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(54) Abstract Title: **Assessing blood concentration of a volatile constituent**

(57) A method of assessing the blood concentration level in a human or animal subject, of a volatile blood constituent (preferably alcohol) is disclosed. The method comprises steps of positioning a sensor within the expiratory gas flow of the subject, wherein the sensor is configured to detect the presence of the constituent and provide a first output signal representative of the concentration of said constituent in air, and also to detect a presence of carbon dioxide and to provide a second output signal representative of the concentration of carbon dioxide in air. The flow of expiratory gases from the subject is sampled to provide a first signal and second signal in respect of the expiratory gases substantially simultaneously and these signals are processed according to an algorithm which is configured so as to make the second signal representative of the degree of dilution of the expiratory air flow. Also claimed is apparatus for carrying out the method, preferably being provided in a motor vehicle.

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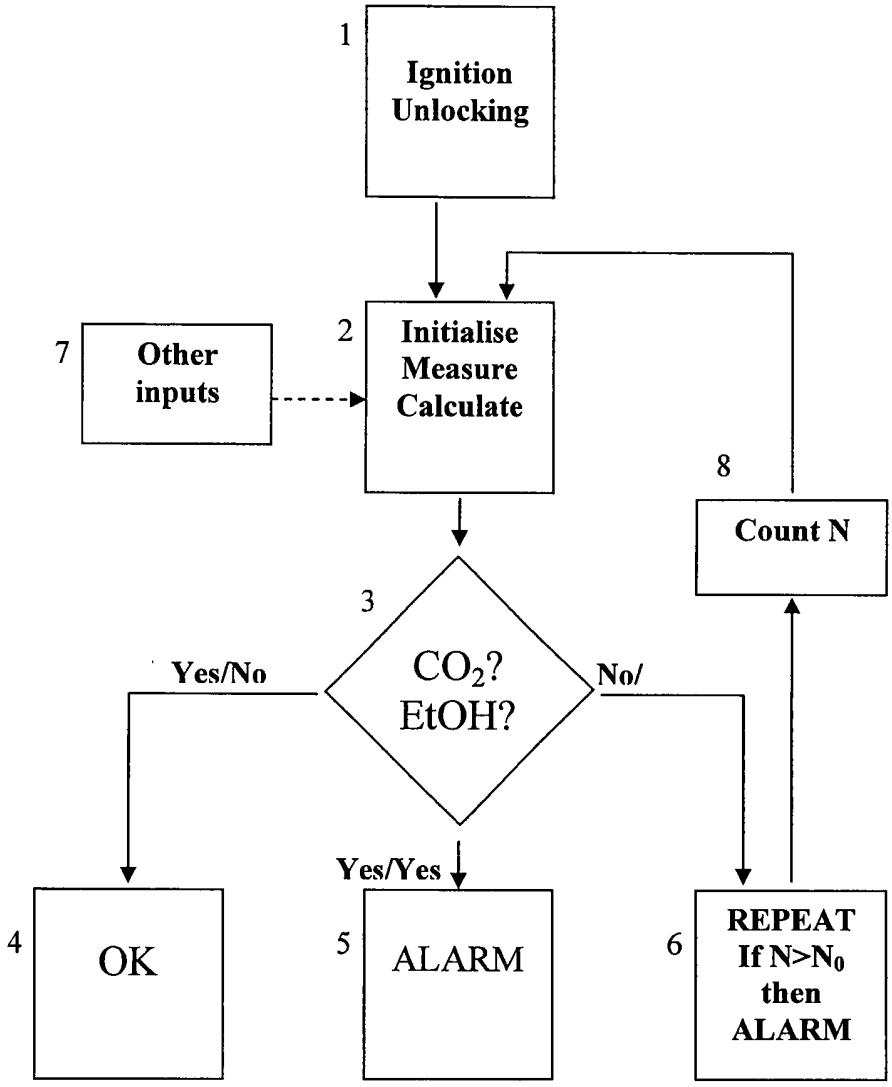

1
Ignition
Unlocking
2
Initialise
Measure
Calculate
7
Other
inputs
8
Count N
3
CO_2?
EtOH?
Yes/No
No/
Yes/Yes
4
OK
5
ALARM
6
REPEAT
If N>N0
then
ALARM

