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Breath Alcohol Sampling Simulator (BASS) for Qualification Testing of Breath Alcohol Measurement Devices

Law Enforcement Equipment Technology

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Breath Alcohol Sampling Simulator (BASS) for Qualification Testing of Breath Alcohol Measurement Devices

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FOREWORD

The National Highway Traffic Safety Administration (NHTSA) is engaged in a continuing effort to fulfill the objectives of the Highway Safety Act of 1968. To this end, NHTSA has implemented the development of Qualified Products Lists (QPL) for breath alcohol analysis instruments, and is pursuing the development of a QPL for speed measuring devices. In this effort, it is receiving technical support from the National Bureau of Standards' Law Enforcement Standards Laboratory (LESL), whose overall program involves the application of science and technology to the problems of crime prevention, law enforcement equipment, and criminal justice.

LESL is assisting the NHTSA Alcohol Countermeasures Program by the development of performance standards for the variety of instruments used to measure the blood alcohol content from breath samples of suspected drunken drivers, and through related research.

Among the tasks being performed by LESL for NHTSA are the preparation and publication of technical reports on the results of its researches. This document is one such report.

Technical comments and suggestions are invited from all interested parties. They may be addressed to the authors, or the Law Enforcement Standards Laboratory, National Bureau of Standards, Washington, DC 20234.

Lawrence K. Eliason, Chief
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EXECUTIVE SUMMARY

The U.S. Department of Transportation (DOT) Alcohol Countermeasures Program was established by authority of the Highway Safety Act of 1968 in an effort to remove the drunken driver from our Nation's roadways. State and local governments participating in this program utilize evidential breath testers as a convenient means of measuring the blood alcohol content (BAC), of individuals suspected of drunken driving, for later use as evidence in the prosecution of those individuals whose BAC exceeds statutory limits. The National Highway Traffic Safety Administration (NHTSA) encourages State and local government participation in the countermeasures program, permitting Federal funds from the program to be used to purchase breath alcohol instrumentation, provided that the equipment is selected from the NHTSA Qualified Products List.

The analysis of the ethanol concentration of a suspect, displayed in units of BAC, is accomplished using a sample collected from a single breath that the accused delivers to the instrument. The physiological characteristics of humans vary widely from one individual to another. Since the BAC of a suspect is measured from a single breath, the differences in the respiratory system of the individuals that comprise the driving population are of critical importance to the design of breath alcohol instruments, for an accurate analysis requires a sample that is essentially "deep lung" or alveolar air.

This report describes a Breath Alcohol Sample Simulator (BASS) that was developed by the DOT Transportation Systems Center in cooperation with the National Bureau of Standards' Law Enforcement Standards Laboratory to provide an objective, reproducible mechanical substitute for human subjects in the evaluation of the performance of the breath sample collecting systems of breath alcohol instruments. Prior to undertaking the design of BASS, the results of earlier studies involving drinking human subjects were reviewed to analyze the relationship of the ethanol concentration in a single breath (exhalation) as a function of time. These data were expanded upon during the current laboratory research with non-drinking human subjects in a series of experiments using individuals with a range of vital capacities and respiratory capability. The concentration of CO_2 as a function of exhalation time for single breath samples was monitored for each subject when blowing into three tubes of different flow resistance, which approximated the range of resistance offered by commercially available evidential breath testers. These data, combined with statistical data on the range of vital capacities of the U.S. driver population, serve to establish the parameters that must be controlled in order to insure that the BASS can reproduce the extremes of single breath exhalations.

Each of the essential parameters that must be controlled to produce a substitute for human breath is discussed, and the capability of the BASS to achieve that degree of control is described, together with the detailed design and operating characteristics of BASS. Data are presented that establish the need for a three-segment ethanol vapor concentration profile, in which the time and volume are controlled to produce a continuous sample that will allow the sample collection system of breath alcohol analysis systems to be evaluated. Three specific BASS delivery cycles are recommended that include the range of vital capacities and flow rates, encountered in the driving population, which must be accommodated by an evidential breath tester to insure that the analysis of BAC is accomplished using a sample that is essentially deep lung air.

It is recommended that the BASS be incorporated into the NHTSA standards for breath alcohol testing instruments as the basis for all future qualification testing to eliminate the need of human subjects to evaluate the breath collecting capability of such instruments.

BREATH ALCOHOL SAMPLING SIMULATOR (BASS) FOR QUALIFICATION TESTING OF BREATH ALCOHOL MEASUREMENT DEVICES

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The blood alcohol content of an individual suspected of driving while intoxicated is often measured through the analysis of a breath sample using an evidential breath tester (EBT). Two factors determine the ability of an EBT to provide an accurate analysis of alcohol concentration: a) the capability of obtaining an appropriate breath sample, and b) the inherent accuracy of the analytical instrument. This report characterizes the relevant breath parameters and describes a breath alcohol sample simulator (BASS) that was developed as a means of reproducing accurate equivalents of human breath. The report discusses measurements made on human subjects to establish values for parameters the BASS must accommodate, and to demonstrate the validity of the BASS as a replacement for human drinking subjects with different levels of alcohol content and a range of physiological characteristics.

Key words: Blood alcohol analysis; blood alcohol content; breath alcohol content; breath sampling; evidential breath testers; human respiratory characteristics; intoxication.

1. INTRODUCTION

The Highway Safety Act of 1968 has resulted in the establishment of a nationwide Alcohol Countermeasures Program of the National Highway Traffic Safety Administration (NHTSA). The goal of the program is to remove drunken drivers from the roads. In pursuing this goal the NHTSA provides funds to assist the State and local governments in the procurement of breath alcohol test equipment.

All states have accepted blood alcohol concentration (BAC) as part of the legal basis for prosecution of individuals arrested for driving while intoxicated.

Blood alcohol concentration (BAC) is universally accepted as evidence in the prosecution of individuals charged with driving while intoxicated. The Uniform Vehicle Code [1][1] recognizes breath alcohol measurement as a means for determining BAC. Trained police officers can perform breath analyses more easily than blood analyses. Moreover, some investigators claim that breath analysis is a better test of impairment of driving ability because of the variability of ethanol content of the blood sample, which is dependent upon the part of the body from which the sample is obtained [2].

A number of commercially available breath alcohol testing devices give sufficiently accurate results to justify their use as evidence in the prosecution of allegedly drunk drivers. These devices, known as evidential breath testers (EBT's), utilize various instrumental techniques and principles of measurement [3].

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[1] Numbers in brackets refer to references in appendix A.

In 1972, NHTSA initiated a program with the Law Enforcement Standards Laboratory (LESL) of the National Bureau of Standards (NBS) to develop standards for EBT's and to establish a Qualified Products List (QPL). (State and local governments may use Federal funds from alcohol countermeasure programs for the procurement of equipment on the QPL only.) The standard for evidential breath testers was published by NHTSA in the Federal Register in 1973 [4], and the standard for calibration equipment in 1975 [5].

Two factors determine the ability of an EBT to provide an accurate analysis of alcohol concentration: a) the capability of obtaining an appropriate breath sample, and b) the inherent accuracy of the analytical instrument. The precision and accuracy of the EBT are readily determined by replicate measurements using vapors of known alcohol concentration. However, in order to determine if a given instrument collects an appropriate human breath sample, it is necessary to correlate the breath-estimated BAC reading of the instrument with either actual blood alcohol concentration, or with breath that is known to have the same concentration of alcohol as air in the alveoli of the lungs. The standard issued in 1973 required determination of the breath sampling characteristics of EBT's through direct correlation of blood analysis with instrument readings of breath alcohol concentration. The breath and blood samples were taken on as nearly a simultaneous basis as possible.

Later, an improved test method to evaluate the breath sampling characteristics of EBT's and other breath alcohol instruments was developed to serve as the basis for QPL acceptance. The alcohol concentration is first determined for a single breath of one subject, then compared to the instrument reading obtained after the same subject repeatedly inhales and exhales (rebreathes) the same air into a collapsed plastic bag. The measured alcohol concentration of the single breath sample is typically about 10 to 20 percent lower than that of the rebreathed levels. Rebreathed breath samples very closely approach the alcohol concentration of that portion of the breath that is in equilibrium with the pulmonary blood [2,6] (see also sec. 2 below). An evidential breath tester is considered to be satisfactory if paired comparisons of blood and breath alcohol concentrations, taken over many subjects, yield a correlation coefficient of at least 0.95. Furthermore, since it has been recognized that breath alcohol readings tend to be biased toward lower values than blood alcohol concentration, a limiting value of –22 percent has been set: that is, the breath alcohol concentration must not be less than 78 percent of the value for blood alcohol concentration.

These procedures are acceptable, but have the following undesirable features:

- It is impractical to obtain a sample of human subjects that (a) is representative of the drinking driver population, and (b) is large enough to account for physiological variability among individuals yet at the same time small enough to manage within the limits of available laboratory resources.
- Federal guidelines require that experimental data be obtained without human experimentation whenever possible.
- Medical monitoring of intoxicated subjects is increasingly difficult to obtain.

There are obvious advantages to the replacement of human subjects with a mechanical system that is essentially an operational equivalent to the human subject for this purpose, and whose performance is more reproducible. Of course, human breath cannot be faithfully reproduced in every respect. Nonetheless, the key physical parameters relevant to breath alcohol content measurement can be closely modeled and simulated. It is the purpose of this report to characterize relevant breath parameters and to describe the Breath Alcohol Sample Simulator (BASS) that was developed by the Transportation Systems Center (TSC) as a means of reproducing accurate equivalents of human breath. The report discusses measurements made on human subjects to establish values for parameters that the BASS must accommodate, and the demonstration of the validity of the BASS as a replacement for human drinking subjects with different levels of alcohol content.

2. PARAMETERS TO BE MODELED BY A SAMPLE SIMULATOR

It is necessary to understand the essential features of the human respiratory system in order to consider the effects of the presence of alcohol and to characterize those attributes which can be measured, modeled, and simulated. A more complete treatment than the summary discussion below can be found in any standard text on human physiology.

