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THE IMPACT OF SYSTEMATICALLY VARYING THE DURATION
OF BREATH SAMPLES DURING INFRARED-BASED
ALCOHOL BREATH TESTING

by

Chris C. Clatterbuck

A Dissertation
Submitted to the
Faculty of The Graduate College
in partial fulfillment of the
requirements for the
Degree of Doctor of Philosophy
Department of Counselor Education and Counseling Psychology

Western Michigan University
Kalamazoo, Michigan
June 2002
The present study set out to investigate the reliability and performance of the BAC DataMaster®, an infrared-based alcohol breath testing instrument. The focus of this study was to determine: (a) the impact of varying breath sample duration during testing, (b) if Blood Alcohol Concentration (BAC) levels produced by the DataMaster® ($BAC_{dm}$) are significantly different from BAC levels produced by analysis of whole blood ($BAC_{wb}$), and (c) if the relationship between $BAC_{dm}$ estimates and $BAC_{wb}$ is influenced by the amount of alcohol an examinee has ingested.

Each of 27 participants was randomly assigned to one of three alcohol intake groups: high intake $BAC = .10g/210ml$; medium intake $BAC = .08g/210ml$; or low alcohol intake $BAC = .06g/210ml$. Participants ingested 100 proof vodka in six drinks spaced at ten-minute intervals. Total alcohol intake was 2.36 ml of alcohol per 1 kg of body weight (high intake), 2.00 ml per 1 kg of body weight (medium intake), or 1.64 ml of alcohol per 1 kg of body weight (low intake). After alcohol ingestion and a 1-hour, 15-minute absorption period, participants provided the researcher with blood and breath samples.

Six breath samples were collected from each participant; two breaths under
each of the follow breath duration conditions: Condition 1—short duration exhale, (SDE); Condition 2—medium duration exhale, (MDE); and Condition 3—long duration exhale, (LDE). Pre- and post-breath testing blood samples were analyzed at a local laboratory and BAC_{WB} results were compared to BAC_{DM} estimates.

Two major findings emerged from this research. First, significant differences were found to exist between BAC_{DM} estimates and BAC_{WB} results, specifically, BAC_{DM} estimates underestimated BAC_{WB} results. Second, BAC_{DM} estimates are significantly affected by the duration of breath samples. In general, BAC_{DM} estimates computed from SDE breath samples are lower than BAC_{DM} estimates computed from LDE breath samples. This effect was seen across all alcohol intake groups, but was most significant in the high alcohol intake group. The practical and theoretical implications of these findings are discussed and recommendations for improving testing procedures are offered.
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CHAPTER I

INTRODUCTION

The use of alcoholic beverages as a means of altering mental/physical states, inducing relaxation, relieving stress, and/or as part of religious and secular rites and celebrations has been part of human culture since the beginning of recorded history (Hanson & Venturelli, 2000). Archeological findings suggest that, "alcohol in the form of wines and beer can be traced back to nearly the same time as the development of agriculture or 8000 B.C." (Goodwin & Gabrielli, 1997, p. 19). The making of mead from fermented honey and brewing beer appears to have been a common practice in the Egyptian culture, and the ancient Greeks are known to have ingested large quantities of wine during early celebrations to honor the god Dionysus.

Archeological evidence suggests that ancient cultures were very serious about their beer and wine making. One recent find by archeologists working in modern day Iraq unearthed numerous pots containing alcohol residue and clay tablets detailing more than 20 recipes for beer making. Carbon dating suggests the relics came from Sumerian/Mesopotamian societies dating from 3500-5400 B.C. While the presence of written recipes indicates the importance of alcohol to these societies, the varieties within the recipes and range of ingredients suggest that Sumerian and Mesopotamian citizens were not simply beer drinkers but, rather, beer connoisseurs (www.erwid.org, 2000). Historical records documenting the use of hard liquor suggest that hard liquor
or "spirits" dates back to approximately 800 AD when the Arabs discovered the distillation process (Inaba & Cohen, 2000). As documented by Hanson and Venturelli (2000), the use of alcoholic beverages (e.g., mead, ale, hard-cider, beer, wine, and distilled liquor) is intimately intertwined through the history of the world.

Historical and religious texts suggest that the people of the ancient world knew not only of the pleasures of indulging in the use of alcoholic beverages, but also the potential problems of alcohol misuse/abuse. In fact, references to and warnings about the dangers of alcohol consumption can be found throughout the sacred texts of the world’s major religions. There are virtually hundreds of references within the Torah, the Christian Bible, the Book of Mormon, and the Koran that speak to the practice of making and drinking alcohol in its various forms and the negative impact of the misuse/abuse of alcohol (Hanson & Venturelli, 2000; Inaba & Cohen, 2000).

Despite the many warnings and prohibitions against alcohol use that can be found in the various religious texts of the world, alcohol use among the world’s cultures flourishes. In the United States of America the use of alcohol has been a major part of our culture since the first European explorers landed in the new world. Among the supplies brought to North America by the first colonists who came to settle in the new world were alcoholic beverages including hard-cider, beer, and wine. In present day United States of America, the use of beverage alcohol is so common that the great majority of people do not even consider alcohol to be a drug. Research by the Gallop organization suggests that most Americans consider alcohol to be a "social substance" (McAneny, 1994). The most recent Gallop poll data Newport (2000) indicate that
64% of the adult population in the United States of America drink alcohol.

While the figure of 64% is certainly a significant proportion of the adult population, the percentage of college-age individuals who identify themselves as drinkers is even higher at 75% (Inaba & Cowan, 2000). Within the college campus environment itself, data from the 1995-1996 academic year indicate that college students across the nation consume an average of 4.3 drinks per week, with males averaging 6.7 drinks and females consuming 3.7 drinks (Presley, Meilman, & Lyea, 1996). In his text, *Alcohol Problems and Alcoholism*, Royce (1989) argues “Americans perceive the drinking of alcoholic beverages as a harmless adjunct to such celebrations as parties, birthdays, weddings, anniversaries, and as an appropriate way to reduce stress and anxiety” (p. 79). In summary, alcohol use within the U.S. is a significant part of life for a large majority of our citizens.

Due to the widespread use of alcohol within the American culture, the negative impact of alcohol use on society is significant. It is clear from the above data that the large majority of Americans consider the use of alcoholic beverages to be a harmless personal indulgence that is enjoyable and relaxing. However, other data suggest the use of alcoholic beverages is far from harmless to society. In fact, the financial costs from alcohol abuse and dependence are tremendous. Experts have estimated that in the United States the direct cost for dealing with the social and health problems resulting from the effects of alcohol use are approximately $140 billion annually (Hanson & Venturelli, 2000).

In addition to the direct costs to society from alcohol misuse, abuse, and
dependence, the indirect or hidden costs to society are also significant. According to a 1996 flyer, entitled *The Hidden Costs of Alcoholism* published by the National Council of Alcoholism and Drug Dependency (NCADD), at least another $100 billion is spent annually by the American public to cover indirect costs of alcohol misuse, abuse, and dependence. These indirect costs include the cost to consumers for increased premiums required for health and automobile insurance, the cost of criminal justice activities such as policing and court expenditures, the cost of incarceration, as well as the cost of lost productivity in the workplace (NCADD, 1996).

While the dollar amount for direct and indirect costs of alcohol abuse to society is noteworthy, these estimates fall short of assessing the emotional upheaval and human suffering caused by this drug (Centerpiece, 1993). Alcohol misuse and abuse can cause severe dependence, disrupt personal, family, social, and professional functioning, and frequently results in multiple illnesses and accidents, violence, and crime (Eronen, Tiihonen, & Hakola, 1996). According to studies of national crime statistics and victim reports, 15% of all robberies, 27% of aggravated assaults, 50% of all homicides, and 37% of rapes and sexual assaults involved alcohol use (Roizen, 1997; U.S. Department of Justice, 1998). To further demonstrate the negative impact of alcohol use, an estimated 25% of all hospital admissions are related to alcohol-induced health problems and 130,000 people die prematurely each year in the United States from alcohol dependence, abuse, and overdose, or from associated diseases (Substance Abuse and Mental Health Services Administration (SAMHSA), 1999: unpublished Centers for Disease Control and Prevention (CDC) data as cited in Inaba & Cohen,
Given the significant economic, social, and emotional cost of alcohol misuse, abuse, and dependence outlined above, it is natural and prudent to consider interventions that may reduce and/or eliminate many of the problems associated with alcohol abuse and dependence. Intervention for alcohol misuse, abuse, and dependence can take different forms. Three major intervention strategies are: (1) prevention programs that are designed to reduce alcohol intake by educating our society to the risks of abusing alcohol, (2) substance abuse treatment programs that are designed to help individuals who have been identified as having patterns of alcohol abuse or dependence to stop using alcohol, and (3) legal/legislative programs that are designed to identify and punish individuals who use alcohol in a manner that places others at risk of harm.

While all these programs are useful tools in reducing the number of individuals with alcohol abuse and dependence issues, the research presented in this document is most applicable to the alcohol treatment programs and legal/legislative programs that utilize infrared-based (IR-based) breath testing to generate Blood Alcohol Concentration (BAC) estimates as part of the screening and treatment process or as evidence in legal proceedings for individuals accused of violating laws prohibiting drinking and driving. The present study is especially important to those individuals and agencies that use the BAC DataMaster®, a popular infrared-based breath testing instrument, as a means of determining BAC levels.
Statement of the Problem

The present study was designed to investigate the ability of infrared-based (IR-based) alcohol breath testing to accurately estimate BAC levels from exhaled breath samples. Specifically, the study investigated the validity of the BAC DataMaster®, a popular commercial, infrared-based, alcohol breath-testing instrument, manufactured by National Patent Analytical Systems Inc. of Mansfield, Ohio. The primary focus of the study was to determine if BAC estimates from IR-based alcohol breath testing are an acceptable substitute for BAC results obtained from laboratory analysis of whole blood (BAC_{WB}). Additionally, the study set out to investigate if BAC DataMaster® (BAC_{DM}) levels vary in relation to the duration of the breath sample.

The manufacturers of the BAC DataMaster® indicate that a built-in thermistor flowmeter automatically adjusts instrument calculations to allow for the testing of breath samples of different rates of flow, volume, and duration. The manufacturers also suggest that if a breath sample is “accepted” the results will be an accurate estimate of the examinee's BAC (National Patent Analytical System, 1997). However, demonstrations by Simpson and Clatterbuck (2000) suggest that while the instrument will “accept” breath samples of different rates of flow, volume, and duration as described by the manufacturers, the resultant BAC_{DM} levels vary depending on the duration of the breath sample. The Simpson and Clatterbuck demonstrations appear to suggest that all breath samples accepted by instrument are not equally predictive of BAC_{WB} results.
In this study, the researcher set out to determine if altering the duration or length of a subject's breath exhalation during an alcohol breath test has the potential to impact the BAC_{DM} estimates in a statistically significant manner. More precisely, the research was undertaken to answer the following five questions:

1. Are there differences in BAC estimates as calculated by the BAC DataMaster® (BAC_{DM}) and BAC levels as calculated by whole blood analysis (BAC_{WB})?

2. If BAC_{DM} estimates and BAC_{WB} results are different, is the magnitude of those differences affected by the amount of alcohol the person ingested?

3. Do the instructions, provided by the operator of the breath-testing instrument concerning breath sample duration, impact BAC_{DM} estimates? More specifically are samples collected using short duration exhalation (SDE), medium duration exhalation (MDE), or long duration exhalation (LDE) different?

4. If BAC_{DM} estimates do, in fact, vary in relation to the duration of the breath sample, is the magnitude of variation affected by the amount of alcohol the person ingested?

5. Finally, which breath sample duration, SDE, MDE, or LDE is the best predictor of BAC_{WB}?

Need for the Study

As previously discussed, the use of alcohol in this country is significant. Because of its popularity and widespread use in our culture, any legislative, executive, or
judicial action involving the production, use, and distribution of alcoholic beverages has the potential to affect a large majority of the population. The use of infrared-based (IR-based) alcohol breath testing to determine BAC within the medical, legal, corporate, and substance abuse treatment arenas is such an issue.

Although individual differences exist in the general population with respect to the behavioral and physiological effect of alcohol on a given individual, it is widely accepted that the concentration of alcohol in the bloodstream, in general, and the brain, in particular, largely determines behavioral and physical responses to alcohol (Hanson et al., 2002; Rockerbie, 1999). Physiologically, the short-term effect of alcohol on the brain and central nervous system (CNS) is most similar to that of sedative-hypnotic agents such as barbiturates. Moderate to low doses of alcohol results in disinhibition: this loss of conditioned reflexes reflects a depression of inhibitory centers of the brain (Hobbs, Rall, & Verdoom, 1995). The effect of a low to moderate dose of alcohol on behavior generally involves impaired motor activity, reflexes, and coordination. At higher doses, the CNS depression incapacitates the individual, causing difficulty walking, talking, and thinking (Hanson et al., 2002, p. 189).

Given the general agreement in the literature that alcohol affects the CNS, impairs judgment and interferes with motor activity, reflexes, and coordination (Holloway, 1994, 1995; Moskowitz & Robinson, 1988), the use of alcohol in moderate to high amounts is frequently prohibited in situations where the user or others may be at risk of injury. One such situation is the operation of a motorized vehicle. Because ingesting alcohol generally impairs motor activities, reflexes, and coordination
as well as affecting mental alertness and judgment, the use of alcohol, even at low to moderate levels, can be problematic and can impact one's ability to operate an automobile (Holloway, 1994, 1995; Moskowitz & Robinson, 1988). In recognition of this fact, rules, procedures and laws have been established to discourage individuals from using alcohol while driving.

In the legal system, *per se* laws have been developed to discourage individuals from driving automobiles or operating other motorized vehicles while under the influence of alcohol. While these laws may differ slightly from state to state, all follow a similar form. Under these *per se* laws, an individual's BAC level is presumptive evidence of an offense if the *per se* limit has been exceeded (Rockerbie, 1999, p. 45). Each of the 50 states have set .10g/100ml of blood or .10g/210ml of breath or lower as the allowable BAC limit for the legal operation of a private vehicle. In each state, the legal codes also indicate acceptable procedures for determining a BAC level (e.g., blood analysis, IR-based breath analysis, or urine analysis).

Generally, special conditions and lower BAC limits are set for drivers of commercial vehicles. For example, a review of the Official Compiled Laws of Michigan finds three statutes that prohibit the operation of a motorized vehicle while using alcohol. Section 257.625 (1), (2), (3) details the following three charges:

1. Operation Under the Influence of Liquor (OUIL). This statute establishes a BAC level of .10g/100ml of blood or .10g/210ml of breath as the *per se* BAC limit for adults over the age of 21 (Note: a minor under the age of 21 may not have a BAC above 0.00g/100ml of blood or 210ml of breath).
2. In cases where a BAC level of .08g/100ml of blood or .08g/210ml of breath is found, a second statute, Unlawful Bodily Alcohol Concentration (UBAC), is applicable. This second statute provides for a lesser punishment for the offender.

3. The third statute, Operating a Commercial Motor Vehicle while Impaired (OCMVI), establishes a BAC level of .04g/100ml of blood or .04g/210ml of breath as the per se limit for anyone who is operating a commercial truck or passenger bus while drinking alcohol (Michigan Compiled Laws, 2001).

A second situation where rules have been established prohibiting alcohol intoxication is in the workplace. Similar to laws prohibiting driving while intoxicated, workplace rules have been adopted that discourage the use of alcohol while operating heavy equipment or while working in situations where clear judgment and mental acuity is necessary for worker safety. These rules are developed within each locality and generally follow guidelines set forth by Occupational Safety and Health Administration (OSHA). To enforce such rules BAC levels have been adopted as an objective method for determining intoxication.

A third situation where BAC levels are used is within mental health and substance abuse therapy settings. In these settings, it is not uncommon for psychiatrists, psychologists, social workers, and other treatment providers to suspect that the client is under the influence of alcohol or other substances because of the client's behavior (Doweiko, 2002). In the case of an established client who appears for therapy or substance abuse treatment after drinking, the treatment provider may become alerted by the smell of alcohol on a client's person or notice that a client's speech is slurred or
mental alertness is altered.

In this situation the treatment professional may 1) decide to confront the client with her or his suspicion that the client is under the influence and/or 2) request that the client submit to an alcohol breath test or provide a blood or urine sample for toxicology testing. (Doweiko, 2002, p. 380)

According to Doweiko (2002), the client’s use of alcohol or other chemicals prior to a therapy session raises two issues: one a clinical issue and the second a matter of liability (p. 382). "The client’s use of chemicals during his or her therapy can hardly be said to be a minor matter. It is impossible to conduct a therapy session when the client is under the influence of recreational chemicals" (Washton, 1995, p. 67). The client’s use of alcohol or other recreational drugs prior to a therapy session also raises a number of liability issues for the client and the therapist. Because of potential liability claims and lawsuits, the treatment provider’s responsibility might not end with rescheduling the session for a later time. Depending on the state law, a therapist might be required to intervene actively in order to protect the client and/or others. For instance, if a therapist believes that her client is intoxicated and she sends the client home and reschedules the appointment for another time, the therapist may be held liable for damages if the client should have an accident on the way home. The liability in this case is based on the fact that the therapist allowed the client to drive while under the influence of alcohol (Doweiko, 2002). As a result, the ability of the therapist to quickly assess a client’s BAC level in the office without costly or time-consuming blood or urine testing has lead many agencies and private practitioners who work with substance dependent populations to purchase breath testing instruments for use in their offices (Washton, 1995).
For psychologists who provide mental health and substance abuse treatment, IR-based alcohol breath-testing results are frequently used to make differential diagnoses, develop treatment plans, or to validate treatment compliance. Additionally, the use of BAC results in support of differential diagnosis is a common practice in emergency psychiatric assessment. According to Fine and Miller (1993), mental health professionals often must differentiate between symptoms of psychotic disorders due to mental illness, such as schizophrenia or bipolar disorder, and psychotic symptoms due to alcohol abuse. The authors argue that symptoms of alcohol intoxication can "mimic" psychotic symptoms leading to inappropriate diagnosis and treatment.

To assist mental health professionals in recognizing and differentiating psychosis due to intoxication and psychosis due to a mental illness, alcohol breath testing (ABT) to determine BAC is often used as part of an emergency psychiatric evaluation. The use of ABT grows out of the fact that the Mental Health Code in many states allows a medical or mental health provider to hold a patient for involuntary psychiatric assessment only if the patient is a risk to self or others and her or his symptoms are due to a diagnosable mental illness. The Mental Health Code in Michigan is a good example. The code specifically prohibits the certification of an individual for involuntary psychiatric commitment if the individual's symptoms are due to drug or alcohol intoxication in the absence of another diagnosable mental illness. Because of this restriction, ABT is used to rule out alcohol intoxication as a cause of psychosis.

For psychologists, the issues of using BAC results obtained through breath analysis also raises ethical concerns. Direct reference to the psychologists' ethical
responsible when using tests or instruments for the purpose of evaluation, assessment, and intervention can be found within the 1992 Ethical Principles of Psychologists and Code of Conduct published by the American Psychological Association (APA). Standard 2. Evaluation, Assessment, or Intervention and Standard 7. Forensic Activities are of critical import. Specifically, standard 2.01(b) states: "(b) Psychologists' assessments, recommendations, reports, psychological diagnostic or evaluative statements are based on information and techniques (including personal interviews of the individual when appropriate) sufficient to provide appropriate substantiation for their findings" (APA, 1992, p. 7).

One interpretation of the above standard is that psychologists should not base their evaluations, assessments, and treatment on instruments that do not have adequate reliability and validation studies. To that end, psychologists must only utilize information that was collected through the use of instruments and techniques "that are appropriate in light of the research on or evidence of the usefulness and proper application of techniques" (APA, 1992, p. 7). Stated more directly, psychologists should not use instruments or techniques that have not been found to be valid and reliable for a given purpose through careful scientific inquiry. The phrase "sufficient to provide appropriate substantiation for their findings" is key to this interpretation of the standard (APA, 1992, p. 7). If a psychologist is not able to support her or his claims because of limited research evidence to support the use of IR-based breath alcohol analysis, then he or she must refrain from making evaluative statements based on IR-based results.
Although the BAC DataMaster® has demonstrated precision within the National Highway Traffic Safety Administration (NHTSA) allowable standard error of less than .0042g/210ml difference for paired repeated air samples, the breath samples were generated using a water bath alcohol simulator and may not apply to actual breath samples. Analysis of in-vivo results that were generated using actual human breath samples collected under field conditions suggests that the standard error for repeated breath samples is considerably higher than the .0042g/210ml allowable standard error (Gullberg & Logan, 1998). Despite growing criticism and concern within the scientific literature regarding the use of breath as a predictor of blood alcohol concentration level, the use of these instruments continues to grow (Caplan, Yohman, & Schaefer, 1985; Harding, Laessing, & Field, 1990; Hlastala, 1995, 1998).

When the results of a single test conducted using a given instrument has the potential to directly impact treatment decisions, or cause a person to lose his or her freedom via incarceration or court mandated treatment, it is critical that the test instrument used is reliable and valid. To assure this, rigorous testing of instruments like the BAC DataMaster® should be undertaken. This study is one such investigation and will add to the body of literature on breath alcohol testing.

**Theoretical Framework**

Breath testing for alcohol is predicated on a belief that the results of breath testing provide an estimate of the blood alcohol concentration in the body that in turn is related to the concentration of alcohol in the brain (Rockerbie, 1999, p. 75). Any
complications resulting from the fact that breath is two steps removed from the point of pharmacological action (e.g., the brain) are sidestepped through the use of per se laws. The theoretical assumptions that underlie modern ABT instruments date to the 1950s when the understanding of pulmonary physiology was limited.

Over the past ten years, modern analytical instruments and techniques have resulted in research (Bui, Dabdub, & George, 1998; George, Babb, & Hlastala, 1993; Hlastala, 1998; Lubkin, Gullberg, & Logan, 1996) that allows for a new understanding of the physiological mechanisms involved in soluble-gas exchange in the lungs. Despite the new understanding of soluble-gas exchange in the lungs, the manufacturers of ABT instruments have not yet embraced these findings. Instead, they continue to operate under a theory that dates back to the work of Harger, Forney, and Barnes (1950).

The theory of alcohol exchange that is the basis for ABT assumes that:

1. Equilibrium is established between pulmonary capillary blood and breath in the alveoli region of the lungs according to Henry’s law, and alcohol exchange only occurs in the alveoli.

2. Once equilibrium was been established in the alveoli the concentration of alcohol in breath will remain constant and unchanged as the exhaled air moves through the airways and exits the body.

3. An anatomic dead space exists in the conducting airways of lungs where no alcohol exchange occurs.

4. As a result of the anatomic dead space, the initial volume of air exhaled
from the lungs contains little 'alveolar air' and a lower concentration of alcohol. Further exhalation is required to reach end-expired air from the alveoli: only end-expired contains alcohol in equilibrium with pulmonary capillary blood.

