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A Non Invasive Approach for Detecting Diabetes Mellitus using Mos Sensors

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Abstract

According to the IDF Diabetes Atlas, 537 million persons aged 20 to 79 have diabetes. By 2030, the population is expected to climb to 643 million, and by 2045, to 783 million. In 2021, diabetes will be responsible for 6.7 million fatalities. Diabetes mellitus (DM) is a syndrome of impaired carbohydrate, fat, and protein metabolism caused by either lack of insulin secretion or decreased the sensitivity of the tissues to insulin. The testing methodology necessarily involves the extraction of body fluids, which is an invasive procedure. There are several ideologies that allow for non-invasive diagnostic methods. These objectives have been accomplished despite significant rapid evolution of sensors. Breath analysis is a method of acquiring non-invasive information about an individual's health condition by analyzing volatile organic compounds in exhaled breath. The presence of acetone in breath is treated as a biomarker for diabetes mellitus. Separate module for analyzing the breath, which constitutes an array of MOS sensors for recognizing disease trends such as diabetes mellitus; have been established depending on these circumstances. For acetone detection, TGS 822 array was used. The experiment was carried out on people of various ages who had been diagnosed with diabetes for a long time. The breath samples were obtained and analyzed with the aid of a signal conditioning unit, and the classification was performed with the help of pattern recognition techniques. In addition, this loom can serve as a non-invasive and cost-effective diabetic monitoring system.

Key words*: Diabetes mellitus, Breath analysis, MOS sensors, Acetone, TGS822, Support vector machine, k-fold cross correlation.*

INTRODUCTION

Diabetes mellitus is a condition in which the body does not produce enough insulin or does not react to it properly, resulting in abnormally high blood sugar (glucose) levels. Relating this it is categorized as

1. *Type I diabetes* – It is called *insulin-dependent diabetes mellitus (T1DM)* and is caused by lack of insulin secretion.
2. *Type II diabetes* – It is called *non–insulin-dependent diabetes mellitus (T2DM)* and is caused by decreased sensitivity of target tissues to the metabolic effect of insulin. This reduced sensitivity to insulin is often called *insulin resistance*.

In both types of diabetes mellitus, metabolism of all the main foodstuffs is altered.

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Diabetic Ketoacidosis

Every cell in the human body needs energy concerning to function. The body's key energy source is glucose, a simple sugar resulting from the digestion of foods containing carbohydrates. Glucose from the digested food circulates in the blood as a prepared energy source for any cells that need it. Insulin is a hormone or chemical produced by cells in the pancreas. Insulin binds to a receptor site on the outside of the cell and acts like a key to open a doorway into the cell through which glucose can enter. Some of the glucose can be converted to concentrated energy sources like glycogen or fatty acids and saved for later use. When there is not enough insulin produced or when the doorway no longer recognizes the insulin key, glucose stays in the blood rather entering the cells. The body will attempt to dilute the high level of glucose in the blood, a condition called hyperglycemia, by drawing water out of the cells and into the bloodstream in an effort to dilute the sugar and excrete it in the urine. It is not unusual for people with undiagnosed diabetes to be constantly thirsty, drink large quantities of water, and urinate frequently as their bodies try to get rid of the extra glucose. This creates high levels of glucose in the urine. When the body is trying to get rid of glucose from the blood, the cells starve for glucose and send signals to the body to eat more food, thus making patients extremely hungry. To provide energy for the starving cells, the body also tries to convert fats and proteins to glucose. The breakdown of fats and proteins for energy causes acid compounds called ketones to form in the blood. Ketones also will be excreted in the urine (ketonuria). As ketones build up in the blood, a condition called ketoacidosis can occur. This condition can be life-threatening if left untreated, leading to coma and death. [1]

Thus Diabetic ketoacidosis (DKA) occurs as a result of marked insulin deficiency associated with an increase in circulating levels of counter - regulatory hormones. It is characterized by hyperglycemia, acidosis, and ketonuria. It mainly occurs in patients with T1DM, but it is not uncommon in some patients with T2DM. [2] Ketosis occurs especially in starvation, in diabetes mellitus, and sometimes even when a person's diet is composed almost entirely of fat. In all these states, essentially no carbohydrates are metabolized. In starvation and with a high-fat diet carbohydrates are not available. In case of diabetes ketosis occurs, since insulin is not available to cause glucose transport into the cells. When carbohydrates are not used for energy, almost all the energy of the body must come from metabolism of fats.

