The Carefree Internal Blood Glucose Monitoring System (CIGM)

Abstract

The Carefree Internal Glucose Monitor System (CIGM) is an in vivo blood glucose monitor that would utilize nanotechnology, a direct oxidation reaction, and a passive RFID tag to continuously measure blood glucose levels in humans. The monitor would be intra-muscular and linked to a waterproof wristband similar to a "LiveStrong" band. The wristband would contain a Bluetooth®/microchip device so that blood glucose data could be stored and later downloaded, as well as two LEDs that would signal trends towards high or low blood glucose levels before they exceed the acceptable range. Our device would contain a small capacitor that would shock the wearer awake if he has not responded to unacceptable glucose level warnings and would alert family members or health care workers of the need to intervene. The CIGM could be easily linked to a programmable insulin pump to allow for much better management of diabetes.

The Carefree Internal Blood Glucose Monitoring System (CIGM)

Diabetes: a disease in which either the pancreas is incapable of generating insulin, is unable to produce enough of it, or the body is not reacting to it. Insulin allows the body to utilize blood glucose. In 2006, diabetes, or complications of diabetes, were listed as the seventh leading cause of death in the United States. Every single hour, 4,100 new cases are diagnosed. Type 1 diabetes is the number one chronic disease in children. Diabetes can cause heart disease, stroke, blindness, kidney failure, neuropathy, or death. Diabetes affects many families around the world.

Present Technology

The current standard for diabetes management includes diabetes monitoring and blood sugar maintenance technology. Today's monitoring technology consists primarily of lancet devices and blood glucose meters. The lancet device is used to prick some part of the body for a blood sample. When a trigger is pressed, the lancet device releases the lancet blade, which then pierces the skin to obtain the drop of blood necessary for an accurate reading. The blood is wiped onto a test strip which is then inserted into the blood glucose meter. The blood glucose meter is a device about the size of a palm. It reads the blood glucose level in the diabetic's blood sample. The response time is relatively short, varying between three seconds to one minute. Using an enzyme reaction, the meter can determine the amount of blood glucose in milligrams per deciliter (mg/dL); anything above 130 mg/dL would be considered high.

Lancet devices and blood glucose meters have many negative aspects, all of which are addressed and corrected by our technology. The first problem is that the blood glucose levels are constantly changing and are affected by diet, metabolism, and exercise. Because it is possible for blood glucose levels to change minute to minute, three-times-per-day testing could miss levels that are silently exceeding limits. Even patients that check levels ten times per day could miss peaks and valleys in blood glucose levels. Diabetics need accurate blood glucose level information throughout the day to know if they require an injection of insulin or need to eat to raise their blood sugar. The better the diabetic patient maintains their blood glucose levels within normal ranges, the lower their risk for long-term complications.

Accuracy of the blood glucose meter is also an area of concern because the accuracy of these monitors is very important in upholding a diabetic's health. If the meter displays an inaccurate reading, whether because of human error or machine malfunction, the patient's life may be put at risk. In the past, blood glucose test strips have proven to be problematic. Regularly, and as recently as late 2010, blood glucose test strips have been recalled on massive scales, due to problems that can endangered the diabetic's life. What's more, the lancet blade can also cause rough skin and calluses to develop on the fingertips. The final negative aspect of monitoring technology is the expense. Current test strips on the market are approximately $1.00 per strip. On average, a patient of type 1 diabetes might check his/her blood sugar levels three to ten times a day. This adds up to an annual rate of about $2,000 for test strips. This investment represents a very high financial burden for the uninsured, and even for the insured; the insurance companies only pay half of the price. The positives of current monitoring technology are that it is a relatively simple process, and it is not very painful with the quick-release mechanism.

