Noninvasive blood glucose monitoring using optical sensors

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Abstract

Over 30.3 million Americans currently have diabetes and a further 1.5 million are estimated to be diagnosed every year. Diabetes remains the 7th leading cause of death in the U.S. For diabetics, managing blood glucose levels is extremely important to maintain their health as high levels of glucose in the blood for extended periods can be fatal. Current glucose monitoring methods are very invasive and can limit physical activities of users. This thesis investigated using a low power optical system to noninvasively read blood glucose levels to determine if this is a feasible method for glucose detection. A low power system is key in this design as it would allow for a smaller, portable unit that average diabetics could use daily. This thesis showed there was a correlation between the optical system and a standard glucose meter.
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1 Introduction

Diabetes is one of the most important disease processes in the United States. It affects more then 30.4 million Americans, accounting for nearly 10% of the population, and it’s incidence is of approximately 1.4 million new cases per year [10]. Diabetes can be described as a dysfunction of the sections of the human body that regulate the amount of glucose in the human body. Extremely high or low blood glucose levels can have toxic, even fatal, effects. Hyperglycemia, when there are high levels of glucose and low amounts of insulin within the blood, can cause ketoacidosis if left untreated. Ketoacidosis is the result of the body beginning to break down fat in the place of insulin, building up ketones in the blood. A build up of ketones is toxic and can lead to hospitalization or death [5, 6]. Hypoglycemia is the opposite of hyperglycemia, where the glucose levels in the blood are too low and the insulin levels are too high. Hypoglycemia is commonly known as insulin shock and can cause a number of problems including seizures and impaired vision [9]. In order to prevent diabetics from entering these situations, a frequent or constant measuring of the blood glucose levels is needed.

Methods for noninvasively measuring blood glucose levels have been researched for over 2 decades to make glucose monitoring easier for users [54]. Diabetic users are expected to measure their blood glucose at least 4 times per day with current meters, if not more [18]. The blood is obtained by puncturing the side of a fingertip, which not only causes discomfort but also increases the chance of infection. Test strips can only be used once and it is recommended that the lancets only be used once with standard glucose meters, increasing the cost and amount of waste produced. The accuracy of current meters is another concern, as International Standards Organization (ISO) only requires marketed glucose meters to have an accuracy of $\pm 15\%$ for 99% of their readings [46]. This level of accuracy is an issue as it can be the difference between having normal or high blood sugar, and a diabetic may take an incorrect amount of insulin based on this inaccurate measurement.

Research into noninvasive glucose monitors focuses on using laser systems to develop devices similar to pulse oximeters [56, 26, 22]. One of the main limitations of these devices is that they often include
large parts, such as a laser system, that requires external power and cooling. While these systems could be appropriate in a clinical setting (e.g., a hospital), users that require portable meters would not be able to use them.

Aiming to overcome the limitations outlined above, this thesis investigates the use of a low-power optical diode and sensor for noninvasive continual monitoring of blood glucose levels. A low power optical system would also allow for a smaller form factor as no external power or cooling system would be needed. The goals of this thesis are to prove that low power optics can be a viable method for glucose monitoring, and to develop a design which targets those who require portability to check their blood glucose levels frequently. This device would also have the potential to connect to other devices via Bluetooth, such as a cellphone or insulin pump. This would allow users to monitor their blood sugar through a cellphone application, or a closed-loop monitoring system could be created with an insulin pump that automatically regulates glucose levels without user input. An Institutional Review Board approved study is conducted for this thesis to determine if the optical system is a feasible method.
2 Literature Review

2.1 Sugar: Glucose, Fructose, and Sucrose

There are three main forms of sugar: sucrose, fructose, and glucose [10]. Sucrose is composed of one glucose molecule and one fructose molecule, and when refined is typically known as table sugar [6]. When sucrose is consumed the fructose and glucose molecules are treated differently by the human body: fructose is absorbed into the bloodstream and transported straight to the liver, because the liver is the only part of the human body that can process it [5]. Fructose can eventually be converted into glucose, however the processes is much slower to raise blood sugar levels then naturally consuming blood sugar. Glucose is transported throughout the human body, as many parts of the body including muscles, fat, the brain, and the liver all use glucose as a form of energy [9]. Regardless if glucose is from consumed food or converted from fructose by the liver, glucose is the type of sugar within the blood that needs to be measured.

If glucose in the blood can’t be absorbed by the cells in a human body, a buildup of glucose occurs in the bloodstream, and if left untreated, can become toxic. Normally, to avoid a buildup of glucose, the human body releases insulin, which allows human muscle and fat cells to absorb glucose and use it for energy. However, diabetics lack the insulin production needed to allow cells to absorb the glucose that builds up within the blood. For this reason, the glucose levels in diabetics are frequently measured and artificial insulin is administered if needed.

2.2 Current Methods for Measuring, Monitoring and Controlling Blood Glucose

The following sections describe commercially available devices and methods to monitor blood glucose levels.
2.2.1 Standard Glucose Meters

Standard glucose meters require users to collect a sample of their own blood for analysis [9]. A user typically punctures their finger with a needle or lancet and applies the blood to a test strip that is then inserted into a blood glucose meter.

