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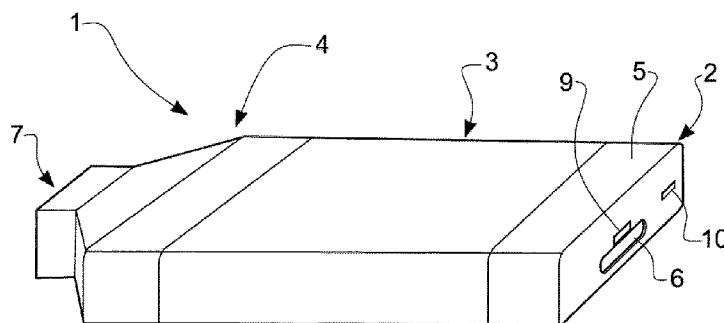


FIG 1

(57) Abstract: A tamper evident breath analyser device is proposed which has an inlet region and a sensor arrangement, the inlet region being configured to receive a breath sample from a test subject via an inlet port and direct the sample to the sensor arrangement, and the sensor arrangement being configured to provide a signal representative of the concentration of a volatile substance within said sample. The device is characterised in that said inlet region includes an inlet microphone adjacent said inlet port, the microphone being positioned and operable to provide an acoustic signal representative of local pressure variations arising from an air flow produced by an exhaled breath sample directed through the sample inlet port. The device further comprises a processor operable to analyse at least a portion of said acoustic signal and produce a signal indicative of an untampered breath sample in dependence on said analysis. A related tamper-evident method of analysing a breath sample is also disclosed.

A BREATH ANALYSER DEVICE AND A RELATED METHOD

The present invention relates to a breath analyser device, and more particularly relates to a tamper evident breath analyser device. The invention also relates to a tamper-evident method of analysing a breath sample.

It is important in a number of situations to be able accurately to analyse the exhaled breath of a test subject. The most common reason for doing this is to detect the presence of alcohol in the test subject's breath, which will of course be indicative of the test subject having a raised blood-alcohol level and thus impaired judgement and reaction times. Testing for alcohol in this way is very important for safety reasons in a large number of situations including, for example, the operation of heavy or dangerous machinery, the operation of aircraft, and the operation of motor vehicles. Breath testing for alcohol is now widely used in the area of law enforcement and is routinely carried out on motor vehicle drivers on the road networks of most major countries, with strict penalties in place for drivers found to be driving under the influence of alcohol.

Alcohol is a major factor in a very large number of road accidents, and so great efforts are made to reduce the incidence of driving under the influence of alcohol. One proposal which is now being considered more widely is the provision of so-called "alco-locks" in motor vehicles which will prevent operation of the motor vehicle until an approved breath sample has been given by the driver having an alcohol content below a predetermined maximum threshold value. It is envisaged that the device of the present invention will be particularly useful in such alco-lock arrangements. However, it is to be appreciated that the invention is not limited to use in alco-lock arrangements, and could find wider application in the field of alcohol breath testing. The present invention could be more widely employed in breath analysis more generally, and may not even be restricted to testing for the presence of alcohol. Nevertheless, the present invention is described herein with specific reference to alcohol testing.

Whilst alcohol testing for evidentiary or diagnostic purposes is generally achieved by infrared spectroscopy which is very accurate, a simpler method of alcohol testing is normally used for screening purposes; for example at the roadside by law enforcement personnel, or in the

case of alco-locks installed in vehicles. Alcohol testing for screening purposes has therefore previously been achieved via catalysis; for example using fuel cells or semiconductor devices. These types of device are advantageous in terms of production cost, but have been found to suffer from problems of unreliability. The catalytic function is difficult to control, and the sensors have a limited lifetime. Furthermore, devices of this type require a test subject to deliver forced expiration into a tight-fitting mouthpiece which can be problematic for people with impaired respiratory function, and will generally be inconvenient and off-putting for drivers in the case of vehicle alco-locks.

It has therefore been proposed to provide improved breath analyser devices that do not require physical contact between the device and the test subject. This type of device is particularly advantageous in the case of alco-locks because it can be conveniently positioned on the dashboard, steering wheel, or A-post of a motor vehicle for receipt of a breath sample from a driver test subject in a normal, or reasonably normal, driving position. However, testing in this manner will of course mean that the breath sample is diluted with ambient air.

US2013/0231871 A1 proposes a type of no-contact breath analyser device which address the issue of ambient air dilution of the breath sample by measuring the concentration of a tracer substance such as carbon dioxide within the sample in order to estimate the degree of dilution and thereby allow the estimation of the true breath concentration of alcohol.

Breath analyser devices of the type described above which do not require physical contact between the device and the test subject can be particularly susceptible to tampering. This can be a particular problem in the case of devices which are configured as alco-locks in motor vehicles. For example, it has been found that test subjects have been known to attempt to "cheat" such devices by interfering with their breath samples upstream of the device so as to cause the device to provide a false negative alcohol signal. One known tamper strategy involves placing a length of cooled tubing between the test subject's mouth and the sample inlet of the breath analyser device so that the test subject's breath sample will be cooled as it passes along the length of tubing before entering the device. Another known strategy involves using a length of tubing filled with charcoal in a similar manner. Both of these strategies involve delaying alcohol-polluted breath from entering the device until after the device has given a negative signal on the basis of unpolluted air initially present in the tube. It is therefore desirable to provide a breath analyser device which is able

to detect these types of tamper strategies and thereby avoid providing a false negative alcohol signal in such situations.

It is an object of the present invention to provide an improved breath analyser device. It is another object of the present invention to provide an improved method of analysing a breath sample.

According to a first aspect of the present invention, there is provided a tamper evident breath analyser device having an inlet region and a sensor arrangement, the inlet region being configured to receive a breath sample from a test subject via an inlet port and direct the sample to the sensor arrangement, and the sensor arrangement being configured to provide a signal representative of the concentration of a volatile substance within said sample, the device being characterised in that said inlet region includes an inlet microphone adjacent said inlet port, the microphone being positioned and operable to provide an acoustic signal representative of local pressure variations arising from an air flow produced by an exhaled breath sample directed through the sample inlet port, the device further comprising: a processor operable to analyse at least a portion of said acoustic signal and produce a signal indicative of an untampered breath sample in dependence on said analysis; and a data buffer configured to receive and temporarily store said acoustic signal from the inlet microphone for subsequent analysis by the processor, and wherein said sensor arrangement includes a carbon dioxide sensor arranged and configured to provide a carbon dioxide signal representative of the concentration of carbon dioxide in an air flow produced by said breath sample and directed through the sensor arrangement; said processor being operable to compare said carbon dioxide signal to a predetermined threshold value, and to retrieve at least a portion of said stored acoustic signal from the data buffer and perform said analysis on the retrieved acoustic signal in response to said carbon dioxide signal exceeding said threshold value.

Preferably, said processor is operable to analyse the power spectrum of said acoustic signal and to produce said signal indicative of an untampered breath sample in response to said power spectrum being dominated by frequencies below 400 Hz.

Advantageously, said processor is operable to determine a point in time at which said carbon dioxide signal exceeds said threshold value, and to retrieve from said data buffer and

analyse a portion of said stored acoustic signal corresponding to a predetermined time period which precedes said point in time.

Conveniently, said predetermined time period is 0.5 seconds.

5 Preferably, said predetermined time period runs from 1 second to 0.5 seconds before said point in time.

Advantageously, said inlet region further includes a second microphone which is spaced further from said inlet port than said inlet microphone, said second microphone being positioned and operable to provide an ambient acoustic signal representative of ambient noise.

10 Conveniently, said processor is operable to subtract the signal provided by the second microphone from the signal provided by the inlet microphone and to perform said analysis on the resulting signal.

According to a second aspect of the present invention, there is provided a tamper-evident method of analysing a breath sample, the method comprising the steps of: providing a breath
15 analyser device having an inlet region and a sensor arrangement, the inlet region being configured to receive a breath sample from a test subject via an inlet port and direct the sample to the sensor arrangement, and the sensor arrangement being configured to provide a signal representative of the concentration of a volatile substance within the sample; providing an inlet microphone adjacent said inlet port; directing a breath sample from a test
20 subject into the inlet region of the device via the inlet port to thereby produce an air flow through the inlet port, obtaining via said microphone an acoustic signal representative of local pressure variations arising from said air flow; analysing at least a portion of said acoustic signal to produce a signal indicative of an untampered breath sample in dependence on said analysis; and temporarily storing said acoustic signal from the inlet
25 microphone in a data buffer prior to said step of analysing the signal; wherein the sensor arrangement of the device includes a carbon dioxide sensor, and the method further comprises the steps of: using said carbon dioxide sensor to provide a carbon dioxide signal representative of the concentration of carbon dioxide in said air flow; comparing said carbon dioxide signal to a predetermined threshold value; and, if said carbon dioxide signal exceeds

said predetermined threshold value, retrieving at least a portion of said stored acoustic signal from the data buffer and performing said analysis on the retrieved acoustic signal.

Preferably, said step of analysing involves analysing the power spectrum of said acoustic signal, said signal indicative of an untampered breath sample being produced in response to said power spectrum being dominated by frequencies below 400 Hz.

Preferably, the method further comprises the steps of: determining a point in time at which said carbon dioxide signal exceeds said threshold value; and retrieving from said data buffer and analysing a portion of said stored acoustic signal corresponding to a predetermined time period which precedes said point in time.

Advantageously, said predetermined time period is 0.5 seconds.

Conveniently, said predetermined time period runs from 1 second to 0.5 seconds before said point in time.

Optionally, a second microphone is provided which is spaced further from the inlet port than said inlet microphone, said second microphone being used to provide an ambient acoustic signal representative of ambient noise.

Advantageously, the method further includes the steps of: subtracting the signal provided by the second microphone from the signal provided by the inlet microphone; and performing said analysis on the resulting signal.

