(57) Abstract:
The invention relates to a novel breath-alcohol measuring instrument, whereby the reliability of the blood alcohol concentration, as determined by means of the alcohol content in the expired air, may be determined in a simple manner by means of determining the carbon dioxide content of the expired air.
Abstract

The invention relates to a novel breathalyzer with which, by measuring the carbon dioxide content in the exhaled air, it is possible easily to determine the reliability of the blood alcohol concentration determined via the alcohol content in the exhaled air.
Breathalyzer

The invention relates to a novel breathalyzer which, in addition to a conventional device for determining the alcohol content in the exhaled air, includes an oxygen sensor via which the partial pressure of the carbon dioxide content in the exhaled air can be determined. The invention also relates to a method by which it is possible to check the reliability of the blood alcohol concentration values which have been determined via the alcohol concentration in the exhaled air.

Breathalyzers are frequently used in practice, particularly in traffic checks. In these devices, the alcohol content in the exhaled air is determined, and the blood alcohol concentration is deduced from the alcohol content in the exhaled air. In doing so, use is made of the fact that the blood alcohol concentration is in a constant equilibrium with the concentration of the alcohol in the deep pulmonary air (alveolar air). However, the blood alcohol concentration determined using a breathalyzer corresponds to the actual blood alcohol concentration only if the person being tested breathes "normally". With a suitable breathing technique, it is possible to falsify the measurement result of a breathalyzer. It then no longer reflects the actual blood alcohol concentration.

For example, the result can be falsified if the person being tested takes shallow breaths during the test and not all of the lung volume flows into the breathalyzer. Whereas such a method of falsifying the measurement result may still in some circumstances be apparent to the monitoring personnel, the measurement result can also be falsified, for example, by the person being tested hyperventilating before the breathalyzer is used. By this means, the alcohol content in the alveolar air is less than the equilibrium value, and the breathalyzer shows too low a value, even though
during the measurement it is not possible to observe any unnatural breathing by the person being tested.

Conversely, in persons who hypoventilate, there may be an accumulation of the alcohol in the alveolar air, and the breathalyzer indicates too high an alcohol value. Finally, there are people with pathological respiratory problems, for example asthmatics, in whom the measurement result of the breathalyzer likewise does not necessarily reflect the correct blood alcohol concentration.

There have been a number of suggestions as to how breathalyzers and the methods of using them can be modified in order to minimize the above sources of error. In particular, there have been a number of suggestions as to how to assess whether the blood alcohol concentration value determined with a breathalyzer corresponds to the real blood alcohol concentration value or whether there is a risk of discrepancies occurring.

At this point, reference can be made, for example, to DE-A 29 28 433 which discloses a device for controlling a breathalyzer, in which a sensor stage responds to pressure variations in the exhaled air and generates a signal corresponding to the amplitude of these pressure variations. Instead of pressure variations in the exhaled air, concentration variations of a gas component in the exhaled air can also be determined. The sensor stage is then for example a CO₂ sensor or an O₂ sensor. The pressure variations or the variations in the CO₂ content or in the O₂ content in the exhaled air ensure that only the alveolar air is used for alcohol measurement. However, the correction of breathalyzers via pressure variations or variations of a gas component in the exhaled air during respiration have in practice proven to be insufficiently reliable. Also, the device described in DE-A-29 28 433 is complex and
expensive.

EP-A 752 584 does not attempt, as does DE-A 29 28 433, to control a breathalyzer via variations in the exhaled air so that only the alveolar air is used to determine the alcohol content in the exhaled air. Said document discloses a method with which it is possible to establish whether the value indicated by a breathalyzer reliably reflects the blood alcohol concentration, or whether manipulations occurred either intentionally or unintentionally during the measurement. In the method in EP-A 752 584, the carbon dioxide content in the exhaled air is determined and is set in relation to the alcohol content measured at the same time. If the carbon dioxide content falls below a specific value defined in advance, the alcohol measurement is regarded as unreliable.

US-A 3,830,630 also discloses a method and a device in which the carbon dioxide content of the exhaled air is first determined, and it is only if this carbon dioxide content exceeds the limit value of 4.5% that the alcohol content in the exhaled air is determined and deemed reliable.

However, the methods described in EP-A 752 584 and in US-A 3,830,630 have the disadvantage that an expensive carbon dioxide sensor is required to accurately determine the carbon dioxide content in the exhaled air. Although the methods described in these documents can therefore predict, in a very simple manner, the reliability of a blood alcohol value determined with a breathalyzer, the devices needed to carry out this method in practical use, particularly in traffic checks, are too expensive if accurate and rapid measurement of the carbon dioxide content is desired.

There is therefore still a need for a method which can be carried out simply and inexpensively in order to
determine the reliability of the blood alcohol concentration determined with a breathalyzer, which method is also suitable in particular for mass use in traffic checks, and there is also a need for inexpensive and simple devices for carrying out such a method.

It is an object of the present invention to make available such a method and such a device. The method and the device are intended in particular to be free from the disadvantages of the corresponding methods and devices in the prior art.

