A STUDY OF CHARACTERISTICS OF A RELIABLE AND PRACTICAL BREATH ALCOHOL SCREENING TEST: PART A

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INTRODUCTION

Analysis of alcohol[1] in breath for traffic law enforcement and related purposes is conveniently classified into two major categories - quantitative evidential breath-alcohol analysis, and breath-alcohol screening tests also sometimes designated "preliminary breath-alcohol tests." The latter have many potential uses, such as for roadside alcohol prevalence studies in motor vehicle drivers or pedestrians and for field (roadside) testing by police officers of suspected drinking drivers prior to or in lieu of more formal enforcement action.

In this country, Bogen (1) was the first, in 1927, to utilize a simple breath-alcohol screening test for estimating the coexisting BAC of patients in a hospital emergency room, collecting mixed expired breath in a rubber football-bladder, bubbling a portion of the specimen through a hot sulfuric acid-potassium dichromate mixture, and estimating the alcohol content from the resultant color change by comparison with visual standards. The first screening test device commercially marketed for law enforcement purposes was the Portable Intoximeter, described in 1941 by Jetter et al. (2), which incorporated into a basic remote breath-collection unit a screening test dependent upon the time interval for decolorization of a purple sulfuric acid-potassium permanganate reagent by passage of mixed expired breath at a fixed flow rate.

Following an experimental evaluation of eight disposable breath-alcohol screening devices from four manufacturers, Prouty and O'Neill (3) reported that "this study indicated poor results for most of these disposable screening devices. Under field conditions the results may be expected to be even worse, since this study was conducted under ideal conditions, without many of the problems expected in the field; for example, poor lighting."

A disposable breath-alcohol screening test device can be visualized as a

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

simple system composed of (1) an alcohol sensor + (2) a breath collection/
storage/measuring unit + (3) a device to couple the foregoing two units.
The breath sampling and alcohol indicating/quantitating units are the crit-
ical components, and both must be capable of functioning acceptably in or-
der for the screening test device to be capable of performing its intended
task properly.

Beginning with the Portable Intoximeter, breath-alcohol screening tests for
several decades took the form of simple, disposable, single-use devices,
most commonly of the length-of-stain indicator type. During the past sev-
eral years, portable reusable self-contained instruments have also been
developed for breath-alcohol screening tests. Both types share a common
requirement for proper and appropriate breath sampling if the results are
to be valid. Since the traditionally-desired result of a breath-alcohol
screening test is an indication of the coexisting *blood*-alcohol concentra-
tions, if any, of the tested subject, it follows that only breath specimens
with a predetermined fixed alcohol-content relation to that of circulating
pulmonary blood can be considered suitable for this purpose. Mixed expired
breath, because of its widely variable proportion of expired alveolar air,
is not a suitable specimen for breath-alcohol analysis. It has, however,
commonly been employed in screening tests; e.g., six of the eight screening
test devices studied by Prouty and O'Neill (3) employed mixed expired breath.

The alcohol detector portion of the screening test is also an obvious poten-
tial source of inadequacy in disposable screening test devices. The length-
of-stain device has been the most commonly employed type in recent years. A
length-of-stain detector tube packed with silica particles coated with anhy-
drous chromic acid serves as the alcohol indicator in the quantitative breath-
alcohol analysis apparatus developed by Kitagawa and Wright (4), which util-
izes expired alveolar breath as the specimen. Paired analyses of alcohol in
postabsorptive blood specimens and in near-simultaneous expired alveolar
breath specimens (with the Kitagawa-Wright instrument) yielded high correlation
(r=0.997), and the standard deviation of individual readings with the Kitagawa-
Wright instrument was not significantly greater (8.37 mg/dl. vs. 7.57 mg/dl.)
than that for breath-alcohol analysis by means of a Breathalyzer (5).

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It thus appeared that length-of-stain type alcohol detectors could be made to perform adequately for screening test purposes, and that improper or inadequate breath sampling might be a more significant factor in the inadequate screening test performance documented by Prouty and O'Neill (3). It had, of course, been long known and fully documented that quantitative evidential analysis of properly selected and collected breath specimens can consistently yield BrAC results closely correlated with BAC values obtained by direct analysis of near-simultaneous blood specimens (6, 12).

Accordingly, this project was planned and executed to investigate this problem. Reduced to essentials, the objectives of this study were (1) to investigate several commercially available breath-alcohol screening test devices of the length-of-stain type, under standardized laboratory conditions, with respect to their ability satisfactorily to detect and quantitate alcohol in vapor specimens; (2) to investigate the several breath parameters, e.g., temperature, volume, pressure, flow rate, which potentially affect the reliability and validity of breath-alcohol screening tests, and (3) to evaluate these findings with respect to their bearing upon breath-alcohol screening tests.

Information concerning various types of breath-alcohol screening test devices is widely available (3,6). Figure 1 is a composite schematic representation of typical commercial screening test devices employing disposable length-of-stain alcohol indicator tubes, as studied in this project.
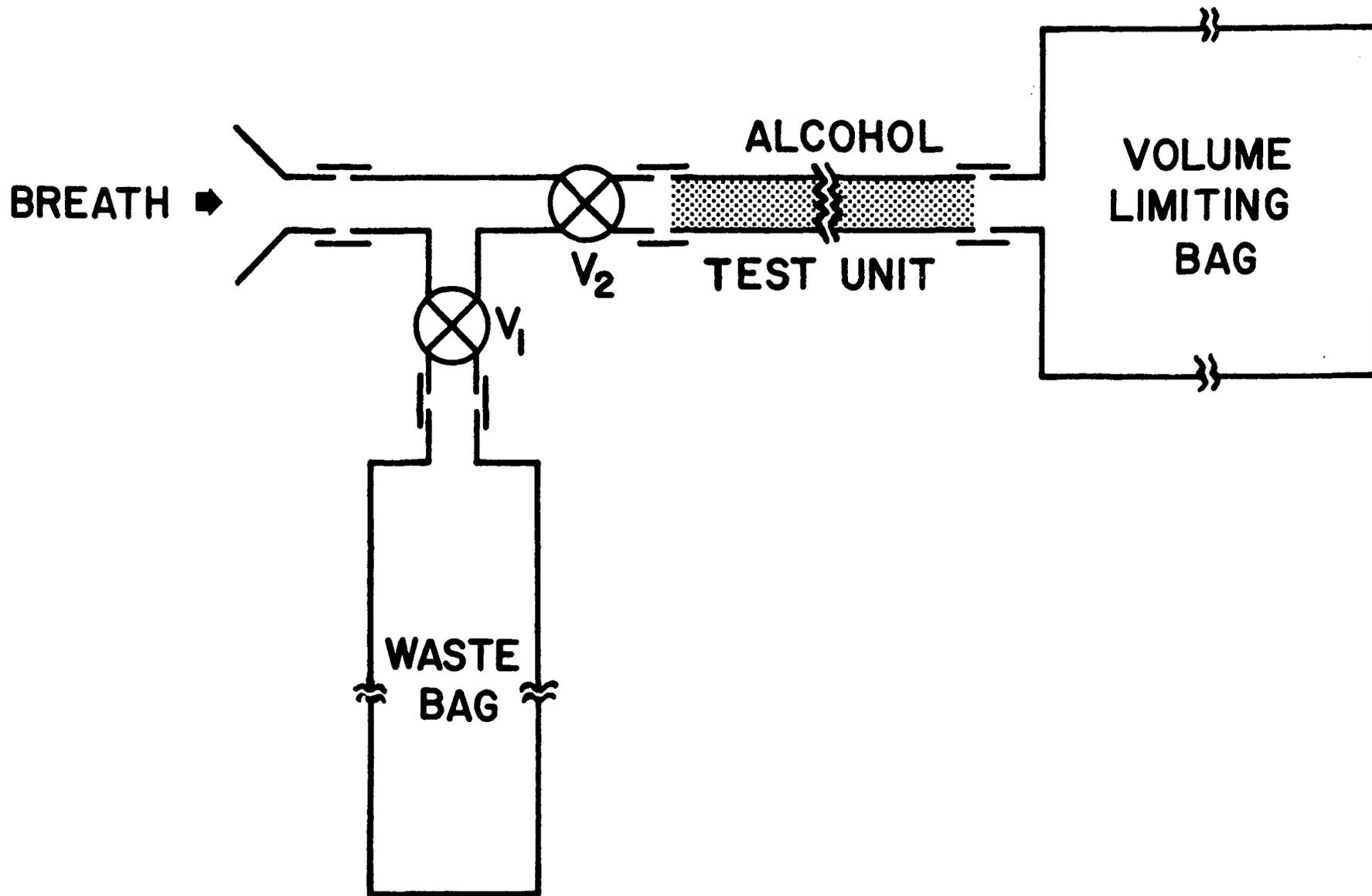
BREATH ➡

Figure 1.   Composite Scheme of a Breath-Alcohol Screening Device.   Not All Commercial Devices Employ a Waste Bag and/or Volume-Limiting Bag.

METHODOLOGY

A. Apparatus, Methods, and Procedures for Alcohol Detector Study

Alcohol Detectors

The following breath-alcohol screening test devices were procured[2] through regular commercial channels:

(1) ALCOLYSER PST (0.10%), Batch No. 1062, Mfr. Lion Laboratories Ltd., Cardiff, Wales, Great Britain, (Intoximeters, Inc., 1901 Locust St., St. Louis, Mo. 63103).

(2) ALCOTEST, Code No. CH-223, Lot No. 104311, Mfr. Drägerwerk Lübeck, 24 Lübeck, Germany, (National Mine Service Co., 3000 Koppers Bldg., Pittsburgh, Pa. 19219).

(3) ALVEOLAR AIR BREATH ALCOHOL SYSTEM, Cat. No. 6090, Lot Control No. 4, Mfr. Becton-Dickinson Div. of Becton, Dickinson and Co., Rutherford, N. J. 07070, (George F. Cake Co., 1162 Security Drive, Dallas Tx. 75247).

(4) ALVEOLAR AIR BREATH ALCOHOL SYSTEM, Cat. No. 6077, Lot Control No. B664232(216) (detector tube only), Mfr. Becton-Dickinson Div. of Becton, Dickinson and Co., Rutherford, N.J. 07070, (Becton-Dickinson, Rutherford, N.J. 07070).

(5) MOBAT SOBER-METER, Model SM-1, Mfr. Luckey Laboratories, Inc., San Bernadino, Calif. 92404, (Luckey Laboratories, Inc., 7252 Osbun Rd., San Bernadino, Calif. 92404).

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[2] Repeated attempts to procure the following breath-alcohol screening test devices and/or detector tubes were unsuccessful:

(1) ALCOLOR BREATHMETER, Mfr. Cotswold Chemical Co. Ltd., Cheltenham, England.

(2) KITAGAWA DRUNKOTESTER, Mfr. Komyo Chemical Industrial Co. Ltd., Meguro, Tokyo, Japan.

(3) KITAGAWA-WRIGHT BREATH-ANALYZER (HERMES), Type 88, Mfr. Minerva Detector Co. Ltd., Twickenham, Middx., England.

(4) STOELTING-KITAGAWA DRUNK-O-TESTER, Cat. No. 57311, Mfr. Komyo Chemical Industrial Co. Ltd., Meguro, Tokyo, Japan, Dstr. C. H. Stoelting Co., Chicago, Ill. 60624.

Apparatus (Major Items)

(1) Breath-Alcohol Simulators

    (a) Luckey Simulator, 34°C, Model LS40, Mfr. Luckey Laboratories, Inc., San Bernadino, Calif. 92404.

    (b) Alcoholic Breath Simulator, 34°C, Part No. 6000 and Model Mark II, Mfr. Stephenson Div. of Bangor-Punta, Red Bank, N.J. 07701.

(2) Digital Electronic Thermometer, Heath-Schlumberger Model EU-200-41/ EU-200-62, Mfr. Heath Co., Benton Harbor, Mich. 49022; with Models No. 703 and 731 Thermolinear Probes, Mfr. Yellow Springs Instrument Co., Yellow Springs, Ohio 45387.

(3) Gas Chromatographs

    (a) Automated Headspace Gas Chromatograph, Multifract, Model F-40, Mfr. Bodenseewerk Perkin-Elmer & Co. GmBH, D-777 Überlingen, Germany (Perkin-Elmer Corp., Main Ave., Norwalk, Conn. 06856).

    (b) Moduline Research Gas Chromatograph, Model 1860-3, Mfr. Varian Aerograph, Walnut Creek, Calif. 94598.