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 perspective view showing an exemplary breath analyser device in accordance with the present invention;

Figure 2 is a schematic illustration showing internal componentry of the device;

Figure 3 comprises two graphs showing exemplary signal patterns relating to carbon dioxide and alcohol levels during use of the device;

Figure 4 shows a series of graphs relating to use of the device in an untampered condition;

Figure 5 shows a series of graphs similar to those of figure 4, but relating to use of the device in a first tampered condition;

Figure 6 shows another series of graphs similar to those of figures 4 and 5, but relating to
5 use of the device in a second tampered condition; and

Figure 7 is a schematic flow chart showing the operational regime of the device.

Turning now to consider the drawings in more detail, figure 1 illustrates the general arrangement of a breath analyser device 1 in accordance with an embodiment of the present invention. In general terms, the device comprises an inlet region 2, a sensor module 3 which
10 incorporates a sensor arrangement, and an outlet region 4. The device 1 may be configured to operate in accordance with the principles disclosed in US2013/0231871A1, such that the sensor arrangement of the sensor module 3 may be configured in a similar manner to the sensor arrangement of the device proposed therein as will be described in more detail below. However, other configurations of sensor arrangement are also possible. In all embodiments
15 it is envisaged that the sensor arrangement will be configured to provide a signal representative of the concentration of at least one volatile substance within a breath sample.

The inlet region 2 comprises an inlet housing 5 having a sample inlet port 6 arranged at one end of the device 1. The inlet port 6 is open to atmospheric air outside the device 1 and is configured to receive a breath sample from a test subject. As will be explained in more detail
20 below, the inlet region 2 of the device is configured to direct the breath sample to the sensor arrangement within the sensor module 3 of the device 1 for analysis.

The outlet region 4 of the device has an exhaust port (indicated generally at 7, but not visible in figure 1) at the opposite end of the device 1 to the sample inlet port 6, through which the diluted breath sample is exhausted to the atmosphere after passing through, and being
25 analysed within, the sensor module 3. The outlet region 4 may be provided with an internal battery operated fan 8 (not shown in figure 1) to pull the gas through the device 1.

The inlet region 2 of the device is provided with a pair of small (typically less than 2 mm across in their longest dimension) microphones 9, 10. The microphones 9, 10 may either be

simply mounted externally on the housing 5 of the inlet region 2, or they may alternatively be accommodated in recesses formed in the housing 5 so as to be substantially flush with an outer surface of the inlet region 2 as illustrated in figure 2.

5 A first one of the two microphones 9 is located adjacent the inlet port 6, and can thus be considered to represent an inlet microphone 9. The inlet microphone 9 is thus positioned immediately adjacent an air flow which will be produced by an exhaled breath sample directed through the sample inlet port 6 by a test subject, and so is positioned to provide an acoustic signal representative of local pressure variations arising from such an air flow.

10 Whilst the inlet microphone 9 is proximal to the sample inlet port 6, it will be noted that the second microphone 10 is distal to the inlet port 6 on account of being spaced further from the inlet port 6. The second microphone 10 is thus positioned to provide an ambient acoustic signal representative of ambient noise in the region of the device 1.

15 Figure 2 illustrates an exemplary layout of internal componentry of the device 1, although it is to be noted that the layout illustrated is in no way limiting and it is envisaged that alternative arrangements may be used instead. However the arrangement of figure 2 is useful in understanding the manner in which the device of the present invention operates.

As will be noted, the sensor module 3 comprises an internal chamber 11 which fluidly interconnects the inlet and outlet regions 2, 4 of the device and thus defines a flow passage through the device along which a breath sample will be directed in use of the device.

20 In the illustrated embodiment of the device 1 there is provided a pair of sensors 12, 13 inside the sensor module 3 and to one side of the internal chamber 11 therethrough. One of the sensors 13 is responsive to the volatile substance of interest (for example ethanol in the case of an alcohol breath analyser), and the other sensor 12 is responsive to CO₂ which will be used as a tracer substance according to the principles taught previously in US2013/0231871.

25 In the proposed embodiment, the sensor module 3 also includes a source 14 of electromagnetic radiation within the infrared (IR) wavelength range and so the sensors 12, 13 are provided in the form of IR detectors equipped with band pass type interference filters tuned to the wavelength intervals which coincide with absorption peaks of the substances

which each respective sensor is configured to sense. For ethanol and CO₂ suitable wavelength intervals are $9.5 \pm 0.3 \mu\text{m}$ and $4.26 \pm 0.05 \mu\text{m}$ respectively.

As illustrated schematically by the dashed arrow in figure 2, It is schematically indicated the sensors 12, 13 receive an IR beam emitted by the source 14 after reflections against the inner wall of the internal chamber 11 which is preferably covered by a thin film of gold or aluminium, or another highly reflecting material. The IR beam is reflected once before reaching the CO₂ sensor 12, and is reflected three times before reaching the ethanol detector 13. Thus the optical path is much longer for the ethanol sensor 13, resulting in a higher sensitivity to absorption.

As also illustrated schematically in figure 2, the IR source 14, the two sensors 12, 13 and the two microphones 9, 10 are all electrically and operatively connected to a processor 15. The processor 15 preferably includes integrated analogue and digital circuit elements for signal processing and control. Preferably one or several microprocessors are included for signal processing, management of signals to a display (not shown) for indication of measurement results.

The device 1 also incorporates a data buffer which is illustrated schematically at 16 and which is operatively connected to the processor 15 and is configured to temporarily store an acoustic signal produced by the inlet microphone 9, and also optionally an acoustic signal produced by the second, distal, microphone 10. As will be described in more detail hereinafter, the microphones 9, 10 and the data buffer 18 are used to provide an indication as to whether or not a breath sample directed into the inlet port 6 of the device has been tampered with. However, it is first relevant to consider the basic function of the device in measuring breath alcohol levels.

The breath analyser device 1 may be provided in the form of an autonomous handheld unit, in which case power is provided by a battery 17 as illustrated schematically in figure 2. However in other embodiments, the device can be provided within the instrument panel of a motor vehicle and may be operable in combination with other equipment of the vehicle. In such an arrangement it is envisaged that the device may be embodied in a so-called alcohol lock arrangement. In either case it is envisaged that the device will not require physical

contact between the device and the test subject. As explained above, this means that a breath sample directed into the device will be diluted with ambient air.

Estimation of the dilution of the breath sample is performed by the use of CO₂ as a tracer substance. The partial pressure of CO₂ within deep (alveolar) breath air is typically 4.8 kPa, corresponding to 4.8% by volume, whereas the background ambient concentration seldom exceeds 0.1 % v/v. The degree of dilution therefore can be calculated from the ratio CO_{2alv} / CO_{2meas} , where CO_{2alv} and CO_{2meas} represent the alveolar and measured concentrations, respectively. The variability of CO_{2alv} between different individuals expressed as one standard deviation is relatively modest; typically of the order of 10% of the average.

Proposed devices in accordance with the present invention function by multiplying the measured concentration of a substance in a diluted breath sample by CO_{2alv} / CO_{2meas} , in order to obtain an estimated value of the undiluted concentration. This mode of operation is extremely rapid and convenient for the test person.

Transfer from a screening mode of operation into one of higher measuring accuracy may be accomplished by identifying an undiluted breath using the CO₂ sensor 12. In the absence of a signal indicating an undiluted sample (which would be the case, for example, if the test subject were to place his or her mouth directly over the inlet port 6 or to fit a length of tube or a mouthpiece to the inlet port 6 and blow directly into it), an estimation of the sample dilution is used in the calculation of the substance concentration. In the presence of such a signal the estimation of dilution may be omitted, resulting in higher accuracy. Thus the dilution signal can be used to enable the breath analyser to switch automatically between screening operational modes and those of high accuracy.

Figure 3 schematically shows the signal patterns when performing breath tests in which the test subject does not have his or her mouth in direct fluid connection with the inlet port 6 of the device. More particularly, figure 3(a) graphically shows the variation of the measured concentration of CO₂ as a function of time, whilst figure 3(b) graphically shows the variation of the substance of primary interest, in this case ethanol (EtOH), as a function of time during a breath test. Both signals are basically zero at the start of the test, and grow to a maximum during the expiratory phase, before then returning to zero as the sensing unit is ventilated. When the CO₂ concentration reaches its maximum, the algorithm will assume a

dilution ratio of $\text{CO}_{2\text{alv}} / \text{CO}_{2\text{meas}}$ and multiply it with the measured ethanol concentration at that time in order to obtain the estimated undiluted EtOH concentration. The entire course of the test shown graphically in Figure 3 has a duration of only a few seconds, which is due to the fact that the test person is instructed to terminate the expiration when the processor 15 determines that a certain threshold value V of CO_2 has been reached; which may be for example 2 kPa, corresponding to a dilution ratio of approximately 2.4.

Turning now to consider figure 4, as further series of graphs are shown which characterise another untampered test using the device. Figure 4(a) shows an acoustic signal produced by the second, distal, microphone 10 and thus represents an ambient acoustic signal representative of ambient noise. Figure 4(b) shows the acoustic signal produced by the inlet microphone 9 and thus represents an acoustic signal arising from local pressure variations in an air flow produced by the exhaled breath sample which is directed into the inlet aperture 6. Both of these graphs denote time in seconds along the horizontal x-axis and acoustic emission amplitude along the vertical y-axis.

The device 1 may include a buzzer or the like which is configured to emit a ready beep to indicate to the test subject that the device is ready to accept a breath sample. The ready beep is indicated at 18 in each graph, and it will be noted that the beep is more significant in the signal from the inlet microphone 6.

Shortly after the ready beep 18, the test subject exhales a breath sample, which is indicated at 19 in the acoustic signals produced by the two microphones 9, 10. Again, it will be noted that the breath sample 19 is more significant (i.e. louder) in the acoustic signal produced by the inlet microphone 9 than in the signal from the second microphone 10 owing to the fact that the inlet microphone is immediately adjacent the inlet 6. In each case, substantially the entire breath component of the signal falls within a time-window 20 of one-second duration, with the highest peaks covering an even smaller time period.

Graphs 4(a) and 4(b) both also show a component of their respective signals which is representative of a subsequent end beep 21 which may be emitted by the buzzer after the sample has been received.