Insulin pumps, insulin injections, blood glucose pills, and diet are four of the current ways of controlling blood glucose levels in a diabetic patient. Type 1 diabetes requires multiple daily insulin injections. Insulin may be injected into the patient's upper arms, the front of the thighs, or the abdomen. Measurements of insulin injections must be precise; too much insulin can cause symptoms such as fatigue, an inability to speak or think clearly, loss of muscle coordination, sweating, twitching, seizures, fainting, and death. Like current monitoring technology, today's insulin controlling technology also has drawbacks. One of the drawbacks for injections is that the diabetic must constantly replenish his or her supply of sterile needles if this is the chosen method. The patient also must carefully measure out each dose of insulin, a procedure in which a single mistake can cost the diabetic his life.

A more precise alternative to insulin injections is the insulin pump, such as the OmniPod This device is attached to an infusion set made out of plastic tubing that is attached to a soft cannula (needle) into which insulin is injected. The cannula is inserted into the skin, usually the abdomen, and secretes a set amount of insulin to maintain healthy blood glucose levels. The pump is about the size of a computer mouse and is water resistant to a certain degree. The insulin injection levels can be programmed to inject insulin periodically throughout the day to help the patient keep his or her blood glucose levels within the appropriate range.

Though the insulin pump offers a much simpler solution, there are still many flaws. For example, it does not monitor blood sugar levels, so the patient still must measure them often. Another potentially significant drawback is that, for a middle school student actively involved in contact sports, the tubing could be easily pulled out. Also, the diabetic must carry this object around with him or her twenty-four hours a day, seven days a week. This can often be quite uncomfortable for some people, both physically and emotionally, often resulting in stigma for adolescents. Yet another downside is that the pump injects a pre-programmed amount of insulin and, seeing as the patient doesn't always need the same amount of medication, a drastic change in blood sugar could result. The last issue is that pumps can malfunction, secreting too little or too much insulin; fortunately however, this is rare if the pump is well managed.

Both injections and the insulin pump cause numerous "hills and valleys" in blood glucose levels which increase the risk of long-term complications. Another drawback that appears again is the price. Insulin costs $20 to $50 for ten milligrams; an annual rate of about $700. But, the biggest problem still remains the same: without constant readings of blood glucose levels, diabetes is a very hazardous disease, both in the short term *and* in the long term.

Unlike insulin, blood glucose pills are used as fast-acting carbohydrates to raise blood sugar levels in the case of an emergency. Diabetics should carry sustenance such as juice, candy, or anything over fifteen grams of fast-acting carbohydrates at all times.

There are many technologies currently possible, as well as some that are experimental and new. One of these is presently under study by Dr. Heather Clark at Northeastern University. Her technology, nanosensor beads, are injected subdermally like a tattoo. These sensors attract blood glucose molecules which cause the beads to fluoresce. This fluorescence can be quantified by a watch-like device secured over the injection site. The more blood glucose molecules found, the brighter the glow. This is a really cutting-edge technology with many advantages, including that it is continuous. It also eliminates the need for a lancet device and a blood glucose monitor. The device is small and accurate. Plus, it lowers the stigma associated with diabetes monitoring, a prominent factor in a diabetic student's life. On the other hand, the tattoo must be reapplied every few months because it is exfoliated with dead skin. To get a reapplication of this device, the patient must visit the doctor's office, which has a cost. Plus, the device is affected by many uncontrollable factors, including skin color. While Dr. Heather Clark's invention does exhibit promise, it is still in the experimental stage.

From Urine Tasting to Blood Testing: a History of Diabetes Monitoring

"...For fluids do not remain in the body, but use the body only as a channel through which they may flow out. Life lasts only for a time, but not very long. For they urinate with pain and painful is the emaciation. For no essential part of the drink is absorbed by the body while great masses of the flesh are liquefied into urine." (www.diabeteshealth.com). These were the exact words that the Greek citizen Aretaeus in the first century of A.D. used to describe this fatal affliction- diabetes.

