

In vitro evaluation of BACtrack®’s smartphone-connected personal breath alcohol analyzers

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Abstract

This study assessed the in vitro accuracy, precision, specificity, and measurement uncertainty of BACtrack®’s line of smartphone-connected breath alcohol analyzers. At the 0.080 g/210L ethanol vapor concentration the measurement uncertainty was determined to be ± 0.013 , 0.004, and 0.006 g/210L for the Pro, C8, and C6 respectively at the 95% coverage interval. The analyzers showed an apparent ethanol response to isopropanol, and methanol, but not to acetone. BACtrack®’s smartphone-connected breath alcohol analyzers showed the ability to measure vaporous ethanol with confidence in the results.

Introduction

The ability to easily monitor one’s breath alcohol concentration (BrAC) may be useful in situations where driving a vehicle above a certain limit constitutes a violation of the law. Other potential uses include remote monitoring of alcohol use (1), self-tracking (2; 3), use in drinking establishments (4), medicine (5; 6), family law (7), research (8) and workplace testing (9).

Scant research exists on the performance of small, inexpensive breath alcohol analyzers marketed for personal use. In 2003, Van Tassel coined the phrase, “pocket model breath tester” (PMBT) to describe such a device and found most of the devices examined to be lacking in analytical performance (10). More recent examinations of these types of devices have shown mixed results (11; 12; 13; 14; 15).

This study assessed BACtrack®’s line of smartphone-connected breath alcohol analyzers in vitro against known reference standards. The analyzers were evaluated for accuracy, preci-

on, specificity, and measurement uncertainty. Special attention was paid to the measurement uncertainty at the 0.080 g/210L ethanol vapor concentration due to its legal implications in the United States and other countries.

Materials

BACtrack® Breath Alcohol Analyzers

The instruments selected for this study were the BACtrack® Pro, C8, and C6 (BACtrack® Breathalyzers, San Francisco CA, USA). One of each instrument was purchased new from an internet retailer. The cost of the instruments was: \$79, \$99, and \$99 for the C6, C8, and Pro respectively. The same instruments were used for the entirety of this study. The instruments cannot be calibrated locally by the end-user but must be sent back to the manufacturer every 6-12 months for recalibration.

The analyzers connect via Bluetooth® to an app installed on the user's smartphone where measurements can be displayed and recorded. Two of the instruments, the C6 and C8, can also be used in a standalone mode where a smartphone app is not required. When used in standalone mode, results display on a small screen built into the device. The Pro model requires the use of the companion smartphone app.

The dimensions of the instruments are: 6.98 x 4.44 x 1.60, 6.35 x 5.58 x 1.67, and 5.61 x 4.76 x 1.67 cm, for the Pro, C8 and C6 respectively (16; 17; 18). Figure 1 shows a picture of the BACtrack® Pro, C8, and C6 from left to right with a AAA size battery included on the far left for scale.



Figure 1: BACtrack® Pro, C8, and C6

Before testing, users must abstain from drinking alcohol for a period of at least 15-minutes. This allows for residual alcohol in the mouth from recent drinking to dissipate so as not to falsely elevate the test (19; 20; 21; 22; 23). The instruments do not have a mechanism to monitor for residual mouth alcohol, such as those used in more advanced infrared breath alcohol analyzers (24).

To start the testing process, the user powers-on the instrument and follows onscreen instructions to blow into the device. The user must provide a breath at a flow rate of 12-14 L/m for approximately 5 seconds, resulting in a total volume of breath provided of approximately 1.2L (email communication, BACtrack® Breathalyzers). The result of the breath alcohol analysis is shown onscreen to the third decimal in g/210L. Users have the ability to change the units of concentration if desired.

As the user blows into the instrument, ethanol is introduced to an electrochemical fuel cell via a miniature solenoid pump (25). Ethanol on the user’s breath is oxidized with the platinum black coated fuel cell, producing electrons (26). The electrical response generated is proportional to the ethanol concentration on the user’s breath (27). There is no exhalation profile of alcohol as seen in more sophisticated infrared breath alcohol analyzers (26).

After analysis, the app will display a predicted “time-to-sober” (BrAC of 0.000), based on an ethanol elimination rate of 0.015 g/210L/hr. The instrument and companion app are programmed to calculate “time-to-sober” using zero-order kinetics, even when results are below 0.020 g/210L and zero-order kinetics cannot be assumed (28). Instruments are pro-

grammed for a single breath sample to be obtained for analysis and cannot be programmed for a duplicate test sequence. Results can be saved in the smartphone app but cannot be exported to a spreadsheet for further analysis.

A novel aspect of the analyzers is the ability to record and share measurements via the companion smartphone app. When paired to the app, users can keep a record of all previous data, guess one's BrAC prior to testing, change the units of the reported concentration, upload photos, number of drinks, notes, share results, view other anonymous results on a map, and call for an Uber ride.