(4) Gas Syringe, Model S-1000, 1.0 Liter, Mfr. Hamilton Co., Reno, Nev. 89510.

Methods and Procedures

Preparation and Delivery of Known Ethanol-in-Gas Mixtures

Vapor mixtures of known alcohol content[3] were prepared by controlled-temperature equilibration in commercial breath-alcohol simulators which were frequently monitored by digital electronic thermometry for proper

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[3] Reference gas mixtures of known alcohol content prepared to our specifications were procured in pressurized steel cylinders from two commercial sources. These anhydrous ethanol mixtures could not be used for testing of dichromate length-of-stain type alcohol detector tubes since the absence of water vapor (normally present in breath) prevented reproducible occurrence of the typical breath-alcohol reaction.

temperature maintenance. Ethanol reference solutions for equilibration with air were prepared by appropriate dilution from a 60.46 g./liter stock solution of ethanol[4] (See Figure 2); and 500 ml. of each dilute solution was used as the simulator charge. The alcohol concentration of each batch of the diluted simulator solution was verified by gas chromatographic analysis.

Simulators were operated with compressed gas (commercial cylinders of $N_2:O_2$ 79:21 by volume) at air input pressure of 50 torr[5] and an exit flow rate of 10 liters/minute, since these conditions were found to be typical for simulator operation with human breath. 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[4].

Dosing of Alcohol-Detector Tubes

For orientation purposes, a composite scheme of a breath-alcohol screening test device is shown in Figure 1.

For those screening tests utilizing a breath collecting or volume-limiting plastic bag (ALCOLYSER, ALCOTEST, B-D ALVEOLAR AIR BREATH ALCOHOL SYSTEM), breath sample volumes required by the factory design were determined by direct and water-displacement gasometry and by weighing of water-fill of the respective bags. For the SM-1 SOBERMETER, the breath volume passed through the detector tube in 1.0 minutes, from a balloon inflated to yield 55 mm. distance between calibration marks on the balloon surface, was measured by direct and water-displacement gasometry.

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[4] Equilibration of air with a 1.209 g/liter ethanol solution maintained at 34.0°C will yield a gas mixture containing 0.476 mg of ethanol per liter (7). The alcohol content of this gas mixture is widely considered equal to that of expired alveolar air from a subject with a BAC of 1.0 g/liter (0.10 g./dl.), according to the generally accepted blood/breath alcohol relation that "2.1 liters of expired alveolar air contain approximately the same quantity of alcohol as 1 milliliter of blood" (8).

[5] 50 torr corresponds to 26.8 inches of H_2O and to 66.6×10^2 Pa

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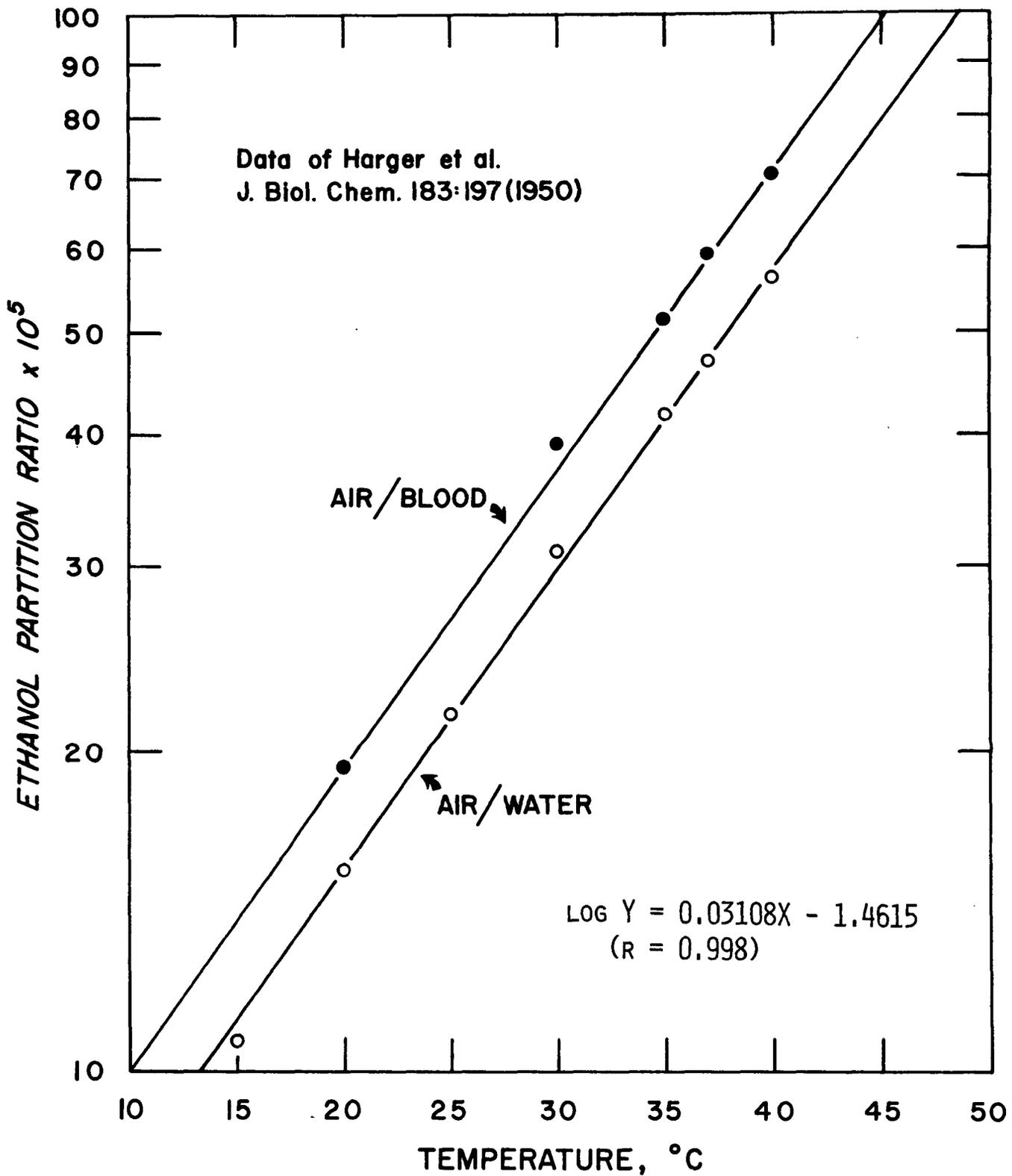
Figure 2. In-Vitro Ethanol Partition Ratios for Air/Blood and Air/Water
{Data of Harger et al.(7)}

A special purpose metering device (Figure 3) was constructed 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 (typical concentration = 0.476 mg/liter corresponding to BAC = 0.10 % w/v) 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 Tygon tubing with minimal deadspace. Delivery times for the alcohol vapor discharge through each indicator tube were recorded.

Conditions for the alcohol-detector tube dosing are given in Table 1.

Result Measurements and Recording

At the end of the factory-specified post-test waiting period, each indicator tube was examined under 1.5x magnification by reflected white fluorescent light and through a Didymium Glass Filter (Figure 4)[6]. The extreme front of the discolored reaction zone was scribed with a diamond point marker, the length of the green-colored zone measured thereafter with dial calipers to the nearest 0.001 inch, and the measurement converted to metric values.

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[6] After observation, through several dozen different color filters in the visible light region, of the typical yellow→green change produced in the indicator tubes by passage of alcohol reference vapor, the didymium glass filter was selected as yielding the greatest contrast for visual observation.
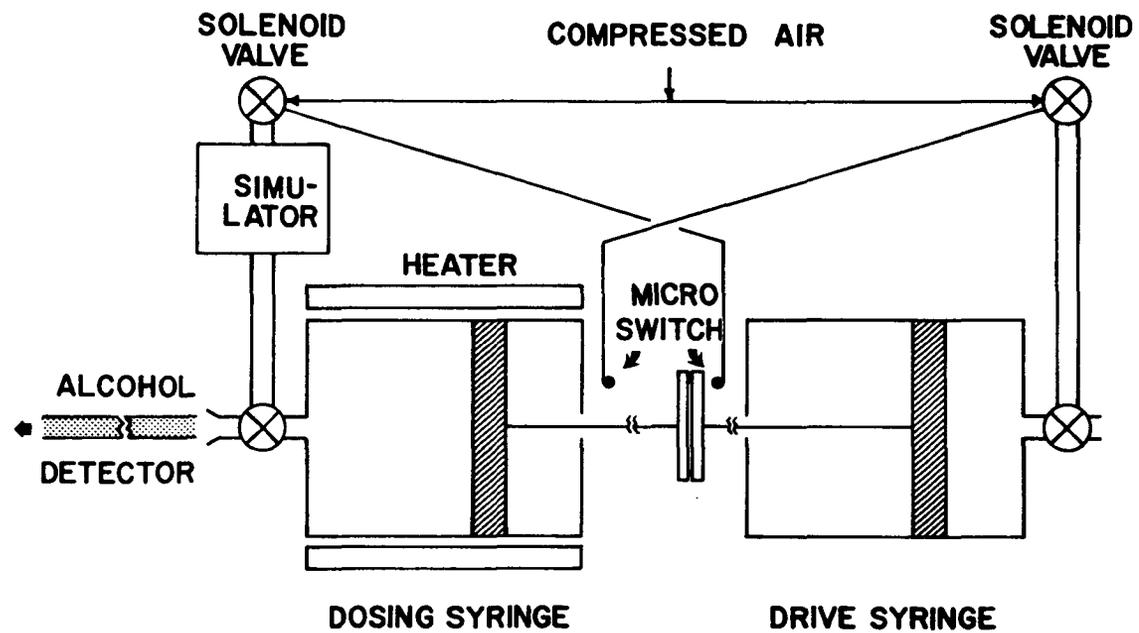
Figure 3. Scheme of Metering Device for Dosing of Breath-Alcohol Detector Tubes.

TABLE 1. EXPERIMENTAL CONDITIONS FOR ALCOHOL-DOSING OF DETECTOR TUBES

No.	Screening Test	Alcohol Vapor Delivery			Target Mean Flow Rate
		Volume	Concentrations	Time	
1	ALCOLYSER	850 ml.	100 mg/210 L.	15-20 sec.	3400 ml/min.
2	ALCOTEST	1000 ml.	80 mg/210 L.	15-20 sec.	4000 ml/min.
3	ALVEOLAR AIR BREATH ALCOHOL SYSTEM [a]	780 ml.	100 mg/210 L.	150 sec.	312 ml/min.
4	ALVEOLAR AIR BREATH ALCOHOL SYSTEM [b]	780 ml.	100 mg/210 L.	150 sec.	312 ml/min.
5	MOBAT SOBER-METER	900 ml.	100 mg/210 L.	60 sec.	900 ml/min.
		900 ml.	70 mg/210 L.	60 sec.	900 ml/min.

[a]Indicator tubes, Lot Control No. 4

[b]Indicator tubes, Lot Control No. B 664232(216)
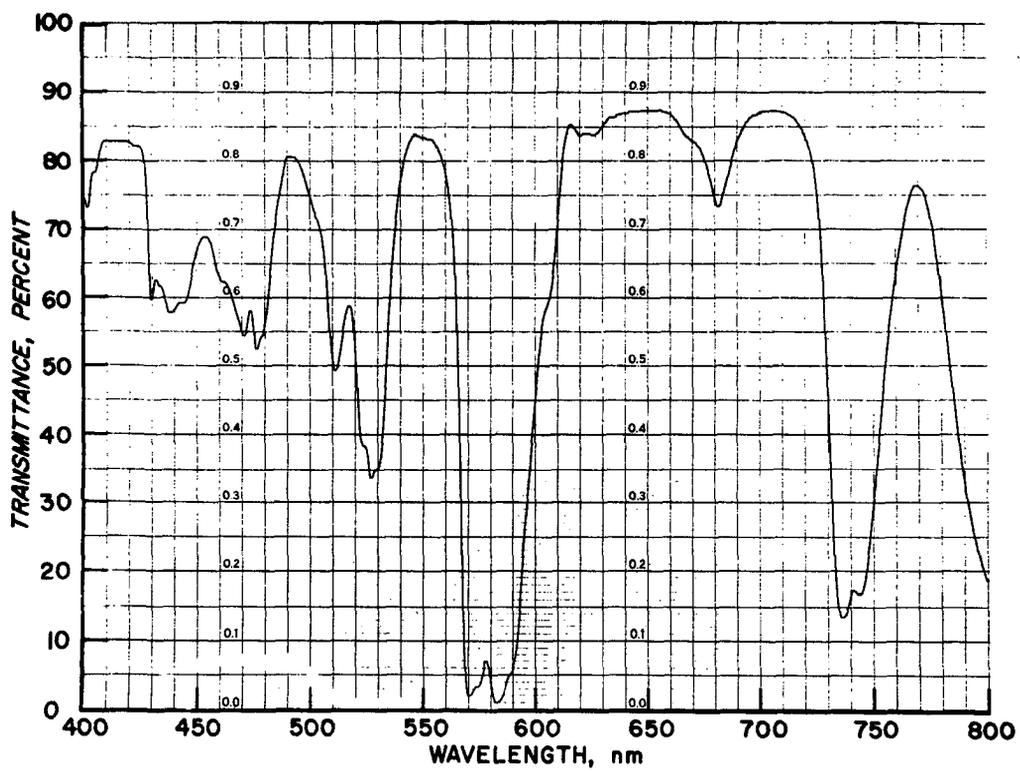
Figure 4. Transmittance Spectrum of Didymium Glass Filter (NBS No. G-51, 3 mm). Spectrum Obtained Against Air Blank on Cary Model 15 Recording Spectrophotometer.

