6-3-2016

MUMS: Mobile Urinalysis for Maternal Screening

Blair Koeneman
Santa Clara University

Amy Miller
Santa Clara University

Joe Neumeyer
Santa Clara University

Jake Prince
Santa Clara University

MUMS: MOBILE URINALYSIS FOR MATERNAL SCREENING

by

Blair Koeneman, Amy Miller, Joe Neumeyer, and Jake Prince

SENIOR DESIGN PROJECT REPORT

Submitted in partial fulfillment of the requirements
for the degree of
Bachelor of Science in Web Design and Engineering
and
Bachelor of Science in Bioengineering
School of Engineering
Santa Clara University

Santa Clara, California
June 3, 2016

Santa Clara University

DEPARTMENTS of COMPUTER ENGINEERING and BIOENGINEERING

Date: June 3, 2016

I HEREBY RECOMMEND THAT THE THESIS
PREPARED UNDER MY SUPERVISION BY

Blair Koeneman, Amy Miller, Joe Neumeyer, and Jake Prince

ENTITLED

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BE ACCEPTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF

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BIOE THESIS ADVISOR

BIOE DEPARTMENT CHAIR

COEN THESIS ADVISOR

COEN DEPARTMENT CHAIR

Abstract

Pregnant women in low-income communities often lack access to the necessary healthcare for successful births. This is frequently due to the high costs of medical care, the remote location of patients, and the infrequency of primary care medical visits. To address this inequity, we have created a mobile application and imaging unit that allows for the low-cost implementation of urinalysis testing, which will aid in the detection of warning signs for prenatal health risks. From a single photo taken with a tablet camera, our application digitizes the results of a standard urinalysis test strip, displays the test results, and tracks the patient test histories. Using early, affordable urinalysis, we can increase the rates early detection, intervention, and successful pregnancies.

Our results have shown that our solution can accurately estimate the concentrations of biological compounds found in urine when compared to visual approximations of color comparison charts. Our device is not only more efficient than the alternative, but also more efficient at screening for and detecting potentially fatal health conditions in pregnant women. Ultimately, our solution is a frugal and mobile urinalysis alternative that can feasibly be implemented in rural communities in order to increase early detection of pregnancy complications, allow for early intervention, and improve the probability of successful pregnancies.

Keywords: urinalysis, pregnant women, low-income, medical, preventative medicine, telemedicine, prenatal, developing world, rural

Acknowledgments

We would like to thank the Santa Clara University School of Engineering for support in the form of advising, resources, equipment, facilities, and funding. Thanks to the Miller Center for Social Entrepreneurship for providing financial support in the form of a Roelandts Grant. Thanks to Ms. Jayshree Ullal for her generous gift to the SITA Foundation Dean's Fund. These contributions allowed us to design, prototype, and test with financial freedom. Thanks the students in the Engineering World Health club who contributed to the project by conducting background market research. Thanks to Heidi Williams for her support for our project and for highlighting it in the School of Engineering newsletter. Special thanks to Dr. Don Riccomini of the English Department for his unwavering commitment to guiding our presentation and thesis to completion.

Web Design Engineering

We would like to thank our adviser, Dr. Silvia Figueira, for offering her support, positive feedback, and encouragement. She provided us with the information and resources we needed, and connected us with Vishvesh Shah, a graduate computer engineering student who became an honorary member of the team.

Bioengineering

Thanks to Dr. Ashley Kim for her guidance and advice. Thanks to Adrian Valones for assistance in ordering and storing chemicals and for supporting us with access to the bioengineering laboratories. Thanks to Fireball, the pet hamster of the Neumeyer family who passed in early 2006, for giving Joe the inspiration to pursue a life rooted in service and social justice. Thanks to our fellow engineering students who allowed us to vent our frustrations without asking us to lower our voices. Thanks to our parents for giving us the spit in our eyes and the pep in our steps. Thanks to our roommates for pretending to care. Thanks to The Hut for giving us refuge. Thanks to the influenza virus for giving us an excuse on particularly tough days. Thanks to El Nino for giving us a reason to spend a few days inside working on this paper. Thanks to Comcast for providing the dismal internet speeds that forced us to stop watching Netflix and focus on this project. Thanks to the entire Santa Clara community for giving us a place to grow, learn, and explore. We already miss you all.

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1 Introduction

1.1 Problem

Rural Poor Lack Access to Pregnancy Screening

Access to medical care and health screens is especially important for pregnant women. Ideally, medical professionals monitor the development of a fetus through a range of screening methods, many of which are simple, urine-based tests. In rural developing communities, however, limited access to care and medical professionals is a particularly pressing issue for pregnant women. The rural poor cannot access personalized care from physicians due to geographical isolation and prohibitively high costs. Because of this, treatable conditions go undiagnosed and unaddressed, often leading to more serious consequences. Every day, 830 women die from preventable causes related to childbirth and pregnancy.[1] Conditions such as gestational diabetes, preeclampsia, malnutrition, infection, and ectopic pregnancy often become life-threatening for both the mother and unborn fetus.[2]

1.2 Existing Solutions

Testing for various biological markers via urine test strips is a common method for screening and diagnosing a range of conditions that affect the health of pregnant women. The problem with conventional urinalysis techniques in this context is that they are luxuries, due to the cost and necessary expertise. Specifically in remote areas of the developing world, this sophisticated medical procedure is not typically an option.

Mobile Medical Clinics

Often, rural communities do not have access to clinical services due to limitations in funding, equipment, and human resources. Therefore, government agencies in cooperation with NGOs periodically deliver health and screening services to rural communities. These services are often subsidized by government programs, allowing low-income families to pursue medical services that might normally be outside their means. By bringing screening services to the field, these programs offer preventative, rather than reactionary, medical care, which is often exponentially less costly in the long run to both the state and the individual.[3]

Unfortunately, these mobile clinics often lack the accurate screening methods utilized in permanent, urban clinics. Additionally, there is no guarantee that even given a positive screen that the mobile clinician will be capable of treating the patient. Nonetheless, reducing the marginal cost of pursuing screens is the first step in decentralizing the comprehensive course of medical care.

[1] Maternal Mortality. World Health Organization. November 2015. Accessed June 02, 2016. http://www.who.int/mediacentre/factsheets/fs348/en/.

[2] Say, Lale, Doris Chou, Alison Gemmill, Özge Tunçalp, Ann-Beth Moller, Jane Daniels, A. Metin Gülmezoglu, Marleen Temmerman, and Leontine Alkema. Global Causes of Maternal Death: A WHO Systematic Analysis. The Lancet Global Health 2, no. 6 (2014).

[3] Mobile Health Clinics in the United States, U.S. Department of Health and Human Services: Office of Minority Health. March 2013.

Clinical Screening Services

Urinalysis tests are commonly administered to diagnose and screen for a variety of health concerns. For patients admitted to a hospital, people visiting their physician for a wellness exam, or expectant mothers receiving a routine pregnancy check-up, administering a urine test is common practice and acts as the first line of defense in discovering health abnormalities.[4] Complications that can be discovered through these tests include diabetes, urinary tract infections, kidney disease, liver disease, among many other conditions. In the past, urinalysis tests were performed by a visual assessment of the urine in tandem with the use of a urine test strip and were indicative of various biological concentrations within the urine, urinalysis of late is becoming more automated.[5]

Today, there are several instruments on the market used by state-of-the-art laboratories to efficiently and accurately analyze urine, minimizing the time, effort, and inaccuracy that results from manual tests. The shortcomings of these instrument is primarily their cost and usability. The cheapest of these instruments are priced around 300 dollars, with the higher end models costing upwards of several thousand dollars.[6] Furthermore, the instruments require trained lab technicians to operate them correctly. These two limitations make this solution unfeasible for much of the developing world, our target market.

Educational SMS Messages

Some organizations, such as Mobile Alliance for Maternal Action (MAMA) help solve the issue of patients' remote locations by developing SMS-based service that educates new and expecting mothers about prenatal and infancy health topics.[7] The system is subscription based, sending text messages with advice for mothers that aligns with their stage of pregnancy or motherhood. Although this organization is taking steps in the right direction, the information they provide is generic and lacks the ability to screen for particular conditions on an individual basis. It also lacks the two-way communication that makes an in-person checkup with a medical professional so valuable and trustworthy. As a preventative and educational system it is effective, but it lacks any sort of reactionary care.

Smartphone-Based Colorimetry

Another idea for a current solution is smartphone-based colorimetry.[8] Researchers have developed an application that digitizes images of reagent test pads, and calculate

[4]Getting a Urinalysis: About Urine Tests. American Pregnancy Association. 2012. Accessed June 02, 2016. http://americanpregnancy.org/prenatal-testing/urine-test/.

[5]Clinical Methods: The History, Physical, and Laboratory Examinations. Annals of Internal Medicine Ann Intern Med 113, no. 7 (1990): 563.

[6]CLINITEK Status Analyzer. CLINITEK Status Plus. Accessed June 02, 2016. http://www.healthcare.siemens.com/point-of-care/urinalysis/clinitek-status-analyzer.

[7]How We Help. MAMA: Mobile Alliance for Maternal Action. Accessed June 02, 2016. http://www.mobilemamaalliance.org/how-we-help.

[8]Hong, Jong Il, and Byoung-Yong Chang. "Development of the Smartphone-Based Colorimetry for Multi-Analyte Sensing Arrays." Lab on a Chip 14, no. 10 (2014): 1725.

biological concentrations from the RGB values of the photographed colors. This application is similar to the image digitizing process of our proposed solutions, but falls short in that the images are obscured by ambient light sources and lack standardization. Additionally, this technology exists as a proof of concept rather than a viable solution as it is not prepared to be integrated into a comprehensive solution, complete with user interface and medical database.

1.3 Proposed Solution

Medical Screening Solution for Pregnant Women in Rural Communities

The goal of our solution is to bridge the distance between rural communities and screening services by leveraging digital urinalysis and packaging it in a web application that provides a healthcare solution targeted towards pregnant women. The web application accurately measures concentrations of biological markers in the urine of pregnant women using urine strip tests. By mapping the colors captured from images of the tested strips to their respective concentrations, the system automatically calculates statistical results. Medical professionals or trained technicians are able to access the information through an interface that tracks patient histories and displays the data in a convenient, accessible manner. These medical personnel can use our solution to efficiently screen patients and track medical histories in order to improve their ability to deliver efficient and effective care.

1.4 Target Market

We are working at the intersection of many complex socioeconomic factors and have conducted market research into a few key areas before designing the solution.

Research Criteria

First, we researched the hierarchy and operations of the existing local medical systems in order to identify the appropriate point at which our device should be implemented. We sought to implement a device at the "minimum viable level" in order to reach patients at the bottom of the economic pyramid. Second, we analyzed communication systems of rural, developing communities, including mobile data access, tablet usage, power access, and existing medical database systems. The willingness of a community or organization to adopt our product will hinge upon their ability to pay for usage, their knowledge of the product's benefits, and their ability to interact with results.

In order to keep this product sustainable in our test market, the population of our proposed target market must adhere to two criteria.

1. The population must be technologically advanced enough to have internet connectivity and medical professionals with access to tablets, such as tablets.
2. The population must not currently have adequate access to prenatal care, which has resulted in health problems.

Proposed Market: Rural Alaska

Rural Alaska serves as a test market that fulfills both of these criteria. According to a study published in 2016 that interviewed physicians using telemedicine in rural Alaska, "the use of telemedicine in chronic disease management has potential to improve patient care in remote indigenous populations and may supplement patient provider relationships"[9]. Internet access in rural Alaska, while in many places not as fast as in more urban areas, still is adequate for the requirements of this device.

GeneXpert

Similar products have been utilized to advance access to healthcare for this population. An STD test device called GeneXpert, serves as a comparative device designed for use in this rural setting. GenXpert is sent to subjects in the mail and sent back to the lab for testing, results are then reported on-line which patients can then read. The device had high utilization with 37% of the tests returned for analysis.[10] "Despite longer time to results than traditional ICT's, the exceptional accuracy and operational benefits makes the GeneXpert device appealing for use where delays to treatment are frequent."[11] Telemetric devices of other kinds have been utilized with Alaskan natives and both doctors and patients have seen positive results.

Indian Health Service

Creation of the IHS (Indian Health Service) in 1955 has greatly decreased the discrepancies between rural and urban Alaska. Rates of neonatal death in Alaska decreased from 8.0 per 1000 live births in the 2004 to 2006 period to 5.7 per 1000 live births in 2010 to 2011. Among Native Alaskan women this decrease was from 13.0 deaths per 1000 live births to 7.2 deaths per 1000 live births.[12] Public health interventions have clearly decreased deaths in relation to pregnancy. However, there are still clear disparities between rural Alaska and urban Alaska. In rural Alaska native mothers were 1.31 times ($p<.001$) as likely to have received an inadequate pattern of prenatal care compared to native mothers in urban areas. Rural women were also 1.23 times ($p<0.01$) as likely to experience a post neonatal death (29 days to 1 year) compared to urban women.[13] No statistical difference was shown between postnatal

[9]Hiratsuka, Vanessa, Rebecca Delafield, Helene Starks, Adrian Jacques Ambrose, and Marjorie Mala Mau. "Patient and Provider Perspectives on Using Telemedicine for Chronic Disease Management among Native Hawaiian and Alaska Native People." International Journal of Circumpolar Health 72 (August 5, 2013). doi:10.3402/ijch.v72i0.21401

[10]Simons, B., C. Jessen, L. Rea, M. Barnes, P. Barnes, and C. Gaydos. "O22. 5 Providing Discrete and Reliable STD Testing in Alaska Via a Web-Based At-Home Service." Sexually Transmitted Infections 89, no. Suppl 1 (2013): A70–A70.

[11]Ibid.

[12]Prince, Cheryl B., Margaret B. Young, William Sappenfield, and Jared W. Parrish. "Investigating the Decline of Fetal and Infant Mortality Rates in Alaska during 2010 and 2011." Maternal and Child Health Journal, January 12, 2016. doi:10.1007/s10995-015-1906-8.

[13]Baldwin, Laura-Mae, David C. Grossman, Elise Murowchick, Eric H. Larson, Walter B. Hollow, Jonathan R. Sugarman, William L. Freeman, and L. Gary Hart. Trends in Perinatal and Infant Health Disparities Between Rural American Indians and Alaska Natives and Rural Whites. Am J Public Health American Journal of Public Health 99, no. 4 (2009).

deaths and overall infant deaths. While these discrepancies are minimal, and far better than in developing regions, it still shows that their as a difference that can be addressed. There is room for improvement and as a test population it proved that our solution could work to improve the health of populations.

Prenatal Health

There exists a discrepancy between the developing and the developed world in regards to perinatal mortality (death of the fetus from 22 weeks after gestation to 7 days after birth), and maternal mortality (death of the mother while pregnant or up to 42 days after pregnancy). According to the World Health Organization the rate of perinatal mortality is 61 deaths per 1000 live births in the least developed regions and only 10 deaths per 1000 live births in the more developed regions.[14] A major cause for this discrepancy is the lack of access to proper antenatal care in rural regions. Receiving full and comprehensive antenatal care is a predictor of prenatal health. A study conducted in 2009 in India demonstrated that women who did not receive 4 antenatal visits (the recommended amount) or more were 3.78 times more likely to give birth to an underweight infant and 2.76 times more likely to have a stillbirth.[15]

The 2005 Indian Human Development Survey showed that 70% of women who gave birth did not attend the recommended number of antenatal visits. However, not everyone has internet connectivity. According to the CIA database, only 33.22% of the country has internet access, but this trend is increasing. While the prototype for this device does not apply to the developing world, it fits in well with rural Alaska and the potential to easily change the current design opens up a plethora of future markets where the modified device can be implemented.

1.5 Stakeholder Analysis

Primary Stakeholders

The primary stakeholders of our solution are pregnant women in rural communities who need access to reliable, low-cost medical screens. These women in our segmented target market do not have access to static health clinics but are serviced by medical professionals via periodic mobile clinics. The primary target markets are areas where lack of early pregnancy screening is a major contribution to high rates of preventable, life-threatening conditions.

Secondary Stakeholders

The secondary stakeholders of our solution are mobile clinic healthcare workers who need a more efficient screening solution and means of tracking patient histories. With access

[14]The State of the World's Children 2009: Maternal and Newborn Health. UNICEF, 2008.

[15]Khatib, Nazli, Quazisyed Zahiruddin, Am Gaidhane, Lalit Waghmare, Tripti Srivatsava, Rc Goyal, Sp Zodpey, and Sr Johrapurkar. "Predictors for Antenatal Services and Pregnancy Outcome in a Rural Area: A Prospective Study in Wardha District, India." Indian Journal of Medical Sciences Indian J Med Sci 63, no. 10 (2009).

to these improvements over existing solutions, the healthcare workers would be more capable of screening pregnant women before their conditions become life-threatening. By identifying red flags earlier, healthcare workers can provide more effective care and have the confidence to know when their patients should seek further treatment.

Tertiary Stakeholders

The tertiary stakeholders of our solution include NGOs and government agencies operating in the medical field who need a means of tracking epidemiological trends on a broad scale. By crowd-sourcing data from last-mile communities that have traditionally been challenging to reach, epidemiological trends may be elucidated that allow these actors to deliver more efficient and effective care.

1.6 Social and Cultural Context

Social and cultural differences play a huge role in the nuances of medical care, which specifically affects our target market of potentially sick, pregnant women in underdeveloped countries. Though our goal is to give them the greatest access to medical care and attention that we can, such care can be extremely private and sensitive in some places, and we must take that into account. When implementing the system, we must combine the best, most relevant medical advice to mothers, while still respecting the cultural values of the women. If these values are overlooked in our implementation, the advice will likely be ignored, jeopardizing the health of the women and their children. The American Congress of Obstetricians and Gynecologists give specific examples where cultural differences can cause discomfort and imperfect care for patients. Some particularly relevant examples can be found in section D of the Appendix.

