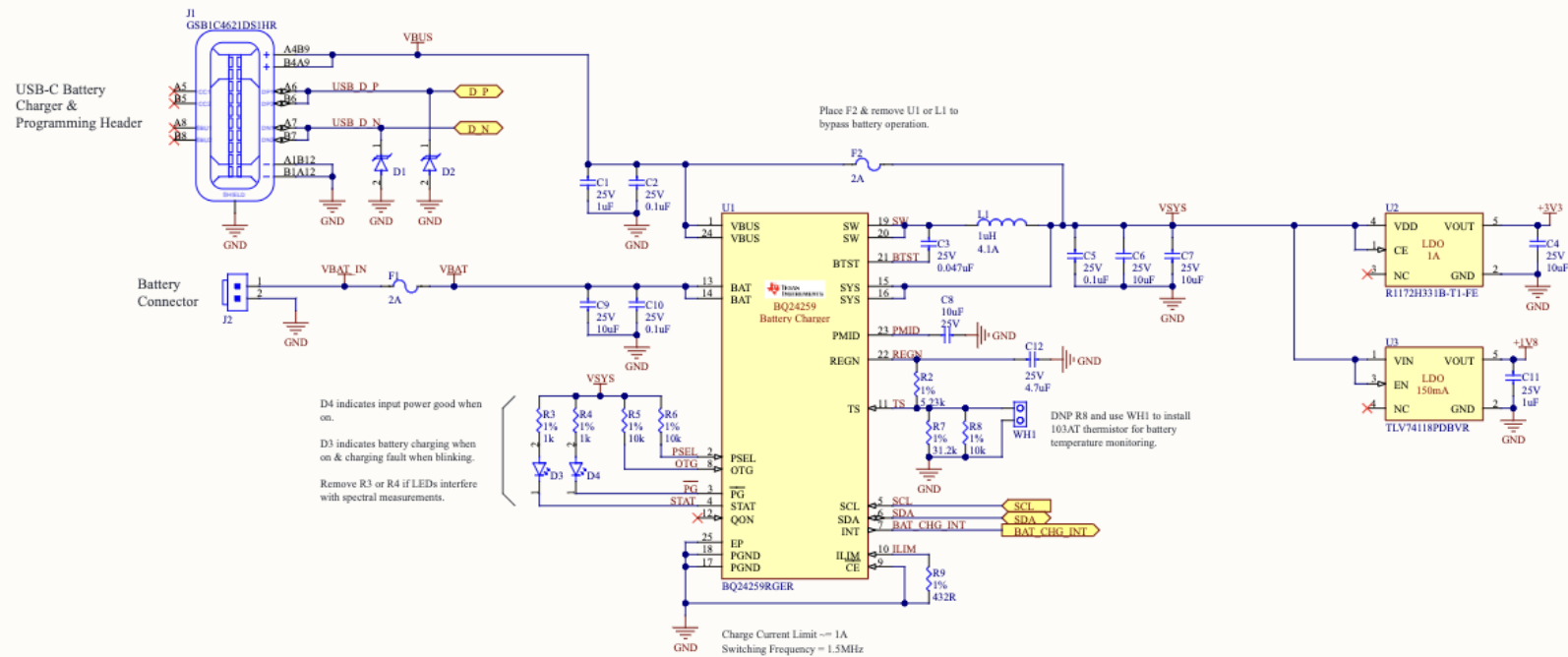


Figure 7-3: Design schematic for PCB



Bill of Materials for Variant [BUILD] of BOM Document [SpectraStream.BomDoc]

Project: SpectraStream.PrfPcb

Variant: BUILD

Date: 2024-03-10

TOTAL (CAD): \$ 70.55 (All Components)

\$ 45.40 (Practical Price Using Price per 500)

