Traceability system for breath-alcohol measurements in Germany

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Abstract

Since 1998, breath-alcohol measurements have been carried out under German traffic law, and that year saw the first type approval of an evidential breath-alcohol measuring instrument in Germany.

Over the following years breath-alcohol measurements met with considerable resistance due to drivers' fear of false positive measurement results. Now, such measurements are established for the determination of the regulatory offence of "Driving under the influence of alcohol". One of the reasons for the acceptance of this method by both drivers and the law courts is the reliability of the results, this reliability being guaranteed by the closed traceability chain from each breath-alcohol measurement to the German national breath-alcohol standard.

This paper describes the specific way in which evidential breath-alcohol measurements are made in Germany, and the traceability chain behind them.

1 Why do we measure breath-alcohol concentration?

Consumption of alcohol influences the driving capability of a person; to ascertain the degree of this influence one should employ psychological tests. For daily use, these tests are too time-consuming and expensive. As an alternative, the alcohol concentration in body fluids (breath, urine, blood, sweat) can be used to obtain a measurable quantity for drink-driving prosecutions.

As Borkenstein et al. showed in the Grand Rapids study [1] in 1964, there is a significant correlation between the alcohol concentration measured in a driver's breath and the accident risk. This study was the basis for the implementation of limits for breath-alcohol concentration in many countries all over the world. The realization of instruments fit for evidential purposes was very difficult due to three totally different scientific areas influencing evidential breath-alcohol measurements:

- Firstly there is the measurement instrumentation, which has to be capable of measuring the breath-alcohol concentration with an appropriate uncertainty.
- Secondly there is the physiology of human beings, which itself leads to various influences on a breath test.
- Thirdly there are the special requirements of the justice system - special precautions are necessary to obtain measurement results that can be used as evidence in court.

2 Legal basics of evidential breath-alcohol measurement in Germany

The advantages of measuring the breath-alcohol concentration in comparison to carrying out a blood analysis are that breath is usually always available, the measurement result is valid very shortly after, and the procedure does not cause discomfort to the subject being tested. These are the main reasons why breath-alcohol testing is used in many countries to check the influence of alcohol on drivers.

For a long time in Germany, blood analysis was the only valid method for testing alcohol content for evidential purposes. Since the 1960's, the police has been obliged to order a blood-alcohol analysis if a driver was suspected of being over the alcohol limit imposed by the traffic law. Thus after a pre-test (using a simple breath-alcohol tester) showing a non-negligible degree of alcohol content, the driver has to be taken to a doctor to take the blood sample which is then analyzed in a specialized laboratory, and the result interpreted. Blood tests are therefore time-consuming and expensive.

In 1987, the former German Health Institute (BGA) was ordered by the German government to check whether breath-alcohol measurements could be used for evidential purposes in Germany.

In 1991, the report "Evidential safety of breath-alcohol analysis" [2] was published; it concluded that breath-alcohol analysis can deliver evidential results provided that special requirements are taken into account.

Another important result was that breath-alcohol and blood-alcohol values cannot be converted into each other directly with the necessary reliable level of uncertainty. It was therefore proposed to define special limits for breath-alcohol concentration. The proposals in the report formed the basis for changing the German traffic law in 1998. Now, not only are the limits in units of blood-alcohol concentration included in the drink-driving law, but also the limits for units of breath-alcohol concentration.

In Germany, the drink-driving limits are determined in a specific way and are traced back to the understated uncertainty of forensic scientists of the 1960's. The limit is a combination of the so-called "danger limit", where the risk of having an accident reaches a certain value, and a so-called "security addition" including all the possible effects which can influence the measurement. For blood analysis, these are effects caused by sampling, by preparation of the sample and by the analysis itself.

To gain an idea of the magnitude of these limits, the value of the former legal limit was 0.8 g/kg, there was a "danger limit" of 0.65 g/kg and a "security addition" of 0.15 g/kg (note: "g/kg" is gram ethanol per kilogram blood that is "‰" or "per-mill"). Thus, if someone is over the legal limit, there is no question about a possible uncertainty of the measured value since the uncertainty is "part of the limit".

