FORM 1 **THE PATENTS ACT, 1970 (39 of 1970)** **&** **The Patents Rules, 2003** **APPLICATION FOR GRANT OF PATENT** *[See section 7,54 & 135 and rule 20(1)]*		**(FOR OFFICE USE ONLY)**	
		Application No.:	
		Filing Date:	
		Amount of Fees Paid:	
		CBR No:	
		Signature:	
1. APPLICANT'S REFERENCE/IDENTIFICATION NO. (AS ALLOTTED BY THE OFFICE)			

2. TYPE OF APPLICATION [Please tick (✓) at the appropriate category]					
Ordinary (✓)		Convention ( )		PCT ()	
Divisional ( )	Patent of Addition ( )	Divisional ()	Patent of Addition ( )	Divisional ( )	Patent of Addition ( )

3A. APPLICANT (S)				
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			City	Patna
			State	Bihar
			Country	India
			Pin code	800007

3B. CATEGORY OF APPLICANT [Please tick (✓) at the appropriate category]			
Natural Person ()	Other than Natural Person **( )**		
	Small Entity ()	Startup (✓)	Country
			Pin code

4. INVENTOR(S) [Please tick (✓) at the appropriate category]

Are all the inventor(s) same as the applicant(s) named above?	**Yes ()**	**No (✓)**

If "No", furnish the details of the inventor(s)

Name in Full	Nationality	Country of Residence	Address of the Applicant	
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			City	
			State	Uttar Pradesh
			Country	India
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5. TITLE OF THE INVENTION:

PORTABLE BREATH ANALYZER DEVICE FOR DETECTION OF DIABETES

7. ADDRESS FOR CORRESPONDENCE OF APPLICANT/AUTHORIZED PATENT AGENT IN INDIA		
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8. IN CASE OF APPLICATION CLAIMING PRIORITY OF APPLICATION FILED IN CONVENTION COUNTRY, PARTICULARS OF CONVENTION APPLICATION

Country	**Application No.**	**Filing Date**	**Name of Applicant**	**Title of Invention**	IPC (as classified in the convention country)
Nil	Nil	Nil	Nil	Nil	Nil

9. IN CASE OF PCT NATIONAL PHASE APPLICATION, PARTICULARS OF INTERNATIONAL APPLICATION FILED UNDER PATENT CO-OPERATION TREATY (PCT):

International Application No.	**International filing date**
Nil	Nil

10. IN CASE OF DIVISIONAL APPLICATION FILED UNDER SECTION 16, PARTICULARS OF ORIGINAL (FIRST) APPLICATION

Original (First) Application No.	**Date of filing of Original (First) Application**
Nil	Nil

11. IN CASE OF PATENT OF ADDITION FILED UNDER SECTION 54, PARTICULARS OF MAIN APPLICATION OR PATENT

Main Application/Patent No.	**Date of filing of Main Application**
Nil	Nil

9. DECLARATIONS

(i) Declarations by Inventor(s)

(**In case the applicant is an assignee**: the inventor(s) may sign herein below or the applicant may upload the assignment or enclose the assignment with this application for patent or send the assignment by post/electronic transmission duly authenticated within the prescribed period).

I/We, the above named inventor(s) is/are the true & first inventor(s) for this invention and declare that the applicant(s) herein is/are my/our assignee or legal representative.

INVENTOR NAME	SIGNATURE	DATE
Achyut Agarwal		
Sarvesh Dhar Dwivedi		

(ii) Declaration by the Applicant(s) in the convention country

(In case the applicant in India is different than the applicant in the convention country: the applicant in the convention country may sign herein below or applicant in India may upload the assignment from the applicant in the convention country or enclose the said assignment with this application for patent or send the assignment by post/electronic transmission duly authenticated within the prescribed period)

I/We, the Applicant(s) in the convention country declare that the applicant(s) herein is/are my/our assignee or legal representative.

(iii) Declaration by the Applicant(s)

I/We the applicant (s) hereby declare(s) that:-

☑ I am /We are in possession of the above mentioned invention.

☑ Complete Specification relating to the invention is filed with this application.

☒ The invention as disclosed in the specification uses the biological material from India and the necessary permission from the competent authority shall be submitted by me/us before the grant of patent to me/us.

☑ There is no lawful ground of objection(s) to the grant of patent to me/us.

☑ I am/we are the true & first inventor(s).

☑ I am / we are the assignee or legal representative of true & first Inventor(s).

☑ The application or each of applications, particulars of which are given in paragraph-8 was the first application in convention country / countries in respect of my/our invention(s).

☒ I / We claim priority from the above mentioned application(s) filed in convention country/countries and state that no application for protection in respect of the invention has been made in a convention country before that date by me/us or by any person from which I/We derive the title.

☒ My/our application is based on International application under Patent Cooperation Treaty as mentioned in paragraph 9.

☒ The application is divided out of my/our application particulars of which is given in paragraph -10 and pray that this application may be treated as deemed to have been filed on N/A under section 16 of the Act.

☒ The said invention is an improvement in or modification of the invention particulars of which are given in paragraph-11.

13. FOLLOWING ARE THE ATTACHMENTS WITH THE APPLICATION:

(a) Form 2

Item	Details	Fee	Remarks
Complete specification	No. of pages 29	-	
No. of Claim (s)	No. of claims 13 and pages 03	-	
Abstract	No. of pages 01	-	
No. of Drawing(s)	No. of drawings 10 No. of pages 09	-	

In case of a complete specification, if the applicant desires to adopt the drawings filed with his provisional specification as the drawings or part of the drawings for the complete specification under rule 13(4), the number of such pages filed with the provisional specification are required to be mentioned here.

b. Complete specification
c. Statement and Undertaking on Form 3
d. Declaration of Inventorship on Form 5
e. Form 28
f. Power of Attorney (To Follow)
g. Fee Rs. 2,880 - Online Filed.

I/We declare that to the best of my/our knowledge, information and belief the fact and matters stated herein are correct and I/We request that a patent may be granted to me/us for the said invention.

Dated this 09th day of October, 2024.

Archana Singh

ARCHANA SINGH
(IN/PA-1936)
AGENT FOR THE APPLICANT

To,
The Controller of Patents,
The Patent Office,
At Delhi

FORM 2

THE PATENTS ACT 1970

(39 of 1970)

&

THE PATENTS RULES, 2003

COMPLETE SPECIFICATION

[See section 10 and rule 13]

TITLE OF THE INVENTION: **PORTABLE BREATH ANALYZER DEVICE FOR DETECTION OF DIABETES**

APPLICANTS

NAME	**NATIONALITY**	**ADDRESS**
Diagnovate Private Limited	Indian	102, Nauzar Ghat, Diwan Mohalla, Tarni Prasad Lane, Das Brothers, Patna, Bihar 800007, India.

The following specification particularly describes the invention and the manner to which it is to be performed.

Field of invention

The present invention generally relates to a medical device and method for use of the medical device for detection of diabetes. The present invention specifically relates to a breath analyzer device for detection of diabetes mellitus which is portable and economical and detects the diabetes mellitus of user accurately.

Background of invention

Diabetes mellitus (DM), which commonly known as diabetes, is a chronic metabolic disorder particularly characterized by elevated blood glucose levels. Its etiology represents distinctive health anomalies such as the lack of insulin secretion, disruptions in insulin activity, and dysfunctions in protein, carbohydrate, and fat metabolism. When disease progression is concerned in diabetes, elevated blood sugar levels often give rise to a condition known as hyperglycemia. As stated above, hyperglycemia deals with fluctuations in blood glucose levels and can affect the functioning of multiple organs in the body. Diabetes is often associated with heart, kidney, and gastrointestinal-related problems and organ damage. With the rising clinical implications of diabetes, diabetes has been classified into four major types: type 1 diabetes mellitus (T1DM), type 2 diabetes mellitus (T2DM), gestational diabetes mellitus (GDM), and secondary diabetes mellitus (spike in blood glucose levels that occurs due to pre-existing medical conditions or disorders).

Conventionally diabetes diagnostic devices are present, but they detect the blood glucose level test which includes fasting plasma glucose (FPG) test, A1C test (to detect the presence of glycosylated and glycated hemoglobin), and random plasma glucose test. So, currently the diagnosis and monitoring of blood glucose and ketone bodies that are used in clinical studies involve the use of blood tests. One of the clinical methods includes taking the blood sample of the patient through needle and then measuring the blood glucose level. Further, in another rapid detection method is also present which entails pricking fingers for a drop of blood and placing a drop on a sensitive area of a strip which is pre-inserted into an electronic reading instrument. Furthermore, it is painful, invasive and expensive, and can be unsafe if proper handling is not undertaken. So, both the blood glucose level detection tests include taking of patient's blood sample which is painful. Therefore, there is a need for other non-painful method to detect diabetes in a patient.

So, human breath analysis has been proposed which offers a non-invasive and rapid method for detecting various volatile organic compounds that are indicators for different diseases. In patients with diabetes mellitus, the body produces excess amounts of ketones such as acetoacetate, beta-hydroxybutyrate and acetone. Therefore, few oral glucose tolerance test devices are present which detect the glucose level of patient based on the acetone level of exhaled air of the patient. However, various techniques that are used to analyse exhaled breath includes Gas Chromatography Mass Spectrometry (GC–MS), Proton Transfer Reaction Mass Spectrometry (PTR–MS), Selected Ion Flow Tube-Mass Spectrometry (SIFT–MS), laser photoacoustic spectrometry and so on. All the available devices that uses these techniques are not portable and they also does not provide the accurate result of the glucose level in patient and also does not provide accurate detection of diabetes. Further, these devices are also expensive and bulky and needs the skilled person to detect the acetone level to detect the glucose level.