It is proposed that the processor 15 will be operable to subtract the acoustic signal from the second, distal, microphone 10 from the acoustic signal from the inlet microphone 9, in order to remove extraneous ambient noise from the inlet signal. The resulting signal will then be stored temporarily in the data buffer 16. However, in other arrangements it is possible to do away with the second microphone, in which case the acoustic signal from the inlet microphone 9 will be stored in the data buffer 16 without compensation for ambient noise.

Figure 4(c) shows the variation of the measured concentration of CO₂ as a function of time, and is thus similar to figure 3(a). As will be noted, the CO₂ concentration begins to peak at a time of approximately 2.2 seconds, which is approximately 0.7 seconds after the breath peaks 19 occur in the acoustic signal graphs of figures 4(a) and 4(b). The device is configured, under the operation of the processor 15, to record and store at least the acoustic signal from the inlet microphone 9 in the data buffer 16 for subsequent retrieval and analysis as and when the CO₂ sensor 12 returns representative of a high CO₂ concentration indicative of a breath sample. The CO₂ signal is thus used as a time reference, and will trigger retrieval and analysis of the acoustic signal if it exceeds the predetermined threshold value V, to thereby assess the acoustic signal in order to determine whether or not the breath sample has been tampered with. The basis of this analysis will be described in more detail below.

Figure 4(d) shows a graph of acoustic frequency (on the y-axis) against time (on the x-axis) for the 1 second time window 20 of the breath sample. Figure 4(e) shows a signal power distribution graph with logarithmic amplitude on the y-axis and frequency on the x-axis. As these graphs show, the portion of the acoustic signal from the inlet microphone 9 which represents the breath sample 20, may be characterised by its power spectrum being dominated by frequencies below 400 Hz, and white noise. In this regard, dominance of frequencies below 400 Hz is used to mean more than approximately 80% of the total signal power is contained within a frequency band between 40 and 400 Hz. This is further highlighted below having regard to the graphs of figures 5 and 6, which represent breath samples obtained via two alternative tamper regimes.

Figure 5 shows similar graphs to those of figure 4, but which are representative of a tampered breath test carried out with a length of cooled plastic tubing placed between the test subject's mouth and the inlet port 6 of the device 1. In this test it will be noted that there was a slightly longer delay between the ready beep 18 and the detected level of CO₂

concentration beginning to peak (at approximately 4.8 seconds) in graph 5(c). This was simply due to a slower reaction time on the part of the test subject. Nevertheless it will be noted that the peaks in graphs 5(a) and 5(b), which represent the acoustic signals from the distal and inlet microphones 10, 9 respectively, still precede the peak in the CO₂ signal by a similar amount of time.

Having regard to figures 5(d) and 5(e), which show similar data to figures 4(d) and 4(e), it will be noted immediately that the acoustic signal from the inlet microphone 9 shows an upward shift in terms of the frequencies detected when compared to the untampered signals of figure 4. Figure 5(e) also shows that the acoustic signal includes a significant number of resonant peaks, which arise from the breath sample having been directed along the cooled plastic tube.

Figures 6 shows similar graphs again, but which are this time representative of a tampered breath test carried out with a length of charcoal-filled tubing placed between the test subject's mouth and the inlet port 6 of the device 1. In comparison to the untampered signal shown, for example, by comparing figure 6(e) with figure 4(e), it will be noted that the power spectrum of this tampered signal shows an even more significant upwards shift in terms of the dominant frequencies.

As will therefore be appreciated, the power spectrum of the acoustic signals can be used to determine whether or not the breath sample has been tampered with, since an untampered breath sample can be characterised by being dominated by frequencies below 400 Hz with few or no resonances, whereas the power spectrum of tampered samples will be shifted towards higher frequencies and in some cases will also include a significant number of resonances.

The generation of a signal indicative of a tampered breath sample is further illustrated in the table below which includes experimental data corresponding to the tests of figures 4, 5 and 6 which represent untampered, cooled tube, and charcoal-filled tube conditions respectively. In the table the signal power within two frequency bands; one at 40-400 Hz and one at 2000-2500 Hz, is tabulated for each of the tamper conditions. The unit of power is mW and includes power amplification in the microphone and preamplifier. The numbers in the table are used for comparison only. The ratio between the signal power within each frequency

band (the bottom row of the table) indicates a significant difference between the untampered and the tampered cases - 20.5 for untampered versus 1.4 for a cooled tube and 1.9 for a charcoal-filled tube.

5

<i>Frequency band</i>	<i>Untampered</i>	<i>Cooled tube</i>	<i>Tube with charcoal</i>
40-400 Hz	$4.5 \cdot 10^{-2}$	$1.1 \cdot 10^{-3}$	$3.3 \cdot 10^{-4}$
2000-2500 Hz	$2.2 \cdot 10^{-3}$	$0.8 \cdot 10^{-3}$	$1.7 \cdot 10^{-4}$
Ratio	20.5	1.4	1.9

In one embodiment of the present invention real time computation of the ratio between the signal power in the frequency bands of 40-400 Hz and 2000-2500 Hz, respectively, is performed by the processor 15. If this ratio is higher than a predetermined value, e.g. 10, a signal indicative of an untampered breath sample is generated.

10

Furthermore, by using the CO₂ signal as a time reference as proposed above, only a relatively short time-period of the acoustic sample (for example 0.5 to 1 second) needs to be analysed in order to achieve a tamper result. By recording temporarily storing the acoustic signal in the data buffer 16 and then only retrieving the predetermined time portion of the signal for analysis, the processing time needed to perform the analysis can be kept to a minimum, thereby ensuring a very fast result. In this regard, it is proposed that preferred embodiments of the present invention will therefore operate by retrieving and analysing a portion of the acoustic signal which corresponds to a predetermined time period (e.g. 0.5 seconds), and which precedes the point in time at which the CO₂ signal is determined by the processor as being in excess of the threshold value V. It is therefore proposed that the predetermined time period will run from 1 second to 0.5 seconds before the point in time at which the CO₂ signal is determined to exceed the threshold value V.

15

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Figure 7 shows an outline flow chart representative of the operating regime of the device 1.

Initially, a test subject is asked to direct an exhaled breath sample into the inlet port 6,

whereupon the inlet microphone 9 will produce an acoustic signal representative of the

breath sample, and the acoustic signal will be stored in the data buffer 16. If the processor

15 determines that a CO₂ signal received from the CO₂ sensor 12 is representative of the

CO₂ concentration in the sample exceeding the predetermined threshold value V (e.g. 2%

v/v), then the processor will retrieve and analyse a small portion of the stored acoustic signal

which preceded the CO₂ signal. Analysis of the acoustic signal will be as described above,

and if the analysis shows that the power spectrum of the signal is dominated by frequencies

10 above 400 Hz, then the processor will return an error signal which may be shown on a

display. If, on the other hand, the acoustic analysis shows that the acoustic signal is

dominated by frequencies below 400 Hz, then the breath will be approved and the processor

will then continue to calculate the concentration of the volatile substance (e.g. ethanol) in the

breath sample as previously described, and to display the result.

15 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 integers.

The features disclosed in the foregoing description, or in the following claims, or in the

accompanying drawings, expressed in their specific forms or in terms of a means for

20 performing the disclosed function, or a method or process for obtaining the disclosed results,

as appropriate, may, separately, or in any combination of such features, be utilised for

realising the invention in diverse forms thereof.

While the invention has been described in conjunction with the exemplary embodiments

described above, many equivalent modifications and variations will be apparent to those

25 skilled in the art when given this disclosure. Accordingly, the exemplary embodiments of the

invention set forth above are considered to be illustrative and not limiting. Various changes

to the described embodiments may be made without departing from the spirit and scope of

the invention.

CLAIMS

1. A tamper evident breath analyser device having an inlet region and a sensor arrangement, the inlet region being configured to receive a breath sample from a test subject via an inlet port and direct the sample to the sensor arrangement, and the sensor arrangement being configured to provide a signal representative of the concentration of a volatile substance within said sample, the device being characterised in that said inlet region includes an inlet microphone adjacent said inlet port, the microphone being positioned and operable to provide an acoustic signal representative of local pressure variations arising from an air flow produced by an exhaled breath sample directed through the sample inlet port, the device further comprising: a processor operable to analyse at least a portion of said acoustic signal and produce a signal indicative of an untampered breath sample in dependence on said analysis; and a data buffer configured to receive and temporarily store said acoustic signal from the inlet microphone for subsequent analysis by the processor, and wherein said sensor arrangement includes a carbon dioxide sensor arranged and configured to provide a carbon dioxide signal representative of the concentration of carbon dioxide in an air flow produced by said breath sample and directed through the sensor arrangement; said processor being operable to compare said carbon dioxide signal to a predetermined threshold value, and to retrieve at least a portion of said stored acoustic signal from the data buffer and perform said analysis on the retrieved acoustic signal in response to said carbon dioxide signal exceeding said threshold value.
2. A device according to claim 1, wherein said processor is operable to analyse the power spectrum of said acoustic signal and to produce said signal indicative of an untampered breath sample in response to said power spectrum being dominated by frequencies below 400 Hz.
3. A device according to claim 1 or claim 2, wherein said processor is operable to determine a point in time at which said carbon dioxide signal exceeds said threshold value, and to retrieve from said data buffer and analyse a portion of said stored acoustic signal corresponding to a predetermined time period which precedes said point in time.

