QUALITY ASSURANCE OF BREATH ALCOHOL MEASUREMENTS

Mirela Adelaida ANGHEL; Prof. univ. dr. ing. **Fănel IACOBESCU**[b]

[a)] National Institute of Metrology Romania; [b)] Romanian Bureau of Legal Metrology,

e-mail: mirela.anghel@inm.ro

Abstract

Romania, as a member state of European Union, started to develop together with its National Institute of Metrology, efficient measures to detect drivers under influence with accurate results and to assure the traceability of mass concentration of alcohol in exhaled breath. The paper describes the complete system used for testing of ethylometers performance and the method applied to prepare and certify the standard solutions. The expanded uncertainty for the complete simulator system was calculated taking into consideration all input quantities which have noticeable contribution to the final uncertainty.

Key Words: Traceability, reference materials, mass concentration, legal metrology

Introduction

The abuse of alcohol is receiving more and more attention due to the latest reported statistics. In order to prevent road fatalities, police organisations implement various enforcement programs that are designed to detect deviant driving behaviours, which increase the risks of serious accidents. Statistics show that risks of accidents maintain an exponential relationship with the concentration of alcohol in the drivers' blood. Romania, as a member state of European Union, needs to develop efficient measures according to The European Road Safety Charter, the largest platform of actions covering all 27 European Union member states. However, requirements with regard to accuracy, speed, test frequency and effective and economic use rose considerably over the years. A screening test must be able to be performed swiftly and supply accurate results[2], and today mainly electronic devices are used. The paper describes the measurement system developed within the INM both to measure and to assure the traceability[4] of mass concentration results of alcohol in exhaled breath[1].

The complete system used to test the ethylometers' and or ethylotests' performances consist of: AlcoCal simulator system, devices used to prepare different sets of standard solutions, such as high purity ethanol, balance for weighing the mass of ethanol, volumetric flasks and high performance breath alcohol analyzer (ethylometer with traceable Calibration Certificate).

For each component of the INM measurement system have been calculated the associated uncertainty budget, such as: uncertainty budget of mass concentration of alcohol in distilled water, uncertainty budget due to the AlcoCal simulator system and uncertainty budget of the breathalyzer, calculated taking into consideration all input quantities which have noticeable contribution to the final uncertainty.

The evaluation of budget uncertainties of mass alcohol solution in distilled water took into consideration the following components: uncertainty due to the weighed mass of alcohol; uncertainty due to the balance, decanting uncertainty - due to the pouring alcohol from graduated pipette in volumetric flask during standard solution preparation, uncertainty due to the evaporation, uncertainty due to the ethanol purity and density, uncertainty due to the volume and temperature.

The budget uncertainty due to the AlcoCal simulator system had been calculated starting from the Dubowski formula. According with this formula, the mass concentration of ethanol present in vapour phase above liquid-water mixture depends on just two factors: the temperature of the mixture and the mass alcohol concentration in the liquid[3].

The input quantities which contributed to the evaluation of the uncertainty budget of breathalyzer were: the uncertainty due to the repeatability; the uncertainty due to the limited resolution of the device and the uncertainty due to the linearity.

The expanded uncertainty for the complete simulator system was calculated taking into account the evaluation of all uncertainties presented above.

General aspect regarding traceability in Romania. Comparison on mixtures of ethanol in water - saturated air

Nowadays, traceability of breath alcohol concentration is not a new field of interest in Romania. There are about 2300 of breath alcohol analysers (ethylometers and ethylotests, Dräger manufacturer) in use, since Ministry of Interior – Police Department had purchased these equipments few years ago, following an European project of endowment of east European police departments. Since than, the traceability of measurement performed with such instruments was a priority in order to assure accuracy measurements and acceptance in court. Measurements made at different times or in different places are directly related to a common reference. Applying the concept of traceability to breath alcohol measurements is not easy, but it has to provide qualitative results and analytical techniques used in calibration laboratories. Specialists from National Institute of Metrology have started[5] to prepare the basis necessary to transmit the specific measuring unit, mg / L, from high level standards (Reference Materials) to the working level measurements.

