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

Report TUW CTA 2015/27EN

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Author of Study Report

Erwin Rosenberg

Further Contributors

Florian Doubek
Vanessa Nürnberger
Sandra Patiño Neira

Translation

Erwin Rosenberg

Layout

Martin Kolossa and Werner F. Sommer
Vienna University of Technology
Karlsplatz 13, A-1040 Vienna, Austria

Cover Photographs and Vignettes

Public Relations Office and
Erwin Rosenberg
Vienna University of Technology

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1 Study Details



1.1 ORDERING CUSTOMER

Klaus Forsthofer, MBA, Managing Director

ACE Handels- und Entwicklungs GmbH
theprotectioncompany

Staufenstrasse 1 / Halls 12 – 14
83395 Freilassing, Germany

E-Mail: klaus.forsthofer@ace-technik.de

1.2 STUDY DIRECTOR

Prof. Erwin Rosenberg, PhD.
Head of Trace Organic Analysis Laboratory

Vienna University of Technology
Institute of Chemical Technologies and Analytics

Getreidemarkt 9/64 AC
A-1060 Vienna, Austria

Phone: +43-1-58801/165190

E-Mail: Erwin.Rosenberg@tuwien.ac.at

1.3 STUDY PERSONNEL AND LOCATION

Florian Doubek
Sandra Patiño Neira
Vanessa Nürnberger

Trace Organic Analysis Laboratory
Vienna University of Technology
Institute of Chemical Technologies and Analytics

Getreidemarkt 9/64 AC
A-1060 Vienna, Austria

1.4 STUDY DURATION

The experimental work of this study was performed between 1 February and 15 May 2015.



2 Introduction



2.1 SCOPE OF THE STUDY

In order to assess the reliability of small portable devices for the measurement of breath alcohol concentrations by the individual user, a study was commissioned by the large German distributor for breath alcohol test devices ('breathalyzers') 'ACE Handels- und Entwicklungs GmbH - *the protectioncompany*' in which the accuracy and the precision of the measurements was to be tested under defined laboratory conditions.

The present report describes the design and the performance of the study and summarizes the results obtained.

2.2 INTRODUCTION

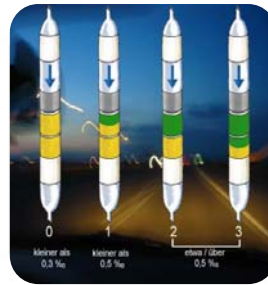
Alcohol and Driving

The consumption of alcohol has a long tradition in many cultures, and is often associated with particular festivities, traditions, or important events. Alcoholic beverages are enjoyed by many people in good company, or on their own. As long as consumed with moderation, the stimulating and positive aspects of alcohol consumption may prevail. However, even small quantities of alcohol may affect the perception ability and the ability to react, and thus the ability to safely drive a car. The legislator has thus set limits after which driving a car is not considered safe anymore. If a person is caught by the police when driving a car while having a higher than permitted blood alcohol level, serious legal consequences may arise.

This calls for accurate and precise measurement techniques and instrumentation to be used by the police, but also evokes the interest of the general public to have as well accurate, precise, robust, easy to use and relatively inexpensive devices available that allow them to measure by themselves their breath alcohol concentration as an estimate of their blood alcohol concentration.

Blood Alcohol and Breath Alcohol

When alcohol is consumed, it is absorbed into the venous portion of the circulatory system. It is through the venous system that blood returns to the heart and lungs to be purified and recirculated as arterial blood throughout the body via a network of capillaries. In the pulmonary alveoli, there is an equilibration between the alcohol ingested and the exhaled breath. The alcohol contained in the peripheral blood is taken up by the inhaled fresh air and is released with the exhaled breath. Although the exhaled breath alcohol concentration is dependent on the venous blood alcohol concentration, this is not a strict correlation, but the ratio is time-dependant, and also depends on various physiological parameters of the person, such as body size and weight, gender and age. It is thus not possible by principle to convert the measured breath alcohol concentration into the exact blood alcohol concentration. However, for a time span of ca. 2 up to 5 hours after the intake of alcohol, the ratio between blood alcohol concentration and breath alcohol concentration is about 1:2100 - this means that 2100 volumes of alveolar air contain the same



amount of alcohol as 1 volume of blood, e.g. the same amount of alcohol that is contained in 10 mL of venous blood is contained in 21 L of exhaled air. In the timeframe before two hours after alcohol consumption, the ratio is smaller, indicating that during this period of time the breath alcohol concentration is larger than the corresponding blood alcohol concentration.

Due to the possible presence of residual mouth alcohol (alcohol that has remained in the oral cavity during the delivery of the breath sample, e.g. in periodontal pockets) a valid measurement is not to be performed earlier than 20 minutes after alcohol intake, otherwise highly elevated alcohol levels can be measured. In case of forensic measurements, an observation time of at least ten minutes before the measurement is to be respected and the results of two individual measurements with a gap of two to five minutes are to be compared, in order to eliminate the effect on the final results from residual alcohol in the mouth.

When determining the concentration of alcohol in the breath, a differentiation is made between a screening test and an (evidential) analysis admissible in court. A screening test provides the police officer on the street with an objective aid to decide whether an evidential breath alcohol analysis should be performed or a blood sample taken [1].

Evidential Measurement

When a screening test was found positive, an alcohol analysis must be performed whose results are admissible in court. Since blood and breath alcohol levels are strongly correlated, however, it is not possible to convert the one into the other, the legislature in Germany has defined two equivalent independent limit values in article 24a of the German Road Traffic Act for the two methods of breath and blood alcohol analysis. The breath alcohol concentration, is a gas concentration, and is specified in milligrams of alcohol (ethanol) per liter of breathing air (mg/L). In contrast to this, the blood alcohol concentration is a liquid concentration, and is specified in tenth of a percent (‰, per mille) and represents the mass of ethanol in grams per liter of blood. In the Road Traffic Act the limit value is defined as a blood alcohol concentration of 0.5 tenths of a percent (‰); the corresponding independent limit value for breath alcohol concentration as 0.25 milligrams per liter (mg/L) of breathing air. The legal limits of breath and blood alcohol concentration represent a ratio of 2000:1 which is slightly more tolerant towards the driver with respect to the physiologically established concentration ratio of 2100:1 and which partially compensates for the larger uncertainty of this ratio.

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. 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 [2].

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 color 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 [3].

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. [4]:

In the 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 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 the time being, there is but one instrument on the



German market that has achieved approval for this task by the Physikalisch-Technische Bundesanstalt (Dräger Alcotest 7110 Evidential).

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 list below 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 content (BAC)** is 0.05% 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% 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 legal limits (in ‰) for Blood Alcohol Content (BAC) when driving a car in various European countries.

Country	Standard	Commercial drivers	Novice drivers
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	0.2	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 (from July 2015)
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 (from January 2015)
Luxembourg	0.5	0.2	0.2



Table 1 (continued):

Country	Standard	Commercial drivers	Novice drivers
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
UK [i]	0.8	0.8	0.8
Switzerland	0.5	0.0	0.0

[i] Scotland 0.5 as of December 2014 for all groups. The rest of the UK (England, Wales and Northern Ireland) remain unchanged.

As of: July 2015

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

BAC Breath 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 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 Test

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 STUDY

For the design of the study, the European Standard DIN EN 16280 (of December 2012) on “Breath alcohol test devices for general public – Requirements and test methods; German version EN 16280:2012” [5] has been taken as a guideline. This standard defines the conditions under which the testing of breathalyzers is to be performed, and what are the general and the specific requirements for the testing.

It was agreed with the commissioning client to test the breathalyzers at the following five blood alcohol concentration (BAC) levels:

- 0.00 ‰ BAC
- 0.10 ‰ BAC
- 0.25 ‰ BAC
- 0.40 ‰ BAC
- 0.60 ‰ BAC

These standards cover the relevant concentration range for blood alcohol and hence also breath alcohol measurements. The reason why blood alcohol measurement was used as reporting unit is that all tested instruments were set by the manufacturer / distributor to report results in 0.1‰ (‰, per mille) or blood alcohol concentration (BAC).

For each instrument, 10 separate measurements were performed on all the concentration levels reported above. These measurements were statistically evaluated in view of precision and accuracy of the readings.

Statistical Data Evaluation

The **precision** of a set of data (repeated measurements) denotes how close the individual measurements are to each other. It is typically expressed as the relative standard deviation (RSD) of the data which is calculated as follows:

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 coincidence of the known and the measured concentration. It is either expressed as the ratio of the measured and the known concentration:

Accuracy [%]:
$$Accuracy = x_{\text{measured}}/x_{\text{known}} [\%] \quad (3)$$

or it is expressed as the lack of coincidence of measured and known value, often also named “**bias**”:

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

For an easier interpretation, bias is also often expressed as relative bias:

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



These parameters are originally calculated for each instrument and each concentration level. In order to have a more robust and easier interpretable representation of the data, results are averaged for each concentration level for the five instruments of same model.

All statistical calculations are performed in Microsoft Excel® 2007.

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

Table 2: Explanation of tabular presentation of study data.

Level [‰]	Nominal blood alcohol concentration [‰]
Reference value [‰]	Concentration of calibration gas [‰] at the given concentration level
Mean value [‰]	Mean of actual measurements [‰]
Accuracy	Ratio of mean and reference value, reported in [%]
RSD%	Relative standard deviation of accuracy, reported in [%]
Bias [‰]	Absolute difference between reference and mean value, reported in [‰]
SD of Bias [‰]	Absolute standard deviation of bias, reported in [‰]
Rel. Bias [%]	Relative difference between reference and mean value, reported in [%]
SD of Rel. Bias [%]	Standard deviation of relative bias, reported in [%]

3.2 PERFORMANCE OF THE STUDY

The following breathalyzer instruments were included in this accuracy study:

Table 3: Identification and characterization of breathalyzer instruments used in the present study.

Manufacturer / Supplier	Model	Use Type	Accuracy Class	Measurement Principle
ACE	Neo	Personal	1	Fuel cell
ACE	II Basic	Personal	1	Fuel cell
ACE	III Basic	Personal	1	Fuel cell
ACE	III Premium	Personal	1	Fuel cell
ACE	AF-33	Personal	1	Fuel cell
ACE	AL5500	Personal	3	Semiconductor sensor
ACE	Pro Med Basic	Personal	1+	Fuel cell
ACE	one	Personal	n/a	Fuel cell
Dräger	Alcotest 3000	Personal	1+	Fuel cell
Dräger	Alcotest 5510	Personal / Police	1+	Fuel cell
Dräger	Alcotest 6820	Personal / Police	1+	Fuel cell
EnviteC	AlcoQuant 6020 Plus	Personal / Police	1+	Fuel cell
ACE	Public V	Stationary	1+	Fuel cell
ACE	Stationary Alcohol Analyzer	Stationary	n/a	Fuel cell



Generation of Test Gas Atmosphere

The test gas atmospheres of precisely known and constant concentrations of ethanol vapor were generated in accordance with the standard DIN EN 16280 [5] with a set-up consisting of two 'simulators' coupled in series, and a membrane pump to produce the alcohol-enriched air flow required for testing the breathalyzers.

A 'simulator' is a device that contains an aqueous solution of alcohol through which a stream of pure air (zero air) is directed so that the gas is saturated with water vapor and with ethanol vapor corresponding to the precisely set temperature of the device. The simulators were precisely thermostatted to $34.0 \pm 0.3^\circ\text{C}$. The serial operation of two simulators in series ensured a calibration gas of constant concentration over an extended period of time.

The two simulators used in this study were two Dräger Mark II A Instruments (Dräger Safety Diagnostics Inc., Irving, TX, USA), Part No. 454 0088, Serial Nos. DDAK-0034 and DDXB-0020.

A membrane pump model DY-20L of unknown manufacturer, Serial No. HB07016-1001B, was used to draw the zero through the ethanol solutions in the simulators and to provide the required calibration gas volume for the testing of the breathalyzers (Figure 1).



Figure 1: Experimental setup for the breathalyzer study with the membrane pump to the left, and the two simulators operated in series on the right. The calibration gas is provided through the silicon tubing. Simulators are not filled.



The mass concentration of alcohol in a calibration gas that bubbles through an aqueous solution of alcohol at a given concentration C_{water} can be described by the following formula, originally derived by Dubowski [6]:

$$C_{\text{air}} = 0.04151 \times 10^{-3} \times C_{\text{water}} \times \exp(0.06583t) \quad (6)$$

Where C_{air} is the mass concentration of alcohol in the air [mg/L], C_{water} the mass concentration of alcohol in the aqueous solution [mg/L] and t is the temperature in °C.