5. A blood:breath ratio (BBR) exists that relates the concentration of alcohol in the blood to that in exhaled air.

6. The BBR used in breath alcohol testing is assumed to be 2100:1. The 2100:1 BBR assumed to be shared by all humans, means alcohol concentrations in the blood are 2100 times greater than alcohol concentrations in breath (Hlastala, 1998, Rockerbie, 1999).

Theoretical Principles Behind Infrared Breath-Alcohol Analysis

The practice of using IR analysis to detect alcohol in human breath is based on the fact that ethanol or beverage alcohol is known to absorb radiation at six major peaks of 3.39, 3.48, 7.25, 9.18, 9.50, and 11.5 microns. Further, no other compound absorbs radiation at these and only these peaks (Taylor, 1995; Rockerbie, 1998). All chemical compounds when exposed to infrared radiation will produce a unique infrared "finger-print" or absorption pattern that can be analyzed. Given this knowledge, detection of alcohol would appear to be quite simple for any instrument that can scan across the entire infrared spectrum or at least scan for the unique 6-band infrared absorption pattern of alcohol or "infrared fingerprint." However, due to the cost of full spectrum infrared analysis, no manufacturer has even attempted to produce a breath-alcohol analysis instrument designed to scan the entire infrared spectrum.
Instead, each manufacturer has selected one or two micron bands to approximate the signature of alcohol (Taylor, 1995). No ABT analyzer currently in use utilizes full spectrum analysis in their instruments. Instead, to produce a more affordable product, each manufacturer of ABT instruments has selected a portion of the infrared spectrum to use in its instruments to “scan” for alcohol. The use of cost saving measures in regards to IR analysis may increase potential for misidentification of other hydrocarbons as alcohol.

Definition of Terms

The following terms are common in the field of forensic analysis of blood alcohol concentration. These terms are defined below:

**Alcohol breath testing (ABT):** Alcohol breath testing is a generic term that refers to a process whereby blood alcohol concentration is estimated from a breath sample. Alcohol breath testing can utilize a variety of methods to compute results. Methods commonly used include fuel cell, chemical reagent, photometric, and infrared. Results are reported in g/210ml of breath.

**Alcohol intake condition:** independent variable manipulated in the present study, three treatment conditions: (1) Condition 1 - target BAC .10g/210ml, (2) Condition 2 - target BAC .08g/210ml, and (3) Condition 3 - target BAC .06g/210ml.

**Alveolar sacs:** These are located within the respiratory zone of the lungs. Respiration takes place in the alveolar sacs and the blood-carrying arterioles that surround the respiratory and alveolar ducts. All current breath testing instruments are
based on the assumption that all alcohol exchange from blood to breath occurs in the alveolar portion of the lungs. Although the alveolar region is critical for respiration, research in the last decade has established that the exchange of alcohol between blood and breath also occurs outside the alveoli.

**Blood alcohol concentration (BAC):** BAC refers to the concentration of alcohol present in a given sample of whole blood. It is common practice to report BAC in terms of grams per 100ml of blood.

**Blood draw (BD):** BD refers to a 6 milliliter blood sample drawn via venipuncture and collected in a Bectin Dickensen brand Vacutainer blood collection vile.

**Blood to breath partition ratio:** This rate is one of the important conceptual issues underlying breath testing. The blood to breath alcohol partition ratio commonly used in breath alcohol testing is assumed to be 2100:1. Simply stated, the concentration of alcohol in blood is assumed to be 2100 times greater than in breath. The concept of a blood partition ratio also assumes that a simple mathematical conversion of breath alcohol to blood alcohol can be made for all humans, an assumption that is frequently debated.

**Breath sample duration condition:** An independent variable manipulated in the study with three levels. The duration of breath sample collected for analysis is hypothesized to effect BAC$_{dm}$ estimates. There were three levels of the independent variable: (1) Short duration exhale (SDE) = 6 seconds $<$ exhalation $>$ 8 seconds; (2) Medium duration exhale (MDE), 12 seconds $<$ exhalation $>$ 14 seconds; and (3) Long duration exhale (LDE) = 18 seconds $<$ exhalation $>$ 20 seconds.
DataMaster® based blood alcohol estimate ($\text{BAC}_{\text{DM}}$): The $\text{BAC}_{\text{DM}}$ is an estimate of BAC calculated from a breath sample using the BAC DataMaster®.

Whole blood alcohol concentration ($\text{BAC}_{\text{WB}}$): This refers to the concentration of alcohol present in whole (unprocessed) blood as determined by laboratory analysis of a whole blood sample.

Limitations of the Study

As with any experimental research some limitations affected this study. One of the more important limitations in the study was the fact that alcohol intake was held to relatively low levels to protect subjects and to minimize liability for the researcher and the university. Because alcohol intake was held to relatively low levels, it is may not be possible to document the full magnitude of the phenomenon under investigation. Specifically, if the differences in $\text{BAC}_{\text{DM}}$ estimates and $\text{BAC}_{\text{WB}}$ results are found to be influenced by increasing amounts of alcohol intake, the results will only be able to indicate a directional trend for BAC levels beyond .10 g/210ml of breath. The fact that the procedures manual for breath testing in Michigan allows for greater error in paired breath samples at higher BAC levels suggests that, in general, error for $\text{BAC}_{\text{DM}}$ estimates is greater as alcohol intake increase. If this is the case, the full nature of the relationship between $\text{BAC}_{\text{DM}}$ estimates and $\text{BAC}_{\text{WB}}$ will remain unclear in cases where BAC levels are above .10g/210ml and below .06g/210ml.

A second limitation for this study involves the sample population and the ability to generalize results to the entire population. The sample population used in this
study was limited to healthy males between 21 and 30 years of age. Although the rationale for this is sound and based on a desire to reduce the risk to the participants, the sample population represents a limitation that will reduce the generalizability of results.

A third important limitation for this study is the fact that results will be limited to the current version of BAC DataMaster®. Although the BAC DataMaster® is the IR-based alcohol breath testing instrument of choice in Michigan, there are other companies that manufacture and sell alcohol breath testing instruments. While all IR-based instruments operate using similar principles, breath-testing instruments from other manufactures may or may not be subject to the same issues as those investigated in this study. As a result, any findings generated from this research will only be applicable to those individuals and agencies that use the BAC DataMaster®.

A fourth limitation of this study results from the definitions used for short, medium, and long exhalation. In this research the duration of breath samples was limited to short, medium, and long short durations. The interval used for short duration samples was defined as 6 to 8 seconds, medium duration samples as 12 to 14 seconds, and long duration samples as 18 to 20 second samples. The decision to select these particular intervals was based on the author's desire to have intervals that would allow all subjects to easily provide six breath samples. The author's experience and observation while operating the BAC DataMaster® suggests that lung capacity and the maximum duration of a breath sample is subject to individual differences. Although longer duration samples were clearly possible, the researcher
selected a maximum duration (18 to 20 seconds) that was well within the normal lung capacity for healthy males, this interval was selected to ensure a more complete data set. The selection of a maximum breath-duration interval of 18 to 20 seconds means that statements about the relationship between $BAC_{DM}$ estimates based on breath samples of longer duration and $BAC_{WB}$ results will not be possible.

A fifth limitation of this study is the fact that it is not possible to ensure that all participants within a given BAC target group will, in fact, have a BAC in the target range at the time of testing. Additionally, it is not possible to ensure that all participants had the same metabolic state with respect to alcohol absorption. Although alcohol dosing and the timing of intake and testing was carefully planned based on "average" gastric emptying and alcohol absorption rates, the fact remains that individual differences exist in the population with respect to these factors. As a result, BAC levels and the absorptive state of participants cannot be guaranteed.

**Review of the Literature**

In this section, relevant literature concerning the history of breath testing as a means of measuring an individual's Blood Alcohol Concentration level (BAC), the use of alcohol testing devices within medical, legal, corporate, and substance abuse treatment arenas, and the assumptions and "known" problems of breath testing instruments are presented.
Alcohol Breath Testing Technology

The earliest recorded use of breath to estimate Blood Alcohol Concentration (BAC) dates back 75 years. ABT was first present in an article published in the Journal of the American Medical Association entitled, “Drunkenness—a quantitative study of acute alcoholic intoxication” (Bogen, 1927). Within English language journals, Bogen’s work stood for nearly 23 years as the only published record of attempts to use breath to estimate blood alcohol concentrations. A second reference regarding the existence of a practical device designed to use breath samples to estimate BAC does not appear in the literature until the 1950’s. In an article presented at the first International Conference on Alcohol and Traffic, Harger et al. (1950) discuss a device that they purported could estimate the concentration of blood alcohol from a sample of human breath. While the Harger et al. device showed promise, another ten years passed before Borkenstein and Smith (1961) discussed practical applications for such a device in the literature (Hlastala, 1998).

The availability of evidential breath testing instruments in the year 2002 is quite broad. The choice of which particular breath testing instrument one chooses depends on the standard of proof required in the collection of evidence, the kind of support services available, and the cost of the instrument. A list of conforming products for evidential breath measurement devices has been published by the US Department of Transportation and is updated periodically (National Highway Transportation Safety Administration (NHTSA), 1998).
Measuring Alcohol Concentration by Chemical Reactions

The first breath-testing instrument was developed by Bogen in 1927. Bogen's procedure for alcohol breath testing was based on the assumption that alveolar air (air that emanates from the alveolar sacs and ducts located deep in the tracheobronchial tree), when adjusted for re-equilibration effects in the airways, was related to the concentration of alcohol in the blood (Rockerbie, 1999, p. 99). Bogen's assumption that a precise, fixed relationship exists between the concentration of alcohol present in air collected from the alveolar region of the lungs and the concentration of alcohol in a subject's blood was re-affirmed by Liljestrand and Linde in 1930. While the procedures developed by Bogen, Liljestrand and Linde for breath testing are no longer in use today, the assumption of a fixed Blood:Breath Ratio (BBR) remains at the heart of modern day alcohol breath testing (Rockerbie, 1999, p. 99).

The Drunkometer was developed by Harger at the University of Indiana in 1938 (Harger, Lamb, & Hulpieu, 1938). His assumption was that the carbon dioxide (CO₂) content of alveolar air is constant, and the amount of alcohol accompanying 190 mg of CO₂ is equal to the amount of alcohol in 1 ml of blood. The original Drunkometer measured CO₂ content by the weight increase of a CO₂-absorbing cartridge and the alcohol content by an oxidimetric reaction with potassium permanganate. In his review of alcohol breath testing instruments, Rockerbie (1998) suggests that "non-constancy of CO₂ in the alveoli, and changes that occur in the alcohol content in the airways after leaving the alveoli that are not paralleled by changes in CO₂, compromised the accuracy of the device" (p. 99). He further reports that, "Although
the assumptions underlying analysis conducted by the *Drunkometer* ultimately proved incorrect, this device served the purpose of introducing breath testing into law enforcement” (p. 99). According to an article by Harger and others, the original *Drunkometer* was modified in 1956 to use rebreathed air and to use the BBR of 2100:1 (Harger, Forney, & Baker, 1956).

Approximately three years after Harger released the original *Drunkometer*, Greenberg developed a portable device for indirect determination of the concentration of alcohol in the blood (Rockerbie, 1999). Greenberg’s instrument, sold under the name *Alcometer®,* measured end-expired air by oxidation with iodine pentoxide, and did not rely on the CO₂ content. As with previous breath testing instruments, the BBR of 2100:1 was used to infer the blood alcohol concentration (Greenberg & Keator, 1941).

**Measuring Alcohol Concentrations by Photometric Analysis**

The *Breathalyzer®* was developed by Borkenstein in 1954 at the University of Indiana (Borkenstein, 1959). The basic configuration and design of the *Breathalyzer®* was widely popular and was used on a large scale. According to Rockerbie (1999) the development of this breath testing device represents “a major landmark in the history of impaired driving law enforcement, second only to the work of Widmark” (p. 100). In fact, the strong association of the *Breathalyzer®* brand name with alcohol breath testing for law enforcement activities has resulted in the generic use of its name by the public at large. “The simple, rugged design, that
enables a maximum of operator control over the analytic procedure, presents features 
that are important to forensic investigations" (Rockerbie, 1999, p. 100).

Following the trend established by the designers of earlier breath testing 
instruments, Borkenstein’s 1954 design relied on end-expired air and the 2100:1 
blood:breath ratio. The early models of the Breathalyzer® analyzed alcohol by an 
oxidimetric reaction in which a color change in a potassium dichromate reagent at 
50°C was measured photometrically. A change was made to the faster reacting silver 
dichromate in 1960. The change in chemical reagents enabled the oxidation of alco­
hol to proceed at ambient temperature and resulted in a reduced sensitivity to acetone 
interference (Rockerbie, 1999). A detailed description of the sampling system used in 
the Breathalyzer® follows.

The sampling system of Breathalyzer® consists of a cylinder in which a piston 
is raised by the incoming breath sample. Vents in the side of the cylinder per­
mit air to escape. When a sample entry stops, the piston that is suspended by a 
free floating spacer held by magnets drops sufficiently to close the vent. The 
sampling system collects the last 57 ml of expired breath from which 52.5 ml 
is delivered for analysis. A simple and unique piston-activated relay inside the 
sample chamber and signal light on the instrument panel, monitor the force of 
airflow as an indicator of subject compliance. (Rockerbie, 1999, pp. 100-101)

The analysis begins when the operator activates the system by closing the 
sample control valve and releasing the piston which, propelled by gravity, falls and 
forces the collected breath sample through the liquid reagent in the test ampul. The 
breath sample bubbling through the reagent causes a chemical reaction and change in 
the color of the reagent solution in the test ampul (Lucas, 1986; National Dräger 
Incorporated, 1979).

The Breathalyzer® has undergone a number of revisions since its first release.
A succession of models includes models REX, RFL, 800, 900, 900A 900B, 1000, and 2000. In addition to the various models, there have been four manufacturers. The historical list of manufacturers includes: The Stephenson Corporation, Radio-Frequency Laboratories, Smith and Wesson, and National Dräger Inc. Models of the Breathalyzer® up to and including Model 900 use a galvanometer in the null balance photometric system to measure the color decrease in the reagent. The design and operation of the Breathalyzer® are detailed in available publications (Lucas, 1986; National Dräger, 1979; Rockerbie, 1999).

A number of breath testing instruments based on infrared (IR) analysis began to appear in the early 1970’s. The Intoxilyzer® was the first commercial alcohol breath testing instrument to use this technology. Introduced in 1979, the Intoxilyzer® measures IR absorption by alcohol vapor in a chamber that contains an end-expired breath sample (Harte, 1981). Like its competitors, the Intoxilyzer® has undergone a series of modifications and changes in manufacturers. Since its introduction as Model 4011 in 1971, the Intoxilyzer® has undergone six revisions: Models 4011A, 4011AS, 4011AS-A, 4011AS-AQ, 4011AW, 4011A27. Currently, there are seven models in use which include: Model 1400, 5000, 5000CD/FG5, 5000EN, 5000VA, and 6000 (Rockerbie, 1999, p. 107).

The basic principal underlying the operation of all of the Intoxilyzer® Models is IR absorption of alcohol. Unlike the instruments previously discussed that measure alcohol by a chemical process, the Intoxilyzer® relies on IR analysis. IR analysis of any chemical, including alcohol, relies on the fact that each pure chemical is a
molecule that absorbs IR light at a specific frequency. The most basic unit of a pure chemical is the molecule, and each molecule is made of atoms. Between each atom there is an atomic bond that holds the atoms together within the molecule. Within any molecule, the atoms will vibrate along the atomic bonds. The vibration resonates with a frequency characteristic of the atoms involved, giving a unique signature to each chemical molecule. When an IR light source is focused on any chemical, any IR light matching the frequency of the atoms contained in that chemical will be absorbed. The pattern of IR light absorbed provides a basis for identification and measurement.

When conducting IR analysis of breath alcohol, the Intoxilyzer® system focuses an IR light source on an end-expired breath sample contained in an 81.4 ml sample chamber. The molecules in the breath sample absorb the IR light at the frequency characteristic of the atoms contained in each molecule of the sample (Harte, 1981). The Intoxilyzer® searches for some specific peaks or elevations characteristic of the full IR absorption signature of the chemical bonds known to exist in alcohol.

Like all currently manufactured infrared breath alcohol testing instruments, the Intoxilyzer® brand breath testing instruments do not scan for the full IR absorption signature for alcohol. Instead, the instrument scans for only a portion of the signature. Specifically, all Intoxilyzer® models before the newest, Model 5000-768GA, employ two analytical wavelengths 3.48μm and 3.39μm, and a 3.80μm reference wavelength. When a breath test is implemented, the intensity of the emerging IR light at the analytical wavelength is compared to the reference wavelength. The difference is related to the concentration of alcohol in the sample. The testing sequence and infrared
analysis is controlled by a Z80 microprocessor (Rockerbie, 1999, p. 108).

Until recently, all versions of the Intoxilyzer® operated on these same basic IR analysis techniques. However, the most recent version of the instrument, Series 768GA of the Intoxilyzer® 5000, now includes five IR filters. The new IR filters center on 3.80, 3.52, 3.47, 3.40, and 3.36μm wavelengths. Like its predecessors, the instrument known as the Intoxilyzer® uses a blood:breath ratio of 2100:1.

Present Day Infrared Alcohol Breath Testing Analysis

IR alcohol breath testing (ABT) has expanded as computer technology and power have increased (Thill & Williams, 1999). The infrared ABT analysis to estimate blood alcohol concentrations (BAC) has become a widely accepted practice in the United States and abroad within the medical, legal, substance abuse treatment, and EAP/business wellness communities (Inaba & Cohan, 2000). Presently, there are five major companies who manufacture ABT analysis instruments. These companies include National Patent Analytical Systems Inc. (BAC DataMaster®), Lion Laboratories Ltd. (Lion Alcometer), Alcohol Countermeasures Systems Inc. (Model J-4 A.L.E.R.T.), CM1 Inc. (Model 5000-D Intoxilyzer®), and Federal Signal Corporation (Model PAC 1200 Intoxilyzer®). Regardless of their manufacturer, all current infrared ABT analyzers rely on similar technology to estimate blood alcohol concentration from expired human breath.
Technology Used in the BAC DataMaster®

The manufacturer of the BAC DataMaster®, the infrared ABT instrument that is the focus of this study, has the 3.44 micron bandwidth to identify alcohol and 3.37 microns bandwidth to identify acetone (National Patent Analytical System, 1997). While National Patent Analytical System has never explicitly stated why they selected these bandwidths, it is widely accepted that they were selected to reduce the cost of the instrument (Taylor, 1995; Thill & Williams, 1999). While the selection of only two infrared bands for the detection of alcohol and the exclusion of acetone allows the BAC DataMaster® to be more cost effective, questions about its ability to accurately distinguish alcohol from other alcohol-like compounds in human breath have been raised.

The National Highway Traffic Safety Administration standards for devices which measure breath alcohol has established the allowable standard error for infrared ABT instruments at ±0.0042 g/210 ml of breath in controlled laboratory settings, using a water bath alcohol simulator to provide test samples. The BAC DataMaster® has demonstrated precision within the NHTSA allowable standard error of less than 0.0042 for paired repeated air samples from a water bath alcohol simulator. However, the accuracy of actual repeated breath samples collected in the field suggest that the standard error is considerably higher when analyzing samples of expired human breath. "As those familiar with breath alcohol instruments know, differences between breath samples are frequently encountered" (Gullberg & Logan, 1998).

In fact, the National Safety Council Committee on Alcohol and Other Drugs...
(NSCCAD) has recognized this and determined that a difference of .02g/210ml breath between successive duplicates is acceptable for any infrared ABT device (NSCCAD, 1979). In the state of Michigan, the allowable variation for repeat ABT test using the BAC DataMaster® are adjusted upwards as a subject’s BAC results increase. For example, if an ABT result falls in the range of 0.00g/210L to 0.14g/210L, the allowable variation for a second ABT is +/- .01g/210L. As a subject’s ABT results increase, so to does the allowable variation for the second ABT result (Thill & Williams, 1999). In the legal arena, violation of the “allowable” error often results in a dismissal of charges, when defense attorneys argue the instrument was not functioning correctly.

**Growing Use of Alcohol Breath Testing Technology**

Infrared ABT analysis is considered an accepted legal standard for estimating blood alcohol concentrations (BAC) in 35 states in the United States. In fact, after eyewitness behavioral observations, data from ABT technology is easily the most common source of evidence presented by law enforcement officials in court hearings involving alcohol-related offenses (Jones, 1988, Taylor, 1995). Charges commonly supported by ABT evidence include: Driving While Intoxicated (DWI), Operation of a motorized vehicle while Under the Influence of Liquor (OUIL), operating a watercraft while impaired and other similar legal charges involving the use of alcohol (Michigan Compiled Laws, 2001).

As discussed previously, the medical/psychological community also uses ABT technology for screening and as a means of verifying abstinence during treatment.
Because infrared ABT analysis is more cost effective and produces results faster than an actual blood draw and/or urinalysis, ABT analysis has become a popular tool within substance abuse treatment facilities. Physicians, psychologists, counselors and other substance abuse treatment professionals working in the field have come to rely on ABT technology to quickly estimate blood alcohol concentration in individuals undergoing alcohol treatment. Because of its ease and ability to quickly provide feedback to clinicians, ABT technology is often used to help determine which patients will require changes in their treatment program.

One recent application of ABT technology for monitoring adherence to treatment can also be found in the Michigan Drug Court program. In these recently created programs, individuals who have been convicted of multiple Operating While Intoxicated (OWI) offenses have the option of going to jail or entering the Drug Court Alcohol Treatment program. There are two unique elements to this program that assists clients in maintaining their treatment goal of abstinence. Specifically, all participants in this program are placed on electronic tether devices, which allow corrections personnel to monitor a client's physical location at all times. The second feature of this program is the use of ABT technology to monitor participants' blood alcohol levels at random periods. The program is designed so that clients can leave their home for work and treatment only. But corrections personnel state that the unique feature of being able to instantly verify that a client is maintaining abstinence has proven to be extremely useful (Finegood, 2001).

Finally, ABT technology can also be found in the work place. The use of
ABT analysis to screen out employees with potential substance abuse problems and to reduce corporate liability has become common in many large U.S. corporations. ABT technology is currently utilized for random alcohol screening of railroad engineers, radio dispatchers, switchmen, and others who are directly involved with the operation of freight and passenger trains. Other industries that have begun using this technology include many of the major U.S. airlines as well as companies who provide cross-country cargo transportation. In many of these settings, individuals with positive ABT results are referred to Employee Assistance Programs for counseling and substance abuse treatment as indicated (Inaba & Cohen, 2000).