In Romania certain limits are set for the accepted mass concentration of alcohol in exhaled air. A concentration up to 0.40 mg / dm^3 of ethanol per litre of expired air would be accepted for the drivers as penalty, and the driver under influence must pay a fee, while a level exceeding 0.40 mg / dm^3 of alcohol per litre of exhaled air is considered a crime. Although only blood test results are admissible in court, there is obviously an increased tendency to expand the use of alcohol tests performed in human breath for legal purposes.

Table 1

Measurement units used to express breath / blood alcohol concentration

Units of measurement for *breath* alcohol concentration		
Microgram alcohol per 100 millilitres breath	Microgram alcohol per litter breath	Milligram alcohol per litter breath
µg/100 mL; µg %	µg/L	mg/L
40	400	0.40

	Units of measurement for *blood* alcohol concentration			
	Microgram alcohol per 100 millilitres blood	Per mille w/v [gram alcohol per litter blood]	Per mille w/w [gram alcohol per kilogram blood]*	Gram alcohol per 100 millilitres blood
2 000 : 1	80	0.80	0.75	0.080
2 100 : 1	84	0.84	0.79	0.084
2 300 : 1	92	0.92	0.87	0.092

[*] The specific weight of the total volume of blood is approximate 1.06

[**] 1 ‰ = 0.476 mg / dm^3 = 0.476 mg / L = 47.6 µg / 100 mL = 0.1 g / 210 L

The concentration of ethanol present in vapor phase above liquid-water mixture depends on just two factors: the temperature of the mixture and the alcohol concentration in the liquid.

$$\gamma_{\text{air}} = \gamma_{\text{eth}} \cdot A \cdot e^{B \cdot t} \qquad (1)$$

where:

γ_{air} is the mass concentration of ethanol in vapor phase above liquid-water mixture, mg/dm^3;

γ_{eth} is the mass concentration of ethanol in solution, g/dm^3;

The following experimental coefficients A and B were established on several studies on partition coefficient air/ethanol solution:

- A = 0.041 45 [mg/dm^3 / g/dm^3];
- B = 0.065 83 [1 / ^{0}C];

Note that the equation (1) is also referred as Dubowski's formula [7]

In the case where *t* is equal to 34.0 ^{0}C, the equation (1) becomes:

$$\gamma_{\text{air}} = 0.388\,66 \cdot \gamma_{\text{eth}} \qquad (2)$$

Experimental system

For dissemination purposes a lot of stages were made step by step, as it follow:

1st step

The breath analyser Alcotest 9510 type was calibrated by LNE, in LNE laboratory, using LNE simulator system and MRC prepared and certified by LNE. The MRC prepared and used by LNE is presented in table 2.

Table 2 – **MRC prepared and used by LNE**

MRC N°	Mass concentration of alcohol in simulated breath	
	γ_{air}, mg/L	*U*, mg/L
1	0.200 0	0.003 3
2	0.400 0	0.003 3
3	0.700 0	0.003 3
4	1.500 0	0.003 3

2nd step

Applying the concept of traceability to breath alcohol measurements is not easy, but traceability has to provide qualitative results using analytical techniques used in calibration laboratories. In this regard a set of 7 standard solutions prepared by LNE were used for calibration the breath analyser Alcotest 9510, using the ALCOCAL simulator system purchased by INM. In order to draw the calibration curve using the INM simulator system, the following MRC prepared by LNE, according to the calibrations certificates no. M060126/01-07, were used and they are presented in table 3.