Fig. 1

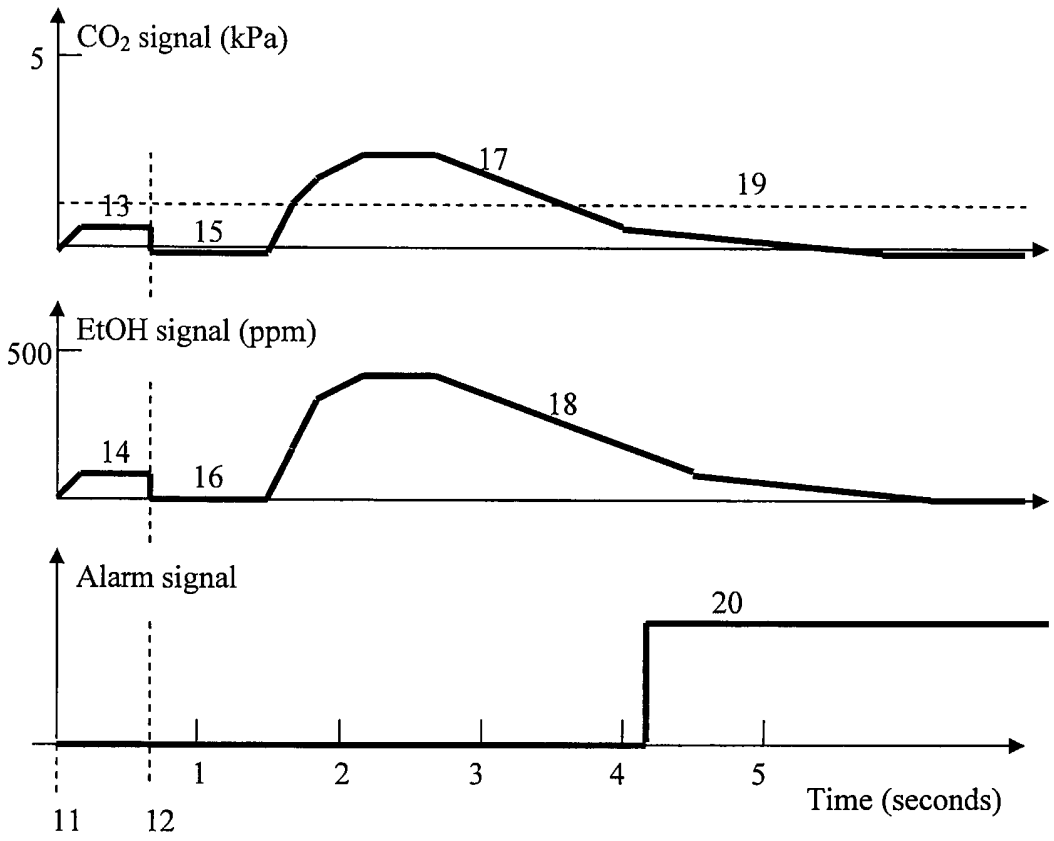

5
CO_2 signal (kPa)
13
15
17
19
500
EtOH signal (ppm)
14
16
18
Alarm signal
20
1
2
3
4
5
Time (seconds)
11
12

Fig. 2

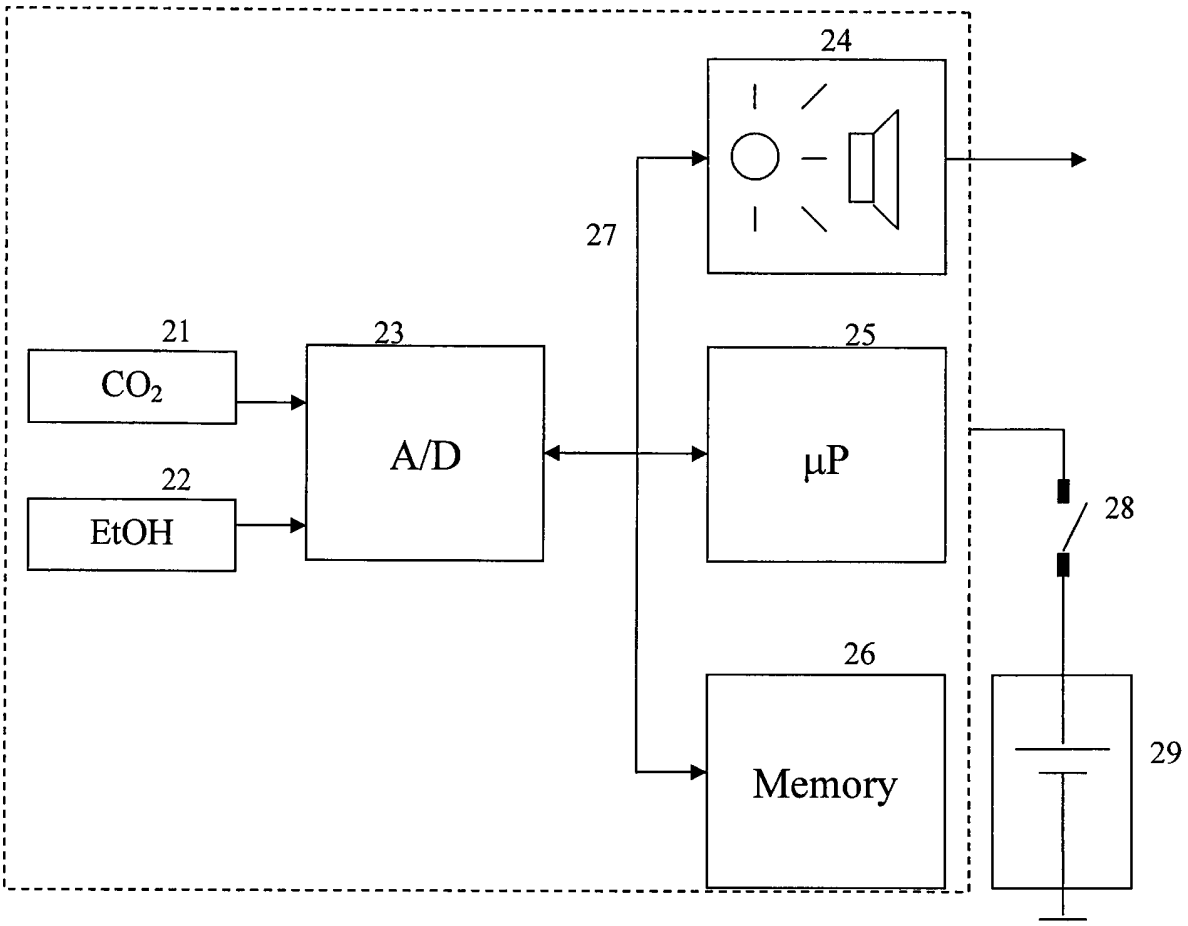
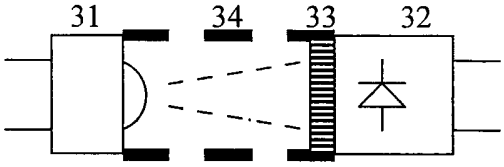
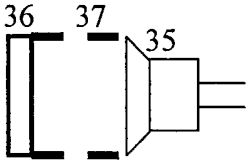


Fig. 3

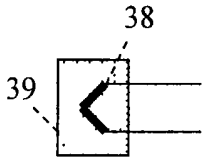
a)



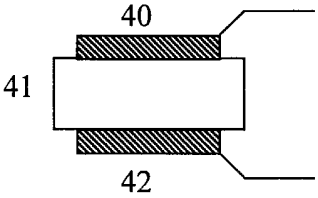
b)



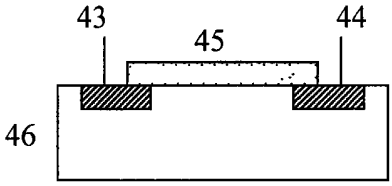
c)



d)



e)



f)

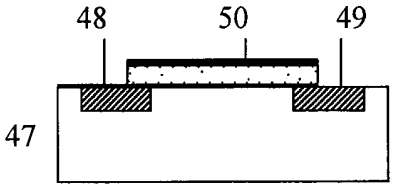


Fig. 4

PATENTS ACT 1977

Agents Ref : P20237GB

A METHOD AND APPARATUS FOR ASSESSING BLOOD-CONCENTRATION OF A VOLATILE CONSTITUENT

THE PRESENT INVENTION relates to a method of assessing the blood concentration level, in a human or animal subject, of a volatile blood constituent, and also relates to an apparatus for implementing the method.