The airways of the respiratory system include (a) the alveolar sacs within the lungs and (b) the upper respiratory tract (URT), which consist of the oro-nasal cavity, pharynx, larynx, trachea, bronchi, and bronchioli. Where blood vessels contact the alveoli, the surface-to-volume ratio is much higher than that in the remainder of the respiratory system. Consequently, the alveoli-blood interface is the primary locus for active gas exchange between blood and breath, with relatively little exchanged elsewhere. Here, then, almost all alcohol exchange takes place.

All components of the entire respiratory system are covered with watery mucus that plays an important role in establishing the alcohol content of expired breath. As air laden with alcohol vapor, carbon dioxide, or other gases passes through the system, some molecules are dissolved into the surface moisture. At any given moment, during a breathing pause, stationary air in the URT contains alcohol vapor tending toward equilibrium with the watery film. Following an inhalation, alcohol deposited in the watery film during the previous expiration is mixed with other gases present. A single expiration at this time manifests an alcohol concentration much lower than that found in the alveoli. However, if the mucus of the URT becomes saturated with respect to alcohol—as would occur with rebreathing exhaled breath several times—the expired breath reaches an alcohol concentration comparable to that deep in the system. The effect of a single (i.e., non-rebreathed) expiration is production of an asymmetric alcohol concentration profile over time; figure 1 shows typical mass spectrometer traces of forced human exhalations, using ions from

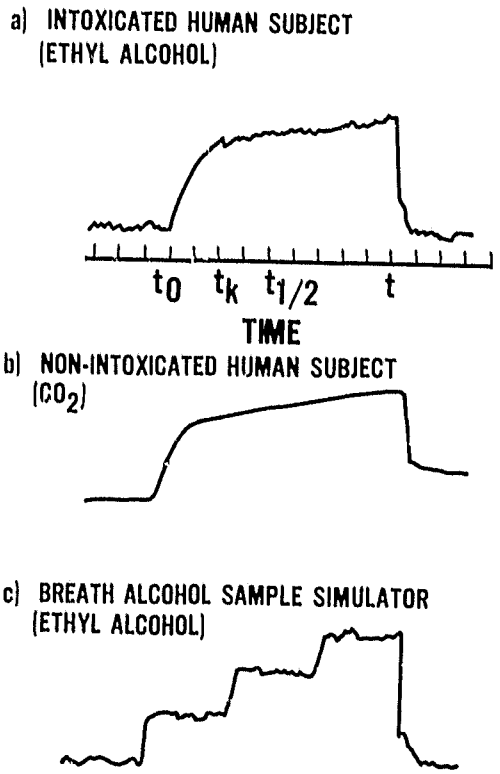

FIGURE 1. *Typical mass spectrometer profiles (concentration vs. time).* (Ion specimen monitored: for ethanol mass 31, for carbon dioxide mass 44. Concentration units are arbitrary). Note: Failure of CO_2 concentration to return to base line after completion of exhalation is an artifact of instrumental set-up.

either ethyl alcohol or carbon dioxide as expired air indicators. The absorption-desorption process underlying this profile is described in more detail elsewhere [2,7,8].

The air-to-blood and air-to-water partition coefficients for ethyl alcohol have been determined [2,9]. *In vitro* measurements yielded the partition ratios shown below (in terms of volume of air containing the same amount of alcohol as one volume of liquid in equilibrium with air):

	Temperature	Liquid/air volume ratio
Blood	37° (Pulmonary blood temperature)	1/1692
	34° (Average single breath temperature)	1/2033
Water	37°	1/2128
	34°	1/2538

In vivo measurement of the alcohol concentration of the end portion of expired breath for single breath [2] and rebreathed breath [2,6,10] yield the following ratios:

	Average breath temperature	Blood/air volume ratio
Single breath	34 °C	1/2300
Rebreathed breath	34°–36 °C	1/2100

These data indicate that, even in the alveoli, alcohol vapor is in equilibrium with surface water, rather than blood. (That the rebreathed temperature does not reach 37 °C is related to the fact that the data were not obtained at 100% relative humidity, i.e., inspiration of dry 37 °C air cools URT by evaporation of surface water.)

The single breath ratio obtained for a given individual varies according to the pattern of breathing prior to sampling, ambient temperature and the volume expired. The National Safety Council has established a ratio of 1/2100 as a firm upper limit when converting single breath alcohol levels to blood alcohol concentration. Application of this ratio (instead of 1/2300) to breath alcohol testing provides a generous margin in favor of the accused in drunk driver proceedings. In other words, any lower ratio (such as 1/2300) would yield higher estimates of blood alcohol concentration.

As is shown in figure 1a, the expired breath profile can be viewed as a sequence of three distinct sections in terms of the relative alcohol concentration and the rate of change: a small initial portion (t_0–t_i) low in alcohol, but with rapidly changing concentration; an intermediate portion (t_i–$t_{1/2}$) with slowly changing concentration; and a final portion ($t_{1/2}$–t) in which a steady state of the highest concentration has been reached. It will be seen in section 4 that the last quarter of the total volume of expired breath is appropriate for determining the "highest" concentration (alveolar alcohol concentration). Since the vital capacity[2] of most adults lies between 2 and 6 liters (L) [7], not more than 500 mL of the final portion of an expired breath should be retained for analysis to ensure that the breath tester sampling system will be applicable to all individuals, including those with the smallest vital capacities.

Given the objective of accurate assessment of alcohol concentration in the deep respiratory system and in view of the asymmetry of the time profile of alcohol concentration of expired air, the optimal measuring device should be designed to discard the first portion of expired breath, retaining only the last portion for analysis. It is similarly obvious that an artificial breath sample must be generated in a controlled sequence to produce an appropriate time-concentration profile at a prescribed flow rate for a specified volume. The volumes of (simulated) breath that are discarded

[2] Vital capacity is the maximum volume of air which can be exhaled by a person following a maximal inhalation.

and retained will then depend on the flow rate. At constant delivery pressure, flow rate is in turn determined by the flow resistance of the breath tester; if that flow resistance is high, resultant high flow pressure undesirably induces a backward flow of air and compression of the air.

A backflow, related to turbulence and system geometry, causes mixing of the air delivered earlier and later, thus diluting the analyzed portion and biasing the measurement of alcohol concentration on the low side. The direction of bias results from compression, which increases the density. In the normal operation of most breath testers, the collected breath sample volume expands upon reverting to atmospheric pressure before analysis; hence the apparent alcohol concentration is less than the actual [8]. (This effect is discussed further below.) To avoid backflow and compression effects, it is desirable to design EBT's with low flow resistance.

In sum, the volume, flow rate, flow pressure, and temperature of the expired air during the collection process are the key parameters which affect the measured value of alcohol concentration. The following section discusses the characteristics of the sample simulator developed by TSC to model these parameters.

3. BASS DESIGN OBJECTIVES

The BASS is a mechanical device that can objectively produce an intended substitute for human breath; its purpose is to test the sampling performance capability of an EBT. The appropriate breath sample for an EBT is that portion of the exhalation that contains an adequate amount of the undiluted portion of expired alveolar air. Since the measured alcohol concentration depends strongly on the parameters discussed in the last section, each parameter requires control, the degree of which depends on the relationship of that parameter to alcohol concentration. A sampling simulator incorporating and properly controlling the required functional parameters should then satisfy the objectives.

The requisite functional parameters and their relationships to the alcohol concentration in the breath sample collection process are discussed in the following sections. Human physiology varies with individuals and also with time in the same individual, hence any given functional relationship is based on statistical averages. In those cases where choices were necessary, a conservative approach was used in the sense that assigned values would result in an estimated BAC on the low side, thus affording greater protection for a driver accused of drunkenness.

Temperature

The average temperature of expired breath is 34 °C. The temperature coefficient for partition of alcohol in the temperature range from 20°–40 °C is about 6 percent per degree. Control of temperature to within ±0.1 °C is required in order to produce samples with ethanol vapor concentrations that meet the requirements of the NHTSA Standard for Calibrating Units [5].

Volume and Time

The volume of breath measured after deep inspiration and forced exhalation (vital capacity) varies among individuals from about 2 to 6 L [7], and may take an adult, depending on age, sex, and physical condition, from 6 to 17 seconds (s) (see sec. 4) to deliver into currently available EBT's. To be able to simulate the undiluted expired alveolar air contained within the last quarter portion of the breath, the BASS must accommodate total volumes equivalent to the full range of vital capacity (2 to 6 L) and deliver the sample over times of 6 to 17 s.

Flow Rate and Pressure

According to the Poseuille equation for laminar flow in a pipe, the flow rate, Q (volume per unit time), is related to the pressure drop from the inlet to the outlet, Δp, by

$$Q = \frac{\pi r^4}{8\mu l} \Delta p \tag{1}$$

where r is the radius and l is the length of the pipe through which the fluid flows and μ is the viscosity of the fluid. Since the flow resistance is inversely related to the pressure drop, it follows that $8\mu l/\pi r^4$ is the flow resistance. If the latter is a constant, the flow rate is directly proportional to the pressure drop. If the pressure drop is to be minimized while keeping the flow rate constant, the flow resistance must be lowered. This may be accomplished by reducing the length or increasing the radius of the flow pipe, or by doing both.

Physiologically, the flow resistance is about 3.3 cm H_2O·s/L in normal breathing through the oro-nasal cavity [11]. For a flow rate of 1 L/s, which corresponds to 6 L of air delivered in 6 s, the pressure drop is only about 3.3 cm H_2O. A BASS whose output is open to the atmosphere should therefore have a flow resistance of 3.3 cm H_2O·s/L to assure that the simulator delivers simulated breath to an EBT without inducing error. The effect of the delivery pressure into EBT's will be discussed in section 4.

Alcohol Concentration

The expirogram shown in figure 1a shows a typical profile of breath alcohol concentration. A sample simulator must generate a sample with an alcohol concentration profile with increasing levels of alcohol concentration, attaining a final concentration plateau comparable to the level of the final concentration in the breath profile. However, the latter portion of the simulation will be adversely affected if flow resistance in the breath tester induces high delivery pressure. This problem will be addressed in the following section.

4. TSC BREATH ALCOHOL SAMPLING SIMULATOR

Design Approach

Typical asymmetric breath alcohol profiles (as shown in fig. 1a) can be approximated (as in fig. 1c) by arranging several commercial simulators in parallel, their exit tubes all connected to a common manifold. By switching air through the several simulators in an appropriate sequence, a series of profile steps, joined together, will produce a single profile. The resultant overall profile can be shaped as desired by adjusting the amount of alcohol in the individual simulators and by regulating the times of switching. This design approach was followed in constructing the BASS, a block diagram of which is shown in figure 2.