The breath-alcohol limits were determined based on the blood-alcohol limits including a "security margin". To be in line with the blood-alcohol limits, even if the legal limits change no special danger limit was proposed, but a calculation was made by means of a conversion factor and an additional security factor. Thus, the uncertainty of the measurement is also "part of the limit" for the breath-alcohol measurements.

Now, breath-alcohol measurements are mainly used for the determination of regulatory offences in Germany. Therefore, special instruments accepted for evidential measurements have to be used. If someone does not want to or is not able to give an appropriate breath sample then a blood analysis is ordered by the police. In Germany, the resulting "injury" to the body is still justified by law.

3 Requirements of evidential instruments and schedule of the measurement in Germany

The requirements of evidential breath-alcohol instruments are defined in the BGA report and in DIN 0405 [6]. They not only fulfill those of OIML R 126 [3] but go much further. The requirements include special arrangements for the instruments, for the schedule of the measurements (method and procedure of execution of measurement, etc. - see Table 2) and, last but not least, type approval and periodic verification of the instruments by verification offices.

The limits for the maximum deviation of the instruments from a reference standard during verification are based on OIML R 126. These limits (as per the verification ordinance - see Eichordnung [4]), can be found in Table 1. The limits for daily use are 1.5 times the test limits.

Table 1 Limits for the maximum deviation from a reference standard of breath-alcohol measuring instruments under test

Measured breath-alcohol concentration	Limit of deviation during tests
$c < 0.4$ mg/l	0.02 mg/l
0.4 mg/l $\leq c <$ 1 mg/l	0.05 × c
1 mg/l $\leq c \leq$ 2 mg/l	0.10 × c
$c >$ 2 mg/l	0.20 × c

The requirements on instrumentation and the measurement schedule are fixed in such a way that one could attain the necessary accuracy of the results and that an intentional or unintentional manipulation is impossible. Table 2 shows the resulting requirements on evidential breath-alcohol measurements according to the BGA report.

The analysis of two breath samples (i.e. expiration time, expiration volume, breath temperature and ethanol concentration), the recalculation of the ethanol concentration according to a breath temperature of 34 °C and the comparison of all measured parameters of both samples reduce the possibility of influencing the measurements by breathing techniques to a minimum. Together with the self-control mechanism of the instrument, this ensures the integrity of the measurement.

The basic/main requirement for evidential breath-alcohol measuring instruments in Germany is the type approval and verification of the instrument by the German verification offices.

4 Realization of the traceability chain

4.1 What is the aim of traceability for breath-alcohol measurements?

One obtains results using instruments for evidential purposes that can have serious consequences for a

Table 2 Special requirements on instrumentation and measurement schedule of evidential breath-alcohol measurements according to the BGA report

What has to be secured?	Resulting requirements according to BGA
Equilibrium of alcohol in breath and blood can be assumed in the alveoli only. Thus, the analyzed sample should be end-exhaled air or "deep lung air".	Breath volume and exhaling time have to be measured. A minimum breath volume depending on age and gender should be achieved. Exhalation time has to be greater than 5 s.
Under German traffic law, "alcohol" means that only the ethanol concentration has to be determined. Other components must not influence the measurement.	During the measurement two different analytical measurands (as, for example, two different wave lengths would do for infrared analysis) have to be obtained.
Body and environmental temperature should have no influence on the measurement.	The temperature of the breath has to be measured and the measured alcohol concentration has to be recalculated for a breath temperature of 34 °C.
Mouth-alcohol or even residual alcohol in the mouth (e.g. after eating a chocolate filled with alcohol) must not influence the measurement of breath-alcohol.	The measurement should only start after a waiting time of at least 20 minutes after drinking. Following a strict protocol, two breath samples (within a time interval of 2 to 5 minutes) have to be analyzed. The resulting difference of the measured ethanol concentration must not exceed 0.02 mg/l.
Breath techniques should have no influence.	First, the flow of breath during sampling is obtained. It has to be higher than 0.1 l/s during the whole sampling. Second, the breath temperature is measured and the ethanol concentration recalculated. Third, the obtained parameters of the two breath samples (volume, time, concentration) are compared and their differences have to be within certain limits.
Substances other than ethanol (e.g. spray, sweets) in the mouth should not influence the measurement.	The measurement should only start if the subject was monitored (by the police) for 10 minutes with no ingestion.
The instrument should be valid during the whole measurement.	The instrument shall use two independent measuring systems (redundancy) and must have self-control mechanisms.