According to standard guidelines, this procedure should be performed at least for times a day. Nonetheless, for those with severe diabetes, doctors may even recommend measuring their blood sugar more frequently, thereby requiring a large number of finger punctures [18]. This method is not only uncomfortable and painful but also produces a lot of waste as the test strips and lancet are single-use. It is, in fact, recommended to only use the lancet once to avoid contamination and dull needles [31]. A dull needle makes it harder to puncture the finger and can increase the level of pain when puncturing the finger. Another limitation of standard glucose meters is that monitoring blood sugar throughout the night is impossible without waking up periodically. With the difficulty of night-time monitoring, diabetics may wake up in the morning with very high or low glucose levels, which can impact them for the rest of the day [75].

Standard glucose meters measure the milligrams per deciliter of glucose in the blood. In 2003, ISO standards permitted that 95% of readings from a standard glucose meter can:

- Have up to a ±20 % variation from the actual blood glucose reading with samples under 75mg/dL.
- Have up to a ±15 % variation from the actual blood glucose reading with samples of 75mg/dL or more.

In 2013, revised International Organization for Standardization (ISO) standards for glucose meters changed the 95% of readings to 99% and all samples must have an accuracy of ±15 %. Following this in 2016, the U.S. FDA increased their standard for meter accuracy from 95% of readings having a ±20% variation, to:

- 95% of readings to be within ±15% and
• 4% of the remaining readings to be within ±20% variation [30, 48].

It is unclear in the standards where the remaining 5% of readings in ISO standard and the remaining 1% of readings in the FDA standards should fall. However the tolerated ISO and FDA ranges for readings still allow for a wide variation in glucose readings from the standard meters and can cause a diabetic to administer too much or too little insulin. Better accuracy for standard glucose meters is sought after, however with current manufacturing processes this standard is hard to enforce.

2.2.2 Invasive Sensors

Invasive or embedded glucose sensors are additional methods for measuring blood glucose levels. These sensors are generally made of two parts: a component that is implanted under the skin and a transmitter that communicates with an insulin pump (Section 2.3) [54]. The insertion point for the glucose sensor differs from that of the insulin delivery line, meaning an additional area needs to be punctured. The multiple injection points can be seen on Figure 1.

Figure 1: Medtronic example of the invasive continuous blood glucose meter. [53]

These sensors must be replaced every few days. While this can be a good continual method for a
diabetic to monitor their glucose levels, pumps and sensors are very invasive and the points where
the insulin delivery tube and embedded sensor enter the body must be kept clean, otherwise an
infection may occur.

2.3 Insulin Injection Methods

There are two main methods for administering artificial insulin: an insulin pen or an insulin pump
[10]. The pen injection method is a syringe filled with insulin that diabetics use to inject a proper
dosage when it is needed. An insulin pump provides a constant supply of insulin to the body,
through continuously invasive methods similar to intravenous therapy [5]. The pump method is
similar to intravenous therapy and can limit physical activities. Currently, many diabetics prefer
the insulin pen since it doesn’t limit their daily activities and is far less invasive; however, some
research has shown that having a continual supply of insulin from a pump may be [3]. Diabetics,
whose bodies cannot absorb insulin properly need to take insulin at a slower rate so their body
can absorb the insulin. This can force them to use the insulin pump as it supplies a stead small
dose of insulin, compared to the larger one time dose of the insulin pen. Insulin pumps generally
integrate wireless communication capabilities (e.g. Bluetooth), and offer some degree of insulin
monitoring [1]. There has been much research into alternative, non-invasive methods for insulin
delivery, however, there is no federally approved, non-invasive method on the market currently [67].

2.3.1 Glucose Monitoring and Insulin

Every diabetic needs to monitor their blood glucose levels, but not all diabetics need to take
insulin. The type of diabetes a person has and their diet play major roles in whether a diabetic
needs artificial insulin.

In Type 1 diabetes, the beta cells in the pancreas which produce insulin typically have been de-
stroyed and the body cannot supply insulin or supplies very little. Artificial insulin must be
administered to maintain the health of a Type 1 diabetic [19].
In Type 2 diabetes, more of the beta cells may still be functional compared to someone with Type 1 and able to produce insulin, however, the amount may still be insufficient or their body may have an increased resistance to insulin. Those with Type 2 diabetes try to limit their sugar intake so that their body can use its natural insulin to prevent glucose build up, rather than artificial insulin or pills. However, 28% of type 2 diabetics do not have enough working beta cells in their pancreas and must take artificial insulin and/or pills [19].

Diabetic pills are prescribed medications that can block the liver from releasing stored sugar, increase the amount of insulin that flows in the blood stream, or slow the digestion of sugar. These pills by themselves are typically not enough for most diabetics, however, they can be used with either insulin injection method for better management. Glucose monitoring is always done regardless if a diabetic takes artificial insulin so that a diabetic can determine if they need artificial insulin, diabetic pills or to limit their sugar intake.

2.4 Glucose Molecular and Optical Properties

In contrast to existing methods, this thesis proposes using optics as a noninvasive method to measure blood sugar. Before that can be discussed, however, the basic physical principles that will be used must be introduced. These physical principles include the chemical properties of glucose and the reaction glucose has to specific wavelengths of light.

2.4.1 Molecular Properties

The molecular structure of glucose consists of six Carbon, twelve Hydrogen, and six Oxygen molecules, denoted as C\textsubscript{6}H\textsubscript{12}O\textsubscript{6}, shown in Figure 2.
Glucose is a monosaccharide, i.e. a group of simple sugar molecules that constitute the most basic components of carbohydrates. Monosaccharides cannot be further broken down (hydrolyzed) into simpler compounds. Dextrose is an older name for glucose derived from the term dextrorotatory, which is a compound that has the property of rotating a polarized light ray to the right. A compound, such as fructose, that rotates light to the left is called levorotatory. The rotation means that any wavelengths that are exposed to a glucose or fructose molecule will be rotated on the other side of the molecule. This rotation is called stereochemistry and the amount of a stereoisomer in a solution (e.g. glucose or fructose) could be measured by the optical rotation.