Questions of Validity

The widespread and growing use of ABT technology into a variety of settings would not present a problem if these ABT instruments can do what they purport to do, i.e., accurately predict an individual’s blood alcohol concentration through an analysis of a relatively small sample of expired breath. Herein lies the problem. While the infrared ABT analysis technology is highly precise and reliable in the laboratory (Duboski & Essary, 1991; Gullberg, 1998), outside the laboratory setting the use of these instruments has not proven to be as accurate as the manufacturers and others would like us to believe (Hlastala, 1998; Inaba & Cohen, 2000; Rockerbie, 1999). A careful review of the literature on ABT technology reveals that there are at least four significant issues that have been raised in refereed journals regarding the use of ABT instruments.
Temperature of Breath Samples

The first issue of note in the research literature is that of variations in breath sample temperature. Jones (1982b) noted that the temperature of expired breath must be considered with caution since the breath's ability to carry alcohol changes with temperature. Jones' research suggests that a 1 degree centigrade increase in breath temperature will result in a 6.5% increase in BAC results. This issue is significant because inter- or intra-individual variations in breath temperature may affect ABT results. Furthermore, all ABT instruments assume air/blood ratios to be a constant. If breath temperature does affect the air/blood ratios as suggested by Jones (1982b), then BAC results will be dependent on the temperature of breath samples. Manufacturers of ABT instruments have attempted to account for this issue of breath temperature indirectly by using heated breath tubes and heated sample chambers. However, the effect of these measures remains unclear. For instance, the operator manual for the BAC DataMaster® continues to require simulator tests to be held at a constant 34 degrees centigrade, suggesting that samples passed through the heated breath tube are still sensitive to temperature variations. Research on ABT instruments similar to the current BAC DataMaster® continue to show evidence of the effect of temperature on ABT results. This pattern is very similar to Jones' earlier findings, that a 1 degree centigrade increase in sample temperature results in a 6.8% increase in reported alcohol concentration (Dubowski 1979; Schoknecht 1989; Wells 1981).
Breath to Blood Partition Ratios

One of the most questioned issues of modern day ABT is the accuracy of BBRs. The BAC DataMaster® and other similar infrared ABT make the assumption that there is a constant and direct relationship between the amount of alcohol in a person's expired breath and the amount of alcohol in the person's blood. This relationship is commonly known as the breath to blood partition ratio (Hlastala, 1998; Jones, 1996; Rockerbie, 1999). The partition ratio refers to the belief that the amount of alcohol in one milliliter of blood is 2100 times greater than the amount of alcohol found in 1 cubic centimeter of expired breath sample. Or conversely, that the amount of alcohol found in a 2100 cubic centimeter sample of expired deep lung breath is equal to the amount of alcohol in one milliliter of blood.

While the 2100 to 1 ratio is common to all currently manufactured infrared ABT instruments this ratio has consistently been questioned by researchers as unrealistic and unsupported by clinical research (Ohlsson, Ralph, Mandelkorn, Babb & Hlastala, 1990; Jones & Andersson, 1996). Recent work using modern technology demonstrated the average blood partition ratio to be 2407:1 with a standard deviation of ± 213. Based on the mean and standard deviation of this data, ± 2 SD or 96% confidence interval for variation of the blood partition ratio in humans would range between from a low of 1981:1 and 2833:1 (Jones, 1996). The level of variability in blood partition ratios demonstrated by Jones is a serious concern for ABT (Hlastala, 1998). If one assumes the 2100:1 ratio to be a common value in all humans, when in fact the mean ratio is closer to 2400:1, the resulting BAC concentrations will be
incorrect in all cases except where a participant's blood partition ratio is actually 2100 to 1 (Rockerbie, 1999).

Source of Alcohol in Breath Sample

The third issue raised in the literature regarding ABT involves the source of the alcohol in the breath sample. As discussed in the theoretical framework section, all ABT instruments, including the BAC DataMaster®, are designed to sample alveolar (or deep lung) air. At the time of the development of early ABT technology, it was generally understood that the initial volume of air exhaled from the lungs arose from the conducting airways and included little "alveolar air." Early models of air exchange suggested that further exhalation would result in exhalation of air from the alveoli containing gas in equilibrium with pulmonary capillary blood (Hlastala, 1998).

Without modern day analytical equipment, the profile of exhaled alcohol could not be measured but was expected to be similar to that for nitrogen (after a single breath of oxygen) (George, Babb, & Hlastala, 1995). All infrared ABT technology currently used in the United States was designed with the assumption that end-expired air would contain alcohol equal to the alveolar alcohol concentration which contains gas in equilibrium with pulmonary capillary blood. Despite growing evidence to the contrary, the BAC DataMaster® and other similar ABT technology still insist that end-expired air approximates alveolar alcohol concentration (George et al., 1995). Further, the manufacturers and advocates contend that expired deep lung air remains unchanged on its journey through the pulmonary airways.
Recent developments in analytic procedures made during the last decade have shed light on the issue of the point of alcohol exchange. Prior to the work of Bui et al. (1998), George et al. (1993), and Hlastala (1998), alcohol exchange was thought to occur entirely in the alveolar region of the lungs. The work of these authors resulted in a mathematical thermodynamic model that closely matches results produced by drinking subjects. According to the new thermodynamic theory alcohol is exchanged throughout the non-respiratory portion of the lungs, not in the alveoli as previously believed (Hlastala, 1998).

The theory suggests that during inhalation the non-respiratory portion of the lungs is cooled. During the early part of an exhalation alcohol is lost to the cooler airway surface. Condensation of water on the airway surfaces dilutes the alcohol, and promotes loss of alcohol from the air stream. Subsequent warming that results from the continued heat exchange than releases alcohol from the mucus layer into the expired air (Hlastala, 1998). The thermodynamic action explains why breath samples from the initial volume of breath have lower concentrations of alcohol then samples from end-expired volume of breath. The theory directly challenges the assumption that all alcohol is exchanged in the alveoli as is believed by the manufactures of all current ABT instruments (Hlastala, 1998; Rockerbie, 1999).

**Duration of Breath Samples**

The final issue to be discussed in the literature involves the impact of variation in the duration of breath samples. Research by Jones (1982a) and Hlastala (1998)
have called into question the quantitative accuracy of one of the more popular breath alcohol testing instruments on the market, the Intoxilyzer® 5000. Both Jones and Hlastala report data that suggests that the results produced by the Intoxilyzer® 5000 are directly affected by the duration of the participant’s breath sample. Specifically, the data suggests that the longer a participant blows into the breath tube, when providing his or her breath sample, the higher her/his BAC results.

The work of Hlastala (1998) calls into question the basic assumptions of alcohol breath. One of the most significant issues raised by the new thermodynamic theory of alcohol exchange is the fact that alcohol concentrations will be expected to vary from initial breath volume to end expired breath volumes. This model of alcohol exchange is very different from the static model of alcohol exchange accepted by the manufactures of ABT instruments in general and the BAC DataMaster® in particular (Rockerbie, 1999).

If the thermodynamic model of alcohol exchange is correct as suggested, then the BAC DataMaster® will be vulnerable to variations in the duration of a participant’s breath sample. However, as of the time of this writing, this issue has not been systematically investigated. Given the growing popularity of ABT analysis within the medical, legal, and business communities these findings are quite troubling.

As noted previously, the use of ABT technology is continuing to increase within the substance abuse treatment, EAP/employee wellness, and legal communities. The continuing growth of this technology comes despite the fact that recent research has raised significant concerns about the fitness of ABT instruments. While
all of these issues demand further investigation, the issue of breath sample duration is critically important because it is one area where the source of the error is not systematic to the instrument itself, but introduced into testing by the instrument operator.

In the proposed study, the researcher will investigate how an operator's directions to a test subject concerning when to stop "blowing" during a breath sample impacts the resultant BAC readings by the BAC DataMaster®. The methods utilized to conduct this study will be presented in detail in Chapter II.
CHAPTER II

METHOD

This chapter is divided into four sections. In the first section, the identification of the study population is presented. Included in this presentation is a discussion of the procedure used and locations solicited. Also included in this section is a brief discussion of inclusion/exclusion criteria. In the second section, the procedures used for screening study participants presented and the screening instruments and laboratory procedures are discussed. In section three, the data collection methods and procedures are presented. Included in this section is a discussion of the group assignment procedure, formulas for estimating BAC and the schedule of participant alcohol intake. In the final section, a description of the design, explanation of the statistical analyses used, and the research hypotheses to be investigated are detailed.

Identification of a Population and Sample

The identification of a population and sample is a critical step in designing a study to investigate the impact of varying the duration of breath samples during alcohol-breath testing. For the present study, a research proposal was submitted and approved by the doctoral committee on March 1, 2001. After gaining approval from the doctoral committee, the research prospectus was submitted to the Western Michigan University Human Subjects Institutional Review Board (HSIRB) for review.
and approval. Approval from the HSIRB was granted on March 31, 2001 and solicitation for research participants began on May 1, 2001 (Appendix A).

Participant Solicitation

All study participants were healthy males between 21 and 30 years of age, inclusive. Participants included in the study were experienced drinkers with a negative personal and familial history of substance abuse or dependence. A careful substance abuse evaluation and psychological screening was used to ensure that individuals who were selected for participation were free from current, or past, psychiatric symptoms and did not suffer from a substance abuse disorder. In addition, all participants were provided with a physical examination and laboratory work to ensure the absence of health conditions that might be exacerbated by the ingestion of ethyl alcohol.

The participants used in this study were individuals who responded to a solicitation for research participants. The solicitation was placed in the Kalamazoo, MI Gazette, the Western Herald, and posted in public areas on the Campuses of Western Michigan University, Davenport University, Kalamazoo College, and Kalamazoo Community College (Texas Township and Arcadia Commons Campuses) in Kalamazoo and Portage Michigan (Appendix B).

The Kalamazoo Gazette is a regional-based, medium-sized, daily newspaper serving the greater Kalamazoo and Portage areas and the surrounding communities in the southwestern corner of Michigan's lower peninsula. The Kalamazoo Gazette is a
local, daily newspaper that reaches homes via daily subscription and through direct sales at newsstands. The Western Herald is a free, student newspaper serving the students, faculty, and employees of Western Michigan University. The Western Herald is a daily newspaper distributed on Campus and in the contiguous University Community Monday through Friday. However, during the summer semester, the period when subjects were solicited, the paper was only distributed on Monday and Wednesday.

The four educational institutions that served as additional points for participant solicitation are described below. "Kalamazoo Valley Community College (KVCC) is a comprehensive, public, two-year college. ...[with] enrollments total[ing] between 10,000 and 11,000 each semester. The college offers certificates in over 20 areas of study and associate of applied sciences degrees in 25 areas" (http://www.kvcc.edu/welcome.htm, October 2, 2001, p. 1). Participant solicitation posters were placed in public areas at both the Texas Township Campus as well as the Downtown Arcadia Commons Campus.

"Kalamazoo College is a private, four-year, co-educational college of liberal arts and sciences. The college offers Bachelor of Arts and Sciences Degrees in 28 areas and serves approximately 1300 students from 41 states and 22 countries" (http://www.kzoo.edu/admiss/facts.html, October 2, 2001, p. 1).

Davenport University in its present makeup was formed in 2001...by the mergers of Davenport College, Detroit College of Business, and Great Lakes College. The focus and purpose of the University is to provide training and education for careers in business although, in recent years, that mission has expanded to include academic programs in a wide variety of careers... Students at Davenport University may earn a master's, bachelor's or associate's...
degree or complete a diploma program, technical specialty, or certification preparation in the fields of business, health, technology or legal studies. ...Davenport University's three regions have 24 campuses across Michigan and Northern Indiana, and serves 15,000 degree-seeking students (http://www/davenport.edu/e3front.dll?durki=62&site=1&return=15, October 2, 2001, p. 1).

For the purpose of participant solicitation only the Kalamazoo Center Location in Kalamazoo, Michigan was used. According to the Davenport University public information department, the Kalamazoo Center Location serves approximately 1200 students (Davenport University, 2001).

Western Michigan University (WMU) is a comprehensive public university granting Bachelor's, Master's, Specialist, and Doctoral Degrees in a wide range of majors and specializations. Total enrollment at WMU for the 2001 academic year was 28,657 consisting of 22,756 undergraduate students and 5901 graduate students. Students at WMU can choose from 254 Bachelor, 165 Master's, 25 Doctoral, and 2 Specialist degree programs (http://www.wmich.edu/sub/facts.html, October 2, 2001, pp. 1-7).

While WMU's off-campus education program consists of eight facilities around the state, subject solicitation was limited to the main campus in Kalamazoo, Michigan.

Exclusion of Female Subjects

The decision to limit participants to only males was made only after careful consideration. Some of the reasons for this decision follow. First, before asking a human female to ingest alcohol, for research purposes, it is critical to determine that the individual is not pregnant. While a woman's reported menstrual and contraceptive history is a useful screen for pregnancy, the risk of alcohol damage to an unborn fetus is such that a standard hormonal pregnancy test is required of all female participants (National Advisory Council on Alcohol Abuse and Alcoholism (NACAAA),
Second, changes in a woman's gonadal hormone levels during the normal menstrual cycle have been shown to affect the rate of alcohol metabolism in woman (National Institute on Alcohol Abuse and Alcoholism [NIAAA], 1990). As a result, the phase of a woman's menstrual cycle would have needed to be determined by hormone testing and women participants would need to have been grouped by the stage of their menstrual cycle. If this factor was not controlled, it had the potential to act as a confounding variable that could affect results. While grouping women participants based on their hormone levels was considered, the number of individuals needed to meet the statistical demands of a study that included both males and females would have increased threefold. An increase in the number of participants of this magnitude would not only increase the number of individuals placed at risk, but would also have prohibitively increased the cost of the research.

Finally, research suggests women metabolize alcohol differently than men. On average, women have less active alcohol dehydrogenase enzymes, higher percentages of body fat, and a lower concentration of water in their bodies than the average male. These differences in body composition result in higher blood alcohol concentrations in women than in men who drink equally based on body weight (Hanson et al., 2002). As a result, woman and men would need to be analyzed separately or results would be confounded by these physiological differences.
Age Restrictions

The selection of the age range of 21 to 30 was based on the following considerations. Research on alcohol use in the United States suggests that 79% of males in late adolescence/early adulthood report using alcohol (Hanson et al., 2002). The lower age limit of 21-years-of-age was established based on the laws of the state of Michigan, where the study was conducted. Section 436.1701 of Michigan’s Compiled Laws states that it is a misdemeanor of law to sell or provide a minor (a person under the age of 21) with alcoholic liquor (Michigan Compiled Laws, 2001).

The upper age limit of 30 years was more arbitrary and was selected after discussions with William Fenn, P.A-C, Ph.D., and Michael Liepman, M.D, who served as medical consultants for the study. Their recommendation of age limit was based on the increased probability of finding individuals who were “healthy” (e.g. individuals who did not take daily medications, did not have cardiovascular problems such as hypertension or coronary artery disease, and did not suffer from diabetes, etc.) in the population of males under the age of 30 (W. Fenn, personal interview, February 12, 2001; M. J. Liepmann, personal interview, February 11, 2001).

The Use of Experienced Drinkers

Only participants who were judged to be “experienced” alcohol users were included in the study. The use of “alcohol-naive” individuals in alcohol research is considered to be an unnecessary risk. According to the National Institute on Alcohol Abuse and Alcoholism guidelines for use of alcohol during research, alcohol-naive
individuals are at increased risk for severe reactions to high doses of alcohol and, therefore, should be excluded from participation in studies involving the intake of ethyl alcohol (NACAAA, 1989).

Screening Procedures

Participant Screening Process

As with any study involving human subjects, protecting the health and well-being of study participants was of paramount concern. When conducting studies that require human subject to ingest ethyl alcohol, it is the researcher’s responsibility to ensure that the risk to participants is minimized. In developing this study, special attention was paid to the *Recommended Council Guidelines on Ethyl Alcohol Administration in Human Experimentation* (The National Institute on Alcohol Abuse and Alcoholism. 1989).

Although the use of alcohol is a common social practice in the United States, particularly for males age 21 to 30, the ingestion of ethyl alcohol to blood concentration levels of .06, .08 1.0 q/210L for the purpose of research requires special consideration to minimize the risk to study participants. Because the ingestion of ethyl alcohol has been shown to be potentially harmful to individuals in poor general health, specific steps were taken to ensure that all study participants were in good physical health prior to participation in this study.

Respondents to the public solicitation for participants were sent a cover letter explaining the study (Appendix C), a copy of the Milcom Health History
Questionnaire (MHHQ) (Appendix D), and two informed consent forms describing the goals and focus of the study, the requirement for participation, the compensation allotted for participation, and the potential risks/benefits of the study (Appendix E). Participants who remained interested in participating in the study were asked to complete the health questionnaire (Appendix F), sign one copy of the informed consent form, and return the questionnaire and consent form using a self addressed/postage paid envelope.

As noted above, a health history questionnaire was completed by all potential study participants. In addition, participants were required to submit to a brief psychiatric interview and complete the Substance Abuse Subtle Screening Inventory 3rd Edition (SASSI-3) (Appendix G) to exclude individuals with symptoms of mental illness and/or substance abuse problems that were not previously reported on the health questionnaire.

As participants cleared the psychiatric interview and the SASSI-3 substance abuse/dependence screening, they were asked to undergo a brief medical evaluation to exclude any participant who was in poor general health or who showed signs of a medical condition that, in the opinion of the physician, placed the participant at increased risk for problems from consuming alcohol. During the medical examination, a glucose test was conducted to screen for diabetes, and blood was drawn and sent to a local laboratory for creatinine and Alanine Aminotransferase (ALT) assays to ensure normal kidney and liver functioning.

In addition to the laboratory assessments, careful attention was given by
clinicians to screen for the presence of medical conditions that might be exacerbated by the use of alcohol. Conditions that resulted in participants being excluded from the study included the following: history of seizure disorder, diseases of the digestive system (i.e. ulcers, gastritis, or colitis), diseases of the liver (i.e. hepatitis, jaundice or cirrhosis), cardiovascular diseases (i.e., heart disease, stroke, or hypertension), diseases of the kidneys (i.e., renal dysfunction or failure), and history of mental illness (i.e. schizophrenia, major depression or bipolar disorder). A detailed description of participants who were excluded from the study is presented in Chapter III.

**Participant Sample**

Individuals who passed all three levels of screening were then placed into the potential participant pool. Using a table of random numbers, a random sample of the participant pool was implemented to identify 27 participants and 12 alternates. Using a standard six-sided die and 39 individual rolls the above identified participants were then randomly sorted into one of three treatment conditions. All identified participants were contacted by telephone and invited to take part in the data collection phase of the study. During the telephone contact, each participant was given a specific time to arrive at the University Substance Abuse Clinic (USAC) on June 16, 2001. To ensure that food in the participants' stomachs did not become a confounding factor, participants were instructed to fast for a minimum of four hours prior to their appointment time.
Participant Screening Instruments

**The Milcom Health History Questionnaire (MHHQ)**

The MHHQ is a paper and pencil inventory developed by Milcom, Inc. and the Society of Teachers of Family Medicine (Milcom, 1988). The MHHQ is intended to be completed by a patient prior to an office visit and asks a series of 88 yes/no questions that review the major physical systems. Systems included in this questionnaire are: (a) head/eyes/ears/nose/throat, (b) respiratory/cardiovascular, (c) gastrointestinal and gastro-urinal, (d) male/female genitalia, (f) skin and extremities, and (g) mood. Additionally, the questionnaire collects data on dietary habits, leisure activities, sexuality, family and social support. The instrument is designed so that patient responses prompt the medical provider to review specific systems during the physical examination. No reliability or validity data on the MHHQ were found.

**The Substance Abuse Subtle Screening Inventory 3rd Edition (SASSI-3)**

Because of the high prevalence of substance dependence disorders in our society, it was probable that some of the individuals who volunteered for participation in this study may have suffered from a diagnosed or undiagnosed drug or alcohol dependence disorder. Because intentionally providing an individual with a known substance abuse disorder with beverages containing alcohol is both unethical and potentially harmful, an intense effort was made to guarantee that the individuals who
participated in this study did not suffer from a substance abuse disorder.

To accomplish this, all participants were screened for indicators of substance abuse using the SASSI-3. The SASSI-3 is an objectively scored, paper pencil inventory that is designed to identify individuals who have a high probability of having a substance dependence disorder. The inventory has an empirically demonstrated accuracy of 94% in identifying individuals who are substance dependent (Miller, Roberts, Brooks, & Lazowski, 1997).

The Mental Health Interview

In addition to the SASSI-3 screening, a face to face interview with a master's level psychologist or social worker was completed to assist in the detection of drug and alcohol dependence disorders. Direct questions were asked regarding substance use, substance abuse treatment history, and legal history pertaining to substance use and abuse were developed. All participants who reported a positive history of alcohol or drug abuse treatment, or referral for screening for treatment, were excluded from participation in this study. Participants were also asked if they had ever been charged with a Minor in Possession (MIP), Driving While Intoxicated (DWI), or Operating a Motorized Vehicle while Impaired (OMVI), or other criminal acts involving the operation of an automobile, motorized watercraft, or other motorized vehicle while impaired. Again, participants who answered these questions in the affirmative were excluded from the study. A list of local substance abuse treatment providers was given to participants who were excluded based on a suspected drug or alcohol dependence
disorder (Appendix H). In addition to a referral list, excluded participants were encouraged to seek follow up treatment/evaluation.

Additional questions were used to assess a participant's mental status and mental well-being were developed. These questions were used to screen for history and/or current symptoms of mental illness. Individuals suspected of current or past psychiatric problems were excluded from the study and provided with a referral list of area mental health clinicians (Appendix I). In addition to the referral list these participants were encouraged to seek follow up mental health treatment/evaluation. Interview questions were adapted from the *Outline of Psychiatric History and Outline of the Mental Status Examination* (Kaplan & Sadock, 1991) (Appendix J).

**Laboratory Procedures**

All laboratory blood analyses for this study were conducted at the Bronson Hospital Laboratories in Kalamazoo, Michigan, under the supervision of laboratory director, Paul Gutherie, M.T., A.S.C.P. Blood samples were collected via venipuncture, using Bectin Dickson, 21-gauge needle/vacutainer blood collection sets by the medical personnel hired by the researcher (Physician Assistant students during pre-study health screening and nursing personnel during data collection). Participants' blood samples were refrigerated at the research location and later transported by the researcher to the laboratory for analysis.
Alanine Aminotransferase Assay Test

Alanine Aminotransferase (ALT) assay tests were conducted on the Roche Modular Analyzer®, using the International Federation of Clinical Chemistry (IFCC) reference method and standard procedures for ALT determination. This method is based on the 1956 work of Wroblewski and LaDue who first described kinetic determination of ALT activity in serum (as cited in Roche Diagnostics, 2000a).

