Diabetic Breathalyzer: Miniaturization and Automatic Volume Sampling

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***Abstract*—Diabetes is one of the most common diseases in the United States and is becoming more prevalent worldwide. Despite the availability of blood glucometers for routine diabetic monitoring, patient compliance remains a challenge due to the pain associated with the fingerstick sampling method. One attractive solution to this issue involves a breathalyzer-based diabetic monitor. This device analyzes the acetone levels on a patient's breath, which are correlated with blood glucose levels. Since the breathalyzer approach is simple and pain-free, patient compliance may increase, resulting in improved outcomes and reduced burden on the healthcare system. In this work we are continuing the development of the diabetic breathalyzer, including further miniaturization and inclusion of additional features such as automatic volume sampling.**

I. Introduction

There are approximately 415 million people living with diabetes around the world, including almost 30 million Americans [1]. Globally, 1.5 million people die each year due to complications from diabetes, and that number is expected to increase [2]. Severe cases of diabetes can result in amputated limbs, blindness, and possibly even death [1]. At the core of diabetes are two key molecules: glucose and insulin. Glucose is the energy source that many of the cells in the body need to function properly, while insulin is the molecule that controls how much glucose enters the cells so that they are not overwhelmed or underwhelmed with their energy source. Insulin is a protein produced by the pancreas that will bind to receptors on the surface of cells that will then cause the glucose channels to open [3].

There are three types of diabetes: Type I, Type II, and gestational. The hallmark of Type I diabetes is the inability of one's pancreas to produce sufficient insulin. Conversely, Type II diabetes is caused by the cells becoming resistant to the insulin in the blood. Gestational diabetes is similar to Type II where the cells in the body become resistant to insulin, but it has a different root cause. Type I (5-10% of the diabetic population) usually develops earlier in life and is linked to complications with the development of the pancreas. Type II diabetes (90-95% of the diabetic population) typically emerges later in life and is often related to a high sugar diet that causes insulin to be overproduced by the pancreas. This overproduction in response to elevated blood glucose levels leads to cells becoming resistant to the abundant insulin. Gestational diabetes is developed during pregnancy when hormones cause the cells in the body to become resistant to insulin, as in Type II. This type of diabetes is more likely to happen if the mother has a high sugar diet; however, gestational diabetes is often reversible after delivery [1].

A critical component of diabetic care is patient self-monitoring of blood glucose levels. However, current diabetic monitoring techniques, which are based on a blood test obtained via fingerstick, are relatively invasive. The pain associated with this test, as well as social stigma and scarring at the fingerstick site, could lead many individuals with diabetes to stop complying with their self-monitoring schedule. As a result, many people with diabetes are not properly monitoring their blood glucose levels, which can lead to poorer outcomes. In the long run this equates to more frequent hospital visits and elevated medical bills leading to increased burden on the healthcare system.

To address these challenges, we are developing a new approach to diabetic self-monitoring that replaces the fingerstick method with a breathalyzer [4, 5]. In this system, a patient provides a breath sample into a device that measures the concentration of acetone. Since breath acetone has been shown to correlate with blood glucose levels, this method can be used for diabetic self-monitoring in a pain-free format that may significantly increase compliance levels. Herein we describe the latest developments of the breathalyzer technology including further miniaturization, inclusion of automatic volume sampling, and creating an easy to use patient interface.

II. Materials & Methods

The core technology involves a disposable sensor slide that reacts with breath acetone [4]. In a typical test the patient breathes into a tube that directs the sample to the sensor slide, and a spectrophotometer is used to read the result and obtain a blood glucose value. The entire system is intended to be handheld to enable its portability and use throughout the patient's typical daily activities.

The device consists of three subsystems or functions: acquiring patient breath, measuring acetone with sensor slide via absorbance spectroscopy, and interpreting/displaying results to the patient. Figure 1 depicts the latest design concept in which all three subsystems are included in a single package.

