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A Study of the Accuracy (= Trueness and Precision) of Selected Breath Alcohol Measurement Devices (‘Alcometers’)

Report TUW CTA 2019/01 EN

Vienna, January 2019



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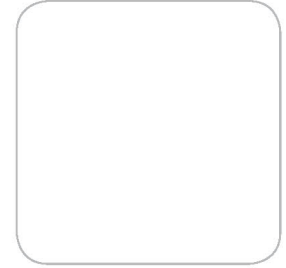
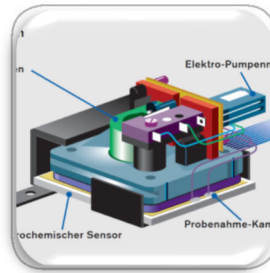
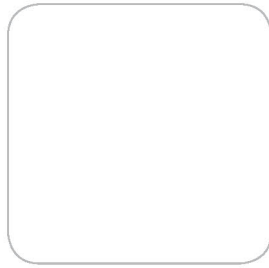
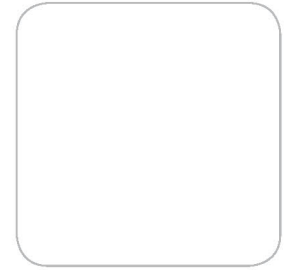
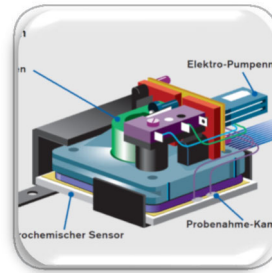


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1 Study Details



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1.3 STUDY PERSONNEL AND LOCATION

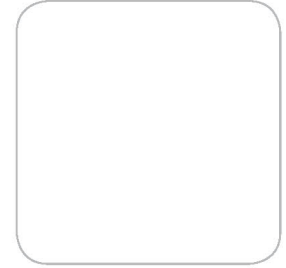
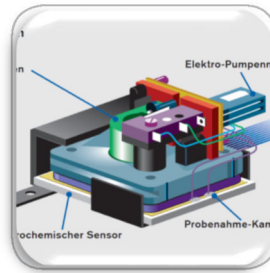
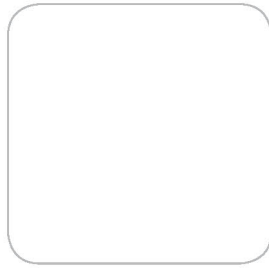
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1.4 DURATION OF THE STUDY

The experimental work related to this study has been performed in the time frame of May 2 – June 30, 2018.



2 Introduction



2.1 OBJECTIVE OF THE STUDY

In order to verify the reliability of small, portable devices for the determination of breath alcohol levels for the private user, the company ACE Handels- und Entwicklungs GmbH, a large distributor of testing devices for breath alcohol measurement („breathalyzer“) located in Freilassing, Germany, initiated in 2015 a comprehensive study in the frame of which the accuracy, that is, the precision and trueness of measurements performed under controlled laboratory conditions, was assessed. The results of this study have been summarized and published in a report [1].

As the model range of ACE Handels- und Entwicklungs GmbH is continuously updated, it became necessary to repeat this study with breathalyzer instruments from the current range of instruments on offer by ACE. In the frame of this study, five breathalyzers of the company ACE were tested (four of which came in the ‚classical‘ format of a stand-alone unit), while one instrument was a smaller instrument that had to be connected to a smartphone via Bluetooth* for instrument control and display of results. Moreover, an instrument of the company Dräger (Lübeck, Germany) was included for reference in this test.

The present report describes in detail the design of the current study, its execution and it is summarizing the most relevant results.

2.2 INTRODUCTION

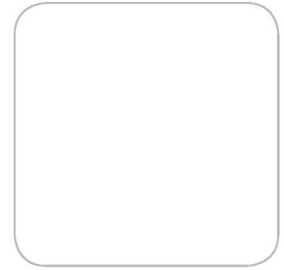
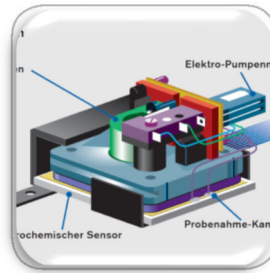
Alcohol Consumption and Driving

In many cultures, the consumption of alcohol has a long tradition and is often associated with particular celebrations, customs or important events. Many people enjoy the consumption of alcoholic drinks in nice company as well as on their own. Consumed in moderation, the stimulating and positive effects of alcohol consumption prevail. Nonetheless, even small amounts of alcohol can seriously affect the sensory perception and compromise the reaction, and thus the ability to safely conduct a vehicle.

For this reason, the legislator has issued legal limits above which the conduction of a vehicle is no longer considered safe. If the police catch a driver with a blood alcohol concentration higher than the legal limit, then significant legal consequences may result.

In view of this situation, the necessity for precise and accurate measurement methods and measurement instrumentation for the police is evident. However, also private users have a considerable interest in having instruments at their disposal that enable them to determine by themselves their breath alcohol concentration as a proxy for the blood alcohol concentration in an accurate, precise, robust and simple way.

* Bluetooth is a registered trademark of Bluetooth SIG Inc.



Driving Under the Influence of Alcohol

The acute effect of alcohol influences virtually any part of our brain and thus affects our perception and ability to act. A further subdivision of effects into physiological-neurological effects and psychological reduction of performance does neither appear possible nor meaningful due to the difficult differentiation between each other [2].

When driving under the influence of alcohol, a number of typical accident situations are described: Among these are falling from the motorbike without any observable cause, swivelling to the left lane, departure from the lane, collisions with parking cars, driving in wavy lines, driving straight on in curves even without excessive speed, starting too late an overtake manoeuvre, wrong estimate of distances or speed, wrong estimate of the distance to an oncoming car, delayed or completely missing breaking manoeuvres (**Figure 1**).

Normally, more than one reason is given as cause of a car accident, and these factors may also become relevant at the same time, such as, impaired attention, compromised reflexes and fine motor skills, difficulties in focusing to the focal point, or to perceive colours, impairment of fixation and fusion[†], of accommodation as well as of the reaction of the papilla to a disturbing glare.

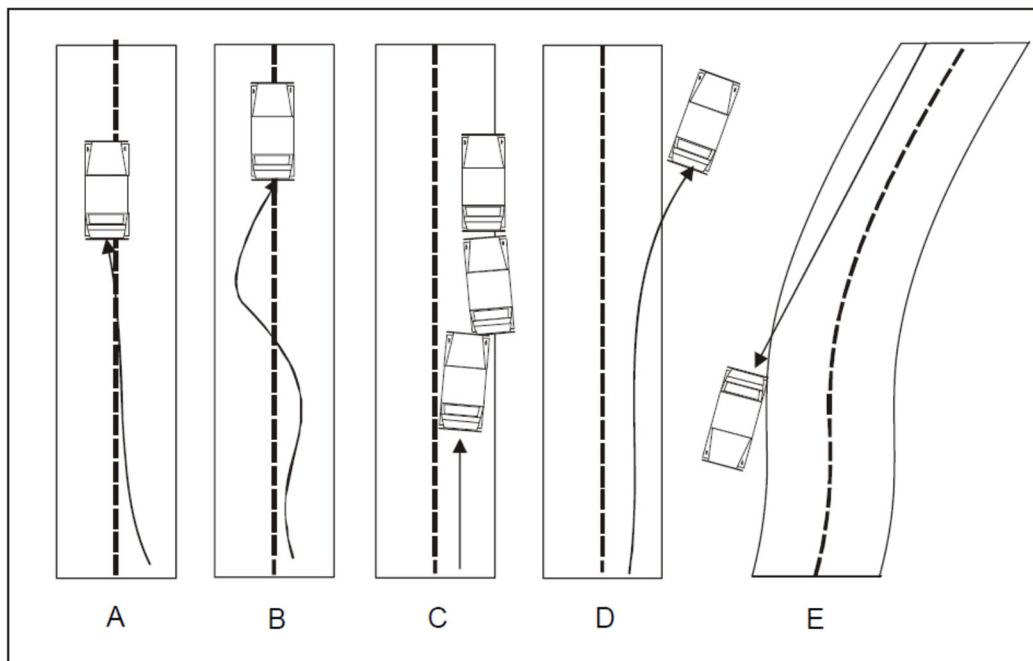
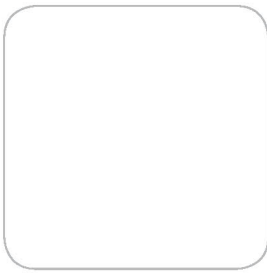


Figure 1: Typical patterns when driving under influence: Psycho-sensoric effects affecting the traffic behaviour: (A) deviating to the opposite lane; (B) driving in wavy lines; (C) colliding with parking or standing cars; (D) deriving from the lane without observable reason; (E) continuing to drive straight ahead in the curve [2].

[†] Fixation and fusion are the acquisition and tracking of a (movable) object with both eyes and the superimposition of the visual impressions of both eyes into a plastic image. Under the influence of alcohol, this is only possible to a limited extent, resulting in double vision and a loss of the ability to estimate distances and to see plastically.



Blood Alcohol and Breath Alcohol

In the case of alcohol consumption, the alcohol will initially be absorbed by the venous part of the blood circuit. The venous blood, transports the alcohol to the heart and the lung to continue, after being cleaned and enriched with oxygen, as arterial blood to be pumped through the entire body. In the pulmonary alveoli, the alcohol present in the blood equilibrates with the air that is exhaled. The alcohol contained in the peripheral blood is taken up by the inhaled air and is removed by the exhaled air. Although there is a relationship of the alcohol concentration in the venous blood and in the exhaled breath, this relationship is not a mathematically strict one: Rather, this ratio depends on the time that has passed between alcohol consumption and the measurement, but as well it depends on the physiological state of the person, such as height, body weight, gender and age.

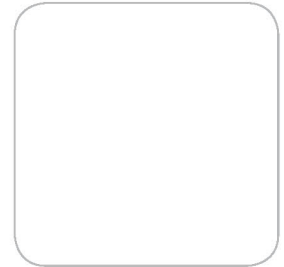
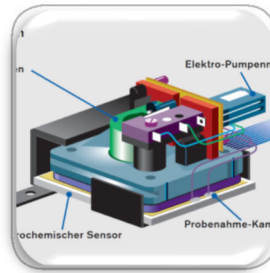
It is therefore virtually impossible to convert the measured breath alcohol concentration into the corresponding blood alcohol concentration. Nevertheless, one can assume for cases in which alcohol intake has been between 2 and 5 hours before the measurement that the ratio between blood alcohol concentration and breath alcohol concentration is approximately 1:2100. This means that 2100 volumes of exhaled breath contain the same amount of alcohol as one volume of blood. In other words, the same amount of alcohol is contained in 10 mL of venous blood and in 21 L of exhaled breath. In the time frame of up to two hours after the consumption of alcohol, this ratio is typically somewhat lower. This means that during this time the breath alcohol concentration is higher than the corresponding blood alcohol concentration.

In order to avoid any falsification of the measurement result by residual mouth alcohol (this is the alcohol that is left in the mouth and pharyngeal cavity – e.g. in pockets of the gum – during the delivery of the breath gas sample), a valid measurement of breath alcohol may only be performed more than 20 minutes after the last intake of alcohol, otherwise an elevated breath alcohol level may be found. In the case of a forensic measurement, an observation interval of at least ten minutes is to be respected before the first measurement, and two results of two independent measurements have to be produced with an interval of two to five minutes. This shall avoid that results are biased by the presence of residual alcohol in the mouth and pharyngeal cavity.

When determining the breath alcohol concentration, it is essential whether this is intended as a preliminary test, or as an evidential measurement that will also be admissible in court. A preliminary test is intended to provide the police officer directly on the spot a means of decision whether an evidential measurement is to be performed whose result can also be used in court, or whether a blood sample is to be taken [3].

