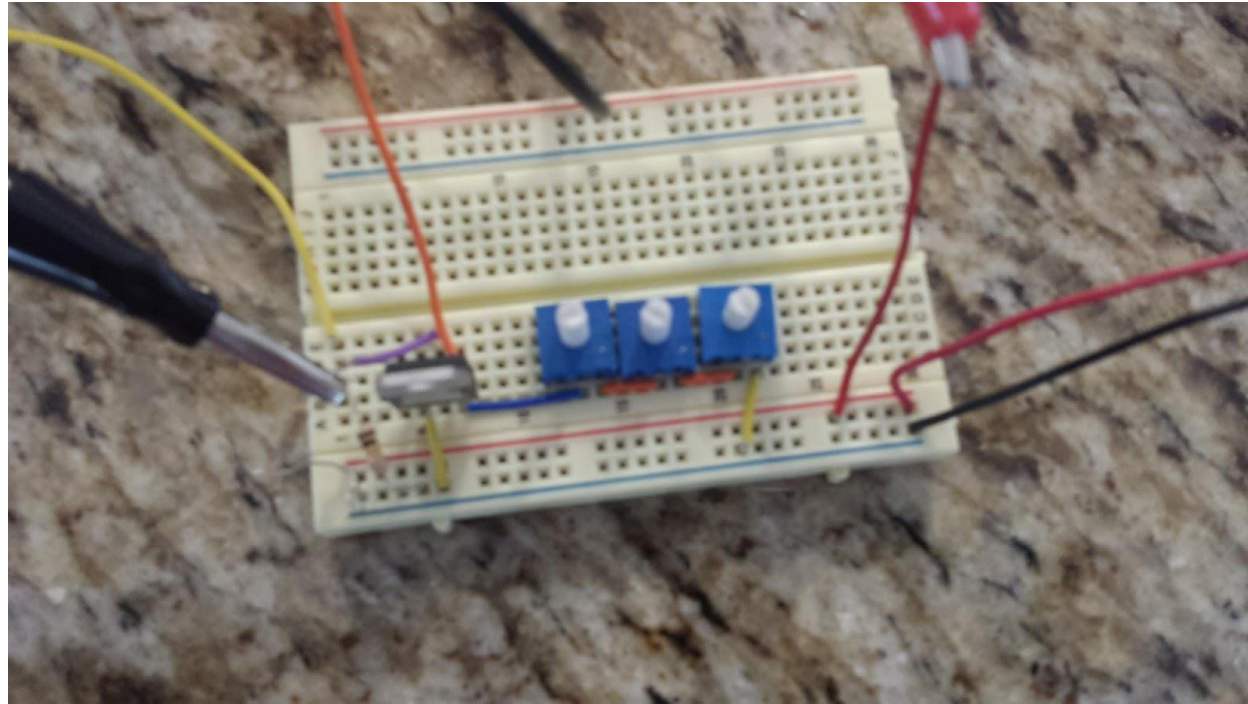


Artificial Pancreas

Automatic Closed Loop System



Waleed Randhawa/ 8th grade
Marshall Middle School/ Mrs. Gillum

Introduction/Statement of the Problem/Purpose

Introduction

Every year, diabetes kills 1.5 million globally, and in the United States alone 8 percent are suffering from it. Diabetes continues to strike the world directly, affecting 422 million people in the world. The disease is a result of a non-working pancreas. The disease is a result of a non functional pancreas. Today, patients with Type I diabetes administer their own glucose levels. Unfortunately, this treatment has multiple disadvantages. Mainly, if the patient fails to monitor their glucose levels or take the proper dose of insulin, the patients' glucose level may drastically increase or decrease leading to major health problems. During this experiment, a Automatic Closed Loop system will be developed to replace a diseased pancreas. The Closed loop system will automatically provide the exact quantity of insulin that is required to maintain healthy glucose levels in the patient's bloodstream.

Statement of the Problem:

Researchers and scientist have been collaborating to construct an automated system to monitor patient's blood glucose levels 24 hours a day and 7 days a week. Previous experiments testing closed loop system failed to show significant progress in the functionality of the artificial pancreas device. The greatest possible threat to the integrity of the artificial pancreas are malfunctions with the sensing of the system. The artificial pancreas should pump insulin when glucose levels become higher than normal. However, after meals or food consumption blood glucose levels spike and the closed loop system cannot keep up. Occasionally, the sensor lags when measuring the patient's glucose levels and thus the control system does not have the accurate glucose level readings. The experiment hopes to discover a cost-effective solution to controlling glucose levels for Type 1 diabetic patients.