Assembly and Operation

The elements of BASS construction are shown in figures 3 through 6 (pressure gage is not shown). Figure 3 shows the operation of the device. A 7-L air-driven floating piston and cylinder assembly delivers air through the three temperature controlled alcohol solution reservoirs. The output mixture of alcohol and air is passed into the breath test instrument being evaluated.

The following discussion identifies by manufacturer and model the equipment used in fabricating the prototype BASS unit. However, mention of an item or manufacturer in no way constitutes an endorsement of the products by either the NBS or the DOT Transportation Systems Center. Any equipment which meets the functional requirements described herein may be used to construct a breath alcohol sample simulator.

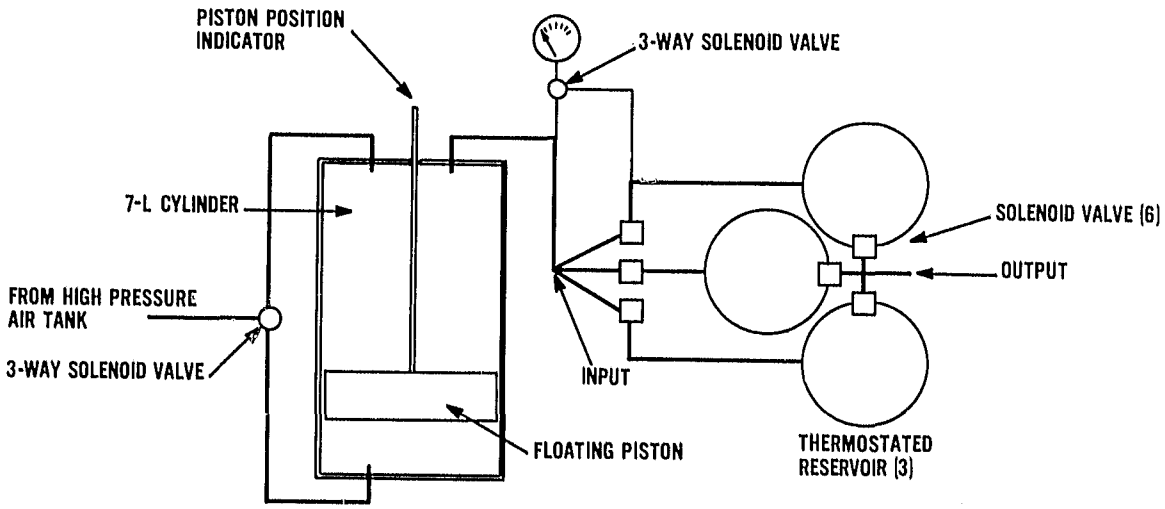

FIGURE 2. *BASS block diagram.*

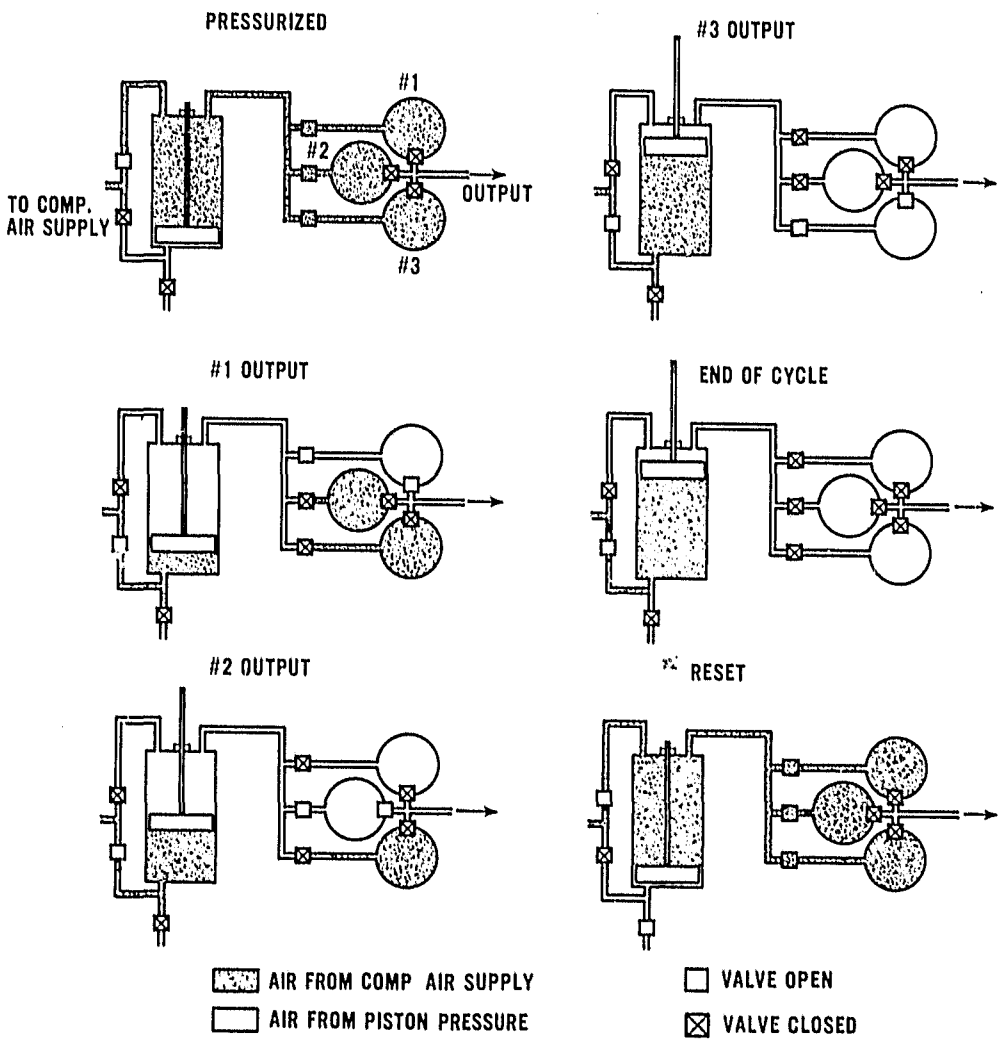

FIGURE 3. *Breath alcohol sample simulator operating diagram.*

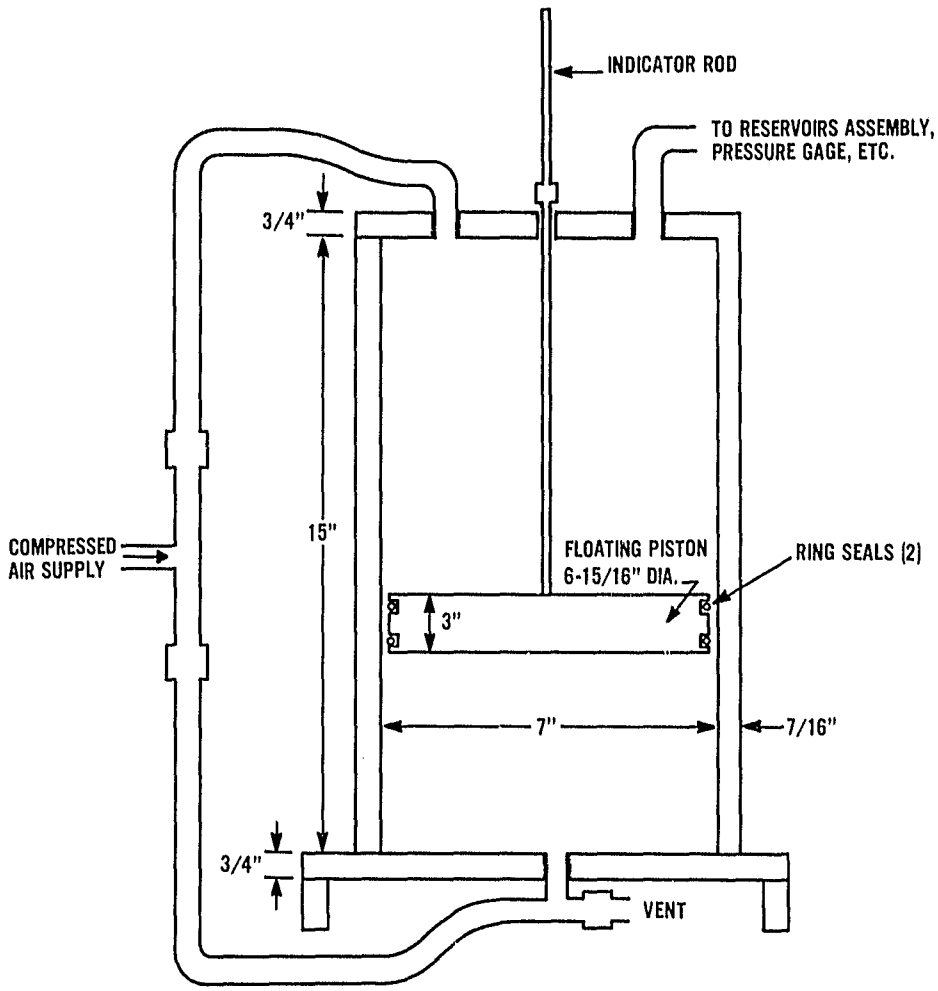

FIGURE 4. *BASS construction.* Air supply assembly.