Table 3 – **MRC prepared by LNE and used by INM**

MRC N°	Mass concentration of alcohol in standard solution		Mass concentration of alcohol in simulated breath	
	γ_{eth}, g/L	*U*, g/L	γ_{air}, mg/L	*U*, mg/L
1	0.2573	0.0005	0.100 0	0.003 3
2	0.5146	0.0006	0.199 5	0.003 3
3	0.9005	0.0011	0.350 0	0.003 3
4	1.0292	0.0012	0.399 0	0.003 3
5	1.8011	0.0021	0.698 0	0.003 3
6	2.4444	0.0028	0.950 0	0.003 3
7	3.8595	0.0044	1.500 0	0.003 3

3rd step

The simulator system used by INM to prepare and certify mass concentration standards of alcohol used in exhaled breath measurements consists of three main functional blocks:

A: **Preparation System**, used to generate the standard solution by gravimetric method, which consists of:

- a calibrated balance, type Mettler Toledo, max. 310 g, d=0,0001 g, according to calibration certificate no. 02.01-1111/2011.
- the calibrated volumetric flasks;
- electronic densimeter, Anton Paar type.
- ethanol reagent of 99.8 % purity,

- distilled water of electrolytic conductivity 0.5 µS·cm^{-1}

B: Simulator system used was ALCOCAL type, produced by Dräger Safety AG & Co, KGaA, Germany, calibration certificate no 30089 from 06.09.2011 issued by PTB – Germania**.** Alcocal operates on the basis of enrichment of a carrier gas with ethanol vapour as the carrier gas is passed through an ethanol-in-water solution. The carrier gas used with Alcocal is air. A mass flow controller regulates the air mass flow rate internally. To determine the current mass flow rate the internal control circuit uses a sensor according to the heat transport principle, with the differential temperature being measured at a heated part of a capillary tube. Due to this principle the mass flow rate is independent of the air temperature and pressure. To prevent the inflow behaviour of the mass flow controller from affecting the volume delivered, the flow rate upstream of the gas exposure process is regulated by a throttle valve set to the same dynamic pressure. Air leaving the mass flow controller passes first through the outer then through the inner of two incident vessels containing ethanol-in-water solutions and there is enriched with water and ethanol vapour according to the current fluid temperature and the associated vapour pressure. To improve the quality of measurement, a calibrated mass flow controller F-201AV-ABD-33-V type was used, manufactured by Bronkhorst, according to calibration certificate from 09.08.2011.

C. Breath analyser/Ethylometer, Alcotest 9510 type
The mass concentration of ethanol gas delivered by simulator system was measured against the calibrated ethylometer, Alcotest 9510 type, manufactured by Dräger Safety AG & Co, KGaA, Germany, according to testing report issued by LNE in 19.01.2012.

Figure 1 – The calibration system used within the INM

The following 7 standard solution were prepared by INM using the experimental system described above. These mass concentration of alcohol are presented in table 4.

Table 4 – **MRC prepared and used by INM**

MRC N^{o}	Mass concentration of alcohol in standard solution, g/L	Mass concentration of alcohol in simulated breath mg/L
1	0.262 83	0.102
2	0.520 64	0.201
3	0.907 32	0.351
4	1.036 30	0.401
5	1.809 70	0.700
6	2.454 30	0.949
7	3.872 30	1.497

4th step

The uncertainty budget was calculated for a number of 20 measurements against the Alcotest 9510 breath analyser using the ALCOCAL system simulator and a standard solution of ethanol in distilled water having a mass concentration of (1.025 ± 0.162) g/L equivalent of a mass concentration of alcohol in simulated breath of 0.398 4 mg/L.
These measurements were: 0.401; 0.401; 0.400; 0.401; 0.400; 0.400; 0.400; 0.400; 0.401; 0.400; 0.400; 0.400; 0.400; 0.398; 0.399; 0.400; 0.399; 0.400; 0.399; 0.399.

Rezults and Discussions

1st step

The calibration curve, using the LNE simulator system and the LNE standard solutions, in LNE laboratory, was draw using the data presented in the table 5.