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Formation of ketones

The liver plays a vital role in the degradation of fatty acids, especially when excessive amounts of lipids are being used for energy. Conversely, the liver uses only a small proportion of the fatty acids for its own intrinsic metabolic processes. The fatty acid chains will split into acetyl-CoA, where two molecules of acetyl-CoA condense to form one molecule of acetoacetic acid and this will be transported in the blood to the other cells throughout the body for energy. Part of the acetoacetic acid is also converted into β-*hydroxybutyric acid,* and minute quantities are converted into *acetone.* The acetoacetic acid, β –hydroxybutyric acid and acetone diffuse freely through the liver cell membranes and are transported by the blood to the peripheral tissues. Here they again diffuse into the cells, where reverse reactions occur and acetyl-CoA molecules are formed. These, in turn, enter the citric acid cycle and are oxidized for energy. The concentrations of acetoacetic acid, β -hydroxybutyric acid, and acetone occasionally rise normally to levels many times in the blood and interstitial fluids this condition is called *ketosis*because acetoacetic acid is a keto acid.[3,4] These three compounds are called *ketone bodie* The chemical process is shown in Figure 1

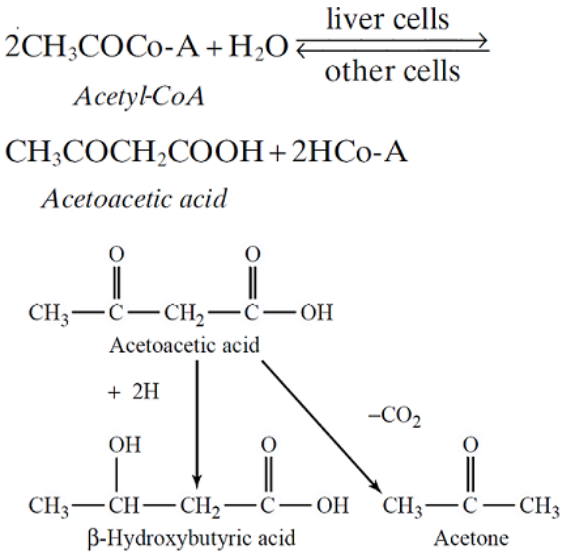

Figure 1Formation of ketones in Liver

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Acetone breath

Some minute quantities of acetoacetic acid in the blood, which increase greatly in severe diabetes, are converted to acetone. The acetone that is formed during ketosis is volatile in nature, some of which is blown off in small quantities in the expired air of the lungs. This gives the breath an acetone smell that is frequently used as a diagnostic criterion of DKA.

Consequently, one can frequently make a diagnosis of type I diabetes mellitus simply by smelling acetone on the breath of a patient. Additionally, keto acids can be detected by chemical means in the urine, and their quantization aids in determining the severity of diabetes.

Monitoring Diabetes

The aim of monitoring glycemic control is to diagnose the nature of any impairment of homeostatic mechanisms like insulin deficiency, which allow the patients to understand the nature of their disorder, determine optimum times for initiating therapeutic intervention; and guide the day to day adjustment of management regimens.