Few of the available devices which detects the blood glucose level are as follows:

US20210315482A1 relates to an apparatus assesses a condition of a patient which contain a patient interface for communicating a treatment generated by a respiratory treatment apparatus to the respiratory system of a patient.

The apparatus includes:

a patient interface which is configured to communicate a pressure treatment generated by a respiratory treatment apparatus to the respiratory system of the patient, the patient interface comprising a cushion configured to provide a pressure seal for the pressure treatment, the cushion being formed of a material; and

a module being removably embedded within the material of the cushion of the patient interface, and including one or more collectors configured to accumulate at least one of exhaled breath that is exhaled to the patient interface, saliva that is in contact with the patient interface; and mucus that is in contact with the patient interface,

wherein a port within the cushion to the module (a) is proximate to a patient's mouth so as to be exposed to patient exhalation gases and (b) provides the collector access to the exhaled breath.

US’482 also discloses that the module comprises one or more of a peroxide sensor, a nitrous oxide sensor, an acetone sensor, a carbon dioxide sensor, a pH sensor, a glucose sensor, and a lactate sensor for the indication of diabetes and renal failure.

US20200281504A1 relates to a portable measurement device for measuring acetone in a breath sample of a user. The measurement device comprises a housing, a user-direct breath input device for engaging in direct fluid communication with a respiratory tract of the user and receiving the breath sample from the respiratory tract, a flow path disposed within the housing, a nanoparticle-based sensor disposed in the housing in fluid communication with the flow path and at an intermediate location between the upstream end and the downstream end, and a flow control device disposed in the housing and in the flow path between the upstream end and the nanoparticle-based sensor that prevents flow of the breath sample in an upstream direction opposite the downstream direction.

US’504 further discloses that the hand-held breath analyzer that senses multiple analytes may be useful to monitor seemingly unrelated disease states, for example, diabetes and asthma. Such a device may utilize disposable cartridges that are application-specific.

CN112394172A relates to a device for monitoring acetone in expired gas of a diabetic patient comprising a skin-friendly layer, a respiratory gas adsorption layer, an outermost layer and a respiratory frequency monitor. The device function as the gas enters the respiratory gas adsorption layer through the skin-friendly layer, and the respiratory gas is adsorbed by the gas adsorption layer. The respiratory gas has a certain humidity, and a certain relation exists between the humidity and the expiratory frequency. So, the acetone sensor on the outermost layer tests the acetone degree of the respiratory gas and transmits the acetone degree value to the respiratory frequency monitor through the Bluetooth module. The device can collect the respiratory gas and monitor the respiratory frequency at the same time, thus improving the working efficiency. Further, a respiratory frequency monitor is also present to monitor the result which is a mobile phone provided with APP software and used for receiving acetone content data in respiratory gas.

RU51849U1 relates to a device for diagnosing human diseases by exhaled air, in particular to outpatient equipment that allows the simultaneous diagnosis of several diseases by means of a multicomponent analysis of the composition of exhaled air.

RU'849 specifically discloses a device for diagnosing a human disease according to the composition of the exhaled air. The device comprises means for taking exhaled air connected to the inlet of the gas pipe, the outlet of which is connected to an aspiration device, while the gas sensors are fixed in the gas pipe body, each of which is designed to detect the expired air of a certain gas, a humidity sensor, a temperature sensor and an air flow rate sensor, installed so that their sensing elements are located in a thermoregulating element is fixed on the inside of the gas pipe's internal cavity, as well as outside the gas pipe's body, its input is connected to the first output of the temperature sensor signal conversion unit, the input of which is connected to the output of the temperature sensor, and the second output is connected to the first input of the digital controller the first output of which is connected to the input of the control unit of the suction device, the output of which is connected to the input of the suction device, and the output of the humidity sensor connected to the input of the humidity sensor signal conversion unit, the output of which is connected to the second input of the digital controller, the second output of which is connected to the control input of the switching unit.

US20090163825A1 relates to a system for determining a hyper or hypoglycemic state in a diabetic patient using acetone concentration in exhaled breath by means of a nasal device containing an acetone sensor. When a hyper or hypoglycemic state is detected, an alarm is issued.

US20090054799A1 relates to a biosensor system with a multifunctional portable electronic device for use by an individual. The biosensor system includes a breath delivery system with a breath sensor capable of detecting an analyte in the individual's breath. The system also includes a portable electronic device capable of receiving breath analyte data from the breath sensor and blood glucose data or other types of personal health data. The portable electronic device is capable of storing, analyzing, and/or transmitting the breath analyte data and the blood glucose data or the other types of personal health data.

IN202341007304 relates to a non-invasive sensor device for measuring a concentration of acetone in an exhaled breath gas. The noninvasive sensor device includes an optical fibre breath sensor and a photo detector. The optical fibre breath sensor includes a modified clad. The modified clad is coated with a first layer of tin oxide (SnO2) and followed by a second layer of Molybdenum disulphide (MoS2) to form a sensing material over the modified clad. The photo detector is connected with the optical fibre breath sensor at one end. When the optical fibre breath sensor is exposed to the exhaled breath gas, the photo detector detects an optical/intensity variation due to presence of acetone in the exhaled breath gas by analysing a change in reflected light intensity inside the optical fibre breath sensor due to an interaction of the acetone from the exhaled breath gas on the sensing material, for measuring a concentration of acetone in the exhaled breath gas.

Valentine Saasa *et al* article, Diagnostics 2018, 8(1), 12, titled "Sensing Technologies for Detection of Acetone in Human Breath for Diabetes Diagnosis and Monitoring"

Saasa *et al* article discloses that various techniques and devices for detection of diabetes are present. It specifically discloses a portable diagnostic device with real-time monitoring as well as outstanding acetone sensitivity and selectivity should be developed. In this regard, semiconductive metal oxides (SMOs) are promising for diagnosis and monitoring diabetes mellitus non-invasively. This is due to their potential in real-time analysis, facile operating principle (resistivity change upon exposure of acetone to the SMO's surface layers), simple device fabrication and ready miniaturization. It also discuses that chemoresistive SMO-based exhaled breath sensors for potential use in diagnosis of diabetes mellitus using acetone as a biomarker. Further, it discloses that there are sophisticated analytical methods for acetone detection, which include GC–MS, SIFT–MS, PTR–MS and so on, and they are being used in research and clinics. Clinical demonstrations showing correlation of blood glucose and blood ketones with breath acetone have been so far successful.

Further, various types of acetone sensors are also known for the detection of glycemia, few of them are as follows:

Andreas T. Güntner *et al* article titled "Monitoring rapid metabolic changes in health and type-1 diabetes with breath acetone sensors", Sensors and Actuators B: Chemical Volume 367, 15 September 2022, 132182 subtle breath acetone changes during fasting, exercise and glucose ingestion are tracked in two model situations: Patients suffering

from type-1 diabetes mellitus (T1DM) and healthy subjects (total: 19 volunteers) were monitored using chemoresistive sensors based on Si/WO3 nanoparticles.

Arpit Verma *et al* article titled "Detection of acetone via exhaling human breath for regular monitoring of diabetes by low-cost sensing device based on perovskite BaSnO3 nanorods", Sensors and Actuators B: Chemical Volume 361, 15 June 2022, 131708, discloses BaSnO3 based quick responsive and highly sensitive acetone biosensor for the sensing of low concentration acetone in the human breath.

Mahendra R. Jadhav *et al* article titled "Breath-based biosensors and system development for noninvasive detection of diabetes: A review", Diabetes & Metabolic Syndrome: Clinical Research & Reviews Volume 18, Issue 1, January 2024, 102931, discloses Breath-based biosensor technologies are capable for diabetes detection. The acetone biosensor detection ranges from 100 ppb to 100 ppm, and it is applicable from room temperature to 400°C. In healthy volunteers, acetone level ranges from 0.32 to 2.19 ppm, while patients with diabetes exhibit a wider range of 0.22–21 ppm depending on the biosensor, detection method, and clinical circumstances of patients and lab conditions. It specifically discloses MOX and MEMS-based acetone biosensors which involves the detection of acetone through its interaction with the sensing material or surface. It specifically discloses that Acetone detection methods are promising but unable to provide concrete correlation between breath acetone and blood glucose level.

So, the available devices are not able to provide concrete correlation between breath acetone and blood glucose level.

Mizaj Shabil Sha *et al* article titled "Breath Analysis for the In Vivo Detection of Diabetic Ketoacidosis", ACS Omega 2022, 7, 4257-4266 discloses the detection of ketones in the breath and blood is key to diagnosing and managing diabetic ketoacidosis (DKA) in patients with type 1 diabetes. The present article specifically states that it evaluates the efficiency of colorimetry for detecting acetone and ethanol in exhaled human breath with the response time, pH effect, temperature effect, concentration effect, and selectivity of dyes.

So, problem is present in the state-of-art is that the available breadth analysing devices are not provide the patient's glucose level and diabetes mellitus accurately and are expensive in nature. Further, few of the available devices needs skilled person to operate and is bulky.

Therefore, there is a need for a portable breath analyzer device for detection of diabetes mellitus which is economical and also provide the accurate result of the glucose level in the diabetic patient.

However, none of these prior art documents effectively address all of the problems with the state of the art. There is, therefore, a need in the art to provide a solution that obviates above-mentioned limitations.

It is desired to address or ameliorate one or more of the shortcomings, disadvantages or problems associated with prior systems or devices, or to at least provide a useful alternative thereto.

OBJECTS OF THE PRESENT INVENTION

Some of the objects of the present disclosure, which at least one embodiment herein satisfies are as listed herein below.

The object of the present invention is to provide a portable breath analyzer device for detection of diabetes mellitus.

Yet another object of the present invention is to provide an economical breath analyzer device for detection of diabetes mellitus.

