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Breath Alcohol Testing

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Disclosures

While I may be mentioning certain products or vendors by name, I have no personal interest or relevant relationships (financial or intellectual) to disclose.

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Learning Objectives

- 1 Review how breath alcohol relates to blood alcohol
- 2 Describe how preliminary breath test instruments work and their advantages and limitations
- 3 Educate about the different types of evidential breath testing instruments
- 4 Review General Breath Testing Requirements
- 5 Inform about important biological considerations
- 6 Discuss common challenges to breath testing
- 7 Provide an update regarding standards affecting the breath alcohol community

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Measuring the Breath Alcohol

Elimination in Breath

- **Unabsorbed Alcohol**
 - Excreted Unchanged
 - Allows for measurement in Breath
- **Measurement**
 - Body ~ 37°C
 - Breath ~34 °C
 - Using a "partition ratio" can account for these differences
 - BrAC = BAC

Alcohol Pharmacology Education Partnership, duke.edu

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Henry's Law

“At a constant temperature, the amount of a given gas that dissolves in a given type and volume of liquid is directly proportional to the partial pressure of that gas in equilibrium with that liquid.”

William Henry, 1803

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Henry's Law and Breath Testing

HENRY'S LAW	HUMAN BODY
When an aqueous solution of a volatile compound comes into equilibrium with air there is a fixed ratio between the concentration in solution and this ratio is constant for a given temperature	blood alcohol in lungs Ratio 2100:1 (assumption) body temperature is constant
Breath Alcohol Reading	Blood alcohol reading is dependent on how much alcohol is present in someone's blood.



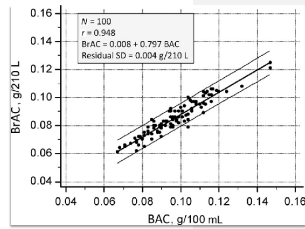
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Partition Ratios

There is a DIRECT correlation between the last volume of "deep lung air" or "end-expiratory breath" and a subject's alcohol concentration in g/210 liters of breath



Jones, AW & Cowan, JM (2020). Reflections on variability in the blood-breath ratio of ethanol and its importance when evidential breath-alcohol instruments are used in law enforcement. Forensic Sciences Research, 5, 1-8. 10.1080/20967790.2020.1780720

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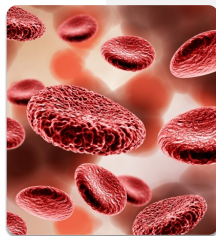


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Blood and Breath Relationship

Last portion of a prolonged breath sample reflects the concentration of arterial blood to which the brain is exposed!

- Blood: Breath Partition Ratio
 - Empirical - Varies based on individual? 2300:1
 - Nominal - Inherent in ALL breath instruments used in the United States 2100:1



¹Alcohol and the Impaired Driver: A Manual on the Medical and Legal Aspects of Chemical Tests for Intoxication. American Medical Association. Reprinted by National Safety Council, Chicago, 1976.

²Jones, AW & Cowan, JM (2020). Reflections on variability in the blood-breath ratio of ethanol and its importance when evidential breath-alcohol instruments are used in law enforcement. Forensic Sciences Research, 5, 1-8. 10.1080/20967790.2020.1780720

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Origin of 2100:1

- Lijestrand and Linde (1930) 2000:1¹
- Harger, Forney and Barnes (1950) 2100:1²
- NSC Committee on Tests for Intoxication (COAD, ADID) (1953) 2100:1³—
“Evaluating Chemical Tests for Intoxication”
- NSC—reaffirmed in 1972 and 1976
- US DOT: “Standard for Devices to Measure Breath Alcohol” (1973)⁴

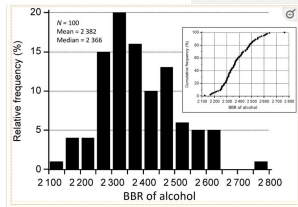
¹Lijestrand, G. and P. Linde. “Über die Ausscheidung des Alkohols mit der Expirationsluft.” *Skandinavisches Archiv Für Physiologie* 60.3 (1930): 273-288.
²Harger, E. N., Robert B. Forney, and Helen B. Barnes. “Estimation of the level of blood alcohol from analysis of breath.” *The Journal of Laboratory and Clinical Medicine* 36:2 (1950): 306-308.
³National Safety Council. “Recommendations of the Committee on Alcohol and Drugs, 1956-1977, Appendix F, Special Report on the Blood/Breath Conversion Factor,” pp. 89-94.
⁴Federal Register Vol 38, No. 212, (1973), 30459-30463.