The ALT assay test is intended to provide a quantitative determination of ALT in human serum or plasma. Transaminases catalyze the interconversion of amino acids and α-ketoacids by transfer of amino groups. Elevated levels of the transaminases can indicate myocardial infarction, hepatic disease, muscular dystrophy, and organ damage. Serum elevations of ALT activities are observed in parenchymal liver disease (Roche Diagnostics, 2000a).

In the present study, ALT levels were evaluated as a part of the health screening of all potential participants to ensure normal liver function. Individuals with abnormal ALT levels (6-37) were excluded from participation in the study. Individuals with abnormal results were informed by certified mail of their results and encouraged to seek follow-up medical care with their personal physician. Receipts from the Post-Master General were checked to ensure that individuals received their mail. A list of local medical providers was included in this mailing for those individuals who did not have a personal physician (Appendix K).
Creatinine Assay Test

Creatinine assay tests were conducted on the Roche Modular Analyzer® using the Jaffé Method. The method is based on the Jaffé reaction as described by Popper (1937), Seelig and Wüst (1969), and modified by Bartells, (1972) (as cited in Roche Diagnostics, 2000b). The test is intended to provide a quantitative determination of creatinine in human blood serum. In muscle metabolism, creatinine is synthesized endogenously from creatine and creatine phosphate. Under conditions of normal renal function, creatinine is excreted by glomerular filtration. Clinically, creatinine determinations are performed for the diagnosis and treatment of acute and chronic renal disease as well as for the monitoring of renal dialysis (Roche Diagnostics, 2000b).

In this study, creatinine levels were evaluated as a part of the health screening of all potential participants to ensure normal renal function. Individuals with abnormal creatinine levels (0.7mg/dl ≤ X ≥ 1.50mg/dl) were excluded from participation in the study. Individuals with abnormal results were informed by certified mail of their results and encouraged to seek follow-up medical care with their personal physician. A list of local medical providers was included in this mailing for those individuals who did not have a personal physician (Appendix K).

Ethanol Assay Test

Ethanol assay tests were conducted on the Abbott TDxFLx REA® using Radiative Energy Attenuation (REA) Technology and the fundamental principles of
Beer's Law. The test is intended to provide a quantitative determination of ethanol in whole human blood (Abbott Laboratories, 1996).

In the study, blood collected pre- and post-breath testing was analyzed. Resulting ethanol levels ($BAC_{WB1}$ and $BAC_{WB2}$) were compared to the BAC levels generated via breath testing conducted on the DataMaster® BAC ($BAC_{DM}$). Whole blood results were also compared to target BAC levels (.06, .08, and .10g/210ml) for each treatment condition as a treatment validity check.

Data Collection

In addition to the use of rigorous screening and strict exclusionary criteria for study participants, steps were taken to ensure the safety and security of individual participants during the data collection period. The specific precautions used to protect participants are outlined below. All participants were asked to be transported to the University Substance Abuse Clinic (USAC) and to arrange for a ride home. Any participants who drove to USAC were required to surrender their car keys. Keys were held in a locked box and participants were prohibited from leaving the facilities until their blood alcohol level returned to 0.0 BAC level as determined by a hand-held, fuel cell presumptive breath test (PBT).

Prior to the ingestion of any alcohol, all participants were asked to demonstrate that they were alcohol. To document this condition, each participant and alternate was required to provide a baseline breath sample. Two participants presented with a BAC greater that 0.00 q/210L at the beginning of the study. These individuals
were identified and their data was not included in the data analysis. In addition, all participants were required to sign a written statement indicating that they would remain in the USAC until such time as their BAC level returned to 0.00g/210L as measured by a PBT.

After providing breath and blood samples, participants were allowed to watch television, play cards or video games or relax in the reception/lounge area. At all times during the detoxification period, a nurse was present to assist any subject who experienced a negative reaction. Additionally, Micheal Liepman, M.D., was available in the building to provide treatment in the case of medical emergency.

**Group Assignment Procedures**

Data collection took place on Saturday, June 16, 2001 from 9:00 am to 9:00 pm at the University Substance Abuse Clinic (USAC), 1000 Oakland Drive, Kalamazoo, Michigan. In order to approximate an actual drinking and breath-testing situation, participants were provided with a known amount of alcohol and were required to consume that alcohol over a period of one hour. As indicated above, a similar situation may occur in reality when an individual is stopped by the police and asked to take a breath alcohol test after consuming moderate to large amounts of alcoholic beverages.

All participants were randomly assigned to one of three experimental conditions based on the expected/targeted BAC level: Group 1 drank a set dose of alcohol based on body weight to reach the target BAC = .06g/100ml, Group 2 drank a set dose
of alcohol based on body weight to reach the target BAC = 0.08 g/100ml. and Group 3 drank a set dose of alcohol based on body weight to reach the target BAC = 1.0 g/100ml.

Each of the 27 participants and 12 alternates, ingested six drinks of equal amounts of Vodka and Orange Juice (one drink every ten-minutes) for a 1-hour alcohol-loading period. The exact amount of alcohol ingested by each participant was based on calculations using the modified Widmark formula for determining alcohol absorption (Widmark, 1932). The computations used for this study are based on the BAC estimation formula used by the Department of Transportation (DOT), National Highway Traffic Safety Administration (NHTSA) for the Blood Alcohol Content Estimator for Microcomputers distributed by National Technical Information Services (NTIS) (NHTSA, 1994).

**BAC Estimation Procedures**

The BAC estimation procedures described below are published in a report entitled, Computing A BAC Estimate, which accompanies the BAC estimation software (NHTSA, 1994). Calculations used in the study are based on the established physiological facts that alcohol distributes itself in the total water of the body, and that it is disposed of primarily by metabolism in the liver (Hanson et al., 2002; NHTSA, 1994; Plapp, 1975). The procedure takes into account the amount of body water in males and an average metabolic rate for alcohol elimination found in the population. The step-by-step procedure used in this study to calculate the dose of alcohol
needed for each participant to reach his assigned target blood alcohol concentration is outlined below.

Because alcohol is ultimately distributed in the water in an individual’s body, the first step in estimating BAC for the study participants was to calculate the amount of water in each participant’s body. On average, males have 58 percent of their body weight as water (Moskowitz, 1992). Therefore, to find the amount of water in each participant’s body, the researcher multiplied the participants body weight in kilograms by .58 (the percentage of total body water found in males). This calculation results in the amount of weight in kilograms for each participant that is due to water (Note: one kilogram equals 2.2046 pounds). A kilogram of water occupies one liter, one can easily convert from weight to volume of water.

**Formula for Computation of BAC**

1. Convert body weight from pounds to kilograms (weight in lbs x 2.2046).
   
   Example: A participant of 128-pounds weighs 58.06 kilograms.

2. Find the total body water, multiply weight in kilograms by .58 (58% of body weight).
   
   Example: In a participant of 128-pounds or 58.06 kg, this equals 33.675 kilograms of water. Which occupies a volume of 33.675 liters or 33,675 milliliters.

3. Determine the concentration of alcohol in water that occurs when a given dose of alcohol is administered.

   One ounce of pure alcohol (i.e., 200 proof) equals 29.57 milliliters. Since
alcohol has a specific gravity of .79, the 29.57 milliliters will weigh 23.36 grams (Moskowitz, 1992).

Example: In our 128-pound participant, one ounce of alcohol (i.e., 23.36 grams), absorbed into a 128-pound male's total body water, produces an alcohol concentration in water of 23.36 grams divided by 33,675 milliliters. Thus, 23.36g/ 33,675ml = .0006937 grams alcohol per milliliter of body water.

4. Find the alcohol concentration in the blood.

On average, blood is composed of 80.6 percent water. Therefore to find alcohol in the blood, the grams of alcohol per milliliter of water is multiplied by .806.

Example: Again, using the 128-pound participant. .0006937 grams alcohol per milliliter of water is multiplied by .806, which results in .000559 grams alcohol per milliliter of blood.

5. Convert grams per milliliters to the BAC standard units grams/100ml. The result is the theoretical, instantaneous BAC increase produced by ingesting one ounce of pure (200 proof) alcohol.

Example: Again, using the 128-pound participant. 0.000559 grams alcohol per milliliter blood equals 0.0559 grams alcohol per 100 milliliters blood. The .0559g/100ml. is the theoretical, instantaneous BAC increase produced when a 128-pound male ingests one ounce of pure (200 proof) alcohol.

It should be noted that the calculations are based on average characteristics for males. While .58 is the mean water body weight, individuals vary with respect to this figure. Another source of variation is the amount of water in the blood that was estimated as averaging 80.6%. However, the amount of water in blood varies as a function of several factors including the red blood cell concentration measured by the hemocrit. But again, .806 is the average value and
deviations typically are small (Moskowitz, 1992).

6. Adjust theoretical instantaneous BAC for one ounce of pure (200 proof) alcohol for the actual content of study alcohol.

To adjust the above calculations to account for the 100 proof study alcohol, the theoretical, instantaneous BAC increase produced by one ounce of pure alcohol was reduced by one-half.

Example: Using the 128-pound male participant, .0559g/100ml (the BAC produced by one ounce of pure alcohol) x .50 equals .0280g/ml.

At this point, the calculations presented above allow for a good estimate of the amount of increase in BAC that will result for every ounce of “study” alcohol ingested.

7. Account for normal alcohol elimination through metabolism during the ingestion and absorption period.

Because alcohol is metabolized from the time that ingestion begins, it takes only a few seconds for alcohol to reach the liver and for metabolism to commence after drinking. Therefore, metabolism would be occurring during the period that alcohol was ingested, absorbed, and distributed throughout the body (Gilbert, 1984; Martin, Moll, Schmid, & Dettli, 1984).

To insure that each participant’s blood alcohol level would fall into a predetermined “Target BAC range” at the time of BAC testing, it was necessary to compute the expected metabolism from the beginning of drinking until BAC testing. In the study, a period of 1.75 hours from onset of drinking to BAC testing was planned (Note: 1.75 hours consisted of a one hour of alcohol load-
ing phase and a 45-minutes post-drinking absorption phase).

To account for this passage of time, it was necessary to decrease to the theoretical instantaneous peak BAC by the amount of alcohol that could be metabolized in one hour and 45-minutes. In this study, “average” metabolism was assumed and a factor of .0170g/100ml decline in BAC per hour was used for all participants. This rate of metabolism was selected based on a review of 19 studies on alcohol elimination rates published (Rockerbie, 1999).

Using the above assumption of average metabolism, it was expected that during the one-hour and 45-minutes following the onset of alcohol ingestion, each participant would metabolize (.0170g/100ml x 1.75 hours) or .0298g/100ml of blood.

8. Calculate the amount of alcohol needed for each participant to reach his assigned Target BAC, with the expected metabolism of .0298g/100ml plus the Target BAC for each participant.

Example: Participant selected for Group 1: Target BAC of .10g/100ml. To assure a BAC in the target range, the participant would need to ingest a sufficient amount of alcohol to raise his maximum desired BAC (0298g/100ml + .10/100ml) = .1298g/ml.

9. Determine how much alcohol was needed for each participant to hit the maximum desired BAC during the one hour ingestion period and 45-minute absorption period with allowance for metabolism. Divide maximum desired BAC by the participant’s expected increase in BAC produced by one ounce of study alcohol.

Example: If our 128-pound male was selected to be member of Group 1: Target BAC = .10g/100ml. From above computation we know that one-ounce of study alcohol was determined to increase the 128-pound male’s BAC by
Therefore, .1298g/100ml (maximum desired BAC) divided by .0280g/100ml (grams of alcohol per 100 milliliters of blood produced by one ounce of study alcohol) = 4.6 ounces of study alcohol needed to reach the .1298g/ml maximum desired BAC.

10. The final step in the process was to divide the total calculated study alcohol into 6 equal units or drinks and convert ounces into milliliters (note 1 oz = 29.84 ml).

Example: In our 128-pound male 4.6 ounces divided by 6 = .767 ounces. Converting to milliliters results in 22.9 ml per drink.

The above calculations were carried out on all 27 participants and 12 alternates. Actual calculations can be found in Appendix L.

**Alcohol Ingestion/Metabolism**

All participants ingested their alcohol in 6 doses spaced at ten-minute intervals. Each dose consisted of one part 100-proof vodka mixed with one part Spartan-brand ready-made orange juice. Following the consumption of the last scheduled drink, the participants were observed for a period of 40-minutes. As suggested by Gullberg (1989), the elapsed time between the last drink and the first breath sample allowed for participants to move beyond the first-order pre-absorptive state. The 40-minute observation period ensured that participant's absorptive state did not influence breath-test variability. Near the end of the 40-minute observation period, a professional nurse hired by the researcher inserted a 21-gauge butterfly intermittent blood collection shunt into each participant's right arm. These butterfly shunts were used to collect two 3-milliliter sample of venous blood from each participant. All blood
samples were collected in a sterile, airtight vacutainer and preserved in a sodium fluoride, potassium oxalate medium.

The original study design called for blood and breath testing to begin 45 minutes after the completion of the 1-hour alcohol intake period. During the actual study, the participants were not tested until 1-hour, 15 minutes after alcohol intake. Once participants were escorted to the testing room, they provided a blood sample, a series of six breath samples, followed by a second blood sample. All participants provided two consecutive samples at each of three exhalation conditions: two samples using a short duration exhale (SDE), two samples using a medium duration exhale (MDE), and two samples using a long duration exhale (LDE). The order of breath samples was varied at random to control for any sequencing effect. Drawing on Gullberg's (1989) recommendations, all six breath samples were collected within an elapsed period of 12 to 15 minutes to ensure that metabolism was not a significant factor contributing to measurement variability. The blood sample pre- and post- breath testing were compared to verify that no significant metabolism had occurred during breath testing.

All whole blood samples were refrigerated and later transported by the researcher to the Bronson Hospital Laboratories where they were analyzed to determine BAC levels. The resultant whole blood BAC levels for each participant were recorded and later compared to the BAC level predicted by the DataMaster® for these same individuals.
Experimental Design

**Split-Plot Research Design**

As noted previously, it is the belief of this researcher that the duration of a breath exhalation during ABT using the BAC DataMaster® will affect the BAC results. In the study, the researcher varied two factors; the amount of alcohol each subject had ingested and the duration of each of the six breath samples delivered for ABT.

Given that there were 27 participants in the study population, three equal groups of 9 participants each were formed. As discussed above, all participants were assigned to groups randomly. All participants were required to provide six breath samples: two SDE, two MDE and, two LDE and two blood samples; one blood sample prior to breath testing and one sample immediately following breath testing. This design allowed for analysis of treatment effects across groups and within groups.

The Split-plot design also known as the A x (B x S) mixed design contains features of the one-factor design with independent groups and features of the one factor design with repeated measures (Keppel, 1991). The design is displayed graphically in Figure 1.

**Research Questions and Hypotheses**

The A x (B x S) design allows for the following 5 questions to be addressed:

**Research Question I:** Are Blood Alcohol Concentration estimates computed
A = Target BAC treatment condition

<table>
<thead>
<tr>
<th>A1: Target BAC</th>
<th>A2: Target BAC</th>
<th>A3: Target BAC</th>
</tr>
</thead>
<tbody>
<tr>
<td>= .06g/210ml</td>
<td>= .08g/210ml</td>
<td>= .10g/210ml</td>
</tr>
</tbody>
</table>

B = Breath/Blood

<table>
<thead>
<tr>
<th>B1</th>
<th>SDE x 2</th>
<th>MDE x 2</th>
<th>LDE x 2</th>
<th>B2</th>
</tr>
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<tbody>
<tr>
<td>S1</td>
<td></td>
<td></td>
<td></td>
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<table>
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<th>MDE x 2</th>
<th>LDE x 2</th>
<th>B2</th>
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<th>MDE x 2</th>
<th>LDE x 2</th>
<th>B2</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>

Figure 1. The A x (B x S) Split-Plot Research Design.

using the BAC DataMaster® (BAC_{DM}) from any of three breath sample duration conditions {e.g. short duration exhale (SDE), medium duration exhale (MDE), long duration exhale (LDE)} an adequate substitute for Blood Alcohol Concentration estimates computed using chemical analysis of Whole Blood samples (BAC_{WB})?

Research Hypothesis I: BAC_{DM}—SDE estimates, BAC_{DM}—MDE estimates and BAC_{DM}—LDE estimates are significantly different from BAC_{WB} results.

Research Question II: Does the amount of alcohol ingested (low, medium or
high intake) interact with breath duration such that the relationship between
BAC_{DM}—SDE estimates, BAC_{DM}—MDE estimates, BAC_{DM}—LDE estimates and
BAC_{WB} is affected?

**Research Hypothesis II:** There is an interaction between alcohol intake level
(low, medium or high intake) and breath duration that affects the relationship between
BAC_{DM}—SDE estimates, BAC_{DM}—MDE estimates, BAC_{DM}—LDE estimates and
BAC_{WB}.

**Research Question III:** Do the examiner instructions regarding the duration of
breath samples impact BAC_{DM} estimates? Specifically, are all BAC estimates com-
puted using the BAC DataMaster® (BAC_{DM}) equal? Or are BAC_{DM} estimates
affected by the duration of the breath sample?

**Research Hypothesis III:** Examiner instructions regarding the duration of
breath samples impact BAC_{DM} estimates. Specifically, BAC_{DM}—SDE estimates,
BAC_{DM}—MDE estimates, and BAC_{DM}—LDE estimates are significantly different.

**Research Question IV:** Does the amount of alcohol ingested (low, medium or
high intake) interact with breath duration such that the relationship between
BAC_{DM}—SDE estimates, BAC_{DM}—MDE estimates, and BAC_{DM}—LDE estimates is
affected?

**Research Hypothesis IV:** There is an interaction between alcohol intake level
(low, medium or high intake) and breath duration that affects the relationship between
BAC_{DM}—SDE estimates, BAC_{DM}—MDE estimates, and BAC_{DM}—LDE estimates.

**Research Question V:** Which breath duration condition produces the BAC_{DM}
estimate that is most predictive of $BAC_{WB}$?

**Research Hypothesis V:** There is one breath duration condition that produces a $BAC_{DM}$ estimate that is more predictive of $BAC_{WB}$ than other breath duration conditions.

**Null Hypotheses**

Testable null forms of the aforementioned research hypotheses are stated below.

**Null Hypothesis I:** There is no significant difference between $BAC_{DM}$—SDE estimates, $BAC_{DM}$—MDE estimates and $BAC_{DM}$—LDE estimates and $BAC_{WB}$ results.

**Null Hypothesis II:** There is no significant interaction between alcohol intake level (low, medium or high intake) and breath duration that affects the relationship between $BAC_{DM}$—SDE estimates, $BAC_{DM}$—MDE estimates, $BAC_{DM}$—LDE estimates and $BAC_{WB}$.

**Null Hypothesis III:** There is no significant difference between $BAC_{DM}$ results collected under short, medium and long exhalation conditions. Specifically, $BAC_{DM}$—SDE estimates, $BAC_{DM}$—MDE estimates, and $BAC_{DM}$—LDE estimates are not significantly different.

**Null Hypothesis IV:** There is no significant interaction between alcohol intake level (low, medium or high intake) and breath duration that affects the relationship between $BAC_{DM}$—SDE estimates, $BAC_{DM}$—MDE estimates, and $BAC_{DM}$—LDE.
Null Hypothesis V: All breath duration condition produces a BAC\textsubscript{DM} estimates that are equally predictive BAC\textsubscript{WB} results.

Planned Analysis

To test the five null hypotheses above, the following analytical procedures were utilized. To test Research Hypotheses I and II, a Split-plot Analysis of Variance for Repeated Measures was implemented. When the presence of a significant interaction was indicated, the Split-plot ANOVA contrasts were conducted to isolate differences between groups where they exist.

To address Research Hypotheses III and IV, a second Split-plot Analysis of Variance for Repeated Measures was utilized. Again, the significant interaction between alcohol group and breath on the Split-plot ANOVA required that follow-up contrasts using Tukey’s HSD test be conducted to isolate differences between groups where they exist.

To address Research Hypothesis V, a series of three regression analyses were conducted and the resulting $R^2$ values were compared. The logic behind this analysis is straightforward and it relies on the fact that the breath condition with the highest $R^2$ value accounts for the greatest amount of variance and, therefore, it is a better predictor. The purpose of this analysis was to determine which exhalation conditions, short duration exhale (SDE), medium duration exhale (MDE), or long duration exhale
(LDE), was most predictive of actual $\text{BAC}_{WB}$. The results of the statistical analyses are presented in Chapter III.
CHAPTER III

RESULTS

This chapter is composed of four sections. In the first section, the results of the multi-level screening process are presented. In the second section, the sample group is described with respect to physiological and demographic factors of interest. Next, the results of the statistical analyses conducted to test the research hypotheses are presented. In the final section, a brief summary of the chapter is provided.

Multi-Level Screening Process

As noted in Chapter II, all participants were required to pass a comprehensive, three-level screening process that took place from May 1, 2001 to June 8, 2001. Thirty-nine individuals successfully passed all three levels of screening and were invited by the researcher to be active participants in the experimental data collection session on Saturday, June 16, 2001. Tables 1, 2, and 3 below provide a summary of the individuals who were included in and excluded from participation during the multi-level screening. These tables also provide the cause for exclusion where available.

Level I Screening

One hundred and thirty-five individuals made inquiry concerning participation
Table 1

Participants Excluded and Selected During Level I Screening

<table>
<thead>
<tr>
<th>Total Inquires</th>
<th>Excluded from participation</th>
<th>Selected for further screening</th>
</tr>
</thead>
<tbody>
<tr>
<td>n = 135</td>
<td>n = 26</td>
<td>n = 109</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th></th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Researcher excluded</td>
<td>19</td>
<td>Participant self-excluded</td>
<td>7</td>
</tr>
<tr>
<td>Cause for exclusion</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disqualifying medical condition</td>
<td>5</td>
<td>Feared needles/blood</td>
<td>4</td>
</tr>
<tr>
<td>Hx of substance abuse / DWI charge</td>
<td>3</td>
<td>collection</td>
<td></td>
</tr>
<tr>
<td>Novice / inexperienced drinker</td>
<td>3</td>
<td>Time commitment too great</td>
<td>2</td>
</tr>
<tr>
<td>Hx of depression/bipolar disorder</td>
<td>3</td>
<td>No reason for withdrawal</td>
<td>1</td>
</tr>
<tr>
<td>Pacific Island ethnicity</td>
<td>2</td>
<td>given</td>
<td></td>
</tr>
<tr>
<td>Over 30 years-of-age</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>1</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

and were interviewed by the researcher. Of the 135 telephone respondents, 109 or 80.75% were sent research materials, and 26 or 19.25% were excluded by the researcher or indicated that they no longer desired to participate after learning more about the study. The specific causes of exclusion for the 26 individuals can be divided into two categories: (1) failure to meet basic study selection criteria, and (2) individual self-selected out of the study.