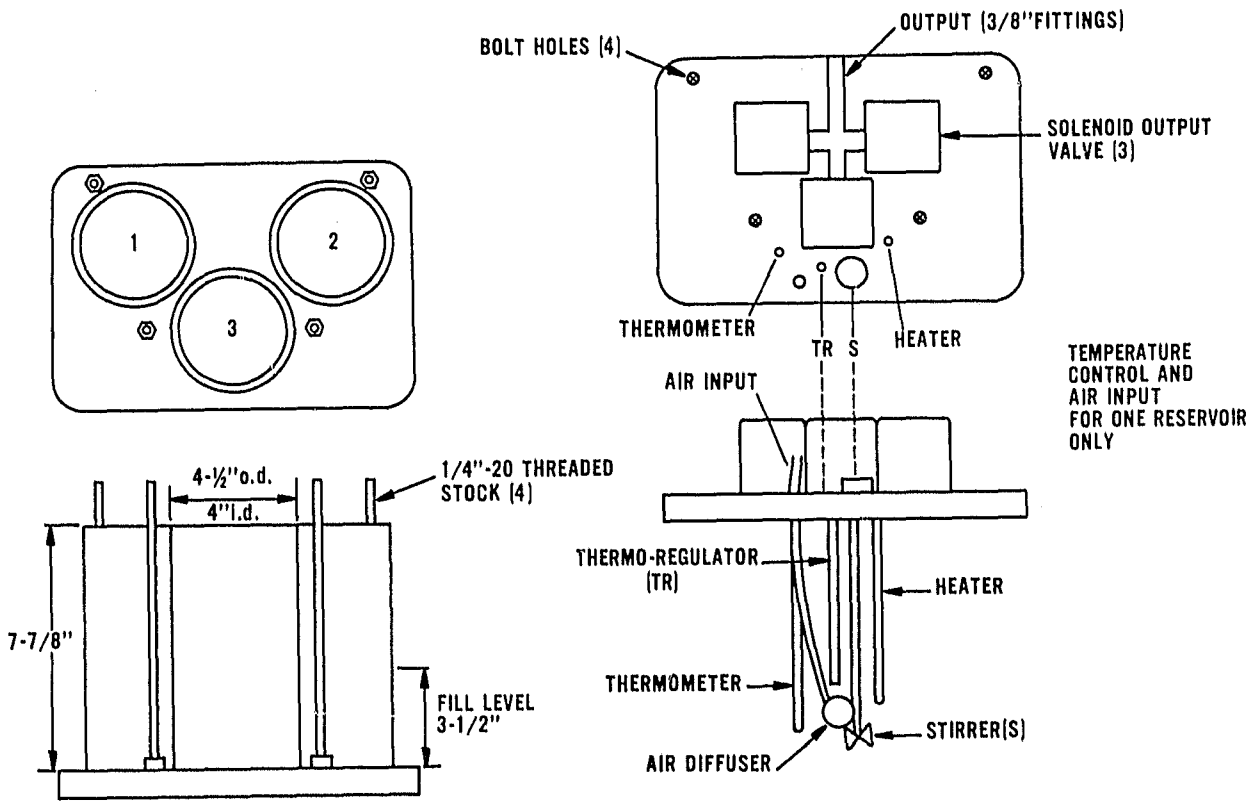

FIGURE 5. *BASS construction.* Reservoir assembly.

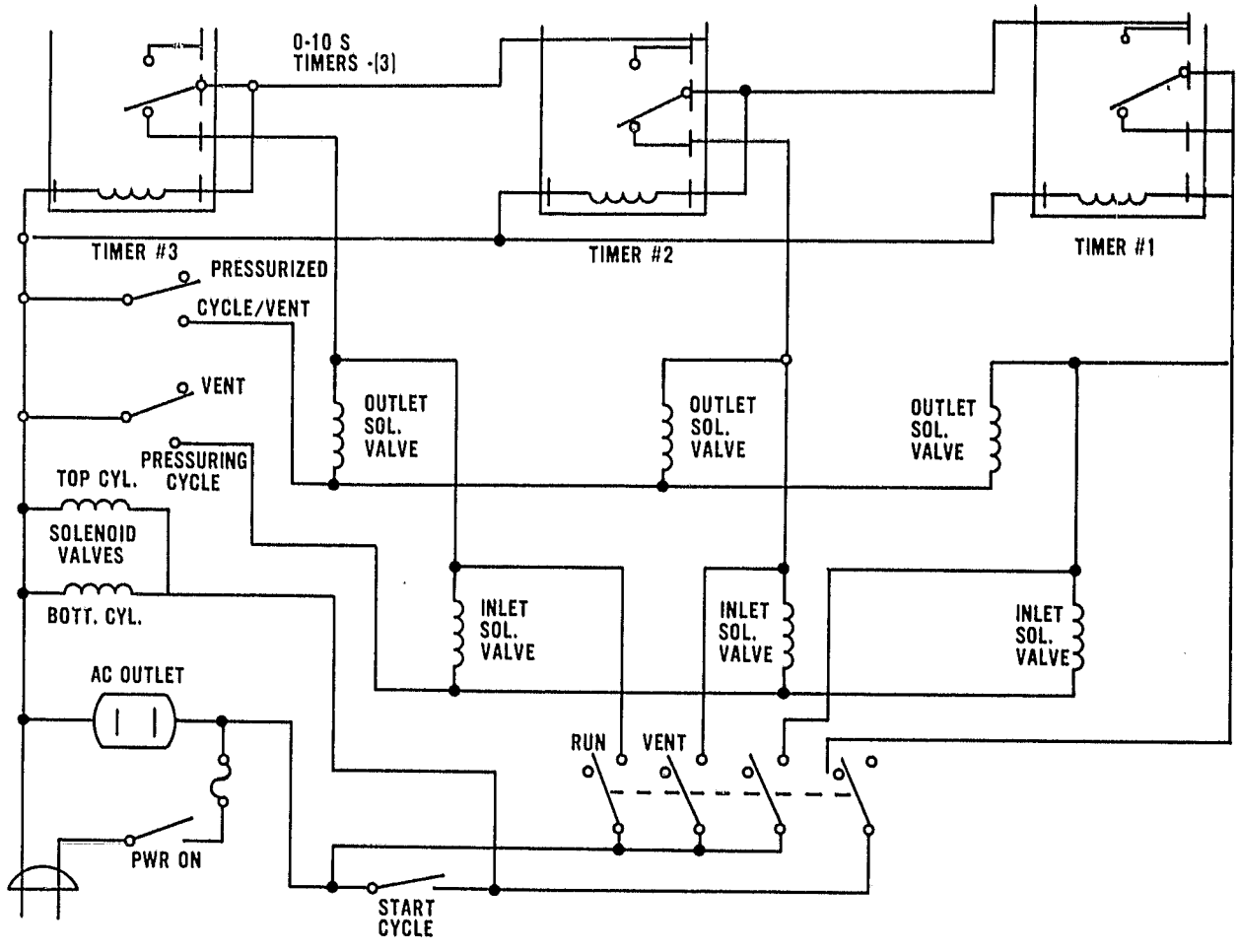

FIGURE 6. *BASS construction.* Wiring diagram.

The cylinder assembly is shown in figure 4 and reservoir assembly in figure 5. Input and output solenoid valves (Model 53C18HN14-2, Valcor Engineering, Kenilworth, NJ) are automatically controlled so that air passes through each solution at the proper time and for the proper duration. The wiring diagram for the control of the solenoid valves and the timers is shown in figure 6.

A typical output alcohol profile is shown in figure 1c. Concentration step heights are determined by alcohol concentrations in solutions 1, 2, and 3, contained in the three reservoirs, respectively. (Solutions are replaced frequently to compensate for alcohol depletion on use.) Step widths are determined by relay timer (Model W21LMASOX-2, Magnecraft Electric Co., Chicago, IL) settings, which control the solenoid valves. Timers are individually adjustable from 1 to 12 s. Heaters, thermo-regulators, and stirrers used in the solution reservoirs were taken from MKII Simulators, Smith and Wesson Electronics, Springfield, MA, the shafts of which were extended. Air diffusers (double) were taken from Model 999 Air Pump, Lew Childre and Sons, Inc., Foley, AL. Precision thermometers were used to monitor temperature. Working pressures are variable from 0 to 500 cm H_2O (0-200 in H_2O). Although maximum human delivery pressures correspond to only about 160 cm H_2O (64 in H_2O) [11], higher working pressures are needed to overcome the high flow resistance of the air diffusers.

If convenient, sample volumes delivered into breath testers can be measured at the breath tester vent port, which is connected to a 9 L recording vitalometer. If the breath tester vent port is not accessible, the unit under test can be placed in an air tight glove box of sufficient size to provide at least 15 cm (6 in) clearance between the sides and top of the interior surfaces of the glove box. The glove box should have internal outlets for 110 V ac power, or connections for dc power as appropriate for the instrument under test and a transparent viewing window that allows observation of all controls and displays of the breath tester. The output of the BASS is connected to the input of the breath tester through an air tight feed through. A fitting is installed in a wall of the glove box, to which the 9 L recording vitalometer is connected. The sample volume delivered to the breath tester is then measured directly as the volume of air displaced from the glove box.

Alternatively, the volume delivered can be calculated from initial and final pressure readings of the BASS as follows: the number of moles of gas, n, delivered by the apparatus, at a constant temperature, T, is

$$n(f)-n(i) = \Delta n = \frac{p_f v_f - p_i v_i}{RT} \tag{2}$$

$$\Delta nRT = \Delta\,(pv) = p_f v_f - p_i v_i = pv, \tag{3}$$

where

p_i, p_f are initial and final driving cylinder pressures,

v_i and v_f are initial and final volumes,

p is ambient atmospheric pressure,

v is volume delivered, corrected to atmospheric pressure, and

R is the universal gas constant.

Since $v_i = \pi r^2 h + V_R$ (volume of reservoirs) and $v_f = \pi r^2 (h-d) + V_R = v_i - \pi r^2 d$ where r is cylinder radius, h is cylinder height, and d is piston displacement,

$$v = \left[(p_i - p_f) \left(h + \frac{V_R}{\pi r^2} \right) + p_f d \right] \frac{\pi r^2}{p}, \tag{4}$$

neglecting air in the lines and valves. Converting p_f in the second term from gage pressure to absolute pressure, volume delivered becomes

$$v = \left[(p_i - p_f) \left(h + \frac{V_R}{\pi r^2} \right) + (2p_0 - p + p_f)\, d \right] \frac{\pi r^2}{p}, \tag{5}$$

where $p_0 = 1$ atmosphere (406.79 in water).

Determination of Sampling Parameters

As discussed earlier, physiological principles and the variability of human capability in delivering breath for determination of alcohol content, indicate that five parameters must be considered. These are: temperature of sample; alcohol concentration profile; pressure drop or delivery pressure; delivery time; and delivery volume. From the last three variables, two important parameters (viz, delivery rate and flow resistance) can be obtained. The following discussion provides an evaluation of each of them in relation to the alcohol content of the sample.