1.7 Ethical Considerations

When combining medicine, the underdeveloped world, and the Internet, there exists a wide variety of ethical issues to be considered. Perhaps the most relevant to our system are cultural conflicts and expectations that change the way our project is implemented.

Although there are many standards by which to measure human progress, some of the most fundamental, addressable, and quantifiable are the United Nation's Millennium Development Goals.[16] These goals range from extreme poverty and hunger to environmental sustainability and include several key issues which our project addresses, specifically the following:

Goal 3: Promote Gender Equality and Empower Women

Goal 3 includes stipulations that target gender gaps in education access and economic independence. Although our device will not directly address these issues, we hope that its long-term use would cause secondary effects in which women are given more reliable

[16]United Nations Millennium Development Goals. UN News Center. Accessed February 06, 2016.

and accessible access to healthcare, decreasing the "marginal costs" of pregnancy and childbearing.

Goal 4: Reduce Mortality Rate

Goal 4 seeks to ensure that new mothers and their newborns, especially in rural and developing communities, are given the support necessary to lead healthy lives. Our device increases pregnant women's access to decentralized, preventative healthcare during an absolutely pivotal phase of the prenatal period. Our device is able to break down the barriers that have historically prevented newborn health.

Goal 5: Improve Maternal Health

Goal 5 is primarily focused on improving the state of prenatal and postnatal maternal health. Poor maternal health is a major issue in developing communities and often leads to the death of the mother or her child–or both. Our device directly addresses this issue by detecting preventable conditions before they progress to the point where more serious and costly medical interventions are necessary.

Broader Societal Considerations

Ethical We have an ethical duty to ensure that our device is used in a manner that contributes to the improvement of healthcare rather than the hindrance. The goal of the system is to help pregnant women in difficult circumstances, rather than for capital gain. The design of the system was created with this goal in mind, which contributed to many of the economic, political, health & safety, etc. decisions that we made.

Social Because the system could potentially be used in a variety of different cultural contexts, we wanted to make sure that the training for the healthcare workers was specific to those cultural contexts. Though this is not specifically addressed in the application or box design, relevant medical sensitivity training would be required before implementing the system in the field. We tried to minimize other areas of training time to allow for this.

Political Since our device includes both a biological analysis and database storage of medical information, it is possible that the information could be accessed or manipulated for the benefit of those beyond the immediate scope of the device. For example, government agencies, NGOs, and healthcare organizations, and medical researches would be delighted to gain access to medical trends which our device would utilize, including geographic and racial distributions of medical conditions. It was essential that we designed our comprehensive solution in manner that guaranteed the privacy and anonymity of the benefactors.

Economic Our device also needs to be examined in the context of the current global market in which alternatives are already available. It is important that our device has improved capabilities over existing solutions must be accurate or it might be purchased

and become obsolete when put into use, costing taxpayers and governments valuable funds which could otherwise have been put to valuable use in advancing medical technologies and access.

Health and Safety The design and testing of our device was crucial to establishing it as a reliable solution. Most importantly, we had to be capable of proving the device's accuracy, both in an absolute sense and in relation to existing solutions. In an absolute sense, the device had to be proven accurate enough to give the benefactors and operators of the device the confidence to trust its results. If our device were to produce results that indicate that a pregnant woman is healthy when, in fact, she actually has serious medical conditions that the device is unable to detect, it may lead her away from pursuing further care. Conversely, if our device detects medical conditions that are, in fact, not actually present, it may lead to a woman seeking costly medical care which is unnecessary. Finding this balance is essential to assuring that the device benefits the stakeholders and any sort of harm is minimized. One way to begin to ensure the accuracy of the device beyond the scope of its clinical testing is to produce literature that clearly and concisely explains its usage to operators. This literature should make very clear the limitations of the device such that operators do not have misplaced confidence in the device to dramatically outperform alternatives solely due to its digital rather than manual operation.

Manufacturability The application and especially box design were created with economic factors in mind. If the device was too expensive, it would not be able to benefit anyone. For this reason, we limited box materials to $50, and created an online application with no need for native application fees. Low cost of development and manufacturing allows our system to be much more realistic.

Sustainability Both of the two main components of this project, the web application and the light box, were designed to be physically sustainable. For the box, this meant using cheap yet durable materials that would stand the wear and tear of use in the field. For the application, this meant creating a web portal that could be easily updated, developed upon, and maintained.

Environmental Impact By bringing a low-cost urinalysis solution to pre-existing mobile medical clinics we hope to decrease the need for women to travel to receive medical screens.By using our pre-screens, we decrease pollution associated with travel.

Usability Usability was a large focus of our system design. The more time that is required to train health care workers how to use the device and application, the more money is needed to implement the system. This would defeat the purpose of creating a frugal device. The web application was created to be not only easy to use, but easy to learn. We also included visual instructions describing how to use the physical component in the application's testing process (See Figure 18.

Lifelong Learning & Compassion As Engineers, we have a responsibility to continue learning throughout our careers and lives. With the knowledge of how to help others comes the responsibility to do so. When our team learned about the unacceptable care that pregnant women receive in the developing world, we decided to use our resources and abilities to try and address that issue.

1.8 Requirements and Constraints

The requirements for the system described in the introduction can be broken down into two categories, functional and non-functional requirements. The former outlines requirements regarding what the system does, while the latter outlines the manner in which the functional requirements will be accomplished. These requirements can be further classified into three categories: critical requirements are essential qualities of the system, recommended requirements are suggested functions, and suggested requirements are processes that can be implemented to greatly improve the system but are not essential. The restricting factors that limit the system in regards to sustainability, scalability, deployment, and implementation are outlined in the design constraints sections.

1.8.1 Functional Requirements: Hardware

Critical: *The imaging unit must...*

- Have tight physical tolerances.
- Eliminate all ambient light from the imaging field to ensure consistent illumination.

Recommended: *The imaging unit should...*

- Have a self contained power source, switch, and light.

1.8.2 Functional Requirements: Software

Critical: *The system will...*

- Allow the healthcare worker to view and edit a patient database.
- Allow the healthcare worker to view and edit an individual patient's profile.
- Allow the healthcare worker to perform a urinalysis test.
- Translate urinalysis tests into statistical results and save them to a database.

Recommended: *The system should...*

- Be connected to a web-based database.
- Keep patient profiles updated with diagnoses for better consultation.
- Store data without internet connection to be later synced with the larger database.

1.8.3 Non-Functional Requirements: Hardware

Critical: *The imaging unit must be...*

- Compact and portable.
- Robust and capable of enduring repeated usage in varying conditions and environments.

- Maintainable and intuitive to the user.
- Able to capture standardized, reproducible images of urine test strips.
- Sanitary to handle as the user, and mitigate cross-contamination between tests.

1.8.4 Non-Functional Requirements: Software

Critical: *The system will be...*

- User-friendly.
- Efficient.
- Maintainable.
- Secure.

Recommended: *The system should...*

- Be scalable, allowing a large collection of patients' information to be stored.
- Have redundancy backups (no duplicate patient entries).
- Have a professional look and feel.

1.8.5 Design Constraints: Hardware

Critical: *The imaging unit must...*

- Utilize the camera of a tablet or other external digital device.
- Be compatible with the range of tablet brands and models used by healthcare personnel in the rural communities.
- Be compatible with existing, commercially-available urine test strips.
- Have all components contained within a portable, durable unit.

1.8.6 Design Constraints: Software

Critical: *The system must...*

- Be web based.
- Be able to access mobile device cameras.
- Be low-cost.
- Have low power-consumption.

2 Project Management

2.1 Team Management

Our project spans several disciplines, and multiple levels of education. Undergraduates, graduates, and advisers, in the fields of bio-engineering, electrical engineering, public health, and web design gives our team a diverse and broad breadth of knowledge. Due to the size of our team, organizational ethics and team management were of the utmost importance. In order to preserve the opinions and integrity of each team member, and guarantee efficient progress toward our shared goal, we implemented a strong communication network among all members to ensure individual voices were heard. Through weekly meetings, online document sharing, and respect, every facet of our project was available to each member, enabling us to work cohesively as a team.

2.2 Development Timeline

This is a schedule for the process of developing, documenting, and testing our system.

Figure 1: A simplified outline of the development of the project. See the Appendix for a more detailed timeline

2.3 Project Risks

Table 1 shows the risks that we proactively planned to encounter during all stages of the project. Each row lists a risk, the chance of it occurring, its severity, the repercussions, and preventative measure. The severity is measured on a scale of 1 to 10, and the impact is the product of the severity and the probability of the risk.

Risk	Probability	Severity	Impact	Consequence	Prevention
GitHub Issues	.4	6	2.4	Redo work that was not saved or overwritten	Communicate before committing to GitHub
Unable to implement features as planned	.2	6	1.2	Code remains unfinished and/or lose time	Ask for assistance to keep up with timeline and do independent research
Group member cannot contribute	.3	4	1.2	Pieces of project fall behind and collectively burdens team	Keep track of member progress collectively and check in for progress
Constraints are not met	.05	9	.45	Incomplete and/or not working	Prioritize implementation features and make sure they align with design constraints
Bioengineering portion incomplete/ behind	.1	3	.3	Full-scale project non-operational, field testing data unattainable	Create web portion independently of external elements, app operational with pilot data

Table 1: Potential risks that the team assumed they might face during the development. Elaboration on this can be found in Section 8.4: Lessons Learned.

For the most part, our team was able to avoid the risks that we predicted. There were a few features that we had hoped to implement that we were unable to address. An example of this was creating a way for the tests to be run while a tablet was not connected to the internet. See further descriptions of potential features for future implementation in Section 8.3: Future Work.

3 Design

3.1 Hardware

3.1.1 Hardware Prototype 1

The first iteration of hardware design was focused on creating a prototype in order to evaluate the feasibility of an imaging unit designed around a tablet. We chose to use an iPad 4 due to its high definition camera capabilities and ease of user interface interaction. The initial prototype was drafted using SOLIDWORKS and was constructed from 1/4" and 1/8" wood sheets that were glued together in three separate components, the main body, test strip slide, and cover. Wood was used for this initial prototype due to its ease of construction and low cost.

Figure 2: Hardware prototype 1 exterior with open lid, closed cover, and partially removed test strip slide

Figure 3: Hardware prototype 1 interior with open lid, removed cover, and partially removed test strip slide

This prototype, affectionately named the "Urinator 5000," had the potential to be highly functional but its development was halted due to the tendency of the material and construction methods of choice leaving too much room for error in urine test strip position. There were slight gaps between the test strip slide and the inside of the main body that allowed the slide too much freedom of movement. Since consistent test strip placement was a critical functional requirement of the design, we chose to move forward with a second prototype of tighter tolerances.

3.1.2 Hardware Prototype 2

The second iteration of hardware design improved the tolerances of the first prototype, redesigned components to be more ergonomic, and expanded the imaging unit's capabilities, including adding tablet support arms, lighting components, and a redesigned slide deck. The second prototype was designed on SOLIDWORKS and was constructed from 1/4" and 1/8" opaque acrylic sheets that were laser cut and assembled using acrylic cement. The acrylic plastic was chosen due to its low cost, ease of manufacturing through precision laser cutting, and ease of assembly through the use of acrylic cement.

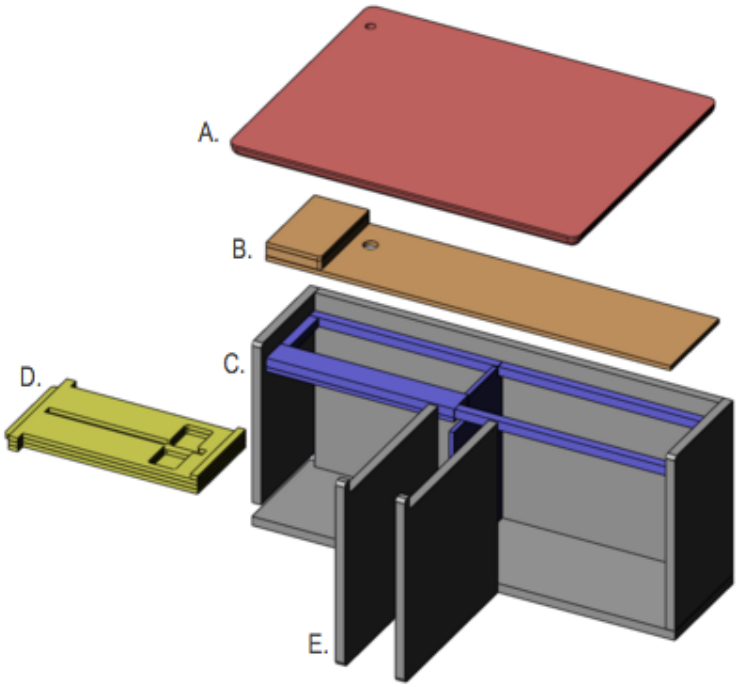

Figure 4: Hardware prototype 2 exploded view. A) Tablet. B) Cover. C) Main unit with LED light mount (shown in purple). D) Test strip slide deck. E) Tablet support arms.

This prototype improved the tolerances of the previous prototype by the nature of the materials and assembly methods. This iteration of design included tablet support arms (E) that were attached to the main unit through spring-loaded hinges that allowed the arms to return to a compact position for transportation. In addition, the spring-loaded hinges acted to stabilize the tablet thanks to the transverse tension across the surface of the iPad and the downward pressure applied by the protruding lips at the top of each support art. These lips alleviated the need for the hinged top that was utilized in the first prototype design.

The slide deck (D) was redesigned for ease of use and sanitation. The recessed design ensures that any excess liquid from the strip will be contained within the deck, which can be fully removed for sanitation. Additionally, it was designed to improve the consistency of test strip position. It also featured an elevated section near the end of strip such that an operator would be able to more easily insert and remove test strips.

The cover (B) was redesigned to be more accommodating of tablets (A) of varying size. Although the cover was designed for use with an iPad 4, unique cover designs can be easily produced that will accept a wider range of tablets and phones.

The interior of the main unit (C) was redesigned to accommodate electrical components for the purpose of illuminating the imaging field. An acrylic strip was added with a recessed space designed to accommodate a downward-facing LED light strip. A vertical section was placed in the middle of the interior of the box to separate the imaging field from the power and switch components while still ensuring that all components are fully self-contained. The switch, a variable-frequency LED dimmer, and power supply, a 12V

battery pack composed of eight AA batteries, were placed in the non-imaging side of the main unit.

Figure 5: Hardware prototype 2 interior view. As seen from left to right: downward-facing LED strip panel, dimmer switch, power supply.

3.2 Imaging Algorithm

3.2.1 Cropping & Color Processing

Our imaging algorithm begins with cropping the image and capturing the color from each reagent pad. After the tablet image is taken, we use HTML5 Canvas to crop the image, capturing only the area of the strip. The algorithm then draws squares on each of the reagent pads that correlate with each of our five selected biological markers. The pixels within each of those squares together constitute the cropped image that the algorithm analyzes.

We determined that the most accurate way to digitally describe the color of the reagent pads was using hue (range in color), saturation (range in intensity), and value (range in lights and darks).[17] Together, these values are referred to as HSV. Within each square, the algorithm records the RGB intensities (red, green, and blue intensities) of each pixel, and then converts the RGB intensities to HSV.[18] Then, for each pixel, the H, S, and V

[17]Although our system initially records the average color in RGB, we chose to convert it to HSV because HSV more intuitively describe color changes that occur on the reagent pads as a result of biological marker concentration changes.

[18]"RGB-to-HSV Volor Conversion," JavaScripter.net. javascripter.net/faq/rgb2hsv.htm

intensities are summed and averaged. Therefore, we end up with the average H, S, and V intensities for the cropped squares of the reagent pads of each biological marker.

3.2.2 Concentration Approximation

Once the image is processed for location and color, the algorithm approximates the concentration of each biological marker in the sample. The algorithm approximates the concentration of each biological marker using the color of the respective reagent pad. This algorithm relies upon experimental calibration in which solutions of known biological marker concentration are tested for reagent pad color, as described by hue, saturation, and value intensities.

Before the device can be functional, it must first be calibrated to establish a baseline that correlates color with biological marker concentration. To do this, we recorded images of urine test strips that had been treated with a range of dilutions of each biological marker. Next, we analyzed the color of each of the given reagent pad in terms of hue, saturation, and value. Then, we plotted the results of these experiments on graphs comparing H, S, and V intensity to biological marker concentration, adding best-fit, second-degree polynomial trendlines. Finally, the equations for each of these trendlines were coded into the imaging algorithm, providing the expected hue, saturation, and value curves for a given biological marker (H_E, S_E, and V_E, respectively). The best fit trendlines produce equations that correlate color to concentration as follows, where A is the concentration of the given biological marker and the letters x through C represent the resulting trendline equation coefficients.

$$H_E = Ax^2 + Bx + C \qquad {R_H}^2 = D \tag{1}$$

$$S_E = Ax^2 + Bx + C \qquad {R_S}^2 = D \tag{2}$$

$$V_E = Ax^2 + Bx + C \qquad {R_V}^2 = D \tag{3}$$

Given these equations for each biological marker, the algorithm predicts hue, saturation, and value using an input of biological marker concentration. The R-squared values represent the coefficient of determination, a measure of the proportion of variance between the regression line and the original data sets.

Once calibration curves are established that associate color to concentration for each biological marker, the algorithm can attempt to reverse the process. In calibration, color is recorded given of known concentration. In calculation, concentration is approximated given known color. The algorithm achieves this approximation using a weighted distance calculation that takes into account the variability of each respective curve given R-squared values.