One of the first recorded ways of diagnosing diabetic patients was through the use of a "water taster", otherwise known as a urine taster. The whole occupation of their chosen career revolved around the tasting of urine. If the savor was sweet, then the patient was diagnosed as a diabetic. Although the doctors of that time period had found a way to analyze whether their patient was a diabetic, they were incapable of finding a cure. As noted in "The History of Diabetes," "...before the discovery of the insulin, a child diagnosed with diabetes was expected to live less than a year." (www.diabeteshealth.com). As time progressed, numerous doctors made attempts to develop a cure for diabetes with poor results. One example of this was when a doctor locked his patients in a room to enforce the diet of 450 calories per day he prescribed. This method merely kept the encaged patients in the state of near starvation but only slightly prolonged their life span.

The discovery of insulin came in 1921 when Fredrick Banting managed to keep a severely diabetic canine alive for seventy days by injecting a milky liquid extracted from the islets of langerhans, which are organs located on the pancreas that produce and secrete insulin. Without having undergone this process, the dog would have died much sooner. This discovery of insulin was the key to saving those with diabetes.

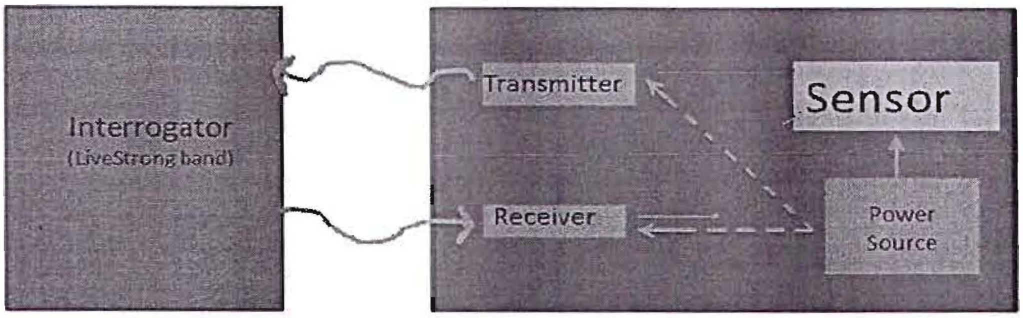
Though blood glucose monitoring was around even before the discovery of insulin, it became much more prominent after the discovery of this hormone. The first monitors were paper strips that the patient would urinate on, causing their color to slightly differ in shade. Because of this, it was very difficult to detect a difference in the color of the paper strips. Also, since urine glucose levels lag behind blood glucose levels, it did not tell the diabetics their current blood glucose level.

Eventually, technology evolved to a point where the blood glucose could be monitored directly from the blood via a needle prick. This was the beginning of our current blood glucose monitors.

Future Technology

Our idea is to utilize nanotechnology, a direct oxidation reaction, and a passive Radio Frequency Identification (RFID) tag to create an in vivo blood glucose monitor that would be implanted into muscle tissue of the diabetic. The patient's body would react to this foreign object by encapsulating it in scar tissue, but blood glucose would still pass through because of its low molecular weight.