This object is achieved by the subject of the patent claims.

The application with application number PCT/EP00/03689, filed in accordance with the PCT treaty and not previously published, discloses a method for determining the CO₂ content in the exhaled air and a respiration device which is configured in such a way that the method can be carried out using it. The method is based on using a rapid oxygen sensor to determine the oxygen partial pressure during breathing. From the oxygen partial pressure it is then possible to deduce the carbon dioxide content in the respiratory air. If, for example, the oxygen partial pressure in the inhaled air is 21 kPa and the oxygen partial pressure in the exhaled air drops to 16 kPa, the difference of 5 kPa in the oxygen partial pressure corresponds in a first approximation to the maximum value of the carbon dioxide partial pressure in the exhaled air. Important conclusions regarding the state of a (ventilated) patient and possible health disturbances can thus be derived from the CO₂ curve shape (corresponding curves in which the CO₂ content (or CO₂ partial pressure) is plotted against time are also known as capnograms). In the method disclosed therein, the maximum value of the carbon dioxide content in the exhaled air is preferably
determined and displayed for each breath.

The present invention is based on taking the method described in patent application PCT/EP00/03689 for determining the carbon dioxide content in the exhaled air and using this method to assess the reliability of a measurement which has been carried out using a conventional breathalyzer.

An embodiment of the invention is therefore preferred in which the CO₂ curve shape is recorded for each breath and shown in graph form on the measurement device. According to the invention, this can also be done in succession for a plurality of CO₂ partial pressure over time functions (capnograms). This embodiment has the advantage that trained operating personnel can tell from the curve shape, and also, if appropriate, by comparing a plurality of curves, whether the person being tested has consciously or unconsciously (due to illness) falsified the results of the blood alcohol concentration measurement.

According to the invention, methods and devices for determining the blood alcohol concentration are preferred in which the methods and devices are similar to those described in EP-A 752 584 and US-A 3,830,630, to whose disclosure reference is to this extent made. However, these methods and devices are modified such that instead of an expensive carbon dioxide sensor, an economical and rapid oxygen sensor is used, and the maximum carbon dioxide content in the exhaled air is determined via the oxygen partial pressure in the exhaled air as determined with the oxygen sensor.

According to the invention, the carbon dioxide content is determined by the measured oxygen partial pressure in the exhaled air being subtracted from the oxygen partial pressure in the surrounding air. The value thus determined corresponds to the carbon dioxide content in
the exhaled air. Here, account must be taken of the fact that the exhaled air, in first approximation, has a temperature of 37°C and a high humidity content. In the context of this application, it is assumed in particular that the air exhaled by the person being breathalyzed has a temperature of 37°C and a relative humidity of 100%. These temperature and humidity values are generally different than those of the surrounding air. This must be taken into consideration when forming the difference in order to increase the measurement accuracy.

The oxygen partial pressure of the surrounding air can be pre-set, e.g. to 21 kPa, although it is preferable according to the invention if the oxygen partial pressure of the surrounding air is determined directly before the measurement of the oxygen partial pressure in the exhaled air, expediently using the same oxygen sensor with which the oxygen partial pressure in the exhaled air is then determined.

According to the invention, an embodiment is likewise preferred in which a conventional breathalyzer, as is used in traffic checks, is equipped with a rapid oxygen sensor. This preferred embodiment according to the invention further comprises an electronic circuit and a display device which, from the oxygen partial pressures determined with the rapid oxygen sensor, determines the minimum value of the oxygen partial pressure in the exhaled air upon each breath and from this determines and displays the maximum value of the carbon dioxide content in the exhaled air upon each breath. As has already been stated, it is preferable here if the rapid oxygen sensor determines the oxygen partial pressure in the surrounding air directly before the determination of the oxygen partial pressure in the exhaled air, account suitably being taken of the differences in humidity and temperature between the exhaled air and the surrounding air. If the maximum value of the carbon
dioxide partial pressure lies below a defined limit value, for example below 4.5%, the operating personnel know that the breathalyzer measurement is not reliable under certain circumstances. Either the measurement can then be repeated, or other suitable measures can be taken. Alternatively, as is described in EP-A 752 584 or US-A 3,830,630, a breathalyzer measurement can be displayed or carried out only if a defined limit value of the carbon dioxide content in the exhaled air is exceeded.

Compared to other methods in which the carbon dioxide content is determined at a specified time or in which it is only checked whether the carbon dioxide content in the exhaled air exceeds a defined value, the method according to the invention, in which the maximum value of the carbon dioxide content in the exhaled air is determined, has the advantage that it is more conclusive and also detects a manipulation of a breathalyzer measurement where other methods fail to do so. Thus, in the method according to the invention, it is noticeable if the exhaled air has an unusually high carbon dioxide pressure, and the method is reliable, even in those persons in whom the capnogram has a much distorted form, for example as a result of illness.

The advantages according to the invention are of course particularly evident when the whole capnogram is recorded and displayed, as is the case in the particularly preferred embodiment of the invention.