First, the algorithm stores the actual intensities of the hue, saturation, and value (H_A, S_A, and V_A, respectively). Second, the algorithm compares the actual intensities of hue, saturation, and value with the expected values at an incremental range of discrete

biological marker concentrations. At each discrete concentration of a given biological marker, the calibration curves are used to determine the expected intensity of the hue, value, and saturation (H_E, S_E, and V_E, respectively). The algorithm finds the difference between the actual and expected intensities of hue, saturation, and value. This difference is divided by the respective R-squared values in order to proportionally assign the most precedent to the curves with the most statistical confidence. Third, the resulting solution is squared to eliminate negative values. The results of these equations are the weighted distances between the actual and expected intensities for hue, saturation, and value, as seen below.

$$D_H = (\frac{H_A - H_E}{{R_H}^2})^2 \tag{4}$$

$$D_S = (\frac{S_A - S_E}{{R_S}^2})^2 \tag{5}$$

$$D_V = (\frac{V_A - V_E}{{R_V}^2})^2 \tag{6}$$

Finally, the three distance values are summed to find the total weighted distance between the expected and actual intensities for the three curves (D_T), as seen below.

$$D_T = D_H + D_S + D_V \tag{7}$$

The algorithm then selects for the minimum D_T for each biological marker and returns the corresponding concentration to the user interface as the best approximation.

3.3 Mobile Application & Database

3.3.1 Conceptual Model

Activity Diagram

The activity diagram describes the possible paths that the user can take to complete various tasks.

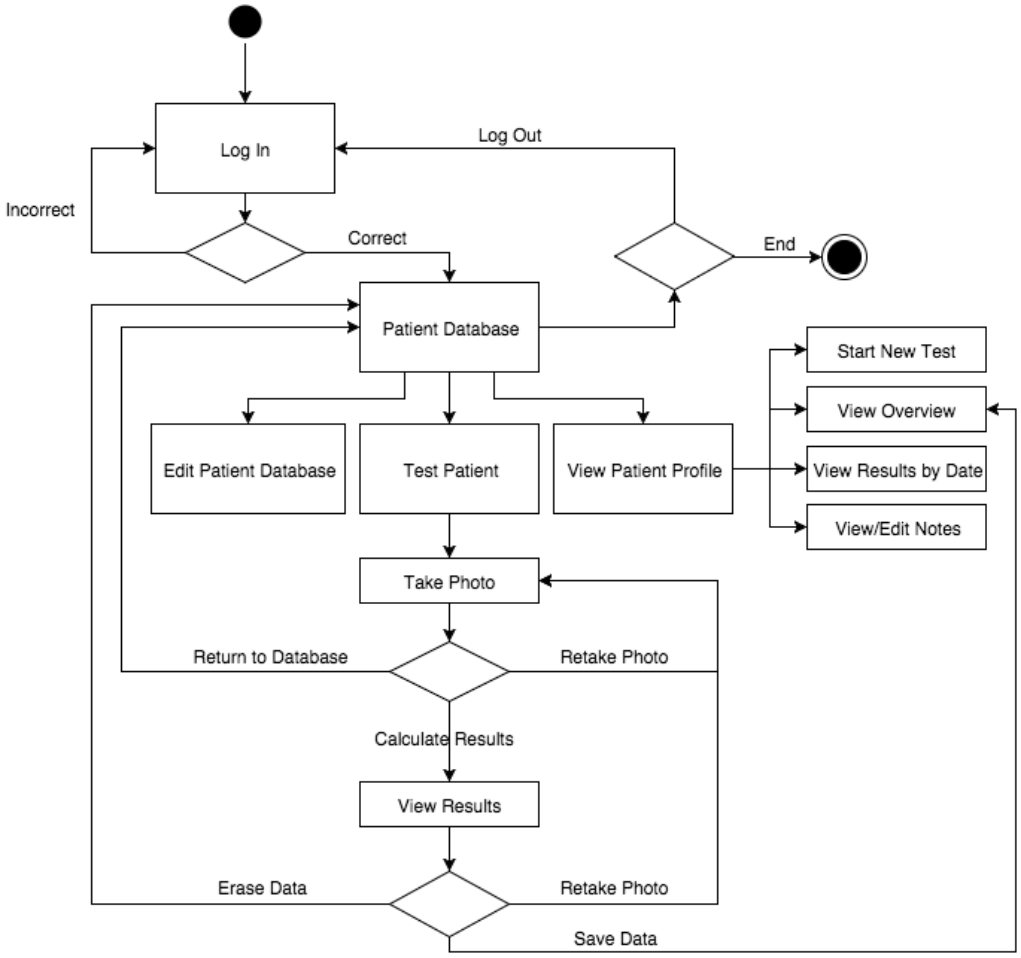

Figure 6: The Activity Diagram for users of the mobile medical application. The functionality is centered around the patient database, which holds all medical information and patient history.

Our user views the "Log In" page upon first opening the application to ensure security. Once a user is authenticated, she gains access to the "Patient Database", from which she can edit the database, start a new test for a particular patient, or view a particular patient profile. After starting a new test, the user takes the photo and can choose to calculate the statistical test results. The user can then choose whether to redo the test, save the data to the database, or erase the data. Saving the data takes the user to that patient's profile where she can also view the patient's health overview, view previous test results, and view and edit notes.

Mock-ups

These mock-ups are a visual aid to represent what we want the user to experience and be able to do with the system. The images below represent the four main areas of our web application.

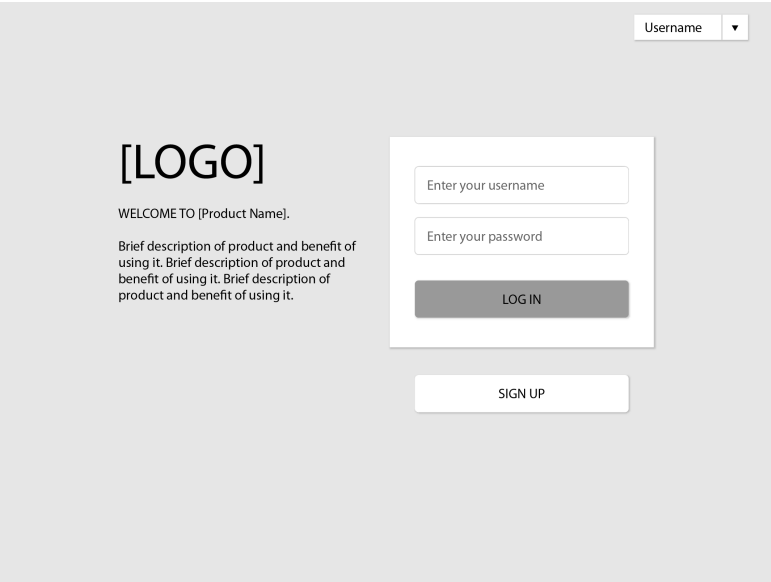

Figure 7: Authentication Page Mock-up. The app's database contains sensitive medical information, so security is highly important. Only authorized users will be given access to the information.

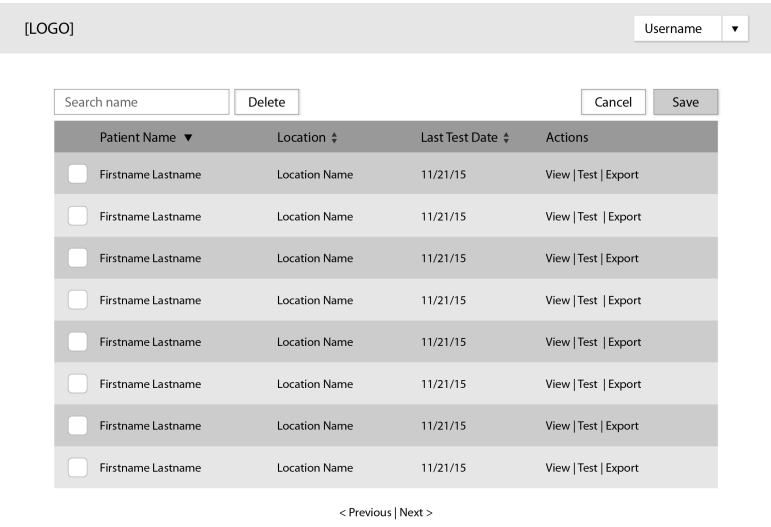

Figure 8: Patient Database Mock-up. This is what healthcare workers will see when searching for a patient in the database.

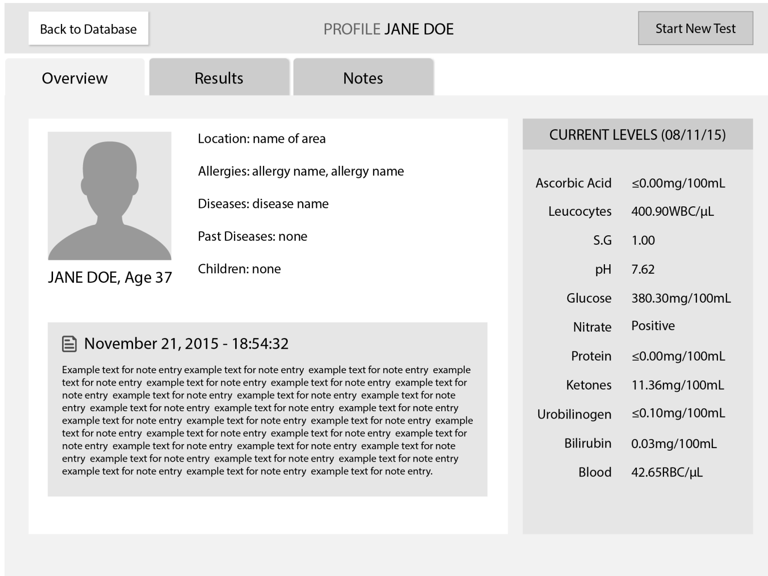

Figure 9: Patient Page Mock-up. This is the digital medical file of the patient where all known medical history and testing will be displayed. Urinalysis tests can be added to the history from this page.

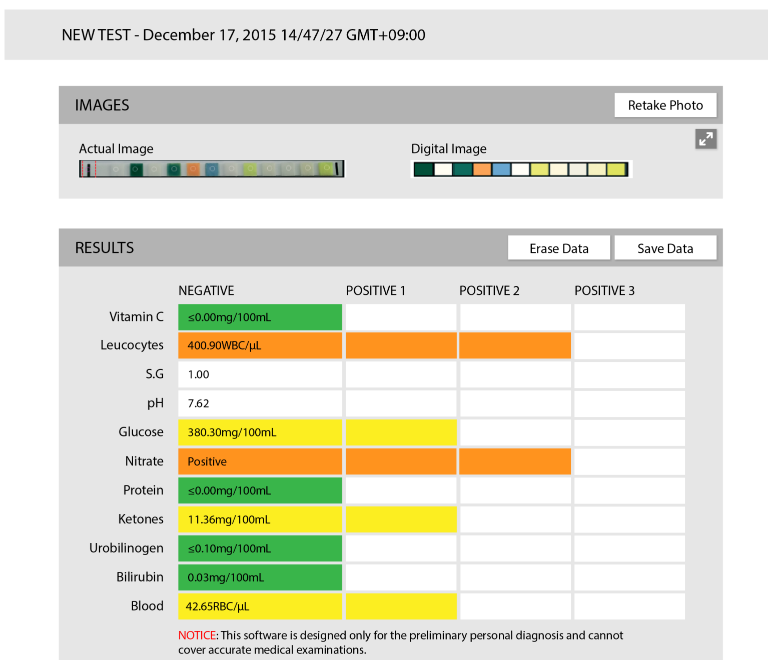

Figure 10: Results Page Mock-up. This page displays the results of patient urinalysis tests in familiar and simple format. The table is color coded to facilitate understanding.

3.3.2 Final Software Prototype

Though the prototype could be developed further in future iterations of this project, these screen shots illustrate the final web application interface.

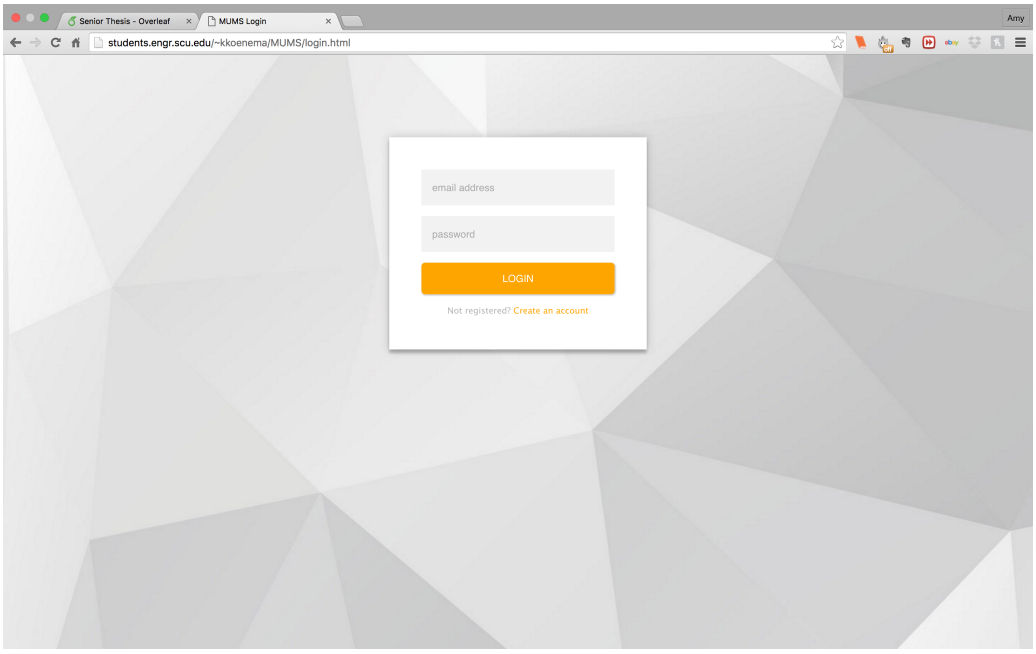

Figure 11: Login page for secure authentication.

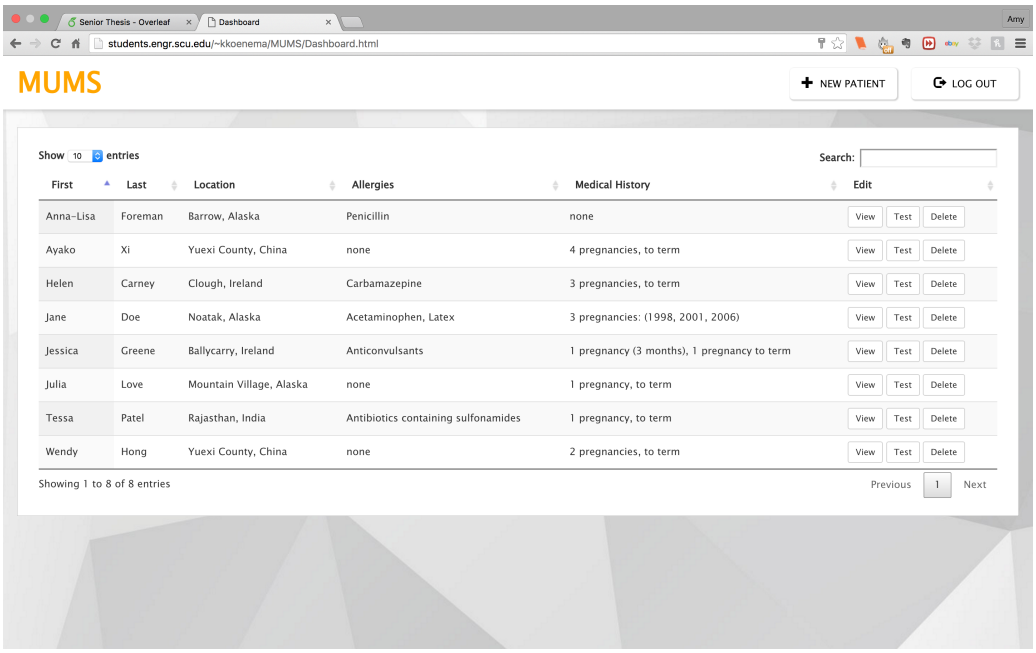

Figure 12: Patient Database. The main screen where users can find, test, edit, and delete patient information.

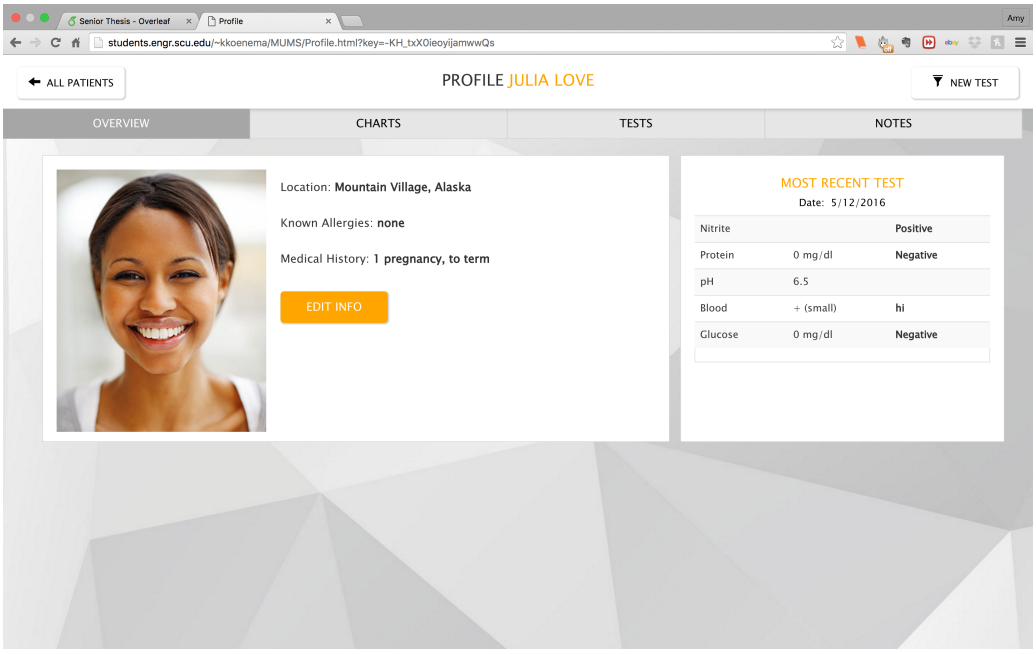

Figure 13: Patient Profile. Each patient has a profile page with information unique to their history and information. From here, a healthcare worker can access old test results or begin a new test.