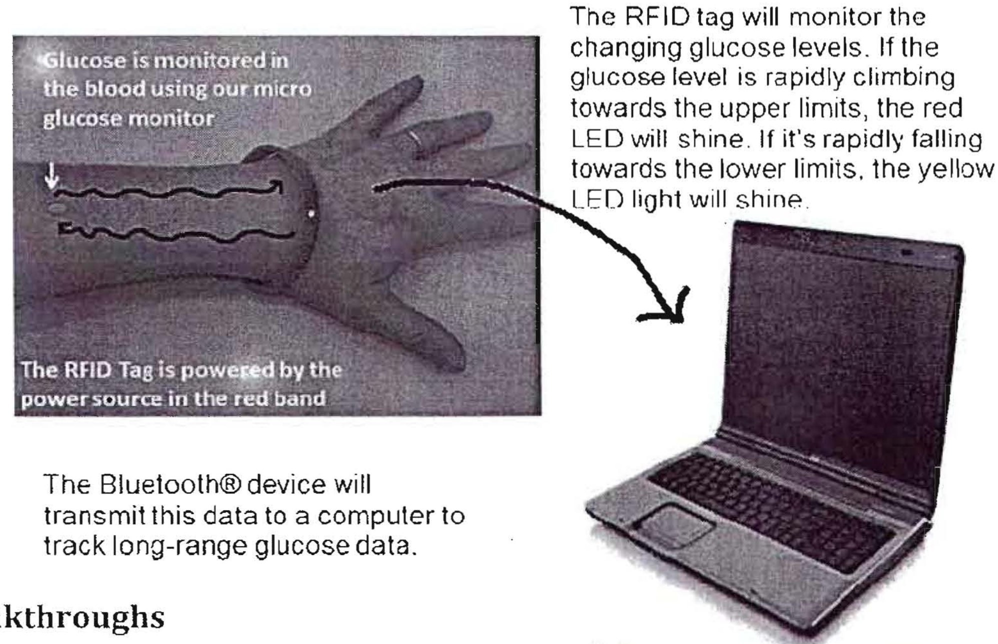
The internal sensor would transmit the blood glucose data to a waterproof wristband using the radio frequency produced by the passive RFID tag. This wristband, similar to a "LiveStrong Band", would contain two LEDs, a microprocessor, a Bluetooth®/4G device, a power source, and a small capacitor. The two LEDs would signal trends toward high (Red LED) or low (Yellow LED) blood glucose levels before they exceed acceptable limits. The microprocessor would analyze and store the blood glucose data. The Bluetooth®/4G device would allow data to be downloaded to a computer to track long-term blood glucose patterns. The power source would energize the passive RFID tag via Radio Frequency coupling inside the sensor unit. The capacitor would be used to deliver a small shock to wake the patient if they didn't respond to the LED warning lights in a timely manner.



The interrogator will have two primary functions: powering the nanosensor RFID tag unit and talking to the nanosensor RFID unit. Ours will be a passive RFID tag, which means it won't have its own power source. Instead, it will be charged by an outside source: the interrogator's radio waves. The power source in the RFID tag will store these waves and use their power to operate the rest of the nanosensor-RFID unit. We also will use these "air waves" to transmit our blood glucose data. Either on a different radio frequency or the same frequency, the interrogator will "ask" the receiver in the RFID tag to get the blood glucose data. The receiver will then tell the sensor to send the data to the transmitter, which, in turn, transmits this information back to the interrogator in an infinite loop.

Our sensor, a carbon nanotube lead nanoparticle, will use direct oxidation to monitor blood glucose levels. Essentially, the sensor just "grabs" each passing blood glucose molecule and then releases it. Based on the speed of attachment, the number of blood glucose molecules in the blood can be determined. This data will be transmitted to the microprocessor via the RFID tag. This microprocessor, or minicomputer, then looks for an increase or decrease in the speed of capture. If this trend continues to the upper or lower limits of the desired range, the microprocessor will light the corresponding LED. If the trend still persists, then our minicomputer will instruct the capacitor to administer a small shock to the patient. If there is still no change in trend after a second shock is given, the wristband will send an emergency prompt to a chosen person using Bluetooth®/4G technology.

This shock/alarm system will alert both the diabetic and his or her family or friends to the impending threat to the diabetic patient's health without creating a stigma. In addition, the alert will allow the patient to deal with the change in blood glucose levels before the situation becomes hazardous to his or her health. If this blood glucose monitoring unit was coupled with an insulin pump, the microprocessor could transfer the trend data directly to the pump. The pump would then increase or decrease the insulin dosage to counteract the change in blood sugar. Overall, this combined technology would function just like a healthy pancreas, thereby eliminating the need for the diabetic to have to change their lifestyle to manage the disease.