Purpose:

Many scientists have been working on invention of artificial pancreas, to help the millions of diabetes patients in the world. The purpose of the experiment is to figure out if a closed loop insulin delivery system will work with high and low glucose levels. Previous research has shown closed loop and hybrid closed loop systems outperforming the current methods to lower glucose levels. If the results in the experiment were to prove the closed loop system worthy for commercial use, the system would appeal to elderly and disabled diabetic patients around the world. The delivery system would lower the potential risk of hyperglycemia and hypoglycemia.

Previous Experiments

Previous Experiment #1:

An experiment, conducted by Roman Hovorka, Janet M. Allen and many other scientists, aimed to discover if closed loop insulin delivery systems could control overnight glucose levels in 17 patients aged from 5 to 18 [1]. The participants have been affected by Type 1 diabetes for 5-7 years. The experiment comprised of three different studies, focusing on patients who consumed self-selected meals, patients who consumed a large meal with a high content of carbohydrates and patients who consumed a light meal with additional exercise in the afternoon. All patients were monitored from 8pm to 8am with closed loop delivery systems to detect nocturnal hypoglycemia. The studies displayed that the time in the target range for plasma glucose was higher during closed loop delivery when compared to standard insulin delivery. In addition, closed loop delivery doubled the target range time after midnight, making all hypoglycemic events asymptomatic. The experiment found that closed-loop delivery with evening exercise allowed the patient's glucose levels to be inside the target zone for the longest period of time. Moreover, closed loop insulin delivery systems consistently outperformed continuous infusion at low and high glucose concentration levels. Despite of all the encouraging results, closed-loop glucose control involved sensing errors which are required to be improved before a safe launch into the public health industry. The study compared closed-loop insulin delivery with standard insulin infusion. The closed loop insulin delivery is proven to be highly effective when controlling glucose levels overnight, thus significantly reducing the risk of nocturnal hypoglycemia. Meal sizes and exercise were taken into consideration. Advancements in automation and sensing can improve insulin delivery to assist patients who suffer from Type 1 diabetes across the globe.

Previous Experiment #2

Stuart A Weinzimer, Garry M Steil, Karena L Swa, Jim Dziura, Natalie Kurtz and William Tamborlane conducted an experimental study to compare fully automated closed-loop insulin delivery system and semi-automated hybrid control [2]. Seventeen adolescents between the age of 15 to 18 underwent 34 hours of closed-loop control, 8 with full closed-loop control and 9 with hybrid closed-loop control. All the subjects were diagnosed with type I diabetes. In the FCL (full closed loop) group, all the insulin was given under the control of computer-based algorithm. Whereas in HCL (hybrid closed loop), a bolus of rapidly acting insulin is manually given about fifteen minutes before the meal. In this experiment, the closed loop delivery system consists of a continuous glucose monitors, insulin pumps, and a control algorithm. The glucose sensor detects the glucose level in the patient's body and inputs the values into the control algorithm. The algorithm provides the insulin pump with the amount of insulin needed to restore normal glucose levels. The insulin pump's only job is to supply the right amount of insulin to the patient's body. During the course of the experiment, the glucose sensors accurately tracked patients' glucose levels. According to the continuous glucose sensor, 85% of all patients' glucose levels were between 70 and 180 mg/dl when using closed loop delivery systems, outperforming open-loop system which only maintained target blood glucose level in 58% of the patients. In addition, HCL displayed better daytime, nighttime and peak postprandial glucose level when compared to FCL. This study clearly exhibits that a closed-loop delivery system must combine subcutaneous insulin sensor and some type of hybrid control mechanism. Such a system will be able to regulate blood glucose level during daytime, after midnight and postprandial to reduce the events of nocturnal hypoglycemia. Accuracy and malfunction of the sensors or sensor alarms is the only concern that can hinder clinical approval. The experiment confirmed that hybrid closed-loop and full closed-loop insulin delivery to potentially be used in the near future.