Evidential Measurements

After a positive pre-test a further alcohol level measurement has to be performed whose results can be used as evidence in court. Such a measurement is called an evidential measurement. Although breath alcohol- and blood alcohol concentrations typically demonstrate a good correlation, it is not possible to convert the result of one type of measurement into the result of the other. For this reason, the German legislator has issued two independent legal limit values in paragraph 24a of the German Road Traffic Act (StVG): The breath alcohol concentration is a gas phase concentration and is reported as mg alcohol (ethanol) per litre of exhaled breath (mg/L).



In contrast to this, the blood alcohol concentration is a liquid phase concentration and is reported in permille (‰), that is in units of a tenth percent. It represents the mass of alcohol (ethanol) in gram per litre of blood. In the German Road Traffic Act the legal limit of the blood alcohol concentration is set as 0.5 permille (‰). The corresponding, independently set legal limit for the breath alcohol concentration is 0.25 milligram per litre exhaled breath (mg/L). The two legal limits for the blood alcohol and the breath alcohol concentration are thus forming a ratio of 2000:1. This means in comparison with the physiologically derived ratio of 2100:1 that a slightly higher concentration is tolerated which shall also take account of the larger uncertainty of this ratio.

In Germany, the preliminary testing is performed with the instrument Alcotest 7410 (since 1988) and currently with the Alcotest 7510 (since 2008) of the company Draeger [4] and the instrument AlcoQuant A 3020 of the company EnviteC.

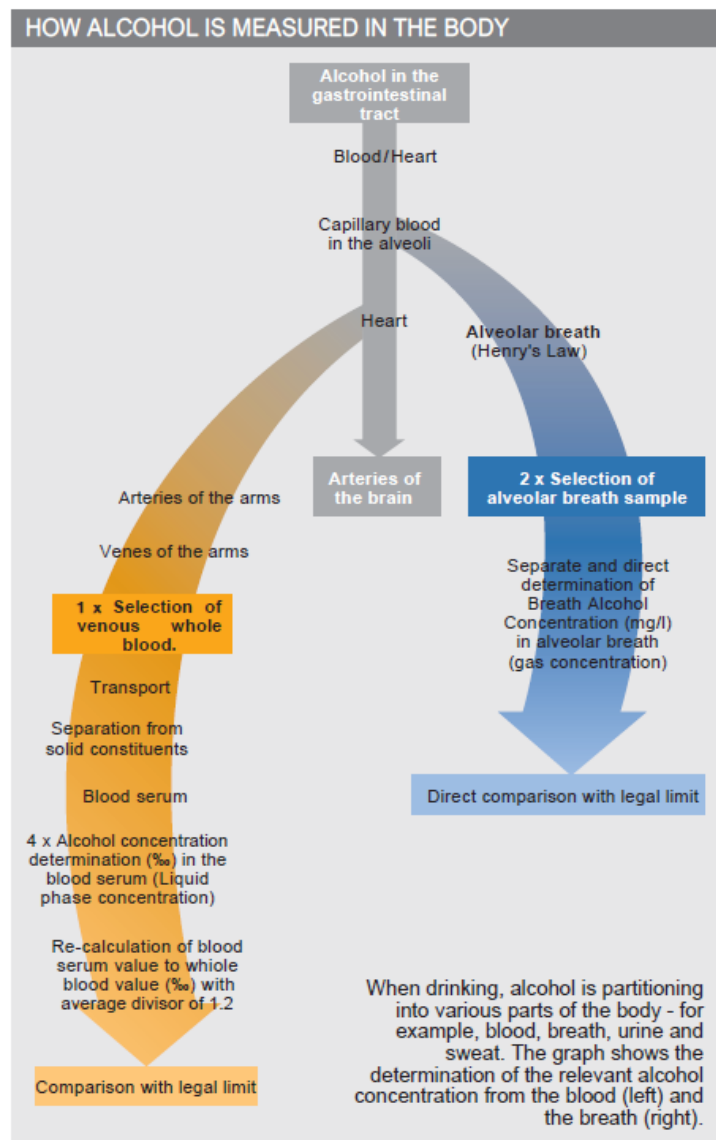
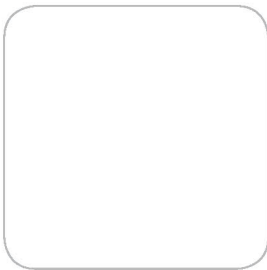


Figure 2: Relationship between alcohol intake in the human body and the measurement of alcohol concentration in whole blood or in exhaled breath, respectively [4].



Measuring Blood Alcohol

A blood alcohol test is the most accurate way to measure an individual's blood alcohol concentration (BAC, or sometimes also BIAC to avoid confusion with the breath alcohol concentration). Because alcohol is quickly absorbed into the bloodstream, this test can be performed just minutes after consuming an alcoholic beverage. However, this test is more expensive and invasive, and it cannot be performed on site.

The measurement of blood alcohol concentration requires that a small volume of venous blood is taken from the person - a medical intervention that necessitates the presence of a medical doctor and the consent of the patient. The analysis is then performed in the analytical laboratory by means of the instrumental technique headspace-gas chromatography (HS-GC) which is used to separate, confirm and quantify the alcohol present in a given sample [5]. Still today, the blood alcohol measurement by HS-GC in a forensic laboratory is the evidential test for blood alcohol measurements, yielding results that are admissible in court.

Measuring Breath Alcohol

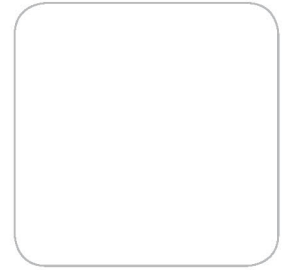
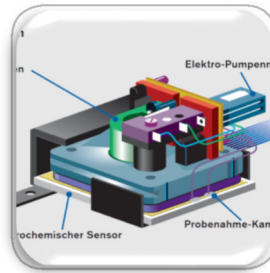
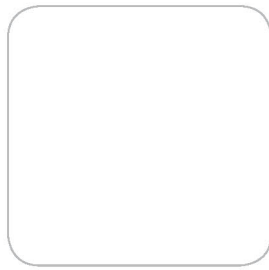
Early breath alcohol tests such as the Alcotest tubes were based on a chemical reaction (of alcohol with potassium dichromate under silver ion catalysis) that led to the colour change of the yellow-orange reagent to a green zone, the extension of which was related to the breath alcohol concentration (in use until ca. 1995). The limited accuracy of the determination clearly restricted its use to that of a fast and simple screening technique [6].

Nowadays, they have been superseded as preliminary test by electrochemical breathalyzers that are either based on solid-state sensor technology, or on the fuel cell technology [7]:

In solid state sensor-based devices (sometimes also called "Taguchi" cells), a metal oxide semiconductor-based sensor is used. The Taguchi cell operates by adsorption of gas molecules on the surface of a semi-conductor. This transfers electrons due to the differing energy levels of the gas molecules on the semi-conductor's surface.

These types of instruments are sold mainly to the consumer markets as opposed to law enforcement. None of these sensor-type instruments are approved by the authorities, or in court as evidential breath testers. However, as the sensors are small in size and rather inexpensive to manufacture, they enjoy great popularity for private use.

The other, nowadays more widely employed electrochemical measurement principle is that of the fuel cell. During an analysis cycle, an air sample of a precise volume is transported to the electrochemical sensor. The sensor selectively determines the alcohol (ethanol) content in the breath sample. The sensor contains a diaphragm soaked in electrolyte housing the measuring electrode and counter electrode. The electrolyte and the electrode material have been chosen to electrochemically oxidize the ethanol in the sample in the catalyst layer of the measuring electrode. This specific reaction at the electrode generates a current in the device electronics. The analysis of sensor current allows calculating the exact amount of alcohol in the sampling chamber. This electrochemical measuring method provides the sensor with significant long-term stability. Moreover, the electrochemical sensor specifically reacts only to alcohol. For example, the presence of acetone in exhaled breath, as observed for diabetic patients or during fasting, does not interfere with the measuring result, as this other substance does not react on the electrodes. This prevents false positive measurements.



Despite the demonstrated reliability of alcohol measurement devices based on the fuel cell technology, these devices have not yet been accepted as a full replacement for the tedious and costly blood alcohol measurements not even in cases of administrative offence. As the acceptance of these devices would imply a comparable accuracy and precision of the breath alcohol measurement as the blood alcohol measurement, this required the use of two independent measurement principles (infrared absorption and fuel cell technology) that are applied to two independently taken breath samples with coinciding results. For many years there was only one device on the German market, which had approval for this task by the German national metrology institute PTB (Physikalisch-Technische Bundesanstalt, Braunschweig): the Dräger Alcotest 7110 Evidential (market launch 1998). With January 2014, the PTB also approved the Dräger Alcotest 9510 DE for use in Germany. With this design approval, the police can procure now the new evidential measurement instrument to control road traffic. The measurement results of the Alcotest 9510 DE are recognized in court in the case of administrative offences [8].

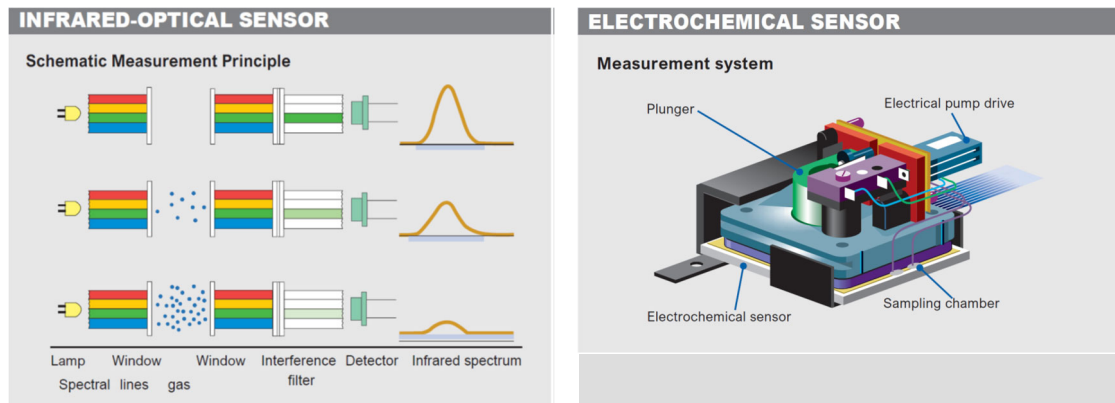
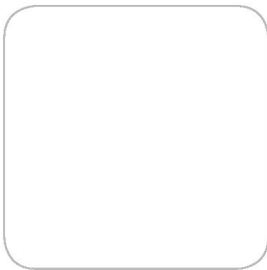


Figure 3: Infrared or electrochemical sensor: The two common measurement methods for determining the concentration of breath alcohol are based on different principles. While the infrared-optical sensor measures the absorption of light by ethanol, the signal of the electrochemical sensor is generated by the oxidation of the molecules at a catalyst layer [4].

The Legal Situation

For purposes of law enforcement, blood alcohol content is used to define intoxication and provides a rough measure of impairment. Although the degree of impairment may vary among individuals with the same blood alcohol content, it can be measured objectively and is therefore legally useful and difficult to contest in court. Most countries disallow operation of motor vehicles and heavy machinery above prescribed levels of blood alcohol content. Operation of boats and aircraft are also regulated.

The alcohol level at which a person is considered legally impaired varies by country. The table on the following page gives limits by country. These are typically blood alcohol content limits for the operation of a vehicle. In Austria, Germany and Switzerland – as well as in several other European countries – you are not allowed to drive a car if your **blood alcohol concentration (BAC)** is 0.05% (0.5‰) or greater, and you are considered to be legally intoxicated and prohibited from driving a vehicle if your blood alcohol content (BAC) is 0.08% (0.8‰) or greater. There are three common methods for testing BAC which are breath, blood, and urine tests. Many states require a breath test, but some allow you to request a blood or urine test.