Factory calibrations for interpretation of screening test results were similarly measured.

Specificity Testing

Exemplars of detector tubes were dosed with air containing known concentrations of acetone produced by controlled-temperature equilibration[7], and the effects were noted.

Time Stability of Alcohol Indication

Periodic examinations and measurements were carried out, as described under "Result Measurements and Recordings" above, on exemplars of the detector tubes at various time intervals from 0 minutes (=factory-specified post-test waiting period) to 0+60 minutes after dosing of the detector tubes with 0.476 mg/L. alcohol reference vapor, with retention at room temperature ($\sim$24°C) and as directed by the manufacturers.

B. Apparatus, Methods, and Procedures for Breath Study

    Apparatus (Key Items)

    (1) Digital Electronic Thermometer, Heath-Schlumberger Model EU-200-41/EU-200-62, Mfr. Heath Co., Benton Harbor, Mich. 49022; with Models No. 703 and 705 Thermolinear Probes, Mfr. Yellow Springs Instrument Co., Yellow Springs, Ohio 45387.

    (2) Flowmeter, Visi-Float, Model VFB-69, Mfr. Dwyer Instruments, Inc., Michigan City, Ind. 46360.

    (3) Godart Capnograph, Model KK146, Mfr. Godart, N.V., De Bilt (U), Holland, (Instrumentation Associates, Inc., New York, N. Y. 10023); with Model 194 10-inch Potentiometric Strip Chart Recorder, Mfr. Honeywell, Inc., Ft. Washington, Pa. 19034.

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[7] Equilibration of air with a 0.334 g./liter acetone solution maintained at 37.0°C will yield a gas mixture containing 1.0 mg. of acetone per liter (9).

(4) Magnehelic Direct-Reading Differential Pressure Gauge, Model 2050C, Mfr. Dwyer Instruments, Inc., Michigan City, Ind. 46360.

(5) Medical Gas Analyzer (Respiratory Mass Spectrometer), Model 1100, Mfr. Perkin-Elmer Corp., Medical Instruments, Pomona, Calif. 91767.

(6) Volumeter, Direct-Reading, Model 2207001, Mfr. Drägerwerk Lübeck, Germany, (North American Dräger, Telford, Pa. 18969).

Methods and Procedures

All human subject studies were conducted on healthy volunteer human subjects (40 males, age 21-50 years; 15 females, age 23-46 years), in accordance with national standards for investigations involving human subjects (10), and pursuant to approval of full experimental protocols by an institutional Human Experimentation Committee.

Breath volume, pressure, and temperature were measured in replicate, in non-fasting subjects, after appropriate preparation and rest period.

The composition of expired breath in several healthy male subjects was measured by continuous mass-spectrometric analysis, in the single-breath test mode, with a Model 1100 Medical Gas Analyzer. The CO_2 and O_2 of the expired breath were recorded, against time, in percent by volume with precautions to assure constant rates of breath flow.

The carbon dioxide content of expired breath, together with the expired breath temperature at the mouth, was measured in physiological samples (BTPS, at body temperature, without removal of water vapor) and under ambient conditions[8], in a series of non-fasting healthy human subjects, by non-dispersive infrared absorbance measurement with a Godart Capnograph. The capnograph and the thermistor thermometer responses for complete expirations were

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[8] The ambient barometric pressure during this set of measurements varied from 734.7 to 740.7 torr, corrected for temperature and gravity (979 x 10^2 to 987 x 10^2 Pa), and room temperature varied between 24.0 and 24.2°C.

recorded, after a period of resting-state normal respiration, during maximum exhalation following both normal and maximum inspirations, the entire exhalation being monitored for CO_2 with the flow-through cell of the capnograph (0.44 ml. sample-cell volume, 80 milliseconds full-scale response) using a by-pass mouthpiece. The time constant[9] of the Model 705 thermolinear probe (designed for air temperature measurements) is given as 600 milliseconds.

RESULTS

Performance Characteristics of Methods

Key characteristics of the principal methods used in these studies are summarized in Table 2, which includes data on the precision, in non-biological reference systems, of the methods used for breath measurements. Precision of breath sample measurements, for typical human subject data, is shown in Table 3. Table 4 summarizes data for volume and concentration of the alcohol reference vapor delivered to the Metering Device (Figure 2), and for the width measurement of alcohol-induced color changes in detector tubes.

Pertinent Characteristics of Length-of-Stain Alcohol Detector Tubes

Only four different breath-alcohol screening test devices utilizing length-of-stain detectors were found to be commercially available in the United States (p.10) during the contract period. Two series of tests were carried out on one of these devices (B-D ALVEOLAR AIR BREATH ALCOHOL SYSTEM), since the first set of detector tubes manifested severe channeling which produced a yellow→green reaction zone change markedly oblique with respect to the long axis of the detector tube, which was difficult to quantitate. All four types of detector tubes employ potassium dichromate in acid solution as the alcohol detection reagent, but only the B-D device specified the composition of the alcohol reagent, in general terms: "... Detector Tube

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[9] 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.

TABLE 2. CHARACTERISTICS OF METHODS EMPLOYED

Fluid-Alcohol Determination by Automated GC Headspace Analysis with Perkin-Elmer Multifract F-40 Instrument

Precision of Replicate Determinations (N = 29, 28, 27, 24):

At 50 mg/dl	SD = ±0.27 mg/dl	CV = 0.55%
100	±1.05	1.05
150	±0.95	0.63
200	±1.77	0.89

Gas Pressure Measurement by Direct-Reading Magnehelic® Pressure Gauge

Precision of Replicate Measurements (N = 20):

At 15 in H_2O SD = ±0.08 in H_2O CV = 0.53%

Gas Temperature Measurement by Heath-Schlumberger Digital Thermometer + YSI Thermolinear Probe #705

Precision of Replicate Measurements (N = 21):

At 34.5° C   SD = ±0.007°C   CV = 0.02%

Gas Volume Measurement by Direct-Reading Dräger Volumeter®

Precision of Replicate Measurements of Gas Syringe Output (N = 10):

At 470 ml Volume   SD = ±1.94 ml   CV = 0.41%

Simulator Solution Measurement by Automated GC Headspace Analysis with Perkin-Elmer Multifract F-40 Instrument

Validation of Ethanol Solution Concentration for Nominal 100 mg/210 L. BrAC Simulator Output at 34°C

For 14 Solutions on 14 Days (Expressed as Corresponding Nominal BrAC):

Mean = 100.3 mg/210 L.   SD = ±1.64 mg/210 L.   CV = 1.64%

Simulator Effluent Measurement by Catalytic Oxidation Device

Validation of Effluent Ethanol Concentration for Nominal 100 mg/210 L. BrAC Simulator Output at 34°C (N = 51):

Mean = 100.8 mg/210 L.   SD = ±1.26 mg/210 L.   CV = 1.25%

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BREATH-SAMPLE CHARACTERISTICS

Precision of Typical Subject Data

	Subject 1 (♀)	Subject 2 (♂)	Subject 3 (♂)
End-Expiratory Temperature:			
Range (N=10)	34.37 - 35.09° C	34.78 - 35.45° C	34.45 - 35.79° C
Average (N=10)	34.76° C	35.16° C	35.35° C
S.D.	0.027° C	0.021° C	0.036° C
C.V.	0.78%	0.60%	1.02%
Forced Vital Capacity:			
Range (N=10)	2810-3320 ml.	4325-5220 ml.	3425-4075 ml.
Average (N=10)	2929 ml.	4586 ml.	3641 ml.
S.D.	149 ml.	367 ml.	283 ml.
C.V.	5.1%	8.0%	7.8%
Maximum Exhalation After Normal Inhalation:			
Range (N=10)	1740-2305 ml.	1175-2305 ml.	1705-2025 ml.
Average (N=10)	2116 ml.	1830 ml.	1893 ml.
S.D.	205 ml.	284 ml.	107 ml.
C.V.	9.7%	15.5%	5.7%

TABLE 4. PRECISION CHARACTERISTICS OF DETECTOR-TUBE STUDY METHODS

Variable	N	Range	Mean	S.D.	C.V.
Volume of Alcohol Reference Vapor Delivered by Metering Device[a]	25	916-920 ml.	918.80 ml.	±1.291 ml.	0.14%
Alcohol Concentration of Reference Vapor Delivered to Metering Device[b]	51	99.0-104 mg/ 210 L.	100.8 mg/ 210 L.	±1.26 mg/ 210 L.	1.25%
Width of Detector-Tube Reaction Zone Change[c]	25	6.59-6.82 mm.	6.65 mm.	±0.070 mm.	1.05%

[a]Measured by water-displacement gasometry

[b]Measured by catalytic oxidation device

[c]Measured with direct-reading dial calipers

containing potassium dichromate, phosphoric acid, sulfuric acid, glass beads, fiberglass tape and silica gel..."

The pertinent characteristics of the alcohol detector tubes and of breath sampling for the four screening tests are listed in Table 5.

Alcohol Quantitation in Vapor Specimens by Detector Tubes

The experimental responses of alcohol detector tubes to exposure to known concentrations of alcohol in air, under the controlled conditions summarized in Tables 4 and 5, are given in Table 6 for each of the breath-alcohol screening tests studied. In carrying out examinations of Test 3 (B-D ALVEOLAR AIR BREATH ALCOHOL SYSTEM, Lot Control No. 4), severe channeling of the indicator tubes was noted, and the color change typically occurred so that the line of yellow→green demarkation was usually irregularly diagonal to the long axis of the detector tube. Additional supplies of the detector tubes were, therefore, obtained from the manufacturer and the experimental alcohol dosing series was repeated, with the results shown under Test 4 in Table 6.