driver, which is why reliable results and low uncertainties are essential. Measurement uncertainties are not used here as is usual practice in engineering, because they are included in the "security margin" of the alcohol concentration limit. Nevertheless, they have to be determined accurately following the rules given by the GUM [5]. The determined measurement uncertainties are important for checking whether the instrument is capable of remaining within the limits given in Table 1 during the verification validity period.

It is not possible to determine a reliable result and its uncertainty if there is no traceability of the measurement to a standard with known uncertainty. So for reliable results, traceability of each evidential breath-alcohol measurement to a national standard of breath-alcohol concentration (or the SI) is essential.

Figure 1 shows the principle of how each breath-alcohol measurement carried out by the police is traced back to the national standard. The breath-alcohol measuring instruments at the police stations can only be used as evidential instruments if they are verified by the verification offices, whose verification standards are under the control of the PTB, the German National Metrology Institute. The national standard for breath-alcohol concentration is located at the PTB.

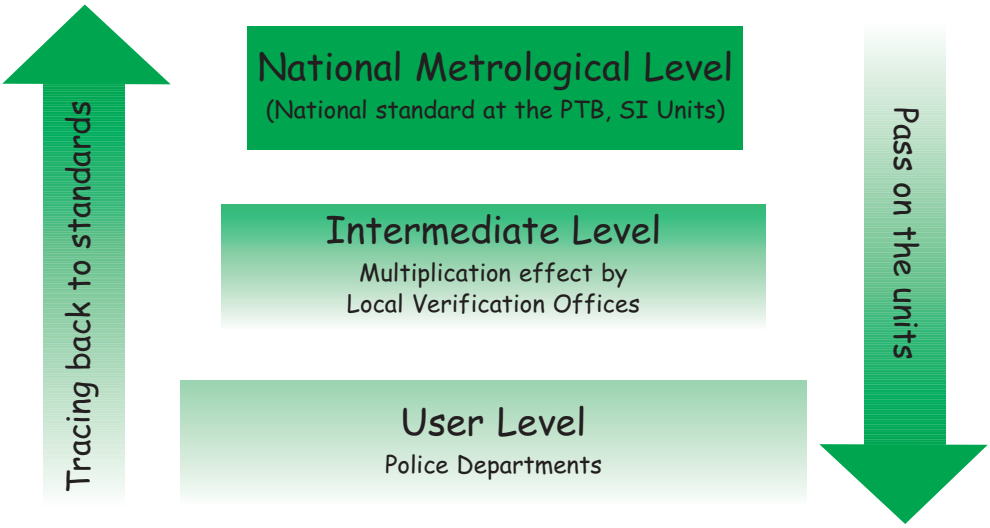

Figure 1 Principle of traceability of breath-alcohol measurements in Germany

4.2 Type approval

Before an evidential breath-alcohol measuring instrument can be used for evidential purposes it requires PTB type approval. The PTB has been involved in the process of establishing evidential breath-alcohol analysis since the outset. Together with the experts (i.e. manufacturers, users (the police), scientists and legal authorities), represented in the German standardization committee of DIN concerning breath-alcohol, it was possible to enforce the standard DIN 0405 [6] in such a way that the essential elements necessary for type approval were directly included.

Type approval includes not only the pure test of the instrument but also the specification of how the traceability chain shall be realized for each breath-alcohol measurement. This means in practice that the method used for testing the device by the local verification offices (*Eichamt*) has to be described, and what these institutes should use as their reference standard has to be specified.

To obtain type approval, three points have to be investigated:

- Is the instrument capable of measuring the breath-alcohol concentration and all additional parameters with the required accuracy according to DIN 0405?
- Are the repeatability and the reproducibility of the instrument within the given limits according to DIN 0405?
- Is it possible to check the parameters of the instrument and its measurement capability by the verification offices?