Traffic injuries related to vehicle drivers influenced by alcohol or other drugs are a major problem in all modern societies. Many casualties and severe injuries can be attributed to this problem, associated with human tragedies of immense proportions, and huge economic losses. The search for preventive measures should be approached from all perspectives, leaving no possible solution untried. It is, however, also important that solutions are realistic from the points of view of human behaviour, reliability and economy.

The legislation concerning drugs and vehicle driving differs from one country to another, but generally reflects the severity of the problem in all modern societies. In Sweden and many other countries, vehicle driving is prohibited if the blood concentration of alcohol exceeds 0.02% (the exact number may vary from one country to another). The distinct concentration value, differentiating legal driving from illegal, calls for measurement routines that are not only reproducible but also legally unobjectable from all possible aspects of judicial security. In Sweden, direct blood sampling is compulsory for conviction of a person for drunk driving against his/her admission. Measurements by breath sampling, or through skin is thus considered less reliable.

Direct blood sampling is not practical for screening purposes or other applications on a large scale, due to cost, the problems of handling, and avoidance of infections. The transcutaneous approach is not likely to become successful for large-scale use for reasons of reliability. Breath sampling, on the other hand, is believed to have potential for development into useful large-scale solutions.

Various types of sensing devices capable of measuring the alcohol concentration within the expired air of a subject are already known. The gas exchange between the lung capillaries and the alveoli is normally highly efficient, thereby ensuring proper correlation between the measured gas concentration and the blood concentration.

Measurement of the concentration of alcohol or other volatile compounds in air can be performed with two distinctly different types of devices. In one type, classified as dispersive devices, the various constituents of the gas sample are dispersed according to a property which exhibits a significant and reproducible difference between each one of the constituents. Mass spectroscopy is one such method, relying on the fact that the molecular mass of each constituent exhibits such variation. Another method is gas chromatography, in which the dispersive property is the relative affinity of each constituent to a mobile gas carrier, and a stationary solid or liquid surface. Dispersive methods have common virtues of generality and precision, whereas they are relatively complex, and therefore expensive. In applications where the constituents are known, and the issue is to determine their relative concentrations, dispersive methods may be considered over-qualified.

Non-dispersive devices are commonly based on some property peculiar to the object of detection or measurement. Such a property could have a qualitative or quantitative nature. The latter means that the property as such is shared also by other substances, but may differ in magnitude, thereby enabling

discrimination of the desirable substance from others. A qualitative nature means that the detection can be carried out regardless of quantity. From a basic perspective, the qualitative approach is favourable, since the risk of false detection is found to be reduced. In practice, however, the quantitative principle may offer other, and overruling advantages. Often, the final choice will depend on actual requirements of a specific application, and it is necessary to adapt the solution to such requirements.

Detection of alcohol is commonly performed by devices relying on the fact that alcohol is combustible, in contrast to the normal constituents of air. The combustion process takes place spontaneously at high temperatures, and at moderate temperatures in the presence of certain catalysts. The presence of alcohol, and its concentration, may be recorded by measuring the heat generated by the combustion, or by the consumption of oxygen. A sensor for this purpose could operate by the interaction between gas and solid elements, or could have a liquid interface. The amount of generated heat energy, or the quantity of oxygen consumed can be directly used for quantitative determination.

Common to all the devices mentioned above is that direct sampling is necessary. If the sample becomes diluted for one reason or another, the devices will record false value of too low a magnitude. Dilution may occur both by accident and deliberately. Leakage in any part of the sampling process may occur, and may in some cases be difficult both to avoid and detect. The risk for deliberate manipulation of the sampling process should be considered in view of the legal aspects of alcohol testing.

There is a close correlation between the blood concentration of a certain volatile constituent, and its concentration in the air expired by the subject being tested. This correlation relies upon the efficient equilibration of dissolved and free gas taking place in the alveoli/capillary interface within the lungs. The

relation between dissolved and free gas is specific to a certain constituent, and is temperature dependent.

Ethyl alcohol, exhibiting a vapour pressure of 15.5 kPa at 37°C, is soluble in water. At equilibrium, the alcohol partial pressure above an alcohol/water solution will be directly related to the alcohol concentration in the solution. The corresponding relationship is valid for the air/blood interface. The efficiency of the equilibration process is dependent upon a large interface area, which is also crucial to the vital lung function within the subject. Disturbances, and thus limitations, of the assumed conditions for correlating expired air concentration with that in blood are thus closely related to healthy or diseased lung function. In subjects with lung disease, conclusions on the basis of measured concentrations within the expired air should be made very cautiously.

There are other problems related to the determination of the alcohol content of the expiratory airflow from a subject. When using conventional prior-proposed breath-testing apparatus, the subject is instructed to exhale into a mouthpiece connected to an alcohol sensor. In order to obtain adequate accuracy, the expired volume and flow must exceed certain limits to avoid dilution. For persons with lung disease, e g asthma, it may be difficult or even impossible to reach this limit. For hygienic reasons, mouthpieces are considered personal. Replacement of mouthpieces between different subjects obviously adds to the cost and time consumption of each measurement.

It is thought to be advantageous to provide a method which is contactless and which requires only a few seconds for completion.

It is an object of the present invention to provide an improved method of assessing the blood concentration level, in a human or animal subject, of a volatile blood constituent, and an apparatus for the implementation of said method.

Accordingly, a first aspect of the present invention provides a method of assessing the blood concentration level, in a human or animal subject, of a volatile blood constituent, the method comprising the steps of: positioning sensor means within the expiratory gas-flow of the subject, the sensor means being configured to detect the presence of said constituent and provide a first output signal representative of the concentration of said constituent in air, and to detect the presence of carbon dioxide and provide a second output signal representative of the concentration of carbon dioxide in air; sampling a flow of expiratory gases from the subject using the sensor to provide a said first signal and a said second signal in respect of the expiratory gases substantially simultaneously; and inputting said first and second signals obtained by the sampling step into an algorithm configured so as to make said second signal representative of the degree of dilution of said expiratory air flow.

Preferably, said constituent is alcohol.

Conveniently, said constituent is ethyl alcohol.

Preferably, said algorithm is configured so as to make said second signal representative of a calculated or estimated value of the subject's blood-volume, thereby making said first signal representative of the blood concentration level of said constituent.