Results of measurements of (the width of) the various factory calibrations for each interpretation of screening test results at BrAC=0.10 g/210 L. (except BrAC=0.08 g/210 L. for ALCOTEST) are shown in Table 7 for each of the devices tested. The indicator criteria for BrACs took three forms:

(1) Marks at a finite distance superimposed upon the alcohol indicator region of the detector tube (ALCOLYSER, ALCOTEST)

(2) A series of discrete alcohol indicator bands, complete color change in each of which indicates attainment of an increment of 0.10 g/210 L. BrAC (MOBAT SOBER-METER)

(3) Initial alignment and incremental result marks, on a paper scale, for measurement of the total yellow→green color change (ALVEOLAR AIR BREATH ALCOHOL SYSTEM)

TABLE 5. PERTINENT CHARACTERISTICS OF BREATH-ALCOHOL SCREENING TESTS

No.	Screening Test	Typical Detector Tube Dimensions			Breath Sample	
		Overall Length, mm.	Diameter, mm.	Reaction Zone Length, mm.	Nominal Volume, ml.	Flow Time, Seconds
1	ALCOLYSER	83.80	8.70	5.08	850	15-20
2	ALCOTEST	91.95	9.85	14.40	1000	10-20
3	ALVEOLAR AIR BREATH-ALCOHOL SYSTEM	91.55	6.60	26.20	780	150
4	MOBAT SOBER-METER	99.50	8.30	5.04^a	900	60

[a] 3 such "color bands" per detector tube

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TABLE 6. RESULTS OF ALCOHOL DOSING OF DETECTOR TUBES

No.	Screening Test	N	Concentration of Alcohol Reference Vapor ($\equiv$BrAC),mg/210 L.	Yellow$\rightarrow$Green Change in Detector Tube Reaction Zone, mm.				Dosing Time, sec.		
				Range	Mean	S.D.	C.V.	Mean	S.D.	C.V.
1	ALCOLYSER	57	100	4.16-5.18	4.70	±0.275	5.85%	12.64	±0.60	4.75%
2	ALCOTEST	50	80	5.03-5.99	5.45	±0.225	4.13%	18.29	±2.04	11.15%
3	ALVEOLAR AIR BREATH ALCOHOL SYSTEM[a]	56	100	10.49-17.65	13.37	±1.816	13.58%	152.2	±20.97	13.78%
4	ALVEOLAR AIR BREATH ALCOHOL SYSTEM[b]	58	100	9.47-12.19	10.94	±0.617	5.64%	151.0	±14.30	9.47%
5	MOBAT SOBER-METER	50	100	3.16-4.56	4.06	±0.336	8.26%	64.88	±2.02	3.11%
		5	70	3.09-3.84	3.52	±0.332	9.42%	58.20	±5.31	9.12%

[a]Indicator Tubes, Lot Control No. 4

[b]Indicator Tubes, Lot Control No. B 664232(216)

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TABLE 7.   MEASUREMENTS OF FACTORY CALIBRATIONS INDICATIVE OF BrAC=100 mg/210 L. RESULTS[a]

No.	Screening Test	N[b]	Length of Indicator Zone, mm.		BrAC=100 mg/210 L.[a]
			Mean	S.D.	Indicator
1	ALCOLYSER	10	5.08	±0.044	Detector Tube[c]
2	ALCOTEST	10	6.52	±0.058	Detector Tube[c]
3	ALVEOLAR AIR BREATH ALCOHOL SYSTEM	10	11.97	±0.017	Paper Scale[d]
4	MOBAT SOBER-METER	40	5.04	±0.388	Detector Tube[e]

[a]BrAC = 80 mg/210 L. for ALCOTEST

[b]Each measurement performed on a separate indicator item

[c]Width of alcohol indicator zone between marks on detector tube

[d]Distance between marks on paper scale

[e]Total width of alcohol indicator zone in detector tube

Based on the raw data on the effects of alcohol dosing given in Table 6 and for the factory calibrations for interpretation of alcohol indicator tube changes given in Table 7, overall results of alcohol quantitation by indicator tubes in reference gases, expressed in terms of the indicated alcohol vapor concentrations and in per cent of the target values represented by the indicated results, are summarized in Table 8 for all screening tests studied. The alcohol concentration results in Table 8 are based on and obtained by use of the interpretation criteria contained in Table 7.

Specificity-Interference Phenomena Study

When exemplars of alcohol detector tubes from each screening test were dosed with known concentrations of acetone in air (1.0 mg/Liter and 10.0 mg/ Liter), the results summarized in Table 9 were obtained. Except for presence of acetone in the reference vapor with which the alcohol detector tubes were dosed, other conditions were identical to those for the alcohol-dosing experiments; dosing volumes of acetone-containing vapor corresponded to those given in Table 1 for alcohol vapor.

Time Stability of Alcohol Indication

In early alcohol dosing series, it was noted that the width of the green zone in the detector tubes changed relatively much less with time in the B-D ALVEOLAR AIR BREATH ALCOHOL SYSTEM than in other screening tests studied. Accordingly, short-term time stability was further studied only in the former screening test, with the results shown in Table 10. The changes shown are means of replicate tests on individual indicator tubes dosed with 100 mg/210 L. alcohol reference vapor; in several instances individual indicator tubes showed no change between 5 and 60 minutes. After 96 hours, B-D ALVEOLAR AIR BREATH ALCOHOL SYSTEM indicator tubes, kept unsealed at room temperature, typically showed a change of only +17 % from initial alcohol indications.

Breath Sample Characteristics in Human Subjects

Results of the studies of breath temperature and breath volume in 55 healthy human subjects are summarized in Tables 11 and 12. All temperatures

TABLE 8.   ALCOHOL QUANTITATION IN REFERENCE GASES BY DETECTOR TUBES

No.	Screening Test	N	Concentration of Alcohol Reference Vapor ($\equiv$BrAC), mg/210 L.	Indicated Alcohol Vapor Concentration, mg/210 L.				Indicated Mean Per Cent of Target Value
				Range	Mean	S.D.	C.V.	
1	ALCOLYSER	57	100	81.9-102.0	92.5	±5.41	5.85%	92.5%
2	ALCOTEST	50	80	61.7-73.5	66.9	±2.76	4.13%	83.6%
3	ALVEOLAR AIR BREATH ALCOHOL SYSTEM[a]	56	100	87.6-147.5	111.7	±15.17	13.58%	111.7%
4	ALVEOLAR AIR BREATH ALCOHOL SYSTEM[b]	58	100	79.1-101.8	91.4	±5.16	5.64%	91.4%
5	MOBAT SOBER-METER	50	100	62.7-90.5	80.6	±6.67	8.26%	80.6%
		5	70	61.3-76.2	69.8	±6.59	9.42%	99.7%

[a]Indicator Tubes, Lot Control No. 4

[b]Indicator Tubes, Lot Control No. B 664232(216)

TABLE 9. RESPONSE OF ALCOHOL DETECTOR TUBES TO ACETONE

No.	Screening Test	Acetone Concentration Delivered to Detector Tube mg/L.	Mean Width of Change in Reaction Zone, mm.	Mean Indicated Putative "Alcohol" Concentration, mg/210 L.
1	ALCOLYSER	1.0	5.08^a	100
		10.0	5.08^a	100
2	ALCOTEST	1.0	10.00	122
		10.0	14.40^a	177
3	ALVEOLAR AIR BREATH ALCOHOL SYSTEM	1.0	0^b	0
		10.0	0^b	0
4	MOBAT SOBER-METER	1.0	0^b	0
		10.0	0^b	0

^{a}Complete change

^{b}No change

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TABLE 10. SHORT-TERM TIME STABILITY OF "BrAC" INDICATIONS

(ALVEOLAR AIR BREATH ALCOHOL SYSTEM)^{a}

Test	Time, min.	Mean Indicated Alcohol Concentration, mg/210 L.	Per Cent Change from Initial Indication [b]
1	0	95.5	—
2	4	95.5	—
3	5	95.5	0
4	10	95.5	0
5	15	98.0	2.6
6	30	98.0	2.6
7	45	98.0	2.6
8	60	98.0	2.6

[a]Indicator tubes, Lot Control B 664232(216)

[b]Manufacturer's directions specify a waiting period of 3-5 minutes between end of sampling and result reading. In this study, all results (with this screening test) were measured 4.0 minutes after completion of dosing.

TABLE 11. END-EXPIRATORY BREATH TEMPERATURES IN HUMAN SUBJECTS,
MEASURED AT THE MOUTH

Subjects	N	End-Expiratory Temperature, °C			
		Range	Mean	S.D.	C.V.
Males	40	32.41-35.57	34.49	± 0.791	2.29%
Females	15	33.53-35.69	34.68	± 0.613	1.77%
Total	55	32.41-35.69	34.54	± 0.747	2.16%

TABLE 12.   EXPIRATORY BREATH VOLUMES IN HUMAN SUBJECTS

Subjects	N	Forced Vital Capacity, ml.				Maximum Exhalation After Normal Inhalation, ml.			
		Range	Mean	S.D.	C.V.	Range	Mean	S.D.	C.V.
Males	40	2245-6550	4500	±770	17.1%	1180-4550	2951	±752	25.5%
Females	15	1825-3200	2800	±386	13.8%	1480-3000	2141	±543	25.4%
Total	55	1825-6550	4037	±1025	25.4%	1180-4550	2730	±786	28.8%

shown were recorded at the end of an expiratory vital capacity maneuver[10] and are therefore end-expiratory temperatures. The breath-volume data include both the maximum forced expiratory volume, as measured by an expiratory forced vital capacity maneuver[10] in standing subjects, and the maximum expiratory volume in the same subjects after a normal inhalation. All volumes shown are for breath at physiological temperature, saturated with water vapor, and at ambient barometric pressure[11].

Breath pressure data for 39 human subjects, during breath sampling against a standard resistance typical of the resistance to airflow offered by the breath sampling arrangements of the screening test devices studied in this project, are shown in Table 13.

The breath pressures shown are peak values attained above the ambient atmospheric pressure during the sampling period, measured at the breath sample inlet of a surrogate screening test device by means of a T-fitting.

Mass-Spectrometric Expirogram

Figure 5 shows a typical mass-spectrometric expirogram for CO_2 and O_2 for a healthy adult male subject. Other mass-spectrometric expirograms in this series were similar in all significant respects to the example illustrated.

Carbon-Dioxide and Temperature Profiles of Expired Breath

Typical simultaneous in-vivo recordings of expiratory temperature and expiratory CO_2 during a single continuous full expiration after normal inhalation are illustrated in Figure 6. This expirogram is typical of the CO_2 and temperature profiles for breath, against time, encountered in our

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[10] Vital capacity (VC) is the volume of air that can be expelled during a maximum exhalation after a maximum inspiration; forced vital capacity (FVC) is the vital capacity performed with expiration as forceful and rapid as possible. In *normal* subjects, VC equals FVC.

[11] The ambient barometric pressure extremes over the duration of these human subject studies were 716.7-747.2 torr, corrected for temperature and gravity (955×10^2-996×10^2 Pa).

TABLE 13. BREATH PRESSURES IN HUMAN SUBJECTS
DURING BREATH SAMPLING AGAINST A STANDARD RESISTANCE

Subjects	N	Breath Pressure, inches of H_2O^a			
		Range	Mean	S.D.	C.V.
Males	24	7-50+	21.2	11.98	56.5%
Females	15	6-34	14.7	8.04	54.6%
Total	39	6-50+	18.7	11.00	58.8%