Additionally, the security level for evidential breath-alcohol analyzers is much higher than, for example, for vehicle exhaust-measuring instruments. For evidential instruments used in court, it is important to investigate whether the device can be handled in such a way that both unintentional misuse and intentional manipulation are rendered impossible.

In 1998, the first request for type approval of a breath-alcohol analyzer was received. The bases for the resulting examinations were the BGA report, DIN 0405 and OIML R 126. Some of the tests were delegated to specialized laboratories, e.g. vibration tests, software security or electromagnetic compatibility. In the PTB laboratory, attention was focused on problems concerning ethanol analysis, e.g. accuracy of the measurements, and cross-sensitivities or other influence parameters. Besides testing these parameters, techniques to intentionally manipulate the measurement results were thought up and applied to counter any possible future misuse in the field.

4.3 The German national breath-alcohol standard

To investigate the capabilities of the instrument, the German national standard for breath-alcohol concentra-

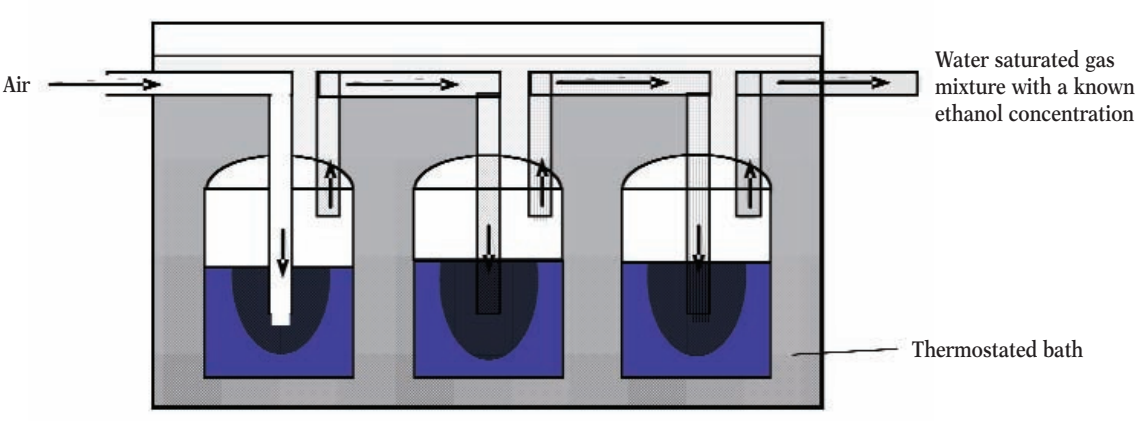

Figure 2 Principle of a bubble train described in OIML R 126

tions was used. The PTB national standard is a three-flask "bubble train" in a thermostated bath as described in OIML R 126. The flasks are filled with an ethanol-water solution of known ethanol concentration and the air flowing through is cleaned and preheated.

Figure 2 shows the bubble train in principle. The ethanol concentration of the air flowing through the flasks increases subject to the ethanol concentration of the solution and to the gas temperature. This effect is, in principle, described by Henry's law. The ethanol concentration of the solution decreases with the amount of gas flowing through and absorbing the ethanol. So, if only one flask was used the ethanol concentration in the resulting gas mixture would decrease immediately. To obtain a nearly stable system (for a limited volume) the three-flask model was designed. In the first two flasks the ethanol concentration of the gas is enriched and in the third flask the resulting concentration is reached and held stable. The volume of calibration gas that can be prepared with a stable ethanol concentration can be calculated.

The mass concentration of ethanol in the resulting gas mixture is calculated using the Dubowski equation described in OIML R 126 based on Henry's law:

$$c\_gas = c\_solution \cdot K_0 \cdot e^{A \cdot T} \qquad (1)$$

$$K_0 = 4.145 \times 10^{-2}$$

$$A = 0.06583\ 1/°C$$

with:

c_gas...	resulting ethanol concentration of the gas mixture in mg/l
c_solution...	ethanol concentration of the water-ethanol solution in g/l
K_0...	constant including the Henry coefficient for ethanol
A...	constant describing the temperature dependency
T...	Celsius temperature of the gas mixture (in °C)

The author is aware of the wide range of Henry coefficients used for the formulation of the Dubowski equation (see [7]) fixed in OIML R 126. Nevertheless, the equation is considered as internationally agreed on. That is why the included Henry coefficients with a zero uncertainty were used as, for example, similarly the extinction coefficient of ozone is used for international comparisons. Whilst this is metrologically unsatisfactory, for the moment it is an acceptable method.