Glycated hemoglobin (HbA_{1c}) and blood glucose are the two most frequently used measures of glycemia in current practice. Glycated hemoglobin provides information about overall control of glucose levels in the previous 6 - 8 weeks allowing assessment of the need for therapy and therapeutic response. Blood glucose which is expressed as plasma glucose concentration; provide information about the day to day level of control, variation in control and response to the therapeutic intervention. The normal blood glucose concentration in a person who has not eaten a meal within the past 3 to 4 hours is about 90 mg/dl. After a meal containing large amounts of carbohydrates, this level seldom rises above 140 mg/dl unless the person has diabetes mellitus. For Individuals with fasting plasma glucose concentration of 100mg/dl to 125mg/dl are considered to have impaired fasting glucose (IFG) , whose fasting glucose levels were above normal but below the diagnostic for diabetes. If these individuals perform oral glucose tolerance test (OGTT) they will be reported as impaired glucose tolerance (IGT),[5] in the case of diabetes, the 2 hours post-load plasma glucose concentration will be $\geq$ 200mg/dl. The laboratory methods of blood glucose measurement are accurate, but for the site of care, capillary blood glucose measurement has become very popular, which provide greater comfort and more rapidly available results. Capillary blood glucose meters use test strips that release gluconic acid

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and hydrogen peroxide from a blood sample. The reaction is quantified by one of a range of methods to measure blood glucose. Though these tests are much uncomplicated, an only tiny drop of blood is required to do the measurement and the advances in technologies deliberate the glucometer with much less pain monitoring, still, people shows a great aversion because they are invasive. Thus we are in demand or obsession to create a non invasive monitoring unit for glucose measurement.

Odor can be defined as an essence that activates the sense of smell, are the sensations that occur when compounds stimulate the receptor cells that are situated in the olfactory epithelium of the nasal cavity. Most of the Odorants are hydrophobic, volatile compounds that have a molecular weight of less than 300 Daltons. Humans can recognize and discriminate up to 10000 different substances based on their odor quality. [6] These substances can be treated as breath markers, which are the distinctive biologically derived indicator (metabolite) of a diseased condition. For the analysis of breath, a number of molecules such as nitric oxide, isoprene, pentane, benzene, acetone, and ammonia may be considered as a biomarker which indicates certain pathologies. The VOCs usually found in normal breath are acetone, ethane, and isoprene which are the metabolic products. Where the isoprene is due to the synthesis of cholesterol, acetone from glucose metabolism and the alkanes from lipid peroxidation of fatty acids, [7] breath VOC analysis is a non invasive and rapid bio-monitoring tool that also offers the potential for early detection and progress tracking of numerous diseases. In breath test their conceivable metabolic routes, a breath VOC generation, and the diagnostic value of the analysis, can also be implemented. The key breath marker in the detection of diabetes mellitus is acetone. [8-14] many researchers came out with different ideas to design a monitoring device for blood glucose using breath acetone and different non invasive methods for glucose monitoring to enhance the painless control of blood glycemic level. [15-20]

A new approach for non-invasive glucose measurement was described using variety of sensors, [21,22] like silicon-wafers based optical reflection sensor, [23,24] WO3nanoprobes, [25] MOS sensors, Si-doped WO3 chemo resistive gas sensors by flame spray pyrolysis, C-doped WO3 materials which showed fast response and recovery toward acetone gas. [26]

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MATERIALS AND METHODS

In this research an attempt is made to develop a non invasive device using metal oxide gas sensors to monitor glucose using breath samples, based on the stipulation that acetone breath is a diagnostic criterion of DKA and T1DM. The proposed system consists of the experimental setup, [27] as shown in Figure 2. In this design, the chamber is made out of indolium metal which can house around 1 liter of vapor, and TGS822 MOS sensors are used to detect the presence of acetone in the breath.