For $t = 34^\circ\text{C}$, $C_{\text{air}} = 0.38866 \times 10^{-3} C_{\text{water}}$.

In order to check the validity of the above approach of generating calibration gases of defined alcohol concentrations, measurements were performed with two calibrated breath alcohol analyzers of metrological class 1+ (meaning that these are accepted for use by the police in screening tests) Dräger Alcotest 6820 (Part No. 8322 620). The Serial Nos. of the two instruments that were used in the frame of this study to assess the test gas concentration are: ARFL-0341 and ARFL-0323. The deviations in the readings of the different instruments were never larger than 0.01‰. These two instruments were calibrated against five breath alcohol analyzers EnviteC AlcoQuant 6020 plus (Part No. 1001 780). The Serial Nos. of the five instruments that were used in the frame of this study are: A406 826, A406 829, A406 830, A406 831 and A406 834.

All measurements were performed according to the individual operating instructions of the particular breathalyzer model.

4 Results of the Study

4.1 PRESENTATION OF RESULTS

On the following pages, the experimental results are presented as instrument-by instrument. The presentation of data includes the summary of data in form of a table plus three graphs per instrument type that present the accuracy (expressed as percentage of the known calibration gas concentration), and the bias in absolute dimension (reported in ‰ BAC) as well as in relative terms (expressed as percentage, %).



4.2 ACE NEO

Figure 2: ACE Neo breath alcohol testing devices.



Table 4: Summary of results for the ACE Neo breath alcohol test

Level [‰]	0	0.100	0.250	0.400	0.600
Reference value [‰]	0	0.092	0.238	0.384	0.576
Mean value [‰]	0.000	0.105	0.247	0.388	0.564
Accuracy	100.0%	114.6%	103.4%	101.2%	97.8%
RSD%	0.0%	4.8%	2.7%	2.5%	3.1%
Bias [‰]	0.000	0.013	0.008	0.005	-0.013
SD of Bias [‰]	0.000	0.004	0.005	0.010	0.017
Rel. Bias [%]	0.0%	14.6%	3.4%	1.2%	-2.2%
SD of Rel. Bias [%]	0.0%	4.7%	2.2%	2.5%	3.0%

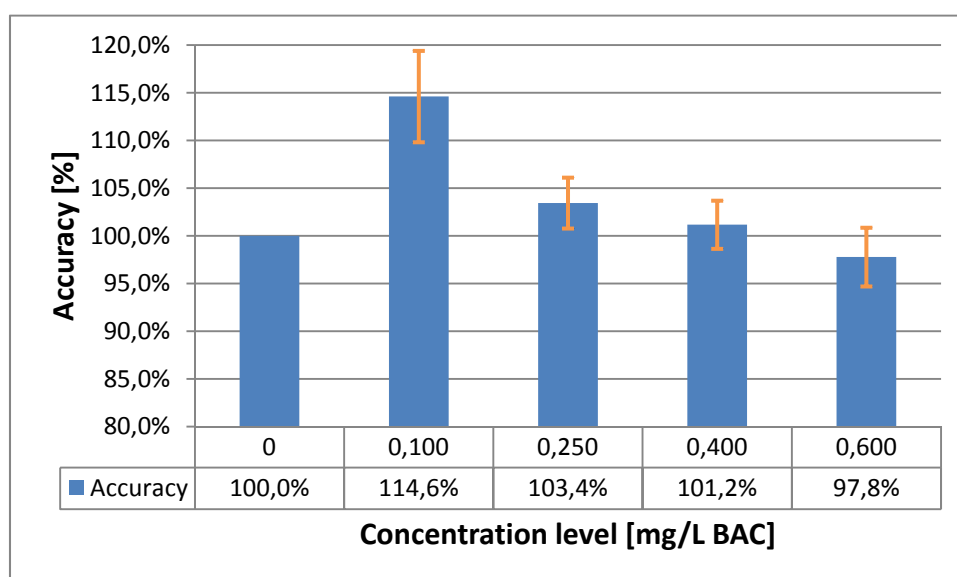


Figure 3: Accuracy of the ACE Neo alcohol testing devices on the five tested breath alcohol concentration levels.

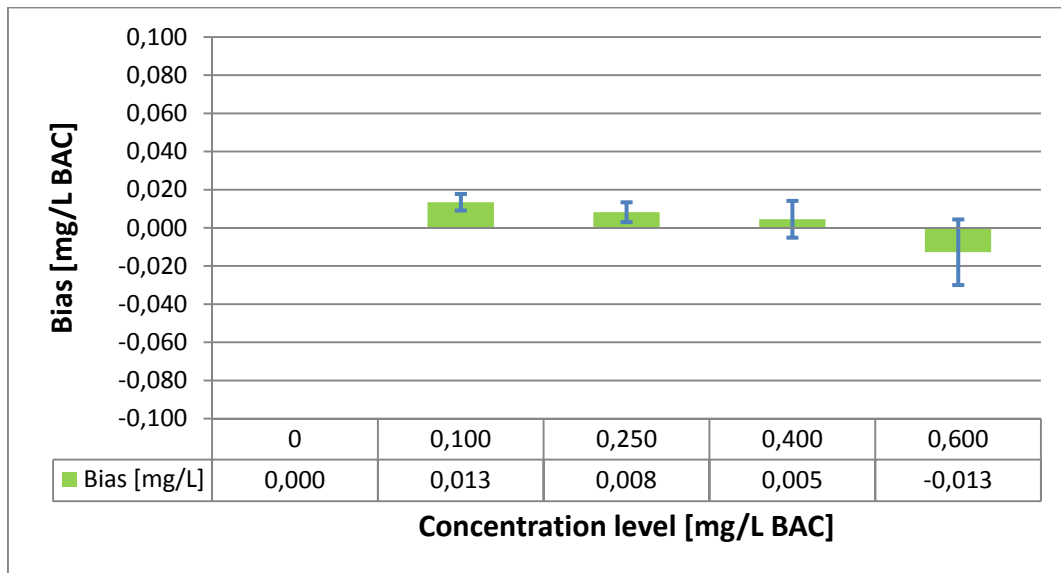


Figure 4: Absolute bias (in %) of the ACE Neo alcohol testing devices on the five tested breath alcohol concentration levels.

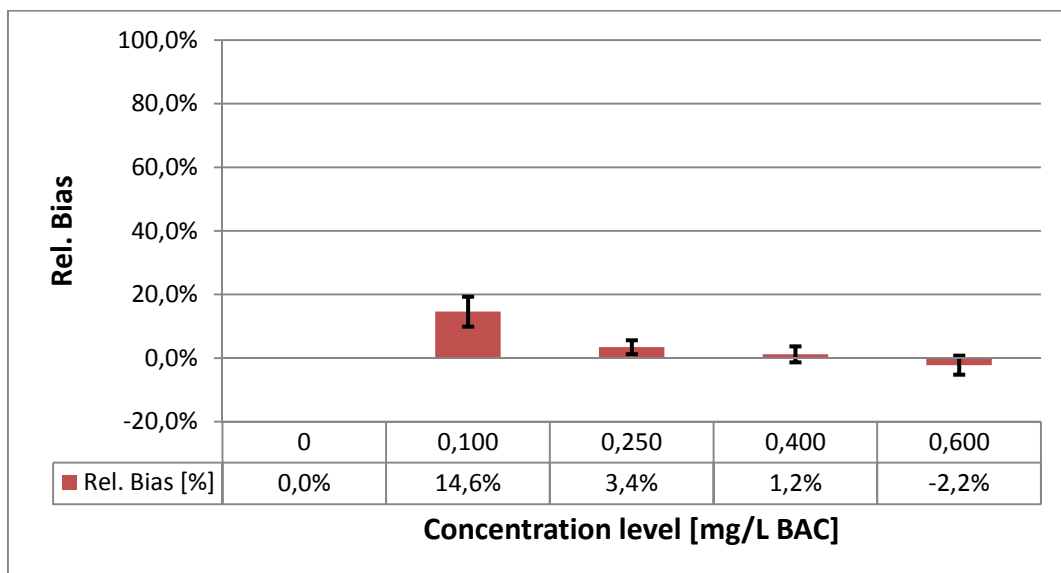


Figure 5: Relative bias (in %rel.) of the ACE Neo alcohol testing devices on the five tested breath alcohol concentration levels.



4.3 ACE II BASIC

Figure 6: ACE II Basic breath alcohol testing device.



Table 5: Summary of results for the ACE II Basic breath alcohol tester.

Level [‰]	0	0.100	0.250	0.400	0.600
Reference value [‰]	0	0.094	0.238	0.382	0.575
Mean value [‰]	0.000	0.100	0.248	0.394	0.584
Accuracy	100.0%	106.5%	104.1%	103.2%	101.6%
RSD%	0.0%	0.0%	1.6%	1.7%	3.4%
Bias [‰]	0.000	0.006	0.010	0.012	0.009
SD of Bias [‰]	0.000	0.000	0.004	0.006	0.019
Rel. Bias [%]	0.0%	6.5%	4.1%	3.2%	1.6%
SD of Rel. Bias [%]	0.0%	0.0%	1.7%	1.5%	3.3%

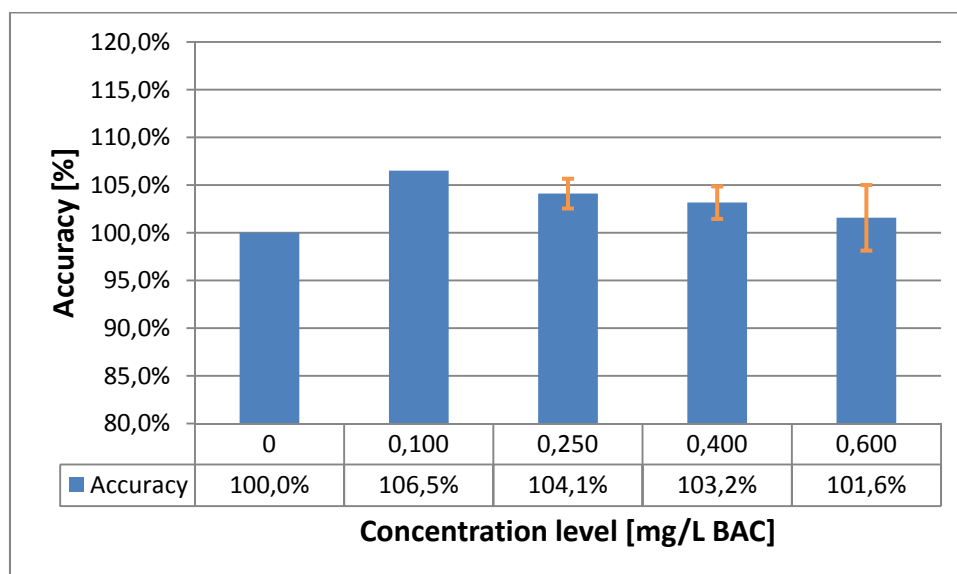


Figure 7: Accuracy of the ACE II Basic alcohol testing devices on the five tested breath alcohol concentration levels.

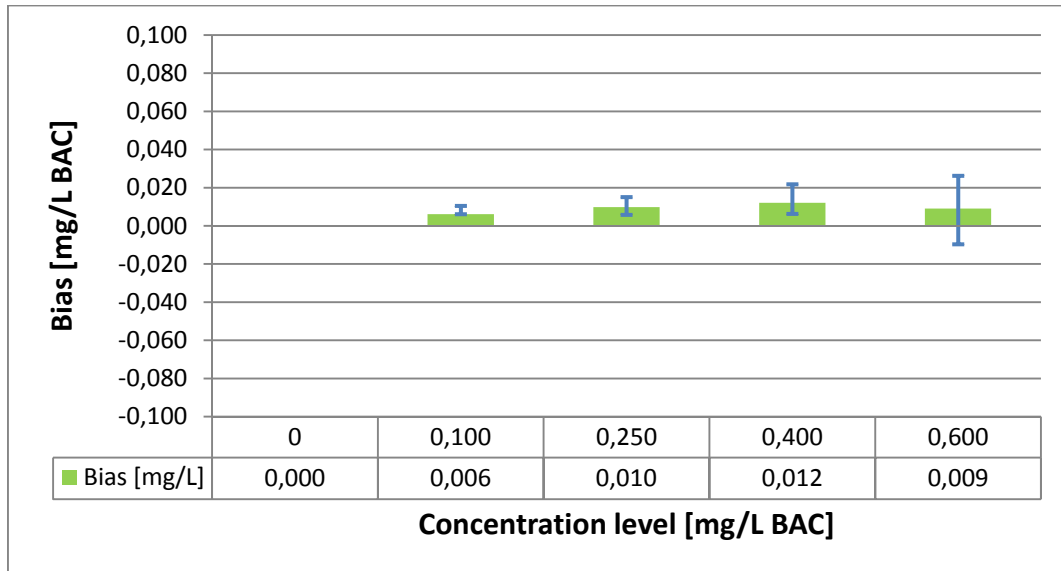


Figure 8: Absolute bias (in %) of the ACE II Basic alcohol testing devices on the five tested breath alcohol concentration levels.