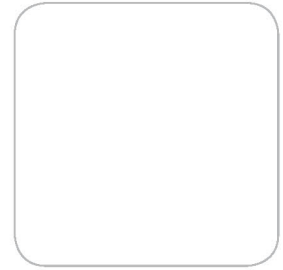
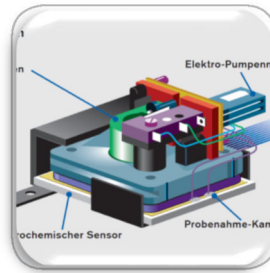
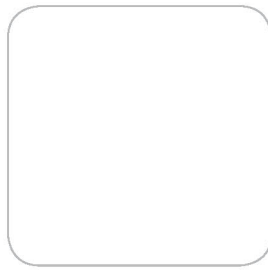
The following **Table 1** gives an overview of these limits in Europe.

Table 1: Overview of the legal limits (in ‰) of the blood alcohol concentration (BAC) for driving a car in different European countries.

Country	General (‰)	Professional drivers (‰)	Driver novices (‰)
Austria	0.5	0.1	0.1
Belgium	0.5	0.2	0.5
Bulgaria	0.5	0.5	0.5
Croatia	0.5	0.0	0.0
Cyprus	0.5	0.2	0.2
Czech Republic	0.0	0.0	0.0
Denmark	0.5	0.5	0.5
Estonia	0.2	0.2	0.2
Finland	0.5	0.5	0.5
France	0.5	0.5 (0.2 Bus drivers)	0.2
Germany	0.5	0.0	0.0
Greece	0.5	0.2	0.2
Hungary	0.0	0.0	0.0
Ireland	0.5	0.2	0.2
Italy	0.5	0.0	0.0
Latvia	0.5	0.5	0.2
Lithuania	0.4	0.0	0.0
Luxemburg	0.5	0.2	0.2
Malta	0.8	0.8	0.8
Netherlands	0.5	0.5	0.2
Poland	0.2	0.2	0.2
Portugal	0.5	0.2	0.2
Romania	0.0	0.0	0.0
Slovakia	0.0	0.0	0.0
Slovenia	0.5	0.0	0.0
Spain	0.5	0.3	0.3
Sweden	0.2	0.2	0.2
Switzerland	0.5	0.1	0.1
United Kingdom [i]	0.8	0.8	0.8

[i] Scotland: 0.5‰ since December 2014 for all groups of drivers. The rest of the United Kingdom (England, Wales and Northern Ireland) remains unchanged. As of: December 2017.

Data source: European Transport Safety Council (ETSC), <http://etsc.eu/blood-alcohol-content-bac-drink-driving-limits-across-europe/>



BrAC - Breath Alcohol Test

Breath testing is the most common method used by law enforcement to estimate BAC because breath analysis devices, or breathalyzers, are lightweight, portable, and provide immediate results. Breathalyzers measure the alcohol that passes through alveoli air sacs as blood flows through vessels in the lungs, and is then expelled on a subject's breath. Breathalyzer results, particularly those derived from fuel cell sensor breath tests, are considered sufficiently accurate to be admitted in a DUI (driving under the influence) prosecution.

Breathalyzers usually do not distinguish one individual from another because they assume a constant conversion factor between breath alcohol concentration and blood alcohol concentration which is a pragmatic generalization and simplification. Such "averaging" can result in inaccurate readings. Various factors, which are mostly related to the tested person's gender, age, size and weight, physical and health state, as well as diet, to name but some few can also skew breath test results. Although breath alcohol measurements can be performed with high accuracy and precision, they represent only a (good) estimate of actual blood alcohol levels as discussed before.

Commercially available breathalyzers do however offer a convenient and affordable way to self-test one's BAC and make informed decisions about drinking and driving.

BAC Blood Alcohol Test

Consent to have your blood drawn and tested is usually required, and refusing to take a blood test can have significant legal consequences, including suspension of driving privileges.

BAC-Urine Tests

Urine tests are less accurate than breath and blood tests, and tend to be used only when other tests are not available. Urine testing is also considered an intrusive testing method, similar to blood tests. Studies have shown that urine test results can be significantly higher or lower than the actual BAC in the blood. And because urine tests usually cannot be performed at the time of an incident, such as a traffic stop, urine samples can be affected by the passage of time. In addition, alcohol takes up to two hours to appear in a person's urine and can remain in a person's system for 6 to 24 hours. As a result, positive urine tests may not prove that a subject was under the influence at the time of an incident. Unlike other testing methods, urine tests can be circumvented by diluting or substituting a sample. To validate urine samples, temperature testing may be employed, but adulteration of urine samples is hard to prove. Urine tests are also subject to the same laboratory errors as blood tests.

3 Study Design



3.1 DESIGN OF THE ACCURACY STUDY

The design of the study is based on the European standard DIN EN 16280 (as amended in December 2012) on “Breath alcohol testing devices for general public – Requirements and test methods; German version EN 16280:2012” [9]. This standard defines the conditions under which breath alcohol testing devices can be tested and also determines what the specific requirements for this test are.

It was agreed with the client that the breath alcohol test devices would be tested at the following breath alcohol concentrations (BrAC), which – using the generally accepted conversion factor of 2000:1 – correspond to the blood alcohol concentrations (BAC, reported in ‰ or mg of ethanol/g whole blood) as specified in each case:

- 0.00 ‰ BAC corresponding to 0.00 mg/L BrAC
- 0.10 ‰ BAC corresponding to 0.05 mg/L BrAC
- 0.25 ‰ BAC corresponding to 0.125 mg/L BrAC
- 0.40 ‰ BAC corresponding to 0.20 mg/L BrAC
- 0.60 ‰ BAC corresponding to 0.30 mg/L BrAC

These standards cover the legally relevant concentration range for blood alcohol measurements and thus, consequently, also for breath alcohol measurements. Since the breathalizers determine in this series of test measurements as well as in real use the concentration of alcohol in the exhaled air, the corresponding blood alcohol concentration is determined only by conversion using the conversion factor of 2000 (which is considered constant by legislation). Despite the fact that the breath alcohol concentration is measured, the results of all measurements are reported in per mille, i.e. in the unit of the blood alcohol concentration (BAC). Due to the constant conversion factor between the concentration of breath alcohol and blood alcohol concentrations, the statements regarding accuracy and precision apply without restriction and independently of the reporting unit used.

For each instrument, 10 independent measurements were performed at each of the specified concentration levels. These measurements were statistically evaluated in terms of accuracy and precision.

Statistical Data Evaluation

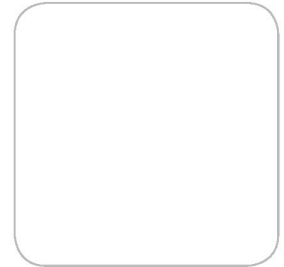
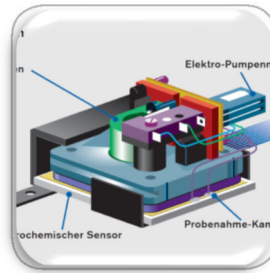
The **precision** of a dataset of individual measurements is a measure of the mutual approximation of each datapoint x_i of this dataset. It is usually reported as the relative standard deviation (RSD) of the dataset and calculated according to:

Standard deviation:
$$s = \sqrt{\frac{\sum(x_i - \bar{x})^2}{(n-1)}} \quad (1)$$

Relative standard deviation:
$$RSD = s/\bar{x} [\%] \quad (2)$$

The **accuracy** is defined as the agreement of known and measured concentrations. It is given either as a ratio of the measured and known concentration of the analyte:

Trueness [%]:
$$Trueness = x_{measured}/x_{known} [\%] \text{ with } x_{measured} < x_{known}, \quad (3)$$



otherwise: $Trueness = x_{known}/x_{measured} [\%]$ with $x_{measured} > x_{known}$, (3')

or it is expressed as a lack of agreement (= difference) between measured and known value, which we will further on denote as “**Bias**”:

Bias [in ‰ or mg/L]: $Bias = x_{measured} - x_{known} [\% \text{ or } \text{mg/L}]$ (4)

To facilitate interpretation, the measurement deviation (bias) is often expressed as relative deviation (**Relative Bias**).

Relative Bias [%]: $Relative\ Bias = \frac{x_{measured} - x_{known}}{x_{known}} [\%]$ (5)

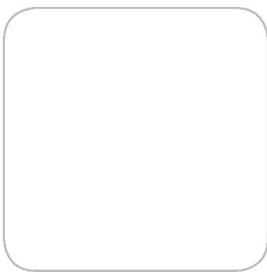
These parameters are first calculated separately for each breath alcohol test device and each concentration level. In order to obtain a more robust and also more easily interpretable presentation of the results, the results for the five instruments of one particular type of device that were examined are averaged for each concentration level.

All statistical calculations were carried out using Microsoft Excel® 2019.

The results of the study are presented in both tabular and graphic form in the following section “4 Results of the Study”.

Table 2: Explanation of the terms and abbreviations used in the tables in the presentation of the study results.

Level [‰]	Nominal value of blood alcohol concentration (BAC) [‰]
Reference value [‰]	Concentration of the calibration gas at the considered concentration level [‰]
Mean value [‰]	Mean value of each set of BAC measurements [‰]
Accuracy	Ratio of mean and reference value, reported in [%]
RSD%	Relative standard deviation of the mean values of the BAC, expressed in [%]
Bias [‰]	Absolute difference between the reference value and the mean value of the BAC, expressed in [‰]
SD of Bias [‰]	Absolute standard deviation of the bias, expressed in [‰]
Rel. Bias [%]	Relative difference between reference and mean value, expressed in [%]
SD of Rel. Bias [%]	Standard deviation of the relative bias, expressed in [%]



3.2 PERFORMANCE OF THE STUDY

The following breath alcohol test devices were examined in this accuracy study:

Table 3: Identification and characterization of the breath alcohol test devices examined in the present study.

Manufacturer / Distributor	Model	Type of Usage	Accuracy Level	Measurement Principle
ACE	X Police	Private users	1+	Electrochem. sensor
ACE	Wave	Private users	2	Electrochem. sensor
ACE	A	Private users	2	Electrochem. sensor
ACE	Solid	Private users	2	Semiconductor sensor
ACE	AFM-5	Private users	1	Electrochem. sensor
Dräger	Alcotest 3820	Private users	1+	Fuel cell

Generation of Test Gas Atmosphere

The calibration gas atmospheres with precisely known and constant alcohol concentration required for the performance of this study were generated in accordance with the standard DIN EN 16280 [9] with an experimental set-up consisting of two ‘simulators’ coupled in series, as well as one membrane pump that was used to generate the stream of air enriched with a precisely controlled level of alcohol needed to test the breath alcohol measurement devices.⁹

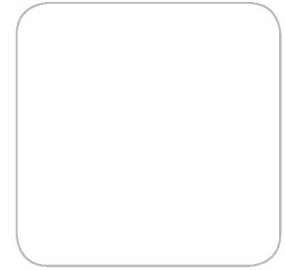
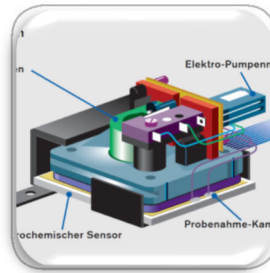
A ‘simulator’ is a device that is filled with a dilute aqueous solution of alcohol through which a stream of pure air (zero air) is passed through. The air flow is saturated with water vapour and equilibrates with gaseous alcohol according to the precisely set temperature of the device. Both simulators were thermostated to $34.00 \pm 0.02^\circ\text{C}$ [10]. When passing air through the simulators, the temperature briefly dropped by up to 0.05°C , but returned again to the target value of 34.00°C within a short period of time which typically was much shorter than the regeneration time of the breath alcohol measuring devices. The operation of both simulators in series ensures that the set gas phase concentration of alcohol remains constant over a longer trial period of the experiment.

The two simulators used in this study were devices of the type Dräger X-Cal 2000 (Dräger Safety AG & Co. KGaA, Lübeck, Germany), part no. 8326 000 with serial numbers ARJL-0016 and ARJL-0023.

Furthermore, two Hi-Blow DongYang DY-20L membrane pumps with the type designation HB07016-1001B were used to pass the zero air through the alcohol solutions, thereby generating the gas stream necessary for the inspection of the respiratory alcohol measuring devices (Figure 4).