Yet another object of the present invention is to provide a portable breath analyzer device that detects acetone level and carbon dioxide level of breath of the patient.

Yet another object of the present invention is to provide a portable breath analyzer device that can detect the glucose level by any person and no skilled person is required to detect the glucose level of user.

Yet another object of the present invention is to provide a breath analyzer that displays the user instruction and device results, the buzzer is also for indicating the user for different device instructions.

SUMMARY

In order to solve or at least alleviate the problems as discussed above, the present invention provides a technical solution for accurate detection of diabetes mellitus and measuring glucose level using acetone level and carbon dioxide level and other gas level of an user using the present breath analyzer device.

The present invention relates to a breath analyzer device for detection of diabetes mellitus which is portable and economical and detects the glucose level and diabetes mellitus of user accurately. Further, the present invention also relates to a method for use of the breath analyzer device for detection of diabetes. In addition, no skilled person is required to detect the glucose level using the present invention.

The present invention also describes a breath analyzer device with a combination of sensors that can detect multiple gases in exhaled human breath.

In one embodiment, a portable breath analyzer device that detects multiple gases in exhaled human breath is described. The portable breath analyzer device comprises

a housing comprising a breath flow pathway within the housing;

a breath inlet positioned at an entrance of the breath flow pathway;

a plurality of sensors positioned in the breath flow pathway, downstream from the breath inlet, wherein each sensor is configured to detect the presence of a biomarker indicative of diabetes mellitus;

a breath outlet positioned at an exit of the breath flow pathway;

a display to show the user instruction and test results;

a buzzer to automatically indicate an audio signal;

a power unit to provide stable and filtered voltage outputs essential;

a. RC filter circuits to enhance the quality of the power supply; and

a controller to communicate with various sensors and converts analog signals to digital for further processing.

In some embodiments, the biomarker may be selected from the group consisting of carbon dioxide(CO_2), acetone, temperature, humidity and airflow. Each sensor may be selected from the group consisting of a CO_2 selective sensor, an acetone sensor, a temperature sensor, a humidity sensor, an airflow sensor.

In another embodiment, a method for detection of glucose level of an user using the breath analyzer device is also described. The method includes:

- flowing a breath gas sample into a housing comprising a breath flow pathway i.e. mouthpiece within the housing;
- flowing the breath gas sample through a breath inlet positioned at an entrance of the housing;
- exposing at least a portion of the breath gas sample to a plurality of sensors positioned in the breath flow pathway, downstream from the breath inlet;
- releasing at least a portion of the breath gas sample through a breath outlet positioned at an exit of the breath flow pathway; and
- showing result on a display as present on the housing.

Each sensor is configured to detect the presence of a biomarker indicative of diabetes mellitus and especially the sensors include carbon dioxide (CO_2), acetone, temperature, humidity and airflow.

In addition, an apparatus for detecting glucose level to detect diabetes mellitus comprises:

a housing, a breath gas inlet, a CO_2 sensor element, an acetone sensor, and a breath outlet. The housing comprises a breath flow pathway disposed within the housing. The breath gas inlet is positioned at an entrance of the breath flow pathway. The CO_2 sensor element is positioned in the breath flow pathway, downstream from the breath inlet.

Further, downstream from the CO_2 sensor element, the acetone sensor element is positioned in the breath flow pathway, and then downstream from the acetone sensor, the temperature and humidity sensors are positioned. Further, the regulators are connected to the temperature and humidity sensors, acetone sensor and CO_2 sensor to regulate the functioning of the sensors. Thereafter, the other end of the sensors is connected to the controller which controls the functioning of the sensors and lastly the display is positioned next to the controller to show the test results. Finally, the breath outlet is positioned at an exit of the breath flow pathway, downstream from the sensor elements to release the air.

Further, described is a method for detecting glucose level to detect diabetes mellitus that includes:

- flowing a breath gas sample through a breath inlet positioned at an entrance of a housing;
- exposing the breath gas sample to a CO_2 sensor detection element positioned in the breath flow pathway, downstream from the breath inlet;
- exposing the breath gas sample to an acetone sensor detection element positioned in the breath flow pathway, downstream from the CO_2 sensor detection element;
- exposing the breath gas sample to a temperature and humidity sensor detection element positioned in the breath flow pathway, downstream from the acetone sensor detection element
- adding temperature correction factor to the breath analysis result;
- implementing filter at the output to remove high frequency noise in the result;
- releasing the breath sample through a breath outlet positioned at an exit of the breath flow pathway; and
- showing result of the test on the display.

In some embodiments, a sensor may include multiple sensor units, each providing one or more signals that may be indicative of the presence or concentration of a particular analyte. The analyte may be detected, or its concentration estimated, based on the signals obtained from the multiple sensor units.

Fewer than the sensors described in the above examples, additional sensors, different combinations, other sensors, or sub - combinations of the described sensors may be used for the detection of respiratory disease. Moreover, the sensors and related components may be positioned in different configurations and breath flow pathways than those described in the above examples.

The summary is provided to introduce the system as a representative concept in a simplified form that is further described below in the detailed description. This summary is not intended to limit the key essential features of the present invention nor its scope and application.

Other objectives, features and advantages of the enclosed embodiments will be apparent from the following detailed disclosure, from the attached dependent claims as well as from the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings are included to provide a further understanding of the present disclosure and are incorporated in and constitute a part of this specification. The drawings illustrate exemplary embodiments of the present disclosure and, together with the description, serve to explain the principles of the present invention.

FIG. 1 provides a block diagram of the breath analyzer device to detect diabetes mellitus in accordance with the present invention.

FIG. 2 illustrates top view of flow sensor cover of a breath analyzer device to detect diabetes mellitus in accordance with the present invention.

FIG.3 illustrates left side view of flow sensor of a breath analyzer device to detect diabetes mellitus in accordance with the present invention.

FIG. 4 illustrates front view of a breath analyzer device to detect diabetes mellitus in accordance with the present invention.

FIG. 5 illustrates bottom view of a breath analyzer device to detect diabetes mellitus in accordance with the present invention.

FIG. 6 illustrates backside view of a breath analyzer device to detect diabetes mellitus in accordance with the present invention.

FIG. 7 illustrates workflow of a breath analyzer device to detect diabetes mellitus in accordance with the present invention.

FIG. 8 illustrates device engagement process of a breath analyzer device to detect diabetes mellitus will work in accordance with the present invention.

FIG. 9 shows a graphical relation between acetone gas PPM with respect to shut and load resistor ratio in accordance with one embodiment of the invention.

FIG. 10 shows a graphical relation between the shunt resistor and load resistor ratio with respect to change in temperature in accordance with one embodiment of the invention.

The present invention can be understood with reference to the detailed figures and description set forth herein. Various embodiments are discussed below with reference to the figures. However, those skilled in the art will readily appreciate that the detailed descriptions given herein with respect to the figures are simply for an explanation of the invention as the methods and systems may extend beyond the described embodiments. For example, the teachings presented and the needs of a particular application yield multiple alternatives and suitable approaches to implement the functionality of any detail described herein. Therefore, any approach extends beyond the particular implementation choices in the following embodiments described and shown.

References to “one embodiment,” “at least one embodiment,” “an embodiment,” “one example,” “an example,” “for example,” and so on indicate that the embodiment(s) or example(s) may include a particular feature, structure, circuit, architecture, characteristic, property, element, or limitation but that not every embodiment or example necessarily includes that particular feature, circuit, architecture, structure, characteristic, property, element, or limitation. Further, repeated use of the phrase “in an embodiment” does not necessarily refer to the same embodiment.

DESCRIPTION:

In order to make the technical solution of the present invention better understood, the technical solution of the embodiments of the present invention will be clearly and completely described below with reference to the accompanying drawings in the embodiments of the present invention, and it is obvious that the described embodiments are only some embodiments of the present invention, not all embodiments. Based on the embodiments in the present invention, all other embodiments obtained by a person skilled in the art without creative efforts shall belong to the protection scope of the present invention.

The present invention relates to a breath analyzer device for detection of diabetes mellitus which is portable and economical and detects the glucose level of user accurately. Further, the present invention also relates to a method for use of the breath analyzer device for detection of diabetes.

The present invention also describes a breath analyzer device with a combination of sensors that can detect multiple gases in exhaled human breath.

As shown in FIG. 1, a block diagram of the breath analyzer device to detect diabetes mellitus in accordance with the present invention is given. The portable breath analyzer device (100) that detects multiple gases in exhaled human breath is described. The portable breath analyzer device (100) comprises:

a housing (101) comprising a breath flow pathway within the housing;
a breath inlet (102) positioned at an entrance of the breath flow pathway;
a plurality of sensors (103, 104, 105) positioned in the breath flow pathway, downstream from the breath inlet, wherein each sensor is configured to detect the presence of a biomarker indicative of diabetes mellitus;
a display (115) to show the user instruction and test results;
a buzzer (116) to automatically indicate an audio signal;
a power unit (125) to provide stable and filtered voltage outputs essential;
a. plurality of regulators (107A &B) to regulate the sensors;
a controller (130) to communicate with various sensors and converts analog signals to digital for further processing; and
a breath outlet (120) positioned at an exit of the breath flow pathway;

The breath inlet (102) is positioned at an entrance of the breath flow pathway is the mouthpiece opening through which the user/patient will pass the breath inside the portable breath analyzer device 100. The portable breath analyzer device (100) includes the housing (101) comprises a breath flow inlet (102) disposed within the housing (101). The breath gas inlet (102) i.e. the mouthpiece is positioned at an entrance of the breath flow pathway. Next to the breath flow inlet (02), the CO_2 sensor element (103) is

positioned in the breath flow pathway, downstream from the breath inlet (102). Further, downstream from the CO_2 sensor element (103), the acetone sensor element (104) is positioned in the breath flow pathway, and then downstream from the acetone sensor (104), the temperature and humidity sensors (105) are positioned. Further, the regulators (107A&B) are connected to the temperature and humidity sensors, acetone sensor and CO_2 sensor to regulate the functioning of the sensors. Thereafter, at the other end of the sensors, the controller (130) is connected to control the functioning of the sensors and lastly the display (115) is positioned next to the controller (130) to show the test results. Finally, the breath outlet (120) is positioned at an exit of the breath flow pathway, downstream from the sensor elements.

