DOT HS-805 897

BREATH-ALCOHOL TESTING: DISPOSABLE BREATH TESTER
Part 1

Kurt M. Dubowski, Ph.D.

The University of Oklahoma Health Sciences Center
Department of Medicine & Toxicology Laboratories
P.O. Box 26901
Oklahoma City, OK 73190

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FINAL REPORT

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16. Abstract

This report includes details of attempts to develop an inexpensive, disposable device for breath-alcohol screening tests which would be legally acceptable. It was found infeasible to develop such a device based on length-of-stain alcohol indicators. Silica gel and various other reagent carriers proved inadequate as nonreactive, non-channeling indicator substrates. Acid potassium dichromate solution and other alcohol reagents proved insufficiently sensitive or stable for the purpose, or did not yield adequately sharp and intensive color changes.

An innovative system was developed for generation of alcohol vapors with high accuracy and precision. Its basis is the use in tandem or series of two matched commercial 34°C breath-alcohol simulators, operated with compressed gases under controlled pressure and flow rate conditions. That system consistently produced alcohol vapor of known concentration with accuracy and precision meeting the DOT "Performance Standard for Calibrating Units for Breath Alcohol Testers" (40 FR 36167, 19 Aug 75).

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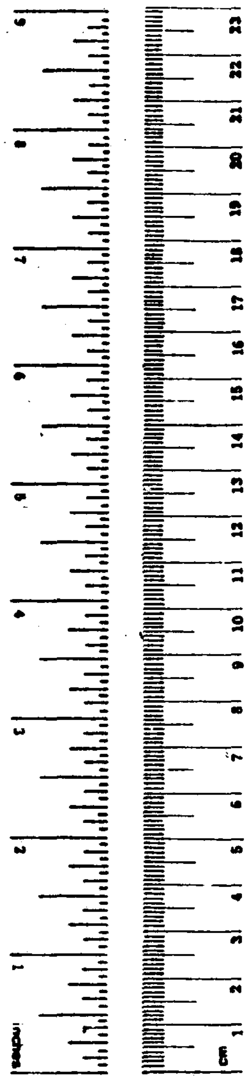
METRIC CONVERSION FACTORS

Approximate Conversions to Metric Measures

Symbol	When You Know	Multiply by	To Find	Symbol
		LENGTH		
in	inches	*2.5	centimeters	cm
ft	feet	30	centimeters	cm
yd	yards	0.9	meters	m
mi	miles	1.6	kilometers	km
		AREA		
in^2	square inches	6.5	square centimeters	cm^2
ft^2	square feet	0.09	square meters	m^2
yd^2	square yards	0.8	square meters	m^2
mi^2	square miles	2.6	square kilometers	km^2
	acres	0.4	hectares	ha
		MASS (weight)		
oz	ounces	28	grams	g
lb	pounds	0.45	kilograms	kg
	short tons (2000 lb)	0.9	tonnes	t
		VOLUME		
tsp	teaspoons	5	milliliters	ml
Tbsp	tablespoons	15	milliliters	ml
fl oz	fluid ounces	30	milliliters	ml
c	cups	0.24	liters	l
pt	pints	0.47	liters	l
qt	quarts	0.95	liters	l
gal	gallons	3.8	liters	l
ft^3	cubic feet	0.03	cubic meters	m^3
yd^3	cubic yards	0.76	cubic meters	m^3
		TEMPERATURE (exact)		
°F	Fahrenheit temperature	5/9 (after subtracting 32)	Celsius temperature	°C

*1 in = 2.54 (exactly). For other exact conversions and more detailed tables, see NBS Misc. Publ. 286, Units of Weights and Measures, Price $2.25, SD Catalog No. C13.10:286.



Approximate Conversions from Metric Measures

Symbol	When You Know	Multiply by	To Find	Symbol
		LENGTH		
mm	millimeters	0.04	inches	in
cm	centimeters	0.4	inches	in
m	meters	3.3	feet	ft
m	meters	1.1	yards	yd
km	kilometers	0.6	miles	mi
		AREA		
cm^2	square centimeters	0.16	square inches	in^2
m^2	square meters	1.2	square yards	yd^2
km^2	square kilometers	0.4	square miles	mi^2
ha	hectares (10,000 m^2)	2.5	acres	
		MASS (weight)		
g	grams	0.035	ounces	oz
kg	kilograms	2.2	pounds	lb
t	tonnes (1000 kg)	1.1	short tons	
		VOLUME		
ml	milliliters	0.03	fluid ounces	fl oz
l	liters	2.1	pints	pt
l	liters	1.06	quarts	qt
l	liters	0.26	gallons	gal
m^3	cubic meters	35	cubic feet	ft^3
m^3	cubic meters	1.3	cubic yards	yd^3
		TEMPERATURE (exact)		
°C	Celsius temperature	9/5 (then add 32)	Fahrenheit temperature	°F

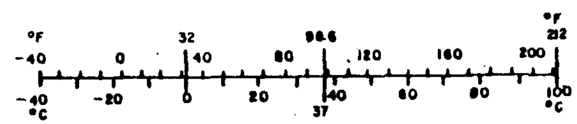


TABLE OF CONTENTS

LIST OF ILLUSTRATIONS

LIST OF TABLES

INTRODUCTION

Analysis of alcohol[1] in breath for traffic law enforcement purposes is generally classified into two categories - quantitative evidential breath-alcohol analysis, and breath-alcohol screening testing also sometimes designated "preliminary breath-alcohol testing." The latter procedures have several potential uses, such as roadside alcohol prevalence studies in motor vehicle drivers or in pedestrians, and for field (roadside) testing by police officers of suspected drinking drivers prior to or in lieu of other enforcement actions in those jurisdictions which permit use of such tests.

In 1927, Bogen (1) reported use in the United States of a simple breath-alcohol screening test to estimate the BAC of patients in a hospital emergency room. His test involved collection of mixed expired breath in a rubber football bladder, bubbling a portion of that specimen[2] through a hot sulfuric acid-potassium dichromate mixture, and estimating the alcohol content of the breath from the resultant color change by comparison with visual color standards. The first single-use device for screening tests marketed for law enforcement purposes was described in 1941. Many additional screening test devices were developed subsequently, mostly outside of the United States and always as disposable single-use units.