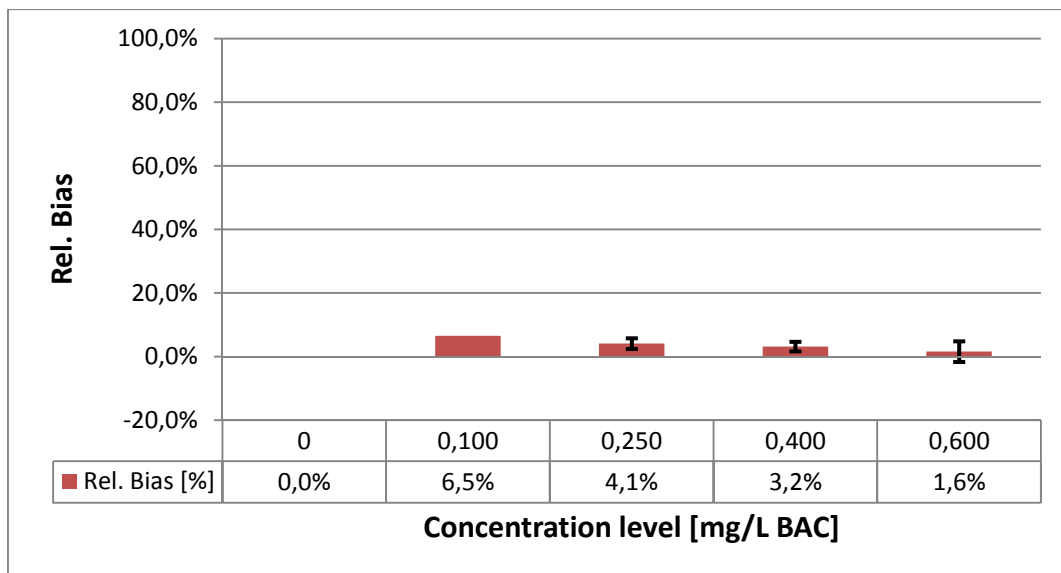


Figure 9: Relative bias (in % rel.) of the ACE II Basic alcohol testing devices on the five tested breath alcohol concentration levels.



4.4 ACE III BASIC

Figure 10: ACE III Basic breath alcohol testing device.



Table 6: Summary of results for the ACE III Basic breath alcohol tester.

Level [‰]	0	0.100	0.250	0.400	0.600
Reference value [‰]	0	0.097	0.229	0.378	0.585
Mean value [‰]	0.000	0.105	0.247	0.388	0.564
Accuracy	100.0%	108.0%	107.7%	102.8%	96.4%
RSD%	0.0%	4.8%	2.7%	2.5%	3.1%
Bias [‰]	0.000	0.008	0.018	0.011	-0.021
SD of Bias [‰]	0.000	0.004	0.005	0.010	0.017
Rel. Bias [%]	0.0%	8.0%	7.7%	2.8%	-3.6%
SD of Rel. Bias [%]	0.0%	4.4%	2.3%	2.6%	2.9%

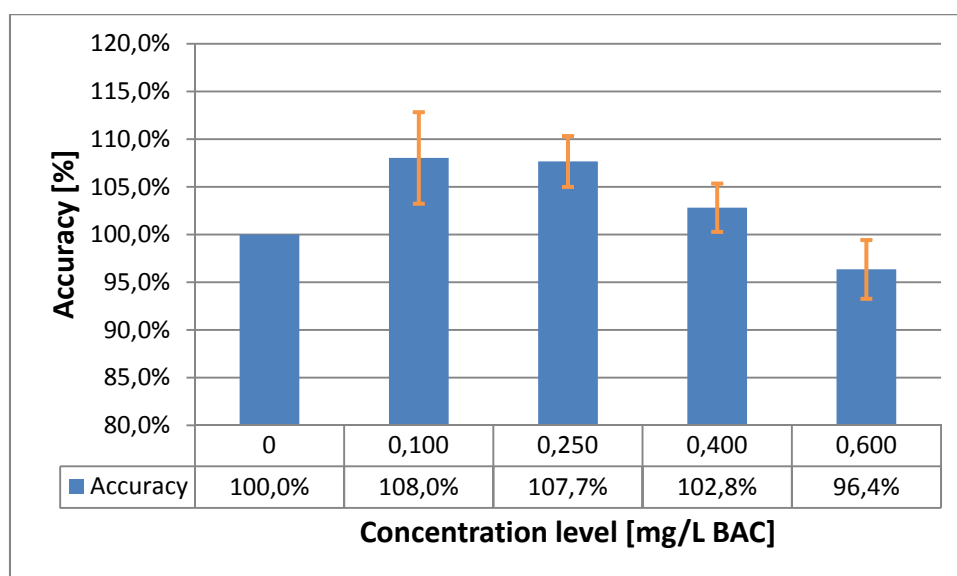


Figure 11: Accuracy of the ACE III Basic alcohol testing devices on the five tested breath alcohol concentration levels.

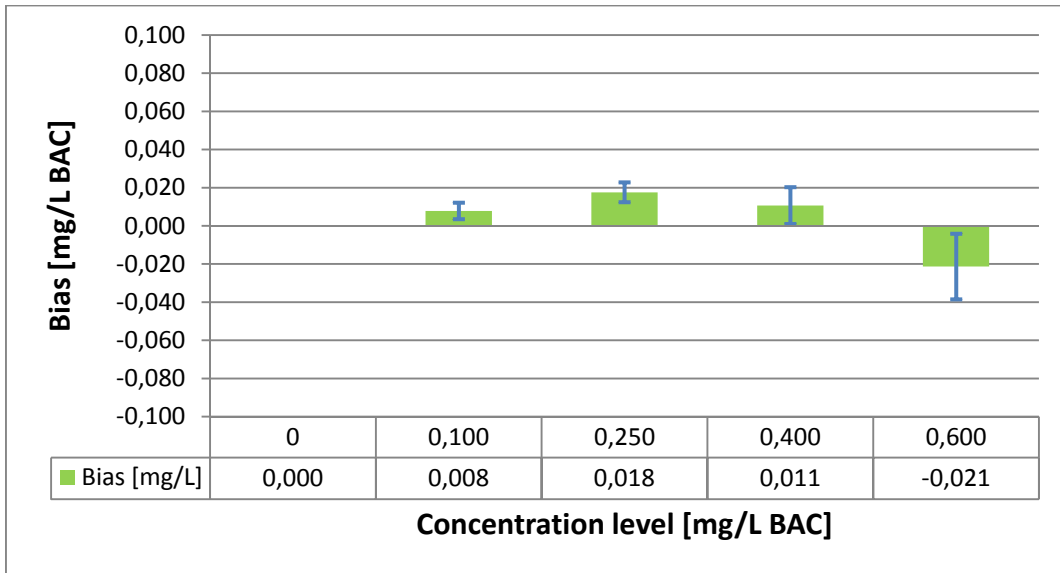


Figure 12: Absolute bias (in %) of the ACE III Basic alcohol testing devices on the five tested breath alcohol concentration levels.

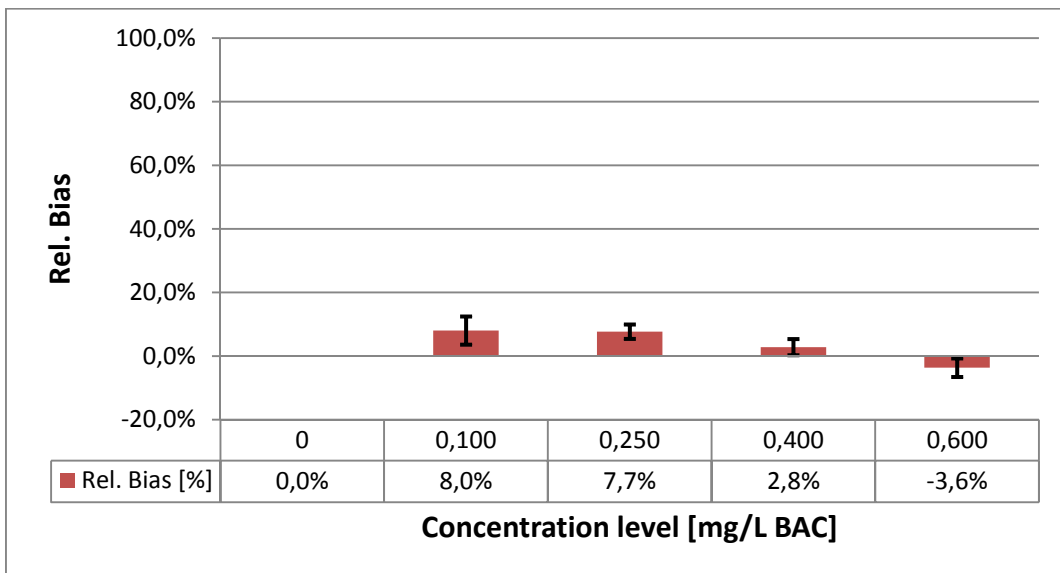


Figure 13: Relative bias (in %rel.) of the ACE III Basic alcohol testing devices on the five tested breath alcohol concentration levels.



4.5 ACE III PREMIUM

Figure 14: ACE III Premium breath alcohol testing device.



Table 7: Summary of results for the ACE III Premium breath alcohol tester.

Level [‰]	0	0.100	0.250	0.400	0.600
Reference value [‰]	0	0.094	0.238	0.382	0.575
Mean value [‰]	0.000	0.008	0.229	0.374	0.584
Accuracy	100.0%	8.5%	96.1%	97.8%	101.6%
RSD%	0.0%	342.6%	3.0%	5.2%	3.4%
Bias [‰]	0.000	-0.086	-0.009	-0.008	0.009
SD of Bias [‰]	0.000	0.018	0.005	0.021	0.019
Rel. Bias [%]	0.0%	-91.5%	-3.9%	-2.2%	1.6%
SD of Rel. Bias [%]	0.0%	19.1%	2.2%	5.4%	3.3%

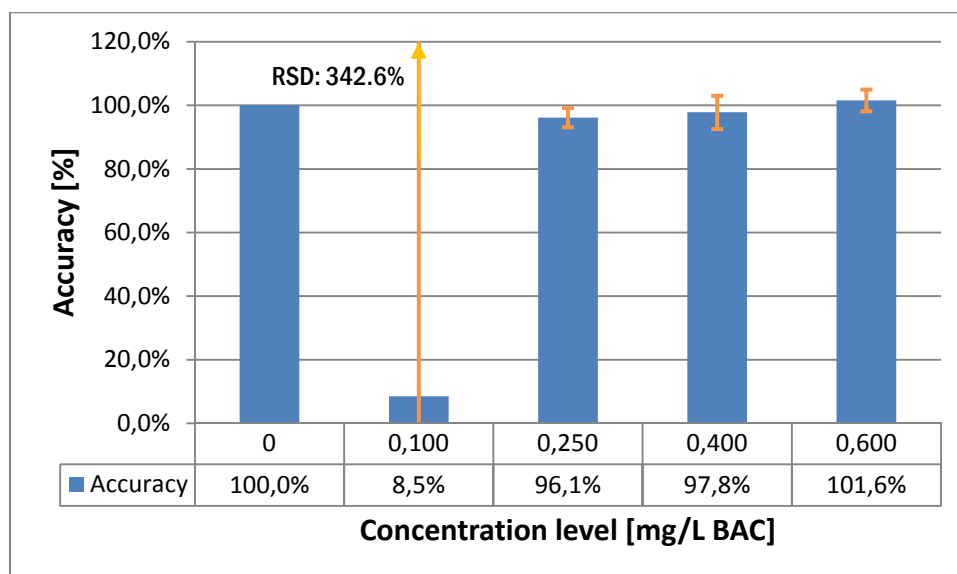


Figure 15: Accuracy of the ACE III Premium alcohol testing devices on the five tested breath alcohol concentration levels.