Further, an air flow sensor (110) is present between the regulators (107) and the controller (130) to properly flow the air inside the portable breath analyzer device (100) for its proper functioning. In addition, a buzzer (116) is also present to automatically indicate an audio signal when there is an abnormality in the device (100) or when any function is completed.

The microcontroller (130) is integrated RF communication in this device, making it ideal for IoT applications. It features dual-core CPUs with clock speeds up to 240 MHz, providing high processing power for complex tasks. The microcontroller (130) supports RF communication technologies like Wi-Fi and Bluetooth (both Classic and BLE), enabling seamless wireless connectivity.

Further, with multiple ADC (Analog-to-Digital Converter) channels, the microcontroller (130) can interface with various sensors such as acetone sensor, CO_2 sensor and other, converting analog signals to digital for further processing. Its built-in UART (Universal Asynchronous Receiver-Transmitter) facilitates reliable serial communication, allowing integration with peripherals like GPS modules, displays, and other serial devices. This combination of RF, processing power, and peripheral

interfaces makes the microcontroller highly versatile for real-time, connected applications.

Further, the power unit (121) is connected to the sensors to provide stable and filtered voltage outputs essential. The power unit (121) is a critical component designed to provide stable and filtered voltage outputs essential for various electronic devices. The power unit (121) includes two primary voltage regulators: regulator 1 i.e. 107A which is a 5V regulator and regulator 2 i.e. 107B which is a 3.3V regulator, each equipped with RC (Resistor-Capacitor) filter circuits to ensure clean and stable power. The 5V regulator, typically using an AMS117_5 linear voltage regulator, converts a higher input voltage (such as 7-12V) to a stable 5V output. This 5V output is then fed into the 3.3V regulator, often anAMS117_3.3, which steps down the voltage further to a stable 3.3V output necessary for components operating at this voltage level.

The power unit (121) further includes a battery (125) and a charging module is also connected to the power unit (121) to charge the device.

Further, to enhance the quality of the power supply, RC filter circuits are implemented at the output of each voltage regulator. These filters, consisting of resistors and capacitors, and they effectively remove high-frequency noise and transient voltage spikes and ensures a smooth and clean DC output.

The non-exhausted breath gas is channeled through a breath flow pathway and the breath will passes through the sensors i.e. the CO_2 sensor, acetone sensor and temperature and humidity sensors.

The CO_2 selective sensor may be selected from a variety of commercially available sensors known in the art for detecting the presence of the compound in a gas. Specifically, MH-Z19 NDIR infrared gas module CO_2 gas sensor is used which is a compact and common sensor designed to detect the presence of CO_2 in the air using the non-dispersive infrared (NDIR) principle. This sensor leverages the ability of gases

to absorb specific wavelengths of infrared light. The sensor contains an infrared light source that emits light across a broad spectrum, including the wavelengths absorbed by CO_2 molecule. As this light passes through a sample chamber filled with air, the CO_2 molecules absorb their specific wavelengths. An optical filter then isolates these wavelengths before the remaining light reaches an infrared detector, which measures the light intensity. The difference between the emitted and detected light is proportional to the CO_2 concentration.

The acetone selective sensor may be selected from a variety of commercially available sensors known in the art for detecting the presence of the compound in a gas. Specifically, WSP2110 VOC gas sensor is utilized which uses multilayer thick film manufacturing technology, integrating a heater and metal oxide semiconductor material onto a ceramic substrate of subminiature Al_2O_3. This assembly is connected through electrode down-leads and encapsulated within a metal socket and cap. For operation, the WSP2110 requires two voltage inputs: a heater voltage (VH) to maintain the sensor at its standard working temperature, and a circuit voltage (VC) to provide the detection voltage to the load resistance (RL) in series with the sensor. VH can be supplied via DC or AC power, while VC should be DC. The voltage across the load resistance (VRL) is used to determine the sensor's response to the gas concentration, making it effective for detecting volatile organic compounds in various applications

The temperature and humidity sensor may be selected from a variety of commercially available sensors known in the art for detecting the presence of the compound in a gas. Specifically, AHT20 is a next-generation temperature and humidity sensor which detects the temperature and humidity of the patient's sample. The temperature sensor is present to compensate for temperature variations, ensuring accurate readings. Encased in a double row, flat, no-lead package suitable for reflow soldering, it measures just 3 x 3 mm at the base and 1.0 mm in height. The sensor outputs calibrated digital signals in a standard I²C format. The AHT20 features a newly designed ASIC

chip, an enhanced MEMS semiconductor capacitive humidity sensing element, and an on-chip temperature sensor. This advanced design significantly improves performance, stability, and durability in harsh environments compared to previous models. Each sensor undergoes calibration and testing, with a batch number printed on its surface for traceability. The miniaturization and enhanced efficiency of the AHT20 make it a cost-effective choice, benefiting all devices through its cutting-edge energy-saving operation mode.

As all the sensors are enclosed in the body of the device, the device needs to have a constant value of breath/air inside the enclosure to make an ideal environment to calculate the correct sensor values, it is also a correction factor to get more accurate values of concentrations. So, the airflow sensor is present to make an ideal environment inside the device to calculate the correct sensor values.

FIG. 2 illustrates the top view of a breath analyzer device to detect diabetes mellitus in accordance with the present invention. It shows the top outer cover (201) for the air flow sensor (110) which includes a cutout (210) for inlet of flow sensor and slots (220) forholding the outer cover to main housing (101). Further, Fig. 3 illustrates the left side vide of the portable breath analyzer device (100) wherein there is place for air flow/breath inlet (102) mouthpiece to enter the air inside the device for the test. The design of the device is such that it is comfortable for the user to hold in a hand and put the proper and/or optimum amount of breath inside the mouthpiece and maximum amount of air can enter inside the device (100).

Fig. 3 illustrates the left side view of the portable breath analyzer device (100) in accordance with the present invention. The breath analyzer device 100 includes the housing (101) which is the outer enclosure for covering the sensors in shape. Further, hinges (151) are also present for connecting and holding the cover with the main enclosure or housing (101).

Fig. 4 illustrates the front view of the portable breath analyzer device (100) in accordance with the present invention. The housing (101) includes a front side with a display 115 to show the result of the breath test and at the top side of the device, the cutout (210) for inlet of flow sensor is present. Thereafter, Fig. 5 illustrated the bottom view of the portable breath analyzer device (100) in accordance with the present invention. At the bottom side of the device, holes (161) are present.

The back side view of the portable breath analyzer device (100) in accordance with the present invention is shown in Fig. 6. It includes a plurality of space for battery cells where the battery cells can be fitted. Further, the battery cell space (191) is also partitioned by the battery cell partition (192) to make partitioned between the batteries. Further, on the top side of the device (100), holes 181 are present for air outlet, so, that there is proper air flow inside the device (100). Thereafter, on the lower side of the device (100) one another hole (182) is present to screw the back cover with the front cover.

Further, on one side of the device a switch button is provided which is a power switch and is used switch ON and OFF the device.

The workflow of the device (100) is illustrated as flow chart in Fig. 7. It illustrates the steps of workflow of device (100) which includes:

At Step 701- the power of the device (100) will be ON, then at step 702, the user display (115) will show the instruction/s to the user. Then at step 703, the user will blow the breath in the mouthpiece (102) and as soon as the breath will enter inside the device (100), at step 704, the sensors (103, 104) will detect the amount required to proceed. Then at next step 705, when the sufficient gas will enter inside the device then the buzzer (116) will beep at step 706. Further, the sensors (103, 104) will get activated and the CO_2 gas sensor (103) will start reading the CO_2 PPM at step 707 and then, at step 708, the acetone sensor (104) will also get activated and will start reading the VOC

PPM. Further, at next step 709, the temperature sensor (105) will get activated and the temperature correction factor is added. Thereafter, at next step 710, the RC filters will be applied to enhance the quality of the power supply, RC filter circuits are implemented at the output of each voltage regulator. Then, at step 711, the result will be shown on the display (115). Thus, the work of the device (100) is completed and then at step 712, the buzzer (116) will again beep that the work has been completed. Then, at step 713, the result will be updated in the server, so, whenever, the result is required, it can be easily accessible to the user. Finally, at step 714, when the work is done, the user will power off the device (100).

Thus, the method for detecting glucose level of the user using the portable breath analyzer device (100) includes that air gas sample through a breath inlet (102) as positioned at an entrance of a housing (101) is flown by the user. Then, the breath gas sample is exposed to the CO_2 sensor detection element (103) positioned in the breath flow pathway, downstream from the breath inlet (102). The CO_2 gas sensor (103) will detect the reading of CO_2 PPM. Further, the breath gas sample will move towards the acetone sensor detection element (104) positioned in the breath flow pathway, downstream from the CO_2 sensor detection element (103). The acetone gas sensor (104) will detect the reading of VOC PPM as present in the user breath. Then, the breath gas sample is exposed to a temperature and humidity sensor detection element (105) positioned in the breath flow pathway, downstream from the acetone sensor detection element (104). The temperature sensor will add temperature correction factor in the sample result. Further, filters are implemented at the output (120) to remove high frequency noise in the result and finally the breath sample is released through the breath outlet (120) positioned at an exit of the breath flow pathway, and finally, the result of the test will be shown on the display (115).