Besides the Henry coefficients, the gas temperature and the ethanol concentration of the ethanol-water solution determine the ethanol concentration of the gas mixture and its uncertainty. The ethanol-water solution used is prepared and spot checked in the PTB laboratory. Its expanded relative uncertainty is ≤ 0.35 % (k = 2). In this value, the preparation of the solution and the impurity of the ethanol used are recognized, but not the decrease in concentration during the use in the bubble train.

The temperature of the gas is determined in the third flask, as here the final enrichment with ethanol occurs. Here, the temperature measured is the temperature of

the solution, since the gas and liquid temperatures should have reached equilibrium at this stage. This means that no change in the solution temperature should be perceived by the PTB thermometer, which has a resolution of 0.01 K.

The expanded relative measurement uncertainty determined for the delivered gas concentration is smaller than 1.1 % (with $k = 2$). The determined uncertainty of the delivered gas composition was confirmed by bilateral comparisons with the Belgian Traffic Institute BIVV (IBSR) which is responsible for the calibration of breath-alcohol analyzers in Belgium.

4.4 Periodical verification by Local Verification Offices

One of the fundamental requirements for evidential breath-alcohol analyzers described by the BGA report is the periodic verification of each instrument by the local verification offices. In 1992, evidential breath-alcohol analyzers were included in the German verification regulations. The limits for the measurement uncertainties of instruments under test and in daily use are described there (see also section 3), and how often the instruments have to be verified is also laid down. As there was no information about the long-term stability of breath-alcohol analyzers, the verification period was fixed at six months.

For the verification offices, the verification of evidential breath-alcohol analyzers is unique because not only one measurand has to be checked but also the other relevant measurands such as sampling volume and gas temperature. The maximum deviation from a "known" value of those secondary measurands is specified in the BGA report and in DIN 0405, i.e. 0.3 K for the gas temperature and 15 % of the measured volume for the sampling volume.

In the German Standardization Committee for Breath-alcohol Measurement, the problem was discussed of how to obtain accurate measurements on the one hand and proper handling on the other hand. The best solution was to make a system available to the local verification offices which provides all the necessary measurands in one step.

4.5 Reference standard for the Local Verification Offices

In cooperation with the University of Applied Sciences (Gießen), Draeger Safety and the PTB, a reference standard for the local verification offices was established. The result is a compact system based on the principle of a "bubble train" (see Figure 4).

For use as a reference standard, a reference water-ethanol solution with a concentration uncertainty of ≤ 1 % traceable to national standards, a high-level calibrated thermometer capable of measuring the temperature with an uncertainty of ≤ 0.1 K, and optionally a computer are needed.

The reference standard consists of a two-flask bubble train and a calibrated flow-control and measuring system. Regularly, a certain amount of the ethanol-water solution inside the bubble train is replaced by a "fresh" solution. Thus, the wash-out effect of the solution is negligible and the concentration of the solution is held stable.

As a result, users in the verification offices do not need to calculate the actual ethanol concentration in the gas with respect to the gas flowing through the bubble train. To maintain the system, only the containers with new and used ethanol-water solutions have to be controlled.

The reference standard delivers an amount of water-saturated gas with a known ethanol concentration, a known temperature and a known volume flow. Therefore it allows the verification officers to check the relevant parameters of the evidential breath-alcohol analyzer in one single step (for detailed information see [8]).

Once a year, the reference standards are serviced by the manufacturer and then checked by the PTB by comparison with the national breath-alcohol standard.

5 Conclusion

In Germany there are detailed and strict requirements for the schedule and instrumentation of evidential breath-alcohol measurements.