The mass concentration of alcohol in the test gas stream is a function of the alcohol concentration in solution, $C_{\text{Lösung}}$, through which the zero air is passed through and can be described by the following formula which was originally derived by Dubowski [11]:

$$C_{\text{Gas phase}} = 0.04145 \times 10^{-3} \times C_{\text{Solution}} \times \exp(0.06583t) \quad (6)$$



Herein is $C_{\text{Gas phase}}$ the mass concentration of alcohol in the gas phase (air) in [mg/L], C_{Solution} the mass concentration of alcohol in the aqueous solution in [mg/L] and t is the temperature in [°C].

For $t = 34^{\circ}\text{C}$ holds: $C_{\text{Gas phase}} = 0.38866 \times 10^{-3} C_{\text{Solution}}$ (7)



Figure 4: Experimental setup for the conduction of the accuracy study for breath alcohol measuring devices. The membrane pump is visible on the left side, the two simulators operated in series are located to the right of it. The test gas is passed through the hose in the foreground at the end of which there is a droplet trap and presented to the measuring devices. Between the simulators an ampoule with an alcohol reference solution is shown, as is used to prepare the standards.

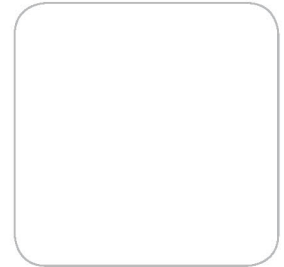
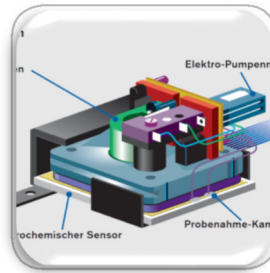
To verify the validity of the formulas reported above for the production of test gas atmospheres with precisely defined alcohol concentrations, reference measurements were carried out using two calibrated breath alcohol measuring devices of the metrological class 1+. Devices of this accuracy class are also approved for the conduction of preliminary-tests by the police. These devices were the EnviteC Type AlcoQuant 6020 plus (parts 1001 780 [Set] and 1001 779 [meter] respectively). The devices actually used in this study had the serial numbers A418 057 and A417 058. The deviations between the target and actual levels of the respective alcohol concentration in the test gas atmosphere are documented in the respective evaluations and were typically less than 2%.

All measurements were carried out according to the instruction manual of the respective alcotesters.

4 Results of the Study

4.1 PRESENTATION OF RESULTS

The following pages show the results of the accuracy check for each device separately. The presentation of the results includes a tabular summary of the data as well as three graphs per type of device examined, in which the accuracy (expressed as the percentage of the measured compared to the known concentration of the test gas), the absolute measurement deviation (indicated in ‰ BAC) as well as the relative measurement deviation (expressed in percentage of the respective calibration level,%) is depicted.



4.2 ACE X

Figure 5: ACE X breath alcohol measurement device.



Table 4: Summary of the results for the ACE X breath alcohol measurement device.

Level [%o BAC]	0	0.100	0.250	0.400	0.600
Reference value [%o]	0	0.105	0.258	0.421	0.606
Mean value [%o]	0.000	0.103	0.261	0.421	0.614
Accuracy	100.0%	98.1%	98.8%	100.0%	98.6%
RSD%	0.0%	5.2%	1.9%	0.9%	1.5%
Bias [%o]	0.000	-0.002	0.003	0.000	0.009
SD of Bias [%o]	0.000	0.003	0.006	0.008	0.016
Rel. Bias [%]	0.0%	-1.9%	1.2%	0.0%	1.4%
SD of Rel. Bias [%]	0.0%	2.6%	2.5%	1.9%	2.6%

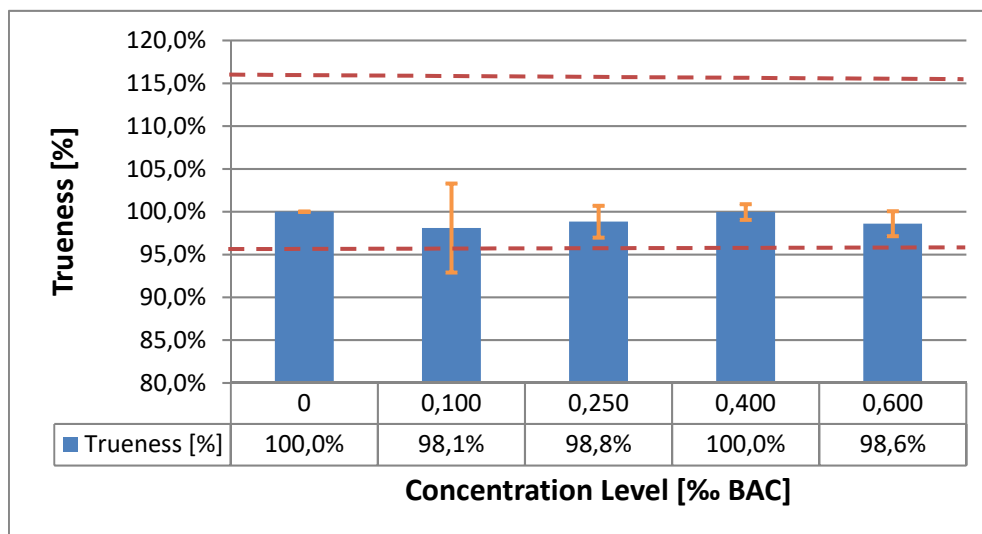


Figure 6: Trueness of the ACE X breath alcohol measuring device at the five alcohol concentration levels studied.

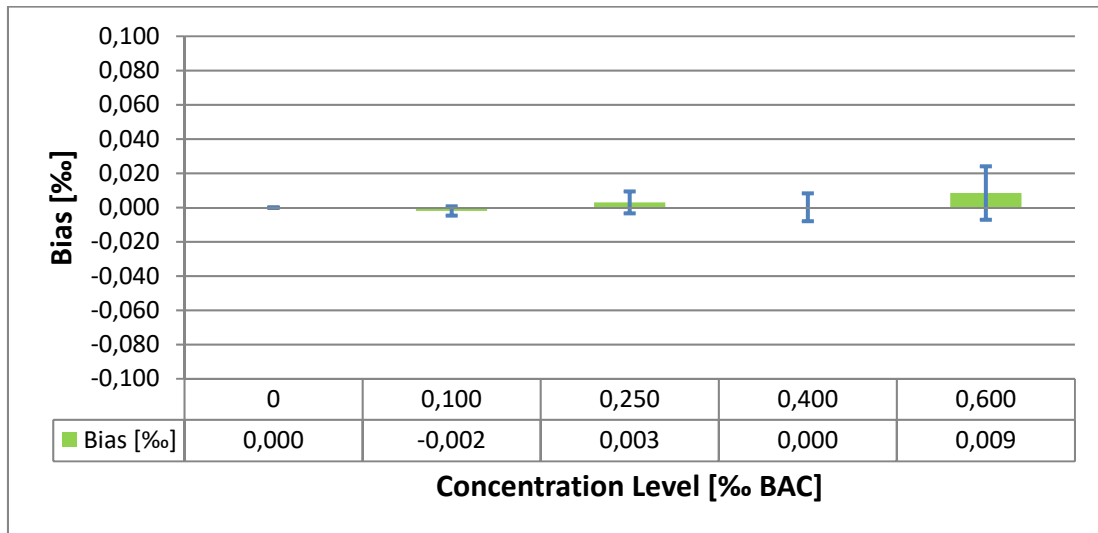
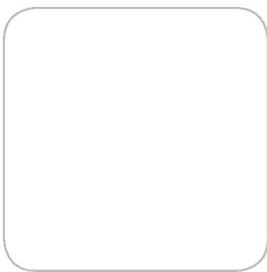


Figure 7: Absolute measurement deviation (Bias, in ‰) of the ACE X breath alcohol measuring device at the five alcohol concentration levels studied.

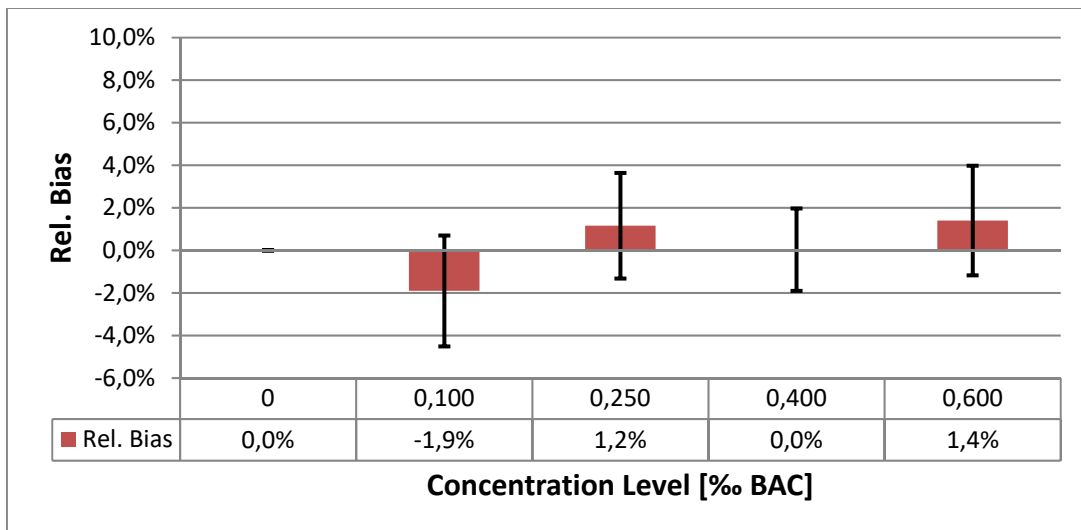
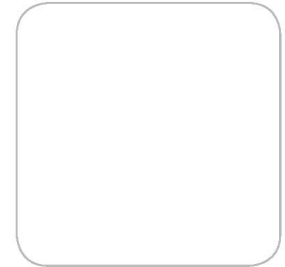
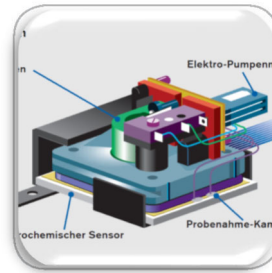


Figure 8: Relative measurement deviation (Rel. Bias, in %) of the ACE X breath alcohol measurement device at the five alcohol concentration levels studied.



4.3 ACE WAVE

Figure 9: ACE Wave breath alcohol measurement device.



Table 5: Summary of the results for the ACE Wave breath alcohol measurement device.

Level [‰ BAC]	0	0.100	0.250	0.400	0.600
Reference value [‰]	0	0.099	0.250	0.414	0.622
Mean value [‰]	0.000	0.094	0.246	0.398	0.592
Accuracy	100.0%	95.9%	98.5%	96.2%	95.3%
RSD%	0.0%	2.3%	1.9%	3.2%	3.4%
Bias [‰]	0.000	-0.004	-0.004	-0.016	-0.029
SD of Bias [‰]	0.000	0.006	0.018	0.026	0.038
Rel. Bias [%]	0.0%	-4.1%	-1.5%	-3.8%	-4.7%
SD of Rel. Bias [%]	0.0%	5.9%	7.4%	6.4%	6.1%

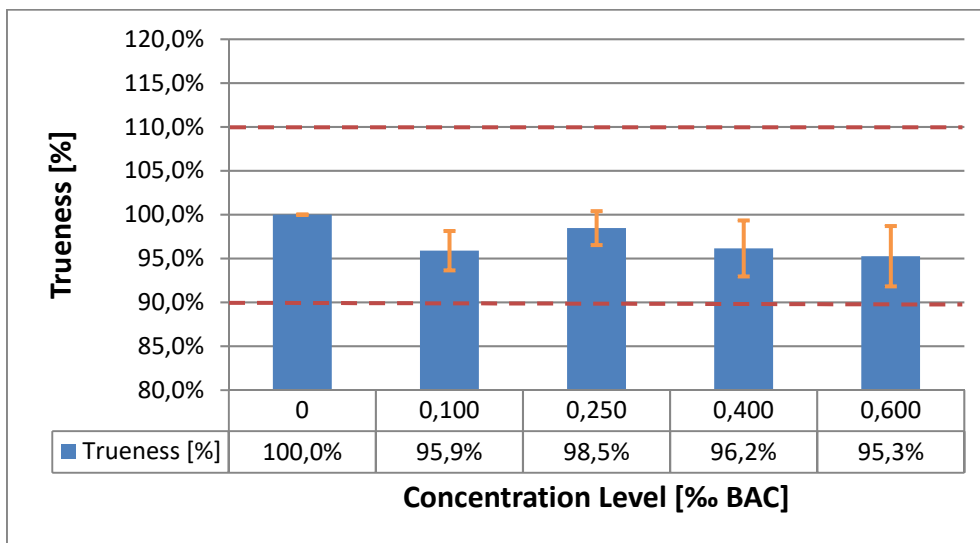


Figure 10: Trueness of the ACE Wave breath alcohol measurement device at the five alcohol concentration levels studied.