Following experimental evaluation of eight disposable breath-alcohol screening test devices from four manufacturers, Prouty and O'Neil (2) reported in 1971 that the tested devices were found unreliable for law enforcement use and concluded that "under no circumstances can these disposable screening devices be expected to produce results free of error."

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[1] In this report, the unmodified term *alcohol* refers to ethanol; *BrAC* refers to breath-alcohol concentration; *BAC* refers to blood-alcohol concentration

[2] In this report, the term *specimen* applies to the entire quantity of a biological material obtained for analysis, while the term *sample* applies to that portion of a specimen which is subjected to analysis.

Based on additional, separate laboratory studies of five then commercially available breath-alcohol screening test devices, Dubowski (3) concluded later that such devices as those studied "should be used only for the limited purpose of indicating presence or absence of alcohol in a breath sample," but his study findings indicated that changes in design and execution of length-of-stain alcohol indicators, together with changes in breath collection, could yield breath-alcohol tests of adequate reliability for law enforcement applications.

A solicitation issued by the U. S. Department of Transportation in July 1977 called, in part, for "development of an inexpensive, disposable device that is legally acceptable as an alcohol screening device or evidential breath tester," and specified that the contractor was to develop such a disposable breath-alcohol tester (DBT) "which will qualify at least as a screening breath tester and, if possible, also as an evidential tester according to DOT standards." Applicable standards were promulgated by the U. S. Department of Transportation in 1973 for quantitative evidential breath-alcohol devices (4), and drafts of a proposed Performance Standard for Breath Alcohol Screening Testers were circulated in January 1975 and March 1977. No final DOT standard for breath-alcohol screening test devices has been issued. Also included in the solicitation was a task involving breath-alcohol simulators, in which an apparatus or procedure for producing vapor-alcohol mixtures of known charateristics was to be developed, in lieu of use of Government-Furnished Equipment.

The activities summarized in this Final Report and relating to Phase 1 of the solicitation were planned and carried out, under contract with the National Highway Traffic Safety Administration of the U.S. Department of Transportation, by the Toxicology Laboratories of the University of Oklahoma under the direction of Kurt M. Dubowski, Ph.D., Professor of Medicine & Director of Toxicology Laboratories, as the Principal Investigator and project director.

Reduced to essentials, the objectives of this phase of the study, reported herein, were (1) to design, develop, produce, and evaluate a scheme, system, or apparatus for preparing vapor-alcohol mixtures of known alcohol content suitable for use in the development and evaluation of breath-alcohol analysis devices, (2) to design and develop an inexpensive, disposable breath-alcohol screening device (DBT) which would be legally acceptable for, at least, performance of breath-alcohol screening tests in traffic law enforcement, and (3) to evaluate and validate the DBT for its intended purpose. The first objective of this phase of the project has been sucessfully accomplished; the last two proved impossible of accomplishment within the constraints of this project.

MATERIALS AND METHODS

Apparatus, Methods, and Procedures

Reference Alcohol Analyses. Analyses for alcohol in simulator solutions and for other purposes were carried out by automated gas chromatographic head-space analysis with the Model F-45 Vapor Space Chromatograph (Perkin-Elmer Corp., Norwalk, CT 06852) as described by Dubowski (5). Results were calculated by least-squares linear regression analysis of the GC output, employing either peak height measurements of the potentiometric strip-chart recorder chromatograms or, usually, automatic integration with a Model 3380A Advanced Reporting Integrator (Hewlett-Packard Co., Palo Alto, CA 04304).

Experimental Disposable Breath Testers (DBT). The experimental versions of the length-of-stain DBT variants made and tested in this project generally consisted of an 8 x 150 mm. OD borosilicate glass tube containing various quantities of a granular carrier material treated with an alcohol-sensitive reagent between breath-permeable nonreacting barriers such as stainless steel mesh. A typical example is 30-40 mesh reagent-grade silica gel saturated with 1% w/v potassium dichromate in 50% v/v sulfuric acid, heat activated for 1 hour at 100°C, and packed in a 40 mm. alcohol detector zone, with external vibration, into an 8 x 150 mm. borosilicate glass Pasteur pipette between layers of borosilicate glass wool as retainers. Numerous other experimental variations with respect to carriers, alcohol reagent, activators, etc. were tested and are summarized under "Results and Findings." Observation was by visual means, with the unaided eye, or with binocular magnifiers of 1.5 to 3.5x magnification, or through nonmagnifying spectacle filters consisting of a variety of glass filters, including didymium. Figure 1 illustrates schematically the DBT alcohol-sensing unit.

Preparation and Delivery of Known Alcohol Mixtures. Vapor mixtures of known alcohol content were prepared by controlled-temperature equilibration of alcohol solutions with air in precision breath-alcohol simulators, which were frequently monitored by digital electronic thermometry for proper temperature maintenance. Ethanol reference solutions for equilibration with air were prepared by appropriate dilution from a 61.30 g/liter stock solution

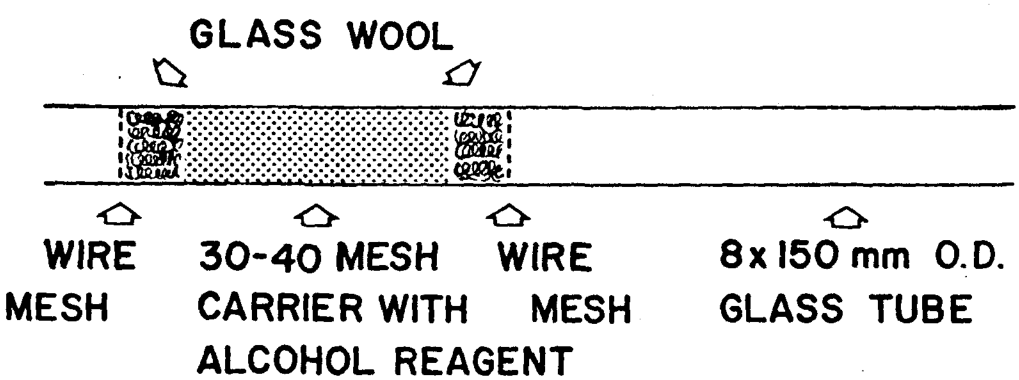

Figure 1. Scheme of a DBT Alcohol-Sensor

of ethanol[3] (See Figure 3); and 500 ml. of each dilute solution was used as the simulator charge. The alcohol content of each batch of the diluted simulator solution was verified by gas chromatographic analysis.