Table 5 – **LNE data using the LNE standard solutions**

LNE standards solutions				
mg/L	**0.200**	**0.400**	**0.700**	**1.500**
Alcotest 9510 Indicated values, mg/L	0.204	0.400	0.723	1.561
	0.201	0.408	0.722	1.569
	0.202	0.409	0.721	1.562
	0.202	0.408	0.718	1.559
	0.202	0.409	0.720	1.559
	0.203	0.410	0.717	1.560
	0.204	0.410	0.717	1.556
	0.204	0.410	0.717	1.566
	0.203	0.406	0.716	1.566
	0.203	0.408	0.717	1.566
mean, mg/L	**0.202 8**	**0.407 8**	**0.718 8**	**1.562 4**
stdev, mg/L	0.001 0	0.003 0	0.002 5	0.004 1
stdev, %	0.51	0.74	0.35	0.27

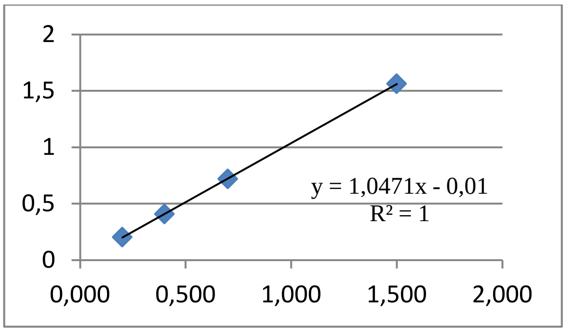

Figure 2 – The calibration curve using LNE standard solutions & LNE simulator system

2nd step

The calibration curve using the INM simulator system and the LNE standard solutions, in INM laboratory is presented in figure 3. The data used for drawing the calibration curve is presented in table 5.

Table 6 – **INM data using the LNE standard solutions**

LNE standards solutions							
mg/L	**0.1000**	**0.1995**	**0.3500**	**0.3990**	**0.6980**	**0.9500**	**1.5000**
Alcotest 9510 Indicated values. mg/L	0.094	0.196	0.354	0.407	0.723	0.981	1.585
	0.094	0.197	0.355	0.408	0.723	0.984	1.577
	0.092	0.196	0.356	0.410	0.724	0.990	1.586
	0.094	0.196	0.354	0.410	0.721	0.991	1.572
	0.093	0.197	0.355	0.410	0.722	0.990	1.584
	0.093	0.196	0.354	0.407	0.725	0.990	1.577
	0.093	0.196	0.355	0.408	0.722	0.985	1.579
	0.094	0.196	0.356	0.408	0.720	0.984	1.584
	0.093	0.196	0.354	0.409	0.722	0.985	1.581
	0.094	0.196	0.355	0.407	0.723	0.984	1.586
mean. mg/L	**0.0934**	**0.1962**	**0.3548**	**0.4084**	**0.7225**	**0.9864**	**1.5811**
stdev. mg/L	**0.0007**	**0.0004**	**0.0008**	**0.0013**	**0.0014**	**0.0035**	**0.0047**
stdev. %	**0.75**	**0.21**	**0.22**	**0.31**	**0.20**	**0.36**	**0.30**

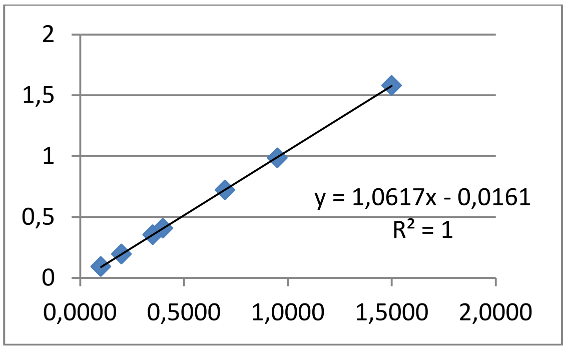

Figure 3 – The calibration curve using INM standard solutions & INM simulator system

3rd step

The calibration curve using the INM simulator system and the INM standard solutions, in INM laboratory.
INM prepared a set of 7 solutions, mixtures of ethanol in distilled water, having the same some mass concentrations of alcohol in simulated breath as those had purchased from LNE. The obtained data is presented in table 7. Un example of budget uncertainty using a mass concentration of alcohol 0.398 4 mg/dm^3 was descriebed, calculated and presented in table 8.

