Testing the Evidenzer Mobile 240 for evidential use in Norway

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Abstract

Background
In Norway a legal limit for alcohol in blood was introduced in 1936. Since 1996 evidential breath tests have been performed with Intoxilyzer 5000N. In 2011 Evidenzer replaced the old instruments according to requirements based on OIML R126 and national demands. Before introducing the new instrument it we documented its performance capabilities. Different areas of application were checked with the old instrument as the standard.

Method
The following test sequences were run: Laboratory tests/in vitro (approx 1600), Controlled tests/in vivo (approx 400) and Field tests (approx 350). The main areas for testing were accuracy, precision, linearity, reproducibility, specificity, functionality, user-friendliness and reliability, as well as necessary and relevant control- and safety functions. 19 randomly selected persons were tested in a controlled drinking study.

Results
In most of the critical areas Evidenzer is better than or on the same level as Intoxilyzer.

Some selected results:
For accuracy the deviation below 0.40 mg/L was determined to 0.007 mg/L.
The precision below 0.40 mg/L was calculated to 0.0016 mg/L and above 0.40 mg/L to 0.3 %.
Specificity tests showed that up to 0.25 mg/L substances that can be found in human breath are either flagged or subtracted.
The average observed breath temperature in the Norwegian tests were 34.58 0 C , while the same values in a Danish reference material were 35.15 0 C.
A controlled drinking study showed that the average metabolism of alcohol with Evidenzer was 0.077 mg/L/hr.

Conclusion
The performed validation showed that Evidenzer Mobile 240 is well suited for evidential documentation of DUI also in the area around low legal limits (0.1 mg/L).

Introduction
Norway has a long tradition for controlling drunk drivers. In 1912 the first law on the subject was introduced, stating among other things that “Drivers must not be intoxicated”. In 1930 clinical examination by medical personnel was established, and 5 years later it was decided that such an examination must include a blood sample. The year after we got the first legal limit.
People were to be considered as intoxicated if they had more than 0.5 ‰ alcohol in their blood. In 1950 screening with alcometer and chemical tests for alcohol were introduced. In 1988 the law got an option for breath testing. The legal limit for intoxication when alcohol was measured in exhaled air was established to 0.25 mg/L. The first generation of evidential breath testing instruments (Intoxilyzer 5000N - 68 series) was taken into service in 1996. In 2001 the legal limits were lowered to respectively 0.2 ‰ in blood and 0.10 mg/L in breath. In 2012 our old evidential breath instruments had reach their retirement age. So a process was started to find new instrument. It must however be said that Intoxilyzer 5000N given the appropriate care, still were able to serve as reliable and accurate evidential instruments.

After a procurement process a choise was made for the new instrument Evidenzer Mobile 240 developed and produced by Nanopuls in Sweden.

Validation

Evidenzer Mobile has been validated against Intoxilyzer 5000N in different areas of application. The old instrument has through more than 15 years proven to be reliable and exact, and has therefore been selected as the standard. Intoxilyzer 5000N has earlier been validated against blood samples in order to establish a traceable link from breath alcohol to blood alcohol. The basis for validating the test results has been the demands in OIML R126 and in our national Specification for requirements. In most aspects the national demands have been set stricter than the ones in OIML.

Main validation areas were: reliability, accuracy, precision, linearity, reproducibility, specificity, functionality, user-friendliness, control- and safety functions. In addition we also looked into breath temperature and back-calculation.

Experiments

Six main series of experiments were performed. They have been named according to where and when they took place. The details of these were as follows:

Laboratory testing/In vitro.

”Uppsala 2010”
Functionality, reliability, accuracy, reproducibility, specificity and temperature of exhaled air were tested. Four Evidencers and four Intoxilyzers were used. A total of approximately 1 600 tests were run.

Controlled Testing/In vivo.

”Stavern 2011”

18 random selected persons of both sexes and with a wide range of age and bodyweights were tested. Controlled drinking up to an alcohol level in breath of max 0.3 – 0.4 mg/L. They were then tested on both instruments every 15. minute until no alcohol readings were registered. We also tested for mouth alcohol, blow pressure/manipulations and temperature of exhaled air. A total of approximately 300 pairs of results were obtained.
"Control 2012"

Three Evidenzer with different versions of software were used. The main goal was to see if some minor changes in the software parameters had any influence on the test results. Two persons drank alcohol. They were then tested on all three instruments until no alcohol readings were registered. The waiting time between the three instruments were reduced as much as possible. Tests were also made for manipulation (hyper-/hypo ventilation) and temperature of exhaled air. A total of 72 tests were run.