Precision alcohol simulators were operated in accordance with the procedure developed under Task 5 of this project. All simulators were operated with compressed gas (commercial cylinders of breathing quality air) at an air input pressure of 50 torr[4] and an exit flow rate of 10 liters/minute. The compressed gas was heated and saturated with water vapor, by passage through distilled water in a gas washing bottle maintained at 34°C, prior to entry into the simulator. Gas throughput through the simulators, per charge, was held below that which would remove 1.0% of the alcohol content of the simulator charge.

Dosing of Alcohol-Detector Tubes. A special purpose metering device (Figure 2) was designed and constructed in this laboratory to fix the volume of standard alcohol vapor delivered to each detector tube and the delivery conditions. Its key features include use of a 1-liter capacity gas syringe with continuously adjustable internal volume, maintenance of a constant temperature (34.30±0.28°C), air-pressure actuation of the syringe piston by micro switch-controlled solenoid valves, flow-rate control by needle valves, and mechanically-fixed limits to the piston excursions for reproducible-volume delivery.

The simulator-produced alcohol reference vapor (typically at a concentration of 0.476 mg/liter) was introduced into the metering device after its volume, temperature, and vapor delivery rate had been suitably adjusted. A 3-way surgical stopcock then controlled inflow, or outflow through a length-of-stain indicator tube horizontally coupled to the stopcock with silicone rubber tubing with minimal deadspace.

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[3] Equilibration of air with a 1.226 g/liter alcohol solution maintained at 34.0°C will yield a gas mixture containing 0.476 mg of alcohol per liter (6)

[4] 50 torr corresponds to 26.8 inches of H_2O and to 66.6×10^2 Pa

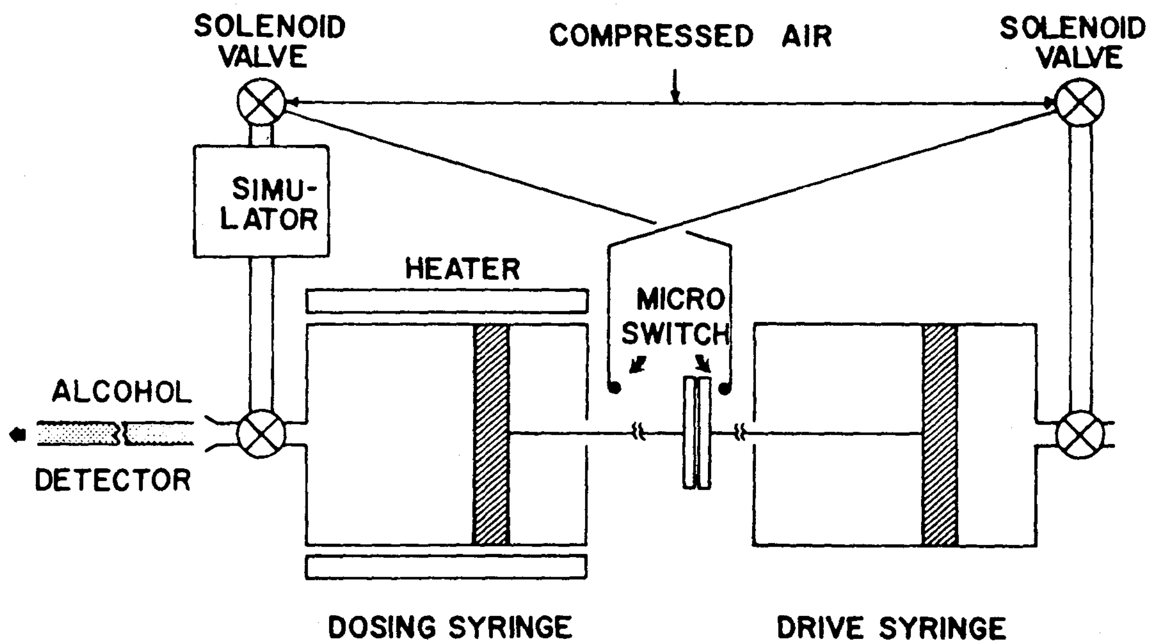

Figure 2. Scheme of Metering Device for Dosing of Breath-Alcohol Detector Tubes.