When used for remote monitoring of alcohol, the results of the test along with a picture of the user blowing into the device, and the GPS location can be uploaded to a database where approved third parties can monitor results. Reports from remote monitoring can be produced in a portable document format (PDF), but cannot be exported to a spreadsheet for further analysis (29).

Rich media available at <https://youtu.be/KbwkqpPBs1o>

Breath Simulators

Reference vapors were produced using two breath simulators, RepCo Model 3402C (RepCo Marketing, Co. Raleigh, NC, USA), in tandem (also known as a bubble train) to improve the performance of reference material as described by Dubowski (30) and others (31; 32; 33; 34). Breath simulators were driven by human breath. Figure 2 shows the tandem breath simulator set-up.



Figure 2: Breath simulator set-up

Aqueous Reference Standards

Aqueous reference standards were volumetrically prepared to produce reference vapors at specified concentrations when used in a breath simulator heated to 34°C, in accordance with Henry's Law (35). Class A glassware, American Chemical Society/United States Pharmacopeia grade chemicals, and purified water were used. Ethanol reference standards were prepared to produce vapor concentrations of 0.020, 0.040, 0.080, 0.160, 0.250 g/210L using Harger's water/air partition coefficient of 2539:1 at 34°C (36). Reference vapors of potentially interfering substances were prepared to produce vapor concentrations of acetone, isopropanol, and methanol at 0.5, 0.1, 0.1 mg/L respectively (34). Water/air partition coefficients for potential interfering substances at 34°C were obtained from the literature (37).

Methods

Ten measurements were taken with each instrument at each ethanol reference vapor concentration, as well as ten measurements of each potentially interfering substance concentration (38). Measurements were alternated with the Pro, C8, and C6 at approximately 2-minute

intervals. The mean, standard deviation (SD), bias, R^2 and ordinary least squares regression (OLSR) were calculated. Apparent ethanol response to potential interfering substances was recorded. An evaluation of the potential sources of uncertainty was evaluated using an Ishikawa diagram (39) as seen in figure 3.

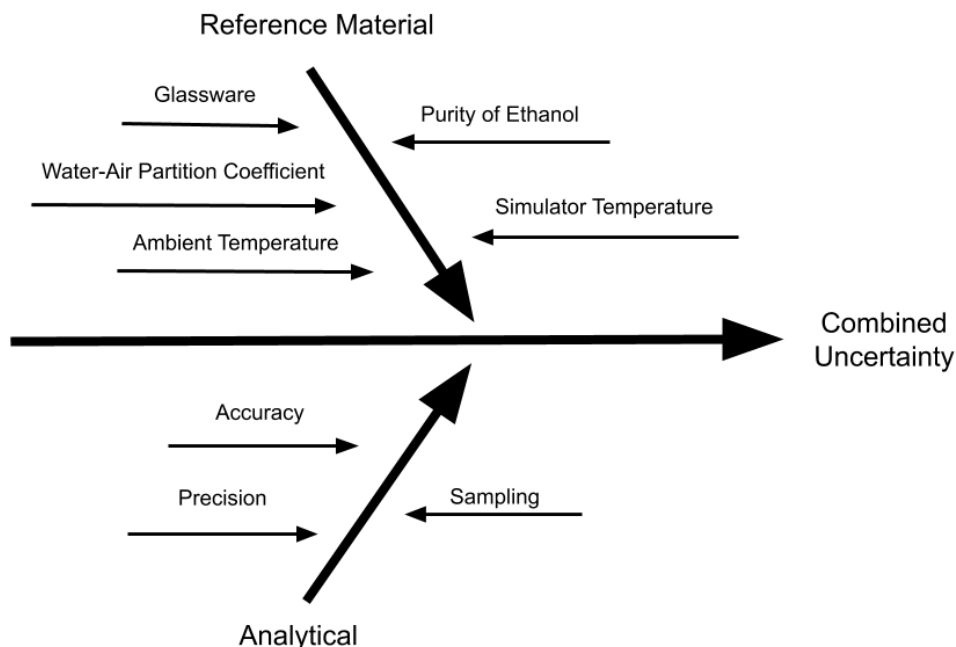


Figure 3: Ishikawa diagram showing uncertainty components

Standard uncertainties were combined using the root-sum-squares approach where, $u_{combined} = \sqrt{u_{precision}^2 + u_{bias}^2 + u_{reference}^2}$ (40; 41). Bias was incorporated as a component under the radical in the estimate of measurement uncertainty, expanding the coverage interval (42; 43). The combined standard uncertainty was expanded to the 95% coverage interval where, $U_{95\%} = 2u_{combined}$. Figure 4 shows the mean individual uncertainty component's percent contribution to the combined standard uncertainty.