Field Tests

"Brandbu 2011"

A number of randomly selected volunteers were tested on both instruments in a social setting. All aspects of the validation areas were checked in addition to the temperature of exhaled air. The order of the tests was varied. A total of 79 pairs of results were obtained.

"Sarpsborg 2011"

A number of randomly selected volunteers were tested on both instruments in a social setting. All aspects of the validation areas were checked in addition to the temperature of exhaled air. A total of 46 pairs of results were obtained.

"Field 2011-2012"

These tests were made during ordinary police controls in local police stations. 15 sets of instruments were used. Intoxilyzer was always used first since this was the only approved evidential instrument. All aspects related to a real testing situation were checked in addition to the temperature of exhaled air. A total of 225 pairs of results were obtained.

Results

Accuracy and precision

Accuracy and precision were expressed through real deviation and standard deviation. Calculations have been made based on the results from 10 samples run with 6 different alcohol standards (0.00 – 0.10 – 0.25 – 0.50 – 0.79* - 1.00 mg/L). When the results were used for calculations, it was discovered that the results obtained with the standard meant to be 0.75 were not consistent with the others. After controlling it was ascertained that it had been wrong prepared and that the “true” value was somewhat higher. Back-calculations afterwards indicated the value to be around 0.79 mg/L, but this is probably too high.

Test gas (simulated breath test) was generated with a test equipment called ProfilerTM Lite.
Two simulators were connected in series and the reference solutions were thermally stabilized for 2 hours before start. The Profiler is programmed to imitate a natural exhalation profile from a human being with alcohol concentration as function of time.

According to the results the Evidenzer has better accuracy and precision than Intoxilyzer, and are within the limits of both the demands in OIML and our own Specification of requirements.

**Linearity**

An evidential instrument is meant to be able to measure over a wide range of alcohol concentrations, and the demand refers that it must show “the right value” over the whole scale. A certain un-linearity will normally always be registered at high levels, but this is usually accepted. The tests show that Evidenzer has a good linearity. The instrument indicates in general a somewhat lower result than the “true value”, and no results are higher than this. The deviation is less compared to Intoxilyzer in the area from 0.0 to 1.0 mg/L, and highest at high values.

**Reproducibility**

Reproducibility means that the instrument shall give the same result within the limits of statistical variations when the same sample is run several times. This should apply to the whole measuring range. The reproducibility of Evidenzer is consistent with the demands given.

An important issue is the so-called “memory-effect” which means that one sample should not be influenced by the previous one(s). This is in particular relevant when changes are made from high to low concentrations. “Memory-effects” have not been registered during the validation tests. This apply without having compensated for the impoverishing of the testing material (references) normally taking place when repeated in vitro tests are run within a short period of time.

**Specificity**

Evidenzer has been tested at three different alcohol concentrations (0.00 – 0.10 – 0.25 mg/L) mixed with the following “interfering substances”: acetaldehyde, acetone, diethyl ether, ethyl acetate and a mixture of acetaldehyde/acetone.

The selection of “interfering substances” has been based on knowledge with what is most probable to be present in a person’s exhaled air, as well as what according to theory/chemical structure, are most likely to represent the biggest challenges for the detection technology inside the instrument.

The quantities of “interfering substances” have been selected in a way so that all concentrations should give approximately the same response from the IR-detector. It means that the instrument will „flag” when the content in the gas stream is equivalent to about 2 volume percents of the total test volume. This is considerably less than saturation at room temperature.

The test gas (simulated exhalation) is generated with the testing equipment called Profiler™ Lite. It has the options for the supply of an adjustable and controllable quantity of “interfering substance”. In this way it is possible to test the deductions the instrument is supposed to make, as well as the “flagging” function when the concentration becomes to high. The testing starts with approx 1 % supply from the ”contaminated” plastic bag and is then throttled gradually until “flagging” ceases. All tests were run on 4 different instruments.

The results show that none of the tested substances provide a false reading as alcohol when alcohol is not present in the exhaled air. The same goes for the real alcohol concentrations. If an
“interfering substance” is present the instrument will “flag” (render a fault message) and subtract more than an eventual contribution from the “interfering substance”. If the contribution from the “interfering substance” is so modest that the instrument does not “flag”, the alcohol result is not affected in a degree worth mentioning.