4. A device according to claim 3, wherein said predetermined time period is 0.5 seconds.
5. A device according to claim 3 or claim 4, wherein said predetermined time period runs from 1 second to 0.5 seconds before said point in time.
- 5 6. A device according to any preceding claim, wherein said inlet region further includes a second microphone which is spaced further from said inlet port than said inlet microphone, said second microphone being positioned and operable to provide an ambient acoustic signal representative of ambient noise.
7. A device according to claim 6, wherein said processor is operable to subtract the
10 signal provided by the second microphone from the signal provided by the inlet microphone and to perform said analysis on the resulting signal.
8. A tamper-evident method of analysing a breath sample, the method comprising the steps of: providing a breath analyser device having an inlet region and a sensor arrangement, the inlet region being configured to receive a breath sample from a test
15 subject via an inlet port and direct the sample to the sensor arrangement, and the sensor arrangement being configured to provide a signal representative of the concentration of a volatile substance within the sample; providing an inlet microphone adjacent said inlet port; directing a breath sample from a test subject into the inlet region of the device via the inlet port to thereby produce an air flow through the inlet
20 port, obtaining via said microphone an acoustic signal representative of local pressure variations arising from said air flow; analysing at least a portion of said acoustic signal to produce a signal indicative of an untampered breath sample in dependence on said analysis; and temporarily storing said acoustic signal from the inlet microphone in a data buffer prior to said step of analysing the signal; wherein the sensor arrangement