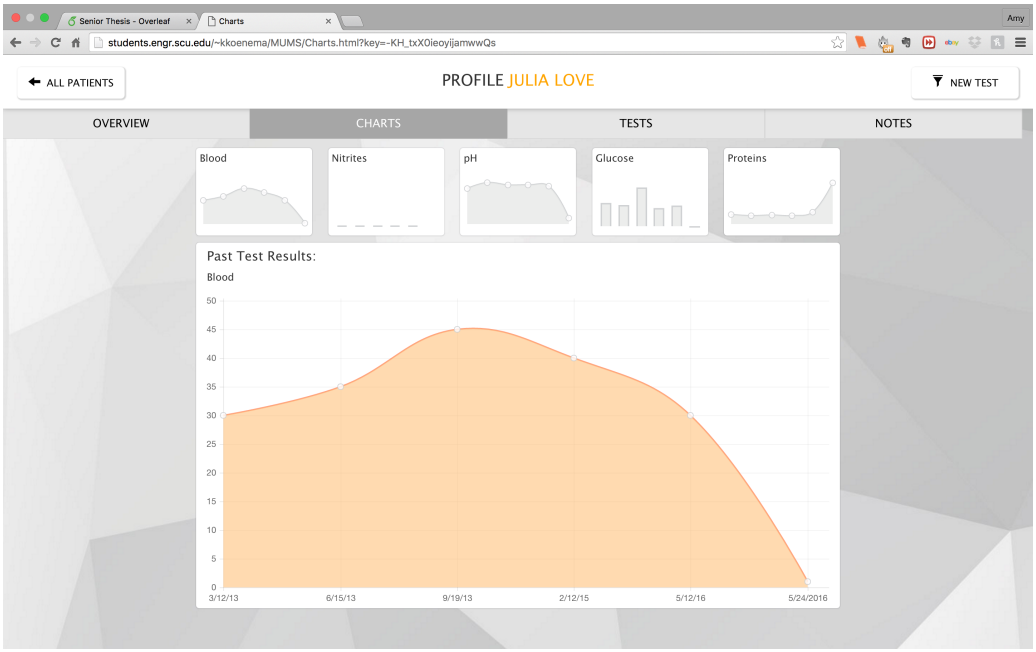

Figure 14: Charts Page. This is one way that the user can view patient data. The results seen are from past tests, for multiple biological markers.

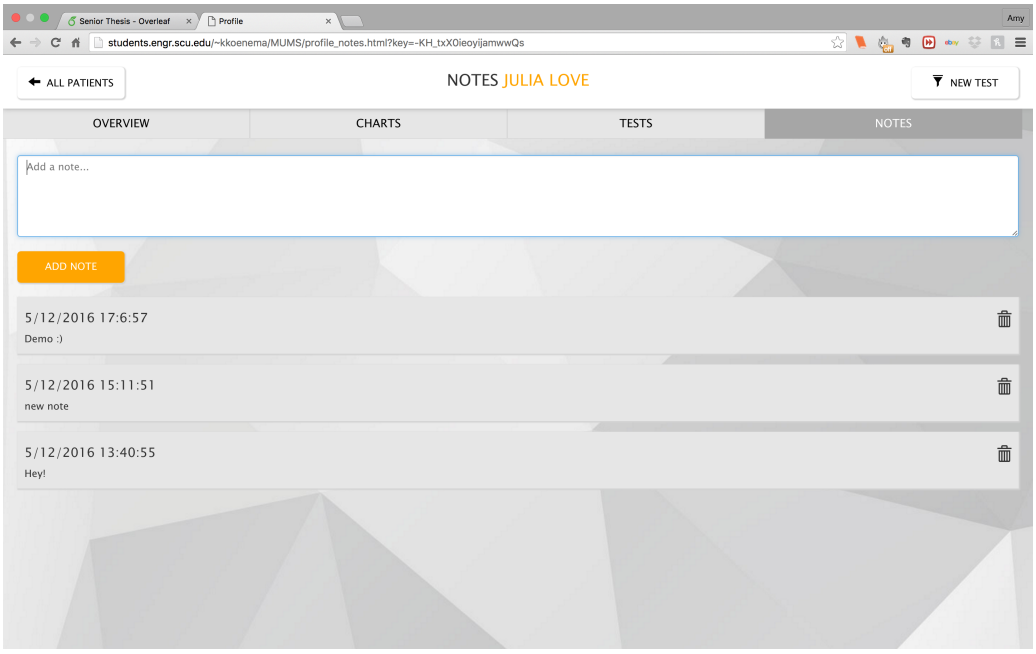

Figure 15: Notes Page. This page holds notes from healthcare workers for future reference.

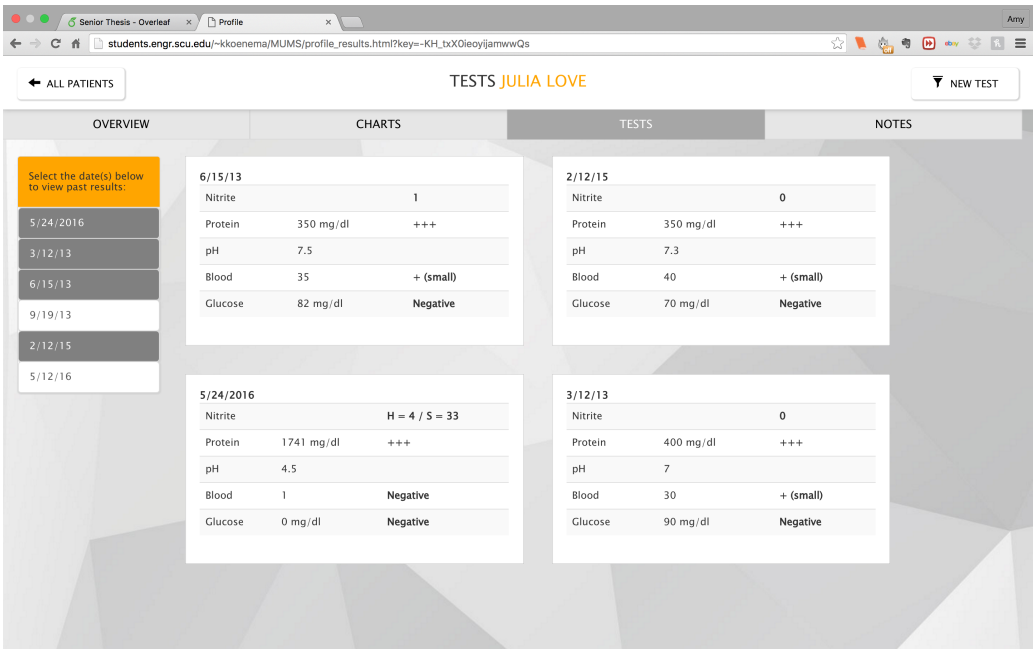

Figure 16: Tests Page. This page allows the user to look at previous test results, and compare different tests side by side.

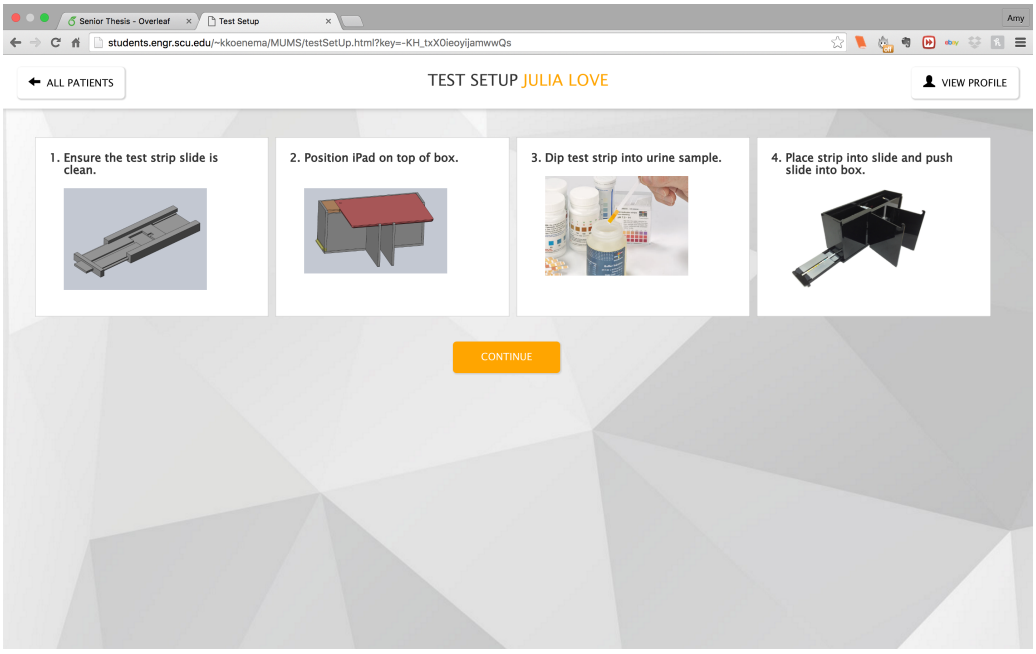

Figure 17: Test Set Up page. This page provides clear instructions on how to position the tablet and box before beginning a test.

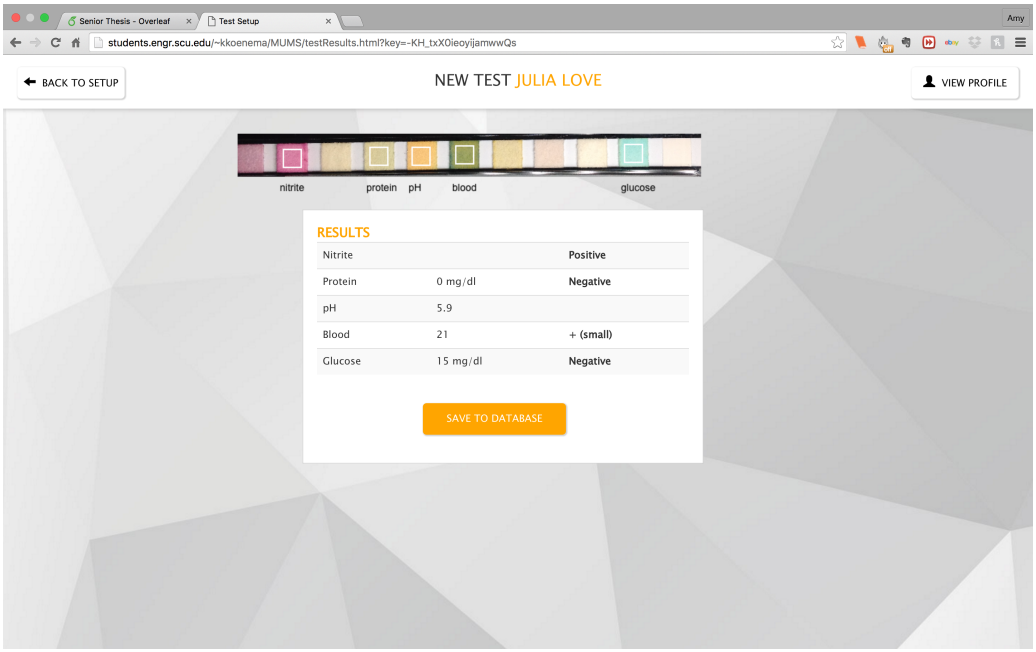

Figure 18: Results Page. This page displays a cropped version of the photo, featuring the test strip. From here users can retake the photo or analyze the results.

3.3.3 Use Cases

The primary users of this system are moderately trained healthcare workers that focus on providing medical care to low-income, pregnant women in the developing world. With our system, these workers are able to perform and record urinalysis tests for

women at risk for medical complications. They also have access to these results during later check-ups and screenings.

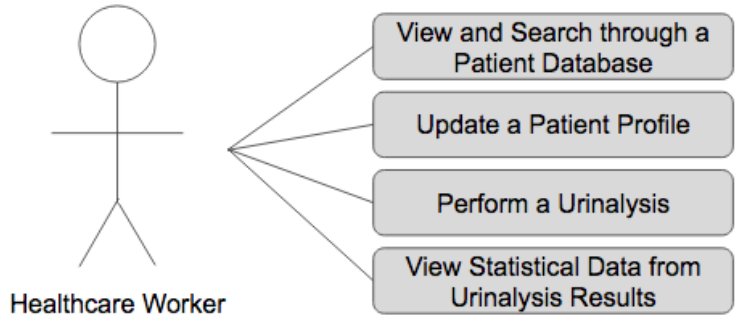

Figure 19: Use case diagram describing the possible use cases healthcare workers would perform when attending to their pregnant patients.

View and Search through a Patient Database

- Actor: Health care worker
- Goal: Be able to keep track of all patients in the database and search for a particular patient.
- Preconditions: There is a populated patient database.
- Post-conditions: The user is able to find the patient(s) for which he is searching.
- Steps:
  1. View full list of patient database.
  2. To search, type patient name in search field and click the "search" button.
  3. To refresh the list, click the "refresh list" button.
- Exceptions: If the query does not match any entries in the database, the text "[Query Name] is not found in the database" appears.

Update a Patient Profile

- Actor: Health care worker
- Goal: Be able to add a patient or update a patient's basic medical information.
- Preconditions: The information for a new or existing patient needs to be edited.
- Post-conditions: A patient's basic medical information will be properly stored and up-to-date.
- Steps:
  1. From the patient database page, click the add new button or select an existing patient.
  2. If selecting an existing patient, click the edit button to change patient information.
  3. In both cases, click the save button to update the new information.
- Exceptions: When adding a new patient, if the patient name already exists in the database, the system will give a warning of a possible duplicate.

Perform a Urinalysis Test

- Actor: Health care worker
- Goal: Take a photo of the urinalysis strip in order for the system to render the values.
- Preconditions: Have a urine strip ready for analysis.
- Post-conditions: Get the digitally rendered image from the photo taken.
- Steps:
  1. Find which patient to test and click the test button to begin a new test.
  2. Following the instructions of the screen, properly align the strip within the control box and align the box in the correct position under the iPad.
  3. Click the "Take Photo" button.
  4. After the photo has been captured, the user can either Retake the photo or calculate the test results by clicking the buttons.
- Exceptions: There is no urine strip to take an image of or the strip is positioned incorrectly.

View Statistical Data from Urinalysis Results

- Actor: Health care worker
- Goal: View the digitally rendered urinalysis image and view and save the statistical data calculated by the colors in the image.
- Preconditions: An image has been taken and is in good condition to be digitally rendered.
- Post-conditions: The original image is digitally rendered and the statistical data is calculated.
- Steps:
  1. After taking the original image, click the "Calculate Results" button.
  2. View the digitally rendered image and view the statistical data of the results.
  3. If necessary, retake the photo by clicking the "Retake Photo" button.
  4. Otherwise, the user can "Erase Data" or "Save Data" to the patient's profile on the database.
- Exceptions: The original image is of bad quality and the system is not able to accurately calculate the statistical data.

3.3.4 Architectural Design

This architectural model breaks down the way that our selected technologies interact with the system.

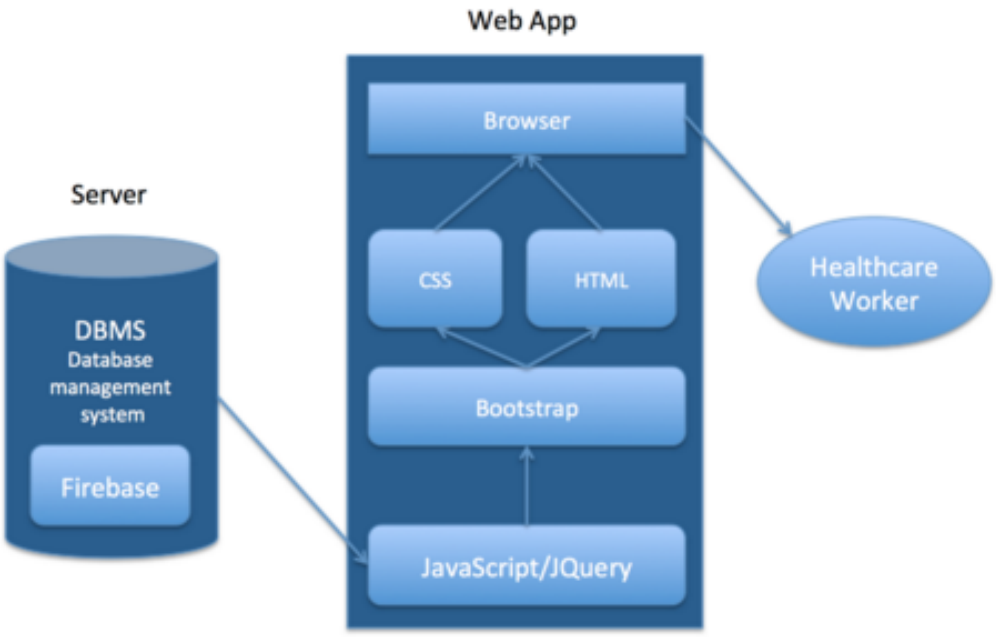

Figure 20: This diagram visualizes the way different technologies interact with the system.