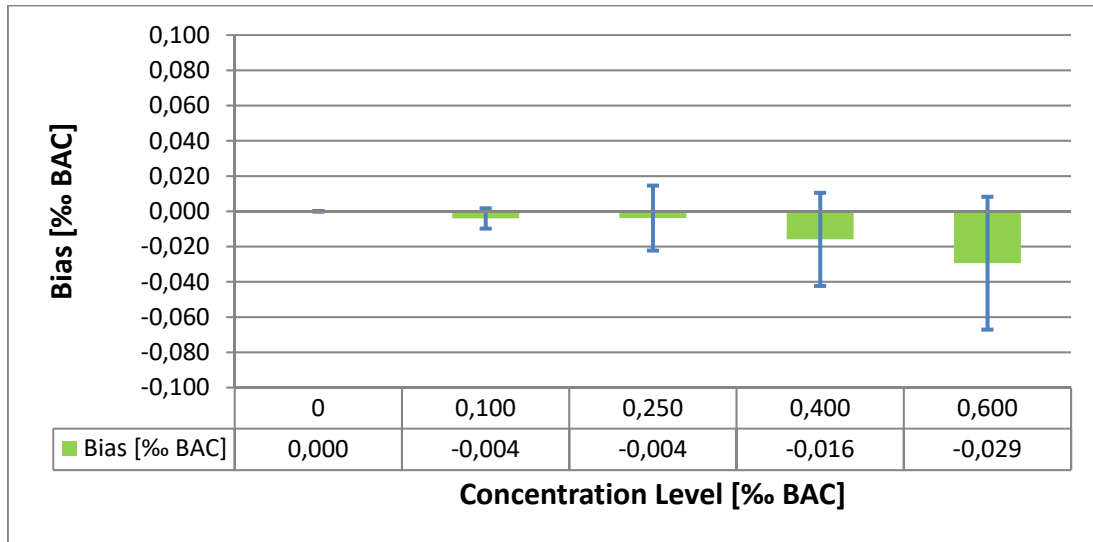
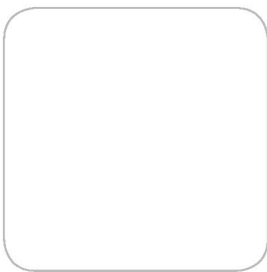


Figure 11: Absolute measurement deviation (Bias, in %) of the ACE Wave breath alcohol measuring device at the five alcohol concentration levels studied.

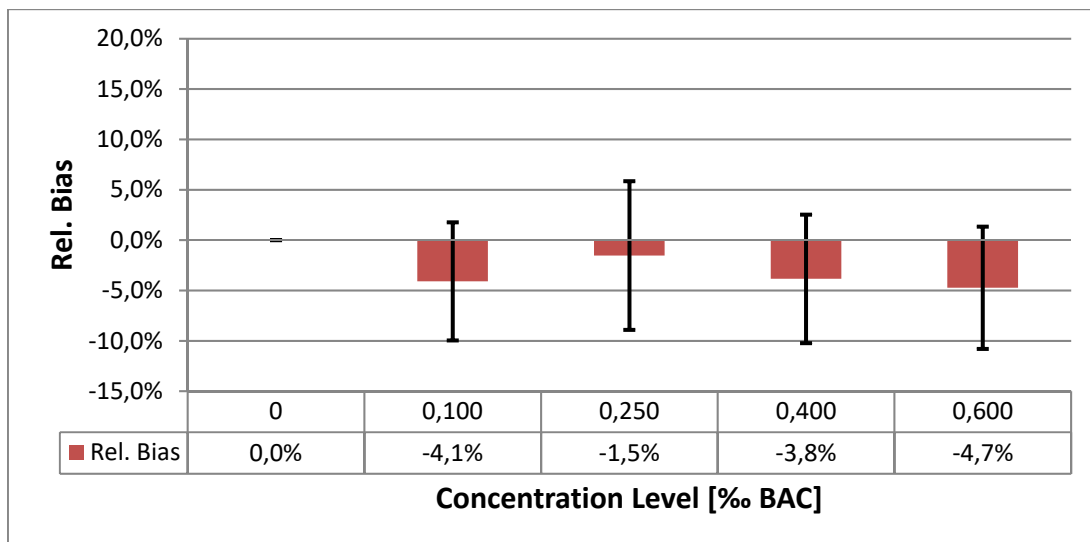
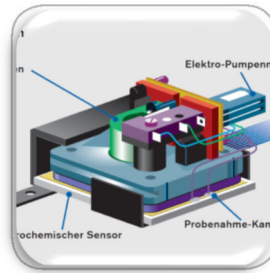


Figure 12: Relative measurement deviation (Rel. Bias, in %) of the ACE Wave breath alcohol measurement device at the five alcohol concentration levels studied.



4.4 ACE A

Figure 13: ACE A breath alcohol measurement device.



Table 6: Summary of the results for the ACE A breath alcohol measurement device.

Level [‰]	0	0.100	0.250	0.400	0.600
Reference value [‰]	0	0.100	0.250	0.400	0.600
Mean value [‰]	0.000	0.079	0.257	0.400	0.626
Accuracy	100.0%	84.5%	99.4%	99.9%	97.9%
RSD%	0.0%	4.8%	2.2%	2.0%	2.0%
Bias [‰]	0.000	-0.015	0.002	-0.001	0.013
SD of Bias [‰]	0.000	0.002	0.006	0.011	0.015
Rel. Bias [%]	0.0%	15.5%	1.9%	1.9%	2.9%
SD of Rel. Bias [%]	0.0%	2.5%	1.0%	1.6%	1.2%

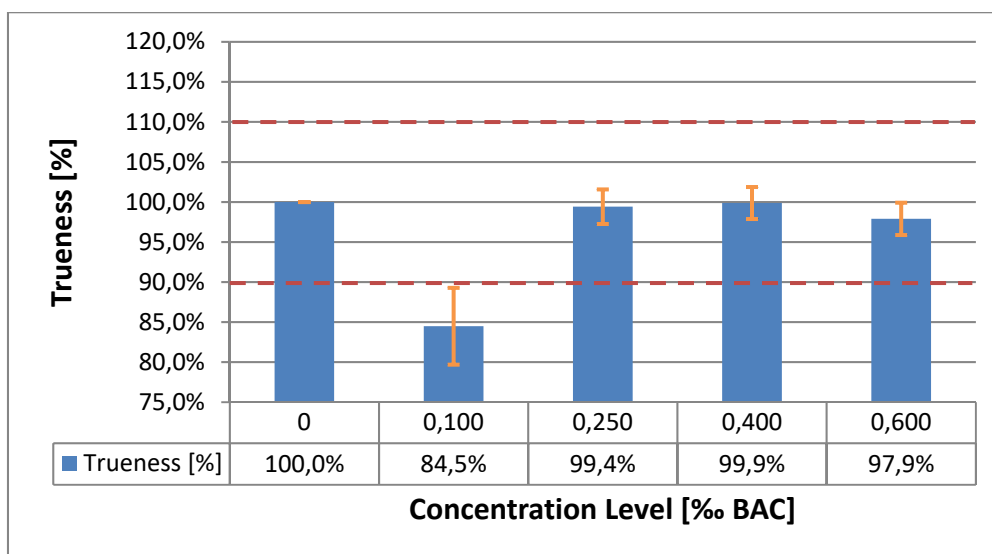


Figure 14: Trueness of the ACE A breath alcohol measurement device at the five alcohol concentration levels studied.

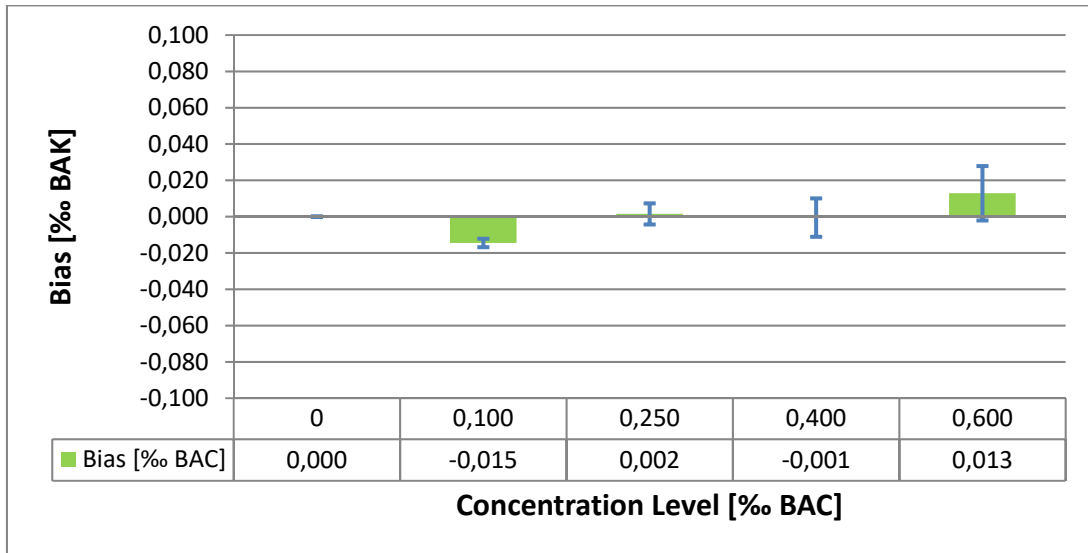


Figure 15: Absolute measurement deviation (Bias, in %) of the ACE A breath alcohol measuring device at the five alcohol concentration levels studied.

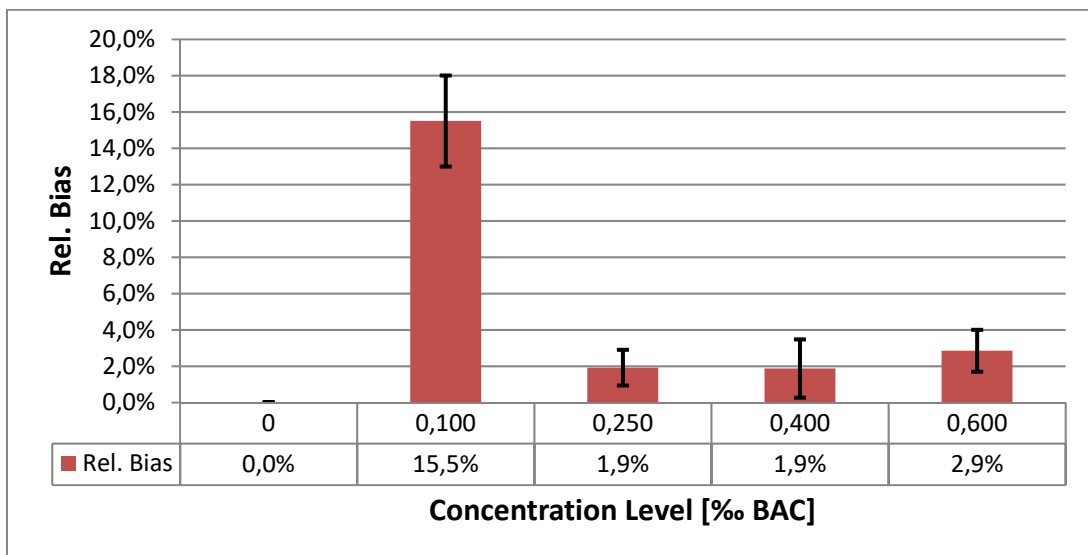
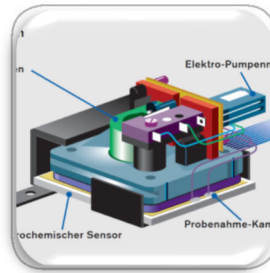


Figure 16: Relative measurement deviation (Rel. Bias, in %) of the ACE A breath alcohol measurement device at the five alcohol concentration levels studied.