Advantageously, said value of blood-volume is calculated from said second signal in combination with an estimation or indirect determination of the subject's alveolar carbon dioxide concentration.

Conveniently, said algorithm is configured to calculate the ratio of said first signal to said second signal, said ratio being representative of the blood concentration level of said constituent.

Advantageously, the method includes the step of multiplying said ratio by a factor representative of the subject's alveolar carbon dioxide concentration.

Preferably, the method includes the step of estimating said factor on the basis of one or more subject-specific parameters selected from the group comprising age, gender, weight, personality index and fitness index.

Advantageously, the method includes the step of measuring the subject's heart rate to calculate said fitness index.

Conveniently, the steps of sampling and inputting are repeated at a repetition rate beyond the control of the subject.

Advantageously, the method further comprises a step of comparing the variance of said first signal over time, with the variance of said second signal over time.

Preferably, said sensor means comprises a constituent-sensor and a carbon dioxide-sensor, the sensor means being configured such that both sensors sample gas at substantially the same location in said expiratory gas-flow.

Advantageously, said step of positioning involves instructing the subject to expire towards the sensor means from a maximum predetermined range.

Conveniently, said range is approximately 0.5 metres.

Preferably, said instruction is given by way of visual and/or audible signals.

Advantageously, the method further comprises an initialisation step conducted prior to the step of positioning, the initialisation step comprising sampling ambient air and using said sensor means to provide a first and second signal

representative of constituent-concentration and carbon-dioxide concentration in the ambient air at the location of the sensor means.

Conveniently, the method further comprises a correction step wherein said first and second signals representative of ambient air are subsequently subtracted, respectively, from the first and second signals in respect of said expiratory gases.

Preferably, said second signal in respect of said expiratory gases is the peak value of carbon dioxide concentration detected during said sampling step.

Advantageously, said second signal is respect of said expiratory gases is an integrated or average value of carbon dioxide concentration detected during said sampling step.

Conveniently, said first signal in respect of said expiratory gases is the peak value of constituent-concentration detected during said sampling step.

Preferably, the subject is the driver of a motor vehicle and the method is conducted within the vehicle.

According to another aspect of the present invention, there is provided an apparatus configured to implement the method as defined above, the apparatus comprising sensor means positionable within the expiratory gas-flow of the subject, the sensor means being configured to detect the presence of said constituent and provide a first output signal representative of the concentration of said constituent in air, and to detect the presence of carbon dioxide and provide a second output signal representative of the concentration of carbon dioxide in air; a memory carrying said algorithm: and a processor configured to process said signals in accordance with the algorithm stored in the memory.

Conveniently, the apparatus is provided in a motor vehicle.

Advantageously, said sensor means comprises at least one sensor element mounted within said motor vehicle at a position in front of the driver's seat of the vehicle.

Preferably, said processor is operatively connected to a switch in the ignition circuit of the vehicle, the processor being configured to close the switch if the result of the algorithm is below a predetermined blood concentration value of said constituent.

So that the invention may be more readily understood, and so that further features thereof may be appreciated, embodiments of the invention will now be described, by way of example, with reference to the accompanying drawings, in which :

Figure 1 is a schematic flow chart illustrating the various steps of a method embodying the invention;

Figure 2 shows a number of plots, against time, for signals used in the method of the present invention;

Figure 3 is a schematic block diagram illustrating components of an apparatus in accordance with an embodiment of the present invention; and

Figure 4 shows several possible sensor elements suitable for use in the method and apparatus of the present invention.

The method of the present invention is based on the measurement of both alcohol-and carbon dioxide- concentrations in the expiratory air flowing from a

subject's mouth, diluted in ambient air. As such, the method enables the use of a sensor arrangement which can be positioned some distance from the mouth and nose of the subject, most preferably up to half a metre from the subject's mouth and nose. At such distances, the expired air flowing from the subject may be diluted as much as ten times with ambient air.

In accordance with the present invention, the concentrations of carbon dioxide and alcohol, C_{extCO2} and $C_{extEtOH}$, are measured simultaneously at locations very close to one another within the expired air-flow from a subject such as a human. The degree of dilution in relation to corresponding alveolar concentrations is assumed to be equal for both gases, and comprised partly of the dead volume V_{ds} in relation to the alveolar volume V_{alv}, and partly from the momentary dilution resulting from passage of the expired gas from the subject's nose and/or mouth to the location of the sensor arrangement. The dead volume V_{ds} represents the volume of the subject's airways not participating in actual gas exchange. For an adult person, the dead volume is approximately 150ml which represents approximately 30% of the tidal volume (i.e. volume of air exchanged in each breath), and mainly consists of the upper airways.

The concentration of carbon dioxide and the concentration of alcohol, as measured within the expired air-flow can thus be defined by the following equations, where C_{alvCO2} and $C_{alvEtOH}$ represent the alveolar carbon dioxide concentration and the alveolar alcohol concentration respectively....

$$C_{extCO2} = D \cdot \frac{V_{alv}}{V_{ds} + V_{alv}} \cdot C_{alvCO2} \qquad (1)$$

$$C_{extEtOH} = D \cdot \frac{V_{alv}}{V_{ds} + V_{alv}} \cdot C_{alvEtOH} \qquad (2)$$

By taking the ratio between (1) and (2), the dilution factors disappear, and the alveolar alcohol concentration can be determined from the following simple expression:

$$C_{alvEtOH} = \frac{C_{extEtOH}}{C_{extCO2}} \cdot C_{alvCO2} \qquad (3)$$

The alveolar or blood concentration of alcohol can thus be determined from the algorithm (3) based on the externally measured ratio of signals representative of $C_{extEtOH}$ and C_{extCO2}, combined with an estimated or indirectly determined value representative of the subject's alveolar CO_2 concentration. In fact, the combined external/alveolar CO_2 measurement and/or estimation provides a representation of the degree of dilution of the expired airflow, allowing the alcohol signal to be related to that particular dilution and thus to represent the blood concentration. The representation is effectuated by the signal corresponding to external carbon dioxide, C_{extCO2}, and the estimation or indirect determination of alveolar carbon dioxide concentration, C_{alvCO2}. Alternatively, the external CO_2 measurement may be considered to represent a certain blood volume, enabling the alcohol signal to be related to that volume and to determination in absolute terms.