Further, the device engagement process is also shown in Fig. 8 as a flow chart. According to one embodiment of the invention, the device engagement process includes the following steps:

- At step 801, the power on the device (100) is switch ON from the side power switch;
- Then, at step 802, the user will wait for ready to use message on the display (115);
- Then at step 803, the user will hold the device (100) in the hand and will put the mouth above the mouthpiece (102);
- Thereafter, at step 804, the user will blow air in the mouthpiece and wait for a beep from the buzzer (116);
- Further, at step 805, the user will wait for the result to be shown on the display (115); and
- Finally, at step 806, the user will power off the device (100) after the use.

WORKING EXAMPLE

According to one embodiment of the present invention, the combined use of these sensors enables the breath analyzer device to account for various physiological and environmental factors that may influence breath analysis and ensure accurate non-invasive glucose monitoring. Further, the process that how the device integrates data from multiple sensors such as acetone, carbon dioxide (CO_2), flow, temperature, and humidity sensors to accurately predict blood glucose levels is shown below:

1. Data Collection from Multiple Sensors

The breath analyzer device is equipped with a suite of sensors that capture various physiological and environmental parameters. These sensors measure:

- Acetone Concentration (in ppm): A biomarker linked to glucose metabolism, correlating with lower blood glucose levels.

- CO_2 Concentration (in ppm): CO_2 levels also act as a biomarker for glucose levels and also provide insights into the user's breathing pattern and lung function, which can help correct for variability in breath composition.

- Flow Rate: The flow sensor captures the user's blowing pattern, which includes the rate and volume of the exhaled breath. This data helps adjust for inconsistencies between individuals and ensures that the breath sample is analyzed under optimal conditions.

- Temperature and Humidity: Environmental factors like temperature and humidity can influence sensor readings. Accurate measurement of these parameters allows for the correction of sensor outputs, ensuring that ambient conditions do not skew the results.

2. Preprocessing of Sensor Data

Each sensor provides real-time data in its respective unit (PPM for acetone and CO_2, liters per minute for flow, and degrees Celsius/relative humidity). The raw data undergoes a preprocessing stage to ensure it is suitable for input into the model to learn the glucose level detection. Preprocessing steps include:

- Noise Reduction: Noise filtering techniques are applied to smooth out fluctuations in sensor data that may arise due to environmental interference or irregular breath patterns.

- Normalization: The raw sensor values are normalized based on expected physiological ranges. This ensures that variations in breathing effort, temperature, or humidity are accounted for, preventing distortions in the glucose predictions.

3. Feature Extraction and Engineering

Once the sensor data is preprocessed, the system extracts relevant features that are critical for predicting glucose levels. These features include:

- Acetone and CO_2 Concentration Patterns: The breath analyzer device identifies trends in acetone and CO_2 concentrations over the course of a breath cycle. Fluctuations in these concentrations provide insights into metabolic activity and the user's glucose state.

- Blow Flow Characteristics: The flow sensor data helps distinguish between shallow and deep breaths, ensuring that only valid breath samples are used for glucose analysis. The breath analyzer device also evaluates flow rate consistency and total breath volume to standardize the breath sample for each user.

- Environmental Adjustments: Temperature and humidity levels are factored into the model to correct any sensor drift caused by changing environmental conditions. These adjustments improve accuracy by ensuring that sensor readings reflect physiological changes rather than environmental noise.

4. Prediction Model

The core of the process is a model that correlates the combined sensor data with glucose levels. This model is trained using a large dataset of breath measurements paired with laboratory-validated blood glucose readings. The training process involves:

- Multimodal Data Integration: The method integrates data from all the sensors (acetone, CO_2, flow, temperature, and humidity) to create a multidimensional feature space. This approach allows the model to identify complex relationships between breath composition, environmental factors, and glucose levels.

- Training and Optimization: The model uses supervised techniques such as regression models, decision trees, or neural networks. These models are trained and optimized to minimize prediction errors. Training involves feeding the model with historical data, which includes paired glucose readings from both invasive methods (e.g., finger-prick tests) and breath analysis.

- Formula: The final prediction model uses a complex, nonlinear function to predict blood glucose levels based on sensor inputs. Following formula is used to determine the blood glucose level of the user:

$$\text{Blood Glucose (mg/dL)} = f(\text{Acetone (ppm)}, \text{CO}_2 \text{ (ppm)}, \text{Flow Rate}, \text{Temperature}, \text{Humidity})$$

where (f) represents the function that optimally combines the sensor readings to predict glucose levels. The model dynamically adjusts based on new data collected during user interaction.

AND

$$\text{Blood Glucose (mg/dL)} = A \times (\text{Acetone (ppm)})^B + C$$

where *A, B, C* are constants derived from the training dataset through curve fitting and optimization techniques. These parameters are dynamically adjusted based on the user's historical data, refining predictions over time.

5. Personalization and Continuous Learning

Since breath composition can vary from person to person due to factors like metabolism, health status, and lifestyle, the breath analyzer device includes a personalization layer:

- Initial Calibration: Upon first use, the device establishes a baseline by comparing breath data with a known blood glucose reading obtained through invasive methods. This calibration ensures that the device tailors its predictions to the user's unique physiological profile.

- Adaptive Learning: As the user continues to use the device, it employs adaptive learning to refine its predictions. By learning from each new breath sample, the system improves its accuracy and reduces fluctuations in glucose level estimates.

6. Error Correction and Validation

To ensure accuracy and clinical validity, the model incorporates error correction techniques and is validated against standard glucose measurement methods:

- Cross-Validation: The model is regularly cross-validated using controlled lab data to ensure that it meets accuracy standards (with the goal of achieving 95%+ accuracy).

7. Output and User Interface

After processing the sensor data's through the model of the breath analyzer device, the breath analyzer device outputs the predicted blood glucose level. The results are displayed on the device interface in a user-friendly manner, providing not only the glucose reading but also feedback on the user's breath pattern and environmental conditions, if necessary.

The device may also offer insights into glucose trends over time and suggest corrective actions for users managing diabetes, such as dietary adjustments or insulin administration, based on their glucose readings.

Thus, this multi-sensor and advance approach enables the breath analyzer device to offer accurate, non-invasive glucose monitoring by considering not just acetone as a biomarker, but also CO_2 levels, breath flow patterns, and environmental factors such as temperature and humidity. This process is designed to ensure high accuracy, personalization, and adaptability, making it a pioneering solution in the field of non-invasive diabetes management.

RESULTS

In the acetone sensor, R_L refers to the load resistor that is part of the sensor circuit. It is connected across the sensor output, and the voltage measured across RL is used to

determine the concentration of acetone in the air. This voltage, in turn, allows the calculation of the acetone concentration in parts per million (PPM) by establishing a relationship between the measured voltage and gas concentration.

Ro represents the baseline resistance of the sensor when it is exposed to clean air. This value is critical because it serves as a reference point to detect the presence of acetone or other gases. Any change in the sensor's resistance (Rs) when exposed to a gas is compared to Ro to measure the gas concentration.

Therefore, the acetone concentration is calculated by measuring the voltage across R_L and using Ro as a reference to detect deviations in sensor resistance caused by acetone. This method ensures accurate detection and quantification of acetone in the environment.

The relationship between acetone and others are shown in the graphs.

Fig. 9 graph shows a relation between acetone gas PPM with respect to shut and load resistor ratio and this graph is helpful to determine the PPM of acetone from the given ratio, so we will extract the best-fit equation from this graph to calculate the acetone PPM value for corresponding ratio.

Further, Fig. 10 graph shows a relation between the shunt resistor and load resistor ratio with respect to change in temperature, it is used to correct the PPM value in different environment conditions.

Thus, a relation between gas PPM and output voltage and resistors are measured which provide an accurate measurement of diabetes mellitus using the present device.

According to a first aspect of the invention, the breath analyzer device 100 comprises a gas flow pathway for passage of exhaled breath from an inlet to an outlet.

When using the device, a subject/user/patient breathes into the device at the inlet of the device air flow pathway. Preferably, the entire exhaled breath of the user is led to the pathway and the pathway is filled with the exhaled breath when the user exhales the device.

To facilitate the user exhaling entirely into the device, the pathway may include at the inlet a facemask or a mouthpiece, for example.

Further, the portable breath analyzer device for detection of diabetes mellitus ensures that the power supplied to sensitive electronic components is free from fluctuations and noise, thereby improving the overall performance and reliability of the electronic system.

Advantageously, the present invention leads to the following outcomes:

- Provides a breath analyzer that is economical;
- Provides a breath analyzer that is portable;
- Provides a breath analyzer that detects the CO2 level and acetone level to detect the blood glucose level in an user;
- Provides a breath analyzer that accurately detects the blood glucose level based on CO_2 and acetone level;
- Provides a breath analyzer that can easily detects the blood glucose level and does not required any skilled person to use the device;

In some instances, the presence of volatile organic compounds (VOC gas) may interfere with the accuracy of the sensor readings, for example the accuracy of the readings for the CO_2 sensor. Thus, a temperature and humidity sensor are present to

detect the temperature and humidity as present inside the device 100. Further, one or more regulators are also present which regulates the proper functioning of the sensors.

It will be appreciated that fewer than the described sensors or additional sensors, different combinations, other sensors, or sub - combinations of the described sensors may be used to monitor medical conditions of interest. The device may also include one or more CO_2 sensors useful for the monitoring of glucose level. The detection of CO_2 may be particularly useful for diabetic patients undergoing therapy.

In another embodiment, a device may include sensors for CO_2 and acetone detection. Detection of these compounds may allow a clinician, patient, or other user to detect the glucose level. Further, the severe patients can continuously monitor their blood glucose levels based on the breath gas analysis.

In yet another embodiment, a device may include sensors for CO_2 and acetone detection to allow for diagnosis of glucose level.