The researcher excluded 19 individuals because they failed to meet published study selection criteria. Specifically, five individuals reported medical conditions that were identified, in advance, as cause for exclusion: three individuals reported a positive history of mental illness; three individuals reported a positive history of substance abuse treatment and/or an arrest for Driving While Intoxicated (DWI) or Minor in Possession (MIP); based on self-reports of alcohol use, three individuals were
determined to be novice or inexperienced drinkers; two individuals were of Asian
decent with a genetic link to a pacific island country identified in the research as hav­
ing a large population of individuals known to have physiological differences in liver
functioning that negatively affect the ability to metabolize alcohol; two individuals
were over 30-years-of-age; and one individual was female. Seven individuals indi­
cated they were no longer interested in participation after learning more about the
study. Of these, four stated that they did not want to provide blood samples, two indi­
cated that they believed that the time commitment was too great and one individual
gave no reason for withdrawing.

Level II Screening

The 109 individuals who met the initial screening criteria and remained inter­
ested in participation were sent a research packet. Each research packet contained the

Table 2

Participants Excluded and Selected During Level II Screening

<table>
<thead>
<tr>
<th>Research packets distributed</th>
<th>No Response</th>
<th>Completed responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>n = 109</td>
<td>n = 38</td>
<td>n = 71</td>
</tr>
<tr>
<td>Invited for additional screening</td>
<td>n = 64</td>
<td>Excluded from participation</td>
</tr>
<tr>
<td>Cause for exclusion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gastric condition/reflux disorder</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Asthma/impaired lung capacity</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>History/treatment for hepatitis-B</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Anti-depressant medication</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>History of seizure disorder</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

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following five items: (1) the Milcom Health History Questionnaire (MHHQ), (2) a health history form, (3) two copies of informed consent documents, (4) a letter with directions for completing and returning the research materials, and (5) a pre-addressed, stamped envelope for returning the completed materials. Seventy-one or 65% of the individuals sent research packets completed and returned the study materials. Of the 71 individuals who returned completed health surveys, 64 or 90% were deemed appropriate for further screening for participation, and were contacted by phone and invited to an appointment for a physical examination and mental health/substance abuse screening.

The seven individuals who were not given an appointment for further screening were also contacted by phone and informed that they had been disqualified from further participation due to their reported medical condition(s) or substance use. Reported conditions that resulted in exclusion varied. Specifically, two individuals reported using prescription or over-the-counter medication for acid reflux disorder or a similar gastric condition, two individuals reported having asthma that might impair their ability to provide adequate breath volume, one individual reported having tested positive for Hepatitis-B, one individual reported using the antidepressant medication, Paxil™, and one individual reported using medication for treatment of seizure disorder.
Table 3

Participants Excluded and Selected During Level III Screening

<table>
<thead>
<tr>
<th>Scheduled n = 64</th>
<th>Did not attend n = 7</th>
<th>Screening completed n = 57</th>
</tr>
</thead>
<tbody>
<tr>
<td>Invited: Passed health screening n = 39</td>
<td>Excluded: Failed health screening n = 18</td>
<td></td>
</tr>
<tr>
<td>Cause for exclusion</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Elevated SPGT/ALT readings</td>
<td>12</td>
<td></td>
</tr>
<tr>
<td>Elevated Creatinine readings</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>High probability of substance abuse/dependence disorder based on SASSI</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Positive sign/symptoms of mental illness</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Medication known to effect metabolism of alcohol</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Total excluded</td>
<td>18</td>
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</tr>
</tbody>
</table>

**Level III Screening**

The third screening level for potential participants included a mental health assessment, substance abuse screening, and physical examination. A total of 64 individuals satisfied level I and II screening criteria and were scheduled to meet with a member of the research staff and to complete a medical examination. Whenever a potential participant missed his scheduled appointment time, attempts were made to contact that individual by phone to schedule a new appointment for him. Any individuals who failed to keep two assigned appointments and who did not contact the researcher to reschedule, were excluded from the study.

Ultimately, 57 or 89% of the individuals who were scheduled for Level III screening met with the researcher or an assistant to complete a mental health interview and the Substance Abuse Subtle Screening Inventory, 3rd Edition (SASSI-3). The focus of the clinical interview and SASSI-3 was to identify and exclude...
individuals with obvious signs or symptoms of mental illness or who were judged to have a "high probability" of a chemical dependency disorder, as indicated by their performance on the SASSI-3. Fifty-seven individuals completed the mental health interview and the SASSI-3 assessment and were given a physical examination. Second-year Western Michigan University Physician Assistant students, under the direct, clinical supervision of Eric Vangsnes, PA-C, Certified Physician Assistant, conducted the physical examinations.

The general purpose of these physical evaluations was to exclude any participant in poor general health. This included persons who showed signs of heart disease, high blood pressure, diabetes, liver disease, or other medical condition that, in the opinion of the physician assistant, placed the participant at increased risk for problems due to consuming alcohol.

During the medical examination, a glucose test was conducted to screen for diabetes and blood was collected and sent to a local laboratory for Creatinine and SPGT/ALT tests to determine normal kidney and liver functioning, respectively. Based on the Mental Health examination, SASSI-3 scores, and the results of the Physical examinations, 18 individuals or 31.5% of those individuals who underwent Level III screening were excluded from participation. The exact cause for exclusion from the study can be seen in Table 3.

Description of the Sample

The design that was implemented called for a sample of 27 healthy males, age
21 to 30 years old, to be identified from the general population of Southwest Michigan. The sample was then randomly assigned to each of three treatment conditions or groups. Descriptions of the sample used are presented in Tables 4 and 5.

As seen in Table 4, individuals who were screened out or excluded from participation had similar mean scores on important physiological and demographic variables to those invited to participate. One area where significant differences were noted were the SGPT/ALT level of invited and excluded individuals. Given the fact that SGPT/ALT levels served as an inclusion criteria, this difference is evidence of

Table 4

Mean Physiological/Demographic Descriptors for Screened Participants
Invited Participants and Excluded Participants

<table>
<thead>
<tr>
<th>Descriptor</th>
<th>Total Screened</th>
<th>Screened Invited</th>
<th>Screened Excluded</th>
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<tbody>
<tr>
<td>N</td>
<td>56</td>
<td>39</td>
<td>17(a)</td>
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<tr>
<td>Age</td>
<td>23.32</td>
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<td>23.10</td>
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<tr>
<td>Height (cm)</td>
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<td>180.98</td>
<td>178.85</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>86.11</td>
<td>83.75</td>
<td>91.55</td>
</tr>
<tr>
<td>Glucose</td>
<td>96.36</td>
<td>96.43</td>
<td>96.18</td>
</tr>
<tr>
<td>Creatinine</td>
<td>.95</td>
<td>0.93</td>
<td>0.98</td>
</tr>
<tr>
<td>SGPT/ALT</td>
<td>30.02*</td>
<td>23.79</td>
<td>46.20</td>
</tr>
<tr>
<td>Alcoholic beverages per week</td>
<td>7.01</td>
<td>6.26</td>
<td>8.72</td>
</tr>
<tr>
<td>Drug use per week</td>
<td>0.14</td>
<td>0.07</td>
<td>0.30</td>
</tr>
<tr>
<td>FVA</td>
<td>4.63</td>
<td>2.72</td>
<td>9.00</td>
</tr>
<tr>
<td>FVOD</td>
<td>3.11</td>
<td>0.72</td>
<td>8.59</td>
</tr>
</tbody>
</table>

* p < .05
(a) A total of 57 individuals were screened for this study. Case, #100004 was excluded from this summary due to his heavy substance use. His reported data of substance use were extreme outliers from other participants and affected analyses disproportionately.
successful screening.

As seen in Table 5, data collected from 27 of the 39 invited participants were used in the study. Of the twelve individuals who were excluded from the study, two participants arrived at the study location with a BAC level above 0.00, three individuals became nauseous and dizzy due to the alcohol intake and were unable to provide breath samples, and the remaining seven invited participants did not show up at the clinic on the day of the study. The three participants who became ill during the study were attended to by the on-call physician. Two of the participants needed only fluids and rest, while the third participant was also provided with 500 mg of Advil™.

Table 5

Mean Physiological/Demographic Descriptors for Invited Participants
Active Participants and Inactive Participants

<table>
<thead>
<tr>
<th>Descriptor</th>
<th>Total Invited</th>
<th>Active Participants</th>
<th>Inactive Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>39</td>
<td>27</td>
<td>12</td>
</tr>
<tr>
<td>Age</td>
<td>23.42</td>
<td>23.32</td>
<td>23.65</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>180.98</td>
<td>180.39</td>
<td>182.30</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>83.75</td>
<td>81.84</td>
<td>88.04</td>
</tr>
<tr>
<td>Glucose</td>
<td>96.43</td>
<td>99.07</td>
<td>90.50</td>
</tr>
<tr>
<td>Creatinine</td>
<td>0.93</td>
<td>0.91</td>
<td>0.98</td>
</tr>
<tr>
<td>SGPT/ALT</td>
<td>23.79*</td>
<td>21.93</td>
<td>28.00</td>
</tr>
<tr>
<td>Alcoholic beverages per week</td>
<td>6.26</td>
<td>6.31</td>
<td>6.16</td>
</tr>
<tr>
<td>Use per week</td>
<td>0.07</td>
<td>0.09</td>
<td>0.01</td>
</tr>
<tr>
<td>FVA</td>
<td>2.72</td>
<td>2.70</td>
<td>2.75</td>
</tr>
<tr>
<td>FVOD</td>
<td>0.72</td>
<td>1.00</td>
<td>0.08</td>
</tr>
</tbody>
</table>

* p < .05

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Follow-up with the three participants revealed no permanent problems. All three cases were reported to HSIRB as adverse events.

Data Analysis

As discussed in Chapter II, five research hypotheses were developed and investigated in this study. In the following section, each of the hypotheses are presented in their testable null format. The hypotheses are followed by the statistical analysis used to test them.

Null Hypothesis I: There is no significant difference between $\text{BAC}_{\text{DM}}$—SDE estimates, $\text{BAC}_{\text{DM}}$—MDE estimates and $\text{BAC}_{\text{DM}}$—LDE estimates and $\text{BAC}_{\text{WB}}$ results.

Null Hypothesis II: There is no significant interaction between alcohol intake level (low, medium or high intake) and breath duration that affects the relationship between $\text{BAC}_{\text{DM}}$—SDE estimates, $\text{BAC}_{\text{DM}}$—MDE estimates, $\text{BAC}_{\text{DM}}$—LDE estimates and $\text{BAC}_{\text{WB}}$.

To test Hypotheses I and II, a computer-based, statistical analysis was conducted using version eight of SAS®. The analysis consisted of a split-plot analysis of variance for repeated measures. The results of the analysis are presented in Table 6.

As evidenced in Table 6, significant differences between $\text{BAC}_{\text{DM}}$ estimates using breath samples of varied duration and $\text{BAC}_{\text{WB}}$ were found. Based on this result, the Null Hypothesis I, that no significant differences exist between $\text{BAC}_{\text{DM}}$ estimates collected under varied breath conditions and $\text{BAC}_{\text{WB}}$, was rejected.
Table 6
ANOVA to Test Ho: BAC\textsubscript{DM} Estimates: SDE=MDE=LDE=BAC\textsubscript{WB} Results and Interaction Effects Due to Alcohol Intake

<table>
<thead>
<tr>
<th>Source</th>
<th>Df</th>
<th>Type III SS</th>
<th>MS</th>
<th>F</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol group</td>
<td>2</td>
<td>.04349</td>
<td>.02175</td>
<td>1513.79</td>
<td>.0001*</td>
</tr>
<tr>
<td>Breath duration</td>
<td>3</td>
<td>.00099</td>
<td>.00033</td>
<td>22.95</td>
<td>.0001*</td>
</tr>
<tr>
<td>Subject (Alcohol intake)</td>
<td>21</td>
<td>.01837</td>
<td>.00087</td>
<td>60.88</td>
<td>.0001*</td>
</tr>
<tr>
<td>Alcohol intake * Breath duration</td>
<td>6</td>
<td>.00020</td>
<td>.00003</td>
<td>2.35</td>
<td>.0344**</td>
</tr>
</tbody>
</table>

*\textbf{p} < .0001

\*\textbf{p} < .05

Also evidenced in Table 6 is the presence of a significant interaction effect between breath duration, alcohol intake, and BAC\textsubscript{WB} results. Based on this result, Null Hypothesis II, that no statistical difference in BAC\textsubscript{DM} estimates and BAC\textsubscript{WB} results were due to an interaction effect of breath duration and the amount of alcohol ingested, was also rejected.

Given the observed interaction effect of alcohol intake by breath duration, an additive model was used to better understand the relationship of breath duration, alcohol intake, and BAC\textsubscript{WB} results. Use of the additive model allowed for data from each alcohol intake condition to be considered independently. To accomplish this task, three ANOVAs were computed, one ANOVA within each of the three alcohol intake conditions. The results of these ANOVAs and follow-up contrasts are presented below.
Table 7 shows the results of an ANOVA analysis that tests the null hypothesis that $H_0$: BAC$_{DM}$ estimates: SDE=MDE=LDE=BAC$_{WB}$ results within alcohol intake group BAC = .08 to .09.

Table 7
ANOVA to Test $H_0$: BAC$_{DM}$ Estimates: SDE=MDE=LDE=BAC$_{WB}$ Results Within Alcohol Intake Group #1: High Alcohol Intake

<table>
<thead>
<tr>
<th>Source</th>
<th>Df</th>
<th>Type III SS</th>
<th>MS</th>
<th>F</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject</td>
<td>7</td>
<td>.00992</td>
<td>.00142</td>
<td>78.35</td>
<td>.0001*</td>
</tr>
<tr>
<td>Breath duration</td>
<td>3</td>
<td>.00062</td>
<td>.00020</td>
<td>11.44</td>
<td>.0001*</td>
</tr>
</tbody>
</table>

*P < .01

As evidenced by Table 7, a significant difference between BAC$_{DM}$ estimates using SDE, MDE, and LDE breath samples and BAC$_{WB}$ results was found to exist within the high (BAC = .08 to .09) alcohol intake group. Based on this result, the null hypothesis, that no differences exist between BAC$_{DM}$ estimates collected under varied breath duration and BAC$_{WB}$ results within alcohol intake group #1 (BAC = .08 to .09), was rejected.

To better understand the significant difference in BAC$_{DM}$ estimates and BAC$_{WB}$ results within alcohol intake group #1, a contrast analysis was conducted to determine directionality of these differences. The results of this analysis are presented in Tables 8 and 9.

As evidenced in Table 8 and 9, all BAC$_{DM}$ estimates were not equal to BAC$_{WB}$.
Table 8

Descriptive Statistics for All Methods Used to Compute BAC Within Alcohol Intake Group #1: High Alcohol Intake

<table>
<thead>
<tr>
<th>Method used to compute BAC</th>
<th>Mean</th>
<th>Std.Deviation</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>SDE</td>
<td>.0838</td>
<td>.0120</td>
<td>16</td>
</tr>
<tr>
<td>MDE</td>
<td>.0900</td>
<td>.0155</td>
<td>16</td>
</tr>
<tr>
<td>LDE</td>
<td>.0919</td>
<td>.0142</td>
<td>16</td>
</tr>
<tr>
<td>BACwb</td>
<td>.0910</td>
<td>.0165</td>
<td>8</td>
</tr>
</tbody>
</table>

results within alcohol intake group #1. Specifically, \( \text{BAC}_{DM} \) estimates computed using SDE breath samples are significantly different than \( \text{BAC}_{WB} \) results. In fact, mean \( \text{BAC}_{DM} \) estimates computed using SDE breath samples underestimate \( \text{BAC}_{WB} \) results by .007g/210ml. \( \text{BAC}_{DM} \) estimates computed using MDE and LDE breath samples were not significantly different than \( \text{BAC}_{WB} \) results.

Table 9

Contrasts to Test Differences Between DataMaster® BAC Estimates and \( \text{BAC}_{WB} \) Results Within Alcohol Intake Group #1: High Alcohol Intake

<table>
<thead>
<tr>
<th>Contrast</th>
<th>Df</th>
<th>SS</th>
<th>MS</th>
<th>F</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>( \text{BAC}_{WB} ) vs SDE</td>
<td>1</td>
<td>.000280</td>
<td>.000280</td>
<td>15.50</td>
<td>.0003*</td>
</tr>
<tr>
<td>( \text{BAC}_{WB} ) vs MDE</td>
<td>1</td>
<td>.000005</td>
<td>.000005</td>
<td>0.29</td>
<td>.5897</td>
</tr>
<tr>
<td>( \text{BAC}_{WB} ) vs LDE</td>
<td>1</td>
<td>.000004</td>
<td>.000004</td>
<td>0.23</td>
<td>.6369</td>
</tr>
</tbody>
</table>

*p < .01

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Table 10 shows the results of an ANOVA analysis that tests the null hypothesis that \( H_0: BAC_{DM} \) estimates: SDE=MDE=LDE=BAC\(_{WB} \) results within the medium alcohol intake group BAC = .05 to .06. As evidenced by Table 10, a significant difference between \( BAC_{DM} \) estimates using SDE, MDE, and LDE breath samples and BAC\(_{WB} \) results was found to exist within the medium (BAC = .05 to .06) alcohol intake group. Based on this result, the null hypothesis, that no differences exist between \( BAC_{DM} \) estimates collected under varied breath duration and BAC\(_{WB} \) results within the medium alcohol intake group (BAC = .05 to .06), was rejected.

Table 10

ANOVA to Test \( H_0: BAC_{DM} \) Estimates: SDE=MDE=LDE=BAC\(_{WB} \) Results
Within Alcohol Intake Group #2: Medium Alcohol Intake

<table>
<thead>
<tr>
<th>Source</th>
<th>Df</th>
<th>Type III SS</th>
<th>MS</th>
<th>F</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject</td>
<td>7</td>
<td>.00478</td>
<td>.00068</td>
<td>39.10</td>
<td>.0001*</td>
</tr>
<tr>
<td>Breath duration</td>
<td>3</td>
<td>.00041</td>
<td>.00014</td>
<td>7.80</td>
<td>.0003*</td>
</tr>
</tbody>
</table>

*\( p < .01 \)

To better understand the significant difference in \( BAC_{DM} \) estimates and BAC\(_{WB} \) results within alcohol intake group #2, a contrast analysis was conducted to determine directionality of these differences. The results of this analysis are presented in Tables 11 and 12.

As evidenced in Table 11 and 12, \( BAC_{DM} \) estimates were not equal to BAC\(_{WB} \) results within alcohol intake group #2. Specifically, \( BAC_{DM} \) estimates computed
Table 11

Descriptive Statistics for All Methods Used to Compute BAC Within Alcohol Intake Group #2: Medium Alcohol Intake

<table>
<thead>
<tr>
<th>Method used to compute BAC</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>SDE</td>
<td>.0569</td>
<td>.0079</td>
<td>16</td>
</tr>
<tr>
<td>MDE</td>
<td>.0613</td>
<td>.0096</td>
<td>16</td>
</tr>
<tr>
<td>LDE</td>
<td>.0619</td>
<td>.0117</td>
<td>16</td>
</tr>
<tr>
<td>BAC_{wb}</td>
<td>.0650</td>
<td>.0131</td>
<td>8</td>
</tr>
</tbody>
</table>

Table 12

Contrasts to Test for Differences Between Breath Durations SDE, MDE, and LDE and BAC_{wb} Results Within Alcohol Intake Group #2: Medium Alcohol Intake

<table>
<thead>
<tr>
<th>Contrast</th>
<th>Df</th>
<th>SS</th>
<th>MS</th>
<th>F</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>BAC_{wb} vs SDE</td>
<td>1</td>
<td>.000352</td>
<td>.000352</td>
<td>20.14</td>
<td>.0001**</td>
</tr>
<tr>
<td>BAC_{wb} vs MDE</td>
<td>1</td>
<td>.000075</td>
<td>.000075</td>
<td>4.29</td>
<td>.0441*</td>
</tr>
<tr>
<td>BAC_{wb} vs LDE</td>
<td>1</td>
<td>.000052</td>
<td>.000052</td>
<td>2.98</td>
<td>.0912</td>
</tr>
</tbody>
</table>

*p<.05  **p < .01

using SDE and MDE breath samples were significantly different than BAC_{wb} results. Mean BAC_{dm} estimates computed using SDE and MDE breath samples underestimate BAC_{wb} results by .008g/210ml and .004g/210ml, respectively. BAC_{dm} estimates computed using LDE breath samples were not significantly different than
BAC\textsubscript{wb} results.

Table 13 shows the results of an ANOVA analysis that tests the null hypothesis that Ho: BAC\textsubscript{dm} estimates: SDE=MDE=LDE=BAC\textsubscript{wb} results within alcohol intake group BAC = .03 to .04.

### Table 13
ANOVA to Test Ho: BAC\textsubscript{dm} Estimates: SDE=MDE=LDE=BAC\textsubscript{wb} Results Within Alcohol Intake Group #3: Low Alcohol Intake

<table>
<thead>
<tr>
<th>Source</th>
<th>Df</th>
<th>Type III SS</th>
<th>MS</th>
<th>F</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject</td>
<td>7</td>
<td>.00366</td>
<td>.00052</td>
<td>80.69</td>
<td>.0001**</td>
</tr>
<tr>
<td>Breath duration</td>
<td>3</td>
<td>.00019</td>
<td>.00006</td>
<td>10.02</td>
<td>.0001**</td>
</tr>
</tbody>
</table>

**\(p < .01\)**

As evidenced by Table 13, a significant difference between BAC\textsubscript{dm} estimates using SDE, MDE, and LDE breath samples and BAC\textsubscript{wb} results was found to exist within the low (BAC=.03 to .04) alcohol intake group. Based on this result, the null hypothesis, that no differences exist between BAC\textsubscript{dm} estimates collected under varied breath duration and BAC\textsubscript{wb} results within the low (BAC=.03 to .04) alcohol intake group, was rejected.