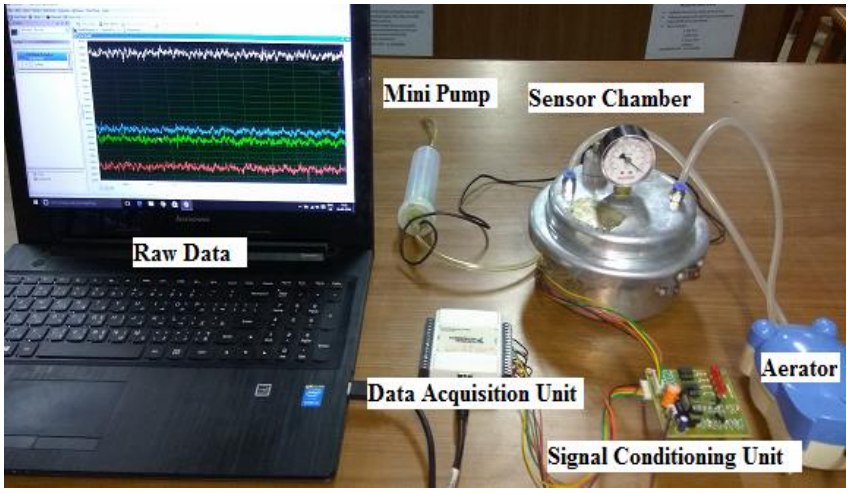

Figure 2 Experimental setup for the detection of acetone breath

Sensor array for acetone detection

TGS 822 MOS sensor is utilized for the detection of acetone from breath. An array of four sensors is used and the sensor array arrangement is shown in Figure 3.

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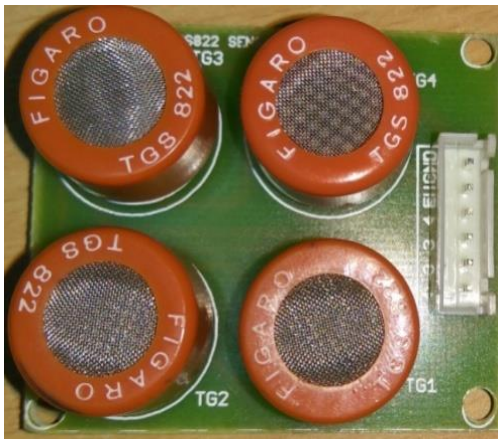

Figure 3 Sensor array arrangements for acetone detection

Sensor TGS 822 Characteristics

The sensor performance is studied by exposing the sensor to a known concentration of acetone. A similar procedure has been followed, the chamber is filled with air from the aerator and the gas is made to pass inside the chamber using microliter syringe, the sensor conductivity changes depending upon the concentration of acetone and the sensor response is logged using data acquisition unit. The raw data of the sensors are processed and pattern classification is done using support vector machine. The sensor's characteristics for different concentration of acetone for the each sensor are shown in Figure 4 which implies that each sensor has its distinctive uniqueness because, for the same concentration of acetone each sensor shows slight deviation in the output voltage, owing to the fact, the sensors response are averaged and used for pattern classification.

The bar plots in the Figure 4 represent the individual response of the four sensors where the line graph corresponds to the average value of the sensors. On the whole, the sensor voltage increases with increase in the concentration of acetone. The sensitivity of the sensor TGS822 is studied by passing vapors like ethanol and carbon monoxide its corresponding plot is shown in Figure 5 which illustrate that the sensor is equally good in detecting both acetone and ethanol.

Subject selection for acetone breath

In this work, the breath samples are collected from two set of groups like diabetic and non-diabetic. Subsequent to blood glucose tests which could be fasting or random, the breath

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samples are collected during fasting and postprandial (2 hours after a meal) from each individual. The details of volunteers who came forward to give their breath samples are given in Table 1. The majority of diabetic participants have a medical history that includes hypertension, ulceration, and 10 years of medication. The only need for breath collection is that the person not be under the influence of alcohol. Collected breath samples are simultaneously communicated to the array of sensors and their responses are recorded using DAQ. The breath samples were collected from the patients who suffer from diabetes mellitus from the Madras Medical College, and the consent from patients was obtained subject to the advice from the ethics committee.