In addition, the sensors and sensor modules may be used in combination with other sensors and sensor modules to test a given breath gas sample for biomarkers associated with multiple medical conditions. For example, the apparatus may include sensors for detecting known biomarkers for glucose level to detect diabetes, along with sensors for detecting known biomarkers for hyperglycemia and hypoglycemia.

In this configuration, the apparatus would allow for the detection of diabetes mellitus from a patient's breath sample using the same apparatus. The sensors and related components may be positioned in different configurations and breath flow pathways than those described in the above examples. For example, breath gas proceeding through the breath flow pathway may be exposed to the sensors in different sequences from those described in the above examples.

It should be understood that any of the embodiments of the present system can be implemented by using hardware or by use of combination of hardware and software.

Based on the disclosure and teaching provided herein, a person of ordinary skill in the art will know and appreciate other ways and/or methods to implement embodiments of the present invention using specific breath analyzer device.

Further, any of the methods describes herein may be totally or partially performed using the breath analyzer device, including one or more processors, which is configured to perform the steps described herein above. Thus, embodiments are directed towards electronic breath analyzer device including specific components to perform specific steps of any of the methods described herein above. Additionally, any of the steps of any of the methods can be performed using specific circuits.

A person with ordinary skills in the art will appreciate that the systems, circuit elements, modules, and sub-modules have been illustrated and explained to serve as examples and should not be considered limiting in any manner. It will be further appreciated that the variants of the above-disclosed circuit elements, modules, and other features and functions, or alternatives thereof, may be combined to create other different systems or applications.

While the present disclosure has been described with reference to certain embodiments and exemplary embodiments, it will be understood by those skilled in the art that various changes may be made and equivalents may be substituted without departing from the scope of the present disclosure. In addition, many modifications may be made to adapt a particular situation or material to the teachings of the present disclosure without departing from its scope.

We claim:

1. A portable breath analyzer device (100) to accurately measure diabetes mellitus comprises:

a housing (101) comprising a breath flow pathway within the housing;
a breath inlet (102) positioned at an entrance of the breath flow pathway;
a plurality of sensors (103, 104, 105) positioned in the breath flow pathway, downstream from the breath inlet, wherein each sensor is configured to detect the presence of a biomarker indicative of diabetes mellitus;
a display (115) to show the user instruction and test results;
a buzzer (116) to automatically indicate an audio signal;
a power unit (125) to provide stable and filtered voltage outputs essential;
a. plurality of regulators (107A &B) to regulate the sensors;
a controller (130) to communicate with various sensors and converts analog signals to digital for further processing; and
a breath outlet (120) positioned at an exit of the breath flow pathway.

2. The portable breath analyzer device (100) as claimed in claim 1, wherein the sensor is selected from the group consisting of acetone sensor (103), carbon dioxide sensor (104), temperature sensor and humidity sensor (105).
3. The portable breath analyzer device (100) as claimed in claim 1, wherein the biomarker may be selected from the group consisting of carbon dioxide (CO_2), acetone, temperature, humidity and airflow.
4. The portable breath analyzer device (100) as claimed in claim 2, wherein the CO_2 sensor element is positioned in the breath flow pathway, downstream from the breath inlet (102).
5. The portable breath analyzer device (100) as claimed in claim 2, wherein the temperature and humidity sensors (105) are positioned in downstream from the acetone sensor (103).
6. The portable breath analyzer device (100) as claimed in claim 2, wherein a plurality of regulator are connected to the temperature and humidity sensors (105), acetone sensor (103) and CO_2 sensor (104) to regulate the functioning of the sensors.
7. A method for detecting glucose level to detect diabetes mellitus with a portable breath analyzer device (100) comprising:

flowing a breath gas sample through a breath inlet (102) positioned at an entrance of a housing;

exposing the breath gas sample to a CO_2 sensor (104) detection element positioned in the breath flow pathway, downstream from the breath inlet;

exposing the breath gas sample to an acetone sensor (103) detection element positioned in the breath flow pathway, downstream from the CO_2 sensor (104) detection element;

exposing the breath gas sample to a temperature and humidity sensor (105) detection element positioned in the breath flow pathway, downstream from the acetone sensor detection element;

detecting raw data from the acetone senor (103), CO_2 sensor (104) and temperature and humidity sensor (105);

adding temperature correction factor to the breath analysis result;

implementing filter at the output to remove high frequency noise in the result;

releasing the breath sample through a breath outlet (120) positioned at an exit of the breath flow pathway; and

showing result of the test on the display.

8. The method for detecting glucose level to detect diabetes mellitus with a portable breath analyzer device (100) as claimed in claim 7, wherein the raw data as captured from sensors (103, 104, 105) undergoes a preprocessing stage to ensure it is suitable for input into the model to learn the glucose level detection.

9. The method for detecting glucose level to detect diabetes mellitus with a portable breath analyzer device (100) as claimed in claim 8, wherein the preprocessing steps comprises:

- Noise Reduction wherein noise filtering techniques are applied to smooth out fluctuations in sensor data that may arise due to environmental interference or irregular breath patterns; and

- Normalization wherein the raw sensor values are normalized based on expected physiological ranges which ensures that variations in breathing effort, temperature, or humidity are accounted for, preventing distortions in the glucose predictions.

10. The method for detecting glucose level to detect diabetes mellitus with a portable breath analyzer device (100) as claimed in claim 8, wherein after the preprocessing step, a prediction tedchnique is used to minimize prediction errors.

11. The method for detecting glucose level to detect diabetes mellitus with a portable breath analyzer device (100) as claimed in claim 10, wherein the prediction technique is regression model, decision trees, or neural networks.

12. The method for detecting glucose level to detect diabetes mellitus with a portable breath analyzer device (100) as claimed in claim 11, wherein the prediction technique uses a complex, nonlinear formula to predict blood glucose levels based on sensor inputs

$$\text{Blood Glucose (mg/dL)} = f(\text{Acetone (ppm)}, \text{CO}_2\text{ (ppm)}, \text{Flow Rate}, \text{Temperature}, \text{Humidity})$$

13. The method for detecting glucose level to detect diabetes mellitus with a portable breath analyzer device (100) as claimed in claim 11, wherein the prediction technique uses a complex, nonlinear formula to predict blood glucose levels based on sensor inputs

$$\text{Blood Glucose (mg/dL)} = A \times (\text{Acetone (ppm)})^B + C$$

Dated this **09th day** of **October, 2024.**

Archana Singh

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PORTABLE BREATH ANALYZER DEVICE FOR DETECTION OF DIABETES

ABSTRACT

The present invention relates to a breath analyzer device (100) with a combination of sensors that can detect multiple gases in exhaled human breath. The portable breath analyzer device (100) that detects multiple gases in exhaled human breath is described. The portable breath analyzer device comprises a housing (101) comprising a breath flow pathway within the housing; a breath inlet (102) positioned at an entrance of the breath flow pathway; a plurality of sensors (103, 104, 105) positioned in the breath flow pathway downstream from the breath inlet (102), wherein each sensor is configured to detect the presence of a biomarker indicative of diabetes mellitus; a breath outlet (120) positioned at an exit of the breath flow pathway; a display (115) to show the user instruction and test results; a buzzer (116) to automatically indicate an audio signal; a power unit (125) to provide stable and filtered voltage outputs essential; a. RC filter circuits to enhance the quality of the power supply; and a controller (130) to communicate with various sensors and converts analog signals to digital for further processing.

Fig.1.