[a](inches of H_2O) x 1.868 = mm Hg = torr

BREATH'O'GRAM MGA-1100

PERKIN ELMER

22%

O₂

12%

10%

CO₂

0%

Gould Inc., Instrument Systems Division

0   2   4   6   8   10
SECONDS
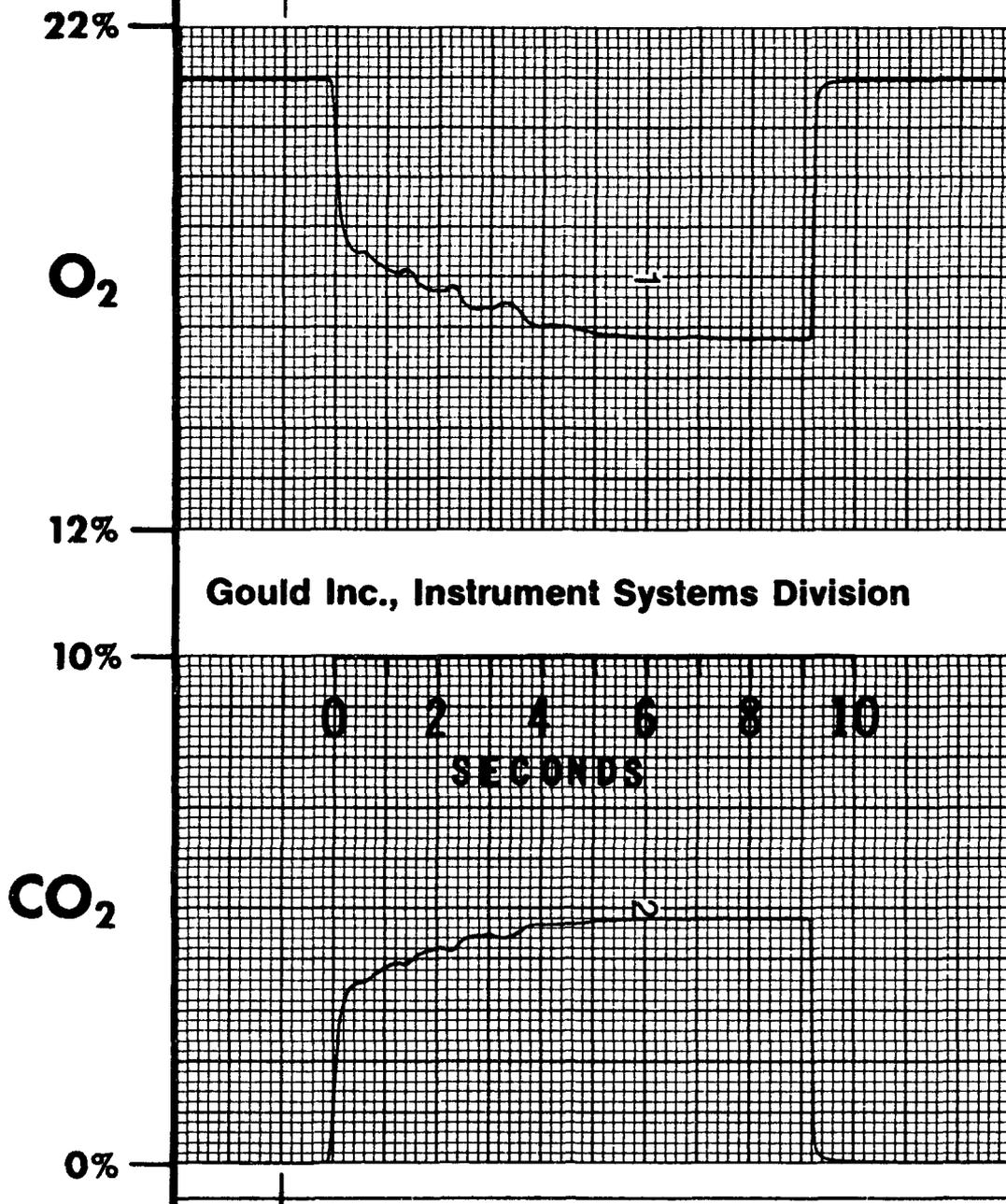
Figure 5. Mass-Spectrometric Single-Breath Expirogram. Upper and Lower Curves Show the Breath O_2 and CO_2 Content, Respectively, (in Per Cent v/v) During a Single Continuous Full Expiration at Constant Breath Flow Rate
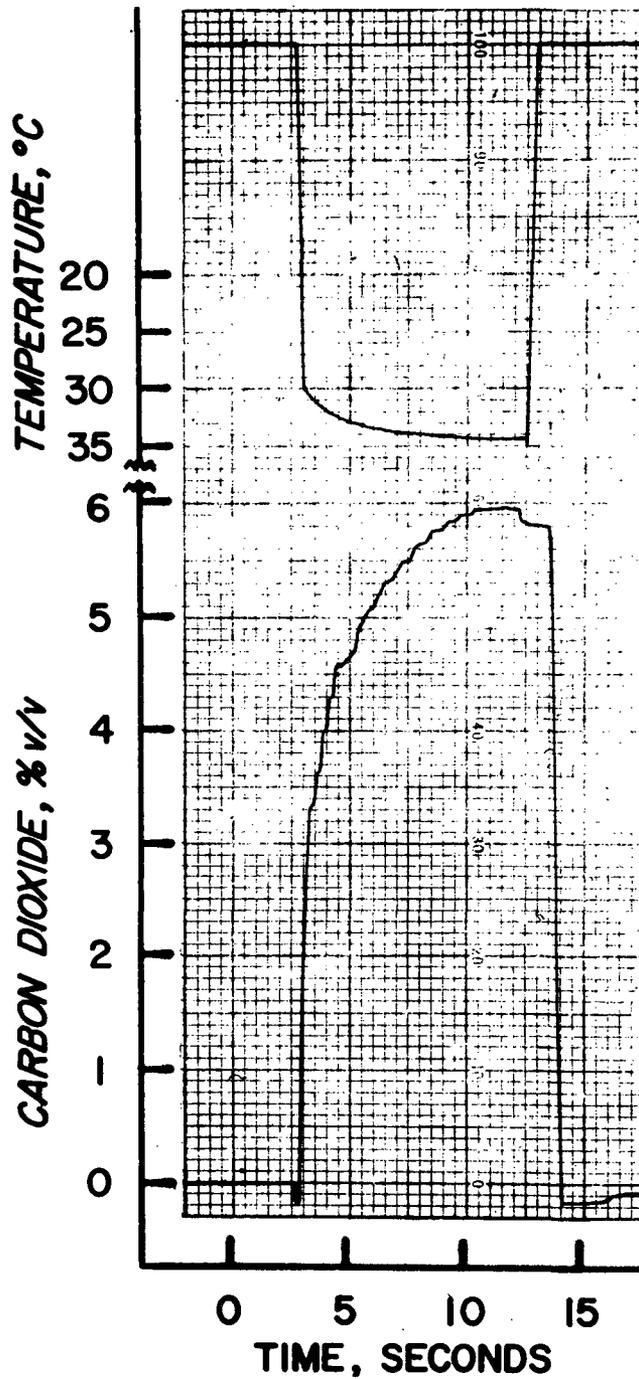
Figure 6. Typical Simultaneous In-Vivo Recording of Temperature (Upper Curve) and CO_2 (Lower Curve) of Breath, During a Single Continuous Full Expiration After a Normal Inhalation, Demonstrating the Simultaneous Alveolar Plateau Indications by Both Procedures.

studies of healthy adult human subjects without significant respiratory obstruction or impairment.

The same simultaneous recordings for an in-vitro system are shown in Figure 7, which illustrates the thermistor response to a nearly instantaneous transfer from a $23.3^\circ C$ to a $34.5^\circ C$ fluid medium and capnograph response to nearly instantaneous change in gas flow from CO_2-free air to medical gas of nominal 5.3% v/v CO_2 content flowing at 2 liters/min. Precision and accuracy of the capnograph response to alternating changes in gas flow between CO_2-free air and reference gas of 4.97 ± 0.01 mol.% CO_2 content flowing at 2 liters/min. are illustrated in Figure 8.
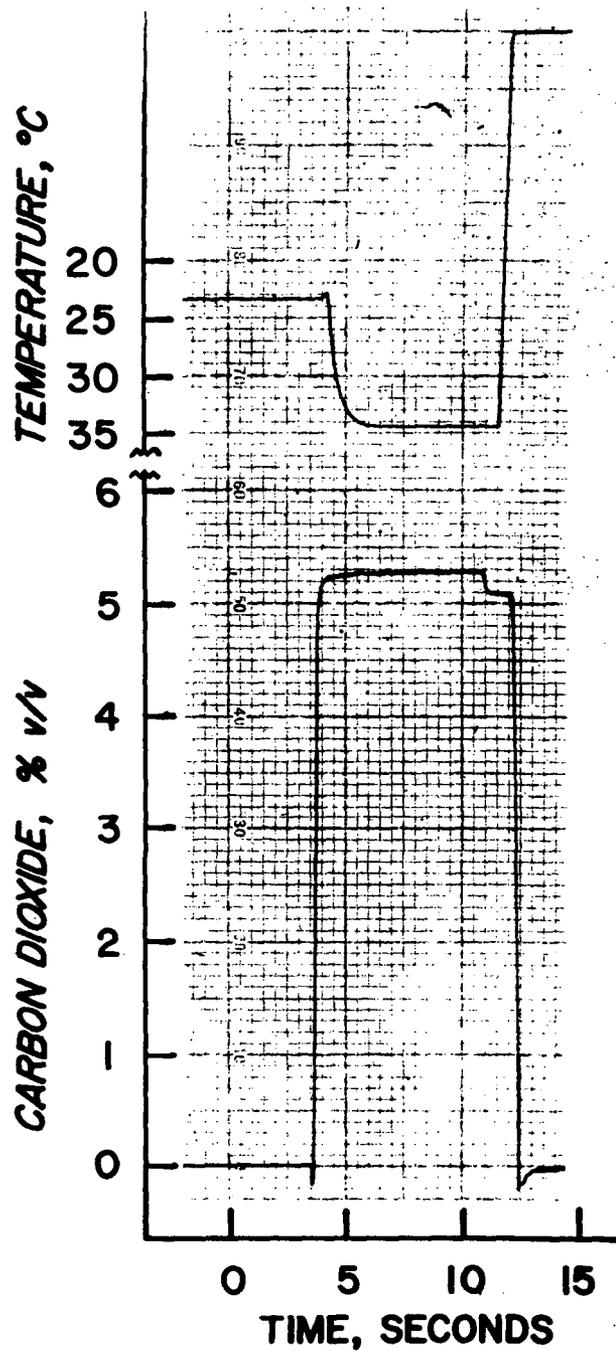
Figure 7. Typical Simultaneous Recording of Temperature (Upper Curve) and CO_2 (Lower Curve) for an In-Vitro System, Illustrating the Rapid Response to Nearly-Instantaneous Changes in the Measured Variables.
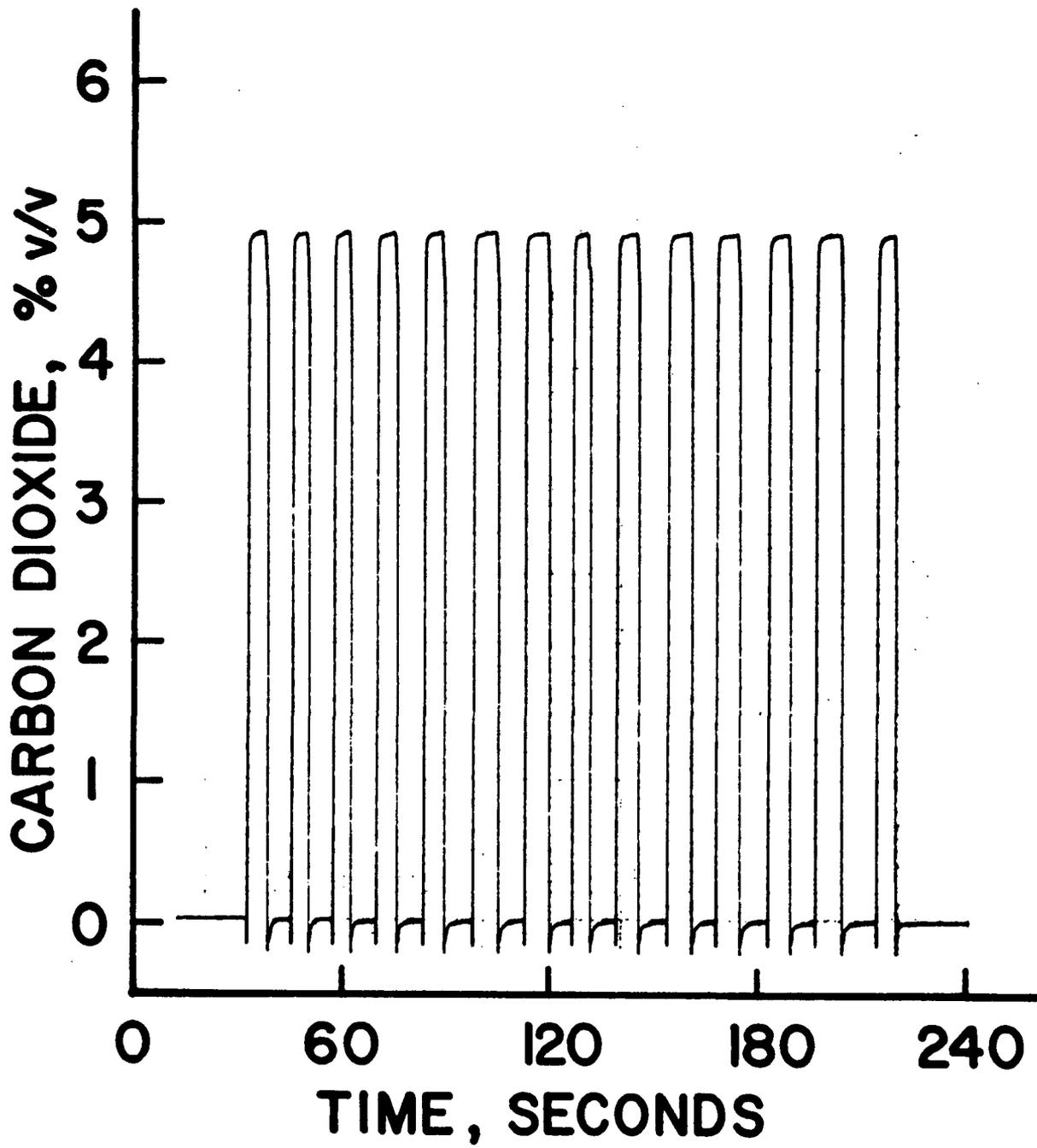
Figure 8.   Replicate Measurement of CO_2 in a Reference Gas with the Capnograph.