Table 1 Subject database for diabetes mellitus patients

Type of Subjects	Number	Male/Female	Age in years
Non -Diabetic	63	33/30	20-60
Diabetic Mellitus	203	121/82	35-65

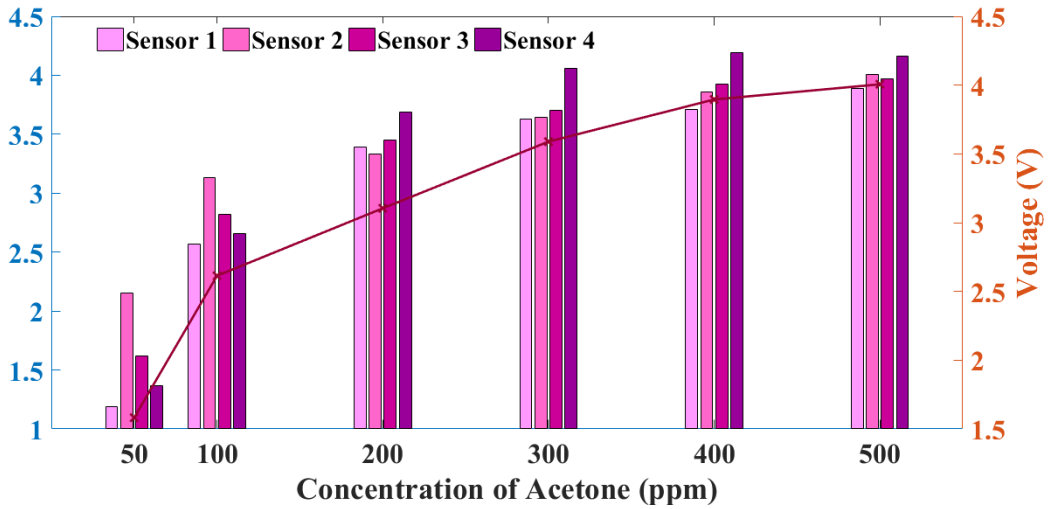

Figure 4 Characteristics of sensor TGS 822

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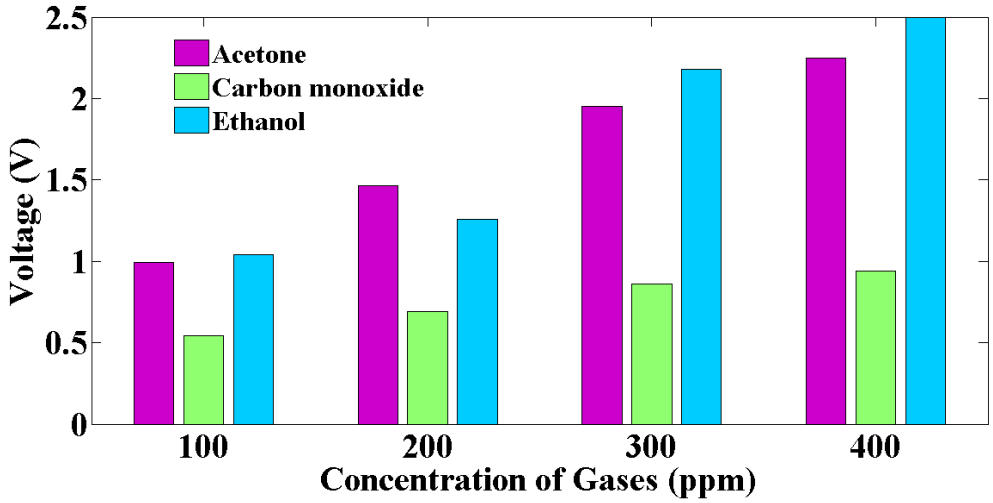