Line	PCB Designator	Description	Manufacturer Part Number	Manufacturer	Supplier	Supplier Part Number	Case/Pack age	Quantity	Unit Price (CAD)	Price per 500 (CAD)	Extended Price (CAD)	Extended Price per 500 (CAD)	Purchase	Receive	Notes
10	C1, C11, C15, C17, C2, C3, C10, C13, C16, C18, C20	CAP CER 1UF 25V XSR 0603	CL10A105KA8NNC	Samsung Electro-Meal	Mouser	187-CL10A105KA8NNC	0603	5	\$ 0.15	\$ 0.00	\$ 0.73	\$ 0.01	Yes	Yes	
20		CAP CER 0.1UF 25V X7R 0603	CC0603KRX7R8BB104	YAGEO	Mouser	603-CC0603KRX7R8BB	0603	7	\$ 0.15	\$ 0.02	\$ 1.02	\$ 0.14	Yes	Yes	
30	C3	CAP CER 0.047UF 25V X7R 0603	CC0603KRX7R8BB47	YAGEO	Mouser	603-CC0603KRX7R8BB	0603	1	\$ 0.15	\$ 0.02	\$ 0.15	\$ 0.02	Yes	Yes	
40	C4, C6, C7, C8, C9	CAP CER 10UF 25V XSR 0805	CL21A106KAYNNN	Samsung Electro-Meal	Mouser	187-CL21A106KAYNNN	0805	5	\$ 0.26	\$ 0.06	\$ 1.31	\$ 0.31	Yes	Yes	
50	C12, C14	CAP CER 4.7UF 25V XSR 0603	C1608XSR1E475K0804	TDK	Mouser	810-C1608XSR1E475K	0603	2	\$ 0.28	\$ 0.08	\$ 0.55	\$ 0.15	Yes	Yes	Substitute of original part GRT188R61E475ME13D listed in the schematic to enable purchasing from Mouser.
60	D1, D2, D5, D6, D7, D8, D9	TVS DIODE 3.3VWM 8.4VC SOD523	ESD523V3	Diotec Semiconductor	Mouser	637-ESD523V3	SOD-523	7	\$ 0.28	\$ 0.13	\$ 1.93	\$ 0.93	Yes	Yes	
70	D3, D4, D10	LED GREEN DIFFUSED 0603 SMD	15060V5V75000	Wurth Elektronik	Mouser	Wurth Elektronik	0603	3	\$ 0.22	\$ 0.17	\$ 0.65	\$ 0.50	Yes	Yes	Substitute of original part B1911PG--20D0005WU1930 listed in the schematic to enable purchasing from Mouser.
80	F1	FUSE BRD MT 2A 125VAC 63VDC 1206	CIF 2	Bel Fuse	Mouser	530-CIF2	1206	1	\$ 0.42	\$ 0.25	\$ 0.42	\$ 0.25	Yes	Yes	
90	J1	USB2.0, TYPE C, MID MOUNT, CENTE	USB4510-03-1-A	GCT	Mouser	640-USB4510031A	N/A	1	\$ 1.16	\$ 0.73	\$ 1.16	\$ 0.73	Yes	Yes	Substitute of original part GSBIC4621DS14R listed in the schematic to enable purchasing from Mouser.
100	J2, J3	CONN HEADER VERT 2POS 2.54MM	640456-2	TE Connectivity	Mouser	571-6404562	N/A	2	\$ 0.23	\$ 0.13	\$ 0.46	\$ 0.26	Yes	Yes	
110	J4	Generic footprint for 2-Pin male breadboard header	N/A	N/A	N/A	N/A	N/A	1	\$ -	\$ -	\$ -	\$ -	Yes		
120	J5, J6	CONN HEADER VERT 4POS 2.54MM	640454-4	TE Connectivity	Mouser	571-6404544	N/A	2	\$ 0.28	\$ 0.18	\$ 0.55	\$ 0.36	Yes	Yes	
