GLUCOSE BIOSENSORS WITH DIABETIC APPLICATIONS

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Prevalence of Diabetes Mellitus

Diabetes mellitus is the seventh leading cause of death in the United States, with 350 million people worldwide currently living with this disease. The estimated prevalence of diabetes in adults in the United States in 2003-2006 has been reported to be 9.6% (20.4 million.) However, it has been predicted by The World Health Organization that 48.3 percent of adults in the United States will have diabetes by 2050.

Relevance and Complications

As a preventive treatment or cure for the disease is yet to be developed, managing the conditions of diabetes is currently the most successful means for its control. Monitoring blood glucose frequently combined with appropriate medication can enhance treatment efficiency and alleviate symptoms.

Further medical complications that can occur:

- Out-of-control blood sugar levels can lead to short-term problems like hypoglycemia, hyperglycemia, or diabetic ketoacidosis. In the long run, not controlling diabetes can damage important organs such as the heart, kidneys, eyes, and nerves. This means that heart disease and stroke, kidney disease, vision problems, and nerve problems can occur in diabetes who do not control their glucose levels.

Accuracy and Effectiveness

In order to be of utmost value to their consumers, the continuous glucose biosensor must be able to consistently provide accurate readings. To put these types of implantable monitors to the test, one experiment closely followed measurements during one of the most difficult times for diabetes management, physical activity.

The Results:

In terms of results for this study, the plasma glucose and continuous glucose monitoring methods were directly compared in cases of the aerobic and anaerobic exercise sessions. While the CGM technology was found to have some levels of variance during the aerobic exercise trials, the overall accuracy of this machine was still found to be very important in improving a patient’s glycemic control.

Diabetes Test Strips

Another biosensor relevant to glucose detection is the small, disposable diabetes test strip. Users prick their finger using a thin needle called a lancet to put blood on the device. Glucose test strips are easy to handle, require minimal amounts of blood and can perform rapid measurements. However, suboptimal measurement quality is frequent in this method and lead to increased patient morbidity and mortality. There are many variables that can affect the accuracy of the disposable test strips such as humidity, storage temperature, interference molecules and red blood count.

Many users do not know that biosensors exposed to humidity or excessive temperatures give falsely elevated results. The FDA requires manufacturers to report whenever they become aware of information that suggests that one of its devices may have caused or contributed to serious death or injury. The Manufacturer and User Facility Device Experience Database (MAUDE) of the FDA website showed 691 reports for test strips; many of which involve instances where the blood glucose monitor indicated high glucose levels, while patient symptoms were consistent with severe hypoglycemia.

Components of the Diabetes Test Strip

- Top Support Layer
- Coating Layer
- Paper/Paper Substrate
- Copper and Gold Foil
- Electrodes
- Carboxylic Acid Product Gluconic Acid

Diabetes Test Strip Kit

- Contour
- Lancets
- Code Reader

A People-Centric Innovation

Abbott, a diabetes care business, released a continuous glucose monitor called the Freestyle Libre system in hopes of alleviating some of the diabetes patient’s responsibilities. Abbott’s social and economic focus on sustainability for users allows the glucose biosensor to be a feasible option for the more than 350 million people living with diabetes on a global scale.

Technology Present

Glucose biosensors generally have three main components: biological recognition elements, a transducer that converts this recognition into a signal, and a processing system that converts the signal into readable form. Glucose measurements are generally based on interactions with glucose oxidase (GOx). Immobilized GOx catalyzes the oxidation of glucose in the presence of molecular oxygen, while producing water and hydrogen peroxide as by-products.

The glucuronolactone further undergoes a reaction with the water to produce the carboxylic acid product gluconic acid. For the GOx to act as a catalyst, it needs a cofactor—flavin adenine dinucleotide. The cofactor is generated by reacting with oxygen which leads to the formation of hydrogen peroxide. The hydrogen peroxide is then oxidized at an anode. The electrode easily recognizes the number of electron transfers, and this electron flow is proportional to the number of glucose molecules present.

Manufacturing Biosensors

There are many obstacles that manufacturing facilities must overcome to keep their staff safe, while working in a timely and cost-effective manner.

- Workers must take multiple safety precautions to prevent fires/explosions from happening and must have an effective evacuation procedure in the case that something goes wrong.
- Facilities used to produce biosensors must be well ventilated, air conditioned, and kept at low humidity so that the staff do not inhale vapors coming off used substances
- Products must be stored correctly, either placed in desiccated container, or individually packaging them in discrete foil sachets. Practicing these techniques may drive up the cost of maintaining a facility but are crucial to the production process.

Abbott’s Freestyle Libre System