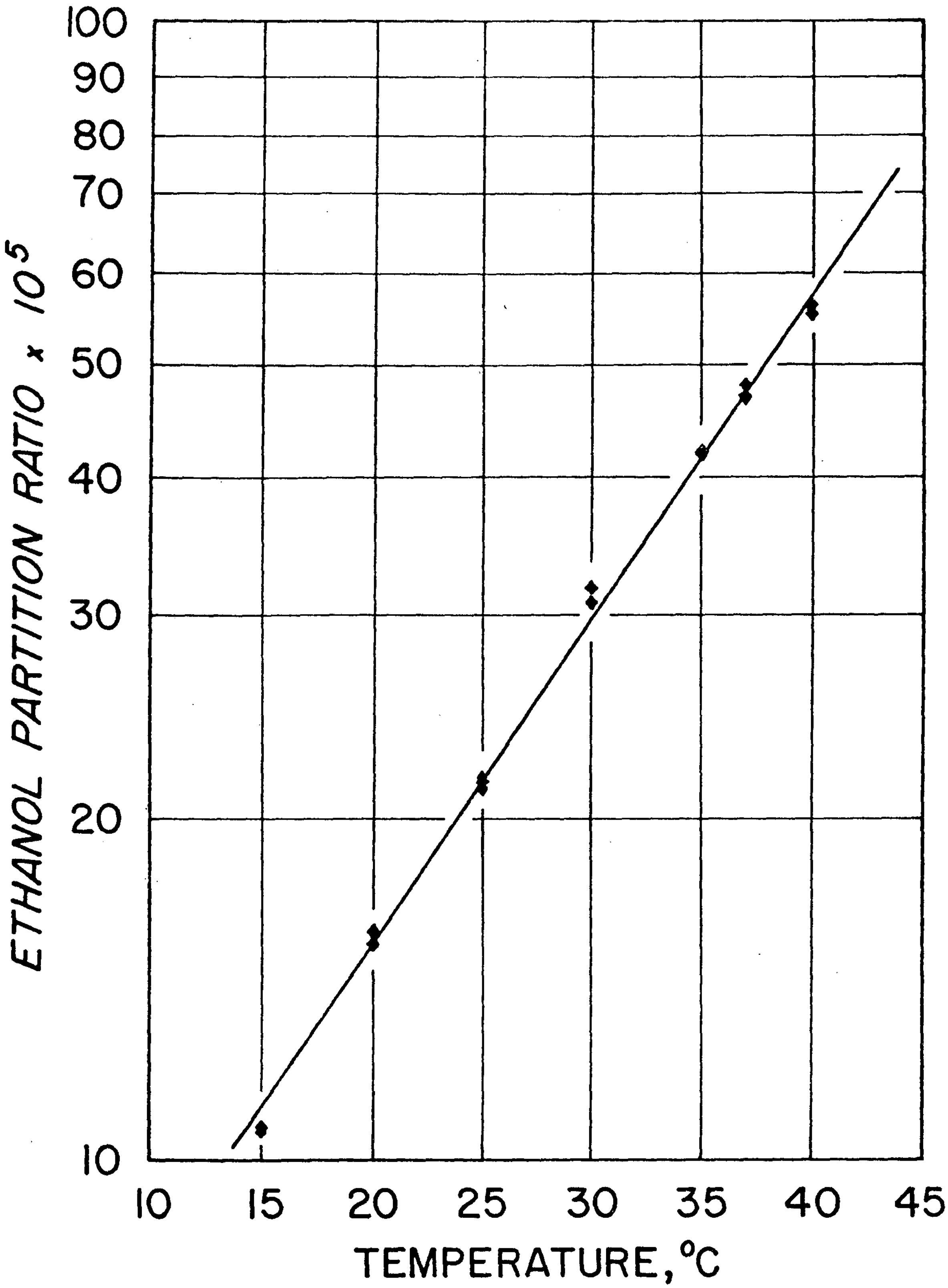

Figure 3. In-Vitro Partition Ratio of Ethanol for the Air/Water System as a Function of Temperature

A typical set of experimental conditions for alcohol-dosing of a detector tube was a delivered alcohol-vapor volume of 250 ml. at a concentration of 0.10 g/210 L, in a delivery time of 10 seconds for a mean target flow rate of 1500 ml/minute.

Human Subject Studies. These studies were conducted on healthy adult subjects (20 males and 12 females) who volunteered to participate in this study and were paid for their services. Experimental activities were carried out in full accordance with all applicable national standards for investigations involving human subjects, (7,8) and only after initial approval and periodic review and reapproval of experimental protocols and of these human subject studies by the OUHSC Institutional Review Board.

Breath pressures against a standard resistance (Model 900 Breathalyzer) were measured with a Model 2050C "Magnehelic" direct-reading differential pressure gauge (Dwyer Instruments, Inc., Michigan City, IN 46340). Breath temperatures were measured with a Heath/Schlumberger Model EU-200-41/EU-200-62 digital thermometer (Heath Co., Benton Harbor, MI 49022) and a Model 705 thermolinear thermistor probe (Yellow Springs Instrument Co., Yellow Springs, OH 45387). Breath volumes were measured with a Model 06001 9-liter water-displacement respirometer (Warren E. Collins, Inc., Braintree, MA 02184) modified by us with a Model 20013 rotary motion potentiometer (Warren E. Collins, Inc.) for direct electronic volume readout via a digital voltmeter. The characteristics of these respiratory measurement procedures have been previously reported by Dubowski (9). The time constant[5] of the Model 705 thermolinear probe (designed for air temperature measurements) is given as 600 milliseconds.

Evaluation and Validation of Precision-Simulator Systems. In lieu of use of Government Furnished Equipment in Task 5 of this project, it was necessary to develop, evaluate, and validate an alternate procedure for producing alcohol-vapor mixtures of known characteristics, which were also

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[5] Time constant, the standard measure of temperature-probe response time, is the time required for a probe to indicate 63% of a newly impressed temperature change

saturated with water vapor to simulate breath appropriately. Based on findings and experience in this laboratory with controlled-temperature equilibration techniques, and with a view toward facilitating use of our approach by others wishing to do so, we decided upon use of two matched 500 ml. commercial breath-alcohol simulators connected in tandem, operated at 34°C, and driven with compressed gas, as the candidate system for precision air/water equilibration of alcohol.

The temperature-cycling of typical commercial simulators was studied, together with other characteristics. Following establishment of standard operating conditions for precision tandem-simulator techniques, the accuracy and precision of vapor-alcohol (effluent) concentrations was studied over the range of 0.05-0.30 g/210 L, by gas chromatographic comparison with ethanol reference samples of known concentration after intervening sorption on calcium sulfate as outlined by Dubowski (10), and by analysis of effluents with a Breathalyzer Model 900-A (Smith & Wesson Electronics Co., Springfield, MA 01101), a Mark IV Gas Chromatographic Intoximeter (Intoximeters, Inc., St. Louis, MO 63103), and a Model 4011A Intoxilyzer (CMI, Inc., Minturn, CO 81645). Temperature measurements were made with a Model 5810 Digitec electronic thermistor thermometer (United Systems Corp., Dayton, OH 45403) with Model 703 linear thermistor probe (Yellow Springs Instrument Co., Yellow Springs, OH 45387), validated against an NBS No. 934 SRM clinical thermometer standard (National Bureau of Standards, Washington, DC 20234).

RESULTS AND FINDINGS

The information developed by the in-vitro and in-vivo studies in this phase of the project are reported under 3 categories encompassing related results and findings.

I. Human Subject Demographic and Respiratory Parameter Data

Demographic Data. The age and sex statistics for the volunteer human subjects who participated in this project are given in Table 1.

Respiratory Parameter Data. The individual experimental data on breath exit temperature, breath volume (both maximum expiratory, i.e., vital capacity, and normal exhalation after a normal inspiration), and breath pressures at a Breathalyzer Model 900 inlet tube distal to the mouthpiece during normal breath sampling are given in Table 2 for the subjects who participated in this project. The same table contains a statistical summary of these data for the 32 subjects. A respiratory data summary for the same experimental findings is given in Table 3.