2.4.2 Optical Properties of Glucose

2.4.2.1 General Wavelength Absorptions of Human Bodies

Based on the fundamental laws of physics, atoms can store only a finite amount of energy. Depending on the element, there can be up to 7 electron shells in an atom where electrons can be located, but the atoms in a glucose molecule all contain 3 or fewer electron shells. When photons of particular wavelengths are absorbed by an electron and the energy level of the photon is equal to the energy difference between levels, it can cause the electron to jump to another shell and the atom is considered to be in an excited state. These different energy levels can be seen in Figure 4.
where the number denotes the level and the letter denotes the shape of the electron path. Atoms may also gain energy, and an excited state achieved, by gaining new electrons. On a molecular level when energy is absorbed the bonds between atoms in the molecule are subjected to vibration and rotational motions. Two examples of vibrational motion are stretching and bending Figure 3 [37].

<table>
<thead>
<tr>
<th>Stretching Vibration</th>
<th>Bending Vibration</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1.png" alt="Stretching Vibration" /></td>
<td><img src="image2.png" alt="Bending Vibration" /></td>
</tr>
</tbody>
</table>

Figure 3: Diagram of stretching and bending vibrations in atomic structures. [37]

vibrations are where the energy state of a molecule changes as energy is absorbed or loss. Fundamental vibrations of a molecule occur where the molecule’s energy level has transitioned from 0 to 1 [20]. Two or more fundamental vibrations can also occur at the same time, which is known as a combinational band. When a molecule’s energy state has transitioned from 0 to 2, this state is called the first overtone. The transition from the 0th to 3rd energy level is the second overtone, and this pattern continues to the transition from the 0th to 5th energy state, the fourth overtone (Figure 4 [82]).
Absorption is a physical process that involves a change in an atom’s energy level because of it’s interaction with an incoming photon. The amount of change in the energy levels indicates how well an element absorbs that wavelength. With this information a wavelength that would enable a device to detect and measure glucose could be found, however the challenge with finding this wavelength is that other chromophores in the blood may also absorb or refract this wavelength.

The following section looks specifically at the behavior of glucose under certain wavelengths. Other artifacts in the human body that also respond to similar wavelengths, such as water, are also briefly discussed.

2.4.2.2 Glucose Wavelength Absorption

Glucose has fundamental absorption bands from around 2.5um to 11um, caused by the stretching and bending vibrations of the Carbon to Carbon (C-C), the Carbon to Hydrogen (C-H) and the Oxygen to Hydrogen (O-H) bonds. The farther part of the fundamental band range (7.5um to 11um) is shown in Figure 5.
The other wavelengths where absorption occurs due to overtone and combinational bands are in the 0.9μm to the 2.3μm range, in the near IR spectrum Table 1 [38, 80]. Fundamental vibrations absorb more than overtone and combination bands [20]. Near IR’s (700-2500nm) lower band intensities can also traverse through human skin with greater ease than the far IR ranges where the fundamental vibration frequencies are located. Because of this, using near IR bands for glucose detection through the skin would be easier than using far IR light.

Table 1: Possible Non-Fundamental Band Peaks of Glucose [42]

<table>
<thead>
<tr>
<th>Wavelength (nm)</th>
<th>Possible Assignment</th>
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<tbody>
<tr>
<td>714</td>
<td>C-H stretch, 4th overtone</td>
</tr>
<tr>
<td>939</td>
<td>O-H stretch, 2nd overtone</td>
</tr>
<tr>
<td>1408</td>
<td>O-H, 1st overtone</td>
</tr>
<tr>
<td>1536</td>
<td>O-H &amp; C-H, combination band</td>
</tr>
<tr>
<td>1688</td>
<td>C-H, 1st overtone</td>
</tr>
<tr>
<td>2261</td>
<td>C-H, stretch; C-C-H &amp; O-C-H, bending combination band</td>
</tr>
<tr>
<td>2326</td>
<td>O-H, 1st overtone</td>
</tr>
</tbody>
</table>
There are several wavelengths where the overtone and combinational spectra of glucose and either water, hemoglobin, fat or protein overlap. This overlap could affect any optical measurements that are for determining glucose levels under the skin[42]. Below is a table that shows the wavelengths where glucose, water, hemoglobin, fat, and protein have overtones or combination bands in the near infrared spectra.

Table 2: Overtone & Combinational Band Peaks(nm) of Glucose, Water, Hemoglobin, Fat and Proteins within the blood.

| Overtone & Combinational Band Peaks (nm) | [42][29] |
| Glucose | Water | Hemoglobin | Fat | Protein |
| 714 | 749 | 760 | 770 | 805,820 |
| 880 | 910 | 920 | 910 |
| 939 | 980 | 1020 | 1040 | 1020 |
| 1126 | 1211 | 1450 | 1536 | 1688 |
| 1408 | 1787 | 1934 | 2260 | 2363 |

The majority of the lower bands in Table 2, 714nm-1408nm, are not used in research because of their proximity to absorption bands of water, fat, protein and hemoglobin. Water has several absorption bands in the higher IR wavelength ranges, which could interfere with any optical readings used to find glucose. Ranges around 1536nm and 2261nm are common in glucose detection research, as they are not close to the absorption bands of water [29]. Water absorption bands are seen in Figure 6 where water has major absorption bands around 1400nm and 1900nm, with minima around the 1530nm and 2200nm ranges.
Figure 6: The absorption of water in the Near Infrared Spectrum. The absorption coefficient is a way of measuring how far light penetrates into a material before it is absorbed: the lower the absorption coefficient, the lower the absorption. Both the 1530nm and 2200nm ranges for water have lower absorption.