4.5 ACE SOLID

Figure 17: ACE Solid breath alcohol measurement device.



Table 7: Summary of the results for the ACE Solid breath alcohol measurement device.

Level [‰]	0	0.100	0.250	0.400	0.600
Reference value [‰]	0	0.155	0.258	0.413	0.627
Mean value [‰]	0.000	0.170	0.237	0.389	0.592
Accuracy	100.0%	89.9%	91.9%	94.2%	94.5%
RSD%	0.0%	3.7%	6.2%	5.0%	5.5%
Bias [‰]	0.000	0.016	-0.021	-0.024	-0.035
SD of Bias [‰]	0.000	0.024	0.025	0.034	0.071
Rel. Bias [%]	0.0%	13.6%	8.8%	6.8%	8.9%
SD of Rel. Bias [%]	0.0%	12.1%	9.1%	7.2%	8.1%

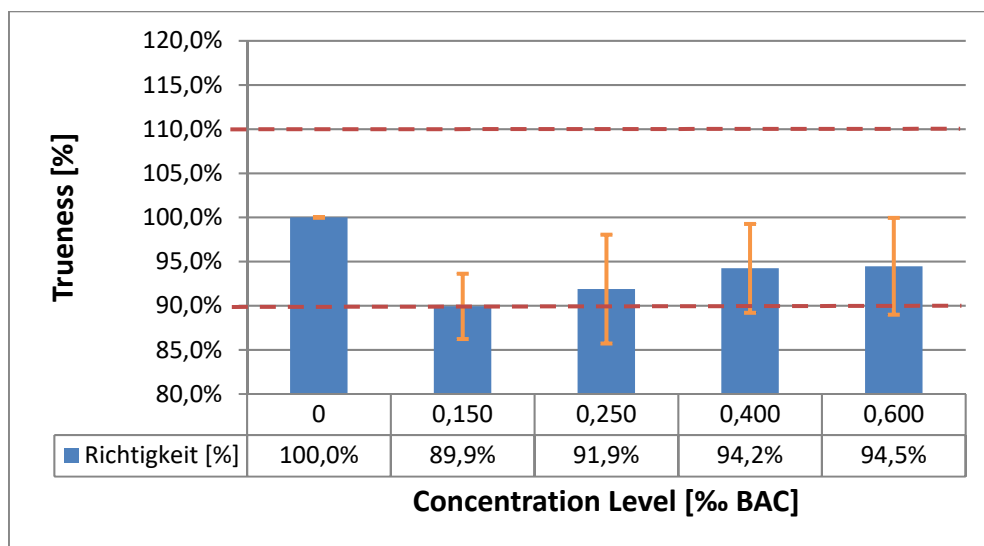


Figure 18: Trueness of the ACE Solid breath alcohol measurement device at the five alcohol concentration levels studied.

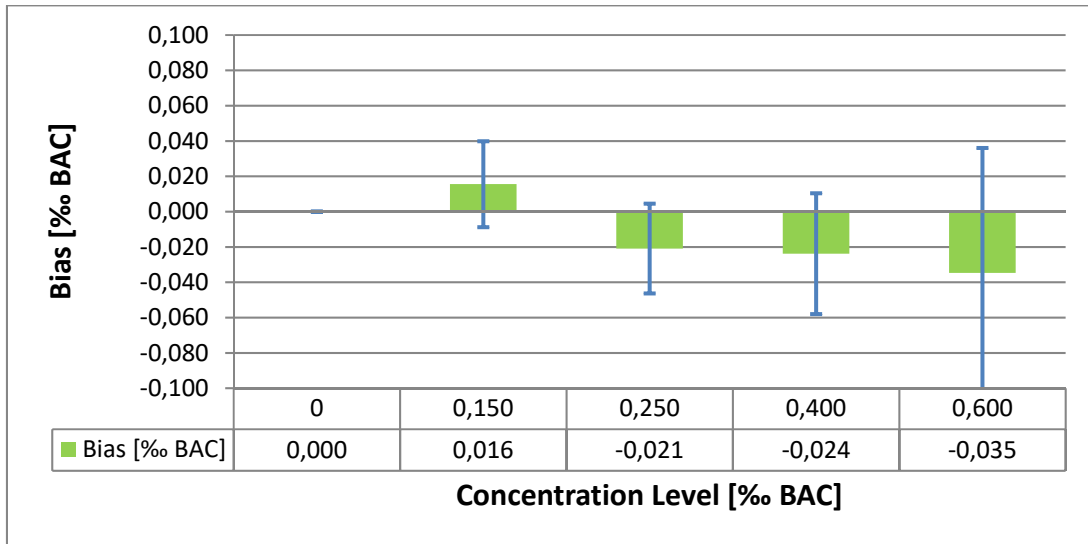


Figure 19: Absolute measurement deviation (Bias, in %) of the ACE Solid breath alcohol measuring device at the five alcohol concentration levels studied.

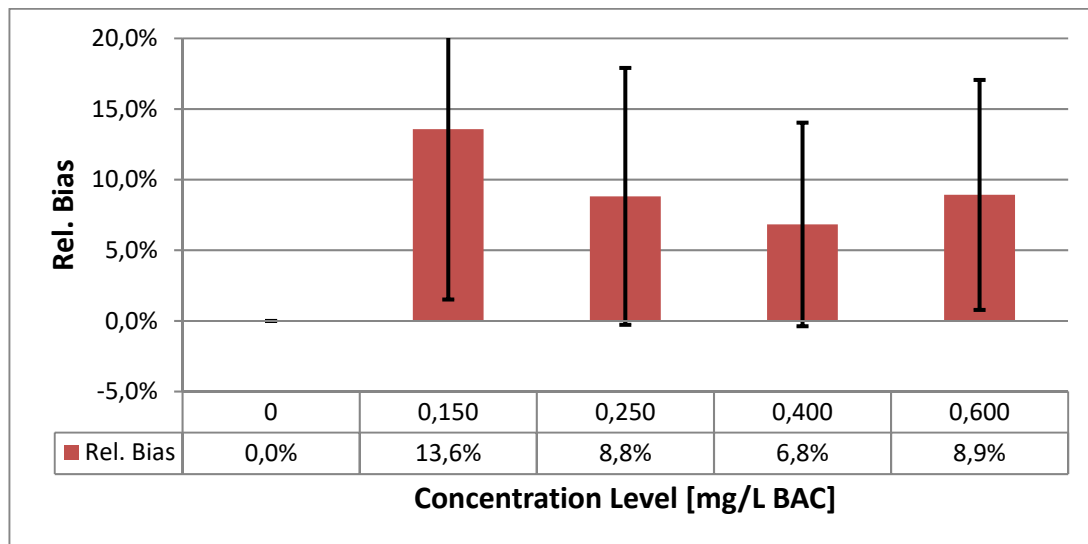
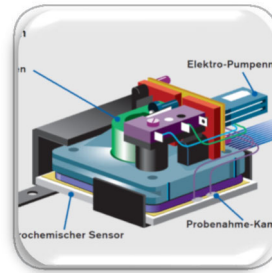


Figure 20: Relative measurement deviation (Rel. Bias, in %) of the ACE Solid breath alcohol measurement device at the five alcohol concentration levels studied..



4.6 ACE AFM-5

Figure 21: ACE AFM-5 breath alcohol measurement device.



Table 8: Summary of the results for the ACE AFM-5 breath alcohol measurement device.

Level [‰]	0	0.100	0.250	0.400	0.600
Reference value [‰]	0	0.100	0.250	0.401	0.604
Mean value [‰]	0.000	0.108	0.267	0.446	0.612
Accuracy	100.0%	92.5%	93.0%	88.7%	98.6%
RSD%	0.0%	4.8%	6.6%	5.2%	2.2%
Bias [‰]	0.000	0.007	0.018	0.045	0.009
SD of Bias [‰]	0.000	0.014	0.033	0.065	0.045
Rel. Bias [%]	0.0%	11.5%	11.0%	14.9%	5.7%
SD of Rel. Bias [%]	0.0%	10.2%	9.5%	12.0%	4.3%

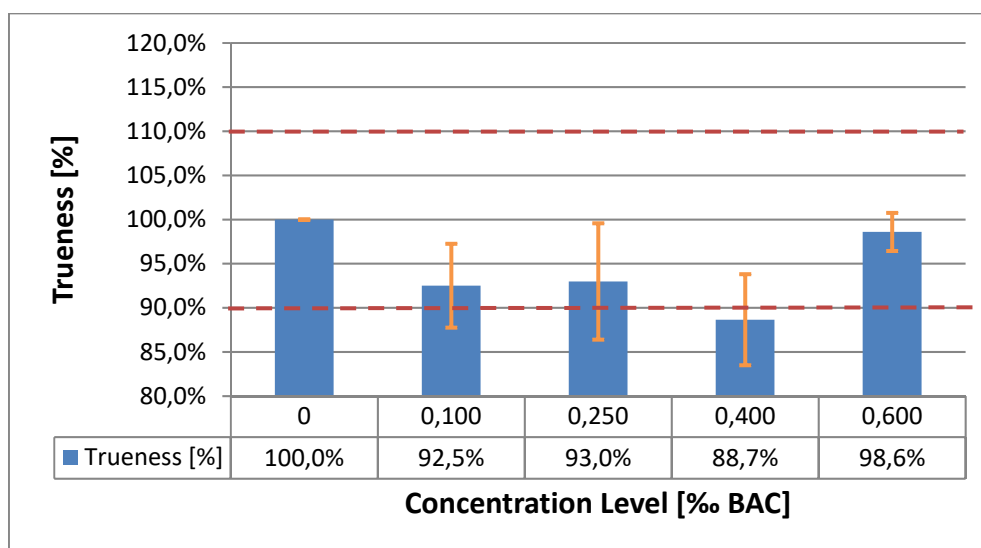


Figure 22: Trueness of the ACE AFM-5 breath alcohol measurement device at the five alcohol concentration levels studied.

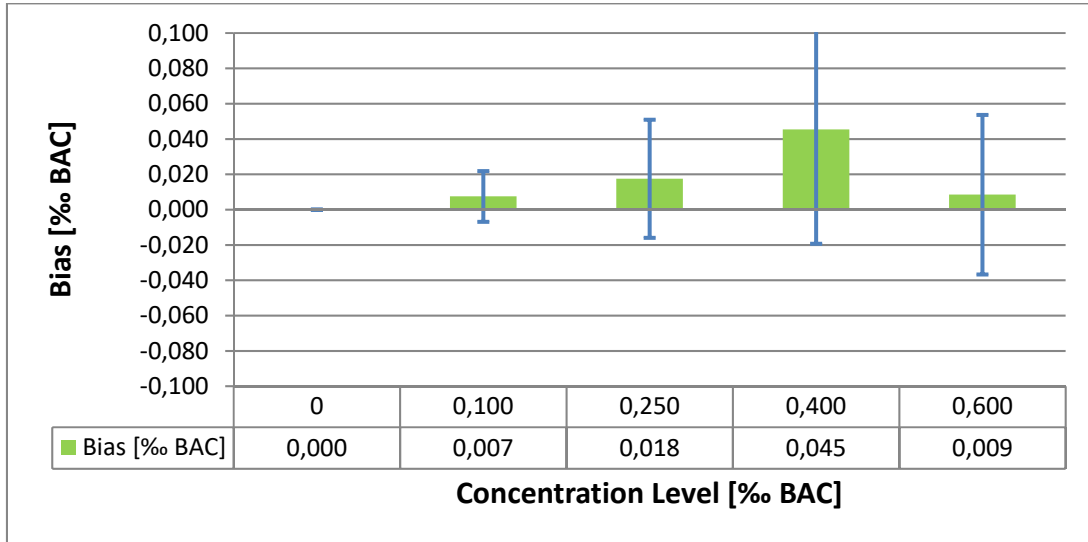
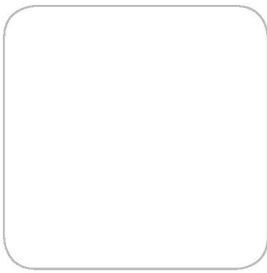


Figure 23: Absolute measurement deviation (Bias, in %) of the ACE AFM-5 breath alcohol measuring device at the five alcohol concentration levels studied.