II. Performance of Precision Tandem-Simulator System.

From the experimental partition data for alcohol between water and air, contained in seven leading studies published between 1911 and 1974 (6), Dubowski has calculated, by least-squares best-fit regression analysis of those data (N=23) the exponential equation governing the equilibrium partition of alcohol between water and air, over the range of temperature interest for equilibrators:

$$y = 0.04145e^{0.06583x} \qquad \text{(I)}$$
$$R = 0.999$$

where x = Equilibrium Temperature, $^{\circ}C$

$y = k_{a/w} \times 10^{3}$ (= Partition coefficient of alcohol for air/water $\times 10^{3}$)

R = Pearson Correlation Coefficient

TABLE 1. Demographic Data on Human Experimental Subjects

Age and Sex of Subjects

Males Age, Yrs.		Females Age, Yrs.	
01-	27	01-	32
02-	36	02-	32
03-	24	03-	26
04-	35	04-	23
05-	31	05-	26
06-	30	06-	24
07-	23	07-	36
08-	22	08-	27
09-	22	09-	32
10-	39	10-	26
11-	41	11-	24
12-	31	12-	26
13-	21		
14-	24		
15-	27		
16-	24		
17-	24		
18-	24		
19-	33		
20-	39		

	RANGE	MEAN
MALES (N=20)	21 - 41	29
FEMALES (N=12)	23 - 36	28
TOTAL (N=32)	21 - 41	28

Subject	Sex & Age		Breath Exit Temp. °C	Breath Expiratory Volume, ml. Vital Capacity	Breath Expiratory Volume, ml. Normal Exhalation	Breath Pressure (Breathalyzer) inches H_2O
1	M	27	34.50	5048	3852	16
2	M	36	34.57	4622	2205	21
3	M	24	35.18	5217	2720	15
4	M	35	34.82	4040	2223	22
5	M	31	35.09	5036	2167	12
6	M	30	34.17	4731	1758	38
7	F	32	34.95	4130	2692	7
8	M	23	35.07	5316	3131	23
9	F	32	34.54	3311	2815	9
10	M	22	34.88	3953	2813	17
11	F	26	33.81	3961	3575	17
12	F	23	35.07	3088	2016	9
13	M	22	34.50	4696	2475	23
14	M	39	33.98	3974	2554	17
15	F	26	35.11	2656	1579	14
16	F	24	34.55	3763	1243	10
17	M	41	34.01	4196	2566	38
18	F	36	34.23	3240	1612	21
19	F	27	33.75	2751	1425	15
20	M	31	34.32	4717	3311	23
21	M	21	34.50	5210	3230	25
22	M	24	34.80	5848	2729	18
23	F	32	35.77	3429	2348	8
24	F	26	34.92	2420	1786	10
25	M	27	34.66	4923	2432	14
26	M	24	35.06	5000	2836	21
27	M	24	34.67	3982	1830	12
28	M	24	34.28	4406	3340	14
29	F	24	33.96	4935	3210	14
30	M	33	34.85	3866	2568	17
31	F	26	34.82	3778	3326	10
32	M	39	33.72	3841	2240	15
Mean		28.5	34.60	4190	2519	17.0
S.D.		±5.6	±0.48	±846.3	±657.4	±7.4
C.V.		19.7%	1.4%	20.2%	26.1%	43.5%
Range		21-41	33.72-35.77	2420-5848	1243-3852	7-38

TABLE 3. Respiratory Data Summary for Human Experimental Subjects

End-Expiratory Breath Temperatures in Human Subjects, Measured at the Mouth

Subjects	N	End-Expiratory Temperature, °C Range	Mean	SD	CV
Men	20	33.72-35.18	34.89	±0.40	1.15%
Women	12	33.75-35.77	34.62	±0.60	1.73%
Total	32	32.72-35.77	34.60	±0.48	1.39%

Expiratory Breath Volumes in Human Subjects - Forced Vital Capacity

Subjects	N	Forced Vital Capacity, ml. Range	Mean	SD	CV
Men	20	3841-5848	4631	±577	12.5%
Women	12	2420-4935	3455	±708	20.5%
Total	32	2420-5848	4190	±846	20.2%

Maximum Expiratory Breath Volumes in Human Subjects after Normal Inhalation

Subjects	N	Maximum Exhalation Volume, ml. Range	Mean	SD	CV
Men	20	1758-3852	2649	±531	20.0%
Women	12	1243-3575	2302	±806	35.0%
Total	32	1243-3852	2519	±657	26.1%

Breath Pressures in Human Subjects Into a Model 900 Breathalyzer

Subjects	N	Breath Pressure, inches H_2O Range	Mean	SD	CV
Men	20	12-38	20.1	±7.3	36.3%
Women	12	7-21	12.0	±4.2	35.0%
Total	32	7-38	17.0	±7.4	43.5%

At 34°C, $k_{a/w} \times 10^3$ = 0.38866, whence it follows that air equilibrated at 34°C with a 1.226 g/L alcohol solution will contain 0.4765 mg alcohol/liter of air or 0.10 g/210 L. The data and the regression line corresponding to Equation I above are shown in Figure 3.

Temperature Measurements on Commercial Simulators. The results of random temperature measurements at 0, 15, 30, 60 and 120 minutes on alcohol solutions contained in 16 different commercial simulators during quiescent operation (i.e., without effluent discharge) are given in Table 4. The simulators remained undisturbed at 24°C room temperature between measurements.

Static temperature measurements on a typical Model 6000 (Stephenson Co.) 34°C simulator, made at consecutive one-minute intervals for 100 minutes, yielded: Mean = 34.16°C, SD = ±0.095°C, CV = 0.28%, Range = 34.01-34.33°C. A histogram of these data, with normal curve overlay, is given in Figure 4.

Accuracy and Precision of Alcohol Content of Simulator Effluents. For simulators used in tandem (i.e., two matched simulators connected in series) and operated at 34°C as described on p. 10, the results of accuracy and precision studies of the alcohol content of the effluent vapor are given in Tables 5-8. Table 5 contains such results at target concentrations of 0.05-0.30 g/210 L in 0.05 steps, obtained by gas chromatographic analysis of simulator effluents, after intervening $CaSO_4$ storage, while Tables 6, 7, and 8 give results obtained by analysis with the Breathalyzer, Gas Chromatographic Intoximeter, and Intoxilyzer, respectively.