25 of the device includes a carbon dioxide sensor, and the method further comprises the steps of: using said carbon dioxide sensor to provide a carbon dioxide signal representative of the concentration of carbon dioxide in said air flow; comparing said carbon dioxide signal to a predetermined threshold value; and, if said carbon dioxide signal exceeds said predetermined threshold value, retrieving at least a portion of

said stored acoustic signal from the data buffer and performing said analysis on the retrieved acoustic signal.

5 9. A method according to claim 8, wherein said step of analysing involves analysing the power spectrum of said acoustic signal, said signal indicative of an untampered breath sample being produced in response to said power spectrum being dominated by frequencies below 400 Hz.

10 10. A method according to claim 8 or claim 9, further comprising the steps of:
determining a point in time at which said carbon dioxide signal exceeds said threshold value; and retrieving from said data buffer and analysing a portion of said stored acoustic signal corresponding to a predetermined time period which precedes said point in time.

11. A method according to claim 10, wherein said predetermined time period is 0.5 seconds.

15 12. A method according to claim 10 or claim 11, wherein said predetermined time period runs from 1 second to 0.5 seconds before said point in time.

13. A method according to any one of claims 8 to 12, wherein a second microphone is provided which is spaced further from the inlet port than said inlet microphone, said second microphone being used to provide an ambient acoustic signal representative of ambient noise.

20 14. A method according to claim 13, further including the steps of: subtracting the signal provided by the second microphone from the signal provided by the inlet microphone; and performing said analysis on the resulting signal.

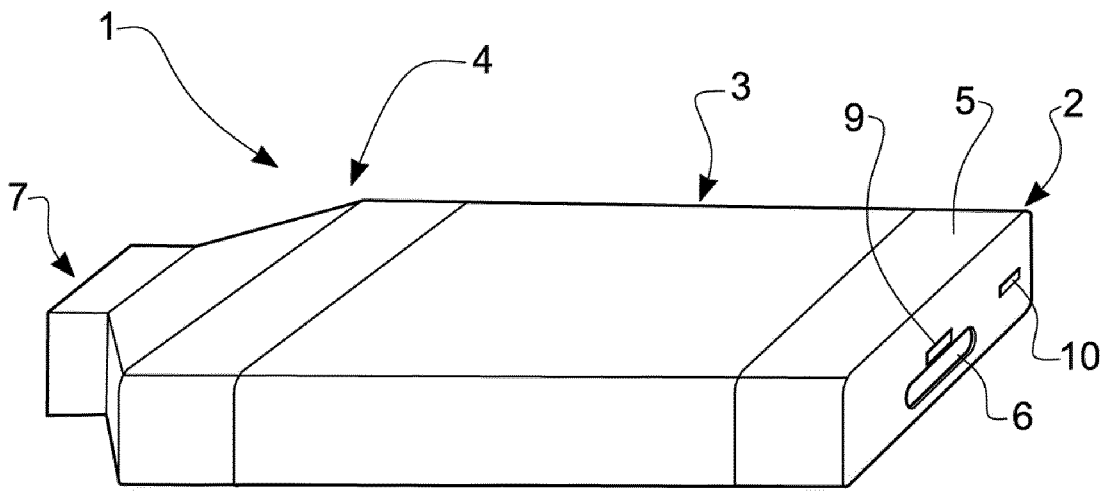


FIG 1

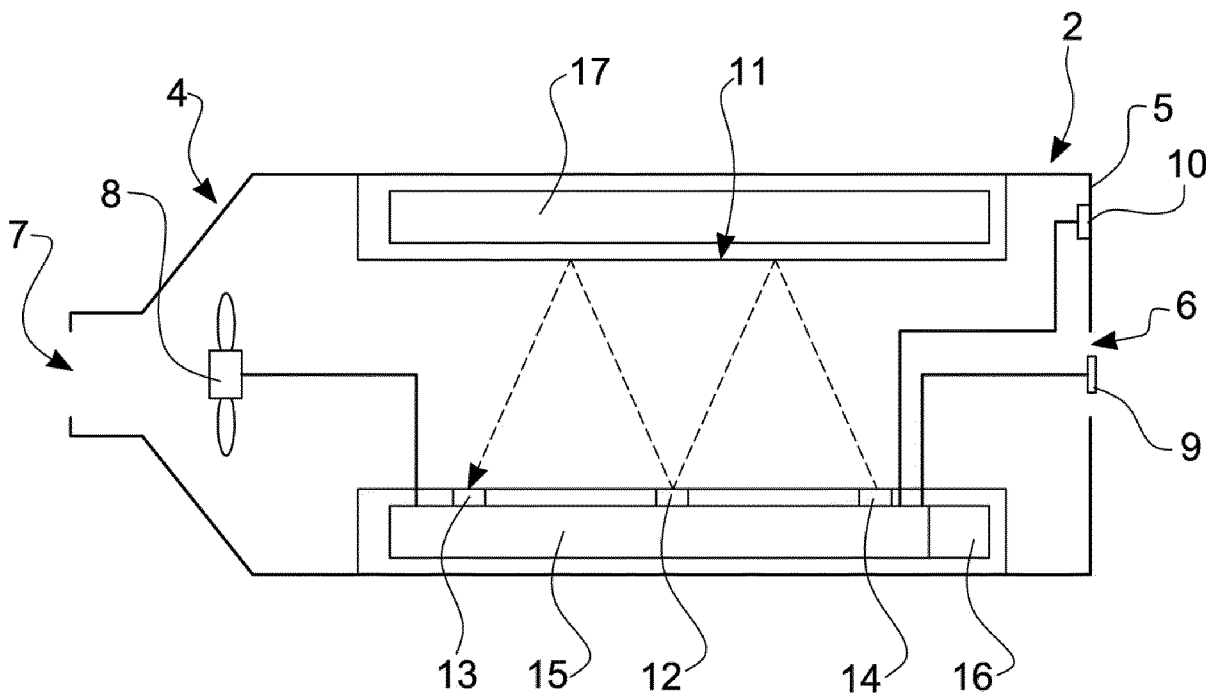
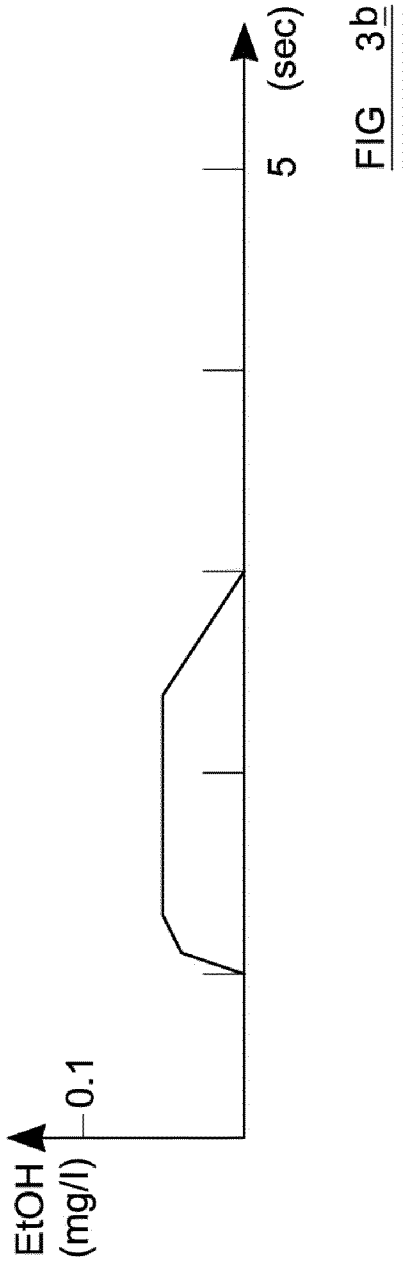
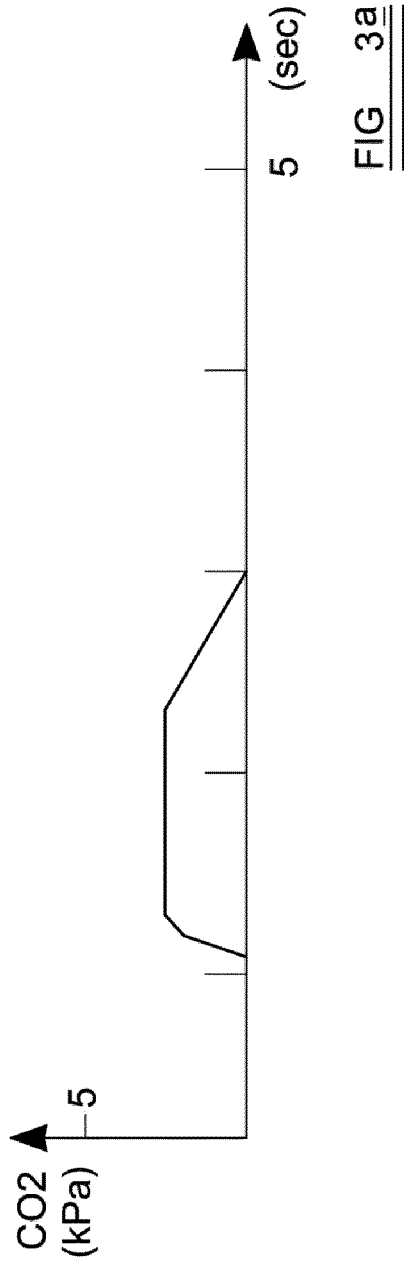
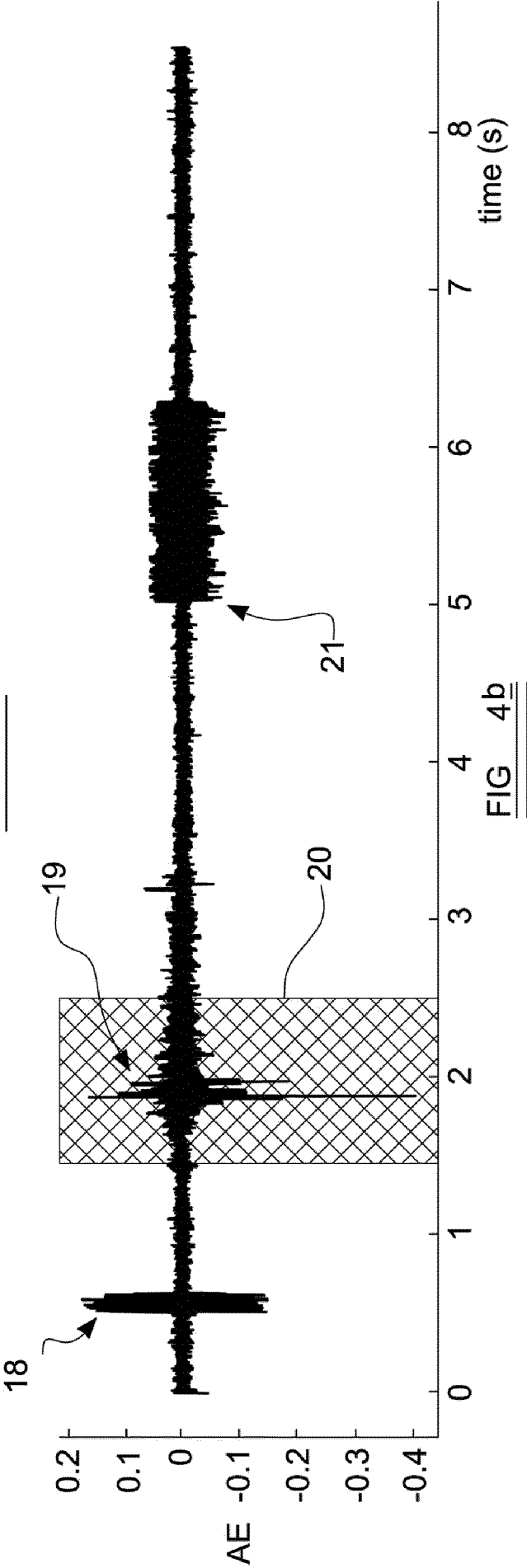
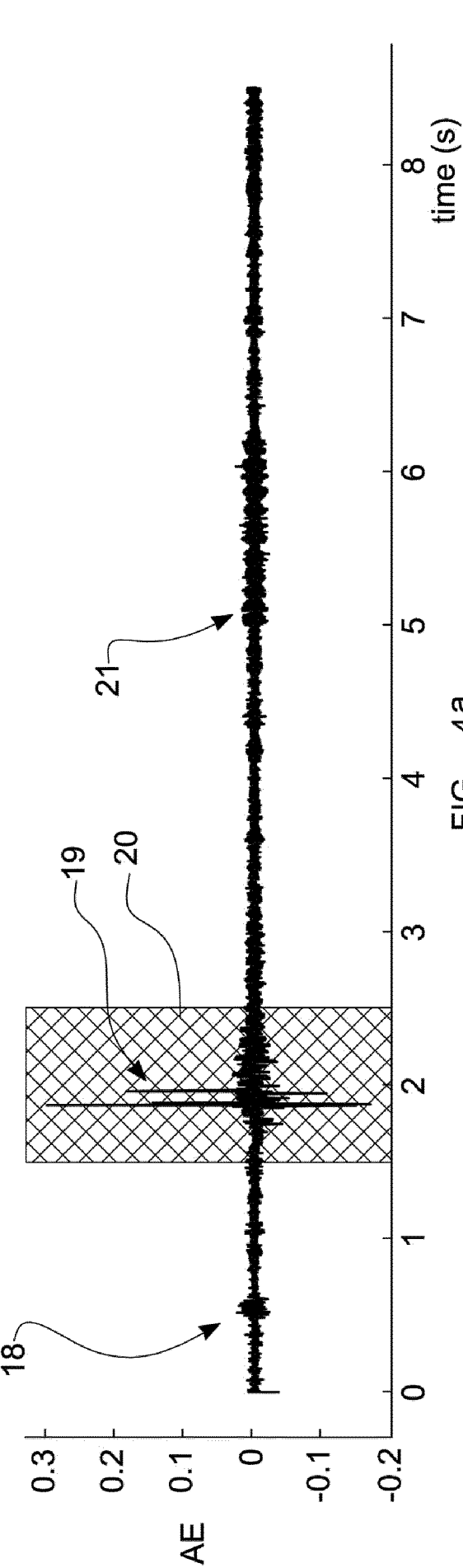