Table 7– **LNE data using the LNE standard solutions**

INM standards solutions							
mg/L	**0.102**	**0.201**	**0.351**	**0.401**	**0.700**	**0.949**	**1.497**
Alcotest 9510 Indicated values. mg/L	0.099	0.198	0.357	0.414	0.718	0.969	1.537
	0.097	0.205	0.360	0.412	0.718	0.975	1.548
	0.098	0.204	0.361	0.410	0.720	0.977	1.547
	0.102	0.205	0.360	0.411	0.727	0.971	1.553
	0.100	0.201	0.362	0.411	0.725	0.980	1.552
	0.101	0.204	0.360	0.416	0.717	0.978	1.548
	0.099	0.202	0.363	0.417	0.725	0.974	1.554
	0.099	0.203	0.360	0.418	0.721	0.985	1.550
	0.099	0.204	0.356	0.412	0.726	0.982	1.554
	0.097	0.201	0.364	0.415	0.715	0.981	1.562
mean. mg/L	**0.0991**	**0.2027**	**0.3603**	**0.4136**	**0.7212**	**0.9772**	**1.5505**
stdev. mg/L	**0.0016**	**0.0022**	**0.0025**	**0.0028**	**0.0043**	**0.0050**	**0.0064**
stdev. %	**1.61**	**1.09**	**0.68**	**0.68**	**0.59**	**0.51**	**0.41**

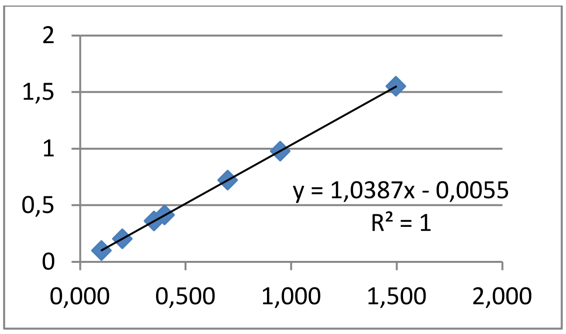

Figure 4 – The calibration curve using INM standard solutions & INM simulator system

Taking into considerations all data presented in tables 6-8 is evidently the fact that the mass concentrations of alcohol prepared by LNE have a better stability than the mass concentrations of alcohol prepared by INM.
The ALCOCAL simulator system used by INM offer a very good stability of the temperature and, in this regard, a very good stability of mass concentrations of alcohol delivered.
The using of ALCOCAL simulator system is a very good way to reduce the standard uncertainty.

Table 2 - **Uncertainty Budget for mass concentration of alcohol from breath exhaled**