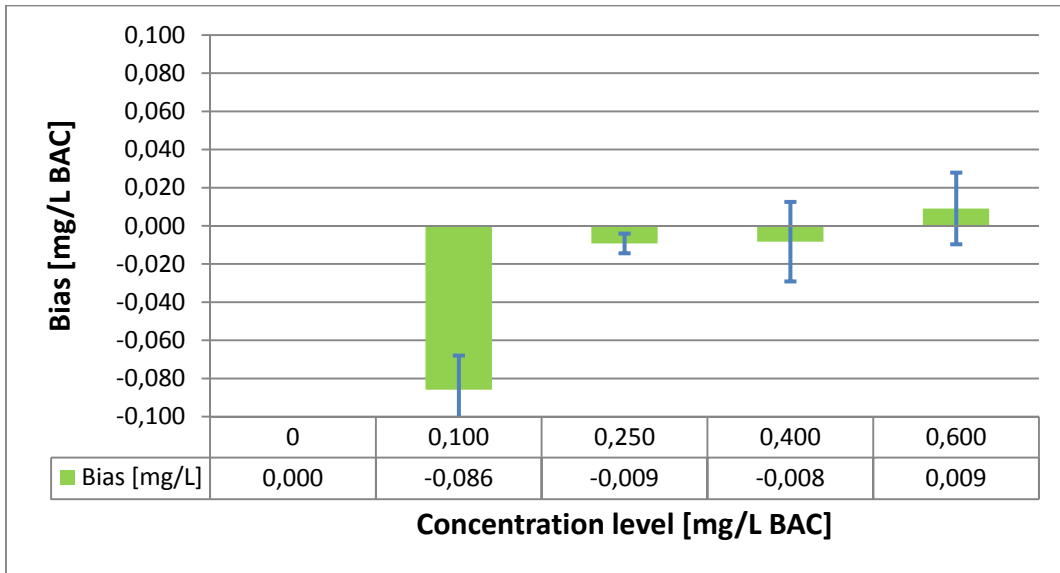


Figure 16: Absolute bias (in %) of the ACE III Premium alcohol testing devices on the five tested breath alcohol concentration levels.

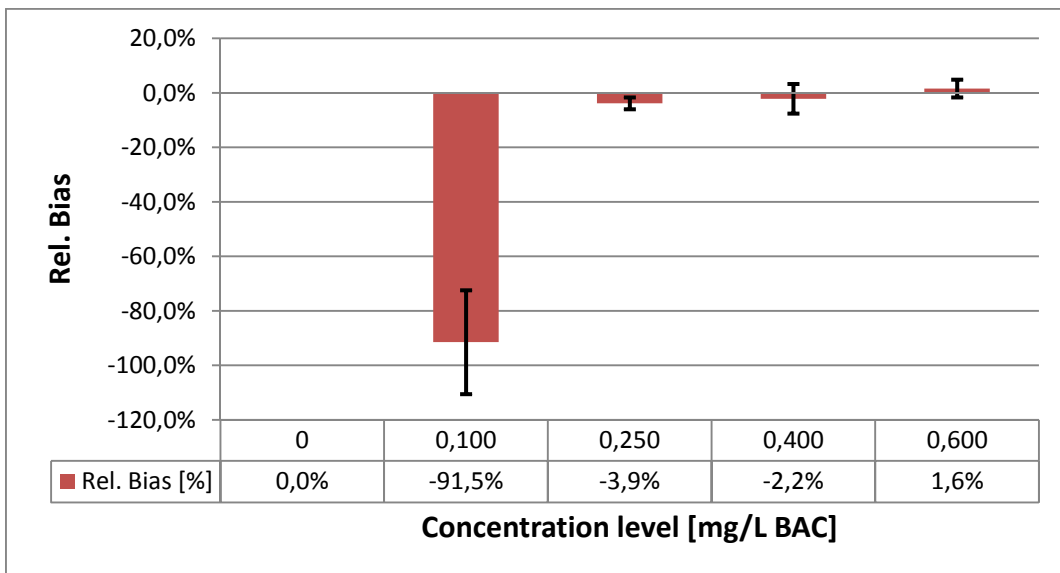


Figure 17: Relative bias (in %) of the ACE III Premium alcohol testing devices on the five tested breath alcohol concentration levels.



4.6 ACE AF-33

Figure 18: ACE AF-33 breath alcohol testing device.



Table 8: Summary of results for the ACE AF-33 breath alcohol tester.

Level [‰]	0	0.100	0.250	0.400	0.600
Reference value [‰]	0	0.098	0.246	0.382	0.576
Mean value [‰]	0.000	0.097	0.229	0.375	0.579
Accuracy	100.0%	98.9%	93.0%	98.0%	100.5%
RSD%	0.0%	4.5%	6.0%	1.5%	1.0%
Bias [‰]	0.000	-0.001	-0.017	-0.007	0.003
SD of Bias [‰]	0.000	0.003	0.010	0.005	0.004
Rel. Bias [%]	0.0%	-1.1%	-7.0%	-2.0%	0.5%
SD of Rel. Bias [%]	0.0%	2.5%	4.1%	1.4%	0.8%

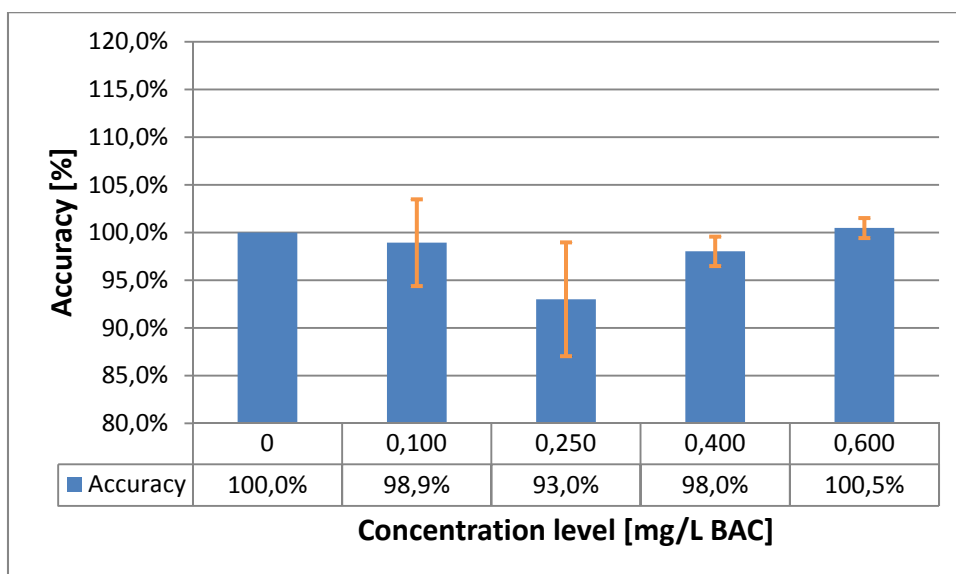


Figure 19: Accuracy of the ACE AF-33 alcohol testing devices on the five tested breath alcohol concentration levels.

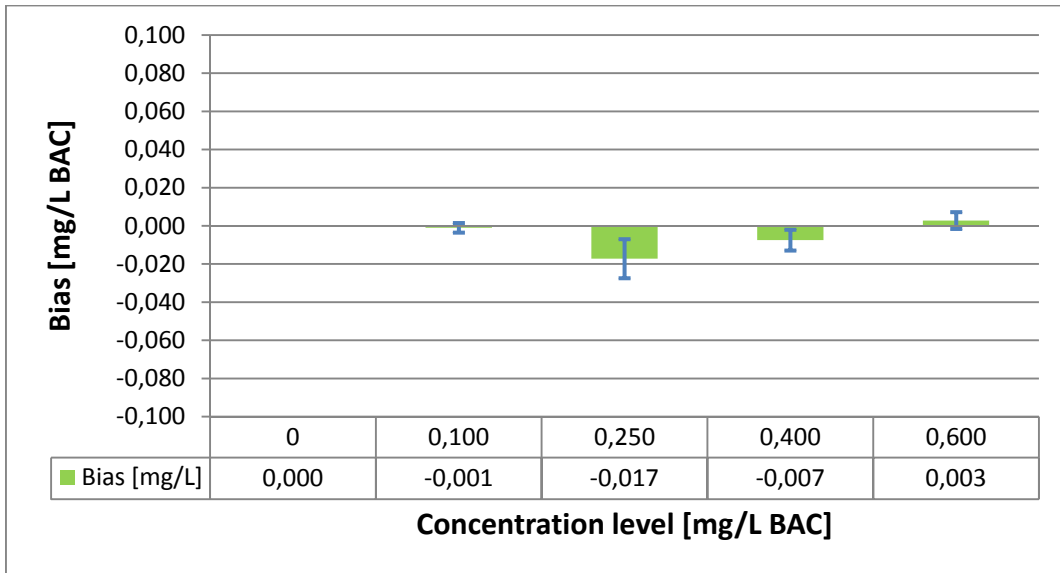


Figure 20: Absolute bias (in %) of the ACE AF-33 alcohol testing devices on the five tested breath alcohol concentration levels.

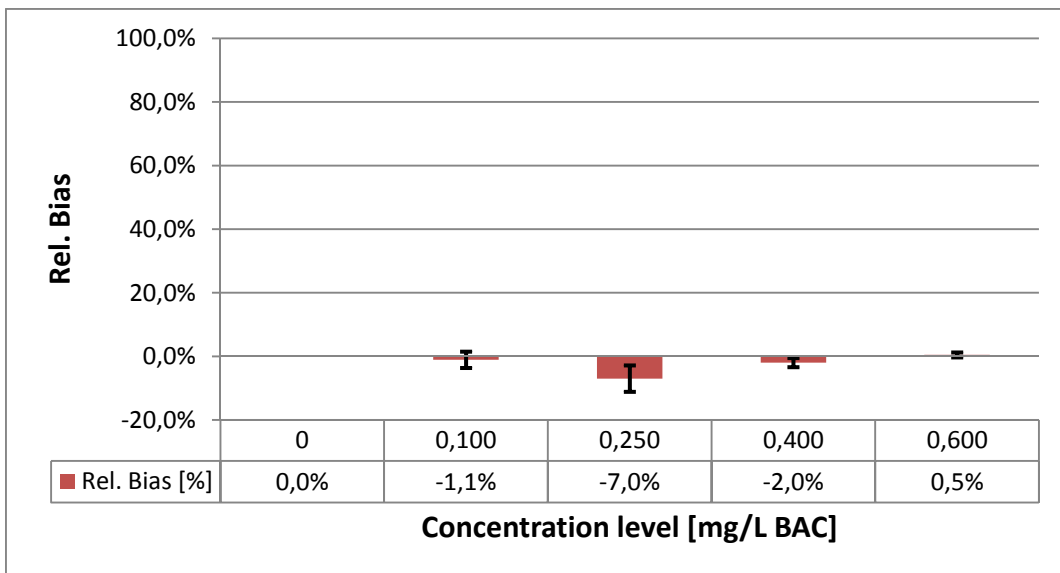
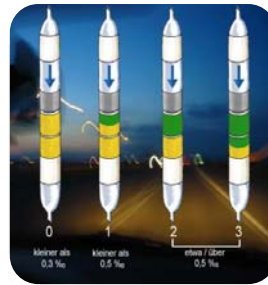


Figure 21: Relative bias (in %) of the ACE AF-33 alcohol testing devices on the five tested breath alcohol concentration levels.



4.7 ACE AL5500

Figure 22: ACE AL5500 breath alcohol testing device.



Table 9: Summary of results for the ACE AL5500 breath alcohol tester.