For the 1536nm wavelength, there are also no major peaks in vibrational spectra for fat or protein near the peaks for glucose. In Figure 7, water and lipid absorption are also shown, where there is less absorption at the 1530nm range compared to the 2200nm range.
2.5 Noninvasive Techniques for Measuring Blood Glucose

Prior research has explored several methods to noninvasively measure glucose in the bloodstream. The following sections provide an overview of the existing literature in this area.

2.5.1 Optics

There are several methods that measure blood glucose using optics. Near infrared spectroscopy [45, 81], far infrared spectrometry [60], optical rotation of polarized light [36] and impedance (dielectric) spectroscopy [17] are all methods that researchers have tested in varying degrees. The following sections discuss previous research results using the aforementioned methods.
2.5.1.1 Near-Infrared & Far-Infrared

For over two decades infrared light has been used to measure blood glucose levels in non-intravenous blood, and within the past couple decades, scientists have begun researching this as a method to noninvasively measure glucose in the blood stream [17, 81, 12, 54]. As we have seen in Section 2.4.2.2, Glucose absorbs infrared light, with absorption peaks in both the near, mid and far infrared. For near IR wavelengths (700-2500nm), there is high transmission through human tissues [68]. For mid and far infrared (2000nm-15um, 15-1000um respectively), the wavelengths do not penetrate the skin as easily, and typically requires laser optical systems to have the light penetrate down to the subdermal layer where the blood vessels lay [26]. Near infrared is closer to the visible light spectrum and easily reaches into the subcutaneous tissue below the dermis layer where all the blood capillaries are located [76]. Below, Figure 8 illustrates the approximate depths that different wavelengths will penetrate the skin.

Figure 8: Depth that wavelengths from sunlight will penetrate the skin. [76]

There is an disagreement between what wavelength or what range of wavelengths to use among researchers for an optical glucose reading. This is due to the transmissive property of the near-infrared range through the human body, the absorption bands of other artifacts in the blood, and the multiple absorption peaks glucose has within the near infrared range.

Other optical methods in the infrared range include include far infrared spectroscopy: glucose molecules also have absorption bands in the microwave frequencies, discussed in Section 2.4.2.2. This method can be more accurate compared to near IR, as wavelengths around 10 microns are
2.5.2 Other Optical Methods

Other optical methods include impedance spectroscopy where the electrochemical impedance is the response of an electrochemical system where a potential has been applied. Electrochemical impedance sensors are placed against the skin to read glucose levels based on the system’s response [11, 41]. Several medical companies have tried to produce a continuous noninvasive meter using this method, however, none have been successful. One example is the medical company, Pendragon Medical, who marketed a noninvasive glucose monitor that used impedance spectroscopy as the method to detect glucose. However, the product failed in clinical testing [52, 24]. The failure of the product was due to the need for frequent calibration of the device that took 2-3 days to complete, and the incorrect readings of the device. Only 35.1% of readings produced by the device showed a correlation with the actual glucose readings [46]. The inaccuracy and frequent need for calibration are due to the sensor type: the sensors used were susceptible to environmental changes, such as sweating, skin conditions and temperature. This was presumably the reason why the calibration method took 2-3 days, in attempt to account for the environmental changes. Another example of a product using the impedance spectroscopy method is the American GlucoWatch, which failed in clinical testing due to inaccuracy and when the sensor’s adhesive caused violent skin rashes.

2.6 Potential Dangers of Optical Systems

There are a couple risks when using light: Phototoxicity or photo-irritation is when overexposure to light has caused tissue or skin irritation, similar to sunburn [76]. There are materials that can cause photo-irritation, such as lime juice, which can cause phototoxic reactions when exposed to sunlight. Photosensitivity is another concern, where one’s skin is sensitive and may easily become irritated if exposed to light. Fortunately, infrared light has lower phototoxicity and photosensitivity
for human skin compared to other wavelengths [15].

IR light is used in many common items, such as household IR heaters to TV Remotes, because safer to use. However IR light can cause burns if the power is high enough and a person is too close to the IR source for an extended period. The burns from IR light differ from sunburns however, which are caused by ultraviolet light: The IR light doesn’t destroy the skin cells in the same way ultraviolet light does, so there is not the risk of skin cancer as there is with ultraviolet light should one get burned with IR light [77]. Household IR heaters come with warning due to the high intensity IR heaters have [23]. However lower power products, such as a TV remote don’t come with such warnings as the intensity is far lower then that of an IR heater. For this thesis however, there should be no potential risk of IR burns as the power levels should be considerably lower then an IR heater.

Another a potential hazard of near IR light is accidental exposure to the eye [66]. Human eyes do not detect infrared light, and therefore the human blink reflex would not be triggered. Because infrared light heats up objects, if the light intensity was strong enough or the user looked at the infrared light too long, the user could slowly heat their eye to the point where permanent blindness may be caused. Adequate warnings should be placed on the device to warn users.