To better understand the significant difference in BAC\textsubscript{dm} estimates and BAC\textsubscript{wb} results within alcohol intake group #3, a contrast analysis was conducted to determine directionality of these differences. The results of this analysis are presented in Tables 14 and 15.
Table 14

Descriptive Statistics for All Methods Used to Compute BAC
Within Alcohol Intake Group #3: Low Alcohol Intake

<table>
<thead>
<tr>
<th>Method used to compute BAC</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>SDE</td>
<td>.0407</td>
<td>.0080</td>
<td>15</td>
</tr>
<tr>
<td>MDE</td>
<td>.0414</td>
<td>.0086</td>
<td>14</td>
</tr>
<tr>
<td>LDE</td>
<td>.0429</td>
<td>.0107</td>
<td>14</td>
</tr>
<tr>
<td>BAC_{WB}</td>
<td>.0469</td>
<td>.0097</td>
<td>7</td>
</tr>
</tbody>
</table>

Table 15

Contrasts to Test for Differences Between Breath Durations SDE, MDE, and LDE and BAC_{WB} Results Within Alcohol Intake Group #3: Low Alcohol Intake

<table>
<thead>
<tr>
<th>Contrast</th>
<th>Df</th>
<th>Contrast SS</th>
<th>MS</th>
<th>F</th>
<th>Sig</th>
</tr>
</thead>
<tbody>
<tr>
<td>BAC_{WB} vs SDE</td>
<td>1</td>
<td>.000176</td>
<td>.000176</td>
<td>27.14</td>
<td>.0001**</td>
</tr>
<tr>
<td>BAC_{WB} vs MDE</td>
<td>1</td>
<td>.000138</td>
<td>.000138</td>
<td>21.20</td>
<td>.0001**</td>
</tr>
<tr>
<td>BAC_{WB} vs LDE</td>
<td>1</td>
<td>.000075</td>
<td>.000075</td>
<td>11.51</td>
<td>.0016**</td>
</tr>
</tbody>
</table>

**p < .01

As evidenced in Table 14 and 15, all BAC_{DM} estimates were not equal to BAC_{WB} results within alcohol intake group #2. Specifically, BAC_{DM} estimates computed using breath samples of any duration were significantly different than BAC_{WB} results. Mean BAC_{DM} estimates computed using SDE, MDE, and LDE breath
samples underestimate \( \text{BAC}_{WB} \) results by .006g/210ml, .006g/ml, and .004g/210ml, respectively.

Research Hypotheses III and IV are presented below in their testable null format. The hypotheses are followed by the results of the statistical analysis used to test them.

**Null Hypothesis III:** There is no significant difference between \( \text{BAC}_{DM} \) results collected under short, medium and long exhalation conditions. Specifically, \( \text{BAC}_{DM} \)--SDE estimates, \( \text{BAC}_{DM} \)--MDE estimates, and \( \text{BAC}_{DM} \)--LDE estimates are not significantly different.

**Null Hypothesis IV:** There is no significant interaction between alcohol intake level (low, medium or high intake) and breath duration that affects the relationship between \( \text{BAC}_{DM} \)--SDE estimates, \( \text{BAC}_{DM} \)--MDE estimates, and \( \text{BAC}_{DM} \)--LDE estimates.

To test the above hypotheses, a computer-based, statistical analysis was conducted using version eight of SAS®. The analysis consisted of a Split-plot Analysis of Variance for Repeated Measures. The results of this analysis is presented in Table 16.

As evidenced in Table 16, significant differences between \( \text{BAC}_{DM} \) estimates using SDE, MDE, and LDE breath samples were found. Based on this result, Null Hypothesis III, that no differences exist between \( \text{BAC}_{DM} \) estimates collected under varied breath duration, was rejected.

Also, evidenced in Table 16 is the presence of a significant interaction effect
Table 16

ANOVA to Test Ho: SDE=MDE=LDE and Interaction Effects Due to Alcohol Intake

<table>
<thead>
<tr>
<th>Source</th>
<th>Df</th>
<th>Type III SS</th>
<th>MS</th>
<th>F</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol group</td>
<td>2</td>
<td>.05621</td>
<td>.02911</td>
<td>2335.87</td>
<td>.0001*</td>
</tr>
<tr>
<td>Breath duration</td>
<td>2</td>
<td>.00082</td>
<td>.00041</td>
<td>32.75</td>
<td>.0001*</td>
</tr>
<tr>
<td>Subject (Alcohol intake)</td>
<td>24</td>
<td>.01625</td>
<td>.00068</td>
<td>54.33</td>
<td>.0001*</td>
</tr>
<tr>
<td>Alcohol intake * Breath duration</td>
<td>4</td>
<td>.00021</td>
<td>.00005</td>
<td>4.21</td>
<td>.0031**</td>
</tr>
</tbody>
</table>

*p < .01

**p < .05

between breath duration and alcohol intake. Based on this result, Null Hypothesis IV, that no statistical difference in BAC_{DM} estimates were due to the amount of alcohol ingested, was rejected.

Because a significant difference in BAC_{DM} estimates using SDE, MDE, and LDE breath samples were found, a follow-up analysis using Tukey’s Studentized Range HSD Test was conducted to determine directionality of these differences. The results of this analysis follow in Table 17.

As evidenced in Table 17, there is directionality among the BAC_{DM} estimates collected under varied breath duration. The results indicate that BAC_{DM} estimates computed from LDE are significantly different from both BAC_{DM} estimates computed from MDE and SDE, and estimates compiled from MDE are not statically different from SDE. The results also indicate that LDEs produce BAC_{DM} estimates that are higher than BAC_{DM} estimates from MDE and SDE. Specifically, the results show that
Table 17
Follow-Up Contrasts to Determine Directionality of Breath Durations

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th>Breath duration</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Alpha</td>
<td>.05</td>
<td></td>
</tr>
<tr>
<td>Error Degrees of Freedom</td>
<td>129</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Error Mean Square</td>
<td>.000012</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Critical Value of Studentized range</td>
<td>3.35325</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Minimum Significant Difference</td>
<td>.0016</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Grouping</td>
<td>Mean</td>
<td>N</td>
</tr>
<tr>
<td>A</td>
<td>.0652</td>
<td>54</td>
<td></td>
</tr>
<tr>
<td>B</td>
<td>.0635</td>
<td>54</td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>.0598</td>
<td>54</td>
<td></td>
</tr>
</tbody>
</table>

*p < .05

LDE > MDE > SDE.

Given the observed interaction effect of alcohol intake by breath duration, an additive model was used to better understand the relationship of the breath duration variable and the alcohol intake variable. Using this model, data from each alcohol intake condition was considered independently. To accomplish this task, three ANOVAs were computed, one ANOVA within each of the three alcohol intake conditions. The result of these ANOVAs and the post-hoc Tukey’s Studentized Range HSD Tests are presented in Tables 18 through 23.

The ANOVA below tests the null hypothesis that Ho: LDE=MDE=SDE within the alcohol intake group #1 (BAC=.08 to .09).
As evidenced by Table 18, a significant difference between $BAC_{DM}$ estimates using SDE, MDE, and LDE breath samples was found within the high alcohol intake group. Based on this result, the null hypothesis that within the high alcohol intake group, no differences exist between $BAC_{DM}$ estimates collected under varied breath duration, was rejected.

To better understand the significant difference in $BAC_{DM}$ estimates found within alcohol intake group #1, a follow-up analysis using Tukey's Studentized Range HSD Test was conducted to determine directionality of these differences. The results of this analysis follow in Table 19.

As evidenced in Table 19, there is clear evidence of directionality among the $BAC_{DM}$ estimates collected under varied breath durations within alcohol intake group #1. The results indicate that $BAC_{DM}$ estimates computed from LDE and MDE are significantly different from $BAC_{DM}$ estimates computed from SDE. The results also indicate that LDEs and MDE produce $BAC_{DM}$ estimates that are significantly higher
Tukey’s Studentized Range HSD Test for Breath Durations SDE, MDE, and LDE Within Alcohol Intake Group #1: High Alcohol Intake

| Alpha                          | .05   |
| Error Degrees of Freedom      | 43    |
| Error Mean Square             | .000016 |
| Critical Value of Studentized range | 3.43292 |
| Minimum Significant Difference| .0032 |

<table>
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<th>Grouping</th>
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<th>Breath duration</th>
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<td>.08889</td>
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<tr>
<td>B</td>
<td>.08278</td>
<td>18</td>
<td>SDE*</td>
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</table>

*p < .05

than BAC_{DM} estimates computed from SDE breath samples. Specifically, the results show that LDE = MDE > SDE.

The ANOVA below tests the null hypothesis that Ho: LDE=MDE=SDE within the moderate alcohol intake group. As evidenced by Table 20, significant

Table 20

Simple ANOVA to Test for Breath Durations SDE, MDE, and LDE Within Alcohol Intake Group # 2: Medium Alcohol Intake

<table>
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<td>.00011</td>
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<td>.0010*</td>
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*p < .01
differences between $BAC_{DM}$ estimates using SDE, MDE, and LDE breath samples were found within the moderate alcohol intake group. Based on this result, the null hypothesis, that within the moderate alcohol intake group no differences exist between $BAC_{DM}$ estimates collected under varied breath duration, was rejected.

To better understand the significant difference in $BAC_{DM}$ estimates found within alcohol intake group #2, a follow-up analysis using Tukey's Studentized Range HSD Test was conducted to determine directionality of these differences. The results of this analysis follow in Table 21.

As evidenced in Table 21, there is directionality among the $BAC_{DM}$ estimates collected under varied breath duration. The results indicate that $BAC_{DM}$ estimates computed from LDE and MDE are significantly different from both $BAC_{DM}$ estimates

Table 21

Tukey's Studentized Range HSD to Test for Directionality of Breath Durations SDE, MDE, and LDE Within Alcohol Intake Group #2: Medium Alcohol Intake

<table>
<thead>
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<th>Grouping</th>
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<td>18</td>
<td>LDE</td>
</tr>
<tr>
<td>A</td>
<td>0.06000</td>
<td>18</td>
<td>MDE</td>
</tr>
<tr>
<td>B</td>
<td>0.05611</td>
<td>18</td>
<td>SDE*</td>
</tr>
</tbody>
</table>

* $p < .05$
computed from SDE breath samples. The results also indicate that LDE and MDE produce $\text{BAC}_{DM}$ estimates that are significantly higher than $\text{BAC}_{DM}$ for SDE. Specifically, the results show that $\text{LDE} = \text{MDE} > \text{SDE}$.

The ANOVA in Table 22 tests the null hypothesis that $\text{Ho: LDE=MDE=SDE}$ within the low (BAC= .03 to .04) alcohol intake group. As evidenced by Table 22, significant differences between $\text{BAC}_{DM}$ estimates using SDE, MDE, and LDE breath samples were found within the low alcohol intake group. Based on this result, the null hypothesis, that in the low alcohol intake group no differences exist between $\text{BAC}_{DM}$ estimates collected between under varied breath duration, was rejected.

Table 22

<table>
<thead>
<tr>
<th>Source</th>
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<th>F</th>
<th>Sig.</th>
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<td>.00042</td>
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<tr>
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<td>.00004</td>
<td>4.17</td>
<td>.0221*</td>
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* $p < .01$

To better understand the significant difference in $\text{BAC}_{DM}$ estimates found within alcohol intake group #3, a follow-up analysis using Tukey's Studentized Range HSD Test was conducted to determine directionality of these differences. The results of this analysis follow in Table 23.

As evidenced in Table 23, there is directionality among the $\text{BAC}_{DM}$ estimates
Table 23
Tukey's Studentized Range HSD to Test for Directionality of Breath Durations SDE, MDE, and LDE Within Alcohol Intake Group #3: Low Alcohol Intake

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<td>Critical Value of Studentized range</td>
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<td>Minimum Significant Difference</td>
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</table>

<table>
<thead>
<tr>
<th>Grouping</th>
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<th>N</th>
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</thead>
<tbody>
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<td>A</td>
<td>.04333</td>
<td>18</td>
<td>LDE</td>
</tr>
<tr>
<td>BA</td>
<td>.04167</td>
<td>18</td>
<td>MDE</td>
</tr>
<tr>
<td>B</td>
<td>.04056</td>
<td>18</td>
<td>SDE*</td>
</tr>
</tbody>
</table>

* p <.05

collected under varied breath duration. The results indicate that BAC_{DM} estimates computed from LDE and MDE are not significantly different from one another. The results also indicated that MDE and SDE are not significantly different from one another. Finally, the results indicate that BAC_{DM} results computed using LDE and SDE breath samples are significantly different from each other. To summarize, the results in Table 23 indicate that LDE breath samples are equal to MDE breath samples, and MDE breath samples are equal to SDE breath samples. Only LDE and SDE breath samples are significantly different from one another. BAC_{DM} estimates computed using LDE are significantly higher than BAC_{DM} estimates computed from SDE. Specifically, the results show the following relationships within the low alcohol group: LDE=MDE, MDE=SDE, and LDE>MDE.
Null Hypothesis V: There is no significant difference in the predictive value of BAC\textsubscript{DM} results collected SDE, MDE, LDE as a predictor of BAC\textsubscript{WB} results.

To test the fifth hypothesis, there is no significant difference in the predictive value of BAC\textsubscript{DM} results collected SDE, MDE, LDE as a predictor of BAC\textsubscript{WB} results, a simple linear regression analysis was conducted using version eight of SAS®. The results of the regression analysis are presented graphically in Figures 2, 3, and 4.

![Graph showing BAC from Short Duration Exhale vs. BAC from Whole Blood](image)

Figure 2. Regression Analysis BAC\textsubscript{WB} by BAC\textsubscript{DM} Short Breath Durations.

As evidenced by Figures 2, 3, and 4, the predictive value of BAC\textsubscript{DM} estimates collected using varied breath samples are not equally predictive of BAC\textsubscript{WB} results. Specifically, BAC\textsubscript{DM} estimates collected using SDE breath samples are less predictive...
Figure 3. Regression Analysis $\text{BAC}_{\text{WB}}$ by $\text{BAC}_{\text{DM}}$ Medium Breath Durations. $\text{BAC}_{\text{DM}}$ estimates collected using MDE and LDE appear to be equally predictive of $\text{BAC}_{\text{WB}}$. Based on these results, Hypothesis V was rejected.

**Summary**

In the first part of this chapter, a description of the results of the multi-level screening process was presented detailing how the study population was selected. In the second section, the sample group was described with respect to physiological and demographic factors of interest. Next, the results of the statistical analyses conducted to test the five research hypotheses were presented. These results, which indicate that
Figure 4. Regression Analysis $BAC_{WB}$ by $BAC_{DM}$ Long Breath Durations.

All hypothesized relationships between $BAC_{DM}$ estimates and $BAC_{WB}$ results should be rejected, will be discussed in terms of their implications to the field in Chapter IV.
CHAPTER IV

CONCLUSIONS AND RECOMMENDATIONS

Twenty-seven healthy males between the ages of 21 and 30 served in the study to determine if BAC\text{DM} estimates are significantly different from BAC\text{WB} results computed by laboratory analysis and to investigate if systematic variations in breath sample duration during alcohol breath testing with the BAC DataMaster® would significantly effect BAC\text{DM} estimates. In addition the study set out to determine if the above differences were influenced by the amount of alcohol an examinee had ingested.

After determining that all 27 volunteers were physically healthy and free from substance abuse/dependence disorders and/or symptoms of a diagnosable mental illness, all participants were randomly assigned to one of three alcohol intake groups: (1) high alcohol intake BAC = .10g/210ml, (2) medium alcohol intake BAC = .08g/210ml, or (3) low alcohol intake BAC = .06g/210ml. Each participant ingested a total of 2.36 ml of alcohol per 1 kg of body weight (high intake), 2.00 ml per 1 kg of body weight (medium intake), or 1.64 ml of alcohol per 1 kg of body weight (low intake). Total alcohol intake for each participant was provided in six drinks containing equal parts of 100 proof Smirnoff® Vodka and Spartan Brand® Orange Juice from concentrate. Each participant was provided with a drink every ten minutes. The exact proportion of each drink was based on the participant’s bodyweight, an estimate of normal human metabolism of alcohol, the proof of the alcohol used, and the
participants assigned alcohol intake group. Exact calculations for each participant are presented elsewhere (Appendix L).

After ingesting their allotted alcohol, all participants were required to provide the researcher with a six milliliter, pre-breath testing blood sample, six breath samples (two at each of three predetermined sample durations), and a six milliliter post-breath testing blood sample. Pre- and post-breath testing blood samples were drawn via venipuncture, using Bectin Dickenson, 21-gauge needle/vacutainer blood collection sets, by a registered nurse.

Breath testing was conducted on a BAC DataMaster® by an off-duty Kalamazoo Michigan public safety officer who holds a level-three certification for operation of the BAC DataMaster®. Alcohol breath testing followed standard breath testing procedures with one noted exception. Specifically, the duration of each participant's breath duration was carefully monitored and controlled. The duration of participants breath samples were carefully timed using a handheld digital stopwatch and participants were instructed to stop their breath samples after one of three duration conditions: (1) a breath sample with a duration of six to eight seconds (short duration exhalation), (2) a duration of 12 to 14 seconds (medium duration exhalation), or (3) a duration of 18 to 20 seconds (long duration exhalation)

Whole blood samples were analyzed at a local laboratory and BAC<sub>WB</sub> levels were reported. The BAC DataMaster® was used to analyze breath samples and BAC<sub>DM</sub> estimates were reported. As documented in Chapter III, statistical analyses were conducted to address the five research questions and to determine: (1) if BAC<sub>WB</sub>
results were equal to $BAC_{DM}$ estimates calculated from SDE, MDE, and LDE breath samples, (2) if differences between $BAC_{WB}$ results and $BAC_{DM}$ estimates were effected by the amount of alcohol ingested, (3) if all $BAC_{DM}$ estimates calculated from SDE, MDE, and LDE breath samples were equal, (4) if differences in $BAC_{DM}$ estimates calculated from SDE, MDE, and LDE breath were affected by the amount of alcohol ingested, and (5) which breath duration produces $BAC_{DM}$ estimates that are the best predictor of $BAC_{WB}$ results.

The results of a split-plot analysis of variance for repeated measures indicated that the null hypothesis, $BAC_{DM}$ estimates calculated from SDE, MDE, and LDE samples were equal to $BAC_{WB}$ results, was rejected. In fact, the data suggest $BAC_{DM}$ estimates consistently underestimate $BAC_{WB}$ results. Follow up contrasts analyses indicate that $BAC_{DM}$ estimates made from SDE showed the greatest differences from $BAC_{WB}$ results. Significant differences were found to exist between $BAC_{DM}$ estimates and $BAC_{WB}$ results. The differences were most pronounced in the low alcohol intake group. Within the low alcohol intake group, mean differences of -.004g/210ml for a LDE, -.0055g/210ml for MDE, and -.0062 g/210ml for the SDE were found. These differences were all significant at $p > .01$. The pattern of differences was also evidenced in the medium intake group. Within the medium alcohol intake group, mean differences of -.0031 g/210ml for a LDE, -.0037g/210ml for MDE, and -.0081 g/210ml for the SDE were found. The differences found for SDE samples were significant at $p < .01$ while differences found for MDE samples were significant at $p < .05$ and differences for LDE were not significant. The pattern of
differences emerged again in the high alcohol intake group. Within the high alcohol intake group, mean difference of -.0009 g/210ml for a LDE, -.001g/210ml for MDE, and -.0075 g/210ml for the SDE were found. The differences found for SDE samples were significant at p < 01 and differences for MDE and LDE samples were not significant.

It was important to note that, regardless of the amount of alcohol ingested BAC_{DM} estimates collected using SDE were significantly lower (.006g/210ml to .008g/210ml) than BAC_{WB} results.

The results of a second split-plot analysis of variance for repeated measures indicated that the null hypothesis, BAC_{DM} estimates calculated from SDE, MDE, and LDE were equal, was also rejected. Follow up contrast analysis using Tukey’s Studentized Range Test indicates that SDE breaths (breath samples lasting between 6 and 8 seconds in duration) are significantly different then breaths of MDE and LDE samples (breaths lasting 12 to 14 seconds and 18 to 20 seconds respectively) at the .05 alpha level. These differences were most pronounced within the medium and high alcohol intake group. Within the medium alcohol intake group mean differences of .05g/210ml were found to exist between BAC_{DM} estimates from LDE breath samples and BAC_{DM} estimates from SDE breath samples. Within the high alcohol intake group mean differences of .009g/210ml were found to exist between BAC_{DM} estimates from LDE breath samples and BAC_{DM} estimates from SDE breath samples.

These finding are notable because the differences were greater than the .0042g/210ml “acceptable error” established by the NHTSA for repeated breath
samples. The findings suggest that, although the BAC DataMaster® has met the National Highway Traffic Safety Administration (NHTSA) standards for devices that measure breath alcohol, variations in breath sample duration can result in $BAC_{DM}$ estimates outside of the acceptable error.

This finding is extremely important because it means error can be introduced into the test process intentionally or unintentionally by the examiner who conducts a breath alcohol test. By virtue of his or her instructions to the examinee, the examiner who conducts the BAC DataMaster® testing can inflate $BAC_{DM}$ estimates by encouraging the examinee to provide a breath sample of longer duration.

The results of the analyses also suggest an interaction due to the amount of alcohol intake. Specifically, the inflation of $BAC_{DM}$ estimates that occurs with increased breath duration is more pronounced as alcohol intake increases. The results of the Tukey’s Studentized Range Test conducted on participants within the high, medium, and low alcohol intake groups indicate that as an individual’s actual alcohol intake and $BAC_{WB}$ level increases the inflation error in $BAC_{DM}$ estimates due to breath durations also increases. This finding suggests that the BAC DataMaster® estimates for individuals who have ingested high amounts of alcohol are subject to a larger estimate error.

In cases were a participant’s actual $BAC_{WB}$ level was at or near .04g/100ml, the mean $BAC_{DM}$ estimate inflation between a SDE and LDE breath samples was .003g/210ml. As a participant’s actual $BAC_{WB}$ levels increase to or near the .06g/100ml level, the inflation of $BAC_{DM}$ estimates from SDE to LDE breath samples...
was observed to be .005g/210ml. The trend continued within the highest alcohol intake group, in those cases where a participant’s actual BAC_{WB} levels were at or near .08g/100ml, the mean BAC_{DM} estimate inflation between a SDE and LDE breath samples was observed to be .009g/210ml.

The trend of increasing inflation of BAC_{DM} estimates as an individual’s alcohol intake and BAC_{WB} increases appears to follow a near linear progression suggesting that the magnitude of inflation of BAC_{DM} estimates due to the duration of breath samples is directly related to the amount of alcohol ingested. The importance of the findings is especially noteworthy in those cases where a participant’s actual BAC_{WB} is near the legal limit. The combination of a higher BAC coupled with a long duration breath sample may result in inflated BAC_{DM} estimates.

In the study, an effort was made to monitor and control the length of sample breath durations to determine if there was a difference in BAC_{DM} estimates as breath durations were varied. The results of this study clearly indicate that breath duration is a critical issue that has the potential to significantly impact BAC_{DM} estimates. Currently, BAC DataMaster® examiners are not trained to collect breath samples of any specific duration. They are simply taught to have examinees provide a steady breath and listen for an audible tone that signifies a sufficient breath sample is being provided for analysis. Because no standardization procedures or means of monitoring breath duration are currently utilized in BAC DataMaster® testing, examiners and/or the examinee may randomly extend or curtail breath samples at will which increase testing error.
Limitations of the Study

All experimental designs for research involve some limitations that can be anticipated and other limitations that are unanticipated and do not become apparent until the research is underway or has been completed. Two issues emerged during the process of research that represent limitations of the study.