No	Quantity	Value	Standard uncertainty	Probability distribution	Relative standard uncertainty
The final value of mass concentration of alcohol from simulated breath is: $(\mathbf{0.399\,9} \pm \mathbf{0.001\,4})$ mg/dm^3 or $(\mathbf{0.399\,9} \pm \mathbf{0.001\,4})$ mg/L , (k=2) ***Note***: 20 measurements (the displayed values were between 0.398 and 0.401 mg/dm^3, the average value was 0.399 9 mg/dm^3)					
1	**Uncertainty budget due to the alcohol breath analyzer, type Alcotest 9510, configured with Infrared and Electrochemical sensors- IR & EC →** $\boldsymbol{\gamma_{Breath\ Analyzer} = \gamma_{air} \cdot f_{repetability} \cdot f_{rezolution} \cdot f_{liniarity}}$				
	$\gamma_{Breath\_Analyzer}$, mg/dm^3	0.398 420	$u_{\gamma_{Breath_{Analyzer}}} = \sqrt{u^2_{c(\gamma_{air})} + u^2_{f_{repeatability}} + u^2_{f_{rezolution}} + u^2_{f_{liniarity}}}$ = 0.000 714	Gaussian	0.179 176
	γ_{air}, mg/dm^3 (see 1.1)	0.398 420	$u_{c(\gamma_{air})} = \sqrt{\left(\frac{\partial\gamma_{air}}{\partial\gamma_{alcohol}}\right)^2 \cdot u^2_{\gamma_{alcohol}} + \left(\frac{\partial\gamma_{air}}{\partial\gamma_t}\right)^2 \cdot u_t^2}$ = 0.000 344	Gaussian	0.086 353
	$f_{repeatability}$, mg/dm^3	1	$u_{f_{repeatability}} = \sqrt{\frac{s^2}{n}} = \sqrt{\frac{0.000\,788^2}{20}}$ = 0.000 176	Gaussian	0.044 229
	$f_{rezolution}$, mg/dm^3	1	$u_{f_{rezolution}} = \frac{0.001}{2\cdot\sqrt{3}} = \frac{0.001}{\sqrt{12}}$ = 0.000 289	Rectangular	0.072 536
	$f_{liniarity}$, mg/dm^3	1	$u(x_{pred}, y) = \frac{\sqrt{\frac{\sum_{i=1}^{n}(y_i-\hat{y}_i)^2}{n-2}}}{m} \cdot \sqrt{\frac{1}{N} + \frac{1}{n} + \frac{\left(\frac{\sum_{i=1}^{N} y_i}{N} - \bar{y}\right)^2}{m^2\left((\sum_{i=1}^{n} x_i^2) - \left((\sum_{i=1}^{n} x_i)^2\right)/n\right)}}$ = 0.000 526	Rectangular	0.132 021
1.1	**Uncertainty budget for mass concentration of alcohol from simulated breath delivered by the wet-simulator system →** $\boldsymbol{\gamma_{air} = \gamma_{alcohol} \cdot A \cdot e^{B\cdot t}}$				
	$\gamma_{alcohol}$, g/dm^3 (see 1.1.1)	1.025 110	$u_c(\gamma_{alcohol}) = \sqrt{\left(\frac{\partial\gamma_{alcohol}}{\partial V}\right)^2 \cdot u^2(V) + \left(\frac{\partial\gamma_{alcohol}}{\partial m}\right)^2 \cdot u^2(m)}$ = 0.000 832	Gaussian	0.081 190
	$t_{34\ (CE)}$, ^{0}C	34.00	u_t = 0.01 (according to the calibration certificate)	Gaussian	0.029 412
1.1.1	**Uncertainty budget of the solution of alcohol in distilled water** $\rightarrow \boldsymbol{\gamma_{alcohol}} = \frac{m_{(alcohol)}}{V_{(total)}}$				
	m, g (see 1.1.1a)	5.135 820	$u_c(m) = \sqrt{u_c^2(m_{weighted}) + u_c^2(purity) + u_c^2(decanting) + u_c^2(evaporation) + u_c^2(density)}$ = 0.003 875	Gaussian	0.075 457
	V, cm^3 (see 1.1.1b)	5 000	$u_c(vol) = \sqrt{u_c^2(vol_{dilatation\ of\ flask}) + u_c^2(vol_{dilatation\ of\ flask\ due\ to\ temperature}) + u_c^2(vol_{water\ dilatation})}$ = 1.498 333	Gaussian	0.029 967
1.1.1a	**Uncertainty budget for mass alcohol** $\rightarrow m = m_{weighed} \cdot f_{decanting} \cdot f_{evaporation} \cdot f_{purity} \cdot f_{density}$				
	$m_{weighed}$, g (see 1.1.1a*)	5.135 820	$u_c(m_{weighted}) = \sqrt{\bar{s}^2(\Delta m) + u_c^2(CE\_balance)}$ = 0.000 0018	Gaussian	0.000 345