Algorithm (3) can also be used in applications where only discreet values of the signals representative of $C_{extEtOH}$ and C_{extCO2} are of interest (for example to determine whether a certain threshold value of alcohol concentration has been exceeded or not, without the need to provide accurate instantaneous values for the detected concentration). In such a situation, the alcohol signal reading can be made at the instant that the CO_2 signal exceeds a certain predefined value.

The time and position dependence of the dilution factor D and the factor $V_{alv}/(V_{ds}+V_{alv})$ will require certain precautions, as will be outlined in more detail hereinafter. Another necessary condition for the method according to the invention is that adequate accuracy can be obtained for the external measurements, and the estimation or indirect measurement of alveolar (and arterial) CO_2 for the subject being tested.

By using presently available CO_2 sensors, based on infrared or electro-acoustic technology, a total measurement error of less than 2 percent for C_{extCO2} has been found to be realistic, to a degree of dilution of ten times that of normal alveolar concentration. Basically the same conclusion can be drawn concerning catalytic alcohol sensors concerning the measurement accuracy of $C_{extEtOH}$, although their accuracy and reliability is still the subject of some controversy.

The variability of C_{alvCO2} has been extensively studied, as evident from the physiological literature. It is generally known that the composition of alveolar gas is remarkably constant under resting conditions. This is largely because the respiratory centre of the brain is sensitive to small changes in the carbon dioxide level of arterial blood. (P.C. Johnson: The Dynamics of Respiratory Structures, in E. E. Selkurt (Ed.) Physiology 2nd Ed., Little, Brown &Co, Boston, USA, 1966, p449-450). Another stabilising factor is that a major part of the carbon dioxide within the blood volume is carried in the form of bicarbonate ions, and thus only a small fraction is exchangeable via the lungs.

It is stated that the most important factor in the control of ventilation under normal conditions is the P_{CO2} of the arterial blood. The sensitivity of this control is remarkable. In the course of daily activity with periods of rests and exercise, the arterial P_{CO2} is probably held to within 7% of its normal value of approximately 5 kPa (J. B. West: Respiratory Physiology – the essentials." 3rd Ed. Williams&Wilkins, Baltimore, USA, 1985, p122). It should be noted that

CO_2 concentration expressed as partial pressure and in unit kPa is approximately equal to that expressed as volume percent, due to the fact that normal atmospheric pressure is approximately 100 kPa.

In a study of alveolar CO_2 concentration in 104 human test subjects, it was found that age and gender presented weak but significant variations. The average value for women was 4.8 kPa, whereas it was 4.9 kPa for men. The age group <30 years exhibited an average of 5.0 kPa, while the group >60 years of age had an average of 4.6 kPa. Differences were also noted with respect to personality indices (A. Dhokalia, D. J. Parsons, D. E. Anderson: "Resting end-tidal CO_2 association with age, gender, and personality", Psychosomatic Medicine 60 (1998) 33-37).

The alveolar CO_2 concentration for a human subject is known to increase somewhat with increasing physical load until a maximum is reached. At higher load, the alveolar CO_2 concentration deceases. The maximum value is reported to be approximately 12% higher than the resting value (M. Folke "Measurements of respiratory carbon dioxide", Department of Computer Science and Electronics, Mälardalen University Doctoral Thesis No. 15, 2005, p. V2).

It has been found that if a subject hyperventilates, C_{alvCO2} will temporarily decrease, and to a minor extent the opposite is possible when the subject holds his or her breath. Such variations may be minimised by repeating the determination with a time interval of a few minutes, preferably beyond the control of the subject, and taking the average of two or several determinations.

The physiological response to ambient environmental factors, such as temperature, humidity, and barometric pressure can principally be taken into account by monitoring these variables, and including their effect as correction factors in the algorithm.

Estimation of a subject's alveolar and arterial CO_2 concentration is thus possible, with or without taking the variations of age, gender and physical workload into account. Measurement of physical workload can be performed indirectly by measuring the subject's heart rate. From the quoted literature it is clear that the remaining error of the estimation will be of the order of ±2% to ±10% depending on whether compensation for age, gender and workload has been made, or not.

The requirements of total accuracy may vary considerably from one application to another. Highest accuracy demands are, of course, valid if the determined concentration is part of a legal process. In screening applications, the requirements may be considerably more relaxed.

From the line of reasoning, it is clear that the described method is applicable not only for the determination of alcohol concentration, but can be used for any volatile constituent within the blood circulation of a subject.

One embodiment of the method according to the invention is represented by the flow chart of Figure 1. Figure 1 illustrates to the function and almost fully automatic procedure of a device provided in a motor vehicle, with the purpose of alarming when the alcohol concentration of the expired air of the driver exceeds a certain threshold. The device is activated by turning on the ignition lock 1 of the vehicle, which is normally done manually by the driver. Alternatively, the activation can be performed automatically by means of a detector of driver presence, such as, for example, a weight sensor provided in the squab of the driver's seat.

After initial activation a sequence 2 is conducted, including an initialisation step in which the ambient air in the region of a sensor means is sampled and

a measurement taken of the output signals from sensor elements, the output of which corresponds to the concentration of carbon dioxide (CO_2) and alcohol (ethanol, EtOH) measured at the device location. The concentration of CO_2 is approximately 0.04 kPa in fresh air, and could rise by 0.03-0.05 kPa due to pollution. The concentration of alcohol or other combustible gases in air is normally below 1 part per million (ppm).

The fact that the background concentrations of both gases are close to zero is employed in the present invention for automatic offset adjustment of the sensor signals. The signals obtained from the initialisation step will correspond to the background concentration, and are stored in a memory and subtracted from all subsequent signals, which will then be referred to that signal level. This procedure will thus minimise eventual offset errors from the sensor elements.

After initialisation, which may only take one or a few seconds, the driver is instructed to expire in the direction of the sensor for a few seconds. The location of the sensor means is such that it is effortlessly accessible for expiration by the driver only, at a distance of 10-50 cm. In a car, suitable locations are at the steering wheel or in the region of the top of the wind shield. The instruction for the driver to breathe against the sensor could be provided as a visual indication by e g light emitting diodes, or a sound signal, or both.

A normal exhaled breath from the driver will result in a rapidly increasing CO_2 concentration to a level of approximately 0.5-5 kPa, depending on the degree of dilution of the expired air in the ambient air within the cabin of the vehicle. It will then slowly return to the background level at a rate depending on the momentary airflow, diffusion etc at the device location. The degree of dilution will also depend on these factors, as well as the position of the driver, his/her ability to make the expired air hit the device, etc. From the measurements, the

peak value, or an integrated or average CO_2 concentration over certain time is calculated for input use of C_{extCO2} in the algorithm (3).