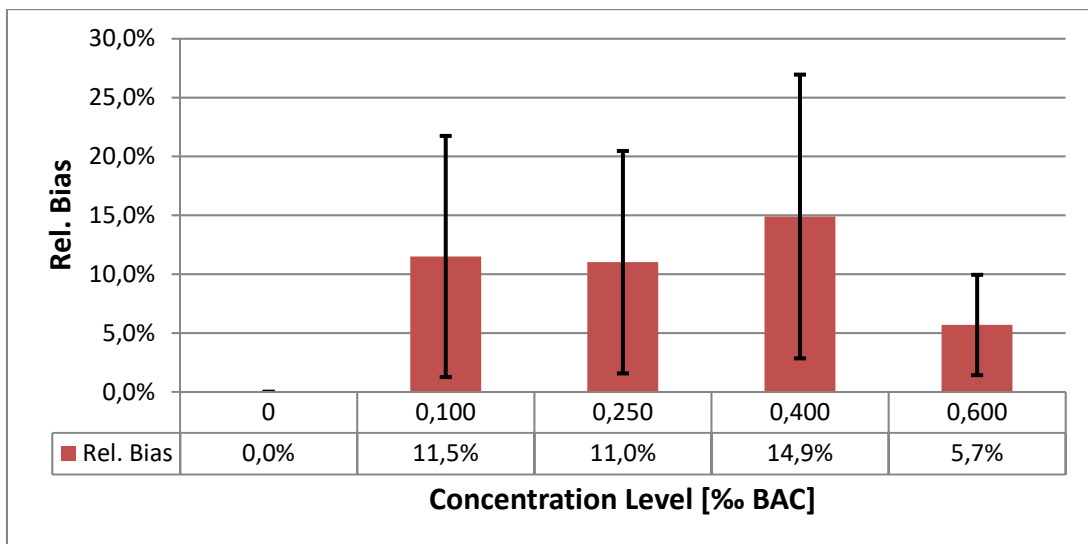
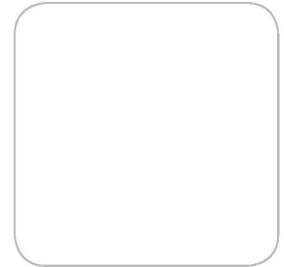
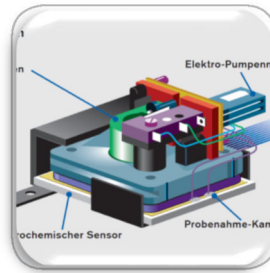


Figure 24: Relative measurement deviation (Rel. Bias, in %) of the ACE AFM-5 breath alcohol measurement device at the five alcohol concentration levels studied..



4.7 DRAEGER ALCOTEST 3820

Figure 25: Dräger Alcotest 3820 breath alcohol measurement device.



Table 9: Summary of the results for the Dräger Alcotest 3820 breath alcohol measurement device.

Level [‰]	0	0.100	0.250	0.400	0.600
Reference value [‰]	0	0.100	0.256	0.414	0.598
Mean value [‰]	0.000	0.103	0.231	0.412	0.627
Accuracy	100.0%	97.2%	90.4%	99.5%	95.1%
RSD%	0.0%	6.8%	6.8%	2.1%	4.2%
Bias [‰]	0.000	0.003	-0.025	-0.002	0.029
SD of Bias [‰]	0.000	0.005	0.009	0.008	0.016
Rel. Bias [%]	0.0%	4.4%	9.6%	1.6%	4.9%
SD of Rel. Bias [%]	0.0%	3.0%	3.5%	0.7%	2.7%

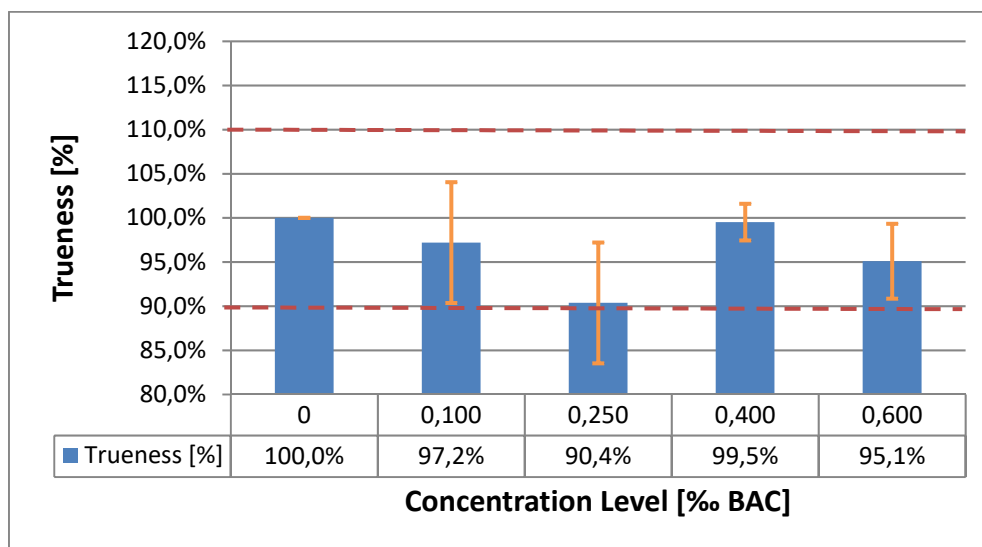


Figure 26: Trueness of the Dräger Alcotest 3820 breath alcohol measurement device at the five alcohol concentration levels studied..

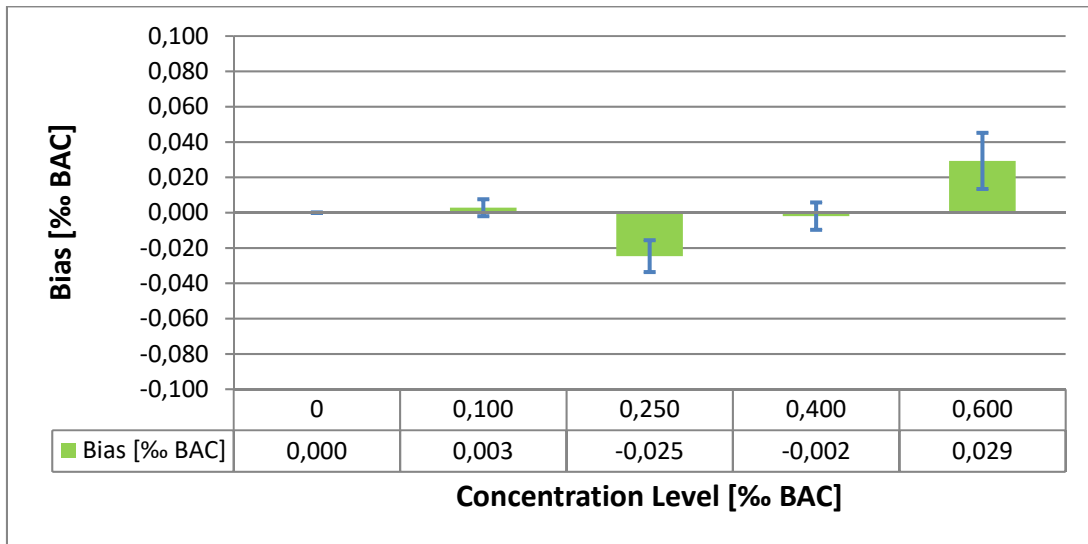
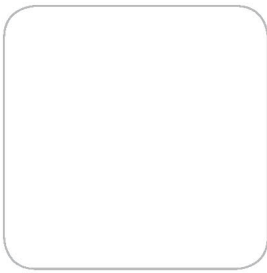


Figure 27: Absolute measurement deviation (Bias, in ‰) of the Dräger Alcotest 3820 breath alcohol measuring device at the five alcohol concentration levels studied.

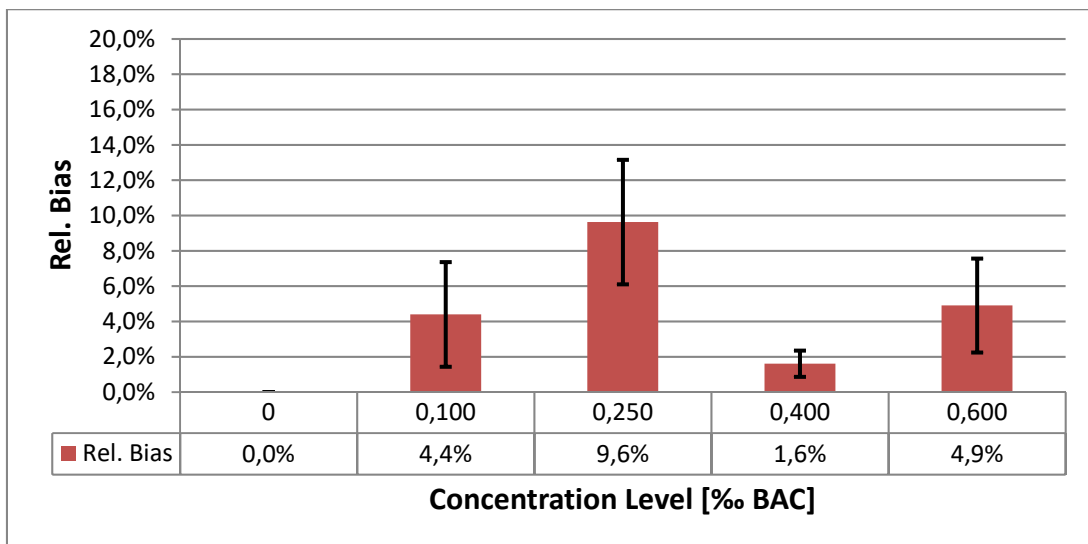
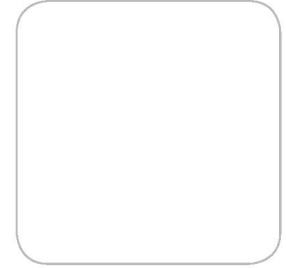
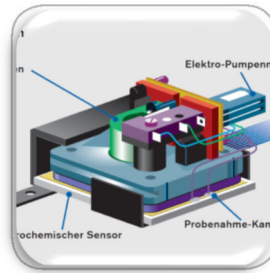
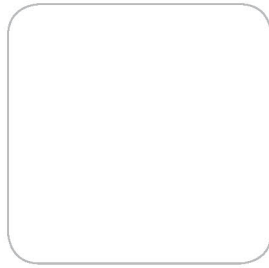


Figure 28: Relative measurement deviation (Rel. Bias, in %) of the Dräger Alcotest 3820 breath alcohol measurement device at the five alcohol concentration levels studied..



5 Summary and Conclusion

In order to provide an overview of the results of the alcotester study as clear and concise as possible, while also allowing a simple interpretation of the data, the results of the study were averaged for each model of the devices examined. The corresponding index values were calculated. These are shown in the tables and graphs below.

The mean accuracy of a device is calculated from the absolute deviation from the reference value measured by one device over all concentration levels and all measurements taken with that specific alcotester instrument. It should approach 100% as close as possible.

The mean precision is derived from the mean value of all the relative standard deviations of all measurement series performed with all instruments of an alcotester type across all the concentration levels studied.

In addition, an index value was calculated, which summarizes the two criteria accuracy and precision: This so-called 'performance index' is the sum of all deviations of each measurement device type from the reference value. The lower this index value, the better the accuracy of the alcometer device under consideration.