Previous Experiment #3

Pratik Choudhary, David Kerr and many other scientists conducted an experiment in United Kingdom to evaluate low glucose suspend(LGS) feature of Veo insulin pump in response to hypoglycemia [3]. Thirty-one patients with a mean age of 41.9 years were studied over a period of three weeks. Patients were divided into four different groups by the average duration of their hypoglycemia. Low glucose suspends systems(LGS) were programmed to sound alarms when the glucose levels reach a certain threshold set by the patient. It was hypothesized that patients with most hypoglycemia at baseline will benefit the most. During the study, the Low Glucose Suspend (LGS) was used for the maximum of two hours after hypoglycemia was detected. 75% of these occasions occurred overnight. Low Glucose suspend largely decreases the risk and duration of nocturnal hypoglycemia. 93% of the patients claimed they felt a difference and rarely experienced hypoglycemia. 166 LGS episodes were detected and 66% of daytime episode were treated within 10 minutes. During night time, mean response time to alarm is more than 60 minutes which further reinforce the need of automated delivery systems. The experiment proved that insulin pump with LGS reduce the nocturnal hypoglycemia among the high-risk patients. This experiment studied the older adults with Type I diabetes suffering for hypoglycemia. LGS feature ensure an improved patient care through the reduction of risk involved in both low or high glucose levels. Insulin pump therapy is even more crucial during nighttime when patient is not as responsive. Furthermore, an insulin pump must be capable to provide additional glucose when needed. The experiment validates the effectiveness of the first fully automated insulin delivery system in response to glucose levels. Choudhary, Pratik, John Shin, Yongyin Wang, Mark L. Evans, Peter J. Hammond, David Kerr, James A.M. Shaw, John C. Pickup, and Stephanie A. Amiel. "Insulin Pump Therapy with Automated Insulin Suspension in Response to Hypoglycemia." *Diabetes Care*. American Diabetes Association, 01 Sept. 2011. Web. 30 June 2017. <http://care.diabetesjournals.org/content/diacare/34/9/2023.full.pdf>

Core Science

In an Automatic Insulin Delivery System. Patient glucose levels are detected by continuous glucose monitor (CGM). The sensor sends the glucose levels to the control algorithm located in the main controller. Based on the sensor's output the algorithm calculates the amount of insulin needed to balance the patient's glucose levels. After calculating the amount of insulin required, it signals the pump to deliver that amount. The delivery is done by an insulin pump and the glucose levels steadily rise or drop according to the amount of insulin that was provided. For example, if the sensor detected the patient's glucose levels rising, it would inform the control algorithm. The algorithm would determine that the insulin pump needs to pump additional insulin to the bloodstream. The process continues until the patient's glucose levels reach healthy levels. The sensor informs the algorithm about the glucose levels. The algorithm would then instruct the insulin pump to stop delivering the insulin.

This experiment is aiming to create a simplified version of a closed loop system. Blood and insulin is inaccessible for the project; the experimenter will use simple liquids instead. A basic solution replaces high blood glucose levels and a neutralized solution represents closed to normal glucose levels. Closed loop systems pump insulin into the bloodstream when the sensor detects increasing glucose levels. Whereas, in the experiment the pump will provide vinegar to neutralize the basicity in a substance. Once the solution is neutralized the conductivity sensor will inform the pump that glucose levels are normal and no more vinegar will be pumped into the substance.

When measuring the acidity or basicity the pH scale is utilized. Acidic substances have a pH level below 7 and give hydrogen ions away. An example of a base is vinegar or lemon juice. Water and most neutral substances have pH levels of 7. Basic substances such as baking soda and bleach have pH levels above 7. They are known to accept hydrogen ions. In the experiment, when pH levels of the solution are acidic or below 7 the pump does not release any vinegar into the solution. However, when the pH levels are above 7 the conductivity sensor will instruct the pump to release vinegar to neutralize the solution. Equal amounts of vinegar and baking soda result in a neutralized solution representing normal blood glucose levels. Basic solutions can conduct electricity because the substance has lower electric resistance. Neutral solutions have high electric resistance making it difficult for electric currents to flow through the liquid. In the experiment, the sensor has the ability to detect if a solution is basic, neutral or acidic. The conductivity sensor contains two metal wires. When the solution is conductive, the electric current is allowed to flow through the conductivity sensor. However, if the substance is not conductive the pump will not turn on.