No	Quantity	Value	Standard uncertainty	Probability distribution	Relative standard uncertainty
	f_{purity}, g	1	$u_c(P) = \frac{\frac{(1-0.998)}{2} \cdot m_{weighted}}{\sqrt{4.5}}$ = 0.002 421	Semi-triunghiular	0.047 140
	$f_{decanting}$, g	1	$u_c(decanting) = \frac{m_{al} \cdot \frac{V_{lost\ alcohol}}{V_{total\ weighed}}}{\sqrt{4.5}} = \frac{m_{weighed} \cdot \frac{0.05(cm^3)}{40\ (cm^3)}}{\sqrt{4.5}}$ = 0.003 026	Semi-triunghiular	0.058 920
	$f_{evaporation}$, g	1	$u_c(evaporation) = \frac{a}{\sqrt{4.5}} = \frac{\frac{0.004}{2}}{\sqrt{4.5}}$ mg = 0.000 001	Semi-triunghiular	0.000 019
	$f_{density}$, g	1	$u_c(density) = 1 \cdot 10^{-5}$ g/cm^3 = 0.000 010	Gaussian	0.000 195
1.1.1b	**Uncertainty budget for volume** $\rightarrow V = V_{water\ (flask)} \cdot f_{dilatation\ of\ flask\ due\ to\ the\ temperature} \cdot f_{dilatation\ of\ water\ due\ to\ the\ temperature}$				
	$V_{water\ (flask)}$, cm^3	5 000	$u_c(vol_{dilatation\ of\ flask}) = \frac{u_{flask}}{\sqrt{6}} = \frac{1.2}{\sqrt{6}}$ = 0.489 898	Triangular	0.009 798
	$f_{dilatation\ of\ flask\ due\ to\ the\ temperature}$, cm^3	1	$u_c(vol_{dilatation\ of\ flask\ due\ to\ temperature}) = \frac{V \cdot \alpha_{Pyrex} \cdot \Delta t}{\sqrt{2}}$ = 0.070 711	Arcsine	0.001 414
	$f_{dilatation\ of\ water\ due\ to\ the\ temperature}$, cm^3	1	$u_c(vol_{water,t}) = \frac{V_{water} \cdot \alpha_{water} \cdot \Delta t}{\sqrt{2}}$ = 1.414 214	Arcsine	0.028 284
1.1.1a*	**Uncertainty budget for weighed mass alcohol** $\rightarrow m_{weighed} = m_{alcohol(CE)} \cdot f_{repeatability(of\ weighed\ mass)}$				
	$m_{alcohol\ CE\_balance}$, g	5.135 820	$u_{m_{alcohol\_CE(balance)}}$ = 0.017 mg = 0.000 017g	Gaussian	0.000 331
	$f_{repeatability}$ of weighed mass, g	1	$\bar{s}(\Delta m) = \sqrt{\frac{\sum_{i=1}^{n-1} \Delta^2 m_i}{n(n-1)}}$ = 0.000 005	Gaussian	0.000 097

Note 1**:** The uncertainty due to the deviation (bias) was not taking into account because the mean of the indicated values did not exceed the limits of the interval. In case of these limits of the interval are exceeded, it must take into consideration a rectangular distribution.
Note 2**: Breathalyzer "zero function" uncertainty** is not taken into account because the breathalyzer carries out an automatic adjustment of the zero value before and after each measurement.
Note 3**:** Due to the fact that the breathalyzer requests for analysis a sample of 1.2 L of air, and it is NOT taken into account more than the last cubic centimetre, cm^3, (which represents the required volume for analysis and corresponds to the alveolar air, fact which was demonstrated by several research studies) than it is NOT necessary to take into account the uncertainty due to the plateau.

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