A number of criteria can be used to signal the occurrence of an 'approved' expiration (i.e. an expiration suitable for an accurate calculation of alcohol concentration), one of the simplest being a signal threshold of C_{extCO2}. The existence of a defined maximum concentration, or plateau is another simple criterion. Others can be related to the timing of events, and the non-existence of various types of interference, e g sharp signal 'spikes' related to electromagnetic interference that may be present in a vehicle. More or less sophisticated techniques of pattern recognition can be used for this purpose.

A simultaneous recording of the signal corresponding to alcohol concentration in the expired air is also made. A peak matching that of CO_2 concentration indicates that alcohol is present in the driver's expired air. The peak or time integrated value is calculated. Using the algorithm (3) with an estimated or indirectly determined value of the alveolar CO_2 concentration, the blood alcohol concentration is computed. The device may also be equipped with other signal inputs 7, e g the heart rate of the driver derived from electrocardiography (ECG) signals, in order to determine the driver's physical activity level.

The flow chart of Figure 1 also includes a logic step 3, categorising the signal pattern into three basic outcomes. If the expired breath is 'approved' in terms of CO_2 peak level, duration, etc, without the determined blood alcohol concentration exceeding a stipulated value, then the device will display an 'OK' signal 4.

If, on the other hand, the CO_2 signal and the determined blood alcohol concentration both exceed certain threshold values, the device will signal an

alarm 5, or may even activate a disabling device disabling the ignition circuit of the vehicle to prevent the driver from operating the vehicle.

A necessary condition for the method according to the invention is that the sensor elements for CO_2 and alcohol are positioned so that the dilution factors of eq. (1) and (2) can be considered equal. This may be accomplished either by substantially coincident positions of the sensing elements, or by arranging connections between the CO_2 and alcohol sensing elements and a common sampling point. Such a connection can take the form of respective tubing combined with active or passive means for gas transportation provided within the tubing.

If the signals from neither the CO_2 nor the alcohol sensor elements have exceeded certain thresholds after some time after initialisation, the device will signal an indeterminate condition 6, instructing the subject to repeat the expiration against the sensor elements . The device is thus returned to the initialising and measuring phase 2 via a counter 8 which indicates the number N or time lapse of unsuccessful attempts. If a certain number N_0=1-5 or time is exceeded, a separate alarm indication is activated.

The method of the invention can, of course, also be used in a measuring device, rather than simply an alarm device. In a measuring device, the logic step 3 may either be simplified or completely omitted, depending on the purpose and the specific application of the device. It is also possible to combine the device with other types of devices, or use it as an embedded function of a larger system.

Figure 2 shows a typical time diagram of the signals used for the determination of blood alcohol concentration in the flow graph of Figure 1. In the diagram of Figure 2, the time evolution of the CO_2 concentration signal, the alcohol concentration signal, and the alarm signal, is displayed as a function

of time. At the starting point 11 of the diagram, the device is switched on by turning the ignition key, as previously described in relation to Figure 1. The CO_2 and alcohol signals relatively quickly obtain a stable value corresponding to the background level of ambient air within the vehicle cabin. At point 12, offset correction is performed by subtracting the background level from the actual signal output, whereby the resulting signal goes to zero, indicated by the curve portions 15 and 16 in the CO_2 and alcohol signals, respectively.

Curve portion 17 indicates the CO_2 signal output from a single exhaled breath of the driver. The signal rapidly rises from zero to a maximum of approximately 2 kPa, indicating a degree of dilution of 2-2.5 compared to alveolar concentration. After reaching the maximum level, the signal declines, and returns to approximately zero after about five seconds.

The curve portion 18 indicates the corresponding output from the alcohol sensor element, and provides clear evidence that alcohol is present in the expired air of the driver. A comparison between the time-variance of the signal from the alcohol sensor element and the time-variance of the signal from the CO_2 sensor element can be performed by matching of curve portions 17 and 18 which can be the subject of more or less sophisticated pattern recognition techniques in order to establish coincidence. Such pattern recognition techniques involve a number of signatures which are compared for the two signals. Examples of signatures could be the number, time of occurrence and magnitude of peaks, or troughs.

If the alcohol peak of curve 18 precedes that of CO_2 in curve 17, it is a strong indication that there is alcohol present in the upper airways of the subject, due to the simple fact that the initial expiration phase emanates from the upper airways, not visible on the CO_2 curve, since CO_2 cannot accumulate in the upper airways and must originate from the subject's lungs. A determination with alcohol present in the upper airways may not be fully representative for

the blood concentration and so an alarm could be sounded or made visually. It may be recommended to repeat the measurement a few minutes after rinsing the mouth with water.

After performing signal analysis of the curve portions 17 and 18, and performing the calculations based on the algorithm (3), a logical decision can be made according to the description related to Figure 1, resulting in this case in a positive alarm signal 20 occurring soon after the occurrence of peak values of 17 and 18.

Depending on the degree of accuracy required in a given application, the algorithm (3) may or may not include correction factors to compensate for known dependence on the subject's physical activity level, e g monitored by means of his/her heart rate. Other correction factors may include dependence of environmental factors, such as temperature, humidity and barometric pressure, as discussed above.

The CO_2 signal is compared to a threshold value 19. If the signal does not reach this value, an accurate estimation of alcohol concentration cannot be made, and the subject will be instructed to repeat the expiration against the sensor elements. If the maximum allowed dilution of expired air is a factor 10, the threshold will be 0.5 kPa.

It should be noted that all the steps included in the method according to the invention are preferably performed completely automatically by apparatus built for the purpose. In the following description, the various elements of such apparatus will be described in some detail.

Figure 3 shows a schematic block diagram representative of one implementation of the apparatus according to the invention. As already pointed out, the apparatus includes sensor elements 21 and 22 for CO_2 and

alcohol, respectively. The range of choices between different types of sensor elements will be described further in relation to Figure 4. In the block diagram of Figure 3, the elements 21 and 22 provide analog output voltages corresponding to their respective signal variable. These signals are converted into digital format by an analog-digital converter 23 which is communicating directly on a digital bus line 27 connecting a microprocessor 25 with a memory device 26 and a peripheral unit 24.