130	L1	FIXED IND 1UH 4.1A 30 MOHM SMD	CIGT252010EH1R0ME	Samsung Electro-Meal	Mouser	187-CIGT252010EH1R0	1008	1	\$ 0.36	\$ 0.19	\$ 0.36	\$ 0.19	Yes	Yes	
140	R1, R3, R4, R14	RES 1K OHM 1%; 1/10W 0603	RC0603FR-071K	YAGEO	Mouser	603-RC0603FR-071K	0603	4	\$ 0.15	\$ 0.01	\$ 0.58	\$ 0.04	Yes	Yes	
150	R2	RES 5.23K OHM 1%; 1/10W 0603	RC0603FR-075K23L	YAGEO	Mouser	603-RC0603FR-075K2	0603	1	\$ 0.15	\$ 0.01	\$ 0.15	\$ 0.01	Yes	Yes	
160	R5, R6, R6, R11, R12, R13, R15, R16, R17, R18, R19	RES 10K OHM 1%; 1/10W 0603	RMCF0603FT10K0	SEI Stripline	Mouser	708-RMCF0603FT10K0	0603	11	\$ 0.01	\$ 0.01	\$ 0.14	\$ 0.08	Yes	Yes	
170	R7	RES 31.2K OHM 0.5%; 1/10W 0603	RT0603DRE0731K2L	YAGEO	Mouser	603-RT0603DRE0731K	0603	1	\$ 0.15	\$ 0.03	\$ 0.15	\$ 0.03	Yes	Yes	
180	R9	RES 432 OHM 1%; 1/10W 0603	RC0603FR-07432RL	YAGEO	Mouser	603-RC0603FR-07432	0603	1	\$ 0.15	\$ 0.01	\$ 0.15	\$ 0.01	Yes	Yes	
190	R10	RES 22 OHM 1%; 1/10W 0603	RC0603FR-0722RL	YAGEO	Mouser	603-RC0603FR-0722R	0603	1	\$ 0.15	\$ 0.01	\$ 0.15	\$ 0.01	Yes	Yes	
200	SW1	SWITCH TACTILE SPST-IND 0.05A 12V	PTS6363K435MTRPL	CK	Mouser	611-PTS6363K435MTRPL	N/A	1	\$ 0.23	\$ -	\$ 0.23	\$ -	Yes	Yes	
210	SW2	SWITCH SLIDE SPDT 0.5A 30V	SLV-863335-2A-D	CUI Devices	Mouser	179-SLV-863335-2A-D	N/A	1	\$ 0.64	\$ -	\$ 0.64	\$ -	Yes	Yes	
220	U1	IC BATT CHG LH-DN ICCELL 24VQFN	BQ24259RGER	Texas Instruments	Mouser	595-BQ24259RGER	N/A	1	\$ 3.13	\$ 1.86	\$ 3.13	\$ 1.86	Yes	Yes	
230	U2	IC REG LINEAR 3.3V 1A SOT89-5	RT172H33B-T1-FE	Nishinbo	Mouser	848-RT172H33B-T1-FE	SOT-89-5	1	\$ 1.73	\$ 1.00	\$ 1.73	\$ 1.00	Yes	Yes	
240	U3	IC REG LINEAR 1.8V 150MA SOT23-5	TLV74118PDBVR	Texas Instruments	Mouser	535-TLV74118PDBVR	SOT-23-5	1	\$ 0.33	\$ 0.10	\$ 0.33	\$ 0.10	Yes	Yes	
250	U4	Multiprotocol Modules SMD Module, ESP8684H2, 2 MB flash inside, -40C +105C	ESP8684-MINI-1-H2	Espressif	Mouser	356-ESP8684MINI1H2	N/A	1	\$ 2.44	\$ 2.44	\$ 2.44	\$ 2.44	Yes	Yes	
260	U5	IC USB SERIAL BASIC UART 16550P	FT230XLS-R	FTDI Chip	Mouser	895-FT230XLS-R	N/A	1	\$ 3.28	\$ -	\$ 3.28	\$ -	Yes	Yes	
270	U6	SENSOR OPT 300-1000NM AMB 80LGA	AS7343-DLGM	ams OSRAM	Mouser	965-AS7343-DLGM	N/A	1	\$ 14.12	\$ 8.40	\$ 14.12	\$ 8.40	Yes	Yes	