FIG 2





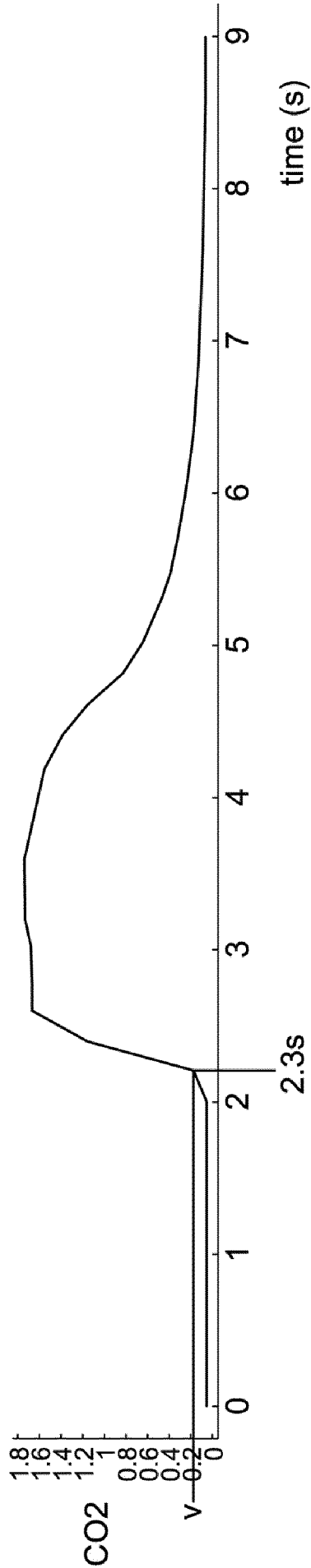


FIG 4c

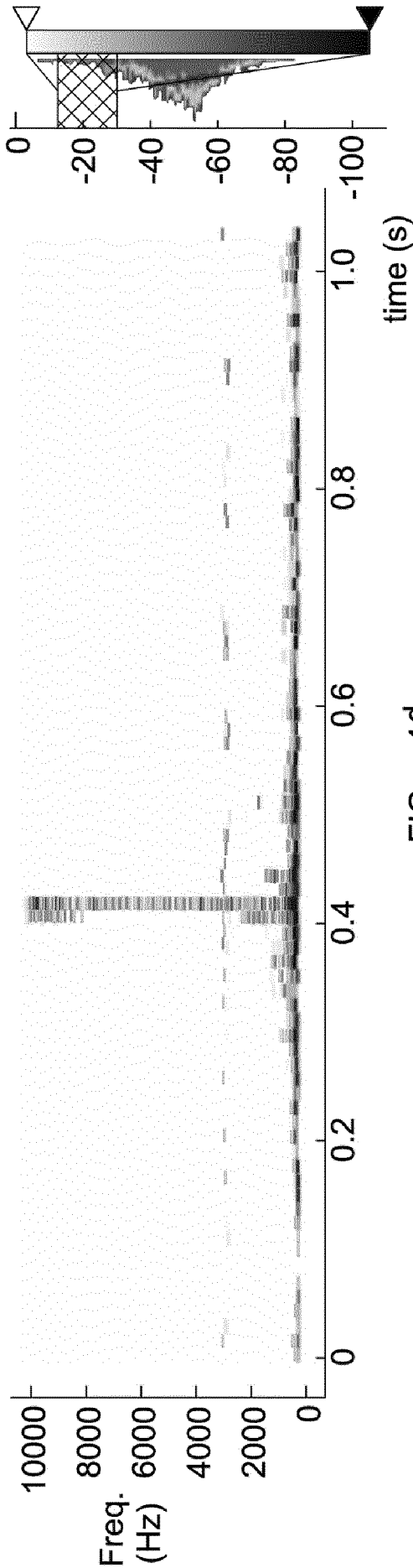


FIG 4d

5 / 12

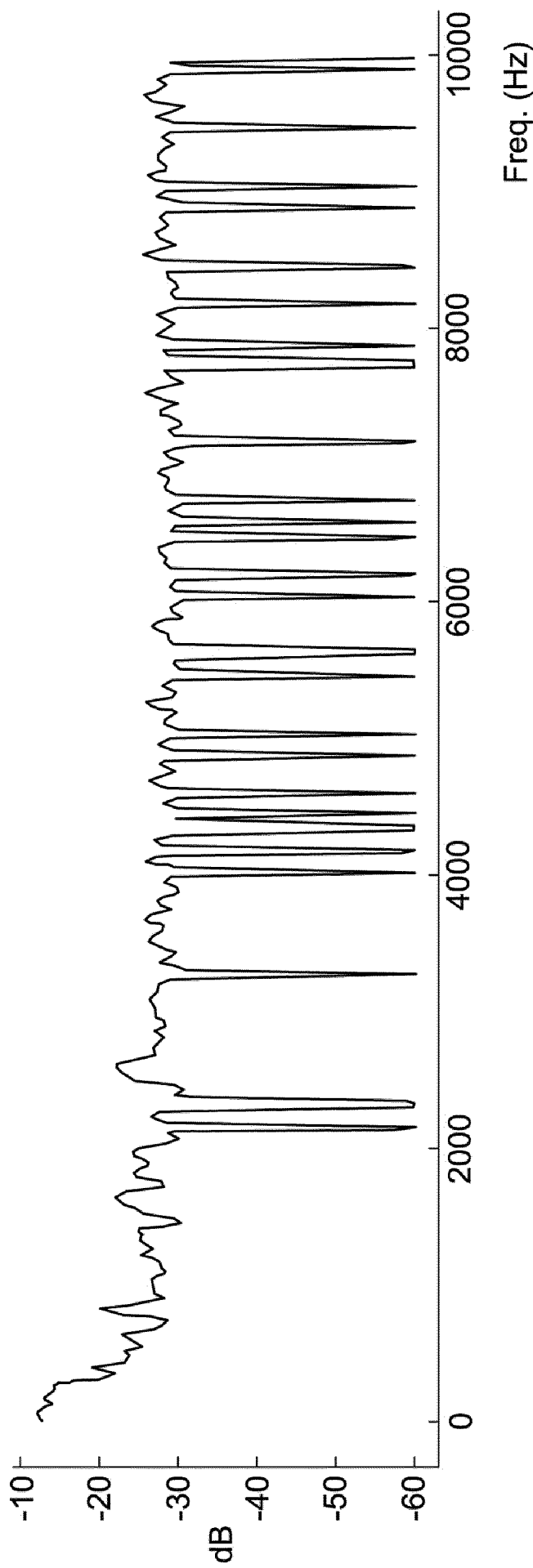
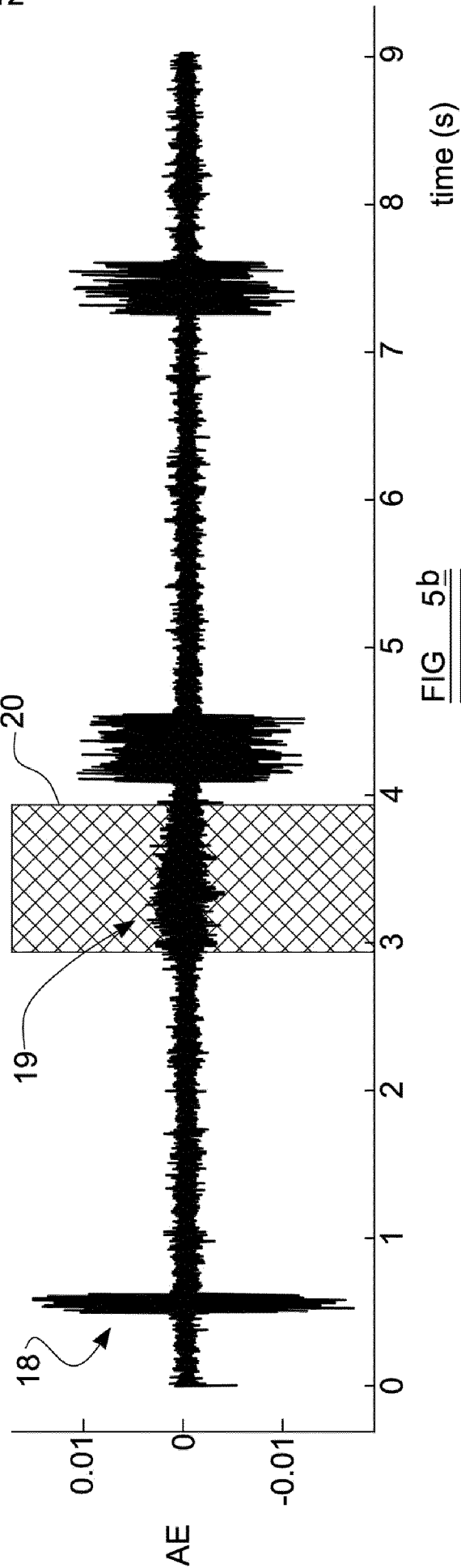
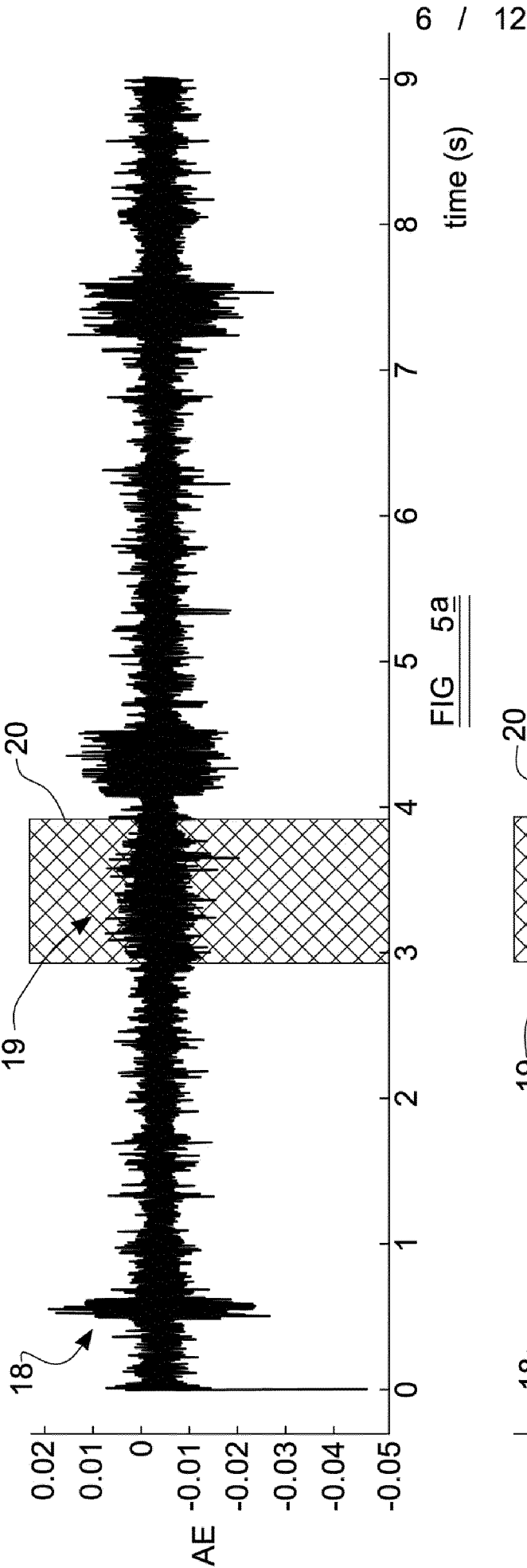