DISCUSSION

The general features of disposable breath-alcohol screening tests, illustrated in Figure 1, apply to the screening tests studied in this project. All employ a single-use alcohol detector tube of the length-of-stain type and some provision for breath sampling, which may involve temporary breath storage after collection. Three of the screening tests studied (ALCOLYSER, ALCOTEST, MOBAT SOBER-METER SM-1) employ mixed expired breath as the specimen in the factory version. The first two devices quantitate the specimen by means of a volume-limiting collapsible, flexible plastic bag attached to the distal end of the alcohol detector tube, while the last named device relies on timed breath flow through the alcohol detector tube from a rubber balloon previously inflated through a one-way valve to a diameter which will yield a fixed distance (55 mm.) between calibration marks ("inflation guide") on the balloon surface. The B-D ALVEOLAR AIR BREATH ALCOHOL SYSTEM employs a double-segmented breath collection bag (Figure 9), with two identical sections of 780 ml. capacity, intended to divert dead-space air into the discard bag section which fills first, after which the breath filling the collection bag segment is assumed by the manufacturer to be expired alveolar air. A separate version of the MOBAT SOBER-METER screening test device (Model SM-7) utilizes the same alcohol detector tube as the Model SM-1 device, but employs a breath collection system consisting of a breath collection rubber balloon with "inflation guide" marks and a 675 ml. waste bag interposed between the balloon and a mouthpiece to effect initial discard of dead space air. The validity of these designs for obtaining expired alveolar breath is discussed later in this report.

Since mixed expired breath has a widely varying, uncontrollable proportion of expired alveolar air (11) we do not consider it a suitable breath specimen for any quantitative or semi-quantitative form of breath-alcohol analysis, including breath-alcohol screening tests. The ethanol quantitation studies were, therefore, conducted on the assumption that expired alveolar air would be the

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BREATH

⬇

COLLECTING
BAG
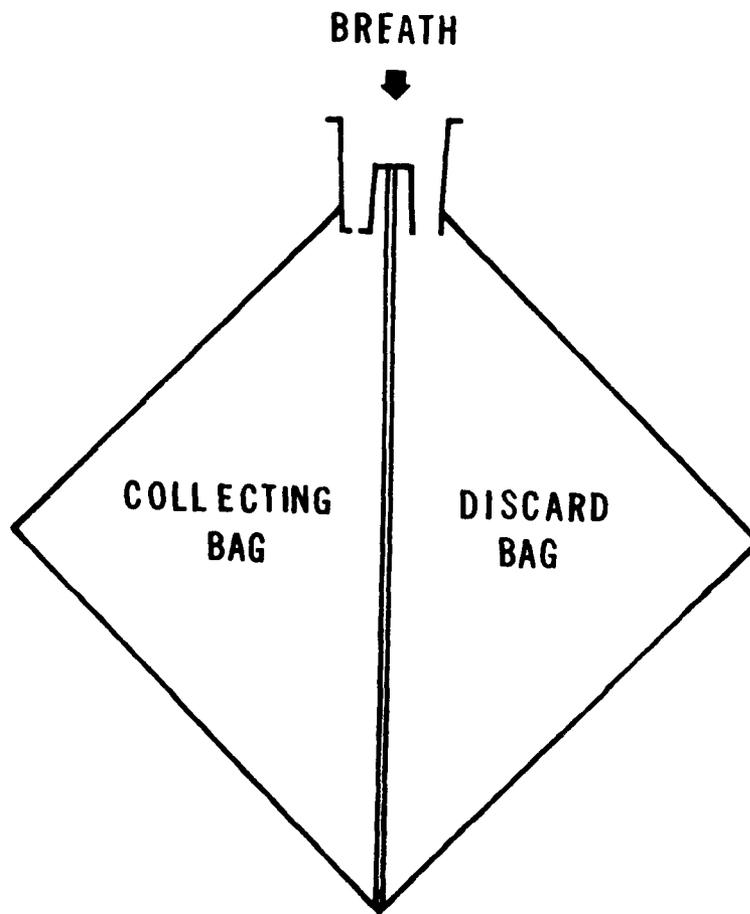
DISCARD
BAG

Figure 9. Breath Sampling Bag for Alcohol Analysis, Intented to Produce Expired Alveolar Air by Discard of Dead-Space Air into Discard Bag, Which Fills First.

specimen analyzed. The alcohol content of expired alveolar air is, on the average, about 1.52X that of mixed expired breath since the latter is usually about two-thirds alveolar in origin as usually collected in breath-alcohol analysis (11). Preliminary range-finding experiments readily demonstrated, however, that dosing the alcohol detector tubes employed in this study with the alcohol equivalent of mixed expired breath/volumes required for each de- vice (Table 5) would consistently yield gross underestimates of the actual alcohol vapor content of the reference samples. All detector tubes included in this study do, in fact, have sufficient alcohol sensing capacity to ac- comodate the alveolar breath alcohol content of the respective nominal breath sample volumes, as demonstrated by the findings in Table 8.

In order to separate the two major validity elements of the screening tests, alcohol quantitation and breath sampling, the alcohol quantitation experiments were conducted uniformly on the alcohol-equivalent of expired alveolar breath, using the 2100:1 BAC:BrAC relation[4] because of its present wide acceptance in traffic law enforcement.

The several methods used in this project have good precision (Tables 2, 3, 4), and the variability found in both alcohol quantitation and human sub- ject studies are, thus, not attributable to methods of measurement. In the alcohol dosing experiments three major variables affected the results: (1) the delivered volume of reference alcohol vapor and the delivery rate, (2) the alcohol concentration of the reference vapor, and (3) its temperature. The metering device constructed for alcohol dosing closely and reproducibly controlled both delivered volume and delivery rate (Table 4), as well as the temperature of the reference vapor. Since dry gas mixtures containing ethanol proved useless for alcohol dosing of the detector tubes which require presence of water vapor for the reaction with alcohol, reliance on controlled- temperature equilibration (12) was necessary. For critical uses, breath- alcohol simulators need rigorous control over (1) alcohol concentration of the simulator solution, (2) absolute value of the equilibration temperature

and its constancy, and (3) gas throughput to prevent detectible alcohol depletion. The data in Tables 2 and 4 indicate that these control conditions were maintained. Seemingly minor factors such as driving simulators with compressed gas regulated for pressure and flow rate, rather than with breath, are important in this connection.

The length-of-stain alcohol detector tubes importantly depend for the result on ability of the observer to discriminate between the original yellow and the resultant green color of the alcohol detector zone after a test, in order to establish the color demarkation line which becomes the criterion for reading the result. Yellow→green discrimination is difficult for the unaided human eye because of its high relative sensitivity to light in the 500-600 nm spectrum region. Our search for a simple device to assist in the yellow→green discrimination for this purpose showed that a didymium glass filter (Corning No. 5120, 3.0 mm. thick, National Bureau of Standards No. G-51) provided significant assistance in this regard. The transmittance spectrum of this filter (Figure 4) explains this observation. Transmittance of yellow light (575-600 nm) is relatively low for this filter, while transmittance of green light (515-550 nm) is relatively high. Enhancement of the green detector zone representing alcohol-induced change, results. Didymium lenses suitable for this application are readily available in the form of glass blowers spectacles or clip-on spectacle attachments.

The principal results of the alcohol dosing experiments are reflected in Table 8, based on the data summarized in Table 6 for alcohol quantitation and Table 7 for interpretation criteria. Several facts emerge. Four of the five tests were found to underestimate the alcohol content of reference vapors even though the alcohol equivalent of expired alveolar breath was used in these studies. From the screening test device construction and the accompanying directions (Appendix B) for Tests 1, 2, and 5 (Table 8), it is clear that mixed expired breath is the anticipated specimen; hence for these tests 0.67X the expired alveolar air alcohol equivalent, per nominal breath sample volume (Tables 1, 5), might have been a/logical dosing choice, but would clearly have
traditional

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yielded unacceptably falsely low values. The detector tubes used in Tests 3 and 4 are designed for use with expired alveolar air. It is evident that, with respect to alcohol quantitation capacity for screening test purposes, all detector tubes examined are capable of being employed with expired alveolar breath.

The ALCOTEST device is designed for a maximum indication of $BrAC \geq 80$ mg/ 210 L. ($\equiv BAC = 0.08$ g/dl.), and alcohol dosing was therefore carried out with 80 mg/210 L. reference vapor. The other devices have factory-stated BrAC calibration limits at or above 100 mg/210 L. and were thus tested at that concentration. Because of severe "channeling" of many alcohol detector tubes in test 3 (Table 8), resulting in a color change demarkation often irregularly diagonal to the long axis of the tube, results were read at the point of maximum green penetration. This accounts for the overestimation, on the average, of the reference vapor alcohol concentration in this test series, the sole such result found in these studies. Repetition of the experiments with a different lot of detector tubes eliminated this difficulty.

The alcohol quantitation results are remarkably similar for the several types of detector tubes tested and all can be considered useable for alcohol detection. The total alcohol quantitation capacity of all of these detector tubes is substantially above that needed for breath-alcohol screening test purposes with appropriate expired alveolar breath volumes. Since the precision of the results is quite similar for tests 1, 2, and 4 (Table 8) despite different tube dimensions (Table 5), it follows that there would be advantages to reducing the diameter of the alcohol sensing reagent column. A similar change in the Kitagawa alcohol detector tubes employed in the Kitagawa-Wright apparatus (4) yielded acceptable accuracy and precision in quantitative breath-alcohol analysis. Feasibly, the proposed change could be effected by using capillary glass tubing of appropriate dimensions (e.g., 2-3 mm. I.D. X 6-8 mm. O.D.) to provide the necessary strength and to employ the lens effect of the glass wall for magnification of the color demarkation line. Alcohol quantitation in breath volumes only 0.05 to 0.1X those presently required (Table 5) should thus be feasible without loss of precision or accuracy.

Results within ±10% of the target value are generally considered acceptable for screening test purposes. The results for test 1, 2, and 4 (Table 8) indicate that at the 95% confidence level (±2 standard deviations) alcohol quantitation results with these indicator tubes can be expected to fall within ±11.7, 8.2, and 10.3% of the mean values, respectively, assuming a normal distribution of individual results. Adjustment of mean results to coincide with the target values could readily be made, for these detector tubes, by proportionate increase in the respective sample volumes analyzed, or proportionate decrease by 7.50%, 16.40%, and 8.60% in the respective interpretation criteria (Table 7) for tests 1, 2, and 4, assuming retention of a 2100:1 BAC:BrAC ratio. Alcohol quantitation results would then be expected, at the 95% confidence level, to fall uniformly distributed within ∿10% of the target values. With present factory interpretation criteria, results are skewed uniformly to the low side and the tests can be expected, at the 95% confidence level, to indicate alcohol content of samples within a range of about 80 to 100% of target values. As presently designed and with factory interpretation criteria, these alcohol detector tubes rarely, if ever, overestimate the alcohol content of samples but may underestimate it by as much as 20%. (The foregoing discussion refers to alcohol quantitation performance, demonstrated or expected, under the experimental conditions of this study or comparable techniques.) In normal screening test practice, of course, test results are limited to whether or not the result does or does not exceed a given predetermined value. The results of this study establish, however, that alcohol quantitation capability is not necessarily responsible for previously reported inadequacies of screening tests such as those documented by Prouty and O'Neill (3).

The most commonly mentioned interferant in breath-alcohol analyses is acetone, supposedly present in breath as the result of severe ketoacidosis in certain diabetic subjects. Without here considering the physiological and clinical merit of/such allegations, a brief investigation of the effect of acetone on the detector tubes studied in this project was made. The applicable literature typically reports mean acetone concentration in expired

alveolar air from healthy subjects of 1.1±0.5 micrograms/liter, and mean expired alveolar breath acetone in diabetic subjects with evidence of ketosis of 5-500 micrograms/liter, with a reported highest value of 1900 micrograms/liter (13). The acetone concentrations of 1.0 mg/L. and 10.0 mg/L. used for dosing of detector tubes thus included and exceeded the entire expectable range. The results shown in Table 9 presumably reflect different reagents and reaction conditions in the several detector tubes with respect to such variables as acid and dichromate concentrations, etc. Only tests 3 and 4 were unaffected by acetone at the tested concentrations. Relatively high specificity, while desirable in any breath-alcohol analysis, is not a requirement for screening tests which are to serve as the basis for further investigations.

Short-term time stability of result indications is a matter of some concern in field use of screening tests. The results shown in Table 10 for the ALVEOLAR AIR ALCOHOL SYSTEM indicate that no significant changes in the result indication of the detector tubes occurred up to 1 hour after alcohol dosing, and no change occurred within 5 minutes after the factory-designated reading time. The short-term time stability of these alcohol detector tubes is, therefore, considered adequate for their intended use.