280	U7	Header pins for ESP32 Pico development	N/A	PTSolns	Amazon	B07WKS2PL	N/A	1	\$ 1.20	\$ -	\$ 1.20	\$ -			Header pins for the ESP-32 Pico Kit are already have.
290	N/A	Headers & Wire Housings TIN CONTACT 26-22AWG	1445336-1	TE Connectivity	Mouser	571-14453361	N/A	16	\$ 0.13	\$ 0.10	\$ 2.10	\$ 1.58	Yes	Yes	Cimps for connectors
300	N/A	Headers & Wire Housings 4P 2.54MM	1375820-4	TE Connectivity	Mouser	571-13758204	N/A	3	\$ 0.39	\$ 0.22	\$ 1.18	\$ 0.67	Yes	Yes	Connectors for buttons & OLED
310	N/A	Headers & Wire Housings 2P 2.54MM	1375820-2	TE Connectivity	Mouser	571-13758202	N/A	2	\$ 0.19	\$ 0.11	\$ 0.39	\$ 0.21	Yes	Yes	Connectors for battery & OLED
320	N/A	Pushbutton Switches SPST 3A MOM PC MNT	PS1024ALBLK	E-Switch	Mouser	612-PS1024AL-BLK	N/A	1	\$ 2.02	\$ 1.52	\$ 2.02	\$ 1.52	Yes	Yes	Black button
330	N/A	Pushbutton Switches SPST 3A MOM PC MNT	PS1024ALRED	E-Switch	Mouser	612-PS1024AL-RED	N/A	1	\$ 2.22	\$ 1.70	\$ 2.22	\$ 1.70	Yes	Yes	Red button
340	N/A	Pack of 10 Pos 18650 Battery Holder Case 3.7V Battery Storage Clip Holder Plastic Box with Wire Leads	N/A	Wishglobal	Amazon	B07M8JM5G3	N/A	1	\$ 1.20	\$ 1.20	\$ 1.20	\$ 1.20			Battery holder
350	N/A	EVE 26V 18650 2550mAh 7.5A Button Top Battery	ICR18650-26V	EVE	18650 Battery Store	ICR18650-26V	N/A	1	\$ 2.50	\$ 2.50	\$ 2.50	\$ 2.50	Yes	Yes	Battery. Using 18650 batteries Evan has.
360	N/A	LED COB CLUTL3 NEUT WHT SQ 4000K	CLUTL3-0104C4-403	Citizen	Digi-Key	1642-CLUTL3-0104C4	N/A	1	\$ 4.81	\$ 2.35	\$ 4.81	\$ 2.35	Yes	Yes	White LED module
370	N/A	Rocker Switches 10A 125VAC 4.8mm Tab Off-OLED Display Module, 128 x 64 0.96 inches	RA11T13121	E-Switch	Mouser	612-RA11T13121	N/A	1	\$ 0.93	\$ 0.67	\$ 0.93	\$ 0.67	Yes	Yes	Battery switch
380	N/A	OLED Display Module, 128 x 64 0.96 inches	N/A	Acouito	Amazon	B07YFNP2L5	N/A	1	\$ 11.00	\$ 11.00	\$ 11.00	\$ 11.00	Yes	Yes	OLED Display
390	N/A	OLED Display Module, 128 x 64 0.96 inches	N/A	Acouito	Amazon	B07YFNP2L5	N/A	1	\$ 11.00	\$ 11.00	\$ 11.00	\$ 11.00	Yes	Yes	OLED Display
390	N/A	LED Light Pipes Light Pipe Rigid 5mm	PLP5-2-375	Bivar	Mouser	749-PLP5-2-375	N/A	1	\$ 0.89	\$ 0.54	\$ 0.89	\$ 0.54	Yes	Yes	Status LED light pipe
400	N/A	Bare PCB	SpectraStream	JLPCB	JLPCB	N/A	N/A	1	\$ 3.64	\$ 3.64	\$ 3.64	\$ 3.64	Yes	Yes	Bare PCB