FIG 4e



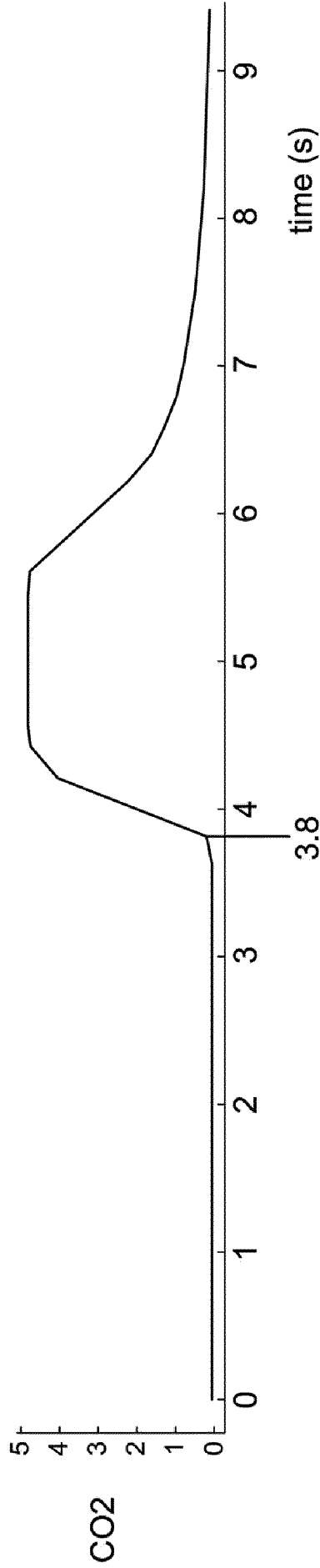


FIG 5c

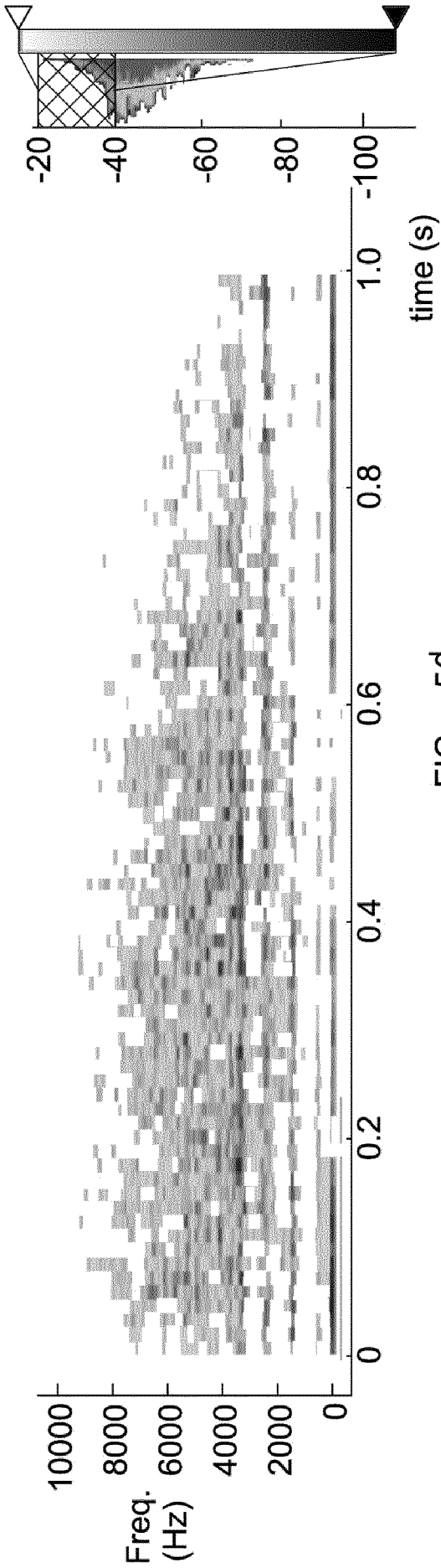


FIG 5d

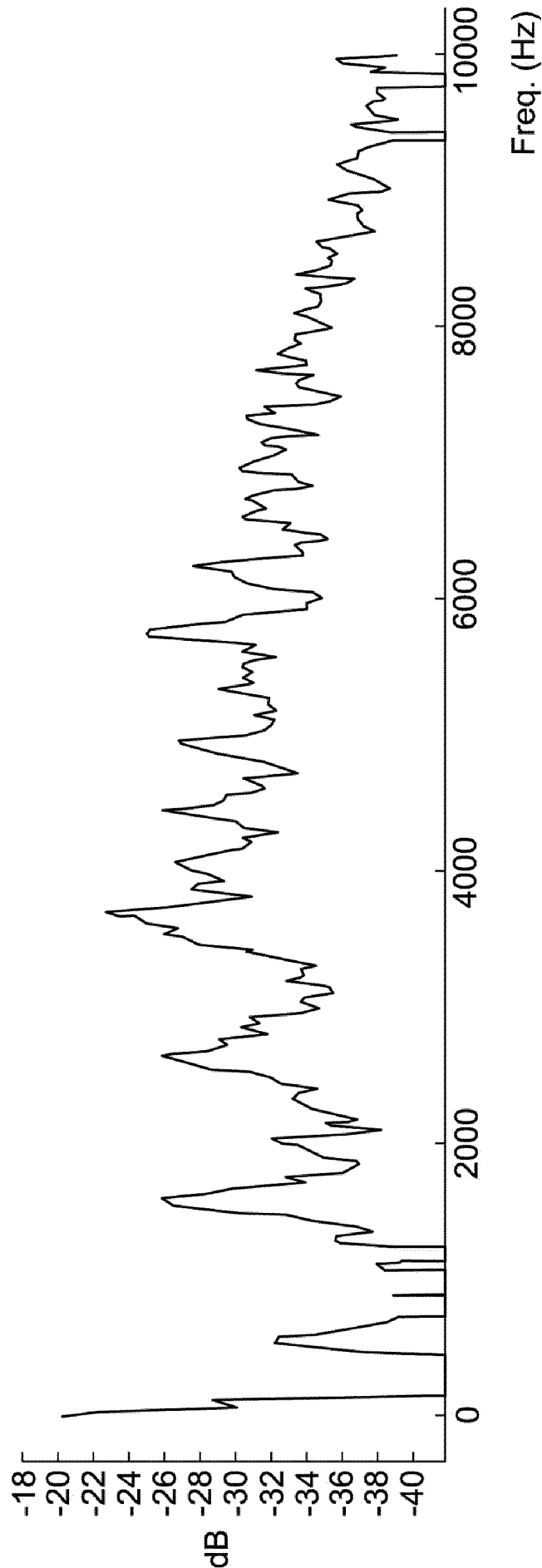
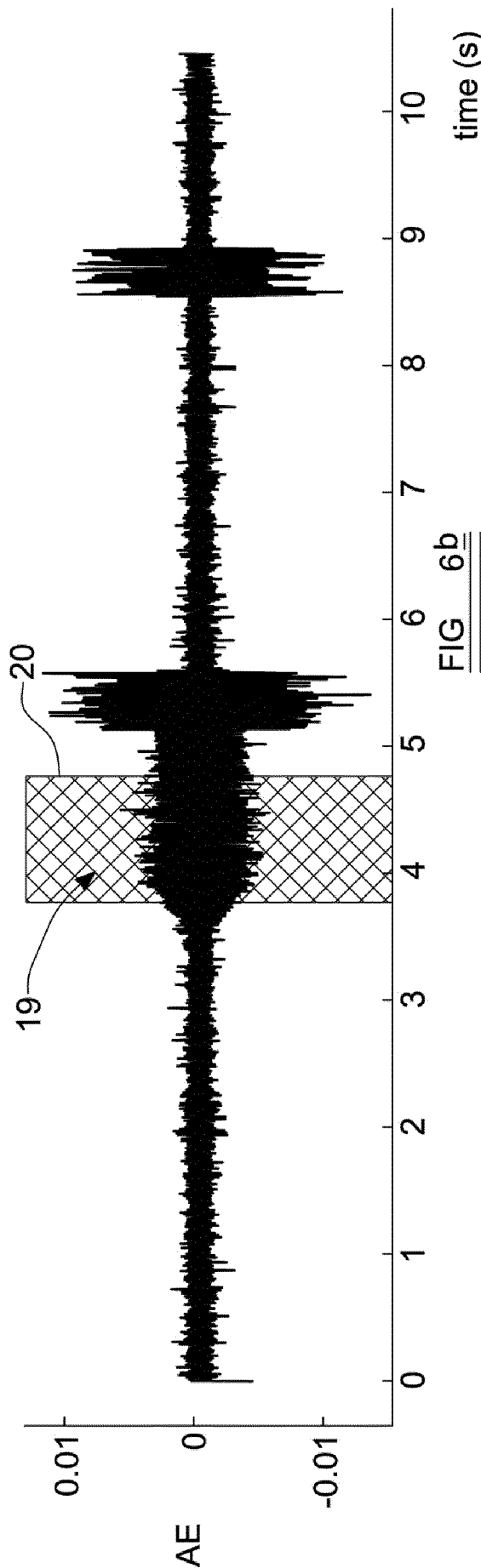
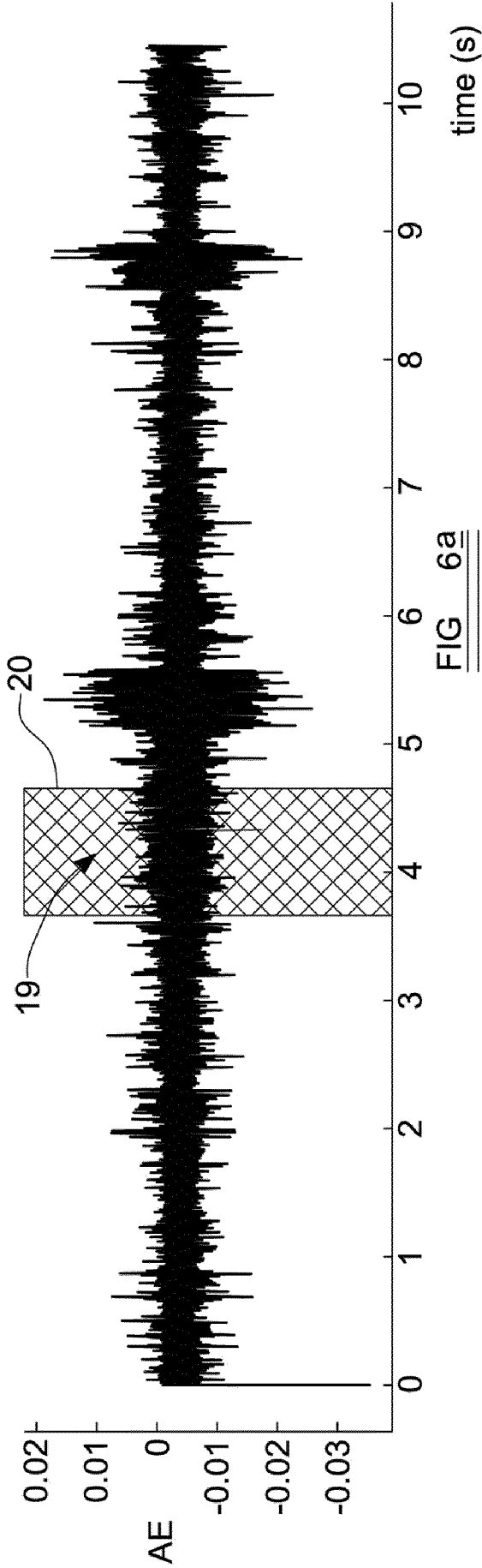