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Partition Ratios

Variable	Min/Max (Median)
Age	21-51 (28)
BMI	18.3-46.2 (27.5)
BAC %	0.067-0.147 (0.096)
BRAC g/210L	0.061-0.125 (0.084)
Avg Temp °C	
Breath	33.3-35.5 (34.5)
Body	35.8-37.3 (36.7)



Jones, AW & Cowan, JM. (2020). Reflections on variability in the blood-breath ratio of ethanol and its importance when evidential breath-alcohol instruments are used in law enforcement. *Forensic Sciences Research*, 5, 1-9. 10.1080/20567790.2020.1790720.



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Summary



- Elimination
 - 5% eliminated unchanged—measured in breath
- Ethanol is highly soluble and diffuses easily across membranes
- Henry's Law is the basis for Breath Testing
- Blood Breath Ratio/Partition Ratio¹
 - United States: 2100:1 (Sweden, Norway, Finland)
 - Other Countries: 2300:1 (UK, Netherlands)
 - 2000:1 (France, Austria, Poland)

¹Jones, Alan Wayne. “Medicolegal alcohol determination—blood- or breath-alcohol concentration?” *Forensic science review* 12:1-2 (2000): 23-47.



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Preliminary Breath Testing Instruments (PBTs)




- What Are They?
- Analytical Approaches
- Calibration and QC
- Advantages and Limitations

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What Are PBTs?

- Screening Devices
- Easy, Simple Operation
- Easy to transport
- Specific for Alcohol*




(AP/Carl Hesse/retrofix)

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PBT Categories

- **Passive Alcohol Sensors (PAS)**
 - Special Events
 - Zero-Tolerance
 - Checkpoints
 - Environment
- **Screening Device (PBT)**
 - Pass/Fail or Numerical Result
 - Establish Probable Cause or Rule Out
- **Interlock Device (BAIID)**
 - Integrated into car system
 - Uses similar technology to PBTs



PAS Systems Intl.
CMI Inc.

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PBTs in Law Enforcement/Workplace



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PBTs For the Public



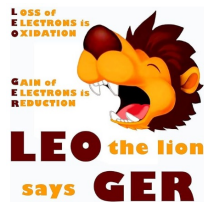
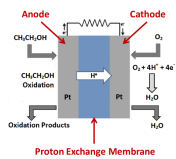
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Science of the PBT-Analytical Approaches

Fuel Cell Technology



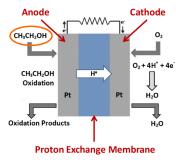
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Science of the PBT-Analytical Approaches

Fuel Cell Technology



Fuel Cell

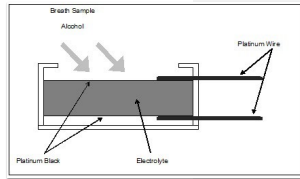


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Science of the PBT-Analytical Approaches

Fuel Cell Technology

- Signal is produced from chemical reaction
- Signal is directly proportional to the BRAC



<https://www.intox.com/fuel-cell-white-paper/>



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Fuel Cell Sensitivity

Alcohols

- Cannot Distinguish Between EtOH and other alcohols
 - Isopropanol
 - Methanol
 - n-Propanol
 - (Acetaldehyde)

NOT reactive with Other Volatiles

- Acetone

DO NOT react with Organic Hydrocarbon Solvents


- Toluene, Hexane




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Calibration of a PBT

- Single Point Calibration**
 - Use a Simulator Solution or a Dry Gas Ethanol Standard
- Accuracy Check**
 - Verify the Calibration
- Calibration Interval**
 - Program or Manufacturer dependent
 - Every 6 or 12 months