The breath temperature data in Table 11 are of significance in several respects. If the breath specimen is not immediately analyzed after procurement and is temporarily stored, measures are required to prevent condensation of water vapor and consequent alcohol loss, especially at low ambient temperatures. Such collection devices should preferably be maintained above 36°C. The overall mean end-expiratory temperature of 34.54°C found in these studies agrees well with the findings of Harger and Forney (14), who reported a mean temperature of 34.4°C in a plastic mouthpiece at the end of an exhalation in a small series of subjects.

In highly simplified terms, an expirate can be considered to consist of physiological dead-space gas and alveolar gas. In subjects without signifi-

cant respiratory disease or pulmonary dysfunction, the composition of the expired air is, therefore, approximately constant after the dead-space gas has been expelled, reflecting the alveolar-air phase of expiration (the so-called "alveolar plateau"). The practical problem is how to know when this has occurred during any single expiration, or how to arrange matters so that breath-specimen collection occurs only after all physiological dead-space gas has been discarded.

The typical single-breath mass-spectrometric expirogram shown in Figure 5 demonstrates that constant breath composition with respect to CO_2 and O_2 was attained at about 6 seconds during a continuous expiration period of 9.2 seconds, or after 65% of the total breath had been exhaled, assuming a constant breath flow rate. This consistent finding indicates that at least two-thirds of the total expiratory volume must be discarded before constant breath concentrations are attained, presumably indicative of the alveolar plateau. Any portion of the remaining breath will have essentially the same composition and can be used for breath analysis. The time course of the breath temperature during a complete exhalation, illustrated in Figure 6, supports these findings that an alveolar plateau is attained when approximately two-thirds of total available breath has been exhaled. For research purposes and in quantitative evidential breath-alcohol analysis, temperature measurements with a sufficiently rapidly responding indicator thus seem useable to indicate when the alveolar plateau has been reached and sampling should occur, when expired alveolar air is the desired specimen.

Certain key findings of this project with respect to breath samples are summarized in Table 12. These breath volume data demonstrate that (1) there is a wide variability in both forced vital capacity and in maximum exhalation after normal inhalation among different persons, and (2) these breath volumes cannot validly be predicted a priori for a given subject, with accuracy adequate for breath-alcohol analysis applications. Several conclusions follow.

The breath sampling device schematically illustrated in Figure 9 is

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intended to accomplish collection of expired alveolar air after wasting of all dead-space gas, by use of a discard bag. The data in Table 12 demonstrate the futility of this approach as utilized in the so-called ALVEOLAR AIR BREATH ALCOHOL SYSTEM and the MOBAT SOBER-METER SM-7 device. As noted above, the gas composition alveolar plateau is attained after about 67% of the total breath has been exhaled. It seems reasonable to hypothesize that the alcohol content of breath, during continuous complete exhalation, parallels the breath CO_2 and O_2 contents. Hence, two-thirds of the maximum expiratory volume available must evidently be discarded before the highest consistent breath-alcohol concentration (or partial pressure) plateau is attained in the specimen. From the data in Table 12, this requires that a *mean* volume of at least 1818 ml. be discarded after a normal inspiration whereas the commercial discard bag volumes are, respectively 780 ml. (B-D ALVEOLAR AIR BREATH ALCOHOL SYSTEM) and 675 ml. (MOBAT SOBER-METER SM-7). These discard volumes are inadequate to assure subsequent collection of expired alveolar air even with the mean breath volumes found in this project, much less at the higher limits. Further, in law enforcement practice, it is common to direct subjects to provide breath specimens after a maximum or near-maximum inhalation (e.g., cf. instruction for use of ALCOLYSER, Appendix B). In such situations, the data in Table 12 indicate that a *mean* breath volume of 2688 ml. must be discarded before sampling to obtain the highest breath-alcohol concentration plateau.

Moreover, the data in Table 12 demonstrate clearly that no single fixed-volume discard can assure collection of expired alveolar breath in an un-selected population. It is recognized that several of the tested devices are intended for use with mixed expired breath. However, these findings can largely explain the demonstrated inadequate performance of breath-alcohol screening test devices employing inadequately-sized breath collection bags (3), whether expired alveolar or mixed expired breath are the intended sample. It should also be noted that posture during breath sampling affects the results, and that freedom of movement and proper position are necessary for complete exhalation.

The breath pressure data in Table 13 are of considerable significance. The variability shown there is considerable among subjects, as reflected by the six-fold difference between breath pressure extremes. These typical breath delivery pressures are presumably reflected in comparable increases above atmospheric pressure in the intrathoracic pressure gradients, which may thus reach 10-12% or more above atmospheric pressure. When breath samples are brought from these physiological pressures to atmospheric pressure, the concentration of alcohol is proportionately decreased below that in the lungs. These factors are complicated further by the fact that some screening test devices interpose the alcohol detector tube directly between the mouth and the volume-limiting bag, in which situation it is impossible to establish a single calibration which will accomodate the widely different breath pressures above atmospheric reflected in Table 13. Clearly, resistance to breath flow should be kept to a minimum, and uniform; and calibration and verification of breath-alcohol testing devices should occur at total pressures corresponding to those to be expected during breath sampling with the device concerned.

As illustrated in Figure 6, both end-expiratory temperature and end-expiratory CO_2 attain their respective alveolar plateaux at or near the same time. Figure 7 shows performance of the same temperature and CO_2 sensors in tracking abrupt changes in an in-vitro system. The rapid rise to the respective final values indicates that the slower responses shown in Figure 6 are the result of biological phenomena rather than instrumental artefacts. The slightly slower initial increase in breath temperature, compared with the time-course of CO_2, is probably largely attributable to the differences in response time of the respective sensors. The precision and accuracy of in-vitro CO_2 response of the capnograph illustrated in Figure 8 further confirm the probable biological origin of the slower response illustrated in Figure 6.

It is evident that expired alveolar air is the sample of choice for breath alcohol analysis, including screening test applications. While fixed volume discard-or-collection schemes are incapable of procuring expired

alveolar air in an unselected population, four different schemes can provide
practical means for determining when the alveolar plateau has been reached dur-
ing continuous expiration, or for securing breath specimens which are essentially
alveolar (or functionally equivalent to alveolar air) in composition:

(1) The expiration can be monitored with a rapidly responding device sen-
sitive to an appropriate breath component (e.g., carbon dioxide, oxygen, or
water vapor) until breath composition becomes essentially constant, or the rate
of composition change approaches zero

(2) A phenomenon known to have a time course that parallels changes in
breath composition (e.g., breath temperature) can similarly be monitored with
rapidly responding instrumentation

(3) A small or moderate breath volume can be exhaled into a suitable
collapsible container, initially empty, and repeatedly inspired and expired
until this "rebreathed air" has attained an essentially fixed composition
with respect to the component of interest

(4) A small or moderate breath volume (e.g., 250 ml. or less) can be
collected at or near the end of a prolonged, uninterrupted full expiration,
by means of a device which traps an end-expiratory specimen.

For screening purposes, especially in field application, the last two pro-
cedures appear most practical, and of these the last is considered preferable
at the present time. Apparatus exist, e.g., the DPC Intoximeter (15) and the
Breathalyzer®Collection Unit (12), which can, in competent hands, be used to
collect and temporarily store a true end-respiratory breath specimen and deliver
it at a fixed rate to a disposable single-use alcohol detector tube. The com-
bination would provide an acceptable breath-alcohol screening test system.

For field use, a screening test employing only single-use components
might be preferable. Figure 10 illustrated our concepts for two disposable
devices for collection and temporary short-term storage of expired alveolar
breath. The upper illustration shows, in cross section, a collapsible double-
walled plastic container. Breath is simultaneously admitted, through one-way
valves, into the inner sample chamber and the outer jacket which provided
breath-derived heat and insulation. The excess breath escapes through exit
valves until expiration stops, and a spring-loaded exit valve on the central
sample chamber then traps the end-expiratory sample. After insertion of an
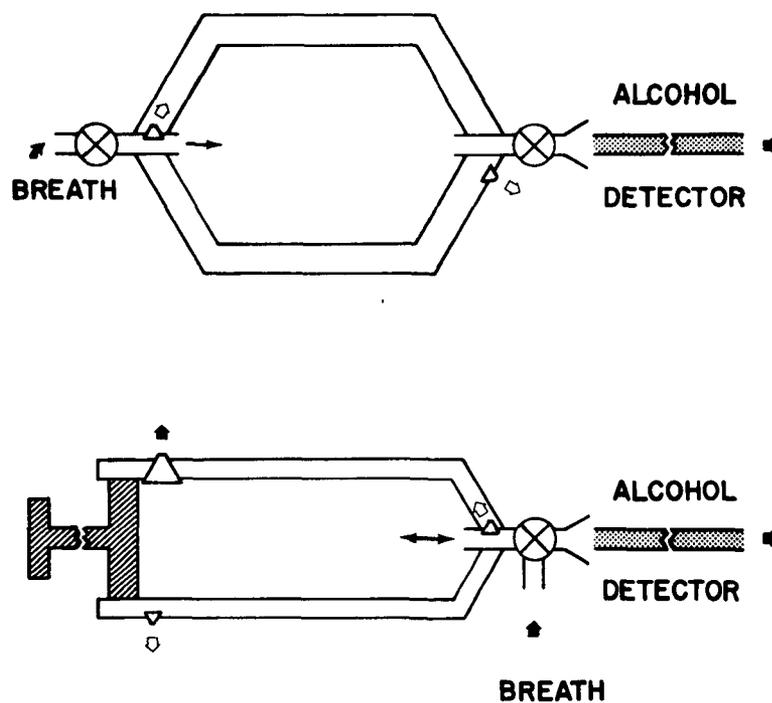
Figure 10. Concepts for Disposable Devices for Collection and Short-Term Storage of End-Expiratory Breath for Breath-Alcohol Screening Tests. The Upper Illustration Represents a Collapsible, Double-Walled Plastic Container; The Lower Illustration Represents a Modified Double-Walled Syringe.

alcohol detector tube, the exit valve is opened and the fixed volume of breath sample forced through the detector tube manually or with a simple spring-activated hinged press.

The lower illustration shows, in cross section, a rigid, double-walled container design based on a modified plastic syringe. Breath is again simultaneously admitted, through directional valves, into the inner syringe barrel and the outer jacket which provided breath-derived heat and insulation. Excess breath escapes through exit valves until expiration stops; a spring-loaded valve on the central chamber then traps the end-expiratory sample. After insertion of an alcohol detector tube, the barrel valve is opened and the fixed volume of sample forced through the detector tube with the syringe plunger. With both devices, the fixed analyzed breath volume would be of the order of 50-100 ml., and the jacket volumes would be of the same order of magnitude. With a breath throughput of 2-4.5 liters (Table 12), retention of only 100-250 ml. would insure that the retained specimen aliquot was end-expiratory. The length-of-stain alcohol detector tubes could readily be modified, as outlined above or otherwise, to bring their alcohol quantitating capacity and sensitivity into conformity with these breath sample volumes.

The results of this study complement and in large measure explain the findings reported by Prouty and O'Neill (3), who concluded, with respect to the breath-alcohol screening test devices tested by them, that "under no circumstances can these disposable screening devices be expected to produce results free of error." Three breath-alcohol screening test devices were evaluated in both the Prouty and O'Neill study and in this project: Alcolyser PST 100, Alveolar Air Breath Alcohol System, and Mobat Sober-Meter SM-1. The limitations and deficiencies in breath sampling with those devices noted in this study can largely account for the inadequacies in performance documented by Prouty and O'Neill. The findings of this study also indicate that such devices, in the respective current versions studied, should be used only for the limited purpose of indicating presence or absence of alcohol in a breath sample; but that modifications in design and execution of length-of-stain devices can yield breath-alcohol screening tests of adequate validity, reliability, and practicability for law enforcement and related applications.

CONCLUSIONS

The principal conclusions resulting from this study are:

(1) The alcohol detector tubes of several commercial breath-alcohol screening test devices investigated in this study are basically capable, under suitable conditions, of quantitating alcohol in gas and vapor samples with adequate accuracy and precision for breath-alcohol screening test applications.

(2) The breath sampling designs and arrangements of the breath-alcohol screening test devices investigated in this study are unsatisfactory and suboptimal in several significant respects.

(3) Expired alveolar breath (or its functional equivalent with respect to alcohol content, such as rebreathed air) is the specimen of choice for breath-alcohol analysis, including breath-alcohol screening tests, and only end-expiratory collection and rebreathing schemes are suitably valid and practical sampling procedures for such tests, the former being currently preferable.

(4) Valid and practical breath sampling schemes for breath-alcohol screening tests must incorporate discard of at least two-thirds of the available breath, provide for adequate temperature control, and involve minimal pressure increase above atmospheric pressure during sampling. Quantitative data bearing on these breath parameters have been obtained.