2.7 Other Optical Medical Systems

Using an optical method for reading blood glucose would be a similar method to how blood oxygen levels are read [33] [73]. Pulse oximetry uses near IR and red wavelengths to measure the amount of oxygen in the blood stream. Two wavelengths are used to measure the de-oxo hemoglobin and the oxy-hemoglobin in the blood stream. Pulse oximetry accounts for the different thickness of people’s fingers and earlobes, as thicker skin tissues, or more fat, could prevent more of the light from passing compared to those without extra skin or fat. To account for this, the person’s heart rate is also used. The blood oxygen that is measured is in the arterial blood, found by taking the minimum and maximum of each pulse in the signal, and comparing the levels to find the oxygen level in the blood. This is because the absorbance by the skin and fat cells would be fairly constant
and should not be affected by the pulse.
3 Methodology

3.1 Optical Glucose Monitoring

3.1.1 Design Goals & Specifications

Certain goals were set to design a device with typical diabetic users in mind. This list of goals is as follows:

1. The device should be approximately the same form factor and size as standard market glucose meters, as these meters are designed to be small and portable for users.

2. The device should have a low voltage level (5V or less)

3. It should not harm the user
   
   (a) Materials in contact with skin should not be a known skin irritant
   
   (b) The device should not constrict user blood flow

4. The device will use a part of the body where the width is small and the tissue is thin (e.x. finger tip or earlobe)

5. The device should inform the user of their glucose reading

The device’s power supply would be a small battery, such as a coin cell battery to meet the first goal. As most coin cell batteries only go up to 3.3V or 5V, the second goal for the device was met. Due to smaller width, the finger and earlobe were both locations on the body the optical device could be placed on. The earlobe was chosen for the 4th goal, due to the thinner width of the earlobe compared to a finger.

Near IR light was selected over far IR and impedance spectroscopy for this thesis research for several reasons. The first reason was due to the minimal penetration depth of far IR light: laser systems would be needed to have the light penetrate the skin and tissues enough to get a reading. This not only increases the required power levels beyond the design goals, but this would also increase the
size of the system past the goal limits. Impedance spectroscopy could achieve the first two goals for the design; however, past research showed that this method will not meet the remaining three goals. Past studies with impedance spectroscopy showed unreliability in glucose readings and some adhesives used with impedance spectroscopy caused violent skin rashes (Section 2.5.2).

3.1.2 Device Design

The overall design of the device is shown in Figure 9 and will be referenced in the following sections. The selection specific parts, such as the LED and the optical sensor, and the communication and recording of the data is discussed in the following sections.

3.1.2.1 Optical Sensor

The target peak wavelength that was selected for this device was around 1536nm. The justification for selecting this wavelength is discussed in Section 2.4.2.2. Other specifications for this part included having lower power consumption, similar to portable pulse oximeter systems, to meet the design goals. Other research systems used lasers to obtain a single wavelength, however, the power requirements for lasers system inhibit portability. Using an LED as a light source would be ideal.
when considering the design goals, as LED’s are low power devices.

The LED that was chosen was the LED1550E by ThorLabs. The peak wavelength is centered around 1550nm; however, 1536nm is still emitted from the LED at a high intensity as shown in the datasheet Figure 10. The viewing angle of the LED is also narrow, which allows for the light to be focused towards the sensor. The LED1550E requires only 1.2V at 20mA to operate [71]. While this LED does not require a driver, a LED driver was used to maintain a constant current flowing though the LED to prevent light intensity fluxuations that could degrade the signal.

![Diagram](image)

Figure 10: Spectral and Viewing Angle Ranges for LED1550E [71]

The optical detector selected was an InGaAs sensor from ThorLabs, model FGA015, that is compatible with the LED1550E LED. The optical detector can detect wavelengths from 800-1700nm, with a peak detection at 1550nm. Below is graph of the wavelength response of the FGA015 which shows the peak at 1550nm, Figure 11

![Diagram](image)

Figure 11: Wavelength Response of FGA015 [71]
3.1.2.2 Processing & Communication

The design of the custom board was based on placing both the LED and detector on one board, and having a plastic part extend the LED to the other side of the earlobe. The was to save space and to decrease the form factor. The initial concept drawing of the design is below (Figure 12).

In this design the detector would not be extended out from the board like the LED. This is due to
the chance of noise contamination increasing as the raw signal lines lengthen. The signal from the optical sensor is first run through a custom amplification and filtering board to obtain a readable signal, shown in Figure 13. The small plastic piece that was molded to extend the LED around the earlobe is shown in Figure 14. The molded piece to hold the LED slips onto the bracket marking on the PCB.

![Figure 13: Board Designed to hold all sensor circuitry.](image)

![Figure 14: Bracket to hold the IR LED in front of the earlobe.](image)

On the custom amplification and filtering board the signal is passed though an amplifier before being filtered by a 5Hz low pass filter, to filter out high frequency signals. The cutoff was based on a human heart rate if the device were to use the pulsatile blood. The maximum possible heart rate is approximately 300beats/minute which is 5Hz frequency. The signal then goes to an internal 12-bit ADC on a Switch mbed®ty5182r3 board. This mbed board was selected based on several specifications:
Only required 5V to operate

- Contained BLE (Bluetooth Low Energy) onboard for external communications with devices (i.e. cellphones or insulin pumps)

- Small - only 1.5” x 0.5”

Bluetooth was selected as it would allow the device to be integrated into current technology: For example a phone application could be developed to receive these messages and alert users if they have high blood sugar. Many insulin pumps (Section 2.3) currently use Bluetooth to communicate with the embedded sensor, so it would be possible to integrate with them as well. For this project the mbed nRF Bluetooth library was used to allow the mbed to communicate with a custom cellphone application, which in turn displayed only the ADC value from the optical device.