In the experiment, a closed loop system will be developed using electronic components and an electric motor used as a pump. The basic principle behind any electric circuit is Ohm's law. The law states the current through a conductor is directly proportional to voltage across it.

Another key component for the circuit developed is MOSFET -- metal oxide semiconductor field effect transistor. As the name suggests, MOSFET is a type of transistor. A MOSFET has three pins: gate, source and drain. The transistor is an electronic switch that is controlled by voltage that is applied to the gate pin. When connected to a motor or pump, the MOSFET can electronically turn motor of the pump on or off. The MOSFET switch state is controlled by the amount of voltage applied at the gate pin. If this voltage is less than the MOSFET's voltage threshold, V_{th} , no current will flow between the source and drain pins i.e. the switch is in off state. If the voltage applied at gate pin exceeds the V_{th} , then the switch would be turned on and current between the source and drain will start flowing.

Next part of the circuit comprises of another voltage divider circuit created by the conductivity sensor and a variable resistor. As previously described, the input to this voltage divider is roughly 3V. The output voltage for this divider circuit depends on the resistance of the conductivity sensor and the variable resistors. The output of this second voltage divider is connected to the gate pin of the MOSFET. The source pin of the MOSFET is connected to the ground. Therefore, the output of the second voltage divider controls whether or not the MOSFET conducts current between the drain and source. The pump is connected to the positive voltage supply and the MOSFET's drain pin. As a result, when the MOSFET switches on, current flows the pump and causes it to pump liquid. When MOSFET is off, no current can flow through the pump, so the pump shuts off. Thus, this configuration means that the pH of the liquid controls whether the pump turns on or off.

Hypothesis/Materials

Hypothesis:

Previous experiments testing closed loop delivery have revealed that automated insulin delivery systems help control hypoglycemia and hyperglycemia round the clock. Compared to other treatments closed loop systems are most helpful overnight. When under closed loop treatment patient glucose levels were in the target zone 85 percent of the time. The glucose sensor rarely detected the wrong glucose levels except postprandial when glucose levels rose exponentially. In Stuart Weinzimer and his associates' experiment delivery rates after meals could not match the rising glucose levels. However, when using Hybrid Closed loop doctors were able to pump additional insulin after meals resulting in HCL outperforming Full Closed Loop.

The experiment is important because it stresses the need for automatic insulin delivery. However, meal announcements need to be made by the patients to inform the system when to send additional insulin. Most existing insulin delivery system require some form of human intervention. Although current systems provide better blood glucose level control, the goal of this experiment is to develop a prototype of fully automated insulin delivery system without any external intervention. This is extremely critical for the nocturnal hypoglycemia and young patients with Type I diabetes.

In this experiment, the flow of the vinegar is proportional to the basicity of the solution. With time, as the solution is neutralized the flow decreases until it completely stops. **Based on the previous research, it is hypothesized that 85 percent of the time the pH level of baking soda solution will rise until it reaches within 5% of pH 7. It is further hypothesized, that the time taken to completely neutralize the baking soda solution would be proportional to the quantity of the solution.**

Materials:

Circuit Board

Solderless breadboard 3 resistors Jumper wires MOSFET 1 M ohms potentiometer, 1 10 k ohms potentiometer and a 100k ohms potentiometer Alligator clips A battery holder that hold 8 batteries and 8 batteries 24 A.W.G copper wire 12 Volts liquid pump

Conductivity Sensor

6 -8 cm. straw 5 by 5-inch block of Styrofoam

Solution and Items related to making the solution

Graduated Cylinder with 250 mL capacity Digital water scale 250 pH strips 1-2 liter of baking soda 1-2 liter of vinegar 3 mixing water/ plastic Tupperware

Procedures

Part I: Building the Sensor and Circuits

- Build the sensor by wrapping the copper wire around an 8-centimeter straw
- Tape the middle of both copper wire strands to a Styrofoam block the shape of the container
- Use alligator clips to attach the ends of the copper wire to the block of Styrofoam
- Attach the MOSFET and the extending wires to the breadboard.
- Insert 8 batteries into the battery holder and attach the two wires of the battery pack unto a socket on the breadboard
- Connect the alligator clips to the top of the motor pump so the pump can become a part of the circuit