Level [‰]	0	0.100	0.250	0.400	0.600
Reference value [‰]	0	0.094	0.238	0.383	0.575
Mean value [‰]	0.000	0.102	0.219	0.384	0.590
Accuracy	100.0%	107.8%	92.1%	100.2%	102.6%
RSD%	0.0%	69.9%	12.1%	3.9%	1.8%
Bias [‰]	0.000	0.007	-0.019	0.001	0.015
SD of Bias [‰]	0.000	0.064	0.021	0.012	0.007
Rel. Bias [%]	0.0%	7.8%	-7.9%	0.2%	2.6%
SD of Rel. Bias [%]	0.0%	67.5%	8.7%	3.2%	1.3%

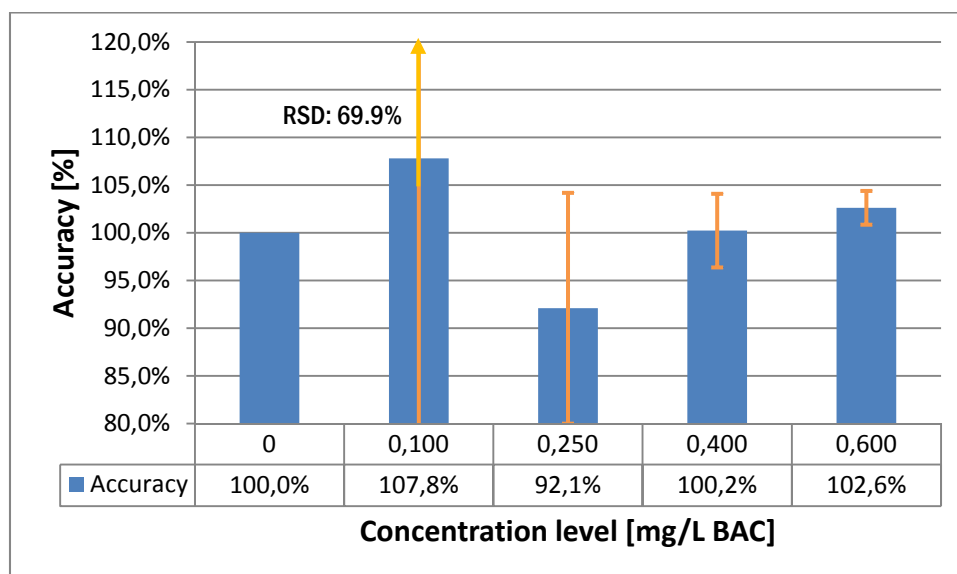


Figure 23: Accuracy of the ACE AL5500 alcohol testing devices on the five tested breath alcohol concentration levels.

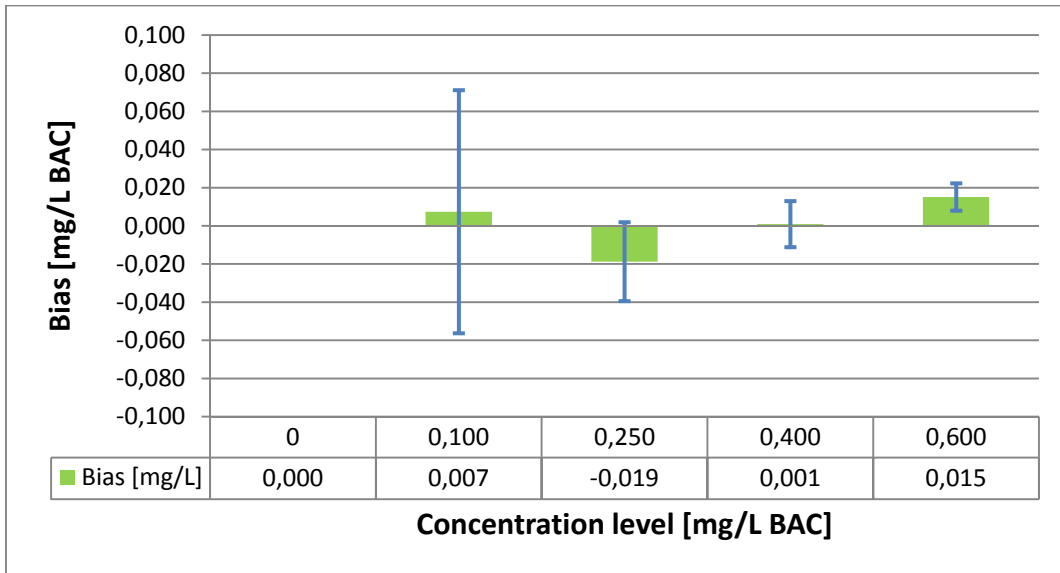


Figure 24: Absolute bias (in %) of the ACE AL5500 alcohol testing devices on the five tested breath alcohol concentration levels.

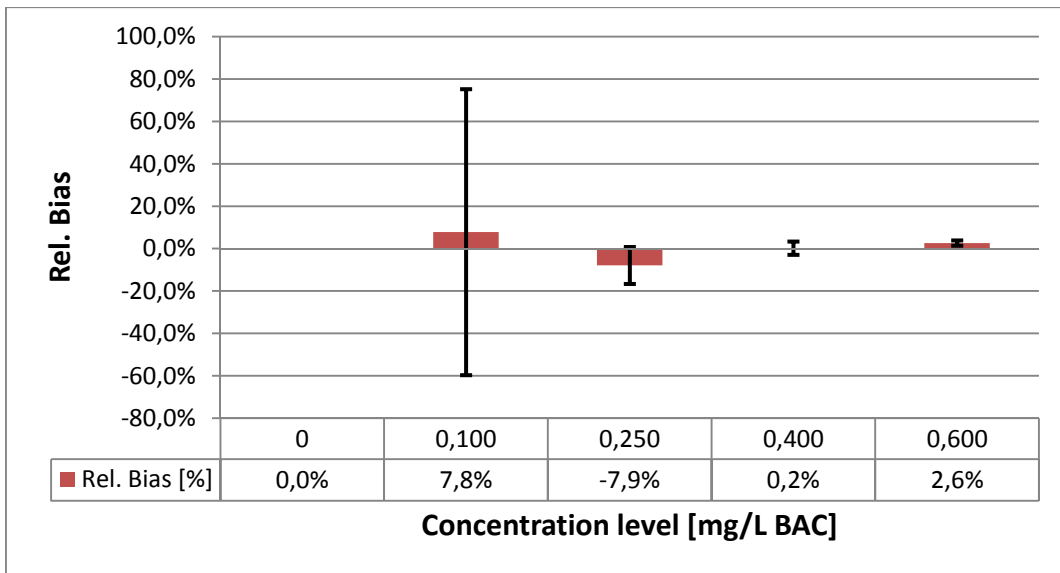


Figure 25: Relative bias (in %rel.) of the ACE AL5500 alcohol testing devices on the five tested breath alcohol concentration levels.



4.8 ACE PRO MED BASIC

Figure 26: ACE Pro Med Basic breath alcohol testing device.



Table 10: Summary of results for the ACE Pro Med Basic breath alcohol tester.

Level [‰]	0	0.100	0.250	0.400	0.600
Reference value [‰]	0	0.100	0.245	0.379	0.576
Mean value [‰]	0.000	0.061	0.228	0.361	0.539
Accuracy	100.0%	60.7%	93.0%	95.1%	93.6%
RSD%	0.0%	86.4%	7.2%	4.9%	4.3%
Bias [‰]	0.000	-0.039	-0.017	-0.019	-0.037
SD of Bias [‰]	0.000	0.056	0.017	0.019	0.025
Rel. Bias [%]	0.0%	-39.3%	-7.0%	-4.9%	-6.4%
SD of Rel. Bias [%]	0.0%	56.0%	7.0%	4.9%	4.3%

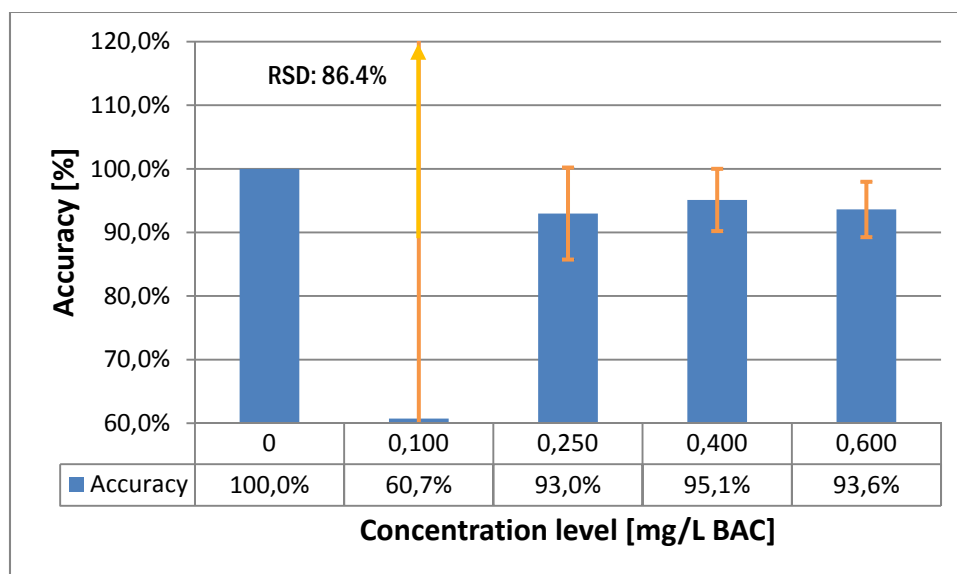


Figure 27: Accuracy of the ACE Pro Med Basic alcohol testing devices on the five tested breath alcohol concentration levels.

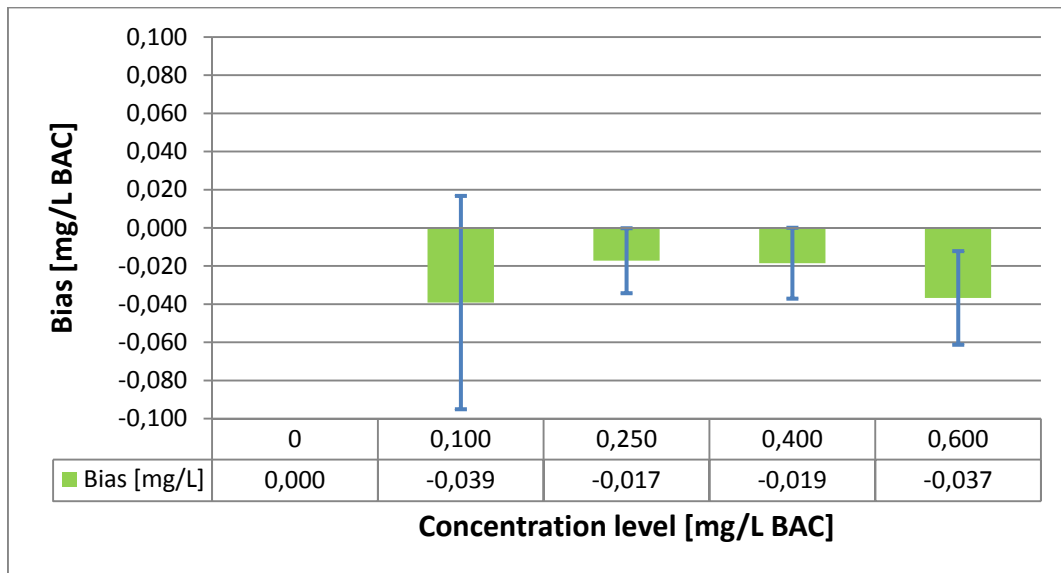


Figure 28: Absolute bias (in %) of the ACE Pro Med Basic alcohol testing devices on the five tested breath alcohol concentration levels.

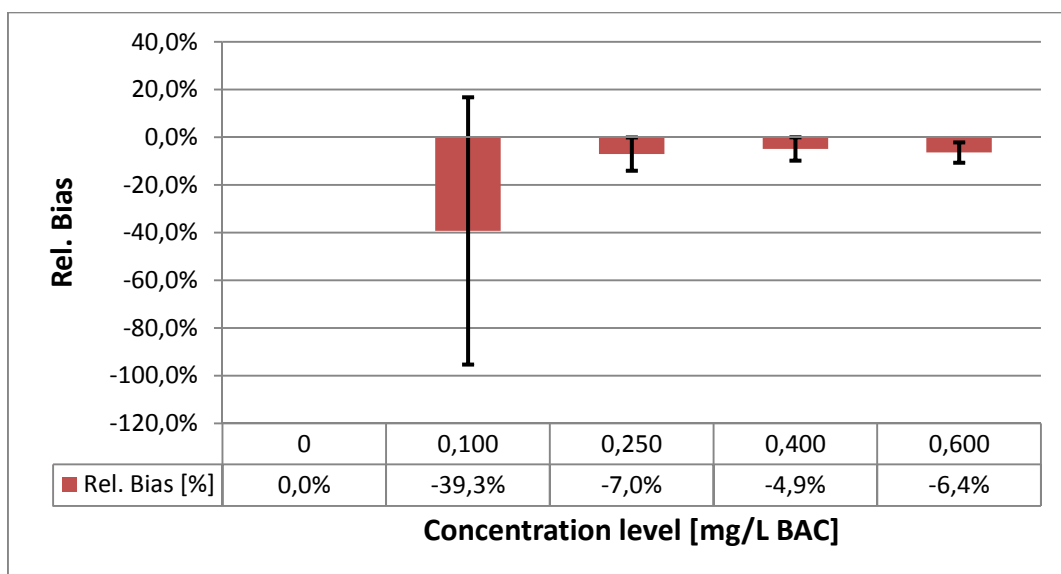


Figure 29: Relative bias (in %) of the ACE Pro Med Basic alcohol testing devices on the five tested breath alcohol concentration levels.