FIG 5e



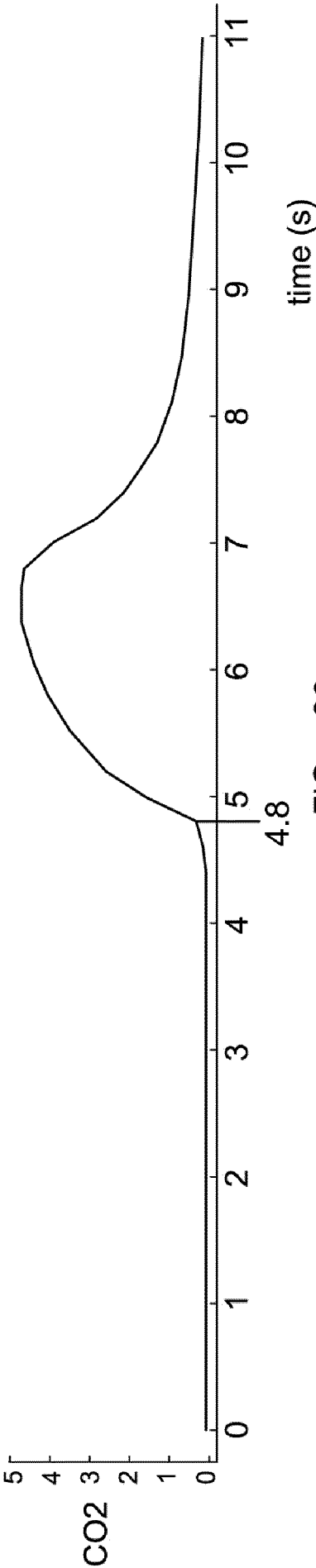


FIG 6c

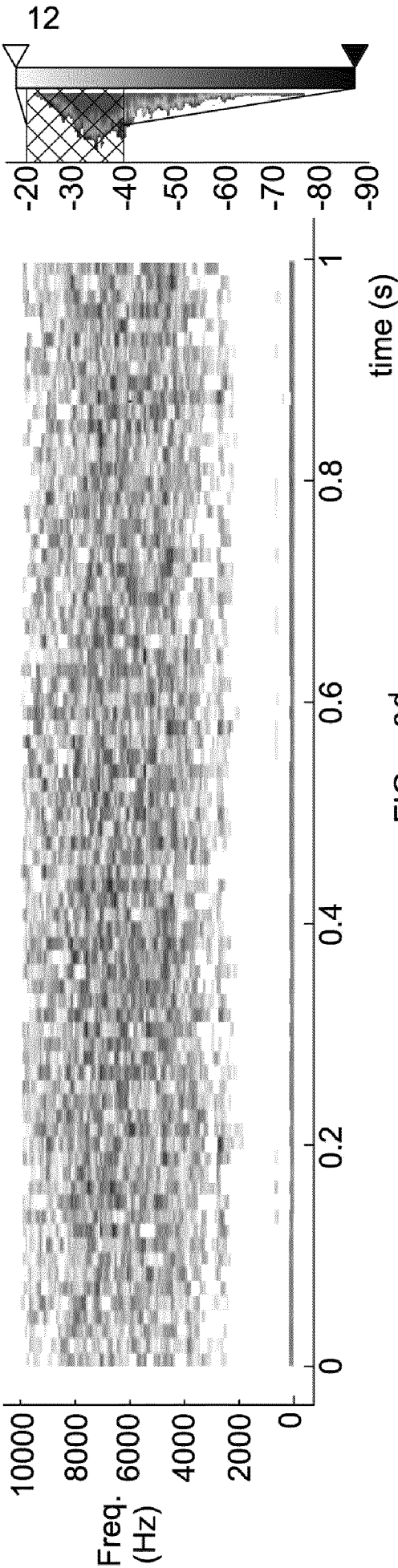


FIG 6d

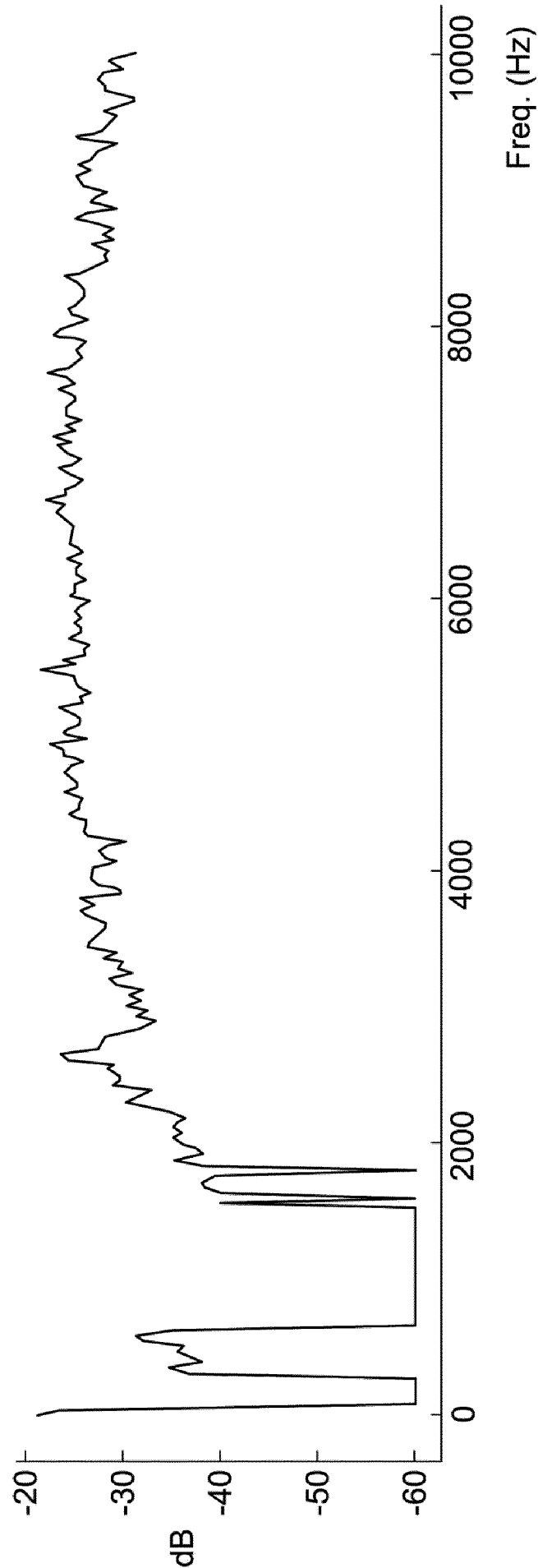
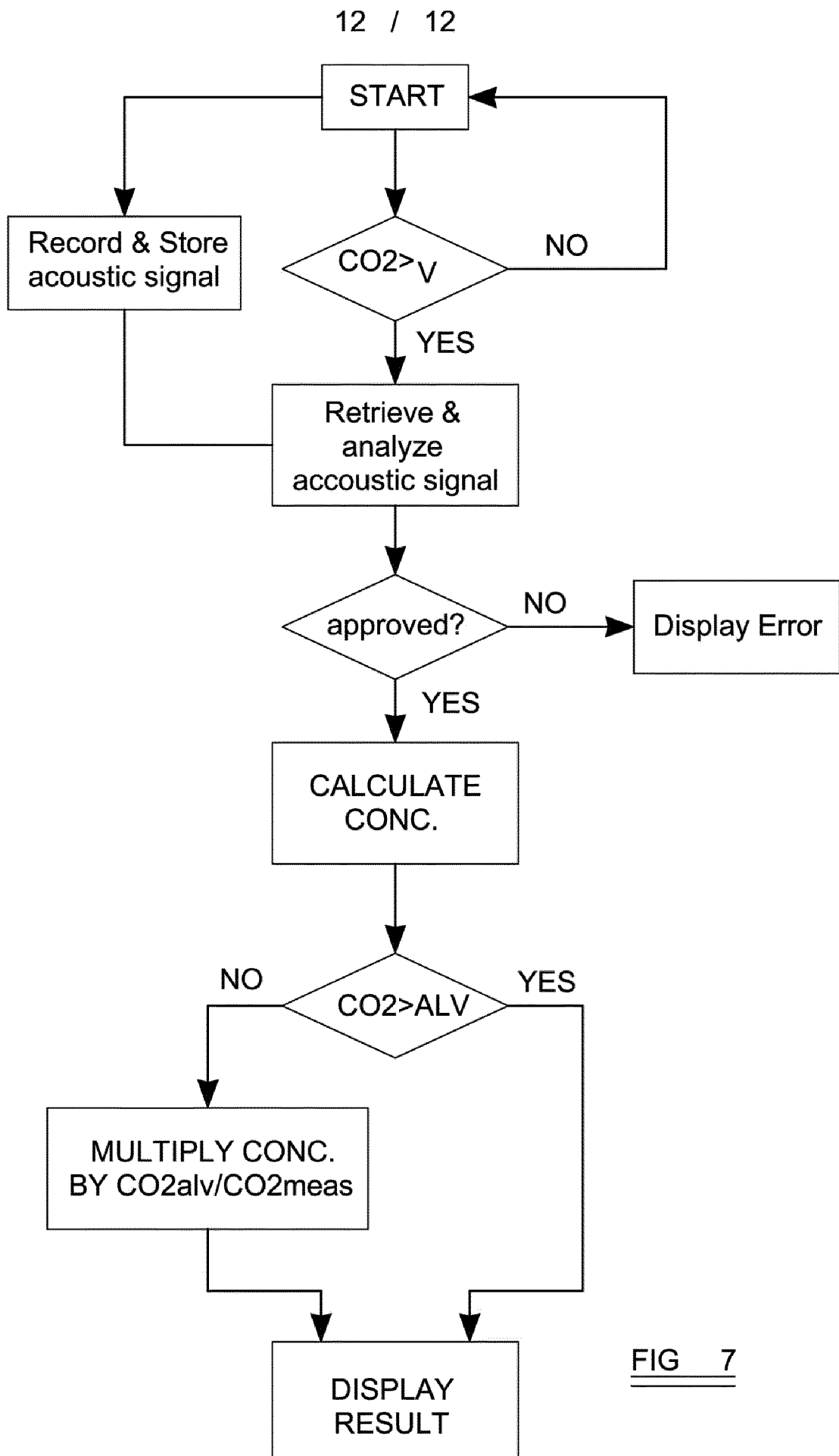


FIG 6e

FIG 7

INTERNATIONAL SEARCH REPORT

International application No

PCT/EP2016/050674

A. CLASSIFICATION OF SUBJECT MATTER

INV. G01N33/497 A61B5/083 A61B5/087 A61B5/00
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

G01N A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2012/064252 A1 (HOEK INSTR AB [SE]; HOEK BERTIL [SE]; TENERZ LARS [SE]; SMITH LEIF [SE] 18 May 2012 (2012-05-18) page 3, line 4 - line 40 page 4, line 4 - line 8 page 4, line 37 - line 42 page 5, line 6 - line 26 page 6, line 33 - line 37 figures 1,3, -----	1-5,8-12
Y A	US 2014/165697 A1 (MOCHIZUKI KEI [JP] ET AL) 19 June 2014 (2014-06-19) paragraph [0117] paragraph [0123] paragraph [0171] - paragraph [0172] paragraph [0263] paragraph [0269] -----	1-5,8-12 6,7,13, 14



Further documents are listed in the continuation of Box C.



See patent family annex.

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"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

6 April 2016

Date of mailing of the international search report

28/04/2016

Name and mailing address of the ISA/

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Authorized officer

Joyce, David

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2016/050674

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