Part II: Creating the Liquid Solution

- Add any quantity of baking soda, however the quantity has to be less than 8 grams
- Mix the baking soda with 200 mL and pour the solution into the container
- Pour 200 or more mL of distilled white vinegar into another container
- Add one teaspoon of bromothymol blue into each container

Part III: Setting up the Experiment

- Make sure all wires are secured tightly on the correct location on the breadboard
- Make sure the pipes are securely attached to the motor to reduces the chances of a leak
- the pipes and sensor have to place in the correct container to the make the experiment proceed accurately
- The ph. levels of the experiment have to be recorded

Part IV: Observations and Findings

- Check what color the neutralized solution is after the motor stops
- Due to the bromothymol, the color of the liquid will show the ph. of the liquid
- Record the color of the liquid
- Record the amount of time the motor took to neutralize the solution by starting the timer when the motor begins to pump and ending the timer when the motor stops and the solution is neutralized

Observations and Results

This experiment was conducted to test the reliability of a closed loop system to help patients suffering from type 1 diabetes. During the experiment, a baking soda solution represented high glucose levels and vinegar represented insulin. Two containers were utilized for every reading. The first container (container A), consisted of the baking soda solution and the conductivity sensor. The second container (container B) consisted of the vinegar, the liquid which was used to neutralize the solution. The experiment contained three parts: constructing the closed loop system, adjusting the system to neutralize the solution and testing. The data collected from the tests displayed the consistency and effectiveness of the closed loop system.

The motor was connected to a conductivity sensor placed in the baking soda solution. The sensor controlled when the motor would pump vinegar into the solution. The motor began when the solution was basic, having a pH higher than 7 and stopped when the solution was neutralized.

The tests were run multiple times with each baking soda solution concentration. Running the test multiple times verified the consistency of the closed loop system. Potential of Hydrogen (pH) of neutralized solution, pH of baking soda and acidic solution and time system took to neutralize the system were recorded and analyzed to find patterns between each test.

The pH of all the solutions were measured by pH strips and verified by bromothymol blue. Bromothymol blue changes the color of the liquid solution according to its pH. The neutralized solution's pH averaged 6.5 across all the experiments. Interestingly, when the additional baking soda was manually added to or removed from the solution the pH of the neutralized solution did not drastically change. Occasionally, the sensor glitched sending incorrectly values to the motor which lead to a slightly acidic solution. The motor slowed down faster when the concentration on baking soda was decreased.

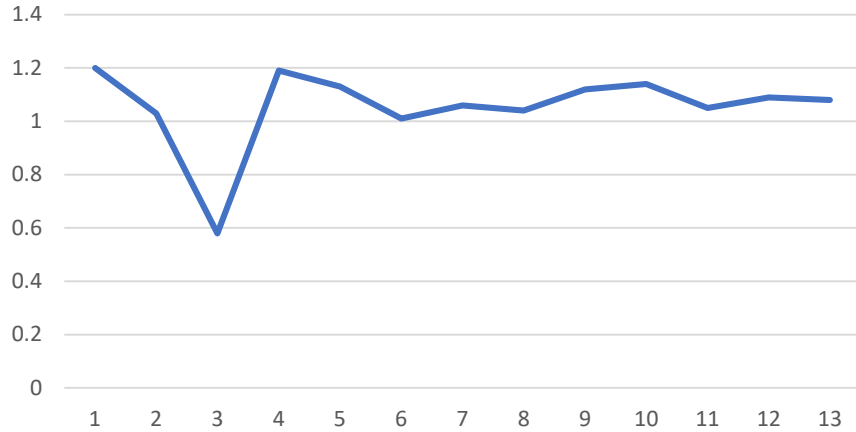
The time was measured by a stopwatch. The time began when the motor began pumping vinegar into the solutions due to the solution's basicity. When the solution had become neutralized or had a pH of 7, the time was stopped. Time varied depending on the concentration of baking soda in the initial solution. Concentrations ranged from 2.5 grams of baking soda per 200 mL to 7.5 grams of sugar per 200 mL of water. Whereas the time the solution became neutralized ranged from 58 seconds to a minute. The motor slowed down faster when the concentration on baking soda was decreased because the solution gets neutralized faster than higher concentrations solutions.

During the experimentation the solution had to be stirred to prevent the sensor from incorrect readings. Often, when the sensor was temporarily removed from the container and placed back in the container the pump stopped, meaning the solution had been neutralized. pH strips confirmed this theory.