The effectiveness of using 2 tandem simulators for stabilizing the alcohol content of the effluent, and improving the accuracy and precision of its alcohol concentration, is illustrated in Table 9 for measurements by automated gas chromatographic analysis with intervening sorption of alcohol on calcium sulfate for several vapor alcohol concentrations.

III. Experience with Experimental "Disposable Breath Testers"

Performance of Alcohol-Delivery System. Two key characteristics of the alcohol-dosing system described on p. 10 and employed for testing the

TABLE 4. Random Temperature Measurements on Commercial Simulators

		Observed Temperature °C at					
Simulator	Mfr. & Model	0 min.	15 min.	30 min.	60 min.	120 min.	Max. Dx
1	S&W MKIIA	34.03	34.17	34.16	34.14	32.12	0.18
2	S&W MKIIA	34.02	34.09	34.13	34.01	34.02	0.12
3	S&W MKIIA	34.11	34.17	34.15	34.25	35.24	0.14
4	S&W MKIIA	34.10	34.11	34.16	34.16	34.19	0.09
5	S&W MKIIA	34.04	34.18	34.19	34.19	34.19	0.15
6	S&W MKIIA	34.00	33.91	33.93	34.07	34.06	0.16
7	S&W MKII	34.17	34.29	34.30	34.21	34.16	0.14
8	S&W MKII	34.14	34.26	34.14	34.18	34.24	0.12
9	S&W MKII	34.28	34.17	34.13	34.26	34.18	0.15
10	S&W MKII	34.23	34.23	34.23	34.20	34.11	0.12
11	Stephenson SK-2	34.05	34.02	34.08	34.01	34.07	0.07
12	Stephenson 6000	33.78	33.86	33.98	34.05	33.91	0.27
13	Stephenson 6000	34.19	33.97	34.07	34.13	34.05	0.22
14	Stephenson 6000	34.11	33.86	34.03	33.98	34.07	0.25
15	Stephenson 6000	36.95	37.16	37.07	37.19	37.05	0.24
16	Luckey LS40	34.18	34.14	34.07	33.95	34.06	0.23

Note: [1] Simulator temperature specifications are 34±0.20°C except for No. 15 which is 37±0.20°C

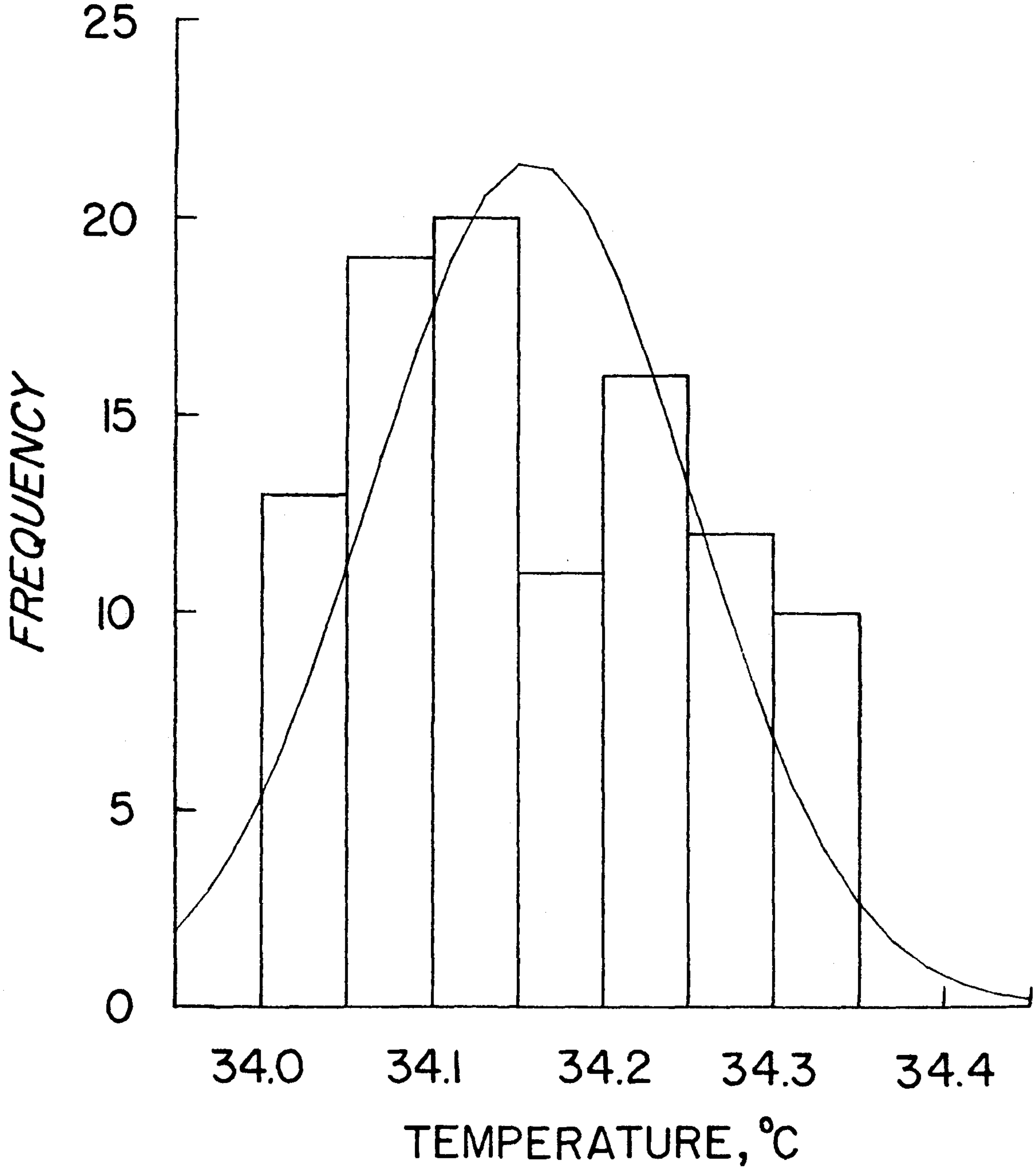

Figure 4. Frequency Distribution of 101 Consecutive Static Temperature Measurements of a 34°C Simulator, at 1-Minute Intervals, with Normal Curve Overlay