<https://ifeloc.com/howto/videos>



YouTube: AlcoPro How to Conduct a Calibration on the Alco-Sensor IV (2016)

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PBT Pros and Cons

Advantages	Disadvantages
<ul style="list-style-type: none"> Minimal size and power requirements Can be used in PBTs and Evidential Units 	<ul style="list-style-type: none"> Acetic Acid can build up on Fuel Cell <ul style="list-style-type: none"> Longer time to Zero baseline Consumable (- battery) <ul style="list-style-type: none"> Lose Sensitivity over time <ul style="list-style-type: none"> Require recalibration Will eventually need to be replaced Not specific to Ethanol only

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Evidential Breath Testing Instruments



- What Are They?
- Analytical Approaches
- Calibration and QC
- Advantages and Limitations

Barkerstein image courtesy of [NJ Analytical](#)

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What Are Evidential Instruments (EBTs)?

- Generally admissible in a court of law
- NHTSA Conforming Products List (CPL)
- Typically in a fixed location, but can be mobile
- May employ multiple types of technology



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NHTSA--EBTs Must be Required to...

- Provide a printed triplicate result
- Assign a unique number to each completed test
- Record the manufacturer's name of the device, serial number and time of test
- Distinguish ethanol from acetone at 0.02% level
- Test an Air Blank
- Perform an external calibration check



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Specificity of Evidential Breath Instruments


- Report from NSC (CAOD)—1994, 1999, 2010
- IACT supported with a Position Statement in 2016
In order for a non-ethanol substance to produce a significant response on any breath alcohol testing instrument, it must...
- Be the breath of living conscious human beings
- Be present in sufficiently high concentration after 15-20 min observation period
- Be able to produce a response that is indistinguishable from ethanol



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Evidential Breath Testing—Analytical Approaches


- Infrared Technology
- Electrochemical (Fuel Cell)
- BOTH Technologies

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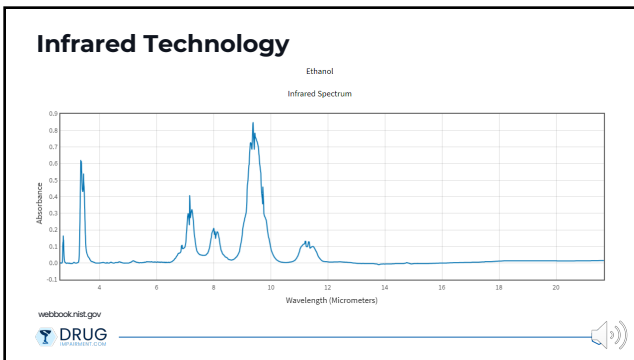
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Infrared Technology

- Ethanol absorbs energy at certain wavelengths
- Absorbs strongly at 3.30 and 3.50 (C-H stretching) microns, as well as 9.50 microns (C-O bond)
- IR energy is directed through the Sample Chamber (cuvette) in EBT
- If Breath Sample has EtOH, the EtOH absorbs some of that energy
- More Energy absorbed = ↑ EtOH

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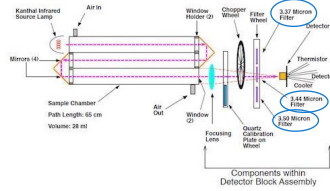
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Infrared Technology

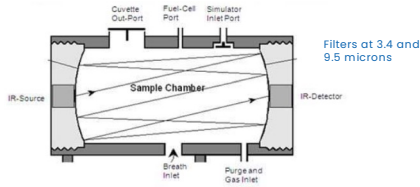
Intoximeters DMT Optical Bench



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Infrared Technology

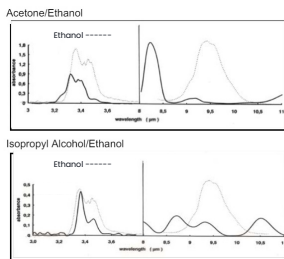
Draeger 9510 Sample Chamber



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Infrared Technology—Other Volatiles

Draeger Alcotest 9510 Idaho Technical Manual V1.0



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Infrared Technology—Other Volatiles