Breakthroughs

The current direct oxidation methods of blood glucose monitoring are not meant to work in vivo. Our chosen electronic sensor (a carbon nanotube, lead nanoparticle) uses whole blood that must be diluted. We would need to refine this nanoparticle sensor to be able to read whole blood inside the body. We are not certain this would be a problem because the scar tissue that would encapsulate our device would filter out the binding proteins that the scientists were worrying about while still allowing blood glucose, because of its low molecular weight, to pass through.

Also, we would need to design a passive RFID tag that could translate the nanosensor information and transmit it to the wrist band using a very small amount of power. If this isn't possible, we would be forced to convert the RFID from a smaller passive state, to an active state. In this case the tag would have a built-in power source, such as a battery, making it much more bulky and hard to work with. If this alteration was required, the technology would no longer be feasible because the battery needed would be quite sizeable.

There are very few technological breakthroughs needed for this technology to become possible since all the components in the CIGM System are either currently available or pending for patent. They just are not combined in a package beneficial for diabetics.

Design Process

There were many aspects that we had to consider when doing this project. We came up with the basic concept, but had no idea on how to go about it. Considering antibodies, we e-mailed Dr. Heather Clark to discuss if this would be a feasible monitoring technique. She explained to us that antibodies weren't very practical with our blood glucose monitoring device because they easily disintegrate in vivo, among other complications. Dr. Clark went on to suggest the use of direct oxidation in our device.

Being intrigued by the idea of direct oxidation reactions, we read her paper that explained them. The more we read, the better it sounded.

Now, we had to choose our sensor. After pouring over the nanosensor chart in Dr. Heather Clark's paper, we eventually decided on the CNT carbon nanotube, lead nanoparticle senor because it is used for direct oxidation, it had the perfect range for our needs, and it could actually work on blood.

We then interviewed Jim Trice, who works with RFID technology every day. This allowed us to reinforce our belief that we should use RFID technology. But, we still had to decide between a passive RFID tag and an active RFID tag. An active RFID tag has a battery included with it, which makes it very bulky. On the other hand, a passive RFID does not have an included power source and instead must get its power from an outside source. Based on this information, we decided to use a passive RFID.

Consequences

Using an RFID tag allows our sensor to be small and permanent, but it also raises serious privacy issues. Because the blood glucose data signal is transmitted over "air waves," anyone with an appropriate reader would have access to that medical information. This could result in the possibility of the diabetic losing his or her job if their boss were to scan them and discover that they aren't controlling their insulin levels. But, for this to happen, the reader would have to be quite close to the patient. This is because we plan to make sure that our RFID tag can only transfer the data over a small range. This range would be more than enough to "talk" to the wristband, but not enough for other devices to pick up on the readings. Plus, new technology allows for password protection, much like that of a secure computer network. A password protected wristband would, therefore, be able to access all the information while other devices wouldn't. Also, other RFID technology may interfere with the sensor, so a frequency would have to be set aside for medical use. Another example of a problem that could occur is the accidental disabling of our device. Since many stores use RFID technology to prevent theft, they could inadvertently turn off the implanted tag while scanning items to deactivate the RFIDs because it is used for direct oxidation, it had the perfect range for our needs, and it could actually work on blood.