The first such limitation arises from time delays due to minor difficulties during blood collection (e.g., difficulty finding a vein and placing the blood collection devices) and time needed to treat participants who became unsteady and/or fainted during blood and breath testing. During the data collection phase of this study, a reusable butterfly-blood collection device was placed in the vein of each participant’s left arm. The blood collection devices were designed to allow for multiple blood draws from one venipuncture site. It quickly became apparent however that the blood collection devices had a tendency to become clogged if they were placed for more than a few minutes prior to the first blood draw. While the clogging issues were resolved by back flushing with a Heperine-Saline solution, this process caused minor time delays that had a cumulative effect.

In addition to the time-delay caused by blood collection problems, three subjects became unsteady or fainted during the blood and breath testing procedure. In each case the participant was immediately removed from the study and appropriate emergency medical care was administered. While all three situations were effectively resolved by the medical personnel hired by the researcher, the time required to treat each of the three participants resulted in a significant delay in the breath and blood
testing procedures. The original design called for participants to ingest alcohol for a period of one hour followed by a 45-minute alcohol absorption period.

While each individual delay due to blood collection problems or medical treatment was relatively brief, these delays were cumulative and caused participants testing to be delayed. As a result approximately 90% of the participants moved into the post-absorptive phase of alcohol metabolism. The fact that participants moved into the post-absorptive phase of alcohol metabolism is not a problem in and of itself. However, the fact that additional time passed between alcohol ingestion and testing means that participants had additional time to "burn off" or metabolize the alcohol in their bloodstream. The impact of this extra, unplanned metabolism is that participant BAC levels were lower than originally planned. As a result, the participant BAC levels across all three, target BAC groups were lower then planned at the time of blood and breath testing.

This fact, coupled with the fact that BAC targets were initially set lower then the researcher desired (lower BAC levels were recommended by the WMU HSIRB to reduce liability and risk), meant that the researcher was unable to document the differences in BAC_{DM} estimates and BAC_{WB} at the .10g/210ml BAC level. As discussed previously, the .10g/210ml BAC level is an important benchmark due to the fact that the .10g/ml BAC is the per se legal limit for operating a privately owned, motorized vehicle in all 50 states in the U.S. Having a wider allowance for emergency medical conditions and using a smaller number of participants and/or spreading out the appointed drinking times would have reduced or eliminated this problem and should
be considered for future research projects.

Although the results of the statistical analyses were not significantly affected, one additional issue came to light during a post-study review of procedures. This being the fact that three blood samples could not be analyzed due to clotting caused by improper mixing. In the study, all blood samples were collected in sealed vaccutainers that contained a potassium-oxalate preservative designed to prevent the clotting and the degradation of the alcohol within each blood sample. The preservative is a powder that requires the vaccutainer be vigorously agitated, to properly mix the preservative with blood sample. If a blood sample is not properly agitated, the anti-clotting agent/preservative will not function correctly. This appears to be the cause of the clotted samples. As noted above, this was a minor problem that did not impact the analyses. However, future researchers may wish to use an automated means for agitating the blood samples to avoid this concern.

Implications of Study

The results of this study have both theoretical and practical implications. On the theoretical front, the results of this study appear to refute the long-standing assumption within the field of forensic breath testing, that alcohol exchange occurs only in the alveoli. According to this long-standing theory, breath captured during the initial expiration of air is thought to emanate from the dead space of the upper airways and as a result are expected to contain little or no air from the alveoli. The data in this study do not support this theory, but instead better fit the more recent thermodynamic
model of alcohol exchange (Bui et al., 1998; George et al., 1993, Hlastala, 1998). The progressive near linear increase in BAC\textsubscript{DM} estimates observed as breath sample duration increased suggests that breath moving through the bronchial tree is not static as assumed but rather is dynamic. Further, the results refute the notion that alcohol exchange only occurs in the alveoli.

On the practical front, the data produced in this study has implications for the BAC DataMaster® examiner. Specifically, the results indicate that it is essential for examiners to carefully monitor breath sample duration during testing because SDE breath samples clearly produce BAC\textsubscript{DM} estimates that are different from BAC\textsubscript{DM} estimates produced from LDE breath samples. One suggestion that would help to resolve this issue is the addition of a timing device that would document the duration of each breath sample. These results should be printed directly on evidence tickets so that there is a permanent record of the breath sample duration. The addition of a timing device of this nature should not be a major problem. In fact, since the BAC DataMaster already contains a digital clock and a flow meter, this addition may be as simple as adding a few new lines of code to the instrument's software.

Short of physical changes to the hardware or software of the BAC DataMaster®, operators could utilize a handheld stopwatch to monitor breath sample duration. While this solution may be less elegant than physical modifications to the instrument, it would certainly help to resolve a legitimate source of testing error.
Recommendations for Further Research

The most important recommendation for future research is simply that more investigation and research is needed to better understand and more fully document the differences between $\text{BAC}_{\text{DM}}$ estimates and $\text{BAC}_{\text{WB}}$ results in general, and in cases of alcohol intake at and beyond the .10g/210ml BAC level, in particular. Although higher alcohol intake will increase the risk to participants, this risk appears to be warranted given the finding reported in this study. The need for future research with increased alcohol intake levels ($\text{BAC} = .10g/210ml$ and above) is recommended given the observed trend in the data that appears to indicate that the error in BAC estimates changes in magnitude in a near linear relationship to the amount of alcohol ingested by the subject. Future research should be conducted to determine the full magnitude of the interaction effect of alcohol intake and $\text{BAC}_{\text{DM}}$ estimate error.

A second area that warrants investigation was raised by the results of the regression analysis. The results of this research indicate that medium to long duration breath samples were better predictors of $\text{BAC}_{\text{WB}}$ results, regardless of the amount of alcohol ingested. While MDE and LDE breath samples were better predictors of $\text{BAC}_{\text{WB}}$ results than were SDE breath samples, the question of optimal breath or "best" breath sample duration for prediction of $\text{BAC}_{\text{WB}}$ results remains unanswered. Research to more fully investigate this question might allow manufactures to redesign their instruments to accept only breath durations of optimal duration or within an optimal range.

A third area of research that is warranted by the results of this study is related
to the blood partition ratio of 2100:1 used to compute \( \text{BAC}_{\text{DM}} \). The results of this study show that \( \text{BAC}_{\text{DM}} \) estimates consistently fail to accurately estimate \( \text{BAC}_{\text{DM}} \) results. The recent research concerning the blood partition ratio suggests that a better estimate for the blood partition ratio is between 2310:1 and 2360:1 (Hlastala, 1998; Jones & Andersson, 1996). The data in this study appear to support the use of the higher blood partition ratio. If the higher ratio were utilized, \( \text{BAC}_{\text{DM}} \) estimates would be improve the accuracy of predictors of \( \text{BAC}_{\text{WB}} \) results.
Appendix A

Human Subjects Institutional Review
Board Approval Letter
Date:

To:  Robert Betz, Principal Investigator
      Chris Clatterbuck, Student Investigator for dissertation

From:  Michael S. Pritchard, Interim Chair

Re:  HSIRB Project Number 01-03-05

This letter will serve as confirmation that your research project entitled "The Impact of Systematically Varying the Duration of Breath Samples During Infrared-based Alcohol Breath Testing on Breath Alcohol" has been approved under the full category of review by the Human Subjects Institutional Review Board. The conditions and duration of this approval are specified in the Policies of Western Michigan University. You may now begin to implement the research as described in the application.

Please note that you may only conduct this research exactly in the form it was approved. You must seek specific board approval for any changes in this project. You must also seek reapproval if the project extends beyond the termination date noted below. In addition if there are any unanticipated adverse reactions or unanticipated events associated with the conduct of this research, you should immediately suspend the project and contact the Chair of the HSIRB for consultation.

The Board wishes you success in the pursuit of your research goals.

Approval Termination: March 21, 2002
Appendix B

Study Solicitation/Advertisement
for Participants
Wanted

Healthy Males 21 to 30 years of age to participate in a research project involving controlled drinking of alcohol. The focus of the study will be to investigate the effectiveness of a commonly used Breath Alcohol Testing Device under varied conditions.

All participants will be required to answer screening questions and submit to a physical examination prior to inclusion in the study. Pre-study screening will take 1½ to 2 hours and the data collection will require a one-day commitment of up to 8 hours.

Participants will earn up to a total of $75.00 in compensation for their participation in the study.

All screening and study activities will be conducted at the WMU University Substance Abuse Clinic, located in the MSU/Kalamazoo Center for Medical Studies 1000 Oakland Drive, Kalamazoo, MI 49008.

Note: Individuals with medical conditions such as heart disease, high blood pressure, diabetes, seizure disorder, G.E.R.D., kidney or liver dysfunction, or any other condition exacerbated by alcohol use will be unable to participate the study. In addition, any individuals with a history of substance abuse/dependence disorders, mental illness, or prior conviction for DWI, OUIL, or MIP will be excluded.
Appendix C

Letter to Subjects
May 17, 2001

Thank you for your interest in my research project, "The Impact of Systematically Varying the Duration of Breath Samples During Infrared-based Alcohol Breath Testing on Breath Alcohol Concentration Results.

My name is Chris Clatterbuck and I am conducting this research project as a Doctoral Student in Counseling Psychology at Western Michigan University.

Enclosed please find the following items that will help explain the study more completely and start you through the screening process.

1) Two copies of the informed consent document. Please read the entire document and return one signed copy.

2) One copy of the Milcom Health History Update and Physical Examination form. Please complete the 88 questions by answering (yes or no) to the questions as they apply to you.

3) One copy of the Health History Supplement. Please complete both pages of this form.

When you have completed all of the enclosed forms and signed the informed consent document. Simply place the materials in the self-addressed, postage-paid, envelope and drop them in a mailbox.

Upon receipt of your materials, I will contact you by phone with the next step. If you should have any questions while completing these materials, please call me at 387-2049.

Thank you in advance for your time.

Sincerely,

Chris C. Clatterbuck, M.S.,
Doctoral Candidate in Counseling Psychology
Appendix D

Milcom Health History Form
Health History Update and Physical Examination

Please begin here.

In order for us to provide you with effective medical care, we need to have some basic information about your past and present health. We also need to ask about your life style because it affects your physical and emotional well being.

The questions on the next two pages cover the topics we will discuss. Please answer them as best you can.

- Mark an X on the blue line following the word No or Yes when either describes your symptoms or history.
- Write in information, where it’s called for. Solid arrow indicates the space to write in.
- Use a question mark (?) when you don’t understand a question or aren’t sure of your answer.
- Skip over those questions that you prefer not to answer.

Thank you for completing this booklet.

**HOW ARE YOU FEELING?**

Mark an X on the blue line to the right of the appropriate response.

During the past year, have you:

- had frequent headaches? ........................................................................ No — Yes
- felt dizzy, faintness, or had blackouts? ................................................ No — Yes
- had sneezes or cold-like symptoms? ......................................................... No — Yes
- noticed any lump on your body or swollen glands? .................................. No — Yes
- had difficulty hearing? ............................................................................. No — Yes
- had troubles with your ears? ...................................................................... No — Yes
- had dental or other mouth problems? ...................................................... No — Yes
- suffered from nose bleeds? ..................................................................... No — Yes
- suffered from allergies or hay fever? ....................................................... No — Yes
- noticed any hoarseness? .......................................................................... No — Yes

During the past year, have you:

- been wheezing or been short of breath? .................................................. No — Yes
- frequently been coughing? ...................................................................... No — Yes
- sweated more than usual or had “night sweats”? ..................................... No — Yes
- had a racing heart or palpitations? ............................................................ No — Yes
- had diarrhea or passage of blood? ........................................................... No — Yes
- had difficulty swallowing? ...................................................................... No — Yes
- had frequent urination during the day or at night? .................................. No — Yes
- had uncomfortable or difficult urinations? .......................................... No — Yes

**For Men Only:** During the past year, have you:

- had a drop in semen or discharge from your penis? .............................. No — Yes
- noticed limits or swellings on your testicles? ....................................... No — Yes
- had difficulty with your erection? ........................................................... No — Yes

**For Women Only:**

- When was your last normal menstrual period? ......................................
  No — Yes
- If you are past menopause, have you noticed vaginal bleeding? ....... No — Yes
- If you are past your menopause, please skip to Q. 341
- Have there been any changes in your periods? ..................................... No — Yes
- Has your menstrual period become heavier? ......................................... No — Yes
- Do you have discomfort during intercourse? ........................................ No — Yes
- Do you have any vaginal itching, burning or discharge? ..................... No — Yes
- Do you have any discomfort or pain in your private parts during
  intercourse? ......................................................................................... No — Yes
- Do you have any problems with your breasts? .................................... No — Yes

- When was your last Pap test? ................................................................. No — Yes
- Have you ever had an abnormal Pap test? ........................................... No — Yes

**For Both Men and Women:** During the past year, have you:

- had any skin problems or noticed any changes
  in your skin? .......................................................................................... No — Yes
- had itching, rashes or burning? ............................................................. No — Yes
- had breath odors or bad breath? ............................................................ No — Yes

During the past year, have you:

- felt exhausted or fatigued most of the time?.......................................... No — Yes
- felt “blue” or extremely depressed? .......................................................... No — Yes
- been more irritable than usual? .............................................................. No — Yes
- had frequent spells of crying or felt like crying? .................................... No — Yes
- had difficulty trying to calm down or relax? .......................................... No — Yes
- been overly anxious or been worried a lot? .......................................... No — Yes
- felt that you or others would be better off if you were dead?.............. No — Yes
- wanted to hurt yourself or your child? ................................................... No — Yes

Please turn to page 2

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EATING AND DRINKING

What did you eat yesterday?

Do you use salt at the table? No Yes
Has your appetite noticeably changed in the past month? No Yes
Have you gained, lost 10 or more pounds in the past 6 months? No Yes
Do you drink caffeinated coffee, tea or soda? No Yes
Do you smoke or use tobacco now? No Yes
If you stopped some time ago, when was it? No Yes
Do you drink more than 2 alcoholic beverages a day? No Yes
Have you ever felt you ought to Cut down on your drinking? No Yes
Ever been Annoyed by people criticizing your drinking? No Yes
Ever felt bad or Guilty about your drinking? No Yes
Ever had a morning "Eye opener" to steady your nerves? No Yes
Are you or have you used prescription drugs without having a prescription? No Yes
Ever used other "recreational" drugs? No Yes

WORK AND PLAY

Are you generally satisfied with your work? Yes No
What kinds of exercise do you do? ________________________
What are your hobbies or leisure activities? ________________________
In what kinds of groups, organizations, or community activities do you participate? ________________________
List the countries that you have visited in the past 6 months: ________________________
Do you usually wear safety belts when riding in a car? Yes No
Are there any guns in your house? Yes No
Are there smoke detectors in your house? Yes No

SEXUALITY

Are you sexually active now? Yes No
Are you generally satisfied with sex? Yes No
What do you do for family planning or birth control? ________________________
Are there sexual concerns that you would like to discuss? No Yes

FAMILY APGAR ASSESSMENT **

Family here refers to the relatives or close friends with whom you usually live or ask for continuing emotional support. How satisfied are you with the way your family:
- helps you when you are in trouble? ________________________
- discusses things and shares your problems? ________________________
- accepts your new interests or changes in your lifestyle? ________________________
- expresses affection and responds to your feelings or moods? ________________________
- spends time together with you? ________________________
Are you concerned about physical, violence or possible incest in your family? No Yes

SOCIAL SUPPORT

Is your time well-balanced between your work, family and leisure activities? Yes No
Is your relationship with your friends as good as it was last year? Yes No
Is your relationship with your spouse/partner as good as it was last year? Yes No
Is there someone with whom you can always discuss your personal problems? Yes No
Would you like patient education on any topic? No Yes

SPECIAL INFORMATION

Please use the lines at the right if there is anything else you would like to mention about your health, family, or social life. Include any important changes that have occurred ________________________

*These questions are taken from the CAGE questions developed by Doctor J.A. Ewing.
**These questions are taken from the Family APGAR developed by Doctor Gabriel Smilkstein.
EATING AND DRINKING
my breakfast was _________________________________________
my lunch was ____________________________________________
my dinner was ____________________________________________
my snacks were ___________________________________________
adds salt to foods
recent changes in appetite
 gained lost 10+ lbs. in last 6 months
drinks caffeinated coffee, tea or relas
smokes or uses tobacco now
2+ alcoholic drinks a day
ought to Cut down on drinking
Annoyed by criticisms of drinking
Guilty about drinking
need occasional “Eye opener”

USE OF MEDICATIONS WITHOUT PRESCRIPTIONS
USE OF RECREATIONAL DRUGS

WORK AND PLAY
not satisfied with my work
exercise is ___________________________________ Frequency ________________
number of leisure activities are _____________________________
special interests are ______________________________________
countries visited in past 6 months ____________________________
often without safety belts
guns are in the house
smoke detectors in the house

SEXUAL
not sexually active now
some sexual dissatisfaction
have don’t practice birth control, or the birth control I use is

SEXUAL CONCERNS TO DISCUSS

FAMILY ORGAN ASSESSMENT
am I satisfied with my family’s: help when I’m in trouble
sharing and discussion of my problems
acceptance and support of my new ventures
affection and response to my feelings
way of sharing our time together

concerned about physical violence or possible incest in family

SOCIAL SUPPORT
poor balance between work, family, leisure activities
relationship with friends worse
relationship with spouse/partner worse
no one to discuss problems with
would like patient education

MEENT
frequent headaches
dizzy, fainted or had blackouts
seizures or convulsions
body lumps or swollen glands
eye trouble
difficulty hearing
dental or other mouth problems
nose bleeds
allergies or has fever
hoarseness in voice

RESPIRO-CARDIOVASCULAR
wheezing or been short of breath
frequent coughing
unusual sweating night sweats
racing heart palpitations
tightness or pain in chest
swollen feet or ankles

GI and GU
heartburn or indigestion
abdominal discomfort or pain
nauseated or vomiting
difficulty swallowing
rectal pain
bloody or tarry stools
change in bowel habits
frequent day night urination
uncomfortable or difficult urination

MALE GENITAL
drop or discharge from penis
lumps or swellings on testicles
difficulties with erection

FEMALE GENITAL
last normal period
post-menopausal bleeding
changes in menstrual periods
bleeding between periods
discomfort during intercourse
post coital vaginal bleeding
vaginal itch, burning, discharge
pelvic discomfort or pain
breast problems
last Pap test was
had abnormal Pap test

SKIN AND EXTREMITIES
skin problems or changes
aching muscles or joints
leg cramps

MOOD
exhausted or fatigued
felt “blue”, lonely or depressed
unusually irritable
felt like or frequently crying
can’t calm down or relax
overly anxious worrying a lot

self others better off if I were dead
desired/sought counseling

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### Physical Examination

Circle items with positive findings. Check "WNL" for items within normal limits.

<table>
<thead>
<tr>
<th>GENERAL</th>
<th>WNL</th>
<th><strong>Description of Abnormal Findings</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Posture</td>
<td>WNL</td>
<td><strong>WNL</strong></td>
</tr>
<tr>
<td>Gait</td>
<td>WNL</td>
<td><strong>WNL</strong></td>
</tr>
<tr>
<td>Hair</td>
<td>WNL</td>
<td>Sinus</td>
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<tr>
<td>Tenderness</td>
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<td><strong>WNL</strong></td>
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<tr>
<td>EYES</td>
<td>R</td>
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<tr>
<td>Iris</td>
<td>R</td>
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<tr>
<td>Sclera</td>
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<tr>
<td>Conjunctiva</td>
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</tr>
<tr>
<td>Muscles</td>
<td>R</td>
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<tr>
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<tr>
<td>Peripheral fields</td>
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<tr>
<td>EARS</td>
<td>WNL</td>
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<td>R</td>
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<tr>
<td>Hearing</td>
<td>R</td>
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<td>NOSE</td>
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<tr>
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<td>MOUTH/THROAT</td>
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<td>Lip</td>
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<tr>
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<td>Inguinal</td>
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<td></td>
</tr>
<tr>
<td>Subcutaneous</td>
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<td>CHEST/LUNGS</td>
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<td>Excursion</td>
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<td>CARDIOVASCULAR</td>
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<tr>
<td>Pulse</td>
<td>Lower Extremity</td>
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</tr>
<tr>
<td>Beating</td>
<td><strong>WNL</strong></td>
<td></td>
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<tr>
<td>Sounds</td>
<td>Lower Extremity</td>
<td></td>
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<tr>
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<td>Extremity</td>
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<td>Murmurs</td>
<td>Abdominal</td>
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<tr>
<td>Neck Bruits</td>
<td>Abdominal</td>
<td></td>
</tr>
<tr>
<td>Upper Extremity Pulsations</td>
<td>Abdominal</td>
<td></td>
</tr>
</tbody>
</table>

### Description of Abnormal Findings

- **MOUTHS:** Rinse with a saline solution
- **THROAT:** Swab for culture
- **TONGUE:** Place a saline swab in the mouth
- **PHARYNX:** Swab for culture

**Remarks:**

- **Neck:** Swelling or tenderness
- **Ears:** Discharge or pain
- **Nose:** Nasal congestion or discharge
- **Mouth:** Ulcers or white patches
- **Throat:** Swollen lymph nodes

**Physician Signature**

Date: __________

Sig: __________
Appendix E

Informed Consent Form
Western Michigan University
Department of Counselor Education & Counseling Psychology

The Impact of Systematically Varying the Duration of Breath Samples During Infrared-based Alcohol Breath Testing on Breath Alcohol Concentration Results

Principal Investigator: Robert L. Betz, Ph.D.
Student Investigator: Chris C. Clatterbuck, MS

I have been invited to participate in a research project entitled The Impact of Systematically Varying the Duration of Breath Samples During Infrared-based Alcohol Breath Testing on Breath Alcohol Concentration Results. This research is intended to study how variations in the length of breath samples provided for Alcohol Breath Testing affect results produced by The BAC DataMaster an infrared Breath Testing Device. I have been informed that this research project will serve as Chris C. Clatterbuck’s doctoral dissertation.

I have been informed in writing, that if I should be randomly drawn from those who qualify to participate in this study, I will be required to drink vodka and orange juice, in a controlled setting and at a carefully controlled rate up to the point where I may become legally intoxicated. I have been informed that after I have reached the desired level of intoxication, I will be required to provide 1) a series of six (7 to 24 second) breath samples and 2) three 3-milliliter blood samples that will be analyzed to determine my Blood Alcohol Concentration level. If selected for participation, I agree that once I have begun drinking I will remain in the University Substance Abuse Clinic under the supervision of research personnel until my blood alcohol level returns to normal.