TABLE 5. Measurement of Alcohol in Vapor-Phase Simulator Effluents[1]

Accuracy and Precision by GC Measurement with Intervening $CaSO_4$ Sorption

Target Value g/210 L	N	Simulator Effluent Alcohol Concentration				
		Mean, g/210 L	SD, g/210 L	CV, %	Range, g/210 L	Systematic Error, %
0.05	25	0.050	±0.0008	1.58	0.049-0.052	0
0.10	22	0.100	±0.0011	1.12	0.099-0.102	0
0.15	22	0.149	±0.0026	1.74	0.143-0.155	-0.7
0.20	25	0.200	±0.0021	1.07	0.194-0.203	0
0.25	22	0.254	±0.0043	1.69	0.248-0.261	+1.6
0.30	22	0.304	±0.0036	1.18	0.297-0.310	+1.3

Note: [1]Effluent from 2 Tandem 34°C Simulators

TABLE 6. Measurement of Alcohol in Vapor-Phase Simulator Effluents[1]

Accuracy and Precision by Measurement with Model 900-A Breathalyzer

Target Value g/210 L	N	Simulator Effluent Alcohol Concentration				
		Mean, g/210 L	SD, g/210 L	CV, %	Range, g/210 L	Systematic Error, %
0.10	20	0.099	±0.0015	1.50	0.096-0.102	-1.0
0.10	20	0.101	±0.0015	1.50	0.098-0.103	+1.0

Note: [1] Effluent from 2 Tandem 34°C Simulators

TABLE 7. Measurement of Alcohol in Vapor-Phase Simulator Effluents[1]

Accuracy and Precision by Measurement with Mark IV Gas Chromatographic Intoximeter

Target Value g/210 L	N	Simulator Effluent Alcohol Concentration				
		Mean, g/210 L	SD, g/210 L	CV, %	Range, g/210 L	Systematic Error, %
0.10	36	0.0999	±0.0013	1.30	0.097-0.102	-0.1

Note: [1] Effluent from 2 Tandem 34°C Simulators

TABLE 8. Measurement of Alcohol in Vapor-Phase Simulator Effluents[1]

Accuracy and Precision by Measurement with Model 4011 Intoxilyzer

Target Value g/210 L	N	Simulator Effluent Alcohol Concentration				
		Mean, g/210 L	SD, g/210 L	CV, %	Range, g/210 L	Systematic Error, %
0.05	25	0.044	±0.0010	2.34	0.042-0.045	+12.0
0.10	25	0.101	±0.0016	1.53	0.099-0.104	+ 1.0
0.15	25	0.152	±0.0013	0.85	0.148-0.154	+ 1.3
0.20	25	0.201	±0.0035	1.73	0.194-0.208	+ 0.5
0.25	25	0.252	±0.0019	0.76	0.248-0.255	+ 0.8
0.30	25	0.303	±0.0018	0.60	0.300-0.306	+ 1.0

Note: [1] Effluent from 2 Tandem 34°C Simulators

TABLE 9. Effect of Using Single vs. Tandem Simulators on Accuracy and Precision of Alcohol Content of Effluents Measured by Gas Chromatography with Intervening $CaSO_4$ Sorption

Technique	Target Value g/210 L	N	Simulator Effluent Alcohol Concentration				
			Mean, g/210 L	SD, g/210 L	CV, %	Range, g/210 L	Systematic Error, %
Single Simulator	0.05	12	0.049	±0.0013	2.73	0.047-0.050	-2.0
	0.10	16	0.098	±0.0027	2.82	0.094-0.104	-2.0
	0.20	10	0.194	±0.0066	3.41	0.186-0.202	-3.0
Tandem Simulators	0.05	25	0.050	±0.0008	1.58	0.049-0.052	0
	0.10	25	0.100	±0.0013	1.33	0.098-0.102	0
	0.20	25	0.200	±0.0021	1.07	0.194-0.203	0

various experimental DBT alcohol-sensors prepared in this phase of the project are shown in Table 10, namely, precision of the volume delivered by the metering device, and accuracy and precision of the alcohol concentration of the test vapors prepared by use of tandem simulators and delivered by the dosing system.

Attempted Variants of DBT Length-of-Stain Alcohol-Sensors. In lieu of tabulation of quantitative results with various length-of-stain alcohol detection tubes, none of which proved satisfactory in our experiments, Table 11 lists the principal variants tried for the reagent carrier and alcohol reagent components of the detector tubes, and problems encountered.

While that situation is probably acceptable for the original purpose of the simulator implied by its name, i.e., as a training aid for breath-alcohol analysis, it is not acceptable for calibration, some control, and most research and development applications. The improvements effected in predictability and stability of the alcohol concentration of simulator effluents used in accordance with our procedures, therefore, have wide utility and broad importance.

The overall improvement in simulator performance by tandem-operation, compared with single simulator use, is illustrated in Table 9. The tandem simulators alcohol-output data show that the effluent alcohol concentrations thus produced meet and exceed all applicable portions of the U. S. Department of Transportation "Performance Standard for Calibrating Units for Breath Alcohol Testers" promulgated in 1975 (13). In part, the Standard requires, as respective measures of accuracy and precision, that the systematic error of a calibrating unit shall not exceed ±2% at any given apparent alcohol concentration and that the relative standard deviation (i.e., the statistical value designated in this report as "coefficient of variation" or "C.V.") not exceed 2% at any given apparent concentration. These accuracy and precision requirements are fully satisfied by tandem-simulator use, as documented in Tables 5, 6, 7, 8, and 9.

The DOT calibrating units standard is not met, in our experience, by commercial simulators used singly, as shown in Table 9.

Disposable Single-Use Breath-Alcohol Testers (DBT).

As summarized in Table 11, none of the experimental variants of the alcohol-sensor portion of the DBT proved satisfactory or adequate. The problems encountered were, in our view, not attributable to the alcohol-dosing scheme employed; its adequacy is documented in Table 10. In brief, the inadequacies encountered were 1) lack of adequate sensitivity to the low alcohol quantities expectable in breath volumes of 250 ml. maximally, 2) deterioration of the alcohol reagent during storage prior to use, 3) uncontrolled channeling, inadequate demarkation of color change, and color diffusion, and 4) assorted other difficulties in preparation and in-vitro use of the various alcohol-sensors. Attempts to separate water vapor from the alcohol content of vapor samples were also unsuccessful.