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TOSHIBA/NSTA EXPLORAVISION AWARDS
SIMULATED WEB PAGE GRAPHICS FORM

Home

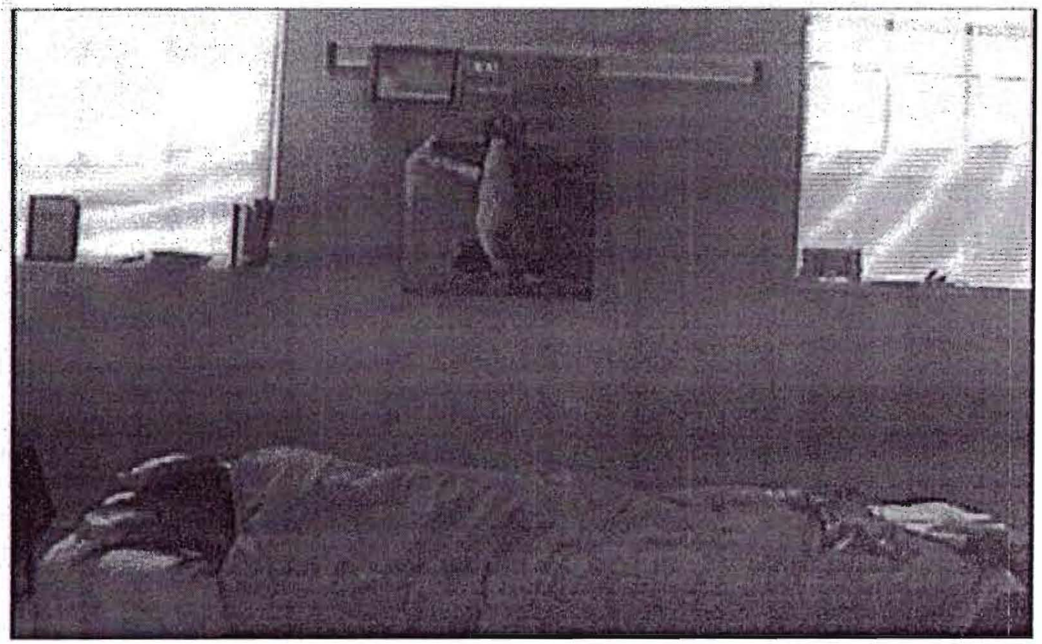
Past & Present of Glucose Technology

Our Technology

Breakthroughs and Consequences

Design Process

The Carefree Internal Glucose Monitoring System (CIGM)



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TOSHIBA/NSTA EXPLORAVISION AWARDS
SIMULATED WEB PAGE GRAPHICS FORM

- Home
- Past & Present of Glucose Technology
- Our Technology
- Breakthroughs and Consequences
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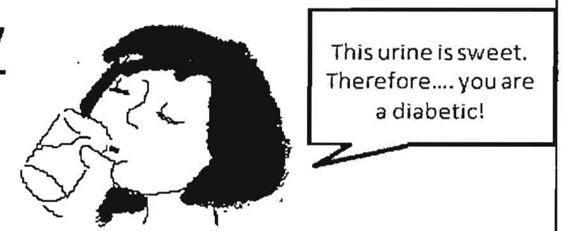
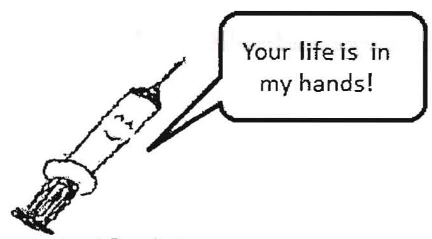
Past and Present of Glucose Technology

In the past, the first recorded ways of diagnosing a patient as a diabetic was through the use of a 'urine taster'. The urine taster would taste the urine, and based upon the taste, he would diagnose the patient as either a diabetic or not a diabetic.



Insulin was first discovered when Fredrick Banting managed to keep a severely diabetic dog alive for 70 days by injecting it with the Islets of Langerhans.



The current standard for diabetes management includes diabetes monitoring and diabetes controlling technology. Today's monitoring technology mainly consists of lancet devices and glucose meters. Today's controlling technology consists mainly of insulin pumps, insulin injections, and glucose pills.

<u>Negatives of Lancet Devices and Glucose Meters.</u>

- •It does not take a constant reading of the patient's blood glucose levels.
- •The information given may not be accurate.
- •The current monitoring technology is expensive.
- •The diabetic is stabbing him/herself with a needle, which can result in damage to the flesh and nerves.