Draeger Alcotest 9510 Idaho Technical Manual V1.0

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Calibration and QC Measures

- Single Point Calibration**
 - Use a Simulator Solution or a Dry Gas Ethanol Standard
- Accuracy Check**
 - Verify the Calibration
- Calibration Interval**
 - Program or Manufacturer dependent
 - Every 6 or 12 months

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EBTs Pros and Cons

Advantages	Disadvantages
<ul style="list-style-type: none">Generally accepted in CourtsCan combine different types of technology to detect Ethanol (IR and Fuel Cell)IR testing provides a safeguard against other types of alcohols	<ul style="list-style-type: none">Large and typically at a police station/testing centerLonger time to get a testOften requires a specific operator permit

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Take Home Points



- Ethanol absorbs energy at certain wavelengths
- Absorbs strongly at 3.30 and 3.50 (C-H stretching) microns, as well as 9.50 microns (C-O bond)
- IR energy is directed through the Sample Chamber (cuvette) in EBT
- If Breath Sample has EtOH, the EtOH absorbs some of that energy
- More Energy absorbed = ↑ EtOH



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Breath Testing Procedures



- Pre-Test Requirements
- Deprivation/Observation Period
- Replicate Samples
- Breath Testing QC Recommendations



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Pre-Test Requirements

Instruments should be approved by an appropriate agency and if used in the US, also appear on the [NHTSA Conforming Products List \(CPL\)](#)

Instruments should be operated by and tests given by trained and qualified breath alcohol test instrument operators.

NSC (CAOD) Report—Subcommittee on Alcohol Technology, Pharmacology and Toxicology
 “Acceptable Practices for Evidential Breath Alcohol Testing”





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Deprivation/Observation Period

- Testing protocols should employ a minimum pre-exhalation mouth alcohol deprivation period of 15 minutes
- No alcoholic beverages
- NOTHING else in mouth—other fluids, mints, cigarettes, eaten
- NO Vomit, Burping, Regurgitation

NSC (CAO3) Report—Subcommittee on Alcohol Technology, Pharmacology and Toxicology
 "Acceptable Practices for Evidential Breath Alcohol Testing"
 Dubowski, Kurt M. "Quality assurance in breath-alcohol analysis." *Journal of analytical toxicology* 18.6 (1994): 306-311.






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Replicate Samples

- NSC Recommendations**
 - Conducted on at least duplicate independently exhaled end-expiratory samples
 - Results should agree with established criteria
 - Collected at interval not less than 2 minutes and not more than 10 minutes
- Typical Agreement Requirement—within 0.02% of each other**



Committee on Alcohol and Other Drugs, National Safety Council. Duplicate breath-alcohol testing. In Committee Handbook. National Safety Council, Chicago, IL, 1992. Recommendation J.
 Dubowski, Kurt M. "Quality assurance in breath-alcohol analysis." *Journal of analytical toxicology* 18.6 (1994): 306-311.

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Quality Assurance in Breath Testing

- "Quality Assurance in Breath-Alcohol Analysis"**
 - Dubowski, K. M. *Journal of analytical toxicology* 18.6 (1994): 306-311.
 - Dubowski, K. M. "Necessary scientific safeguards in breath alcohol analysis." *Journal of Forensic Sciences* 5. HS-038 257 (1960).
- Table II. Elements of a Quality Assurance Program for Forensic Breath-Alcohol Testing**
 - Comprehensive Federal- or state-level regulation of the system
 - Facilities, apparatus, and equipment
 - Personnel aspects
 - The testing process
 - Performance and proficiency testing
 - Records and reports
 - Inspections, reviews, and evaluations

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Quality Assurance in Breath Testing

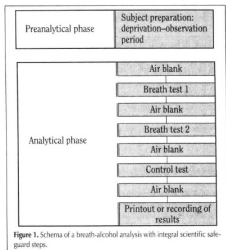


Figure 1. Schema of a breath-alcohol analysis with integral scientific safeguard steps.