In substantial measure, the failure to develop a DBT deemed adequate and acceptable by us rests upon the requirement imposed by the solicitation that the attempt be made to develop "an inexpensive, disposable device that is legally acceptable as an alcohol screening device or evidential breath tester." Two further requirements are implied by the Questions 3 and 4 posed in the solicitation (Cf. p. 39 of this report), namely that the DBT be usable by police and/or public with only minimal training, and be capable of manufacture, at low cost, on a large scale with existing technology. In our opinion, those various specifications and requirements cannot be fulfilled, given current cost and economic factors and recent and current statutory and case law experience with chemical tests for alcoholic influence evidence.

The principal intended applications of the DBT were to be pre-arrest screening of breath-alcohol by police officers in the field, and field verification of the breath-alcohol concentration in alcohol-related arrests. In both applications, it is evident that substantial errors in results yielded by the DBT are intolerable. False positive BrAC indications or falsely-high BrAC results are unacceptable under constitutional due process and other legal doctrines since they would lead to false arrests and not be sustained as "probable cause" and "reasonable grounds" elements by later quantitative evidential breath-alcohol analysis results under the implied consent law. False negative or falsely-low BrAC results would defeat the purpose of DBT use by causing lack of or inappropriate enforcement action and thus inadequate protection of the public interest. Length-of-stain alcohol sensors were unequal to the demands imposed by these factors, especially when the potential lack of specificity, in response to ethanol only, is also considered. The chemical limitations and problems added to the inherent biological limitations and variability associated with certain aspects of breath-alcohol analysis (9, 11) could not be overcome in this project.

CONCLUSIONS

Based on the experience, data, and findings of Phase 1 of this study, we have reached the following conclusions:

1) Improvements devised by us in commercial breath-alcohol simulators, and in their use in tandem and under otherwise controlled conditions, made it readily possible to produce vapor-alcohol specimens of known alcohol content meeting the applicable accuracy and precision requirements of the U. S. Department of Transportation "Performance Standard for Calibrating Units for Breath Alcohol Testers" (13).

2) The nature and details of these improvements in design and operation of commercial simulators are such as to make it feasible and practical for the field at large to utilize them.

3) Development of an inexpensive Disposable Breath-Alcohol Tester (DBT) for screening test purposes capable of meeting the U. S. Department of Transportation quantitative evidential device standards incorporated in the "Standard for Devices to Measure Breath Alcohol" (4) is deemed to be infeasible.

4) Development of an inexpensive DBT for screening test purposes which would prove legally acceptable is also deemed to be infeasible.

RECOMMENDATIONS FOR FUTURE IMPROVEMENT

Based on experience in this project and the above conclusions, it does not appear likely that an inexpensive, disposable, single-use and legally acceptable breath-alcohol device for screening test purposes will be developed spontaneously or soon. Should it become desirable to pursue further development efforts for such a device because of widespread adoption of pre-arrest screening-test laws, we suggest that the following factors be considered.

An ideal DBT for screening test purposes in traffic law enforcement should have the following characteristics:

- Be capable of use by persons with no prior training in its use
- Be simple in concept, manufacture, and use
- Be cheap to produce and use
- Yield an unequivocal, totally valid result under all conditions of use
- Produce a result rapidly or instantaneously and retain it permanently
- Require minimal subject cooperation.

Certain limitations and constraints for use of DBTs should be recognized:

- DBTs are used by police officers and others with very limited or no training in their use, and are used so infrequently that experience and practice-derived skill is not a factor
- Testing is carried out in the field, under varying and often adverse circumstances (e.g., commonly at night with little, if any, illumination and under widely varying weather conditions)
- The tests are performed on uncooperative or minimally cooperative subjects who will receive no instruction in the testing procedure
- Infrequent use means long storage under adverse conditions before the need to use without prior notice.

Some obvious and some subtle technical requirements for such devices arise out of the above circumstances and/or the basic problems attending breath-alcohol analyses:

- Provision must be made for obviating, or overcoming the effects of, water vapor condensation from breath, especially in cold weather
- Unequivocal, preferably direct, readout not depending on operator skill, judgment, or manipulation is required - perhaps under dim artificial illumination
- Long-term stability in storage is important, as are safety in use (absence of hazards), and low unit cost
- Ability to discriminate between closely-adjacent BrACs is required, especially at lower and upper bounds
- Reasonable stability of the final result indication is necessary, and that indication should not depend upon a critical time element.

For practical reasons, the result indication should preferably be an "all-or-none" type; i.e., the DBT should simply indicate by an unequivocal indication such as sudden appearance of a highly visible effect whether the BrAC of the tested subject is above or below a fixed threshold value, such as 0.05 g/210 L. Quantitation beyond such a binary above-or-below indication is, in our view, contraindicated.

Because the DBT is to be disposable, it is unlikely that a cheap momentary-exposure system not requiring breath sampling per se can be developed for it. The remaining alternative is a DBT which encompasses a scheme for collecting (and perhaps briefly storing) a suitable breath specimen and a scheme for detecting and indicating the concentration of ethanol in such a specimen. The desired breath specimen is end-expiratory air (which is functionally equivalent to expired alveolar breath). The alcohol concentration of greatest interest is 0.05 g/210 liters of breath, with the additional capability of indicating complete absence of alcohol desirable.

It seems probable that large-scale use of breath-alcohol screening tests would make it economically feasible to develop and market a re-usable electronic screening test device analogous to individual radio transceivers used by police. If a chemical DBT is to be pursued instead, we suggest that the most likely avenue for future success is to abandon the total disposability requirement for the screening test, and instead to aim for a unit consisting of two components:

1) A permanent, flashlight-like, heated "Sampler" apparatus for breath sampling, momentary breath-storage, and mechanically-assisted breath-sample delivery via spring action or electric pumping. Electrical power, if required, should be provided by internal rechargeable batteries.

2) A disposable, single use, chemical alcohol "Indicator" which can be inserted into the sensor port of the Sampler, and which will indicate the presence of a greater alcohol concentration than a specified threshold value in the breath by a quick unequivocal signal such as appearance of a black marker in a previously colorless or white area.

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