The microprocessor 25 includes an arithmetic-logical unit, a random access memory, and digital control circuitry, enabling relatively complex sequential operations to be performed according to a program stored in the memory 26 for permanent information storage and retrieval. The microprocessor 25 also includes a clock oscillator with precisely controlled frequency, allowing precise timing of events. Connection of an internal or external power supply 29 is performed by means of a switch 28 which could be identical to, or connected to the ignition circuit of the motor vehicle or a driver presence detector of a vehicle as described above.

The peripheral unit 24 may be an alphanumerical or graphical signal display, and may also be configured to emit audible alarm signals.

The various steps and operations described in relation to Figure 1 and 2 are contained in a sequential program stored in the memory 26, and executed upon activation of the switch 28. The program will control the microprocessor to perform all sequential operations, including the execution of the algorithm (3). It will also handle drive routines to the peripheral unit 24, and communication with other units or subsystems. The alarm output of the unit 24 may be fed back to the switch 28 (in the ignition circuit), disabling the vehicle in case of an alarm signal.

The apparatus according to the invention may also include other input elements or sensors in order to incorporate correction factors to the algorithm (3) as already discussed above. Such input elements may include a pulse sensor or electrocardiography (ECG) devices to enable the recording of the subject's heart rate, which is closely related to his/her physical activity level. Other input elements may be sensors for measuring ambient temperature, humidity and barometric pressure, enabling the algorithm (3) to be corrected for the influence of these variables.

Most of the elements of Figure 3 are made from components which are already being produced in high volume. Their cost is therefore already low, and can be further reduced by integration. Instead of employing a general purpose microprocessor, it is possible to use a dedicated field programmable gate array (FPGA), or designing one or several application specific integrated cicuits (ASICs), whereby the number of components, and hence the cost, can be further reduced.

The requirements on the sensor elements 21 and 22 are partly general and partly specific to the application, and may therefore call for specific solutions. It is required that the elements have adequate resolution, linearity, response time, stability, and immunity to other influences such as temperature, humidity, pressure and flow.

The requirement of immunity against spurious inputs can generally be solved by introducing additional sensing elements to the variables in question. Low cost sensing elements for temperature, humidity, pressure and flow are commercially available. The standard compensation technique is a simple differential arrangement between the output signals of the gas sensing element and the compensating element. Such arrangement is generally applicable, although it adds to the cost and complexity of the system.

In figure 4a)-f), six alternative gas sensing elements are schematically depicted. They all exhibit various properties of relevance to the present application. In the first two examples, 4a) and b), an inherent physical property of the gas is being measured, whereas the remaining examples rely on catalysis. It should be observed that the catalytic devices will be useful for alcohol detection only, since CO_2 is not combustible.

Figure 4 a) shows an optical gas sensing element, the basic function of which is to measure variations in optical transmission within a cylindrical enclosure 34, which is permeable to air or other gases. The sensing element includes a light source 31, a detector 32, and an optical bandpass filter 33 defining the wavelength region, which will differ from one gas to another, but will generally be located within the infrared spectrum range. CO_2 and alcohol have partly separated absorption bands at 4.3 and 3.5μm, respectively. Therefore, it is basically possible to use a common light source 31 and enclosure 34 but separate detectors 32 and filters 33 for CO_2 and alcohol. The light source is commonly a black body radiator built from a small tungsten filament, and the detector is typically a thermopile based on the Seebeck effect, or a pyroelectric device.

To obtain high resolution at low gas concentrations, it is necessary for the optical path between the light source 31 and the detector 32 to have a length of the order of hundreds of millimetres, which may still be attainable within a small enclosure using multiple reflections. It is, however, conflicting with the requirement of short response time. Other complications with state of the art infrared solutions are that they require fine-tuning of the wavelength bands, and compensation for ageing effects.

Figure 4 b) shows an electro-acoustic gas sensing element including a two-terminal sound source 35, and an acoustic resonator built up from a

permeable enclosure 37 and a sound reflecting wall 36. The sound source 35 is typically a piezoelectric device dimensioned for efficient acoustic coupling from membrane vibrations into air-borne acoustic waves. The two-terminal device will exhibit a resonance frequency determined by the average molecular mass of the gas. The presence of heavy gases, like CO_2 and alcohol, will lead to a decreasing resonance frequency. The arrangement has the virtue of simplicity and possibility to obtain high resolution and fast response simultaneously. However, in the present application, the response to alcohol will be completely masked by that of CO_2.

The sensing element shown in Fig 4 c) may be considered generic for many possible types of catalytic gas sensing devices. A heating element 38 is thus included in most catalytic devices, since the combustion of alcohol does not appear spontaneously at normal temperatures. The heating element 38 is typically a two-terminal resistive device element. Also included is the catalyst material 39 which could be tin oxide, platinum or other noble metals. Such inorganic catalysts are not specific to any particular reaction, but promote combustion processes generally. In principle, it is also possible to make use of organic catalysts, such as enzymes, which could be highly selective, and which could also operate at much lower temperatures than the inorganic catalysts. On the other hand, enzymes require an aqueous environment, and are thus poorly compatible with typical vehicle requirements.

The signal readout from the element of Fig 4 c) is based on temperature dependence of resistance. In the presence of a combustible gas, additional heat will be generated, which will alter the resistance of the element, and thus give rise to a signal. It is, of course, possible also to physically separate the resistive heating element from the heat detecting element.

A fuel cell driven by catalytic alcohol combustion is another type of alcohol sensing element, schematically depicted in Figure 4 d). A solid state

electrolyte 41, is being used for ion transport between an anode 40 and a cathode 42. The combustion generates a change of the current voltage characteristics between the anode and the cathode which can be attributed to the combustion process, and hence to the presence and concentration of alcohol present.

In Figure 4 e) another catalytic device is depicted, which makes use of the resistivity variations occurring in a conductive polymer 45. The polymer is deposited on an isolating substrate 46, and the resistance is measured between two electrodes 43, 44, also deposited on the substrate.

Figure 4 f) shows a fourth example of catalytic gas sensing element based on a metal oxide semiconductor field effect transistor (MOSFET), in which the gate 50 includes a catalytic metal, e g platinum or palladium, or other noble metal. The transistor is built from a silicon substrate 47 with source 48 and drain 49 connections in addition to the gate electrode 50. Specific sensitivities to certain gases can be obtained by using an array of several such elements with different gate metal combinations ("electronic nose").