Concentration-Time Profile

The typically measured asymmetric time profile of alcohol concentration, characterized by an early, sharp rise followed by a gradual leveling, is simulated by the BASS in the form of stepwise variations in alcohol concentration. We have found that this permits more precise and reproducible time-concentration control than can be obtained by continuous changes; hence, air samples can be controlled more accurately.

Human subjects participated in tests to obtain data and time-concentration profiles for expired breath. The subjects did not ingest alcohol and were not intoxicated, removing the element of risk from the test program and eliminating the need for medical supervision.

As can be seen in figures 1a and 1b, the CO_2 concentration profile is similar to that for alcohol. Consequently, the CO_2 concentration in the expired breath of the test subjects was monitored and analyzed continuously to serve as an indicator of the percentage of that gas in alveolar air.

A total of 19 human subjects participated in the test program; their ages, sex, and other characteristics are summarized in table 1 along with test results. This limited sample should not be considered as definitively representative of the entire driving population—and certainly not of the subset of drunk drivers. Rather, the aim was to identify and calibrate physiological (and, to some extent, behavioral) variability in collecting breath samples, along with estimating the values over which pertinent EBT sampling parameters may be expected to range. The ultimate aim, of course, is to establish the effective ranges for the simulator to ensure that it produces the characteristics of simulated breath that are needed for the evaluation of EBT's.

The human breath sampling tests were conducted with simple laboratory surrogates for actual EBTs. Three polyethylene tubes [(0.635 cm o.d.×0.437 cm i.d.) (1/4 in×11/64 in)] were used to produce the resistance appropriate for simulating breath tester sample simulation. The pressure drops measured for actual EBT's were duplicated by varying the length of the polyethylene tubing. Thus, a 97 cm tube length has a flow resistance that corresponds to the lowest value achieved by any of the EBT's measured; a tube length of 230 cm produces the greatest observed EBT flow resistance. The simple geometry of the tubes obviously did not exactly reproduce the flow characteristics of actual breath testers. Nevertheless, this laboratory device did make it possible to determine relationships between "alcohol" content and the various flow parameters which were investigated.

To obtain data for this investigation, two side arms were attached to the tube inlet: one was attached to a capacitance manometer, the other to the differentially pumped inlet of a mass spectrometer for real time analysis of expired air CO_2 content (which represented alcohol). Each

subject was asked to empty his or her lungs a number of times into each simulated tester without special coaching. Results are shown in table 1, from which the parameters of interest here can be evaluated.

A statistical description of the results for time and concentration is summarized in table 2.

TABLE 1. *Breath sample of human subject*

Subject	Sex	Age	VC	Tube	t	t_4	v	p_t	p_f	C_t/C_f	$C_{1/2}/C_f$	C_f
1	F	41	2.5	A	6.9	0.8	2.0	14	11	69	86	15
				B	8.6	0.8	1.8	18	16	75	86	14
				C	7.5	0.6	1.7	14	12	59	86	11
2	M	44	4.8	A	13.2	1.9	4.7	62	38	76	94	25
				B	14.4	1.1	4.5	53	36	69	94	25
				C	16.0	2.2	3.8	44	34	73	93	20
3	F	28	2.8	A	5.1	1.0	1.8	13	12	63	89	14
				B	8.8	1.1	1.4	16	13	61	86	14
				C	9.8	1.2	2.3	18	15	57	83	15
4	M	40	5.0	A	15.1	1.3	4.6	16	27	60	85	20
				B	19.5	1.4	4.6	28	14	53	88	17
				C	21.1	1.6	4.5	29	20	60	95	20
5	F	27	1.8	A	10.4	0.8	0.9	.	.	63	85	14
				B	14.0	1.0	1.6	1.0	0	65	84	16
				C	11.3	1.1	1.8	1.0	0	59	83	15
6	M	46	3.3	A	8.9	2.2	2.7	49	50	76	95	29
				B	10.0	1.6	2.7	35	44	83	90	33
				C	9.4	1.4	2.7	36	41	69	93	23
7	M	35	4.6	A	13.3	1.8	3.8	55	27	64	87	28
				B	14.0	1.3	4.2	54	28	63	86	22
				C	17.9	1.1	3.9	51	20	59	86	22
8	M	60	4.0	A	7.8	1.3	3.1	23	15	73	93	22
				B	12.4	1.1	3.1	22	17	53	88	17
				C	16.1	1.1	3.1	26	16	53	85	20
9	M	46	4.3	A	8.1	1.1	4.3	59	38	54	76	19
				B	11.8	1.5	4.4	66	42	64	93	14
				C	13.5	1.3	4.3	70	44	59	88	16
10	M	34	4.8	A	10.9	0.4	4.0	27	0	58	85	17
				B	11.5	0.8	3.5	40	6	39	89	18
				C	11.5	0.7	2.8	40	12	48	90	15
11	M	36	3.6	A	7.6	0.9	3.1	44	27	70	90	20
				B	12.0	1.2	3.1	44	44	73	88	24
				C	12.6	1.1	3.0	33	44	67	89	23
12	M	53	3.1	A	5.5	0.8	2.7	72	17	80	95	20
				B	9.3	1.3	2.7	80	25	69	90	21
				C	8.6	1.2	2.9	81	22	70	90	20
13	M	43	6.0	A	12.0	1.4	4.4	41	0	69	91	18
				B	18.7	2.7	4.9	54	5	70	88	17
				C	19.7	1.9	4.6	55	0	54	86	18
14	M	47	4.0	A	8.4	1.0	3.6	48	32	56	80	13
				B	9.9	1.4	3.6	56	29	55	88	17
				C	13.0	1.5	3.7	74	35	57	83	18
15	M	44	5.1	A	7.5	0.8	4.1	76	26	56	91	17
				B	9.4	1.1	3.9	88	26	68	89	19
				C	10.5	1.2	3.9	95	26	62	86	21

TABLE 1. *Breath sample of human subject (continued)*

Subject	Sex	Age	VC	Tube	t	t_k	v	p_i	p_f	C_k/C_f	$C_{1/2}/C_f$	C_f
16	M	56	5.2	A	12.1	0.9	3.9	30	35	60	86	18
				B	16.1	1.5	3.6	15	22	58	89	19
				C	14.6	2.4	3.4	12	35	47	82	17
17	M	50	4.3	A	11.1	1.4	4.1	.	.	69	94	16
				B	14.4	1.6	3.9	.	.	60	94	15
				C	16.4	1.8	3.7	.	.	57	93	14
18	M	47	3.1	A	7.4	1.1	3.2	51	32	67	89	18
				B	9.3	1.2	2.7	52	38	56	83	18
				C	10.5	1.1	2.6	52	29	61	89	18
19	M	38	4.0	A	7.4	1.2	2.8	43	42	52	85	14
				B	8.0	1.4	3.6	42	51	50	86	14
				C	8.7	1.2	2.7	43	45	57	86	14
	μ	42.9	4.0									
	σ	8.73	1.10									

A 97 cm tube
B 164 cm tube
C 230 cm tube
VC Vital capacity
t Exhalation time
t_k Time for exhalation concentration to reach "knee" in curve
v Exhalation volume
p_i Initial delivery pressure
p_f Final delivery pressure
C_k/C_f Ratio CO_2 concentration at "knee" to final concentration
$C_{1/2}/C_f$ Ratio CO_2 concentration at midpoint of exhalation to final concentration
C_f Final CO_2 concentration
μ Mean value
σ Standard deviation

TABLE 2. *Human subject exhalation parameters* $n = 19$

Tube	t s	t_k s	v L	$\overline{Q}$ L/s	p_i cm H_2O (mmHg)	p_f cm H_2O (mmHg)	C_k/C_f %	$C_{1/2}/C_f$ %	C_f Arb. units
A	9.4	1.2	3.4	0.36	25.4 (47.5)	11.5 (47.5)	65	89	19
σ	2.8	0.4	1.0	....	11.1 (20.7)	7.2 (13.5)	8.5	5.3	4.6
B	12.2	1.3	3.3	0.27	28.3 (52.9)	13.0 (24.3)	62	88	19
σ	3.4	0.4	1.0	....	11.2 (21.0)	7.4 (13.8)	10	3.0	4.8
C	13.1	1.4	3.2	0.25	28.0 (52.4)	12.7 (23.8)	59	88	18
σ	3.9	0.5	0.8	....	12.4 (23.1)	7.4 (13.8)	6.8	3.9	3.4

Notes:

$\overline{Q}$	Average exhalation flow rate.
A	97 cm tube
B	164 cm tube
C	230 cm tube
VC	Vital capacity
t	Exhalation time
t_k	Time for exhalation concentration to reach "knee" in curve
v	Exhalation volume
p_i	Initial delivery pressure
p_f	Final delivery pressure
C_k/C_f	Ratio CO_2 concentration at "knee" to final concentration
$C_{1/2}/C_f$	Ratio CO_2 concentration at midpoint of exhalation to final concentration
C_f	Final CO_2 concentration
μ	Mean value
σ	Standard deviation

The total delivery time averaged 9 1/2 s (ranging from 5.1 to 15.1 s) for the low resistance simulated tester, and 13 s for the high resistance one (with a range of 7.5 to 21.2 s). The average time-concentration profiles (from the data of table 1) are plotted in figure 7. Here, the final CO_2 concentration is taken as the (100%) alveolar concentration.