As Figure 20 illustrates, our database is run on a cloud-based service called Firebase, which is connected to the HTML through Javascript and JQuery. On the front end, the CSS and HTML (assisted by the Bootstrap framework) allows us to easily create a user-friendly, well-formatted look to the front end of the app. Using JavaScript and JQuery will allow dynamic pages and continual database access.

3.3.5 Technologies Used

The technologies used are a combination of coding languages and web frameworks that will help us to create a stable yet flexible system.

Languages

1. **HTML** - HyperText Markup Language is the standard markup language used to create web pages. It will hold the main content and formatting within the app via PhoneGap (see below).
2. **CSS** – Cascading Style Sheets is commonly used to "describe" or design the presentation of the document written in a markup language(HTML).
3. **JavaScript** - A high level, dynamic scripting language that runs client side. Typically, used in conjunction with HTML and CSS.

Frameworks

1. **Bootstrap** - A framework made available by Twitter. Used for added design and to make the web-application user friendly and pretty.

Other

1. **JQuery** - a fast, small, and feature-rich JavaScript library. It makes things like HTML document traversal and manipulation, event handling, animation, and Ajax much simpler with an easy-to-use API that works across a multitude of browsers.
2. **Firebase** - provides a realtime database and backend as a service. The service provides application developers an API that allows application data to be synchronized across clients and stored on Firebase's cloud. Though Firebase offers other services, their database system is what we will be using most.
3. **GitHub** - a Web-based Git repository hosting service that allows multiple people to work on code at the same time, and has other helpful features for group work.

3.3.6 Design Rationale

Aesthetic Design

We designed our system to be as simple as possible while still displaying all collected patient data in an informative and effective way. The patient database is the homepage of our application that the user is directed to once logged in (see Figure 12). This page is the starting point because a urinalysis test must be associated with a patient in the database so that the data can be stored. The user can start a new test from the patient database by clicking the "New Test" icon next to the patient's name. Or, after navigating to the patient's profile, they can start the test from there (see Figure 13). As for the urinalysis test, we wanted to ensure that the user would have clear, visual directions to using the camera and have the options of retaking the image or saving/erasing the data (see Figure 17). The results of this and previous tests can then be viewed in chart format for easy comparison and evaluation (see Figure 14).

Technology Design

Our device consists of three major components: urine test strips, an imaging unit, and a web application optimized for tablets. The system utilizes inexpensive, single-use test strips to detect up to 11 biological markers in the patient's urine. These strips are analyzed inside of an illuminated box constructed of hard plastic. A tablet mounts onto the box, allowing it to capture an image of the urine test strip. Our design eliminates ambient light sources, secures and stabilizes the tablet, and illuminates the test strip with calibrated LED lights. The web application's main function is to perform the urinalysis test by taking an image of the test strip, find the average Hue, Saturation, and Value of each biological marker, and interpolate biological concentrations from predetermined gradient curves. The test results can then be saved in the application's patient database, and reviewed remotely via network connectivity.

The primary technologies used to create the application are be HTML5, CSS3, JavaScript, and Firebase. These languages and database are simple yet powerful web building tools that allow our project to meet the specifications required while also maintaining simplicity. A secondary technology we use is called Bootstrap, which is a popular, open-source web framework that allows the system to be more dynamic and effective across different platforms.

3.3.7 Aesthetics Analysis

Audience

The web application was created with the understanding that it would be used primarily by healthcare workers in the field. Because of this, we created a minimalist design, trying to eliminate any buttons or options that were non-essential. We also created multiple logical paths toward performing urinalysis tests, as this is the main function of the application. This option can be selected from patient profiles or directly from the database for efficiency. This could be especially useful in high-density clinical situations.

We also needed to ensure that the interface is intuitive. The more time that it takes to train healthcare workers to use the system, the higher the cost of implementation. As a frugal system, this is a highly important factor that affects the viability of the system being used in the field.

Facilitates Function

The bulk of design considerations are implemented in the web application, which represents patient data in a very simple and elegant way. The dashboard is a tool that helps healthcare workers, rather than hindering them. There are multiple visual and graphical data representation tools on the portal, which are logically designed, spaced, and color-coded. Without comprehensible visualization tools, the data collected from the urinalysis tests could not be easily decoded by users, and would therefore be unhelpful to patients. A very user-friendly, beautiful interface also serves to encourage the system's potential use in real-world situations. In professional situations, businesses and individuals won't use a product that is not attractive and usable. The system must attract users, not just exist.

Aesthetics and Function

Many essential functional requirements can be either addressed or enhanced by certain aesthetic elements. Table 2 highlights some of those relationships.

Table 2: Selected examples of how specific functional design requirements affect the aesthetic design of the product.

	Functional Requirement	Aesthetic Solution
I	Transmit health data to professional	Modular design to specifically highlight data and make it easy for the user to find. Graphs and visuals to convey data in a more comprehensive manner
IV	Clear understanding of data presented	Graphs and visuals to convey data in a more comprehensive manner Color coding and coordination to make data distinction easy
VIII	Secure environment for medical information and records	Intuitive login and authentication will be used. Symbols that represent this authentication will be used to communicate even between languages.
IX	View multiple patient's profiles and histories	Design elements that mirror real-life systems will be used for intuitive, easy navigation. An example of this is a tab, which resembles a file tab, and can connect the user from on patient portfolio to the next. Simple dropdowns will also allow users to view past medical screenings and data.

Expertise Level

Although there is an assumption that the primary users of our systems will be health care workers, who are relatively educated, that does not mean that they are technically inclined. Digital and web systems are new to the health world, so we cannot assume that a web portal will be particularly intuitive to workers initially. Therefore, we made the portal to be uncluttered, and ensured that the data was presented in the most comprehensible and natural way. We chose to label everything very obviously, and use visual aids. For example, on the test setup page, we included a series of diagrams to explain how to correctly lock the tablet into place before taking a test. This visual language is more universally understood than wordy descriptions.

4 Test Plan & Expected Results

4.1 Visual Assessment Accuracy

In order to determine whether our device is more accurate than simple visual assessment methods utilized by medical personnel in the field, we planned to conduct tests to establish the accuracy of visual assessments methods. The method of visually assessing urinalysis test strip results consists of comparing each resulting reagent pad color to a standardized reference chart that correlates color with concentration (see Figure 21).

We hypothesized that the accuracy of visual assessment method would be relatively low due to a range of reasons. First, the reactive dyes that give the reagent pads their functionality may be inconsistently concentrated, may be inconsistently washed away when the strip is tested, and may inconsistently react with their respective biological marker. Second, the dyes of some biological markers are designed to react with a range of marker types rather than one specific molecule. Each individual molecule in a class may have a slightly different reactive potential with the dye than other molecules in the same class. Third, human error is expected to increase errors in visual assessment due to variance in lighting conditions and individual nuances in perception of color.

4.2 Imaging Algorithm Accuracy

We planned to conduct tests to determine the accuracy of the imaging algorithm once the software was calibrated with the reagent pad color changes with respect to known biological concentrations. The ability of our device to accurately estimate the concentration of the tested biological markers is a key requirement of design. In order for our solution to be relevant, it must be able to estimate biological marker concentrations with equal or higher accuracy than the default visual assessment methods most commonly used my medical personnel servicing last-mile communities.

We hypothesized that the imaging algorithm would be more accurate than visual assessment methods due to the limitations of visual assessment, discussed in detail above. Nonetheless, we anticipated that variance in the accuracy of the imaging algorithm would be due, in part, to the limitations of the hardware, including consistent test strip placement, tablet placement, and illumination. In addition, we predicted that the imaging algorithm accuracy would be limited given the low number of trials conducted.

4.3 User Testing

Our implementation has four main use cases catering to the healthcare workers. To adequately test the system, we will test each use case with participants from a wide variety of backgrounds.

The first tests are focused on usability and front-end features like interface stability and readability. The insights gained from speaking with participants is very valuable for improving our application's usability. We want to make sure the information displayed

in the patient profiles are added completely and accurately. We ensure that all page links lead to where they are supposed to as well as loading elements in a logical order. By populating the patient database with sample patients and patient profiles we can mimic how the application would eventually be used. While the patient completes these tasks, we take note of their actions and questions.

The people selected for Black Box testing (people who have no prior knowledge of the system) would have a range of computer expertise. Though ideally the healthcare workers would have some kind of training with the app before using it in the field, every step is as intuitive as possible. For this reason, we test the computer-savvy, the medically trained, and the technologically inept throughout the testing process.

Tasks:

1. Log into the system.
2. Add a new patient to the database.
3. Search for the new patient within the database.
4. Begin a new urinalysis test for the patient.
5. Complete the test and save the data.
6. View the new test results in the patient's profile.
7. Add notes to the patient profile.

Questions to Improve Usability:

- At the end of each task, ask the participants about how easy the task was and if they would make any suggestions to improve usability.
- How intuitive are the instructions to complete a urinalysis test?
- How intuitive is searching within the database?
- Are there any features within the application you would add or remove?

Additional Questions for Medical Professionals:

- How accurate is the data collected from the urinalysis results?
- Is there any information contained in the patient profile that should be added or removed?
- How intuitive would this device be for a healthcare worker to use it with minimal instruction?

The second tests are focused on back-end features like data resilience and efficiency. We want to make sure our database is stable and the elements were linked correctly within the database. On top of that, we wanted to ensure that any reads or writes to the database were executed correctly and consistently. We simulated scenarios based on parameters we defined while creating the database.

5 Materials & Methods

5.1 Experimental Calibrations

Given the limited human capital, financial resources, and time for this project, we chose to pursue calibrations for only five of the ten biological markers capable of being detected by the Siemens Multistix 10 SG urinalysis strips that were used throughout the project. Nitrite, protein, pH, blood ("hemoglobin"), and glucose were tested. Leukocyte, urobilinogen, standard gravity, ketone, and bilirubin were not tested.

Nitrite was tested using sodium nitrite. Protein was tested using albumin from chicken egg white in the form of lyophilized powder. pH was tested using buffers of pH=4.01, 7.00, 10.01. Blood was tested using porcine hemoglobin in the form of lyophilized powder. Glucose was tested using dextrose. See the Section 10: Appendix for specification sheets for each of these reagents.

The range of potential concentrations for each biological marker was determined based on the respective concentration ranges prescribed by the visual assessment tables printed on the urinalysis strip bottle. The biological marker was diluted, in deionized water, to a series of samples, the concentrations of which spanned the aforementioned range. We submerged the test strips in each solution and tapped against the side of the test tube forcefully enough to remove air bubbles from the reagent pads and ensure full saturation yet gently enough to ensure the dyes contained by the reagent pads were not disturbed.

After approximately one second the test strip was removed, tapped gently against the lab bench to remove excess fluid, and placed in the slide deck, at which point a timer was initiated. The slide deck was inserted into the main unit for the duration of wait time before an image was recorded through the standard iPad camera application.[19] Each sample was tested, using different test strips, three times such that there were three images for each given biological marker concentration (n=3).

Each of the images was uploaded to the mobile application and processed to return the average hue, saturation, and value intensities of the cropped region of the reagent pad. Those intensities were plotted against the concentrations of the biological markers from which they originated. We applied second-degree polynomial, best-fit curves to the three data sets and recorded the equations for the curves as well as the R-squared value of each for statistical significance.

[19]The wait time varied by biological marker as prescribed by the instructions in the urinalysis strip documentation ($T_{Glucose}$=30s. T_{Blood}, T_{pH}, $T_{Protein}$, $T_{Nitrite}$=60 s. The selected times allow the reagent pad color to develop fully without over-developing

5.2 Visual Assessment Accuracy

Immediately following the procedure described above, we assessed the test strips visually based on the color scale provided on the urinalysis test strip bottle, as seen in Figure 21.

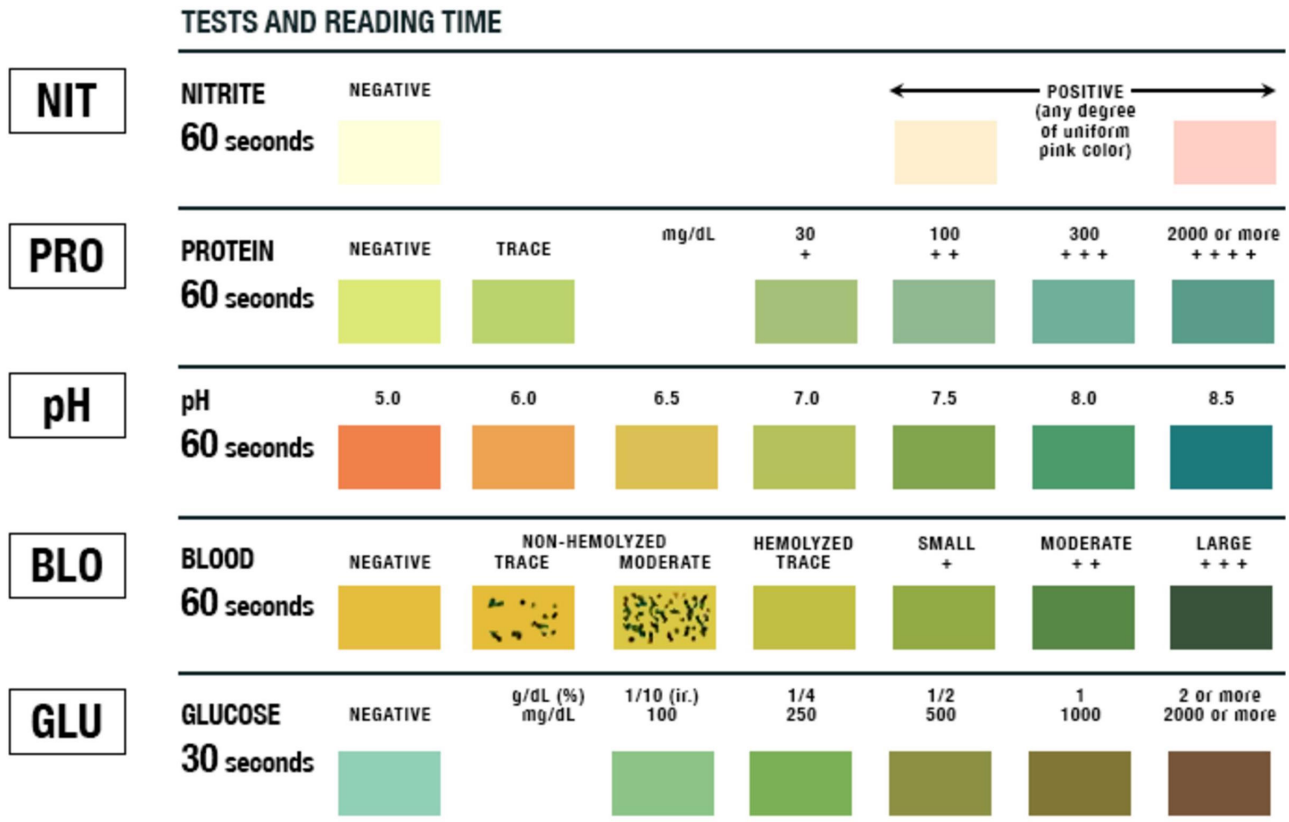

Figure 21: Color chart of select biological markers from the Siemens Multistix 10 SG urinalysis strip bottle. For the full chart with all biological markers, see the Appendix.

The two individuals conducting the tests separately held the used strip to the color chart provided on the test strip bottle and estimated the actual concentration of the biological marker. The absolute concentration was known only to the individual preparing the dilutions. The individual recording images was aware that the samples were being assessed in order of increasing dilution and was therefore aware of the relative concentrations, but was not informed of the actual concentrations. The two individuals recorded their visual assessments independently in order to avoid confirmation biases.

In the case of +/- scales, such as that of nitrite, only negative and positive results were recorded.[20] In the case of range scales, such as that of pH, actual values were recorded. When the reagent pad color fell between two discrete colors on the color chart, the two individuals made an effort to approximate the intermediate value on a linear basis.

[20]Negative values were recorded as concentrations equal to zero. Positive values were converted into discrete concentrations based on the test strip technical specification literature (See Appendix).

5.3 Imaging Algorithm Accuracy

The images used to calibrate the device were also utilized to determine the accuracy of the imaging algorithm after its development. They were loaded onto the mobile application, which returned estimated concentration values for each of the five relevant biological markers. These concentrations were recorded and compared to the known actual concentration values for each biological marker to determine the accuracy of the device. This accuracy was compared to the visual assessment accuracy as described above.