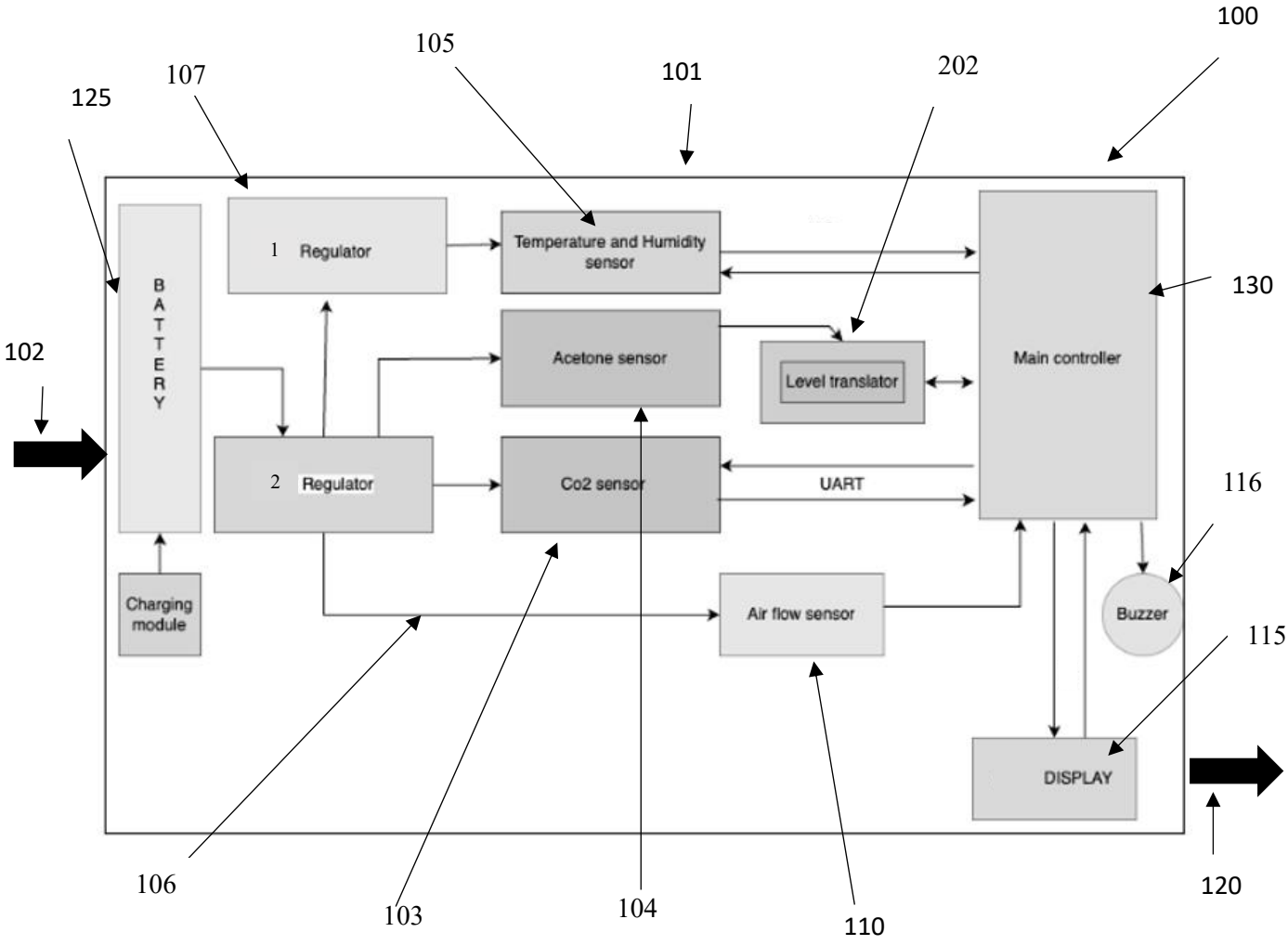

Fig.1.

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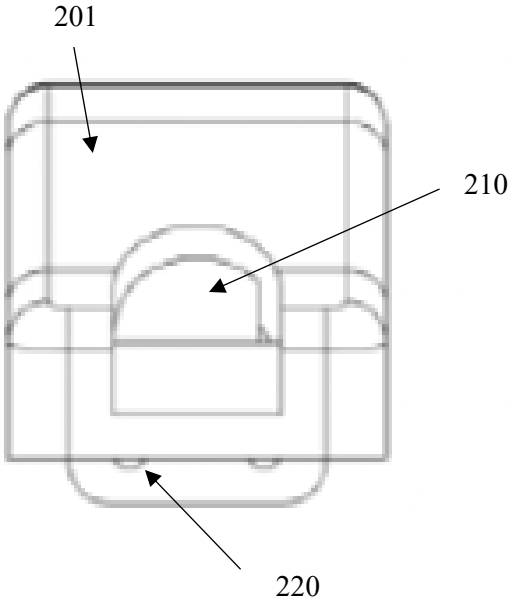

Fig.2.

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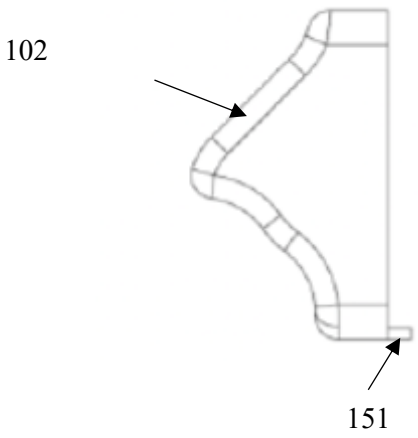

Fig.3.

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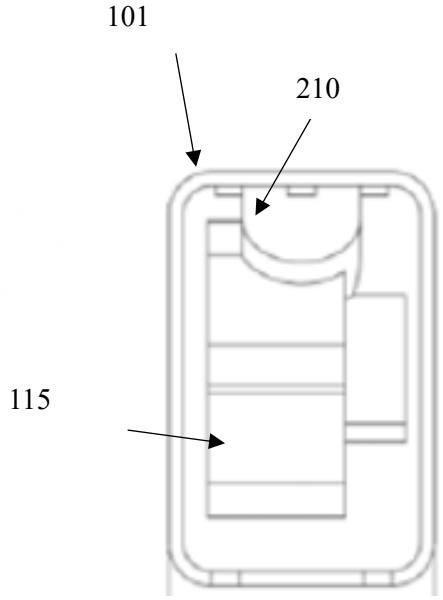

Fig.4.

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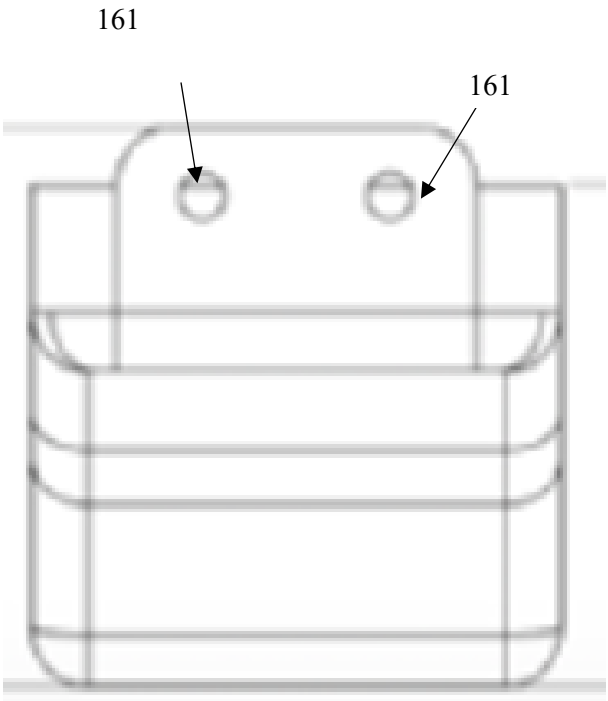

Fig. 5.

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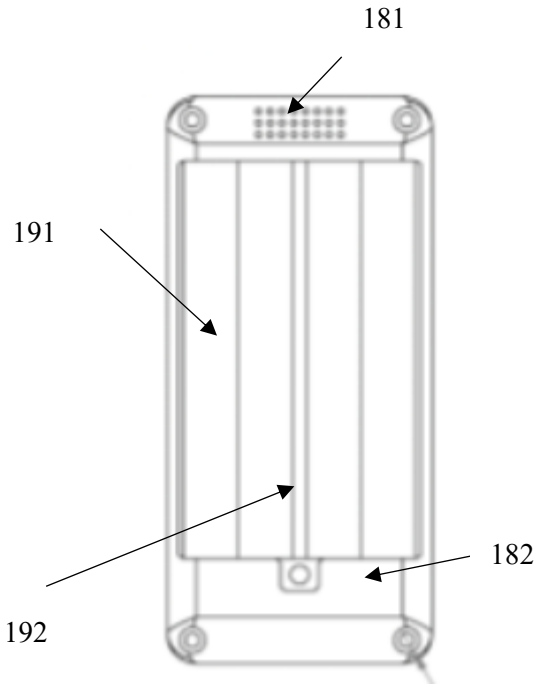

Fig. 6.

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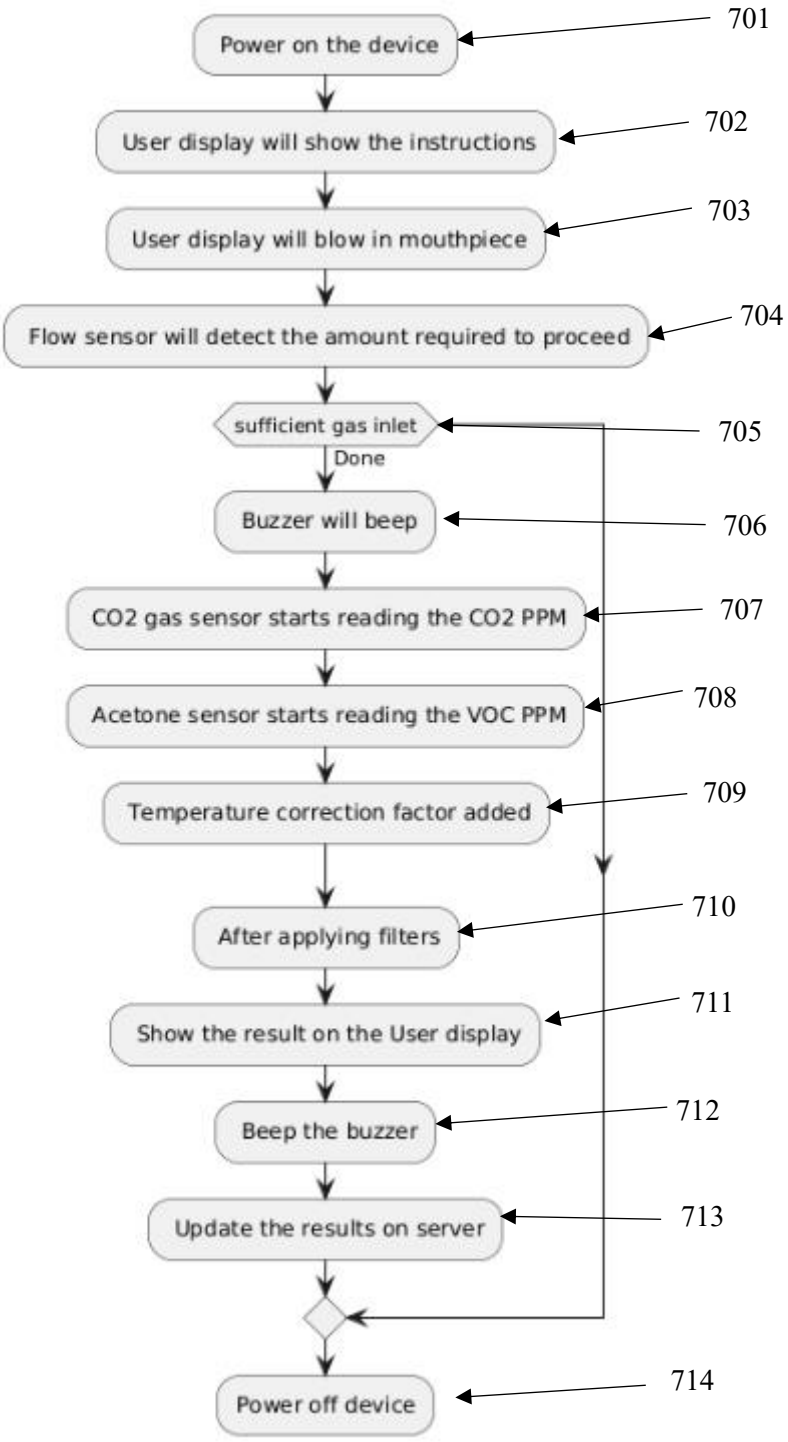