### 3.1.3 Signal Recording & Analysis

The signal was sent using serial communications to a computer where it was recorded. The recorded data was later processed and analyzed to determine if there was a correlation to glucose readings. There are many different processing algorithms with varying levels of complexity that could be used for biomedical signal analysis. Complex algorithms should not be needed for this application, however, as the absorption of light based on glucose quantity should be along an absorption curve. While a mapping function would be later needed to map the ADC values from the optical sensor to mg/dL, it is not necessary to prove a correlation between the readings.

An algorithm that associates the heart rate and optical readings might be needed to ensure that the pulsatile blood, and the glucose within, is being read and not the absorbance from tissues. However it is not necessary to see the correlation that this thesis is arguing: tissue absorbance will be greater for those with thicker skin, however, it will be a constant absorbance which should be reflected in the results. After the data was collected from the Institutional Review Board (IRB) studies which is discussed in the following section, the data was analyzed to determine if there is any correlation in the results between the optical readings and the standard glucose readings.
3.2 Experimental Evaluation

To test the device, an Institutional Review Board (IRB) approved study was conducted. These trials (Appendix A) measure a participant’s blood glucose levels three times with a standard glucose meter and the optical device. The study was conducted to see any possible relationship between the readings in the optical device and the standard glucose meter to determine if using optics is a feasible method for measuring blood glucose.

3.2.1 Experimental Protocol

The first glucose measurement was taken after the participant had not eaten for at least an hour to obtain a lower reading. The second measurement was taken 15 minutes after the participant consumed a sugary drink or meal to obtain a higher reading. The final reading was measured 30-45 minutes after the second one to obtain a mid-range or lower glucose reading. The data collected from the standard meter was then compared to the data from the optical device to determine the strength of the correlation and to determine if using lower power optical systems would be a viable method.
4 Results

Below is a figure of the custom PCB, with the optical sensor and LED, Figure 15. The black plastic bracket allowed for the LED to extend around the front of the ear, while the optical sensor rested behind the ear. To demonstrate how the optical board fits around a person’s earlobe, a disconnected optical board is shown in Figure 16. The board has two power pins for the board, two pins to power the LED and one signal pin. The signal pin outputs the optical sensor signal after it passes through amplification and the 5Hz low pass filter. This signal is sent to an analog pin on the mbed ty5182r3 for recording.

Figure 15: Bracket to hold the IR LED in front of the earlobe.
There were 4 IRB-Approved human trials done on 2 healthy females and 2 healthy males. None of the trial participants had a history of diabetes. The protocol of this study was summarized earlier in this paper and in full in Appendix A.

All study participants were between 5’6” and 6’ tall, with Subjects 1-3 weighing between 150-170lbs and Subject 4 weighing around 220lbs. The optical reading values were in the range of 0 to 4096 as a 12-bit ADC is provided on the mbed ty51822r3 board. The voltage range on this ADC was 0 to 1.5V so that the resolution was .366mV per ADC count.

**Subject 1 Results:** These test results were collected in the morning, before the subject had eaten. After drinking an 16oz ice coffee with 4 sugar packets, the second measurement was taken. The third measurement was taken 45 minutes later.

<table>
<thead>
<tr>
<th></th>
<th>Measurement 1</th>
<th>Measurement 2</th>
<th>Measurement 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard Meter (mg/dL)</td>
<td>94</td>
<td>135</td>
<td>96</td>
</tr>
<tr>
<td>Optical Readings (ADC Val.)</td>
<td>2654</td>
<td>2720</td>
<td>2673</td>
</tr>
<tr>
<td>Heart Rate (bpm)</td>
<td>90</td>
<td>91</td>
<td>91</td>
</tr>
</tbody>
</table>
Subject 2 Results: These test results were collected in the morning, before the subject had eaten. After drinking an 16oz ice coffee with 4 sugar packets, the second measurement was taken. The third measurement was taken 45 minutes later.

Table 4: Subject 2 Readings

<table>
<thead>
<tr>
<th></th>
<th>Measurement 1</th>
<th>Measurement 2</th>
<th>Measurement 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard Meter (mg/dL)</td>
<td>96</td>
<td>126</td>
<td>96</td>
</tr>
<tr>
<td>Optical Readings (ADC Vals.)</td>
<td>2673</td>
<td>2724</td>
<td>2673</td>
</tr>
<tr>
<td>Heart Rate (bpm)</td>
<td>95</td>
<td>96</td>
<td>95</td>
</tr>
</tbody>
</table>

Subject 3 Results: These test results were collected in the morning, before the subject had eaten. After drinking a 10oz tomato juice drink, the second measurement was taken. Unfortunately, the
participant was not able to complete the trial due to personal reasons that required the participant to leave the laboratory. The trial was therefore aborted.

### Table 5: Subject 3 Readings

<table>
<thead>
<tr>
<th></th>
<th>Measurement 1</th>
<th>Measurement 2</th>
<th>Measurement 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard Meter (mg/dL)</td>
<td>75</td>
<td>92</td>
<td></td>
</tr>
<tr>
<td>Optical Readings (ADC Val.)</td>
<td>2635</td>
<td>2659</td>
<td></td>
</tr>
<tr>
<td>Heart Rate (bpm)</td>
<td>96</td>
<td>98</td>
<td></td>
</tr>
</tbody>
</table>

![Subject 3 Standard Meter](image1)

![Subject 3 Optical Meter](image2)

Figure 19: Subject 3 Study Results

**Subject 4 Results:** These test results were collected in the morning. The first measurement was taken before the subject had eaten. After drinking coffee and eating bread with jam, the second measurement was taken. The third measurement was then taken 50 min later.