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Graphics Page # 2 of 5 (must include 5 forms)

TOSHIBA/NSTA EXPLORAVISION AWARDS
SIMULATED WEB PAGE GRAPHICS FORM

- Home
- Past & Present of Glucose Technology
- Our Technology
- Breakthroughs and Consequences
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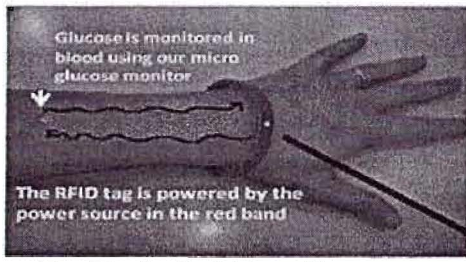
Our Technology

Our sensor unit contains:
•A carbon nanotube lead nanoparticle which uses direct oxidation to monitor blood glucose levels.
•A passive radio frequency identification (RFID) tag to translate data and transfer data to the wristband.
Our waterproof wristband contains:
•2 LEDs to signal trends
•A microprocessor to store data
•A Bluetooth®/4G device used for transferring data to outside sources.
•A power source to power the unit.
•A small capacitor to shock an unresponsive patient.

Shock/Alarm System
•If the patient doesn't respond to LED=small capacitor shocks patient
•Two shocks and the patient still hasn't responded=emergency prompt sent to chosen person via Bluetooth/4G technology

Unit can be combined with an insulin pump to function just like a real pancreas.

The RFID tag will monitor the changing blood glucose levels. If the glucose level is rapidly rising towards the upper limit, then the red LED will shine, and if its rapidly falling towards the lower limit, then the yellow LED light will shine.



The Bluetooth device will transmit this data to a computer to track long range glucose data.

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Graphics Page # 3 of 5 (must include 5 forms)

TOSHIBA/NSTA EXPLORAVISION AWARDS
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- Home
- Past & Present of Glucose Technology
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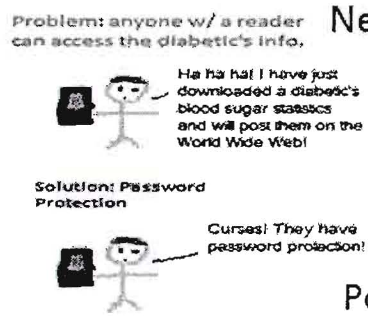
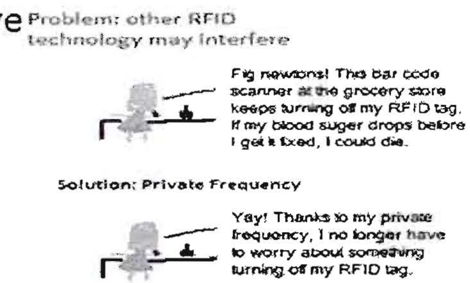
Breakthroughs

- Refine nanosensor to work in whole blood in vivo.
- Design passive RFID tag that could run with very little power.

Consequences

Negative





Positive

- No needles= healthy flesh & nerves.
- Continuous tracking of blood glucose levels= see trends= prevents highs & lows
- Accurate data storage= look at long term trends=predict highs/lows
- Shock system= notify an unaware patient of pending high/low
- The whole unit broadcasting to an insulin pump= functioning just like real pancreas (potential)
- The sensor only implanted once= lowers medical costs
- Only component of our technology that is outside body is wristband system= lowered stigma
- Most , of this technology has been implanted into humans in the past, with no dangerous side effects.
- Almost every component in this technology already exists

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Design Process

When doing this project, there were many aspects of our technology that we had to consider:

•We had the basic idea, but we were still unsure of how to make it happen. At first we considered antibodies as a feasible monitoring technology but there were too many complications linked to it. With the advice of Doctor Heather Clark, we explored the use of direct oxidation reaction in our device; this proved to be proficient for our needs.

•We then had to chose our sensor. We selected the CNT carbon nanotube, lead nanoparticle sensor because it is used for direct oxidation, had the perfect blood glucose detection range for our needs, and could actually work on blood.

•The interview that we had had with Jim Trice also proved to be helpful as he works daily with RFID tag technology and this was a major aspect of the CIGM. This interview helped us decide between a passive RFID tag and an active RFID tag. We choose passive because it was much smaller.

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