Figure 5 Sensitivity characteristics of sensor TGS 822

Signal Processing for TGS 822 sensor

The preserved data of the four sensors are averaged and processed using Gaussian window that prevents the glitches in the signal repetitively. The processed signal for the breath sample of the diabetic subject is shown in Figure 6. During fasting the energy for the body is utilized from the fat metabolism, where Ketone bodies are produced from fatty acids and are used for energy when liver glycogen is entirely depleted thus the body enters into ketosis. So obviously the level of acetone in blood will be elevated, after consuming food the energy will be taken from the carbohydrates that we eat, so fat metabolism will be minimized and the release of acetone will also be reduced. Looking at this context, the Figure 6 clarifies that the response of the sensor during fasting is more than the response obtained for postprandial which indicates that acetone level is more during fasting and after 2 hours of taking food (postprandial) the level of acetone in the breath is reduced. The fasting and postprandial values for 10 diabetic subjects are tabulated in Table 2 and the values are plotted as a bar graph which is depicted in Figure 7, which indicates that the level of acetone in breath decreases for all the subjects on condition to postprandial.

FEATURE EXTRACTION AND CLASSIFICATION

Two sets of classes are formed for classification using support vector machine, and k-fold cross validation

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i. Non-diabetic versus Diabetic (fasting)

ii. Non- diabetic versus Diabetic (postprandial)

is followed and the corresponding features V_{max}, rise time, steady state time, mean, and standard deviation are calculated. [28-30]

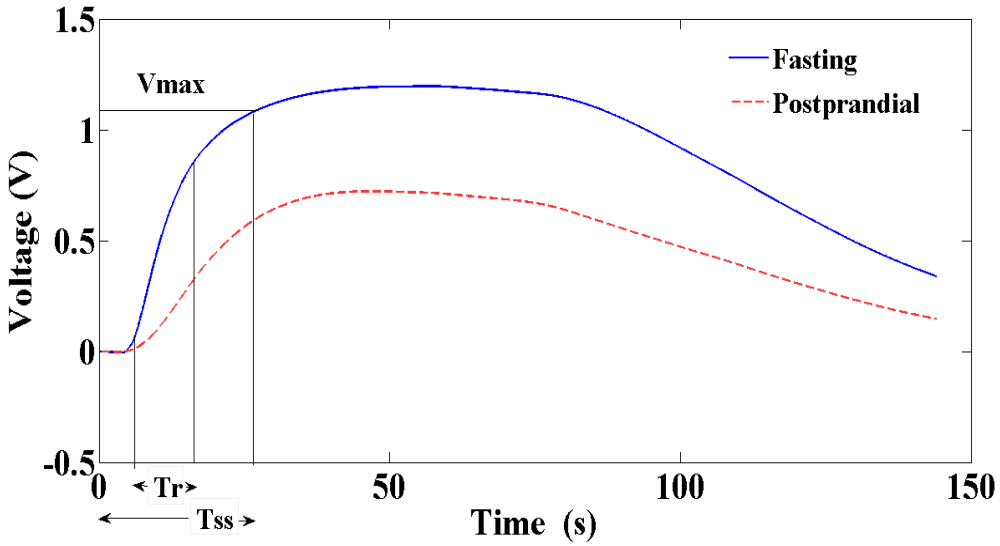

Figure 6 Sensor responses for a breath of DM subject for fasting and postprandial