### Table 6: Subject 4 Readings

<table>
<thead>
<tr>
<th></th>
<th>Measurement 1</th>
<th>Measurement 2</th>
<th>Measurement 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard Meter (mg/dL)</td>
<td>80</td>
<td>116</td>
<td>93</td>
</tr>
<tr>
<td>Optical Readings (ADC Val.)</td>
<td>1908</td>
<td>1965</td>
<td>1930</td>
</tr>
<tr>
<td>Heart Rate (bpm)</td>
<td>95</td>
<td>96</td>
<td>96</td>
</tr>
</tbody>
</table>
Figure 20: Subject 4 Study Results

For a comparison of all the results, the following graphs show all the standard glucose meter readings, while the other graph shows all the optical readings.

Figure 21: All Subjects, Standard Glucose Meter Readings.
In Figure 21, all the standard meter readings are around the same range regardless of the weight of the participant. However, without matching the optical readings to the pulse, the participant with the heavier weight had lower optical readings due to the increased amount of skin and fat absorbing more of the light emitted by the LED, Figure 22. Participant weights are shown in Table 7.

<table>
<thead>
<tr>
<th>Subject 1</th>
<th>Subject 2</th>
<th>Subject 3</th>
<th>Subject 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>170lbs</td>
<td>165lbs</td>
<td>165lbs</td>
<td>230lbs</td>
</tr>
</tbody>
</table>

The changes in glucose levels were still detected for each participant with the optical device despite the offset. This relationship can be seen in Figure 23, where the scale of the linear trendline of Subject 1-3 readings is approximately the same as Subject 4, while the offset varies. This offset is most likely due to increased tissue absorption due to the higher weight of Subject 4.
For Subject 1, the differences between the measurements are shown in Table 8.

Table 8: Subject 1 Reading Differences

<table>
<thead>
<tr>
<th>Subject 1 Measurement Differences</th>
<th>Standard (mg/dL)</th>
<th>Optical (ADC Values)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Between 1st &amp; 2nd</td>
<td>41</td>
<td>41</td>
</tr>
<tr>
<td>Between 2nd &amp; 3rd</td>
<td>39</td>
<td>33</td>
</tr>
</tbody>
</table>

The first difference ended up being identical on the optical device and meter while the second decrease showed the optical ADC values were slightly lower than the glucose meter drop. Subject 2’s reading increase and decrease were both equal and so the differences remained the same, Table 9. When the same blood sugar level was detected again in Subject 2 on the 3rd measurement, the optical sensor returned to the 1st measurement’s reading: this could indicate towards the reliability of the optical sensor.

Table 9: Subject 2 Reading Differences

<table>
<thead>
<tr>
<th>Subject 2 Measurement Differences</th>
<th>Standard (mg/dL)</th>
<th>Optical (ADC Values)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Between 1st &amp; 2nd</td>
<td>30</td>
<td>51</td>
</tr>
<tr>
<td>Between 2nd &amp; 3rd</td>
<td>30</td>
<td>51</td>
</tr>
</tbody>
</table>
Subject 3 (Table 10) only has the increase difference between the low and high blood sugar as the third reading was not taken. The differences in the reading do not vary much from Subject 1 and Subject 2.

**Table 10: Subject 3 Reading Differences**

<table>
<thead>
<tr>
<th>Subject 3 Measurement Differences</th>
<th>Standard (mg/dL)</th>
<th>Optical (ADC Values)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Between 1st &amp; 2nd</td>
<td>17</td>
<td>25</td>
</tr>
</tbody>
</table>

Subject 4’s readings (Table 11) were around the same levels on the standard meter, however, they were lower than previous participants on the optical meter. This Subject was much heavier than the previous participants and had much thicker earlobes, which was noted when placing the optical device around Subject 4’s ear. There still was a positive correlation between the readings: the optical device’s readings followed the standard glucose meter’s.

**Table 11: Subject 4 Reading Differences**

<table>
<thead>
<tr>
<th>Subject 4 Measurement Differences</th>
<th>Standard (mg/dL)</th>
<th>Optical (ADC Values)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Between 1st &amp; 2nd</td>
<td>30</td>
<td>57</td>
</tr>
<tr>
<td>Between 2nd &amp; 3rd</td>
<td>22</td>
<td>35</td>
</tr>
</tbody>
</table>

The thickness of the ear is a factor that must be considered in the same way that pulse oximetry does as discussed in Section 2.7. While the subject’s heart rates were recorded in the IRB Study, the actual pulses were not able to be synced with the optical readings. This was due to using an external heart rate monitor that used a different analog channel. Subject 1 and 2’s optical reading are the most similar because the body types (i.e. height, weight) were nearly identical, while Subject 4 varied more from the other three.

To statistically determine if the results had a strong correlation, a two sided t-test was performed. The data was first normalized between the optical data set and the standard meter data set as their ranges varied. The t-test was then performed and the p-value was calculated to be 0.39. The p-value is greater then .05 which indicates there is strong evidence that the two sets are correlated. The p-value increase significantly to .9363 when removing subject 4 who had a very different weight.
than the other subjects, showing an even stronger correlation.