The two graphs in figure 7 reveal that the concentration of CO_2 reaches 60 percent at the knee, t_4 of the profile and 90 percent by the midpoint, $t_{1/2}$ (in time). The CO_2 profile of human breath is approximately linear from the midpoint until the maximum concentration is attained (see also fig. 1a). Thus, it can be seen that air expired through the low resistance simulated tester reaches a concentration of about 95 percent of that of pure alveolar air after an average of 7 1/2 s; it takes an average of 10 s to reach the 95 percent level of alveolar air when the breath is passed through the high resistance tester. In general, the process of exhalation is steady, so that the volume of exhaled air is directly proportional to the time of exhalation (i.e., the exhalation rate

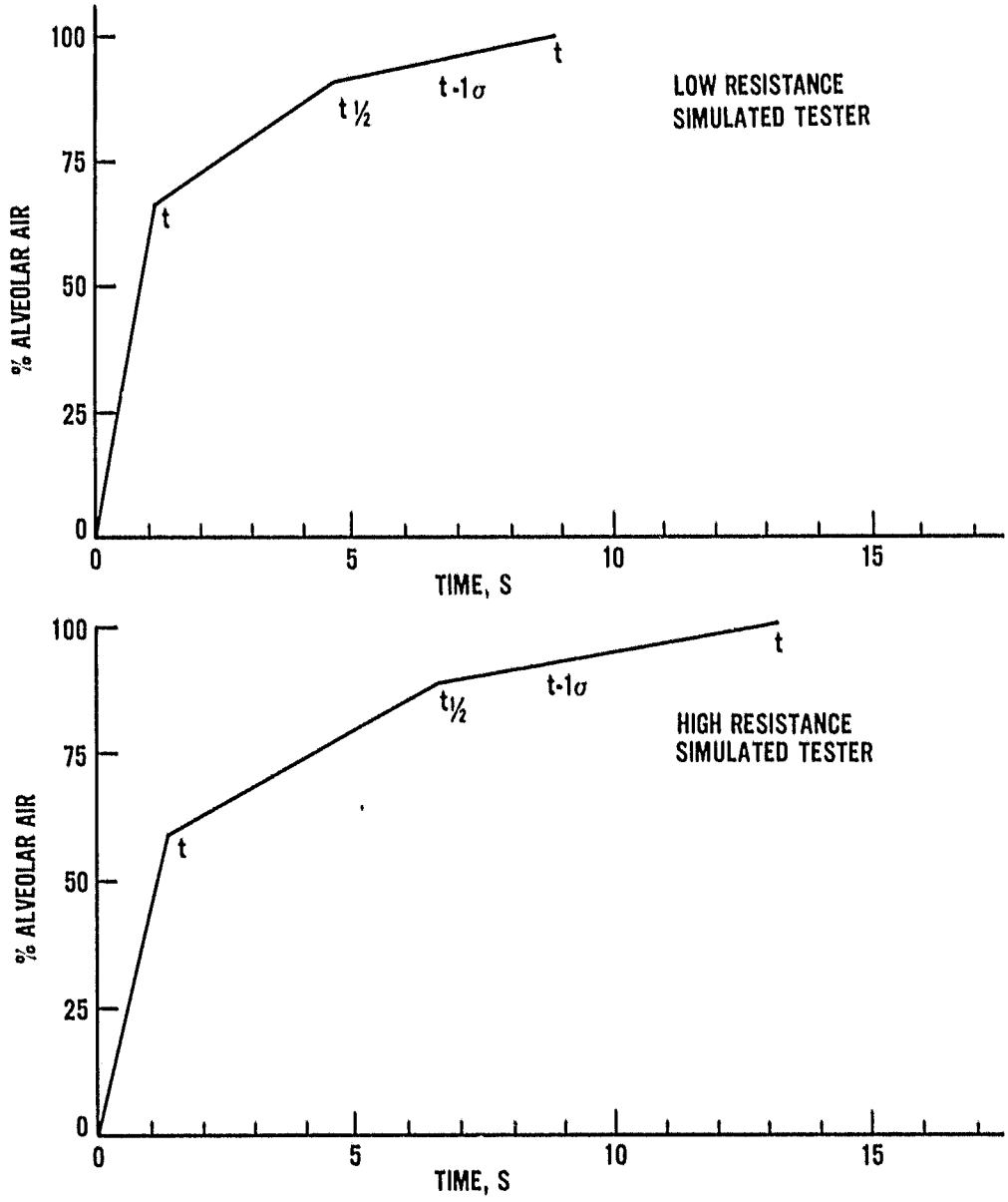

FIGURE 7. *Averaged human expired breath profile.*

is constant). As seen in figure 8, the total time to empty the lungs in forced expiration with low resistance, is typically about 5.5 s. Since the 95 percent level of alveolar air is reached in three-quarters of the total time of exhalation with resistance, it may be inferred that the expired volume for reaching the same level of alveolar air will also be approximately three-quarters of the total expired volume. Based on this logic, the last 25 percent of the total expired volume is essentially deep lung air and provides an appropriate sample for alcohol analysis. Indeed, if the last third of the total volume were to be selected to represent deep lung concentration, this would afford an even greater margin of protection for the suspected drunk driver.

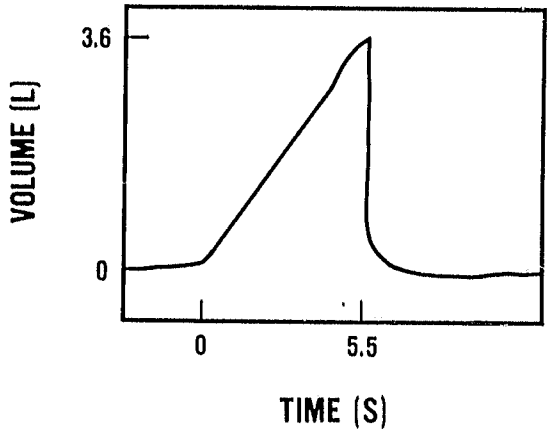

FIGURE 8. *Volume of exhalation vs. time.*

Since the volumes of the first two steps are not as important as the last, the concentrations for those two steps are not critical. Concentration of alcohol in each segment, as indicated in figure 7, are most appropriately 60, 90, and 100 percent, respectively, of that of deep lung concentration. The artificial profile then becomes:

Concentration step	(1)	(2)	(3)
Volume fraction	1/3	1/3	1/3
Alcohol concentration, BAC	.060	.090	.100

Pressure, Volume, and Rate of Delivery

The partial vapor pressure of alcohol over aqueous solution depends only on solution concentration and temperature; it is not influenced by total pressure. The alcohol vapor pressure therefore remains constant when the BASS delivers compressed air at a given pressure above atmosphere by forcing it through each diffuser into the head space of the alcohol solution reservoir. As a result, the head space gas pressure is increased throughout the constant volume. Releasing the head space gas and vapor mixture to a sample collector at atmospheric pressure then allows the mixture to expand, with a resultant decrease in alcohol concentration.[3] The effect, as shown in figure 9, is that the greater the delivery pressure, the more the alcohol concentration decreases. The effect is governed by the following relationship:

$$\frac{C'}{C} = \frac{p_0}{p_0+\Delta p}, \tag{6}$$

where C and C' are, respectively, the true (i.e., original) concentration and the (apparent)

[3]This discussion does not apply to those breath testers which are designed to analyze the sample at delivery pressure or higher pressure.

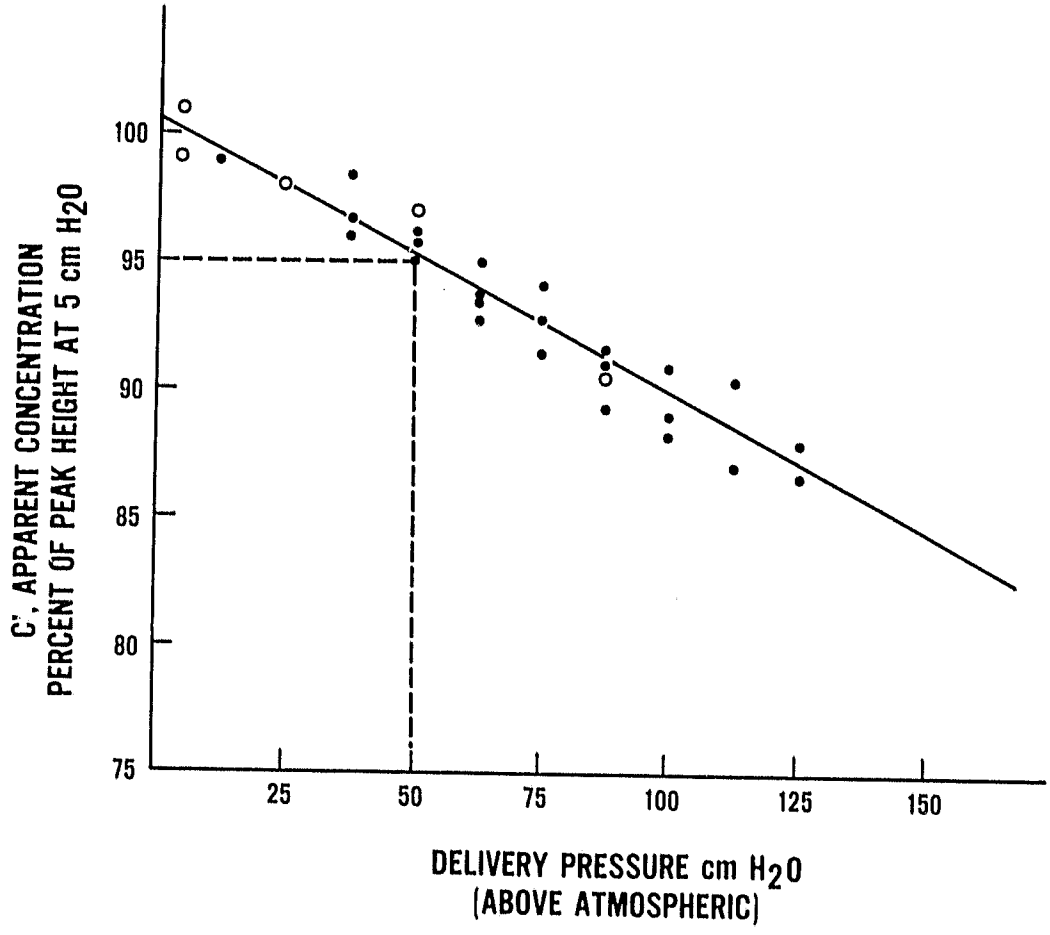

FIGURE 9. *Effect of delivery pressure on output concentrations of commercial simulator.*

concentration measured after relaxation of delivery pressure in the collected sample; Δp is the delivery pressure above atmospheric pressure (p_0).