4.9 ACE ONE

Figure 30: ACE one breath alcohol testing devices.



Table 11: Summary of results for the ACE one breath alcohol tester.

Level [‰]	0	0.100	0.250	0.400	0.600
Reference value [‰]	0.000	0.091	0.234	0.379	0.573
Mean value [‰]	0	0.088	0.236	0.383	0.583
Accuracy	100.0%	96.3%	100.6%	101.0%	101.7%
RSD%	0.0%	4.6%	2.1%	1.6%	1.6%
Bias [‰]	0.000	-0.003	0.001	0.004	0.010
SD of Bias [‰]	0.000	0.004	0.001	0.001	0.009
Rel. Bias [%]	0.0%	-3.7%	0.6%	1.0%	1.7%
SD of Rel. Bias [%]	0.0%	4.9%	0.4%	0.4%	1.5%

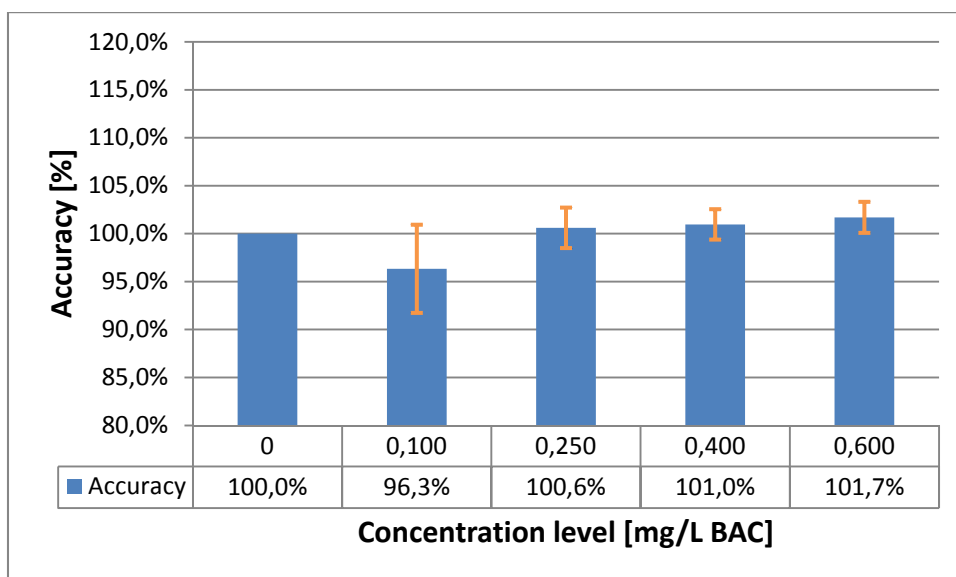


Figure 31: Accuracy of the ACE one alcohol testing devices on the five tested breath alcohol concentration levels.

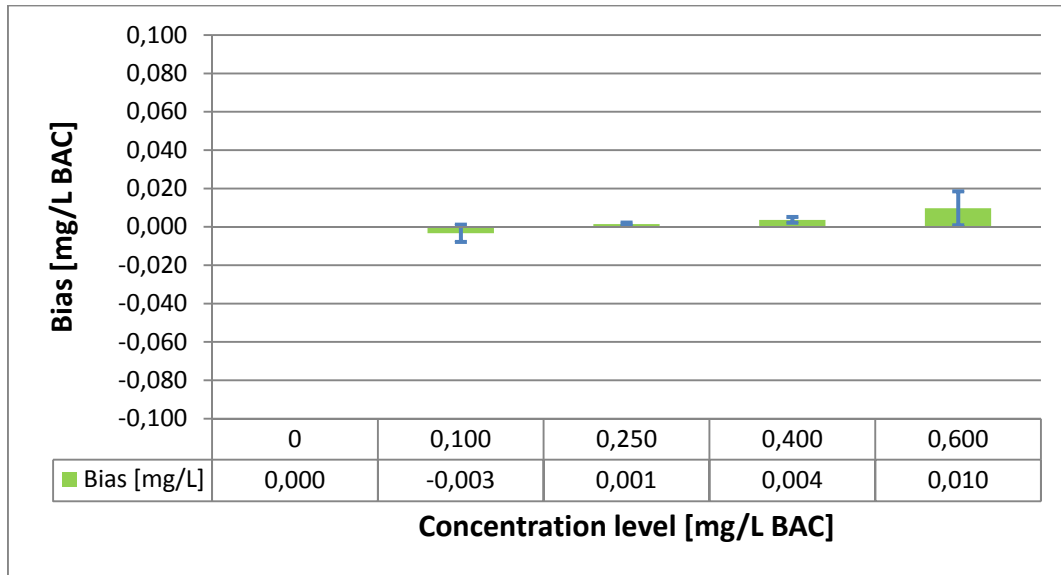


Figure 32: Absolute bias (in %) of the ACE one alcohol testing devices on the five tested breath alcohol concentration levels.

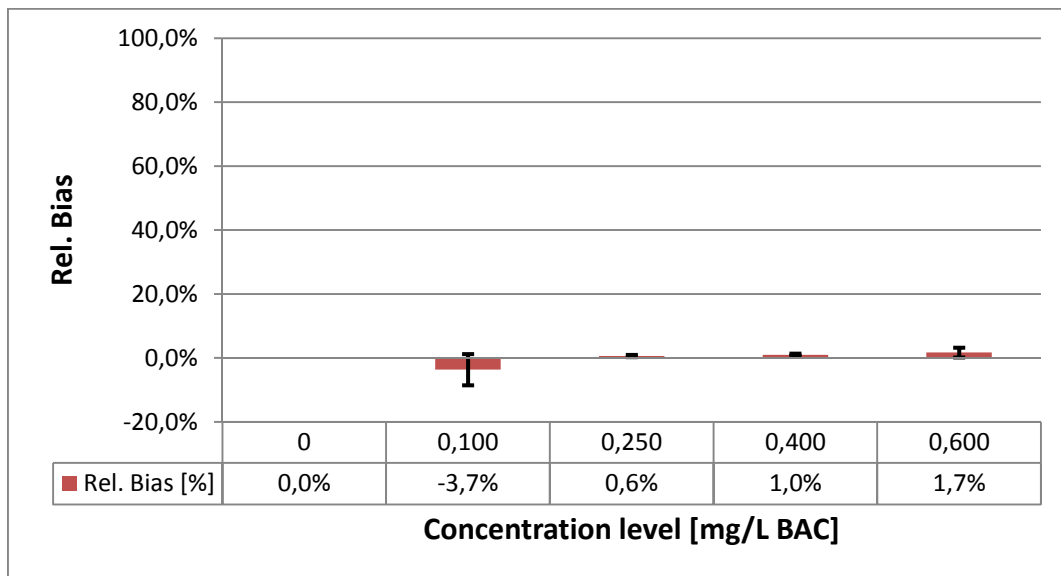


Figure 33: Relative bias (in %) of the ACE one alcohol testing devices on the five tested breath alcohol concentration levels.



4.10 DRÄGER ALCOTEST 3000

Figure 34: Dräger Alcotest 3000 breath alcohol testing device.



Table 12: Summary of results for the Dräger Alcotest 3000 breath alcohol tester.

Level [‰]	0	0.100	0.250	0.400	0.600
Reference value [‰]	0.000	0.091	0.245	0.397	0.584
Mean value [‰]	0.000	0.091	0.245	0.397	0.584
Accuracy	100.0%	100.8%	101.2%	101.9%	101.5%
RSD%	0.0%	6.1%	2.1%	2.3%	3.1%
Bias [‰]	0.003	0.001	0.003	0.008	0.009
SD of Bias [‰]	0.000	0.005	0.005	0.008	0.018
Rel. Bias [%]	0.0%	0.8%	1.2%	1.9%	1.5%
SD of Rel. Bias [%]	0.0%	5.1%	1.9%	2.1%	3.1%

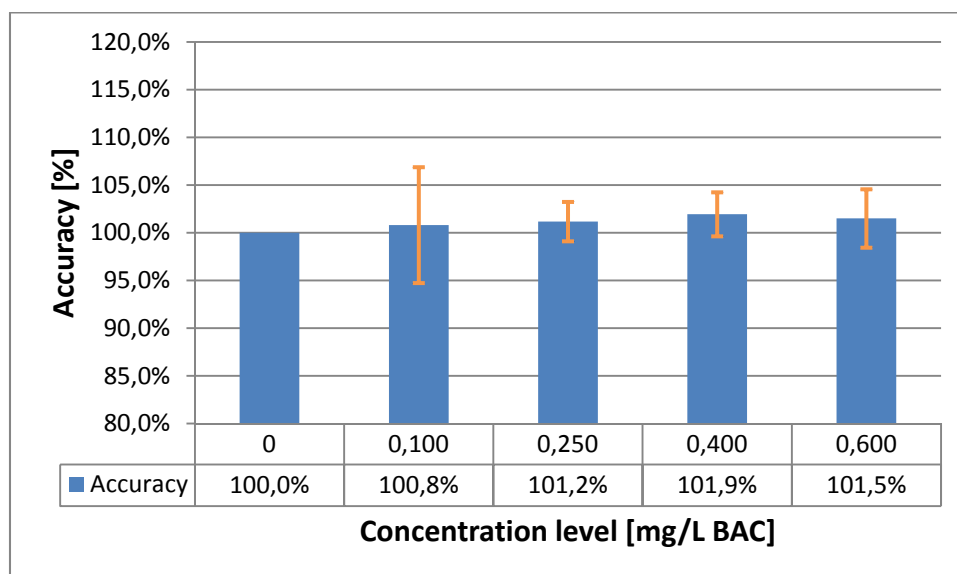


Figure 35: Accuracy of the Dräger Alcotest 3000 alcohol testing devices on the five tested breath alcohol concentration levels.

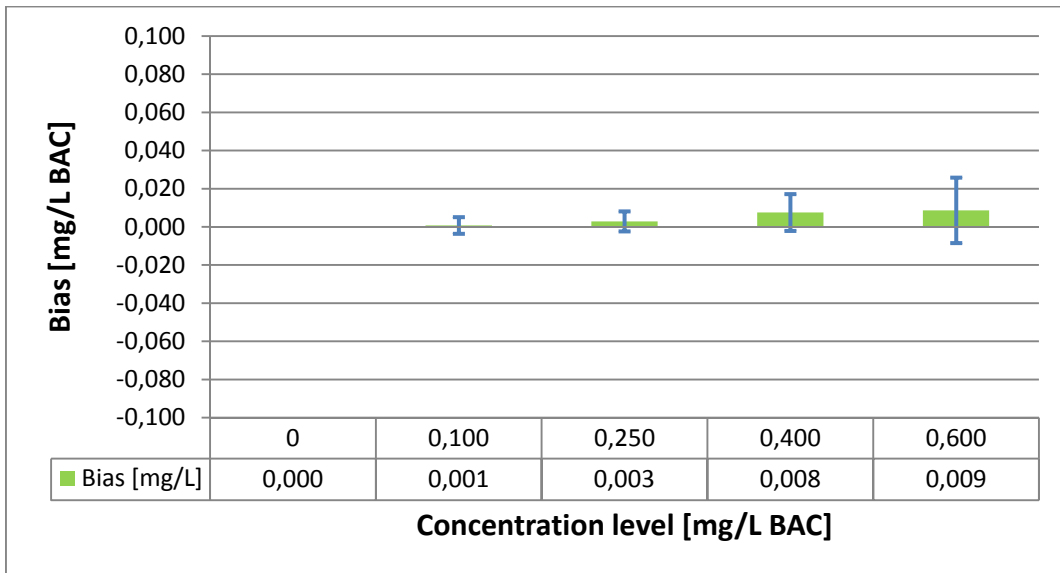


Figure 36: Absolute bias (in %) of the Dräger Alcotest 3000 alcohol testing devices on the five tested breath alcohol concentration levels.