For communicating with the device, the IRB study data was recorded though serial port communications. However Bluetooth communications were successful on the mbed. The nRF BLE library was used to help show ADC Values transmitted to a cellphone over Bluetooth. This research could be further expanded to have a full cellphone application that works with the optical device.

5 Discussion

The results showed that the optical device’s reading followed the standard glucose meters, which could be seen visually. It was also shown that using the heart rate to detect the blood within the arteries is needed, so that the constant absorption from the tissues and bone is not taken into account. This could adjust all study participants to be within the same range of ADC Values and allow for possible mapping of the ADC to mg\dL values.

Improving the structure of the device could also improve readings. One structural fault was blocking out other light sources from interfering, similar to what pulse oximeters do. Several times during the studies, the optical readings had to be retaken right away when the optical data was full of noise due to external light when the ear piece was misaligned. While there was some external light protection on the optical device, it could be improved.

The structure of the optical device did have a form factor and size similar to the standard meter used even combined with the processing board, the mbed ty51822r3, as shown in Figure 24. Bluetooth communications with the mbed ty51822r3 board were also successfully completed. The optical readings could be read from a computers COM port or on a cell phone via a Bluetooth connection.
More studies need to be conducted after a structural change in the device to determine if a calibration sequence for each user is needed or if gating to the pulse would provide enough accuracy. Even if individual user calibration was needed, it is unclear if frequent calibrations will be needed, as the hardware is not affected by natural environmental changes such as temperature however the human body may be. With season temperature changes, parts of the body can swell or unswell as blood vessels dilate in the heat or constrict in the cold which could affect the readings. Typically lower limbs and extremities are affected most by the swelling caused by temperature changes, and not the earlobes however. This would need to be addressed in future designs and studies.

For the long term maintenance of this device, the optical sensor lens would need to be cleaned when it’s applied. Batteries on the device would also need to be replaced or recharged.
6 Conclusion

Overall, this thesis proved successful in showing a correlation in reading blood glucose using a low powered light source and a device with a small form factor. More IRB-Approved human testing is needed to find the function that accurately maps the optical sensor’s voltage readings to glucose units (mg/dL). Including a pulse monitor on the board would also improve the accuracy: the optical readings and pulse signal could be synchronized so that only the absorption of glucose in the blood is read and not the absorption from the tissues. Improvements could also be made to the structure to better eliminate any external light contamination that could interfere with the light sensor. A continuation of this project could include a cellphone application for glucose readings or an integration with a Bluetooth insulin pump.
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A Appendix

A.1 IRB Study Procedure

Study Protocols

Overview

Participants will have their blood glucose measured three times during this study, with both the noninvasive optical device and the standard glucose meter. The expected total study time will be around 50 minutes and will not extend beyond 1.5 hours.

Setup

Before the study participants will be asked not to eat for at least 1 hour before the testing. During testing, the participant will sit on the chair or may lie on the couch. We will start by asking participants general health questions that are shown in the attached form. The participant may choose not to answer these questions.

The FDA approved standard blood glucose meter that will be used is the OneTouch Select Simple meter. Each measurement done with the standard meter will be done on the different sides of each ring finger to minimize the discomfort that could be caused by repeatedly testing on the same area. Fingers of the participants that have healing cuts will be avoided. The optical device that will measure the participant’s blood glucose level will be placed around the ear lobe, but it does not place any pressure or pinch the ear lobe. The participant’s heart beat will also be recorded while the optical readings are being taken, as this information could greatly assist in analyzing the optical data. The participant’s heart rate will be recorded by using a pulse oximeter, which can record the heart rate information.

The participant will be asked to drink something sugary before another measurement is taken. Several different options will be present, including ones that are safe for common allergies (e.g. peanuts, gluten); however, they will all contain approximately the same amount of sugar and
carbohydrates. Carbohydrates from liquids, such as soda, are digested faster compared to most solid foods, which would allow the participant’s blood sugar to increase more rapidly and waiting times will be shortened.

**Measurement 1:**

First, the participant will have their blood glucose measured by the standard blood glucose meter. This involves using a glucose meter lancet to draw a small drop of blood from the end of a finger. A new lancet will be used for each participant and the lancet needle will always be sterilized between participant measurements before being discarded at the end of the trial. Test strips for the meter that come into contact with the participant’s blood will only be used once, and be properly discarded. The reading from the standard glucose meter will then be recorded. The optical device will then be placed around the participant’s earlobe and reading will be recorded. The participant’s heart rate will be recorded simultaneously with the pulse oximeter.

These measurements should give a lower blood glucose reading, due to the fact the participant will not have eaten within an hour. However the participant’s low blood glucose level, due to the request of one hour fasting, should not be low enough to cause any harm or discomfort.

**Measurement 2:**

The participant will then be asked to drink 8-12oz of a sugary drink, within 5 minutes. To allow for blood sugar levels to increase, readings for the second measurement will happen 15-20 minutes after the participant consumes the sugary drink. The consumption of the sugary drink should raise blood glucose levels and give a higher blood glucose reading. However the participant should feel neither uncomfortable nor ill from the drink.

The participant will have their blood glucose measured by a standard blood glucose meter again following the same steps in Measurement 1. Then the optical device measurements and the participant’s heart rate will be recorded.

**Measurement 3:**

The third measurement will occur approximately 30 minutes after the second measurement. This
measurement should give a more baseline glucose reading in between the previous two readings. The standard glucose meter would be used as in Measurement 1, and then the lancet needle will be properly discarded. The optical device and heart rate measurements would then be taken.