Figure 7-4: Electrical BOM

7.5 SUPPLEMENTARY FIGURES FOR MECHANICAL IMPLEMENTATION

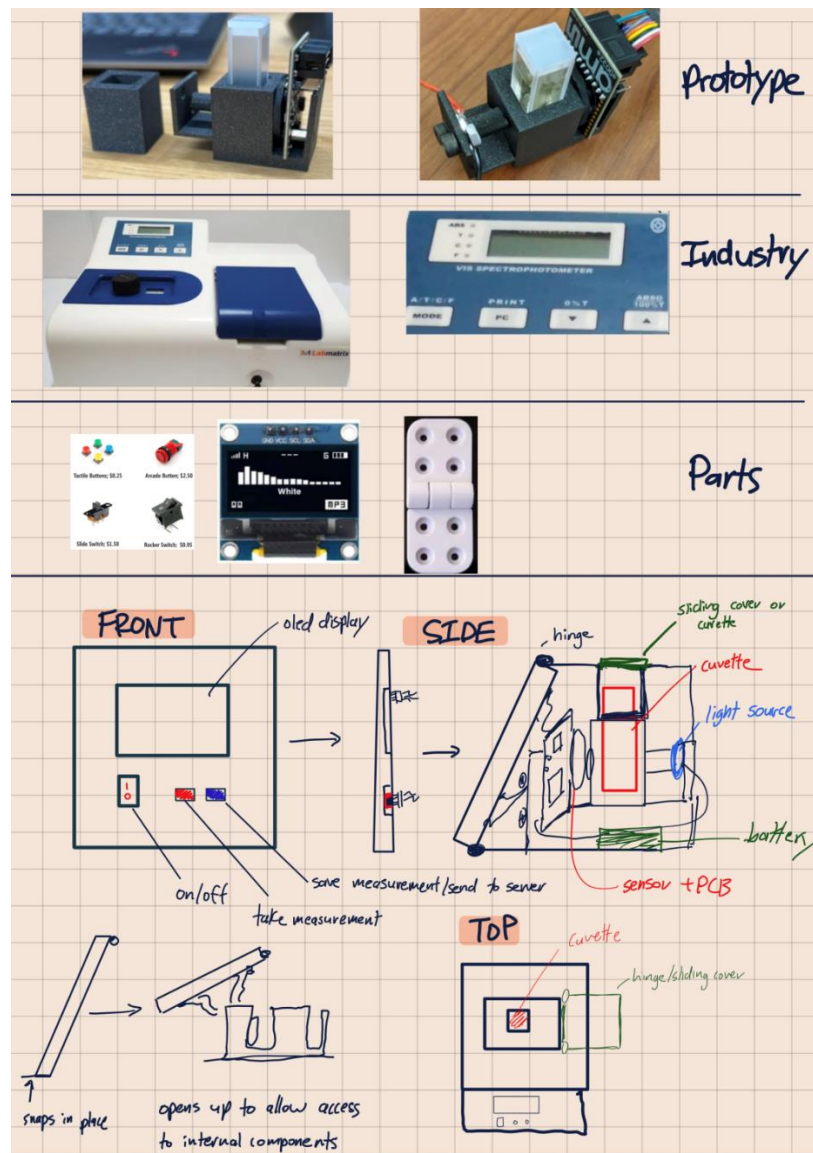


Figure 7-6: Initial hand-drawn sketch of the final chassis

7.6 SUPPLEMENTARY INFORMATION FOR SOFTWARE IMPLEMENTATION

Github Repository: <https://github.com/ErnestSpahiu/Capstone>

7.6.1 Server

```
server.on("/bluechannel", HTTP_GET, [](AsyncWebServerRequest *request){
  request->send_P(200, "text/plain", allStrings.c_str());
});
```

7.6.2 Client

```
function fetchDataArrValues() {
  var xhttp = new XMLHttpRequest();
  xhttp.onreadystatechange = function() {
    if (this.readyState === 4 && this.status === 200) {
      // Split the response text into an array of values
      let values = this.responseText.split(",");
      // Update only the numeric values in dataArr
      for (let i = 0; i < dataArr.length; i++) {
        let valueIndex = i * 2 + 1; // Calculate index based on response structure
        if (values[valueIndex]) { // Check if the value exists to avoid errors
          let channelValue = parseFloat(values[valueIndex].trim());
          dataArr[i][1] = channelValue; // Update only the value, keep name and wavelength unchanged
        }
      }
      console.log('Updated values in dataArr:', dataArr);
      // Optionally, trigger any updates needed to refresh visualizations using dataArr
    }
  };
  xhttp.open("GET", "/bluechannel", true);
  xhttp.send();
}
```

7.6.3 Server C Code

```
#include "RegisterMappings.h"
#include "Arduino.h"
#include "Wire.h"
#include <WiFi.h>
#include "arduino_secrets.h"
#include <AsyncTCP.h>
#include "ESPAsyncWebServer.h"
#include "SPIFFS.h" //if not recognized reupload the sketch
```

```

#define BUTTON_RED 18
#define BUTTON_BLACK 23
int measurementReq = 0; //if 0 continuous measurementReq, 1 discrete measurementReq
int lastState = HIGH; // the previous state from the input pin
int currentState; // the current reading from the input pin

int loopC = 0;
AsyncWebServer server(80);
char formattedStrings[9][50];
String allStrings;

uint16_t readChannel(byte address)
{
  uint8_t readingL; uint16_t readingH; uint16_t reading = 0;
  Wire.beginTransmission(COLOR16_DEVICE_ADDRESS);
  Wire.write(address);
  Wire.endTransmission();

  Wire.requestFrom(COLOR16_DEVICE_ADDRESS, 2);

  if (2 <= Wire.available())
  {
    readingL = Wire.read();
    readingH = Wire.read();
    readingH = readingH << 8;
    reading = (readingH | readingL);
    return (reading);
  }
  else
  {
    return (0xFFFF); //Error
  }
}

byte readRegister(byte address)
{
  Wire.beginTransmission(COLOR16_DEVICE_ADDRESS);
  Wire.write(address);
  Wire.endTransmission();

  Wire.requestFrom(COLOR16_DEVICE_ADDRESS, 1);

  if (Wire.available())
  {
    return (Wire.read());
  }
}