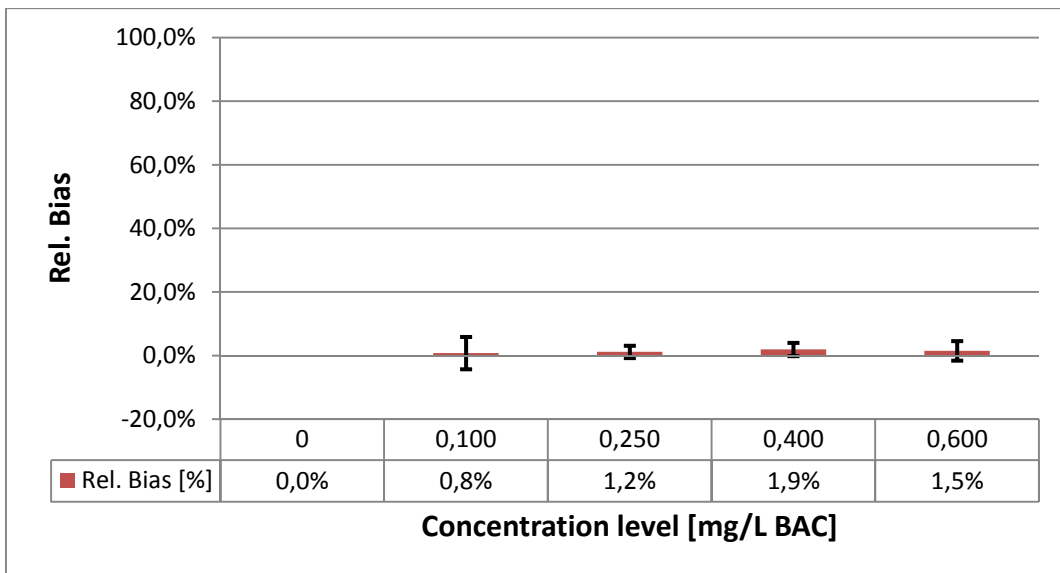


Figure 37: Relative bias (in %rel.) of the Dräger Alcotest 3000 alcohol testing devices on the five tested breath alcohol concentration levels.



4.11 ACE PUBLIC V

Figure 38: ACE Public V breath alcohol testing device.



Table 13: Summary of results for the ACE Public V breath alcohol tester.

Level [‰]	0	0.100	0.250	0.400	0.600
Reference value [‰]	0	0.094	0.138	0.374	0.568
Mean value [‰]	0.000	0.097	0.239	0.385	0.582
Accuracy	100.0%	103.1%	101.7%	102.8%	102.6%
RSD%	0.0%	5.0%	2.8%	3.2%	3.1%
Bias [‰]	0.000	0.003	0.004	0.010	0.015
SD of Bias [‰]	0.000	0.002	0.004	0.013	0.020
Rel. Bias [%]	0.0%	3.1%	1.7%	2.8%	2.6%
SD of Rel. Bias [%]	0.0%	2.5%	1.9%	3.6%	3.6%

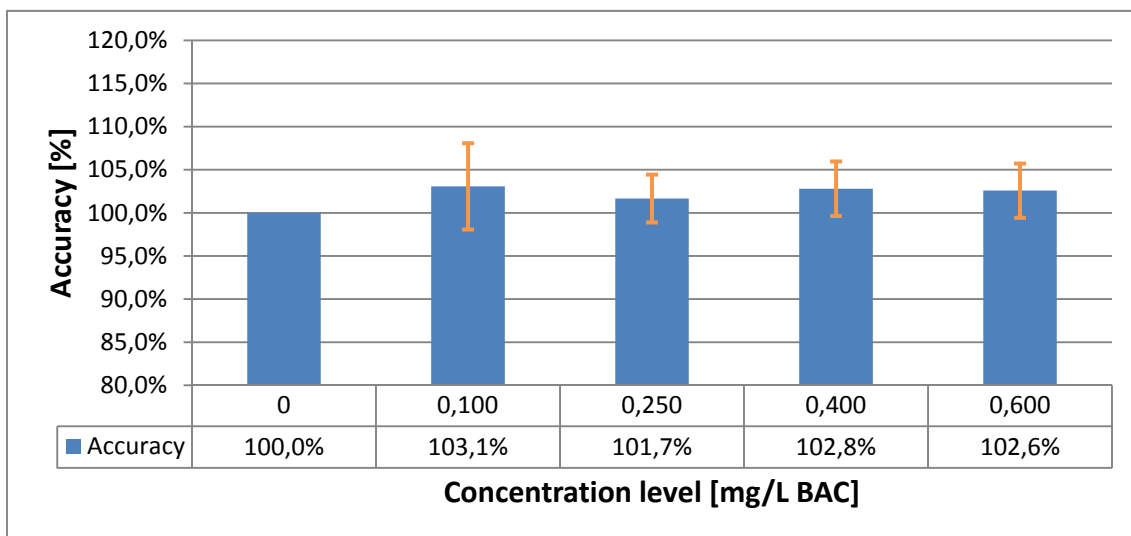


Figure 39: Accuracy of the ACE Public V alcohol testing devices on the five tested breath alcohol concentration levels.

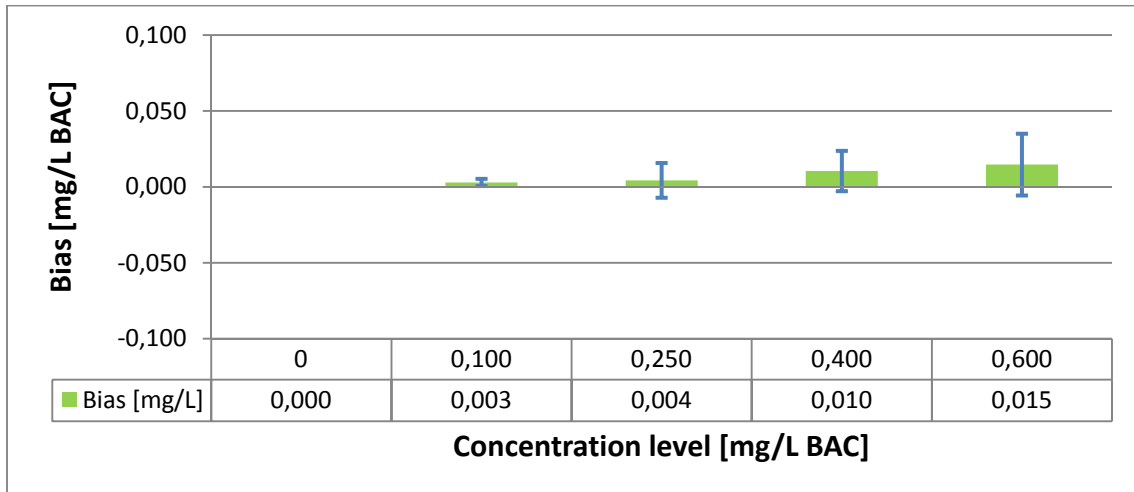


Figure 40: Absolute bias (in %) of the ACE Public V alcohol testing devices on the five tested breath alcohol concentration levels.

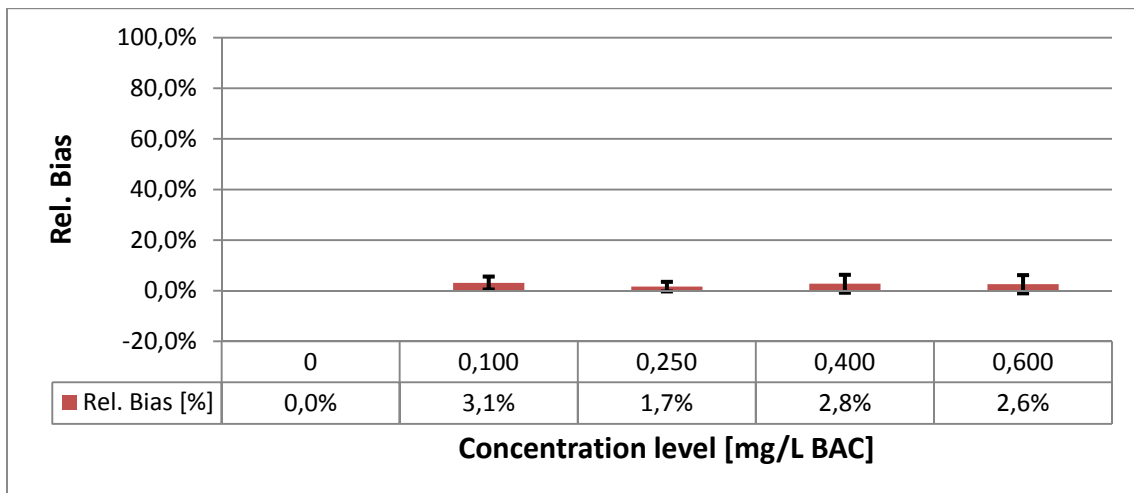


Figure 41: Relative bias (in %rel.) of the ACE Public V alcohol testing devices on the five tested breath alcohol concentration levels.



4.12 ACE STATIONARY ALCOHOL ANALYZER

Figure 42: ACE stationary breath alcohol analyzer.



Table 14: Summary of results for the ACE stationary breath alcohol analyzer.

Level [‰]	0	0.100	0.250	0.400	0.600
Reference value [‰]	0	0.094	0.238	0.382	0.578
Mean value [‰]	0.000	0.000	0.224	0.370	0.544
Accuracy	100.0%	0.0%	94.3%	97.0%	94.1%
RSD%	0.0%	0.0%	2.3%	1.8%	2.8%
Bias [‰]	0.003	-0.094	-0.014	-0.012	-0.034
SD of Bias [‰]	0.000	0.000	0.005	0.007	0.015
Rel. Bias [%]	0.0%	-100.0%	-5.7%	-3.0%	-5.9%
SD of Rel. Bias [%]	0.0%	0.0%	2.2%	1.7%	2.6%

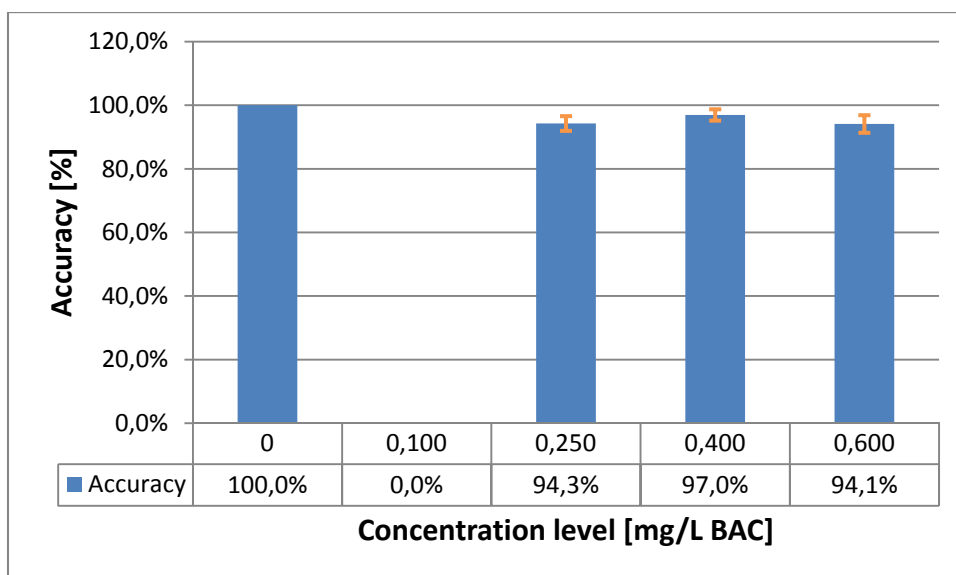


Figure 43: Accuracy of the ACE stationary breath alcohol analyzer on the five tested breath alcohol concentration levels.

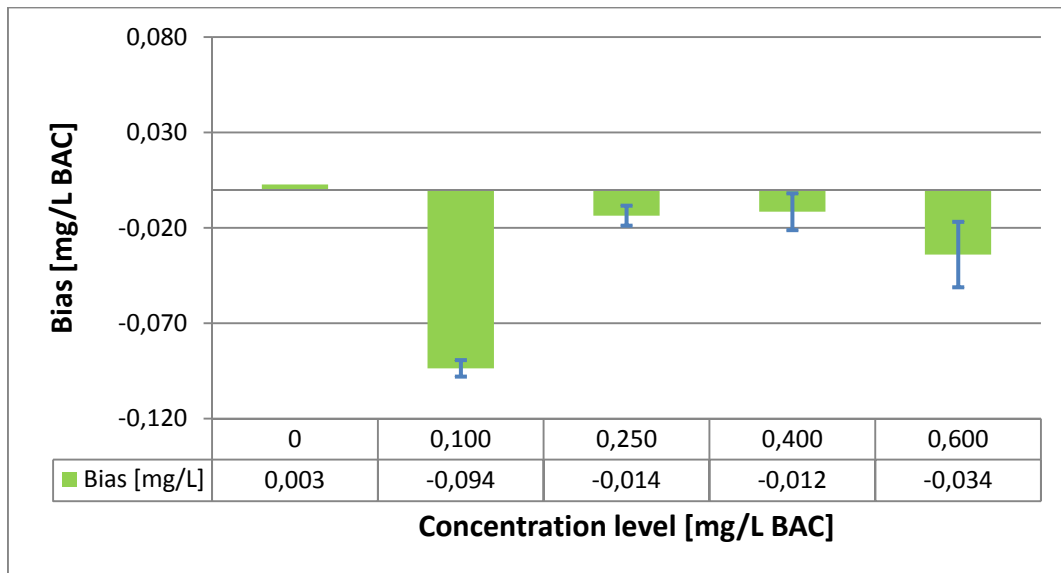


Figure 44: Absolute bias (in %) of the ACE stationary breath alcohol analyzer on the five tested breath alcohol concentration levels.