6 Results

6.1 Visual Assessment Accuracy

Visual approximations were conducted by comparing the resulting reagent pad color to the test strip color comparison chart provided by the manufacturer.[21]

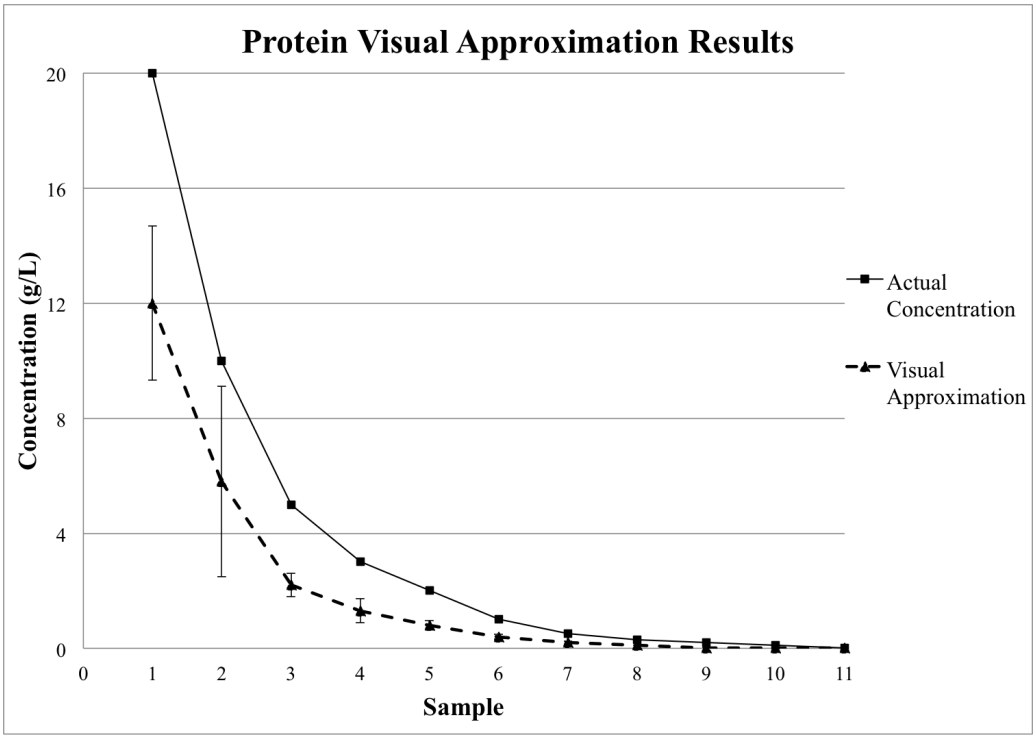

Figure 22: Comparison of protein solutions of varying known concentrations to their corresponding visual approximations (n=3).

[21]Nitrite visual assessment results were not compatible with a graphical format. The tabulated data for nitrite can be found in the Appendix.

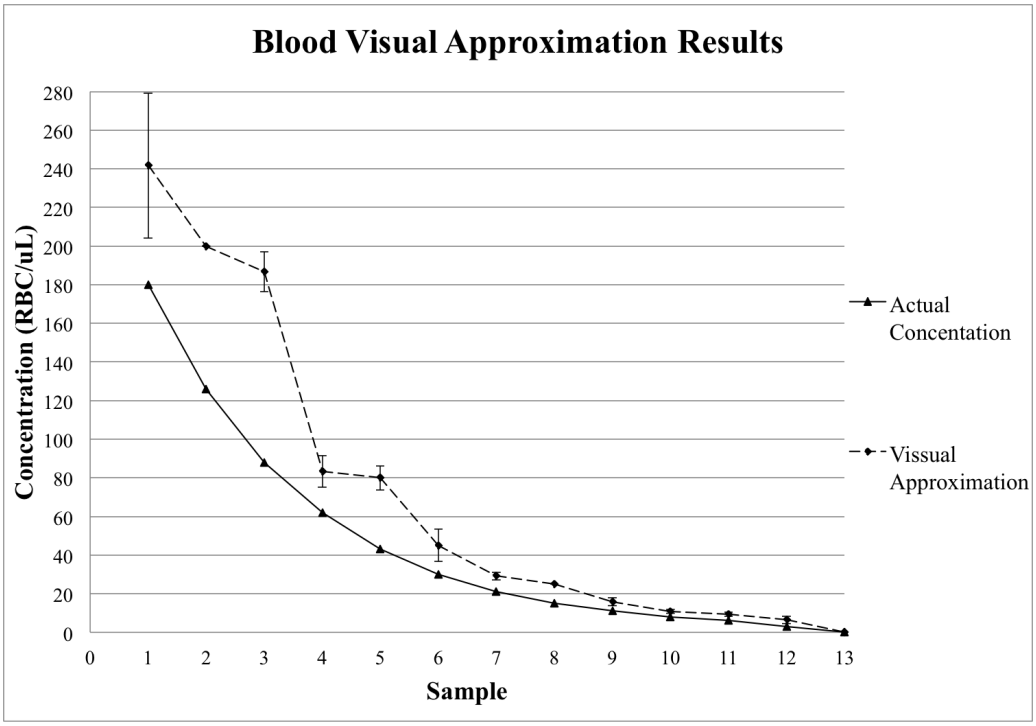

Figure 23: Comparison of red blood cell suspensions of varying known concentrations to their corresponding visual approximations (n=3).

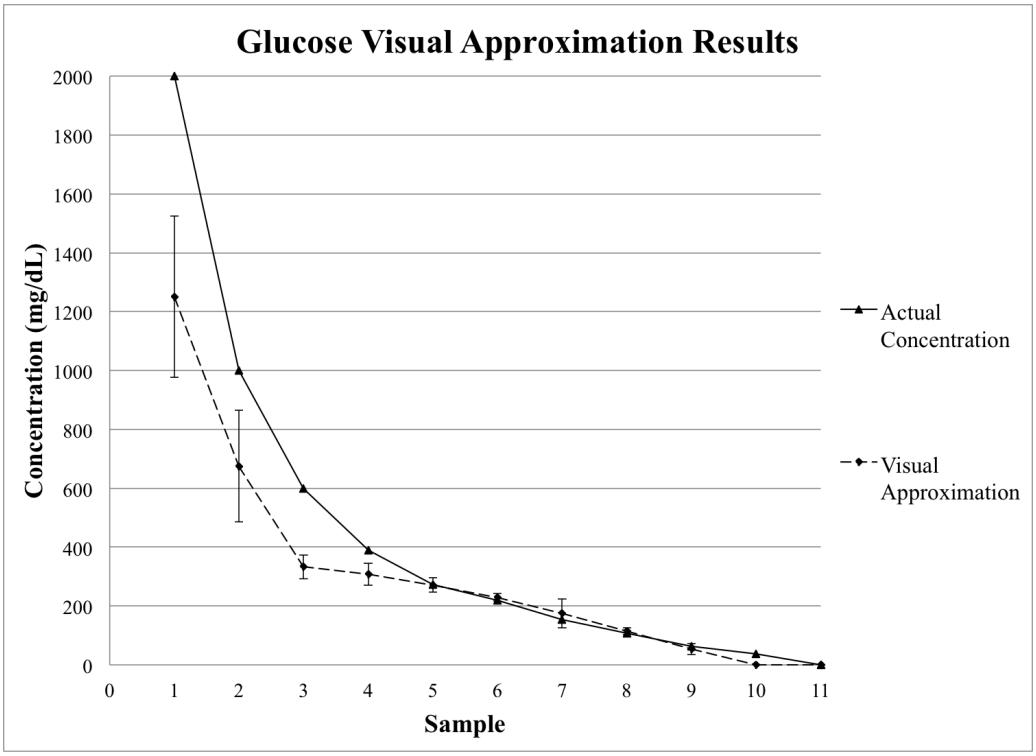

Figure 24: Comparison of glucose solutions of varying known concentrations to their corresponding visual approximations (n=3).

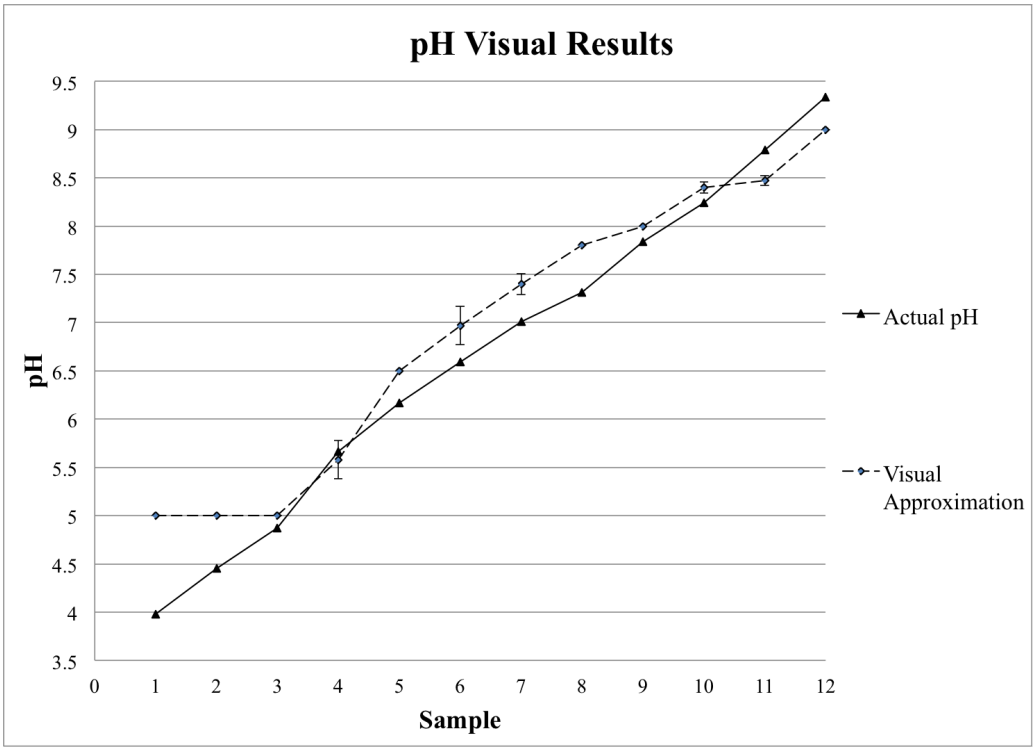

Figure 25: Comparison of pH buffered solutions of varying known concentrations to their corresponding visual approximations (n=3).

6.2 Imaging Algorithm Accuracy

Imaging algorithm estimations were conducted by processing the resulting test strip image with the imaging algorithm.

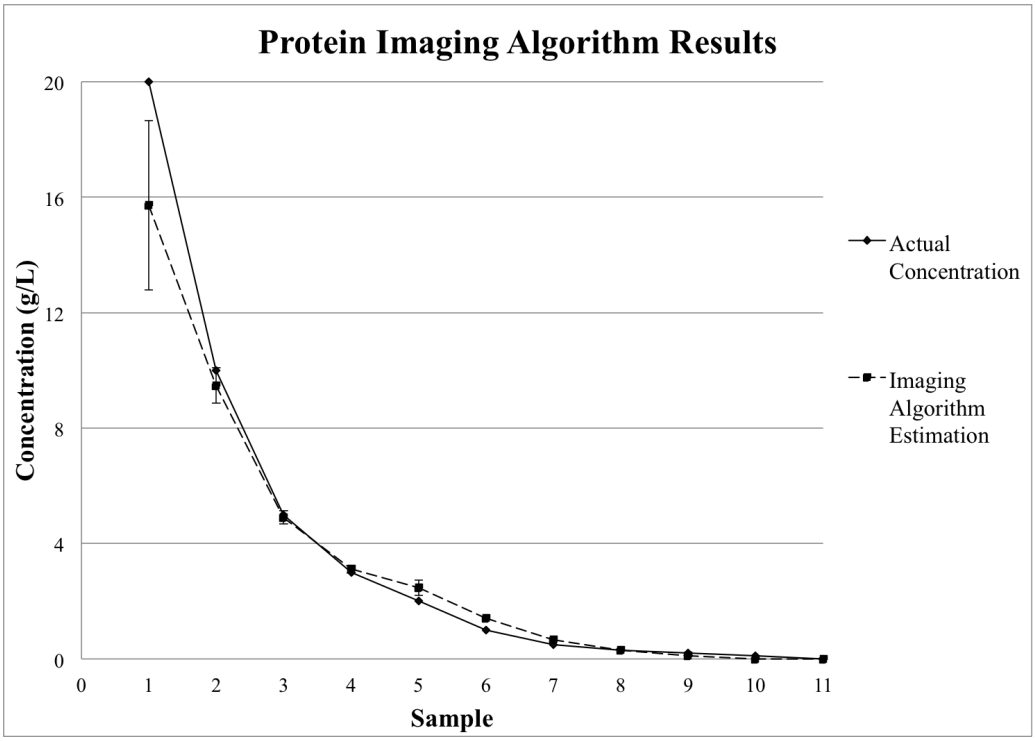

Figure 26: Comparison of protein solutions of varying known concentrations to their corresponding imaging algorithm estimations (n=3).

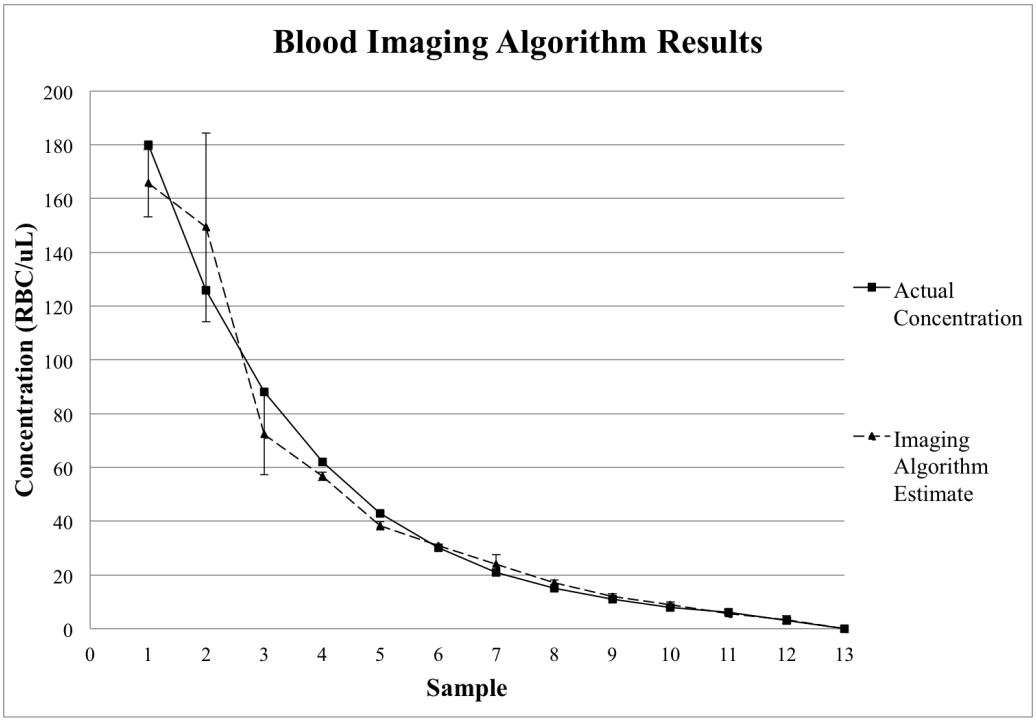

Figure 27: Comparison of red blood cell suspensions of varying known concentrations to their corresponding imaging algorithm estimations (n=3).

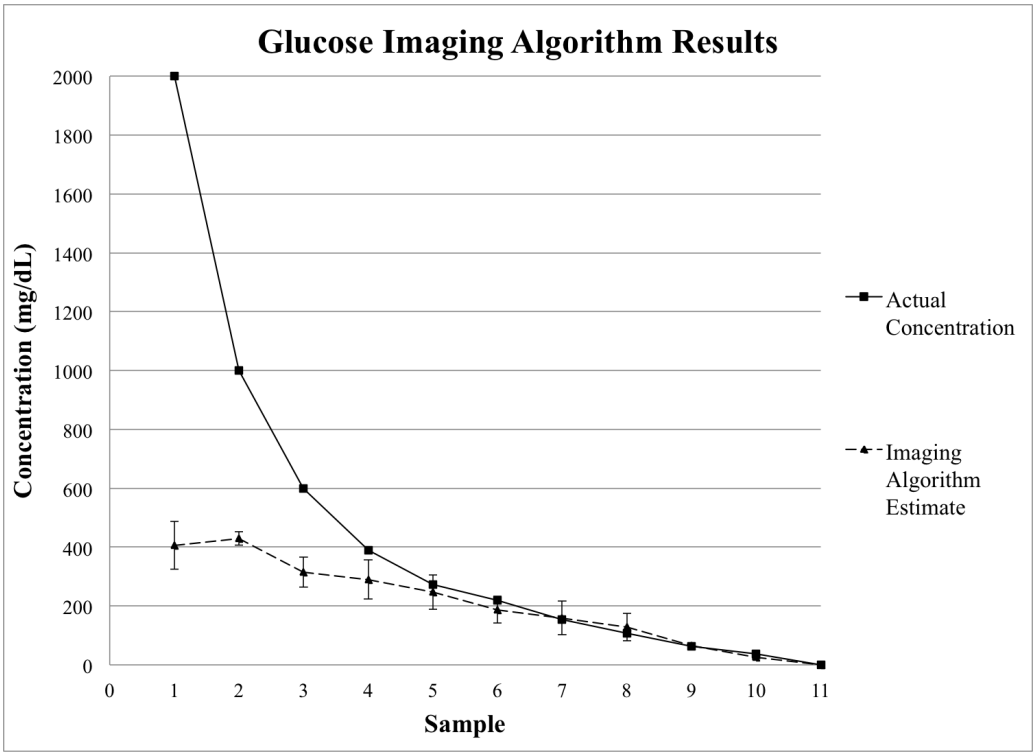

Figure 28: Comparison of glucose solutions of varying known concentrations to their corresponding imaging algorithm estimations (n=3).