According to the invention, it is advantageous that a rapid oxygen sensor can in principle work together with known breathalyzer devices. For this purpose, it is only necessary to connect an additional adapter piece onto the breathalyzer.

Evaluation and display devices which can process and display the signals delivered by the oxygen sensors are
known in principle and can be adapted by a skilled person in the customary way and integrated into the device according to the invention.

If the breathalyzer or the oxygen sensor is coupled to a temperature and/or humidity sensor, the temperature and/or humidity value determined in this way can of course be used both for the surrounding air and also for the exhaled air in order to reduce the measurement error in the determination of the oxygen partial pressure and of the carbon dioxide partial pressure calculated from this. Appropriate correction formulas are known.

For the method according to the invention or the device according to the invention, a rapid oxygen sensor should be used. Oxygen sensors with a response time of, for example, 500 milliseconds or less are preferred. The use of a rapid oxygen sensor is preferred so that the minimum of the oxygen partial pressure or the maximum of the carbon dioxide content in the exhaled air can be determined with good precision.

If capnograms are additionally recorded, then a rapid oxygen sensor has the advantage that the resolution of the capnograms increases as the response time of the oxygen sensor falls.

Rapid oxygen sensors which are suitable for the method according to the invention are known and are commercially available. For example, galvanic, paramagnetic or optic oxygen sensors can be used. Oxygen sensors which operate with laser diodes are also known and can be used. According to the invention, a rapid electrochemical oxygen sensor is preferred for cost reasons, such as is sold for example by the company Teledyne Analytical Instruments and by the Applicant.
According to the invention, the oxygen sensor should be applied as near as possible to the mouth of the patient who is to be tested, in order to avoid inaccurate measurements.

The invention is described in more detail below with reference to Figure 1.

Figure 1 shows diagrammatically a preferred embodiment of a device for carrying out the method according to the invention. In Figure 1, reference number 1 denotes a mouthpiece which should be exchangeable, for hygiene reasons, and into which the person to be tested blows. Reference number 2 represents an adapter piece which can be fitted onto a conventional breathalyzer. Reference number 3 represents a conventional breathalyzer. Reference number 4 shows the oxygen sensor, and reference number 5 the evaluation and display device connected to the oxygen sensor.

When carrying out the method according to the invention, the oxygen partial pressure in the surrounding air is automatically determined and stored after the device is switched on. The person to be tested will then blow into the mouthpiece 1. The air coming from the person being tested is conveyed via the adapter piece 2 on the one hand to the conventional breathalyzer 3 and on the other hand also to the rapid oxygen sensor 4. Via the evaluation and display device 5, the oxygen partial pressure in the exhaled air is converted in a manner known per se into the carbon dioxide content, by forming the difference from the oxygen content in the surrounding air and the oxygen content in the exhaled air. If the device has a temperature and/or humidity sensor, the exact temperature or humidity values of the surrounding air or exhaled air can be used to correct the measured oxygen partial pressures.
The carbon dioxide content thus determined in the exhaled air is then displayed. The maximum value of the carbon dioxide content in the exhaled air upon each breath is likewise determined and displayed. From the carbon dioxide partial pressure in the exhaled air, the operating personnel can then decide whether the blood alcohol concentration value determined with the breathalyzer 3 is accurate or not.

In an alternative embodiment, there can also be a connection between the oxygen sensor and the conventional breathalyzer 3, so that an alcohol value is displayed only when the maximum value of the carbon dioxide content in the exhaled air exceeds a defined value or so that the breath alcohol measurement is triggered only in such a case.
Patent Claims

1. A breathalyzer with a device for determining the carbon dioxide partial pressure in the respiratory air, characterized in that the device for determining the carbon dioxide partial pressure in the respiratory air is an oxygen sensor in combination with an electronic circuit which determines the minimum value of the oxygen partial pressure in the exhaled air and displays the absolute value of the difference of the minimum value of the oxygen partial pressure in the exhaled air and of the oxygen partial pressure in the surrounding air as the maximum value of the carbon dioxide partial pressure in the exhaled air.

2. The breathalyzer as claimed in claim 1, characterized in that the oxygen sensor is an electrochemical oxygen sensor.

3. The breathalyzer as claimed in claim 1 or 2, characterized in that the device determines and displays the CO₂ curve shape for each breath.

4. A method for checking the reliability of a blood alcohol concentration which has been determined via a breathalyzer, in which method the carbon dioxide partial pressure is determined at the same time as the alcohol concentration in the exhaled air, characterized in that the carbon dioxide partial pressure is determined by the fact that the minimum value of the oxygen partial pressure in the exhaled air is determined using an oxygen sensor, and the absolute value of the difference of the minimum value of the oxygen partial pressure in the exhaled air and of the oxygen partial pressure in the surrounding air is
displayed as a maximum value of the carbon dioxide partial pressure in the exhaled air.

5. The method as claimed in claim 4, characterized in that the oxygen sensor used is an electrochemical oxygen sensor.

6. The method as claimed in claim 4 or 5, characterized in that the CO$_2$ curve shape is determined and displayed for each breath.
Figur 1/1