```

```

else
{
return (0xFF); // Error
}
}

void writeRegister(byte address, byte value)
{
Wire.beginTransmission(COLOR16_DEVICE_ADDRESS);
Wire.write(address);
Wire.write(value);
Wire.endTransmission();
}

void setup() {
Serial.begin(115200);
Wire.begin(); // Initialize I2C communication
const char* ssid = "";
const char* password = "";
delay(10);
Serial.println("Connecting to ");
Serial.println(ssid);
WiFi.begin(ssid, password);

while (WiFi.status() != WL_CONNECTED) {
delay(500);
Serial.print(".");
}

pinMode(BUTTON_RED, INPUT_PULLUP);
Serial.println("");
Serial.println("WiFi connected");
Serial.println("IP address: ");
Serial.println(WiFi.localIP());
// set bit 0 PON to 1 on ENABLE to turn on sensor // everything else OFF for setup
readRegister(COLOR16_REG_ENABLE);
writeRegister(COLOR16_REG_ENABLE, 0x01);
readRegister(COLOR16_REG_ENABLE);

writeRegister(0xe2, 0xf2); // CFG 10
byte val = readRegister(COLOR16_REG_CFG_20);
byte newVal = val | 0x60;
writeRegister(COLOR16_REG_CFG_20, newVal); // SMUX

writeRegister(COLOR16_REG_AZ_CONFIG, 0xff);
writeRegister(COLOR16_REG_AGC_GAIN_MAX, 0x99);

```

```

writeRegister(0xdf, 0xa1); //CFG 0
writeRegister(0xe0, 0x67); // CFG 1
writeRegister(0xe1, 0x64); // CFG 2
writeRegister(0xe2, 0x21); // CFG 3

// set LED on bit 7 and set current with other bits
writeRegister(COLOR16_REG_LED, 0x82);
readRegister(COLOR16_REG_LED);

// as7341.setATIME(1);
// as7341.setASTEP(999);
// as7341.setGain(AS7341_GAIN_256X)

writeRegister(COLOR16_REG_ETIME, 0); // set ATIME to 0
readRegister(COLOR16_REG_ETIME);

writeRegister(COLOR16_REG_ASTEP_LSB, 0xA11A); // set ASTEP to 0xA11A
readRegister(COLOR16_REG_ASTEP_LSB);

writeRegister(COLOR16_REG_AS7343_CFG1, 0x0C); // set GAIN to 0x0C
readRegister(COLOR16_REG_AS7343_CFG1);

// turn on Spectral measurements and enable SMUX
writeRegister(COLOR16_REG_ENABLE, 0x03);
readRegister(COLOR16_REG_ENABLE);

// read REG_BANK -> 0x58 to 0x66 needs 1 else 0
byte value = readRegister(COLOR16_CFG_0_REG_BANK);

byte registerValue = 0; // Initialize with the current value of the register
byte bitmask = 0b00000011; // Bits 0, 1, and 4 are set to 1 in binary

// Set the bits by performing a bitwise OR operation
registerValue |= bitmask;
// Start measurements - set bit 1 SP_EN of ENABLE REG to enable readings
writeRegister(COLOR16_REG_ENABLE, registerValue);
value = readRegister(COLOR16_REG_ENABLE);
for (int bit = 7; bit >= 0; bit--) {
  byte bitValue = (value >> bit) & 0x01;
}
// Initialize SPIFFS
if(!SPIFFS.begin()){
  Serial.println("An Error has occurred while mounting SPIFFS");
  return;
}

// Print ESP32 Local IP Address
Serial.println(WiFi.localIP());