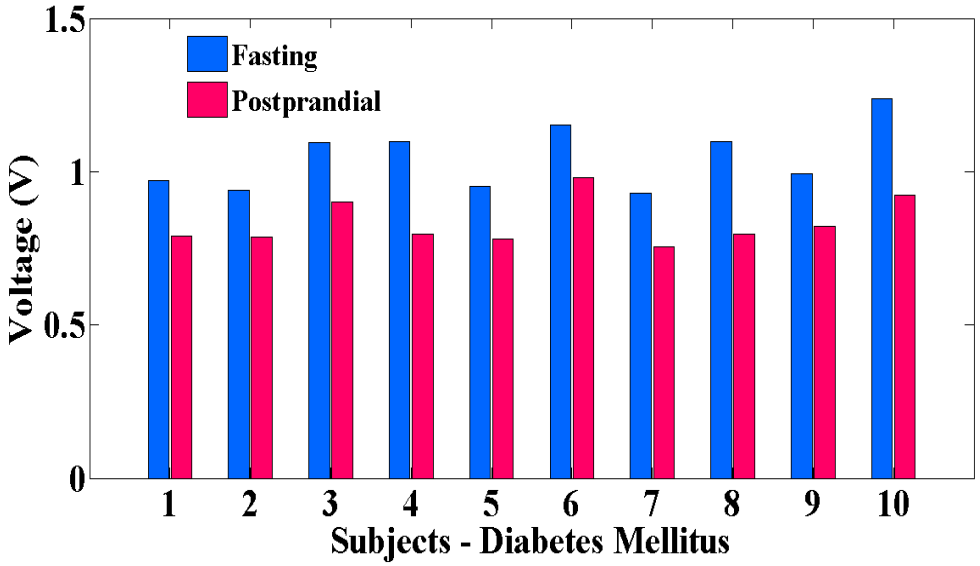

Figure7 Sensor responses for a breath of 10 DM subjects for fasting and postprandial

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Table2 Fasting & Postprandial Blood glucose and voltage level of 10 Diabetes mellitus subjects

No of Subjects	Gender	Blood Glucose in mg/dl		Sensor Response in Volts	
		Fasting	Postprandial	Fasting	Postprandial
1	F	160	132	0.9724	0.7891
2	M	214	139	0.9401	0.7881
3	F	243	170	1.0942	0.8996
4	M	285	117	1.0992	0.7962
5	M	297	180	0.9523	0.779
6	F	336	245	1.1508	0.9789
7	F	346	235	0.9305	0.7538
8	M	357	218	1.0992	0.7962
9	M	381	227	0.9933	0.821
10	M	417	321	1.2384	0.9225

RESULTS AND DISCUSSION

The classification is performed for a total of 266 subjects were 63 (N-negative) are non-diabetic and remaining 203 (P-Positive) is diabetic. The classifier performance is studied by calculating the accuracy based on the stipulation that true negative (TN) and true positive (TP) and the related values are tabulated in Table 3.

In classification between fasting samples almost equivalent accuracy was achieved in all the three conditions, maximum accuracy of 94% was attained in training 80% of the data set. Even for postprandial samples nearly similar accuracy reached utmost 96% was obtained when trained with 80% of the data set. Based on the perception that, after consumption of food the ketosis process will be diminished so the release of acetone will be reduced, we thought the features of non-diabetic and the postprandial features will synchronize, but higher accuracy was secured in that group.

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Table 3 Performance evaluation of the classifier for the sensor TGS822

Conditions	Classification Accuracy = (TP+TN)/(P+N)		
	60%-Training 40%-Testing	80%-Training 20%-Testing	k-fold
Non-Diabetic Vs. Diabetic (Fasting)	92%	94%	85%
Non-Diabetic Vs. Diabetic (Postprandial)	89%	96%	90%

However, this result was utilized in identifying whether the person is diabetic or not. When comparing the values of blood glucose and the sensor voltage as given in Table 2, it is seen that the values were not only non-linear but also not correlated in respect of blood glucose and sensor response. [31, 32] this may be due to the subjects being untrained, no food regime was followed and the postprandial sample collection time was not uniform. [33-35] when the work was conducted under controlled environment acceptable linearity could be expected.

So, the similar work has been conducted for 10 non-diabetic subjects between the age limit of (25-40) years out of which six are female, four are male and 8 diabetic subjects with age group of (60-70) years where 6 female and two male. The sensor response for non-diabetic subjects is shown in Table 4 along with the random blood glucose value which illustrate that for non-diabetic the sensor response appear to be undeviating the minimum value of 0.736729 V and maximum of 0.890746 V were obtained . In case of diabetes mellitus the subjects are requested to eat (100-110) calories for their breakfast like (2-4) idli or (1-2) dosa and are asked to do their regular activities and the corresponding response and the fasting and postprandial blood glucose value acquired using standard method is tabulated in Table 5 and the related bar graph is shown in Figure 8