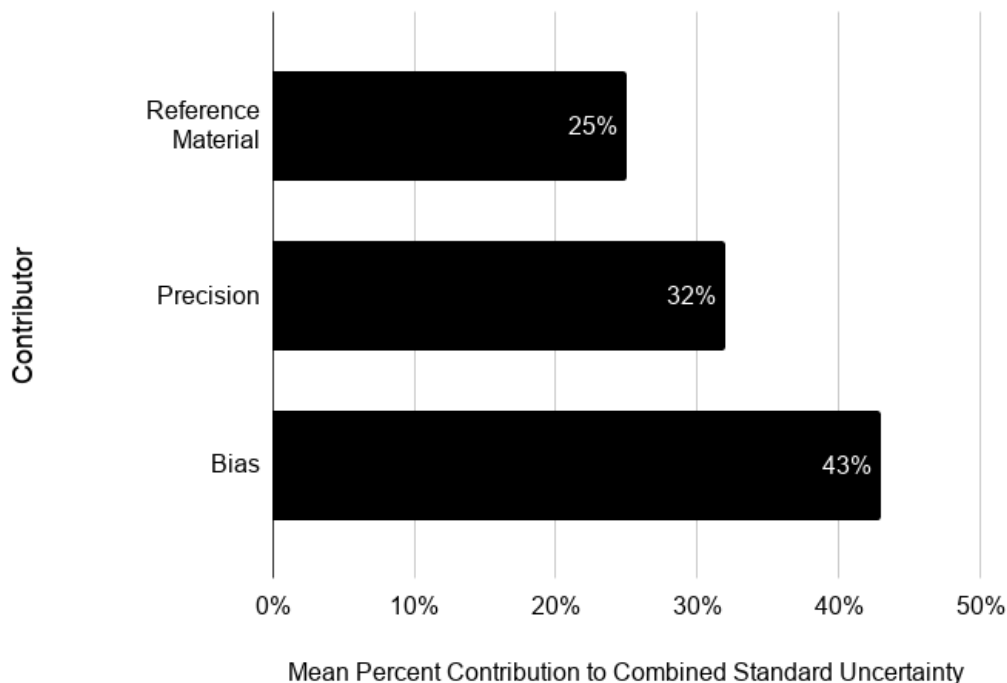


Figure 4: Percent contribution to the combined standard standard uncertainty

Results

The mean, R^2 , and OLSR are summarized in table 1. The SD of the measurements are displayed in table 2. Bias is shown in table 3. At the 0.080 g/210L concentration, the combined expanded measurement uncertainty was determined to be ± 0.013 , 0.004, and 0.006 g/210L at the 95% coverage interval for the Pro, C8, and C6 respectively. Instruments did not respond to acetone but did respond to isopropanol and methanol as seen in table 4.

Concentration (g/210L)	0.020	0.040	0.080	0.160	0.250	R^2	OLSR
Pro	0.0230	0.0460	0.0909	0.1780	0.2720	0.99	$y=1.08x + 0.003$
C8	0.0205	0.0390	0.0793	0.1495	0.2258	0.99	$y=0.89x + 0.005$
C6	0.0196	0.0369	0.0762	0.1403	0.2125	0.99	$y=0.84x + 0.005$

Table 1: Mean, R^2 , OLSR

Concentration (g/210L)	0.020	0.040	0.080	0.160	0.250
Pro	0.0000	0.0000	0.0007	0.0005	0.0029
C8	0.0007	0.0012	0.0015	0.0040	0.0034
C6	0.0005	0.0012	0.0021	0.0051	0.0081

Table 2: Standard Deviation

Concentration (g/210L)	0.020	0.040	0.080	0.160	0.250
Pro	0.0030	0.0060	0.0109	0.0180	0.0220
C8	0.0005	-0.0010	-0.0007	-0.0105	-0.0242
C6	-0.0004	-0.0031	-0.0038	-0.0197	-0.0375

Table 3: Bias

Instrument	Acetone 0.5 mg/L	Isopropanol 0.1 mg/L	Methanol 0.1 mg/L
Pro	0.000	0.010	0.043
C8	0.000	0.008	0.027
C6	0.000	0.009	0.032

Table 4: Apparent Ethanol Response to Interfering Substances

Discussion

Analytical Performance

The analyzers exhibited good performance at measuring vaporous ethanol in vitro, especially considering the low cost of the devices. At the 0.080 g/210L concentration, for example, both the C6 and the C8 showed levels of uncertainty similar to those found in more advanced breath alcohol analyzers used for evidential purposes (44; 45).