(5) Suitable combination of proper breath sampling and alcohol detectors of the length-of-stain type can yield breath-alcohol screening tests of adequate validity, reliability, and practicability for law enforcement and related applications.

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REPORT OF INVENTIONS APPENDIX

After a diligent review of the work performed

under this contract, no new invention, discovery,

improvement or invention deemed patentable was

made.

INSTRUCTIONS FOR USE OF BREATH-ALCOHOL SCREENING TESTS

ALCOLYSER

**Alcohol in breath turns Yellow
Crystals Green**

Green stain in the lower part of the tube but NOT EXTENDING to the red mark

BELOW LIMIT

Green stain extending UP TO the red mark

ABOVE LIMIT

INSTRUCTIONS FOR USE

Wait 15 minutes after alcoholic drink before testing.

(a) Cut and break-off each end of the tube in the saw aperture provided. Remove mouthpiece cap.

(b) Push red band end of the tube into the neck of the plastic bag, and insert the arrow end of the tube firmly into the exposed mouthpiece.

(c) Take a deep breath and blow steadily until the bag is fully inflated (blowing time 10-20 seconds), more than one breath may be used if necessary.

INSTRUCTIONS FOR USE OF BREATH-ALCOHOL SCREENING TESTS

10.72 12 36

DR. K.M. DUBOWSKI

ALCOTEST®

Alcohol indication in expired air

Approved by the Secretary of
State for the Home Depart-
ment and the Secretary of
State for Scotland for the pur-
pose of the Road Safety Act
1967

INSTRUCTIONS FOR USE OF BREATH-ALCOHOL SCREENING TESTS

General

A considerable weight of evidence exists to indicate that the consumption of alcohol may impair the judgement and reduce the efficiency of drivers of vehicles. From both the legal and the analytical standpoints it is necessary for Police and Traffic Control Authorities to be in a position to relate the effects of alcohol consumption to traffic offences. The most reliable method of ascertaining the blood alcohol concentration (B.A.C.) is by the examination of blood samples. This, however, presents certain difficulties of administration, time, and general inconvenience to officials, hospital authorities and the driving public.

The need, therefore, became apparent for a simple, visual, accurate, on-the-spot device capable of providing an immediate indication of whether or not a driver, implicated in a traffic offence, and suspected of having consumed alcohol, should be submitted to a blood examination.

The Alcotest unit for measuring alcohol indication in expired air was developed for this purpose. Since its introduction, some five million Alcotests have been carried out in the countries of Western Europe by Police Forces, and Traffic Control, and Health Authorities.

The measurement of accuracy of the Alcotest is the comparison of its indication with the B.A.C. measured in subsequent blood tests. The results of such comparisons show a good agreement.

Description of the apparatus

The Alcotest unit comprises:
1. A breathing bag with a collared neck and having a capacity of 1 litre
2. An Alcotest indication tube
3. A mouthpiece.

The indication tube contains a yellow reaction layer and a bisectional annular marking to facilitate evaluation.

Conditions of the test

Immediately after alcohol has been taken a relatively high alcohol concentration is present in a relatively small quantity of saliva. An Alcotest taken at such a time would primarily be a measurement of "mouth-alcohol" as opposed to "blood alcohol" and would thus provide a falsely high indication

It is therefore essential that at least 15 minutes should elapse between the drinking of alcohol and the taking of the Alcotest .

The time taken, and the number of exhalations required to inflate the bag, is of significance. In practice it is not possible to inflate the bag in less than 10 seconds because of the resistance of the testing tube. A prolonged inflation time or repeated attempts at inflation give a false evaluation because of the increased proportion of tidal air in the expired sample.

The time of inflation of the bag should be 15 seconds ± 5 seconds and the bag should be inflated by one breath only.

Description of the test

An Alcotest indication tube is taken from the packet. Both ends are broken off in the seal breaker provided. The breathing bag is squeezed empty. The tube is inserted into the collar of the bag with its arrowed markings pointing towards the bag. The mouthpiece is fitted to the other end of the indication tube.

The bag is inflated by one exhalation in 15 seconds ± 5 seconds.

The Alcotest indication tube is inspected and the extent of GREEN discolouration of the yellow indicating layer is observed.

Fig. 2
The ALCOTEST tube is removed from the packet. Both ends of the tube are scratched on the built in ampoule saw and broken off in the snap hole.

Fig. 3
The green end of the tube is then inserted into the collar of the empty measuring bag, so that the arrow points towards the bag.

Fig. 1
Alcotest opened packet.

▼ Fig. 1

▲ Fig 2

▼ Fig 3

INSTRUCTIONS FOR USE OF BREATH-ALCOHOL SCREENING TESTS

Results of the test

Three points must be borne in mind when assessing the results of the Alcotest

1 The accuracy of the results depends on the fulfillment of the **conditions of test** given above

2 The results are a diagnosis. That is to say, they indicate a condition at a given time, namely, the alcohol concentration in the blood at the time of the test. They do not permit conclusions to be drawn on **how much** alcohol has been taken, nor whether the **alcohol concentration will increase or decrease.**

3 On a strict basis of the factual results of the Alcotest the decision must be made as to whether or not a blood examination is justified.

The blood alcohol concentration (B.A.C.) is indicated by the green discolouration of the yellow reaction layer. The lowest limit of indication is 0.1 mg which, under conditions of test, corresponds to a B.A.C. of 0.03 %. In the case of B.A.C. values of **less than** 0.07 %, the green colour zone should **not** extend to the annular marking **(a)**. In the case of B.A.C. values **in excess** of 0.07 % the green zone **will reach or pass** the marking **(b)**.

Miscellaneous

A high proportion of tobacco smoke tends to colour the reaction layer BROWN. Smoking immediately before or during the test should not be allowed.
For reasons of hygiene a new sterile mouthpiece should be used for each test. The breathing bag may, however, be used repeatedly.
If kept in a closed container at normal room temperatures, and protected from light, Alcotest® indication tubes may be stored for at least three years.
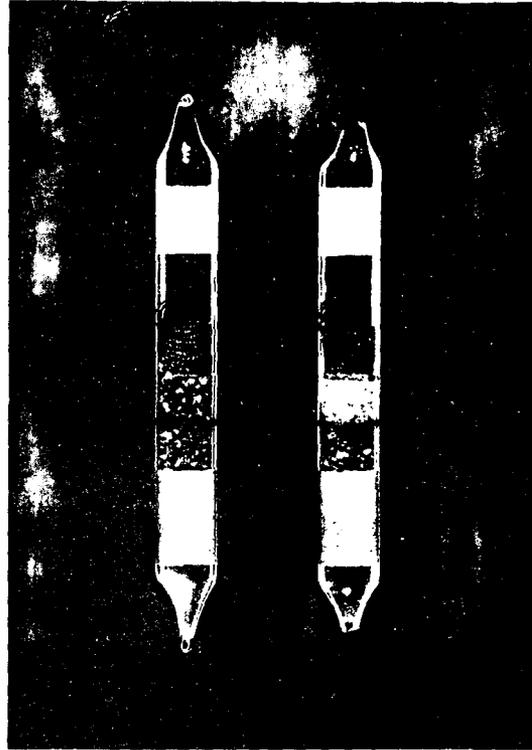
22 334 o

Fig. 4
The protective paper is then removed from the set of mouthpieces.

Fig. 5
The white end of the tube is then pushed firmly into the mouthpiece.
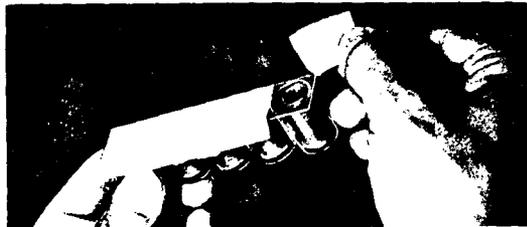
Fig. 6
The subject being tested must blow through the mouthpiece and tube into the bag until the latter is fully inflated. This should be done with one single breath in not less than 10 and not more than 20 seconds.

▼ Fig. 6

▲ Fig. 4

▼ Fig. 5

INSTRUCTIONS FOR USE OF BREATH-ALCOHOL SCREENING TESTS

**ALVEOLAR AIR
BREATH
ALCOHOL
SYSTEM**

B-D **BECTON-DICKINSON**
DIVISION OF BECTON, DICKINSON AND COMPANY
RUTHERFORD, NEW JERSEY   07070
B-D T.M. REG. U. S. PAT. OFF.   •   MADE IN U.S.A.

100·110·007

The Alveolar Air Breath Alcohol System provides law enforcement personnel with a rapid, on the spot preliminary breath alcohol screening test.

TEST PROCEDURE

1. Wait 15 minutes following apprehension. Do not allow suspect to smoke or drink.

2. Air temperature should be above 60°F during test. (If necessary, use interior of patrol car.)

3. Ask subject to blow through mouthpiece into bag with one long expired breath. Both sides of bag inflate. The last side to inflate is the side containing *alveolar air and is the side to be tested.*

4. Then use the metal tube breaker to snap both ends of the glass detector tube.

5. After subject fully inflates bag, grasp bag below mouthpiece to insure no loss of air. Place unfilled end of the detector tube into the unrestricted tapered hole of the mouthpiece. Tube *should be firmly seated in this hole.*

INSTRUCTIONS FOR USE OF BREATH-ALCOHOL SCREENING TESTS

6. Taking 2½ minutes, squeeze the full chamber and force all of the air back through the detector tube with a steady even pressure. Note the time required for this procedure. If more than 2½ minutes, the result will tend to be lower than the true value. If less than 2½ minutes, the result will tend to be higher than the true value.

7. When the chamber is empty, wait 3-5 minutes for the chemical in the detector tube to develop. In the presence of alcohol, the yellow crystals will turn green in a proportion to the amount of alcohol in the sample alveolar air.

8. AT THE END OF THE 3-5 MINUTES, position the tube on the scale provided. The empty end is below the zero point on the scale, and the beginning of the green crystals lines up with the zero on the scale. The upper end of the green stain will indicate the % alcohol in the breath which is equivalent to the precentage of alcohol contained in the blood.

9. Do not reuse kit. Discard after one use.

DATE _____ TIME _____ AM·PM

PLACE _____

POLICE OFFICER _____

WITNESS _____
  I have observed the placement of the tube as well as the color change up to the inked line and hereby verify same.

SUBJECT _____
  I have granted permission to have this test performed.

mark scale at horizontal termination of green stain with pen

.15 ——
.10 ——
.05 ——

.00 ——

place tube so first green crystals are at zero line

scale indicates equivalent percentage of alcohol in blood w/v

place tube here

SEAL

SEAL
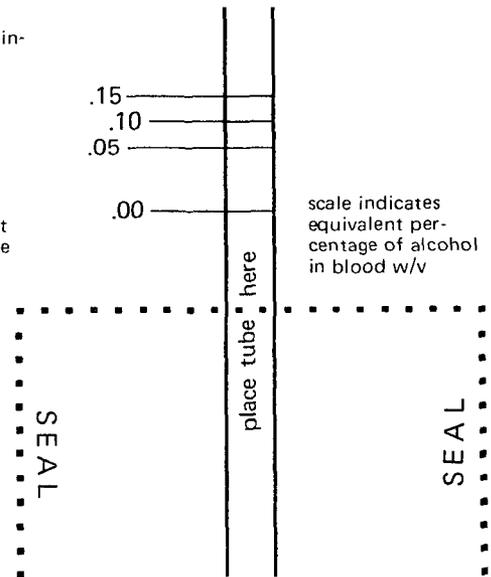
INSTRUCTIONS FOR USE OF BREATH-ALCOHOL SCREENING TESTS

sober-meter.   DIRECTIONS: Before testing avoid smoking and wait 15 minutes after an alcoholic drink.

1. Remove caps and discard loose, white crystals from both ends of color tube. Connect one end to balloon sleeve and replace cap in other end. 2. Inflate balloon until end of box lid fits between markers on balloon. 3 Remove cap and permit breath to pass through tube EXACTLY ONE MINUTE. Replace caps and wait 5 minutes for color to darken. 4. Read color tube like a thermometer observing the highest position of the green color. (See bottom of box for interpretation.) ©1967

Name _____ Date _____

Location _____ Time _____

Remarks _____

Color Change   Mark highest green position detectable in 5 minutes.

Each color band in this testor ☐ Three color bands

corresponds to a blood alcohol ☐ Two color bands

content of 10 grams%. ☐ One color band