The auto-volume sampler component of the device is being designed to detect how much air has entered the slide chamber, and once it reaches 200 mL of breath to close and seal the chamber. The component being used to detect the flow of the breath into the device is the wind sensor rev. C (Modern Device). Once the desired air volume has been reached, the device triggers a small valve. This will seal the chamber and allow the slide to react with the breath sample so that the spectrophotometer can then measure the absorbance. All of these actions are controlled through an Arduino microcontroller.

The absorbance of the sensor slide is measured via the combination of an LED and UV sensor. The UV sensor relays a voltage-based absorbance reading that is correlated to the acetone concentration on the patient's breath. The acetone absorbance is then used to determine the blood glucose level through a calibration curve that has been generated through extensive testing.

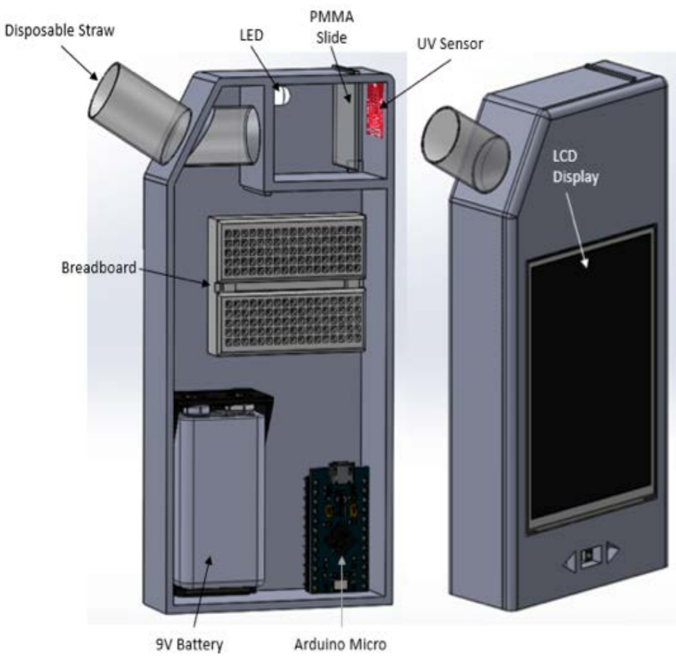

Fig. 1: Final proposed concept for the diabetic breathalyzer.

The diabetic breathalyzer utilizes an Arduino Micro as the microcontroller that outputs the blood glucose readings to the LCD TFT display. The Arduino board will also store up to 1,000 user breath acetone/blood glucose measurements. These measurements will be able to be transferred from the diabetic breathalyzer to a computer through a USB connection.

Finally, the entire device must be packaged in a handheld unit to ensure portability for daily use by diabetic patients. As shown in Figure 1, the packaging should be able to house all of the internal components (e.g., spectrophotometer) as well as external components (e.g., display). The latest device concept has dimensions 5.5 x 2.8 x 1 inches. These dimensions are comparable to that of a typical alcohol breathalyzer, which was used as a benchmark when designing the model.

III. VERIFICATION AND VALIDATION

The diabetic breathalyzer will be subjected to a series of tests in order to verify and validate the subsystem components and the final integrated device. Mechanical tests will be run in order to determine if the device can withstand normal wear (i.e. a drop from shoulder height) and if the system is resistant to changes in temperature and humidity. In addition, a statistical analysis of the volume sampler will be performed in order to determine its precision and accuracy. Once the entire diabetic breathalyzer is assembled, the overall precision and accuracy of the device will be measured against a standard blood glucometer. User feedback will also be solicited to ensure the device is user-friendly and comfortable for daily patient use.

IV. DISCUSSION

Currently, the fingerstick method of blood glucose measurement is the primary way that individuals with diabetes throughout the world monitor their condition. Due to the pain associated with this test, and the need to perform it up to 10 times each day, compliance with self-monitoring regimens is limited. If successful, the diabetic breathalyzer could allow individuals with diabetes to monitor their disease in a pain-free format, increasing compliance, improving outcomes, and reducing the burden on the healthcare system.

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