According to the specifications of the standard [4], breath alcohol concentration must be measurable with an accuracy of ±5 percent at levels typical of testing conditions. Referring to figure 9, it can be seen that apparent concentration, C', will be 95 percent or more of actual concentration, C, only if delivery pressure is not more than 50 cm H_2O above atmospheric (with a 2σ error band of approximately ±7.6 cm H_2O). Thus, figure 10 depicts the air pressure above the solution vs. the flow rate from the output solenoid valve connected directly (that is, without the intermediary tester tube) to the spirometer. Based on eq (7), intrinsic resistance of the BASS can therefore be determined from the slope of the line, which is approximately 3 cm $H_2O{\cdot}s/L$ even for flow rates in excess of $Q=0.6$ L/s. This is comparable to human breathing resistance in normal expiration.

The discussions below treat the implications of limiting Δp on the delivered value, or (equivalently) the delivery rate, Q, with respect to EBT's.

Rewriting eq (1), the flow resistance, R_f, for laminar flow is given by:

$$R_f = \Delta p/Q. \tag{7}$$

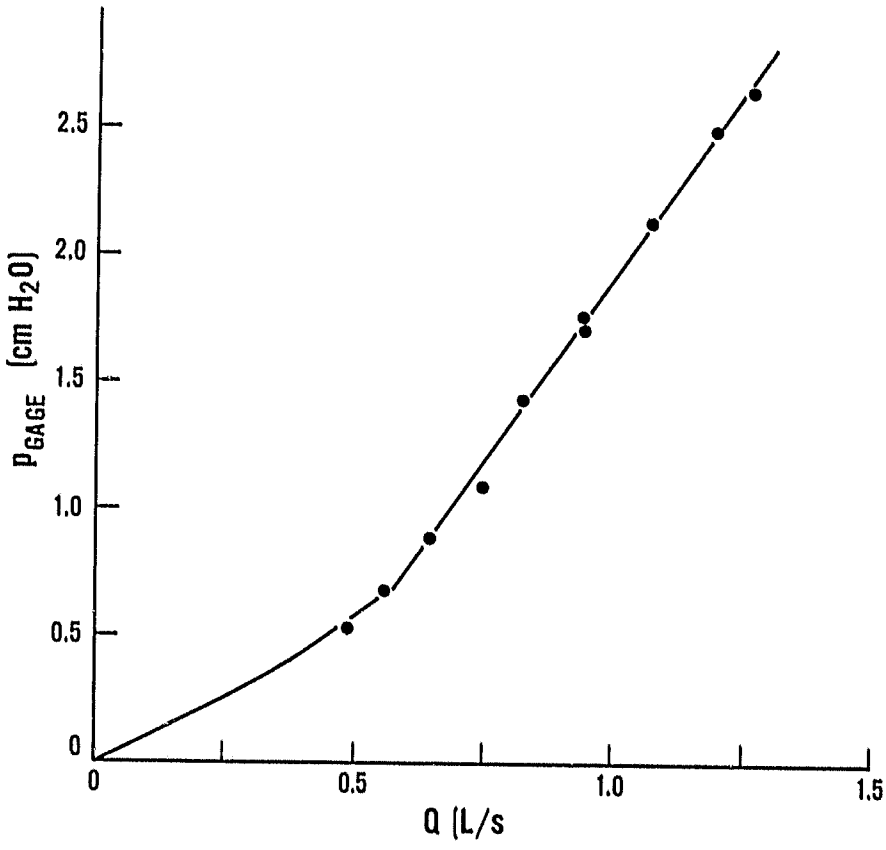

FIGURE 10. *Pressure above BASS alcohol solution vs. air flow rate.* Above $Q=0.6$, flow resistance (slope) equals 3 cm H_2O·s/L which is similar to that for human subjects (see text).

Depending on the geometry of a collecting system and on the delivery rate, the flow may not be laminar. According to Rohrer [12], the pressure drop for non-laminar flow may be better expressed by adding a second degree term related to delivery rate:

$$\Delta p = K_1 Q + K_2 Q^2, \tag{8}$$

whence,

$$R_f = \Delta p/Q = K_1 + K_2 Q, \tag{9}$$

where k_1 and k_2 are constants for a given collecting system.

Using the polyethylene tubes described earlier as surrogate breath testers, a series of laboratory tests were run to determine pressure drop as a function of varied flow rates (i.e., volume measured against time). This permits an examination of flow resistance calculated under the assumptions of laminar or non-laminar flow, and estimation of the constant terms for the two expressions.

According to eq (7) for laminar flow, delivery pressure (or pressure drop) should be linearly related to flow rate. Figure 11, a plot of Δp vs. Q for each of the three simulated testers, exhibits considerable deviation from linearity, contradicting the assumption that the flow is laminar. On the other hand, when $\Delta p/Q$ vs. Q is plotted for the same data (see fig. 12), straight lines can be easily fitted. Values of K_1 and K_2 can be estimated for each simulated tester based on the intercept on the Y-axis and the slope of the line. The desired values are listed in the table below. Figure 13 shows a plot of K_1 and K_2 as a function of the length of the simulated tester tubes.