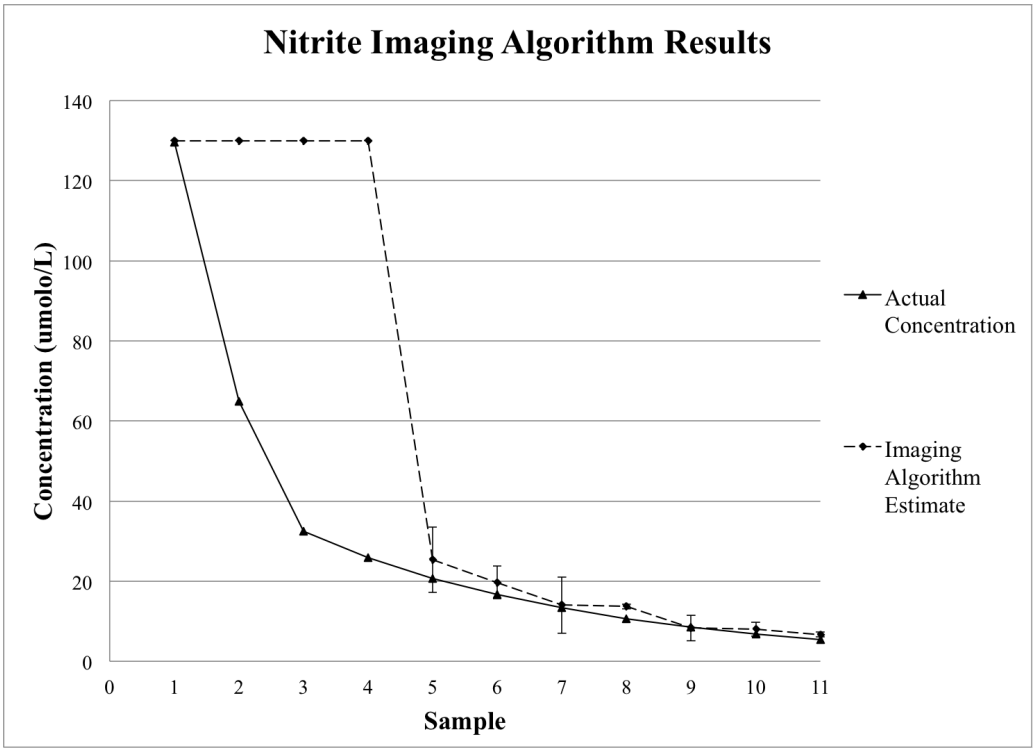

Figure 29: Comparison of nitrite solutions of varying known concentrations to their corresponding imaging algorithm estimations (n=3).

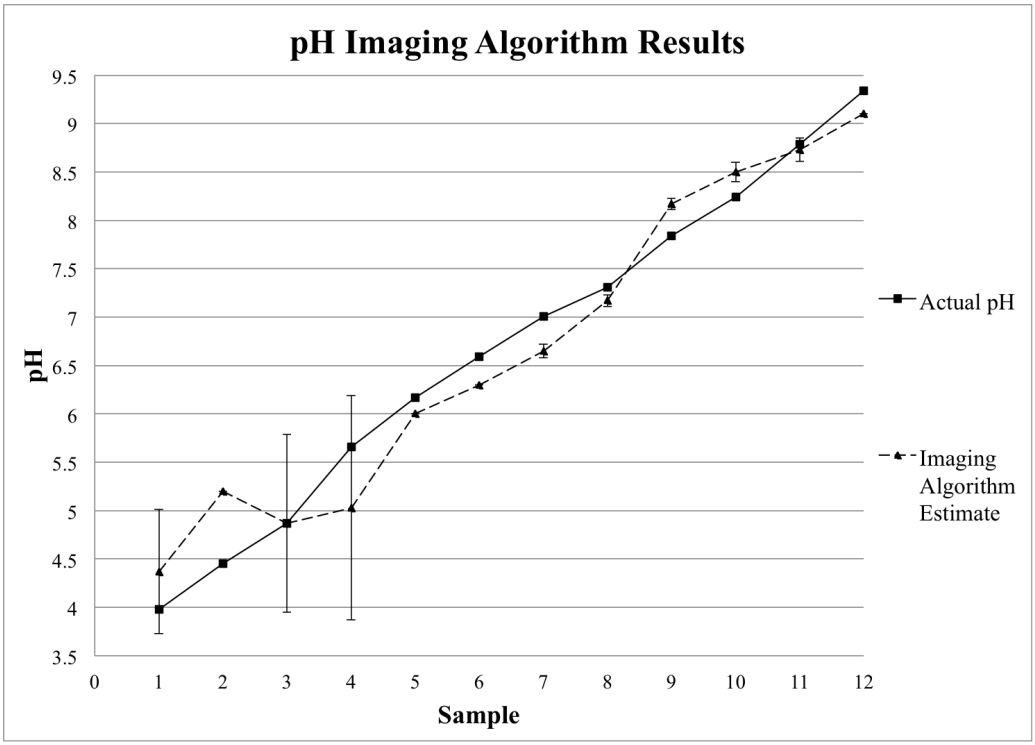

Figure 30: Comparison of pH buffer solutions of varying known pH to their corresponding imaging algorithm estimations (n=3).

6.3 User Experience Testing

Questions to Improve Usability

- **At the end of each task, ask the participants about how easy the task was and if they would make any suggestions to improve usability.** The majority of the participants were able to complete our tasks without assistance from us. Some made some suggestions such as the placement of buttons, choices in icons, and the overall look and feel.
- **How intuitive are the instructions to complete a urinalysis text?** Our instructions were originally simply a list of directions for how to assemble and administer the urinalysis tests. After receiving feedback from participants about how to make these instructions more intuitive, we decided to include images and clear steps of the process. When asking the same participants about our updates, we received positive feedback.
- **How intuitive is searching within the database?** All of the participants responded that the database was very simple to search through because of the filtering options and the search field. They also liked the option of limiting the number of entries shown on one page. One participant suggested that we have a button that could allow the user to delete multiple participants, but we decided to not implement this feature for simplicity reasons.
- **Are there any features within the application you would add or remove?** Some of the participants found certain sections to be unnecessary such as the notes section or the "Most Recent Test" section. However, others found these features helpful, so we kept them to make the application useful for different types of users.

7 Discussion

7.1 Visual Assessment Accuracy

To determine the necessity of a frugal, mobile, automated urine test strip analyzer, and gauge the potential room for improvement, we quantified the accuracy of analyzing urine test strips with the conventional method that is currently being used by healthcare workers in the field, that method being visually comparing the individual post-test reagent pad colors with a color comparison chart provided by the test strip manufacturer.

After testing five of the ten biological markers screened for by the test strips, we discovered that there were significant discrepancies between actual concentrations, and visual approximations for several of the tested biological markers. Specifically for protein, in figure 22 there can be seen a clear deviation between visual approximation and actual concentration of protein concentrations at high concentrations. This trend is represented numerically in Table 3, which displays that the visual approximations of protein concentration had on a average a 116.45% error from the known concentration. The four other biological markers returned similar results, the specific data for these tests can be found in the appendix.

Table 3: A comparison of actual concentration and average visual approximation of protein in varying dilutions. Percent error compares the difference between actual and visual for a given concentration (n=3), and average percent error averages all of the individual percent errors for each dilution.

C (g/L)	Avg. Visual Approx.	% Error	Average % Error
20.00	12.00	66.67	116.35
10.00	5.80	72.41	
5.00	2.20	127.27	
3.00	1.30	130.77	
2.00	0.80	150.00	
1.00	0.40	150.00	
0.50	0.20	150.00	
0.30	0.10	200.00	
0.20	0.00	-	
0.10	0.00	-	
0.00	0.00	0.00	

With discovering that visual approximations of urine test strips have a fair amount of inaccuracy, we successfully proved that the common method of analyzing these test strips is inadequate in providing reliable medical screens for patients. Furthermore, these results "set the bar" for achievable accuracy of urine tests strips utilized in a clinical setting.

7.2 Imaging Algorithm Accuracy

As stated earlier, the key requirement of our device is to accurately estimate the concentration of biological components within urine, depending on the color of various reagent pads present on a urine test strip. The results from our imaging algorithm tests suggests that our device does exactly that, and outperforms visually approximating biological concentrations using the archaic color comparison charts provided by the strip manufacturer.

When comparing the graphs of visual approximation results with the graphs of imaging algorithm results (graphs are found in the Results section), it can be deduced that the biological concentration estimated by the imaging algorithm deviates less from the actual biological concentration for each dilution than the majority of the visual approximations. For example, for the blood concentration reagent pad, the imaging algorithm returned concentration values with 10.01% error, whereas the visual approximation returned a concentration error of 33.44%.

Table 4: A comparison of imaging algorithm and visual approximation estimates for varying concentrations of blood (hemoglobin, ug/L).

C	Avg. Imaging Algorithm	% Error	Average % Error
180.00	165.67	8.65	
126.00	149.33	15.62	
88.00	72.33	21.66	
62.00	56.70	9.35	
43.00	38.33	12.18	
30.00	31.00	3.23	
21.00	24.00	12.50	10.01
15.00	17.00	11.76	
11.00	12.00	8.33	
8.00	9.00	11.11	
6.00	5.67	5.82	
3.00	3.33	9.91	
0.00	0.00	0.00	
C	Avg. Visual Approx.	% Error	Average % Error
180.00	241.67	25.52	
126.00	200.00	37.00	
88.00	186.67	52.86	
62.00	83.33	25.60	
43.00	80.00	46.25	
30.00	45.00	33.33	
21.00	29.17	28.01	33.44
15.00	25.00	40.00	
11.00	15.83	30.51	
8.00	10.83	26.13	
6.00	9.33	35.69	
3.00	6.50	53.85	
0.00	0.00	0.00	

For the five biological markers we tested, all but one returned more accurate concentration estimates using the imaging algorithm, as opposed to the traditional visual approximations (tables for all of biological markers their corresponding percent errors can be found in the appendix). We believe that the color-changing nature of the dies utilized in a few reagent pads may be the source of error in our imaging algorithm estimates for the particular biological markers that or more accurately approximated visually. A few biological marker reagent pads do not follow a simple color-changing trend, namely Nitrite, that can easily be reproduced by unknown concentrations. This limitation can easily be overcome by tailoring the imaging algorithm for each specific biological marker, which would mitigate the peculiarities of the dyes in each reagent pad.

7.3 User Experience Testing

Based on the feedback we received and incorporated into designing our user interface, we believe our interface is efficient and immediately intuitive. We were only able to test our interface from peers rather than experts in the field; however, if an average person with little knowledge of the field can understand how to use the application, we believe this speaks to the simplicity and intuitiveness of using the application for the first time. Something to consider if our project is expanded upon in the future is how adding more features can reduce the simplicity of the interface.

8 Conclusion

8.1 Summary

Pregnant women in low-income communities often lack access to the necessary healthcare for successful births. This is frequently due to the high costs of medical care, the remote location of patients, and the infrequency of primary care medical visits. To address this inequity, we have created a mobile application and imaging unit that allows for the low-cost implementation of urinalysis testing, which will aid in the detection of warning signs for prenatal health risks. From a single photo taken with a tablet camera, our application digitizes the results of a standard urinalysis test strip, displays the test results, and tracks the patient test histories.

Our results have shown that our solution can accurately estimate the concentrations of biological compounds found in urine when compared to visual approximations of color comparison charts. Our device is not only more efficient than the alternative, but also more efficient at screening for and detecting potentially fatal health conditions in pregnant women. Ultimately, our solution is a frugal and mobile urinalysis alternative that can feasibly be implemented in rural communities in order to increase early detection of pregnancy complications, allow for early intervention, and improve the probability of successful pregnancies.

8.2 Design Assessment

Advantages

- The entire solution is intuitive for use. The hardware requires minimal operational training and the user interface provides clear instructions for use.
- The solution is compact and portable relative to clinical urinalysis instruments.
- The solution is inexpensive. The total cost of materials, not including a tablet, is approximately 50 USD. This device is orders of magnitude more affordable than existing clinical urinalysis instruments.
- The hardware requires little maintenance besides changing batteries and cleaning the test strip slide deck between uses.
- The mobile application is efficient and versatile. It is web-based and therefore can be utilized by any device that can access the internet.
- The solution leverages the increasing rate of tablet usage among medical personnel servicing last-mile communities.
- The hardware is fully self-contained, reducing the probability that separate components will be lost or broken.
- The system utilizes existing, commercially-available urinalysis test strips.
- Although the hardware can currently only accommodate an iPad 4, it was designed to allow for unique covers to be manufactured that can accommodate other tablet and mobile phone models.
- The lighting components consume very little power and can function independent of an external power source.

Disadvantages

- The dimmer functions by reducing the frequency of electrical pulses to the LED strip. This makes it incompatible with the imaging process due to the fact that frequency dimming creates interference with digital cameras that was not visible to the naked eye. Therefore, we are only able to utilize the dimmer as an on/off switch.
- Any user can create and account and access all of the patient data, a clear security vulnerability.
- The urine test strip, slide deck, and tablet placements are not consistent between tests.
- The assembly method of manually applying acrylic cement was inefficient and unable to produce the tight tolerances necessary for the device to produce consistent strip placement.
- The urinalysis test results are not flagged when they are out of the standard healthy ranges, requiring the operator to trained in interpreting the results.
- Acrylic is relatively heavy, fragile, and expensive. It was useful as a prototyping material but is not practical if this solution was manufactured as a commercial product.
- The switch is only accessible if the cover is removed.
- The light intensity varies as the batteries are drained and the voltage drops.
- The static position and illumination method requires the operating conditions to be very similar to those utilized when the imaging algorithm was being calibrated.

8.3 Future Work

There are various ways in which this project can be expanded and improved. Listed below are potential improvements categorized by the project components they address.

Hardware

- Utilize a more lightweight, durable, and cost-efficient material than acrylic for the imaging unit.
- Use a more efficient manufacturing method to decrease tolerances between components in order to improve strip, strip tray, and tablet placement consistency.
- Improve the design of the electrical system in order to make the device more ergonomic, intuitive, and robust.
  - Relocate the switch to the outside of the box rather than the inside to improve ease of access.
  - Change the switch style from a frequency dimmer to a resistance dimmer.
  - Incorporate a rechargeable battery pack with an external charging port.
- Design unique covers that are capable of accommodating other tablets or possibly mobile phones.
- Incorporate a wide-angle lens into the imaging unit in order to allow the camera to capture the full imaging field with a shallower total depth.

- Place an in-line voltage regulator to ensure that constant voltage levels are provided to the lighting component to ensure consistent illumination.
- Incorporate diffusers on all internal sides of the imaging field to reduce glare reflecting off the reagent pads after they are saturated with liquid.

Imaging Algorithm

- Expand the system to address the five biological markers that were not tested: leukocyte, urobilinogen, standard gravity, ketone, and bilirubin.
- Incorporate a more complex timing and imaging system that records multiple images at the times prescribed in the urinalysis strip literature. The algorithm should crop only the relevant reagent pads at each time point (T=30,45,60,90 seconds).
- Retest the image algorithm accuracy using images of unique samples rather than the same images used to calibrate the device.
- Conduct more trials at a higher resolution of dilutions in order to improve calibration accuracy.
- Incorporate automatic strip position and illumination detection. If the application were capable of detecting the exact position of the strip and was calibrated for use in dynamic lighting conditions, the need for hardware could be reduced or entirely eliminated.

User Interface & Database

- Revise software system to allow for data to be recorded and stored locally without data access and then synced when internet connectivity is again available. This is an issue that large technology companies are currently tackling and doing so would greatly improve the practicality of the device to function in remote, last-mile communities that lack both Wi-fi and data access.
- Expand the database structure to incorporate different groups of authentication. The database can be expanded to incorporate different organizations and different levels of security to create a more dimensional user system.
- Incorporate automatic geolocation that would allow big data analysis of regional medical trends. Governmental agencies and NGOs can collect geolocational data to analyze epidemiological trends in and between developing regions.
- Patient profiles can be flagged for abnormal biological marker concentrations in order to improve the ease of use for operators.

8.4 Lessons Learned

Communication is Key

Due to the interdisciplinary nature of this project, coordinating efficient communication between teammates was essential. One of the most challenging facets of this project was ensuring that the teammates, all of unique educational and experiential backgrounds, were capable of understanding one another during technical discussions. For example, to create a web interface specifically tailored to display screening results in a manner

intuitive to healthcare personnel, the web design sub-team needed the guidance of the bioengineering sub-team, which was more familiar with the medical landscape.

In addition, to be able to code an imaging algorithm capable of efficiently processing the screens, the bioengineering sub-team needed the technical capabilities of the web design engineering sub-team. Finally, the entire team had to be capable of concisely communicating the project goals, needs, and progress to external supporters, such as our faculty advisers, the students of the Engineering World Health club, and Vishvesh Shah, a graduate computer engineering student. These supporters provided valuable knowledge and background research to the project but would not have been able to contribute had our team been unable to communicate in an efficient manner.

Be Flexible and Adaptable

Throughout our project, problems arose that we could not have predicted in the planning phase. Since our project was largely synthesized from scratch rather than an incremental technical advancement, it was difficult to predict all upcoming obstacles far in advance. We had to be prepared to face issues as they appeared and to ensure that, even if a small design pivot was made, that the overall value of the project remained. This lesson was further magnified by the interdisciplinary cooperation, which forced the sub-team's to constantly reexamine and reassess their designs based on small changes to that of the other.

Project Management Skills

In addition to the fact that the project advanced each of our technical knowledge and skills, we are also confident that it profoundly improved our ability to manage a significantly large project. Perhaps the most important contribution to this experience was the fact that our project was self-initiated, developed by ourselves rather than being assigned to us by the university or a commercial partner. We conducted background research, sought the advice of other students, faculty, and professionals, and pieced together a project that suited our passions and skills. Yet, as much as this gave us pride and ownership in our project, it also meant that we had to conduct our research more independently than other senior design teams. This required discipline in planning and project management to ensure that the project was completed on time and within the financial and design bounds that were initially established.

Document as You Go

This is the first time that we have pursued a project of such scope, budget, and time. It was essential that we recorded detailed notes as early as preliminary brainstorming meetings at the beginning of the academic year. We found that, as an interdisciplinary team made of two separate sub-teams, it was essential that we share our data, notes, presentations, and status updates in a live, common space. We chose to utilize a Google Drive folder in order to organize and share all such material. If we had not begun organizing our documentation early, the project would have certainly been more

challenging to complete within budget and time restrictions. In addition, the careful record-keeping made it far easier to efficiently pull together things like presentations, reports, and this thesis.