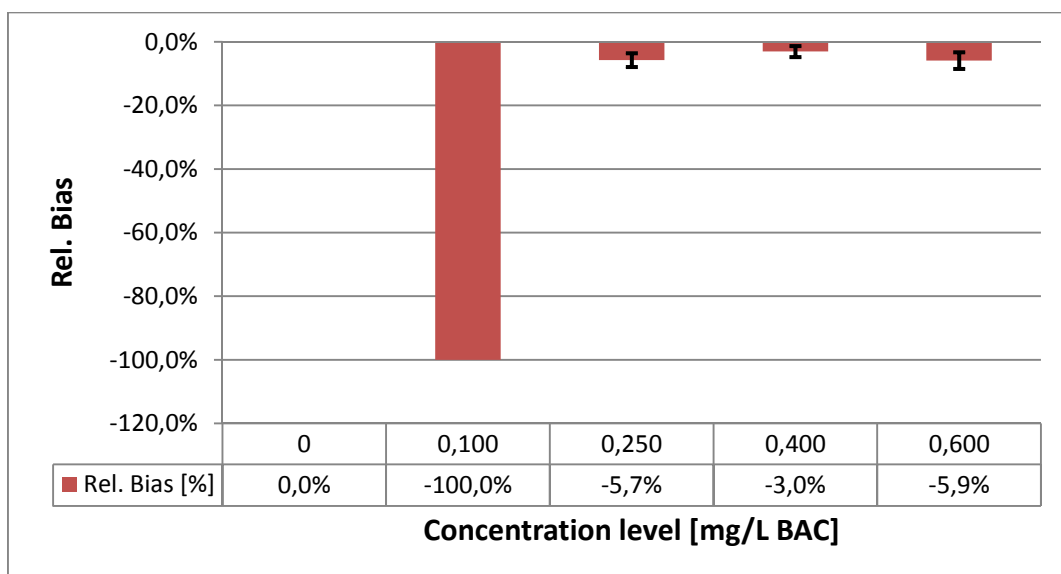


Figure 45: Relative bias (in %rel.) of the ACE stationary breath alcohol analyzer on the five tested breath alcohol concentration levels.

5 Summary and Conclusion

In order to present the results of the study in the most condensed and at the same time still meaningful manner, the experimental data for each breathalyzer model was averaged over all individual instruments of one type used, and over all investigated concentration levels. This allowed to calculate an average accuracy (reported as the average of the accuracy values obtained for all instruments of one make and for the measurements on all concentration levels), as well as an average precision which is the averaged standard deviation, again considering all experiments and all concentration levels investigated.

The two graphs in which these data are presented (Figure 46 and Figure 47) are the most succinct summary of this experimental study.

Judging from this presentation of the results and the underlying experimental data, it can be concluded that about half of the investigated number of instruments (6 out of 13) match the criteria for excellent performance in terms of accuracy, and even more do so (8 out of 13) when precision is considered. Among these are not only the instrument that is used by the German police for preliminary testing (Dräger Alcotest 3000), but several other – also less expensive – models of other manufacturers.

Table 15: Classification of breathalyzer performance

Classification	Accuracy	Precision
Excellent to Very good	97 - 100%	≤2.5%
Very good to Good	90 - 97%	2.5 - 5.0%
Good to Satisfactory	<90%	>5.0%

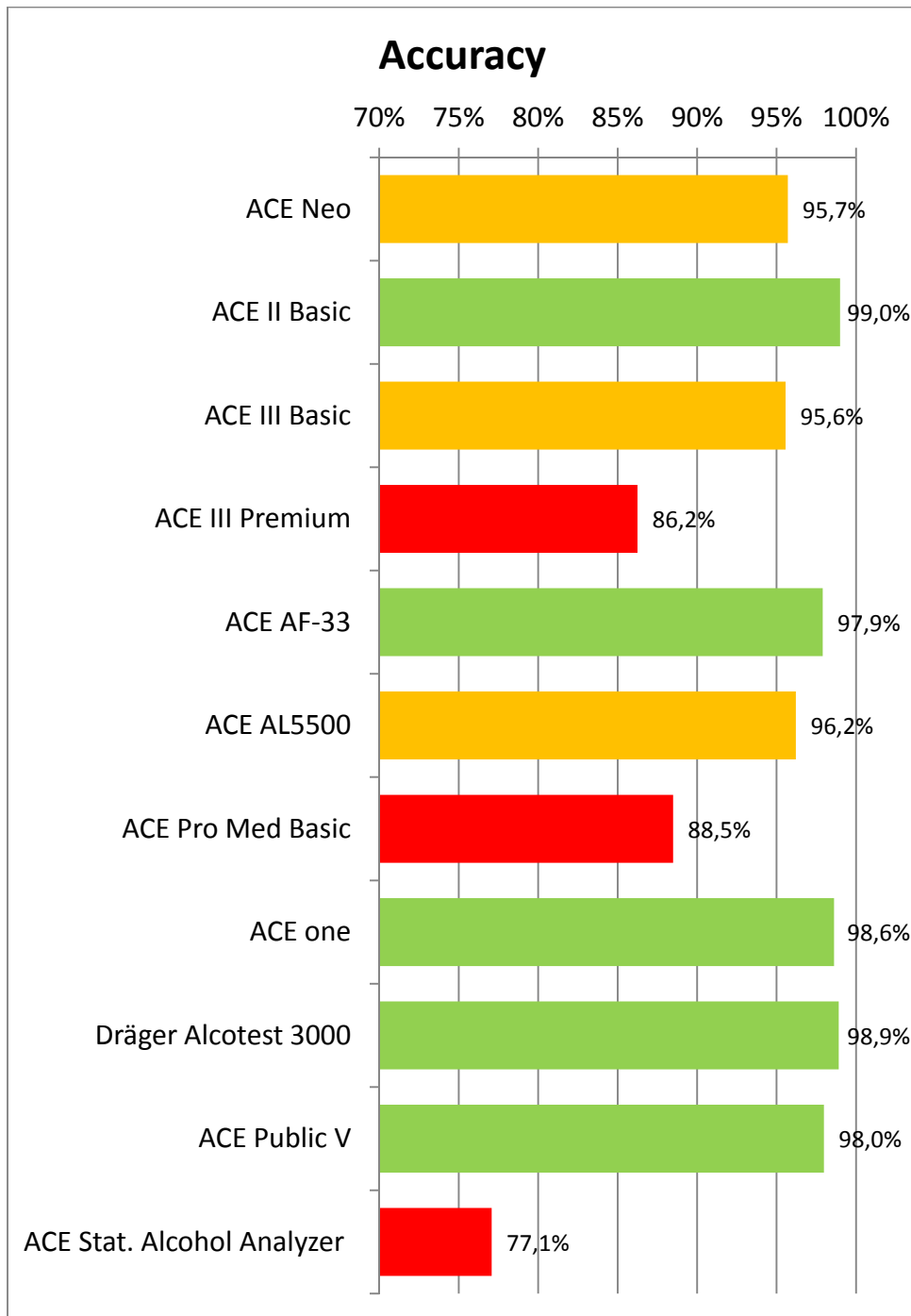


Figure 46: Summary of the average accuracy achieved with the different breathalyzers in this study. Colour coding denotes: **Green:** Excellent to very good performance; **orange:** very good to good performance; **red:** relatively good to satisfactory performance.

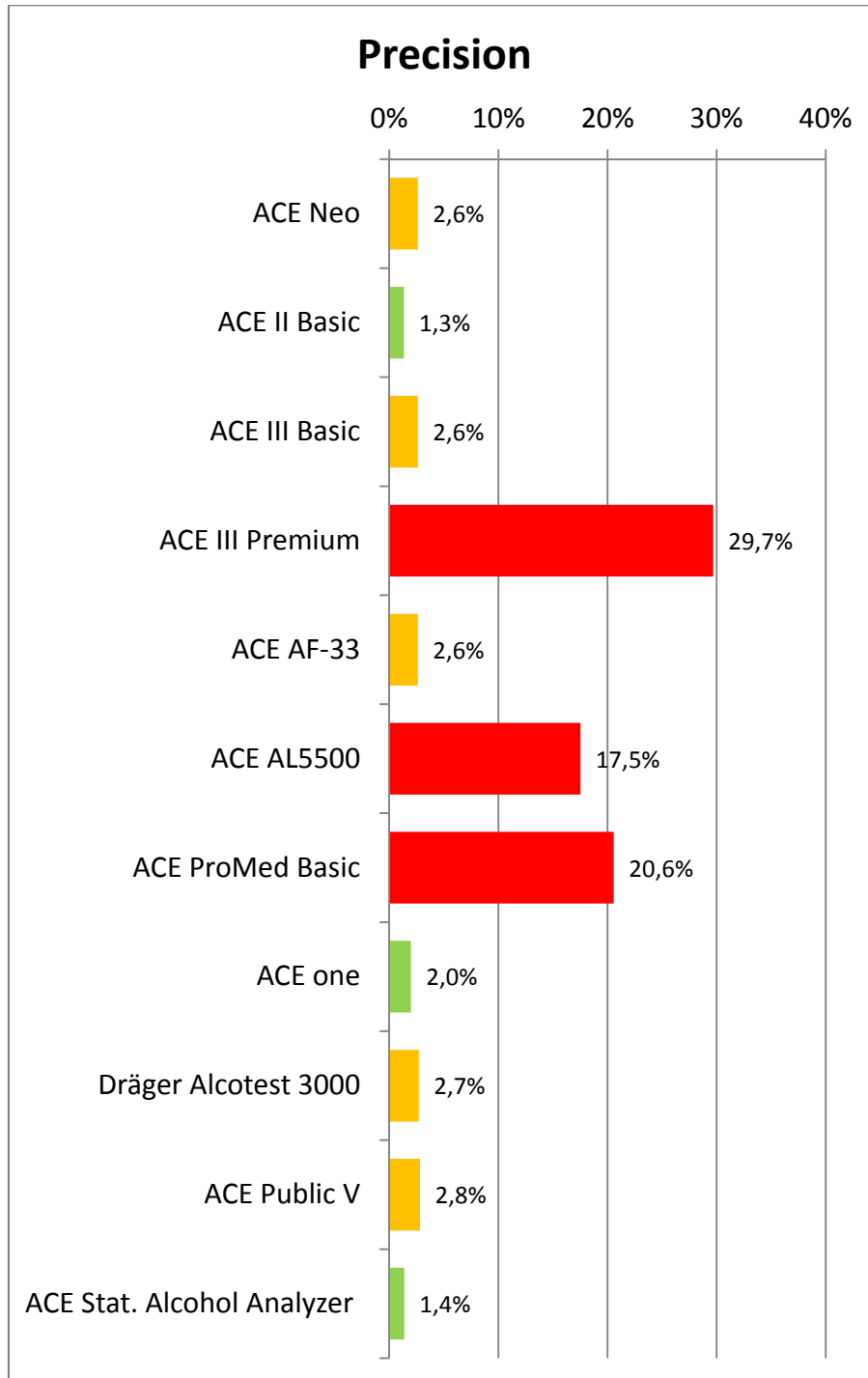


Figure 47: Summary of the average precision (expressed as average of the standard deviations) achieved with the different breathalyzers in this study. Colour coding denotes: **Green**: Excellent to very good performance; **orange**: very good to good performance; **red**: relatively good to satisfactory performance.



6 References

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 - 5 DIN Deutsches Institut für Normung e.V., *Breath alcohol test devices for general public – Requirements and test methods*, German version EN 16280:2012. Beuth Verlag, Berlin.
 - 6 OIML Recommendation R 126:2012 (E) *Evidential breath analyzers*. Organisation Internationale de Métrologie Légale / International Organisation of Legal Metrology (www.oiml.org)

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Getreidemarkt 9/164 AC, Vienna, Austria.
Email: Erwin.Rosenberg@tuwien.ac.at

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www.alkomat.net

A short video on the breathalyzer study was published at Youtube under the link: <https://youtu.be/unwCOBx6hc>