In fasting the sensor response for the subjects are between (1.064084 to 1.534845 Volts) and for postprandial the sensor response was between (0.947683-1.315678 Volts) which emphasize that reasonable discrimination can be done between non-diabetic and diabetic mellitus subject for both the conditions fasting and postprandial. Further, it is noted that diabetic and non-

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diabetic conditions could be ascertained efficiently between the voltages recorded for random blood glucose of non-diabetic when compared to diabetic under fasting conditions. In addition to this for all the diabetic subjects the sensor response for the postprandial is decreased when comparing the response of fasting. The linearity among the DM groups can be ensured if more number of patients is encountered. Thus TGS 822 sensor can be used to detect the presence of acetone in breath and eventualize that the person is diabetic or non-diabetic. With the proper correlation of the blood glucose value and the sensor response a non-invasive monitoring unit for diabetes mellitus can be developed which is absolutely going to be a remarkable achievement in sensor technology.

Table 4 Random blood glucose and sensor response for 10 non-diabetic subjects

Subject	Gender	Blood Glucose in mg/dl	Sensor response in volts
1	F	81	0.763116
2	F	86	0.748536
3	F	90	0.752963
4	F	94	0.822514
5	F	98	0.765351
6	F	107	0.736729
7	M	110	0.858789
8	M	112	0.808988
9	M	113	0.837039
10	M	120	0.890746

Table 5 Blood glucose and sensor response for 8 DM subjects

Subject	Gender	Blood Glucose in mg/dl		Sensor Response (V)	
		Fasting	Postprandial	Fasting	Postprandial
1	F	98	154	1.064084	0.947683
2	F	101	256	1.082532	1.045329
3	F	108	252	1.197273	1.066814
4	F	113	245	1.238335	0.999477
5	F	115	172	1.37299	1.239865

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6	F	117	183	1.495994	1.224771
7	M	123	190	1.519306	1.18002
8	M	125	184	1.534845	1.315678

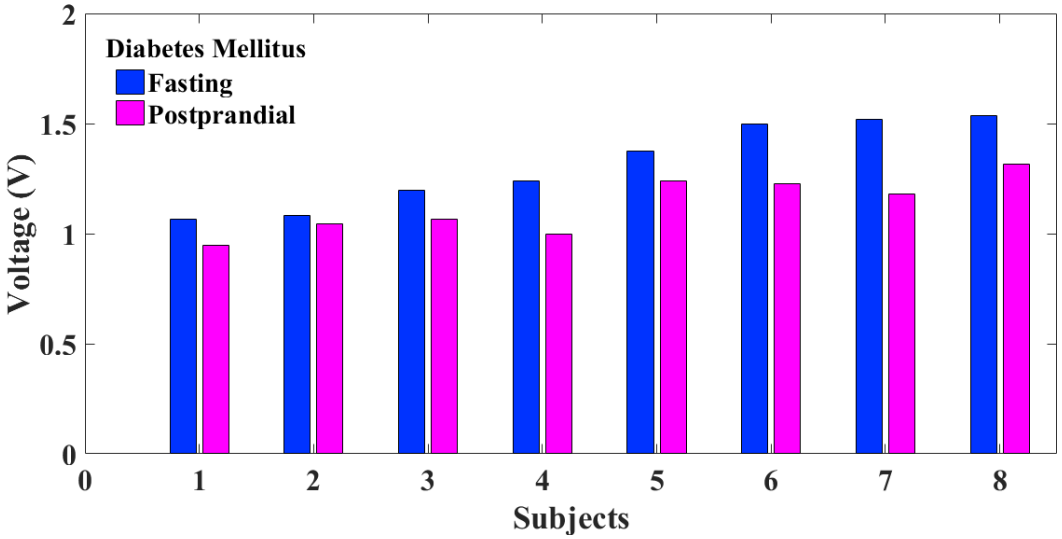

Figure 8 Sensor responses for a breath of 8 DM subjects for fasting and postprandial

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