It was observed the potentiometers inserted on the breadboard change the sensor's reaction to different conductivities. After long periods of testing's the potentiometers needed to be adjusted to ensure proper results. If not adjusted, the motor would continue to pump vinegar into the solution following neutralization creating an acidic solution. When testing the lower concentrations of baking soda, occasionally the motor failed to begin the process of neutralization independently. After a single sensor had been used from 20 readings, the copper wires and straw become chorded due to the acidic solution. The sensor was replaced. Following the adjustment, the readings became consistent and the solution was always neutralized.

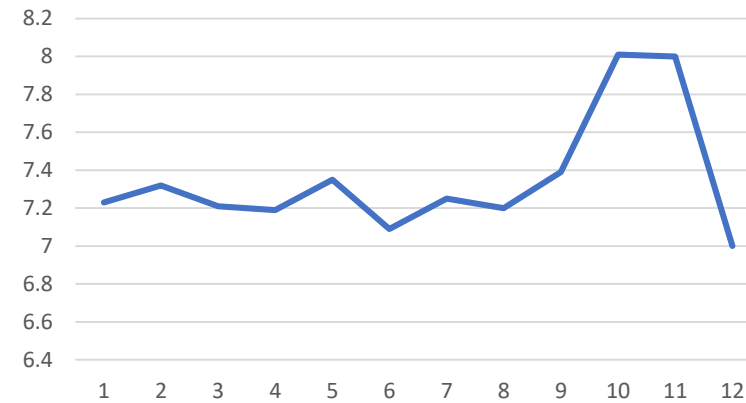
Data Tables/ Graph Summary

Concentration 2.5 grams



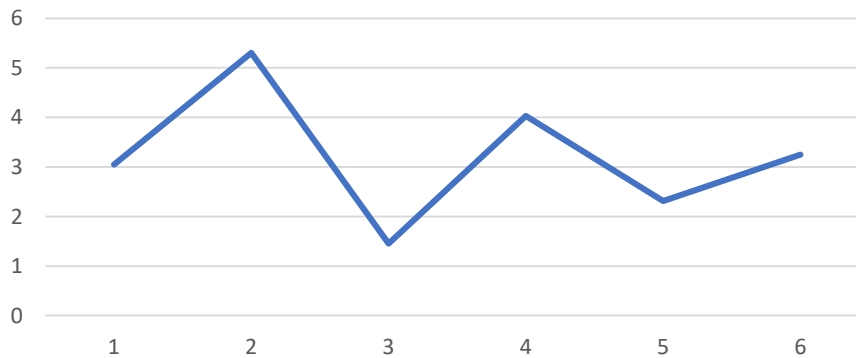
Time	Concentration
1.2	2.5
1.03	2.5
13:55	2.5
1.19	2.5
1.13	2.5
1.01	2.5
1.06	2.5
1.04	2.5
1.12	2.5
1.14	2.5
1.05	2.5
1.09	2.5
1.08	2.5

Concentration of 7.5 grams



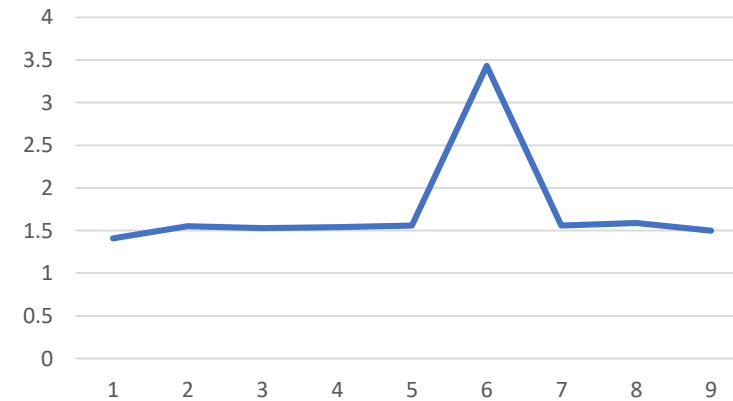
Time	Concentration
7.23	7.5
7.32	7.5
7.21	7.5
7.19	7.5
7.35	7.5
7.09	7.5
7.25	7.5
7.2	7.5
7.39	7.5
8.01	7.5
8	7.5
7	7.5