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Take Home Points



- Need for Quality in Breath Alcohol Testing has existed almost as long as the first EBT was in use
- Recommendations
 - Dr. Kurt Dubowski
 - National Safety Council
 - Canadian Society for Forensic Science (Alcohol Test Committee)
- Following these recommendations for breath alcohol testing lends an even higher degree of credibility to the breath test



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Biological Sample Considerations



- Tidal Volume and End Expiratory Breath
- Sample Variability/Breathing Patterns
- Factors Affecting Blood/Breath Ratio

"With testing her husband has the picture brought out." Print Ad for WD McKeely's "breath analyzer" from Nov 1927 issue of Science and Invention magazine



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Tidal Volume and End Expiratory Breath

- Tidal Volume → Volume of air moved into or out of the lungs in one breath
- End Expiratory Breath → Deep Lung Air
- Breath Testing Instructions
- Instrument Safeguards
 - Time
 - Volume
 - Rate

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Breath Profile

Blood-alcohol concentration = 0.10 g/100 ml

VC exhalation 0.095 g/210 L

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Sample Variability/Breathing Patterns

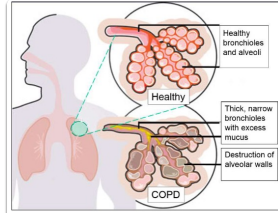
- Hyper/Hypo-Ventilation**
 - Hyper:** rapid, shallow breathing
 - Cools airways (lowers breath T)
 - Lowers BrAC (10.6 ± 1.37 %)
 - Effect goes away very quickly
 - Hypo:** holding breath (~30 seconds)
 - Greater equilibration time
 - Increases BrAC (15.7 ± 2.24 %)
 - Effect goes away very quickly
- Officer Observation**

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Sample Variability/Breathing Patterns

- COPD**
 - Chronic Obstructive Pulmonary Disease
 - Obstructed Airflow from Lungs
 - Result of long-term bronchitis or emphysema
 - Breath Alcohol Sample COPD
 - "Curve" is essentially flat
 - Decreases at end of expiration
 - Exhaled air at end of maximal expiration does not always provide a close indication of BAC



Russell, J. C. and R. L. Jones. "Breath ethyl alcohol concentration and analysis in the presence of chronic obstructive pulmonary disease." *Clinical Biochemistry* 16.3 (1983): 182-187.



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Factors Affecting Blood/Breath Ratio

- Temperature**
 - Normal **body** temp is 37 °C
 - Normal **breath** temp is 34 °C
 - For every 1 °C increase in **body** temp, ratio changes by ~6.5-7%
 - Breath Temperature Correction
 - Not an issue if Breath Instrument is reporting in g/210L and not reporting as BAC



Cowan, J. Mack, et al. "The relationship of normal body temperature, end-expired breath temperature, and BAC/BrAC ratio in 98 physically fit human test subjects." *Journal of analytical toxicology* 34.5 (2010): 238-242.

Fox, Glyn R., and John S. Hayward. "Effect of hyperthermia on breath-alcohol analysis." *Journal of forensic sciences* 34.4 (1989): 839-844.

Wignone, James G. "Up to their necks in hot water: body temperature and the BAC/BrAC ratio." *Journal of analytical toxicology* 34.9 (2010): 605-608.



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Factors Affecting Blood/Breath Ratio

- Individual Bias**
 - Gender Bias** (gender is the term used in this paper, but it should be noted that this is really biological sex)
 - Women at disadvantage
 - Smaller Lungs
 - Exhale Longer → Higher BAC
 - 5.6% greater BrAC than the males
 - Race Bias**
 - Males Same Height/Age (67in/40 yo)
 - African American 3% greater BrAC
 - Age Bias**
 - 60 yo Male vs 20 yo Male
 - Older Male 2% greater BrAC




Hlastala, Michael P., and Joseph C. Anderson. "The impact of breathing pattern and lung size on the alcohol breath test." *Annals of Biomedical Engineering* 35 (2007): 264-272.