In the United States, the National Highway Traffic Safety Administration (NHTSA) promulgates performance recommendations for alcohol screening devices (ASDs) (46). The NHTSA's total allowable error for ASDs at the 0.020 g/210L ethanol vapor concentration is ± 0.012 g/210L at the 95% coverage interval. The analyzers examined met this requirement, showing a total error of $\leq \pm 0.003$ g/210L at 0.020 g/210L concentration, although they are not listed on the NHTSA's ASDs conforming products list (47).

For in vivo use, manufacturers of these devices should consider programming the instrument for a duplicate breath test sequence, reporting the mean of the two measurements along with the associated uncertainty. An uncertainty function could be built into the software of the smartphone app to provide users with additional information about the uncertainty of the measurements obtained (48). Also, calibration reports could be recorded by the smartphone app and notify the user when recalibration is needed.

Potential Interfering Substances

Potential interfering substances are volatile organic substances other than ethanol on a person's breath which has the potential to interfere with the accurate analysis of vaporous ethanol (49; 50; 51; 52; 53). These substances have an impairing effect similar to or greater than ethanol (54; 37). Normally, potential interfering substances are found in such low concentrations that they are unlikely to interfere with an ethanol breath test (55). However, there are some circumstances in which interfering substances may be present in high enough concentrations that they may falsely elevate an ethanol breath test (56; 57; 58). The analyzers examined do not have an interfering substance detection mechanism such as those found in more advanced electrochemical analyzers (59).

Acetone

Acetone has been found in the breath of people with diabetes, during times of fasting, and in very low carbohydrate dieters (60). Electrochemical fuel cell breath alcohol analyzers are known to be unaffected by acetone (61). The analyzers examined in this study use a fuel cell and did not respond to acetone.

Isopropanol

Isopropanol may be present in elevated concentrations on a person's breath after drinking denatured alcohol (62; 63; 53) or produced endogenously from the biotransformation of acetone to isopropanol (64). In one case study, a self-reported teetotaler obtained a false positive result on an electrochemical fuel cell breath alcohol analyzer after following a very low carbohydrate ketogenic diet (57). In another study, isopropanol in the breath was found to be elevated after eating a ketogenic meal (65). The analyzers showed an apparent ethanol response to isopropanol. Users engaged in very low carbohydrate ketogenic dieting should be aware of the possibility of obtaining elevated BrAC results based on their diet.

Methanol

Methanol may be present in elevated concentrations on a person's breath after consuming large amounts of fruit (66), in alcoholics (67; 68), or through accidental exposure due to the improper production of distilled spirits (69; 70; 71). There are two unfortunate cases reported in the literature where a breath alcohol analyzer mistook methanol for ethanol, delaying medical treatment, resulting in the subjects dying from methanol poisoning (51). Users of these devices should be aware of the potential, but the unlikely possibility of elevated BrAC results due to methanol.

Limitations

Vaporous ethanol reference material produced by breath simulators cannot account for the complex physiologic gas exchange taking place in the lungs and airways of live subjects (72; 22; 73; 74; 75; 76). The SD of measurements taken in vivo has been shown to be greater than the SD produced by breath simulators (77). Further research is needed to determine the measurement uncertainty for in vivo results.

The calibration longevity of the analyzers was not examined in this study. An important consideration for those wishing to use these instruments is that the device must be sent back to the manufacturer regularly for recalibration. Individuals or institutions using these instruments may need to keep several on hand while periodic recalibrations are performed.

Users of these instruments should incorporate quality assurance practices to ensure the accuracy meets the requirements of the intended use (78). The use of compressed ethanol-gas reference standards would be a convenient way to perform accuracy checks (79; 80). Further investigation with these analyzers using compressed ethanol-gas standards is needed, as the efficacy was not assessed in this study.

Conclusions

The breath alcohol analyzers examined in this study showed the ability to measure vaporous ethanol with confidence in the results, especially at concentrations ≤ 0.080 g/210L. At the 0.080 g/210L ethanol vapor concentration, the combined expanded measurement uncertainty was $\leq \pm 0.013$ g/210L at the 95% coverage interval for all instruments. The likelihood of false readings from potential interfering substances appears to be small but may be a concern for those engaged in ketogenic diets with elevated levels of isopropanol. More work needs to be conducted with these instruments in vivo to determine the measurement uncertainty for the results which include a biological component.

Conflicts of Interest

None.

Declaration

All statements and opinions are solely that of the author.

Supplementary Data

Hosted file

BACtrack Testing Process.mp4 available at <https://authorea.com/users/308674/articles/441398-in-vitro-evaluation-of-bactrack-s-smartphone-connected-personal-breath-alcohol-analyzers>

Hosted file

Supplementary data BACtrack study.xlsx available at <https://authorea.com/users/308674/articles/441398-in-vitro-evaluation-of-bactrack-s-smartphone-connected-personal-breath-alcohol-analyzers>

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