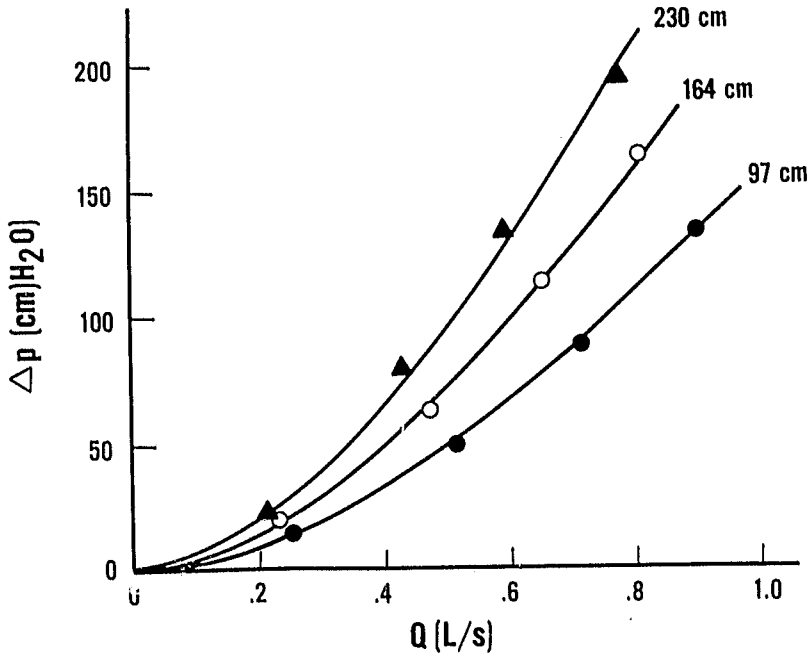

FIGURE 11. *Delivery pressure vs. flow rate through tubes.*

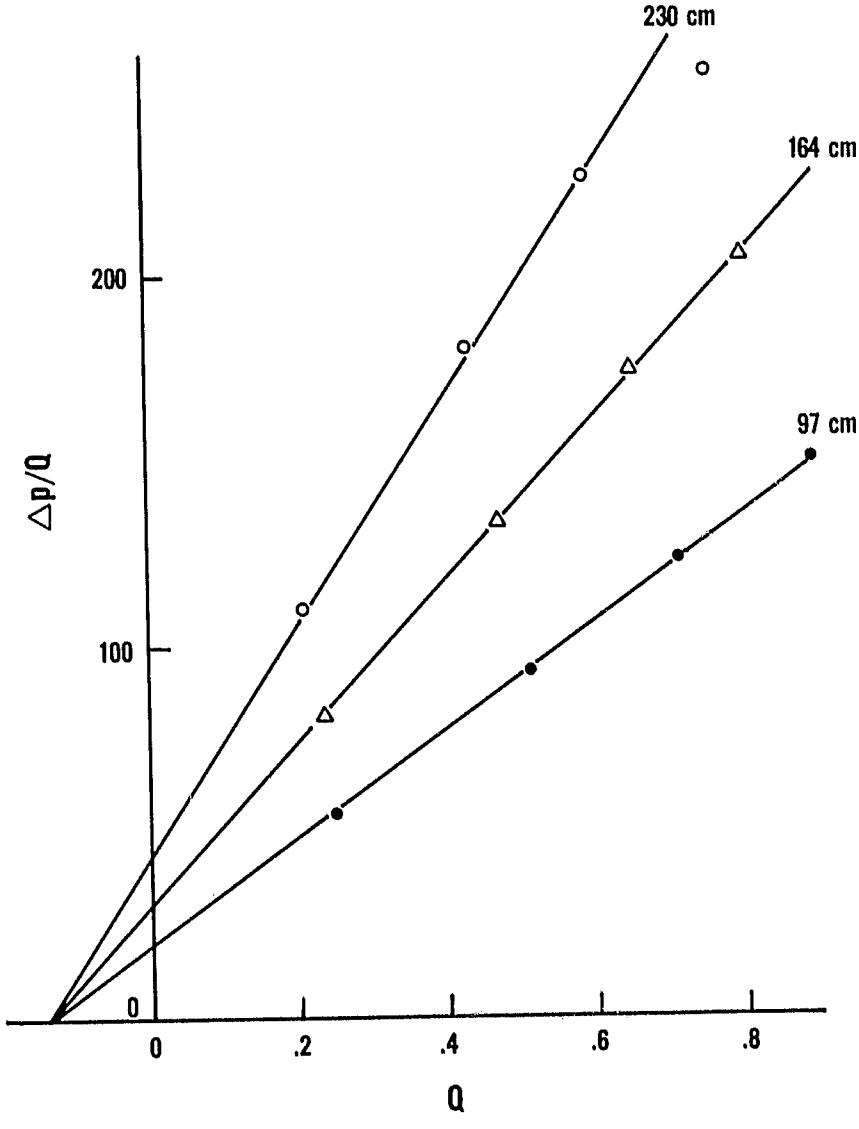

FIGURE 12. $\Delta p/Q$ *as a function of* Q *for three tube lengths.*

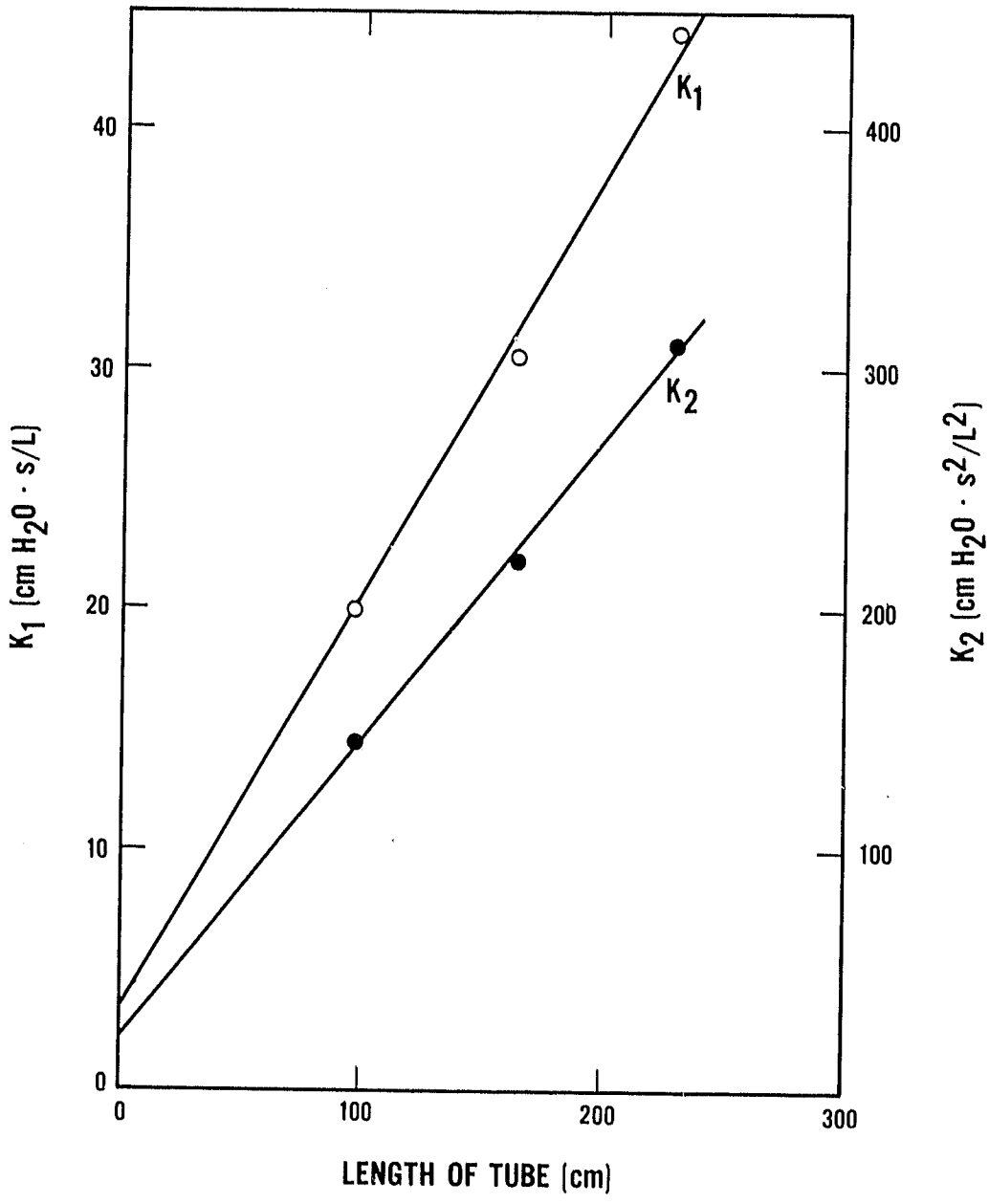

FIGURE 13. *K_1 and K_2 as a function of tube length.*

Having established these parameter values, along with the limiting value for Δp to insure an apparent concentration, C', within 5 percent of the actual, C, eq (8) can then be used to solve for Q and calculate the maximum permissible-delivery rate, Q_{max}:

$$Q_{max} = \frac{1}{2K_2}\left[\left(K_1^2 + 4\Delta p_{max}K_2\right)^{1/2} - K_1\right]. \tag{10}$$

Using eq (10), values for Q_{max} have been calculated for each of the three simulated testers, the derived estimates of K_1 and K_2, and three values for the pressure drop, Δp as presented in table 3. In particular, $\Delta p = 50$ cm H_2O corresponds to the limiting value for assuring accuracy of measured concentration (i.e., $C' = C \pm 5\%$). Since the data for figure 9 showed a standard error of estimate of 13 cm H_2O for Δp, Q_{max} was also computed for $\Delta p = 37$ and 63 cm H_2O, the latter providing slightly higher estimates of maximum flow rates. The last column of table 3 shows an alternative assessment of maximum flow rate, Q_{pmax}, based on the physiological data (summarized in table 2) obtained from the volume and elapsed time for expiring air by the human subjects. The values shown were computed from:

$$Q_{pmax} = \frac{\bar{v} + \sigma v}{t - \sigma_t}, \tag{11}$$

that is to say, an air volume one standard deviation above average over a period of time one standard deviation below average.

TABLE 3

Tube length, cm	K_1 (cm $H_2O \cdot s/L$)	K_2 (cm $H_2O/s^2/L^2$)	Q_{max}(L/s) ($\Delta p = 37$ cm H_2O)	($\Delta p = 50$ cm H_2O)	($\Delta p = 63$ cm H_2O)	Q_{pmax} (L/s)
97	20	144	0.44	0.52	0.60	0.67
164	30.5	218	0.35	0.41	0.47	0.49
230	44	310	0.28	0.34	0.39	0.43

While the BASS is capable of delivering a sample over the full range of pressure necessary to overcome the flow resistances tabulated in table 2, a comparison of the values for Q_{max} and Q_{pmax} suggests that the flow resistance of some present breath testers *may* be marginally acceptable in terms of flow rate which might be produced by individuals who are capable of above average air delivery (i.e., higher volume and/or shorter time). At the same time, it should also be noted that physiological delivery rates typically decrease significantly from high initial values to much lower ones at the end of sample delivery (see table 2, and fig. 14). Thus the values of Q_{pmax} in the table are not representative of the flow rate at the end of expiration, which are significantly lower. Nevertheless, the foregoing discussion tends to support reducing flow resistance in breath testers and, perhaps, revision of the existing standard for breath testers to encourage designers to accomplish this. To this end, a conservative recommendation for maximum allowable back pressure for future breath testers at a delivery rate of 0.50 L/s, 6 L total volume, would be no more than 50 cm H_2O. Since the effect of excessive delivery pressure is to underestimate BAC, it would not appear to be necessary to impose the above requirement on present testers, for these testers tend to make up a progressively smaller portion of the market. A lower limit for delivery rate is not critical and may be set more arbitrarily at about 0.20 L/s and 2 L total volume.

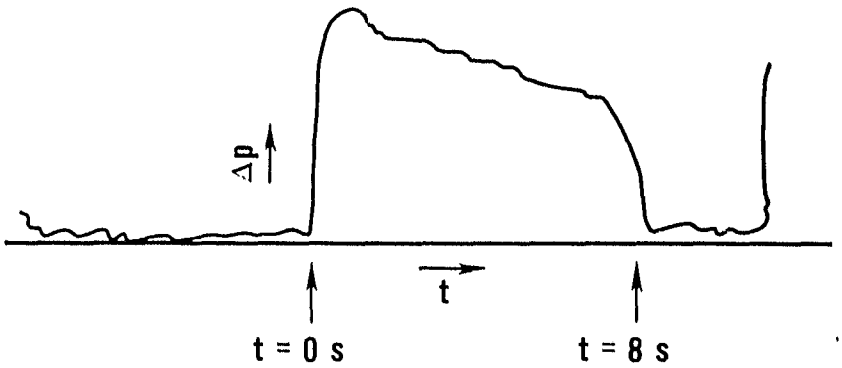

FIGURE 14. *Typical delivery pressure profile of human subject.* In the example, final pressure is about 60 percent of initial pressure.

5. CONCLUSIONS AND RECOMMENDATIONS

There are large physiological differences between individuals that result in a wide range of vital capacities and breath pressure. Ideally, the sample collection system of an evidential breath tester should be adjustable to accommodate the exhalation characteristics of the individual that is being tested (i.e., one or more breath samples should be collected to determine the total time of exhalation and the total volume, and the discard volume then adjusted to ensure that the last third or fourth of the sample is used for analysis). Depending upon the analytical method employed by the EBT, this may be difficult to accomplish. Further, the increased operating complexity might be objectionable to the users of EBT's.

From a practical standpoint, then, it appears at the present time, that the most reasonable approach to establishing performance standards for the breath sample collection capability of EBT's is to evaluate the ability of such devices to analyze the appropriate portion of a breath sample at the high and low ends of the vital capacity range of the U.S. adult population. That portion of the population lying outside of the range that is selected would not be penalized by this action, if subjected to an EBT test, for in either case (unusually large or small vital capacities and breath delivery capabilities) the measured BAC would be the same, or less than that which would be measured if they were a member of the population range that is selected.

It is recommended that the existing NHTSA standards for breath alcohol testing devices be modified to eliminate the use of human subjects, and that the breath sample collection capability of such devices be evaluated using the BASS as the sample source.

The concentration, time, and delivery volumes appropriate for this test are summarized below:

Concentration Profile

Concentration Step	1	2	3
Time, %	33 1/3	33 1/3	33 1/3
Alcohol Concentration, BAC	0.060	0.090	0.100

Sample Volume and Delivery Rate

a) 2 L at 0.20 L/s
b) 2 L at 0.333 L/s
c) 6 L at 0.50 L/s

The use of the BASS test profiles noted above will apply only to the evaluation of the breath sampling capability of breath alcohol devices. The other tests within the NHTSA standards, such as precision and accuracy and environmental testing would be retained without change.

The BASS test profiles have been selected to ensure that EBT's are capable of accurately measuring the BAC of a large portion of the adult U.S. population, without placing unduly restrictive requirements upon the manufacturers of such devices. For example, while tests with human subjects have shown that in some cases the delivery time for an individual might be as long as 17 s, a test time of 12 s at a flow rate of 0.5 L has been selected. This is a consequence of the fact that under prolonged delivery times, the delivery rate of an indivdual decreases rapidly. It would not be realistic to require that the unit under test accommodates the 0.5 L constant flow for a period as long as 17 s.

Appendix A—References

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