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10 Appendix

A LED Specification Sheets

Static Color Indoor
NFLS X3 LED Flexible Light Strip
Part Number: NFLS-X3

Features

Features 5050SMD high powered LEDs delivering up to 6,600 lumens

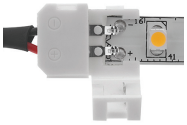
12 VDC operating voltage

Available in Black and White finish options

LED Light Strip features adhesive backing & cuttable 3-LED segments for easy installation

180° optics improve visibility with wider area illumination

Applications include back lighting, task lighting, cove lighting, retail, sign illumination, under cabinet, display case, accent decor, and automotive accents



Standards and Certifications

2 YEAR WARRANTY

Accessories

Remote Dimmers & Switches

Strip Interconnects

Mounting Hardware & Extrusions

Power Supplies

General Product Specifications

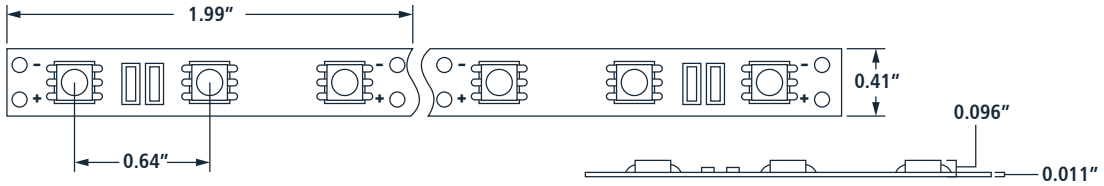
Beam Angle	180 Degree	Type	Flexible Light Strips
LED Type	5050 SMD	Color	9 Different Color Options
Voltage	9~14.8 VDC	Life Span	≥30,000 Hrs
LEDs Per Segment	3	Strip Width	10.15mm
Lumens (Max)	6600	Strip Finish Options	White / Black
Water Resistance	Non-Weatherproof	Strip Length Options	0.5m / 1m / 5m
Polarized	Yes	Strip Connection Options	Connector / No Connector
Wire Length	9in		

Custom Length Options Available for Cool White, Natural White, and Warm White (#NFLS-x3X3-CL)

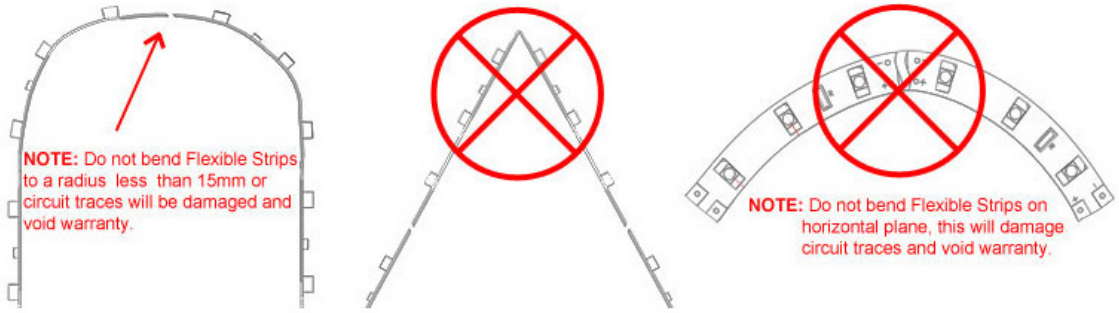
Product Specifications

	Emitting Color	Wavelength	Intensity Per Foot	Power Consumption
	Cool White	7500 K	360 lm/ft	292 mA (3.5 W)
	Natural White	4000 K	380 lm/ft	274 mA (3.3 W)
	Warm White	3250 K	380 lm/ft	292 mA (3.5 W)
	UV	440 nm	57000 mcd/ft	305 mA (3.7 W)
	Blue	470 nm	32918 mcd/ft	292 mA (3.5 W)
	Green	525 nm	100584 mcd/ft	292 mA (3.5 W)
	Yellow	605 nm	57000 mcd/ft	335 mA (4 W)
	Amber	610 nm	54864 mcd/ft	335 mA (4 W)
	Red	626 nm	54864 mcd/ft	335 mA (4 W)

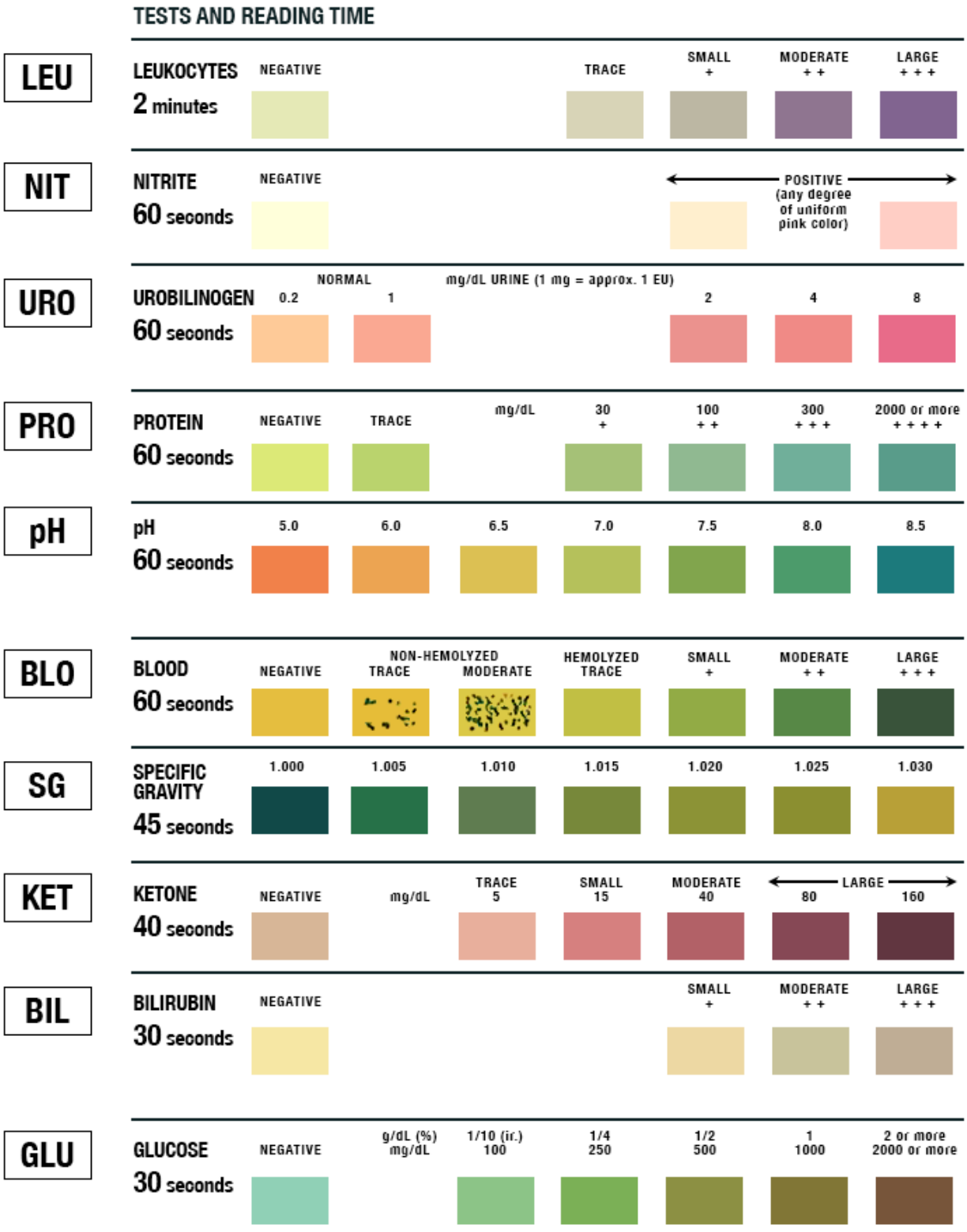
Dimensions



Maximum Flexibility Precaution



B Siemens Multistix SG 10 Color Chart



C Nitrite Visual Assessment Accuracy Results

Since the nitrite color scale does not list an explicit correlation between color and concentration, we are unable to offer results in graphical form as was done for the other biological markers in Section 6.1: Visual Assessment Accuracy. We recorded visual assessments of the nitrite reagent pad color as negative (-) and a degree of positive (+,++,+++) given the manufacturer color scale as seen in Appendix B.

Table 5: Comparison of nitrite solutions of varying known concentrations to their corresponding visual approximations (n=3).

Concentration (umol/L)	Visual Approximation Trial	Jake	Joe
129.60	1	+++	+++
	2	+++	+++
	3	+++	+++
64.80	1	+++	+++
	2	+++	+++
	3	+++	+++
32.40	1	++	+++
	2	++	+++
	3	++	+++
25.90	1	++	+++
	2	++	+++
	3	++	+++
20.70	1	++	++
	2	++	++
	3	++	++
16.60	1	++	+
	2	++	+
	3	++	+
13.30	1	+	+
	2	+	+
	3	+	+
10.61	1	+	+
	2	+	+
	3	+	+
8.49	1	+	+
	2	+	+
	3	+	+
6.79	1	+	+
	2	+	+
	3	+	+
5.43	1	+/-	+/-
	2	+/-	+/-
	3	+/-	+/-
2.72	1	-	-
	2	-	-
	3	-	-
0.00	1	-	-
	2	-	-
	3	-	-

D Imaging Algorithm Accuracy Statistics

Table 6: A comparison of imaging algorithm and visual approximation estimates for varying concentrations of protein.

C (g/L)	Avg. Imaging Algorithm	% Error	Average % Error
20.00	15.72	27.23	19.26
10.00	9.48	5.49	
5.00	4.90	2.04	
3.00	3.11	3.54	
2.00	2.46	18.70	
1.00	1.42	29.58	
0.50	0.66	24.24	
0.30	0.30	0.00	
0.20	0.11	81.82	
0.10	0.00	-	
0.00	0.00	0.00	
C (g/L)	Avg. Visual Approx.	% Error	Average % Error
20.00	12.00	66.67	116.35
10.00	5.80	72.41	
5.00	2.20	127.27	
3.00	1.30	130.77	
2.00	0.80	150.00	
1.00	0.40	150.00	
0.50	0.20	150.00	
0.30	0.10	200.00	
0.20	0.00	-	
0.10	0.00	-	
0.00	0.00	0.00	

Table 7: A comparison of imaging algorithm and visual approximation estimates for varying concentrations of blood (hemoglobin, ug/L).

C	Avg. Imaging Algorithm	% Error	Average % Error
180.00	165.67	8.65	
126.00	149.33	15.62	
88.00	72.33	21.66	
62.00	56.70	9.35	
43.00	38.33	12.18	
30.00	31.00	3.23	
21.00	24.00	12.50	10.01
15.00	17.00	11.76	
11.00	12.00	8.33	
8.00	9.00	11.11	
6.00	5.67	5.82	
3.00	3.33	9.91	
0.00	0.00	0.00	
C	Avg. Visual Approx.	% Error	Average % Error
180.00	241.67	25.52	
126.00	200.00	37.00	
88.00	186.67	52.86	
62.00	83.33	25.60	
43.00	80.00	46.25	
30.00	45.00	33.33	
21.00	29.17	28.01	33.44
15.00	25.00	40.00	
11.00	15.83	30.51	
8.00	10.83	26.13	
6.00	9.33	35.69	
3.00	6.50	53.85	
0.00	0.00	0.00	

Table 8: A comparison of imaging algorithm and visual approximation estimates for varying concentrations of glucose (mg/dL).

C	Avg. Imaging Algorithm	% Error	Average % Error (>200)
2000.00	406.00	392.61	56.92
1000.00	429.33	132.92	
600.00	315.33	90.28	
390.00	290.33	34.33	
273.00	246.67	10.67	
218.40	187.67	16.37	Average % Error (<200)
152.90	159.33	4.04	
107.00	128.33	16.62	15.28
64.20	65.33	1.73	
38.50	25.00	54.00	
0.00	0.00	0.00	
C	Avg. Visual Approx.	% Error	Average % Error (>200)
2000.00	1250.00	60.00	36.69
1000.00	675.00	48.15	
600.00	333.33	80.00	
390.00	308.33	26.49	
273.00	270.83	0.80	
218.40	229.17	4.70	Average % Error (<200)
152.90	175.00	12.63	
107.00	114.17	6.28	9.36
64.20	54.17	18.52	
38.50	0.00	undefined	
0.00	0.00	0.00	

Table 9: A comparison of imaging algorithm and visual approximation estimates for varying concentrations of nitrite (umol/L).

C	Avg. Imaging Algorithm	% Error	Average % Error (>25)
129.60	130.00	0.31	51.40
64.80	130.00	50.15	
32.40	130.00	75.08	
25.90	130.00	80.08	Average % Error (<25)
20.70	25.33	18.28	
16.60	19.67	15.61	23.91
13.30	14.00	5.00	
10.61	13.67	22.38	
8.49	8.33	1.92	
6.79	8.00	15.13	
5.43	6.67	18.59	
2.72	3.33	18.32	
0.00	1.00	100.00	

Table 10: A comparison of imaging algorithm and visual approximation estimates for varying pH values.

C	Avg. Imaging Algorithm	% Error	Average % Error
3.98	4.37	8.92	5.09
4.45	5.20	14.42	
4.87	4.87	0.00	
5.66	5.03	12.52	
6.17	6.00	2.83	
6.59	6.30	4.60	
7.01	6.65	5.41	
7.31	7.17	1.95	
7.84	8.17	4.04	
8.24	8.50	3.06	
8.79	8.73	0.69	
9.34	9.10	2.64	
C	Avg. Visual Approx.	% Error	Average % Error
3.98	5.00	20.40	5.75
4.45	5.00	11.00	
4.87	5.00	2.60	
5.66	5.58	1.43	
6.17	6.50	5.08	
6.59	6.97	5.45	
7.01	7.40	5.27	
7.31	7.80	6.28	
7.84	8.00	2.00	
8.24	8.40	1.90	
8.79	8.47	3.78	
9.34	9.00	3.78	

E Miscellaneous

Cultural Sensitivity and Awareness in the Delivery of Health Care Guidelines

Table 11: Selected examples from the Cultural Sensitivity and Awareness in the Delivery of Health Care Guidelines from the American Congress of Obstetricians and Gynecologists Website: www.acog.org.

Original Scenario	Culturally Sensitive Approach
A 17-year-old Hispanic woman has an arrest of labor for several hours and it is decided that a cesarean delivery needs to be performed. Labor and delivery is extremely busy, and a nurse brings in the standard surgical consent form, hands the patient a pen, and insists that the patient sign it. She and her family are clearly uncomfortable.	The nurse realizes that there are many members of the family crowded in the patient's room and also understands that for many women of Hispanic heritage, it is customary to involve family members in medical and personal decisions. The nurse and resident caring for the patient explain to the entire family the reason that a cesarean delivery is needed and the family understands. The patient is then asked to sign the surgical consent form.
A 30-year-old physician enters the examination room to see his next patient who is a 50-year-old African American woman; he introduces himself, addresses her by her first name, and asks why she has come to the office today. The patient becomes visually upset and gets up to leave. She tells the office staff as she leaves that she will never return to that doctor.	The clinician is aware that addressing patients by their first names may be perceived as disrespectful, especially for certain minority groups. Every patient can be asked an open-ended question about how she would like to be addressed (Miss, Ms., Mrs., Dr., Professor) by the health care provider. The name by which she wishes to be addressed may vary by many factors, including whether the patient resides in a rural or urban setting, whether she knows the health care provider or is a stranger, and what her age is. The patient in this example should be addressed by all members of the health care team by her preferred mode of address. This preference can be noted in the medical record to remind everyone how she wishes to be addressed.
An elderly Chinese woman is asked by her physician to go to the laboratory to have blood drawn for tests. She takes the laboratory slip but does not get the tests, nor does she return to see that physician.	The primary care physician orders laboratory tests on his patient, but notes the woman's hesitation and asks her why she is worried. She tells the physician that she believes that blood taken from her body will never be replenished and she is weak already. The physician spends time explaining how blood is replaced and the importance of the tests. The patient has the blood tests as the physician requested.

Extended Timeline

Meaning	Color
Blair Koeneman	
Amy Miller	
Web Engineering Team	
All Members (Web & Bio)	
DUE	

	Quarter 1									
	Sep 21-25	Sep 28-Oct 2	Oct 5-9	Oct 12-16	Oct 19-23	Oct 26-30	Nov 2-6	Nov 9-13	Nov 16-20	Nov 30-Dec 4
Initial Research										
Define Problem to Solve										
Problem Statement										
Define Audience										
Mock Activity Diagram										
Design Report										

	Quarter 2									
	Jan 4-8	Jan 11-15	Jan 18-22	Jan 25-29	Feb 1-5	Feb 8-12	Feb 15-19	Feb 22-26	Feb 29-Mar 4	Mar 7-11
Design Review										
Revised Design Report										
Design Interface										
Prototype Interface										
Public Health Feedback										
Database Setup										
Back End										
Front End										
Family Wknd. (Feb. 27)										
Testing										
Operational System										

	Quarter 3									
	Mar 28-Apr 1	Apr 4-8	Apr 11-15	Apr 18-22	Apr 25-29	May 2-6	May 9-13	May 16-20	May 23-27	May 30 - Jun 3
Preview Days										
SEEDs Day										
Design Confrence										
Comprehensive Report										
Completed Implementation										

Figure 31: A more detailed outline of the timeline of the project and individual assignments.