```

```

//route to load html page
server.on("/", HTTP_ANY, [](AsyncWebServerRequest *request){
request->send(SPIFFS, "/index.html");
});
//route to load css
server.on("/main.css", HTTP_GET, [](AsyncWebServerRequest *request){
request->send(SPIFFS, "/main.css", "text/css");
});
// image
server.on("/teamlogoT.png", HTTP_GET, [](AsyncWebServerRequest *request){
request->send(SPIFFS, "/teamlogoT.png", "image/png");
});
//jquery
server.on("/breakpoints.min.js", HTTP_GET, [](AsyncWebServerRequest *request){
request->send(SPIFFS, "/breakpoints.min.js", "text/javascript");
});
server.on("/browser.min.js", HTTP_GET, [](AsyncWebServerRequest *request){
request->send(SPIFFS, "/browser.min.js", "text/javascript");
});
server.on("/jquery.dropotron.min.js", HTTP_GET, [](AsyncWebServerRequest *request){
request->send(SPIFFS, "/jquery.dropotron.min.js", "text/javascript");
});
server.on("/jquery.min.js", HTTP_GET, [](AsyncWebServerRequest *request){
request->send(SPIFFS, "/jquery.min.js", "text/javascript");
});
server.on("/main.js", HTTP_GET, [](AsyncWebServerRequest *request){
request->send(SPIFFS, "/main.js", "text/javascript");
});
server.on("/util.js", HTTP_GET, [](AsyncWebServerRequest *request){
request->send(SPIFFS, "/util.js", "text/javascript");
});

server.on("/bluechannel", HTTP_GET, [](AsyncWebServerRequest *request){
request->send_P(200, "text/plain", allStrings.c_str());
});
server.on("/measurementReq", HTTP_GET, [](AsyncWebServerRequest *request){
request->send_P(200, "text/plain", String(measurementReq).c_str());
});
//start server
server.begin();
}

void loop() {
// read ENABLE REG
int value = readRegister(COLOR16_REG_ENABLE);
for (int bit = 7; bit >= 0; bit--) {
byte bitValue = (value >> bit) & 0x01;

```

```

} // Print a newline after all bits

// Read LED REG
value = readRegister(COLOR16_REG_LED);
for (int bit = 7; bit >= 0; bit--) {
    byte bitValue = (value >> bit) & 0x01;
}
Serial.println(); // Print a newline after all bits

// Read ATIME
value = readRegister(COLOR16_REG_ETIME);

for (int bit = 7; bit >= 0; bit--) {
    byte bitValue = (value >> bit) & 0x01;
}; // Print a newline after all bits

// Read ASTEP
byte astepValue = readRegister(COLOR16_REG_ASTEP_LSB);
for (int bit = 7; bit >= 0; bit--) {
    byte bitValue = (astepValue >> bit) & 0x01;
}
// Print a newline after all bits

// Read GAIN
byte gainValue = readRegister(COLOR16_REG_AS7343_CFG1);

for (int bit = 7; bit >= 0; bit--) {
    byte bitValue = (gainValue >> bit) & 0x01;
}
// Print a newline after all bits

// Read ASTATUS to latch spectral channels
byte astatusValue = readRegister(COLOR16_REG_ASTATUS);

byte firstDataReg = 0x95;
byte lastDataReg = 0xB8;
const int totalChannels = (lastDataReg - firstDataReg) / 2 + 1;

// Buffer to store spectral data
uint16_t spectralData[totalChannels];

for (int channel = 0; channel < totalChannels; channel++) {
    int regAddress = firstDataReg + 2 * channel;
    spectralData[channel] = readChannel(regAddress);
}

/**
Cycle 1: FZ, FY, FXL, NIR, 2xVIS, FD

```

```

Cycle 2: F2, F3, F4, F6, 2xVIS, FD
Cycle 3: F1, F7, F8, F5, 2xVIS, FD
*/
}
// Read the state of the switch/button:
currentState = digitalRead(BUTTON_RED);

// Check if the button is pressed (i.e., if the current state is LOW,
// and the last state was HIGH, meaning the button state has changed to pressed)
if (currentState == LOW && lastState == HIGH) {
// Toggle measurementReq
measurementReq = !measurementReq; // This toggles the measurementReq between 0 and 1.
delay(50); // Debounce delay. Adjust as necessary for your specific button.

if (measurementReq == 1) {
Serial.println("Discrete measurementReq");
} else {
Serial.println("Continuous measurementReq");
}
}
// Update lastState to the current state
lastState = currentState;

if (measurementReq == 1) {
// Actions for discrete measurementReq
// Note: Depending on your requirements, you might want to move or remove
// this block to prevent "Discrete measurementReq" from being printed continuously.
} else {
// Actions for continuous mode
// Note: As above, you may want to adjust this behavior based on your needs.
}

// Clear or re-initialize allStrings before starting to concatenate new data
allStrings = ""; // Reset allStrings to empty

// Format strings with channel names and values
sprintf(formattedStrings[0], "F4 Blue:, %u", spectralData[8]);
sprintf(formattedStrings[1], "F7 Red:, %u", spectralData[13]);
sprintf(formattedStrings[2], "FY Green:, %u", spectralData[1]);
sprintf(formattedStrings[3], "FXL Orange:, %u", spectralData[2]);
sprintf(formattedStrings[4], "F1 Violet:, %u", spectralData[12]);
sprintf(formattedStrings[5], "F5 Lime:, %u", spectralData[15]);
sprintf(formattedStrings[6], "F8 Dark Red:, %u", spectralData[14]);
sprintf(formattedStrings[7], "F6 Brown:, %u", spectralData[9]);
sprintf(formattedStrings[8], "F3 Cyan:, %u", spectralData[7]);

// Concatenate formatted strings into allStrings
for (int i = 0; i < 9; i++) {
allStrings += formattedStrings[i]; // Concatenate each string