All three arrangements shown in Figure 4 d) – f) require heating elements which are not shown in the figure. Also not shown are the standard preamplifiers required to provide a signal output voltage for the analog/digital converter 23 of Figure 3.

The arrangements shown in Figure 4 a)-f) may be miniaturised and produced at very low cost using micro electro mechanical systems (MEMS) technology. This technology allows batch fabrication by micromachining, whereby relatively complex structures are determined by photolithography, and a combination of additive deposition or bonding, and subtractive etching. The physical dimensions of the entire system of Figure 3 may be 50 x 50 x 20 mm or less, and the unit cost could be very low in high production volume.

When used in this specification and claims, the terms "comprises" and "comprising" and variations thereof mean that the specified features, steps or integers are included. The terms are not to be interpreted to exclude the presence of other features, steps or components.

The features disclosed in the foregoing description, or the following claims, or the accompanying drawings, expressed in their specific forms or in terms of a means for performing the disclosed function, or a method or process for attaining the disclosed result, as appropriate, may, separately, or in any combination of such features, be utilised for realising the invention in diverse forms thereof.

Claims

1. A method of assessing the blood concentration level, in a human or animal subject, of a volatile blood constituent, the method comprising the steps of: positioning sensor means within the expiratory gas-flow of the subject, the sensor means being configured to detect the presence of said constituent and provide a first output signal representative of the concentration of said constituent in air, and to detect the presence of carbon dioxide and provide a second output signal representative of the concentration of carbon dioxide in air; sampling a flow of expiratory gases from the subject using the sensor to provide a said first signal and a said second signal in respect of the expiratory gases substantially simultaneously; and inputting said first and second signals obtained by the sampling step into an algorithm configured so as to make said second signal representative of the degree of dilution of said expiratory airflow.

2. A method according to claim 1, wherein said constituent is alcohol.

3. A method according to claim 2, wherein said constituent is ethyl alcohol.

4. A method according to any preceding claim, wherein said algorithm is configured so as to make said second signal representative of a calculated or estimated value of the subject's blood-volume, thereby making said first signal representative of the blood concentration level of said constituent.

5. A method according to claim 4, wherein said value of blood-volume is calculated from said second signal in combination with an estimation or indirect determination of the subject's alveolar carbon dioxide concentration.

6. A method according to any one of claims 1 to 3, wherein said algorithm is configured to calculate the ratio of said first signal to said second signal, said ratio being representative of the blood concentration level of said constituent.

7. A method according to claim 6, including the step of multiplying said ratio by a factor representative of the subject's alveolar carbon dioxide concentration.

8. A method according to claim 7, including the step of estimating said factor on the basis of one or more subject-specific parameters selected from the group comprising age, gender, weight, personality index and fitness index.

9. A method according to claim 8, including the step of measuring the subject's heart rate to calculate said fitness index.

10. A method according to any preceding claim, wherein the steps of sampling and inputting are repeated at a repetition rate beyond the control of the subject.

11. A method according to any preceding claim, further comprising a step of comparing the variance of said first signal over time, with the variance of said second signal over time.

12. A method according to any preceding claim, wherein said sensor means comprises a constituent-sensor and a carbon dioxide-sensor, the sensor means being configured such that both sensors sample gas at substantially the same location in said expiratory gas-flow.

13. A method according to any preceding claim, wherein said step of positioning involves instructing the subject to expire towards the sensor means from a maximum predetermined range.

14. A method according to claim 13, wherein said range is approximately 0.5 metres.

15. A method according to claim 13 or 14, wherein said instruction is given by way of visual and/or audible signals.

16. A method according to any preceding claim, further comprising an initialisation step conducted prior to the step of positioning, the initialisation step comprising sampling ambient air and using said sensor means to provide a first and second signal representative of constituent-concentration and carbon-dioxide concentration in the ambient air at the location of the sensor means.

17. A method according to claim 16, further comprising a correction step wherein said first and second signals representative of ambient air are subsequently subtracted, respectively, from the first and second signals in respect of said expiratory gases.

18. A method according to any preceding claim, wherein said second signal in respect of said expiratory gases is the peak value of carbon dioxide concentration detected during said sampling step.

19. A method according to any one of claims 1 to 17, wherein said second signal is respect of said expiratory gases is an integrated or average value of carbon dioxide concentration detected during said sampling step.

20. A method according to any preceding claim, wherein said first signal in respect of said expiratory gases is the peak value of constituent-concentration detected during said sampling step.

21. A method according to any preceding claim, wherein the subject is the driver of a motor vehicle and the method is conducted within the vehicle.

22. Apparatus configured to implement the method of any preceding claim, the apparatus comprising sensor means positionable within the expiratory gas-flow of the subject, the sensor means being configured to detect the presence of said constituent and provide a first output signal representative of the concentration of said constituent in air, and to detect the presence of carbon dioxide and provide a second output signal representative of the concentration of carbon dioxide in air; a memory carrying said algorithm: and a processor configured to process said signals in accordance with the algorithm stored in the memory.

23. Apparatus according to claim 22 provided in a motor vehicle.

24. Apparatus according to claim 23, wherein said sensor means comprises at least one sensor element mounted within said motor vehicle at a position in front of the driver's seat of the vehicle.

25. Apparatus according to claim 23 or 24, wherein said processor is operatively connected to a switch in the ignition circuit of the vehicle, the processor being configured to close the switch if the result of the algorithm is below a predetermined blood concentration value of said constituent.

26. A method substantially as hereinbefore described, with reference to and as shown in the accompanying drawings.

27. An apparatus substantially as hereinbefore described with reference to and as shown in the accompanying drawings.

28. Any novel feature or combination of features disclosed herein.

Application No: GB0521502.5 **Examiner:** Miss Carrie-Ann Elias

Claims searched: 1-27 **Date of search:** 29 March 2006

Patents Act 1977: Search Report under Section 17

Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular relevance
X	1-3,13,21	EP 1441212 A1 (DELPHI) see column 5 paragraph [0014] and column 8 paragraph [0022]
A	--	US 3830630 A (KIEFER) whole document relevant
A	--	EP 0752584 A2 (INSTRUMENTARIUM) whole document relevant

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&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application

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Search of GB, EP, WO & US patent documents classified in the following areas of the UKC^{X} :

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Worldwide search of patent documents classified in the following areas of the IPC

G01N

The following online and other databases have been used in the preparation of this search report

Online: WPI, EPODOC