Concentration of 4 grams



Time	Concentration
1.41	3
1.55	3
1.53	3
1.54	3
1.56	3
3.43	3
1.56	3
1.59	3
1.5	3

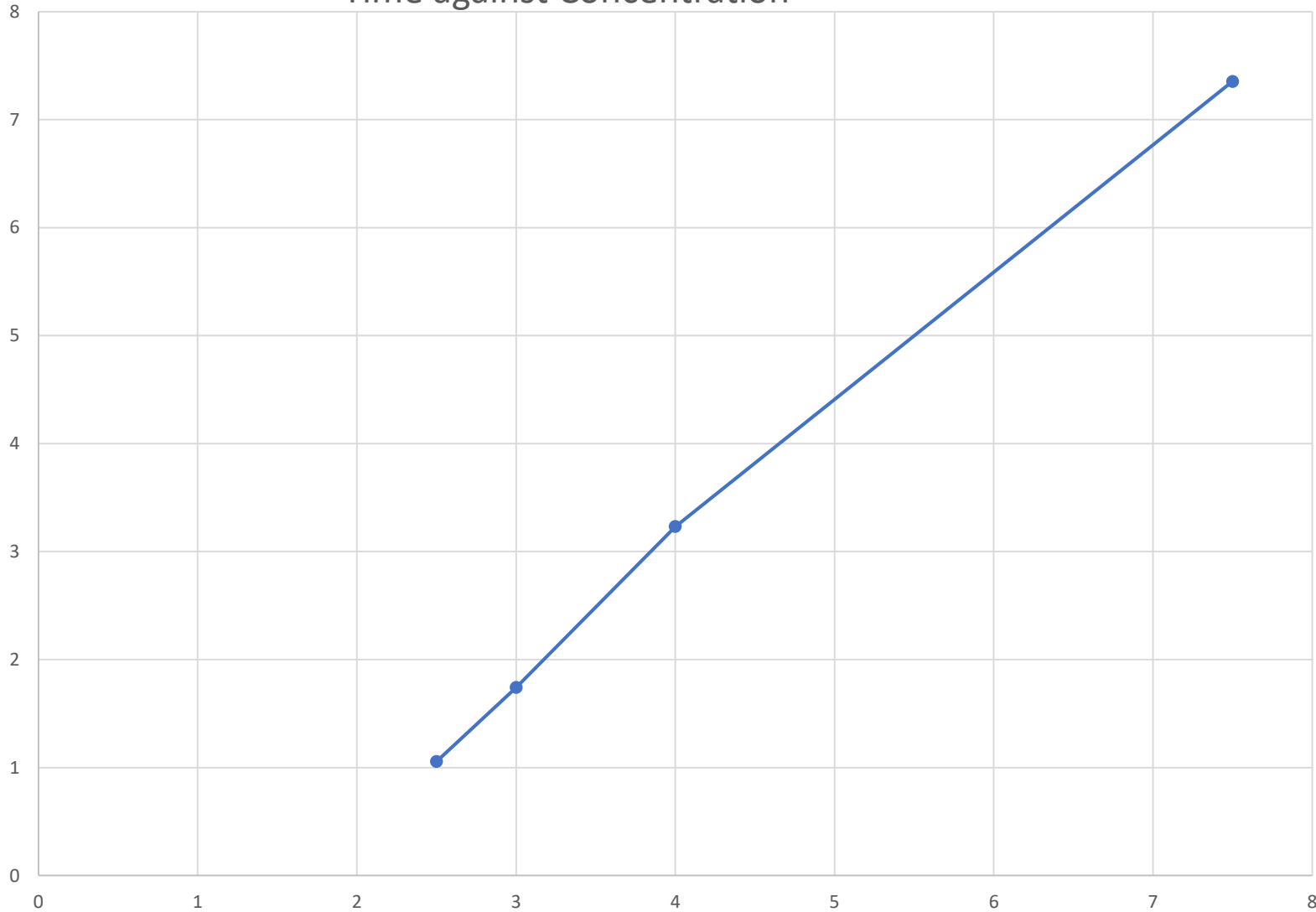
Concentration of 3 grams



Time	Concentration
3.05	4
5.3	4
1.45	4
4.03	4
2.31	4
3.25	4

Data Tables Part Two

Time against Concentration



Time	Concentration
2.5	1.05538462
3	1.74111111
4	3.23166667
7.5	7.35333333

Conclusions/ Recommendations

Conclusions:

415 million people in the world suffer from diabetes. The current cure for Type 1 diabetes is not automated or reliable. Patients utilize glucose meters to constantly monitor glucose levels. If glucose levels rise, insulin needs to be injected into the bloodstream. Patients' may incorrectly monitor glucose levels and inject an incorrect dose resulting in extremely high or low blood sugar levels. Automatic closed systems continuously sense an increase or decrease in blood glucose levels using a Continuous Glucose Sensor (CGM). The information collected from the CGM is sent to the main controller which calculates the amount of insulin the patient's body needs. The insulin is delivered to the body by an Insulin Pump. The Closed Loop System can prevent any fatalities related to hypoglycemia or hyperglycemia. When using the closed loop systems, maintaining normal blood glucose levels was successful for many experimenters.

In the experiment, a simplified closed loop system was constructed to neutralize a basic solution. **it is hypothesized that 85 percent of the time the pH level of baking soda solution will rise until it reaches within 5% of pH 7. It is further hypothesized, that the time taken to completely neutralize the baking soda solution would be proportional to the quantity of the solution.** The automatic closed loop system was tested with 4 different concentrations of a baking soda solution. Throughout the experiment two containers were utilized. The conductivity sensor was always submerged in the Baking Soda solution and testing tubes placed in each containers were attached to the motor. Often, the sensor failed to give the motor correct readings resulting in a acidic or basic solution.

The hypothesis was correct, the concentration of the Baking Soda directly corresponded with the time the Automatic Closed Loop System took to neutralize the solution. When the concentration of baking soda per 200 mL of water was 2.5 grams, the automatic system usually neutralized the solution under 1 minute and 25 seconds. When the quantity of the solution was 200 mL and the concentration was 7.5 grams the solution took over seven minutes to neutralize.

More baking soda leads to more conductivity. The sensor can better recognize larger quantities of conductivity. Furthermore, when the quantity of the solution is higher, the sensor is completely submerged in the solution leading to more accurate results. The sensor's conductivity depends on the basicity of the solution. When the solution is more conductive the electric current flows through the sensor that causes the motor to run. The larger the concentrations of baking soda more acid is required to neutralize the basic solution. Although the motor runs slightly faster in higher concentrations, the speed is not capable of compensating for the higher concentration of basicity.

Performance of the sensor varies from each experiment due to the acid chording the metal wires surrounding the sensor. Thus creating outliers in the readings. Due to crudeness of the sensing equipment, the potentiometers placed on the breadboard of the circuit had to be adjusted to create consistent results. During the experiment the MOSFET became extremely hot. This can change the characteristics of the semiconductor device and cause test results errors. The automatic closed loop system was successful when neutralizing baking soda solution with different concentrations. The system can be used for controlling blood glucose levels of diabetic patients.

Recommendations

The experiment proved the hypothesis right. A semi-automatic closed loop system was built and tested to help global diabetic patients. The closed loop system was a prototype and cost effective model representing the effectiveness of a future system used around the world. A central breadboard container multiple wires, a MOSFET and potentiometers was used during the testing. The motor was a liquid pump and the conductivity sensor was made from a drinking plastic straw and copper wires. The automatic closed loop system neutralized the solution by pumping vinegar. More than 90% of the time , pH strips confirmed the system was effective and accurate when neutralizing the solution. The experiment can be improved by using a higher capacity motor. The relationship between the concentration of the basic solution and time is critical when modeling actual blood glucose levels. An improved prototype would neutralize all solutions around the same time. The motor needed to react faster when the solution was basic. To further advance the experiment a digital system can be attached to the main control panel.

The system will automatically begin the process without the adjustment of potentiometers. A cell phone or computational device will be connected the sensor and motor constantly adjusting the motor's speed based upon the sensor's readings. The experiment can be further improved by replacing the sensor with a more accurate one. The current sensor was crude and acid corroded the wires resulting in inaccurate and erroneous results. Instead of using pH strips to verify the neutralization of the solution, a pH monitor can be utilized. The monitor will accurately judge the performance of the closed loop system. The combination of a more accurate sensor and a better pH meter will result in a more effective automatic closed loop system

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