The requirements for these instruments not only conform to OIML R 126, but go much further. The PTB is not only responsible for testing the instruments for type approval but also for the evaluation of test procedures for periodic verification of the instruments by the local verification offices.

Analogous to other measurands, a system of reference standards with traceability to the national standard was realized. Because of its special design the reference standard used by the local verification offices allows the relevant measurands of a breath-alcohol analyzer to be tested in one single step.

In this way, an effective procedure was drawn up which allows the instruments to be tested at a high metrological level with an acceptable amount of work taking reasonable time and being reasonably cost-effective. ■

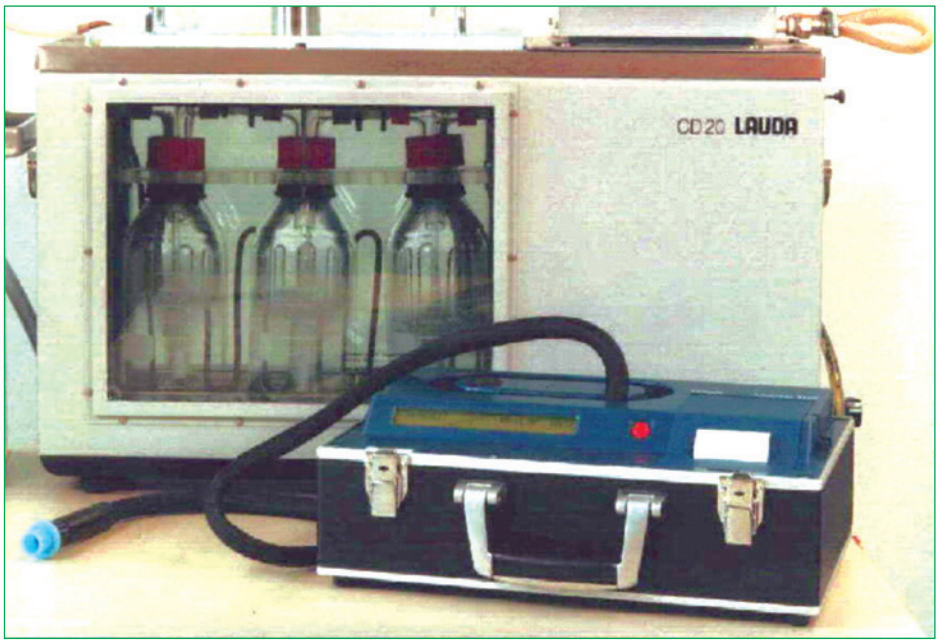

Figure 3 German national standard for breath-alcohol concentration with equipment under test

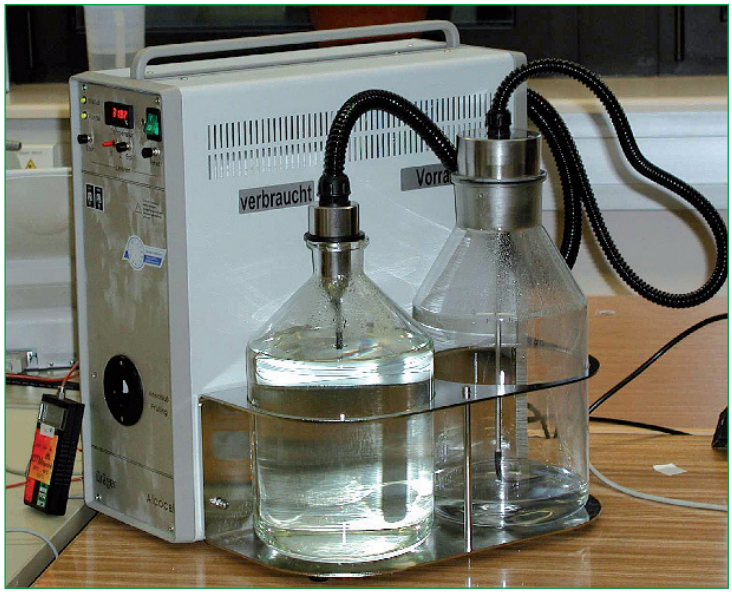

Figure 4 Reference standard for the local verification offices

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