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Take Home Points



- We can't control everything in Breath Testing
- Subject Variability
- Mitigate Other Factors with Observation and Detailed Procedures

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Challenges in Breath Testing



- Mouth Alcohol
- Specificity/Interferences
- GERD
- "Paradigm Shift"

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Mouth Alcohol

- **Residual Alcohol**
 - Not indicative of true BrAC
 - Mouthwash
 - Breath Freshening tablets
 - Blood in the Mouth
 - Inhalers
 - Airbag deployment
 - ALCOHOL
- **NOT Responsible for Residual Alcohol**
 - Dentures
 - Mouth Jewelry/Piercings



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Mouth Alcohol

Evidential Breath Testers

- Slope Detection
- Checking for Deep Lung Air

The graph plots BFAC % on the y-axis against Time (sec) on the x-axis. Two curves are shown: a blue curve labeled 'Mouth Alcohol' which rises sharply to a peak and then decays, and a green curve labeled 'Valid Breath Sample' which rises to a lower, more stable peak. A small icon of a person blowing into a device is visible in the bottom right corner of the slide.

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Mouth Alcohol

Avoidable Argument

- Proper Observation by Officer
 - Paperwork
 - Preparing instrument
 - Mouth not checked prior to observation period
 - Turned away
- Administrative Rules
 - Comply with them
 - 15-20 min observation time
 - Best to use time on instrument for ease of documentation

A close-up photograph of a person's mouth as they blow into a handheld breathalyzer device. The device is held in their right hand, and a white mist is visible coming from the mouthpiece.

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GERD

Gastroesophageal Reflux Disease

- Stomach contents move into esophagus
 - Alcohol in stomach
- Regurgitation

Rebuttals to GERD

- Observation
- Not a factor when post-absorptive
- Duplicate testing
- Instrument safeguards ("slope detector")

The diagram shows two cross-sections of the upper digestive tract. The left diagram shows the 'Sphincter closed' state, where stomach contents (blue liquid) are contained within the stomach. The right diagram shows the 'Sphincter open, allowing reflux' state, where blue liquid is shown moving from the stomach up into the esophagus.

Booker, James L, and Kathryn Renfro. "The effects of gastroesophageal reflux disease on forensic breath alcohol testing." Journal of forensic sciences 60.6 (2015): 1516-1522.
Gulberg. "Real-time breath alcohol analysis in one subject with gastroesophageal reflux disease." Journal of Forensic Sciences 45.5 (2003): 1499-1503.

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Specificity or "Interferences"

- IR Instruments Can Respond to 100s of Compounds
- Fuel Cells Can detect alcohols other than ETHANOL
- Citing NSC (CAOD Report):
 - A volatile organic compound (VOC) capable of appearing in the breath of a living, conscious human being
 - In sufficiently high concentration to be measured by the instrument after a 20min deprivation period
 - Able to produce a response on the instrument that is indistinguishable from ethanol

NSC (CAOD) Report—Subcommittee on Alcohol Technology, Pharmacology and Toxicology
"Report on the Specificity of Breath Alcohol Analyzers", 1999.

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Specificity or "Interferences"

- Diabetics (or Fasting) and Acetone
 - Acetone not detected on Fuel Cell
 - IR only instruments: <0.01% contribution from acetone to EtOH reading
- Almost all potential interferences are more toxic than EtOH
- Most have distinct odors (occupational exposure)
- IR instruments use multiple wavelengths
 - "Interfering Substance", "Interferent Detected"
- Conclusion: short half lives in breath, characteristic odors, significant toxicity

NSC (CAOD) Report—Subcommittee on Alcohol Technology, Pharmacology and Toxicology
"Report on the Specificity of Breath Alcohol Analyzers", 1999.

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Paradigm Shift – MP Hlastala, Ph.D.

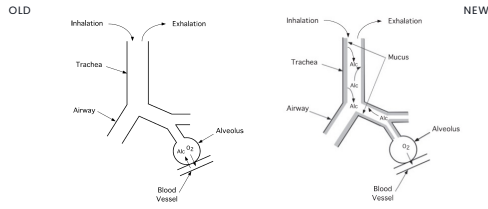
OLD Paradigm	NEW Paradigm
<ul style="list-style-type: none"> Alcohol Exchange <ul style="list-style-type: none"> Alveolus ONLY NO Exchange in the airways 	<ul style="list-style-type: none"> Inhalation <ul style="list-style-type: none"> Alcohol picked up from airway tissue Exhalation <ul style="list-style-type: none"> Alcohol redeposited on the airway tissue

Hlastala, Michael P. "Paradigm shift for the alcohol breath test." Journal of forensic sciences 55:2 (2010): 451-456.