*Mouth alcohol/observation time*

Mouth alcohol is detected both by analysing of the profile of the ethanol curve (curve-analysis) and by comparing the two partial samples delivered with at least 2 minutes waiting time (difference-analysis). The curve-analysis consists of two elements. The elevation of the curve (Rise) from 1.5 seconds after blowing has started until the end is determined. At the same time the stability of the curve shape is determined. By introducing a long waiting time between the two partial samples and optimizing the curve- and difference-analysis, it is possible to drop the observation time prior to a test is performed. The two control functions will then have to be adjusted in such a way that they detect all real cases of mouth alcohol. The occurrence of mouth alcohol in the data from the tests seems statistically to be overrepresented. This is probably due to incorrect calibration levels. Tests where mouth alcohol has been simulated in controlled drinking experiments have also been performed. The instruments have then warned with a fault message as expected.

*Functionality/user-friendliness*

An inquiry amongst the operators (police officers) in charge of the tests performed during the Field experiments revealed that 88 % of them were satisfied (good + very good) with the instrument’s functionality and user-friendliness in general. What scored lowest was the keyboard which is a standard version and not one of the modern touch-screens you today can find on most electronic consumer goods. Among the positive comments these were most frequent:
- Very user friendly
- Small and light/reduced blowing resistance
- Spares us the long observation time
- A very positive general impression
- Much easier to use than Intoxilyzer
- Easier to blow, no observation time and easy to use
- More convenient instrument

*Breath temperature/Body temperature*

The average value for all registered temperature readings from the Norwegian test series is 34.58 °C (min 28.90 – max 37.67), while the corresponding value for samples from Denmark is 35.15 °C (min 29.70 – max 37.50). The cause for this discrepancy is not known, but assumed to be related to the calibration of the temperature sensors or to the way the tests have been performed. It is also evident that the temperature of the second exhalation is consistently higher than the first one. The difference is between 3 and 4 %.
An increased body temperature will normally result in a similar increase of the temperature of the exhaled air and an increase of the passage/evaporation of the alcohol from blood to breath in the deeper part of the lungs. Limited previous experiments have indicated that an increase in body temperature of 1 °C may result in an increase of the alcohol concentration in the exhaled air of up to 10 %.

Since Evidenzer has a temperature sensor built into the blowing tube, we wanted to test if an increased temperature led to an elevated alcohol reading. Three alcohol solutions (0.00 – 0.10 – 0.25 mg/L) were tested at 6 temperatures (34, 35, 36, 37, 38, 39 °C) with a test equipment (SimulatorET) that produced wet gas saturated with vapour. The results increase with increasing temperature for those samples containing alcohol. At a concentration of 0.10 mg/L the increase is 22.1 % when the temperature is increased by 5 °C (4.4 %/degree), and likewise 31.1 % (6.2 %/degree) at a concentration of 0.25 mg/L. Compensation for impoverishing of the standards has not been done.

Manipulation by breathing techniques

Previous practice has revealed that the result of a breath test can be manipulated by intentionally breathing. By hypoventilation a higher reading can be obtained, while by hyperventilation the reading can be lowered. In a real situation it is assumable that only hyperventilation is relevant. Evidenzer was tested in vivo at low alcohol concentrations (up to 0.2 mg/L). Hyperventilation was performed either before the first or the second partial blowing in order to reduce the effect of metabolism. Compared to ordinary tests (without hyperventilation) it revealed that very intense and deep hyperventilation could reduce the reading in average with around 7 %. At the same time the breath temperature was reduced by an average of 0.8 °C.

Metabolism/Back-calculations

Randomly selected persons (10 men and 9 women) were given alcohol, respectively beer, red wine or vodka in adjusted doses that, based on individual body weights should result in an alcohol concentration in the blood of about 0.7 – 0.8 ‰. The candidates were tested then every 15 minute until no positive readings were done. The experiments showed that the instruments function as expected. The alcohol curves (metabolism as a function of time) for all candidates seem to be in accordance with what can be found when blood samples are drawn and analysed. In the phase of declining intoxication (1-2 hours after alcohol intake) this can intimate an average rate of metabolism. The average rate of metabolism for the persons tested was 0.077 mg/L for both instruments.

Conclusion

The validation experiments have shown that concerning essential features the Evidenzer Mobile 240 fulfils the international demands (OIML) set for instruments intended for evidential alcohol testing, as well as the Norwegian spec. Evidenzer Mobile 240 is in most of the critical areas better than or on the same level as Intoxilyzer 5000N. Evidenzer Mobile 240 is well suited for evidential documentation of DUI also in the area around low legal limits (0.1 mg/L).