```

```

if (i < 8) { // If not the last string, add a separator
allStrings += ",";
}

delay(50); // Your existing delay or other logic
}

```

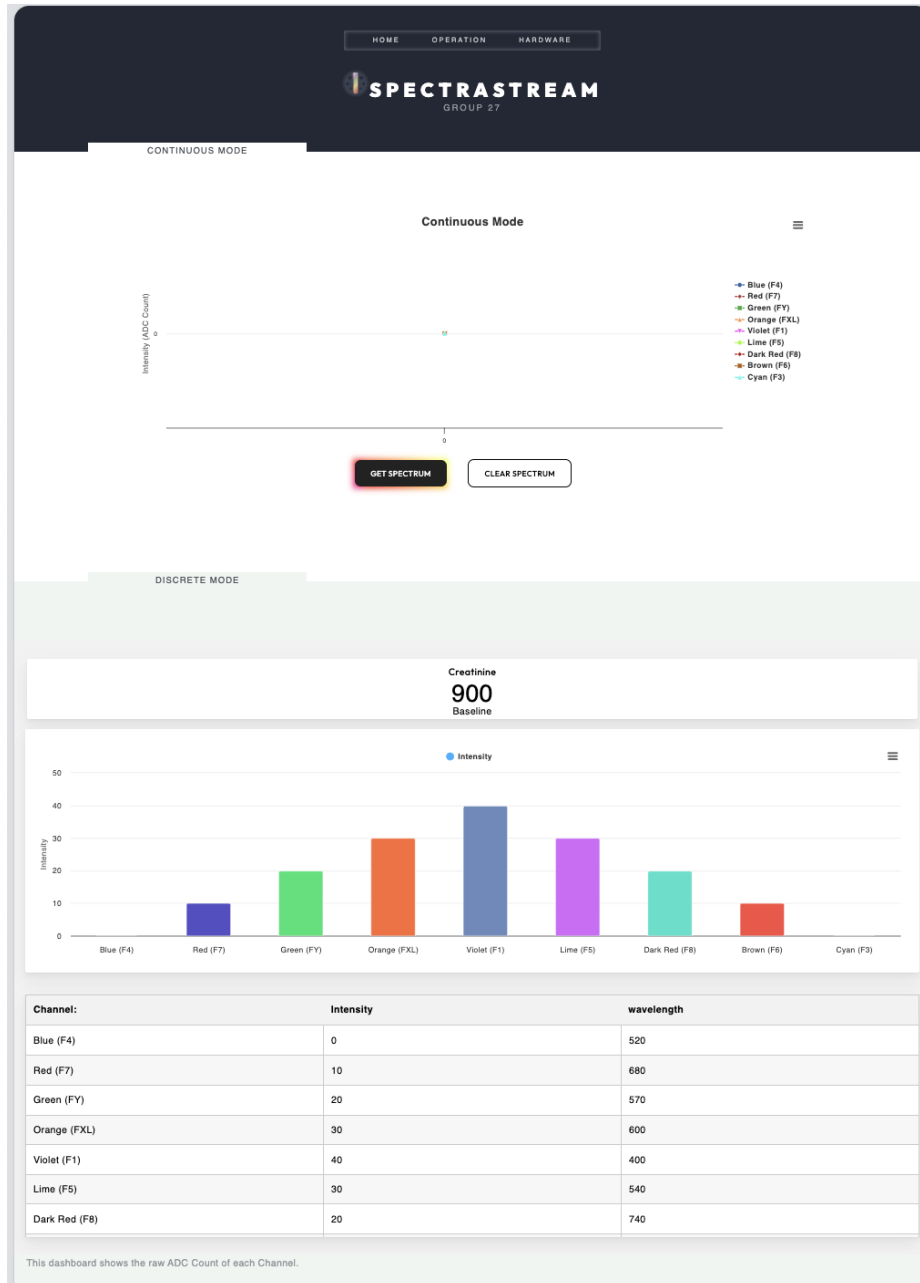


Figure 7-7: Web interface for SpectraStream