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Paradigm Shift – MP Hlastala, Ph.D.



Hlastala, Michael P. "Paradigm shift for the alcohol breath test." *Journal of forensic sciences* 55:2 (2010): 451-456.



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Paradigm Shift – MP Hlastala, Ph.D.

Experimental Research and Mathematical Modeling

- BrAC depends on:
 - Inhaled/Exhaled volume
 - Prebreathing (hypo/hyper ventilation)
 - Rate of exhalation
 - Arterial blood concentration
 - Lung volume

Rebuttals to Paradigm Shift

- His work is highly theoretical; no empirical studies
- Cowan article (2004)-gender* (biological sex)
 - 13 year study—women did NOT produce disproportionately higher breath alcohol results compared to men

Hlastala, Michael P. "Paradigm shift for the alcohol breath test." *Journal of forensic sciences* 55:2 (2010): 451-456.
Cowan, J. Mack. "Is there a "Gender Factor"? A comparison of blood:breath differences and ratios between men and women." *Journal of the Alcohol Testing Alliance* 10 (2004).



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Take Home Points



- Follow Testing Protocols
- OBSERVE!
- Use your Resources (Toxicologists, Regional Toxicology Liaisons (RTLs), Other Experts, DA's offices, TSRPs)
- PREPARE!



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Standards in Breath Testing



- AAFS ASB
- Toxicology Consensus Body
- Breath Alcohol Documents
 - ASB 055 (Standard)
 - ASB 118 (Best Practice)
- OSAC Document
 - Breath Testing

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ASB 055—Standard for Breath Alcohol Measuring Instrument Calibration (2024)

Published 2024
[\(AAFS ASB link\)](#)

Scope:
Applicable to the calibration of breath alcohol measuring instruments for evidentiary purposes.

Does NOT cover:

- Preliminary breath testing
- Ignition interlock
- Federally-regulated testing

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ASB 055—Standard for Breath Alcohol Measuring Instrument Calibration (2024)

(4) Development of a Calibration Method

- ULOQ, ULOQ (triplicate)
- Adjust at concentration(s) that will produce a linear response
- Linearity (5 non-zero concentrations, 10 replicates)
 - $r^2 \geq 0.990$
 - All bias ± 0.005 g/210L or 5% (whichever is greater)
- Calculate Bias and Precision

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ASB 055—Standard for Breath Alcohol Measuring Instrument Calibration (2024)

(5) Elements of a Calibration Method

- Method Name
- Instrument Make/Model
- Computer System
- Reference Materials (traceable)
 - 4 non-zero calibrators is linear (6 if not)
 - 5 replicates
- Limits of Quantitation
- Reporting Range
 - Calibration Range SHALL define the reporting range
 - Cal Range: 0.010%–400%
 - Breath Result (0.420%)—instrument reports >0.400%
- Calibration Sequence
- Acceptance Criteria



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ASB 055—Standard for Breath Alcohol Measuring Instrument Calibration (2024)

(6) Validation of a Calibration Method

- When to Validate
 - New method
 - Existing method that doesn't meet this standard
 - Modifications to established method
 - Demonstrate uniformity between established and new method
- Establishing a Validation Plan
 - In place before starting any validation experiments
- Specify acceptance criteria
- Number of instruments used (min 1)
- Consider Uncertainty of Measurement
- Validation Parameters
 - Bias/Precision Calculations (within and between run)
 - Carryover
 - Reference Material Stability
 - Environmental Conditions



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ASB 055—Standard for Breath Alcohol Measuring Instrument Calibration (2024)

(8) Validation Documentation Requirements

- Retain until 10 years following method expiration
 - Validation Plan
 - Original Data
 - Summary
 - Date of Approval




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ASB 055—Standard for Breath Alcohol Measuring Instrument Calibration (2024)