The two illustrations (Figure 29 and Figure 30) summarise the results of the present study in terms of accuracy and precision. Moreover, Figure 31 finally presents the amalgamation of these two parameters into a 'performance index' as a measure of the overall accuracy of the alcometer.

As can be seen from the presentation of the results of this study and the underlying experimental data, all the devices tested meet the basic requirements in terms of accuracy and precision of breath alcohol measurement with simulated test gas atmospheres.

Three of the six devices tested can be rated as 'Very Good' to 'Excellent'. At the top of the field is the alcotest device "ACE X", which is both leading in terms of accuracy as well as of the precision achieved. But also all other devices – and in particular the equally well-performing alcotesters "ACE Wave" and "ACE A" – meet the requirements for correct and precise, hence accurate breath alcohol measurement to a very high extent.

Table 10: Criteria for assessing the performance of breath alcohol measuring devices.

Assessment	Trueness	Precision
Excellent	99 - 100%	≤2.5%
Very Good	95 - 99%	≤2.5%
Good	90 - 95%	2.5 - 5.0%
Satisfying	<90%	>5.0%

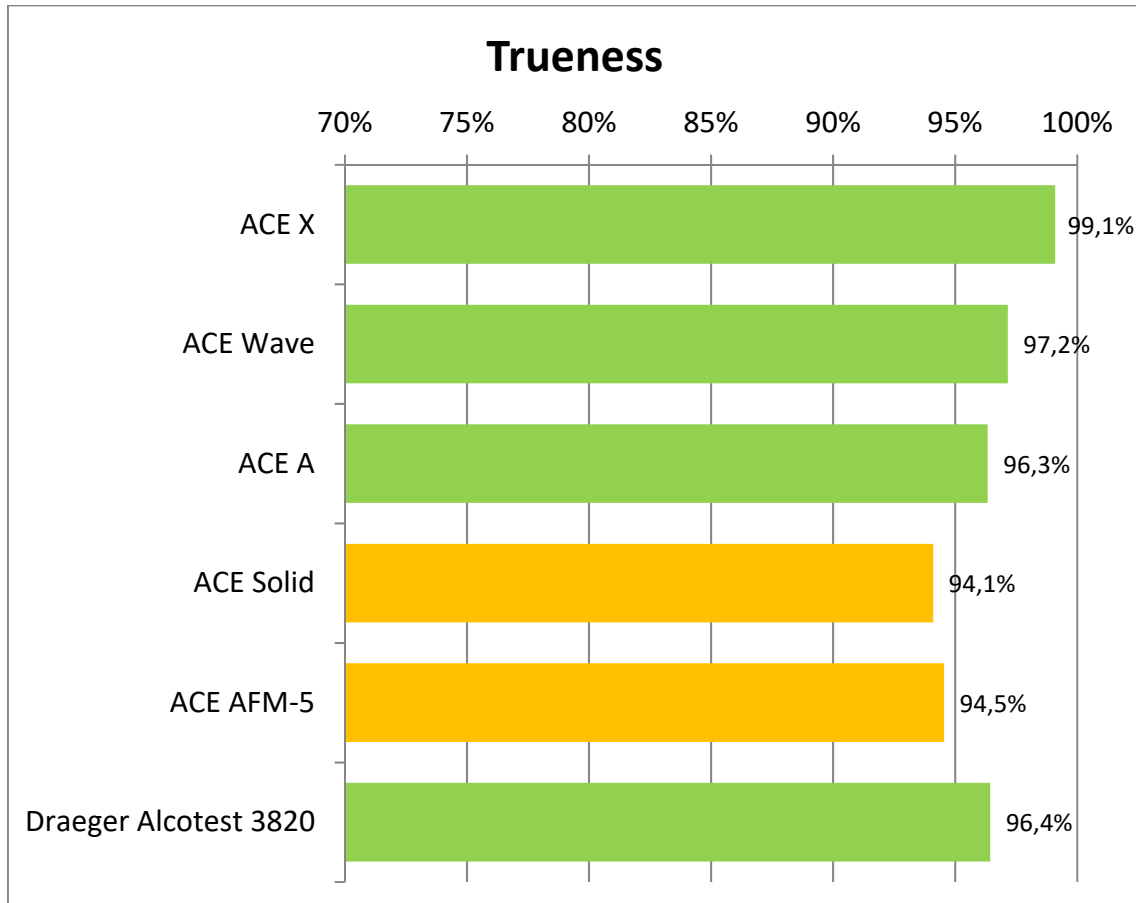
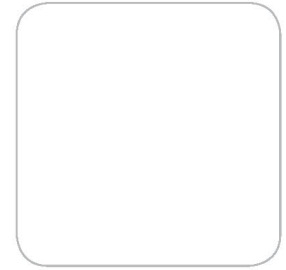
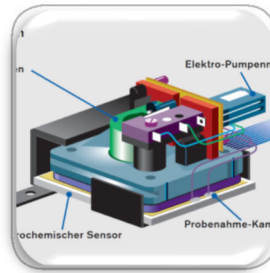


Figure 29: Summary of mean accuracy for each breath alcohol gauge tested as part of this study. Green: Excellent or very good; Orange: Good; Red: Satisfying.

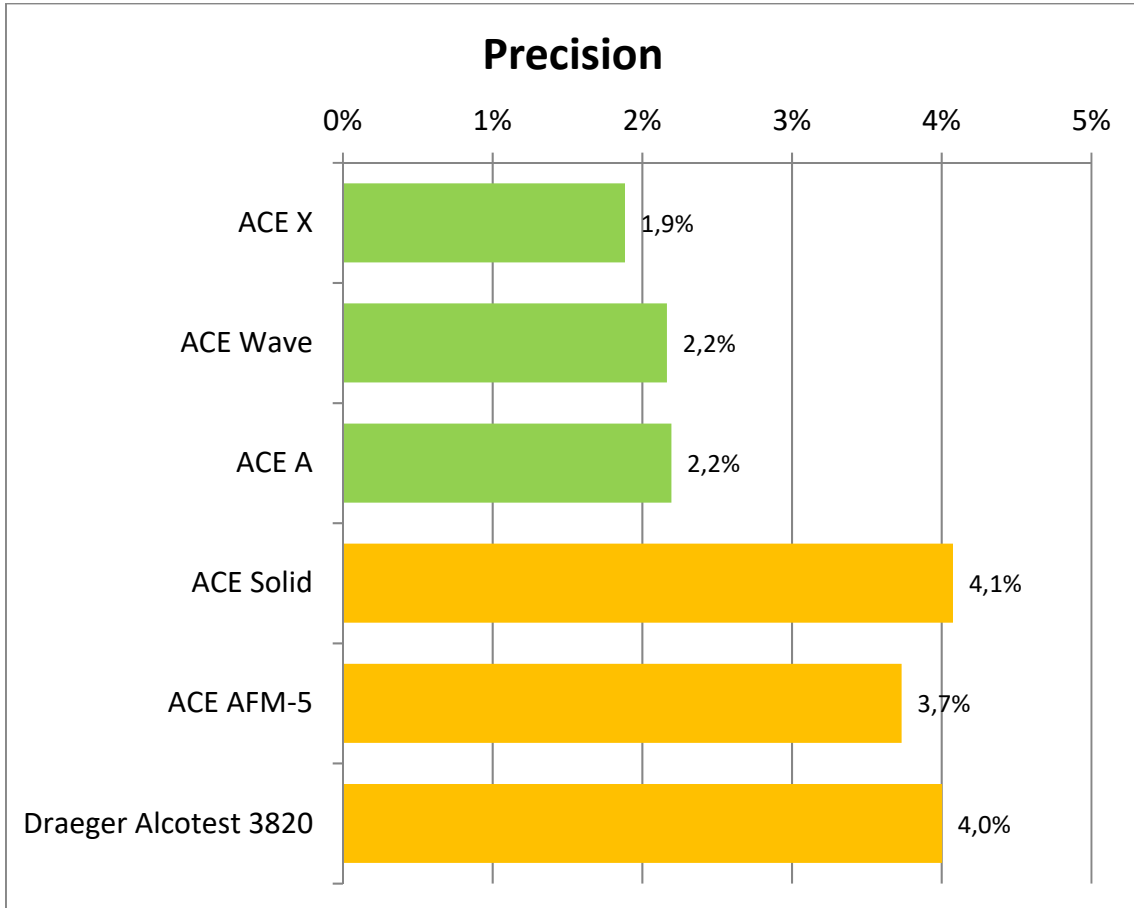


Figure 30: Summary of the mean precision (expressed as the mean of individual standard deviations) calculated from the measurements with the different breath alcohol measuring devices of this study. The colors encode: **Green:** Excellent or very good; **Orange:** Good; **Red:** Satisfying.

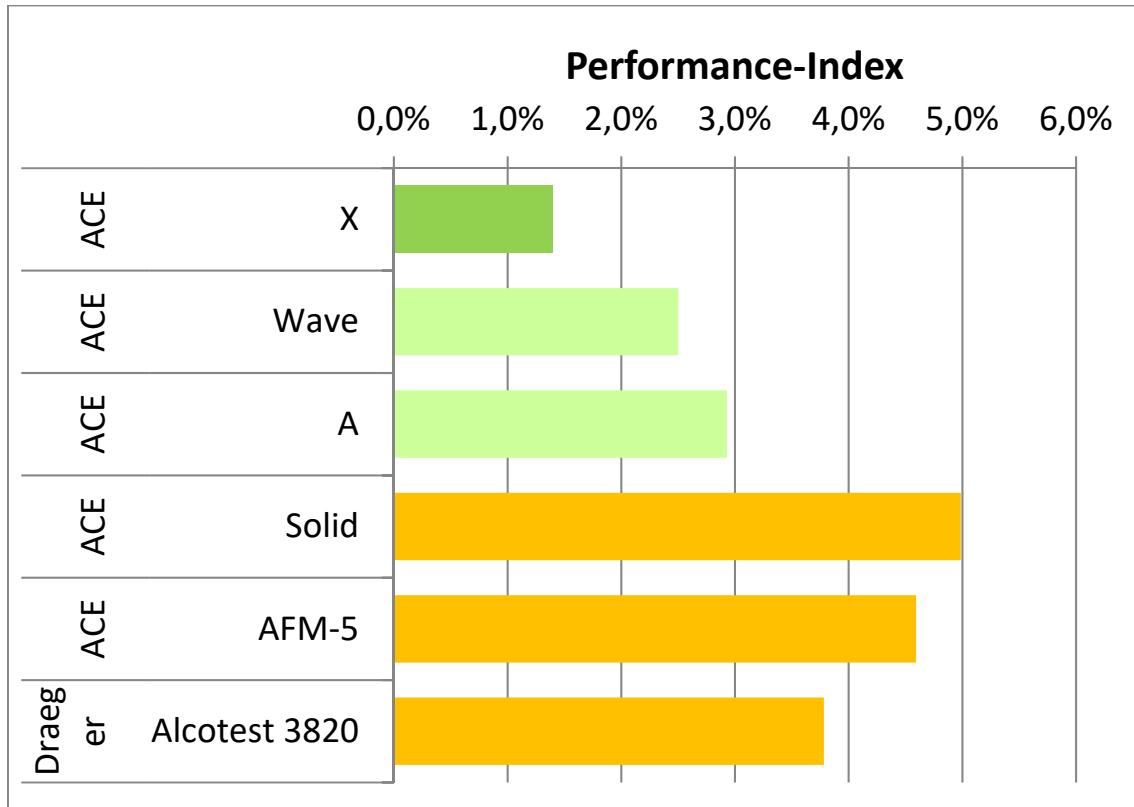
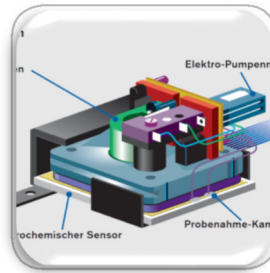


Figure 31: Presentation of the 'Performance Index' for the six tested breath alcohol measuring devices, determined from the medium accuracy and the mean precision of the respective measurement series. The colors encode: **Green:** Excellent, **light green:** Very good; **Orange:** Good; **Red:** Satisfying.

6 References

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