Because the use of alcoholic beverages has been demonstrated to pose an increased health risk for individuals with a history of substance abuse/dependence disorders and certain health conditions, it has been explained to me that to be considered for participation in this study, I will be required to pass a series four fitness for participation screenings before I am approved to take part in this study.

1) Level I Screening. I have been instructed that I will be asked to complete a health survey that I will submit with a signed copy of this document. I am aware that the health questionnaire is designed to collect personal health information that may be embarrassing or difficult for me to disclose. I will be ask to list all medications that I am presently taking or have taken during the past 30-days and I will be required to discuss my use of both legal and illegal drugs, as well as my daily, weekly, monthly alcohol intake. Additionally, I understand that I am expected to disclose any substance abuse treatment I have undergone and legal charges involving drugs or alcohol that I have had in my past. It is estimated that Level I Screening should take no longer than 20 minutes.

2) Level II Screening. I am aware that after I submit this document and the health questionnaire to the address provided by Mr. Clatterbuck, I will be contacted by telephone and required to complete a brief (10 to 15-minute) telephone interview with the researcher or one of his research assistants. During this telephone interview, the researcher will ask general information about myself, such as my age, race, and ethnicity, level of education, annual income, and employment status. In addition to the general questions, the telephone interviewer may review my responses to the health questionnaire to complete, or clarify, my answers. It was also explained to me that during this telephone interview, I will be notified if I have been excluded as a potential participant or if I qualify for further screening. Should I qualify for further screening, I will be offered an appointment to meet with Mr. Clatterbuck, or a research assistant, at the WMU University Substance Abuse Clinic at the MSU/KCMS Center for Medical Research 1000 Oakland Drive, Kalamazoo, MI 49008.
3) Level III Screening. The third fitness for participation screening will be scheduled on Fridays from 9:30 a.m. to 3:30 p.m. from May 4th through June 8th. The Level III Screen will include a 45 minute to 1-hour private, interview session with Mr. Clatterbuck or one of his research assistants. During this face-to-face interview, I will be asked questions about my mental health and will complete a substance abuse screening instrument called the Substance Abuse Subtle Screening Inventory 3rd Edition (SASSI-3). If the results of my interview session and/or my scores on the SASSI-3 questionnaire indicate signs of mental illness and/or a substance abuse/dependence problem, I will be excluded from the remainder of the study and will be provided with a therapist referral list where I may seek treatment, should I choose.

4) Level IV Screening. If my interview responses and SASSI-3 scores are determined to be satisfactory, I will be introduced to the an advanced level Physicians Assistant student who will immediately show me to an examination room where she or he will conduct a physical examination to determine that I am good general health. This examination should last approximately 1 hour. The medical examination will serve as the final screening and will be provided at no cost to me. During the examination, I will experience a needle stick to my finger to test my blood glucose levels, and will be required to provide two blood samples of approximately 1.5 milliliters each that will be analyzed to determine if my liver and kidneys are functioning properly. In addition to the blood testing, the Physicians Assistant will assess my general health by performing a review of all major systems. For example she or he will weigh me, check my vital signs; examine my head and neck; check my eyes, ears, mouth/throat, and lymph nodes; listen to my chest/lungs and heart; check my reflexes and neurological responses, examine my abdomen for tenderness or hernia, and examine my skin for signs of disease or illness. I have been informed that given the invasive nature of the Level III and IV screenings. I have been informed that I will receive a $15.00 payment for my time and personal discomfort after I have completed these screenings.

Should my mental health interview or physical examination reveal a medical or psychological condition that is in need of immediate treatment, the interviewing Psychologist or Physician's Assistant, in consultation with her or his supervisor will determine the appropriate course of action. If the condition is life threatening and emergency treatment is deemed necessary, I understand that I will be transported via ambulance to a local emergency room of my choice. If the medical condition is not life threatening, but requires follow-up medical attention the condition will be discussed with me and I will be provided with a medical referral list where I can seek follow-up care. In either case, I understand that the presence of a medical condition that requires treatment will exclude me from participation in the study.

When my laboratory results become known, a member of the medical staff will contact me to discuss the results. If my results are abnormal in any way, I will be provided with a referral for appropriate follow-up care. If my results are normal, I understand that my name will be placed in the pool of eligible participants from which the final study participants will be randomly drawn. Whether or not I am selected to participate in the study, I will be contacted by phone by Mr. Clatterbuck within one week of my interview, testing and physical examination.

If I am one of the 30 individuals randomly selected to participate in the study, I will be offered the opportunity to return to the WMU University Substance Abuse Clinic on Saturday June 16th and take part in the research study itself. I will be assigned an appointment time between 9 a.m. and 1 p.m. when I am to arrive at the clinic to "check in." After checking in with the research staff and reviewing the requirements for the day, I will be assigned to group 1, 2, or 3 escorted to the alcohol intake station. In the alcohol intake station, I will be provided with a beverage alcohol (vodka and orange juice) in measured doses and on a predetermined schedule based on my body weight and my assigned group.
Following the alcohol intake session, I will be escorted into the “pre-testing rest area” where I will “rest” for 40-minutes to ensure proper metabolism. Following the 40-minute “rest” period I will be escorted to the sample collection area where a nurse will insert a butterfly blood collection device into a vein in my forearm. The nurse will draw three blood 3-ml samples and I will “blow” 6 breath samples into the BAC DataMaster for analysis. Once I have provided my blood and breath samples to the researcher, the nurse will then remove the butterfly blood collection device and I will be escorted to the “post-testing alcohol detoxification area” where I will remain under supervision until my blood alcohol concentration level returns to a 0.00 BAC.

During the detoxification I may relax in a quiet area and or spend my time in a social area where I can interact with others (e.g., talk to others, watch television, read, or play cards). The designated detoxification area will have access to its own bathroom facilities so that I need not leave this area for any reason. This designated area will be monitored at all times by a nurse, and at least four other research assistants to ensure my safety and well being. Depending on my bodies’ rate of metabolism and the amount of alcohol I drank, I will be required to stay in the detoxification area for between 4 ½ to 7 ½ hours. For my time and discomfort I will be paid $60.00.

Confidentiality the results of all screenings and assessments and my responses to all health questions will only be shared with trained medical personnel who will be evaluating my fitness for participation and/or who are responsible for blood collection. At no time will my personal health information be shared with any person or persons outside the study team without my written permission. Should I desire that my doctor to have a copy of my study record to include in her or his files, I may request a copy from the researcher.

Risks of participation. As in all research, there may be unforeseen risks to the participant. If an accidental injury occurs, appropriate emergency measures will be taken; however, no compensation or treatment will be made available to me except as otherwise specified in this consent form. In the case of this project, attempts will be made to reduce or eliminate sources of potential risk to individuals wherever possible. Some examples of these efforts include; intensive pre-screening of participants, not allowing participants to drive or operate machinery while intoxicated, providing a controlled environment for the experiment, and securing trained medical personnel to monitor participants following ingestion of alcohol. Despite these precautions, human participation in a project of this nature is not without some measure of risk.

Pharmacologically, ethyl alcohol (beverage alcohol) is a known central nervous system depressant that in moderate to high doses can result in behavioral disinhibition and intensification of emotions, difficulty with decision-making abilities, and mild loss of motor control and/or impaired coordination. As a result of these pharmacological effects, persons who drink alcohol are at some increased risk of injury to self.

In this proposed study, the first potential risk faced by participants is the possibility that the participant will behave in a manner that may cause embarrassment. Specifically, the changes in behavioral disinhibition and intensification of emotional reactions to internal and external stimuli may cause a participant to do or say things that he may later regret.

A second potential risk faced by participants is due to the changes in motor control and impaired coordination. Individuals who drink alcohol at moderate to high doses may experience changes in coordination and motor control. These physiological changes, while temporary, may increase risk of falls or minor accidents during the period of intoxication. These risks are minimized by the physical layout of the facilities at the University Substance Abuse Clinic (USAC) and by the presence of 3 to 1 participant to staff ratio. Additionally, medical personnel will be available on-site to provide basic first aid as needed. In the case of a serious accident, emergency personnel will be summoned and the participant will be transported to a local emergency room.
Additionally, some individuals may become dizzy or nauseated to the point that they will feel the need to vomit. If a participant should experience this type of reaction, a rest area will be available where participants can sit quietly under supervision until these symptoms resolve. Should a subject become violently ill the physician, Dr. Michael Liepman, will evaluate him and provide appropriate medical care as needed. If the physician determines that on-site care is insufficient, emergency personnel will be summoned and the participant will be transported to a local emergency room.

On very rare occasions, participants who drink alcohol at moderate to high doses may experience hallucinations and or alcohol induced psychosis. This is a very rare situation and usually occurs in participants with a history of mental illness and/or a history of substance dependence. Pre-screening of participants should minimize or eliminate this as a risk. However, should a participant experience a severe reaction 2 nurses and a physician certified in the treatment of substance abuse will be available on-site to provide triage and care as needed.

One final risk of participation in this study is experiencing an “alcohol hangover.” Consumption of moderate to high doses of alcohol may cause some participants to experience withdrawal symptoms commonly known as a “hangover” (e.g., general feelings of malaise, minor aches and pains, stomach distress, headaches, nausea, or dizziness). While these symptoms will resolve without treatment, they can be uncomfortable. Participants will be advised to increase their fluid intake during the 24 hours following the study to help counter-act this potential problem.

**Benefits of Participation**

One way in which I might directly benefit from this activity is that I will be receiving a physical examination at no cost to me. Good medical care is expensive and often overlooked by men in my age group. My participation in this study gives me access to health care that I may not have encountered otherwise. The data that is collected during this study will help to improve breath alcohol analysis technology. This technology is currently used in medicine and psychology as a treatment screening device, by airplane pilots and train engineers to determine fitness to fly or to operate a train, in the legal system to catch and convict drunk drivers and in personnel offices for pre-employment screening and safety checks for employees. Allowing researchers to better understand the potential problems with this technology, which will ultimately produce improvements in these instruments. These improvements one day may ground a pilot who was planning to fly after drinking alcohol, or convict a drunk drive before she or her takes a life in an automobile accident.

All of the information collected from me is confidential and will only be used by the researcher and the medical personnel overseeing this project. After I have returned this document and my health questionnaire I will be assigned a participant number and from that point forward only this number will identify my records. During the study period a master file with my name and my participation number will be kept in a locked file in a locked office at the University Substance Abuse Clinic. My name will be stripped from all sources of data and replaced with my participant number. The numbered documents such as answers to the telephone questions, my health history, and the results of my physical examination and diagnostic tests as well as my SASSI-3 scores will be held in a locked file cabinet located at the University Substance Abuse Clinic. As soon as a final study population has been selected, data from individuals who were excluded from this final group will be summarized so that an accurate description of the respondent pool can be maintained. Personally identifying data will not be included in these summaries. Any identifying information, such as original interview notes, consent forms, etc, from those excluded from the study will be destroyed in a crosscut shredder.
Following the completion of data collection and analysis the master name sheet will be destroyed so that no one will be able to link my name to my personal information. All number coded original forms, interview notes, physical examination notes, SASSI-3 will be retained for 3-years in a locked cabinet located within the offices of Dr. Joe Morris, Chair of the Department of Counselor Education and Counseling Psychology. At the end of the 3-year period all study data will be destroyed in a crosscut shredder.

I may refuse to participate or quit at any time during the study without prejudice or penalty. However, I agree that if I refuse or decide to quit after I have consumed any amount of alcohol, I will remain at the study site until my blood alcohol concentration levels have returned to a safe level. If I have any questions or concerns about this study, I may contact either Chris C. Clatterbuck at 387-2049 or Dr. Robert L. Betz at 343-5495. I may also contact the chair of Human Participants Institutional Review Board at 387-8293 or the vice president for research at 387-8298 with any concerns that I have.

This consent document has been approved for use for one year by the Human Participants Institutional Review Board as indicated by the stamped date and signature of the board chair in the upper right corner. Participants should not sign this document if the corner does not have a stamped date and signature.

My signature below indicates that I have read and/or had explained to me the purpose and requirements of the study and that I agree to participate.

______________________________
Signature

Consent obtained by: _______________________
Initials of researcher

______________________________
Date

______________________________
Consent obtained by: _______________________
Initials of researcher

______________________________
Date
Appendix F

Supplemental Health History Form
HEALTH HISTORY SUPPLEMENT

NAME: ___________________________  BIRTHDATE: ________________

AGE: _______  HEIGHT: _______  WEIGHT: _______

RACE: __________________________________________________________

OCCUPATION: __________________________________________________

RELATIONSHIP STATUS: ________________________________________

FAMILY DOCTOR: ______________________________________________

ALLERGIES TO MEDICATIONS:

(Name of Drug)  (Reaction to Drug)

Example: Penicillin  Break out in hives

CURRENT MEDICATIONS:

(Name of Drug & Dosage)  (Times taken per day)

Example: Paxil 25mg  Twice a day

RECREATIONAL DRUG & ALCOHOL USE:

(Name of Substance)  (Amount use per day/week/month)

Example: Rum and Coke  6 drinks per week

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HEALTH HISTORY SUPPLEMENT
(please mark all conditions that apply to you)

<table>
<thead>
<tr>
<th>Neurological</th>
<th>Respiratory</th>
</tr>
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<tbody>
<tr>
<td>Alzheimers</td>
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<tr>
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<td>Emphysema</td>
</tr>
<tr>
<td>Stroke</td>
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<td>Bleeding disorder</td>
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<td>Sickle cell anemia</td>
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<tr>
<td>Kidney stones</td>
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<td>Kidney infection</td>
</tr>
<tr>
<td>Kidney failure</td>
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<tr>
<td>Urinary infection</td>
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<td>Irregular beat</td>
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<tr>
<td>Pacemaker</td>
</tr>
<tr>
<td>Defibrillator</td>
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<tr>
<td>High blood pressure</td>
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<td>Congestive heart failure</td>
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<td>Hepatitis</td>
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A__  B__  C__

<table>
<thead>
<tr>
<th>Medical conditions not listed above</th>
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Have you ever been treated for substance abuse?  
Yes ____  No ____

Have you ever been arrested for DWI or OMVI?  
Yes ____  No ____

Have you been diagnosed with HIV or AIDS  
Yes ____  No ____
SASSI-3 Substance Abuse Subtle Screening Inventory

For free consultation on this profile 1-888-898-3377 - M-Th 8-5 - Fri 8-5 EST

**Adult Male Profile**

<table>
<thead>
<tr>
<th>Rule</th>
<th>FVA</th>
<th>FVCD</th>
<th>SYM</th>
<th>CAT</th>
<th>SAT</th>
<th>OFF</th>
<th>SSM</th>
<th>PAM</th>
<th>COR</th>
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**The Decision Rule:**

- Any rule answered 'yes' → High Probability of having a Substance Dependence Disorder
- All rules answered 'no' → Low Probability of having a Substance Dependence Disorder

**Check every rule, yes or no**

1. FVA 18 or more? [ ]
2. FVCD 16 or more? [ ]
3. SYM 7 or more? [ ]
4. CAT 10 or more? [ ]
5. SAT 6 or more? [ ]
6. CAT 7 or more and SAT 5 or more Both? [ ]
7. FVA 9 or more or FVCD 15 or more SAT 8 or more Both? [ ]
8. CAT 5 or more and DEF 6 or more and SAM 8 or more All three? [ ]
9. FVA 8 or more or FVCD 6 or more SAT 2 or more and DEF 4 or more and SAM 4 or more All four? [ ]

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For each item below, circle the number which reflects how often you have experienced the situation described during:
- your entire life
- the past six months
- the six months before
- the six months since

### ALCOHOL (FVA)

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### OTHER DRUGS (FVOD)

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</table>

### Mental Status
- Unemployed
- Married
- Divorced
- Widowed
- Separated

### Employment Status
- Fulltime
- Parttime
- Not employed
- Student
- Homemaker
- Unemployed
- Retired

### Highest Grade Completed
- ... Ethnic Origin

### Weekly Family Take Home Income

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<tr>
<td>$15</td>
<td>70-75</td>
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</table>

### Miscellaneous
- A
- B
- C

---

SASSI 129
If a statement tends to be TRUE for you, fill in the square in the column headed T. If a statement tends to be FALSE for you, fill in the square in the column headed F. Please try to answer all questions.

**SASSI - 3 ADULT FORM**

1. T | Most people would lie to get what they want.
2. T | Most people make some mistakes in their life.
3. T | I usually "go along" and do what others are doing.
4. T | I have never been in trouble with the police.
5. T | I was always well behaved in school.
6. T | My troubles are not all my fault.
7. T | I have not lived the way I should.
8. T | I can be friendly with people who do many wrong things.
9. T | I do not like to sit and daydream.
10. T | No one has ever criticized or punished me.
11. T | Sometimes I have a hard time acting still.
12. T | People would be better off if they took my advice.
13. T | At times I feel worn out for no special reason.
14. T | I think I would enjoy moving to an area I've never been before.
15. T | It is better not to talk about personal problems.
16. T | I have had days, weeks or months when I couldn't get much done because I just wasn't up to it.
17. T | I am very respectful of authority.
18. T | I like to obey the law.
19. T | I have never been tempted to leave home.
20. T | I often feel that strangers look at me with disapproval.
21. T | Other people would fall apart if they had to deal with what I handle.
22. T | I have avoided people I did not wish to speak to.
23. T | Some crooks are so clever that I hope they get away with what they have done.
24. T | My school teachers had some problems with me.
25. T | I have never done anything dangerous just for fun.
26. T | I need to have something to do so I don't get bored.
27. T | I have sometimes drunk too much.
28. T | Much of my life is unsatisfying.
29. T | Sometimes I wish I could control myself better.
30. T | I believe that people sometimes get confused.
31. T | Sometimes I am no good for anything at all.
32. T | I break more laws than many people.
33. T | If some friends and I were in trouble together, I would rather take the whole blame than fall on them.

[Form SASSI-3] 42 14 97
Substance Abuse Treatment Providers Referral List

University Substance Abuse Clinic (USAC) ........................................................... 387-7000
3rd Floor MSU/Kalamazoo Center for Medical Studies
1000 Oakland Drive,
Kalamazoo, MI 49008

New-Way Counseling Center .................................................................................... 552-9134
1128 S. Westnedge
Kalamazoo, MI 49008

New Directions Counseling ...................................................................................... 372-0961
5380 Holiday Terrace
Kalamazoo, MI 49009

SPGB Services Inc ..................................................................................................... 342-7348
914 S Burdick Street
Kalamazoo, MI 49001

New Life House ......................................................................................................... 344-3144
806 South Rose
Kalamazoo, MI 49001
Mental Health Treatment Providers Referral List

Center for Counseling and Psychological Services .................................................. 387-5105
3109 Sangren Hall
Kalamazoo, MI 49008

University Counseling and Testing Center (WMU Students Only) ......................... 387-1850
Western Michigan University
Faunce Hall
Kalamazoo, MI 49008

Delano Outpatient Clinic .................................................................................. 226-5600
1722 Shaffer Road
Kalamazoo, MI 49000

Child & Family Services .................................................................................. 372-4140
5380 Holiday Terrace
Kalamazoo, MI 49009

Family and Childrens Services ..................................................................... 344-0202
1608 Lake Street
Kalamazoo, MI 49001

Desert Streams ......................................................................................... 345-0909
1324 S. Park Street
Kalamazoo, MI

Pine Rest Contact Center ............................................................................ 343-6700
1530 Nichols Road
Kalamazoo, MI 49008
Appendix J

Emotional/Behavioral Assessment and Mental Status Form
EMOTIONAL/BEHAVIORAL ASSESSMENT AND MENTAL STATUS

APPEARANCE: appropriate, physically unclean, clothing disheveled, unusual, seductive

POSTURE: normal, slumped, rigid, atypical

PSYCHOMOTOR ACTIVITY: normal, catatonic, agitated, retarded

BODY MOVEMENTS: normal, rapid, slowed, peculiar

FACIAL EXPRESSION: unremarkable, sad, angry, perplexed, fearful, elated, flat, anxious

SPEECH: normal, abnormalities in the production of speech, flight of ideas, loose, circumstantial, perseveration, halting, blocking, confused, pressured, incoherence

ARTICULATION: normal, stammers, stutters, lisos, slurs, mute

MOOD: normal, depressed, elevated, irritable, marked mood shifts

AFFECT: composed, fearful, angry, euphoric, labile, shallow, blunted, appropriate, anxious, sad, irritable, inconsistent with thought content

PERCEPTION: normal, delusions, increased sensitivity to stimuli, hallucinations-auditory, visual, tactile, somatic, gustatory, olfactory

STREAM OF THOUGHT: normal, associational disturbance, increased flow, decreased flow, incomprehensible, perseverative

THOUGHT CONTENT: unremarkable, suicidal, assaultive, delusional, paranoid, ideas of reference, depersonalization, derealization, grandiosity, hopelessness, obsessions, compulsions

CONSCIOUSNESS/INTELLECTUAL FUNCTIONING: alert, clouded, fluctuating, stuporous/normal, bright, retarded

ORIENTATION: normal, disoriented to time, disoriented to person, disoriented to place

MEMORY: normal, impaired short term, impaired long term

JUDGMENT: good, impaired life decisions, poor management of daily activities

INSIGHT: good, projects blame, acknowledges problems, denies problems

IMPULSE CONTROL: normal, impulsive, overcontrolled

HISTORY OF MENTAL ILLNESS:

PAST PSYCHIATRIC TREATMENT:
Appendix K

Medical Provider Referral List
Sindecuse Health Center (WMU Students Only) ................................................... 387-3239
1903 West Michigan Avenue
Kalamazoo, MI 49008

MSU/Kalamazoo Center for Medical Studies .......................................................... 337-4400
1000 Oakland Drive
Kalamazoo, MI 49008

Joseph A. Bruno, MD ................................................................................................385-4671
6010 Gull Road at 26th Street
Kalamazoo, MI

ProMed Family Practice ............................................................................................ 226-2500
8450 North 32th Street
Richland, MI 49803

The Family Health Center ......................................................................................... 349-2641
117 W. Paterson
Kalamazoo, MI
Appendix L

Formula for Determining Participant Alcohol Intake
<table>
<thead>
<tr>
<th>Time (Minutes)</th>
<th>Alcohol Intake Group</th>
<th>Weight (Kg)</th>
<th>Weight (Lbs)</th>
<th>Body Water (liters)</th>
<th>Body Water (milliters)</th>
<th>Grams Ethanol per 1.0 Milliters</th>
<th>Grams Ethanol per 100 Milliters</th>
<th>BAC Produced by 10 oz of 100 Proof Spirits</th>
<th>Minutes of 100 Proof Spirits</th>
<th>Minutes per 10 Minutes</th>
<th>Minutes Drunk every 10 Minutes</th>
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</thead>
<tbody>
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