(10) Performance

- When to Calibrate (10.1)
 - After a change to the computer system that affects analytical results
 - After any system component that impacts an analytical result is replaced or repaired
 - After an adjustment
 - When acceptance criteria are not met (failed calibration)
 - Prior to being used the first time for evidential testing
- Measurement Assurance (10.2)
 - Programs shall have a scheduled process for monitoring the validity of their calibration activities

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ASB 118—Best Practice Recommendation for Breath Alcohol Instrument Specifications

OSAC Draft ~2017, ASB ~2022
ASB Working Group April 2024

<p>Scope:</p> <ul style="list-style-type: none"> • Instruments used in law enforcement applications. 	<p>Does NOT cover:</p> <ul style="list-style-type: none"> • Preliminary breath testing • Ignition interlock • Federally-regulated testing 	<p>Emphasis:</p> <ul style="list-style-type: none"> • Analytical performance • quality assurance measures • Design features that can affect analytical performance
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ASB 118—Best Practice Recommendation for Breath Alcohol Instrument Specifications

Electrical Safety Standards Conformance

Environmental Operating Conditions:

- Temperature (10 - 40 °C) or (10 - 50 °C)
- Barometric Pressure (867 - 1040 mBar)
- Humidity (10 - 100%)

Reference Standards:

- Wet, Dry, Both
- Compensation for atmospheric pressure and wet/dry offset

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ASB 118—Best Practice Recommendation for Breath Alcohol Instrument Specifications

- Analytical Specifications**
 - Bias/Precision
 - Meet $\pm 5\%$ or $0.005 \text{ g}/210\text{L}$, whichever is greater
 - %CV not greater than $\pm 10\%$
 - LLOQ and Measurement Range
 - $0.02 \text{ g}/210\text{L}$ to at least $0.40 \text{ g}/210\text{L}$
- Physiological Interference**
 - Any Concentration of Acetone, Methanol and IPA
 - Max $0.01 \text{ g}/210\text{L}$ result from any interferent
 - Max variation of $0.01 \text{ g}/210\text{L}$ from known ETOH conc.
 - Detect the presence of interferent



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ASB 118—Best Practice Recommendation for Breath Alcohol Instrument Specifications

- Sample Acceptance**
 - Volume
 - Detection of alcohol in upper respiratory tract
- Quality Control**
 - Hardware/Software Integrity**
 - Unique serial number
 - Self diagnostics
 - Automated QC Test Sequences**
 - Manual or automatic QC check with reference materials
 - Capability for interval-based QC check, lockout
 - Reference material information stored as part of test record
- Security and Memory**
 - Access levels, record retention



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ASB 118—Best Practice Recommendation for Breath Alcohol Instrument Specifications

- Next Steps**
 - Adjudication
 - Internal ASB/ANSI Approval Process for Scope Change (moving from Standards to BPR)
 - Public Comment



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OSAC Breath Testing Recommendations

Scope:
Applicable to breath alcohol subject testing for evidentiary purposes.

Does NOT cover:

- Preliminary breath testing
- Ignition interlock
- Federally-regulated testing

Emphasis:
Minimum requirements for development of subject testing protocols on evidentiary instruments

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OSAC Breath Testing Recommendations

Subject Test Sequence MINIMUM

- Names (Subject and Operator)
- Date/Time of Test
- Test #
- Instrument Serial Number

Subject Test Sequence

- Deprivation Time at least 15 minutes
 - Each step separated by Blank
- Include at least ONE external standard
- Include at least TWO subject samples (2-10 min)
- Agree within ± 0.020 g/210L
- Requirements when they don't agree

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OSAC Breath Testing Recommendations

Reporting

- All raw data to 3 decimal points
- All blank, controls, sample values
- Reported Value (lower of two)—if reporting to 2 decimal points, TRUNCATE

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Standards in Breath Testing

Standards are HERE

READ and Understand

ASK Questions


COMMENT!



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Conclusions



- Blood and Breath Correlation
- PBTs and EBTs and Technology
- Breath Testing Requirements
- Biological Variations
- Challenges to the Breath Test
- Standards

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THANK YOU

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