Fig. 7

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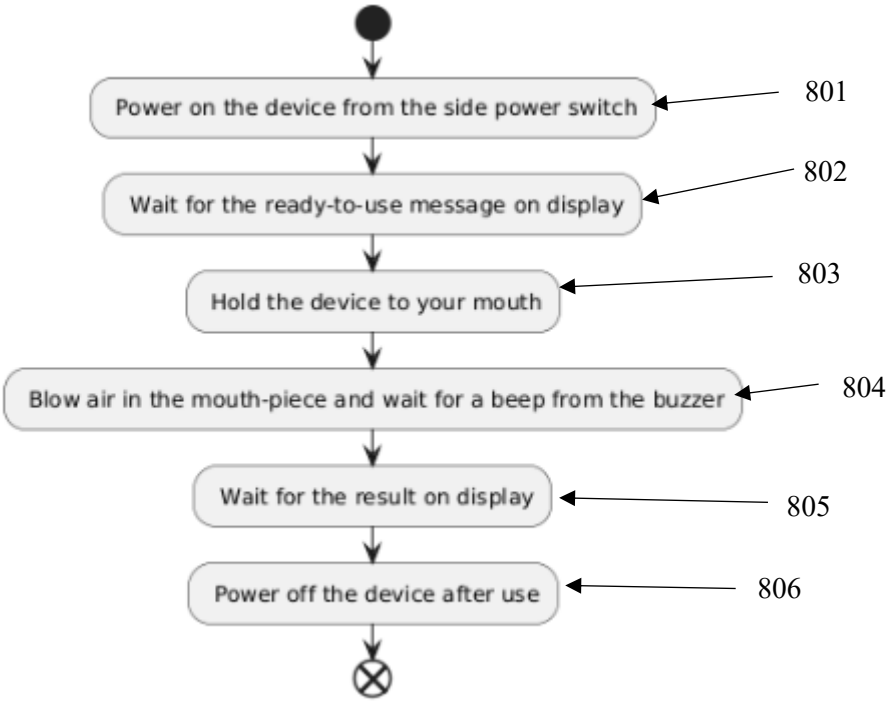

Fig. 8

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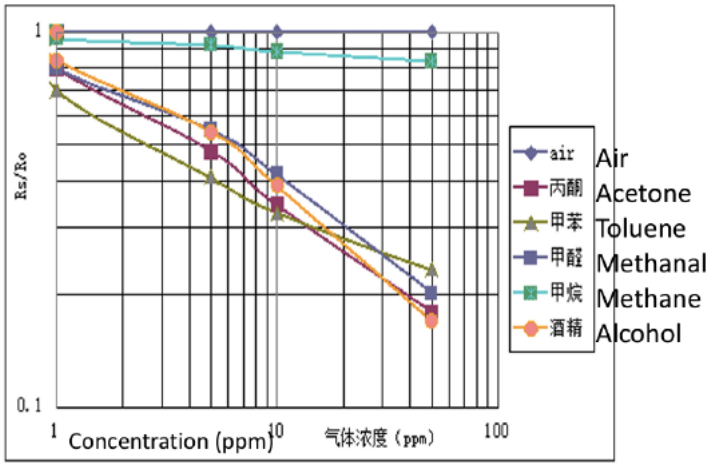

Fig. 9

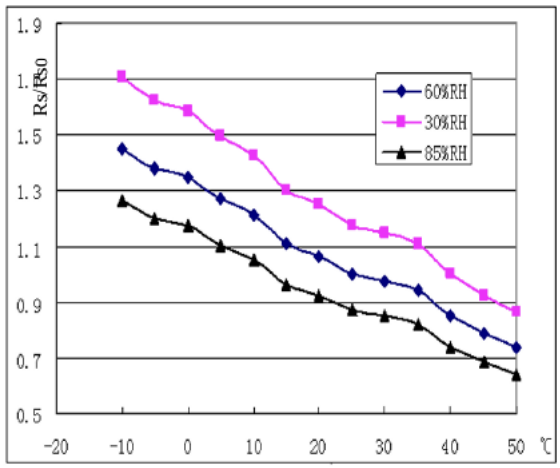

Fig. 10

Archana Singh

ARCHANA SINGH
(IN/PA-1936)
AGENT FOR THE APPLICANT

FORM 28
THE PATENTS ACT, 1970
(39 of 1970)
AND
THE PATENTS RULES, 2003
TO BE SUBMITTED BY A SMALL ENTITY / STARTUP
[See rules 2 (fa), 2(fb) and 7]

1	Insert name, address and nationality.	We **Diagnovate Private Limited** having address 102, Nauzar Ghat, Diwan Mohalla, Tarni Prasad Lane, Das Brothers, Patna, Bihar 800007, India applicant/ patentee in respect of the patent application no. …….or patent no…… hereby declare that we are a startup in accordance with rule 2(fb) and submit the following document(s) as proof:
2	Documents to be submitted	
	ii. For claiming the status of a startup	
	A. For an Indian applicant: Any document as evidence of eligibility, as defined in rule 2(fb).	
	B. In case of a foreign entity: Any other document.	

The information provided herein is correct to the bestof my/our knowledge and belief.

Dated this **09th day** of **October, 2024**

ARCHANA SINGH
(IN/PA-1936)
AGENT FOR THE APPLICANT

To
The Controller of Patents,
The Patent Office,
At New Delhi

CERTIFICATE NO:
DIPP176500

सत्यमेव जयते

Government of India
Ministry of Commerce & Industry
Department for Promotion of Industry and Internal Trade

#startupindia

CERTIFICATE OF RECOGNITION

This is to certify that ***DIAGNOVATE PRIVATE LIMITED*** *incorporated as a* ***Private Limited Company*** *on* ***24-06-2024****, is recognized as a startup by the Department for Promotion of Industry and Internal Trade. The startup is working in 'Healthcare & Lifesciences' Industry and 'Medical Devices Biomedical' sector as self-certified by them.*

This certificate shall only be valid for the Entity up to **Ten** years from the date of its incorporation only if its turnover for any of the financial years has not extended ₹ **100 Cr.**

06-09-2024
DATE OF ISSUE

Scan to Verify

23-06-2034
VALID UPTO

FORM 5

THE PATENT ACT, 1970

(39 OF 1970)

&

THE PATENT RULES, 2003

DECLARATION AS TO INVENTORSHIP

[*See* section 10(6); rule 13 (6)]

1. APPLICANT(S)

NAME	**NATIONALITY**	**ADDRESS**
Diagnovate Private Limited	Indian	102, Nauzar Ghat, Diwan Mohalla, Tarni Prasad Lane, Das Brothers, Patna, Bihar 800007, India.

hereby declare that the true and first inventor of the invention disclosed in the complete specification filed in pursuance of our application numbered _____, dated_____**;** are

2.INVENTOR(S)

NAME	NATIONALITY	ADDRESS
Achyut Agrawal	Indian	102, Nauzar Ghat, Diwan Mohalla, Das Brothers, Patna, Bihar 800007, India.
Sarvesh DharDwivedi	Indian	Vill - Bargadi, Bansi, Siddharth Nagar, Uttar pardesh, 110016, India.

3. DECLARATION TO BE GIVEN WHEN THE APPLICATION IN INDIA IS FILED BY APPLICANT(S) IN THE CONVENTION COUNTRY:

I/We the applicant(s) in the convention country hereby declare that our right to apply for a patent by way of assignment from the true and first inventor(s).

Dated this **09th day** of **October, 2024.**

Archana Singh

ARCHANA SINGH
(IN/PA-1936)
AGENT FOR THE APPLICANT

To,
The Controller of Patents,
The Patent Office,
at New Delhi

FORM 3
THE PATENTS ACT, 1970
(39 of 1970)
and
THE PATENTS RULES, 2003
STATEMENT AND UNDERTAKING UNDER SECTION 8
(See section 8; Rule 12)

1. Name of the applicant(s).	We, **Diagnovate Private Limited** having address 102, Nauzar Ghat, Diwan Mohalla, Tarni Prasad Lane, Das Brothers, Patna, Bihar 800007 who have made this Application No. _____ dated_____**;** have made for the same/substantially same invention application(s) for patent in the other countries as well as PCT, the particulars of which are given below:

Name of the country	Date of application	Application No.	Status of the application	Publication Number and Date	Date of grant
-	-	-	-	-	-

3. Name and address of the assignee	(i) that the rights in the application(s) has/have been assigned to **Diagnovate Private Limited;** (ii) that we undertake that upto the date of grant of the patent by the Controller, we would keep him informed in writing the details regarding corresponding applications for patents filed outside India within six months from the date of filing of such application. Dated this **09th day** of **October, 2024.**
4. To be signed by the applicant or his authorized registered patent agent.	 **ARCHANA SINGH** **(IN/PA-1936)** AGENT FOR THE APPLICANT
	To, The Controller of Patents, The Patent Office, At New Delhi